

Inhaltsverzeichnis

COMMODORE 2	3
Charakterisierung der Studienpopulationen	3
Mortalität	80
Gesamtüberleben	80
Primäre Analysepopulation	80
Gesamte Population	83
Morbidität	86
Transfusionsvermeidung	86
Durchbruchhämolyse.....	88
Schwere unerwünschte vaskuläre Ereignisse	90
Primäre Analysepopulation	90
Gesamte Population	92
Patientenberichtete Endpunkte	95
EORTC QLQ-C30 (Funktionsskalen)	95
Compliance-Mean	95
Responderanalyse.....	101
MMRM	108
FACIT-Fatigue	111
Compliance-Mean	111
Responderanalyse.....	113
MMRM	115
EQ-5D VAS.....	116
Compliance-Mean	116
Responderanalyse.....	118
MMRM	119
EORTC IL 40	121
TSQM-9.....	127
QLQ-AA/PNH.....	130
PGIS.....	142
Verträglichkeit	143
Generelle Verträglichkeit	143
Patienten mit UE	143
Patienten mit UE >= Grad 3.....	144
Patienten mit UE Grad 3	145
Patienten mit UE Grad 4	146
Patienten mit UE Grad 5	147
Patienten mit SUE.....	148
Patienten mit Behandlungsabbruch wegen UE	149
SOC/PT	150
Spezifische Verträglichkeit.....	443
Outcome of Adverse Events	452
Crovalimab Safety Period.....	454
Generelle Verträglichkeit	454
Spezifische Verträglichkeit	461
COMMODORE 1	466
Charakterisierung der Studienpopulationen	466
Mortalität	527
Gesamtüberleben	527
Primary Efficacy Period	527
Gesamte Studiendauer.....	530
Morbidität	533
Transfusionsvermeidung	533
Durchbruchhämolyse.....	535
Schwere unerwünschte vaskuläre Ereignisse	537
Patientenberichtete Endpunkte	539
EORTC QLQ-C30 (Funktionsskalen)	539
Compliance-Mean	539
Responderanalyse.....	545
MMRM	552

FACIT-Fatigue	555
Compliance-Mean	555
Responderanalyse.....	557
MMRM	559
EQ-5D VAS.....	560
Compliance-Mean	560
Responderanalyse.....	562
MMRM	564
EORTC IL 40	565
TSQM-9	571
Verträglichkeit	574
Generelle Verträglichkeit	574
Patienten mit UE	574
Patienten mit UE >= Grad 3.....	575
Patienten mit UE Grad 3	576
Patienten mit UE Grad 4	577
Patienten mit UE Grad 5	578
Patienten mit SUE	579
Patienten mit Behandlungsabbruch wegen UE	581
SOC/PT	582
Spezifische Verträglichkeit.....	701
Outcome of Adverse Events	715
Crovalimab Safety Period.....	715
Generelle Verträglichkeit	715
Spezifische Verträglichkeit	722

POPULATION: Primary Analysis Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42162

Demographics and Baseline Characteristics

	Crovalimab (N=134)	Eculizumab (N=69)	Total (N=203)
Age (years)			
n	134	69	203
Mean (SD)	40.3 (15.1)	41.9 (16.0)	40.9 (15.4)
Median	36	38	36
Min - Max	18 - 76	17 - 78	17 - 78
Age group (years)			
n	134	69	203
<65	122 (91.0%)	60 (87.0%)	182 (89.7%)
>=65	12 (9.0%)	9 (13.0%)	21 (10.3%)
Sex			
n	134	69	203
Male	77 (57.5%)	35 (50.7%)	112 (55.2%)
Female	57 (42.5%)	34 (49.3%)	91 (44.8%)
Race			
n	134	69	203
Asian	86 (64.2%)	51 (73.9%)	137 (67.5%)
Black or African American	3 (2.2%)	1 (1.4%)	4 (2.0%)
White	44 (32.8%)	16 (23.2%)	60 (29.6%)
Unknown	1 (0.7%)	1 (1.4%)	2 (1.0%)
Ethnicity			
n	134	69	203

Hispanic or Latino	18 (13.4%)	6 (8.7%)	24 (11.8%)
Not Hispanic or Latino	113 (84.3%)	61 (88.4%)	174 (85.7%)
Not Reported	3 (2.2%)	2 (2.9%)	5 (2.5%)
Region 2			
n	134	69	203
North America/ Central and South America/ Europe	49 (36.6%)	18 (26.1%)	67 (33.0%)
Japan/Rest of Asia Pacific	85 (63.4%)	51 (73.9%)	136 (67.0%)
Weight (kg) at Baseline			
n	134	69	203
Mean (SD)	68.24 (15.79)	67.13 (15.26)	67.86 (15.59)
Median	65,8	62,2	65
Min - Max	42.0 - 140.3	47.0 - 122.0	42.0 - 140.3
Weight (kg) category at Baseline			
n	134	69	203
< 100kg	130 (97.0%)	66 (95.7%)	196 (96.6%)
>= 100kg	4 (3.0%)	3 (4.3%)	7 (3.4%)
BMI (kg/m ²) at Baseline			
n	133	69	202
Mean (SD)	24.19 (4.40)	24.13 (4.57)	24.17 (4.45)
Median	23,86	23,05	23,6
Min - Max	16.7 - 45.6	17.1 - 40.9	16.7 - 45.6
History of Smoking			
n	134	69	203
Never	114 (85.1%)	59 (85.5%)	173 (85.2%)
Current	7 (5.2%)	4 (5.8%)	11 (5.4%)
Former	13 (9.7%)	6 (8.7%)	19 (9.4%)
History of Alcohol Use			
n	134	69	203
Never	112 (83.6%)	53 (76.8%)	165 (81.3%)
Current	17 (12.7%)	8 (11.6%)	25 (12.3%)
Former	5 (3.7%)	8 (11.6%)	13 (6.4%)

History of Aplastic Anaemia			
n	134	69	203
Yes	52 (38.8%)	26 (37.7%)	78 (38.4%)
No	82 (61.2%)	43 (62.3%)	125 (61.6%)
Stratification factor: Number of pRBCs received within 6 months prior to randomization			
n	134	69	203
0 UNITS	33 (24.6%)	17 (24.6%)	50 (24.6%)
>0 TO<=6 UNITS	67 (50.0%)	34 (49.3%)	101 (49.8%)
>6 UNITS	34 (25.4%)	18 (26.1%)	52 (25.6%)
Stratification factor: Local LDH level prior to randomization			
n	134	69	203
>=2 TO <=4 X ULN	24 (17.9%)	11 (15.9%)	35 (17.2%)
>4 X ULN	110 (82.1%)	58 (84.1%)	168 (82.8%)

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_dm.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_dm_PAP_16NOV2022_42162.xls

12JAN2024 17:26

POPULATION: Primary Analysis Population

ENDPOINT:--

MODEL: --

STUDY: BO42162

Summary of PNH History

	Crovalimab (N=134)	Eculizumab (N=69)
Age at PNH diagnosis (yr)		
n	134	69
Mean (SD)	35.59 (15.38)	37.41 (16.39)
Median	30,7	32,11
Min - Max	11.5 - 74.7	11.2 - 76.8
Time from PNH diagnosis to enrollment (yr)		
n	134	69
Mean (SD)	5.25 (7.44)	4.97 (5.91)
Median	2,61	2,93
Min - Max	0.0 - 48.5	0.0 - 31.0
History of PNH-relevant conditions prior to enrollment (n, %)		
History of aplastic anemia		
n	134	69
Yes	52 (38.8%)	26 (37.7%)
No	82 (61.2%)	43 (62.3%)
History of myelodysplastic syndrome		
n	134	69
Yes	6 (4.5%)	6 (8.7%)
No	128 (95.5%)	63 (91.3%)
History of renal impairment		
n	134	69
Yes	11 (8.2%)	6 (8.7%)
No	123 (91.8%)	63 (91.3%)
History of major vascular events		
n	134	69
Yes	20 (14.9%)	10 (14.5%)

No	114 (85.1%)	59 (85.5%)
History of pRBC transfusion within 12 months prior to screening		
Number of patients with pRBC transfusion		
n	132	68
Yes	102 (77.3%)	50 (73.5%)
No	30 (22.7%)	18 (26.5%)
Number of units of pRBC transfused		
n	131	67
Mean (SD)	6.47 (8.30)	6.63 (8.70)
Median	3,5	3
Min - Max	0.0 - 43.5	0.0 - 41.0
Number of units of pRBC transfused		
n	131	67
0	30 (22.9%)	18 (26.9%)
0> to <4	36 (27.5%)	16 (23.9%)
>=4 to <14	46 (35.1%)	22 (32.8%)
>=14	19 (14.5%)	11 (16.4%)
Hemoglobin value at Baseline (g/L)		
n	134	69
Mean (SD)	87.20 (14.11)	99.68 (87.86)
Median	84,5	87
Min - Max	63.0 - 135.0	58.0 - 810.0
Haptoglobin value at Baseline (g/L)		
n	84	42
Mean (SD)	0.050 (0.000)	0.050 (0.000)
Median	0,05	0,05
Min - Max	0.05 - 0.05	0.05 - 0.05
LDH Value at Baseline (U/L)*		
n	133	69
Mean (SD)	1772.84 (792.59)	1817.50 (829.09)
Median	1648	1811
Min - Max	458.0 - 3804.0	475.5 - 4761.5
LDH value at Baseline (xULN)*		
n	133	69
Mean (SD)	7.58 (3.39)	7.77 (3.54)

Median	7,04	7,74
Min - Max	2.0 - 16.3	2.0 - 20.3
LDH Level at Baseline		
n	133	69
<2xULN	1 (0.8%)	0
>=2-<=4xULN	22 (16.5%)	10 (14.5%)
>4xULN	110 (82.7%)	59 (85.5%)

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_dm_pnh.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_dm_pnh_PAP_16NOV2022_42162.xls

12JUN2024 7:26

POPULATION: Randomized Safety Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42162

Demographics and Baseline Characteristics

	Crovalimab (N=135)	Eculizumab (N=69)	Total (N=204)
Age (years)			
n	135	69	204
Mean (SD)	40.5 (15.2)	41.9 (16.0)	41.0 (15.5)
Median	36	38	36,5
Min - Max	18 - 76	17 - 78	17 - 78
Age group (years)			
n	135	69	204
<65	122 (90.4%)	60 (87.0%)	182 (89.2%)
>=65	13 (9.6%)	9 (13.0%)	22 (10.8%)
Sex			
n	135	69	204
Male	77 (57.0%)	35 (50.7%)	112 (54.9%)
Female	58 (43.0%)	34 (49.3%)	92 (45.1%)
Race			
n	135	69	204
Asian	86 (63.7%)	51 (73.9%)	137 (67.2%)
Black or African American	3 (2.2%)	1 (1.4%)	4 (2.0%)
White	45 (33.3%)	16 (23.2%)	61 (29.9%)
Unknown	1 (0.7%)	1 (1.4%)	2 (1.0%)
Ethnicity			
n	135	69	204

Hispanic or Latino	18 (13.3%)	6 (8.7%)	24 (11.8%)
Not Hispanic or Latino	114 (84.4%)	61 (88.4%)	175 (85.8%)
Not Reported	3 (2.2%)	2 (2.9%)	5 (2.5%)
Region 2			
n	135	69	204
North America/ Central and South America/ Europe	50 (37.0%)	18 (26.1%)	68 (33.3%)
Japan/Rest of Asia Pacific	85 (63.0%)	51 (73.9%)	136 (66.7%)
Weight (kg) at Baseline			
n	135	69	204
Mean (SD)	68.32 (15.76)	67.13 (15.26)	67.92 (15.57)
Median	66,1	62,2	65
Min - Max	42.0 - 140.3	47.0 - 122.0	42.0 - 140.3
Weight (kg) category at Baseline			
n	135	69	204
< 100kg	131 (97.0%)	66 (95.7%)	197 (96.6%)
>= 100kg	4 (3.0%)	3 (4.3%)	7 (3.4%)
BMI (kg/m^2) at Baseline			
n	134	69	203
Mean (SD)	24.21 (4.39)	24.13 (4.57)	24.18 (4.44)
Median	23,99	23,05	23,67
Min - Max	16.7 - 45.6	17.1 - 40.9	16.7 - 45.6
History of Smoking			
n	135	69	204
Never	115 (85.2%)	59 (85.5%)	174 (85.3%)
Current	7 (5.2%)	4 (5.8%)	11 (5.4%)
Former	13 (9.6%)	6 (8.7%)	19 (9.3%)
History of Alcohol Use			
n	135	69	204
Never	113 (83.7%)	53 (76.8%)	166 (81.4%)
Current	17 (12.6%)	8 (11.6%)	25 (12.3%)
Former	5 (3.7%)	8 (11.6%)	13 (6.4%)

History of Aplastic Anaemia			
n	135	69	204
Yes	53 (39.3%)	26 (37.7%)	79 (38.7%)
No	82 (60.7%)	43 (62.3%)	125 (61.3%)
Stratification factor: Number of pRBCs received within 6 months prior to randomization			
n	135	69	204
0 UNITS	33 (24.4%)	17 (24.6%)	50 (24.5%)
>0 TO<=6 UNITS	68 (50.4%)	34 (49.3%)	102 (50.0%)
>6 UNITS	34 (25.2%)	18 (26.1%)	52 (25.5%)
Stratification factor: Local LDH level prior to randomization			
n	135	69	204
>=2 TO <=4 X ULN	24 (17.8%)	11 (15.9%)	35 (17.2%)
>4 X ULN	111 (82.2%)	58 (84.1%)	169 (82.8%)

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_dm.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_dm_SE1_16NOV2022_42162.xls

12JAN2024 17:24

POPULATION: Randomized Safety Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42162

Randomization Stratification Factors per arm

	Crovalimab (N=135)			Eculizumab (N=69)		
	eCRF data			eCRF data		
IxRS data	>=2 TO <=4 X ULN	>4 X ULN	Total	>=2 TO <=4 X ULN	>4 X ULN	Total
>=2 TO <=4 X ULN	21 (15.6%)	2 (1.5%)	23 (17.0%)	11 (15.9%)	0	11 (15.9%)
>4 X ULN	2 (1.5%)	109 (80.7%)	111 (82.2%)	0	58 (84.1%)	58 (84.1%)
Missing	1 (0.7%)	0	1 (0.7%)	0	0	0
Total	24 (17.8%)	111 (82.2%)	135 (100%)	11 (15.9%)	58 (84.1%)	69 (100%)

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_dm_str.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_dm_str_LDH_SE1_16NOV2022_42162.xls

06FEB2024 10:13

POPULATION: Randomized Safety Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42162

Randomization Stratification Factors per arm

	Crovalimab (N=135)				Eculizumab (N=69)			
	eCRF data				eCRF data			
IxRS data	0 UNITS	>0 TO<=6 UNITS	>6 UNITS	Total	0 UNITS	>0 TO<=6 UNITS	>6 UNITS	Total
0 UNITS	33 (24.4%)	3 (2.2%)	0	36 (26.7%)	17 (24.6%)	0	0	17 (24.6%)
>0 TO<=6 UNITS	0	62 (45.9%)	4 (3.0%)	66 (48.9%)	0	31 (44.9%)	3 (4.3%)	34 (49.3%)
>6 UNITS	0	3 (2.2%)	30 (22.2%)	33 (24.4%)	0	3 (4.3%)	15 (21.7%)	18 (26.1%)
Total	33 (24.4%)	68 (50.4%)	34 (25.2%)	135 (100%)	17 (24.6%)	34 (49.3%)	18 (26.1%)	69 (100%)

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_dm_str.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_dm_str_PRBC_SE1_16NOV2022_42162.xls

06FEB2024 10:13

POPULATION: Randomized Safety Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42162

Disposition of Patients

	Crovalimab (N=135)	Eculizumab (N=69)	Total (N=204)
Number of Screenings	135 (100%)	69 (100%)	204 (100%)
Screening number 1	128 (94.8%)	64 (92.8%)	192 (94.1%)
Screening number 2	3 (2.2%)	3 (4.3%)	6 (2.9%)
Screening number 3	4 (3.0%)	2 (2.9%)	6 (2.9%)
Discontinued Study	7 (5.2%)	2 (2.9%)	9 (4.4%)
Adverse Event	0	0	0
Death	2 (1.5%)	1 (1.4%)	3 (1.5%)
Lost To Follow-Up	2 (1.5%)	0	2 (1.0%)
Protocol Deviation	0	0	0
Non-Compliance	0	0	0
Withdrawal By Subject	3 (2.2%)	1 (1.4%)	4 (2.0%)
Physician Decision	0	0	0
Other	0	0	0
Discontinued Treatment	8 (5.9%)	4 (5.8%)	12 (5.9%)
Adverse event	0	1 (1.4%)	1 (0.5%)
Pregnancy	0	0	0
Death	1 (0.7%)	1 (1.4%)	2 (1.0%)
Lost to follow-up	1 (0.7%)	0	1 (0.5%)
Lack of Efficacy	0	0	0
Protocol Deviation	0	0	0
Non-Compliance With Study Drug	0	0	0
Non-Compliance	0	0	0
Withdrawal By Subject	4 (3.0%)	2 (2.9%)	6 (2.9%)

Physician Decision	2 (1.5%)	0	2 (1.0%)
Progressive Disease	0	0	0
Symptomatic deterioration	0	0	0
Other	0	0	0

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ds.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ds_SE1_16NOV2022_42162.xls

12JAN2024 17:36

POPULATION: Intent-to-Treat Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42162

Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm (ITT Population)

	Center				Country				Geographical region (3)			
	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)
Overall	66	100,0	204	100,0	25	100,0	204	100,0	2	100,0	204	100,0
with <10 patients per arm (1)	66	100,0	204	100,0	24	96,0	127	62,3	0	NE	NE	NE
with >=10 patients per arm (2)	0	NE	NE	NE	1	4,0	77	37,7	2	100,0	204	100,0

(1): ' <10 patients category ' if at least one treatment arm has <10 patients. (2): ' >=10 patients ' category if all treatment arms have >=10 patients.

(3): Geographical regions:North America/ Central and South America/ Europe; Japan/Rest of Asia Pacific. (4): Number of centers.

(5): % of centers compared to overall number of centers. (6): Number of patients randomized in the corresponding category (e.g .Number of patients randomized in centers with <10 pts per arm). (7): % of randomized patients compared to overall number of randomized patients (e.g . % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients).

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_center.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_center_IT_16NOV2022_42162.xls
12JAN2024 17:17

POPULATION: Randomized Population

ENDPOINT: Primary Efficacy Period

MODEL: descriptive

STUDY: BO42162

Summary of concomitant medication per arm

ATC Class Level 2 Medication	Crovalimab (N=135)	Eculizumab (N=69)
Total number of patients with at least one treatment	113 (83.7%)	60 (87.0%)
Total number of treatments	933	435
OPHTHALMOLOGICALS		
Total number of patients with at least one treatment	60 (44.4%)	40 (58.0%)
Total number of treatments	205	123
CICLOSPORIN	10 (7.4%)	6 (8.7%)
METHYLPREDNISOLONE	9 (6.7%)	5 (7.2%)
PREDNISOLONE	10 (7.4%)	4 (5.8%)
CIPROFLOXACIN	8 (5.9%)	4 (5.8%)
PREDNISONE ACETATE	10 (7.4%)	2 (2.9%)
LEVOFLOXACIN	6 (4.4%)	4 (5.8%)
POTASSIUM CHLORIDE	6 (4.4%)	4 (5.8%)
ACETYLCYSTEINE	5 (3.7%)	1 (1.4%)
DEXAMETHASONE SODIUM PHOSPHATE	3 (2.2%)	3 (4.3%)
HYDROCORTISONE	2 (1.5%)	3 (4.3%)
PREDNISONE	1 (0.7%)	4 (5.8%)
AZITHROMYCIN	1 (0.7%)	3 (4.3%)
DEXAMETHASONE	2 (1.5%)	2 (2.9%)
GLUTATHIONE	1 (0.7%)	3 (4.3%)
LIDOCAINE HYDROCHLORIDE	1 (0.7%)	2 (2.9%)
ALBUMIN HUMAN	1 (0.7%)	1 (1.4%)
ASCORBIC ACID	1 (0.7%)	1 (1.4%)
ATROPINE	1 (0.7%)	1 (1.4%)
BENZATHINE BENZYL PENICILLIN	0	2 (2.9%)
CEFUROXIME	1 (0.7%)	1 (1.4%)
CETIRIZINE HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
EPINEPHRINE	1 (0.7%)	1 (1.4%)
HYDROCORTISONE SODIUM SUCCINATE	2 (1.5%)	0

NAPROXEN	1 (0.7%)	1 (1.4%)
POTASSIUM	1 (0.7%)	1 (1.4%)
VANCOMYCIN	1 (0.7%)	1 (1.4%)
ACICLOVIR	0	1 (1.4%)
ADENOSINE	1 (0.7%)	0
AMINO ACIDS NOS	1 (0.7%)	0
ATROPINE SULFATE	1 (0.7%)	0
BENZYLPENICILLIN SODIUM	1 (0.7%)	0
BEPOTASTINE SALICYLATE	1 (0.7%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (0.7%)	0
CETYLPYRIDINIUM CHLORIDE	1 (0.7%)	0
CIPROFLOXACIN LACTATE	1 (0.7%)	0
COLISTIN	0	1 (1.4%)
CYANOCOBALAMIN	1 (0.7%)	0
DESONIDE	1 (0.7%)	0
DICLOFENAC	1 (0.7%)	0
DIMETICONE	1 (0.7%)	0
FLUCONAZOLE	1 (0.7%)	0
FLUROMETHOLONE	0	1 (1.4%)
FLURBIPROFEN	0	1 (1.4%)
GATIFLOXACIN	0	1 (1.4%)
GLUCOSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	0	1 (1.4%)
HEPARIN	1 (0.7%)	0
HYALURONATE SODIUM	0	1 (1.4%)
HYPROMELLOSE	1 (0.7%)	0
INOSINE	1 (0.7%)	0
LEVOFLOXACIN HEMIHYDRATE	1 (0.7%)	0
MOXIFLOXACIN	1 (0.7%)	0
MOXIFLOXACIN HYDROCHLORIDE	0	1 (1.4%)
NEOSTIGMINE METILSULFATE	1 (0.7%)	0
OXYTETRACYCLINE HYDROCHLORIDE; POLYMYXIN B SULFATE	0	1 (1.4%)
PHOSPHORIC ACID	1 (0.7%)	0
PREDNISOLONE VALEROACETATE	0	1 (1.4%)
PROXYMETACAINE HYDROCHLORIDE	0	1 (1.4%)
RIFAMPICIN	0	1 (1.4%)
SEA WATER	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.7%)	0
SPAGLUMIC ACID	0	1 (1.4%)
TETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0
VIDARABINE	0	1 (1.4%)
ANTIBACTERIALS FOR SYSTEMIC USE		

Total number of patients with at least one treatment	39 (28.9%)	29 (42.0%)
Total number of treatments	108	52
CIPROFLOXACIN	8 (5.9%)	4 (5.8%)
LEVOFLOXACIN	6 (4.4%)	4 (5.8%)
PHENOXYMETHYLPENICILLIN	7 (5.2%)	3 (4.3%)
AMOXICILLIN;CLAVULANATE POTASSIUM	4 (3.0%)	1 (1.4%)
AMOXICILLIN	4 (3.0%)	0
AZITHROMYCIN	1 (0.7%)	3 (4.3%)
CEFTRIAZONE	3 (2.2%)	1 (1.4%)
CEFUROXIME AXETIL	1 (0.7%)	3 (4.3%)
CEFACTOR	2 (1.5%)	1 (1.4%)
CEFALEXIN	0	3 (4.3%)
DOXYCYCLINE	3 (2.2%)	0
AMPICILLIN SODIUM;SULBACTAM SODIUM	2 (1.5%)	0
BENZATHINE BENZYL PENICILLIN	0	2 (2.9%)
CEFOPERAZONE SODIUM;SULBACTAM SODIUM	1 (0.7%)	1 (1.4%)
CEFTAZIDIME	1 (0.7%)	1 (1.4%)
CEFTRIAZONE SODIUM	2 (1.5%)	0
CEFUROXIME	1 (0.7%)	1 (1.4%)
CLARITHROMYCIN	0	2 (2.9%)
MEROPENEM	0	2 (2.9%)
METRONIDAZOLE	2 (1.5%)	0
PENICILLIN NOS	2 (1.5%)	0
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	2 (1.5%)	0
SULFAMETHOXAZOLE;TRIMETHOPRIM	1 (0.7%)	1 (1.4%)
VANCOMYCIN	1 (0.7%)	1 (1.4%)
AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	1 (0.7%)	0
AMOXICILLIN TRIHYDRATE	0	1 (1.4%)
AMOXICILLIN;CLAVULANIC ACID	1 (0.7%)	0
BENZYL PENICILLIN SODIUM	1 (0.7%)	0
CEFAZOLIN	0	1 (1.4%)
CEFDINIR	0	1 (1.4%)
CEFEPIME HYDROCHLORIDE	1 (0.7%)	0
CEFIXIME	1 (0.7%)	0
CEFMINOX	1 (0.7%)	0
CEFODIZIME DISODIUM	1 (0.7%)	0
CEFOPERAZONE;SULBACTAM	1 (0.7%)	0
CEFOTAXIME SODIUM	0	1 (1.4%)
CIPROFLOXACIN LACTATE	1 (0.7%)	0
CLINDAMYCIN	0	1 (1.4%)
COLISTIN	0	1 (1.4%)
DAPTOMYCIN	1 (0.7%)	0

DICLOXACILLIN	1 (0.7%)	0
ERTAPENEM	1 (0.7%)	0
GATIFLOXACIN	0	1 (1.4%)
LEVOFLOXACIN HEMIHYDRATE	1 (0.7%)	0
LINEZOLID	0	1 (1.4%)
MECILLINAM	0	1 (1.4%)
MEROPENEM TRIHYDRATE	1 (0.7%)	0
MOXIFLOXACIN	1 (0.7%)	0
MOXIFLOXACIN HYDROCHLORIDE	0	1 (1.4%)
NITROFURANTOIN	0	1 (1.4%)
PHENOXYMETHYLPENICILLIN POTASSIUM	1 (0.7%)	0
PIPERACILLIN;TAZOBACTAM	0	1 (1.4%)
RIFAMPICIN	0	1 (1.4%)
TEICOPLANIN	1 (0.7%)	0
TETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0
TIGECYCLINE	1 (0.7%)	0
VACCINES		
Total number of patients with at least one treatment	46 (34.1%)	16 (23.2%)
Total number of treatments	87	27
TOZINAMERAN	14 (10.4%)	7 (10.1%)
ELASOMERAN	10 (7.4%)	4 (5.8%)
COVID-19 VACCINE	7 (5.2%)	1 (1.4%)
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)	4 (3.0%)	1 (1.4%)
INFLUENZA VACCINE	4 (3.0%)	1 (1.4%)
MENINGOCOCCAL VACCINE A/C/Y/W	5 (3.7%)	0
MENINGOCOCCAL VACCINE B	5 (3.7%)	0
COVID-19 VACCINE INACT (VERO) CZ02	3 (2.2%)	1 (1.4%)
INFLUENZA VACCINE INACT SPLIT 4V	3 (2.2%)	1 (1.4%)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (TET TOX)	3 (2.2%)	1 (1.4%)
MENINGOCOCCAL VACCINE B RFHBP/NADA/NHBA OMV	4 (3.0%)	0
HEPATITIS B VACCINE	2 (1.5%)	1 (1.4%)
PNEUMOCOCCAL VACCINE	3 (2.2%)	0
PNEUMOCOCCAL VACCINE POLYSACCH 23V	1 (0.7%)	2 (2.9%)
COVID-19 VACCINE INACT (VERO)	1 (0.7%)	0
COVID-19 VACCINE NRVV AD26 (JNJ 78436735)	1 (0.7%)	0
DIPHThERIA VACCINE	0	1 (1.4%)
HEPATITIS A VACCINE	1 (0.7%)	0
HEPATITIS A VACCINE INACT	0	1 (1.4%)
HEPATITIS B VACCINE RHBSAG (YEAST)	0	1 (1.4%)
HIB VACCINE	1 (0.7%)	0
INFLUENZA VACCINE INACT SAG 4V	1 (0.7%)	0

MENINGOCOCCAL VACCINE A/C/Y/W POLYSACCH	1 (0.7%)	0
TETANUS VACCINE	0	1 (1.4%)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS		
Total number of patients with at least one treatment	37 (27.4%)	22 (31.9%)
Total number of treatments	106	67
METHYLPREDNISOLONE	9 (6.7%)	5 (7.2%)
PREDNISOLONE	10 (7.4%)	4 (5.8%)
PREDNISON ACETATE	10 (7.4%)	2 (2.9%)
DEXAMETHASONE SODIUM PHOSPHATE	3 (2.2%)	3 (4.3%)
HYDROCORTISONE	2 (1.5%)	3 (4.3%)
PREDNISON	1 (0.7%)	4 (5.8%)
DEXAMETHASONE	2 (1.5%)	2 (2.9%)
METHYLPREDNISOLONE SODIUM SUCCINATE	2 (1.5%)	1 (1.4%)
FLUTICASONE	1 (0.7%)	1 (1.4%)
HYDROCORTISONE SODIUM SUCCINATE	2 (1.5%)	0
BETAMETHASONE DIPROPIONATE;CLOTRIMAZOLE;GENTAMICIN SULFATE	1 (0.7%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (0.7%)	0
BUDESONIDE	1 (0.7%)	0
CLOBETASOL PROPIONATE	1 (0.7%)	0
DESONIDE	1 (0.7%)	0
FLUOROMETHOLONE	0	1 (1.4%)
MOMETASONE	1 (0.7%)	0
PREDNISOLONE VALEROACETATE	0	1 (1.4%)
CORTICOSTEROIDS FOR SYSTEMIC USE		
Total number of patients with at least one treatment	36 (26.7%)	21 (30.4%)
Total number of treatments	102	65
METHYLPREDNISOLONE	9 (6.7%)	5 (7.2%)
PREDNISOLONE	10 (7.4%)	4 (5.8%)
PREDNISON ACETATE	10 (7.4%)	2 (2.9%)
DEXAMETHASONE SODIUM PHOSPHATE	3 (2.2%)	3 (4.3%)
HYDROCORTISONE	2 (1.5%)	3 (4.3%)
PREDNISON	1 (0.7%)	4 (5.8%)
DEXAMETHASONE	2 (1.5%)	2 (2.9%)
METHYLPREDNISOLONE SODIUM SUCCINATE	2 (1.5%)	1 (1.4%)
HYDROCORTISONE SODIUM SUCCINATE	2 (1.5%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (0.7%)	0
BETAMETHASONE;DEXCHLORPHENIRAMINE MALEATE	1 (0.7%)	0
MEPREDNISON	1 (0.7%)	0
PREDNISOLONE VALEROACETATE	0	1 (1.4%)

OTOLOGICALS		
Total number of patients with at least one treatment	30 (22.2%)	20 (29.0%)
Total number of treatments	80	66
PREDNISOLONE	10 (7.4%)	4 (5.8%)
CIPROFLOXACIN	8 (5.9%)	4 (5.8%)
SODIUM BICARBONATE	5 (3.7%)	6 (8.7%)
LEVOFLOXACIN	6 (4.4%)	4 (5.8%)
DEXAMETHASONE SODIUM PHOSPHATE	3 (2.2%)	3 (4.3%)
HYDROCORTISONE	2 (1.5%)	3 (4.3%)
DEXAMETHASONE	2 (1.5%)	2 (2.9%)
LIDOCAINE HYDROCHLORIDE	1 (0.7%)	2 (2.9%)
HYDROCORTISONE SODIUM SUCCINATE	2 (1.5%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (0.7%)	0
CHOLINE SALICYLATE	1 (0.7%)	0
LEVOFLOXACIN HEMIHYDRATE	1 (0.7%)	0
PREDNISOLONE VALEROACETATE	0	1 (1.4%)
SEA WATER	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.7%)	0
TETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS		
Total number of patients with at least one treatment	31 (23.0%)	18 (26.1%)
Total number of treatments	97	40
PREDNISOLONE	10 (7.4%)	4 (5.8%)
PREDNISONE ACETATE	10 (7.4%)	2 (2.9%)
HYDROCORTISONE	2 (1.5%)	3 (4.3%)
PREDNISONE	1 (0.7%)	4 (5.8%)
HYDROCORTISONE SODIUM SUCCINATE	2 (1.5%)	0
NYSTATIN	2 (1.5%)	0
VANCOMYCIN	1 (0.7%)	1 (1.4%)
ATROPINE SULFATE;DIPHENOXYLATE HYDROCHLORIDE	0	1 (1.4%)
BACILLUS LICHENFORMIS	0	1 (1.4%)
BACILLUS SUBTILIS	1 (0.7%)	0
BERBERINE	1 (0.7%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (0.7%)	0
BIFIDOBACTERIUM LONGUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	0	1 (1.4%)
BUDESONIDE	1 (0.7%)	0
COLISTIN	0	1 (1.4%)
ELECTROLYTES NOS;GLUCOSE	1 (0.7%)	0
ENTEROCOCCUS FAECIUM;LACTOBACILLUS RHAMNOSUS	0	1 (1.4%)
GLUCOSE;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	0	1 (1.4%)
GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	0	1 (1.4%)

GLUCOSE; POTASSIUM; SODIUM	1 (0.7%)	0
LOPERAMIDE	1 (0.7%)	0
MACROGOL 4000; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE	1 (0.7%)	0
MONTMORILLONITE	0	1 (1.4%)
ORAL REHYDRATION SALT FORMULATIONS	0	1 (1.4%)
SACCHAROMYCES BOULARDII	1 (0.7%)	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
ANALGESICS		
Total number of patients with at least one treatment	36 (26.7%)	12 (17.4%)
Total number of treatments	65	27
PARACETAMOL	28 (20.7%)	10 (14.5%)
ACETYLSALICYLIC ACID; CAFFEINE; PARACETAMOL	2 (1.5%)	0
METAMIZOLE SODIUM	2 (1.5%)	0
PARACETAMOL; TRAMADOL HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
AMANTADINE HYDROCHLORIDE; CAFFEINE; CHLORPHENAMINE MALEATE; COW BEZOAR; PARACETAMOL	1 (0.7%)	0
CAFFEINE; CHLORPHENAMINE MALEATE; DIHYDROCODEINE PHOSPHATE; GUAIFENESIN; METHYLEPHEDRINE HYDROCHLORIDE-DL; PARACETAMOL; RIBOFLAVIN	0	1 (1.4%)
CAFFEINE; CHLORPHENAMINE; PARACETAMOL	1 (0.7%)	0
CHLORPHENAMINE MALEATE; PARACETAMOL; PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.7%)	0
CHOLINE SALICYLATE	1 (0.7%)	0
DEZOCINE	1 (0.7%)	0
FENTANYL	0	1 (1.4%)
FENTANYL CITRATE	0	1 (1.4%)
METOPROLOL	1 (0.7%)	0
OXYCODONE	0	1 (1.4%)
PHLOMOIDES ROTATA HERB	1 (0.7%)	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
SUFENTANIL	1 (0.7%)	0
TRAMADOL	0	1 (1.4%)
VITEX NEGUNDO	1 (0.7%)	0
STOMATOLOGICAL PREPARATIONS		
Total number of patients with at least one treatment	28 (20.7%)	18 (26.1%)
Total number of treatments	96	63
PREDNISOLONE	10 (7.4%)	4 (5.8%)
SODIUM BICARBONATE	5 (3.7%)	6 (8.7%)
DEXAMETHASONE SODIUM PHOSPHATE	3 (2.2%)	3 (4.3%)
HYDROCORTISONE	2 (1.5%)	3 (4.3%)
DEXAMETHASONE	2 (1.5%)	2 (2.9%)
DOXYCYCLINE	3 (2.2%)	0
LIDOCAINE HYDROCHLORIDE	1 (0.7%)	2 (2.9%)
TRANEXAMIC ACID	2 (1.5%)	1 (1.4%)

EPINEPHRINE	1 (0.7%)	1 (1.4%)
HYDROCORTISONE SODIUM SUCCINATE	2 (1.5%)	0
METRONIDAZOLE	2 (1.5%)	0
NAPROXEN	1 (0.7%)	1 (1.4%)
NYSTATIN	2 (1.5%)	0
POTASSIUM	1 (0.7%)	1 (1.4%)
CETYLPYRIDINIUM CHLORIDE	1 (0.7%)	0
CHOLINE SALICYLATE	1 (0.7%)	0
CLOBETASOL PROPIONATE	1 (0.7%)	0
DICLOFENAC	1 (0.7%)	0
DIMETICONE	1 (0.7%)	0
FLURBIPROFEN	0	1 (1.4%)
HYALURONATE SODIUM	0	1 (1.4%)
KETOPROFEN	1 (0.7%)	0
NIMESULIDE	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.7%)	0
TETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0
NASAL PREPARATIONS		
Total number of patients with at least one treatment	25 (18.5%)	15 (21.7%)
Total number of treatments	66	56
PREDNISOLONE	10 (7.4%)	4 (5.8%)
SODIUM BICARBONATE	5 (3.7%)	6 (8.7%)
ACETYLCYSTEINE	5 (3.7%)	1 (1.4%)
DEXAMETHASONE SODIUM PHOSPHATE	3 (2.2%)	3 (4.3%)
DEXAMETHASONE	2 (1.5%)	2 (2.9%)
EPINEPHRINE	1 (0.7%)	1 (1.4%)
FLUTICASONE	1 (0.7%)	1 (1.4%)
MUPIROCIN	1 (0.7%)	1 (1.4%)
PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE	2 (1.5%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (0.7%)	0
BUDESONIDE	1 (0.7%)	0
FLUTICASONE FUROATE	1 (0.7%)	0
HYALURONATE SODIUM	0	1 (1.4%)
HYPROMELLOSE	1 (0.7%)	0
IPRATROPIUM BROMIDE	1 (0.7%)	0
MOMETASONE	1 (0.7%)	0
SEA WATER	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.7%)	0
SPAGLUMIC ACID	0	1 (1.4%)
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS		

Total number of patients with at least one treatment	24 (17.8%)	16 (23.2%)
Total number of treatments	63	51
PREDNISOLONE	10 (7.4%)	4 (5.8%)
CIPROFLOXACIN	8 (5.9%)	4 (5.8%)
LEVOFLOXACIN	6 (4.4%)	4 (5.8%)
DEXAMETHASONE SODIUM PHOSPHATE	3 (2.2%)	3 (4.3%)
DEXAMETHASONE	2 (1.5%)	2 (2.9%)
BETAMETHASONE SODIUM PHOSPHATE	1 (0.7%)	0
CIPROFLOXACIN LACTATE	1 (0.7%)	0
GATIFLOXACIN	0	1 (1.4%)
LEVOFLOXACIN HEMIHYDRATE	1 (0.7%)	0
OXYTETRACYCLINE HYDROCHLORIDE;POLYMYXIN B SULFATE	0	1 (1.4%)
PREDNISOLONE VALEROACETATE	0	1 (1.4%)
TETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0
ANTIHISTAMINES FOR SYSTEMIC USE		
Total number of patients with at least one treatment	24 (17.8%)	15 (21.7%)
Total number of treatments	45	42
CHLORPHENAMINE	10 (7.4%)	5 (7.2%)
PROMETHAZINE	0	5 (7.2%)
CHLORPHENAMINE MALEATE	2 (1.5%)	1 (1.4%)
HYDROXYZINE	2 (1.5%)	1 (1.4%)
LORATADINE	1 (0.7%)	2 (2.9%)
PROMETHAZINE HYDROCHLORIDE	2 (1.5%)	1 (1.4%)
CETIRIZINE HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
BEPOTASTINE SALICYLATE	1 (0.7%)	0
DESLORATADINE	1 (0.7%)	0
DEXCHLORPHENIRAMINE MALEATE	1 (0.7%)	0
DIMENHYDRINATE	1 (0.7%)	0
DIPHENHYDRAMINE	1 (0.7%)	0
DOXYLAMINE SUCCINATE	1 (0.7%)	0
HYDROXYZINE HYDROCHLORIDE	0	1 (1.4%)
LEVOCETIRIZINE	1 (0.7%)	0
LEVOCETIRIZINE DIHYDROCHLORIDE	1 (0.7%)	0
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.		
Total number of patients with at least one treatment	22 (16.3%)	16 (23.2%)
Total number of treatments	43	45
CHLORPHENAMINE	10 (7.4%)	5 (7.2%)
PROMETHAZINE	0	5 (7.2%)
CHLORPHENAMINE MALEATE	2 (1.5%)	1 (1.4%)

HYDROXYZINE	2 (1.5%)	1 (1.4%)
LIDOCAINE HYDROCHLORIDE	1 (0.7%)	2 (2.9%)
LORATADINE	1 (0.7%)	2 (2.9%)
PROMETHAZINE HYDROCHLORIDE	2 (1.5%)	1 (1.4%)
CETIRIZINE HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
DES Loratadine	1 (0.7%)	0
DEXCHLORPHENIRAMINE MALEATE	1 (0.7%)	0
DIPHENHYDRAMINE	1 (0.7%)	0
HYDROXYZINE HYDROCHLORIDE	0	1 (1.4%)
LEVOCETIRIZINE	1 (0.7%)	0
LEVOCETIRIZINE DIHYDROCHLORIDE	1 (0.7%)	0
ANTI-ACNE PREPARATIONS		
Total number of patients with at least one treatment	20 (14.8%)	15 (21.7%)
Total number of treatments	63	42
METHYLPREDNISOLONE	9 (6.7%)	5 (7.2%)
IBUPROFEN	4 (3.0%)	3 (4.3%)
DEXAMETHASONE SODIUM PHOSPHATE	3 (2.2%)	3 (4.3%)
AZITHROMYCIN	1 (0.7%)	3 (4.3%)
DEXAMETHASONE	2 (1.5%)	2 (2.9%)
DOXYCYCLINE	3 (2.2%)	0
METHYLPREDNISOLONE SODIUM SUCCINATE	2 (1.5%)	1 (1.4%)
CLINDAMYCIN	0	1 (1.4%)
DIMETICONE	1 (0.7%)	0
FLUOROMETHOLONE	0	1 (1.4%)
ANTIANEMIC PREPARATIONS		
Total number of patients with at least one treatment	21 (15.6%)	12 (17.4%)
Total number of treatments	29	15
FOLIC ACID	8 (5.9%)	8 (11.6%)
VITAMIN B12 NOS	3 (2.2%)	0
DARBEPOETIN ALFA	2 (1.5%)	0
EPOETIN ALFA	2 (1.5%)	0
EPOETIN BETA	2 (1.5%)	0
FERROUS SULFATE	2 (1.5%)	0
MECOBALAMIN	0	2 (2.9%)
VITAMIN B NOS	0	2 (2.9%)
ASCORBIC ACID;FERROUS SULFATE	1 (0.7%)	0
CYANOCOBALAMIN	1 (0.7%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE	1 (0.7%)	0
ERYTHROPOIETIN	1 (0.7%)	0

FERRIC HYDROXIDE POLYMALTOSE COMPLEX	1 (0.7%)	0
FERROUS SUCCINATE	0	1 (1.4%)
FERROUS SULFATE;FOLIC ACID	0	1 (1.4%)
IRON	1 (0.7%)	0
IRON POLYSACCHARIDE COMPLEX	0	1 (1.4%)
ROXADUSTAT	1 (0.7%)	0
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE		
Total number of patients with at least one treatment	18 (13.3%)	13 (18.8%)
Total number of treatments	30	16
CIPROFLOXACIN	8 (5.9%)	4 (5.8%)
LEVOFLOXACIN	6 (4.4%)	4 (5.8%)
DOXYCYCLINE	3 (2.2%)	0
CLARITHROMYCIN	0	2 (2.9%)
METRONIDAZOLE	2 (1.5%)	0
MUPIROCIN	1 (0.7%)	1 (1.4%)
ACICLOVIR	0	1 (1.4%)
INOSINE	1 (0.7%)	0
MOXIFLOXACIN	1 (0.7%)	0
OXYTETRACYCLINE HYDROCHLORIDE;POLYMYXIN B SULFATE	0	1 (1.4%)
RIFAMPICIN	0	1 (1.4%)
TETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0
VIDARABINE	0	1 (1.4%)
VASOPROTECTIVES		
Total number of patients with at least one treatment	19 (14.1%)	12 (17.4%)
Total number of treatments	61	48
PREDNISOLONE	10 (7.4%)	4 (5.8%)
DEXAMETHASONE SODIUM PHOSPHATE	3 (2.2%)	3 (4.3%)
HYDROCORTISONE	2 (1.5%)	3 (4.3%)
DEXAMETHASONE	2 (1.5%)	2 (2.9%)
LIDOCAINE HYDROCHLORIDE	1 (0.7%)	2 (2.9%)
HYDROCORTISONE SODIUM SUCCINATE	2 (1.5%)	0
ASCORBIC ACID;RUTOSIDE	1 (0.7%)	0
BENZOCAINE;BISMUTH SUBGALLATE;DIPHENHYDRAMINE HYDROCHLORIDE;ZINC OXIDE	1 (0.7%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (0.7%)	0
DIETHYLAMINE SALICYLATE;ESGIN	1 (0.7%)	0
FLUOROMETHOLONE	0	1 (1.4%)
HEPARIN	1 (0.7%)	0
HYALURONATE SODIUM	0	1 (1.4%)
PREDNISOLONE VALEROACETATE	0	1 (1.4%)
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0

DRUGS FOR ACID RELATED DISORDERS		
Total number of patients with at least one treatment	15 (11.1%)	13 (18.8%)
Total number of treatments	34	29
SODIUM BICARBONATE	5 (3.7%)	6 (8.7%)
FAMOTIDINE	2 (1.5%)	2 (2.9%)
OMEPRAZOLE	1 (0.7%)	3 (4.3%)
ESOMEPRAZOLE	2 (1.5%)	1 (1.4%)
PANTOPRAZOLE	1 (0.7%)	2 (2.9%)
ALUMINIUM HYDROXIDE	1 (0.7%)	0
ANTACIDS WITH ANTIFLATULENTS	0	1 (1.4%)
ANTACIDS, OTHER COMBINATIONS	1 (0.7%)	0
CALCIUM CARBONATE	0	1 (1.4%)
ESOMEPRAZOLE SODIUM	1 (0.7%)	0
GLYCYRRHIZA GLABRA	0	1 (1.4%)
ILAPRAZOLE SODIUM	1 (0.7%)	0
LANSOPRAZOLE	1 (0.7%)	0
MAGNESIUM OXIDE	1 (0.7%)	0
MONTMORILLONITE	0	1 (1.4%)
OMEPRAZOLE SODIUM	0	1 (1.4%)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	1 (0.7%)	0
PERIPLANETA AMERICANA	1 (0.7%)	0
RABEPRAZOLE SODIUM	1 (0.7%)	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
VONOPRAZAN FUMARATE	0	1 (1.4%)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN		
Total number of patients with at least one treatment	16 (11.9%)	11 (15.9%)
Total number of treatments	19	13
FOLIC ACID	8 (5.9%)	8 (11.6%)
IBUPROFEN	4 (3.0%)	3 (4.3%)
NAPROXEN	1 (0.7%)	1 (1.4%)
DICLOFENAC	1 (0.7%)	0
DIETHYLAMINE SALICYLATE;ESGIN	1 (0.7%)	0
FLURBIPROFEN	0	1 (1.4%)
KETOPROFEN	1 (0.7%)	0
NIMESULIDE	1 (0.7%)	0
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS		
Total number of patients with at least one treatment	13 (9.6%)	13 (18.8%)
Total number of treatments	107	23
SODIUM BICARBONATE	5 (3.7%)	6 (8.7%)

POTASSIUM CHLORIDE	6 (4.4%)	4 (5.8%)
ALBUMIN HUMAN	1 (0.7%)	1 (1.4%)
POTASSIUM	1 (0.7%)	1 (1.4%)
ALANYL GLUTAMINE	1 (0.7%)	0
AMINO ACIDS NOS	1 (0.7%)	0
AMINO ACIDS NOS;CARBOHYDRATES NOS;ELECTROLYTES NOS	1 (0.7%)	0
AMINO ACIDS NOS;ELECTROLYTES NOS;GLUCOSE	1 (0.7%)	0
AMINO ACIDS NOS;ELECTROLYTES NOS;GLUCOSE;THIAMINE HYDROCHLORIDE	1 (0.7%)	0
AMINO ACIDS NOS;FATS NOS;GLUCOSE	1 (0.7%)	0
BLOOD PLASMA	1 (0.7%)	0
CALCIUM CHLORIDE;GLUCOSE	1 (0.7%)	0
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE	1 (0.7%)	0
CALCIUM GLUCONATE	1 (0.7%)	0
CALCIUM GLUCONATE;CALCIUM SACCHARATE	1 (0.7%)	0
CETYLPIRIDINIUM CHLORIDE	1 (0.7%)	0
CHROMIC CHLORIDE;COPPER CHLORIDE DIHYDRATE;FERRIC CHLORIDE HEXAHYDRATE;MANGANESE CHLORIDE TETRAHYDRATE;POTASSIUM IODIDE;SODIUM FLUORIDE;SODIUM MOLYBDATE DIHYDRATE;SODIUM SELENITE;ZINC CHLORIDE	1 (0.7%)	0
ELECTROLYTES NOS;GLUCOSE	1 (0.7%)	0
FATS NOS	1 (0.7%)	0
GLUCONATE SODIUM;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	0	1 (1.4%)
GLUCOSE;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	0	1 (1.4%)
GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	0	1 (1.4%)
GLUCOSE;POTASSIUM;SODIUM	1 (0.7%)	0
MAGNESIUM SULFATE	1 (0.7%)	0
MANNITOL	1 (0.7%)	0
NUTRIENTS NOS	1 (0.7%)	0
PHOSPHORIC ACID	1 (0.7%)	0
PLATELETS	0	1 (1.4%)
PLATELETS, CONCENTRATED	1 (0.7%)	0
POTASSIUM PHOSPHATE MONOBASIC	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.7%)	0
VITAMINS NOS	1 (0.7%)	0
IMMUNOSTIMULANTS		
Total number of patients with at least one treatment	13 (9.6%)	10 (14.5%)
Total number of treatments	27	18
GRANULOCYTE COLONY STIMULATING FACTOR	5 (3.7%)	5 (7.2%)
FILGRASTIM	4 (3.0%)	1 (1.4%)
GLUTATHIONE	1 (0.7%)	3 (4.3%)
LENOGRASTIM	0	1 (1.4%)
LEUCOGEN	1 (0.7%)	0

MANNITOL;NARTOGRASTIM	1 (0.7%)	0
PEGYLATED GRANULOCYTE COLONY STIMULATING FACTOR	1 (0.7%)	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
OTHER GYNECOLOGICALS		
Total number of patients with at least one treatment	14 (10.4%)	9 (13.0%)
Total number of treatments	15	16
SODIUM BICARBONATE	5 (3.7%)	6 (8.7%)
IBUPROFEN	4 (3.0%)	3 (4.3%)
NAPROXEN	1 (0.7%)	1 (1.4%)
HYALURONATE SODIUM	0	1 (1.4%)
METHOTREXATE	1 (0.7%)	0
PHLOMOIDES ROTATA HERB	1 (0.7%)	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
VITEX NEGUNDO	1 (0.7%)	0
PSYCHOLEPTICS		
Total number of patients with at least one treatment	12 (8.9%)	11 (15.9%)
Total number of treatments	42	12
PROMETHAZINE	0	5 (7.2%)
ESTAZOLAM	3 (2.2%)	0
HYDROXYZINE	2 (1.5%)	1 (1.4%)
PROMETHAZINE HYDROCHLORIDE	2 (1.5%)	1 (1.4%)
ALPRAZOLAM	1 (0.7%)	1 (1.4%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
LORAZEPAM	2 (1.5%)	0
BROMAZEPAM	1 (0.7%)	0
CHLORPROMAZINE	0	1 (1.4%)
CHLORPROMAZINE HYDROCHLORIDE	1 (0.7%)	0
DEXMEDETOMIDINE HYDROCHLORIDE	1 (0.7%)	0
DIPHENHYDRAMINE	1 (0.7%)	0
DOXYLAMINE SUCCINATE	1 (0.7%)	0
HYDROXYZINE HYDROCHLORIDE	0	1 (1.4%)
LITHIUM CARBONATE	1 (0.7%)	0
MIDAZOLAM	0	1 (1.4%)
OXAZEPAM	1 (0.7%)	0
PROCHLORPERAZINE MESILATE	1 (0.7%)	0
QUETIAPINE FUMARATE	1 (0.7%)	0
REMIMAZOLAM BESYLATE	1 (0.7%)	0
VITEX NEGUNDO	1 (0.7%)	0
ZOLPIDEM TARTRATE	1 (0.7%)	0

ALL OTHER THERAPEUTIC PRODUCTS		
Total number of patients with at least one treatment	15 (11.1%)	7 (10.1%)
Total number of treatments	32	9
ACETYLCYSTEINE	5 (3.7%)	1 (1.4%)
GLUTATHIONE	1 (0.7%)	3 (4.3%)
DEFERASIROX	3 (2.2%)	0
VITAMIN B12 NOS	3 (2.2%)	0
ASCORBIC ACID	1 (0.7%)	1 (1.4%)
ATROPINE	1 (0.7%)	1 (1.4%)
ADENOSINE	1 (0.7%)	0
ALL OTHER THERAPEUTIC PRODUCTS	1 (0.7%)	0
ALUMINIUM HYDROXIDE	1 (0.7%)	0
ATROPINE SULFATE	1 (0.7%)	0
CALCIUM CARBONATE	0	1 (1.4%)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE	1 (0.7%)	0
DEFERIPRONE	0	1 (1.4%)
DEFEROXAMINE	1 (0.7%)	0
DEFEROXAMINE MESILATE	1 (0.7%)	0
INOSINE	1 (0.7%)	0
IRON	1 (0.7%)	0
PHOSPHORIC ACID	1 (0.7%)	0
MINERAL SUPPLEMENTS		
Total number of patients with at least one treatment	13 (9.6%)	9 (13.0%)
Total number of treatments	37	13
POTASSIUM CHLORIDE	6 (4.4%)	4 (5.8%)
CALCIUM CARBONATE;COLECALCIFEROL	1 (0.7%)	1 (1.4%)
POTASSIUM	1 (0.7%)	1 (1.4%)
POTASSIUM CITRATE	1 (0.7%)	1 (1.4%)
CALCIUM CARBONATE	0	1 (1.4%)
CALCIUM CARBONATE;ERGOCALCIFEROL	1 (0.7%)	0
CALCIUM CHLORIDE;GLUCOSE	1 (0.7%)	0
CALCIUM GLUCONATE	1 (0.7%)	0
CALCIUM GLUCONATE;CALCIUM SACCHARATE	1 (0.7%)	0
CALCIUM PHOSPHATE;COLECALCIFEROL	1 (0.7%)	0
CHROMIC CHLORIDE;COPPER CHLORIDE DIHYDRATE;FERRIC CHLORIDE HEXAHYDRATE;MANGANESE CHLORIDE TETRAHYDRATE;POTASSIUM IODIDE;SODIUM FLUORIDE;SODIUM MOLYBDATE DIHYDRATE;SODIUM SELENITE;ZINC CHLORIDE	1 (0.7%)	0
MAGNESIUM ASPARTATE;POTASSIUM ASPARTATE	0	1 (1.4%)
MAGNESIUM OXIDE	1 (0.7%)	0
MAGNESIUM SULFATE	1 (0.7%)	0
MAGNESIUM;PYRIDOXINE HYDROCHLORIDE	0	1 (1.4%)
POTASSIUM GLUCONATE	1 (0.7%)	0

POTASSIUM PHOSPHATE MONOBASIC	1 (0.7%)	0
SODIUM	0	1 (1.4%)
SODIUM CHLORIDE	1 (0.7%)	0
ZINC OXIDE	1 (0.7%)	0
OTHER DERMATOLOGICAL PREPARATIONS		
Total number of patients with at least one treatment	13 (9.6%)	9 (13.0%)
Total number of treatments	22	20
SODIUM BICARBONATE	5 (3.7%)	6 (8.7%)
IBUPROFEN	4 (3.0%)	3 (4.3%)
TRANEXAMIC ACID	2 (1.5%)	1 (1.4%)
ASCORBIC ACID	1 (0.7%)	1 (1.4%)
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID, AMMONIUM SALT	1 (0.7%)	1 (1.4%)
PHYTOMENADIONE	1 (0.7%)	1 (1.4%)
CALCIUM GLUCONATE	1 (0.7%)	0
DICLOFENAC	1 (0.7%)	0
HYALURONATE SODIUM	0	1 (1.4%)
MAGNESIUM SULFATE	1 (0.7%)	0
PYRIDOXINE HYDROCHLORIDE	1 (0.7%)	0
UROLOGICALS		
Total number of patients with at least one treatment	12 (8.9%)	10 (14.5%)
Total number of treatments	14	17
SODIUM BICARBONATE	5 (3.7%)	6 (8.7%)
LIDOCAINE HYDROCHLORIDE	1 (0.7%)	2 (2.9%)
DROTAVERINE HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
POTASSIUM CITRATE	1 (0.7%)	1 (1.4%)
BUDESONIDE	1 (0.7%)	0
HYALURONATE SODIUM	0	1 (1.4%)
OXYBUTYNIN HYDROCHLORIDE	1 (0.7%)	0
POTASSIUM PHOSPHATE MONOBASIC	1 (0.7%)	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
SILDENAFIL	1 (0.7%)	0
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS		
Total number of patients with at least one treatment	13 (9.6%)	8 (11.6%)
Total number of treatments	21	9
CIPROFLOXACIN	8 (5.9%)	4 (5.8%)
ASCORBIC ACID	1 (0.7%)	1 (1.4%)
METRONIDAZOLE	2 (1.5%)	0
NYSTATIN	2 (1.5%)	0
POTASSIUM	1 (0.7%)	1 (1.4%)

BERBERINE	1 (0.7%)	0
CIPROFLOXACIN LACTATE	1 (0.7%)	0
CLINDAMYCIN	0	1 (1.4%)
INOSINE	1 (0.7%)	0
OXYTETRACYCLINE HYDROCHLORIDE;POLYMYXIN B SULFATE	0	1 (1.4%)
SERTACONAZOLE NITRATE	1 (0.7%)	0
ANTIEMETICS AND ANTINAUSEANTS		
Total number of patients with at least one treatment	9 (6.7%)	11 (15.9%)
Total number of treatments	35	11
PROMETHAZINE	0	5 (7.2%)
HYDROXYZINE	2 (1.5%)	1 (1.4%)
PROMETHAZINE HYDROCHLORIDE	2 (1.5%)	1 (1.4%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
METOCLOPRAMIDE	2 (1.5%)	0
CHLORPROMAZINE	0	1 (1.4%)
CHLORPROMAZINE HYDROCHLORIDE	1 (0.7%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE	1 (0.7%)	0
DIMENHYDRINATE	1 (0.7%)	0
DIPHENHYDRAMINE	1 (0.7%)	0
DOMPERIDONE	0	1 (1.4%)
HYDROXYZINE HYDROCHLORIDE	0	1 (1.4%)
METOCLOPRAMIDE DIHYDROCHLORIDE	1 (0.7%)	0
METOCLOPRAMIDE HYDROCHLORIDE	1 (0.7%)	0
PROCHLORPERAZINE MESILATE	1 (0.7%)	0
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS		
Total number of patients with at least one treatment	13 (9.6%)	7 (10.1%)
Total number of treatments	21	8
IBUPROFEN	4 (3.0%)	3 (4.3%)
CELECOXIB	2 (1.5%)	1 (1.4%)
NAPROXEN	1 (0.7%)	1 (1.4%)
ADEMETHIONINE	1 (0.7%)	0
BAICALIN;BUFFALO HORN;CHOLIC ACID;CONCHA MARGARITIFERA;GARDENIA JASMINOIDES FRUIT;HYODEOXYCHOLIC ACID;ISATIS TINCTORIA ROOT;LONICERA JAPONICA FLOWER	0	1 (1.4%)
CORYDALIS BUNGEANA HERB;ISATIS TINCTORIA ROOT;SCUTELLARIA BAICALENSIS ROOT;TARAXACUM MONGOLICUM HERB	0	1 (1.4%)
DICLOFENAC	1 (0.7%)	0
ETORICOXIB	1 (0.7%)	0
FISH OIL	1 (0.7%)	0
FLURBIPROFEN	0	1 (1.4%)
KETOPROFEN	1 (0.7%)	0
NIMESULIDE	1 (0.7%)	0

TENOXCAM	1 (0.7%)	0
VITEX NEGUNDO	1 (0.7%)	0
BILE AND LIVER THERAPY		
Total number of patients with at least one treatment	11 (8.1%)	9 (13.0%)
Total number of treatments	15	23
ACETYLCYSTEINE	5 (3.7%)	1 (1.4%)
LACTULOSE	0	4 (5.8%)
URSODEOXYCHOLIC ACID	3 (2.2%)	1 (1.4%)
DIAMMONIUM GLYCYRRHIZINATE	1 (0.7%)	2 (2.9%)
POLYENE PHOSPHATIDYLCHOLINE	0	3 (4.3%)
BICYCLOL	0	2 (2.9%)
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID, AMMONIUM SALT	1 (0.7%)	1 (1.4%)
DROTAVERINE HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
GLYCYRRHIZA GLABRA	0	1 (1.4%)
INOSINE	1 (0.7%)	0
ORNITHINE ASPARTATE	0	1 (1.4%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES		
Total number of patients with at least one treatment	11 (8.1%)	8 (11.6%)
Total number of treatments	18	29
DEXAMETHASONE SODIUM PHOSPHATE	3 (2.2%)	3 (4.3%)
DEXAMETHASONE	2 (1.5%)	2 (2.9%)
CHLORPHENAMINE MALEATE;GUAIFENESIN;THEOPHYLLINE	0	2 (2.9%)
EPINEPHRINE	1 (0.7%)	1 (1.4%)
FLUTICASONE	1 (0.7%)	1 (1.4%)
AMINOPHYLLINE;CHLORPHENAMINE MALEATE;METHOXYPHENAMINE HYDROCHLORIDE;NOSCAPINE	1 (0.7%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (0.7%)	0
BUDESONIDE	1 (0.7%)	0
BUDESONIDE;FORMOTEROL FUMARATE DIHYDRATE	1 (0.7%)	0
FENOTEROL HYDROBROMIDE;IPRATROPIUM BROMIDE	0	1 (1.4%)
FLUTICASONE FUROATE	1 (0.7%)	0
IPRATROPIUM BROMIDE	1 (0.7%)	0
MOMETASONE	1 (0.7%)	0
MONTELUKAST SODIUM	0	1 (1.4%)
VILANTEROL	1 (0.7%)	0
THROAT PREPARATIONS		
Total number of patients with at least one treatment	11 (8.1%)	8 (11.6%)
Total number of treatments	11	13
IBUPROFEN	4 (3.0%)	3 (4.3%)
AMBROXOL	0	3 (4.3%)

LIDOCAINE HYDROCHLORIDE	1 (0.7%)	2 (2.9%)
AMBROXOL HYDROCHLORIDE	0	1 (1.4%)
AMMONIUM CHLORIDE;GLYCYRRHIZA GLABRA	1 (0.7%)	0
CETYLPYRIDINIUM CHLORIDE	1 (0.7%)	0
DICLOFENAC	1 (0.7%)	0
FLURBIPROFEN	0	1 (1.4%)
GARDENIA JASMINOIDES FRUIT;ISATIS TINCTORIA ROOT;PHELLODENDRON CHINENSE BARK;SCAPHIUM AFFINE SEED;SCUTELLARIA BAICALENSIS ROOT	1 (0.7%)	0
KETOPROFEN	1 (0.7%)	0
TETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0
CARDIAC THERAPY		
Total number of patients with at least one treatment	13 (9.6%)	5 (7.2%)
Total number of treatments	21	9
IBUPROFEN	4 (3.0%)	3 (4.3%)
LIDOCAINE HYDROCHLORIDE	1 (0.7%)	2 (2.9%)
ATROPINE	1 (0.7%)	1 (1.4%)
EPINEPHRINE	1 (0.7%)	1 (1.4%)
ADENOSINE	1 (0.7%)	0
ATROPINE SULFATE	1 (0.7%)	0
EMPAGLIFLOZIN	1 (0.7%)	0
INOSINE	1 (0.7%)	0
IPRATROPIUM BROMIDE	1 (0.7%)	0
MAGNESIUM ASPARTATE;POTASSIUM ASPARTATE	0	1 (1.4%)
MAGNESIUM TANSINOATE B	1 (0.7%)	0
MELDONIUM	1 (0.7%)	0
NOREPINEPHRINE	1 (0.7%)	0
NOREPINEPHRINE BITARTRATE	1 (0.7%)	0
VITEX NEGUNDO	1 (0.7%)	0
COUGH AND COLD PREPARATIONS		
Total number of patients with at least one treatment	10 (7.4%)	8 (11.6%)
Total number of treatments	15	15
ACETYLCYSTEINE	5 (3.7%)	1 (1.4%)
AMBROXOL	0	3 (4.3%)
AMBROXOL HYDROCHLORIDE	0	1 (1.4%)
AMMONIUM CHLORIDE;CHLORPHENAMINE MALEATE;DIHYDROCODEINE BITARTRATE;METHYLEPHEDRINE HYDROCHLORIDE-DL	1 (0.7%)	0
AMMONIUM CHLORIDE;EPHEDRINE HYDROCHLORIDE;MENTHOL;PLATYCODON GRANDIFLORUS ROOT;POLYGALA SPP. ROOT;STEMONA SPP. ROOT TUBER	0	1 (1.4%)
AMMONIUM CHLORIDE;GLYCYRRHIZA GLABRA	1 (0.7%)	0
BROMHEXINE	1 (0.7%)	0
CHLORPHENAMINE MALEATE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.7%)	0

DEXTROMETHORPHAN	0	1 (1.4%)
EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;PRUNUS SPP. SEED;ZINGIBER OFFICINALE RHIZOME	0	1 (1.4%)
GLYCYRRHIZA GLABRA	0	1 (1.4%)
MAGNOLIA OFFICINALIS	0	1 (1.4%)
MANNITOL	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.7%)	0
VITEX NEGUNDO	1 (0.7%)	0
HOMEOPATHIC PREPARATION		
Total number of patients with at least one treatment	11 (8.1%)	7 (10.1%)
Total number of treatments	19	9
POTASSIUM CHLORIDE	6 (4.4%)	4 (5.8%)
ASCORBIC ACID	1 (0.7%)	1 (1.4%)
EPINEPHRINE	1 (0.7%)	1 (1.4%)
POTASSIUM	1 (0.7%)	1 (1.4%)
BACILLUS SUBTILIS	1 (0.7%)	0
CALCIUM CARBONATE	0	1 (1.4%)
CYANOCOBALAMIN	1 (0.7%)	0
IRON	1 (0.7%)	0
PHOSPHORIC ACID	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.7%)	0
IMMUNOSUPPRESSANTS		
Total number of patients with at least one treatment	12 (8.9%)	6 (8.7%)
Total number of treatments	32	9
CICLOSPORIN	10 (7.4%)	6 (8.7%)
AZATHIOPRINE	1 (0.7%)	0
BARICITINIB	1 (0.7%)	0
BELIMUMAB	1 (0.7%)	0
COLCHICINE	1 (0.7%)	0
HYDROXYCHLOROQUINE SULFATE	1 (0.7%)	0
LEFLUNOMIDE	1 (0.7%)	0
METHOTREXATE	1 (0.7%)	0
TOFACITINIB	1 (0.7%)	0
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS		
Total number of patients with at least one treatment	11 (8.1%)	7 (10.1%)
Total number of treatments	17	13
SODIUM BICARBONATE	5 (3.7%)	6 (8.7%)
ACETYLCYSTEINE	5 (3.7%)	1 (1.4%)
ADEMETHIONINE 1,4-BUTANEDISULFONATE	1 (0.7%)	1 (1.4%)
ADEMETHIONINE	1 (0.7%)	0

ALANYL GLUTAMINE	1 (0.7%)	0
AMINO ACIDS NOS	1 (0.7%)	0
DIAGNOSTIC AGENTS		
Total number of patients with at least one treatment	9 (6.7%)	8 (11.6%)
Total number of treatments	14	8
FOLIC ACID	8 (5.9%)	8 (11.6%)
MAGNESIUM SULFATE	1 (0.7%)	0
MANNITOL	1 (0.7%)	0
ANTITHROMBOTIC AGENTS		
Total number of patients with at least one treatment	9 (6.7%)	5 (7.2%)
Total number of treatments	31	6
WARFARIN	3 (2.2%)	1 (1.4%)
ENOXAPARIN SODIUM	2 (1.5%)	1 (1.4%)
ENOXAPARIN	1 (0.7%)	1 (1.4%)
BEMIPARIN	1 (0.7%)	0
CILOSTAZOL	1 (0.7%)	0
EDOXABAN TOSILATE	1 (0.7%)	0
HEPARIN	1 (0.7%)	0
LOW MOLECULAR WEIGHT HEPARIN	0	1 (1.4%)
RIVAROXABAN	0	1 (1.4%)
WARFARIN SODIUM	1 (0.7%)	0
ANTIHEMORRHAGICS		
Total number of patients with at least one treatment	10 (7.4%)	3 (4.3%)
Total number of treatments	18	4
ELTROMBOPAG	4 (3.0%)	0
TRANEXAMIC ACID	2 (1.5%)	1 (1.4%)
EPINEPHRINE	1 (0.7%)	1 (1.4%)
PHYTOMENADIONE	1 (0.7%)	1 (1.4%)
AMINO ACIDS NOS	1 (0.7%)	0
AMINOCAPROIC ACID	1 (0.7%)	0
FACTOR I (FIBRINOGEN);FACTOR VIII (ANTIHAEMOPHILIC FACTOR);FACTOR XIII (FIBRIN STABILISING FACTOR);VON WILLEBRAND FACTOR	1 (0.7%)	0
LEUCOGEN	1 (0.7%)	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
VITEX NEGUNDO	1 (0.7%)	0
VITAMINS		
Total number of patients with at least one treatment	8 (5.9%)	5 (7.2%)
Total number of treatments	13	7
ASCORBIC ACID	1 (0.7%)	1 (1.4%)

COLECALCIFEROL	1 (0.7%)	1 (1.4%)
VITAMIN B NOS	0	2 (2.9%)
ASCORBIC ACID;VITAMIN B COMPLEX	1 (0.7%)	0
CALCITRIOL	1 (0.7%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE	1 (0.7%)	0
FOLIC ACID;VITAMIN B COMPLEX	1 (0.7%)	0
FURSULTIAMINE	1 (0.7%)	0
MAGNESIUM;PYRIDOXINE HYDROCHLORIDE	0	1 (1.4%)
PYRIDOXINE HYDROCHLORIDE	1 (0.7%)	0
THIAMINE HYDROCHLORIDE	1 (0.7%)	0
VITAMIN D NOS	0	1 (1.4%)
VITAMIN E NOS	0	1 (1.4%)
VITAMINS NOS	1 (0.7%)	0
DIURETICS		
Total number of patients with at least one treatment	9 (6.7%)	3 (4.3%)
Total number of treatments	24	22
FUROSEMIDE	7 (5.2%)	3 (4.3%)
SPIRONOLACTONE	1 (0.7%)	1 (1.4%)
HYDROCHLOROTHIAZIDE	1 (0.7%)	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
TORASEMIDE	1 (0.7%)	0
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS		
Total number of patients with at least one treatment	6 (4.4%)	5 (7.2%)
Total number of treatments	31	5
ATROPINE	1 (0.7%)	1 (1.4%)
DROTAVERINE HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
METOCLOPRAMIDE	2 (1.5%)	0
ATROPINE SULFATE	1 (0.7%)	0
DIMETICONE	1 (0.7%)	0
DOMPERIDONE	0	1 (1.4%)
GLYCYRRHIZA GLABRA	0	1 (1.4%)
ITOPRIDE HYDROCHLORIDE	0	1 (1.4%)
METOCLOPRAMIDE DIHYDROCHLORIDE	1 (0.7%)	0
METOCLOPRAMIDE HYDROCHLORIDE	1 (0.7%)	0
PARGEVERINE HYDROCHLORIDE	1 (0.7%)	0
OTHER NERVOUS SYSTEM DRUGS		
Total number of patients with at least one treatment	8 (5.9%)	3 (4.3%)
Total number of treatments	8	3
VITAMIN B12 NOS	3 (2.2%)	0

MECOBALAMIN	0	2 (2.9%)
BETAHISTINE	0	1 (1.4%)
CYANOCOBALAMIN	1 (0.7%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE	1 (0.7%)	0
DIMENHYDRINATE	1 (0.7%)	0
MELDONIUM	1 (0.7%)	0
NEOSTIGMINE METILSULFATE	1 (0.7%)	0
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE		
Total number of patients with at least one treatment	6 (4.4%)	5 (7.2%)
Total number of treatments	10	13
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	2 (1.5%)	0
AMMONIUM CHLORIDE;EPHEDRINE HYDROCHLORIDE;MENTHOL;PLATYCODON GRANDIFLORUS ROOT;POLYGALA SPP. ROOT;STEMONA SPP. ROOT TUBER	0	1 (1.4%)
ASPERGILLUS ORYZAE	1 (0.7%)	0
BAICALIN;BUFFALO HORN;CHOLIC ACID;CONCHA MARGARITIFERA;GARDENIA JASMINOIDES FRUIT;HYODEOXYCHOLIC ACID;ISATIS TINCTORIA ROOT;LONICERA JAPONICA FLOWER	0	1 (1.4%)
CALCIUM SULFATE DIHYDRATE;DRYOPTERIS CRASSIRHIZOMA RHIZOME;EPHEDRA SPP. HERB;FORSYTHIA SUSPENSIA;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;HOULTUYNIA CORDATA HERB;ISATIS TINCTORIA ROOT;LONICERA JAPONICA FLOWER;MENTHOL;POGOSTEMON CABLIN HERB;PRUNUS SPP. SEED;RHEUM SPP. ROOT WITH RHIZOME;RHODIOLA CREMULATA ROOT WITH RHIZOME	1 (0.7%)	0
CORYDALIS BUNGEANA HERB;ISATIS TINCTORIA ROOT;SCUTELLARIA BAICALENSIS ROOT;TARAXACUM MONGOLICUM HERB	0	1 (1.4%)
EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;PRUNUS SPP. SEED;ZINGIBER OFFICINALE RHIZOME	0	1 (1.4%)
GARDENIA JASMINOIDES FRUIT;ISATIS TINCTORIA ROOT;PHELLODENDRON CHINENSE BARK;SCAPHIUM AFFINE SEED;SCUTELLARIA BAICALENSIS ROOT	1 (0.7%)	0
GLYCYRRHIZA GLABRA	0	1 (1.4%)
HIBISCUS SPP.	0	1 (1.4%)
MAGNOLIA OFFICINALIS	0	1 (1.4%)
PERIPLANETA AMERICANA	1 (0.7%)	0
PHLOMOIDES ROTATA HERB	1 (0.7%)	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
VITEX NEGUNDO	1 (0.7%)	0
DRUGS FOR CONSTIPATION		
Total number of patients with at least one treatment	4 (3.0%)	4 (5.8%)
Total number of treatments	15	6
LACTULOSE	0	4 (5.8%)
BISACODYL	1 (0.7%)	0
ELECTROLYTES NOS;MACROGOL	1 (0.7%)	0
MACROGOL 4000;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	1 (0.7%)	0
MAGNESIUM OXIDE	1 (0.7%)	0
MAGNESIUM SULFATE	1 (0.7%)	0

MANNITOL	1 (0.7%)	0
PHOSPHORIC ACID	1 (0.7%)	0
SENNOSIDE A+B	1 (0.7%)	0
SENNOSIDE A+B CALCIUM	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.7%)	0
ANESTHETICS		
Total number of patients with at least one treatment	3 (2.2%)	4 (5.8%)
Total number of treatments	5	6
LIDOCAINE HYDROCHLORIDE	1 (0.7%)	2 (2.9%)
ARTICAINE	1 (0.7%)	0
FENTANYL	0	1 (1.4%)
FENTANYL CITRATE	0	1 (1.4%)
PROPOFOL	1 (0.7%)	0
REMIFENTANIL HYDROCHLORIDE	1 (0.7%)	0
SUFENTANIL	1 (0.7%)	0
ANTIVIRALS FOR SYSTEMIC USE		
Total number of patients with at least one treatment	3 (2.2%)	4 (5.8%)
Total number of treatments	5	5
VALACICLOVIR HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
ACICLOVIR	0	1 (1.4%)
CALCIUM SULFATE DIHYDRATE;DRYOPTERIS CRASSIRHIZOMA RHIZOME;EPHEDRA SPP. HERB;FORSYTHIA SUSPENSUM;GLYCYRRHIZA SPP. ROOT WITH RHIZOME;HOUTTUYNIA CORDATA HERB;ISATIS TINCTORIA ROOT;LONICERA JAPONICA FLOWER;MENTHOL;POGOSTEMON CABLIN HERB;PRUNUS SPP. SEED;RHEUM SPP. ROOT WITH RHIZOME;RHODIOLA CRENULATA ROOT WITH RHIZOME	1 (0.7%)	0
FAVIPIRAVIR	0	1 (1.4%)
TENOFOVIR	1 (0.7%)	0
VIDARABINE	0	1 (1.4%)
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM		
Total number of patients with at least one treatment	5 (3.7%)	1 (1.4%)
Total number of treatments	7	1
CAPTOPRIL	2 (1.5%)	0
BISOPROLOL FUMARATE;PERINDOPRIL ARGININE	1 (0.7%)	0
ENALAPRIL	1 (0.7%)	0
IRBESARTAN	1 (0.7%)	0
LOSARTAN	0	1 (1.4%)
PERINDOPRIL	1 (0.7%)	0
ALL OTHER NON-THERAPEUTIC PRODUCTS		
Total number of patients with at least one treatment	5 (3.7%)	1 (1.4%)
Total number of treatments	5	1

ASCORBIC ACID	1 (0.7%)	1 (1.4%)
PENICILLIN NOS	2 (1.5%)	0
HYPROMELLOSE	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.7%)	0
LIPID MODIFYING AGENTS		
Total number of patients with at least one treatment	3 (2.2%)	3 (4.3%)
Total number of treatments	3	4
POLYENE PHOSPHATIDYLCHOLINE	0	3 (4.3%)
BERBERINE	1 (0.7%)	0
FISH OIL	1 (0.7%)	0
PITAVASTATIN CALCIUM	1 (0.7%)	0
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS		
Total number of patients with at least one treatment	5 (3.7%)	1 (1.4%)
Total number of treatments	20	1
DIMETICONE	1 (0.7%)	0
FISH OIL	1 (0.7%)	0
HYALURONATE SODIUM	0	1 (1.4%)
PERIPLANETA AMERICANA	1 (0.7%)	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.7%)	0
VITEX NEGUNDO	1 (0.7%)	0
ANTIEPILEPTICS		
Total number of patients with at least one treatment	4 (3.0%)	1 (1.4%)
Total number of treatments	8	1
LORAZEPAM	2 (1.5%)	0
LAMOTRIGINE	1 (0.7%)	0
MAGNESIUM SULFATE	1 (0.7%)	0
MIDAZOLAM	0	1 (1.4%)
PHENYTOIN	1 (0.7%)	0
ANTIFUNGALS FOR DERMATOLOGICAL USE		
Total number of patients with at least one treatment	3 (2.2%)	2 (2.9%)
Total number of treatments	8	2
NYSTATIN	2 (1.5%)	0
BETAMETHASONE VALERATE;CLOTRIMAZOLE	1 (0.7%)	0
BIFONAZOLE	0	1 (1.4%)
CLOBETASOL PROPIONATE;KETOCONAZOLE	0	1 (1.4%)
FLUCONAZOLE	1 (0.7%)	0
SERTACONAZOLE NITRATE	1 (0.7%)	0

ANTIGOUT PREPARATIONS		
Total number of patients with at least one treatment	5 (3.7%)	0
Total number of treatments	6	0
FEBUXOSTAT	3 (2.2%)	0
BENZBROMARONE	1 (0.7%)	0
COLCHICINE	1 (0.7%)	0
OTHER RESPIRATORY SYSTEM PRODUCTS		
Total number of patients with at least one treatment	1 (0.7%)	4 (5.8%)
Total number of treatments	15	6
AMBROXOL	0	3 (4.3%)
AMBROXOL HYDROCHLORIDE	0	1 (1.4%)
DIMETICONE	1 (0.7%)	0
CALCIUM CHANNEL BLOCKERS		
Total number of patients with at least one treatment	4 (3.0%)	0
Total number of treatments	7	0
AMLODIPINE	2 (1.5%)	0
AMLODIPINE BESILATE	2 (1.5%)	0
LERCANIDIPIINE HYDROCHLORIDE	1 (0.7%)	0
DRUGS USED IN DIABETES		
Total number of patients with at least one treatment	2 (1.5%)	2 (2.9%)
Total number of treatments	5	3
EMPAGLIFLOZIN	1 (0.7%)	0
INSULIN HUMAN	1 (0.7%)	0
ISOPHANE INSULIN	0	1 (1.4%)
METFORMIN	1 (0.7%)	0
METFORMIN HYDROCHLORIDE	0	1 (1.4%)
EMOLLIENTS AND PROTECTIVES		
Total number of patients with at least one treatment	3 (2.2%)	1 (1.4%)
Total number of treatments	20	1
DIMETICONE	1 (0.7%)	0
FATS NOS	1 (0.7%)	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
VITAMIN E NOS	0	1 (1.4%)
ZINC OXIDE	1 (0.7%)	0
PSYCHOANALEPTICS		
Total number of patients with at least one treatment	3 (2.2%)	1 (1.4%)

Total number of treatments	4	1
ADEMETIONINE 1,4-BUTANEDISULFONATE	1 (0.7%)	1 (1.4%)
ADEMETIONINE	1 (0.7%)	0
LAMOTRIGINE	1 (0.7%)	0
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM		
Total number of patients with at least one treatment	3 (2.2%)	1 (1.4%)
Total number of treatments	4	1
DANAZOL	2 (1.5%)	1 (1.4%)
MEGESTROL	1 (0.7%)	0
MEGESTROL ACETATE	1 (0.7%)	0
ANABOLIC AGENTS FOR SYSTEMIC USE		
Total number of patients with at least one treatment	2 (1.5%)	1 (1.4%)
Total number of treatments	2	1
DANAZOL	2 (1.5%)	1 (1.4%)
ANTI-PARKINSON DRUGS		
Total number of patients with at least one treatment	2 (1.5%)	1 (1.4%)
Total number of treatments	8	1
DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.7%)	1 (1.4%)
DIPHENHYDRAMINE	1 (0.7%)	0
ANTINEOPLASTIC AGENTS		
Total number of patients with at least one treatment	2 (1.5%)	1 (1.4%)
Total number of treatments	7	1
CELECOXIB	2 (1.5%)	1 (1.4%)
METHOTREXATE	1 (0.7%)	0
IMMUNE SERA AND IMMUNOGLOBULINS		
Total number of patients with at least one treatment	1 (0.7%)	2 (2.9%)
Total number of treatments	1	2
IMMUNOGLOBULIN HUMAN NORMAL	0	1 (1.4%)
IMMUNOGLOBULINS NOS	1 (0.7%)	0
SOTROVIMAB	0	1 (1.4%)
MEDICATED DRESSINGS		
Total number of patients with at least one treatment	3 (2.2%)	0
Total number of treatments	4	0
CETYLPYRIDINIUM CHLORIDE	1 (0.7%)	0
SODIUM CHLORIDE	1 (0.7%)	0
ZINC OXIDE	1 (0.7%)	0

MUSCLE RELAXANTS		
Total number of patients with at least one treatment	2 (1.5%)	1 (1.4%)
Total number of treatments	2	1
CHLORZOXAZONE	1 (0.7%)	0
CISATRACURIUM BESILATE	1 (0.7%)	0
DICLOFENAC;THIOLCHICOSIDE	0	1 (1.4%)
ANTIHYPERTENSIVES		
Total number of patients with at least one treatment	2 (1.5%)	0
Total number of treatments	7	0
HYDRALAZINE HYDROCHLORIDE	1 (0.7%)	0
MAGNESIUM SULFATE	1 (0.7%)	0
SILDENAFIL	1 (0.7%)	0
ANTIMYCOTICS FOR SYSTEMIC USE		
Total number of patients with at least one treatment	2 (1.5%)	0
Total number of treatments	8	0
NYSTATIN	2 (1.5%)	0
ANIDULAFUNGIN	1 (0.7%)	0
FLUCONAZOLE	1 (0.7%)	0
MICAFUNGIN SODIUM	1 (0.7%)	0
ANTIPROTOZOALS		
Total number of patients with at least one treatment	2 (1.5%)	0
Total number of treatments	7	0
METRONIDAZOLE	2 (1.5%)	0
HYDROXYCHLOROQUINE SULFATE	1 (0.7%)	0
APPETITE STIMULANTS		
Total number of patients with at least one treatment	2 (1.5%)	0
Total number of treatments	2	0
MEGESTROL	1 (0.7%)	0
MEGESTROL ACETATE	1 (0.7%)	0
BETA BLOCKING AGENTS		
Total number of patients with at least one treatment	1 (0.7%)	1 (1.4%)
Total number of treatments	1	1
CARVEDILOL	0	1 (1.4%)
METOPROLOL	1 (0.7%)	0
ENDOCRINE THERAPY		

Total number of patients with at least one treatment	2 (1.5%)	0
Total number of treatments	2	0
MEGESTROL	1 (0.7%)	0
MEGESTROL ACETATE	1 (0.7%)	0
GENERAL NUTRIENTS		
Total number of patients with at least one treatment	2 (1.5%)	0
Total number of treatments	8	0
ALANYL GLUTAMINE	1 (0.7%)	0
AMINO ACIDS NOS	1 (0.7%)	0
AMINO ACIDS NOS;CARBOHYDRATES NOS;ELECTROLYTES NOS	1 (0.7%)	0
CARBOHYDRATES NOS;FATS NOS;FIBRE, DIETARY;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1 (0.7%)	0
FATS NOS	1 (0.7%)	0
FISH OIL	1 (0.7%)	0
NUTRIENTS NOS	1 (0.7%)	0
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM		
Total number of patients with at least one treatment	1 (0.7%)	1 (1.4%)
Total number of treatments	1	1
BROMELAINS;TRYPSIN	1 (0.7%)	0
HYALURONATE SODIUM	0	1 (1.4%)
OTHER HEMATOLOGICAL AGENTS		
Total number of patients with at least one treatment	2 (1.5%)	0
Total number of treatments	2	0
BROMELAINS;TRYPSIN	1 (0.7%)	0
MANNITOL;NARTOGRASTIM	1 (0.7%)	0
THYROID THERAPY		
Total number of patients with at least one treatment	2 (1.5%)	0
Total number of treatments	2	0
LEVOTHYROXINE SODIUM	1 (0.7%)	0
THIAMAZOLE	1 (0.7%)	0
TONICS		
Total number of patients with at least one treatment	2 (1.5%)	0
Total number of treatments	2	0
SANGUISORBA OFFICINALIS ROOT	1 (0.7%)	0
VITEX NEGUNDO	1 (0.7%)	0
ANTHELMINTICS		
Total number of patients with at least one treatment	1 (0.7%)	0

Total number of treatments	1	0
VITEX NEGUNDO	1 (0.7%)	0
ANTIMYCOBACTERIALS		
Total number of patients with at least one treatment	0	1 (1.4%)
Total number of treatments	0	4
ETHAMBUTOL DIHYDROCHLORIDE	0	1 (1.4%)
ISONIAZID	0	1 (1.4%)
PYRAZINAMIDE	0	1 (1.4%)
RIFAMPICIN	0	1 (1.4%)
ANTIPSORIATICS		
Total number of patients with at least one treatment	1 (0.7%)	0
Total number of treatments	1	0
CALCITRIOL	1 (0.7%)	0
ANTISEPTICS AND DISINFECTANTS		
Total number of patients with at least one treatment	1 (0.7%)	0
Total number of treatments	1	0
CETYLPYRIDINIUM CHLORIDE	1 (0.7%)	0
DIGESTIVES, INCL. ENZYMES		
Total number of patients with at least one treatment	0	1 (1.4%)
Total number of treatments	0	4
MAGNOLIA OFFICINALIS	0	1 (1.4%)
ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS		
Total number of patients with at least one treatment	1 (0.7%)	0
Total number of treatments	15	0
DIMETICONE	1 (0.7%)	0
No Coding available		
Total number of patients with at least one treatment	1 (0.7%)	0
Total number of treatments	1	0
No Coding available	1 (0.7%)	0
PERIPHERAL VASODILATORS		
Total number of patients with at least one treatment	0	1 (1.4%)
Total number of treatments	0	1
BETAHISTINE	0	1 (1.4%)

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_cm_cncm.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_cm_cncm_RND1_EF1_16NOV2022_42162.xls

12FEB2024 18:19

POPULATION: Randomized Safety Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42162

Number of Patients who Died including Primary Reason

Endpoint, Primary Safety Period	Crovalimab (N=135)		Eculizumab (N=69)	
	n	%	n	%
All Deaths	2	1,5	1	1,4
Ischaemic stroke	0	NE	1	1,4
Myocardial infarction	1	0,7	0	NE
Respiratory tract haemorrhage	1	0,7	0	NE

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_death.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_death_SE1_DTHPSP_16NOV2022_42162.xls

12JAN2024 17:40

POPULATION: Primary Analysis Population

ENDPOINT:--

MODEL: --

STUDY: BO42162

Parameters	Crovalimab (N=134)	Eculizumab (N=69)
PNH-related signs or symptoms within 3 months prior to screening		
Abdominal pain	21 (15.7%)	11 (15.9%)
Anemia [hemoglobin <10 g/dL]	108 (80.6%)	57 (82.6%)
Dysphagia	8 (6.0%)	2 (2.9%)
Erectile dysfunction	13 (9.7%)	4 (5.8%)
Fatigue	112 (83.6%)	63 (91.3%)
Hemoglobinuria	78 (58.2%)	45 (65.2%)
MAVE (including Thrombosis)	9 (6.7%)	5 (7.2%)
Shortness of breath(Dyspnea)	29 (21.6%)	14 (20.3%)

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_pnh_symp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_pnh_symp_PAP_16NOV2022_42162.xls

14JUN2024 9:45

POPULATION: Randomized Safety Population

ENDPOINT: Number and Percentage of SAEs between randomization date and treatment start date

MODEL: --

STUDY: BO42162

		Crovalimab (N=135)				Eculizumab (N=69)			
		All AEs		SAEs between randomization date and treatment start date		All AEs		SAEs between randomization date and treatment start date	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	592	100,0	0	0	390	100,0	0	0

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_rndtrt1.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_rndtrt1_SE1_16NOV2022_42162.xls

12JAN2024 17:44

POPULATION: Randomized Population with an history of Aplastic Anemia

ENDPOINT: Arms A and B, RBC Clone size

MODEL: descriptive

STUDY: BO42162

Summary of clone size per arm (RBC)

Analyte: Percent of Erythrocytes Clone Size (%)

Visit	Crovalimab (N=53)		Eculizumab (N=26)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	35		11	
Mean	29,32		43,02	
95% Lower CL for Mean	22,61		27,45	
95% Upper CL for Mean	36,03		58,6	
SD	19,55		23,19	
CV % Mean	66,67		53,9	
Median	25,8		40,08	
Interquartile Range	21,82		26,51	
Minimum	3,48		7,81	
Maximum	96,02		82,94	
Geometric Mean	23,45		36,43	
CV % Geometric Mean	81,87		74,71	
Week 13				
n	32	29	12	11
Mean	43,96	13,89	65,97	24,66
95% Lower CL for Mean	33,19	7,14	47,57	10,18
95% Upper CL for Mean	54,73	20,64	84,36	39,13
SD	29,87	17,75	28,96	21,54
CV % Mean	67,95	127,72	43,89	87,38
Median	34,36	7,95	68,13	18,28
Interquartile Range	45,83	22,68	48,82	37,68
Minimum	6,2	-9,01	12,52	-0,63
Maximum	99,81	69,33	97,6	63,06
Geometric Mean	33,44	NE	57,91	NE
CV % Geometric Mean	96,84	NE	66,16	NE

Week 25				
n	31	28	10	9
Mean	46,05	16,84	67,34	29,16
95% Lower CL for Mean	35,81	5,44	46,58	15,28
95% Upper CL for Mean	56,28	28,25	88,11	43,04
SD	27,9	29,41	29,03	18,06
CV % Mean	60,6	174,62	43,1	61,91
Median	37,83	6,2	65,91	27,4
Interquartile Range	48,4	29,87	46,04	32,95
Minimum	8,58	-48,95	12,53	4,72
Maximum	99,66	87,49	99,96	53,3
Geometric Mean	37,58	NE	58,99	NE
CV % Geometric Mean	77,54	NE	69,36	NE
Week 29				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	82,09	3,47
Maximum	NE	NE	82,09	3,47
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		12	
Mean	ND		70,91	
95% Lower CL for Mean	ND		53,32	
95% Upper CL for Mean	ND		88,51	
SD	ND		27,7	
CV % Mean	ND		39,06	
Median	ND		78,9	
Interquartile Range	ND		45,45	
Minimum	NE		12,53	
Maximum	NE		99,96	
Geometric Mean	ND		63,12	
CV % Geometric Mean	ND		64,45	

Switch Week 13				
n	0	0	7	7
Mean	ND	ND	44,76	-10,15
95% Lower CL for Mean	ND	ND	19,57	-32,45
95% Upper CL for Mean	ND	ND	69,95	12,16
SD	ND	ND	27,24	24,12
CV % Mean	ND	ND	60,85	-237,74
Median	ND	ND	45,68	-1,79
Interquartile Range	ND	ND	41,72	13,46
Minimum	NE	NE	12,01	-63,7
Maximum	NE	NE	92,95	5,12
Geometric Mean	ND	ND	37,03	NE
CV % Geometric Mean	ND	ND	80,9	NE

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_RBC_RND1APL_ARMAB_16NOV2022_42162.xls
12FEB2024 18:57

POPULATION: Randomized Population with an history of Myelodysplastic Syndrome

ENDPOINT: Arms A and B, RBC Clone size

MODEL: descriptive

STUDY: BO42162

Summary of clone size per arm (RBC)

Analyte: Percent of Erythrocytes Clone Size (%)

Visit	Crovalimab (N=6)		Eculizumab (N=6)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	6		4	
Mean	23,1		39,1	
95% Lower CL for Mean	8,88		-17,51	
95% Upper CL for Mean	37,32		95,71	
SD	13,55		35,58	
CV % Mean	58,67		90,99	
Median	22,69		37,85	
Interquartile Range	23,58		56,86	
Minimum	8,52		0,11	
Maximum	42,15		80,59	
Geometric Mean	19,48		10,06	
CV % Geometric Mean	74,88		10872,84	
Week 13				
n	6	6	4	4
Mean	27,08	3,98	45,21	6,11
95% Lower CL for Mean	5,32	-5,18	-13,19	-35,93
95% Upper CL for Mean	48,84	13,14	103,61	48,15
SD	20,73	8,73	36,7	26,42
CV % Mean	76,56	219,13	81,18	432,58
Median	23,08	4,38	40,21	6,58
Interquartile Range	38,16	13,07	55,92	33,62
Minimum	2,92	-6,56	7,98	-26,69
Maximum	50,9	17,28	92,43	37,96
Geometric Mean	18,44	NE	32,04	NE
CV % Geometric Mean	153,96	NE	143,73	NE

Week 25				
n	5	5	3	3
Mean	34,28	8,46	70,69	25,63
95% Lower CL for Mean	9,06	-4,8	-18,39	-18,77
95% Upper CL for Mean	59,51	21,72	159,76	70,03
SD	20,32	10,68	35,86	17,87
CV % Mean	59,26	126,19	50,73	69,73
Median	33,46	5,06	86,73	29,5
Interquartile Range	25,54	1,03	66,11	35,11
Minimum	8,81	0,29	29,61	6,14
Maximum	60,27	27,21	95,72	41,25
Geometric Mean	28,31	NE	62,64	NE
CV % Geometric Mean	88,02	NE	72,62	NE
Switch Week 1 Day 1				
n	0		4	
Mean	ND		59,65	
95% Lower CL for Mean	ND		1,29	
95% Upper CL for Mean	ND		118	
SD	ND		36,67	
CV % Mean	ND		61,48	
Median	ND		58,17	
Interquartile Range	ND		63,16	
Minimum	NE		26,52	
Maximum	NE		95,72	
Geometric Mean	ND		50,53	
CV % Geometric Mean	ND		77,16	
Switch Week 13				
n	0	0	3	3
Mean	ND	ND	43,26	-4,36
95% Lower CL for Mean	ND	ND	-59,94	-24,79
95% Upper CL for Mean	ND	ND	146,46	16,07
SD	ND	ND	41,54	8,22
CV % Mean	ND	ND	96,03	-188,61
Median	ND	ND	20,77	-5,75
Interquartile Range	ND	ND	73,39	16,27
Minimum	NE	NE	17,81	-11,8
Maximum	NE	NE	91,2	4,47
Geometric Mean	ND	ND	32,31	NE
CV % Geometric Mean	ND	ND	112,05	NE

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_RBC_RND1MYS_ARMAB_16NOV2022_42162.xls

12FEB2024 18:58

POPULATION: Randomized Population
 ENDPOINT: Arms A and B, RBC Clone size
 MODEL: descriptive
 STUDY: BO42162
 Summary of clone size per arm (RBC)

Analyte: Percent of Erythrocytes Clone Size (%)

Visit	Crovalimab (N=135)		Eculizumab (N=69)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	78		41	
Mean	29,12		43,2	
95% Lower CL for Mean	25,2		35,36	
95% Upper CL for Mean	33,04		51,04	
SD	17,38		24,85	
CV % Mean	59,7		57,52	
Median	25,26		44,63	
Interquartile Range	22,25		33,47	
Minimum	3,48		0,11	
Maximum	96,02		88,87	
Geometric Mean	24,27		30,75	
CV % Geometric Mean	70,63		177,02	
Week 13				
n	77	71	39	38
Mean	42,71	12,08	61,78	17,47
95% Lower CL for Mean	36,52	7,21	51,37	10,35
95% Upper CL for Mean	48,9	16,95	72,19	24,58
SD	27,27	20,57	32,11	21,65
CV % Mean	63,87	170,29	51,97	123,98
Median	37,81	4,34	55,27	10,61
Interquartile Range	40,89	16,5	54,2	32,73
Minimum	2,92	-11,69	5,4	-26,69
Maximum	99,81	80,14	99,73	63,06
Geometric Mean	33,06	NE	49,08	NE

CV % Geometric Mean	93,66	NE	97,21	NE
Week 25				
n	74	68	37	36
Mean	44,03	13,56	63,63	20,09
95% Lower CL for Mean	37,85	7,43	53,17	13,42
95% Upper CL for Mean	50,22	19,68	74,08	26,77
SD	26,7	25,3	31,35	19,73
CV % Mean	60,63	186,63	49,28	98,17
Median	39,08	4,81	70,93	17,18
Interquartile Range	38,67	19,6	50,96	31,7
Minimum	6,39	-48,95	7,98	-9,11
Maximum	99,66	87,49	100,17	53,3
Geometric Mean	35,46	NE	52,46	NE
CV % Geometric Mean	81,02	NE	83,42	NE
Week 29				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	82,09	3,47
Maximum	NE	NE	82,09	3,47
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		41	
Mean	ND		62,71	
95% Lower CL for Mean	ND		52,64	
95% Upper CL for Mean	ND		72,77	
SD	ND		31,89	
CV % Mean	ND		50,85	
Median	ND		70,93	
Interquartile Range	ND		55,33	
Minimum	NE		7,98	

Maximum	NE		100,17	
Geometric Mean	ND		51,14	
CV % Geometric Mean	ND		85,66	
Switch Week 13				
n	0	0	26	26
Mean	ND	ND	55,41	-4,5
95% Lower CL for Mean	ND	ND	42,15	-12,15
95% Upper CL for Mean	ND	ND	68,66	3,14
SD	ND	ND	32,82	18,92
CV % Mean	ND	ND	59,23	-420,06
Median	ND	ND	53,82	-1,39
Interquartile Range	ND	ND	70,43	6,38
Minimum	NE	NE	1,2	-63,7
Maximum	NE	NE	99,36	48,47
Geometric Mean	ND	ND	39,8	NE
CV % Geometric Mean	ND	ND	143,9	NE

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_RBC_RND1_ARMAB_16NOV2022_42162.xls

22FEB2024 12:56

POPULATION: Randomized Population with an history of Aplastic Anemia

ENDPOINT: Arms A and B, WBC Clone size

MODEL: descriptive

STUDY: BO42162

Summary of clone size per arm (WBC)

Analyte: Granulocytes: FLAERneg Gran%ofGran,NHepLDTCL (%)

Visit	Crovalimab (N=53)		Eculizumab (N=26)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	34		11	
Mean	49,94		53,01	
95% Lower CL for Mean	39,25		28,96	
95% Upper CL for Mean	60,64		77,06	
SD	30,66		35,8	
CV % Mean	61,39		67,53	
Median	58,74		72,52	
Interquartile Range	58,76		68,98	
Minimum	0,83		3,28	
Maximum	93,76		91,52	
Geometric Mean	32,28		35,93	
CV % Geometric Mean	198,13		156,19	
Week 13				
n	31	27	12	11
Mean	56,89	3,93	62,45	8,4
95% Lower CL for Mean	46,44	-6,45	44,66	-5,6
95% Upper CL for Mean	67,34	14,3	80,23	22,41
SD	28,49	26,22	27,99	20,85
CV % Mean	50,09	667,99	44,82	248,08
Median	68,68	4,73	74,92	-0,7
Interquartile Range	46,29	18,19	42,9	25,34
Minimum	0,41	-66,25	2,42	-12,28
Maximum	91,09	72,07	90,77	61,63
Geometric Mean	42,53	NE	48,53	NE
CV % Geometric Mean	151,39	NE	135,27	NE

Week 25				
n	29	25	10	9
Mean	52,33	9,58	70,21	8,06
95% Lower CL for Mean	41,04	-2,48	55,53	-8,38
95% Upper CL for Mean	63,63	21,64	84,9	24,51
SD	29,69	29,21	20,53	21,39
CV % Mean	56,73	304,94	29,24	265,43
Median	56,41	5,69	70,74	2,75
Interquartile Range	51,83	23,44	22,48	9,39
Minimum	0,6	-62,17	22,6	-19,6
Maximum	95,51	70,72	91,1	45,27
Geometric Mean	37,45	NE	66,16	NE
CV % Geometric Mean	157,84	NE	42,85	NE
Week 29				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	0,94	-2,34
Maximum	NE	NE	0,94	-2,34
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		12	
Mean	ND		65,64	
95% Lower CL for Mean	ND		47,93	
95% Upper CL for Mean	ND		83,36	
SD	ND		27,88	
CV % Mean	ND		42,47	
Median	ND		70,74	
Interquartile Range	ND		26,08	
Minimum	NE		0,94	
Maximum	NE		91,1	
Geometric Mean	ND		47,36	
CV % Geometric Mean	ND		207,54	

Switch Week 13				
n	0	0	7	7
Mean	ND	ND	61,88	-4,21
95% Lower CL for Mean	ND	ND	41,45	-29,63
95% Upper CL for Mean	ND	ND	82,32	21,21
SD	ND	ND	22,1	27,48
CV % Mean	ND	ND	35,71	-653,04
Median	ND	ND	70,65	1,14
Interquartile Range	ND	ND	36,52	18,76
Minimum	NE	NE	25,52	-62,09
Maximum	NE	NE	85,59	23,05
Geometric Mean	ND	ND	57,69	NE
CV % Geometric Mean	ND	ND	45,43	NE

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_WBC_RND1APL_ARMAB_16NOV2022_42162.xls
12FEB2024 19:00

POPULATION: Randomized Population with an history of Aplastic Anemia

ENDPOINT: Arms A and B, WBC Clone size

MODEL: descriptive

STUDY: BO42162

Summary of clone size per arm (WBC)

Analyte: Monocytes: FLAERneg Mono%ofMono,NHepLDTCL (%)

Visit	Crovalimab (N=53)		Eculizumab (N=26)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	34		11	
Mean	86,13		86,49	
95% Lower CL for Mean	80,65		74,38	
95% Upper CL for Mean	91,61		98,6	
SD	15,71		18,03	
CV % Mean	18,24		20,84	
Median	92,22		94,61	
Interquartile Range	23,7		24,83	
Minimum	54,39		52,02	
Maximum	99,91		99,88	
Geometric Mean	84,5		84,43	
CV % Geometric Mean	20,95		24,59	
Week 13				
n	31	27	12	11
Mean	87,2	0,99	88,42	2,13
95% Lower CL for Mean	81,79	-1,93	80,05	-1,67
95% Upper CL for Mean	92,61	3,9	96,78	5,94
SD	14,76	7,36	13,17	5,66
CV % Mean	16,92	745,69	14,9	265,44
Median	92,62	0,34	92,65	0,26
Interquartile Range	17,04	3,24	15,4	6,22
Minimum	46,72	-15,44	57	-4,53
Maximum	99,98	26,83	99,67	16,88
Geometric Mean	85,72	NE	87,37	NE
CV % Geometric Mean	20,13	NE	16,91	NE

Week 25				
n	29	25	10	9
Mean	87,13	1,38	90,64	2,12
95% Lower CL for Mean	81,35	-0,8	82,37	-1,65
95% Upper CL for Mean	92,91	3,57	98,9	5,9
SD	15,2	5,29	11,55	4,91
CV % Mean	17,44	383,02	12,75	231,27
Median	93,17	0,36	93,22	0,01
Interquartile Range	18,2	2,17	8,36	6,66
Minimum	48,77	-6,72	60,72	-3,53
Maximum	100	19,01	99,88	10,06
Geometric Mean	85,59	NE	89,84	NE
CV % Geometric Mean	20,41	NE	14,79	NE
Week 29				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	59,18	4,08
Maximum	NE	NE	59,18	4,08
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		12	
Mean	ND		88,62	
95% Lower CL for Mean	ND		79,64	
95% Upper CL for Mean	ND		97,59	
SD	ND		14,13	
CV % Mean	ND		15,94	
Median	ND		93,22	
Interquartile Range	ND		10,95	
Minimum	NE		59,18	
Maximum	NE		99,88	
Geometric Mean	ND		87,39	
CV % Geometric Mean	ND		18,43	

Switch Week 13				
n	0	0	7	7
Mean	ND	ND	89,15	0,74
95% Lower CL for Mean	ND	ND	77,4	-0,09
95% Upper CL for Mean	ND	ND	100,9	1,57
SD	ND	ND	12,7	0,9
CV % Mean	ND	ND	14,25	121,07
Median	ND	ND	93,42	0,43
Interquartile Range	ND	ND	14,36	1,62
Minimum	NE	NE	62,85	-0,29
Maximum	NE	NE	99,49	2,13
Geometric Mean	ND	ND	88,25	NE
CV % Geometric Mean	ND	ND	16,09	NE

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_WBC_RND1APL_ARMAB_16NOV2022_42162.xls
12FEB2024 19:00

POPULATION: Randomized Population with an history of Myelodysplastic Syndrome

ENDPOINT: Arms A and B, WBC Clone size

MODEL: descriptive

STUDY: BO42162

Summary of clone size per arm (WBC)

Analyte: Granulocytes: FLAERneg Gran%ofGran,NHepLDTCL (%)

Visit	Crovalimab (N=6)		Eculizumab (N=6)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	5		4	
Mean	64,21		54,67	
95% Lower CL for Mean	26,79		-7,96	
95% Upper CL for Mean	101,63		117,31	
SD	30,13		39,36	
CV % Mean	46,93		72	
Median	72,58		58,23	
Interquartile Range	25,56		62,93	
Minimum	14,43		7,03	
Maximum	89,14		95,21	
Geometric Mean	54,36		37,75	
CV % Geometric Mean	88,12		174,57	
Week 13				
n	6	5	4	4
Mean	63,62	11,88	57,36	2,69
95% Lower CL for Mean	29,64	-11,99	2,01	-5,09
95% Upper CL for Mean	97,6	35,74	112,72	10,47
SD	32,38	19,22	34,79	4,89
CV % Mean	50,9	161,84	60,65	181,67
Median	77,43	2,98	59,16	0,93
Interquartile Range	25,99	17,42	56,1	6,83
Minimum	1,27	-7,09	16,67	-0,75
Maximum	87,45	41,63	94,46	9,64
Geometric Mean	38,08	NE	47,39	NE
CV % Geometric Mean	394,23	NE	91,01	NE

Week 25				
n	4	4	3	3
Mean	82,27	24,3	59,44	-0,32
95% Lower CL for Mean	73,6	-18,62	-52,3	-9,75
95% Upper CL for Mean	90,95	67,21	171,19	9,11
SD	5,45	26,97	44,98	3,8
CV % Mean	6,63	110,99	75,68	-1180,06
Median	80,72	14,6	79,81	0,85
Interquartile Range	7,07	36,43	82,77	7,31
Minimum	77,58	4,85	7,88	-4,57
Maximum	90,08	63,15	90,64	2,75
Geometric Mean	82,14	NE	38,48	NE
CV % Geometric Mean	6,49	NE	237,18	NE
Switch Week 1 Day 1				
n	0		4	
Mean	ND		55,07	
95% Lower CL for Mean	ND		-5	
95% Upper CL for Mean	ND		115,15	
SD	ND		37,76	
CV % Mean	ND		68,55	
Median	ND		60,89	
Interquartile Range	ND		60,31	
Minimum	NE		7,88	
Maximum	NE		90,64	
Geometric Mean	ND		39,32	
CV % Geometric Mean	ND		159,19	
Switch Week 13				
n	0	0	3	3
Mean	ND	ND	41,63	-5,2
95% Lower CL for Mean	ND	ND	-46,16	-29,19
95% Upper CL for Mean	ND	ND	129,42	18,8
SD	ND	ND	35,34	9,66
CV % Mean	ND	ND	84,89	-185,84
Median	ND	ND	29,82	-9,28
Interquartile Range	ND	ND	67,65	17,98
Minimum	NE	NE	13,71	-12,15
Maximum	NE	NE	81,36	5,83
Geometric Mean	ND	ND	32,16	NE
CV % Geometric Mean	ND	ND	110,41	NE

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_WBC_RND1MYS_ARMAB_16NOV2022_42162.xls
12FEB2024 19:01

POPULATION: Randomized Population with an history of Myelodysplastic Syndrome

ENDPOINT: Arms A and B, WBC Clone size

MODEL: descriptive

STUDY: BO42162

Summary of clone size per arm (WBC)

Analyte: Monocytes: FLAERneg Mono%ofMono,NHepLDTCL (%)

Visit	Crovalimab (N=6)		Eculizumab (N=6)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	6		4	
Mean	93,36		92,6	
95% Lower CL for Mean	87,21		72,04	
95% Upper CL for Mean	99,51		113,16	
SD	5,86		12,92	
CV % Mean	6,28		13,95	
Median	93,59		98,84	
Interquartile Range	10,06		13,29	
Minimum	84,69		73,23	
Maximum	99,47		99,5	
Geometric Mean	93,21		91,86	
CV % Geometric Mean	6,35		15,2	
Week 13				
n	6	6	4	4
Mean	92,56	-0,8	92,18	-0,42
95% Lower CL for Mean	85,98	-1,67	72,65	-1,82
95% Upper CL for Mean	99,14	0,07	111,72	0,97
SD	6,27	0,83	12,28	0,88
CV % Mean	6,77	-103,16	13,32	-207,04
Median	92,89	-0,89	98,02	-0,38
Interquartile Range	10,82	1,64	13,37	1,3
Minimum	83,98	-1,82	73,81	-1,51
Maximum	99,65	0,18	98,88	0,58
Geometric Mean	92,38	NE	91,51	NE
CV % Geometric Mean	6,83	NE	14,43	NE

Week 25				
n	5	5	3	3
Mean	92,81	-0,15	98,32	-0,74
95% Lower CL for Mean	84,61	-0,81	94,49	-3,85
95% Upper CL for Mean	101,02	0,51	102,16	2,37
SD	6,61	0,53	1,54	1,25
CV % Mean	7,12	-362,49	1,57	-169,54
Median	91,74	-0,08	99,18	-0,33
Interquartile Range	9,09	0,59	2,71	2,4
Minimum	83,83	-0,86	96,54	-2,15
Maximum	99,61	0,52	99,25	0,26
Geometric Mean	92,62	NE	98,32	NE
CV % Geometric Mean	7,19	NE	1,58	NE
Switch Week 1 Day 1				
n	0		4	
Mean	ND		92,19	
95% Lower CL for Mean	ND		72,58	
95% Upper CL for Mean	ND		111,81	
SD	ND		12,32	
CV % Mean	ND		13,37	
Median	ND		97,86	
Interquartile Range	ND		14,04	
Minimum	NE		73,81	
Maximum	NE		99,25	
Geometric Mean	ND		91,51	
CV % Geometric Mean	ND		14,47	
Switch Week 13				
n	0	0	3	3
Mean	ND	ND	90,84	0,09
95% Lower CL for Mean	ND	ND	54,39	-1,17
95% Upper CL for Mean	ND	ND	127,28	1,35
SD	ND	ND	14,67	0,51
CV % Mean	ND	ND	16,15	556,27
Median	ND	ND	98,83	0,1
Interquartile Range	ND	ND	25,87	1,02
Minimum	NE	NE	73,91	-0,42
Maximum	NE	NE	99,77	0,6
Geometric Mean	ND	ND	89,99	NE
CV % Geometric Mean	ND	ND	17,18	NE

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_WBC_RND1MYS_ARMAB_16NOV2022_42162.xls
12FEB2024 19:01

POPULATION: Randomized Population
 ENDPOINT: Arms A and B, WBC Clone size
 MODEL: descriptive
 STUDY: BO42162
 Summary of clone size per arm (WBC)

Analyte: Granulocytes: FLAERneg Gran%ofGran,NHepLDTCL (%)

Visit	Crovalimab (N=135)		Eculizumab (N=69)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	76		41	
Mean	55,24		61,74	
95% Lower CL for Mean	49,09		52,43	
95% Upper CL for Mean	61,4		71,05	
SD	26,93		29,5	
CV % Mean	48,75		47,78	
Median	60,14		74,58	
Interquartile Range	39,87		45,63	
Minimum	0,83		1,3	
Maximum	96,09		95,21	
Geometric Mean	42,61		47,43	
CV % Geometric Mean	123,02		125,2	
Week 13				
n	76	68	39	38
Mean	62,89	7,02	66,01	3,15
95% Lower CL for Mean	57,16	2,02	57,62	-3,46
95% Upper CL for Mean	68,61	12,02	74,41	9,76
SD	25,05	20,66	25,9	20,1
CV % Mean	39,84	294,19	39,23	637,62
Median	73,51	6,84	76,36	-0,27
Interquartile Range	33,29	18,65	35,35	16,84
Minimum	0,41	-66,25	2,42	-62,92
Maximum	95,73	72,07	95,91	61,63
Geometric Mean	51,29	NE	55,02	NE

CV % Geometric Mean	113,61	NE	97,87	NE
Week 25				
n	71	64	36	35
Mean	60,3	8,25	70,26	4,03
95% Lower CL for Mean	53,84	2,31	62,78	-2,49
95% Upper CL for Mean	66,76	14,19	77,73	10,55
SD	27,29	23,78	22,1	18,98
CV % Mean	45,27	288,13	31,46	470,65
Median	71,58	5,76	75,61	-0,65
Interquartile Range	45,88	21,66	16,95	14,06
Minimum	0,6	-62,17	4,96	-38,01
Maximum	95,51	70,72	93,54	45,27
Geometric Mean	48,83	NE	62,54	NE
CV % Geometric Mean	104,58	NE	70,49	NE
Week 29				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	0,94	-2,34
Maximum	NE	NE	0,94	-2,34
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		40	
Mean	ND		67,94	
95% Lower CL for Mean	ND		60,21	
95% Upper CL for Mean	ND		75,67	
SD	ND		24,17	
CV % Mean	ND		35,57	
Median	ND		74,53	
Interquartile Range	ND		22,94	
Minimum	NE		0,94	

Maximum	NE		93,54	
Geometric Mean	ND		56,13	
CV % Geometric Mean	ND		111,61	
Switch Week 13				
n	0	0	25	24
Mean	ND	ND	56,44	-4,28
95% Lower CL for Mean	ND	ND	45,33	-11,1
95% Upper CL for Mean	ND	ND	67,56	2,54
SD	ND	ND	26,93	16,15
CV % Mean	ND	ND	47,71	-376,98
Median	ND	ND	62,38	-2,7
Interquartile Range	ND	ND	38,09	15,52
Minimum	NE	NE	1,63	-62,09
Maximum	NE	NE	91,86	23,05
Geometric Mean	ND	ND	42,54	NE
CV % Geometric Mean	ND	ND	141,87	NE

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_WBC_RND1_ARMAB_16NOV2022_42162.xls

12FEB2024 18:59

POPULATION: Randomized Population
ENDPOINT: Arms A and B, WBC Clone size
MODEL: descriptive
STUDY: BO42162
Summary of clone size per arm (WBC)

Analyte: Monocytes: FLAERneg Mono%ofMono,NHepLDTCL (%)

Visit	Crovalimab (N=135)		Eculizumab (N=69)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	77		41	
Mean	84,79		88,08	
95% Lower CL for Mean	81,15		83,09	
95% Upper CL for Mean	88,43		93,07	
SD	16,05		15,81	
CV % Mean	18,93		17,95	
Median	90,64		95,12	
Interquartile Range	17,03		13,62	
Minimum	42,54		41,49	
Maximum	99,95		99,92	
Geometric Mean	82,98		86,33	
CV % Geometric Mean	22,3		21,89	
Week 13				
n	76	69	39	38
Mean	86,09	0,97	90,35	1,26
95% Lower CL for Mean	82,55	-0,3	86,49	-0,08
95% Upper CL for Mean	89,64	2,25	94,2	2,6
SD	15,53	5,31	11,9	4,07
CV % Mean	18,04	545,44	13,17	323,33
Median	92,53	0,27	96,26	0,07
Interquartile Range	17,12	2,35	12,89	1,71
Minimum	40,13	-15,44	54,49	-4,53
Maximum	99,98	26,83	99,9	16,88
Geometric Mean	84,37	NE	89,44	NE

CV % Geometric Mean	21,79	NE	15,14	NE
Week 25				
n	72	65	37	36
Mean	86,6	1,37	89,07	0,06
95% Lower CL for Mean	83,2	0,16	83,73	-1,8
95% Upper CL for Mean	90	2,58	94,42	1,92
SD	14,47	4,88	16,04	5,5
CV % Mean	16,7	355,81	18	9284,11
Median	92,47	0,5	96,27	-0,18
Interquartile Range	16,82	2,47	10,19	1,97
Minimum	48,77	-15,67	38,57	-17,95
Maximum	100	19,01	99,93	20,62
Geometric Mean	85,19	NE	87,14	NE
CV % Geometric Mean	19,34	NE	23,43	NE
Week 29				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	59,18	4,08
Maximum	NE	NE	59,18	4,08
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		41	
Mean	ND		88,2	
95% Lower CL for Mean	ND		83,1	
95% Upper CL for Mean	ND		93,3	
SD	ND		16,15	
CV % Mean	ND		18,31	
Median	ND		95,87	
Interquartile Range	ND		11,2	
Minimum	NE		38,57	

Maximum	NE		99,93	
Geometric Mean	ND		86,28	
CV % Geometric Mean	ND		23,28	
Switch Week 13				
n	0	0	25	25
Mean	ND	ND	86,19	0,62
95% Lower CL for Mean	ND	ND	78,71	-2,33
95% Upper CL for Mean	ND	ND	93,67	3,57
SD	ND	ND	18,12	7,15
CV % Mean	ND	ND	21,02	1144,27
Median	ND	ND	95,04	-0,04
Interquartile Range	ND	ND	20,87	1
Minimum	NE	NE	36,95	-8,9
Maximum	NE	NE	99,89	32,83
Geometric Mean	ND	ND	83,76	NE
CV % Geometric Mean	ND	ND	26,9	NE

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_WBC_RND1_ARMAB_16NOV2022_42162.xls

12FEB2024 18:59

POPULATION: Crovalimab, Primary Analysis Population
 ENDPOINT: --
 MODEL: --
 STUDY: BO42162
 Characterization of BTHs (Arm A)

BTH number	New or worsening symptom or sign of intravascular hemolysis									
	Fatigue	Hemoglobinuria	Abdominal pain	Dyspnea	Anemia [hemoglobin <10 g/dL]	MAVE (including thrombosis)	Dysphagia	Erectile dysfunction	Other	Transfusion needed?
1	y	y	y	y	y	n	n	n	n	y
2	y	n	n	n	y	n	n	n	n	n
3	y	y	n	n	y	n	n	n	n	n
4	y	n	n	n	y	n	n	n	n	n
5	n	n	n	n	y	n	n	n	n	n
6	y	n	n	n	y	n	n	n	n	y
7	y	y	n	n	n	n	n	n	n	n
8	n	n	n	n	y	n	n	n	n	n
9	y	y	n	y	y	n	n	n	n	n
10	n	n	n	n	y	n	n	n	y	n
11	n	y	n	n	n	n	n	n	n	n
12	n	n	n	n	y	n	n	n	y	n
13	n	n	n	n	n	n	y	n	n	n
14	y	n	n	n	y	n	n	n	n	y
15	y	y	n	n	n	n	n	n	y	n
16	y	n	n	n	y	n	n	n	n	y
17	n	n	n	n	y	n	n	n	n	y
18	y	n	n	n	y	n	n	n	n	y
Total	11	6	1	2	14	0	1	0	3	6

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_bth.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_bth_PAP_arma_16NOV2022_42162.xls
 12FEB2024 15:35

POPULATION: Eculizumab, Primary Analysis Population
 ENDPOINT: --
 MODEL: --
 STUDY: BO42162
 Characterization of BTHs (Arm B)

BTH number	New or worsening symptom or sign of intravascular hemolysis									
	Fatigue	Hemoglobinuria	Abdominal pain	Dyspnea	Anemia [hemoglobin <10 g/dL]	MAVE (including thrombosis)	Dysphagia	Erectile dysfunction	Other	Transfusion needed?
1	y	n	n	n	y	n	n	n	n	n
2	y	n	n	n	y	n	n	n	n	n
3	n	n	n	n	y	n	n	n	n	n
4	n	n	n	n	y	n	n	n	n	n
5	n	y	y	n	y	n	n	n	n	n
6	n	n	n	n	y	n	n	n	n	n
7	y	y	n	n	n	n	n	n	n	n
8	n	y	y	n	n	n	y	n	n	n
9	y	y	n	n	n	n	n	n	n	n
10	y	y	y	n	n	n	n	n	n	n
11	y	y	n	n	y	n	n	n	n	n
12	y	n	n	n	y	n	n	n	n	n
13	y	y	n	n	n	n	n	n	n	n
14	y	n	n	n	n	n	n	n	n	n
15	n	y	n	n	n	n	n	n	n	n
16	y	n	n	n	y	n	n	n	n	y
17	y	y	n	y	y	n	n	n	n	y
18	y	n	n	n	n	n	n	n	n	n
19	n	n	n	n	y	n	n	n	n	n
20	n	y	n	n	y	n	n	n	y	y
21	n	n	n	n	y	n	n	n	n	n
22	y	y	n	n	y	n	n	n	n	n
23	y	y	n	n	y	n	n	n	n	n
24	n	n	n	n	y	n	n	n	n	y
25	n	y	n	y	y	n	n	n	n	y
Total	14	13	3	2	17	0	1	0	1	5

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_bth.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_bth_PAP_armb_16NOV2022_42162.xls
 12FEB2024 15:37

POPULATION: Primary Analysis Population
 ENDPOINT: Overall Survival, Primary Efficacy Period
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: B042162
 Time to Event Analysis (Efficacy)

		Crovalimab (N=134)										Eculizumab (N=69)										Crovalimab vs. Eculizumab									
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank		Hazard Ratio			
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CI for Q1	95% Upper CI for Q1	Median (months)	95% Lower CI for Median	95% Upper CI for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CI for Q1	95% Upper CI for Q1	Median (months)	95% Lower CI for Median	95% Upper CI for Median	p-value	Hazard Ratio	95% Lower CI	95% Upper CI	Convergence Status	
All	n/a	134	100,0	1	0,7	133	99,3	NE	NE	NE	NE	NE	NE	69	100,0	1	1,4	68	98,6	NE	NE	NE	NE	NE	NE	0,6649	0,55	0,03	8,74	Convergence criterion (GCONV-IE-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

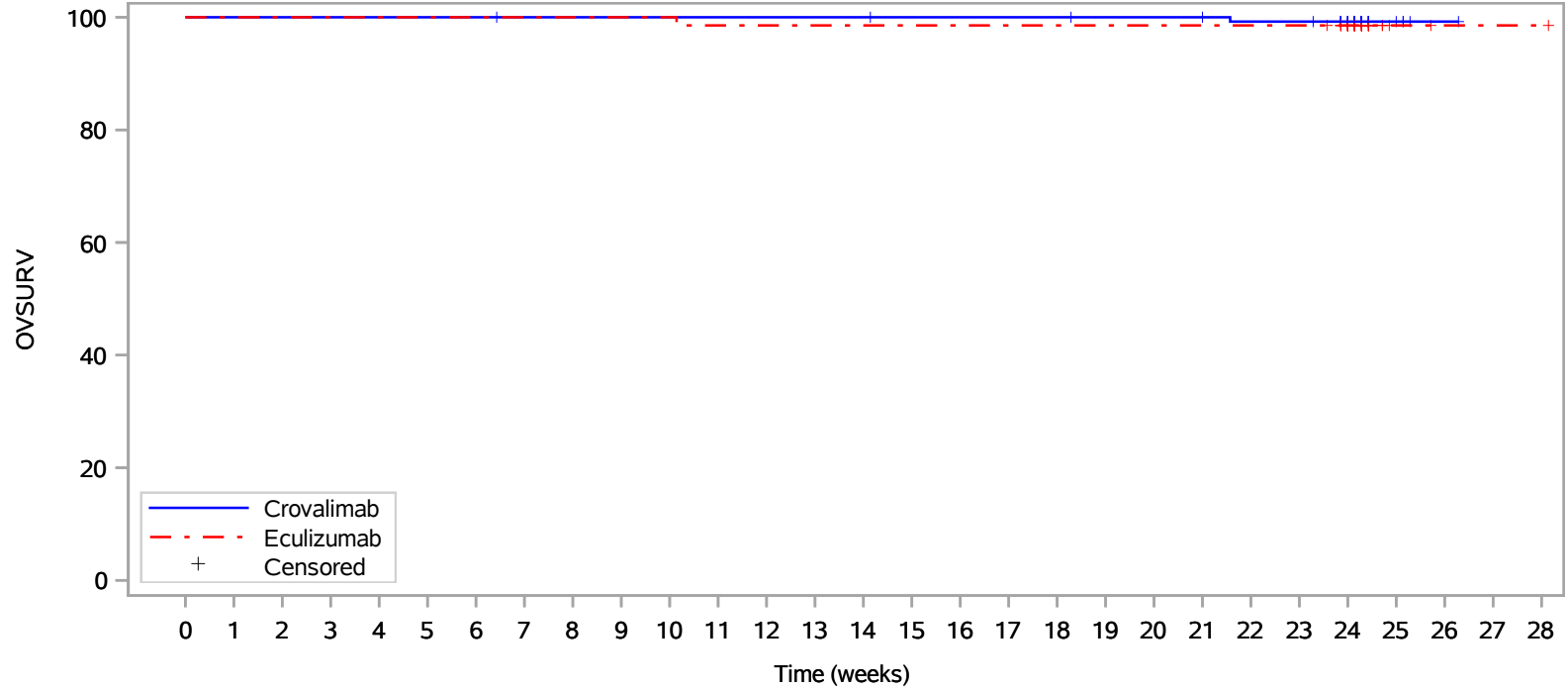
Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_eff_tte.sas

Output: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_eff_tte_str_OVSURV_PAP_16NOV2022_42162.xls

10APR2024 11:35

POPULATION: Primary Analysis Population
ENDPOINT: Overall Survival
STUDY: BO42162



Patients at risk		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Crovalimab		134	134	134	134	134	134	134	133	133	133	133	133	133	133	132	132	132	132	131	131	131	129	129	115	5	1	NE	NE	
Eculizumab		69	69	69	69	69	69	69	69	69	69	68	68	68	68	68	68	68	68	68	68	68	68	68	68	62	2	1	1	1
Patients censored		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Crovalimab		0	0	0	0	0	0	0	1	1	1	1	1	1	1	2	2	2	2	3	3	4	4	4	4	29	129	132	NE	NE
Eculizumab		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	20	66	67	67	67

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/g_km.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/g_km_OVSURV_PAP_16NOV2022_42162.pdf
08JUN2024 9:12

POPULATION: Primary Analysis Population
 ENDPOINT: Overall Survival, Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042162
 Time to Event Analysis by Subgroups (Efficacy)

Name	Level	Crovalimab (N=134)											Eculisumab (N=69)											Crovalimab vs. Eculisumab															
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event					log-rank	Hazard Ratio			Interaction Test											
		n	%	n	%	n	%	Q1 (months)	95% Lower CI for Q1	95% Upper CI for Q1	Median (months)	95% Lower CI for Median	95% Upper CI for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CI for Q1	95% Upper CI for Q1	Median (months)	95% Lower CI for Median	95% Upper CI for Median	p-value	Hazard Ratio	95% Lower CI	95% Upper CI	Convergence Status	p-value (likelihood ratio)								
All	n/s	134	100.0	1	0.7	133	99.3	NE	NE	NE	NE	NE	NE	NE	69	100.0	1	1.4	68	98.6	NE	NE	NE	NE	NE	NE	NE	0.6388	0.52	0.03	8.33	Convergence criterion (GCONV=1E-8) satisfied.							
Sex	Male	77	57.5	1	1.3	76	98.7	NE	NE	NE	NE	NE	NE	NE	35	50.7	1	2.9	34	97.1	NE	NE	NE	NE	NE	NE	NE	0.5666	0.45	0.03	7.26	Convergence criterion (GCONV=1E-8) satisfied.	-						
	Female	57	42.5	0	0.0	57	100.0	NE	NE	NE	NE	NE	NE	NE	34	49.3	0	0.0	34	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Age	<65	122	91.0	0	0.0	122	100.0	NE	NE	NE	NE	NE	NE	NE	60	87.0	1	1.7	59	98.3	NE	NE	NE	NE	NE	NE	NE	NE	0.1556	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-					
	≥65	12	9.0	1	8.3	11	91.7	NE	NE	NE	NE	NE	NE	NE	9	13.0	0	0.0	9	100.0	NE	NE	NE	NE	NE	NE	NE	0.3865	>999.9	9	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.						
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24.6	0	0.0	33	100.0	NE	NE	NE	NE	NE	NE	NE	17	24.6	1	5.9	16	94.1	NE	NE	NE	NE	NE	NE	NE	0.1635	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-						
	>0 to <=6 units	67	50.0	1	1.5	66	98.5	NE	NE	NE	NE	NE	NE	NE	34	49.3	0	0.0	34	100.0	NE	NE	NE	NE	NE	NE	NE	0.4661	>999.9	9	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.						
	>6 units	34	25.4	0	0.0	34	100.0	NE	NE	NE	NE	NE	NE	NE	18	26.1	0	0.0	18	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Geographic region	Japan/Rest of Asia Pacific	85	63.4	1	1.2	84	98.8	NE	NE	NE	NE	NE	NE	NE	51	73.9	0	0.0	51	100.0	NE	NE	NE	NE	NE	NE	NE	NE	0.4275	>999.9	9	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-				
	North America/ Central and South America/ Europe	49	36.6	0	0.0	49	100.0	NE	NE	NE	NE	NE	NE	NE	18	26.1	1	5.6	17	94.4	NE	NE	NE	NE	NE	NE	NE	NE	0.0980	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.						
Eculisumab availability	Yes	55	41.0	1	1.8	54	98.2	NE	NE	NE	NE	NE	NE	NE	26	37.7	0	0.0	26	100.0	NE	NE	NE	NE	NE	NE	NE	NE	0.4878	>999.9	9	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-				
	No	79	59.0	0	0.0	79	100.0	NE	NE	NE	NE	NE	NE	NE	43	62.3	1	2.3	42	97.7	NE	NE	NE	NE	NE	NE	NE	NE	0.1753	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.						
Race/ethnicity	White	44	32.8	0	0.0	44	100.0	NE	NE	NE	NE	NE	NE	NE	16	23.2	1	6.3	15	93.8	NE	NE	NE	NE	NE	NE	NE	NE	0.0973	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-					
	Asian	86	64.2	1	1.2	85	98.8	NE	NE	NE	NE	NE	NE	NE	51	73.9	0	0.0	51	100.0	NE	NE	NE	NE	NE	NE	NE	NE	0.4303	>999.9	9	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.					
	Black or African American	3	2.2	0	0.0	3	100.0	NE	NE	NE	NE	NE	NE	NE	1	1.4	0	0.0	1	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
	Unknown	1	0.7	0	0.0	1	100.0	NE	NE	NE	NE	NE	NE	NE	1	1.4	0	0.0	1	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
LDH value	>=2 to <=4 x ULN	26	17.9	0	0.0	26	100.0	NE	NE	NE	NE	NE	NE	NE	11	15.9	0	0.0	11	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	>4 x ULN	110	82.1	1	0.9	109	99.1	NE	NE	NE	NE	NE	NE	NE	58	84.1	1	1.7	57	98.3	NE	NE	NE	NE	NE	NE	NE	NE	0.6505	0.51	0.03	8.51	Convergence criterion (GCONV=1E-8) satisfied.	-					
Anaplastic anemia	Yes	52	38.8	0	0.0	52	100.0	NE	NE	NE	NE	NE	NE	NE	26	37.7	0	0.0	26	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	No	82	61.2	1	1.2	81	98.8	NE	NE	NE	NE	NE	NE	NE	43	62.3	1	2.3	42	97.7	NE	NE	NE	NE	NE	NE	NE	NE	0.6427	0.52	0.03	8.19	Convergence criterion (GCONV=1E-8) satisfied.	-					
Baseline Weight Category	<100	130	97.0	1	0.8	129	99.2	NE	NE	NE	NE	NE	NE	NE	66	95.7	1	1.5	65	98.5	NE	NE	NE	NE	NE	NE	NE	NE	0.6314	0.51	0.03	8.21	Convergence criterion (GCONV=1E-8) satisfied.	-					
	≥100	4	3.0	0	0.0	4	100.0	NE	NE	NE	NE	NE	NE	NE	3	4.3	0	0.0	3	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 †Clinical cut-off: 16NOV2022

Program: root/clinical studies/RO7112689/CD70115/B042162/data analysis/ACE_CSR_1/prod/program/t_eff tte.sas
 Output: root/clinical studies/RO7112689/CD70115/B042162/data analysis/ACE_CSR_1/prod/output/t_eff tte.sas QVSRV_PAP_16NOV2022_42162.xls
 10APR2024 11:28

POPULATION: All Patients Population

ENDPOINT: Overall Survival

MODEL: Stratified Analysis by LDH value, Transfusion history [total pREC units administered in the 6 months pre-randomization]

STUDY: BO42162

Time to Event Analysis (Efficacy)

		Crovalimab (N=135)												Eculizumab (N=69)												Crovalimab vs. Eculizumab				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio			
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	135	100,0	2	1,5	133	98,5	NE	NE	NE	NE	NE	NE	69	100,0	1	1,4	68	98,6	NE	NE	NE	NE	NE	NE	0,9539	1,07	0,10	11,84	Convergence criterion (GCONV=1E-8) satisfied.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

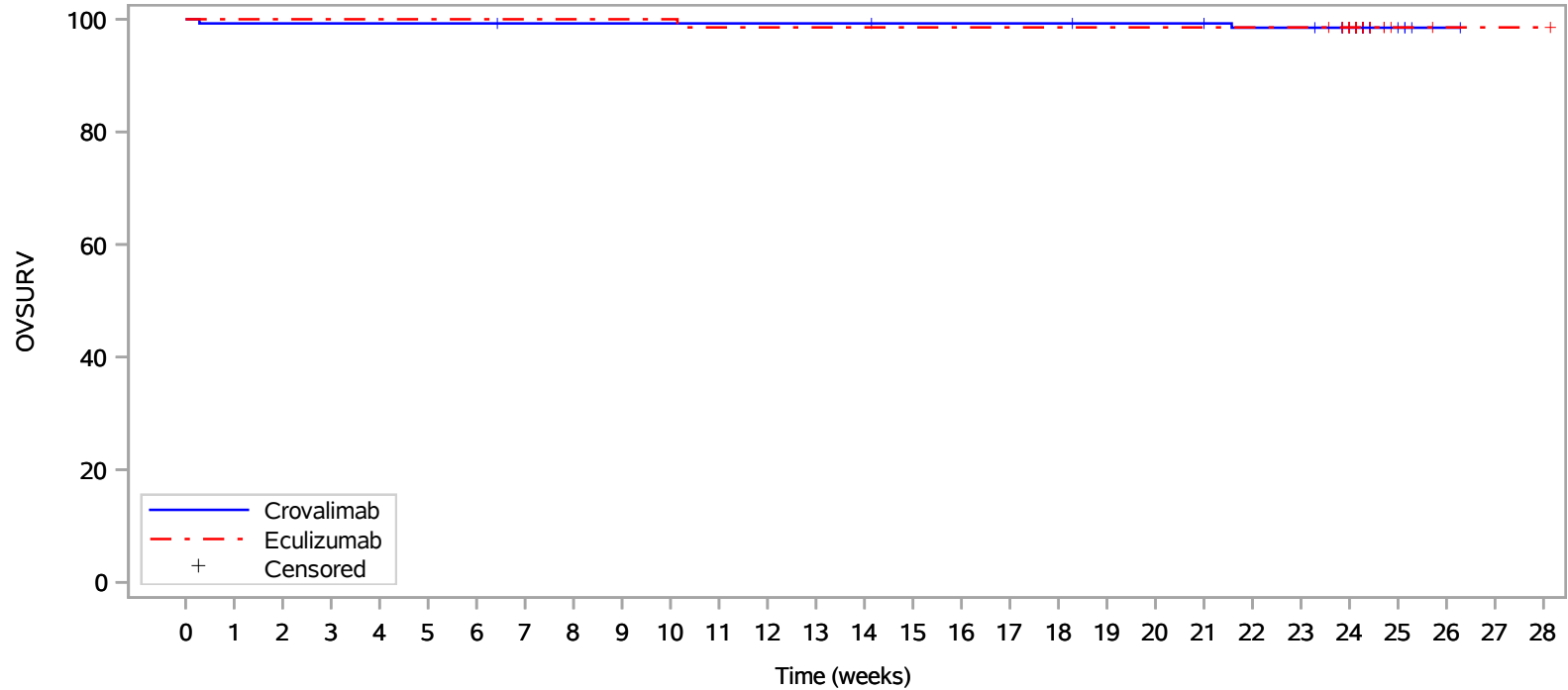
Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_tte.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_tte_str_OVSURV_ALL_16NOV2022_42162.xls

25APR2024 15:16

POPULATION: All Patients Population
ENDPOINT: Overall Survival
STUDY: BO42162



Patients at risk																																									
Crovalimab	135	134	134	134	134	134	134	133	133	133	133	133	133	133	132	132	132	132	131	131	131	129	129	115	5	1										NE	NE				
Eculizumab	69	69	69	69	69	69	69	69	69	69	69	69	68	68	68	68	68	68	68	68	68	68	68	62	2	1										1	1				
Patients censored																																									
Crovalimab	0	0	0	0	0	0	0	1	1	1	1	1	1	1	2	2	2	2	3	3	4	4	4	29	129	132										NE	NE				
Eculizumab	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	20	66	67	67	67													

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/g_km.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/g_km_OVSURV_ALL_16NOV2022_42162.pdf
 08JUN2024 9:09

POPULATION: All Patients Population
 ENDPOINT: Overall Survival
 MODEL: Unstratified Analysis
 STUDY: R042162
 Time to Event Analysis by Subgroups (Efficiency)

Covariate	Level	Pembrolizumab (HR163)											Enfortumab (HR60)											Overall vs. Enfortumab				Tolerability Tests
		Patients		Patients with Event		Observed		Time to event			Pembrolizumab		Patients with Event		Observed		Time to event			Low-rank		Hazard Ratio		Convergence Status	p-value (Likelihood Ratio)			
		n	%	n	%	n	%	95% Lower CI, For Q1	95% Upper CI, For Q1	Median (months)	95% Lower CI, For Median	95% Upper CI, For Median	n	%	n	%	95% Lower CI, For Q1	95% Upper CI, For Q1	Median (months)	95% Lower CI, For Median	95% Upper CI, For Median	CI Lower	CI Upper					
All	133	100.0	2	1.5	133	99.5	HR	HR	HR	HR	HR	133	100.0	3	2.3	130	97.7	HR	HR	HR	HR	HR	0.973	1.04	0.50	11.41	Convergence criterion (COCONV=1-1) satisfied.	
Sex	Male	71	53.4	1	1.4	70	98.6	HR	HR	HR	HR	71	53.4	0	0.0	71	97.1	HR	HR	HR	HR	HR	0.644	0.43	0.03	7.20	Convergence criterion (COCONV=1-1) satisfied.	
	Female	59	43.8	1	1.7	57	96.6	HR	HR	HR	HR	59	43.8	2	3.4	57	96.6	HR	HR	HR	HR	HR	0.433	0.93	0.50	19.4	Convergence criterion (COCONV=1-1) satisfied.	
Age	65+	124	92.4	2	1.6	122	100.0	HR	HR	HR	HR	124	92.4	2	1.6	122	98.4	HR	HR	HR	HR	HR	0.644	0.50	0.50	HR	Convergence criterion (COCONV=1-1) satisfied.	
	<65	11	8.1	0	0.0	11	100.0	HR	HR	HR	HR	11	8.1	1	9.1	10	90.9	HR	HR	HR	HR	HR	0.226	0.93	0.50	HR	Convergence criterion (COCONV=1-1) satisfied.	
Transfusion history (total RBC units administered in the 6 months prior randomization)	0 units	31	23.3	0	0.0	31	100.0	HR	HR	HR	HR	31	23.3	1	3.2	30	96.8	HR	HR	HR	HR	HR	0.633	0.50	0.50	HR	Convergence criterion (COCONV=1-1) satisfied.	
	>0 to <=4 units	69	51.1	2	2.9	67	97.1	HR	HR	HR	HR	69	51.1	0	0.0	69	100.0	HR	HR	HR	HR	HR	0.306	0.93	0.50	HR	Convergence criterion (COCONV=1-1) satisfied.	
	>4 units	33	24.6	0	0.0	33	100.0	HR	HR	HR	HR	33	24.6	2	6.1	31	93.9	HR	HR	HR	HR	HR	HR	HR	HR	HR	Convergence criterion (COCONV=1-1) satisfied.	
Geographic Region	East/South of Asia Pacific	85	63.9	1	1.2	84	98.8	HR	HR	HR	HR	85	63.9	1	1.2	84	98.8	HR	HR	HR	HR	HR	0.427	0.93	0.50	HR	Convergence criterion (COCONV=1-1) satisfied.	
	North America/ Central and South America/ Europe	50	37.1	1	2.0	49	98.0	HR	HR	HR	HR	50	37.1	2	3.8	48	96.0	HR	HR	HR	HR	HR	0.455	0.38	0.50	5.81	Convergence criterion (COCONV=1-1) satisfied.	
Enfortumab availability	Yes	58	43.6	2	3.4	56	96.6	HR	HR	HR	HR	58	43.6	3	5.2	55	94.8	HR	HR	HR	HR	HR	0.338	0.93	0.50	HR	Convergence criterion (COCONV=1-1) satisfied.	
	No	70	52.3	0	0.0	70	100.0	HR	HR	HR	HR	70	52.3	0	0.0	70	100.0	HR	HR	HR	HR	HR	0.176	0.50	0.50	HR	Convergence criterion (COCONV=1-1) satisfied.	
Race/Ethnicity	White	44	33.1	1	2.3	43	97.7	HR	HR	HR	HR	44	33.1	0	0.0	44	100.0	HR	HR	HR	HR	HR	0.405	0.38	0.50	5.31	Convergence criterion (COCONV=1-1) satisfied.	
	Asian	86	63.9	2	2.3	84	96.6	HR	HR	HR	HR	86	63.9	2	2.3	84	96.6	HR	HR	HR	HR	HR	0.433	0.93	0.50	HR	Convergence criterion (COCONV=1-1) satisfied.	
	Black or African American	7	5.2	0	0.0	7	100.0	HR	HR	HR	HR	7	5.2	0	0.0	7	100.0	HR	HR	HR	HR	HR	HR	HR	HR	Convergence criterion (COCONV=1-1) satisfied.		
	Unknown	1	0.7	0	0.0	1	100.0	HR	HR	HR	HR	1	0.7	0	0.0	1	100.0	HR	HR	HR	HR	HR	HR	HR	HR	HR	Convergence criterion (COCONV=1-1) satisfied.	
LDL value	<= 10 and <= HDL	23	17.3	0	0.0	23	100.0	HR	HR	HR	HR	23	17.3	0	0.0	23	100.0	HR	HR	HR	HR	HR	HR	HR	HR	HR	Convergence criterion (COCONV=1-1) satisfied.	
	> 10 and > HDL	111	82.7	2	1.8	109	98.2	HR	HR	HR	HR	111	82.7	2	1.8	109	98.2	HR	HR	HR	HR	HR	0.862	1.04	0.10	11.67	Convergence criterion (COCONV=1-1) satisfied.	
Dolastatid status	Yes	51	38.1	1	1.9	50	98.1	HR	HR	HR	HR	51	38.1	1	1.9	50	98.1	HR	HR	HR	HR	HR	0.487	0.93	0.50	HR	Convergence criterion (COCONV=1-1) satisfied.	
	No	82	61.1	1	1.2	81	98.8	HR	HR	HR	HR	82	61.1	2	2.4	80	97.6	HR	HR	HR	HR	HR	0.642	0.52	0.03	8.33	Convergence criterion (COCONV=1-1) satisfied.	
Baseline Weight Category	<100	131	97.0	2	1.5	129	98.5	HR	HR	HR	HR	131	97.0	3	2.3	128	98.5	HR	HR	HR	HR	HR	0.864	1.02	0.00	11.24	Convergence criterion (COCONV=1-1) satisfied.	
	>=100	2	1.5	0	0.0	2	100.0	HR	HR	HR	HR	2	1.5	0	0.0	2	100.0	HR	HR	HR	HR	HR	HR	HR	HR	HR	Convergence criterion (COCONV=1-1) satisfied.	

Test for interaction based on Likelihood Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 180000000

Program: rmc/clinical_studies/207112469/CCT015/R042162/data_analysis/ACC_CSR_1/psmd/output/eff_time_opp_covcovr_all_18000000_42162.sas
 Output: rmc/clinical_studies/207112469/CCT015/R042162/data_analysis/ACC_CSR_1/psmd/output/eff_time_opp_covcovr_all_18000000_42162.sas
 25APR2024 15:10

POPULATION: Primary Analysis Population
 ENDPOINT: Transfusion avoidance, Primary Efficacy Period
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Dichotomous Analysis (Efficacy)

		Crovalimab (N=134)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio		Weighted difference (Crovalimab - Eculizumab)			Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	134	100,0	88	65,7	69	100,0	47	68,1	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,45	1,68	-2,8	-15,67	11,14	0,99	Algorithm converged.	0,83	1,17	0,6655	1,01	Algorithm converged.	0,85	1,20

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_TA_PAP_16NOV2022_42162.xls
 10APR2024 10:42

POPULATION: Primary Analysis Population
 ENDPPOINT: Transfusion avoidance, Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Efficacy)

Name	Level	Crovalimab (N=134)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab						
		Patients		Patients with		Patients		Patients with		Odds Ratio		Weighted difference (Crovalimab - Eculizumab)		Relative Risk		Interaction Test		Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	134	100,0	88	65,7	69	100,0	47	68,1	0,90	Convergence criterion (GCONV+IE-8) satisfied.	0,48	1,66	-2,4	-15,33	11,43	0,96	Algorithm converged.	0,79	1,18	0,7251		1,04	Algorithm converged.	0,85	1,27
Sex	Male	77	57,5	54	70,1	35	50,7	25	71,4	0,94	Convergence criterion (GCONV+IE-8) satisfied.	0,39	2,27	-1,3	-17,75	17,51	0,98	Algorithm converged.	0,76	1,27	0,8883	0,7662	1,02	Algorithm converged.	0,79	1,31
	Female	57	42,5	34	59,6	34	49,3	22	64,7	0,81	Convergence criterion (GCONV+IE-8) satisfied.	0,33	1,94	-5,1	-23,99	15,43	0,92	Algorithm converged.	0,66	1,28	0,6288		1,08	Algorithm converged.	0,78	1,51
Age	<65	122	91,0	81	66,4	60	87,0	43	71,7	0,78	Convergence criterion (GCONV+IE-8) satisfied.	0,40	1,53	-5,3	-18,44	9,33	0,93	Algorithm converged.	0,76	1,14	0,4652	0,4299	1,08	Algorithm converged.	0,88	1,32
	>=65	12	9,0	7	58,3	9	13,0	4	44,4	1,75	Convergence criterion (GCONV+IE-8) satisfied.	0,31	10,02	13,9	-25,23	47,84	1,31	Algorithm converged.	0,55	3,14	0,5248		0,76	Algorithm converged.	0,32	1,82
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,6	29	87,9	17	24,6	14	82,4	1,55	Convergence criterion (GCONV+IE-8) satisfied.	0,31	7,91	5,5	-13,51	30,02	1,07	Algorithm converged.	0,83	1,38	0,6106	0,6647	0,94	Algorithm converged.	0,73	1,21
	>0 to <=6 units	67	50,0	47	70,1	34	49,3	25	73,5	0,85	Convergence criterion (GCONV+IE-8) satisfied.	0,34	2,13	-3,4	-20,12	15,85	0,95	Algorithm converged.	0,74	1,23	0,7194		1,05	Algorithm converged.	0,81	1,35
	>6 units	34	25,4	12	35,3	18	26,1	8	44,4	0,68	Convergence criterion (GCONV+IE-8) satisfied.	0,21	2,19	-9,2	-34,99	16,88	0,79	Algorithm converged.	0,40	1,58	0,5221		1,26	Algorithm converged.	0,63	2,51
Geographic region	Japan/Rest of Asia Pacific	85	63,4	57	67,1	51	73,9	35	68,6	0,93	Convergence criterion (GCONV+IE-8) satisfied.	0,44	1,96	-1,6	-16,83	14,82	0,98	Algorithm converged.	0,77	1,24	0,8494	0,9007	1,02	Algorithm converged.	0,81	1,30
	North America/Central and South America/Europe	49	36,6	31	63,3	18	26,1	12	66,7	0,86	Convergence criterion (GCONV+IE-8) satisfied.	0,28	2,69	-3,4	-25,47	22,50	0,95	Algorithm converged.	0,64	1,40	0,7947		1,05	Algorithm converged.	0,71	1,56
Eculizumab availability	Yes	55	41,0	35	63,6	26	37,7	18	69,2	0,78	Convergence criterion (GCONV+IE-8) satisfied.	0,29	2,11	-5,6	-25,04	16,77	0,92	Algorithm converged.	0,66	1,27	0,6154	0,7108	1,09	Algorithm converged.	0,79	1,51
	No	79	59,0	53	67,1	43	62,3	29	67,4	0,98	Convergence criterion (GCONV+IE-8) satisfied.	0,45	2,17	-0,4	-16,64	17,26	0,99	Algorithm converged.	0,77	1,29	0,9683		1,01	Algorithm converged.	0,78	1,30
Race/ethnicity	White	44	32,8	27	61,4	16	23,2	11	68,8	0,72	Convergence criterion (GCONV+IE-8) satisfied.	0,21	2,44	-7,4	-29,95	20,17	0,89	Algorithm converged.	0,60	1,34	0,5902	NE	1,12	Algorithm converged.	0,75	1,68
	Asian	86	64,2	57	66,3	51	73,9	35	68,6	0,90	Convergence criterion (GCONV+IE-8) satisfied.	0,43	1,89	-2,3	-17,59	14,06	0,97	Algorithm converged.	0,76	1,23	0,7761		1,04	Algorithm converged.	0,82	1,32
	Black or African American	3	2,2	3	100,0	1	1,4	1	100,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Unknown	1	0,7	1	100,0	1	1,4	0	0,0																	
LDH value	>=2 to <=4 x ULN	24	17,9	19	79,2	11	15,9	7	63,6	2,17	Convergence criterion (GCONV+IE-8) satisfied.	0,45	10,49	15,5	-13,36	46,07	1,24	Algorithm converged.	0,76	2,03	0,3526	0,2173	0,80	Algorithm converged.	0,49	1,31
	>4 x ULN	110	82,1	69	62,7	58	84,1	40	69,0	0,76	Convergence criterion (GCONV+IE-8) satisfied.	0,38	1,49	-6,2	-20,21	9,08	0,91	Algorithm converged.	0,73	1,14	0,4133		1,10	Algorithm converged.	0,88	1,38
Aplastic anemia	Yes	52	38,8	34	65,4	26	37,7	20	76,9	0,57	Convergence criterion (GCONV+IE-8) satisfied.	0,19	1,66	-11,5	-29,69	10,63	0,85	Algorithm converged.	0,64	1,13	0,2752	0,3064	1,18	Algorithm converged.	0,88	1,57
	No	82	61,2	54	65,9	43	62,3	27	62,8	1,14	Convergence criterion (GCONV+IE-8) satisfied.	0,53	2,46	3,1	-13,69	20,68	1,05	Algorithm converged.	0,79	1,38	0,7348		0,95	Algorithm converged.	0,72	1,26
Baseline Weight Category	<100	130	97,0	85	65,4	66	95,7	44	66,7	0,94	Convergence criterion (GCONV+IE-8) satisfied.	0,50	1,77	-1,3	-14,55	12,95	0,98	Algorithm converged.	0,79	1,21	0,8576	NE	1,02	Algorithm converged.	0,83	1,26
	>=100	4	3,0	3	75,0	3	4,3	3	100,0		Quasi-complete separation of data points detected.			NE	NE	NE										

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_ag2_PA_PAP_16NOV2022_42162.xls
 10APR2024 10:37

POPULATION: Primary Analysis Population
 ENDPOINT: Breakthrough Hemolysis, Primary Efficacy Period
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Dichotomous Analysis (Efficacy)

		Crovalimab (N=134)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	134	100,0	14	10,4	69	100,0	10	14,5	0,70	Convergence criterion (GCONV=1E-8) satisfied.	0,29	1,67	-3,9	-14,82	5,26	0,72	Algorithm converged.	0,34	1,54	0,4358	1,38	Algorithm converged.	0,65	2,93

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_BTH25_PAP_16NOV2022_42162.xls
 10APR2024 10:44

POPULATION: Primary Analysis Population
 ENDPOINT: Breakthrough Hemolysis, Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Efficacy)

Name	Level	Crovalimab (N=134)				Eculizumab (N=69)				Odds Ratio	Crovalimab vs. Eculizumab					Eculizumab vs. Crovalimab										
		Patients		Patients with		Patients		Patients with			Convergence Reason	Weighted difference (Crovalimab - Eculizumab)		Relative Risk		Interaction Test p-value (Likelihood ratio)	Relative Risk	Relative Risk								
		n	%	n	%	n	%	n	%			95% Lower CL	95% Upper CL	95% Lower CL	95% Upper CL			p-value (Cochran-Mantel-Haenszel)	95% Lower CL	95% Upper CL						
All	n/a	134	100,0	14	10,4	69	100,0	10	14,5	0,69	Convergence criterion (GCONV=1E-8) satisfied.	0,29	1,64	-4,0	-15,02	4,97	0,72	Algorithm converged.	0,34	1,54	0,4180	1,39	Algorithm converged.	0,65	2,96	
Sex	Male	77	57,5	9	11,7	35	50,7	7	20,0	0,53	Convergence criterion (GCONV=1E-8) satisfied.	0,18	1,56	-8,3	-25,10	5,15	0,58	Algorithm converged.	0,24	1,44	0,2797	0,5215	1,71	Algorithm converged.	0,69	4,22
	Female	57	42,5	5	8,8	34	49,3	3	8,8	0,99	Convergence criterion (GCONV=1E-8) satisfied.	0,22	4,45	-0,1	-15,04	11,65	0,99	Algorithm converged.	0,25	3,90	0,9933	1,01	Algorithm converged.	0,26	3,95	
Age	<65	122	91,0	11	9,0	60	87,0	9	15,0	0,56	Convergence criterion (GCONV=1E-8) satisfied.	0,22	1,44	-6,0	-17,76	3,44	0,60	Algorithm converged.	0,26	1,37	0,2579	0,2119	1,66	Algorithm converged.	0,73	3,80
	>=65	12	9,0	3	25,0	9	13,0	1	11,1	2,67	Convergence criterion (GCONV=1E-8) satisfied.	0,23	31,07	13,9	-22,28	43,56	2,25	Algorithm converged.	0,28	18,22	0,3944	0,44	Algorithm converged.	0,05	3,60	
Transfusion history (total pRBC units administered in the 6 months pre-randomization)	0 units	33	24,6	1	3,0	17	24,6	3	17,6	0,15	Convergence criterion (GCONV=1E-8) satisfied.	0,01	1,53	-14,6	-38,13	2,18	0,17	Algorithm converged.	0,02	1,53	0,1325	0,2138	5,82	Algorithm converged.	0,65	51,84
	>0 to <=6 units	67	50,0	8	11,9	34	49,3	3	8,8	1,40	Convergence criterion (GCONV=1E-8) satisfied.	0,35	5,66	3,1	-12,15	14,57	1,35	Algorithm converged.	0,38	4,78	0,6193	0,74	Algorithm converged.	0,21	2,61	
	>6 units	34	25,4	5	14,7	18	26,1	4	22,2	0,60	Convergence criterion (GCONV=1E-8) satisfied.	0,14	2,60	-7,5	-31,95	12,80	0,66	Algorithm converged.	0,20	2,16	0,5144	1,51	Algorithm converged.	0,46	4,94	
Geographic region	Japan/Rest of Asia Pacific	85	63,4	9	10,6	51	73,9	7	13,7	0,74	Convergence criterion (GCONV=1E-8) satisfied.	0,26	2,14	-3,1	-16,10	7,68	0,77	Algorithm converged.	0,31	1,94	0,5925	0,7805	1,30	Algorithm converged.	0,51	3,27
	North America/ Central and South America/ Europe	49	36,6	5	10,2	18	26,1	3	16,7	0,57	Convergence criterion (GCONV=1E-8) satisfied.	0,12	2,67	-6,5	-29,74	9,37	0,61	Algorithm converged.	0,16	2,30	0,5092	1,63	Algorithm converged.	0,43	6,15	
Eculizumab availability	Yes	55	41,0	6	10,9	26	37,7	4	15,4	0,67	Convergence criterion (GCONV=1E-8) satisfied.	0,17	2,63	-4,5	-23,53	9,82	0,71	Algorithm converged.	0,22	2,30	0,5866	0,9764	1,41	Algorithm converged.	0,44	4,57
	No	79	59,0	8	10,1	43	62,3	6	14,0	0,69	Convergence criterion (GCONV=1E-8) satisfied.	0,22	2,15	-3,8	-18,01	7,52	0,73	Algorithm converged.	0,27	1,96	0,5423	1,38	Algorithm converged.	0,51	3,71	
Race/ethnicity	White	44	32,8	5	11,4	16	23,2	2	12,5	0,90	Convergence criterion (GCONV=1E-8) satisfied.	0,16	5,16	-1,1	-25,52	14,36	0,91	Algorithm converged.	0,20	4,23	0,9053	NE	1,10	Algorithm converged.	0,24	5,11
	Asian	86	64,2	9	10,5	51	73,9	7	13,7	0,73	Convergence criterion (GCONV=1E-8) satisfied.	0,26	2,11	-3,3	-16,20	7,50	0,76	Algorithm converged.	0,30	1,92	0,5767	1,31	Algorithm converged.	0,52	3,31	
	Black or African American	3	2,2	0	0,0	1	1,4	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Unknown	1	0,7	0	0,0	1	1,4	1	100,0	*	Complete separation of data points detected.			NE	NE	NE	NE	*					*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		
LDH value	>=2 to <=4 x ULN	24	17,9	2	8,3	11	15,9	2	18,2	0,41	Convergence criterion (GCONV=1E-8) satisfied.	0,05	3,37	-9,8	-39,97	11,99	0,46	Algorithm converged.	0,07	2,84	0,4461	0,5959	2,18	Algorithm converged.	0,35	13,54
	>4 x ULN	110	82,1	12	10,9	58	84,1	8	13,8	0,77	Convergence criterion (GCONV=1E-8) satisfied.	0,29	1,99	-2,9	-14,91	6,90	0,79	Algorithm converged.	0,34	1,82	0,5944	1,26	Algorithm converged.	0,55	2,92	
Aplastic anemia	Yes	52	38,8	2	3,8	26	37,7	1	3,8	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,57	0,0	-15,30	9,67	1,00	Algorithm converged.	0,10	10,53	1,0000	0,7740	1,00	Algorithm converged.	0,10	10,53
	No	82	61,2	12	14,6	43	62,3	9	20,9	0,65	Convergence criterion (GCONV=1E-8) satisfied.	0,25	1,69	-6,3	-21,80	6,95	0,70	Algorithm converged.	0,52	1,53	0,3903	1,43	Algorithm converged.	0,65	3,12	
Baseline Weight Category	<100	130	97,0	13	10,0	66	95,7	9	13,6	0,70	Convergence criterion (GCONV=1E-8) satisfied.	0,28	1,74	-3,6	-14,70	5,31	0,73	Algorithm converged.	0,33	1,63	0,4650	0,9857	1,36	Algorithm converged.	0,61	3,02
	>=100	4	3,0	1	25,0	3	4,3	1	33,3	0,67	Convergence criterion (GCONV=1E-8) satisfied.	0,02	18,06	-8,3	-58,58	44,19	0,75	Algorithm converged.	0,07	7,73	0,8106	1,33	Algorithm converged.	0,13	13,74	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical studies/RO7112689/CDT70115/B042162/data analysis/ACE CSR 1/prod/program/t_eff resp.sas
 Output: root/clinical studies/RO7112689/CDT70115/B042162/data analysis/ACE CSR 1/prod/output/t_eff resp sa2 BTH25 PAP 16NOV2022 42162.x1s
 10APR2024 10:39

POPULATION: Primary Analysis Population
 ENDPOINT: Major adverse vascular event, Primary Efficacy Period
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Dichotomous Analysis (Efficacy)

		Crovalimab (N=134)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio		Weighted difference (Crovalimab - Eculizumab)				Relative Risk				Relative Risk							
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
All	n/a	134	100,0	0	0	69	100,0	1	1,4	0,00	Convergence criterion (GCONV=1E-8) satisfied.	0,00	NE	NE	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_MAVE25_PAP_16NOV2022_42162.xls
 25APR2024 19:13

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_sg2_MAVE25_PAP_16NOV2022_42162.xls
25APR2024 19:18

POPULATION: All Patients Population
 ENDPOINT: Major adverse vascular event, Primary Efficacy Period
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Dichotomous Analysis (Efficacy)

		Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab						
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk						
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,53	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,53	-0,7	-10,66	5,34	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_MAVE25_ALL_16NOV2022_42162.xls
 25APR2024 19:25

POPULATION: Primary Analysis Population

ENDPOINT: EORTC QLQ-C30 Physical Functioning, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	134	100,0	74,08	18,26	69	100,0	67	97,1	73,03	23,19
Week 2	All	134	100,0	132	98,5	80,91	14,87	69	100,0	67	97,1	81,99	18,42
Week 5	All	134	100,0	130	97,0	83,95	14,20	69	100,0	66	95,7	82,32	14,68
Week 9	All	134	100,0	132	98,5	84,79	13,69	69	100,0	66	95,7	85,15	13,88
Week 17	All	133	99,3	129	97,0	86,15	12,21	68	98,6	66	97,1	84,85	14,30
Week 25	All	132	98,5	128	97,0	86,25	13,27	68	98,6	66	97,1	86,87	12,54

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

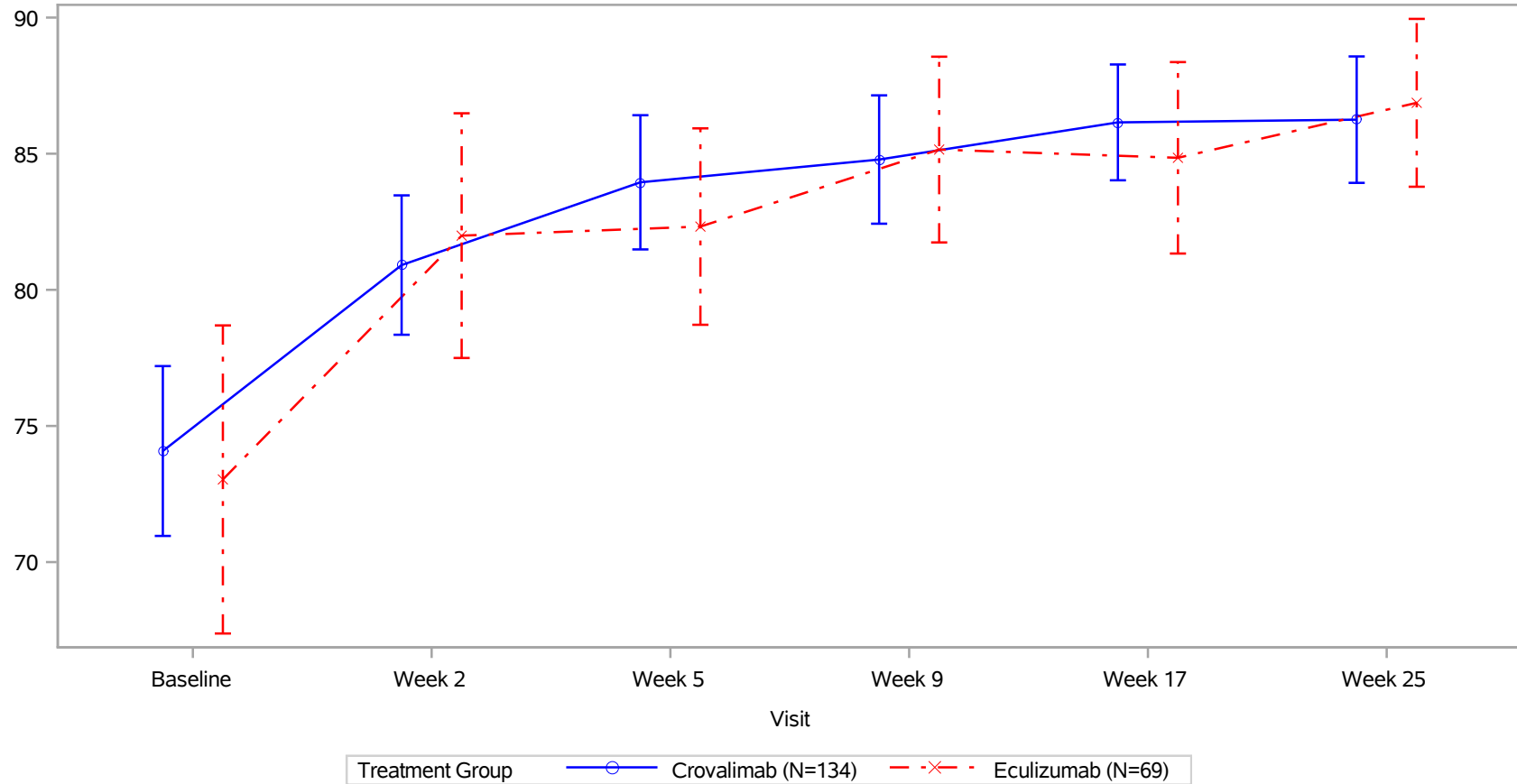
Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_C30PHYS_PAP_16NOV2022_42162.xls

07JUN2024 12:36

POPULATION: Primary Analysis Population
ENDPOINT: EORTC QLQ-C30 Physical Functioning, Primary Efficacy Period
STUDY: BO42162



Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/g_mean_plot.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/g_mean_plot_C30PHYS_PAP_16NOV2022_42162.pdf
07JUN2024 13:18

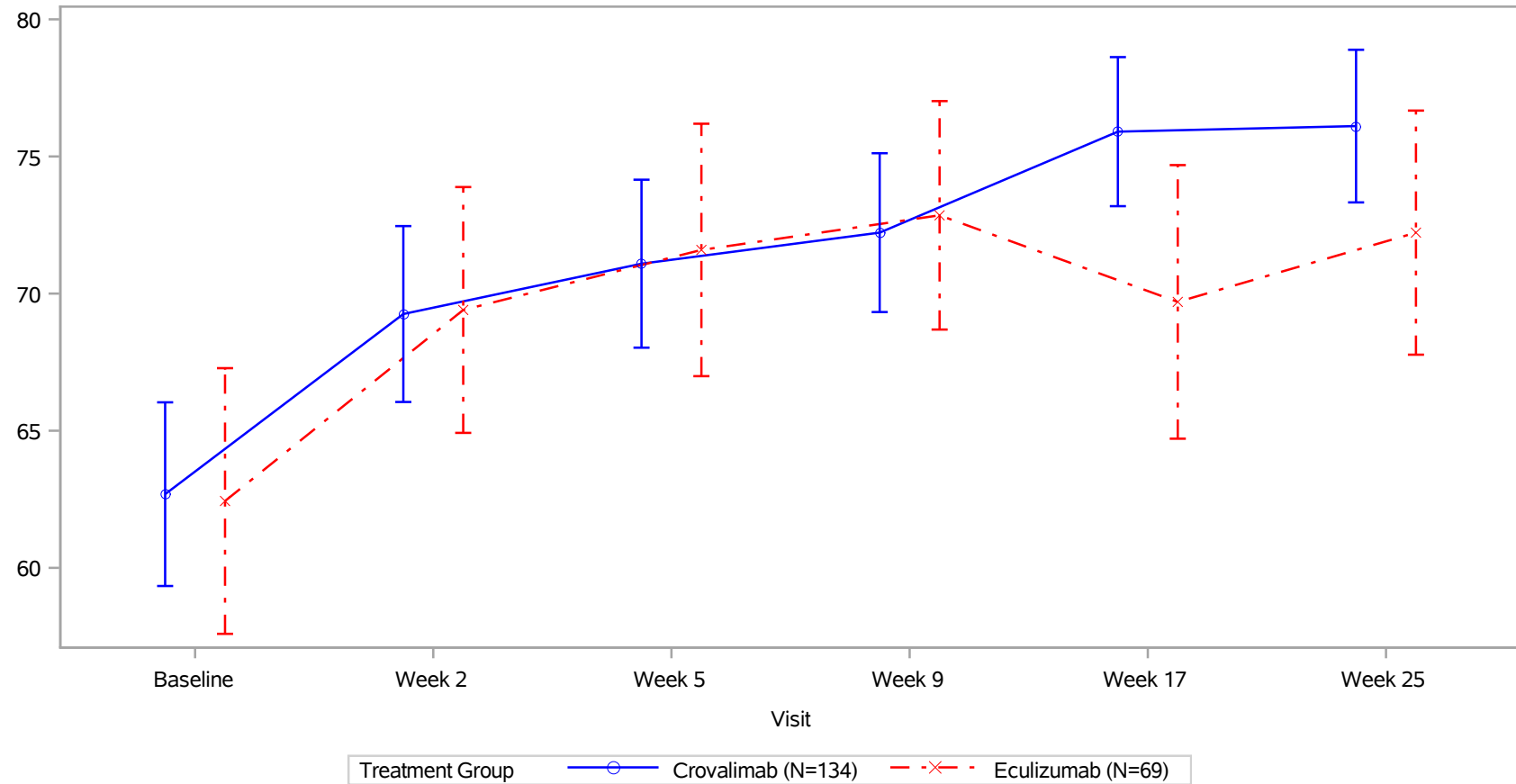
POPULATION: Primary Analysis Population
 ENDPOINT: EORTC QLQ-C30 GHS/QoL, Primary Efficacy Period
 MODEL: --
 STUDY: BO42162
 Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	134	100,0	62,69	19,60	69	100,0	67	97,1	62,44	19,86
Week 2	All	134	100,0	132	98,5	69,26	18,62	69	100,0	67	97,1	69,40	18,37
Week 5	All	134	100,0	130	97,0	71,09	17,65	69	100,0	66	95,7	71,59	18,72
Week 9	All	134	100,0	132	98,5	72,22	16,81	69	100,0	66	95,7	72,85	16,94
Week 17	All	133	99,3	129	97,0	75,90	15,60	68	98,6	66	97,1	69,70	20,29
Week 25	All	132	98,5	128	97,0	76,11	15,91	68	98,6	66	97,1	72,22	18,10

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP
 with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
² mean: descriptive statistics - absolute values
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_C30QOL_PAP_16NOV2022_42162.xls
 07JUN2024 12:38

POPULATION: Primary Analysis Population
ENDPOINT: EORTC QLQ-C30 GHS/QoL, Primary Efficacy Period
STUDY: BO42162



Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/g_mean_plot.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/g_mean_plot_C30QOL_PAP_16NOV2022_42162.pdf
07JUN2024 13:20

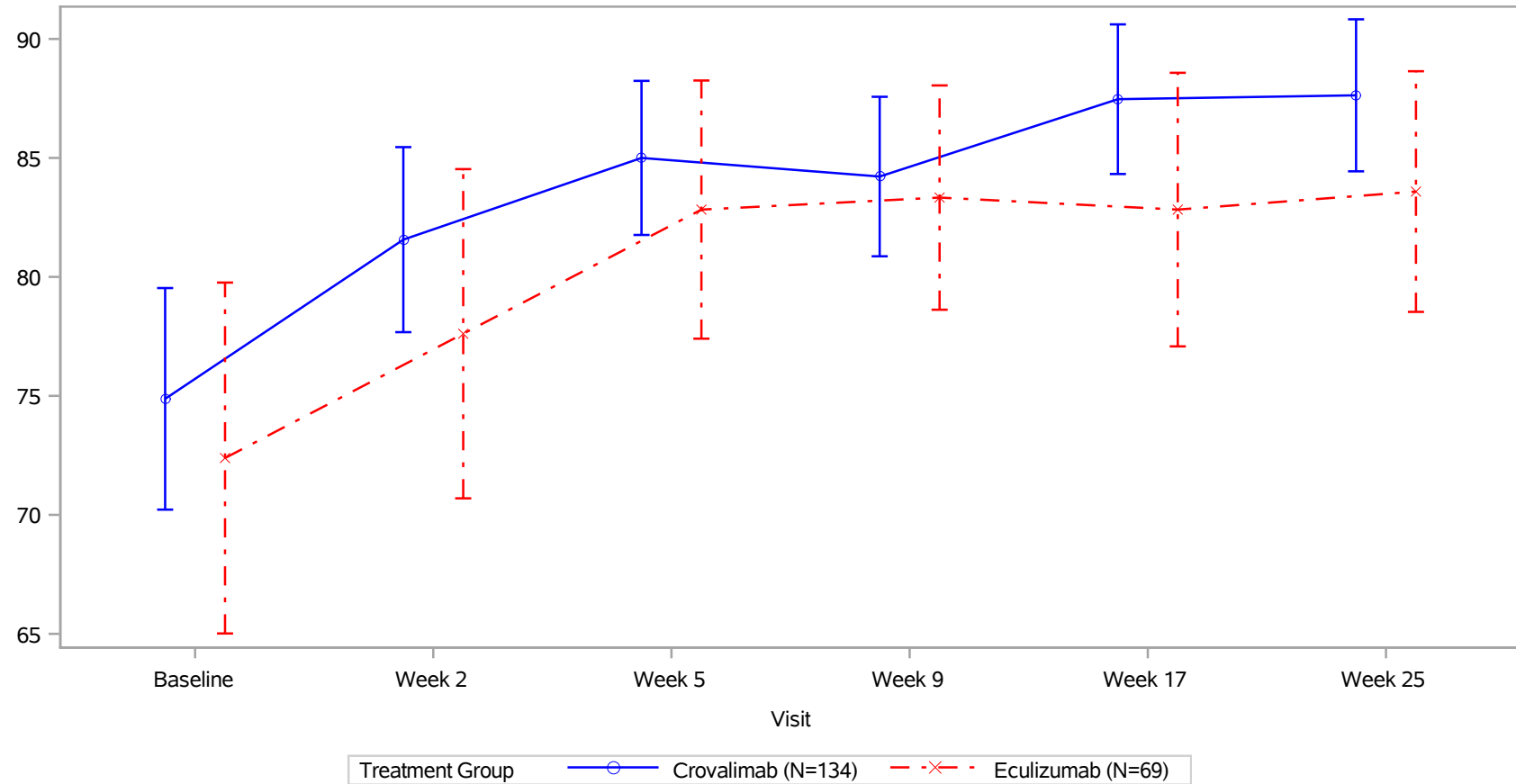
POPULATION: Primary Analysis Population
 ENDPOINT: EORTC QLQ-C30 Role Functioning, Primary Efficacy Period
 MODEL: --
 STUDY: BO42162
 Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	134	100,0	74,88	27,25	69	100,0	67	97,1	72,39	30,23
Week 2	All	134	100,0	132	98,5	81,57	22,58	69	100,0	67	97,1	77,61	28,36
Week 5	All	134	100,0	130	97,0	85,00	18,66	69	100,0	66	95,7	82,83	22,07
Week 9	All	134	100,0	132	98,5	84,22	19,46	69	100,0	66	95,7	83,33	19,17
Week 17	All	133	99,3	129	97,0	87,47	18,05	68	98,6	66	97,1	82,83	23,38
Week 25	All	132	98,5	128	97,0	87,63	18,26	68	98,6	66	97,1	83,59	20,57

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP
 with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
² mean: descriptive statistics - absolute values
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_C3ORF_PAP_16NOV2022_42162.xls
 07JUN2024 12:39

POPULATION: Primary Analysis Population
ENDPOINT: EORTC QLQ-C30 Role Functioning, Primary Efficacy Period
STUDY: BO42162



Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/g_mean_plot.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/g_mean_plot_C30RF_PAP_16NOV2022_42162.pdf
07JUN2024 13:21

POPULATION: PRO-evaluable Population
 ENDPOINT: EORTC QLQ-C30 Responder Analysis (response criterium: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Dichotomous Analysis (Efficacy)

Physical Functioning

		Crovalimab (N=128)				Eculizumab (N=66)				Crovalimab vs. Eculizumab															
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Eculizumab vs. Crovalimab					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	128	100,0	42	32,8	66	100,0	23	34,8	0,91	Convergence criterion (GCONV=1E-8) satisfied.	0,48	1,73	-1,9	-16,16	11,52	0,940	Algorithm converged.	0,622	1,419	0,7830	1,064	Algorithm converged.	0,705	1,607

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_C30PHYS10_PRO2_16NOV2022_42162.xls
 08JUN2024 6:28

POPULATION: PRO-evaluable Population
 ENDPOINT: EORTC QLQ-C30 Responder Analysis (response criterium: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Efficacy)

Physical Functioning

Name	Level	Crossover (N=128)				Eucizumab (N=66)				Odds Ratio	Crossover vs. Eucizumab						Eucizumab vs. Crossover									
		Patients		Patients with		Patients		Patients with			Odds Ratio			Weighted difference (Crossover - Eucizumab)			Relative Risk			Relative Risk						
		n	%	n	%	n	%	n	%		95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	128	100,0	42	32,8	66	100,0	23	34,8	0,91	Convergence criterion (GCONV=1E-8) satisfied.	0,49	1,71	-2,0	-16,24	11,39	0,942	Algorithm converged.	0,623	1,423	0,7769		1,062	Algorithm converged.	0,703	1,605
Sex	Male	73	57,0	28	38,4	34	51,5	11	32,4	1,30	Convergence criterion (GCONV=1E-8) satisfied.	0,55	3,07	6,0	-13,71	23,51	1,186	Algorithm converged.	0,673	2,089	0,5417	0,1962	0,843	Algorithm converged.	0,479	1,486
	Female	55	43,0	14	25,5	32	48,5	12	37,5	0,57	Convergence criterion (GCONV=1E-8) satisfied.	0,22	1,45	-12,0	-31,80	7,38	0,679	Algorithm converged.	0,359	1,282	0,2459		1,473	Algorithm converged.	0,780	2,783
Age	<65	118	92,2	40	33,8	57	86,4	21	36,8	0,88	Convergence criterion (GCONV=1E-8) satisfied.	0,45	1,70	-2,9	-18,15	11,47	0,920	Algorithm converged.	0,603	1,405	0,7035	0,9807	1,087	Algorithm converged.	0,712	1,659
	>=65	10	7,8	2	20,0	9	13,6	2	22,2	0,87	Convergence criterion (GCONV=1E-8) satisfied.	0,10	7,95	-2,2	-37,76	32,60	0,900	Algorithm converged.	0,158	5,132	0,9057		1,111	Algorithm converged.	0,195	6,336
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	32	25,0	11	34,4	15	22,7	3	20,0	2,10	Convergence criterion (GCONV=1E-8) satisfied.	0,49	9,03	14,4	-14,42	36,00	1,719	Algorithm converged.	0,561	5,266	0,2801	0,4020	0,582	Algorithm converged.	0,190	1,783
	>0 to <=6 units	63	49,2	19	30,2	33	50,0	13	39,4	0,66	Convergence criterion (GCONV=1E-8) satisfied.	0,28	1,60	-9,2	-28,85	9,88	0,766	Algorithm converged.	0,435	1,348	0,3692		1,306	Algorithm converged.	0,742	2,300
	>6 units	33	25,8	12	36,4	18	27,3	7	38,9	0,90	Convergence criterion (GCONV=1E-8) satisfied.	0,27	2,93	-2,5	-29,11	22,67	0,935	Algorithm converged.	0,449	1,949	0,8590		1,069	Algorithm converged.	0,513	2,229
Geographic region	Japan/Rest of Asia Pacific	80	62,5	24	30,0	49	74,2	15	30,6	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,45	2,10	-0,6	-17,15	14,85	0,980	Algorithm converged.	0,572	1,679	0,9415	0,6254	1,020	Algorithm converged.	0,596	1,748
	North America/Central and South America/Europe	48	37,5	18	37,5	17	25,8	8	47,1	0,67	Convergence criterion (GCONV=1E-8) satisfied.	0,22	2,06	-9,6	-34,74	15,67	0,797	Algorithm converged.	0,428	1,485	0,4941		1,255	Algorithm converged.	0,673	2,339
Eucizumab availability	Yes	52	40,6	21	40,4	26	39,4	11	42,3	0,92	Convergence criterion (GCONV=1E-8) satisfied.	0,36	2,40	-1,9	-24,30	19,63	0,955	Algorithm converged.	0,547	1,667	0,8710	0,9317	1,048	Algorithm converged.	0,600	1,829
	No	76	59,4	21	27,6	40	60,6	12	30,0	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,38	2,07	-2,4	-20,13	13,82	0,921	Algorithm converged.	0,507	1,673	0,7896		1,086	Algorithm converged.	0,598	1,972
Race/ethnicity	White	43	33,6	14	32,6	15	22,7	6	40,0	0,72	Convergence criterion (GCONV=1E-8) satisfied.	0,22	2,44	-7,4	-34,53	17,65	0,814	Algorithm converged.	0,383	1,731	0,6085	NE	1,229	Algorithm converged.	0,578	2,612
	Asian	81	63,3	24	29,6	49	74,2	15	30,6	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,44	2,07	-1,0	-17,47	14,42	0,968	Algorithm converged.	0,565	1,659	0,9059		1,033	Algorithm converged.	0,603	1,771
	Black or African American	3	2,3	3	100,0	1	1,5	1	100,0	NE		NE	NE					NE	NE	NE	NE	NE	NE	NE	NE	NE
	Unknown	1	0,8	1	100,0	1	1,5	1	100,0	NE		NE	NE					NE	NE	NE	NE	NE	NE	NE	NE	NE
LDH value	>=2 to <=4 x ULN	22	17,2	7	31,8	10	15,2	3	30,0	1,09	Convergence criterion (GCONV=1E-8) satisfied.	0,21	5,52	1,8	-32,22	30,19	1,061	Algorithm converged.	0,344	3,274	0,9176	0,8221	0,943	Algorithm converged.	0,305	2,911
	>4 x ULN	106	82,8	35	33,0	56	84,8	20	35,7	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,45	1,75	-2,7	-18,15	11,98	0,925	Algorithm converged.	0,593	1,441	0,7318		1,082	Algorithm converged.	0,694	1,686
Aplastic anemia	Yes	50	39,1	17	34,0	24	36,4	9	37,5	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,31	2,36	-3,5	-26,42	17,92	0,907	Algorithm converged.	0,476	1,728	0,7694	0,8909	1,103	Algorithm converged.	0,579	2,102
	No	78	60,9	25	32,1	42	63,6	14	33,3	0,94	Convergence criterion (GCONV=1E-8) satisfied.	0,42	2,10	-1,3	-19,03	15,23	0,962	Algorithm converged.	0,563	1,643	0,8866		1,040	Algorithm converged.	0,608	1,778
Baseline Weight Category	<100	124	96,9	40	32,3	63	95,5	22	34,9	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,47	1,68	-2,7	-17,14	11,02	0,924	Algorithm converged.	0,605	1,410	0,7163	0,6047	1,083	Algorithm converged.	0,709	1,652
	>=100	4	3,1	2	50,0	3	4,5	1	33,3	2,00	Convergence criterion (GCONV=1E-8) satisfied.	0,09	44,35	16,7	-41,05	60,98	1,500	Algorithm converged.	0,230	9,796	0,6520		0,667	Algorithm converged.	0,102	4,354

POPULATION: PRO-evaluable Population
 ENDPOINT: EORTC QLQ-C30 Responder Analysis (response criterium: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Dichotomous Analysis (Efficacy)

GHS/QoL

Name	Level	Crovalimab (N=128)				Eculizumab (N=66)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio		Weighted difference (Crovalimab - Eculizumab)					Relative Risk					Relative Risk			
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	128	100,0	67	52,3	66	100,0	32	48,5	1,17	Convergence criterion (GCONV=1E-8) satisfied.	0,65	2,11	3,9	-10,73	18,33	1,087	Algorithm converged.	0,807	1,465	0,6052	0,920	Algorithm converged.	0,683	1,240

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_C30QOL10_PRO2_16NOV2022_42162.xls
 08JUN2024 6:27

POPULATION: PRO-evaluable Population
 ENDPOINT: EORTC QLQ-C30 Responder Analysis (response criterion: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Efficacy)

GHS/QoL

Name	Level	Crovalimab (N=128)				Eculizumab (N=66)				Crovalimab vs. Eculizumab								Eculizumab vs. Crovalimab								
		Patients		Patients with		Patients		Patients with		Odds Ratio				Weighted difference (Crovalimab - Eculizumab)				Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	128	100,0	67	52,3	66	100,0	32	48,5	1,17			3,9	-10,74	18,25	1,080	Algorithm converged.	0,801	1,455	0,6103		0,926	Algorithm converged.	0,687	1,249	
Sex	Male	73	57,0	40	54,8	34	51,5	14	41,2	1,73			13,6	-6,50	32,00	1,331	Algorithm converged.	0,846	2,092	0,1842	0,1691	0,751	Algorithm converged.	0,478	1,182	
	Female	55	43,0	27	49,1	32	48,5	18	56,3	0,75			-7,2	-27,27	14,08	0,873	Algorithm converged.	0,581	1,311	0,5175		1,146	Algorithm converged.	0,763	1,722	
Age	<65	118	92,2	63	53,4	57	86,4	30	52,6	1,03			0,8	-14,53	16,19	1,014	Algorithm converged.	0,753	1,367	0,9250	0,4248	0,986	Algorithm converged.	0,731	1,329	
	>=65	10	7,8	4	40,0	9	13,6	2	22,2	2,33			17,8	-22,16	50,62	1,800	Algorithm converged.	0,427	7,588	0,3924		0,556	Algorithm converged.	0,132	2,342	
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	32	25,0	18	56,3	15	22,7	7	46,7	1,47			9,6	-19,15	36,43	1,205	Algorithm converged.	0,648	2,244	0,5386	0,3409	0,830	Algorithm converged.	0,446	1,544	
	>0 to <=6 units	63	49,2	30	47,6	33	50,0	18	54,5	0,76			-6,9	-26,52	13,59	0,873	Algorithm converged.	0,582	1,309	0,5178		1,145	Algorithm converged.	0,764	1,717	
	>6 units	33	25,8	19	57,6	18	27,3	7	38,9	2,13			18,7	-9,37	42,69	1,481	Algorithm converged.	0,774	2,833	0,1930		0,675	Algorithm converged.	0,353	1,292	
Geographic region	Japan/Rest of Asia Pacific	80	62,5	39	48,8	49	74,2	23	46,9	1,08			1,8	-15,52	18,87	1,039	Algorithm converged.	0,715	1,508	0,8415	0,8532	0,963	Algorithm converged.	0,663	1,398	
	North America/ Central and South America/ Europe	48	37,5	28	58,3	17	25,8	9	52,9	1,24			5,4	-19,79	30,83	1,102	Algorithm converged.	0,663	1,831	0,7010		0,908	Algorithm converged.	0,546	1,508	
Eculizumab availability	Yes	52	40,6	27	51,9	26	39,4	14	53,8	0,93			-1,9	-23,78	20,58	0,964	Algorithm converged.	0,620	1,500	0,8725	0,5289	1,037	Algorithm converged.	0,667	1,613	
	No	76	59,4	40	52,6	40	60,6	18	45,0	1,36			7,6	-11,15	25,56	1,170	Algorithm converged.	0,781	1,751	0,4329		0,855	Algorithm converged.	0,571	1,280	
Race/ethnicity	White	43	33,6	25	58,1	15	22,7	8	53,3	1,22			4,8	-21,60	31,65	1,090	Algorithm converged.	0,637	1,865	0,7473	0,4386	0,917	Algorithm converged.	0,536	1,569	
	Asian	81	63,3	39	48,1	49	74,2	23	46,9	1,05			1,2	-16,07	18,24	1,026	Algorithm converged.	0,706	1,491	0,8935		0,975	Algorithm converged.	0,671	1,417	
	Black or African American	3	2,3	2	66,7	1	1,5	0	0,0	*																
	Unknown	1	0,8	1	100,0	1	1,5	1	100,0	NE																
LDH value	>=2 to <=4 x ULN	22	17,2	10	45,5	10	15,2	4	40,0	1,25			5,5	-28,74	36,00	1,136	Algorithm converged.	0,468	2,757	0,7715	0,9080	0,880	Algorithm converged.	0,363	2,135	
	>4 x ULN	106	82,8	57	53,8	56	84,8	28	50,0	1,16			3,8	-12,04	19,43	1,075	Algorithm converged.	0,784	1,475	0,6475		0,930	Algorithm converged.	0,678	1,275	
Aplastic anemia	Yes	50	39,1	26	52,0	24	36,4	9	37,5	1,81			14,5	-9,45	35,51	1,387	Algorithm converged.	0,776	2,479	0,2326	0,2712	0,721	Algorithm converged.	0,403	1,289	
	No	78	60,9	41	52,6	42	63,6	23	54,8	0,92			-2,2	-19,98	16,07	0,960	Algorithm converged.	0,679	1,357	0,8177		1,042	Algorithm converged.	0,737	1,473	
Baseline Weight Category	<100	124	96,9	64	51,6	63	95,5	31	49,2	1,10			2,4	-12,45	17,13	1,049	Algorithm converged.	0,774	1,421	0,7557	0,3096	0,953	Algorithm converged.	0,704	1,291	
	>=100	4	3,1	3	75,0	3	4,5	1	33,3	6,00			41,7	-22,57	75,68	2,250	Algorithm converged.	0,412	12,284	0,2309		0,444	Algorithm converged.	0,081	2,426	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical studies/R07112689/CDT70115/B042162/data analysis/ACE CSR 1/prod/program/t eff resp.sas
 Output: root/clinical studies/R07112689/CDT70115/B042162/data analysis/ACE CSR 1/prod/output/t eff resp sq2 C30QoL10 PRO2 16NOV2022 42162.xls
 08JUN2024 6:35

POPULATION: PRO-evaluable Population
 ENDPOINT: EORTC QLQ-C30 Response Analysis (response criterion: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period
 NOTE: Stratified Analysis by ISM value, Transfusion history (total pMC units administered in the 6 months pre-randomization)
 STUDY: B042162
 Dichotomous Analysis (Efficacy)

Role Functioning

		Cisplatin (n=12)				Epirubicin (n=6)				Cisplatin vs. Epirubicin							Epirubicin vs. Cisplatin								
Base	Level	Patients		Patients with Event		Patients		Patients with Event		Odds Ratio		Weighted difference (Cisplatin - Epirubicin)			Relative Risk		Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Weighted difference in proportion	95% Lower CI for difference in proportion	95% Upper CI for difference in proportion	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
All	0/A	128	100.0	59	46.1	66	100.0	27	40.9	1.23	Convergence criterion (GCONV=1E-8) satisfied.	0.68	2.2	5.2	-3.48	19.2	1.114	Algorithm converged.	0.789	1.571	0.4850	0.896	Algorithm converged.	0.431	1.27

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 1.6000022

Program: root\clinical_studies\B07112689\CD770115\B042162\data_analysis\ACR_C30_1\prod\program\1_eff_resp.sas
 Output: root\clinical_studies\B07112689\CD770115\B042162\data_analysis\ACR_C30_1\prod\output\1_eff_resp_atr_C30R30_PROD_1600V2022_42162.xls
 08JUN2024 6:30

POPULATION: PRO-evaluable Population
 ENDPPOINT: EORTC QLQ-C30 Responder Analysis (response criterion: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Efficacy)

Role Functioning

Name	Level	Crossover (N=128)				Eucilzumab (N=66)				Odds Ratio	Crossover vs. Eucilzumab					Eucilzumab vs. Crossover										
		Patients		Patients with		Patients		Patients with			Weighted difference (Crossover - Eucilzumab)		Relative Risk			Interaction Test		Relative Risk								
		n	%	n	%	n	%	n	%		95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	95% Lower CL	95% Upper CL			
All	n/a	128	100,0	59	46,1	66	100,0	27	40,9	1,24	Convergence criterion (GCQV=IE-8) satisfied.	0,68	2,25	5,2	-9,49	19,19	1,127	Algorithm converged.	0,798	1,591	0,4886		0,888	Algorithm converged.	0,628	1,253
Sex	Male	73	57,0	34	46,6	34	51,5	15	44,1	1,10	Convergence criterion (GCQV=IE-8) satisfied.	0,49	2,50	2,5	-17,30	21,44	1,056	Algorithm converged.	0,672	1,657	0,8118	0,6976	0,947	Algorithm converged.	0,603	1,487
	Female	55	43,0	25	45,5	32	48,5	12	37,5	1,39	Convergence criterion (GCQV=IE-8) satisfied.	0,57	3,39	8,0	-13,30	27,49	1,212	Algorithm converged.	0,711	2,965	0,4646		0,825	Algorithm converged.	0,484	1,406
Age	<65	118	92,2	55	46,6	57	86,4	26	45,6	1,04	Convergence criterion (GCQV=IE-8) satisfied.	0,55	1,96	1,0	-14,51	16,17	1,022	Algorithm converged.	0,725	1,440	0,9034	0,1590	0,979	Algorithm converged.	0,694	1,379
	>=65	10	7,8	4	40,0	9	13,6	1	11,1	5,33	Convergence criterion (GCQV=IE-8) satisfied.	0,47	60,77	28,9	-10,94	59,03	3,600	Algorithm converged.	0,488	26,540	0,1224		0,278	Algorithm converged.	0,038	2,048
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	32	25,0	15	46,9	15	22,7	3	20,0	3,53	Convergence criterion (GCQV=IE-8) satisfied.	0,83	14,94	26,9	-2,97	47,99	2,344	Algorithm converged.	0,798	6,883	0,0479	0,2213	0,427	Algorithm converged.	0,145	1,253
	>0 to <=6 units	63	49,2	29	46,0	33	50,0	15	45,5	1,02	Convergence criterion (GCQV=IE-8) satisfied.	0,44	2,38	0,6	-19,71	20,38	1,013	Algorithm converged.	0,640	1,603	0,9570		0,987	Algorithm converged.	0,624	1,563
	>6 units	33	25,8	15	45,5	18	27,3	9	50,0	0,83	Convergence criterion (GCQV=IE-8) satisfied.	0,26	2,63	-4,5	-30,69	22,17	0,909	Algorithm converged.	0,502	1,647	0,7560	1,100	Algorithm converged.	0,607	1,993	
Geographic region	Japan/Rest of Asia Pacific	80	62,5	36	45,0	49	74,2	20	40,8	1,19	Convergence criterion (GCQV=IE-8) satisfied.	0,58	2,44	4,2	-13,22	20,83	1,102	Algorithm converged.	0,728	1,670	0,6405	0,8891	0,907	Algorithm converged.	0,599	1,374
	North America/Central and South America/Europe	48	37,5	23	47,9	17	25,8	7	41,2	1,31	Convergence criterion (GCQV=IE-8) satisfied.	0,43	4,03	6,7	-19,74	30,66	1,164	Algorithm converged.	0,614	2,207	0,6289		0,859	Algorithm converged.	0,453	1,630
Eucilzumab availability	Yes	52	40,6	21	40,4	26	39,4	10	38,5	1,08	Convergence criterion (GCQV=IE-8) satisfied.	0,41	2,84	1,9	-20,67	22,91	1,050	Algorithm converged.	0,583	1,890	0,8697	0,7597	0,952	Algorithm converged.	0,529	1,714
	No	76	59,4	38	50,0	40	60,6	17	42,5	1,35	Convergence criterion (GCQV=IE-8) satisfied.	0,63	2,93	7,5	-11,33	25,28	1,176	Algorithm converged.	0,769	1,799	0,4392		0,850	Algorithm converged.	0,556	1,300
Race/ethnicity	White	43	33,6	19	44,2	15	22,7	6	40,0	1,19	Convergence criterion (GCQV=IE-8) satisfied.	0,36	3,93	4,2	-23,70	29,15	1,105	Algorithm converged.	0,546	2,236	0,7765	NE	0,905	Algorithm converged.	0,447	1,822
	Asian	81	63,3	36	44,4	49	74,2	20	40,8	1,16	Convergence criterion (GCQV=IE-8) satisfied.	0,57	2,38	3,6	-13,72	20,24	1,089	Algorithm converged.	0,718	1,650	0,6846		0,918	Algorithm converged.	0,606	1,392
	Black or African American	3	2,3	3	100,0	1	1,5	0	0,0	NE	Complete separation of data points detected.	NE	NE					WARNING: Negative of Hessian not positive definite.	NE	NE	NE	NE	NE	NE	NE	NE
	Unknown	1	0,8	1	100,0	1	1,5	1	100,0	NE		NE	NE					WARNING: Negative of Hessian not positive definite.	NE	NE	NE	NE	NE	NE	NE	NE
LDH value	>=2 to <=4 x ULN	22	17,2	11	50,0	10	15,2	3	30,0	2,33	Convergence criterion (GCQV=IE-8) satisfied.	0,48	11,44	20,0	-15,93	47,22	1,667	Algorithm converged.	0,592	4,691	0,2663	0,3839	0,600	Algorithm converged.	0,213	1,689
	>4 x ULN	106	82,8	48	45,3	56	84,8	24	42,9	1,10	Convergence criterion (GCQV=IE-8) satisfied.	0,57	2,12	2,4	-13,47	17,79	1,057	Algorithm converged.	0,731	1,526	0,7671		0,946	Algorithm converged.	0,655	1,367
Aplastic anemia	Yes	50	39,1	23	46,0	24	36,4	9	37,5	1,42	Convergence criterion (GCQV=IE-8) satisfied.	0,52	3,84	8,5	-15,19	29,76	1,227	Algorithm converged.	0,675	2,229	0,4838	0,7256	0,815	Algorithm converged.	0,449	1,482
	No	78	60,9	36	46,2	42	63,6	18	42,9	1,14	Convergence criterion (GCQV=IE-8) satisfied.	0,54	2,43	3,3	-15,03	20,89	1,077	Algorithm converged.	0,705	1,645	0,7285		0,929	Algorithm converged.	0,608	1,418
Baseline Weight Category	<100	124	96,9	56	45,2	63	95,5	26	41,3	1,17	Convergence criterion (GCQV=IE-8) satisfied.	0,63	2,16	3,9	-11,06	18,21	1,094	Algorithm converged.	0,769	1,557	0,6107	0,3444	0,914	Algorithm converged.	0,642	1,300
	>=100	4	3,1	3	75,0	3	4,5	1	33,3	6,00	Convergence criterion (GCQV=IE-8) satisfied.	0,22	162,53	41,7	-22,57	75,68	2,250	Algorithm converged.	0,412	12,284	0,2309		0,444	Algorithm converged.	0,081	2,426

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical studies/RO7112689/CD770115/B042162/data analysis/ACE CSR 1/prod/program/t eff resp.sas
 Output: root/clinical studies/RO7112689/CD770115/B042162/data analysis/ACE CSR 1/prod/output/t eff resp sg2 C30RF10 PRO2 16NOV2022 42162.xls
 08JUN2024 6:38

POPULATION: Primary Analysis Population
 ENDPOINT: Questionnaire planned visits, EORTC QLQ-C30 Physical Functioning through Week 25
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Change from Baseline (Analysis of MMRM)

Endpoint	Name	Level	Crovalimab (N=134)				Eculizumab (N=69)				Difference between Treatments (Crovalimab - Eculizumab)					
			N		Statistics		N		Statistics		Statistics					
			With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)
Change from Baseline in EORTC QLQ-C30: Physical Functioning (revised)	All	n/a	134	134	128	11,36	1,22	67	67	66	12,46	1,64	-1,10	1,85	-4,75	2,56

[1] Patients with a value at baseline and at least one post-baseline value at Week 2,Week 5,Week 9,Week 17,Week 25.

[2] LSMeans of change from baseline to Week 25. Early Termination (ET) visit was mapped to closest regular visit.

[3] Contrasts from MMRM. Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value.

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mmrn.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mmrn_str_C30PHYS_QV_PAP_16NOV2022_42162.xls
 13JUN2024 13:14

POPULATION: Primary Analysis Population
 ENDPOINT: Questionnaire planned visits, EORTC QLQ-C30 GHS/QoL through Week 25
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: B042162
 Change from Baseline (Analysis of MMRM)

Endpoint	Name	Level	Crovalimab (N=134)					Eculizumab (N=69)					Difference between Treatments (Crovalimab - Eculizumab)			
			N			Statistics		N			Statistics		Statistics			
			With baseline value	With baseline value and at least one post-baseline value [1]	With baseline value and a value at Week 25	LSMeans [2]	SE (LSMeans)	With baseline value	With baseline value and at least one post-baseline value [1]	With baseline value and a value at Week 25	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)
Change from Baseline in EORTC QLQ-C30: Global Health Status/QoL (revised)	All	n/a	134	134	128	12,52	1,51	67	67	66	8,99	2,03	3,54	2,33	-1,05	8,13

[1] Patients with a value at baseline and at least one post-baseline value at Week 2, Week 5, Week 9, Week 17, Week 25.
 [2] LSMeans of change from baseline to Week 25. Early Termination (ET) visit was mapped to closest regular visit.
 [3] Contrasts from MMRM. Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_eff_mmrn.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_eff_mmrn_str_C30QOL_OV_PAP_16NOV2022_42162.xls
 13JUN2024 13:15

POPULATION: Primary Analysis Population
 ENDPOINT: Questionnaire planned visits, EORTC QLQ-C30 Role Functioning through Week 25
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Change from Baseline (Analysis of MMRM)

Endpoint	Crovalimab (N=134)										Eculizumab (N=69)				Difference between Treatments (Crovalimab - Eculizumab)			
	Name	Level	N			Statistics		With baseline value	N		Statistics		LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)		
			With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)		With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)						
Change from Baseline in EORTC QLQ-C30: Role Functioning (revised)	All	n/a	134	134	128	12,11	1,79	67	67	66	9,07	2,37	3,03	2,66	-2,21	8,28		

[1] Patients with a value at baseline and at least one post-baseline value at Week 2,Week 5,Week 9,Week 17,Week 25.

[2] LSMeans of change from baseline to Week 25. Early Termination (ET) visit was mapped to closest regular visit.

[3] Contrasts from MMRM. Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value.

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mmrn.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mmrn_str_C30RF_QV_PAP_16NOV2022_42162.xls
 13JUN2024 13:17

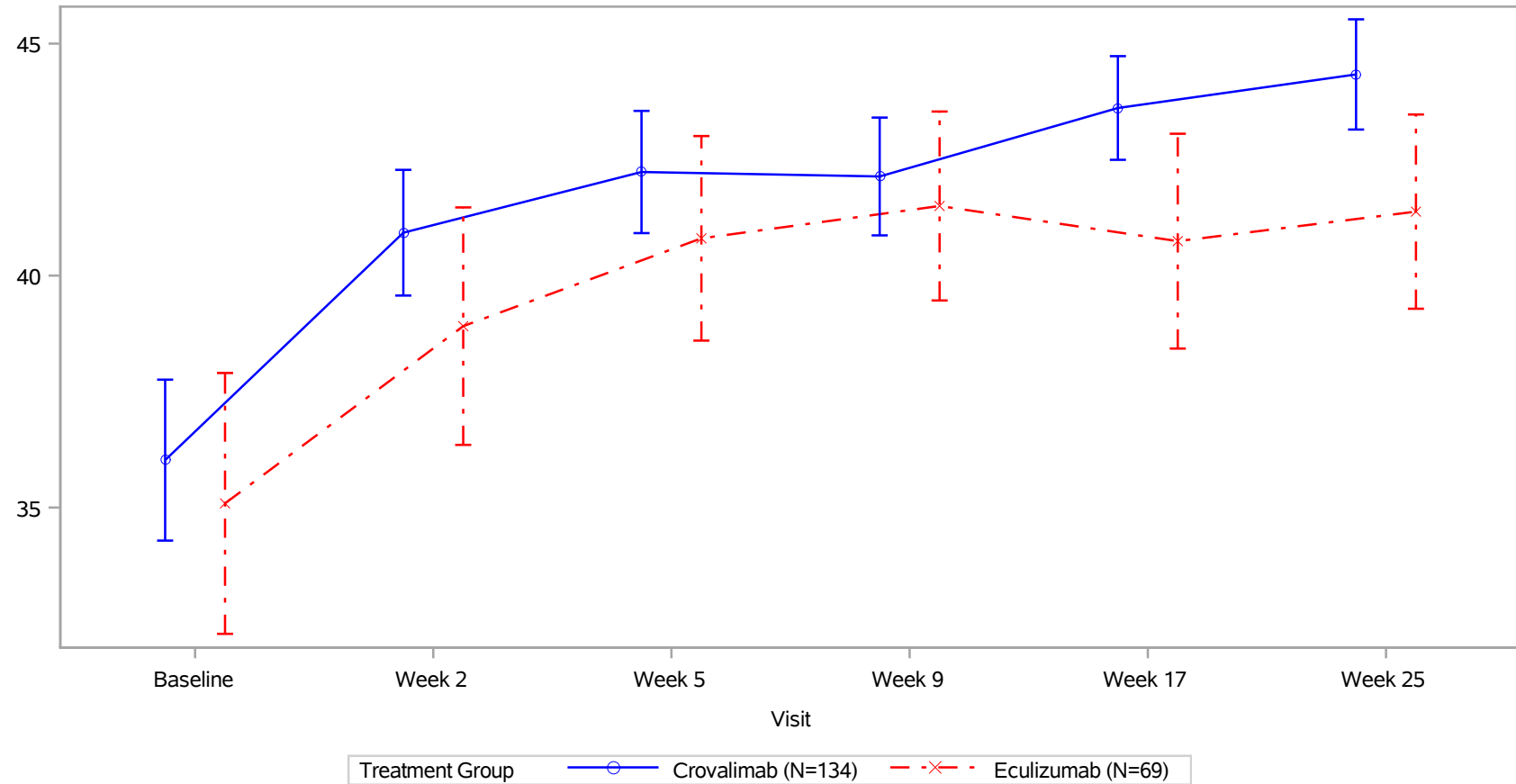
POPULATION: Primary Analysis Population
 ENDPOINT: FACIT-F, Primary Efficacy Period
 MODEL: --
 STUDY: BO42162
 Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	134	100,0	36,02	10,15	69	100,0	67	97,1	35,09	11,53
Week 2	All	134	100,0	132	98,5	40,92	7,87	69	100,0	67	97,1	38,91	10,49
Week 5	All	134	100,0	130	97,0	42,23	7,59	69	100,0	66	95,7	40,80	8,97
Week 9	All	134	100,0	132	98,5	42,14	7,37	69	100,0	66	95,7	41,50	8,28
Week 17	All	133	99,3	129	97,0	43,61	6,41	68	98,6	66	97,1	40,74	9,42
Week 25	All	132	98,5	128	97,0	44,34	6,79	68	98,6	66	97,1	41,38	8,51

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP
 with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
² mean: descriptive statistics - absolute values
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_FAT_PAP_16NOV2022_42162.xls
 07JUN2024 12:41

POPULATION: Primary Analysis Population
ENDPOINT: FACIT-F, Primary Efficacy Period
STUDY: BO42162



Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/g_mean_plot.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/g_mean_plot_FAT_PAP_16NOV2022_42162.pdf
07JUN2024 13:22

POPULATION: PRO-evaluable Population
 ENDPOINT: FACIT-F Responder Analysis (response criterium: improvement of at least 8 pts from BL at week 25), Primary Efficacy Period
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Dichotomous Analysis (Efficacy)

		Crovalimab (N=128)				Eculizumab (N=66)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	Lower CL	Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	Lower CL	Upper CL
All	n/a	128	100,0	55	43,0	66	100,0	23	34,8	1,42	Convergence criterion (GCONV=1E-8) satisfied.	0,77	2,65	8,3	-6,34	21,88	1,285	Algorithm converged.	0,881	1,876	0,2613	0,778	Algorithm converged.	0,533	1,135

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_FAT8_PRO_16NOV2022_42162.xls
 08JUN2024 6:23

POPULATION: PRO-evaluable Population
 ENDPOINT: FACT-F Responder Analysis (response criterion: improvement of at least 8 pts from BL at week 25), Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Efficacy)

Name	Level	Crovalimab (N=128)				Eculizumab (N=66)				Odds Ratio	Crovalimab vs. Eculizumab					Eculizumab vs. Crovalimab											
		Patients		Patients with		Patients		Patients with			Odds Ratio		Weighted difference (Crovalimab - Eculizumab)			Relative Risk		Relative Risk									
		n	%	n	%	n	%	n	%		Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test P-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	128	100,0	55	43,0	66	100,0	23	34,8	1,41	Convergence criterion (GCONV-IE-8) satisfied.	0,76	2,61	8,1	-6,47	21,63	1,233	Algorithm converged.	0,839	1,813	0,2671		0,811	Algorithm converged.	0,552	1,193	
Sex	Male	73	57,0	35	47,9	34	51,5	11	32,4	1,93	Convergence criterion (GCONV-IE-8) satisfied.	0,82	4,52	15,6	-4,53	32,97	1,482	Algorithm converged.	0,862	2,547	0,1163	0,2879	0,675	Algorithm converged.	0,393	1,160	
	Female	55	43,0	20	36,4	32	48,5	12	37,5	0,95	Convergence criterion (GCONV-IE-8) satisfied.	0,39	2,35	-1,1	-21,83	18,53	0,970	Algorithm converged.	0,550	1,711	0,9157		1,031	Algorithm converged.	0,585	1,819	
Age	<65	118	92,2	51	43,2	57	86,4	21	36,8	1,30	Convergence criterion (GCONV-IE-8) satisfied.	0,68	2,50	6,4	-9,18	20,85	1,173	Algorithm converged.	0,788	1,746	0,4165	0,5615	0,852	Algorithm converged.	0,573	1,268	
	>=65	10	7,8	4	40,0	9	13,6	2	22,2	2,33	Convergence criterion (GCONV-IE-8) satisfied.	0,31	17,54	17,8	-22,16	50,62	1,800	Algorithm converged.	0,427	7,588	0,3924		0,556	Algorithm converged.	0,132	2,342	
Transfusion history [total pRBC units administered in the 6 months pre-randomisation]	0 units	32	25,0	20	62,5	15	22,7	3	20,0	6,67	Convergence criterion (GCONV-IE-8) satisfied.	1,56	28,52	42,5	11,98	61,99	3,125	Algorithm converged.	1,097	8,904	0,0015	0,0128	0,320	Algorithm converged.	0,112	0,912	
	>0 to <=6 units	63	49,2	23	36,5	33	50,0	16	48,5	0,61	Convergence criterion (GCONV-IE-8) satisfied.	0,26	1,43	-12,0	-31,52	8,22	0,753	Algorithm converged.	0,466	1,216	0,2588		1,328	Algorithm converged.	0,822	2,145	
	>6 units	33	25,8	12	36,4	18	27,3	4	22,2	2,00	Convergence criterion (GCONV-IE-8) satisfied.	0,54	7,47	14,1	-12,87	35,69	1,638	Algorithm converged.	0,617	4,338	0,2726		0,611	Algorithm converged.	0,231	1,620	
Geographic region	Japan/Rest of Asia Pacific	80	62,5	30	37,5	49	74,2	16	32,7	1,24	Convergence criterion (GCONV-IE-8) satisfied.	0,58	2,62	4,8	-12,22	20,69	1,148	Algorithm converged.	0,702	1,878	0,5736		0,813	0,871	Algorithm converged.	0,533	1,424
	North America/Central and South America/Europe	48	37,5	25	52,1	17	25,8	7	41,2	1,55	Convergence criterion (GCONV-IE-8) satisfied.	0,51	4,76	10,9	-15,74	34,65	1,265	Algorithm converged.	0,674	2,374	0,4341		0,791	Algorithm converged.	0,421	1,484	
Eculizumab availability	Yes	52	40,6	29	55,8	26	39,4	11	42,3	1,72	Convergence criterion (GCONV-IE-8) satisfied.	0,66	4,45	13,5	-9,60	34,45	1,318	Algorithm converged.	0,792	2,195	0,2575	0,7094	0,759	Algorithm converged.	0,456	1,263	
	No	76	59,4	26	34,2	40	60,6	12	30,0	1,21	Convergence criterion (GCONV-IE-8) satisfied.	0,53	2,77	4,2	-14,00	20,57	1,140	Algorithm converged.	0,647	2,010	0,6422		0,877	Algorithm converged.	0,498	1,546	
Race/ethnicity	White	43	33,6	22	51,2	15	22,7	7	46,7	1,20	Convergence criterion (GCONV-IE-8) satisfied.	0,37	3,89	4,5	-22,83	30,57	1,096	Algorithm converged.	0,593	2,027	0,7639		0,4746	0,912	Algorithm converged.	0,493	1,687
	Asian	81	63,3	30	37,0	49	74,2	16	32,7	1,21	Convergence criterion (GCONV-IE-8) satisfied.	0,57	2,56	4,4	-12,62	20,18	1,134	Algorithm converged.	0,693	1,856	0,6095		0,882	Algorithm converged.	0,539	1,442	
Race/ethnicity	Black or African American	3	2,3	2	66,7	1	1,5	0	0,0		Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.							WARNING: Negative of Hessian not positive definite.		
	Unknown	1	0,8	1	100,0	1	1,5	0	0,0		Complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.							WARNING: Negative of Hessian not positive definite.		
LDH value	>=2 to <=4 x ULN	22	17,2	8	36,4	10	15,2	2	20,0	2,29	Convergence criterion (GCONV-IE-8) satisfied.	0,39	13,50	16,4	-18,80	41,53	1,818	Algorithm converged.	0,468	7,065	0,3150	0,5280	0,550	Algorithm converged.	0,142	2,137	
	>4 x ULN	106	82,8	47	44,3	56	84,8	21	37,5	1,33	Convergence criterion (GCONV-IE-8) satisfied.	0,68	2,58	6,8	-9,10	21,74	1,182	Algorithm converged.	0,793	1,764	0,3967		0,846	Algorithm converged.	0,567	1,261	
Aplastic anemia	Yes	50	39,1	17	34,0	24	36,4	8	33,3	1,03	Convergence criterion (GCONV-IE-8) satisfied.	0,37	2,89	0,7	-22,40	21,35	1,020	Algorithm converged.	0,514	2,023	0,9547	0,4974	0,980	Algorithm converged.	0,494	1,945	
	No	78	60,9	38	48,7	42	63,6	15	35,7	1,71	Convergence criterion (GCONV-IE-8) satisfied.	0,79	3,70	13,0	-5,56	29,75	1,364	Algorithm converged.	0,857	2,172	0,1625		0,733	Algorithm converged.	0,460	1,167	
Baseline Weight Category	<100	124	96,9	52	41,9	63	95,5	22	34,9	1,35	Convergence criterion (GCONV-IE-8) satisfied.	0,72	2,52	7,0	-7,86	20,79	1,201	Algorithm converged.	0,808	1,784	0,3473	0,4209	0,833	Algorithm converged.	0,561	1,237	
	>=100	4	3,1	3	75,0	3	4,5	1	33,3	6,00	Convergence criterion (GCONV-IE-8) satisfied.	0,22	162,53	41,7	-22,57	75,68	2,250	Algorithm converged.	0,412	12,284	0,2309		0,444	Algorithm converged.	0,081	2,426	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical studies/B07112689/CD70115/B042162/data analysis/ACE CSR 1/prod/program/t_eff_resp.sas
 Output: root/clinical studies/B07112689/CD70115/B042162/data analysis/ACE CSR 1/prod/output/t_eff_resp_so2_FACT8 PRO 16NOV2022 42162.xls
 08JUN2024 6:32

POPULATION: Primary Analysis Population
 ENDPOINT: Questionnaire planned visits, FACIT-F through Week 25
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Change from Baseline (Analysis of MMRM)

Endpoint	Name	Level	Crovalimab (N=134)					Eculizumab (N=69)					Difference between Treatments (Crovalimab - Eculizumab)			
			N			Statistics		N			Statistics		Statistics			
			With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)
Change from Baseline in FAC070-Fatigue Subscale Score	All	n/a	134	134	128	7,79	0,66	67	67	66	5,15	0,88	2,64	0,99	0,68	4,59

[1] Patients with a value at baseline and at least one post-baseline value at Week 2,Week 5,Week 9,Week 17,Week 25.
 [2] LSMeans of change from baseline to Week 25. Early Termination (ET) visit was mapped to closest regular visit.
 [3] Contrasts from MMRM. Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mmrn.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mmrn_str_FAT_OV_PAP_16NOV2022_42162.xls
 13JUN2024 13:19

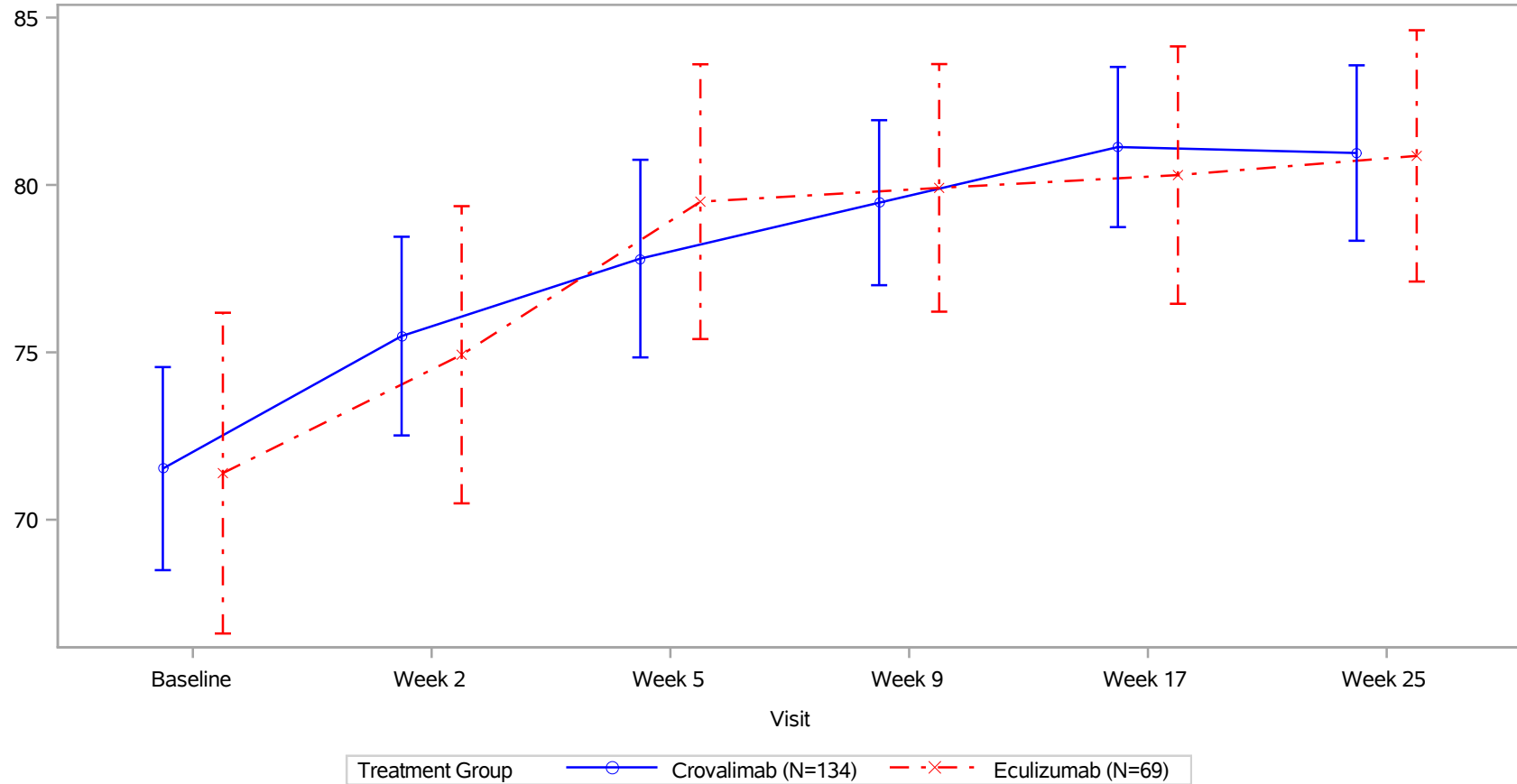
POPULATION: Primary Analysis Population
 ENDPOINT: EQ-5D-5L VAS, Primary Efficacy Period
 MODEL: --
 STUDY: BO42162
 Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	133	99,3	71,53	17,68	69	100,0	69	100,0	71,39	19,94
Week 2	All	134	100,0	132	98,5	75,48	17,24	69	100,0	69	100,0	74,93	18,48
Week 5	All	134	100,0	130	97,0	77,80	17,01	69	100,0	68	98,6	79,50	16,96
Week 9	All	134	100,0	132	98,5	79,47	14,31	69	100,0	68	98,6	79,91	15,28
Week 17	All	133	99,3	129	97,0	81,13	13,73	68	98,6	68	100,0	80,29	15,88
Week 25	All	132	98,5	128	97,0	80,95	14,98	68	98,6	68	100,0	80,87	15,51

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP
 with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
² mean: descriptive statistics - absolute values
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_VAS_PAP_16NOV2022_42162.xls
 07JUN2024 12:59

POPULATION: Primary Analysis Population
ENDPOINT: EQ-5D-5L VAS, Primary Efficacy Period
STUDY: BO42162



Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/g_mean_plot.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/g_mean_plot_VAS_PAP_16NOV2022_42162.pdf
07JUN2024 13:23

POPULATION: PRO-evaluable Population
 ENDPOINT: EQ-5D-VAS Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Dichotomous Analysis (Efficacy)

		Crovalimab (N=127)				Eculizumab (N=68)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio				Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	127	100,0	31	24,4	68	100,0	17	25,0	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,49	1,92	-0,6	-13,86	11,43	0,960	Algorithm converged.	0,579	1,593	0,9205	1,041	Algorithm converged.	0,628	1,728

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_VAS15_PRO1_16NOV2022_42162.xls
 08JUN2024 6:25

POPULATION: PRO-evaluable Population
 ENDPOINT: EQ-SD-VAS Responder Analysis (response criterion: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Efficacy)

Name	Level	Crowlimab (N=127)				Eculizumab (N=68)				Odds Ratio	Crowlimab vs. Eculizumab					Eculizumab vs. Crowlimab											
		Patients		Event		Patients		Event			95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
		n	%	n	%	n	%	n	%																	Odds Ratio	
All	n/a	127	100,0	31	24,4	68	100,0	17	25,0	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,49	1,92	-0,6	-13,82	11,38	0,976	Algorithm converged.	0,585	1,631	0,9275		1,024	Algorithm converged.	0,613	1,711	
Sex	Male	73	57,5	24	32,9	34	50,0	9	26,5	1,36	Convergence criterion (GCONV=1E-8) satisfied.	0,55	3,36	6,4	-12,85	22,86	1,242	Algorithm converged.	0,649	2,377	0,4934	0,1527	0,803	Algorithm converged.	0,421	1,541	
Sex	Female	54	42,5	7	13,0	34	50,0	8	23,5	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,16	1,49	-10,6	-28,28	5,38	0,551	Algorithm converged.	0,220	1,381	0,2187		1,835	Algorithm converged.	0,724	4,551	
Age	<65	116	91,3	27	23,3	59	86,8	17	28,8	0,75	Convergence criterion (GCONV=1E-8) satisfied.	0,37	1,52	-5,5	-19,81	7,55	0,808	Algorithm converged.	0,460	1,358	0,4343	0,0128	1,238	Algorithm converged.	0,736	2,081	
Age	>=65	11	8,7	4	36,4	9	13,2	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	0,0122		NE	Algorithm converged.	NE	NE
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	26,0	8	24,2	16	23,5	3	18,8	1,39	Convergence criterion (GCONV=1E-8) satisfied.	0,31	6,13	5,5	-21,32	26,22	1,293	Algorithm converged.	0,395	4,229	0,6548	0,5517	0,773	Algorithm converged.	0,236	2,530	
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	>0 to <=6 units	61	48,0	17	27,9	34	50,0	12	35,3	0,71	Convergence criterion (GCONV=1E-8) satisfied.	0,29	1,74	-7,4	-26,81	11,07	0,790	Algorithm converged.	0,430	1,451	0,4580		1,266	Algorithm converged.	0,689	2,327	
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	>6 units	33	26,0	6	18,2	18	26,5	2	11,1	1,78	Convergence criterion (GCONV=1E-8) satisfied.	0,32	9,88	7,1	-16,64	25,15	1,636	Algorithm converged.	0,367	7,288	0,4794		0,611	Algorithm converged.	0,137	2,722	
Geographic region	Japan/Rest of Asia Pacific	80	63,0	14	17,5	51	75,0	11	21,6	0,77	Convergence criterion (GCONV=1E-8) satisfied.	0,32	1,86	-4,1	-18,78	9,26	0,811	Algorithm converged.	0,400	1,646	0,5697	0,6537	1,232	Algorithm converged.	0,608	2,500	
Geographic region	North America/Central and South America/	47	37,0	17	36,2	17	25,0	6	35,3	1,04	Convergence criterion (GCONV=1E-8) satisfied.	0,33	3,31	0,9	-25,52	23,85	1,025	Algorithm converged.	0,485	2,164	0,9484		0,976	Algorithm converged.	0,462	2,060	
Eculizumab availability	Yes	51	40,2	18	35,3	26	38,2	10	38,5	0,87	Convergence criterion (GCONV=1E-8) satisfied.	0,33	2,32	-3,2	-25,46	17,93	0,918	Algorithm converged.	0,498	1,692	0,7858	0,8323	1,090	Algorithm converged.	0,591	2,010	
Eculizumab availability	No	76	59,8	13	17,1	42	61,8	7	16,7	1,03	Convergence criterion (GCONV=1E-8) satisfied.	0,38	2,83	0,4	-15,08	13,46	1,026	Algorithm converged.	0,444	2,373	0,9514		0,974	Algorithm converged.	0,421	2,252	
Race/ethnicity	White	62	33,1	14	33,3	15	22,1	5	33,3	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,29	3,49	0,0	-27,83	23,62	1,000	Algorithm converged.	0,434	2,302	1,0000	0,3561	1,000	Algorithm converged.	0,434	2,302	
Race/ethnicity	Asian	81	63,8	14	17,3	51	75,0	11	21,6	0,76	Convergence criterion (GCONV=1E-8) satisfied.	0,31	1,83	-4,3	-18,96	8,97	0,801	Algorithm converged.	0,395	1,626	0,5478		1,248	Algorithm converged.	0,615	2,532	
Race/ethnicity	Black or African American	3	2,4	2	66,7	1	1,5	0	0,0	*	Quasi-complete separation of data points detected.							*	WARNING: Negative or Hessian not positive definite.				*	WARNING: Negative or Hessian not positive definite.			
Race/ethnicity	Unknown	1	0,8	1	100,0	1	1,5	1	100,0	NE		NE	NE					NE	NE	NE	NE		NE	NE	NE	NE	
LDH value	>=2 to <=4 x ULN	23	18,1	5	21,7	11	16,2	3	27,3	0,74	Convergence criterion (GCONV=1E-8) satisfied.	0,14	3,88	-5,5	-37,22	21,18	0,797	Algorithm converged.	0,231	2,749	0,7286	0,7279	1,253	Algorithm converged.	0,364	4,326	
LDH value	>4 x ULN	104	81,9	26	25,0	57	83,8	14	24,6	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,48	2,16	0,4	-14,09	13,48	1,018	Algorithm converged.	0,579	1,789	0,9508		0,982	Algorithm converged.	0,559	1,726	
Isolated anemia	Yes	49	38,6	13	26,5	26	38,2	5	19,2	1,32	Convergence criterion (GCONV=1E-8) satisfied.	0,47	4,85	7,3	-14,01	24,72	1,380	Algorithm converged.	0,552	3,445	0,4643	0,3340	0,725	Algorithm converged.	0,290	1,810	
Isolated anemia	No	78	61,4	18	23,1	42	61,8	12	28,6	0,75	Convergence criterion (GCONV=1E-8) satisfied.	0,32	1,76	-5,5	-22,47	9,99	0,808	Algorithm converged.	0,432	1,512	0,5154		1,238	Algorithm converged.	0,662	2,317	
Baseline Weight Category	<100	123	96,9	31	25,2	65	95,6	16	24,6	1,03	Convergence criterion (GCONV=1E-8) satisfied.	0,51	2,07	0,6	-12,96	12,76	1,024	Algorithm converged.	0,607	1,728	0,9293	0,1656	0,977	Algorithm converged.	0,579	1,648	
Baseline Weight Category	>=100	4	3,1	0	0,0	3	4,4	1	33,3	*	Quasi-complete separation of data points detected.							0,000	Algorithm converged.	0,000	NE	0,2207	>999,9	99	Algorithm converged.	0,000	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/B07112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.exe
 Output: root/clinical_studies/B07112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_sq_VAS15_PR01_16NOV2022_42162.xls
 08JUN2024 6:33

POPULATION: Primary Analysis Population
 ENDPOINT: Questionnaire planned visits, EQ-5D-5L VAS through Week 25
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: B042162
 Change from Baseline (Analysis of MMRM)

Endpoint	Name	Level	Crovalimab (N=134)				Eculizumab (N=69)				Difference between Treatments (Crovalimab - Eculizumab)					
			N		Statistics		N		Statistics		Statistics		Statistics			
			With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)
Change from Baseline in EQ-5D-5L: VAS Score	All	n/a	133	133	127	8,91	1,22	69	69	68	8,33	1,62	0,58	1,88	-3,13	4,30

[1] Patients with a value at baseline and at least one post-baseline value at Week 2,Week 5,Week 9,Week 17,Week 25.
 [2] LSMeans of change from baseline to Week 25. Early Termination (ET) visit was mapped to closest regular visit.
 [3] Contrasts from MMRM. Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_eff_mmr.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_eff_mmr_str_VAS_QV_PAP_16NOV2022_42162.xls
 13JUN2024 13:21

POPULATION: PRO-evaluable Population
 ENDPOINT: EQPHH1-Head Pain in Your Chest Responder Analysis (response criterion: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period
 MODEL: Stratified Analysis by LDU value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: B042162
 Dichotomous Analysis (Efficacy)

Stratum	Crovalimab (N=128)				Eculizumab (N=66)				Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk																						
	Patients		Patients with		Patients		Patients with		Odds Ratio	95% Lower CI	95% Upper CI	Weighted difference in proportion	95% Lower CI for difference in proportion	95% Upper CI for difference in proportion	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI														
	n	%	n	%	n	%	n	%																Convergence Reason	Convergence Reason	Convergence Reason											
All	128	100.0	5	3.9	66	100.0	4	6.1	0.56	Convergence criterion (CCONVW1E-8) satisfied.	0.14	2.22	-2.6															ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 16NOV2022

Program: root/clinical studies/S07112689/CDT70115/B042162/data analysis/ACE CSR 1/prod/program/t_eff_resp.sas
 Output: root/clinical studies/S07112689/CDT70115/B042162/data analysis/ACE CSR 1/prod/output/t_eff_resp_str_ILCHEST15 PRO107 16NOV2022 42162.xls
 11JUN2024 10:07

POPULATION: PRO-evaluable Population
 ENDPOINT: EQPH1-Had Problems Swallowing Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period
 MODEL: Stratified Analysis by LDH value, Transfusion history (total pRBC units administered in the 6 months pre-randomization)
 STUDY: B042162
 Dichotomous Analysis (Efficacy)

		Crovalimab (N=128)				Ecuzimab (N=66)				Odds Ratio		Crovalimab vs. Ecuzimab			Relative Risk			Ecuzimab vs. Crovalimab						
Stratum	Level	Patients		Patients with		Patients		Patients with		Odds Ratio	95% Lower CI	95% Upper CI	Weighted difference in proportion	95% Lower CI for difference in proportion	95% Upper CI for difference in proportion	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI
		n	%	n	%	n	%	n	%															
All	n/a	128	100,0	3	2,3	66	100,0	5	7,6	0,29			-5,3	-15,16	1,72	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/B07112689/CD70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/B07112689/CD70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_1107SPH15_PROD105_16NOV2022_42162.xls
 11JUN2024 10:05

POPULATION: PRO-evaluable Population
 ENDPOINT: EQPNH1-Dyspnea Score Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period
 MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]
 STUDY: BO42162
 Dichotomous Analysis (Efficacy)

		Crovalimab (N=128)				Eculizumab (N=66)				Crovalimab vs. Eculizumab								Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	128	100,0	6	4,7	66	100,0	5	7,6	0,62	Convergence criterion (GCONV=1E-8) satisfied.	0,18	2,11	-2,7	-12,21	4,07	0,602	Algorithm converged.	0,198	1,833	0,4588	1,660	Algorithm converged.	0,546	5,052

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_ILDYSPN15_PRODYS_16NOV2022_42162.xls
 11JUN2024 10:03

POPULATION: PRO-evaluable Population

ENDPOINT: EQPNH1-Difficulty Get/Maintain Erection Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]

STUDY: BO42162

Dichotomous Analysis (Efficacy)

Name	Level	Crovalimab (N=65)				Eculizumab (N=30)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	65	100,0	1	1,5	30	100,0	3	10,0	0,13	Convergence criterion (GCONV=1E-8) satisfied.	0,01	1,32	-9,1	-26,12	3,44	0,127	Algorithm converged.	0,015	1,102	0,1279	7,849	Algorithm converged.	0,908	67,871

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 16NOV2022

Program: root/clinical studies/RO7112689/CDT70115/BO42162/data analysis/ACE CSR 1/prod/program/t eff resp.sas

Output: root/clinical studies/RO7112689/CDT70115/BO42162/data analysis/ACE CSR 1/prod/output/t eff resp str ILERECT15 PRO108 16NOV2022 42162.xls

11JUN2024 10:11

POPULATION: PRO-evaluable Population

ENDPOINT: EQPNH1-Have You Had Headaches Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]

STUDY: BO42162

Dichotomous Analysis (Efficacy)

		Crovalimab (N=128)				Eculizumab (N=66)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	128	100,0	14	10,9	66	100,0	5	7,6	1,55	Convergence criterion (GCONV=1E-8) satisfied.	0,53	4,53	3,6	-7,06	11,61	1,448	Algorithm converged.	0,555	3,777	0,3877	0,690	Algorithm converged.	0,265	1,801

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_ILHEAD15_PRO101_16NOV2022_42162.xls

11JUN2024 10:01

POPULATION: PRO-evaluable Population

ENDPOINT: EQPNH1-Had Pain in Your Stomach Area Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by LDH value, Transfusion history [total pRBC units administered in the 6 months pre-randomization]

STUDY: BO42162

Dichotomous Analysis (Efficacy)

		Crovalimab (N=128)				Eculizumab (N=66)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	128	100,0	8	6,3	66	100,0	8	12,1	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,18	1,35	-5,9	-16,63	2,35	0,502	Algorithm converged.	0,198	1,271	0,1994	1,994	Algorithm converged.	0,787	5,052

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_ILSTOMACH15_PRO106_16NOV2022_42162.xls

11JUN2024 10:09

POPULATION: Primary Analysis Population

ENDPOINT: Primary Efficacy Period, Treatment Satisfaction Questionnaire for Medication-9

STUDY: BO42162

Questionnaire Visit	Crovalimab (N=134)			Eculizumab (N=69)			Hedges g (95% CI) *
	n	Mean	SD (Mean)	n	Mean	SD (Mean)	
Perceived effectiveness							
Week 13	119	76,98	17,71	59	77,31	17,64	-0.018 (-0.022, -0.014)
Week 25	126	77,82	19,21	65	77,09	20,02	0.037 (0.030, 0.045)
How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?							
Week 13	119	78,15	19,86	59	79,94	18,77	-0.092 (-0.111, -0.073)
Week 25	126	77,12	23,16	65	77,95	20,22	-0.037 (-0.045, -0.030)
How satisfied or dissatisfied are you with the way the medication relieves your symptoms?							
Week 13	119	77,45	18,74	59	78,81	19,53	-0.072 (-0.087, -0.057)
Week 25	126	79,76	19,39	65	77,69	20,89	0.104 (0.083, 0.125)
How satisfied or dissatisfied are you with the amount of time it takes the medication to start working?							
Week 13	119	75,35	19,14	59	73,16	19,58	0.113 (0.090, 0.137)
Week 25	126	76,59	20,13	65	75,64	21,06	0.046 (0.037, 0.056)
Convenience of medication							
Week 13	119	72,92	16,88	59	66,29	20,00	0.369 (0.292, 0.446)
Week 25	126	75,79	17,56	65	66,24	20,40	0.515 (0.411, 0.618)

Taking all things into account, how satisfied or dissatisfied are you with this medication?							
Week 13	119	77,73	17,12	59	79,94	17,17	-0.129 (-0.156, -0.102)
Week 25	126	80,56	15,60	65	80,00	17,48	0.034 (0.027, 0.041)

* 95% CI is calculated using Hedges g method.

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_qs_g.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_qs_g_TSQM_EF1_PAP_16NOV2022_42162.xls

15MAY2024 18:29

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Body Image, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	12	9,0	41,67	21,90	69	100,0	9	13,0	38,89	23,57
Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHBODY_PAP_16NOV2022_42162.xls

07JUN2024 12:43

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Cognitive Functioning, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients			Statistics			Patients			Statistics		
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	13	9,7	12,82	21,68	69	100,0	9	13,0	40,74	36,43
Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHCOGF_PAP_16NOV2022_42162.xls

07JUN2024 12:45

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Emotional Functioning, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients			Statistics			Patients			Statistics		
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	12	9,0	27,78	22,89	69	100,0	9	13,0	40,00	20,55
Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHEMO_PAP_16NOV2022_42162.xls

07JUN2024 12:46

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Fatigue, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients			Statistics			Patients			Statistics		
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	13	9,7	27,18	20,09	69	100,0	9	13,0	37,04	29,65
Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHFAT_PAP_16NOV2022_42162.xls

07JUN2024 12:48

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Fear of Progression, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients			Statistics			Patients			Statistics		
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	13	9,7	42,42	28,55	69	100,0	9	13,0	42,86	22,59
Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHFEAR_PAP_16NOV2022_42162.xls

07JUN2024 12:49

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Illness Intrusiveness, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)						
		Patients				Statistics		Patients				Statistics		
Name	Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All														
	BASELINE	All	134	100,0	13	9,7	32,55	18,00	69	100,0	9	13,0	38,27	23,42
	Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHILL_PAP_16NOV2022_42162.xls

07JUN2024 12:50

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Infections, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)						
		Patients			Statistics			Patients			Statistics			
Name	Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All														
	BASELINE	All	134	100,0	13	9,7	25,64	30,89	69	100,0	9	13,0	31,48	29,40
	Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHINF_PAP_16NOV2022_42162.xls

07JUN2024 12:51

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Other Symptoms, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	13	9,7	19,19	17,59	69	100,0	9	13,0	23,81	21,30
Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHOTHES_PAP_16NOV2022_42162.xls

07JUN2024 12:53

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Physical Functioning, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)					
		Patients			Statistics			Patients			Statistics		
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	134	100,0	13	9,7	34,19	29,21	69	100,0	9	13,0	32,10	32,61
Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHPHY_PAP_16NOV2022_42162.xls

07JUN2024 12:54

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Role Functioning, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)						
		Patients			Statistics			Patients			Statistics			
Name	Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All														
	BASELINE	All	134	100,0	13	9,7	33,24	20,25	69	100,0	9	13,0	38,62	26,13
	Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHRFUNC_PAP_16NOV2022_42162.xls

07JUN2024 12:55

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Social Support, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)						
		Patients				Statistics		Patients				Statistics		
Name	Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All														
BASELINE	All		134	100,0	12	9,0	19,44	19,89	69	100,0	9	13,0	29,63	27,36
Week 23	All		132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHSOC_PAP_16NOV2022_42162.xls

07JUN2024 12:56

POPULATION: Primary Analysis Population

ENDPOINT: QLQ-AA/PNH: Stigmatisation, Primary Efficacy Period

MODEL: --

STUDY: BO42162

Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)						
		Patients				Statistics		Patients				Statistics		
Name	Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All														
	BASELINE	All	134	100,0	13	9,7	25,64	18,15	69	100,0	9	13,0	29,63	25,38
	Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit

² mean: descriptive statistics - absolute values

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PNHSTY_PAP_16NOV2022_42162.xls

07JUN2024 12:58

POPULATION: Primary Analysis Population
 ENDPOINT: PGSP1-PNH Symptoms Past 14 Days, Primary Efficacy Period
 MODEL: --
 STUDY: BO42162
 Compliance/Mean

		Crovalimab (N=134)						Eculizumab (N=69)						
		Patients				Statistics		Patients				Statistics		
Name	Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD (Mean)	in study ¹	%	with value ¹	%	Mean ²	SD (Mean)
All														
	BASELINE	All	134	100,0	16	11,9	3,00	2,34	69	100,0	9	13,0	4,22	3,07
	Week 23	All	132	98,5	0	NE	NE	NE	68	98,6	0	NE	NE	NE

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP
 with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
² mean: descriptive statistics - absolute values
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_PGIS_PAP_16NOV2022_42162.xls
 07JUN2024 12:42

POPULATION: Randomized Safety Population
 ENDPOINT: Any AEs, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=135)				Eculizumab (N=69)				Odds Ratio	Crovalimab vs. Eculizumab					Eculizumab vs. Crovalimab											
		Patients		Patients with		Patients		Patients with			Absolute Risk Difference			Relative Risk		Relative Risk											
		n	%	n	%	n	%	n	%		95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	135	100,0	105	77,8	69	100,0	55	79,7	0,89	Convergence criterion (GCONV=1E8) satisfied.	0,44	1,82	-0,019	Algorithm converged.	-0,137	0,099	0,98	Algorithm converged.	0,84	1,13	0,7474		1,02	Algorithm converged.	0,88	1,19
Sex	Male	77	57,0	56	72,7	35	50,7	20	85,7	0,44	Convergence criterion (GCONV=1E8) satisfied.	0,15	1,30	-0,130	Algorithm converged.	-0,283	0,023	0,85	Algorithm converged.	0,70	1,03	0,0941	0,0453	1,18	Algorithm converged.	0,97	1,43
	Female	58	43,0	49	84,5	34	49,3	25	73,5	1,96	Convergence criterion (GCONV=1E8) satisfied.	0,69	5,56	0,110	Algorithm converged.	-0,066	0,285	1,15	Algorithm converged.	0,91	1,45	0,2364		0,87	Algorithm converged.	0,69	1,10
Age	<65	122	90,4	97	79,5	60	87,0	49	81,7	0,87	Convergence criterion (GCONV=1E8) satisfied.	0,40	1,92	-0,022	Algorithm converged.	-0,143	0,100	0,97	Algorithm converged.	0,84	1,13	0,7263	0,8728	1,03	Algorithm converged.	0,88	1,19
	>=65	13	9,6	8	61,5	9	13,0	6	66,7	0,80	Convergence criterion (GCONV=1E8) satisfied.	0,13	4,74	-0,051	Algorithm converged.	-0,457	0,355	0,92	Algorithm converged.	0,49	1,73	0,8036		1,08	Algorithm converged.	0,58	2,04
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	20	60,6	17	24,6	12	70,6	0,64	Convergence criterion (GCONV=1E8) satisfied.	0,18	2,25	-0,100	Algorithm converged.	-0,373	0,174	0,86	Algorithm converged.	0,57	1,30	0,4684	0,3907	1,16	Algorithm converged.	0,77	1,76
	>0 to <=6 units	68	50,4	56	82,4	34	49,3	26	76,5	1,44	Convergence criterion (GCONV=1E8) satisfied.	0,52	3,94	0,059	Algorithm converged.	-0,110	0,228	1,08	Algorithm converged.	0,87	1,34	0,5023		0,93	Algorithm converged.	0,75	1,15
	>6 units	34	25,2	29	85,3	18	26,1	17	94,4	0,34	Convergence criterion (GCONV=1E8) satisfied.	0,04	3,17	-0,092	Algorithm converged.	-0,251	0,068	0,90	Algorithm converged.	0,76	1,08	0,2644		1,11	Algorithm converged.	0,93	1,32
Geographic region	Japan/Rest of Asia Pacific	85	63,0	64	75,3	51	73,9	41	80,4	0,74	Convergence criterion (GCONV=1E8) satisfied.	0,32	1,74	-0,051	Algorithm converged.	-0,193	0,091	0,94	Algorithm converged.	0,78	1,12	0,4810	0,4707	1,07	Algorithm converged.	0,89	1,28
	North America/ Central and South America/ Europe	50	37,0	41	82,0	18	26,1	14	77,8	1,30	Convergence criterion (GCONV=1E8) satisfied.	0,35	4,90	0,042	Algorithm converged.	-0,177	0,262	1,05	Algorithm converged.	0,80	1,39	0,7104		0,95	Algorithm converged.	0,72	1,25

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 clinical cut-off: 16NOV2022

Program: root/clinical studies/RO7112689/CDT70115/B042162/data analysis/ACE CSR 1/prod/program/t ae raw.sas
 Output: root/clinical studies/RO7112689/CDT70115/B042162/data analysis/ACE CSR 1/prod/output/t ae raw sg AE SE1 16NOV2022 42162.xls
 09APR2024 21:51

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade >= 3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab											
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk											
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL						
All	n/a	135	100,0	24	17,8	69	100,0	17	24,6	0,66				Convergence criterion (GCONV=1E-8) satisfied.	0,33	1,34	-0,069	Algorithm converged.	-0,189	0,052	0,72			Algorithm converged.	0,42	1,25	0,2444		1,39	Algorithm converged.	0,80	2,40
Sex	Male	77	57,0	11	14,3	35	50,7	8	22,9	0,56				Convergence criterion (GCONV=1E-8) satisfied.	0,20	1,55	-0,086	Algorithm converged.	-0,245	0,074	0,63			Algorithm converged.	0,28	1,42	0,2603	0,5895	1,60	Algorithm converged.	0,71	3,63
	Female	58	43,0	13	22,4	34	49,3	9	26,5	0,80				Convergence criterion (GCONV=1E-8) satisfied.	0,30	2,14	-0,041	Algorithm converged.	-0,224	0,142	0,85			Algorithm converged.	0,41	1,77	0,6582		1,18	Algorithm converged.	0,57	2,47
Age	<65	122	90,4	21	17,2	60	87,0	16	26,7	0,57				Convergence criterion (GCONV=1E-8) satisfied.	0,27	1,20	-0,095	Algorithm converged.	-0,225	0,036	0,65			Algorithm converged.	0,36	1,14	0,1338	0,2508	1,55	Algorithm converged.	0,87	2,75
	>=65	13	9,6	3	23,1	9	13,0	1	11,1	2,40				Convergence criterion (GCONV=1E-8) satisfied.	0,21	27,72	0,120	Algorithm converged.	-0,188	0,427	2,08			Algorithm converged.	0,25	16,92	0,4946		0,48	Algorithm converged.	0,06	3,92
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	4	12,1	17	24,6	4	23,5	0,45				Convergence criterion (GCONV=1E-8) satisfied.	0,10	2,08	-0,114	Algorithm converged.	-0,344	0,116	0,52			Algorithm converged.	0,15	1,81	0,3008	0,6853	1,94	Algorithm converged.	0,55	6,82
	>0 to <=6 units	68	50,4	13	19,1	34	49,3	7	20,6	0,91				Convergence criterion (GCONV=1E-8) satisfied.	0,33	2,55	-0,015	Algorithm converged.	-0,180	0,150	0,93			Algorithm converged.	0,41	2,11	0,8597		1,08	Algorithm converged.	0,47	2,45
	>6 units	34	25,2	7	20,6	18	26,1	6	33,3	0,52				Convergence criterion (GCONV=1E-8) satisfied.	0,14	1,87	-0,127	Algorithm converged.	-0,384	0,129	0,62			Algorithm converged.	0,24	1,56	0,3092		1,62	Algorithm converged.	0,64	4,10
Geographic region	Japan/Rest of Asia Pacific	85	63,0	18	21,2	51	73,9	15	29,4	0,64				Convergence criterion (GCONV=1E-8) satisfied.	0,29	1,43	-0,082	Algorithm converged.	-0,235	0,070	0,72			Algorithm converged.	0,40	1,30	0,2758	0,6131	1,39	Algorithm converged.	0,77	2,51
	North America/ Central and South America/ Europe	50	37,0	6	12,0	18	26,1	2	11,1	1,09				Convergence criterion (GCONV=1E-8) satisfied.	0,20	5,97	0,009	Algorithm converged.	-0,162	0,180	1,08			Algorithm converged.	0,24	4,87	0,9203		0,93	Algorithm converged.	0,21	4,18

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_GE3_SE1_16NOV2022_42162.xls
 09APR2024 21:54

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade 3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab								
		Patients		Patients with		Patients		Patients with		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	135	100,0	16	11,9	69	100,0	13	18,8	0,58	Convergence criterion (GCONV=1E-8) satisfied.	0,26	1,29	-0,070	Algorithm converged.	-0,177	0,037	0,63	Algorithm converged.	0,32	1,23	0,1763			1,59	Algorithm converged.	0,81	3,11
Sex	Male	77	57,0	7	9,1	35	50,7	5	14,3	0,60	Convergence criterion (GCONV=1E-8) satisfied.	0,18	2,04	-0,052	Algorithm converged.	-0,184	0,081	0,64	Algorithm converged.	0,22	1,87	0,4103	0,9594		1,57	Algorithm converged.	0,54	4,61
	Female	58	43,0	9	15,5	34	49,3	8	23,5	0,60	Convergence criterion (GCONV=1E-8) satisfied.	0,21	1,73	-0,080	Algorithm converged.	-0,250	0,090	0,66	Algorithm converged.	0,28	1,55	0,3389			1,52	Algorithm converged.	0,65	3,56
Age	<65	122	90,4	15	12,3	60	87,0	12	20,0	0,56	Convergence criterion (GCONV=1E-8) satisfied.	0,24	1,29	-0,077	Algorithm converged.	-0,194	0,040	0,61	Algorithm converged.	0,31	1,23	0,1690	0,9320		1,63	Algorithm converged.	0,81	3,25
	>=65	13	9,6	1	7,7	9	13,0	1	11,1	0,67	Convergence criterion (GCONV=1E-8) satisfied.	0,04	12,27	-0,034	Algorithm converged.	-0,285	0,217	0,69	Algorithm converged.	0,05	9,68	0,7847			1,44	Algorithm converged.	0,10	20,21
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	3	9,1	17	24,6	3	17,6	0,47	Convergence criterion (GCONV=1E-8) satisfied.	0,08	2,61	-0,086	Algorithm converged.	-0,292	0,120	0,52	Algorithm converged.	0,12	2,28	0,3828	0,8297		1,94	Algorithm converged.	0,44	8,61
	>0 to <=6 units	68	50,4	8	11,8	34	49,3	5	14,7	0,77	Convergence criterion (GCONV=1E-8) satisfied.	0,23	2,57	-0,029	Algorithm converged.	-0,171	0,112	0,80	Algorithm converged.	0,28	2,26	0,6737			1,25	Algorithm converged.	0,44	3,53
	>6 units	34	25,2	5	14,7	18	26,1	5	27,8	0,45	Convergence criterion (GCONV=1E-8) satisfied.	0,11	1,82	-0,131	Algorithm converged.	-0,369	0,108	0,53	Algorithm converged.	0,18	1,59	0,2572			1,89	Algorithm converged.	0,63	5,67
Geographic region	Japan/Rest of Asia Pacific	85	63,0	13	15,3	51	73,9	12	23,5	0,59	Convergence criterion (GCONV=1E-8) satisfied.	0,24	1,41	-0,082	Algorithm converged.	-0,222	0,057	0,65	Algorithm converged.	0,32	1,31	0,2302	0,6550		1,54	Algorithm converged.	0,76	3,11
	North America/ Central and South America/ Europe	50	37,0	3	6,0	18	26,1	1	5,6	1,09	Convergence criterion (GCONV=1E-8) satisfied.	0,11	11,15	0,004	Algorithm converged.	-0,120	0,129	1,08	Algorithm converged.	0,12	9,73	0,9453			0,93	Algorithm converged.	0,10	8,34

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sq_G3_SE1_16NOV2022_42162.xls
 09APR2024 21:56

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade 4, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovlimab (N=135)				Eculizumab (N=69)				Odds Ratio	Crovlimab vs. Eculizumab				Relative Risk				Eculizumab vs. Crovlimab								
		Patients		Patients with		Patients		Patients with			Absolute Risk Difference				Relative Risk				Relative Risk								
		n	%	n	%	n	%	n	%		95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
All	n/a	135	100,0	6	4,4	69	100,0	3	4,3	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,25	4,22	0,001	Algorithm converged.	-0,058	0,060	1,02	Algorithm converged.	0,26	3,96	0,9746		0,98	Algorithm converged.	0,25	3,79
Sex	Male	77	57,0	3	3,9	38	50,7	2	5,7	0,67	Convergence criterion (GCONV=1E-8) satisfied.	0,11	4,19	-0,018	Algorithm converged.	-0,106	0,070	0,68	Algorithm converged.	0,12	3,80	0,6669	0,5026	1,47	Algorithm converged.	0,26	8,39
	Female	58	43,0	3	5,2	31	45,3	1	2,9	1,80	Convergence criterion (GCONV=1E-8) satisfied.	0,18	18,02	0,022	Algorithm converged.	-0,058	0,103	1,76	Algorithm converged.	0,19	16,24	0,6187		0,57	Algorithm converged.	0,06	5,25
Age	<65	122	90,4	6	4,9	60	87,0	3	5,0	0,98	Convergence criterion (GCONV=1E-8) satisfied.	0,24	4,07	-0,001	Algorithm converged.	-0,068	0,066	0,98	Algorithm converged.	0,25	3,80	0,9809	NE	1,02	Algorithm converged.	0,26	3,93
	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	0,6233	NE	Algorithm converged.	NE	NE
	>0 to <=6 units	69	50,4	3	4,4	34	49,3	2	5,9	0,74	Convergence criterion (GCONV=1E-8) satisfied.	0,12	4,64	-0,015	Algorithm converged.	-0,108	0,078	0,75	Algorithm converged.	0,13	4,28	0,7461		1,33	Algorithm converged.	0,23	7,61
	>6 units	34	25,2	2	5,9	18	26,1	1	5,6	1,06	Convergence criterion (GCONV=1E-8) satisfied.	0,09	12,58	0,003	Algorithm converged.	-0,129	0,135	1,06	Algorithm converged.	0,10	10,90	0,9617		0,94	Algorithm converged.	0,09	9,72
Geographic region	Japan/Rest of Asia Pacific	85	63,0	4	4,7	51	73,9	3	5,9	0,79	Convergence criterion (GCONV=1E-8) satisfied.	0,17	3,68	-0,012	Algorithm converged.	-0,090	0,067	0,80	Algorithm converged.	0,19	3,43	0,7639	0,2488	1,25	Algorithm converged.	0,29	5,36
	North America/ Central and South America/ Europe	50	37,0	2	4,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 2.1572052206 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE

* Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 clinical cut-off: 16NOV2022

Program: root/clinical studies/R07112689/CD770115/B042162/data analysis/ACE CSR 1/prod/program/t ae raw sas
 Output: root/clinical studies/R07112689/CD770115/B042162/data analysis/ACE CSR 1/prod/output/t ae raw sa 04 01 16NOV2022 42162.xls
 09APR2024 21:57

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade 5 (AEs leading to death), Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Covelimab (N=135)				Eculizumab (N=69)				Odds Ratio	Absolute Risk Difference				Relative Risk				Relative Risk									
		Patients		Patients with		Patients		Patients with			Convergence Reason	95% Lower CI	95% Upper CI	Absolute Risk	Convergence Reason	95% Lower CI	95% Upper CI	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
		n	%	n	%	n	%	n	%																			
All	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCNV=IE-8) satisfied.	0,09	11,48	0,000	Algorithm converged.	-0,034	0,035	1,02	Algorithm converged.	0,09	11,08	0,9856		0,98	Algorithm converged.	0,09	10,60	
Sex	Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45	Convergence criterion (GCNV=IE-8) satisfied.	0,03	7,36	-0,016	Algorithm converged.	-0,076	0,045	0,45	Algorithm converged.	0,03	7,06	0,5732	0,2658	2,20	Algorithm converged.	0,14	34,17	
	Female	58	43,0	1	1,7	34	49,3	0	0,0		Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Age	<=65	122	90,4	0	0,0	60	87,0	1	1,7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.085838312 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999		>999,9	NE	Algorithm converged.	0,00	NE
	>=65	13	9,6	2	15,4	9	13,0	0	0,0		Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	0	0,0	17	24,6	1	5,9		Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999		>999,9	NE	Algorithm converged.	0,00	NE
	>0 to <=6 units	68	50,4	2	2,9	34	49,3	0	0,0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 3.7292778593 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Geographic region	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		0,2294	NE	Algorithm converged.	NE	NE
	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	1	5,6	0,35	Convergence criterion (GCNV=IE-8) satisfied.	0,02	5,85	-0,036	Algorithm converged.	-0,148	0,077	0,36	Algorithm converged.	0,02	5,46	0,4614		2,78	Algorithm converged.	0,18	42,12	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical studies/R07112689/CDT70115/B042162/data analysis/ACE CSR 1/prod/program/t ae raw.sas
 Output: root/clinical studies/R07112689/CDT70115/B042162/data analysis/ACE CSR 1/prod/output/t ae raw sq 05 SE1 16NOV2022 42162.xls
 09APR2024 21:59

POPULATION: Randomized Safety Population
 ENDPOINT: Any SAEs, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab											
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk											
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL					
All	n/a	135	100,0	14	10,4	69	100,0	9	13,0	0,77				Convergence criterion (GCONV=1E-8) satisfied.	0,32	1,88	-0,027	Algorithm converged.	-0,121	0,068	0,80	Algorithm converged.	0,36	1,74	0,5672		1,26	Algorithm converged.	0,57	2,76	
Sex	Male	77	57,0	9	11,7	35	50,7	4	11,4	1,03				Convergence criterion (GCONV=1E-8) satisfied.	0,29	3,59	0,003	Algorithm converged.	-0,125	0,130	1,02	Algorithm converged.	0,34	3,10	0,9683	0,4941	0,98	Algorithm converged.	0,32	2,96	
	Female	58	43,0	5	8,6	34	49,3	5	14,7	0,55				Convergence criterion (GCONV=1E-8) satisfied.	0,15	2,05	-0,061	Algorithm converged.	-0,200	0,078	0,59	Algorithm converged.	0,18	1,88	0,3689		1,71	Algorithm converged.	0,53	5,47	
Age	<65	122	90,4	12	9,8	60	87,0	9	15,0	0,62				Convergence criterion (GCONV=1E-8) satisfied.	0,24	1,56	-0,052	Algorithm converged.	-0,156	0,053	0,66	Algorithm converged.	0,29	1,47	0,3055	0,0887	1,52	Algorithm converged.	0,68	3,42	
	>=65	13	9,6	2	15,4	9	13,0	0	0,0	*				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	0	0,0	17	24,6	3	17,6	*				Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				0,00	Algorithm converged.	0,00	NE	0,9999	0,0297	>999,99	Algorithm converged.	0,00	NE
	>0 to <=6 units	68	50,4	11	16,2	34	49,3	4	11,8	1,45				Convergence criterion (GCONV=1E-8) satisfied.	0,42	4,93	0,044	Algorithm converged.	-0,095	0,183	1,37	Algorithm converged.	0,47	4,00	0,5589		0,73	Algorithm converged.	0,25	2,12	
	>6 units	34	25,2	3	8,8	18	26,1	2	11,1	0,77				Convergence criterion (GCONV=1E-8) satisfied.	0,12	5,12	-0,023	Algorithm converged.	-0,197	0,151	0,79	Algorithm converged.	0,15	4,33	0,7899		1,26	Algorithm converged.	0,23	6,86	
Geographic region	Japan/Rest of Asia Pacific	85	63,0	11	12,9	51	73,9	7	13,7	0,93				Convergence criterion (GCONV=1E-8) satisfied.	0,34	2,59	-0,008	Algorithm converged.	-0,126	0,111	0,94	Algorithm converged.	0,39	2,28	0,8959	0,5759	1,06	Algorithm converged.	0,44	2,56	
	North America/Central and South America/ Europe	50	37,0	3	6,0	18	26,1	2	11,1	0,51				Convergence criterion (GCONV=1E-8) satisfied.	0,08	3,34	-0,051	Algorithm converged.	-0,211	0,108	0,54	Algorithm converged.	0,10	2,97	0,4790		1,85	Algorithm converged.	0,34	10,20	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_SAE_SE1_16NOV2022_42162.xls
 09APR2024 21:52

POPULATION: Randomized Safety Population
 ENDPOINT: AEs leading to treatment discontinuation, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab															
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk					Interaction Test		Relative Risk													
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL											
All	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51						Algorithm converged.	-0,039	0,025	0,51		Algorithm converged.	0,03	0,05	0,6332		1,96		Algorithm converged.	0,12	0,81						
Sex	Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45						Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,36	-0,016		Algorithm converged.	-0,076	0,045	0,45		Algorithm converged.	0,02	7,06	0,5732		1,0000	2,20	Algorithm converged.	0,14	0,17	
	Female	58	43,0	0	0,0	34	49,3	0	0,5	NE							NE	NE	NE		NE	NE	NE	NE		NE		NE	NE	NE	NE					
Age	<65	122	90,4	1	0,8	60	87,0	1	1,7	0,49						Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,93	-0,008		Algorithm converged.	-0,045	0,028	0,49		Algorithm converged.	0,03	7,73	0,6136		1,0000	2,03	Algorithm converged.	0,13	0,95	
	>=65	13	9,6	0	0,0	9	13,0	0	0,5	NE							NE	NE	NE		NE	NE	NE	NE		NE		NE	NE	NE	NE					
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	0	0,0	17	24,6	1	5,9	*						Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00		Algorithm converged.	0,00	NE	0,9999		NE	>999,9	9	Algorithm converged.	0,00	NE
	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,5	NE							NE	NE	NE		NE	NE	NE	NE		NE		NE	NE	NE	NE					
	>6 units	34	25,2	1	2,9	18	26,1	0	0,5	*						Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			NE		Algorithm converged.	NE	NE	NE		NE	NE	NE	NE		
Geographic region	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*						Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		0,0672	NE	NE	NE		
	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*						Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 12,774840148 is greater than the limit of 0,0001. The convergence is questionable.			0,00		Algorithm converged.	0,00	NE	1,0000		>999,9	9	Algorithm converged.	0,00	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_Dis_SE1_16NOV2022_42162.xls
 09APR2024 22:01

Cardiac disorders	Bradycardia	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 22.085838312 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE		
Cardiac disorders	Bradycardia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Cardiac disorders	Cardiac failure	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 22.085838312 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE		
Cardiac disorders	Cardiac failure	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Cardiac disorders	Lupus endocarditis	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Cardiac disorders	Lupus endocarditis	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE		
Cardiac disorders	Myocardial infarction	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Cardiac disorders	Myocardial infarction	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE		
Cardiac disorders	Palpitations	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE		
Cardiac disorders	Palpitations	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Cardiac disorders	Supraventricular tachycardia	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 9.2580253613 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE		
Cardiac disorders	Supraventricular tachycardia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Congenital, familial and genetic disorders		<65	122	90,4	1	0,8	60	87,0	1	1,7	0,49	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,045	0,028	0,49	Algorithm converged.	0,03	7,73	0,6136	0,2498	2,03	Algorithm converged.	0,13	31,95
Congenital, familial and genetic disorders		>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Congenital, familial and genetic disorders	Familial periodic paralysis	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE		

General disorders and administration site conditions		<65	122	90,4	25	20,5	60	87,0	10	16,7	1,29	Convergence criterion (GCONV=1E-8) satisfied.	0,57	2,89	0,038	Algorithm converged.	-0,080	0,157	1,23	Algorithm converged.	0,63	2,39	0,5426	0,3421	0,81	Algorithm converged.	0,42	1,58
General disorders and administration site conditions		>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Application site haemorrhage	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Application site haemorrhage	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Application site pain	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Application site pain	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Asthenia	<65	122	90,4	2	1,6	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Asthenia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Chest pain	<65	122	90,4	2	1,6	60	87,0	2	3,3	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,52	-0,017	Algorithm converged.	-0,068	0,034	0,49	Algorithm converged.	0,07	3,41	0,4723	1,0000	2,03	Algorithm converged.	0,29	14,09
General disorders and administration site conditions	Chest pain	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Early satiety	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Early satiety	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Fatigue	<65	122	90,4	2	1,6	60	87,0	1	1,7	0,98	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,06	0,000	Algorithm converged.	-0,040	0,039	0,98	Algorithm converged.	0,09	10,63	0,9891	1,0000	1,02	Algorithm converged.	0,09	10,99
General disorders and administration site conditions	Fatigue	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Feeling cold	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Feeling cold	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Influenza like illness	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 9.2580253305 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Infections and infestations	Lower respiratory tract infection	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Infections and infestations	Lower respiratory tract infection	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.		NE			Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE					
Infections and infestations	Nasopharyngitis	<65	122	90,4	2	1,6	60	87,0	2	3,3	0,48		0,07	3,52	-0,017				Algorithm converged.	-0,068	0,034	0,49			Algorithm converged.	0,07	3,41	0,4723	1,0000	2,03	Algorithm converged.	0,29	14,09
Infections and infestations	Nasopharyngitis	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Oral herpes	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.			0,00				Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Infections and infestations	Oral herpes	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Otitis media acute	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 9.2580252996 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.			NE				Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Otitis media acute	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Pharyngitis	<65	122	90,4	2	1,6	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.					Algorithm converged.			NE			Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Pharyngitis	>=65	13	9,6	0	0,0	9	13,0	1	11,1	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.					Algorithm converged.			0,00			Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Infections and infestations	Pneumonia	<65	122	90,4	1	0,8	60	87,0	2	3,3	0,24		0,02	2,70	-0,025				Algorithm converged.	-0,073	0,023	0,25			Algorithm converged.	0,02	2,66	0,2481	0,1416	4,07	Algorithm converged.	0,38	43,96
Infections and infestations	Pneumonia	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.					Algorithm converged.			NE			Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Pyelonephritis	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 9.2580253922 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.			NE			Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Pyelonephritis	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Rhinitis	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.					Algorithm converged.			0,00			Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE

Injury, poisoning and procedural complications		<65	122	90,4	27	22,1	60	87,0	11	18,3	1,27	Convergence criterion (GCONV=1E-8) satisfied.	0,58	2,77	0,038	Algorithm converged.	-0,085	0,161	1,21	Algorithm converged.	0,64	2,26	0,5576	0,1728	0,83	Algorithm converged.	0,44	1,55
Injury, poisoning and procedural complications		>=65	13	9,6	2	15,4	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Contusion	<65	122	90,4	1	0,8	60	87,0	1	1,7	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,93	-0,008	Algorithm converged.	-0,045	0,028	0,49	Algorithm converged.	0,03	7,73	0,6136	1,0000	2,03	Algorithm converged.	0,13	31,95
Injury, poisoning and procedural complications	Contusion	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Foot fracture	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Foot fracture	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Incorrect dose administered	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 9.258025395 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Incorrect dose administered	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Infusion related reaction	<65	122	90,4	20	16,4	60	87,0	9	15,0	1,11	Convergence criterion (GCONV=1E-8) satisfied.	0,47	2,61	0,014	Algorithm converged.	-0,098	0,126	1,09	Algorithm converged.	0,53	2,25	0,8098	0,3200	0,92	Algorithm converged.	0,44	1,89
Injury, poisoning and procedural complications	Infusion related reaction	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injection related reaction	<65	122	90,4	6	4,9	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injection related reaction	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Limb injury	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Limb injury	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Muscle strain	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 9.2580253613 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Injury, poisoning and procedural complications	Muscle strain	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE							
Injury, poisoning and procedural complications	Procedural pain	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.								0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	
Injury, poisoning and procedural complications	Procedural pain	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Skin abrasion	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.								NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Skin abrasion	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Underdose	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.								NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Underdose	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Wrong schedule	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.								NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Wrong schedule	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Investigations		<65	122	90,4	21	17,2	60	87,0	9	15,0	1,18	Convergence criterion (GCONV=1E-8) satisfied.	0,50	2,76	0,022	Algorithm converged.	-0,090	0,135	1,15	Algorithm converged.	0,56	2,35	0,7068		0,6050	0,87	Algorithm converged.	0,43	1,79	
Investigations		>=65	13	9,6	2	15,4	9	13,0	2	22,2	0,64	Convergence criterion (GCONV=1E-8) satisfied.	0,07	5,61	-0,068	Algorithm converged.	-0,403	0,267	0,69	Algorithm converged.	0,12	4,05	0,6832		1,44	Algorithm converged.	0,25	8,45		
Investigations	Alanine aminotransferase increased	<65	122	90,4	2	1,6	60	87,0	1	1,7	0,98	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,06	0,000	Algorithm converged.	-0,040	0,039	0,98	Algorithm converged.	0,09	10,63	0,9891		1,0000	1,02	Algorithm converged.	0,09	10,99	
Investigations	Alanine aminotransferase increased	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Investigations	Blood bilirubin increased	<65	122	90,4	2	1,6	60	87,0	2	3,3	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,52	-0,017	Algorithm converged.	-0,068	0,034	0,49	Algorithm converged.	0,07	3,41	0,4723		1,0000	2,03	Algorithm converged.	0,29	14,09	
Investigations	Blood bilirubin increased	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Investigations	International normalised ratio increased	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.								0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	

Metabolism and nutrition disorders	Hyperglycemia	<65	122	90,4	1	0,8	60	87,0	1	1,7	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,93	-0,008	Algorithm converged.	-0,045	0,028	0,49	Algorithm converged.	0,03	7,73	0,6136	1,0000	2,03	Algorithm converged.	0,13	31,95
Metabolism and nutrition disorders	Hyperglycemia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Hyperuricemia	<65	122	90,4	11	9,0	60	87,0	6	10,0	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,31	2,54	-0,010	Algorithm converged.	-0,101	0,082	0,90	Algorithm converged.	0,35	2,32	0,8301	1,0000	1,11	Algorithm converged.	0,43	2,85
Metabolism and nutrition disorders	Hyperuricemia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Hypocalcemia	<65	122	90,4	8	6,6	60	87,0	7	11,7	0,53	Convergence criterion (GCONV=1E-8) satisfied.	0,18	1,54	-0,051	Algorithm converged.	-0,143	0,041	0,56	Algorithm converged.	0,21	1,48	0,2425	1,0000	1,78	Algorithm converged.	0,68	4,68
Metabolism and nutrition disorders	Hypocalcemia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Hypoglycemia	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE
Metabolism and nutrition disorders	Hypoglycemia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Hypokalemia	<65	122	90,4	15	12,3	60	87,0	9	15,0	0,79	Convergence criterion (GCONV=1E-8) satisfied.	0,33	1,94	-0,027	Algorithm converged.	-0,135	0,080	0,82	Algorithm converged.	0,38	1,76	0,6111	NE	1,22	Algorithm converged.	0,57	2,63
Metabolism and nutrition disorders	Hypokalemia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Hypomagnesemia	<65	122	90,4	2	1,6	60	87,0	1	1,7	0,98	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,06	0,000	Algorithm converged.	-0,040	0,039	0,98	Algorithm converged.	0,09	10,63	0,9891	1,0000	1,02	Algorithm converged.	0,09	10,99
Metabolism and nutrition disorders	Hypomagnesemia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Vitamin B12 deficiency	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Metabolism and nutrition disorders	Vitamin B12 deficiency	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders		<65	122	90,4	10	8,2	60	87,0	2	3,3	2,59	Convergence criterion (GCONV=1E-8) satisfied.	0,55	12,21	0,049	Algorithm converged.	-0,018	0,115	2,46	Algorithm converged.	0,56	10,87	0,2355	0,2778	0,41	Algorithm converged.	0,09	1,80
Musculoskeletal and connective tissue disorders		>=65	13	9,6	2	15,4	9	13,0	2	22,2	0,64	Convergence criterion (GCONV=1E-8) satisfied.	0,07	5,61	-0,068	Algorithm converged.	-0,403	0,267	0,69	Algorithm converged.	0,12	4,05	0,6832		1,44	Algorithm converged.	0,25	8,45
Musculoskeletal and connective tissue disorders	Arthralgia	<65	122	90,4	3	2,5	60	87,0	1	1,7	1,49	Convergence criterion (GCONV=1E-8) satisfied.	0,15	14,61	0,008	Algorithm converged.	-0,035	0,050	1,48	Algorithm converged.	0,16	13,89	0,7338	0,0670	0,68	Algorithm converged.	0,07	6,38
Musculoskeletal and connective tissue disorders	Arthralgia	>=65	13	9,6	0	0,0	9	13,0	2	22,2	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	0,9999	>999.9	Algorithm converged.	0,00	NE	

Neoplasms benign, malignant and unspecified (incl cysts and polyps)		<65	122	90,4	2	1,6	60	87,0	1	1,7	0,98	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,06	0,000	Algorithm converged.	-0,040	0,039	0,98	Algorithm converged.	0,09	10,63	0,9891	0,3462	1,02	Algorithm converged.	0,09	10,99
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*				ERROR: Error in computing the link function, its derivatives, or the variance function.	NE		Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*				ERROR: Error in computing the link function, its derivatives, or the variance function.	NE		Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Myelodysplastic syndrome	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	*				WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.	0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999,9	Algorithm converged.	0,00	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Myelodysplastic syndrome	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*				ERROR: Error in computing the link function, its derivatives, or the variance function.	NE		Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE		Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders		<65	122	90,4	13	10,7	60	87,0	7	11,7	0,90	Convergence criterion (GCONV=1E-8) satisfied.	0,34	2,40	-0,010	Algorithm converged.	-0,108	0,088	0,91	Algorithm converged.	0,38	2,17	0,8373	0,8451	1,09	Algorithm converged.	0,46	2,60
Nervous system disorders		>=65	13	9,6	1	7,7	9	13,0	1	11,1	0,67	Convergence criterion (GCONV=1E-8) satisfied.	0,04	12,27	-0,034	Algorithm converged.	-0,285	0,217	0,69	Algorithm converged.	0,05	9,68	0,7847		1,44	Algorithm converged.	0,10	20,21
Nervous system disorders	Dizziness	<65	122	90,4	1	0,8	60	87,0	1	1,7	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,93	-0,008	Algorithm converged.	-0,045	0,028	0,49	Algorithm converged.	0,03	7,73	0,6136	0,8606	2,03	Algorithm converged.	0,13	31,95
Nervous system disorders	Dizziness	>=65	13	9,6	1	7,7	9	13,0	1	11,1	0,67	Convergence criterion (GCONV=1E-8) satisfied.	0,04	12,27	-0,034	Algorithm converged.	-0,285	0,217	0,69	Algorithm converged.	0,05	9,68	0,7847		1,44	Algorithm converged.	0,10	20,21

Nervous system disorders	Headache	<65	122	90,4	11	9,0	60	87,0	3	5,0	1,88	Convergence criterion (GCONV=1E-8) satisfied.	0,51	7,02	0,040	Algorithm converged.	-0,035	0,115	1,80	Algorithm converged.	0,52	6,22	0,3508	1,0000	0,55	Algorithm converged.	0,16	1,91	
Nervous system disorders	Headache	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Nervous system disorders	Ischaemic stroke	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 22.085838312 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Nervous system disorders	Ischaemic stroke	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Nervous system disorders	Migraine	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 22.085838312 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Nervous system disorders	Migraine	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders	Neuropathy peripheral	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Nervous system disorders	Neuropathy peripheral	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Nervous system disorders	Paraesthesia	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Nervous system disorders	Paraesthesia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders		<65	122	90,4	2	1,6	60	87,0	3	5,0	0,32	Convergence criterion (GCONV=1E-8) satisfied.	0,05	1,95	-0,034	Algorithm converged.	-0,093	0,026	0,33	Algorithm converged.	0,06	1,91	0,2149	0,1546	3,05	Algorithm converged.	0,52	17,77	
Psychiatric disorders		>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Psychiatric disorders	Abnormal dreams	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 22.085838312 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Psychiatric disorders	Abnormal dreams	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders	Affective disorder	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Psychiatric disorders	Affective disorder	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders	Insomnia	<65	122	90,4	1	0,8	60	87,0	3	5,0	0,16	Convergence criterion (GCONV=1E-8) satisfied.	0,02	1,54	-0,042	Algorithm converged.	-0,099	0,016	0,16	Algorithm converged.	0,02	1,54	0,1139	NE	6,10	Algorithm converged.	0,65	57,41	

Reproductive system and breast disorders	Perineal rash	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	0,00	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	0,00	NE						
Reproductive system and breast disorders	Perineal rash	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Reproductive system and breast disorders	Spontaneous penile erection	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	0,00	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	0,00	NE						
Reproductive system and breast disorders	Spontaneous penile erection	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Respiratory, thoracic and mediastinal disorders		<65	122	90,4	11	9,0	60	87,0	5	8,3	1,09	Convergence criterion (GCONV=1E-8) satisfied.	0,36	3,29	0,007	Algorithm converged.	-0,080	0,093	1,08	Algorithm converged.	0,39	2,97	0,8786	0,1651	0,92	Algorithm converged.	0,34	2,54	
Respiratory, thoracic and mediastinal disorders		>=65	13	9,6	2	15,4	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Cough	<65	122	90,4	3	2,5	60	87,0	2	3,3	0,73	Convergence criterion (GCONV=1E-8) satisfied.	0,12	4,50	-0,009	Algorithm converged.	-0,062	0,044	0,74	Algorithm converged.	0,13	4,30	0,7351	1,0000	1,36	Algorithm converged.	0,23	7,90	
Respiratory, thoracic and mediastinal disorders	Cough	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Dysphonia	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Dysphonia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	<65	122	90,4	2	1,6	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Epistaxis	<65	122	90,4	2	1,6	60	87,0	2	3,3	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,52	-0,017	Algorithm converged.	-0,068	0,034	0,49	Algorithm converged.	0,07	3,41	0,4723	1,0000	2,03	Algorithm converged.	0,29	14,09	
Respiratory, thoracic and mediastinal disorders	Epistaxis	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Hiccups	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Hiccups	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	

Respiratory, thoracic and mediastinal disorders	Hypoxia	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Respiratory, thoracic and mediastinal disorders	Hypoxia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Respiratory, thoracic and mediastinal disorders	Nasal congestion	<65	122	90,4	2	1,6	60	87,0	1	1,7	0,98	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,06	0,000	Algorithm converged.	-0,040	0,039	0,98	Algorithm converged.	0,09	10,63	0,9891	1,0000	1,02	Algorithm converged.	0,09	10,99
Respiratory, thoracic and mediastinal disorders	Nasal congestion	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 9.2580253305 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	<65	122	90,4	3	2,5	60	87,0	3	5,0	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,09	2,45	-0,025	Algorithm converged.	-0,087	0,036	0,49	Algorithm converged.	0,10	2,36	0,3757	1,0000	2,03	Algorithm converged.	0,42	9,78
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Skin and subcutaneous tissue disorders		<65	122	90,4	10	8,2	60	87,0	4	6,7	1,25	Convergence criterion (GCONV=1E-8) satisfied.	0,38	4,16	0,015	Algorithm converged.	-0,064	0,095	1,23	Algorithm converged.	0,40	3,76	0,7171	0,1129	0,81	Algorithm converged.	0,27	2,49
Skin and subcutaneous tissue disorders		>=65	13	9,6	3	23,1	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Skin and subcutaneous tissue disorders	Alopecia	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Skin and subcutaneous tissue disorders	Alopecia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Skin and subcutaneous tissue disorders	Ecchymosis	<65	122	90,4	2	1,6	60	87,0	1	1,7	0,98	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,06	0,000	Algorithm converged.	-0,040	0,039	0,98	Algorithm converged.	0,09	10,63	0,9891	0,3462	1,02	Algorithm converged.	0,09	10,99

Vascular disorders		<65	122	90,4	2	1,6	60	87,0	2	3,3	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,52	-0,017	Algorithm converged.	-0,068	0,034	0,49	Algorithm converged.	0,07	3,41	0,4723	0,2162	2,03	Algorithm converged.	0,29	14,09	
Vascular disorders		>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.		NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Vascular disorders	Hypertension	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.		0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	
Vascular disorders	Hypertension	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.		NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Vascular disorders	Hypotension	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 22.085838312 is greater than the limit of 0.0001. The convergence is questionable.		0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	
Vascular disorders	Hypotension	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypovolaemic shock	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypovolaemic shock	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Peripheral coldness	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Peripheral coldness	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_AE_SE1_16NOV2022_42162.xls
 10APR2024 9:54

POPULATION: Randomized Safety Population
 ENDPPOINT: Any AEs, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

All		Crovalimab (N=135)								Eculizumab (N=69)								Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab			
		Patients				Patients with				Patients				Patients with				Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL			
Blood and lymphatic system disorders		n/a	135	100,0	13	9,6	69	100,0	7	10,1	0,94	Convergence criterion (GCONV=1E-8) satisfied.	0,36	2,49	-0,005	Algorithm converged.	-0,092	0,082	0,95	Algorithm converged.	0,40	2,27	0,9067		NE	1,05	Algorithm converged.	0,44	2,52		
Blood and lymphatic system disorders	Anaemia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Aplastic anaemia	n/a	135	100,0	3	2,2	69	100,0	1	1,4	1,55	Convergence criterion (GCONV=1E-8) satisfied.	0,16	15,14	0,008	Algorithm converged.	-0,030	0,045	1,53	Algorithm converged.	0,16	14,47	0,7090		NE	0,65	Algorithm converged.	0,07	6,15		
Blood and lymphatic system disorders	Extravascular haemolysis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Febrile neutropenia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	0,9999		NE	>999.99	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders	Haemolysis	n/a	135	100,0	2	1,5	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 6.3162357217 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Increased tendency to bruise	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Lymphadenopathy	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	0,9999		NE	>999.99	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders	Neutropenia	n/a	135	100,0	3	2,2	69	100,0	2	2,9	0,76	Convergence criterion (GCONV=1E-8) satisfied.	0,12	4,67	-0,007	Algorithm converged.	-0,054	0,040	0,77	Algorithm converged.	0,13	4,48	0,7680		NE	1,30	Algorithm converged.	0,22	7,62		
Blood and lymphatic system disorders	Fancytopenia	n/a	135	100,0	2	1,5	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 6.3162357217 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Pernicious anaemia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Thrombocytopenia	n/a	135	100,0	1	0,7	69	100,0	2	2,9	0,25	Convergence criterion (GCONV=1E-8) satisfied.	0,02	2,81	-0,022	Algorithm converged.	-0,064	0,021	0,26	Algorithm converged.	0,02	2,77	0,2618		NE	3,91	Algorithm converged.	0,36	42,40		
Cardiac disorders		n/a	135	100,0	4	3,0	69	100,0	3	4,3	0,67	Convergence criterion (GCONV=1E-8) satisfied.	0,15	3,09	-0,014	Algorithm converged.	-0,070	0,042	0,68	Algorithm converged.	0,16	2,96	0,6088		NE	1,47	Algorithm converged.	0,34	6,37		

Cardiac disorders	Angina pectoris	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.												WARNING: Negative of Hessian not positive definite.									NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE																							
Cardiac disorders	Atrioventricular block first degree	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.												WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.																	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE															
Cardiac disorders	Bradycardia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.												WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.																		0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE														
Cardiac disorders	Cardiac failure	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.												WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.																			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE													
Cardiac disorders	Lupus endocarditis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.												WARNING: Negative of Hessian not positive definite.																					NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE											
Cardiac disorders	Myocardial infarction	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.												WARNING: Negative of Hessian not positive definite.																							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE									
Cardiac disorders	Palpitations	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.												WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.																									0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE							
Cardiac disorders	Supraventricular tachycardia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.												WARNING: Negative of Hessian not positive definite.																										NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE						
Congenital, familial and genetic disorders		n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000									Algorithm converged.	-0,034	0,035	1,02																									0,09	11,08	0,9856	NE	0,98	Algorithm converged.	0,09	10,60						
Congenital, familial and genetic disorders	Familial periodic paralysis	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.												WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.																														0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Congenital, familial and genetic disorders	Gilbert's syndrome	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.												WARNING: Negative of Hessian not positive definite.																													NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Congenital, familial and genetic disorders	Neurofibromatosis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.												WARNING: Negative of Hessian not positive definite.																													NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Ear and labyrinth disorders		n/a	135	100,0	0	0,0	69	100,0	2	2,9	*	Quasi-complete separation of data points detected.												WARNING: The relative Hessian convergence criterion of 14.376564041 is greater than the limit of 0.0001. The convergence is questionable.																															0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	
Ear and labyrinth disorders	Ear pain	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.												WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.																																0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE

Gastrointestinal disorders	Food poisoning	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.		0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Gastrointestinal disorders	Gastritis	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.		0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.		NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Gastrointestinal disorders	Gingival pain	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.		NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Gastrointestinal disorders	Haemorrhoids	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.		0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Gastrointestinal disorders	Hyperaesthesia teeth	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.		NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Gastrointestinal disorders	Nausea	n/a	135	100,0	6	4,4	69	100,0	2	2,9	1,56	Convergence criterion (GCONV=1E-8) satisfied.	0,31	7,93	0,015				Algorithm converged.		-0,037	0,068	1,53	Algorithm converged.	0,32	7,40	0,5945	NE	0,65	Algorithm converged.	0,14	3,15
Gastrointestinal disorders	Odynophagia	n/a	135	100,0	3	2,2	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.		NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Gastrointestinal disorders	Rectal haemorrhage	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.		NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Gastrointestinal disorders	Small intestinal haemorrhage	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.		NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Gastrointestinal disorders	Stomatitis	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.		0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Gastrointestinal disorders	Toothache	n/a	135	100,0	2	1,5	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 6.3162357217 is greater than the limit of 0.0001. The convergence is questionable.		NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Gastrointestinal disorders	Umbilical hernia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 23.402555586 is greater than the limit of 0.0001. The convergence is questionable.		0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Gastrointestinal disorders	Vomiting	n/a	135	100,0	3	2,2	69	100,0	1	1,4	1,55	Convergence criterion (GCONV=1E-8) satisfied.	0,16	15,14	0,008				Algorithm converged.		-0,030	0,045	1,53	Algorithm converged.	0,16	14,47	0,7090	NE	0,65	Algorithm converged.	0,07	6,15
General disorders and administration site conditions		n/a	135	100,0	26	19,3	69	100,0	10	14,5	1,41	Convergence criterion (GCONV=1E-8) satisfied.	0,64	3,12	0,048				Algorithm converged.		-0,059	0,154	1,33	Algorithm converged.	0,68	2,59	0,4049	NE	0,75	Algorithm converged.	0,39	1,47

General disorders and administration site conditions	Application site haemorrhage	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
General disorders and administration site conditions	Application site pain	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
General disorders and administration site conditions	Asthenia	n/a	135	100,0	2	1,5	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 6.3162357217 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Chest pain	n/a	135	100,0	2	1,5	69	100,0	2	2,9	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,66	-0,014			Algorithm converged.	-0,059	0,030	0,51	Algorithm converged.	0,07	3,55	0,4974	NE	1,96	Algorithm converged.	0,28	13,59
General disorders and administration site conditions	Early satiety	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Fatigue	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000			Algorithm converged.	-0,034	0,035	1,02	Algorithm converged.	0,09	11,08	0,9856	NE	0,98	Algorithm converged.	0,09	10,60
General disorders and administration site conditions	Feeling cold	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Influenza like illness	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Injection site reaction	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Malaise	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Oedema peripheral	n/a	135	100,0	2	1,5	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 6.3162357272 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Pain	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Peripheral swelling	n/a	135	100,0	2	1,5	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 6.3162357272 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Pyrexia	n/a	135	100,0	12	8,9	69	100,0	7	10,1	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,32	2,30	-0,013			Algorithm converged.	-0,098	0,073	0,88	Algorithm converged.	0,36	2,12	0,7700	NE	1,14	Algorithm converged.	0,47	2,77
Hepatobiliary disorders		n/a	135	100,0	1	0,7	69	100,0	3	4,3	0,16	Convergence criterion (GCONV=1E-8) satisfied.	0,02	1,61	-0,036			Algorithm converged.	-0,086	0,014	0,17	Algorithm converged.	0,02	1,61	0,1222	NE	5,87	Algorithm converged.	0,62	55,38
Hepatobiliary disorders	Cholecystitis chronic	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 23.40255564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9 9	Algorithm converged.	0,00	NE

Hepatobiliary disorders	Hepatic function abnormal	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81
Hepatobiliary disorders	Hypertransaminasaemia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Immune system disorders		n/a	135	100,0	3	2,2	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.6910017695 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Immune system disorders	Hypersensitivity	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Immune system disorders	Immunisation reaction	n/a	135	100,0	2	1,5	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 6.3162357272 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations		n/a	135	100,0	32	23,7	69	100,0	25	36,2	0,55	Convergence criterion (GCONV=1E-8) satisfied.	0,29	1,03	-0,125	Algorithm converged.	-0,259	0,009	0,65	Algorithm converged.	0,42	1,01	0,0561	NE	1,53	Algorithm converged.	0,99	2,36
Infections and infestations	Bronchitis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations	COVID-19	n/a	135	100,0	11	8,1	69	100,0	4	5,8	1,44	Convergence criterion (GCONV=1E-8) satisfied.	0,44	4,70	0,024	Algorithm converged.	-0,048	0,095	1,41	Algorithm converged.	0,46	4,25	0,5467	NE	0,71	Algorithm converged.	0,24	2,15
Infections and infestations	Central nervous system infection	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Diarrhoea infectious	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Fungal foot infection	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Gastroenteritis	n/a	135	100,0	0	0,0	69	100,0	2	2,9	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.376564028 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Helicobacter gastritis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations	Herpes virus infection	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Influenza	n/a	135	100,0	4	3,0	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Infections and infestations	Lower respiratory tract infection	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations	Nasopharyngitis	n/a	135	100,0	2	1,5	69	100,0	2	2,9	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,66	-0,014				Algorithm converged.	-0,059	0,030	0,51		Algorithm converged.	0,07	3,55	0,4974	NE	1,96	Algorithm converged.	0,28	13,59
Infections and infestations	Oral herpes	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 23.40255564 is greater than the limit of 0.0001. The convergence is questionable.			0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Infections and infestations	Otitis media acute	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations	Pharyngitis	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000				Algorithm converged.	-0,034	0,035	1,02		Algorithm converged.	0,09	11,08	0,9856	NE	0,98	Algorithm converged.	0,09	10,60
Infections and infestations	Pneumonia	n/a	135	100,0	2	1,5	69	100,0	2	2,9	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,66	-0,014				Algorithm converged.	-0,059	0,030	0,51		Algorithm converged.	0,07	3,55	0,4974	NE	1,96	Algorithm converged.	0,28	13,59
Infections and infestations	Pyelonephritis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations	Rhinitis	n/a	135	100,0	0	0,0	69	100,0	2	2,9	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 14.376564041 is greater than the limit of 0.0001. The convergence is questionable.			0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Infections and infestations	Sepsis	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 23.40255586 is greater than the limit of 0.0001. The convergence is questionable.			0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Infections and infestations	Skin infection	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 23.40255586 is greater than the limit of 0.0001. The convergence is questionable.			0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Infections and infestations	Soft tissue infection	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations	Tonsillitis	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 23.40255564 is greater than the limit of 0.0001. The convergence is questionable.			0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Infections and infestations	Tuberculosis	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 23.40255564 is greater than the limit of 0.0001. The convergence is questionable.			0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Infections and infestations	Upper respiratory tract infection	n/a	135	100,0	11	8,1	69	100,0	9	13,0	0,59	Convergence criterion (GCONV=1E-8) satisfied.	0,23	1,50	-0,049				Algorithm converged.	-0,141	0,043	0,62		Algorithm converged.	0,27	1,44	0,2676	NE	1,60	Algorithm converged.	0,70	3,68
Infections and infestations	Urinary tract infection	n/a	135	100,0	2	1,5	69	100,0	4	5,8	0,24	Convergence criterion (GCONV=1E-8) satisfied.	0,04	1,37	-0,043				Algorithm converged.	-0,102	0,016	0,26		Algorithm converged.	0,05	1,36	0,1098	NE	3,91	Algorithm converged.	0,73	20,84
Infections and infestations	Viral infection	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Injury, poisoning and procedural complications		n/a	135	100,0	29	21,5	69	100,0	11	15,9	1,44	Convergence criterion (GCONV=1E-8) satisfied.	0,67	3,10	0,055	Algorithm converged.	-0,055	0,166	1,35	Algorithm converged.	0,72	2,53	0,3539	NE	0,74	Algorithm converged.	0,40	1,39
Injury, poisoning and procedural complications	Contusion	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81
Injury, poisoning and procedural complications	Foot fracture	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Incorrect dose administered	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injury related reaction	n/a	135	100,0	21	15,6	69	100,0	9	13,0	1,23	Convergence criterion (GCONV=1E-8) satisfied.	0,53	2,85	0,025	Algorithm converged.	-0,075	0,125	1,19	Algorithm converged.	0,58	2,46	0,6340	NE	0,84	Algorithm converged.	0,41	1,73
Injury, poisoning and procedural complications	Injection related reaction	n/a	135	100,0	7	5,2	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 2.5057792342 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Limb injury	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Muscle strain	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Procedural pain	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9 9	Algorithm converged.	0,00	NE
Injury, poisoning and procedural complications	Skin abrasion	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Underdose	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Wrong schedule	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Investigations		n/a	135	100,0	23	17,0	69	100,0	11	15,9	1,08	Convergence criterion (GCONV=1E-8) satisfied.	0,49	2,37	0,011	Algorithm converged.	-0,096	0,118	1,07	Algorithm converged.	0,55	2,06	0,8430	NE	0,94	Algorithm converged.	0,48	1,81
Investigations	Alanine aminotransferase increased	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000	Algorithm converged.	-0,034	0,035	1,02	Algorithm converged.	0,09	11,08	0,9856	NE	0,98	Algorithm converged.	0,09	10,60
Investigations	Blood bilirubin increased	n/a	135	100,0	2	1,5	69	100,0	2	2,9	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,66	-0,014	Algorithm converged.	-0,059	0,030	0,51	Algorithm converged.	0,07	3,55	0,4974	NE	1,96	Algorithm converged.	0,28	13,59
Investigations	International normalised ratio increased	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9 9	Algorithm converged.	0,00	NE
Investigations	Neutrophil count decreased	n/a	135	100,0	17	12,6	69	100,0	7	10,1	1,28	Convergence criterion (GCONV=1E-8) satisfied.	0,50	3,24	0,024	Algorithm converged.	-0,066	0,115	1,24	Algorithm converged.	0,54	2,85	0,6102	NE	0,81	Algorithm converged.	0,35	1,85

Investigations	Occult blood positive	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Investigations	Platelet count decreased	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Investigations	White blood cell count decreased	n/a	135	100,0	16	11,9	69	100,0	7	10,1	1,19	Convergence criterion (GCONV=1E-8) satisfied.	0,47	3,05	0,017			Algorithm converged.	-0,073	0,107	1,17	Algorithm converged.	0,50	2,70	0,7166	NE	0,86	Algorithm converged.	0,37	1,98
Metabolism and nutrition disorders		n/a	135	100,0	26	19,3	69	100,0	15	21,7	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,42	1,75	-0,025			Algorithm converged.	-0,143	0,093	0,89	Algorithm converged.	0,50	1,56	0,6746	NE	1,13	Algorithm converged.	0,64	1,99
Metabolism and nutrition disorders	Decreased appetite	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.		0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Metabolism and nutrition disorders	Diabetes mellitus	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.		0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Metabolism and nutrition disorders	Haemochromatosis	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.		0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Metabolism and nutrition disorders	Hyperglycaemia	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007			Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81
Metabolism and nutrition disorders	Hyperuricaemia	n/a	135	100,0	11	8,1	69	100,0	6	8,7	0,93	Convergence criterion (GCONV=1E-8) satisfied.	0,33	2,64	-0,005			Algorithm converged.	-0,086	0,075	0,94	Algorithm converged.	0,36	2,43	0,8934	NE	1,07	Algorithm converged.	0,41	2,76
Metabolism and nutrition disorders	Hypocalcaemia	n/a	135	100,0	8	5,9	69	100,0	7	10,1	0,56	Convergence criterion (GCONV=1E-8) satisfied.	0,19	1,61	-0,042			Algorithm converged.	-0,124	0,039	0,58	Algorithm converged.	0,22	1,54	0,2783	NE	1,71	Algorithm converged.	0,65	4,53
Metabolism and nutrition disorders	Hypoglycaemia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 23.402555586 is greater than the limit of 0.0001. The convergence is questionable.		0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Metabolism and nutrition disorders	Hypokalaemia	n/a	135	100,0	15	11,1	69	100,0	9	13,0	0,83	Convergence criterion (GCONV=1E-8) satisfied.	0,34	2,01	-0,019			Algorithm converged.	-0,115	0,076	0,85	Algorithm converged.	0,39	1,85	0,6847	NE	1,17	Algorithm converged.	0,54	2,55
Metabolism and nutrition disorders	Hypomagnesaemia	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000			Algorithm converged.	-0,034	0,035	1,02	Algorithm converged.	0,09	11,08	0,9856	NE	0,98	Algorithm converged.	0,09	10,60
Metabolism and nutrition disorders	Vitamin B12 deficiency	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Musculoskeletal and connective tissue disorders		n/a	135	100,0	12	8,9	69	100,0	4	5,8	1,59	Convergence criterion (GCONV=1E-8) satisfied.	0,49	5,11	0,031			Algorithm converged.	-0,042	0,104	1,53	Algorithm converged.	0,51	4,58	0,4437	NE	0,65	Algorithm converged.	0,22	1,95
Musculoskeletal and connective tissue disorders	Arthralgia	n/a	135	100,0	3	2,2	69	100,0	3	4,3	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,10	2,55	-0,021			Algorithm converged.	-0,075	0,033	0,51	Algorithm converged.	0,11	2,47	0,4032	NE	1,96	Algorithm converged.	0,41	9,44
Musculoskeletal and connective tissue disorders	Arthritis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Musculoskeletal and connective tissue disorders	Back pain	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007			Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81

Musculoskeletal and connective tissue disorders	Fasciitis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Muscle spasms	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51		Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Myalgia	n/a	135	100,0	4	3,0	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Neck pain	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	135	100,0	3	2,2	69	100,0	1	1,4	1,55	Convergence criterion (GCONV=1E-8) satisfied.	0,16	15,14	0,008	Algorithm converged.	-0,030	0,045	1,53		Algorithm converged.	0,16	14,47	0,7090	NE	0,65	Algorithm converged.	0,07	6,15
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Myelodysplastic syndrome	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Nervous system disorders		n/a	135	100,0	14	10,4	69	100,0	8	11,6	0,88	Convergence criterion (GCONV=1E-8) satisfied.	0,35	2,22	-0,012	Algorithm converged.	-0,104	0,079	0,89		Algorithm converged.	0,38	2,03	0,7895	NE	1,12	Algorithm converged.	0,49	2,54
Nervous system disorders	Dizziness	n/a	135	100,0	2	1,5	69	100,0	2	2,9	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,66	-0,014	Algorithm converged.	-0,059	0,030	0,51		Algorithm converged.	0,07	3,55	0,4974	NE	1,96	Algorithm converged.	0,28	13,59
Nervous system disorders	Headache	n/a	135	100,0	11	8,1	69	100,0	3	4,3	1,95	Convergence criterion (GCONV=1E-8) satisfied.	0,53	7,24	0,038	Algorithm converged.	-0,029	0,105	1,87		Algorithm converged.	0,54	6,50	0,3221	NE	0,53	Algorithm converged.	0,15	1,85
Nervous system disorders	Ischaemic stroke	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Nervous system disorders	Migraine	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE

Nervous system disorders	Neuropathy peripheral	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81
Nervous system disorders	Paraesthesia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Psychiatric disorders		n/a	135	100,0	3	2,2	69	100,0	3	4,3	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,10	2,55	-0,021	Algorithm converged.	-0,075	0,033	0,51	Algorithm converged.	0,11	2,47	0,4032	NE	1,96	Algorithm converged.	0,41	9,44
Psychiatric disorders	Abnormal dreams	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Psychiatric disorders	Affective disorder	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Psychiatric disorders	Insomnia	n/a	135	100,0	2	1,5	69	100,0	3	4,3	0,33	Convergence criterion (GCONV=1E-8) satisfied.	0,05	2,03	-0,029	Algorithm converged.	-0,081	0,024	0,34	Algorithm converged.	0,06	1,99	0,2320	NE	2,93	Algorithm converged.	0,50	17,15
Renal and urinary disorders		n/a	135	100,0	5	3,7	69	100,0	1	1,4	2,61	Convergence criterion (GCONV=1E-8) satisfied.	0,30	22,83	0,023	Algorithm converged.	-0,020	0,065	2,56	Algorithm converged.	0,30	21,45	0,3873	NE	0,39	Algorithm converged.	0,05	3,28
Renal and urinary disorders	Chromaturia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Renal and urinary disorders	Chronic kidney disease	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Renal and urinary disorders	Nephrolithiasis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Renal and urinary disorders	Faroxysmal nocturnal haemoglobinuria	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000	Algorithm converged.	-0,034	0,035	1,02	Algorithm converged.	0,09	11,08	0,9856	NE	0,98	Algorithm converged.	0,09	10,60
Reproductive system and breast disorders		n/a	135	100,0	1	0,7	69	100,0	2	2,9	0,25	Convergence criterion (GCONV=1E-8) satisfied.	0,02	2,81	-0,022	Algorithm converged.	-0,064	0,021	0,26	Algorithm converged.	0,02	2,77	0,2618	NE	3,91	Algorithm converged.	0,36	42,40
Reproductive system and breast disorders	Gynaecomastia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Reproductive system and breast disorders	Perineal rash	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Reproductive system and breast disorders	Spontaneous penile erection	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Respiratory, thoracic and mediastinal disorders		n/a	135	100,0	13	9,6	69	100,0	5	7,2	1,36	Convergence criterion (GCONV=1E-8) satisfied.	0,47	4,00	0,024	Algorithm converged.	-0,055	0,103	1,33	Algorithm converged.	0,49	3,58	0,5734	NE	0,75	Algorithm converged.	0,28	2,02
Respiratory, thoracic and mediastinal disorders	Cough	n/a	135	100,0	3	2,2	69	100,0	2	2,9	0,76	Convergence criterion (GCONV=1E-8) satisfied.	0,12	4,67	-0,007	Algorithm converged.	-0,054	0,040	0,77	Algorithm converged.	0,13	4,48	0,7680	NE	1,30	Algorithm converged.	0,22	7,62

Respiratory, thoracic and mediastinal disorders	Dysphonia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	n/a	135	100,0	3	2,2	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Epistaxis	n/a	135	100,0	2	1,5	69	100,0	2	2,9	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,66	-0,014			Algorithm converged.	-0,059	0,030	0,51		Algorithm converged.	0,07	3,55	0,4974		NE	1,96	Algorithm converged.	0,28	13,59
Respiratory, thoracic and mediastinal disorders	Hiccups	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Hypoxia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000			Algorithm converged.	-0,034	0,035	1,02		Algorithm converged.	0,09	11,08	0,9856		NE	0,98	Algorithm converged.	0,09	10,60
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	135	100,0	3	2,2	69	100,0	3	4,3	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,10	2,55	-0,021			Algorithm converged.	-0,075	0,033	0,51		Algorithm converged.	0,11	2,47	0,4032		NE	1,96	Algorithm converged.	0,41	9,44
Skin and subcutaneous tissue disorders		n/a	135	100,0	13	9,6	69	100,0	4	5,8	1,73	Convergence criterion (GCONV=1E-8) satisfied.	0,54	5,53	0,038			Algorithm converged.	-0,036	0,113	1,66		Algorithm converged.	0,56	4,90	0,3582		NE	0,60	Algorithm converged.	0,20	1,78
Skin and subcutaneous tissue disorders	Alopecia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Skin and subcutaneous tissue disorders	Ecchymosis	n/a	135	100,0	3	2,2	69	100,0	1	1,4	1,55	Convergence criterion (GCONV=1E-8) satisfied.	0,16	15,14	0,008			Algorithm converged.	-0,030	0,045	1,53		Algorithm converged.	0,16	14,47	0,7090		NE	0,65	Algorithm converged.	0,07	6,15
Skin and subcutaneous tissue disorders	Eczema	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	n/a	135	100,0	2	1,5	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 6.3162357272 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Skin and subcutaneous tissue disorders	Hyperkeratosis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Skin and subcutaneous tissue disorders	Night sweats	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	

Skin and subcutaneous tissue disorders	Papule	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.											WARNING: Negative of Hessian not positive definite.					NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders	Petechiae	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.											WARNING: Negative of Hessian not positive definite.					NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders	Pruritus	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8)	0,09	11,48	0,000								Algorithm converged.	-0,034	0,035	1,02	Algorithm converged.	0,09	11,08	0,9856		NE	0,98	Algorithm converged.	0,09	10,60			
Skin and subcutaneous tissue disorders	Rash	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000								Algorithm converged.	-0,034	0,035	1,02	Algorithm converged.	0,09	11,08	0,9856		NE	0,98	Algorithm converged.	0,09	10,60			
Skin and subcutaneous tissue disorders	Rash erythematous	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.											WARNING: The relative Hessian convergence criterion of 23.40255564 is greater than the limit of 0.0001. The convergence is questionable.						0,00	Algorithm converged.	0,00	NE	0,9999		NE	>999.99	Algorithm converged.	0,00	NE
Vascular disorders		n/a	135	100,0	3	2,2	69	100,0	2	2,9	0,76	Convergence criterion (GCONV=1E-8) satisfied.	0,12	4,67	-0,007								Algorithm converged.	-0,054	0,040	0,77	Algorithm converged.	0,13	4,48	0,7680		NE	1,30	Algorithm converged.	0,22	7,62			
Vascular disorders	Hypertension	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007								Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332		NE	1,96	Algorithm converged.	0,12	30,81			
Vascular disorders	Hypotension	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.											WARNING: The relative Hessian convergence criterion of 23.40255564 is greater than the limit of 0.0001. The convergence is questionable.						0,00	Algorithm converged.	0,00	NE	0,9999		NE	>999.99	Algorithm converged.	0,00	NE
Vascular disorders	Hypovolaemic shock	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.											WARNING: Negative of Hessian not positive definite.					NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Vascular disorders	Peripheral coldness	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.											WARNING: Negative of Hessian not positive definite.					NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_AE_SE1_16NOV2022_42162.xls
10APR2024 9:54

POPULATION: Randomized Safety Population
 ENDPPOINT: Any AEs, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

Transfusion history [total pRBC units administered in the 6 months pre-randomization]

			Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab							
			Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		0 units	33	24,4	3	9,1	17	24,6	1	5,9	1,60	Convergence criterion (GCONV=1E-8) satisfied.	0,15	16,66	0,032	Algorithm converged.	-0,117	0,181	1,55	Algorithm converged.	0,17	13,76	0,6963	0,1342	0,65	Algorithm converged.	0,07	5,76	
Blood and lymphatic system disorders		>0 to <=6 units	68	50,4	8	11,8	34	49,3	2	5,9	2,13	Convergence criterion (GCONV=1E-8) satisfied.	0,43	10,65	0,059	Algorithm converged.	-0,051	0,169	2,00	Algorithm converged.	0,45	8,91	0,3631		0,50	Algorithm converged.	0,11	2,23	
Blood and lymphatic system disorders		>6 units	34	25,2	2	5,9	18	26,1	4	22,2	0,22	Convergence criterion (GCONV=1E-8) satisfied.	0,04	1,34	-0,163	Algorithm converged.	-0,371	0,044	0,26	Algorithm converged.	0,05	1,31	0,1031		3,78	Algorithm converged.	0,76	18,68	
Blood and lymphatic system disorders	Anaemia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Anaemia	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Anaemia	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Aplastic anaemia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Aplastic anaemia	>0 to <=6 units	68	50,4	2	2,9	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 3.729277866 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Aplastic anaemia	>6 units	34	25,2	1	2,9	18	26,1	1	5,6	0,52	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,75	-0,026	Algorithm converged.	-0,146	0,094	0,53	Algorithm converged.	0,04	7,97	0,6458		1,89	Algorithm converged.	0,13	28,45	
Blood and lymphatic system disorders	Extravascular haemolysis	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Extravascular haemolysis	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravascular haemolysis	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile neutropenia	0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 8.5838859021 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9	Algorithm converged.	0,00	NE

Blood and lymphatic system disorders	Febrile neutropenia	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Blood and lymphatic system disorders	Febrile neutropenia	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Blood and lymphatic system disorders	Haemolysis	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.									NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Haemolysis	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.									NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Haemolysis	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Increased tendency to bruise	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Increased tendency to bruise	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.									NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Increased tendency to bruise	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Lymphadenopathy	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Lymphadenopathy	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Lymphadenopathy	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.									0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE		
Blood and lymphatic system disorders	Neutropenia	0 units	33	24,4	2	6,1	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.									NE	Algorithm converged.	NE	NE	NE	0,1313	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Neutropenia	>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.									0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE		
Blood and lymphatic system disorders	Neutropenia	>6 units	34	25,2	1	2,9	18	26,1	1	5,6	0,52	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,75	-0,026	Algorithm converged.	-0,146	0,094	0,53	Algorithm converged.	0,04	7,97	0,6458	1,89	Algorithm converged.	0,13	28,45				

Eye disorders	Pterygium	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.6996663729 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE						
Gastrointestinal disorders		0 units	33	24,4	5	15,2	17	24,6	3	17,6	0,83	Convergence criterion (GCONV=1E-8) satisfied.	0,17	4,00	-0,025	Algorithm converged.	-0,244	0,194	0,86	Algorithm converged.	0,23	3,17	0,8191	0,8935	1,16	Algorithm converged.	0,32	4,30	
Gastrointestinal disorders		>0 to <=6 units	68	50,4	15	22,1	34	49,3	6	17,6	1,32	Convergence criterion (GCONV=1E-8) satisfied.	0,46	3,78	0,044	Algorithm converged.	-0,118	0,206	1,25	Algorithm converged.	0,53	2,93	0,6080		0,80	Algorithm converged.	0,34	1,88	
Gastrointestinal disorders		>6 units	34	25,2	6	17,6	18	26,1	3	16,7	1,07	Convergence criterion (GCONV=1E-8) satisfied.	0,23	4,90	0,010	Algorithm converged.	-0,205	0,224	1,06	Algorithm converged.	0,30	3,74	0,9293		0,94	Algorithm converged.	0,27	3,34	
Gastrointestinal disorders	Abdominal distension	0 units	33	24,4	0	0,0	17	24,6	2	11,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.		0,00				Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE	
Gastrointestinal disorders	Abdominal distension	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Abdominal distension	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE		Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Abdominal pain	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 3.7542276434 is greater than the limit of 0.0001. The convergence is questionable.				NE		Algorithm converged.	NE	NE	NE	NE	0,7699	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Abdominal pain	>0 to <=6 units	68	50,4	3	4,4	34	49,3	1	2,9	1,52	Convergence criterion (GCONV=1E-8) satisfied.	0,15	15,22	0,015	Algorithm converged.	-0,060	0,090	1,50	Algorithm converged.	0,16	13,89	0,7210		0,67	Algorithm converged.	0,07	6,17	
Gastrointestinal disorders	Abdominal pain	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Abdominal pain upper	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Abdominal pain upper	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.				NE		Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Abdominal pain upper	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE		Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Constipation	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Constipation	>0 to <=6 units	68	50,4	1	1,5	34	49,3	2	5,9	0,24	Convergence criterion (GCONV=1E-8) satisfied.	0,02	2,73	-0,044	Algorithm converged.	-0,128	0,040	0,25	Algorithm converged.	0,02	2,66	0,2506		4,00	Algorithm converged.	0,38	42,57	

Gastrointestinal disorders	Constipation	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.														ERROR: Error in computing the link function, its derivatives, or the variance function.							0,00	Algorithm converged.	0,00	NE	0,9999		>999,99	Algorithm converged.	0,00	NE					
Gastrointestinal disorders	Dental caries	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE															NE	NE	NE	NE							NE	NE	NE	NE	NE							
Gastrointestinal disorders	Dental caries	>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.														WARNING: The relative Hessian convergence criterion of 14.539905139 is greater than the limit of 0.0001. The convergence is questionable.												0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE
Gastrointestinal disorders	Dental caries	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE															NE	NE	NE	NE							NE	NE	NE	NE	NE							
Gastrointestinal disorders	Diarrhoea	0 units	33	24,4	2	6,1	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.													WARNING: The relative Hessian convergence criterion of 2.2552715928 is greater than the limit of 0.0001. The convergence is questionable.											NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE		
Gastrointestinal disorders	Diarrhoea	>0 to <=6 units	68	50,4	7	10,3	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.													WARNING: Negative of Hessian not positive definite.											NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE		
Gastrointestinal disorders	Diarrhoea	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.													ERROR: Error in computing the link function, its derivatives, or the variance function.											NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE		
Gastrointestinal disorders	Dyspepsia	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.													WARNING: The relative Hessian convergence criterion of 3.7542276501 is greater than the limit of 0.0001. The convergence is questionable.											NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE		
Gastrointestinal disorders	Dyspepsia	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE														NE	NE	NE	NE							NE	NE	NE	NE	NE								
Gastrointestinal disorders	Dyspepsia	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.													ERROR: Error in computing the link function, its derivatives, or the variance function.											NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE		
Gastrointestinal disorders	Food poisoning	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE														NE	NE	NE	NE							NE	NE	NE	NE	NE								

General disorders and administration site conditions	Application site pain	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
General disorders and administration site conditions	Application site pain	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Application site pain	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
General disorders and administration site conditions	Asthenia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
General disorders and administration site conditions	Asthenia	>0 to <=6 units	68	50,4	2	2,9	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 3.729277866 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Asthenia	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
General disorders and administration site conditions	Chest pain	0 units	33	24,4	1	3,0	17	24,6	2	11,8	0,23	Convergence criterion (GCONV=1E-8) satisfied.	0,02	2,79	-0,087	Algorithm converged.	-0,251	0,077	0,26	Algorithm converged.	0,03	2,64	0,2535	NE	3,88	Algorithm converged.	0,38	39,82
General disorders and administration site conditions	Chest pain	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
General disorders and administration site conditions	Chest pain	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Early satiety	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 3.7542276434 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
General disorders and administration site conditions	Early satiety	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
General disorders and administration site conditions	Early satiety	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
General disorders and administration site conditions	Fatigue	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 3.7542276467 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		

General disorders and administration site conditions	Fatigue	>0 to <=6 units	68	50,4	1	1,5	34	49,3	1	2,9	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,12	-0,015	Algorithm converged.	-0,078	0,049	0,50	Algorithm converged.	0,03	7,75	0,6202	2,00	Algorithm converged.	0,13	31,01
General disorders and administration site conditions	Fatigue	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Feeling cold	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Feeling cold	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Feeling cold	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Influenza like illness	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Influenza like illness	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Influenza like illness	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Injection site reaction	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Injection site reaction	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Injection site reaction	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Malaise	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Malaise	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Malaise	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Oedema peripheral	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Oedema peripheral	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE

General disorders and administration site conditions	Oedema peripheral	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Oedema peripheral	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Pain	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Pain	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Pain	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Peripheral swelling	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Peripheral swelling	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Peripheral swelling	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Pyrexia	0 units	33	24,4	2	6,1	17	24,6	2	11,8	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,06	3,78	-0,057		Algorithm converged.	-0,230	0,116	0,52	Algorithm converged.	0,08	3,34	0,4871	0,7757	1,94	Algorithm converged.	0,30	12,60
General disorders and administration site conditions	Pyrexia	>0 to <=6 units	68	50,4	5	7,4	34	49,3	2	5,9	1,27	Convergence criterion (GCONV=1E-8) satisfied.	0,23	6,91	0,015		Algorithm converged.	-0,086	0,115	1,25	Algorithm converged.	0,26	6,11	0,7829	0,80	Algorithm converged.	0,16	3,91	
General disorders and administration site conditions	Pyrexia	>6 units	34	25,2	5	14,7	18	26,1	3	16,7	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,18	4,11	-0,020		Algorithm converged.	-0,229	0,190	0,88	Algorithm converged.	0,24	3,28	0,8517	1,13	Algorithm converged.	0,31	4,21	
Hepatobiliary disorders		0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 8.5838859101 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	0,4264	>999,99	Algorithm converged.	0,00	NE
Hepatobiliary disorders		>0 to <=6 units	68	50,4	1	1,5	34	49,3	1	2,9	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,12	-0,015		Algorithm converged.	-0,078	0,049	0,50	Algorithm converged.	0,03	7,75	0,6202	2,00	Algorithm converged.	0,13	31,01	
Hepatobiliary disorders		>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE	

Infections and infestations		0 units	33	24,4	4	12,1	17	24,6	6	35,3	0,25	Convergence criterion (GCONV=1E-8) satisfied.	0,06	1,07	-0,232	Algorithm converged.	-0,485	0,021	0,34	Algorithm converged.	0,11	1,05	0,0618	0,2228	2,91	Algorithm converged.	0,95	8,94	
Infections and infestations		>0 to <=6 units	68	50,4	19	27,9	34	49,3	10	29,4	0,93	Convergence criterion (GCONV=1E-8) satisfied.	0,38	2,31	-0,015	Algorithm converged.	-0,201	0,172	0,95	Algorithm converged.	0,50	1,81	0,8763		1,05	Algorithm converged.	0,55	2,01	
Infections and infestations		>6 units	34	25,2	9	26,5	18	26,1	9	50,0	0,36	Convergence criterion (GCONV=1E-8) satisfied.	0,11	1,19	-0,235	Algorithm converged.	-0,510	0,039	0,53	Algorithm converged.	0,26	1,09	0,0860		1,89	Algorithm converged.	0,91	3,90	
Infections and infestations	Bronchitis	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Bronchitis	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Bronchitis	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
Infections and infestations	COVID-19	0 units	33	24,4	0	0,0	17	24,6	2	11,8	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	0,0165	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	COVID-19	>0 to <=6 units	68	50,4	7	10,3	34	49,3	2	5,9	1,84	Convergence criterion (GCONV=1E-8) satisfied.	0,36	9,36	0,044	Algorithm converged.	-0,063	0,151	1,75	Algorithm converged.	0,38	7,97	0,4695		0,57	Algorithm converged.	0,13	2,60	
Infections and infestations	COVID-19	>6 units	34	25,2	4	11,8	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Central nervous system infection	0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Central nervous system infection	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
Infections and infestations	Central nervous system infection	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
Infections and infestations	Diarrhoea infectious	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
Infections and infestations	Diarrhoea infectious	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
Infections and infestations	Diarrhoea infectious	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE	
Infections and infestations	Fungal foot infection	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE

Infections and infestations	Sepsis	>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 14.539905165 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999,99	Algorithm converged.	0,00	NE					
Infections and infestations	Sepsis	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Skin infection	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Skin infection	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Skin infection	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE					
Infections and infestations	Soft tissue infection	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Soft tissue infection	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Soft tissue infection	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Tonsillitis	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Tonsillitis	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Tonsillitis	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE					
Infections and infestations	Tuberculosis	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Tuberculosis	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Tuberculosis	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE					
Infections and infestations	Upper respiratory tract infection	0 units	33	24,4	2	6,1	17	24,6	2	11,8	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,06	3,78	-0,057	Algorithm converged.	-0,230	0,116	0,52	Algorithm converged.	0,08	3,34	0,4871	0,6617	1,94	Algorithm converged.	0,30	12,60
Infections and infestations	Upper respiratory tract infection	>0 to <=6 units	68	50,4	7	10,3	34	49,3	4	11,8	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,23	3,17	-0,015	Algorithm converged.	-0,145	0,115	0,88	Algorithm converged.	0,28	2,78	0,8211	1,14	Algorithm converged.	0,36	3,64	
Infections and infestations	Upper respiratory tract infection	>6 units	34	25,2	2	5,9	18	26,1	3	16,7	0,31	Convergence criterion (GCONV=1E-8) satisfied.	0,05	2,07	-0,108	Algorithm converged.	-0,297	0,082	0,35	Algorithm converged.	0,06	1,92	0,2286	2,83	Algorithm converged.	0,52	15,44	

Infections and infestations	Urinary tract infection	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Urinary tract infection	>0 to <=6 units	68	50,4	1	1,5	34	49,3	3	8,8	0,15	0,02	1,54	-0,074	Algorithm converged.	-0,173	0,026	0,17	Algorithm converged.	0,02	1,54	0,1146	6,00	Algorithm converged.	0,65	55,54	
Infections and infestations	Urinary tract infection	>6 units	34	25,2	1	2,9	18	26,1	1	5,6	0,52	0,03	8,75	-0,026	Algorithm converged.	-0,146	0,094	0,53	Algorithm converged.	0,04	7,97	0,6458	1,89	Algorithm converged.	0,13	28,45	
Infections and infestations	Viral infection	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Viral infection	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Viral infection	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	
Injury, poisoning and procedural complications		0 units	33	24,4	8	24,2	17	24,6	3	17,6	1,49	0,34	6,56	0,066	Algorithm converged.	-0,167	0,299	1,37	Algorithm converged.	0,42	4,52	0,6013	0,9983	0,73	Algorithm converged.	0,22	2,40
Injury, poisoning and procedural complications		>0 to <=6 units	68	50,4	11	16,2	34	49,3	4	11,8	1,45	0,42	4,93	0,044	Algorithm converged.	-0,095	0,183	1,37	Algorithm converged.	0,47	4,00	0,5589	0,73	Algorithm converged.	0,25	2,12	
Injury, poisoning and procedural complications		>6 units	34	25,2	10	29,4	18	26,1	4	22,2	1,46	0,38	5,53	0,072	Algorithm converged.	-0,174	0,318	1,32	Algorithm converged.	0,48	3,63	0,5861	0,76	Algorithm converged.	0,28	2,07	
Injury, poisoning and procedural complications	Contusion	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Contusion	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE
Injury, poisoning and procedural complications	Contusion	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE	NE	NE		
Injury, poisoning and procedural complications	Foot fracture	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Foot fracture	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE
Injury, poisoning and procedural complications	Foot fracture	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Incorrect dose administered	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Incorrect dose administered	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Incorrect dose administered	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE

Injury, poisoning and procedural complications	Infusion related reaction	0 units	33	24,4	5	15,2	17	24,6	3	17,6	0,83	Convergence criterion (GCONV=1E-8) satisfied.	0,17	4,00	-0,025	Algorithm converged.	-0,244	0,194	0,86	Algorithm converged.	0,23	3,17	0,8191	0,8429	1,16	Algorithm converged.	0,32	4,30	
Injury, poisoning and procedural complications	Infusion related reaction	>0 to <=6 units	68	50,4	8	11,8	34	49,3	3	8,8	1,38	Convergence criterion (GCONV=1E-8) satisfied.	0,34	5,56	0,029	Algorithm converged.	-0,093	0,152	1,33	Algorithm converged.	0,38	4,71	0,6549		0,75	Algorithm converged.	0,21	2,65	
Injury, poisoning and procedural complications	Infusion related reaction	>6 units	34	25,2	8	23,5	18	26,1	3	16,7	1,54	Convergence criterion (GCONV=1E-8) satisfied.	0,35	6,70	0,069	Algorithm converged.	-0,155	0,292	1,41	Algorithm converged.	0,43	4,68	0,5725		0,71	Algorithm converged.	0,21	2,35	
Injury, poisoning and procedural complications	Injection related reaction	0 units	33	24,4	3	9,1	17	24,6	0	0,0		Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Injury, poisoning and procedural complications	Injection related reaction	>0 to <=6 units	68	50,4	3	4,4	34	49,3	0	0,0		Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Injury, poisoning and procedural complications	Injection related reaction	>6 units	34	25,2	1	2,9	18	26,1	0	0,0		Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Injury, poisoning and procedural complications	Limb injury	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Limb injury	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0		Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Injury, poisoning and procedural complications	Limb injury	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Muscle strain	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Muscle strain	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Muscle strain	>6 units	34	25,2	1	2,9	18	26,1	0	0,0		Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Injury, poisoning and procedural complications	Procedural pain	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Procedural pain	>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9		Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	1,0000	>999,9	9	Algorithm converged.	0,00	NE	

Investigations	Alanine aminotransferase increased	>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 14.539905139 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999,99	Algorithm converged.	0,00	NE			
Investigations	Alanine aminotransferase increased	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Investigations	Blood bilirubin increased	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 3.7542276467 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	0,2479	NE	Algorithm converged.	NE	NE		
Investigations	Blood bilirubin increased	>0 to <=6 units	68	50,4	1	1,5	34	49,3	1	2,9	0,49	Convergence criterion (GCONV=1E-8) satisfied.		Algorithm converged.	-0,078	0,049	0,50	Algorithm converged.	0,03	7,75	0,6202	2,00	Algorithm converged.	0,13	31,01	
Investigations	Blood bilirubin increased	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE			
Investigations	International normalised ratio increased	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Investigations	International normalised ratio increased	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Investigations	International normalised ratio increased	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE			
Investigations	Neutrophil count decreased	0 units	33	24,4	1	3,0	17	24,6	2	11,8	0,23	Convergence criterion (GCONV=1E-8) satisfied.		Algorithm converged.	-0,251	0,077	0,26	Algorithm converged.	0,03	2,64	0,2535	0,1096	3,88	Algorithm converged.	0,38	39,82
Investigations	Neutrophil count decreased	>0 to <=6 units	68	50,4	9	13,2	34	49,3	1	2,9	5,03	Convergence criterion (GCONV=1E-8) satisfied.		Algorithm converged.	0,004	0,201	4,50	Algorithm converged.	0,59	34,08	0,1454	0,22	Algorithm converged.	0,03	1,68	
Investigations	Neutrophil count decreased	>6 units	34	25,2	7	20,6	18	26,1	4	22,2	0,91	Convergence criterion (GCONV=1E-8) satisfied.		Algorithm converged.	-0,252	0,219	0,93	Algorithm converged.	0,31	2,75	0,8905	1,08	Algorithm converged.	0,36	3,20	
Investigations	Occult blood positive	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Investigations	Occult blood positive	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		

Investigations	Occult blood positive	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE					NE	NE	NE	NE					NE	NE	NE	NE						
Investigations	Platelet count decreased	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE					NE	NE	NE	NE					NE	NE	NE	NE						
Investigations	Platelet count decreased	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.					NE	Algorithm converged.				NE	Algorithm converged.		NE						
Investigations	Platelet count decreased	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE					NE	NE	NE	NE					NE	NE	NE	NE						
Investigations	White blood cell count decreased	0 units	33	24,4	0	0,0	17	24,6	2	11,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.					0,00	Algorithm converged.	0,00	NE	0,9999	0,0224	>999.99	Algorithm converged.	0,00	NE					
Investigations	White blood cell count decreased	>0 to <=6 units	68	50,4	9	13,2	34	49,3	1	2,9	5,03		Convergence criterion (GCONV=1E-8) satisfied.		0,61	41,50	0,103			Algorithm converged.	0,004	0,201	4,50		Algorithm converged.	0,59	34,08	0,1454	0,22	Algorithm converged.	0,03	1,68	
Investigations	White blood cell count decreased	>6 units	34	25,2	7	20,6	18	26,1	4	22,2	0,91		Convergence criterion (GCONV=1E-8) satisfied.		0,23	3,63	-0,016			Algorithm converged.	-0,252	0,219	0,93		Algorithm converged.	0,31	2,75	0,8905	1,08	Algorithm converged.	0,36	3,20	
Metabolism and nutrition disorders		0 units	33	24,4	2	6,1	17	24,6	1	5,9	1,03		Convergence criterion (GCONV=1E-8) satisfied.		0,09	12,26	0,002			Algorithm converged.	-0,137	0,140	1,03		Algorithm converged.	0,10	10,57	0,9799	0,9516	0,97	Algorithm converged.	0,09	9,96
Metabolism and nutrition disorders		>0 to <=6 units	68	50,4	15	22,1	34	49,3	8	23,5	0,92		Convergence criterion (GCONV=1E-8) satisfied.		0,35	2,45	-0,015			Algorithm converged.	-0,188	0,159	0,94		Algorithm converged.	0,44	1,99	0,8666	1,07	Algorithm converged.	0,50	2,26	
Metabolism and nutrition disorders		>6 units	34	25,2	9	26,5	18	26,1	6	33,3	0,72		Convergence criterion (GCONV=1E-8) satisfied.		0,21	2,49	-0,069			Algorithm converged.	-0,332	0,195	0,79		Algorithm converged.	0,34	1,88	0,5996	1,26	Algorithm converged.	0,53	2,98	
Metabolism and nutrition disorders	Decreased appetite	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE				NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	
Metabolism and nutrition disorders	Decreased appetite	>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 14.539905152 is greater than the limit of 0.0001. The convergence is questionable.					0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE						
Metabolism and nutrition disorders	Decreased appetite	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE				NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE		
Metabolism and nutrition disorders	Diabetes mellitus	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE				NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE		
Metabolism and nutrition disorders	Diabetes mellitus	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE				NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE		
Metabolism and nutrition disorders	Diabetes mellitus	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.					0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE						
Metabolism and nutrition disorders	Haemochromatosis	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE				NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE		

Metabolism and nutrition disorders	Haemochromatosis	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE													
Metabolism and nutrition disorders	Haemochromatosis	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.											>999,99	Algorithm converged.	0,00	NE											
Metabolism and nutrition disorders	Hyperglycemia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE											
Metabolism and nutrition disorders	Hyperglycemia	>0 to <=6 units	68	50,4	1	1,5	34	49,3	1	2,9	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,12	-0,015										Algorithm converged.	0,03	7,75	0,6202	2,00	Algorithm converged.	0,13	31,01					
Metabolism and nutrition disorders	Hyperglycemia	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Metabolism and nutrition disorders	Hyperuricemia	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.													Algorithm converged.	NE	NE	NE	NE	0,6302	NE	Algorithm converged.	NE	NE			
Metabolism and nutrition disorders	Hyperuricemia	>0 to <=6 units	68	50,4	5	7,4	34	49,3	3	8,8	0,82	Convergence criterion (GCONV=1E-8) satisfied.	0,18	3,66	-0,015										Algorithm converged.	-0,128	0,099	0,83		Algorithm converged.	0,21	3,28	0,7943	1,20	Algorithm converged.	0,30	4,73
Metabolism and nutrition disorders	Hyperuricemia	>6 units	34	25,2	5	14,7	18	26,1	3	16,7	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,18	4,11	-0,020										Algorithm converged.	-0,229	0,190	0,88		Algorithm converged.	0,24	3,28	0,8517	1,13	Algorithm converged.	0,31	4,21
Metabolism and nutrition disorders	Hypocalcemia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Metabolism and nutrition disorders	Hypocalcemia	>0 to <=6 units	68	50,4	5	7,4	34	49,3	6	17,6	0,37	Convergence criterion (GCONV=1E-8) satisfied.	0,10	1,32	-0,103										Algorithm converged.	-0,245	0,039	0,42		Algorithm converged.	0,14	1,27	0,1232	2,40	Algorithm converged.	0,79	7,31
Metabolism and nutrition disorders	Hypocalcemia	>6 units	34	25,2	3	8,8	18	26,1	1	5,6	1,65	Convergence criterion (GCONV=1E-8) satisfied.	0,16	17,07	0,033										Algorithm converged.	-0,110	0,175	1,59		Algorithm converged.	0,18	14,19	0,6788	0,63	Algorithm converged.	0,07	5,63
Metabolism and nutrition disorders	Hypoglycemia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Metabolism and nutrition disorders	Hypoglycemia	>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.													Algorithm converged.	0,00	NE	1,0000		Algorithm converged.	0,00	NE	1,0000	>999,99	Algorithm converged.	0,00	NE
Metabolism and nutrition disorders	Hypoglycemia	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Metabolism and nutrition disorders	Hypokalaemia	0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.													Algorithm converged.	0,00	NE	0,9999	0,3053	>999,99	Algorithm converged.	0,00	NE				
Metabolism and nutrition disorders	Hypokalaemia	>0 to <=6 units	68	50,4	8	11,8	34	49,3	5	14,7	0,77	Convergence criterion (GCONV=1E-8) satisfied.	0,23	2,57	-0,029										Algorithm converged.	-0,171	0,112	0,80		Algorithm converged.	0,28	2,26	0,6737	1,25	Algorithm converged.	0,44	3,53
Metabolism and nutrition disorders	Hypokalaemia	>6 units	34	25,2	7	20,6	18	26,1	3	16,7	1,30	Convergence criterion (GCONV=1E-8) satisfied.	0,29	5,77	0,039										Algorithm converged.	-0,180	0,259	1,24		Algorithm converged.	0,36	4,21	0,7355	0,81	Algorithm converged.	0,24	2,76

Musculoskeletal and connective tissue disorders	Muscle spasms	>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.										0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE
Musculoskeletal and connective tissue disorders	Muscle spasms	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.										NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE											NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE											NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.										NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Myalgia	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.										NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Myalgia	>0 to <=6 units	68	50,4	3	4,4	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.										NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Myalgia	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE											NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Neck pain	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE											NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Neck pain	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE											NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Neck pain	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.										0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE											NE	NE	NE	NE	NE	NE	NE	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		>0 to <=6 units	68	50,4	3	4,4	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.										NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE

Respiratory, thoracic and mediastinal disorders	Epistaxis	>0 to <=6 units	68	50,4	2	2,9	34	49,3	1	2,9	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,43	0,000	Algorithm converged.	-0,070	0,070	1,00	Algorithm converged.	0,09	10,64	1,0000	1,00	Algorithm converged.	0,09	10,64		
Respiratory, thoracic and mediastinal disorders	Epistaxis	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	>999,99	Algorithm converged.	0,00	NE		
Respiratory, thoracic and mediastinal disorders	Hiccups	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Hiccups	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Respiratory, thoracic and mediastinal disorders	Hiccups	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Hypoxia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Hypoxia	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Respiratory, thoracic and mediastinal disorders	Hypoxia	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Nasal congestion	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Nasal congestion	>0 to <=6 units	68	50,4	2	2,9	34	49,3	1	2,9	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,43	0,000	Algorithm converged.	-0,070	0,070	1,00	Algorithm converged.	0,09	10,64	1,0000	1,00	Algorithm converged.	0,09	10,64		
Respiratory, thoracic and mediastinal disorders	Nasal congestion	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 3.7542276434 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE		

Skin and subcutaneous tissue disorders	Papule	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Skin and subcutaneous tissue disorders	Papule	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.													ERROR: Error in computing the link function, its derivatives, or the variance function.		
Skin and subcutaneous tissue disorders	Petechiae	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Skin and subcutaneous tissue disorders	Petechiae	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Skin and subcutaneous tissue disorders	Petechiae	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.													ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		
Skin and subcutaneous tissue disorders	Pruritus	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Skin and subcutaneous tissue disorders	Pruritus	>0 to <=6 units	68	50,4	1	1,5	34	49,3	1	2,9	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,12	-0,015	Algorithm converged.	-0,078	0,049	0,50	Algorithm converged.	0,03	7,75	0,6202	2,00	Algorithm converged.	0,13	31,01
Skin and subcutaneous tissue disorders	Pruritus	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.													ERROR: Error in computing the link function, its derivatives, or the variance function.		
Skin and subcutaneous tissue disorders	Rash	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Skin and subcutaneous tissue disorders	Rash	>0 to <=6 units	68	50,4	1	1,5	34	49,3	1	2,9	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,12	-0,015	Algorithm converged.	-0,078	0,049	0,50	Algorithm converged.	0,03	7,75	0,6202	2,00	Algorithm converged.	0,13	31,01
Skin and subcutaneous tissue disorders	Rash	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.													ERROR: Error in computing the link function, its derivatives, or the variance function.		
Skin and subcutaneous tissue disorders	Rash erythematous	0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.													ERROR: Error in computing the link function, its derivatives, or the variance function.		
Skin and subcutaneous tissue disorders	Rash erythematous	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Skin and subcutaneous tissue disorders	Rash erythematous	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Vascular disorders		0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.													WARNING: The relative Hessian convergence criterion of 3.7542276467 is greater than the limit of 0.0001. The convergence is questionable.		
Vascular disorders		>0 to <=6 units	68	50,4	2	2,9	34	49,3	2	5,9	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,60	-0,029	Algorithm converged.	-0,118	0,059	0,50	Algorithm converged.	0,07	3,40	0,4783	2,00	Algorithm converged.	0,29	13,59

Vascular disorders		>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Vascular disorders	Hypertension	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Vascular disorders	Hypertension	>0 to <=6 units	68	50,4	1	1,5	34	49,3	1	2,9	0,49		0,03	8,12	-0,015		Algorithm converged.	-0,078	0,049	0,50	Algorithm converged.	0,03	7,75	0,6202	2,00	Algorithm converged.	0,13	31,01	
Vascular disorders	Hypertension	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Vascular disorders	Hypotension	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Vascular disorders	Hypotension	>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.								0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE	
Vascular disorders	Hypotension	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Vascular disorders	Hypovolaemic shock	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Vascular disorders	Hypovolaemic shock	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.								NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypovolaemic shock	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Vascular disorders	Peripheral coldness	0 units	33	24,4	1	3,0	17	24,6	0	0,0	*	Quasi-complete separation of data points detected.								NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Peripheral coldness	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Vascular disorders	Peripheral coldness	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_AE_SE1_16NOV2022_42162.xls
 10APR2024 9:54

Blood and lymphatic system disorders	Haemolysis	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE				
Blood and lymphatic system disorders	Haemolysis	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE				
Blood and lymphatic system disorders	Increased tendency to bruise	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE				
Blood and lymphatic system disorders	Increased tendency to bruise	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE								NE	NE	NE	NE		NE	NE	NE	NE	NE				
Blood and lymphatic system disorders	Lymphadenopathy	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE								NE	NE	NE	NE		NE	NE	NE	NE	NE				
Blood and lymphatic system disorders	Lymphadenopathy	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE				
Blood and lymphatic system disorders	Neutropenia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	2	3,9	0,29	Convergence criterion (GCONV=1E-9) satisfied.	0,03	3,30	-0,027				Algorithm converged.	-0,085	0,031	0,30			0,03	3,23	0,3205	0,1367	3,33	Algorithm converged.	0,31	35,84
Blood and lymphatic system disorders	Neutropenia	North America/ Central and South America/ Europe	50	37,0	2	4,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE				
Blood and lymphatic system disorders	Pancytopenia	Japan/Rest of Asia Pacific	85	63,0	2	2,4	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE				
Blood and lymphatic system disorders	Pancytopenia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE								NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE		
Blood and lymphatic system disorders	Pernicious anaemia	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE								NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE		

Congenital, familial and genetic disorders		Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*							0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Congenital, familial and genetic disorders		North America/Central and South America/ Europe	50	37,0	2	4,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Congenital, familial and genetic disorders	Familial periodic paralysiss	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Congenital, familial and genetic disorders	Familial periodic paralysiss	North America/Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE						NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Congenital, familial and genetic disorders	Gilbert's syndrome	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE						NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Congenital, familial and genetic disorders	Gilbert's syndrome	North America/Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.					NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Congenital, familial and genetic disorders	Neurofibromatosis	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE						NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Congenital, familial and genetic disorders	Neurofibromatosis	North America/Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.					NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Gastrointestinal disorders	Abdominal pain upper	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.														ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE			
Gastrointestinal disorders	Constipation	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	2	3,9	0,29	Convergence criterion (GCONV=1E-8) satisfied.	0,03	3,30	-0,027											Algorithm converged.	-0,085	0,031	0,30	Algorithm converged.	0,03	3,23	0,3205		0,3210	3,33	Algorithm converged.	0,31	35,84
Gastrointestinal disorders	Constipation	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.														WARNING: The relative Hessian convergence criterion of 12.774840148 is greater than the limit of 0.0001. The convergence is questionable.	0,00		Algorithm converged.	0,00	NE	1,0000		>999.99		Algorithm converged.	0,00	NE	
Gastrointestinal disorders	Dental caries	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Dental caries	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.														WARNING: The relative Hessian convergence criterion of 12.774840148 is greater than the limit of 0.0001. The convergence is questionable.	0,00		Algorithm converged.	0,00	NE	1,0000		>999.99		Algorithm converged.	0,00	NE	
Gastrointestinal disorders	Diarrhoea	Japan/Rest of Asia Pacific	85	63,0	3	3,5	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.														ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Diarrhoea	North America/ Central and South America/ Europe	50	37,0	7	14,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.														WARNING: The relative Hessian convergence criterion of 0.8926056505 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Dyspepsia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.														WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE		1,0000	NE	Algorithm converged.	NE	NE	NE	NE

Infections and infestations	Herpes virus infection	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 12.774840136 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE		
Infections and infestations	Influenza	Japan/Rest of Asia Pacific	85	63,0	3	3,5	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 3.8893790028 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE	
Infections and infestations	Influenza	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Infections and infestations	Lower respiratory tract infection	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Lower respiratory tract infection	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Infections and infestations	Nasopharyngitis	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 16.211068646 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	0,2576	>999.99	Algorithm converged.	0,00	NE	
Infections and infestations	Nasopharyngitis	North America/ Central and South America/ Europe	50	37,0	2	4,0	18	26,1	1	5,6	0,71	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,135	0,103	0,72	Algorithm converged.	0,07	7,47	0,7831	1,39	Algorithm converged.	0,13	14,41

Infections and infestations	Oral herpes	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 16.211068646 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE					
Infections and infestations	Oral herpes	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Otitis media acute	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Otitis media acute	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE					
Infections and infestations	Pharyngitis	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	1	2,0	0,60	Convergence criterion (GCONV=1E-8) satisfied.	0,04	9,73	-0,008	Algorithm converged.	-0,052	0,037	0,60	Algorithm converged.	0,04	9,39	0,7158	0,3861	1,67	Algorithm converged.	0,11	26,07
Infections and infestations	Pharyngitis	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Infections and infestations	Pneumonia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	2	3,9	0,29	Convergence criterion (GCONV=1E-8) satisfied.	0,03	3,30	-0,027	Algorithm converged.	-0,085	0,031	0,30	Algorithm converged.	0,03	3,23	0,3205	0,2576	3,33	Algorithm converged.	0,31	35,84
Infections and infestations	Pneumonia	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Infections and infestations	Pyelonephritis	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Infections and infestations	Pyelonephritis	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Infections and infestations	Rhinitis	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	2	3,9	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE					

Infections and infestations	Tuberculosis	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 16.211068616 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
Infections and infestations	Tuberculosis	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Infections and infestations	Upper respiratory tract infection	Japan/Rest of Asia Pacific	85	63,0	5	5,9	51	73,9	9	17,6	0,29	Convergence criterion (GCONV=1E-8) satisfied.	0,09	0,93	-0,118	Algorithm converged.	-0,234	-0,002	0,33	Algorithm converged.	0,12	0,94	0,0378	0,0067	3,00	Algorithm converged.	1,06	8,46
Infections and infestations	Upper respiratory tract infection	North America/ Central and South America/ Europe	50	37,0	6	12,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 0.9859004444 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Urinary tract infection	Japan/Rest of Asia Pacific	85	63,0	2	2,4	51	73,9	3	5,9	0,39	Convergence criterion (GCONV=1E-8) satisfied.	0,06	2,39	-0,035	Algorithm converged.	-0,107	0,037	0,40	Algorithm converged.	0,07	2,31	0,3062	0,2508	2,50	Algorithm converged.	0,43	14,46
Infections and infestations	Urinary tract infection	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.774840136 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999.99	Algorithm converged.	0,00	NE	NE			
Infections and infestations	Viral infection	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Viral infection	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Injury, poisoning and procedural complications		Japan/Rest of Asia Pacific	85	63,0	14	16,5	51	73,9	9	17,6	0,92	Convergence criterion (GCONV=1E-8) satisfied.	0,37	2,31	-0,012	Algorithm converged.	-0,143	0,119	0,93	Algorithm converged.	0,44	2,00	0,8592	0,1475	1,07	Algorithm converged.	0,50	2,30

Injury, poisoning and procedural complications		North America/ Central and South America/ Europe	50	37,0	15	30,0	18	26,1	2	11,1	3,43	Convergence criterion (GCONV=1E-8) satisfied.	0,70	16,80	0,189	Algorithm converged.	-0,004	0,382	2,70	Algorithm converged.	0,68	10,66	0,1564	0,37	Algorithm converged.	0,09	1,46	
Injury, poisoning and procedural complications	Contusion	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 16.211068631 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	0,1281	>999.99	Algorithm converged.	0,00	NE
Injury, poisoning and procedural complications	Contusion	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Foot fracture	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Foot fracture	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Incorrect dose administered	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Incorrect dose administered	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Infusion related reaction	Japan/Rest of Asia Pacific	85	63,0	11	12,9	51	73,9	7	13,7	0,93	Convergence criterion (GCONV=1E-8) satisfied.	0,34	2,59	-0,008	Algorithm converged.	-0,126	0,111	0,94	Algorithm converged.	0,39	2,28	0,8959	0,4293	1,06	Algorithm converged.	0,44	2,56
Injury, poisoning and procedural complications	Infusion related reaction	North America/ Central and South America/ Europe	50	37,0	10	20,0	18	26,1	2	11,1	2,00	Convergence criterion (GCONV=1E-8) satisfied.	0,39	10,16	0,089	Algorithm converged.	-0,094	0,272	1,80	Algorithm converged.	0,44	7,44	0,4170	0,56	Algorithm converged.	0,13	2,30	
Injury, poisoning and procedural complications	Injection related reaction	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Injury, poisoning and procedural complications	Wrong schedule	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Injury, poisoning and procedural complications	Wrong schedule	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Investigations		Japan/Rest of Asia Pacific	85	63,0	22	25,9	51	73,9	11	21,6	1,27	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,103	0,189	1,20			Algorithm converged.	0,64	2,26	0,5737	0,4695	0,83	Algorithm converged.	0,44	1,57	
Investigations		North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Investigations	Alanine aminotransferase increased	Japan/Rest of Asia Pacific	85	63,0	2	2,4	51	73,9	1	2,0	1,20	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,046	0,054	1,20			Algorithm converged.	0,11	12,90	0,8804	NE	0,83	Algorithm converged.	0,08	8,96	
Investigations	Alanine aminotransferase increased	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Investigations	Blood bilirubin increased	Japan/Rest of Asia Pacific	85	63,0	2	2,4	51	73,9	2	3,9	0,59	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,078	0,047	0,60			Algorithm converged.	0,09	4,13	0,6037	1,0000	1,67	Algorithm converged.	0,24	11,47	
Investigations	Blood bilirubin increased	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Investigations	International normalized ratio increased	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 16.211068631 is greater than the limit of 0.0001. The convergence is questionable.			0,00			Algorithm converged.	0,00	NE	0,9993	NE	>999.99	Algorithm converged.	0,00	NE	
Investigations	International normalized ratio increased	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Investigations	Neutrophil count decreased	Japan/Rest of Asia Pacific	85	63,0	16	18,8	51	73,9	7	13,7	1,46	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,075	0,177	1,37			Algorithm converged.	0,61	3,11	0,4489	0,4967	0,73	Algorithm converged.	0,32	1,65	

Metabolism and nutrition disorders	Diabetes mellitus	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*																Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 16.211068631 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Metabolism and nutrition disorders	Diabetes mellitus	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE												NE	NE	NE	NE					NE	NE	NE	NE		
Metabolism and nutrition disorders	Haemochromatosis	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*																Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 16.211068616 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Metabolism and nutrition disorders	Haemochromatosis	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE												NE	NE	NE	NE					NE	NE	NE	NE		
Metabolism and nutrition disorders	Hyperglycaemia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	1	2,0	0,60		0,04	9,73	-0,008												Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,052	0,037	0,60	Algorithm converged.	0,04	9,39	0,7158	1,0000	1,67	Algorithm converged.	0,11	26,07
Metabolism and nutrition disorders	Hyperglycaemia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE												NE	NE	NE	NE					NE	NE	NE	NE		
Metabolism and nutrition disorders	Hyperuricaemia	Japan/Rest of Asia Pacific	85	63,0	11	12,9	51	73,9	6	11,8	1,11		0,39	3,22	0,012												Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,102	0,125	1,10	Algorithm converged.	0,43	2,79	0,8412	NE	0,91	Algorithm converged.	0,36	2,31
Metabolism and nutrition disorders	Hyperuricaemia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE												NE	NE	NE	NE					NE	NE	NE	NE		
Metabolism and nutrition disorders	Hypocalcaemia	Japan/Rest of Asia Pacific	85	63,0	8	9,4	51	73,9	7	13,7	0,65		0,22	1,92	-0,043												Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,156	0,070	0,69	Algorithm converged.	0,26	1,78	0,4378	1,0000	1,46	Algorithm converged.	0,56	3,78
Metabolism and nutrition disorders	Hypocalcaemia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE												NE	NE	NE	NE					NE	NE	NE	NE		
Metabolism and nutrition disorders	Hypoglycaemia	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*																Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 16.211068631 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		

Metabolism and nutrition disorders	Hypoglycaemia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Metabolism and nutrition disorders	Hypokalaemia	Japan/Rest of Asia Pacific	85	63,0	15	17,6	51	73,9	8	15,7	1,15	Convergence criterion (GCONV=1E-8) satisfied.	0,45	2,94	0,020	Algorithm converged.	-0,109	0,148	1,12	Algorithm converged.	0,51	2,47	0,7686	0,0950	0,89	Algorithm converged.	0,41	1,95
Metabolism and nutrition disorders	Hypokalaemia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.				* questionable.			0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Hypomagnesaemia	Japan/Rest of Asia Pacific	85	63,0	2	2,4	51	73,9	1	2,0	1,20	Convergence criterion (GCONV=1E-8) satisfied.	0,11	13,63	0,004	Algorithm converged.	-0,046	0,054	1,20	Algorithm converged.	0,11	12,90	0,8804	NE	0,83	Algorithm converged.	0,08	8,96
Metabolism and nutrition disorders	Hypomagnesaemia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Vitamin B12 deficiency	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Vitamin B12 deficiency	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders		Japan/Rest of Asia Pacific	85	63,0	5	5,9	51	73,9	2	3,9	1,53	Convergence criterion (GCONV=1E-8) satisfied.	0,29	8,20	0,020	Algorithm converged.	-0,053	0,093	1,50	Algorithm converged.	0,30	7,45	0,6200	0,8755	0,67	Algorithm converged.	0,13	3,31
Musculoskeletal and connective tissue disorders		North America/ Central and South America/ Europe	50	37,0	7	14,0	18	26,1	2	11,1	1,30	Convergence criterion (GCONV=1E-8) satisfied.	0,24	6,94	0,029	Algorithm converged.	-0,145	0,203	1,26	Algorithm converged.	0,29	5,51	0,7590		0,79	Algorithm converged.	0,18	3,47
Musculoskeletal and connective tissue disorders	Arthralgia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	1	2,0	0,60	Convergence criterion (GCONV=1E-8) satisfied.	0,04	9,73	-0,008	Algorithm converged.	-0,052	0,037	0,60	Algorithm converged.	0,04	9,39	0,7158	0,7644	1,67	Algorithm converged.	0,11	26,07
Musculoskeletal and connective tissue disorders	Arthralgia	North America/ Central and South America/ Europe	50	37,0	2	4,0	18	26,1	2	11,1	0,33	Convergence criterion (GCONV=1E-8) satisfied.	0,04	2,56	-0,071	Algorithm converged.	-0,226	0,084	0,36	Algorithm converged.	0,05	2,37	0,2880		2,78	Algorithm converged.	0,42	18,29
Musculoskeletal and connective tissue disorders	Arthritis	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Arthritis	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Musculoskeletal and connective tissue disorders	Back pain	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 16.211068616 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	0,1281	>999.99	Algorithm converged.	0,00	NE
Musculoskeletal and connective tissue disorders	Back pain	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Fasciitis	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Fasciitis	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Muscle spasms	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	0,0672	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Muscle spasms	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 12.774840148 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE	
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Musculoskeletal and connective tissue disorders	Myalgia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE				
Musculoskeletal and connective tissue disorders	Myalgia	North America/ Central and South America/ Europe	50	37,0	3	6,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE				
Musculoskeletal and connective tissue disorders	Neck pain	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.							Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
Musculoskeletal and connective tissue disorders	Neck pain	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Japan/Rest of Asia Pacific	85	63,0	3	3,5	51	73,9	1	2,0	1,83	Convergence criterion (GCONV=1E-8) satisfied.	0,19	18,07	0,016				Algorithm converged.	-0,039	0,070	1,80		0,19	16,85	0,6065	1,0000	0,56	Algorithm converged.	0,06	5,20
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Myelodysplastic syndrome	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.							Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				

Nervous system disorders	Ischaemic stroke	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	+	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 12.774840148 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE			
Nervous system disorders	Migraine	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Nervous system disorders	Migraine	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	+	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 12.774840148 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE			
Nervous system disorders	Neuropathy peripheral	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	+	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 16.211068646 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	0,1281	>999.99	Algorithm converged.	0,00	NE		
Nervous system disorders	Neuropathy peripheral	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	+	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE		
Nervous system disorders	Paraesthesia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	+	Quasi-complete separation of data points detected.	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE		
Nervous system disorders	Paraesthesia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Psychiatric disorders		Japan/Rest of Asia Pacific	85	63,0	3	3,5	51	73,9	1	2,0	1,83	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,039	0,070	1,80	Algorithm converged.	0,19	16,85	0,6065	0,0242	0,56	Algorithm converged.	0,06	5,20

Respiratory, thoracic and mediastinal disorders	Dyspnoea	North America/ Central and South America/ Europe	50	37,0	2	4,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.														WARNING: The relative Hessian convergence criterion of 2.1572052226 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Epistaxis	Japan/Rest of Asia Pacific	85	63,0	2	2,4	51	73,9	1	2,0	1,20	Convergence criterion (GCONV=1E-8) satisfied.	0,11	13,63	0,004											Algorithm converged.	-0,046	0,054	1,20	Algorithm converged.	0,11	12,90	0,8804		0,1274	0,83	Algorithm converged.	0,08	8,96	
Respiratory, thoracic and mediastinal disorders	Epistaxis	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.														WARNING: The relative Hessian convergence criterion of 12.774840136 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE	
Respiratory, thoracic and mediastinal disorders	Hiccups	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.														WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Hiccups	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE											NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Hypoxia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.														WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Hypoxia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE											NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE											NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Nasal congestion	North America/ Central and South America/ Europe	50	37,0	2	4,0	18	26,1	1	5,6	0,71	Convergence criterion (GCONV=1E-8) satisfied.	0,06	8,32	-0,016											Algorithm converged.	-0,135	0,103	0,72	Algorithm converged.	0,07	7,47	0,7831		1,39		Algorithm converged.	0,13	14,41	
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE											NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.														ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	

Skin and subcutaneous tissue disorders	Henoch-Schönlein purpura	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	+	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE					
Skin and subcutaneous tissue disorders	Henoch-Schönlein purpura	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	+	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE					
Skin and subcutaneous tissue disorders	Hyperkeratosis	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Skin and subcutaneous tissue disorders	Hyperkeratosis	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	+	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE					
Skin and subcutaneous tissue disorders	Night sweats	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Skin and subcutaneous tissue disorders	Night sweats	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	+	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE					
Skin and subcutaneous tissue disorders	Papule	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Skin and subcutaneous tissue disorders	Papule	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	+	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE					
Skin and subcutaneous tissue disorders	Petechiae	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	+	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE					
Skin and subcutaneous tissue disorders	Petechiae	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Skin and subcutaneous tissue disorders	Pruritus	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	1	2,0	0,60	Convergence criterion (GCONV=1E-8) satisfied.		0,04	9,73	-0,008	Algorithm converged.	-0,052	0,037	0,60	Algorithm converged.	0,04	9,39	0,7158	0,3861	1,67	Algorithm converged.	0,11	26,07
Skin and subcutaneous tissue disorders	Pruritus	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	+	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE					
Skin and subcutaneous tissue disorders	Rash	Japan/Rest of Asia Pacific	85	63,0	2	2,4	51	73,9	1	2,0	1,20	Convergence criterion (GCONV=1E-8) satisfied.		0,11	13,63	0,004	Algorithm converged.	-0,046	0,054	1,20	Algorithm converged.	0,11	12,90	0,8804	NE	0,83	Algorithm converged.	0,08	8,96

Skin and subcutaneous tissue disorders	Rash	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE						NE	NE	NE	NE	NE	NE	NE	NE	NE							
Skin and subcutaneous tissue disorders	Rash erythematous	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 16.211068646 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Skin and subcutaneous tissue disorders	Rash erythematous	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE						NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Vascular disorders		Japan/Rest of Asia Pacific	85	63,0	2	2,4	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	0,0482	NE	Algorithm converged.	NE	NE		
Vascular disorders		North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	2	11,1	0,16	Convergence criterion (GCONV=1E-8) satisfied.	0,01	1,92	-0,091		Algorithm converged.	-0,241	0,059	0,18		Algorithm converged.	0,02	1,87	0,1508		5,56	Algorithm converged.	0,54	57,63		
Vascular disorders	Hypertension	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	0,0672	NE	Algorithm converged.	NE	NE		
Vascular disorders	Hypertension	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 12.774840136 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999.99	Algorithm converged.	0,00	NE		
Vascular disorders	Hypotension	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE						NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypotension	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 12.774840148 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999.99	Algorithm converged.	0,00	NE		
Vascular disorders	Hypovolemic shock	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		

POPULATION: Randomized Safety Population
 ENDPPOINT: Any AEs, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

Sex

			Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab							
			Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Rati o	Convergence Reason	95% Lowe r CL	95% Upper CL	Absolu te Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Upper CL	p- value (Wald)	Interaction Test p-value (likelihood ratio)	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Upper CL	
Blood and lymphatic system disorders		Male	77	57,0	8	10,4	35	50,7	5	14,3	0,70	Convergence criterion (GCONV=1E-8) satisfied.	0,21	2,30	-0,039	Algorithm converged.	-0,173	0,096	0,73	Algorithm converged.	0,26	2,06	0,5497	0,4603	1,37	Algorithm converged.	0,48	3,90	
Blood and lymphatic system disorders		Female	58	43,0	5	8,6	34	49,3	2	5,9	1,51	Convergence criterion (GCONV=1E-8) satisfied.	0,28	8,24	0,027	Algorithm converged.	-0,080	0,134	1,47	Algorithm converged.	0,30	7,15	0,6363		0,68	Algorithm converged.	0,14	3,33	
Blood and lymphatic system disorders	Anaemia	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 6.2305304579 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Anaemia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Aplastic anaemia	Male	77	57,0	3	3,9	35	50,7	1	2,9	1,38	Convergence criterion (GCONV=1E-8) satisfied.	0,14	13,73	0,010	Algorithm converged.	-0,060	0,080	1,36	Algorithm converged.	0,15	12,65	0,7849		0,73	Algorithm converged.	0,08	6,80	
Blood and lymphatic system disorders	Aplastic anaemia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Extravascular haemolysis	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Extravascular haemolysis	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Febrile neutropenia	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders	Febrile neutropenia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Haemolysis	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		1,0000	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Haemolysis	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Increased tendency to bruise	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Increased tendency to bruise	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Lymphadenopathy	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders	Lymphadenopathy	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	

Cardiac disorders	Myocardial infarction	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE					NE	NE	NE					NE	NE	NE	NE									
Cardiac disorders	Myocardial infarction	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.					NE	Algorithm converged.	NE	NE							
Cardiac disorders	Palpitations	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999.99	Algorithm converged.	0,00	NE							
Cardiac disorders	Palpitations	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE					NE	NE	NE							NE	NE	NE	NE							
Cardiac disorders	Supraventricular tachycardia	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.								NE	Algorithm converged.				NE	NE	NE	NE							
Cardiac disorders	Supraventricular tachycardia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE					NE	NE	NE							NE	NE	NE	NE							
Congenital, familial and genetic disorders		Male	77	57,0	2	2,6	35	50,7	1	2,9	0,91	Convergence criterion (GCONV=1E-8) satisfied.				0,08	10,34	-0,003		Algorithm converged.				-0,068	0,063	0,91	Algorithm converged.	0,09	9,70	0,9371	1,0000	1,10	Algorithm converged.	0,10	11,73
Congenital, familial and genetic disorders		Female	58	43,0	0	0,0	34	49,3	0	0,0	NE					NE	NE	NE								NE	NE	NE	NE						
Congenital, familial and genetic disorders	Familial periodic paralysis	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.								0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999.99	Algorithm converged.	0,00	NE						
Congenital, familial and genetic disorders	Familial periodic paralysis	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE					NE	NE	NE								NE	NE	NE	NE						
Congenital, familial and genetic disorders	Gilbert's syndrome	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.								NE	Algorithm converged.				NE	NE	NE	NE	NE						
Congenital, familial and genetic disorders	Gilbert's syndrome	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE					NE	NE	NE							NE	NE	NE	NE							
Congenital, familial and genetic disorders	Neurofibromatosis	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.								NE	Algorithm converged.				NE	NE	NE	NE	NE						
Congenital, familial and genetic disorders	Neurofibromatosis	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE					NE	NE	NE								NE	NE	NE	NE						
Ear and labyrinth disorders		Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.								0,00	Algorithm converged.	0,00	NE	1,0000	1,0000	>999.99	Algorithm converged.	0,00	NE						
Ear and labyrinth disorders		Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.								0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE						
Ear and labyrinth disorders	Ear pain	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.								0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999.99	Algorithm converged.	0,00	NE						
Ear and labyrinth disorders	Ear pain	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE					NE	NE	NE							NE	NE	NE	NE							

Ear and labyrinth disorders	Vertigo	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Ear and labyrinth disorders	Vertigo	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.					0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE	
Endocrine disorders		Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.					0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE	
Endocrine disorders		Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Endocrine disorders	Hypothyroidism	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.					0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE	
Endocrine disorders	Hypothyroidism	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Eye disorders		Male	77	57,0	2	2,6	35	50,7	1	2,9	0,91	Convergence criterion (GCONV=1E-8) satisfied.	0,08	10,34	-0,003			Algorithm converged.	-0,068	0,063	0,91			Algorithm converged.	0,10	11,73	
Eye disorders		Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Eye disorders	Cataract	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.						Algorithm converged.						Algorithm converged.			
Eye disorders	Cataract	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Eye disorders	Eye haemorrhage	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.						Algorithm converged.						Algorithm converged.			
Eye disorders	Eye haemorrhage	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Eye disorders	Pterygium	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.						Algorithm converged.	0,00		NE	1,0000		>999,99	Algorithm converged.	0,00	NE
Eye disorders	Pterygium	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Gastrointestinal disorders		Male	77	57,0	11	14,3	35	50,7	5	14,3	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,32	3,13	0,000			Algorithm converged.	-0,140	0,140	1,00			Algorithm converged.	0,38	2,66	
Gastrointestinal disorders		Female	58	43,0	15	25,9	34	49,3	7	20,6	1,35	Convergence criterion (GCONV=1E-8) satisfied.	0,49	3,72	0,053			Algorithm converged.	-0,124	0,229	1,26			Algorithm converged.	0,57	2,77	
Gastrointestinal disorders	Abdominal distension	Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45	Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,36	-0,016			Algorithm converged.	-0,076	0,045	0,45			Algorithm converged.	0,03	7,06	
Gastrointestinal disorders	Abdominal distension	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.						Algorithm converged.	0,00		NE	1,0000		>999,99	Algorithm converged.	0,00	NE
Gastrointestinal disorders	Abdominal pain	Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45	Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,36	-0,016			Algorithm converged.	-0,076	0,045	0,45			Algorithm converged.	0,03	7,06	
Gastrointestinal disorders	Abdominal pain	Female	58	43,0	3	5,2	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.						Algorithm converged.			NE			Algorithm converged.			

Gastrointestinal disorders	Haemorrhoids	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Gastrointestinal disorders	Haemorrhoids	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.					0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE				
Gastrointestinal disorders	Hyperaesthesia teeth	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.					NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE			
Gastrointestinal disorders	Hyperaesthesia teeth	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE	NE	NE	NE			
Gastrointestinal disorders	Nausea	Male	77	57,0	2	2,6	35	50,7	2	5,7	0,44		Convergence criterion (GCONV=1E-8) satisfied.	0,06	3,26	-0,031		Algorithm converged.	-0,116	0,054	0,45		0,07	3,10	0,4206	0,0430	2,20	Algorithm converged.	0,32	14,99
Gastrointestinal disorders	Nausea	Female	58	43,0	4	6,9	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.					NE	Algorithm converged.			NE		NE	NE	NE		Algorithm converged.	NE	NE	
Gastrointestinal disorders	Odynophagia	Male	77	57,0	3	3,9	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.					NE	Algorithm converged.			NE		NE	NE	NE		Algorithm converged.	NE	NE	
Gastrointestinal disorders	Odynophagia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	
Gastrointestinal disorders	Rectal haemorrhage	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.					NE	Algorithm converged.			NE		NE	NE	NE		Algorithm converged.	NE	NE	
Gastrointestinal disorders	Rectal haemorrhage	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	
Gastrointestinal disorders	Small intestinal haemorrhage	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.					NE	Algorithm converged.			NE		NE	NE	NE		Algorithm converged.	NE	NE	
Gastrointestinal disorders	Small intestinal haemorrhage	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	
Gastrointestinal disorders	Stomatitis	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	
Gastrointestinal disorders	Stomatitis	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.					0,00	Algorithm converged.			NE	1,0000		>999,99	Algorithm converged.	0,00	NE			
Gastrointestinal disorders	Toothache	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.					NE	Algorithm converged.			NE		NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Toothache	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.					NE	Algorithm converged.			NE		NE	NE	NE		Algorithm converged.	NE	NE	
Gastrointestinal disorders	Umbilical hernia	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.					0,00	Algorithm converged.			NE	1,0000		>999,99	Algorithm converged.	0,00	NE			
Gastrointestinal disorders	Umbilical hernia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	

General disorders and administration site conditions	Influenza like illness	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
General disorders and administration site conditions	Influenza like illness	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
General disorders and administration site conditions	Injection site reaction	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
General disorders and administration site conditions	Injection site reaction	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link separation of data points detected.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
General disorders and administration site conditions	Malaise	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
General disorders and administration site conditions	Malaise	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
General disorders and administration site conditions	Oedema peripheral	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE					
General disorders and administration site conditions	Oedema peripheral	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link separation of data points detected.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE				
General disorders and administration site conditions	Pain	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE				
General disorders and administration site conditions	Pain	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
General disorders and administration site conditions	Peripheral swelling	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link separation of data points detected.	NE	Algorithm converged.	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE	NE				
General disorders and administration site conditions	Peripheral swelling	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link separation of data points detected.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE				
General disorders and administration site conditions	Pyrexia	Male	77	57,0	7	9,1	35	50,7	4	11,4	0,77	Convergence criterion (GCONV=1E-8) satisfied.	0,21	2,84	-0,023	Algorithm converged.	-0,147	0,100	0,80	Algorithm converged.	0,25	2,54	0,6994	0,8221	1,26	Algorithm converged.	0,39	4,02
General disorders and administration site conditions	Pyrexia	Female	58	43,0	5	8,6	34	49,3	3	8,8	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,22	4,36	-0,002	Algorithm converged.	-0,122	0,118	0,98	Algorithm converged.	0,25	3,83	0,9734	1,02	Algorithm converged.	0,26	4,02	
Hepatobiliary disorders		Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45	Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,36	-0,016	Algorithm converged.	-0,076	0,045	0,45	Algorithm converged.	0,03	7,06	0,5732	0,2203	2,20	Algorithm converged.	0,14	34,17
Hepatobiliary disorders		Female	58	43,0	0	0,0	34	49,3	2	5,9	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 7.5477623015 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	>999.9	9	Algorithm converged.	0,00	NE	NE				

Hepatobiliary disorders	Cholecystitis chronic	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Hepatobiliary disorders	Cholecystitis chronic	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177153 is greater than the limit of 0.0001. The convergence is questionable.		0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE				
Hepatobiliary disorders	Hepatic function abnormal	Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45	Convergence criterion (GCONV=1E-8) satisfied.		0,03	7,36	-0,016	Algorithm converged.	-0,076	0,045	0,45	Algorithm converged.	0,03	7,06	0,5732	1,0000	2,20	Algorithm converged.	0,14	34,17
Hepatobiliary disorders	Hepatic function abnormal	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Hepatobiliary disorders	Hypertransaminasaemia	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Hepatobiliary disorders	Hypertransaminasaemia	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177153 is greater than the limit of 0.0001. The convergence is questionable.		0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE				
Immune system disorders		Male	77	57,0	2	2,6	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.		NE	Algorithm converged.	NE	NE	NE		1,0000	NE	Algorithm converged.	NE	NE			
Immune system disorders		Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.		NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	
Immune system disorders	Hypersensitivity	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.		NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	
Immune system disorders	Hypersensitivity	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Immune system disorders	Immunisation reaction	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.		NE	Algorithm converged.	NE	NE	NE		1,0000	NE	Algorithm converged.	NE	NE			
Immune system disorders	Immunisation reaction	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.		NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	
Infections and infestations		Male	77	57,0	23	29,9	35	50,7	11	31,4	0,93	Convergence criterion (GCONV=1E-8) satisfied.		0,39	2,21	-0,016	Algorithm converged.	-0,200	0,169	0,95	Algorithm converged.	0,52	1,73	0,8674	0,0465	1,05	Algorithm converged.	0,58	1,91
Infections and infestations		Female	58	43,0	9	15,5	34	49,3	14	41,2	0,26	Convergence criterion (GCONV=1E-8) satisfied.		0,10	0,70	-0,257	Algorithm converged.	-0,446	-0,067	0,38	Algorithm converged.	0,18	0,78	0,0081		2,65	Algorithm converged.	1,29	5,47
Infections and infestations	Bronchitis	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.		NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Bronchitis	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	COVID-19	Male	77	57,0	9	11,7	35	50,7	1	2,9	4,50	Convergence criterion (GCONV=1E-8) satisfied.		0,55	36,99	0,088	Algorithm converged.	-0,002	0,179	4,09	Algorithm converged.	0,54	31,05	0,1731	0,0588	0,24	Algorithm converged.	0,03	1,86
Infections and infestations	COVID-19	Female	58	43,0	2	3,4	34	49,3	3	8,8	0,37	Convergence criterion (GCONV=1E-8) satisfied.		0,06	2,33	-0,054	Algorithm converged.	-0,160	0,053	0,39	Algorithm converged.	0,07	2,22	0,2895		2,56	Algorithm converged.	0,45	14,55
Infections and infestations	Central nervous system infection	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.		0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE				

Infections and infestations	Central nervous system infection	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Diarrhoea infectious	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999,99	Algorithm converged.	0,00	NE	NE	NE	NE	NE
Infections and infestations	Diarrhoea infectious	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Fungal foot infection	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999,99	Algorithm converged.	0,00	NE	NE	NE	NE	NE
Infections and infestations	Fungal foot infection	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Gastroenteritis	Male	77	57,0	0	0,0	35	50,7	2	5,7	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE	NE	NE	NE	NE
Infections and infestations	Gastroenteritis	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Helicobacter gastritis	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Helicobacter gastritis	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE
Infections and infestations	Herpes virus infection	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Herpes virus infection	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177141 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999,99	Algorithm converged.	0,00	NE	NE	NE	NE	NE
Infections and infestations	Influenza	Male	77	57,0	3	3,9	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 2.7579987137 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE	NE	NE	NE	
Infections and infestations	Influenza	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.4408027849 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	
Infections and infestations	Lower respiratory tract infection	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	
Infections and infestations	Lower respiratory tract infection	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Nasopharyngitis	Male	77	57,0	2	2,6	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	0,0235	NE	Algorithm converged.	NE	NE	NE	NE	NE	
Infections and infestations	Nasopharyngitis	Female	58	43,0	0	0,0	34	49,3	2	5,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 7.5477623015 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE	NE	NE	NE	NE

Infections and infestations	Upper respiratory tract infection	Male	77	57,0	8	10,4	35	50,7	3	8,6	1,24	Convergence criterion (GCONV=1E-8) satisfied.	0,31	4,97	0,018	Algorithm converged.	-0,097	0,133	1,21	Algorithm converged.	0,34	4,30	0,7657	0,1117	0,83	Algorithm converged.	0,23	2,92
Infections and infestations	Upper respiratory tract infection	Female	58	43,0	3	5,2	34	49,3	6	17,6	0,25	Convergence criterion (GCONV=1E-8) satisfied.	0,06	1,09	-0,125	Algorithm converged.	-0,265	0,015	0,29	Algorithm converged.	0,08	1,10	0,0684		3,41	Algorithm converged.	0,91	12,77
Infections and infestations	Urinary tract infection	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	0,1260	NE	Algorithm converged.	NE	NE
Infections and infestations	Urinary tract infection	Female	58	43,0	1	1,7	34	49,3	4	11,8	0,13	Convergence criterion (GCONV=1E-8) satisfied.	0,01	1,23	-0,100	Algorithm converged.	-0,214	0,013	0,15	Algorithm converged.	0,02	1,26	0,0800		6,82	Algorithm converged.	0,79	58,58
Infections and infestations	Viral infection	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations	Viral infection	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications		Male	77	57,0	15	19,5	35	50,7	8	22,9	0,82	Convergence criterion (GCONV=1E-8) satisfied.	0,31	2,15	-0,034	Algorithm converged.	-0,199	0,131	0,85	Algorithm converged.	0,40	1,82	0,6799	0,0846	1,17	Algorithm converged.	0,55	2,51
Injury, poisoning and procedural complications		Female	58	43,0	14	24,1	34	49,3	3	8,8	3,29	Convergence criterion (GCONV=1E-8) satisfied.	0,87	12,42	0,153	Algorithm converged.	0,007	0,299	2,74	Algorithm converged.	0,85	8,84	0,0926		0,37	Algorithm converged.	0,11	1,18
Injury, poisoning and procedural complications	Contusion	Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45	Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,36	-0,016	Algorithm converged.	-0,076	0,045	0,45	Algorithm converged.	0,03	7,06	0,5732	1,0000	2,20	Algorithm converged.	0,14	34,17
Injury, poisoning and procedural complications	Contusion	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Foot fracture	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Foot fracture	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Incorrect dose administered	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Incorrect dose administered	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Infusion related reaction	Male	77	57,0	12	15,6	35	50,7	6	17,1	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,31	2,61	-0,016	Algorithm converged.	-0,164	0,133	0,91	Algorithm converged.	0,37	2,22	0,8346	0,3882	1,10	Algorithm converged.	0,45	2,69
Injury, poisoning and procedural complications	Infusion related reaction	Female	58	43,0	9	15,5	34	49,3	3	8,8	1,90	Convergence criterion (GCONV=1E-8) satisfied.	0,48	7,56	0,067	Algorithm converged.	-0,066	0,200	1,76	Algorithm converged.	0,51	6,05	0,3707		0,57	Algorithm converged.	0,17	1,96
Injury, poisoning and procedural complications	Injection related reaction	Male	77	57,0	4	5,2	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injection related reaction	Female	58	43,0	3	5,2	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Limb injury	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Investigations	Neutrophil count decreased	Male	77	57,0	4	5,2	35	50,7	5	14,3	0,33	Convergence criterion (GCONV=1E-8) satisfied.	0,08	1,31	-0,091	Algorithm converged.	-0,217	0,035	0,36	Algorithm converged.	0,10	1,27	0,1135	0,0091	2,75	Algorithm converged.	0,79	9,62	
Investigations	Neutrophil count decreased	Female	58	43,0	13	22,4	34	49,3	2	5,9	4,62	Convergence criterion (GCONV=1E-8) satisfied.	0,98	21,91	0,165	Algorithm converged.	0,032	0,299	3,81	Algorithm converged.	0,91	15,88	0,0662		0,26	Algorithm converged.	0,06	1,09	
Investigations	Occult blood positive	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Investigations	Occult blood positive	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Investigations	Platelet count decreased	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Investigations	Platelet count decreased	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*						NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Investigations	White blood cell count decreased	Male	77	57,0	4	5,2	35	50,7	5	14,3	0,33	Convergence criterion (GCONV=1E-8) satisfied.	0,08	1,31	-0,091	Algorithm converged.	-0,217	0,035	0,36	Algorithm converged.	0,10	1,27	0,1135	0,0122	2,75	Algorithm converged.	0,79	9,62	
Investigations	White blood cell count decreased	Female	58	43,0	12	20,7	34	49,3	2	5,9	4,17	Convergence criterion (GCONV=1E-8) satisfied.	0,87	19,93	0,148	Algorithm converged.	0,017	0,279	3,52	Algorithm converged.	0,84	14,78	0,0860		0,28	Algorithm converged.	0,07	1,20	
Metabolism and nutrition disorders		Male	77	57,0	14	18,2	35	50,7	9	25,7	0,64	Convergence criterion (GCONV=1E-8) satisfied.	0,25	1,67	-0,075	Algorithm converged.	-0,244	0,093	0,71	Algorithm converged.	0,34	1,48	0,3559	0,3858	1,41	Algorithm converged.	0,68	2,95	
Metabolism and nutrition disorders		Female	58	43,0	12	20,7	34	49,3	6	17,6	1,22	Convergence criterion (GCONV=1E-8) satisfied.	0,41	3,61	0,030	Algorithm converged.	-0,135	0,196	1,17	Algorithm converged.	0,48	2,84	0,7243		0,85	Algorithm converged.	0,35	2,06	
Metabolism and nutrition disorders	Decreased appetite	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.	*						0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999,99	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Decreased appetite	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Diabetes mellitus	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Diabetes mellitus	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*						0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Haemochromatosis	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Haemochromatosis	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*						0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Hyperglycaemia	Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45	Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,36	-0,016	Algorithm converged.	-0,076	0,045	0,45	Algorithm converged.	0,03	7,06	0,5732	1,0000	2,20	Algorithm converged.	0,14	34,17	
Metabolism and nutrition disorders	Hyperglycaemia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Hyperuricaemia	Male	77	57,0	8	10,4	35	50,7	4	11,4	0,90	Convergence criterion (GCONV=1E-8) satisfied.	0,25	3,21	-0,010	Algorithm converged.	-0,136	0,115	0,91	Algorithm converged.	0,29	2,82	0,8689	0,9749	1,10	Algorithm converged.	0,35	3,41	

Nervous system disorders	Paraesthesia	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Nervous system disorders	Paraesthesia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Psychiatric disorders		Male	77	57,0	2	2,6	35	50,7	2	5,7	0,44	Convergence criterion (GCONV=1E-8) satisfied.		0,06	3,26	-0,031	Algorithm converged.	-0,116	0,054	0,45	Algorithm converged.	0,07	3,10	0,4206	0,8816	2,20	Algorithm converged.	0,32	14,99
Psychiatric disorders		Female	58	43,0	1	1,7	34	49,3	1	2,9	0,58	Convergence criterion (GCONV=1E-8) satisfied.		0,04	9,57	-0,012	Algorithm converged.	-0,078	0,054	0,59	Algorithm converged.	0,04	9,07	0,7024		1,71	Algorithm converged.	0,11	26,40
Psychiatric disorders	Abnormal dreams	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.					0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999.99	Algorithm converged.	0,00	NE	
Psychiatric disorders	Abnormal dreams	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders	Affective disorder	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders	Affective disorder	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.4408027849 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders	Insomnia	Male	77	57,0	2	2,6	35	50,7	2	5,7	0,44	Convergence criterion (GCONV=1E-8) satisfied.		0,06	3,26	-0,031	Algorithm converged.	-0,116	0,054	0,45	Algorithm converged.	0,07	3,10	0,4206	0,3161	2,20	Algorithm converged.	0,32	14,99
Psychiatric disorders	Insomnia	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177141 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE		
Renal and urinary disorders		Male	77	57,0	4	5,2	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	0,1260	NE	Algorithm converged.	NE	NE	
Renal and urinary disorders		Female	58	43,0	1	1,7	34	49,3	1	2,9	0,58	Convergence criterion (GCONV=1E-8) satisfied.		0,04	9,57	-0,012	Algorithm converged.	-0,078	0,054	0,59	Algorithm converged.	0,04	9,07	0,7024		1,71	Algorithm converged.	0,11	26,40
Renal and urinary disorders	Chromaturia	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders	Chromaturia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders	Chronic kidney disease	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders	Chronic kidney disease	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders	Nephrolithiasis	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders	Nephrolithiasis	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders	Paroxysmal nocturnal haemoglobinuria	Male	77	57,0	2	2,6	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	0,0605	NE	Algorithm converged.	NE	NE	

Renal and urinary disorders	Paroxysmal nocturnal haemoglobinuria	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 12.420177141 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999,99	Algorithm converged.	0,00	NE			
Reproductive system and breast disorders		Male	77	57,0	1	1,3	35	50,7	2	5,7	0,22	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,125	0,037	0,23	Algorithm converged.	0,02	2,42	0,2199	1,0000	4,40	Algorithm converged.	0,41	46,93
Reproductive system and breast disorders		Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Reproductive system and breast disorders	Gynaecomastia	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Reproductive system and breast disorders	Gynaecomastia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Reproductive system and breast disorders	Perineal rash	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999,99	Algorithm converged.	0,00	NE	NE	NE
Reproductive system and breast disorders	Perineal rash	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Reproductive system and breast disorders	Spontaneous penile erection	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999,99	Algorithm converged.	0,00	NE	NE	NE
Reproductive system and breast disorders	Spontaneous penile erection	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders		Male	77	57,0	9	11,7	35	50,7	3	8,6	1,41	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,086	0,148	1,36	Algorithm converged.	0,39	4,73	0,6251	0,8860	0,73	Algorithm converged.	0,21	2,54
Respiratory, thoracic and mediastinal disorders		Female	58	43,0	4	6,9	34	49,3	2	5,9	1,19	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,092	0,113	1,17	Algorithm converged.	0,23	6,07	0,8496		0,85	Algorithm converged.	0,16	4,41
Respiratory, thoracic and mediastinal disorders	Cough	Male	77	57,0	2	2,6	35	50,7	2	5,7	0,44	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,116	0,054	0,45	Algorithm converged.	0,07	3,10	0,4206	0,2336	2,20	Algorithm converged.	0,32	14,99
Respiratory, thoracic and mediastinal disorders	Cough	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Dysphonia	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Dysphonia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Male	77	57,0	2	2,6	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Epistaxis	Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,076	0,045	0,45	Algorithm converged.	0,03	7,06	0,5732	0,8977	2,20	Algorithm converged.	0,14	34,17
Respiratory, thoracic and mediastinal disorders	Epistaxis	Female	58	43,0	1	1,7	34	49,3	1	2,9	0,58	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,078	0,054	0,59	Algorithm converged.	0,04	9,07	0,7024		1,71	Algorithm converged.	0,11	26,40

Skin and subcutaneous tissue disorders	Alopecia	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders	Ecchymosis	Male	77	57,0	2	2,6	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	0,2203	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders	Ecchymosis	Female	58	43,0	1	1,7	34	49,3	1	2,9	0,58	Convergence criterion (GCONV=1E-8) satisfied.		Algorithm converged.	-0,078	0,054	0,59	Algorithm converged.	0,04	9,07	0,7024	1,71	Algorithm converged.	0,11	26,40	
Skin and subcutaneous tissue disorders	EczeMa	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders	EczeMa	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders	Hyperkeratosis	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Skin and subcutaneous tissue disorders	Hyperkeratosis	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders	Night sweats	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders	Night sweats	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Skin and subcutaneous tissue disorders	Papule	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders	Papule	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Skin and subcutaneous tissue disorders	Petechiae	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders	Petechiae	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Skin and subcutaneous tissue disorders	Pruritus	Male	77	57,0	2	2,6	35	50,7	1	2,9	0,91	Convergence criterion (GCONV=1E-8) satisfied.		Algorithm converged.	-0,068	0,063	0,91	Algorithm converged.	0,09	9,70	0,9371	1,0000	1,10	Algorithm converged.	0,10	11,73
Skin and subcutaneous tissue disorders	Pruritus	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Skin and subcutaneous tissue disorders	Rash	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	0,00	NE	1,0000	0,0401	>999.99	Algorithm converged.	0,00	NE

Skin and subcutaneous tissue disorders	Rash	Female	58	43,0	2	3,4	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: Negative of Hessian not positive definite.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Rash erythematous	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	
Skin and subcutaneous tissue disorders	Rash erythematous	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 12.420177153 is greater than the limit of 0.0001. The convergence is questionable.					0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE	
Vascular disorders		Male	77	57,0	2	2,6	35	50,7	1	2,9	0,91	Convergence criterion (GCONV=1E-8) satisfied.	0,08	10,34	-0,003				Algorithm converged.	-0,068	0,063	0,91			Algorithm converged.	0,09	9,70	0,9371		0,8116	1,10	Algorithm converged.	0,10	11,73
Vascular disorders		Female	58	43,0	1	1,7	34	49,3	1	2,9	0,58	Convergence criterion (GCONV=1E-8) satisfied.	0,04	9,57	-0,012				Algorithm converged.	-0,078	0,054	0,59			Algorithm converged.	0,04	9,07	0,7024			1,71	Algorithm converged.	0,11	26,40
Vascular disorders	Hypertension	Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45	Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,36	-0,016				Algorithm converged.	-0,076	0,045	0,45			Algorithm converged.	0,03	7,06	0,5732		1,0000	2,20	Algorithm converged.	0,14	34,17
Vascular disorders	Hypertension	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypotension	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypotension	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 12.420177141 is greater than the limit of 0.0001. The convergence is questionable.					0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE	
Vascular disorders	Hypovolaemic shock	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypovolaemic shock	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.							ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE	
Vascular disorders	Peripheral coldness	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.							ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE		NE	NE	NE	NE	
Vascular disorders	Peripheral coldness	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_AE_SE1_16NOV2022_42162.xls
 10APR2024 9:54

Hepatobiliary disorders	Hepatic function abnormal	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Hepatobiliary disorders	Hypertran saminasae mia	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
Hepatobiliary disorders	Hypertran saminasae mia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Infections and infestations		<65	122	90,4	3	2,5	60	87,0	3	5,0	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,09	2,45	-0,025	Algorithm converged.	-0,087	0,036	0,49	Algorithm converged.	0,10	2,36	0,3757	1,0000	2,03	Algorithm converged.	0,42	9,78
Infections and infestations		>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	COVID-19	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations	COVID-19	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Central nervous system infection	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 22.085838312 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	NE	NE	NE	
Infections and infestations	Central nervous system infection	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Pneumonia	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Infections and infestations	Urinary tract infection	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE					
Infections and infestations	Urinary tract infection	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Investigations		<65	122	90,4	9	7,4	60	87,0	5	8,3	0,88	Convergence criterion (GCONV=1E-8) satisfied.		0,28	2,74	-0,010	Algorithm converged.	-0,093	0,074	0,89	Algorithm converged.	0,31	2,53	0,8198	0,2033	1,13	Algorithm converged.	0,40	3,22
Investigations		>=65	13	9,6	0	0,0	9	13,0	1	11,1	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE					
Investigations	Alanine aminotransferase increased	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE					
Investigations	Alanine aminotransferase increased	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Investigations	Blood bilirubin increased	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Investigations	Blood bilirubin increased	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Investigations	Neutrophil count decreased	<65	122	90,4	7	5,7	60	87,0	4	6,7	0,85	Convergence criterion (GCONV=1E-8) satisfied.		0,24	3,03	-0,009	Algorithm converged.	-0,085	0,066	0,86	Algorithm converged.	0,26	2,83	0,8046	0,2109	1,16	Algorithm converged.	0,35	3,82

Nervous system disorders		<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 22.085838312 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	9	Algorithm converged.	0,00	NE
Nervous system disorders		>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders	Ischaemic stroke	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 22.085838312 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	9	Algorithm converged.	0,00	NE
Nervous system disorders	Ischaemic stroke	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders		<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Psychiatric disorders		>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders	Affective disorder	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Psychiatric disorders	Affective disorder	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders		<65	122	90,4	0	0,0	60	87,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders		>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Respiratory, thoracic and mediastinal disorders	Epistaxis	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Epistaxis	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders		<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders		>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders		<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders		>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypertension	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypertension	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade >= 3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

All

		Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab									
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk									
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		n/a	135	100,0	5	3,7	69	100,0	4	5,8	0,62	Convergence criterion (GCONV=1E-8) satisfied.	0,16	2,41	-0,021	Algorithm converged.	-0,085	0,043	0,64	Algorithm converged.	0,18	2,30	0,4935	NE	1,57	Algorithm converged.	0,43	5,64	
Blood and lymphatic system disorders	Anaemia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Aplastic anaemia	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000	Algorithm converged.	-0,034	0,035	1,02	Algorithm converged.	0,09	11,08	0,9856	NE	0,98	Algorithm converged.	0,09	10,60	
Blood and lymphatic system disorders	Febrile neutropenia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Blood and lymphatic system disorders	Neutropenia	n/a	135	100,0	2	1,5	69	100,0	2	2,9	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,66	-0,014	Algorithm converged.	-0,059	0,030	0,51	Algorithm converged.	0,07	3,55	0,4974	NE	1,96	Algorithm converged.	0,28	13,59	
Blood and lymphatic system disorders	Pancytopenia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Thrombocytopenia	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81	
Cardiac disorders		n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Cardiac failure	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE

Cardiac disorders	Myocardial infarction	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Gastrointestinal disorders	Small intestinal haemorrhage	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
General disorders and administration site conditions	Pyrexia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Hepatobiliary disorders		n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81
Hepatobiliary disorders	Cholecystitis chronic	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
Hepatobiliary disorders	Hepatic function abnormal	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Hepatobiliary disorders	Hypertransaminasemia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
Infections and infestations		n/a	135	100,0	3	2,2	69	100,0	3	4,3	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,10	2,55	-0,021	Algorithm converged.	-0,075	0,033	0,51	Algorithm converged.	0,11	2,47	0,4032	NE	1,96	Algorithm converged.	0,41	9,44
Infections and infestations	COVID-19	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				

Infections and infestations	Central nervous system infection	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Infections and infestations	Pneumonia	n/a	135	100,0	2	1,5	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.3162357328 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Infections and infestations	Pyelonephritis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Infections and infestations	Sepsis	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 23.402555586 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Infections and infestations	Tuberculosis	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Infections and infestations	Urinary tract infection	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE		
Investigations		n/a	135	100,0	9	6,7	69	100,0	6	8,7	0,75	Convergence criterion (GCONV=1E-8) satisfied.		Algorithm converged.	-0,099	0,058	0,77	Algorithm converged.	0,28	2,07	0,5994	NE	1,30	Algorithm converged.	0,48	3,52

Investigations	Alanine aminotransferase increased	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 23.40255586 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE					
Investigations	Blood bilirubin increased	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE					
Investigations	Neutrophil count decreased	n/a	135	100,0	7	5,2	69	100,0	5	7,2	0,70	Convergence criterion (GCONV=1E-8) satisfied.	0,21	2,29	-0,021	Algorithm converged.	-0,092	0,051	0,72	Algorithm converged.	0,24	2,17	0,5547	NE	1,40	Algorithm converged.	0,46	4,24
Investigations	Platelet count decreased	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE					
Investigations	White blood cell count decreased	n/a	135	100,0	3	2,2	69	100,0	1	1,4	1,55	Convergence criterion (GCONV=1E-8) satisfied.	0,16	15,14	0,008	Algorithm converged.	-0,030	0,045	1,53	Algorithm converged.	0,16	14,47	0,7090	NE	0,65	Algorithm converged.	0,07	6,15
Metabolism and nutrition disorders		n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 23.40255564 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE					
Metabolism and nutrition disorders	Haemochromatosis	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 23.40255564 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE					
Metabolism and nutrition disorders	Hypokalaemia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 23.40255564 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE					

Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Myelodysplastic syndrome	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				* WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Nervous system disorders		n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				* WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE	
Nervous system disorders	Ischaemic stroke	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				* WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE	
Psychiatric disorders		n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				* WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Psychiatric disorders	Affective disorder	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				* WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders		n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				* WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Respiratory, thoracic and mediastinal disorders	Epistaxis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				* WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	

Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders		n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders		n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypertension	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypovolaemic shock	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sq_GE3_SE1_16NOV2022_42162.xls
10APR2024 10:03

Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 6.2207823303 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders		0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Nervous system disorders		>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders		>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders	Ischaemic stroke	0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Nervous system disorders	Ischaemic stroke	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders	Ischaemic stroke	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders		0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders		>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders		>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Psychiatric disorders	Affective disorder	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders	Affective disorder	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders	Affective disorder	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade >= 3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

Geographic region

			Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab								
			Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk								
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		Japan/Rest of Asia Pacific	85	63,0	3	3,5	51	73,9	4	7,8	0,43	Convergence criterion (GCONV=1E-8) satisfied.	0,09	2,00	-0,043	Algorithm converged.	-0,127	0,040	0,45	Algorithm converged.	0,10	1,93	0,2825	0,1523	2,22	Algorithm converged.	0,52	9,53	
Blood and lymphatic system disorders		North America/ Central and South America/ Europe	50	37,0	2	4,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 2.1572052245 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Anaemia	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Anaemia	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Aplastic anaemia	Japan/Rest of Asia Pacific	85	63,0	2	2,4	51	73,9	1	2,0	1,20	Convergence criterion (GCONV=1E-8) satisfied.	0,11	13,63	0,004	Algorithm converged.	-0,046	0,054	1,20	Algorithm converged.	0,11	12,90	0,8804		NE	0,93	Algorithm converged.	0,08	8,96
Blood and lymphatic system disorders	Aplastic anaemia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile neutropenia	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 16.211068646 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Blood and lymphatic system disorders	Febrile neutropenia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	2	3,9	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE

Blood and lymphatic system disorders	Neutropenia	North America/ Central and South America/ Europe	50	37,0	2	4,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 2.1572052245 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Blood and lymphatic system disorders	Pancytopenia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Blood and lymphatic system disorders	Pancytopenia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Blood and lymphatic system disorders	Thrombocytopenia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	1	2,0	0,60	Convergence criterion (GCONV=1E-8) satisfied.	0,04	9,73	-0,008	Algorithm converged.	-0,052	0,037	0,60	Algorithm converged.	0,04	9,39	0,7158	1,0000	1,67	Algorithm converged.	0,11	26,07
Blood and lymphatic system disorders	Thrombocytopenia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Cardiac disorders		Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Cardiac disorders		North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Cardiac disorders	Cardiac failure	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Cardiac disorders	Cardiac failure	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.774840148 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE					
Cardiac disorders	Myocardial infarction	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Cardiac disorders	Myocardial infarction	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Gastrointestinal disorders	Small intestinal haemorrhage	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				

Investigations	Platelet count decreased	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		
Investigations	Platelet count decreased	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Investigations	White blood cell count decreased	Japan/Rest of Asia Pacific	85	63,0	3	3,5	51	73,9	1	2,0	1,83	Convergence criterion (GCONV=1E-8) satisfied.		Algorithm converged.	-0,039	0,070	1,80	Algorithm converged.	0,19	16,85	0,6065	1,0000	0,56	Algorithm converged.	0,06	5,20
Investigations	White blood cell count decreased	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Metabolism and nutrition disorders		Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 16.211068646 is greater than the limit of 0.0001. The convergence is questionable .		0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Metabolism and nutrition disorders		North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Haemochromatosis	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 16.211068616 is greater than the limit of 0.0001. The convergence is questionable .		0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Metabolism and nutrition disorders	Haemochromatosis	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Hypokalaemia	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 16.211068646 is greater than the limit of 0.0001. The convergence is questionable .		0,00		Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Metabolism and nutrition disorders	Hypokalaemia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	1	2,0	0,60	Convergence criterion (GCONV=1E-8) satisfied.		Algorithm converged.	-0,052	0,037	0,60	Algorithm converged.	0,04	9,39	0,7158	1,0000	1,67	Algorithm converged.	0,11	26,07

Psychiatric disorders	Affective disorder	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Psychiatric disorders	Affective disorder	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders		Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders		North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Epistaxis	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Epistaxis	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Skin and subcutaneous tissue disorders		Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders		North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders		Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders		North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypertension	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypertension	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypovolaemic shock	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypovolaemic shock	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_GE3_SE1_16NOV2022_42162.xls

Hepatobiliary disorders		Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177153 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE					
Hepatobiliary disorders	Cholecystitis chronic	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Hepatobiliary disorders	Cholecystitis chronic	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177153 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE					
Hepatobiliary disorders	Hepatic function abnormal	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE					
Hepatobiliary disorders	Hepatic function abnormal	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Hepatobiliary disorders	Hypertranasaminasemia	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Hepatobiliary disorders	Hypertranasaminasemia	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177153 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE					
Infections and infestations		Male	77	57,0	2	2,6	35	50,7	1	2,9	0,91	Convergence criterion (GCONV=1E-8) satisfied.	0,08	10,34	-0,003	Algorithm converged.	-0,068	0,063	0,91	Algorithm converged.	0,09	9,70	0,9371	0,4956	1,10	Algorithm converged.	0,10	11,73

Metabolism and nutrition disorders	Haemochromatosis	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177141 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Hypokalaemia	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Metabolism and nutrition disorders	Hypokalaemia	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177153 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305304365 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	0,1106	NE	Algorithm converged.	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177153 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE	

Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Skin and subcutaneous tissue disorders		Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders		Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Vascular disorders		Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Vascular disorders		Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Vascular disorders	Hypertension	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypertension	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Vascular disorders	Hypovolaemic shock	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Vascular disorders	Hypovolaemic shock	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_GE3_SE1_16NOV2022_42162.xls
 10APR2024 10:03

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade 3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous analysis by Subgroups (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab									
		Patients		Patients with		Patient		Patients with		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
Blood and lymphatic system disorders		<65	122	90,4	2	1,6	60	87,0	3	5,0	0,32				Convergence criterion (GCONV=1E-8) satisfied.	0,05	1,95	-0,034		Algorithm converged.	-0,093	0,026	0,33		1,0000	3,05	Algorithm converged.	0,52	17,77
Blood and lymphatic system disorders		>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Anaemia	<65	122	90,4	1	0,8	60	87,0	0	0,0	*				Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			NE		NE	NE	NE	NE	
Blood and lymphatic system disorders	Anaemia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Aplastic anaemia	<65	122	90,4	0	0,0	60	87,0	1	1,7	*				Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.			0,00		NE	>999.99	Algorithm converged.	0,00	NE
Blood and lymphatic system disorders	Aplastic anaemia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Febrile neutropenia	<65	122	90,4	0	0,0	60	87,0	1	1,7	*				Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable.			0,00		NE	>999.99	Algorithm converged.	0,00	NE
Blood and lymphatic system disorders	Febrile neutropenia	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	<65	122	90,4	2	1,6	60	87,0	2	3,3	0,48				Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,52	-0,017		Algorithm converged.	-0,068	0,034	0,49		1,0000	2,03	Algorithm converged.	0,29	14,09

Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations .	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders		<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations .	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders		>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypertension	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypertension	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypovolaemic shock	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations .	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypovolaemic shock	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_G3_SE1_16NOV2022_42162.xls
 10APR2024 10:01

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade 3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous analysis by Subgroups (Safety)

All

		Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab								
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk								
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		n/a	135	100,0	2	1,5	69	100,0	3	4,3	0,33			-0,029	Convergence criterion (GCONV=1E-8) satisfied.	0,05	2,03	0,34	Algorithm converged.	-0,081	0,024	0,34	0,2320	NE	2,93	Algorithm converged.	0,50	17,15
Blood and lymphatic system disorders	Anaemia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*				Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Aplastic anaemia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*				Quasi-complete separation of data points detected.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders	Febrile neutropenia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*				Quasi-complete separation of data points detected.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders	Neutropenia	n/a	135	100,0	2	1,5	69	100,0	2	2,9	0,50	0,07	3,66	-0,014	Convergence criterion (GCONV=1E-8) satisfied.	0,07	3,66	0,51	Algorithm converged.	-0,059	0,030	0,51	0,4974	NE	1,96	Algorithm converged.	0,28	13,59
Blood and lymphatic system disorders	Pancytopenia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*				Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Small intestinal haemorrhage	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*				Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Pyrexia	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*				Quasi-complete separation of data points detected.			NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Hepatobiliary disorders		n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81	
Hepatobiliary disorders	Cholecystitis chronic	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				* questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	
Hepatobiliary disorders	Hepatic function abnormal	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hypertranasaminasemia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				* questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	
Infections and infestations		n/a	135	100,0	2	1,5	69	100,0	3	4,3	0,33	Convergence criterion (GCONV=1E-8) satisfied.	0,05	2,03	-0,029	Algorithm converged.	-0,081	0,024	0,34	Algorithm converged.	0,06	1,99	0,2320	NE	2,93	Algorithm converged.	0,50	17,15	
Infections and infestations	COVID-19	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations	Pneumonia	n/a	135	100,0	2	1,5	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				* questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Infections and infestations	Sepsis	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				* questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade 3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

Transfusion history [total pRBC units administered in the 6 months pre-randomization]

			Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab							
			Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Rati o	Convergence Reason	95% Lower CL	95% Upper CL	Absolu te Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relati ve Risk	Convergence Reason	95% Lower CL	95% Upper CL	p- value (Wald)	Interaction Test p-value (likelihood ratio)	Relati ve Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		0 units	33	24,4	2	6,1	17	24,6	1	5,9	1,03	Convergence criterion (GCONV=1E-8) satisfied.	0,09	12,26	0,002	Algorithm converged.	-0,137	0,140	1,03	Algorithm converged.	0,10	10,57	0,9799	NE	0,97	Algorithm converged.	0,09	9,96	
Blood and lymphatic system disorders		>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.				* questionable.			0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE		
Blood and lymphatic system disorders		>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.				* ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE		
Blood and lymphatic system disorders	Anaemia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Anaemia	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.				* WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Anaemia	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Aplastic anaemia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Aplastic anaemia	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Aplastic anaemia	>6 units	34	25,2	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.				* ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE		

POPULATION: Randomized Safety Population
 ENDFPOINT: AEs Grade 3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

Geographic region

			Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab							
			Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	3	5,9	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders		North America/ Central and South America/ Europe	50	37,0	2	4,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 2.1572052245 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Anaemia	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Anaemia	North America/ Central and South America/ Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Aplastic anaemia	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 16.211068616 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders	Aplastic anaemia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile neutropenia	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	1	2,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 16.211068646 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders	Febrile neutropenia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	2	3,9	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.9	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders	Neutropenia	North America/ Central and South America/ Europe	50	37,0	2	4,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 2.1572052245 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Pancytopenia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	

General disorders and administration site conditions	Pyrexia	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Pyrexia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Hepatobiliary disorders		Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	0,1106	NE	Algorithm converged.	NE	NE	
Hepatobiliary disorders		Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177153 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE		
Hepatobiliary disorders	Cholecystitis chronic	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Hepatobiliary disorders	Cholecystitis chronic	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177153 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE		

Infections and infestations	Pneumonia	Male	77	57,0	2	2,6	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 3.733053906 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Infections and infestations	Pneumonia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Sepsis	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Sepsis	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177153 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE		
Infections and infestations	Tuberculosis	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE		
Infections and infestations	Tuberculosis	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Infections and infestations	Urinary tract infection	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Infections and infestations	Urinary tract infection	Female	58	43,0	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 12.420177141 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE		
Investigations		Male	77	57,0	1	1,3	35	50,7	3	8,6	0,14	Convergence criterion (GCONV=1E-8) satisfied.		Algorithm converged.	-0,169	0,023	0,15	Algorithm converged.	0,02	1,41	0,0968	0,0533	6,60	Algorithm converged.	0,71	61,23

Respiratory, thoracic and mediastinal disorders	Epistaxis	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Epistaxis	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Skin and subcutaneous tissue disorders		Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders		Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders		Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders		Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Vascular disorders	Hypertension	Male	77	57,0	1	1,3	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 6.2305305007 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypertension	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Vascular disorders	Hypovolaemic shock	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Vascular disorders	Hypovolaemic shock	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_G3_SE1_16NOV2022_42162.xls
 10APR2024 10:01

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade 4, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

All

			Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab								
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk								
			n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		n/a	135	100,0	3	2,2	69	100,0	1	1,4	1,55	Convergence criterion (GCONV=1E-8) satisfied.	0,16	15,14	0,008	Algorithm converged.	-0,030	0,045	1,53	Algorithm converged.	0,16	14,47	0,7090	NE	0,65	Algorithm converged.	0,07	6,15	
Blood and lymphatic system disorders	Aplastic anaemia	n/a	135	100,0	2	1,5	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 6.3162357272 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Thrombocytopenia	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81	
Cardiac disorders		n/a	135	100,0	0	0,0	69	100,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Cardiac failure	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9	Algorithm converged.	0,00	NE	
Infections and infestations		n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Infections and infestations	Central nervous system infection	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9	Algorithm converged.	0,00	NE	
Infections and infestations	Pyelonephritis	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Investigations		n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000	Algorithm converged.	-0,034	0,035	1,02	Algorithm converged.	0,09	11,08	0,9856	NE	0,98	Algorithm converged.	0,09	10,60	
Investigations	Neutrophil count decreased	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000	Algorithm converged.	-0,034	0,035	1,02	Algorithm converged.	0,09	11,08	0,9856	NE	0,98	Algorithm converged.	0,09	10,60	
Investigations	Platelet count decreased	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade 4, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

Transfusion history [total pRBC units administered in the 6 months pre-randomization]

MedDRA System Organ Class	MedDRA Preferred Term	Level	Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab								
			Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk								
			n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
Blood and lymphatic system disorders		0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE													0,4029	NE	NE	NE	NE		
Blood and lymphatic system disorders		>0 to <=6 units	68	50,4	1	1,5	34	49,3	1	2,9	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,12	-0,015	Algorithm converged.	-0,078	0,049	0,50	Algorithm converged.	0,03	7,75	0,6202			2,00	Algorithm converged.	0,13	31,01	
Blood and lymphatic system disorders		>6 units	34	25,2	2	5,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Aplastic anaemia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE														NE	NE	NE	NE		
Blood and lymphatic system disorders	Aplastic anaemia	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Aplastic anaemia	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Thrombocytopenia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE														NE	NE	NE	NE		
Blood and lymphatic system disorders	Thrombocytopenia	>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 14.539905139 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	1,0000			>999.99	Algorithm converged.	0,00	NE
Blood and lymphatic system disorders	Thrombocytopenia	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Cardiac disorders		0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE														NE	NE	NE	NE		

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade 4, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

Sex

			Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab							
			Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk			Relative Risk							
MedDRA System	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		Male	77	57,0	3	3,9	35	50,7	1	2,9	1,38	Convergence criterion (GCONV=1E-8) satisfied.	0,14	13,73	0,010	Algorithm converged.	-0,060	0,080	1,36	Algorithm converged.	0,15	12,65	0,7849	NE	0,73	Algorithm converged.	0,08	6,80	
Blood and lymphatic system disorders		Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Aplastic anaemia	Male	77	57,0	2	2,6	35	50,7	0	0,0	*	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Aplastic anaemia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Thrombocytopenia	Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45	Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,36	-0,016	Algorithm converged.	-0,076	0,045	0,45	Algorithm converged.	0,03	7,06	0,5732	1,0000	2,20	Algorithm converged.	0,14	34,17	
Blood and lymphatic system disorders	Thrombocytopenia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Cardiac disorders		Male	77	57,0	0	0,0	35	50,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Cardiac disorders		Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Cardiac disorders	Cardiac failure	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE	0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999,99	Algorithm converged.	0,00	NE
Cardiac disorders	Cardiac failure	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations		Male	77	57,0	0	0,0	35	50,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations		Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations	Central nervous system infection	Male	77	57,0	0	0,0	35	50,7	1	2,9	*	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE	0,00	Algorithm converged.	0,00	NE	1,0000	NE	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Central nervous system infection	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Eyelonephritis	Male	77	57,0	0	0,0	35	50,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Eyelonephritis	Female	58	43,0	1	1,7	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE
---	-------------------------------	------	----	-----	---	-----	---	------	---	-----	---	--	---	---	----	----------------------	----	----	----	----	----------------------	----	----

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_G5_SE1_16NOV2022_42162.xls
 10APR2024 10:09

POPULATION: Randomized Safety Population
 ENDPPOINT: AEs Grade 5 (AEs leading to death), Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous analysis by Subgroups (Safety)

All

			Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
			Patients		Patients with		Patients		Patients with		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Rati o	Convergence Reason	95% Lowe r CL	95% Uppe r CL	Absolu te Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL	p- value (Wald)	Interaction Test p-value (likelihood ratio)	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL
Cardiac disorders		n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Myocardial infarction	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Nervous system disorders		n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Nervous system disorders	Ischaemic stroke	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Respiratory, thoracic and mediastinal disorders		n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_G5_SE1_16NOV2022_42162.xls
 10APR2024 10:09

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade 5 (AEs leading to death), Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

Transfusion history [total pRBC units administered in the 6 months pre-randomization]

			Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab												Eculizumab vs. Crovalimab						
			Patients		Patients with		Patient		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk						
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Cardiac disorders		0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders		>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Cardiac disorders		>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Myocardial infarction	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Myocardial infarction	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Cardiac disorders	Myocardial infarction	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders		0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9	Algorithm converged.	0,00	NE	
Nervous system disorders		>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders		>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders	Ischaemic stroke	0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9	Algorithm converged.	0,00	NE	
Nervous system disorders	Ischaemic stroke	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders	Ischaemic stroke	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders		0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders		>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders		>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE

POPULATION: Randomized Safety Population
 ENDPOINT: AEs Grade 5 (AEs leading to death), Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

Geographic region

			Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab							
			Patients		Patients with		Patient		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk							
MedDRA System	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Cardiac disorders		Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders		North America/Central and South America/Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.		NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Cardiac disorders	Myocardial infarction	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Myocardial infarction	North America/Central and South America/Europe	50	37,0	1	2,0	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.		NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Nervous system disorders		Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders		North America/Central and South America/Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 12.774840148 is greater than the limit of 0.0001. The convergence is questionable.		0,00	Algorithm converged.	0,00	NE	1,0000			>999,99	Algorithm converged.	0,00	NE
Nervous system disorders	Ischaemic stroke	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders	Ischaemic stroke	North America/Central and South America/Europe	50	37,0	0	0,0	18	26,1	1	5,6	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 12.774840148 is greater than the limit of 0.0001. The convergence is questionable.		0,00	Algorithm converged.	0,00	NE	1,0000			>999,99	Algorithm converged.	0,00	NE

Cardiac disorders		>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Cardiac failure	<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 22.085838312 is greater than the limit of 0.0001. The convergence is questionable .	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Cardiac disorders	Cardiac failure	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Cardiac disorders	Myocardial infarction	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Cardiac disorders	Myocardial infarction	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders		<65	122	90,4	0	0,0	60	87,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Gastrointestinal disorders		>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Small intestinal haemorrhage	<65	122	90,4	0	0,0	60	87,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Gastrointestinal disorders	Small intestinal haemorrhage	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		<65	122	90,4	0	0,0	60	87,0	1	1,7	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 22.085838292 is greater than the limit of 0.0001. The convergence is questionable .	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE

Respiratory, thoracic and mediastinal disorders	Respiratory tract haemorrhage	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders		<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations .	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders		>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations .	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders		<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations .	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders		>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypovolaemic shock	<65	122	90,4	1	0,8	60	87,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations .	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypovolaemic shock	>=65	13	9,6	0	0,0	9	13,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sq_SAE_SE1_16NOV2022_42162.xls
10APR2024 9:58

POPULATION: Randomized Safety Population
 ENDPOINT: Any SAEs, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous analysis by Subgroups (Safety)

All

		Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab												Eculizumab vs. Crovalimab						
		Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk						
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Rati o	Convergence Reason	95% Lowe r CL	95% Upper CL	Absolu te Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Upper CL	p- value (Wald)	Interaction Test p-value (likelihood ratio)	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Upper CL
Blood and lymphatic system disorders		n/a	135	100,0	3	2,2	69	100,0	3	4,3	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,10	2,55	-0,021	Algorithm converged.	-0,075	0,033	0,51	Algorithm converged.	0,11	2,47	0,4032	NE	1,96	Algorithm converged.	0,41	9,44
Blood and lymphatic system disorders	Aplastic anaemia	n/a	135	100,0	2	1,5	69	100,0	1	1,4	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,09	11,48	0,000	Algorithm converged.	-0,034	0,035	1,02	Algorithm converged.	0,09	11,08	0,9856	NE	0,98	Algorithm converged.	0,09	10,60
Blood and lymphatic system disorders	Febrile neutropenia	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9	Algorithm converged.	0,00	NE
Blood and lymphatic system disorders	Thrombocytopenia	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81
Cardiac disorders		n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81
Cardiac disorders	Cardiac failure	n/a	135	100,0	0	0,0	69	100,0	1	1,4	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 23.402555564 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9	Algorithm converged.	0,00	NE
Cardiac disorders	Myocardial infarction	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders		n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Small intestinal haemorrhage	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81
General disorders and administration site conditions	Fyrexia	n/a	135	100,0	1	0,7	69	100,0	1	1,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,24	-0,007	Algorithm converged.	-0,039	0,025	0,51	Algorithm converged.	0,03	8,05	0,6332	NE	1,96	Algorithm converged.	0,12	30,81

Skin and subcutaneous tissue disorders		n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders		n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypovolaemic shock	n/a	135	100,0	1	0,7	69	100,0	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_SAE_SE1_16NOV2022_42162.xls
10APR2024 9:58

POPULATION: Randomized Safety Population
 ENDPPOINT: Any SAEs, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous analysis by Subgroups (Safety)

Transfusion history [total pRBC units administered in the 6 months pre-randomization]

			Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab							
			Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk			Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 8.5838859021 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	0,00	NE	0,9999	0,4063	>999.99	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders		>0 to <=6 units	68	50,4	1	1,5	34	49,3	1	2,9	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,12	-0,015	Algorithm converged.	-0,078	0,049	0,50	Algorithm converged.	0,03	7,75	0,6202		2,00	Algorithm converged.	0,13	31,01	
Blood and lymphatic system disorders		>6 units	34	25,2	2	5,9	18	26,1	1	5,6	1,06	Convergence criterion (GCONV=1E-8) satisfied.	0,09	12,58	0,003	Algorithm converged.	-0,129	0,135	1,06	Algorithm converged.	0,10	10,90	0,9617		0,94	Algorithm converged.	0,09	9,72	
Blood and lymphatic system disorders	Aplastic anaemia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Aplastic anaemia	>0 to <=6 units	68	50,4	1	1,5	34	49,3	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Aplastic anaemia	>6 units	34	25,2	1	2,9	18	26,1	1	5,6	0,52	Convergence criterion (GCONV=1E-8) satisfied.	0,03	8,75	-0,026	Algorithm converged.	-0,146	0,094	0,53	Algorithm converged.	0,04	7,97	0,6458		1,89	Algorithm converged.	0,13	28,45	
Blood and lymphatic system disorders	Febrile neutropenia	0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 8.5838859021 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders	Febrile neutropenia	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile neutropenia	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Thrombocytopenia	0 units	33	24,4	0	0,0	17	24,6	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Thrombocytopenia	>0 to <=6 units	68	50,4	0	0,0	34	49,3	1	2,9	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.539905139 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE	
Blood and lymphatic system disorders	Thrombocytopenia	>6 units	34	25,2	1	2,9	18	26,1	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Cardiac disorders		0 units	33	24,4	0	0,0	17	24,6	1	5,9	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE	

Vascular disorders	Hypovolaemic shock	>6 units	34	25,2	0	0,0	18	26,1	0	0,0	NE			NE	NE	NE		NE	NE	NE	NE			NE	NE	NE	NE
--------------------	--------------------	----------	----	------	---	-----	----	------	---	-----	----	--	--	----	----	----	--	----	----	----	----	--	--	----	----	----	----

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_SAE_SE1_16NOV2022_42162.xls
 10APR2024 9:58

Vascular disorders		Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders		North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Vascular disorders	Hypovolaemic shock	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: Negative of Hessian not positive definite.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypovolaemic shock	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_SAE_SE1_16NOV2022_42162.xls
 10APR2024 9:58

POPULATION: Randomized Safety Population
 ENDPOINT: Any SAEs, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BC42162
 Dichotomous analysis by Subgroups (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab							
		Patients		Patients with		Patient		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk					Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		Male	77	57,0	3	3,9	35	50,7	3	8,6	0,43				Convergence criterion (GCONV=1E-8) satisfied.	0,08	2,26	-0,047	Algorithm converged.	-0,149	0,056	0,45		1,0000	2,20	Algorithm converged.	0,47	10,36
Blood and lymphatic system disorders		Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Blood and lymphatic system disorders	Aplastic anaemia	Male	77	57,0	2	2,6	35	50,7	1	2,9	0,91				Convergence criterion (GCONV=1E-8) satisfied.	0,08	10,34	-0,003	Algorithm converged.	-0,068	0,063	0,91		1,0000	1,10	Algorithm converged.	0,10	11,73
Blood and lymphatic system disorders	Aplastic anaemia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Blood and lymphatic system disorders	Febrile neutropenia	Male	77	57,0	0	0,0	35	50,7	1	2,9	*				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00		>999.99	Algorithm converged.	0,00	NE
Blood and lymphatic system disorders	Febrile neutropenia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Blood and lymphatic system disorders	Thrombocytopenia	Male	77	57,0	1	1,3	35	50,7	1	2,9	0,45				Convergence criterion (GCONV=1E-8) satisfied.	0,03	7,36	-0,016	Algorithm converged.	-0,076	0,045	0,45		1,0000	2,20	Algorithm converged.	0,14	34,17
Blood and lymphatic system disorders	Thrombocytopenia	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Cardiac disorders		Male	77	57,0	0	0,0	35	50,7	1	2,9	*				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00		>999.99	Algorithm converged.	0,00	NE
Cardiac disorders		Female	58	43,0	1	1,7	34	49,3	0	0,0	*				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE		NE	Algorithm converged.	NE	NE
Cardiac disorders	Cardiac failure	Male	77	57,0	0	0,0	35	50,7	1	2,9	*				Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00		>999.99	Algorithm converged.	0,00	NE
Cardiac disorders	Cardiac failure	Female	58	43,0	0	0,0	34	49,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	

POPULATION: Randomized Safety Population
 ENDPOINT: Adverse event leading to treatment discontinuation, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous Analysis by Subgroups (Safety)

Age

			Crovalimab (N=135)				Eculizumab (N=69)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		<65	122	90,4	1	0,8	60	87,0	0	0,0
Blood and lymphatic system disorders		>=65	13	9,6	0	0,0	9	13,0	0	0,0
Blood and lymphatic system disorders	Thrombocytopenia	<65	122	90,4	1	0,8	60	87,0	0	0,0
Blood and lymphatic system disorders	Thrombocytopenia	>=65	13	9,6	0	0,0	9	13,0	0	0,0
Nervous system disorders		<65	122	90,4	0	0,0	60	87,0	1	1,7
Nervous system disorders		>=65	13	9,6	0	0,0	9	13,0	0	0,0
Nervous system disorders	Ischaemic stroke	<65	122	90,4	0	0,0	60	87,0	1	1,7
Nervous system disorders	Ischaemic stroke	>=65	13	9,6	0	0,0	9	13,0	0	0,0

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_soc_descriptive_sg_WDAE_SE1_16NOV2022_42162.xls
 21MAR2024 16:12

POPULATION: Randomized Safety Population

ENDPOINT: Adverse event leading to treatment discontinuation, Primary Safety Period

MODEL: Unstratified analysis

STUDY: BO42162

Dichotomous Analysis by Subgroups (Safety)

All

			Crovalimab (N=135)				Eculizumab (N=69)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	135	100,0	1	0,7	69	100,0	0	0,0
Blood and lymphatic system disorders	Thrombocytopenia	n/a	135	100,0	1	0,7	69	100,0	0	0,0
Nervous system disorders		n/a	135	100,0	0	0,0	69	100,0	1	1,4
Nervous system disorders	Ischaemic stroke	n/a	135	100,0	0	0,0	69	100,0	1	1,4

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_soc_descriptive_sg_WDAE_SE1_16NOV2022_42162.xls

21MAR2024 16:12

POPULATION: Randomized Safety Population

ENDPOINT: Adverse event leading to treatment discontinuation, Primary Safety Period

MODEL: Unstratified analysis

STUDY: BO42162

Dichotomous Analysis by Subgroups (Safety)

Transfusion history [total pRBC units administered in the 6 months pre-randomization]

			Crovalimab (N=135)				Eculizumab (N=69)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		0 units	33	24,4	0	0,0	17	24,6	0	0,0
Blood and lymphatic system disorders		>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0
Blood and lymphatic system disorders		>6 units	34	25,2	1	2,9	18	26,1	0	0,0
Blood and lymphatic system disorders	Thrombocytopenia	0 units	33	24,4	0	0,0	17	24,6	0	0,0
Blood and lymphatic system disorders	Thrombocytopenia	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0
Blood and lymphatic system disorders	Thrombocytopenia	>6 units	34	25,2	1	2,9	18	26,1	0	0,0
Nervous system disorders		0 units	33	24,4	0	0,0	17	24,6	1	5,9
Nervous system disorders		>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0
Nervous system disorders		>6 units	34	25,2	0	0,0	18	26,1	0	0,0
Nervous system disorders	Ischaemic stroke	0 units	33	24,4	0	0,0	17	24,6	1	5,9
Nervous system disorders	Ischaemic stroke	>0 to <=6 units	68	50,4	0	0,0	34	49,3	0	0,0
Nervous system disorders	Ischaemic stroke	>6 units	34	25,2	0	0,0	18	26,1	0	0,0

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_soc_descriptive.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_soc_descriptive_sg_WDAE_SE1_16NOV2022_42162.xls

21MAR2024 16:12

POPULATION: Randomized Safety Population
 ENDPOINT: Adverse event leading to treatment discontinuation, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Crovalimab (N=135)				Eculizumab (N=69)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0
Blood and lymphatic system disorders		North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0
Blood and lymphatic system disorders	Thrombocytopenia	Japan/Rest of Asia Pacific	85	63,0	1	1,2	51	73,9	0	0,0
Blood and lymphatic system disorders	Thrombocytopenia	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	0	0,0
Nervous system disorders		Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0
Nervous system disorders		North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6
Nervous system disorders	Ischaemic stroke	Japan/Rest of Asia Pacific	85	63,0	0	0,0	51	73,9	0	0,0
Nervous system disorders	Ischaemic stroke	North America/ Central and South America/ Europe	50	37,0	0	0,0	18	26,1	1	5,6

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_soc_descriptive_sg_WDAE_SE1_16NOV2022_42162.xls
 21MAR2024 16:12

POPULATION: Randomized Safety Population
 ENDPOINT: Adverse event leading to treatment discontinuation, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous Analysis by Subgroups (Safety)

Sex

			Crovalimab (N=135)				Eculizumab (N=69)			
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with Event		Patients		Patients with Event	
			n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Male	77	57,0	1	1,3	35	50,7	0	0,0
Blood and lymphatic system disorders		Female	58	43,0	0	0,0	34	49,3	0	0,0
Blood and lymphatic system disorders	Thrombocytopenia	Male	77	57,0	1	1,3	35	50,7	0	0,0
Blood and lymphatic system disorders	Thrombocytopenia	Female	58	43,0	0	0,0	34	49,3	0	0,0
Nervous system disorders		Male	77	57,0	0	0,0	35	50,7	1	2,9
Nervous system disorders		Female	58	43,0	0	0,0	34	49,3	0	0,0
Nervous system disorders	Ischaemic stroke	Male	77	57,0	0	0,0	35	50,7	1	2,9
Nervous system disorders	Ischaemic stroke	Female	58	43,0	0	0,0	34	49,3	0	0,0

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_soc_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_soc_descriptive_sg_WDAE_SE1_16NOV2022_42162.xls
 21MAR2024 16:12

POPULATION: Randomized Safety Population
 ENDPOINT: DILI, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	135	100,0	0	0	69	100,0	0	0
Sex	Male	77	57,0	0	0	35	50,7	0	0
	Female	58	43,0	0	0	34	49,3	0	0
Age	<65	122	90,4	0	0	60	87,0	0	0
	>=65	13	9,6	0	0	9	13,0	0	0
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	0	0	17	24,6	0	0
	>0 to <=6 units	68	50,4	0	0	34	49,3	0	0
	>6 units	34	25,2	0	0	18	26,1	0	0
Geographic region	Japan/Rest of Asia Pacific	85	63,0	0	0	51	73,9	0	0
	North America/ Central and South America/ Europe	50	37,0	0	0	18	26,1	0	0

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_DILI_SE1_16NOV2022_42162.xls
 09APR2024 22:12

POPULATION: Randomized Safety Population
 ENDPOINT: Type III hypersensitivity reactions Grade >=3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	135	100,0	0	0	69	100,0	0	0
Sex	Male	77	57,0	0	0	35	50,7	0	0
	Female	58	43,0	0	0	34	49,3	0	0
Age	<65	122	90,4	0	0	60	87,0	0	0
	>=65	13	9,6	0	0	9	13,0	0	0
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	0	0	17	24,6	0	0
	>0 to <=6 units	68	50,4	0	0	34	49,3	0	0
	>6 units	34	25,2	0	0	18	26,1	0	0
Geographic region	Japan/Rest of Asia Pacific	85	63,0	0	0	51	73,9	0	0
	North America/ Central and South America/ Europe	50	37,0	0	0	18	26,1	0	0

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_H3G3_SE1_16NOV2022_42162.xls
 09APR2024 22:14

POPULATION: Randomized Safety Population
 ENDPOINT: Serious Type III hypersensitivity reactions, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	135	100,0	0	0	69	100,0	0	0
Sex	Male	77	57,0	0	0	35	50,7	0	0
	Female	58	43,0	0	0	34	49,3	0	0
Age	<65	122	90,4	0	0	60	87,0	0	0
	>=65	13	9,6	0	0	9	13,0	0	0
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	0	0	17	24,6	0	0
	>0 to <=6 units	68	50,4	0	0	34	49,3	0	0
	>6 units	34	25,2	0	0	18	26,1	0	0
Geographic region	Japan/Rest of Asia Pacific	85	63,0	0	0	51	73,9	0	0
	North America/ Central and South America/ Europe	50	37,0	0	0	18	26,1	0	0

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_H3S_SE1_16NOV2022_42162.xls
 09APR2024 22:16

POPULATION: Randomized Safety Population
 ENDPOINT: Hypersensitivity reactions other than Type III hypersensitivity, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=135)				Eculizumab (N=69)				Odds Ratio	Crovalimab vs. Eculizumab					Eculizumab vs. Crovalimab															
		Patients		Patients with		Patients		Patients with			Absolute Risk Difference					Relative Risk															
		n	%	n	%	n	%	n	%		95% Lower CL	95% Upper CL	Absolute Risk	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL						
All	n/a	135	100.0	8	5.9	69	100.0	0	0	+	Quasi-complete separation of data points detected.					+	WARNING: The relative Hessian convergence criterion of 2.2744022207 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Sex	Male	77	57.0	5	6.5	35	50.7	0	0	+	Quasi-complete separation of data points detected.					+	ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE
	Female	58	43.0	3	5.2	34	49.3	0	0	+	Quasi-complete separation of data points detected.					+	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Age	<65	122	90.4	7	5.7	60	87.0	0	0	+	Quasi-complete separation of data points detected.					+	WARNING: The relative Hessian convergence criterion of 2.2415507582 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	>=65	13	9.6	1	7.7	9	13.0	0	0	+	Quasi-complete separation of data points detected.					+	ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24.4	3	9.1	17	24.6	0	0	+	Quasi-complete separation of data points detected.					+	WARNING: Negative of Hessian not positive definite.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	>0 to <=6 units	68	50.4	4	5.9	34	49.3	0	0	+	Quasi-complete separation of data points detected.					+	WARNING: Negative of Hessian not positive definite.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	>6 units	34	25.2	1	2.9	18	26.1	0	0	+	Quasi-complete separation of data points detected.					+	ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Geographic region	Japan/Rest of Asia Pacific	85	63.0	2	2.4	51	73.9	0	0	+	Quasi-complete separation of data points detected.					+	WARNING: The relative Hessian convergence criterion of 5.2462595092 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	North America/ Central and South America/ Europe	50	37.0	6	12.0	18	26.1	0	0	+	Quasi-complete separation of data points detected.					+	WARNING: The relative Hessian convergence criterion of 0.9859004453 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical studies/B07112689/CD770115/B042162/data analysis/ACE CSR 1/prod/program/t ae raw.sas
 Output: root/clinical studies/B07112689/CD770115/B042162/data analysis/ACE CSR 1/prod/output/t ae raw sg RR SEI 16NOV2022 42162.xls
 09APR2024 22:10

POPULATION: Randomized Safety Population
 ENDPOINT: Type III hypersensitivity reactions, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	135	100,0	0	0	69	100,0	0	0
Sex	Male	77	57,0	0	0	35	50,7	0	0
	Female	58	43,0	0	0	34	49,3	0	0
Age	<65	122	90,4	0	0	60	87,0	0	0
	>=65	13	9,6	0	0	9	13,0	0	0
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	0	0	17	24,6	0	0
	>0 to <=6 units	68	50,4	0	0	34	49,3	0	0
	>6 units	34	25,2	0	0	18	26,1	0	0
Geographic region	Japan/Rest of Asia Pacific	85	63,0	0	0	51	73,9	0	0
	North America/ Central and South America/ Europe	50	37,0	0	0	18	26,1	0	0

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_HYP3_SE1_16NOV2022_42162.xls
 09APR2024 22:13

POPULATION: Randomized Safety Population
 ENDPOINT: Infections, including meningococcal meningitis, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous Analysis by Subgroups (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab												
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk												
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL						
All	n/a	135	100,0	32	23,7	69	100,0	25	36,2	0,55				Convergence criterion (GCONV=1E-8) satisfied.	0,29	1,03	-0,125	Algorithm converged.	-0,259	0,009	0,65			Algorithm converged.	0,42	1,01	0,0561	1,53	Algorithm converged.	0,99	2,36	
Sex	Male	77	57,0	23	29,9	35	50,7	11	31,4	0,93				Convergence criterion (GCONV=1E-8) satisfied.	0,39	2,21	-0,016	Algorithm converged.	-0,200	0,169	0,95			Algorithm converged.	0,52	1,73	0,8674	0,0465	1,05	Algorithm converged.	0,58	1,91
	Female	58	43,0	9	15,5	34	49,3	14	41,2	0,26				Convergence criterion (GCONV=1E-8) satisfied.	0,10	0,70	-0,257	Algorithm converged.	-0,446	-0,067	0,38			Algorithm converged.	0,18	0,78	0,0081		2,65	Algorithm converged.	1,29	5,47
Age	<65	122	90,4	28	23,0	60	87,0	23	38,3	0,48				Convergence criterion (GCONV=1E-8) satisfied.	0,25	0,94	-0,154	Algorithm converged.	-0,298	-0,010	0,60			Algorithm converged.	0,38	0,95	0,0278	0,2650	1,67	Algorithm converged.	1,06	2,64
	>=65	13	9,6	4	30,8	9	13,0	2	22,2	1,56				Convergence criterion (GCONV=1E-8) satisfied.	0,22	11,08	0,085	Algorithm converged.	-0,284	0,455	1,38			Algorithm converged.	0,32	6,02	0,6642		0,72	Algorithm converged.	0,17	3,14
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	4	12,1	17	24,6	6	35,3	0,25				Convergence criterion (GCONV=1E-8) satisfied.	0,06	1,07	-0,232	Algorithm converged.	-0,485	0,021	0,34			Algorithm converged.	0,11	1,05	0,0618	0,2228	2,91	Algorithm converged.	0,95	8,94
	>0 to <=6 units	68	50,4	19	27,9	34	49,3	10	29,4	0,93				Convergence criterion (GCONV=1E-8) satisfied.	0,38	2,31	-0,015	Algorithm converged.	-0,201	0,172	0,95			Algorithm converged.	0,50	1,81	0,8763		1,05	Algorithm converged.	0,55	2,01
	>6 units	34	25,2	9	26,5	18	26,1	9	50,0	0,36				Convergence criterion (GCONV=1E-8) satisfied.	0,11	1,19	-0,235	Algorithm converged.	-0,510	0,039	0,53			Algorithm converged.	0,26	1,09	0,0860		1,89	Algorithm converged.	0,91	3,90
Geographic region	Japan/Rest of Asia Pacific	85	63,0	14	16,5	51	73,9	19	37,3	0,33				Convergence criterion (GCONV=1E-8) satisfied.	0,15	0,74	-0,208	Algorithm converged.	-0,362	-0,053	0,44			Algorithm converged.	0,24	0,80	0,0073	0,0547	2,26	Algorithm converged.	1,25	4,11
	North America/ Central and South America/ Europe	50	37,0	18	36,0	18	26,1	6	33,3	1,12				Convergence criterion (GCONV=1E-8) satisfied.	0,36	3,51	0,027	Algorithm converged.	-0,229	0,282	1,08			Algorithm converged.	0,51	2,29	0,8407		0,93	Algorithm converged.	0,44	1,96

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sq_INFEC_SEI_16NOV2022_42162.xls
 09APR2024 22:08

POPULATION: Randomized Safety Population
 ENDPOINT: Infusion-related reactions, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042162
 Dichotomous Analysis by Subgroups (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk							
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	135	100,0	21	15,6	69	100,0	9	13,0	1,23	Convergence criterion (GCONV=1E-8) satisfied.	0,53	2,85	0,025	Algorithm converged.	-0,075	0,125	1,19	Algorithm converged.	0,58	2,46	0,6340			0,84	Algorithm converged.	0,41	1,73
Sex	Male	77	57,0	12	15,6	35	50,7	6	17,1	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,31	2,61	-0,016	Algorithm converged.	-0,164	0,133	0,91	Algorithm converged.	0,37	2,22	0,8346	0,3882	1,10	Algorithm converged.	0,45	2,69	
	Female	58	43,0	9	15,5	34	49,3	3	8,8	1,90	Convergence criterion (GCONV=1E-8) satisfied.	0,48	7,56	0,067	Algorithm converged.	-0,066	0,200	1,76	Algorithm converged.	0,51	6,05	0,3707			0,57	Algorithm converged.	0,17	1,96
Age	<65	122	90,4	20	16,4	60	87,0	9	15,0	1,11	Convergence criterion (GCONV=1E-8) satisfied.	0,47	2,61	0,014	Algorithm converged.	-0,098	0,126	1,09	Algorithm converged.	0,53	2,25	0,8098	0,3200	0,92	Algorithm converged.	0,44	1,89	
	>=65	13	9,6	1	7,7	9	13,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	5	15,2	17	24,6	3	17,6	0,83	Convergence criterion (GCONV=1E-8) satisfied.	0,17	4,00	-0,025	Algorithm converged.	-0,244	0,194	0,86	Algorithm converged.	0,23	3,17	0,8191	0,8429	1,16	Algorithm converged.	0,32	4,30	
	>0 to <=6 units	68	50,4	8	11,8	34	49,3	3	8,8	1,38	Convergence criterion (GCONV=1E-8) satisfied.	0,34	5,56	0,029	Algorithm converged.	-0,093	0,152	1,33	Algorithm converged.	0,38	4,71	0,6549		0,75	Algorithm converged.	0,21	2,65	
	>6 units	34	25,2	8	23,5	18	26,1	3	16,7	1,54	Convergence criterion (GCONV=1E-8) satisfied.	0,35	6,70	0,069	Algorithm converged.	-0,155	0,292	1,41	Algorithm converged.	0,43	4,68	0,5725		0,71	Algorithm converged.	0,21	2,35	
Geographic region	Japan/Rest of Asia Pacific	85	63,0	11	12,9	51	73,9	7	13,7	0,93	Convergence criterion (GCONV=1E-8) satisfied.	0,34	2,59	-0,008	Algorithm converged.	-0,126	0,111	0,94	Algorithm converged.	0,39	2,28	0,8959	0,4293	1,06	Algorithm converged.	0,44	2,56	
	North America/ Central and South America/ Europe	50	37,0	10	20,0	18	26,1	2	11,1	2,00	Convergence criterion (GCONV=1E-8) satisfied.	0,39	10,16	0,089	Algorithm converged.	-0,094	0,272	1,80	Algorithm converged.	0,44	7,44	0,4170		0,56	Algorithm converged.	0,13	2,30	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_IRR_SE1_16NOV2022_42162.xls
 09APR2024 22:06

POPULATION: Randomized Safety Population
 ENDPOINT: Suspected transmission of an infectious agent by the study drug, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42162
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	135	100,0	0	0	69	100,0	0	0
Sex	Male	77	57,0	0	0	35	50,7	0	0
	Female	58	43,0	0	0	34	49,3	0	0
Age	<65	122	90,4	0	0	60	87,0	0	0
	>=65	13	9,6	0	0	9	13,0	0	0
Transfusion history [total pRBC units administered in the 6 months pre-randomization]	0 units	33	24,4	0	0	17	24,6	0	0
	>0 to <=6 units	68	50,4	0	0	34	49,3	0	0
	>6 units	34	25,2	0	0	18	26,1	0	0
Geographic region	Japan/Rest of Asia Pacific	85	63,0	0	0	51	73,9	0	0
	North America/ Central and South America/ Europe	50	37,0	0	0	18	26,1	0	0

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_RBL_SE1_16NOV2022_42162.xls
 09APR2024 22:03

POPULATION: Randomized Safety Population
 ENDPOINT: Primary Safety Period
 MODEL: --
 STUDY: B042162
 Outcome of Adverse Events - Complete Follow-Up

Endpoint Grade	Crovalimab (N=135)														Eculizumab (N=69)																	
	Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs	All	421	378	89,8	0	0,0	37	8,8	2	0,5	4	1,0	0	0,0	0	0,0	223	201	90,1	1	0,4	13	6,7	1	0,4	5	2,2	0	0,0	0	0,0	
e 1	244	229	93,9	0	0,0	12	4,9	0	0,0	3	1,2	0	0,0	0	0,0	139	137	98,6	0	0,0	2	1,4	0	0,0	0	0,0	0	0,0	0	0,0		
e 2	129	115	89,1	0	0,0	14	10,9	0	0,0	0	0,0	0	0,0	0	0,0	61	52	85,2	1	1,6	5	8,2	0	0,0	3	4,9	0	0,0	0	0,0		
e 3	36	28	77,8	0	0,0	8	22,2	0	0,0	0	0,0	0	0,0	0	0,0	17	11	64,7	0	0,0	5	29,4	0	0,0	1	5,9	0	0,0	0	0,0		
e 4	10	8	80,0	0	0,0	3	30,0	0	0,0	1	10,0	0	0,0	0	0,0	5	1	20,0	0	0,0	3	60,0	0	0,0	1	20,0	0	0,0	0	0,0		
e 5	2	0	0,0	0	0,0	0	0,0	2	100,0	0	0,0	0	0,0	0	0,0	1	0	0,0	0	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0		
Any SAEs	All	21	16	76,2	0	0,0	2	9,5	2	9,5	1	4,8	0	0,0	0	0,0	13	5	38,5	0	0,0	6	46,2	1	7,7	1	7,7	0	0,0	0	0,0	
e 1	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0		
e 2	3	2	66,7	0	0,0	1	33,3	0	0,0	0	0,0	0	0,0	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0		
e 3	10	10	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	6	2	33,3	0	0,0	4	66,7	0	0,0	0	0,0	0	0,0	0	0,0		
e 4	6	4	66,7	0	0,0	1	16,7	0	0,0	1	16,7	0	0,0	0	0,0	4	1	25,0	0	0,0	2	50,0	0	0,0	1	25,0	0	0,0	0	0,0		
e 5	2	0	0,0	0	0,0	0	0,0	2	100,0	0	0,0	0	0,0	0	0,0	1	0	0,0	0	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0		
Any AESI	All	82	78	95,1	0	0,0	3	3,7	0	0,0	1	1,2	0	0,0	0	0,0	49	45	91,8	0	0,0	4	8,2	0	0,0	0	0,0	0	0,0	0	0,0	
e 1	38	35	92,1	0	0,0	2	5,3	0	0,0	1	2,6	0	0,0	0	0,0	18	18	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0		
e 2	40	39	97,5	0	0,0	1	2,5	0	0,0	0	0,0	0	0,0	0	0,0	27	26	96,3	0	0,0	1	3,7	0	0,0	0	0,0	0	0,0	0	0,0		
e 3	3	3	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	3	1	33,3	0	0,0	2	66,7	0	0,0	0	0,0	0	0,0	0	0,0		
e 4	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	0	0,0	0	0,0	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0		

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CD70115/B042162/data_analysis/ACE_CSR_1/prod/program/t_ae_resolved.sas
 Output: root/clinical_studies/RO7112689/CD70115/B042162/data_analysis/ACE_CSR_1/prod/output/t_ae_resolved_SRI_SP1_16NOV2022_42162.xls
 21MAY2024 18:54

POPULATION: Randomized Safety Population
ENDPOINT: Any AEs, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42162
Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	118	87,4	69	100,0	50	72,5

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_AE_SE1_16NOV2022_42162.xls
 12FEB2024 22:02

POPULATION: Randomized Safety Population
ENDPOINT: AEs Grade >= 3, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42162
Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	32	23,7	69	100,0	13	18,8

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_GE3_SE1_16NOV2022_42162.xls
 12FEB2024 22:05

POPULATION: Randomized Safety Population
ENDPOINT: AEs Grade 3, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42162
Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	24	17,8	69	100,0	10	14,5

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/R07112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/R07112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_G3_SE1_16NOV2022_42162.xls
 12FEB2024 22:10

POPULATION: Randomized Safety Population
ENDPOINT: AEs Grade 4, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42162
Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	6	4,4	69	100,0	3	4,3

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/R07112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/R07112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_G4_SE1_16NOV2022_42162.xls
 12FEB2024 22:11

POPULATION: Randomized Safety Population

ENDPOINT: AEs Grade 5 (AEs leading to death), Crovalimab Safety Period

MODEL: Unstratified analysis

STUDY: BO42162

Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	2	1,5	69	100,0	0	0

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/R07112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas

Output: root/clinical_studies/R07112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_G5_SE1_16NOV2022_42162.xls

12FEB2024 22:13

POPULATION: Randomized Safety Population
ENDPOINT: Any SAEs, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42162
Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	22	16,3	69	100,0	6	8,7

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_SAE_SE1_16NOV2022_42162.xls

12FEB2024 22:04

POPULATION: Randomized Safety Population
ENDPOINT: AEs leading to treatment discontinuation, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42162
Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	1	0,7	69	100,0	1	1,4

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_DIS_SE1_16NOV2022_42162.xls
 12FEB2024 22:14

POPULATION: Randomized Safety Population
ENDPOINT: DILI, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42162
Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	0	0	69	100,0	0	0

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_DILI_SE1_16NOV2022_42162.xls
 12FEB2024 22:24

POPULATION: Randomized Safety Population
ENDPOINT: Type III hypersensitivity reactions Grade >=3, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42162
Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	0	0	69	100,0	4	5,8

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_H3G3_SE1_16NOV2022_42162.xls
 12FEB2024 22:08

POPULATION: Randomized Safety Population
ENDPOINT: Serious Type III hypersensitivity reactions, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42162
Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	0	0	69	100,0	0	0

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_H3S_SE1_16NOV2022_42162.xls
 12FEB2024 22:09

POPULATION: Randomized Safety Population
ENDPOINT: Type III hypersensitivity reactions, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42162
Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	0	0	69	100,0	11	15,9

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_HYP3_SE1_16NOV2022_42162.xls
 12FEB2024 22:06

POPULATION: Randomized Safety Population
ENDPOINT: Infections, including meningococcal meningitis, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42162
Dichotomous Analysis (Safety)

		Crovalimab (N=135)				Eculizumab (N=69)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	135	100,0	61	45,2	69	100,0	21	30,4

Clinical cut-off: 16NOV2022

Program: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42162/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_INFEC_SE1_16NOV2022_42162.xls
 12FEB2024 22:21

POPULATION: Primary Analysis Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42161

Demographics and Baseline Characteristics

	Crovalimab (N=44)	Eculizumab (N=42)	Total (N=86)
Age (years)			
n	44	42	86
Mean (SD)	44.7 (15.6)	49.5 (14.9)	47.0 (15.4)
Median	42,5	49	47
Min - Max	21 - 81	22 - 85	21 - 85
Age group (years)			
n	44	42	86
<65	39 (88.6%)	35 (83.3%)	74 (86.0%)
>=65	5 (11.4%)	7 (16.7%)	12 (14.0%)
Sex			
n	44	42	86
Male	20 (45.5%)	21 (50.0%)	41 (47.7%)
Female	24 (54.5%)	21 (50.0%)	45 (52.3%)
Race			
n	44	42	86
Asian	9 (20.5%)	7 (16.7%)	16 (18.6%)
Black or African American	2 (4.5%)	1 (2.4%)	3 (3.5%)
White	33 (75.0%)	30 (71.4%)	63 (73.3%)
Unknown		4 (9.5%)	4 (4.7%)
Ethnicity			
n	44	42	86

Hispanic or Latino	7 (15.9%)	8 (19.0%)	15 (17.4%)
Not Hispanic or Latino	36 (81.8%)	29 (69.0%)	65 (75.6%)
Not Reported	1 (2.3%)	5 (11.9%)	6 (7.0%)
Region 2			
n	44	42	86
North America/ Central and South America/ Europe	36 (81.8%)	35 (83.3%)	71 (82.6%)
Japan/Rest of Asia Pacific	8 (18.2%)	7 (16.7%)	15 (17.4%)
Weight (kg) at Baseline			
n	44	42	86
Mean (SD)	77.01 (17.47)	76.54 (18.03)	76.78 (17.64)
Median	80	75,1	78,5
Min - Max	45.2 - 120.0	47.2 - 126.4	45.2 - 126.4
Weight (kg) category at Baseline			
n	44	42	86
< 100kg	41 (93.2%)	38 (90.5%)	79 (91.9%)
>= 100kg	3 (6.8%)	4 (9.5%)	7 (8.1%)
BMI (kg/m^2) at Baseline			
n	42	41	83
Mean (SD)	26.58 (5.18)	26.65 (5.02)	26.62 (5.07)
Median	26,27	25,85	26,12
Min - Max	17.2 - 37.0	18.8 - 39.2	17.2 - 39.2
History of Smoking			
n	44	42	86
Never	39 (88.6%)	31 (73.8%)	70 (81.4%)
Current	3 (6.8%)	1 (2.4%)	4 (4.7%)
Former	2 (4.5%)	10 (23.8%)	12 (14.0%)
History of Alcohol Use			
n	44	42	86
Never	32 (72.7%)	28 (66.7%)	60 (69.8%)
Current	10 (22.7%)	10 (23.8%)	20 (23.3%)
Former	2 (4.5%)	4 (9.5%)	6 (7.0%)

History of Aplastic Anaemia			
n	44	42	86
Yes	15 (34.1%)	15 (35.7%)	30 (34.9%)
No	29 (65.9%)	27 (64.3%)	56 (65.1%)
Stratification factor: Transfusion history [pRBC infusion in the last 12 months]			
n	44	42	86
Yes	12 (27.3%)	10 (23.8%)	22 (25.6%)
No	32 (72.7%)	32 (76.2%)	64 (74.4%)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_dm.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_dm_PAP_31MAY2023_42161.xls

30APR2024 19:30

POPULATION: Primary Analysis Population

ENDPOINT:--

MODEL: --

STUDY: BO42161

Summary of PNH History

	Crovalimab (N=44)	Eculizumab (N=42)
Age at PNH diagnosis (yr)		
n	42	40
Mean (SD)	36.37 (15.53)	39.49 (15.01)
Median	32,52	39,6
Min - Max	17.2 - 79.3	20.0 - 83.7
Time from PNH diagnosis to enrollment (yr)		
n	42	40
Mean (SD)	8.18 (6.57)	10.77 (6.69)
Median	6,55	10,43
Min - Max	0.0 - 26.8	0.8 - 26.5
History of PNH-relevant conditions prior to enrollment (n, %)		
History of aplastic anemia		
n	44	42
Yes	15 (34.1%)	15 (35.7%)
No	29 (65.9%)	27 (64.3%)
History of myelodysplastic syndrome		
n	44	42
Yes	0	0
No	44 (100%)	42 (100%)
History of renal impairment		
n	44	42
Yes	7 (15.9%)	7 (16.7%)
No	37 (84.1%)	35 (83.3%)
History of major vascular events		
n	44	42
Yes	10 (22.7%)	9 (21.4%)
No	34 (77.3%)	33 (78.6%)
History of pRBC transfusion within 12 months prior to screening		
Number of patients with pRBC transfusion		

n	43	42
Yes	10 (23.3%)	10 (23.8%)
No	33 (76.7%)	32 (76.2%)
Number of units of pRBC transfused		
n	43	42
Mean (SD)	1.58 (3.76)	2.40 (5.54)
Median	0	0
Min - Max	0.0 - 14.0	0.0 - 24.0
Number of units of pRBC transfused		
n	43	42
0	33 (76.7%)	32 (76.2%)
0> to <4	4 (9.3%)	2 (4.8%)
>=4 to <14	4 (9.3%)	5 (11.9%)
>=14	2 (4.7%)	3 (7.1%)
Hemoglobin value at Baseline (g/L)		
n	44	42
Mean (SD)	109.74 (19.96)	107.27 (17.66)
Median	112,5	106,5
Min - Max	72.0 - 153.0	68.0 - 144.0
Haptoglobin value at Baseline (g/L)		
n	43	42
Mean (SD)	0.265 (0.447)	0.198 (0.269)
Median	0,05	0,05
Min - Max	0.05 - 2.18	0.05 - 1.09
LDH Value at Baseline (U/L)*		
n	44	42
Mean (SD)	249.16 (65.54)	234.20 (55.27)
Median	237,5	225,5
Min - Max	138.0 - 406.0	155.5 - 455.5
LDH value at Baseline (xULN)*		
n	44	42
Mean (SD)	1.06 (0.28)	1.00 (0.24)
Median	1,01	0,96
Min - Max	0.6 - 1.7	0.7 - 1.9
LDH Level at Baseline		

n	44	42
<ULN	20 (45.5%)	24 (57.1%)
>=ULN<=1.5xULN	21 (47.7%)	16 (38.1%)
>1.5xULN	3 (6.8%)	2 (4.8%)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/R07112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_dm_pnh.sas

Output: root/clinical_studies/R07112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_dm_pnh_PAP_31MAY2023_42161.xls

12JUN2024 7:15

POPULATION: Randomized Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42161

Demographics and Baseline Characteristics

	Crovalimab (N=44)	Eculizumab (N=42)	Total (N=86)
Age (years)			
n	44	42	86
Mean (SD)	44.7 (15.6)	49.5 (14.9)	47.0 (15.4)
Median	42,5	49	47
Min - Max	21 - 81	22 - 85	21 - 85
Age group (years)			
n	44	42	86
<65	39 (88.6%)	35 (83.3%)	74 (86.0%)
>=65	5 (11.4%)	7 (16.7%)	12 (14.0%)
Sex			
n	44	42	86
Male	20 (45.5%)	21 (50.0%)	41 (47.7%)
Female	24 (54.5%)	21 (50.0%)	45 (52.3%)
Race			
n	44	42	86
Asian	9 (20.5%)	7 (16.7%)	16 (18.6%)
Black or African American	2 (4.5%)	1 (2.4%)	3 (3.5%)
White	33 (75.0%)	30 (71.4%)	63 (73.3%)
Unknown		4 (9.5%)	4 (4.7%)
Ethnicity			
n	44	42	86

Hispanic or Latino	7 (15.9%)	8 (19.0%)	15 (17.4%)
Not Hispanic or Latino	36 (81.8%)	29 (69.0%)	65 (75.6%)
Not Reported	1 (2.3%)	5 (11.9%)	6 (7.0%)
Region 2			
n	44	42	86
North America/ Central and South America/ Europe	36 (81.8%)	35 (83.3%)	71 (82.6%)
Japan/Rest of Asia Pacific	8 (18.2%)	7 (16.7%)	15 (17.4%)
Weight (kg) at Baseline			
n	44	42	86
Mean (SD)	77.01 (17.47)	76.54 (18.03)	76.78 (17.64)
Median	80	75,1	78,5
Min - Max	45.2 - 120.0	47.2 - 126.4	45.2 - 126.4
Weight (kg) category at Baseline			
n	44	42	86
< 100kg	41 (93.2%)	38 (90.5%)	79 (91.9%)
>= 100kg	3 (6.8%)	4 (9.5%)	7 (8.1%)
BMI (kg/m^2) at Baseline			
n	42	41	83
Mean (SD)	26.58 (5.18)	26.65 (5.02)	26.62 (5.07)
Median	26,27	25,85	26,12
Min - Max	17.2 - 37.0	18.8 - 39.2	17.2 - 39.2
History of Smoking			
n	44	42	86
Never	39 (88.6%)	31 (73.8%)	70 (81.4%)
Current	3 (6.8%)	1 (2.4%)	4 (4.7%)
Former	2 (4.5%)	10 (23.8%)	12 (14.0%)
History of Alcohol Use			
n	44	42	86
Never	32 (72.7%)	28 (66.7%)	60 (69.8%)
Current	10 (22.7%)	10 (23.8%)	20 (23.3%)
Former	2 (4.5%)	4 (9.5%)	6 (7.0%)

History of Aplastic Anaemia			
n	44	42	86
Yes	15 (34.1%)	15 (35.7%)	30 (34.9%)
No	29 (65.9%)	27 (64.3%)	56 (65.1%)
Stratification factor: Transfusion history [pRBC infusion in the last 12 months]			
n	44	42	86
Yes	12 (27.3%)	10 (23.8%)	22 (25.6%)
No	32 (72.7%)	32 (76.2%)	64 (74.4%)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_dm.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_dm_RND1_31MAY2023_42161.xls

30APR2024 19:31

POPULATION: Randomized Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42161

Randomization Stratification Factors per arm

Stratification factor: Transfusion history (pRBC infusion in the last 12 months)

	Crovalimab (N=44)			Eculizumab (N=42)		
	eCRF data			eCRF data		
IxRS data	Yes	No	Total	Yes	No	Total
Yes	12 (27.3%)	0	12 (27.3%)	10 (23.8%)	0	10 (23.8%)
No	0	32 (72.7%)	32 (72.7%)	0	32 (76.2%)	32 (76.2%)
Total	12 (27.3%)	32 (72.7%)	44 (100%)	10 (23.8%)	32 (76.2%)	42 (100%)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_dm_str.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_dm_str_RND1_31MAY2023_42161.xls

30APR2024 19:34

POPULATION: Randomized Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42161

Disposition of Patients per Arm

	Crovalimab (N=44)	Eculizumab (N=42)	Total (N=86)
Number of Screenings	44 (100%)	42 (100%)	86 (100%)
Screening number 1	43 (97.7%)	41 (97.6%)	84 (97.7%)
Screening number 2	1 (2.3%)	1 (2.4%)	2 (2.3%)
Discontinued Study	2 (4.5%)	1 (2.4%)	3 (3.5%)
Adverse Event	0	0	0
Death	1 (2.3%)	0	1 (1.2%)
Lost To Follow-Up	0	0	0
Protocol Deviation	0	1 (2.4%)	1 (1.2%)
Non-Compliance	0	0	0
Withdrawal By Subject	1 (2.3%)	0	1 (1.2%)
Physician Decision	0	0	0
Other	0	0	0
Discontinued Treatment	2 (4.5%)	5 (11.9%)	7 (8.1%)
Adverse event	0	1 (2.4%)	1 (1.2%)
Pregnancy	0	0	0
Death	1 (2.3%)	0	1 (1.2%)
Lost to follow-up	0	0	0
Lack of Efficacy	0	0	0
Protocol Deviation	0	1 (2.4%)	1 (1.2%)
Non-Compliance With Study Drug	0	0	0
Non-Compliance	0	0	0
Withdrawal By Subject	1 (2.3%)	1 (2.4%)	2 (2.3%)
Physician Decision	0	1 (2.4%)	1 (1.2%)

Progressive Disease	0	0	0
Symptomatic deterioration	0	0	0
Other	0	1 (2.4%)	1 (1.2%)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ds.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ds_RND1_31MAY2023_42161.xls

03MAY2024 19:42

POPULATION: Primary Analysis Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42161

Number of Centers/Countries/Geographical Regions with <10, >=10 patients per arm

	Center				Country				Geographical region (3)			
	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)
Overall	52	100,0	86	100,0	20	100,0	86	100,0	2	100,0	86	100,0
with <10 patients per arm (1)	52	100,0	86	100,0	20	100,0	86	100,0	1	50,0	15	17,4
with >=10 patients per arm (2)	0	NE	NE	NE	0	NE	NE	NE	1	50,0	71	82,6

(1): ' <10 patients category ' if at least one treatment arm has <10 patients. (2): ' >=10 patients ' category if all treatment arms have >=10 patients.

(3): Geographical regions:North America/ Central and South America/ Europe; Japan/Rest of Asia Pacific. (4): Number of centers.

(5): % of centers compared to overall number of centers. (6): Number of patients randomized in the corresponding category (e.g .Number of patients randomized in centers with <10 pts per arm). (7): % of randomized patients compared to overall number of randomized patients (e.g . % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients).

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_center.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_center_FAP_31MAY2023_42161.xls

20MAY2024 14:59

POPULATION: Randomized Population

ENDPOINT: Primary Efficacy Period

MODEL: descriptive

STUDY: BO42161

Summary of concomitant medication per arm

ATC Class Level 2 Medication	Crovalimab (N=44)	Eculizumab (N=42)
Total number of patients with at least one treatment	34 (77.3%)	31 (73.8%)
Total number of treatments	278	157
VACCINES		
Total number of patients with at least one treatment	18 (40.9%)	22 (52.4%)
Total number of treatments	35	30
TOZINAMERAN	8 (18.2%)	11 (26.2%)
INFLUENZA VACCINE	3 (6.8%)	4 (9.5%)
MENINGOCOCCAL VACCINE B	4 (9.1%)	3 (7.1%)
ELASOMERAN	1 (2.3%)	4 (9.5%)
INFLUENZA VACCINE INACT SPLIT 4V	2 (4.5%)	1 (2.4%)
MENINGOCOCCAL VACCINE A/C/Y/W	2 (4.5%)	1 (2.4%)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (TET TOX)	3 (6.8%)	0
MENINGOCOCCAL VACCINE B RFHBP/NADA/NHBA OMV	2 (4.5%)	1 (2.4%)
COVID-19 VACCINE	1 (2.3%)	1 (2.4%)
COVID-19 VACCINE NRVV AD26 (JNJ 78436735)	1 (2.3%)	0
HIB VACCINE	1 (2.3%)	0
INFLUENZA VACCINE INACT SAG 4V	1 (2.3%)	0
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (DIP TOX)	1 (2.3%)	0
MENINGOCOCCAL VACCINE A/C/Y/W POLYSACCH	1 (2.3%)	0
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	1 (2.3%)	0
OPHTHALMOLOGICALS		
Total number of patients with at least one treatment	21 (47.7%)	11 (26.2%)
Total number of treatments	75	22
CIPROFLOXACIN	3 (6.8%)	3 (7.1%)
PREDNISOLONE	3 (6.8%)	2 (4.8%)
LEVOFLOXACIN	3 (6.8%)	0
LIDOCAINE	2 (4.5%)	1 (2.4%)

METHYLPREDNISOLONE	3 (6.8%)	0
ACETYLCYSTEINE	2 (4.5%)	0
AZITHROMYCIN	2 (4.5%)	0
CYANOCOBALAMIN	1 (2.3%)	1 (2.4%)
DICLOFENAC	2 (4.5%)	0
FLURBIPROFEN	2 (4.5%)	0
HYDROCORTISONE	2 (4.5%)	0
SODIUM CHLORIDE	2 (4.5%)	0
ACICLOVIR	1 (2.3%)	0
AMPICILLIN	0	1 (2.4%)
ASCORBIC ACID	1 (2.3%)	0
BETAMETHASONE	1 (2.3%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (2.3%)	0
BIMATOPROST;TIMOLOL MALEATE	0	1 (2.4%)
BROMFENAC SODIUM	1 (2.3%)	0
CETIRIZINE HYDROCHLORIDE	1 (2.3%)	0
CHLORAMPHENICOL;HYDROCORTISONE;RETINOL	0	1 (2.4%)
CHONDROITIN SULFATE SODIUM;HYALURONATE SODIUM	1 (2.3%)	0
CICLOSPORIN	0	1 (2.4%)
CIPROFLOXACIN HYDROCHLORIDE	1 (2.3%)	0
CLOTRIMAZOLE	1 (2.3%)	0
COLISTIN	1 (2.3%)	0
DEXAMETHASONE	1 (2.3%)	0
DICLOFENAC SODIUM	1 (2.3%)	0
DIMETICONE	0	1 (2.4%)
EPINASTINE HYDROCHLORIDE	0	1 (2.4%)
EPINEPHRINE	1 (2.3%)	0
EPINEPHRINE HYDROCHLORIDE	1 (2.3%)	0
FLUDROCORTISONE ACETATE;GRAMICIDIN;NEOMYCIN SULFATE	1 (2.3%)	0
FLUOCINOLONE ACETONIDE	1 (2.3%)	0
GATIFLOXACIN	1 (2.3%)	0
HEPARIN	0	1 (2.4%)
HYALURONATE SODIUM	1 (2.3%)	0
HYDROCORTISONE SODIUM SUCCINATE	0	1 (2.4%)
KETOROLAC TROMETHAMINE	1 (2.3%)	0
LIDOCAINE HYDROCHLORIDE	1 (2.3%)	0
MOXIFLOXACIN HYDROCHLORIDE	1 (2.3%)	0
NAPROXEN	1 (2.3%)	0
NEOMYCIN SULFATE	1 (2.3%)	0
NEOMYCIN SULFATE;TYROTHRIN	1 (2.3%)	0
OFLOXACIN	1 (2.3%)	0
OXIGLUTATIONE	1 (2.3%)	0

OXYMETAZOLINE HYDROCHLORIDE	1 (2.3%)	0
PHENYLEPHRINE HYDROCHLORIDE	1 (2.3%)	0
PHENYLEPHRINE HYDROCHLORIDE;TROPICAMIDE	1 (2.3%)	0
PIROXICAM	1 (2.3%)	0
POTASSIUM CHLORIDE	1 (2.3%)	0
POVIDONE-IODINE	1 (2.3%)	0
PREDNISONE	1 (2.3%)	0
REBAMIPIDE	0	1 (2.4%)
TOBRAMYCIN	0	1 (2.4%)
VANCOMYCIN	1 (2.3%)	0
ANALGESICS		
Total number of patients with at least one treatment	16 (36.4%)	11 (26.2%)
Total number of treatments	29	20
PARACETAMOL	11 (25.0%)	6 (14.3%)
METAMIZOLE SODIUM	3 (6.8%)	2 (4.8%)
HYOSCINE;METAMIZOLE SODIUM	2 (4.5%)	0
TRAMADOL	2 (4.5%)	0
ACETYLSALICYLIC ACID	0	1 (2.4%)
CAFFEINE;CODEINE PHOSPHATE;PARACETAMOL	1 (2.3%)	0
FENTANYL	0	1 (2.4%)
FENTANYL CITRATE	1 (2.3%)	0
HYOSCINE BUTYLBROMIDE;METAMIZOLE SODIUM	1 (2.3%)	0
NAPROXEN;SUMATRIPTAN	1 (2.3%)	0
OXCARBAZEPINE	0	1 (2.4%)
PREGABALIN	0	1 (2.4%)
VENLAFAXINE	1 (2.3%)	0
ANTIBACTERIALS FOR SYSTEMIC USE		
Total number of patients with at least one treatment	20 (45.5%)	7 (16.7%)
Total number of treatments	52	22
AMOXICILLIN	5 (11.4%)	1 (2.4%)
CIPROFLOXACIN	3 (6.8%)	3 (7.1%)
AMOXICILLIN;CLAVULANATE POTASSIUM	2 (4.5%)	1 (2.4%)
CLAVULANIC ACID	3 (6.8%)	0
LEVOFLOXACIN	3 (6.8%)	0
AZITHROMYCIN	2 (4.5%)	0
CEFALEXIN	1 (2.3%)	1 (2.4%)
CEFTRIAZONE	1 (2.3%)	1 (2.4%)
CEFTRIAZONE SODIUM SESQUATERHYDRATE	2 (4.5%)	0
DOXYCYCLINE	1 (2.3%)	1 (2.4%)
NITROFURANTOIN	0	2 (4.8%)

PHENOXYMETHYLPENICILLIN	0	2 (4.8%)
AMOXICILLIN;CLAVULANIC ACID	1 (2.3%)	0
AMPICILLIN	0	1 (2.4%)
CEFAZOLIN	1 (2.3%)	0
CEFCAPENE PIVOXIL HYDROCHLORIDE HYDRATE	1 (2.3%)	0
CEFDITOREN PIVOXIL	0	1 (2.4%)
CEFTAZIDIME	1 (2.3%)	0
CEFTRIAXONE SODIUM	0	1 (2.4%)
CIPROFLOXACIN HYDROCHLORIDE	1 (2.3%)	0
CLINDAMYCIN	0	1 (2.4%)
COLISTIN	1 (2.3%)	0
FLOMOXEF	1 (2.3%)	0
FLUCLOXACILLIN	1 (2.3%)	0
GATIFLOXACIN	1 (2.3%)	0
MEROPENEM	1 (2.3%)	0
METRONIDAZOLE	1 (2.3%)	0
MOXIFLOXACIN HYDROCHLORIDE	1 (2.3%)	0
NEOMYCIN SULFATE	1 (2.3%)	0
OFLOXACIN	1 (2.3%)	0
OXACILLIN	1 (2.3%)	0
PHENOXYMETHYLPENICILLIN BENZATHINE	1 (2.3%)	0
SULFAMETHOXAZOLE;TRIMETHOPRIM	0	1 (2.4%)
TOBRAMYCIN	0	1 (2.4%)
VANCOMYCIN	1 (2.3%)	0
STOMATOLOGICAL PREPARATIONS		
Total number of patients with at least one treatment	15 (34.1%)	11 (26.2%)
Total number of treatments	40	15
PREDNISOLONE	3 (6.8%)	2 (4.8%)
KETOPROFEN	3 (6.8%)	0
LIDOCAINE	2 (4.5%)	1 (2.4%)
NIMESULIDE	1 (2.3%)	2 (4.8%)
DICLOFENAC	2 (4.5%)	0
DOXYCYCLINE	1 (2.3%)	1 (2.4%)
FLURBIPROFEN	2 (4.5%)	0
HYDROCORTISONE	2 (4.5%)	0
SODIUM CHLORIDE	2 (4.5%)	0
ACETYLSALICYLIC ACID	0	1 (2.4%)
BENZYDAMINE HYDROCHLORIDE	0	1 (2.4%)
BETAMETHASONE	1 (2.3%)	0
CLOBETASOL	1 (2.3%)	0
CLOBETASOL PROPIONATE	1 (2.3%)	0

CLOTRIMAZOLE	1 (2.3%)	0
DEXAMETHASONE	1 (2.3%)	0
DICLOFENAC SODIUM	1 (2.3%)	0
DIMETICONE	0	1 (2.4%)
EPINEPHRINE	1 (2.3%)	0
EPINEPHRINE HYDROCHLORIDE	1 (2.3%)	0
HEXAMIDINE ISETIONATE;TETRACAINE HYDROCHLORIDE	0	1 (2.4%)
HYALURONATE SODIUM	1 (2.3%)	0
HYDROCORTISONE SODIUM SUCCINATE	0	1 (2.4%)
LIDOCAINE HYDROCHLORIDE	1 (2.3%)	0
METRONIDAZOLE	1 (2.3%)	0
NAPROXEN	1 (2.3%)	0
NEOMYCIN SULFATE	1 (2.3%)	0
NYSTATIN	1 (2.3%)	0
OXYGEN	1 (2.3%)	0
POVIDONE-IODINE	1 (2.3%)	0
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN		
Total number of patients with at least one treatment	15 (34.1%)	7 (16.7%)
Total number of treatments	30	8
FOLIC ACID	4 (9.1%)	1 (2.4%)
IBUPROFEN	4 (9.1%)	0
KETOPROFEN	3 (6.8%)	0
NIMESULIDE	1 (2.3%)	2 (4.8%)
DICLOFENAC	2 (4.5%)	0
FLURBIPROFEN	2 (4.5%)	0
ACECLOFENAC	0	1 (2.4%)
ACETYLSALICYLIC ACID	0	1 (2.4%)
BENZYDAMINE HYDROCHLORIDE	0	1 (2.4%)
CAMPHOR;CHLORPHENAMINE MALEATE;HEXACHLOROPHENE;LIDOCAINE HYDROCHLORIDE;MENTHOL;METHYL SALICYLATE	1 (2.3%)	0
DICLOFENAC SODIUM	1 (2.3%)	0
KETOROLAC TROMETHAMINE	1 (2.3%)	0
LOXOPROFEN	1 (2.3%)	0
LOXOPROFEN SODIUM	1 (2.3%)	0
LOXOPROFEN SODIUM DIHYDRATE	0	1 (2.4%)
NAPROXEN	1 (2.3%)	0
PIROXICAM	1 (2.3%)	0
OTOLOGICALS		
Total number of patients with at least one treatment	15 (34.1%)	6 (14.3%)
Total number of treatments	36	11
CIPROFLOXACIN	3 (6.8%)	3 (7.1%)

PREDNISOLONE	3 (6.8%)	2 (4.8%)
LEVOFLOXACIN	3 (6.8%)	0
LIDOCAINE	2 (4.5%)	1 (2.4%)
HYDROCORTISONE	2 (4.5%)	0
SODIUM CHLORIDE	2 (4.5%)	0
BETAMETHASONE	1 (2.3%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (2.3%)	0
CIPROFLOXACIN HYDROCHLORIDE	1 (2.3%)	0
CLOTRIMAZOLE	1 (2.3%)	0
DEXAMETHASONE	1 (2.3%)	0
FLUOCINOLONE ACETONIDE	1 (2.3%)	0
GRAMICIDIN;NEOMYCIN SULFATE;NYSTATIN;TRIAMCINOLONE ACETONIDE	1 (2.3%)	0
HYDROCORTISONE SODIUM SUCCINATE	0	1 (2.4%)
LIDOCAINE HYDROCHLORIDE	1 (2.3%)	0
NEOMYCIN SULFATE	1 (2.3%)	0
OFLOXACIN	1 (2.3%)	0
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS		
Total number of patients with at least one treatment	14 (31.8%)	6 (14.3%)
Total number of treatments	27	7
IBUPROFEN	4 (9.1%)	0
KETOPROFEN	3 (6.8%)	0
NIMESULIDE	1 (2.3%)	2 (4.8%)
DICLOFENAC	2 (4.5%)	0
FLURBIPROFEN	2 (4.5%)	0
ACECLOFENAC	0	1 (2.4%)
BENZYDAMINE HYDROCHLORIDE	0	1 (2.4%)
BROMFENAC SODIUM	1 (2.3%)	0
DICLOFENAC SODIUM	1 (2.3%)	0
GLUCOSAMINE SULFATE SODIUM CHLORIDE	0	1 (2.4%)
KETOROLAC TROMETHAMINE	1 (2.3%)	0
LOXOPROFEN	1 (2.3%)	0
LOXOPROFEN SODIUM	1 (2.3%)	0
LOXOPROFEN SODIUM DIHYDRATE	0	1 (2.4%)
NAPROXEN	1 (2.3%)	0
PIROXICAM	1 (2.3%)	0
OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS		
Total number of patients with at least one treatment	13 (29.5%)	4 (9.5%)
Total number of treatments	27	5
CIPROFLOXACIN	3 (6.8%)	3 (7.1%)
PREDNISOLONE	3 (6.8%)	2 (4.8%)

LEVOFLOXACIN	3 (6.8%)	0
BETAMETHASONE	1 (2.3%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (2.3%)	0
CIPROFLOXACIN HYDROCHLORIDE	1 (2.3%)	0
DEXAMETHASONE	1 (2.3%)	0
FLUDROCORTISONE ACETATE;GRAMICIDIN;NEOMYCIN SULFATE	1 (2.3%)	0
GATIFLOXACIN	1 (2.3%)	0
NEOMYCIN SULFATE	1 (2.3%)	0
OFLOXACIN	1 (2.3%)	0
ANTI-ACNE PREPARATIONS		
Total number of patients with at least one treatment	11 (25.0%)	5 (11.9%)
Total number of treatments	15	5
IBUPROFEN	4 (9.1%)	0
METHYLPREDNISOLONE	3 (6.8%)	0
AZITHROMYCIN	2 (4.5%)	0
DOXYCYCLINE	1 (2.3%)	1 (2.4%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	2 (4.8%)
CLINDAMYCIN	0	1 (2.4%)
DEXAMETHASONE	1 (2.3%)	0
DIMETICONE	0	1 (2.4%)
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS		
Total number of patients with at least one treatment	11 (25.0%)	5 (11.9%)
Total number of treatments	25	9
PREDNISOLONE	3 (6.8%)	2 (4.8%)
METHYLPREDNISOLONE	3 (6.8%)	0
HYDROCORTISONE	2 (4.5%)	0
METHYLPREDNISOLONE SODIUM SUCCINATE	0	2 (4.8%)
BETAMETHASONE	1 (2.3%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (2.3%)	0
CLOBETASOL	1 (2.3%)	0
CLOBETASOL PROPIONATE	1 (2.3%)	0
DESOXIMETASONE	1 (2.3%)	0
DEXAMETHASONE	1 (2.3%)	0
FLUDROCORTISONE ACETATE;GRAMICIDIN;NEOMYCIN SULFATE	1 (2.3%)	0
FLUCINOLONE ACETONIDE	1 (2.3%)	0
GRAMICIDIN;NEOMYCIN SULFATE;NYSTATIN;TRIAMCINOLONE ACETONIDE	1 (2.3%)	0
HYDROCORTISONE SODIUM SUCCINATE	0	1 (2.4%)
MOMETASONE	1 (2.3%)	0
PREDNISONE	1 (2.3%)	0

ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE		
Total number of patients with at least one treatment	10 (22.7%)	4 (9.5%)
Total number of treatments	18	4
CIPROFLOXACIN	3 (6.8%)	3 (7.1%)
LEVOFLOXACIN	3 (6.8%)	0
DOXYCYCLINE	1 (2.3%)	1 (2.4%)
ACICLOVIR	1 (2.3%)	0
CIPROFLOXACIN HYDROCHLORIDE	1 (2.3%)	0
METRONIDAZOLE	1 (2.3%)	0
NEOMYCIN SULFATE	1 (2.3%)	0
NEOMYCIN SULFATE;TYROTHRICIN	1 (2.3%)	0
OFLOXACIN	1 (2.3%)	0
THROAT PREPARATIONS		
Total number of patients with at least one treatment	11 (25.0%)	3 (7.1%)
Total number of treatments	23	3
IBUPROFEN	4 (9.1%)	0
KETOPROFEN	3 (6.8%)	0
LIDOCAINE	2 (4.5%)	1 (2.4%)
DICLOFENAC	2 (4.5%)	0
FLURBIPROFEN	2 (4.5%)	0
BENZYDAMINE HYDROCHLORIDE	0	1 (2.4%)
DICLOFENAC SODIUM	1 (2.3%)	0
HEXAMIDINE ISETIONATE;TETRACAINE HYDROCHLORIDE	0	1 (2.4%)
LIDOCAINE HYDROCHLORIDE	1 (2.3%)	0
NEOMYCIN SULFATE	1 (2.3%)	0
NEOMYCIN SULFATE;TYROTHRICIN	1 (2.3%)	0
POVIDONE-IODINE	1 (2.3%)	0
VASOPROTECTIVES		
Total number of patients with at least one treatment	8 (18.2%)	5 (11.9%)
Total number of treatments	19	9
PREDNISOLONE	3 (6.8%)	2 (4.8%)
LIDOCAINE	2 (4.5%)	1 (2.4%)
HYDROCORTISONE	2 (4.5%)	0
BETAMETHASONE	1 (2.3%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (2.3%)	0
DEXAMETHASONE	1 (2.3%)	0
FLUOCINOLONE ACETONIDE	1 (2.3%)	0
HEPARIN	0	1 (2.4%)
HYALURONATE SODIUM	1 (2.3%)	0
HYDROCORTISONE SODIUM SUCCINATE	0	1 (2.4%)

LIDOCAINE HYDROCHLORIDE	1 (2.3%)	0
PHENYLEPHRINE HYDROCHLORIDE	1 (2.3%)	0
CORTICOSTEROIDS FOR SYSTEMIC USE		
Total number of patients with at least one treatment	7 (15.9%)	5 (11.9%)
Total number of treatments	17	9
PREDNISOLONE	3 (6.8%)	2 (4.8%)
METHYLPREDNISOLONE	3 (6.8%)	0
HYDROCORTISONE	2 (4.5%)	0
METHYLPREDNISOLONE SODIUM SUCCINATE	0	2 (4.8%)
BETAMETHASONE	1 (2.3%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (2.3%)	0
DEXAMETHASONE	1 (2.3%)	0
HYDROCORTISONE SODIUM SUCCINATE	0	1 (2.4%)
PREDNISON	1 (2.3%)	0
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS		
Total number of patients with at least one treatment	8 (18.2%)	4 (9.5%)
Total number of treatments	13	4
CIPROFLOXACIN	3 (6.8%)	3 (7.1%)
ASCORBIC ACID	1 (2.3%)	0
CIPROFLOXACIN HYDROCHLORIDE	1 (2.3%)	0
CLINDAMYCIN	0	1 (2.4%)
CLOTRIMAZOLE	1 (2.3%)	0
LACTOBACILLUS NOS	1 (2.3%)	0
METRONIDAZOLE	1 (2.3%)	0
NYSTATIN	1 (2.3%)	0
OFLOXACIN	1 (2.3%)	0
POVIDONE-IODINE	1 (2.3%)	0
ANTIANEMIC PREPARATIONS		
Total number of patients with at least one treatment	7 (15.9%)	4 (9.5%)
Total number of treatments	12	6
FOLIC ACID	4 (9.1%)	1 (2.4%)
CYANOCOBALAMIN	1 (2.3%)	1 (2.4%)
IRON	1 (2.3%)	1 (2.4%)
CALCIUM LEVOMEFOLATE	0	1 (2.4%)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE	1 (2.3%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	1 (2.3%)	0
DARBEPOETIN ALFA	1 (2.3%)	0
EPOETIN ALFA	1 (2.3%)	0
FERRIC CARBOXYMALTOSE	0	1 (2.4%)

HYDROXOCOBALAMIN	1 (2.3%)	0
ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS		
Total number of patients with at least one treatment	8 (18.2%)	3 (7.1%)
Total number of treatments	18	7
PREDNISOLONE	3 (6.8%)	2 (4.8%)
HYDROCORTISONE	2 (4.5%)	0
BETAMETHASONE	1 (2.3%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (2.3%)	0
COLISTIN	1 (2.3%)	0
HYDROCORTISONE SODIUM SUCCINATE	0	1 (2.4%)
LACTOBACILLUS NOS	1 (2.3%)	0
NEOMYCIN SULFATE	1 (2.3%)	0
NYSTATIN	1 (2.3%)	0
PREDNISONE	1 (2.3%)	0
VANCOMYCIN	1 (2.3%)	0
ANTI-HISTAMINES FOR SYSTEMIC USE		
Total number of patients with at least one treatment	6 (13.6%)	5 (11.9%)
Total number of treatments	12	17
LEVOCETIRIZINE DIHYDROCHLORIDE	0	3 (7.1%)
LORATADINE	2 (4.5%)	1 (2.4%)
CHLORPHENAMINE MALEATE	1 (2.3%)	1 (2.4%)
CETIRIZINE HYDROCHLORIDE	1 (2.3%)	0
CINNARIZINE	1 (2.3%)	0
DIPHENHYDRAMINE HYDROCHLORIDE	1 (2.3%)	0
EPINASTINE HYDROCHLORIDE	0	1 (2.4%)
HYDROXYZINE HYDROCHLORIDE	1 (2.3%)	0
ANTI-PRURITICS, INCL. ANTI-HISTAMINES, ANESTHETICS, ETC.		
Total number of patients with at least one treatment	6 (13.6%)	5 (11.9%)
Total number of treatments	17	18
LEVOCETIRIZINE DIHYDROCHLORIDE	0	3 (7.1%)
LIDOCAINE	2 (4.5%)	1 (2.4%)
LORATADINE	2 (4.5%)	1 (2.4%)
CHLORPHENAMINE MALEATE	1 (2.3%)	1 (2.4%)
CAMPHOR;CHLORPHENAMINE MALEATE;HEXACHLOROPHENE;LIDOCAINE HYDROCHLORIDE;MENTHOL;METHYL SALICYLATE	1 (2.3%)	0
CETIRIZINE HYDROCHLORIDE	1 (2.3%)	0
DIPHENHYDRAMINE HYDROCHLORIDE	1 (2.3%)	0
DOXEPIN HYDROCHLORIDE	1 (2.3%)	0
EPINASTINE HYDROCHLORIDE	0	1 (2.4%)
HYDROXYZINE HYDROCHLORIDE	1 (2.3%)	0

LIDOCAINE HYDROCHLORIDE	1 (2.3%)	0
OTHER DERMATOLOGICAL PREPARATIONS		
Total number of patients with at least one treatment	10 (22.7%)	1 (2.4%)
Total number of treatments	19	1
IBUPROFEN	4 (9.1%)	0
DICLOFENAC	2 (4.5%)	0
ASCORBIC ACID	1 (2.3%)	0
DICLOFENAC SODIUM	1 (2.3%)	0
DIMETHYL SULFOXIDE;FLUOROURACIL;SALICYLIC ACID	0	1 (2.4%)
ESTRADIOL	1 (2.3%)	0
HYALURONATE SODIUM	1 (2.3%)	0
NITROUS OXIDE	1 (2.3%)	0
OXYGEN	1 (2.3%)	0
OXYMETAZOLINE HYDROCHLORIDE	1 (2.3%)	0
POVIDONE-IODINE	1 (2.3%)	0
HOMEOPATHIC PREPARATION		
Total number of patients with at least one treatment	7 (15.9%)	3 (7.1%)
Total number of treatments	9	4
CYANOCOBALAMIN	1 (2.3%)	1 (2.4%)
IRON	1 (2.3%)	1 (2.4%)
SODIUM CHLORIDE	2 (4.5%)	0
ACTAEA RACEMOSA;LACHESIS MUTA;SANGUINARIA CANADENSIS;SEPIA OFFICINALIS;STRYCHNOS IGNATII	0	1 (2.4%)
ASCORBIC ACID	1 (2.3%)	0
EPINEPHRINE	1 (2.3%)	0
POTASSIUM CHLORIDE	1 (2.3%)	0
SILYBUM MARIANUM	1 (2.3%)	0
NASAL PREPARATIONS		
Total number of patients with at least one treatment	8 (18.2%)	2 (4.8%)
Total number of treatments	22	2
PREDNISOLONE	3 (6.8%)	2 (4.8%)
ACETYLCYSTEINE	2 (4.5%)	0
SODIUM CHLORIDE	2 (4.5%)	0
BETAMETHASONE	1 (2.3%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (2.3%)	0
DEXAMETHASONE	1 (2.3%)	0
EPINEPHRINE	1 (2.3%)	0
EPINEPHRINE HYDROCHLORIDE	1 (2.3%)	0
HYALURONATE SODIUM	1 (2.3%)	0
IPRATROPIUM BROMIDE	1 (2.3%)	0

MOMETASONE	1 (2.3%)	0
OXYMETAZOLINE HYDROCHLORIDE	1 (2.3%)	0
PHENYLEPHRINE HYDROCHLORIDE	1 (2.3%)	0
POVIDONE-IODINE	1 (2.3%)	0
ALL OTHER THERAPEUTIC PRODUCTS		
Total number of patients with at least one treatment	6 (13.6%)	3 (7.1%)
Total number of treatments	8	4
ACETYLCYSTEINE	2 (4.5%)	0
IRON	1 (2.3%)	1 (2.4%)
ACTAEA RACEMOSA;LACHESIS MUTA;SANGUINARIA CANADENSIS;SEPIA OFFICINALIS;STRYCHNOS IGNATII	0	1 (2.4%)
ASCORBIC ACID	1 (2.3%)	0
CALCIUM POLYSTYRENE SULFONATE	0	1 (2.4%)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE	1 (2.3%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	1 (2.3%)	0
HYDROXOCOBALAMIN	1 (2.3%)	0
OXYGEN	1 (2.3%)	0
PSYCHOLEPTICS		
Total number of patients with at least one treatment	7 (15.9%)	2 (4.8%)
Total number of treatments	10	8
ALPRAZOLAM	2 (4.5%)	0
DIAZEPAM	1 (2.3%)	0
DIPHENHYDRAMINE HYDROCHLORIDE	1 (2.3%)	0
DOXEFIN HYDROCHLORIDE	1 (2.3%)	0
HYDROXYZINE HYDROCHLORIDE	1 (2.3%)	0
OXAZEPAM	0	1 (2.4%)
PREGABALIN	0	1 (2.4%)
QUETIAPINE FUMARATE	0	1 (2.4%)
SERTRALINE	1 (2.3%)	0
VENLAFAXINE	1 (2.3%)	0
CARDIAC THERAPY		
Total number of patients with at least one treatment	7 (15.9%)	1 (2.4%)
Total number of treatments	16	1
IBUPROFEN	4 (9.1%)	0
LIDOCAINE	2 (4.5%)	1 (2.4%)
EPINEPHRINE	1 (2.3%)	0
EPINEPHRINE HYDROCHLORIDE	1 (2.3%)	0
IPRATROPIUM BROMIDE	1 (2.3%)	0
LIDOCAINE HYDROCHLORIDE	1 (2.3%)	0
LIDOCAINE HYDROCHLORIDE MONOHYDRATE	1 (2.3%)	0

PHENYLEPHRINE HYDROCHLORIDE	1 (2.3%)	0
OTHER GYNECOLOGICALS		
Total number of patients with at least one treatment	6 (13.6%)	2 (4.8%)
Total number of treatments	12	2
IBUPROFEN	4 (9.1%)	0
BENZYLAMINE HYDROCHLORIDE	0	1 (2.4%)
CHONDROITIN SULFATE SODIUM;HYALURONATE SODIUM	1 (2.3%)	0
HYALURONATE SODIUM	1 (2.3%)	0
NAPROXEN	1 (2.3%)	0
PROGESTERONE	0	1 (2.4%)
DRUGS FOR ACID RELATED DISORDERS		
Total number of patients with at least one treatment	4 (9.1%)	3 (7.1%)
Total number of treatments	4	3
OMEPRAZOLE	2 (4.5%)	1 (2.4%)
CHONDROITIN SULFATE SODIUM;HYALURONATE SODIUM	1 (2.3%)	0
LANSOPRAZOLE	1 (2.3%)	0
PANTOPRAZOLE	0	1 (2.4%)
REBAMIPIDE	0	1 (2.4%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES		
Total number of patients with at least one treatment	7 (15.9%)	0
Total number of treatments	9	0
BETAMETHASONE	1 (2.3%)	0
BETAMETHASONE SODIUM PHOSPHATE	1 (2.3%)	0
DEXAMETHASONE	1 (2.3%)	0
EPINEPHRINE	1 (2.3%)	0
EPINEPHRINE HYDROCHLORIDE	1 (2.3%)	0
IPRATROPIUM BROMIDE	1 (2.3%)	0
MOMETASONE	1 (2.3%)	0
PROMELASE	1 (2.3%)	0
PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS		
Total number of patients with at least one treatment	5 (11.4%)	2 (4.8%)
Total number of treatments	5	3
SODIUM CHLORIDE	2 (4.5%)	0
ALGINIC ACID;GLUCOSE;GLUCOSE OXIDASE;GUAIACOL;LACTOPEROXIDASE;MACROGOL	0	1 (2.4%)
CAMPHOR;CHLORPHENAMINE MALEATE;HEXACHLOROPHENE;LIDOCAINE HYDROCHLORIDE;MENTHOL;METHYL SALICYLATE	1 (2.3%)	0
COPPER GLUCONATE;HYALURONATE SODIUM;MADECASSOSIDE;MANGANESE GLUCONATE;ZINC GLUCONATE	0	1 (2.4%)
DIMETICONE	0	1 (2.4%)
HYALURONATE SODIUM	1 (2.3%)	0

PROMELASE	1 (2.3%)	0
ANTIEMETICS AND ANTINAUSEANTS		
Total number of patients with at least one treatment	5 (11.4%)	1 (2.4%)
Total number of treatments	10	1
HYOSCINE;METAMIZOLE SODIUM	2 (4.5%)	0
CINNARIZINE	1 (2.3%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE	1 (2.3%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	1 (2.3%)	0
DIPHENHYDRAMINE HYDROCHLORIDE	1 (2.3%)	0
HYDROXYZINE HYDROCHLORIDE	1 (2.3%)	0
HYOSCINE BUTYLBROMIDE;METAMIZOLE SODIUM	1 (2.3%)	0
METOCLOPRAMIDE	1 (2.3%)	0
METOCLOPRAMIDE HYDROCHLORIDE	0	1 (2.4%)
ONDANSETRON	1 (2.3%)	0
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS		
Total number of patients with at least one treatment	3 (6.8%)	3 (7.1%)
Total number of treatments	5	4
HYOSCINE;METAMIZOLE SODIUM	2 (4.5%)	0
ANGELICA ARCHANGELICA ROOT;CARUM CARVI FRUIT;CHELIDONIUM MAJUS HERB;GLYCYRRHIZA GLABRA ROOT;IBERIS AMARA;MATRICARIA CHAMOMILLA FLOWER;MELISSA OFFICINALIS LEAF;MENTHA X PIPERITA LEAF;SILYBUM MARIANUM FRUIT	0	1 (2.4%)
BROMOPRIDE	0	1 (2.4%)
DIMETICONE	0	1 (2.4%)
HYOSCINE BUTYLBROMIDE;METAMIZOLE SODIUM	1 (2.3%)	0
METOCLOPRAMIDE	1 (2.3%)	0
METOCLOPRAMIDE HYDROCHLORIDE	0	1 (2.4%)
SIMETICONE	1 (2.3%)	0
MINERAL SUPPLEMENTS		
Total number of patients with at least one treatment	5 (11.4%)	1 (2.4%)
Total number of treatments	6	2
SODIUM CHLORIDE	2 (4.5%)	0
CALCIUM	1 (2.3%)	0
MAGNESIUM	1 (2.3%)	0
MAGNESIUM L-THREONATE	0	1 (2.4%)
MAGNESIUM MALATE	0	1 (2.4%)
POTASSIUM CHLORIDE	1 (2.3%)	0
POTASSIUM GLUCONATE	1 (2.3%)	0
ANTITHROMBOTIC AGENTS		
Total number of patients with at least one treatment	1 (2.3%)	4 (9.5%)

Total number of treatments	2	15
WARFARIN	1 (2.3%)	1 (2.4%)
ACENOCOUMAROL	0	1 (2.4%)
ACETYLSALICYLIC ACID	0	1 (2.4%)
CLOPIDOGREL	0	1 (2.4%)
ENOXAPARIN	0	1 (2.4%)
ENOXAPARIN SODIUM	0	1 (2.4%)
HEPARIN	0	1 (2.4%)
COUGH AND COLD PREPARATIONS		
Total number of patients with at least one treatment	4 (9.1%)	1 (2.4%)
Total number of treatments	5	1
ACETYLCYSTEINE	2 (4.5%)	0
SODIUM CHLORIDE	2 (4.5%)	0
GENTIANA LUTEA ROOT;PRIMULA SPP. FLOWER;RUMEX SPP. HERB;SAMBUCUS NIGRA FLOWER;VERBENA OFFICINALIS HERB	1 (2.3%)	0
LEVODROPROPIZINE	0	1 (2.4%)
DIAGNOSTIC AGENTS		
Total number of patients with at least one treatment	4 (9.1%)	1 (2.4%)
Total number of treatments	5	1
FOLIC ACID	4 (9.1%)	1 (2.4%)
DIURETICS		
Total number of patients with at least one treatment	5 (11.4%)	0
Total number of treatments	5	0
FUROSEMIDE	2 (4.5%)	0
AZOSEMIDE	1 (2.3%)	0
HYDROCHLOROTHIAZIDE	1 (2.3%)	0
SPIRONOLACTONE	1 (2.3%)	0
OTHER NERVOUS SYSTEM DRUGS		
Total number of patients with at least one treatment	4 (9.1%)	1 (2.4%)
Total number of treatments	5	1
CYANOCOBALAMIN	1 (2.3%)	1 (2.4%)
CINNARIZINE	1 (2.3%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE	1 (2.3%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	1 (2.3%)	0
HYDROXOCOBALAMIN	1 (2.3%)	0
VITAMINS		
Total number of patients with at least one treatment	5 (11.4%)	0
Total number of treatments	5	0

ALFACALCIDOL	1 (2.3%)	0
ASCORBIC ACID	1 (2.3%)	0
COLECALCIFEROL	1 (2.3%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE	1 (2.3%)	0
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	1 (2.3%)	0
ANESTHETICS		
Total number of patients with at least one treatment	2 (4.5%)	2 (4.8%)
Total number of treatments	8	2
LIDOCAINE	2 (4.5%)	1 (2.4%)
FENTANYL	0	1 (2.4%)
FENTANYL CITRATE	1 (2.3%)	0
LIDOCAINE HYDROCHLORIDE	1 (2.3%)	0
LIDOCAINE HYDROCHLORIDE MONOHYDRATE	1 (2.3%)	0
NITROUS OXIDE	1 (2.3%)	0
PROPOFOL	1 (2.3%)	0
BILE AND LIVER THERAPY		
Total number of patients with at least one treatment	3 (6.8%)	1 (2.4%)
Total number of treatments	5	2
ACETYLCYSTEINE	2 (4.5%)	0
URSODEOXYCHOLIC ACID	1 (2.3%)	1 (2.4%)
ADENINE HYDROCHLORIDE;BIFENDATE;CARNITINE OROTATE;CYANOCOBALAMIN;LIVER;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN	0	1 (2.4%)
SILYBUM MARIANUM	1 (2.3%)	0
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS		
Total number of patients with at least one treatment	4 (9.1%)	0
Total number of treatments	5	0
SODIUM CHLORIDE	2 (4.5%)	0
GLUCOSE;SODIUM CHLORIDE;SODIUM LACTATE	1 (2.3%)	0
NEOMYCIN SULFATE	1 (2.3%)	0
POTASSIUM CHLORIDE	1 (2.3%)	0
MUSCLE RELAXANTS		
Total number of patients with at least one treatment	3 (6.8%)	1 (2.4%)
Total number of treatments	5	1
CAFFEINE;METAMIZOLE SODIUM;ORPHENADRINE CITRATE	1 (2.3%)	0
CHLORZOXAZONE;PARACETAMOL	1 (2.3%)	0
CYCLOBENZAPRINE	0	1 (2.4%)
DIAZEPAM	1 (2.3%)	0
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE		

Total number of patients with at least one treatment	3 (6.8%)	1 (2.4%)
Total number of treatments	4	1
ANGELICA ACUTILOBA ROOT;ASTRAGALUS SPP. ROOT;ATRACTYLODES LANCEA RHIZOME;CINNAMOMUM CASSIA BARK;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PANAX GINSENG ROOT;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA ROOT	1 (2.3%)	0
ANGELICA ARCHANGELICA ROOT;CARUM CARVI FRUIT;CHELIDONIUM MAJUS HERB;GLYCYRRHIZA GLABRA ROOT;IBERIS AMARA;MATRICARIA CHAMOMILLA FLOWER;MELISSA OFFICINALIS LEAF;MENTHA X PIPERITA LEAF;SILYBUM MARIANUM FRUIT	0	1 (2.4%)
GENTIANA LUTEA ROOT;PRIMULA SPP. FLOWER;RUMEX SPP. HERB;SAMBUCUS NIGRA FLOWER;VERBENA OFFICINALIS HERB	1 (2.3%)	0
SILYBUM MARIANUM	1 (2.3%)	0
ALL OTHER NON-THERAPEUTIC PRODUCTS		
Total number of patients with at least one treatment	3 (6.8%)	0
Total number of treatments	3	0
SODIUM CHLORIDE	2 (4.5%)	0
ASCORBIC ACID	1 (2.3%)	0
ANTIHEMORRHAGICS		
Total number of patients with at least one treatment	3 (6.8%)	0
Total number of treatments	4	0
ELTROMBOPAG OLAMINE	1 (2.3%)	0
EPINEPHRINE	1 (2.3%)	0
EPINEPHRINE HYDROCHLORIDE	1 (2.3%)	0
ANTIPROTOZOALS		
Total number of patients with at least one treatment	3 (6.8%)	0
Total number of treatments	3	0
CLOTRIMAZOLE	1 (2.3%)	0
METRONIDAZOLE	1 (2.3%)	0
OFLOXACIN	1 (2.3%)	0
DRUGS FOR CONSTIPATION		
Total number of patients with at least one treatment	3 (6.8%)	0
Total number of treatments	3	0
SODIUM CHLORIDE	2 (4.5%)	0
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 (2.3%)	0
DRUGS USED IN DIABETES		
Total number of patients with at least one treatment	3 (6.8%)	0
Total number of treatments	10	0
GLIBENCLAMIDE	1 (2.3%)	0
GLIMEPIRIDE;METFORMIN HYDROCHLORIDE	1 (2.3%)	0

INSULIN HUMAN	1 (2.3%)	0
INSULIN LISPRO;INSULIN LISPRO PROTAMINE SUSPENSION	1 (2.3%)	0
LINAGLIPTIN	1 (2.3%)	0
METFORMIN	1 (2.3%)	0
METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	1 (2.3%)	0
IMMUNOSTIMULANTS		
Total number of patients with at least one treatment	3 (6.8%)	0
Total number of treatments	3	0
ANGELICA ACUTILOBA ROOT;ASTRAGALUS SPP. ROOT;ATRACTYLODES LANCEA RHIZOME;CINNAMOMUM CASSIA BARK;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PAEONIA LACTIFLORA ROOT;PANAX GINSENG ROOT;PORIA COCOS SCLEROTIUM;REHMANNIA GLUTINOSA ROOT	1 (2.3%)	0
LENOGRASTIM	1 (2.3%)	0
OXIGLUTATIONE	1 (2.3%)	0
MEDICATED DRESSINGS		
Total number of patients with at least one treatment	3 (6.8%)	0
Total number of treatments	3	0
SODIUM CHLORIDE	2 (4.5%)	0
POVIDONE-IODINE	1 (2.3%)	0
PSYCHOANALEPTICS		
Total number of patients with at least one treatment	3 (6.8%)	0
Total number of treatments	5	0
DOXEPIN HYDROCHLORIDE	1 (2.3%)	0
SERTRALINE	1 (2.3%)	0
VENLAFAXINE	1 (2.3%)	0
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM		
Total number of patients with at least one treatment	2 (4.5%)	1 (2.4%)
Total number of treatments	3	2
DYDROGESTERONE	1 (2.3%)	0
ESTRADIOL	1 (2.3%)	0
ETHINYLESTRADIOL;LEVONORGESTREL	1 (2.3%)	0
PRASTERONE	0	1 (2.4%)
PROGESTERONE	0	1 (2.4%)
UROLOGICALS		
Total number of patients with at least one treatment	2 (4.5%)	1 (2.4%)
Total number of treatments	5	1
LIDOCAINE	2 (4.5%)	1 (2.4%)
CHONDROITIN SULFATE SODIUM;HYALURONATE SODIUM	1 (2.3%)	0
HYALURONATE SODIUM	1 (2.3%)	0

LIDOCAINE HYDROCHLORIDE	1 (2.3%)	0
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM		
Total number of patients with at least one treatment	1 (2.3%)	1 (2.4%)
Total number of treatments	1	1
LOSARTAN	0	1 (2.4%)
VALSARTAN	1 (2.3%)	0
ANTIEPILEPTICS		
Total number of patients with at least one treatment	1 (2.3%)	1 (2.4%)
Total number of treatments	1	7
DIAZEPAM	1 (2.3%)	0
OXCARBAZEPINE	0	1 (2.4%)
PREGABALIN	0	1 (2.4%)
ANTIFUNGALS FOR DERMATOLOGICAL USE		
Total number of patients with at least one treatment	2 (4.5%)	0
Total number of treatments	2	0
CLOTRIMAZOLE	1 (2.3%)	0
NYSTATIN	1 (2.3%)	0
DIGESTIVES, INCL. ENZYMES		
Total number of patients with at least one treatment	1 (2.3%)	1 (2.4%)
Total number of treatments	2	1
PEPSIN	0	1 (2.4%)
SILYBUM MARIANUM	1 (2.3%)	0
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS		
Total number of patients with at least one treatment	2 (4.5%)	0
Total number of treatments	2	0
ACETYLCYSTEINE	2 (4.5%)	0
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM		
Total number of patients with at least one treatment	2 (4.5%)	0
Total number of treatments	3	0
CHONDROITIN SULFATE SODIUM;HYALURONATE SODIUM	1 (2.3%)	0
HYALURONATE SODIUM	1 (2.3%)	0
PROMELASE	1 (2.3%)	0
ANABOLIC AGENTS FOR SYSTEMIC USE		
Total number of patients with at least one treatment	0	1 (2.4%)
Total number of treatments	0	1

PRASTERONE	0	1 (2.4%)
ANTI-PARKINSON DRUGS		
Total number of patients with at least one treatment	1 (2.3%)	0
Total number of treatments	1	0
DIPHENHYDRAMINE HYDROCHLORIDE	1 (2.3%)	0
ANTIMYCOTICS FOR SYSTEMIC USE		
Total number of patients with at least one treatment	1 (2.3%)	0
Total number of treatments	2	0
NYSTATIN	1 (2.3%)	0
VORICONAZOLE	1 (2.3%)	0
ANTINEOPLASTIC AGENTS		
Total number of patients with at least one treatment	0	1 (2.4%)
Total number of treatments	0	1
FLUOROURACIL	0	1 (2.4%)
ANTISEPTICS AND DISINFECTANTS		
Total number of patients with at least one treatment	1 (2.3%)	0
Total number of treatments	1	0
POVIDONE-IODINE	1 (2.3%)	0
ANTIVIRALS FOR SYSTEMIC USE		
Total number of patients with at least one treatment	1 (2.3%)	0
Total number of treatments	1	0
ACICLOVIR	1 (2.3%)	0
CALCIUM CHANNEL BLOCKERS		
Total number of patients with at least one treatment	1 (2.3%)	0
Total number of treatments	1	0
AMLODIPINE	1 (2.3%)	0
CONTRAST MEDIA		
Total number of patients with at least one treatment	1 (2.3%)	0
Total number of treatments	1	0
IOHEXOL	1 (2.3%)	0
ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS		
Total number of patients with at least one treatment	0	1 (2.4%)
Total number of treatments	0	1
DIMETICONE	0	1 (2.4%)

EMOLLIENTS AND PROTECTIVES		
Total number of patients with at least one treatment	0	1 (2.4%)
Total number of treatments	0	1
DIMETICONE		
	0	1 (2.4%)
ENDOCRINE THERAPY		
Total number of patients with at least one treatment	1 (2.3%)	0
Total number of treatments	1	0
ESTRADIOL		
	1 (2.3%)	0
IMMUNE SERA AND IMMUNOGLOBULINS		
Total number of patients with at least one treatment	0	1 (2.4%)
Total number of treatments	0	1
TETANUS ANTITOXIN		
	0	1 (2.4%)
IMMUNOSUPPRESSANTS		
Total number of patients with at least one treatment	0	1 (2.4%)
Total number of treatments	0	2
CICLOSPORIN		
	0	1 (2.4%)
OTHER RESPIRATORY SYSTEM PRODUCTS		
Total number of patients with at least one treatment	0	1 (2.4%)
Total number of treatments	0	1
DIMETICONE		
	0	1 (2.4%)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_cm_cncm.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_cm_cncm_RND1_EF1_31MAY2023_42161.xls

03MAY2024 22:24

POPULATION: Safety Population

ENDPOINT: --

MODEL: descriptive

STUDY: BO42161

Number of Patients who Died including Primary Reason

Endpoint, Primary Safety Period	Crovalimab (N=44)		Eculizumab (N=42)	
	n	%	n	%
All Deaths	1	2,3	0	NE
Colorectal cancer	1	2,3	0	NE

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_death.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_death_SE1_31MAY2023_42161.xls

20MAY2024 14:50

POPULATION: Safety Population

ENDPOINT: --

MODEL: --

STUDY: BO42161

Number and Percentage of SAEs between randomization date and treatment start date

		Crovalimab (N=44)				Eculizumab (N=42)			
		All AEs		SAEs between randomization date and treatment start date		All AEs		SAEs between randomization date and treatment start date	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	194	100,0	0	0	188	100,0	0	0

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_rndtrt1.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_rndtrt1_SE1_31MAY2023_42161.xls

03MAY2024 20:18

POPULATION: Randomized Population with an history of Aplastic Anemia

ENDPOINT: Arms A and B, RBC Clone size

MODEL: descriptive

STUDY: BO42161

Summary of clone size per arm (RBC)

Analyte: Percent of Erythrocytes Clone Size (%)

Visit	Crovalimab (N=15)		Eculizumab (N=15)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	15		13	
Mean	55,73		50,08	
95% Lower CL for Mean	36,78		28,57	
95% Upper CL for Mean	74,69		71,59	
SD	34,24		35,6	
CV % Mean	61,43		71,08	
Median	51,62		46,52	
Interquartile Range	58,16		55,29	
Minimum	2,62		2,6	
Maximum	99,86		100	
Geometric Mean	40,22		33,2	
CV % Geometric Mean	137,94		162,04	
Week 13				
n	13	13	14	12
Mean	55,57	4,59	45,79	-8,97
95% Lower CL for Mean	34,99	0,52	26,9	-22,54
95% Upper CL for Mean	76,16	8,66	64,68	4,6
SD	34,07	6,73	32,71	21,36
CV % Mean	61,3	146,64	71,43	-238,07
Median	56,09	3,73	35,82	-0,1
Interquartile Range	51,85	4,94	53,45	6,23
Minimum	4,71	-1,09	2,59	-64,88
Maximum	99,82	23,86	99,82	2,68
Geometric Mean	41,02	NE	32,53	NE
CV % Geometric Mean	124,9	NE	131,95	NE

Week 25				
n	13	13	11	11
Mean	61,75	0,63	48,3	-4,54
95% Lower CL for Mean	41,83	-1,2	23,24	-11,95
95% Upper CL for Mean	81,66	2,45	73,35	2,86
SD	32,96	3,02	37,29	11,02
CV % Mean	53,37	481,18	77,22	-242,72
Median	74,04	1,45	32,25	-0,47
Interquartile Range	50,45	2,54	76,73	3,6
Minimum	4,92	-6,82	2,13	-36,83
Maximum	99,84	5,01	99,93	2,82
Geometric Mean	48,65	NE	31,23	NE
CV % Geometric Mean	106,54	NE	174	NE
Week 27				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	4,12	-3,81
Maximum	NE	NE	4,12	-3,81
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		14	
Mean	ND		49,11	
95% Lower CL for Mean	ND		27,83	
95% Upper CL for Mean	ND		70,4	
SD	ND		36,86	
CV % Mean	ND		75,05	
Median	ND		38,58	
Interquartile Range	ND		67,34	
Minimum	NE		2,13	
Maximum	NE		99,93	
Geometric Mean	ND		30,64	
CV % Geometric Mean	ND		187,72	

Switch Week 13				
n	0	0	10	10
Mean	ND	ND	57,39	6,72
95% Lower CL for Mean	ND	ND	29,75	-4,4
95% Upper CL for Mean	ND	ND	85,03	17,83
SD	ND	ND	38,64	15,54
CV % Mean	ND	ND	67,33	231,26
Median	ND	ND	72,84	-0,22
Interquartile Range	ND	ND	71,58	3,98
Minimum	NE	NE	1,55	-2,77
Maximum	NE	NE	98,34	45,77
Geometric Mean	ND	ND	34,85	NE
CV % Geometric Mean	ND	ND	239,15	NE

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_RBC_RND1APL_ARMAB_31MAY2023_42161.xls
03MAY2024 21:56

POPULATION: Randomized Population with an history of Myelodysplastic Syndrome

ENDPOINT: Arms A and B, RBC Clone size

MODEL: descriptive

STUDY: BO42161

Summary of clone size per arm (RBC)

Null Report: No observations met the reporting criteria for inclusion in this output.

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_RBC_RND1MYS_ARMAB_31MAY2023_42161.xls
03MAY2024 21:57

POPULATION: Randomized Population
 ENDPOINT: Arms A and B, RBC Clone size
 MODEL: descriptive
 STUDY: BO42161
 Summary of clone size per arm (RBC)

Analyte: Percent of Erythrocytes Clone Size (%)

Visit	Crovalimab (N=44)		Eculizumab (N=42)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	41		35	
Mean	50,09		54,71	
95% Lower CL for Mean	40,33		43,44	
95% Upper CL for Mean	59,85		65,97	
SD	30,92		32,8	
CV % Mean	61,73		59,96	
Median	44,62		46,52	
Interquartile Range	51,53		61,65	
Minimum	2,62		1,26	
Maximum	99,98		100	
Geometric Mean	38,4		38,59	
CV % Geometric Mean	102,14		149,24	
Week 1 Day 1 (Post Dose)				
n	0	0	2	0
Mean	ND	ND	99,01	ND
95% Lower CL for Mean	ND	ND	88,72	ND
95% Upper CL for Mean	ND	ND	109,3	ND
SD	ND	ND	1,15	ND
CV % Mean	ND	ND	1,16	ND
Median	ND	ND	99,01	ND
Interquartile Range	ND	ND	1,62	ND
Minimum	NE	NE	98,2	NE
Maximum	NE	NE	99,82	NE
Geometric Mean	ND	ND	99,01	ND

CV % Geometric Mean	ND	ND	1,16	ND
Week 13				
n	39	36	36	30
Mean	50,33	4,37	55,91	-1,37
95% Lower CL for Mean	41,3	0,37	44,42	-7,78
95% Upper CL for Mean	59,36	8,36	67,41	5,04
SD	27,86	11,81	33,98	17,17
CV % Mean	55,35	270,39	60,77	-1256,5
Median	49,48	1,94	54,26	0,31
Interquartile Range	47,02	8,19	58,89	2,32
Minimum	4,71	-19,16	1,09	-64,88
Maximum	99,82	45,4	99,98	42,67
Geometric Mean	40,24	NE	39,37	NE
CV % Geometric Mean	90,64	NE	149,4	NE
Week 25				
n	37	34	29	27
Mean	53,26	4,14	56,74	-1,44
95% Lower CL for Mean	43,59	0,24	43,28	-5,5
95% Upper CL for Mean	62,93	8,05	70,21	2,63
SD	29	11,18	35,39	10,28
CV % Mean	54,45	269,75	62,37	-715,36
Median	54,62	1,42	58,65	-0,47
Interquartile Range	43,82	6,35	65,11	4,6
Minimum	4,92	-8,75	0,78	-36,83
Maximum	99,84	49,12	100	21,39
Geometric Mean	42,59	NE	37,61	NE
CV % Geometric Mean	91,5	NE	187,67	NE
Week 27				
n	0	0	2	2
Mean	ND	ND	51,99	-1,92
95% Lower CL for Mean	ND	ND	-556,26	-25,93
95% Upper CL for Mean	ND	ND	660,24	22,09
SD	ND	ND	67,7	2,67
CV % Mean	ND	ND	130,21	-139,21
Median	ND	ND	51,99	-1,92
Interquartile Range	ND	ND	95,74	3,78
Minimum	NE	NE	4,12	-3,81

Maximum	NE	NE	99,86	-0,03
Geometric Mean	ND	ND	20,28	NE
CV % Geometric Mean	ND	ND	1264,91	NE
Week 29				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	7,02	-3,78
Maximum	NE	NE	7,02	-3,78
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		35	
Mean	ND		55,42	
95% Lower CL for Mean	ND		43,09	
95% Upper CL for Mean	ND		67,74	
SD	ND		35,89	
CV % Mean	ND		64,77	
Median	ND		58,65	
Interquartile Range	ND		66,4	
Minimum	NE		0,78	
Maximum	NE		100	
Geometric Mean	ND		35,8	
CV % Geometric Mean	ND		189,7	
Switch Week 13				
n	0	0	25	25
Mean	ND	ND	61,41	5,38
95% Lower CL for Mean	ND	ND	45,55	0,12
95% Upper CL for Mean	ND	ND	77,27	10,63
SD	ND	ND	38,42	12,73
CV % Mean	ND	ND	62,57	236,79
Median	ND	ND	73,54	0,19

Interquartile Range	ND	ND	68,46	5,19
Minimum	NE	NE	0,97	-11,65
Maximum	NE	NE	100,01	45,77
Geometric Mean	ND	ND	37,22	NE
CV % Geometric Mean	ND	ND	239,48	NE

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_RBC_RND1_ARMAB_31MAY2023_42161.xls

03MAY2024 21:55

POPULATION: Randomized Population with an history of Aplastic Anemia

ENDPOINT: Arms A and B, WBC Clone size

MODEL: descriptive

STUDY: BO42161

Summary of clone size per arm (WBC)

Analyte: Granulocytes: FLAERneg Gran%ofGran,NHepLDTCL (%)

Visit	Crovalimab (N=15)		Eculizumab (N=15)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	15		13	
Mean	51,85		64,86	
95% Lower CL for Mean	35,88		49,33	
95% Upper CL for Mean	67,81		80,39	
SD	28,83		25,7	
CV % Mean	55,6		39,62	
Median	52,63		66,74	
Interquartile Range	52,4		37,27	
Minimum	1,66		4,73	
Maximum	91,02		93,23	
Geometric Mean	37,77		54,78	
CV % Geometric Mean	147,87		93,23	
Week 13				
n	13	13	13	11
Mean	49,77	0,87	61,3	-1,77
95% Lower CL for Mean	30,55	-9,97	43,47	-10,84
95% Upper CL for Mean	68,99	11,7	79,14	7,3
SD	31,8	17,93	29,52	13,5
CV % Mean	63,9	2068,66	48,15	-763,11
Median	41,89	6	72,46	-5,89
Interquartile Range	59,13	14,31	28,54	8,82
Minimum	8,19	-39,32	2,06	-13,97
Maximum	92,02	34,56	88,67	36,55
Geometric Mean	38,11	NE	44,77	NE
CV % Geometric Mean	100,18	NE	160,66	NE

Week 25				
n	13	13	11	11
Mean	52,42	-0,2	71,6	2,98
95% Lower CL for Mean	34,01	-8,14	56,67	-9,74
95% Upper CL for Mean	70,83	7,75	86,52	15,71
SD	30,47	13,15	22,21	18,94
CV % Mean	58,12	-6676,42	31,03	634,67
Median	53,84	-0,12	82,54	0,72
Interquartile Range	51,41	13,53	36,34	18,91
Minimum	7,08	-22,51	24,32	-22,95
Maximum	93,31	22,76	90,98	49,33
Geometric Mean	40,41	NE	67,33	NE
CV % Geometric Mean	106,86	NE	42,14	NE
Week 27				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	32,89	-12,32
Maximum	NE	NE	32,89	-12,32
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		14	
Mean	ND		69,8	
95% Lower CL for Mean	ND		56,91	
95% Upper CL for Mean	ND		82,7	
SD	ND		22,33	
CV % Mean	ND		32	
Median	ND		78,39	
Interquartile Range	ND		34,54	
Minimum	NE		24,32	
Maximum	NE		90,98	
Geometric Mean	ND		65,38	
CV % Geometric Mean	ND		42,76	

Switch Week 13				
n	0	0	10	10
Mean	ND	ND	56,35	-14,97
95% Lower CL for Mean	ND	ND	36,89	-29,63
95% Upper CL for Mean	ND	ND	75,82	-0,31
SD	ND	ND	27,21	20,5
CV % Mean	ND	ND	48,29	-136,89
Median	ND	ND	62,38	-8,57
Interquartile Range	ND	ND	36	30,77
Minimum	NE	NE	4,99	-49,58
Maximum	NE	NE	92,3	11,71
Geometric Mean	ND	ND	45,73	NE
CV % Geometric Mean	ND	ND	103,79	NE

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_WBC_RND1APL_ARMAB_31MAY2023_42161.xls
03MAY2024 22:00

POPULATION: Randomized Population with an history of Aplastic Anemia

ENDPOINT: Arms A and B, WBC Clone size

MODEL: descriptive

STUDY: BO42161

Summary of clone size per arm (WBC)

Analyte: Monocytes: FLAERneg Mono%ofMono,NHepLDTCL (%)

Visit	Crovalimab (N=15)		Eculizumab (N=15)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	15		13	
Mean	78,1		90,58	
95% Lower CL for Mean	62,49		84,67	
95% Upper CL for Mean	93,71		96,49	
SD	28,19		9,78	
CV % Mean	36,09		10,8	
Median	89,59		93,98	
Interquartile Range	37,22		13,16	
Minimum	13,83		68,93	
Maximum	99,96		99,89	
Geometric Mean	69,87		90,05	
CV % Geometric Mean	62,73		11,5	
Week 13				
n	13	13	13	11
Mean	75,29	0,13	91,8	0,35
95% Lower CL for Mean	57,06	-1,08	85,76	-0,64
95% Upper CL for Mean	93,52	1,33	97,84	1,35
SD	30,17	2	10	1,48
CV % Mean	40,07	1601,56	10,9	420,93
Median	86,23	-0,2	94,42	0,22
Interquartile Range	34,33	2,03	13,23	0,62
Minimum	10,09	-3,74	64,42	-2,18
Maximum	99,9	4,23	99,94	4,07
Geometric Mean	64,99	NE	91,22	NE
CV % Geometric Mean	77,21	NE	12,2	NE

Week 25				
n	13	13	11	11
Mean	80,43	-1,15	90,82	-1,21
95% Lower CL for Mean	63,78	-2,68	83,69	-3,59
95% Upper CL for Mean	97,07	0,39	97,96	1,17
SD	27,55	2,54	10,62	3,54
CV % Mean	34,25	-220,98	11,69	-293,5
Median	94,56	-0,29	96,85	-0,6
Interquartile Range	24,04	1,82	18,29	3,97
Minimum	9,51	-7,59	69,22	-8,68
Maximum	100	2,05	99,9	5,67
Geometric Mean	71,09	NE	90,22	NE
CV % Geometric Mean	72,93	NE	12,43	NE
Week 27				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	62,98	-5,94
Maximum	NE	NE	62,98	-5,94
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		14	
Mean	ND		89,51	
95% Lower CL for Mean	ND		82,48	
95% Upper CL for Mean	ND		96,54	
SD	ND		12,17	
CV % Mean	ND		13,6	
Median	ND		95,54	
Interquartile Range	ND		18,18	
Minimum	NE		62,98	
Maximum	NE		99,9	
Geometric Mean	ND		88,65	
CV % Geometric Mean	ND		14,89	

Switch Week 13				
n	0	0	10	10
Mean	ND	ND	91,92	0,91
95% Lower CL for Mean	ND	ND	85,38	-1,34
95% Upper CL for Mean	ND	ND	98,45	3,15
SD	ND	ND	9,14	3,13
CV % Mean	ND	ND	9,94	345,92
Median	ND	ND	96,2	0,54
Interquartile Range	ND	ND	12,8	2,35
Minimum	NE	NE	74,95	-4,14
Maximum	NE	NE	99,88	5,73
Geometric Mean	ND	ND	91,48	NE
CV % Geometric Mean	ND	ND	10,49	NE

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_WBC_RND1APL_ARMAB_31MAY2023_42161.xls
03MAY2024 22:00

POPULATION: Randomized Population with an history of Myelodysplastic Syndrome

ENDPOINT: Arms A and B, WBC Clone size

MODEL: descriptive

STUDY: BO42161

Summary of clone size per arm (WBC)

Null Report: No observations met the reporting criteria for inclusion in this output.

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_WBC_RND1MYS_ARMAB_31MAY2023_42161.xls
03MAY2024 22:02

POPULATION: Randomized Population
ENDPOINT: Arms A and B, WBC Clone size
MODEL: descriptive
STUDY: BO42161
Summary of clone size per arm (WBC)

Analyte: Granulocytes: FLAERneg Gran%ofGran,NHepLDTCL (%)

Visit	Crovalimab (N=44)		Eculizumab (N=42)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	40		36	
Mean	54,87		61,71	
95% Lower CL for Mean	45,76		51,66	
95% Upper CL for Mean	63,97		71,76	
SD	28,47		29,69	
CV % Mean	51,89		48,12	
Median	66,46		67,94	
Interquartile Range	47,93		46,86	
Minimum	1,66		2,16	
Maximum	92,37		97,76	
Geometric Mean	41,62		46,97	
CV % Geometric Mean	124,56		128,66	
Week 1 Day 1 (Post Dose)				
n	0	0	1	0
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	82,74	NE
Maximum	NE	NE	82,74	NE
Geometric Mean	ND	ND	ND	ND

CV % Geometric Mean	ND	ND	ND	ND
Week 13				
n	39	36	35	30
Mean	50,92	-2,28	58,89	0,7
95% Lower CL for Mean	41,29	-7,21	48,05	-4,56
95% Upper CL for Mean	60,55	2,65	69,73	5,95
SD	29,71	14,57	31,55	14,07
CV % Mean	58,35	-638,35	53,58	2014,31
Median	49,32	-1,71	75,79	-2,59
Interquartile Range	54,94	14,19	53,91	12,93
Minimum	1,6	-39,32	0,58	-21,59
Maximum	94,9	34,56	94,85	37,88
Geometric Mean	38,66	NE	39,36	NE
CV % Geometric Mean	111,47	NE	199,27	NE
Week 25				
n	37	34	29	28
Mean	51,46	-2,58	61,46	0,27
95% Lower CL for Mean	41,26	-7,42	49,99	-7,4
95% Upper CL for Mean	61,67	2,25	72,93	7,95
SD	30,6	13,85	30,16	19,79
CV % Mean	59,46	-536,37	49,07	7269,25
Median	53,84	0,61	69,72	-2,33
Interquartile Range	56,27	10,3	47,59	12,73
Minimum	0,34	-46,38	3,83	-60,62
Maximum	93,78	22,76	94,9	49,33
Geometric Mean	34,97	NE	47,41	NE
CV % Geometric Mean	184,48	NE	117,65	NE
Week 27				
n	0	0	2	2
Mean	ND	ND	55,29	-11,8
95% Lower CL for Mean	ND	ND	-229,31	-18,46
95% Upper CL for Mean	ND	ND	339,88	-5,13
SD	ND	ND	31,68	0,74
CV % Mean	ND	ND	57,3	-6,29
Median	ND	ND	55,29	-11,8
Interquartile Range	ND	ND	44,8	1,05
Minimum	NE	NE	32,89	-12,32

Maximum	NE	NE	77,68	-11,27
Geometric Mean	ND	ND	50,54	NE
CV % Geometric Mean	ND	ND	66,85	NE
Week 29				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	12,75	-22,33
Maximum	NE	NE	12,75	-22,33
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		35	
Mean	ND		61,22	
95% Lower CL for Mean	ND		51,05	
95% Upper CL for Mean	ND		71,4	
SD	ND		29,63	
CV % Mean	ND		48,4	
Median	ND		73,65	
Interquartile Range	ND		49,8	
Minimum	NE		3,83	
Maximum	NE		94,9	
Geometric Mean	ND		47,88	
CV % Geometric Mean	ND		110,75	
Switch Week 13				
n	0	0	25	25
Mean	ND	ND	54,26	-5,5
95% Lower CL for Mean	ND	ND	41,52	-14,2
95% Upper CL for Mean	ND	ND	67	3,2
SD	ND	ND	30,87	21,08
CV % Mean	ND	ND	56,89	-383,5
Median	ND	ND	64,81	-3,17

Interquartile Range	ND	ND	54,28	13,71
Minimum	NE	NE	1,68	-49,58
Maximum	NE	NE	92,3	59,55
Geometric Mean	ND	ND	37,73	NE
CV % Geometric Mean	ND	ND	161,04	NE

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_WBC_RND1_ARMAB_31MAY2023_42161.xls

03MAY2024 21:58

POPULATION: Randomized Population
ENDPOINT: Arms A and B, WBC Clone size
MODEL: descriptive
STUDY: BO42161
Summary of clone size per arm (WBC)

Analyte: Monocytes: FLAERneg Mono%ofMono,NHepLDTCL (%)

Visit	Crovalimab (N=44)		Eculizumab (N=42)	
	Value at Visit	Change from Baseline	Value at Visit	Change from Baseline
Week 1 Day 1				
n	40		36	
Mean	80,84		86,62	
95% Lower CL for Mean	73,77		79,27	
95% Upper CL for Mean	87,92		93,96	
SD	22,12		21,71	
CV % Mean	27,36		25,06	
Median	88,62		96,32	
Interquartile Range	27,41		15,97	
Minimum	13,83		7,6	
Maximum	99,96		99,89	
Geometric Mean	76,11		80,53	
CV % Geometric Mean	42,52		53,11	
Week 1 Day 1 (Post Dose)				
n	0	0	1	0
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	99,39	NE
Maximum	NE	NE	99,39	NE
Geometric Mean	ND	ND	ND	ND

CV % Geometric Mean	ND	ND	ND	ND
Week 13				
n	39	36	35	30
Mean	80,08	0,22	86,78	-0,22
95% Lower CL for Mean	72,7	-0,61	79,02	-2,07
95% Upper CL for Mean	87,46	1,06	94,53	1,64
SD	22,77	2,47	22,56	4,96
CV % Mean	28,43	1113,36	26	-2299,77
Median	90,66	-0,02	96,66	0,08
Interquartile Range	33,15	1,95	14,45	1,2
Minimum	10,09	-9,05	6,02	-19,44
Maximum	99,9	5,91	99,94	13,96
Geometric Mean	74,62	NE	79,93	NE
CV % Geometric Mean	47,85	NE	58,14	NE
Week 25				
n	37	34	29	28
Mean	82,22	-0,32	85,84	-1,09
95% Lower CL for Mean	74,94	-1,11	77,02	-2,28
95% Upper CL for Mean	89,49	0,47	94,66	0,09
SD	21,82	2,27	23,18	3,05
CV % Mean	26,53	-715,27	27,01	-279,45
Median	91,64	-0,14	96,85	-0,48
Interquartile Range	23,42	2,54	18,14	1,87
Minimum	9,51	-7,59	4,54	-9,07
Maximum	100	5,06	99,9	5,67
Geometric Mean	77,13	NE	77,82	NE
CV % Geometric Mean	46,29	NE	67,58	NE
Week 27				
n	0	0	2	2
Mean	ND	ND	81,46	-2,92
95% Lower CL for Mean	ND	ND	-153,38	-41,38
95% Upper CL for Mean	ND	ND	316,31	35,54
SD	ND	ND	26,14	4,28
CV % Mean	ND	ND	32,09	-146,75
Median	ND	ND	81,46	-2,92
Interquartile Range	ND	ND	36,97	6,05
Minimum	NE	NE	62,98	-5,94

Maximum	NE	NE	99,95	0,11
Geometric Mean	ND	ND	79,34	NE
CV % Geometric Mean	ND	ND	33,54	NE
Week 29				
n	0	0	1	1
Mean	ND	ND	ND	ND
95% Lower CL for Mean	ND	ND	ND	ND
95% Upper CL for Mean	ND	ND	ND	ND
SD	ND	ND	ND	ND
CV % Mean	ND	ND	ND	ND
Median	ND	ND	ND	ND
Interquartile Range	ND	ND	ND	ND
Minimum	NE	NE	51,2	-0,93
Maximum	NE	NE	51,2	-0,93
Geometric Mean	ND	ND	ND	ND
CV % Geometric Mean	ND	ND	ND	ND
Switch Week 1 Day 1				
n	0		35	
Mean	ND		85,44	
95% Lower CL for Mean	ND		77,7	
95% Upper CL for Mean	ND		93,18	
SD	ND		22,53	
CV % Mean	ND		26,37	
Median	ND		95,8	
Interquartile Range	ND		18,18	
Minimum	NE		4,54	
Maximum	NE		99,95	
Geometric Mean	ND		78,35	
CV % Geometric Mean	ND		61,61	
Switch Week 13				
n	0	0	25	25
Mean	ND	ND	84,01	0,43
95% Lower CL for Mean	ND	ND	73,23	-1,41
95% Upper CL for Mean	ND	ND	94,8	2,26
SD	ND	ND	26,13	4,45
CV % Mean	ND	ND	31,1	1043,29
Median	ND	ND	97,06	0,1

Interquartile Range	ND	ND	19,46	1,84
Minimum	NE	NE	6,11	-8,96
Maximum	NE	NE	99,92	14,05
Geometric Mean	ND	ND	74,6	NE
CV % Geometric Mean	ND	ND	72,45	NE

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_bm_cfb.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_bm_cfb_WBC_RND1_ARMAB_31MAY2023_42161.xls

03MAY2024 21:58

POPULATION: Crovalimab, Primary Analysis Population
 ENDPOINT: --
 MODEL: --
 STUDY: BO42161
 Characterization of BTHs (Arm A)

BTH number	New or worsening symptom or sign of intravascular hemolysis									
	Fatigue	Hemoglobinuria	Abdominal pain	Dyspnea	Anemia [hemoglobin <10 g/dL]	MAVE (including thrombosis)	Dysphagia	Erectile dysfunction	Other	Transfusion needed?
1	n	n	n	n	y	n	n	n	n	n
2	y	n	n	n	y	n	n	n	n	y
3	y	n	n	n	n	n	n	n	n	n
4	n	n	n	n	y	n	n	n	n	n
5	n	n	n	n	y	n	n	n	n	n
6	n	n	n	n	y	n	n	n	n	n
7	n	n	n	n	y	n	n	n	n	n
8	y	n	n	n	y	n	n	n	n	y
9	y	y	n	n	y	n	n	n	n	n
10	n	n	n	n	y	n	n	n	n	n
11	y	y	n	n	y	n	y	n	n	n
12	y	n	n	n	y	n	n	n	n	y
13	y	n	n	n	y	n	n	n	n	y
14	y	y	n	n	n	n	n	n	n	n
15	y	y	y	n	y	n	n	n	n	n
16	y	y	n	n	y	n	n	n	n	n
Total	10	5	1	0	14	0	1	0	0	4

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_bth.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_bth_PAP_arma_31MAY2023_42161.xls
 03MAY2024 20:56

POPULATION: Eculizumab, Primary Analysis Population
 ENDPOINT: --
 MODEL: --
 STUDY: BO42161
 Characterization of BTHs (Arm B)

BTH number	New or worsening symptom or sign of intravascular hemolysis										
	OTHER:DARK URINE	Fatigue	Hemoglobinuria	Abdominal pain	Dyspnea	Anemia [hemoglobin <10 g/dL]	MAVE (including thrombosis)	Dysphagia	Erectile dysfunction	Other	Transfusion needed?
1	n	y	y	n	n	y	n	n	n	n	y
2	n	n	y	n	n	n	n	n	n	n	n
3	y	n	y	n	n	y	n	n	n	n	n
4	n	n	n	n	n	y	n	n	n	n	n
5	n	n	n	n	n	y	n	n	n	n	n
6	n	n	y	n	n	n	n	n	n	n	y
7	n	n	n	n	n	y	n	n	n	n	n
8	n	n	y	n	n	n	n	n	n	n	n
9	n	n	y	n	n	n	n	n	n	n	n
10	n	n	y	n	n	n	n	n	n	n	n
11	n	n	y	n	n	n	n	n	n	n	n
12	n	n	y	n	n	n	n	n	n	n	n
13	n	n	n	n	n	y	n	n	n	n	n
14	n	y	n	n	n	y	n	n	n	n	y
15	n	n	y	n	n	n	n	n	n	n	n
16	n	y	y	n	n	y	n	n	n	n	n
Total	1	3	11	0	1	3	8	0	0	0	3

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_bth.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_bth_PAP_armb_31MAY2023_42161.xls
 03MAY2024 20:57

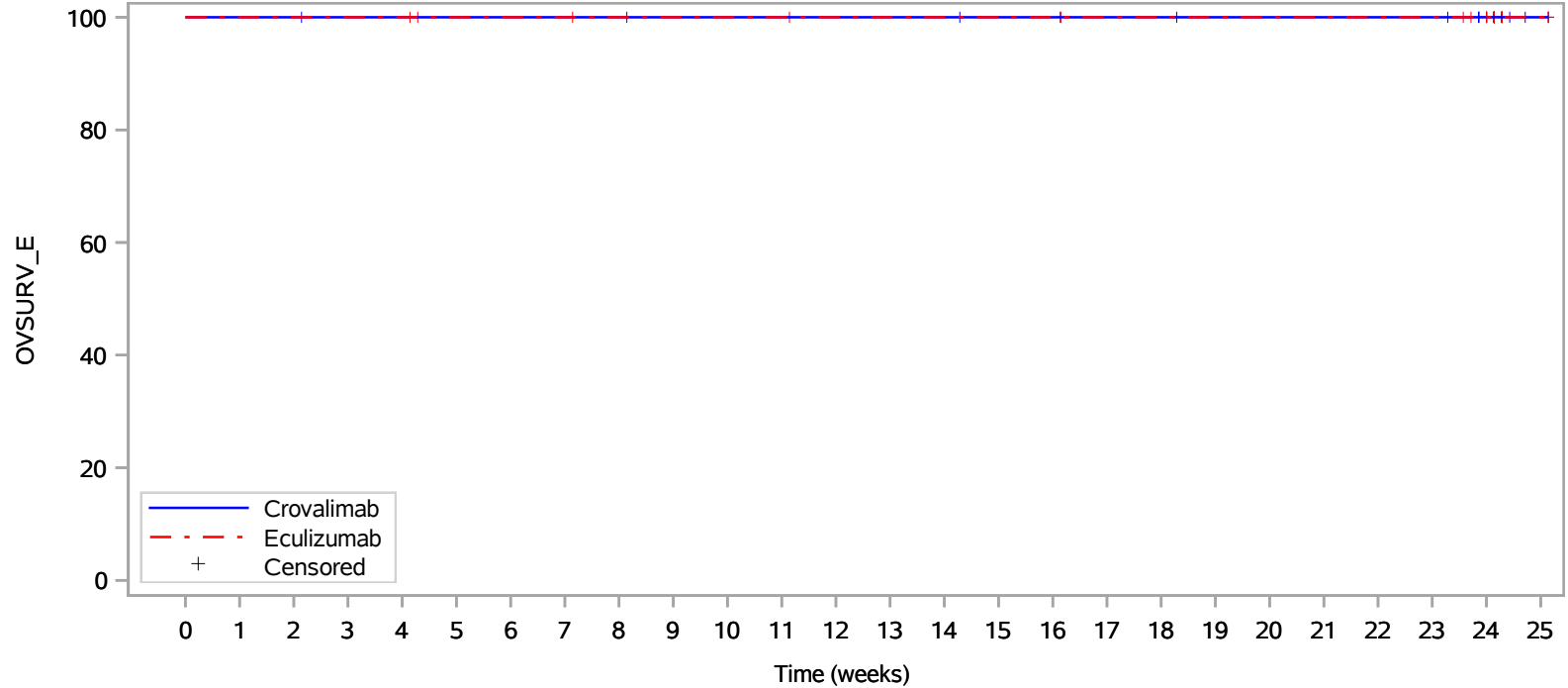
POPULATION: Primary Analysis Population
 ENDPOINT: Primary Efficacy Period, Overall Survival
 MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]
 STUDY: BO42161
 Time to Event Analysis (Efficacy)

		Crovalimab (N=44)										Eculizumab (N=42)										Crovalimab vs. Eculizumab								
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event					log-rank	Hazard Ratio					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	
All	n/a	44	100,0	0	0	44	100,0	NE	NE	NE	NE	NE	NE	42	100,0	0	0	42	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_tte.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_tte_str_OVSURV_EF1_PAP_31MAY2023_42161.xls
 04JUN2024 16:20

POPULATION: Primary Analysis Population
ENDPOINT: Overall Survival
STUDY: BO42161



	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Patients at risk																										
Crovalimab	44	44	44	43	43	43	43	43	43	42	42	42	42	42	42	41	41	40	40	39	39	39	39	39	35	1
Eculizumab	42	42	42	42	42	40	40	40	39	39	39	39	38	38	38	38	36	36	36	36	36	36	36	36	34	3
Patients censored																										
Crovalimab	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	4	4	5	5	5	5	5	10	43
Eculizumab	0	0	0	0	0	2	2	2	3	3	3	3	4	4	4	4	6	6	6	6	6	6	6	6	15	39

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/g_km.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/g_km_OVSURVEF1_PAP_31MAY2023_42161.pdf
 10JUN2024 20:00

POPULATION: Primary Analysis Population
 ENDPOINT: Primary Efficacy Period, Overall Survival
 MODEL: Unstratified Analysis
 STUDY: BO42161
 Time to Event Analysis by Subgroups (Efficacy)

		Crovalimab (N=44)												Eculizumab (N=42)												Crovalimab vs. Eculizumab						
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio			Interaction Test		
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	p-value (likelihood ratio)		
All	n/a	44	100,0	0	0	44	100,0	NE	NE	NE	NE	NE	NE	42	100,0	0	0	42	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Age	<65	39	88,6	0	0	39	100,0	NE	NE	NE	NE	NE	NE	35	83,3	0	0	35	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
	>=65	5	11,4	0	0	5	100,0	NE	NE	NE	NE	NE	NE	7	16,7	0	0	7	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Sex	Male	20	45,5	0	0	20	100,0	NE	NE	NE	NE	NE	NE	21	50,0	0	0	21	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Female	24	54,5	0	0	24	100,0	NE	NE	NE	NE	NE	NE	21	50,0	0	0	21	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	0	0	12	100,0	NE	NE	NE	NE	NE	NE	10	23,8	0	0	10	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	No	32	72,7	0	0	32	100,0	NE	NE	NE	NE	NE	NE	32	76,2	0	0	32	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Geographic region	Japan/Rest of Asia Pacific	8	18,2	0	0	8	100,0	NE	NE	NE	NE	NE	NE	7	16,7	0	0	7	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	North America/Central and South America/Europe	36	81,8	0	0	36	100,0	NE	NE	NE	NE	NE	NE	35	83,3	0	0	35	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Aplastic anemia	Yes	15	34,1	0	0	15	100,0	NE	NE	NE	NE	NE	NE	15	35,7	0	0	15	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	No	29	65,9	0	0	29	100,0	NE	NE	NE	NE	NE	NE	27	64,3	0	0	27	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Baseline Weight Category	<100	41	93,2	0	0	41	100,0	NE	NE	NE	NE	NE	NE	38	90,5	0	0	38	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	>=100	3	6,8	0	0	3	100,0	NE	NE	NE	NE	NE	NE	4	9,5	0	0	4	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_tte.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_tte_sg2_OVSURV_EF1_PAP_31MAY2023_42161.xls

04JUN2024 16:22

POPULATION: Primary Analysis Population

ENDPOINT: Overall Survival

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: BO42161

Time to Event Analysis (Efficacy)

		Crovalimab (N=44)												Eculizumab (N=42)												Crovalimab vs. Eculizumab				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event				log-rank	Hazard Ratio					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status
All	n/a	44	100,0	1	2,3	43	97,7	NE	NE	NE	NE	NE	NE	42	100,0	0	0	42	100,0	NE	NE	NE	NE	NE	NE	0,3173	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect

* indicates convergence problem. Result is uninterpretable.

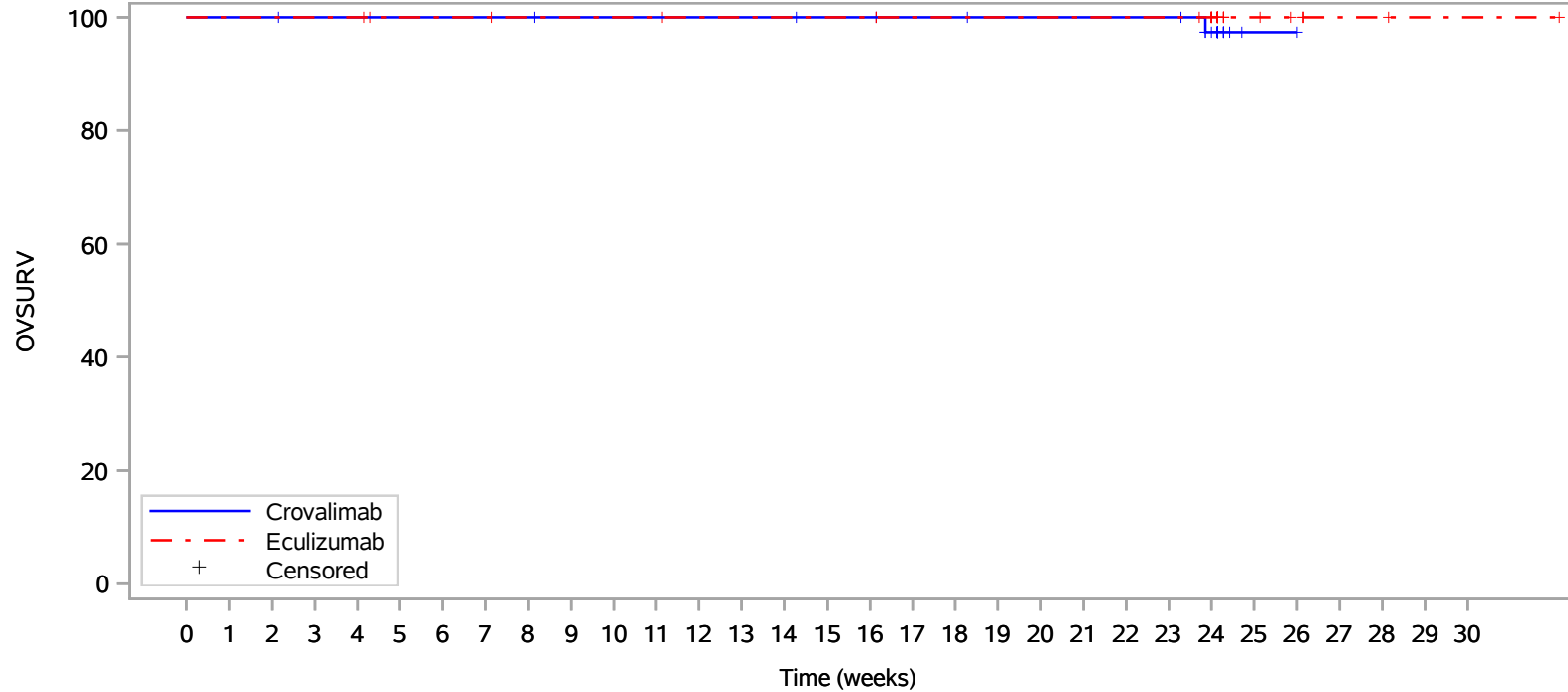
Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_tte.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_tte_str_OVSURV_PAP_31MAY2023_42161.xls

29APR2024 10:58

POPULATION: Primary Analysis Population
ENDPOINT: Overall Survival
STUDY: BO42161



Patients at risk																																								
Crovalimab	44	44	44	43	43	43	43	43	43	42	42	42	42	42	42	41	41	40	40	39	39	39	39	39	39	35	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Eculizumab	42	42	42	42	42	40	40	40	39	39	39	39	38	38	38	38	38	36	36	36	36	36	36	36	36	35	7	5	2	2	1	1								
Patients censored																																								
Crovalimab	0	0	0	1	1	1	1	1	1	2	2	2	2	2	2	3	3	4	4	5	5	5	5	5	9	42	43	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Eculizumab	0	0	0	0	0	2	2	2	2	3	3	3	3	4	4	4	4	6	6	6	6	6	6	6	14	35	37	40	40	41	41									

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/g_km.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/g_km_OVSURV_PAP_31MAY2023_42161.pdf
 10JUN2024 20:02

POPULATION: Primary Analysis Population
 ENDPOINT: Overall Survival
 MODEL: Unstratified Analysis
 STUDY: B042161
 Time to Event Analysis by Subgroups (Efficacy)

Base	Label	Covariate (N=64)												Covariate (N=42)												Covariate vs. Covariate								
		Patients		Patients with Event		Censored		Time to event				Patients		Patients with Event		Censored		Time to event				Log-rank	Hazard Ratio	95% Lower CI	95% Upper CI	Interaction Test								
		n	%	n	%	n	%	95% Lower CI (months)	95% Upper CI (months)	Median (months)	95% Lower CI (months)	95% Upper CI (months)	n	%	n	%	n	%	95% Lower CI (months)	95% Upper CI (months)	Median (months)						95% Lower CI (months)	95% Upper CI (months)						
All	0/0	44	100.0	1	2.3	43	97.7	NE	NE	NE	NE	NE	NE	42	100.0	0	0	42	100.0	NE	NE	NE	NE	NE	NE	5.3372	>>>9.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.				
Age	<65	33	89.4	1	2.8	33	97.2	NE	NE	NE	NE	NE	NE	33	100.0	0	0	33	100.0	NE	NE	NE	NE	NE	NE	5.3476	>>>9.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0.9910			
	>=65	11	31.4	0	0.0	11	100.0	NE	NE	NE	NE	NE	NE	7	16.7	0	0	7	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.			
Sex	Male	20	45.5	0	0.0	20	100.0	NE	NE	NE	NE	NE	NE	21	50.0	0	0	21	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0.9961	
	Female	24	54.5	1	4.2	23	95.8	NE	NE	NE	NE	NE	NE	21	50.0	0	0	21	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.		
Transfusion history (pRBC infusion in the last 12 months)	Yes	12	27.3	1	8.3	11	91.7	NE	NE	NE	NE	NE	NE	10	23.8	0	0	10	100.0	NE	NE	NE	NE	NE	NE	NE	5.3173	>>>9.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0.9949		
	No	32	72.7	0	0.0	32	100.0	NE	NE	NE	NE	NE	NE	32	76.2	0	0	32	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.		
Geographic region	Japan/East of Asia Pacific	8	18.2	0	0.0	8	100.0	NE	NE	NE	NE	NE	NE	7	16.7	0	0	7	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0.9968	
	North America/Central and South America/Europe	36	81.8	1	2.8	35	97.2	NE	NE	NE	NE	NE	NE	35	83.3	0	0	35	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.		
Asiatic anemia	Yes	15	34.1	0	0.0	15	100.0	NE	NE	NE	NE	NE	NE	15	35.7	0	0	15	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	0.9985
	No	29	65.9	1	3.4	28	96.6	NE	NE	NE	NE	NE	NE	27	64.3	0	0	27	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline Weight Category	<100	41	93.2	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	38	90.5	0	0	38	100.0	NE	NE	NE	NE	NE	NE	NE	NE	5.3600	>>>9.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0.9971	
	>=100	3	6.8	0	0.0	3	100.0	NE	NE	NE	NE	NE	NE	4	9.5	0	0	4	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.		

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
 * Indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/B07112689/CD70115/B042161/data_analysis/ACE_CSR_1/prod/program/_eff_tte.sas
 Output: root/clinical_studies/B07112689/CD70115/B042161/data_analysis/ACE_CSR_1/prod/output/_eff_tte_spl_OVSURV_PAP_31MAY2023_42161.xls
 29APR2024 10:54

POPULATION: Efficacy Evaluable Population
 ENDPOINT: Transfusion avoidance, Primary Efficacy Period
 MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]
 STUDY: BO42161
 Dichotomous Analysis (Efficacy)

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab							Eculizumab vs. Crovalimab								
		Patients		Patients with		Patients		Patients with		Odds Ratio		Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk						
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	44	100,0	35	79,5	42	100,0	34	81,0	1,07	Convergence criterion (GCONV=1E-8) satisfied.	0,27	4,21	0,6	-16,30	17,45	0,97	Algorithm converged.	0,87	1,08	0,9230	1,03	Algorithm converged.	0,93	1,15

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_TA_PAP1_31MAY2023_42161.xls
 26APR2024 15:05

POPULATION: Efficacy Evaluable Population
 ENDPOINT: transfusion avoidance, Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Efficacy)

Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab								Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio		Weighted difference (Crovalimab - Eculizumab)				Relative Risk				Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	44	100,0	35	79,5	42	100,0	34	81,0	0,92			-1,4	-18,12	15,61	0,98	Algorithm converged.	0,80	1,21	0,8698		1,02	Algorithm converged.	0,83	1,26
Age	<65	39	88,6	31	79,5	35	83,3	29	82,9	0,80			-3,4	-20,90	14,97	0,96	Algorithm converged.	0,77	1,19	0,7104	0,6606	1,04	Algorithm converged.	0,84	1,30
	>=65	5	11,4	4	80,0	7	16,7	5	71,4	1,60			8,6	-38,50	47,70	1,12	Algorithm converged.	0,59	2,13	0,7289		0,89	Algorithm converged.	0,47	1,70
Sex	Male	20	45,5	17	85,0	21	50,0	17	81,0	1,33			4,0	-19,87	27,16	1,05	Algorithm converged.	0,80	1,39	0,7297	0,5562	0,95	Algorithm converged.	0,72	1,26
	Female	24	54,5	18	75,0	21	50,0	17	81,0	0,71			-6,0	-28,88	18,71	0,93	Algorithm converged.	0,68	1,26	0,6287		1,08	Algorithm converged.	0,79	1,47
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	5	41,7	10	23,8	3	30,0	1,67			11,7	-26,00	44,31	1,39	Algorithm converged.	0,44	4,43	0,5657	0,5331	0,72	Algorithm converged.	0,23	2,30
	No	32	72,7	30	93,8	32	76,2	31	96,9	0,48			-3,1	-17,26	10,28	0,97	Algorithm converged.	0,87	1,08	0,5532		1,03	Algorithm converged.	0,93	1,15
Geographic region	Japan/Rest of Asia Pacific	8	18,2	4	50,0	7	16,7	6	85,7	0,17			-35,7	-66,51	11,00	0,58	Algorithm converged.	0,27	1,24	0,1057	0,1021	1,71	Algorithm converged.	0,80	3,65
	Central and South America/Europe	36	81,8	31	86,1	35	83,3	28	80,0	1,55			6,1	-11,70	23,82	1,08	Algorithm converged.	0,87	1,33	0,4916		0,93	Algorithm converged.	0,75	1,15
Aplastic anemia	Yes	15	34,1	12	80,0	15	35,7	12	80,0	1,00			0,0	-28,32	28,32	1,00	Algorithm converged.	0,70	1,43	1,0000	0,9046	1,00	Algorithm converged.	0,70	1,43
	No	29	65,9	23	79,3	27	64,3	22	81,5	0,87			-2,2	-22,67	19,00	0,97	Algorithm converged.	0,75	1,26	0,8378		1,03	Algorithm converged.	0,79	1,33
Baseline Weight Category	<100	41	93,2	34	82,9	38	90,5	30	78,9	1,30			4,0	-13,37	21,50	1,05	Algorithm converged.	0,85	1,30	0,6529	NE	0,95	Algorithm converged.	0,77	1,18
	>=100	3	6,8	1	33,3	4	9,5	4	100,0	*						*	WARNING: Negative of Hessian not positive definite.					*	WARNING: Negative of Hessian not positive definite.		

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_ag2_TA_PAP1_31MAY2023_42161.xls
 26APR2024 15:00

POPULATION: Efficacy Evaluable Population
 ENDPOINT: Breakthrough Hemolysis, Primary Efficacy Period
 MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]
 STUDY: BO42161
 Dichotomous Analysis (Efficacy)

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio				Weighted difference (Crovalimab - Eculizumab)			Relative Risk			Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	44	100,0	5	11,4	42	100,0	5	11,9	0,90	Convergence criterion (GCONV=1E-8) satisfied.	0,24	3,40	-1,1	-15,60	13,04	0,94	Algorithm converged.	0,30	2,92	0,8757	1,07	Algorithm converged.	0,34	3,32

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_BTH25_PAP1_31MAY2023_42161.xls
 26APR2024 15:07

POPULATION: Efficacy Evaluable Population
 ENDPOINT: Breakthrough Hemolysis, Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Efficacy)

Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Odds Ratio	Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with			Odds Ratio		Weighted difference (Crovalimab - Eculizumab)				Relative Risk				Relative Risk					
		n	%	n	%	n	%	n	%		95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	44	100,0	5	11,4	42	100,0	5	11,9	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,25	3,55	-0,5	-15,12	13,75	0,95	Algorithm converged.	0,30	3,06	0,9377		1,05	Algorithm converged.	0,33	3,36
Age	<65	39	88,6	5	12,8	35	83,3	4	11,4	1,14	Convergence criterion (GCONV=1E-8) satisfied.	0,28	4,63	1,4	-14,83	16,89	1,12	Algorithm converged.	0,33	3,85	0,8545	0,2801	0,89	Algorithm converged.	0,26	3,06
	>=65	5	11,4	0	0,0	7	16,7	1	14,3	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	0,2801	>999,99	Algorithm converged.	0,00	NE	
Sex	Male	20	45,5	2	10,0	21	50,0	4	19,0	0,47	Convergence criterion (GCONV=1E-8) satisfied.	0,08	2,92	-9,0	-31,21	14,05	0,53	Algorithm converged.	0,11	2,56	0,4057	0,2134	1,90	Algorithm converged.	0,39	9,28
	Female	24	54,5	3	12,5	21	50,0	1	4,8	2,86	Convergence criterion (GCONV=1E-8) satisfied.	0,27	29,79	7,7	-11,94	26,65	2,62	Algorithm converged.	0,29	23,36	0,3451		0,38	Algorithm converged.	0,04	3,39
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	3	25,0	10	23,8	2	20,0	1,33	Convergence criterion (GCONV=1E-8) satisfied.	0,18	10,12	5,0	-29,92	36,66	1,25	Algorithm converged.	0,26	6,07	0,7786	0,5939	0,80	Algorithm converged.	0,16	3,88
	No	32	72,7	2	6,3	32	76,2	3	9,4	0,64	Convergence criterion (GCONV=1E-8) satisfied.	0,10	4,14	-3,1	-18,64	12,07	0,67	Algorithm converged.	0,12	3,73	0,6408		1,50	Algorithm converged.	0,27	8,38
Geographic region	Japan/Rest of Asia Pacific	8	18,2	2	25,0	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	0,1025	0,0647	NE	Algorithm converged.	NE	NE
	North America/Central and South America/Europe	36	81,8	3	8,3	35	83,3	5	14,3	0,55	Convergence criterion (GCONV=1E-8) satisfied.	0,12	2,48	-6,0	-22,00	9,75	0,58	Algorithm converged.	0,15	2,26	0,4272		1,71	Algorithm converged.	0,44	6,64
Aplastic anemia	Yes	15	34,1	3	20,0	15	35,7	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	0,0528	0,0124	NE	Algorithm converged.	NE	NE
	No	29	65,9	2	6,9	27	64,3	5	18,5	0,33	Convergence criterion (GCONV=1E-8) satisfied.	0,06	1,85	-11,6	-30,47	6,65	0,37	Algorithm converged.	0,08	1,76	0,1883		2,69	Algorithm converged.	0,57	12,70
Baseline Weight Category	<100	41	93,2	5	12,2	38	90,5	3	7,9	1,62	Convergence criterion (GCONV=1E-8) satisfied.	0,36	7,30	4,3	-10,32	18,62	1,54	Algorithm converged.	0,40	6,03	0,5226	0,0730	0,65	Algorithm converged.	0,17	2,53
	>=100	3	6,8	0	0,0	4	9,5	2	50,0	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	0,0455	>999,99	Algorithm converged.	0,00	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_sq2_BTH25_PAP1_31MAY2023_42161.xls
 26APR2024 15:01

POPULATION: Primary Analysis Population
 ENDPOINT: Major adverse vascular event, Primary Efficacy Period
 MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]
 STUDY: BO42161
 Dichotomous Analysis (Efficacy)

Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)				Relative Risk			Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
All	n/a	44	100,0	0	0	42	100,0	1	2,4	0,00	Convergence criterion (GCONV=1E-8) satisfied.	0,00	NE	NE	NE	NE	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_MAVE25_PAP_31MAY2023_42161.xls
 26APR2024 15:08

POPULATION: Primary Analysis Population
 ENDPOINT: Major adverse vascular event, Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Efficacy)

Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab						
		Patients		Patients with		Patients		Patients with		Odds Ratio		Weighted difference (Crovalimab - Eculizumab)				Relative Risk				Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	44	100,0	0	0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.			NE	NE	NE	0,00	Algorithm converged.	0,00	NE	0,3115		>999,99	Algorithm converged.	0,00	NE
Age	<65	39	88,6	0	0	35	83,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	>=65	5	11,4	0	0	7	16,7	1	14,3	*	Quasi-complete separation of data points detected.			NE	NE	NE	0,00	Algorithm converged.	0,00	NE	0,2801		>999,99	Algorithm converged.	0,00	NE
Sex	Male	20	45,5	0	0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.			NE	NE	NE	0,00	Algorithm converged.	0,00	NE	0,3055		>999,99	Algorithm converged.	0,00	NE
	Female	24	54,5	0	0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	0	0	10	23,8	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	No	32	72,7	0	0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.			NE	NE	NE	0,00	Algorithm converged.	0,00	NE	0,3096		>999,99	Algorithm converged.	0,00	NE
Geographic region	Japan/Rest of Asia Pacific	8	18,2	0	0	7	16,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	North America/Central and South America/Europe	36	81,8	0	0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.			NE	NE	NE	0,00	Algorithm converged.	0,00	NE	0,3103		>999,99	Algorithm converged.	0,00	NE
Aplastic anemia	Yes	15	34,1	0	0	15	35,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	No	29	65,9	0	0	27	64,3	1	3,7	*	Quasi-complete separation of data points detected.			NE	NE	NE	0,00	Algorithm converged.	0,00	NE	0,3082		>999,99	Algorithm converged.	0,00	NE
Baseline Weight Category	<100	41	93,2	0	0	38	90,5	1	2,6	*	Quasi-complete separation of data points detected.			NE	NE	NE	0,00	Algorithm converged.	0,00	NE	0,3109		>999,99	Algorithm converged.	0,00	NE
	>=100	3	6,8	0	0	4	9,5	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_sg2_MAVE25_PAP_31MAY2023_42161.xls
 26APR2024 15:03

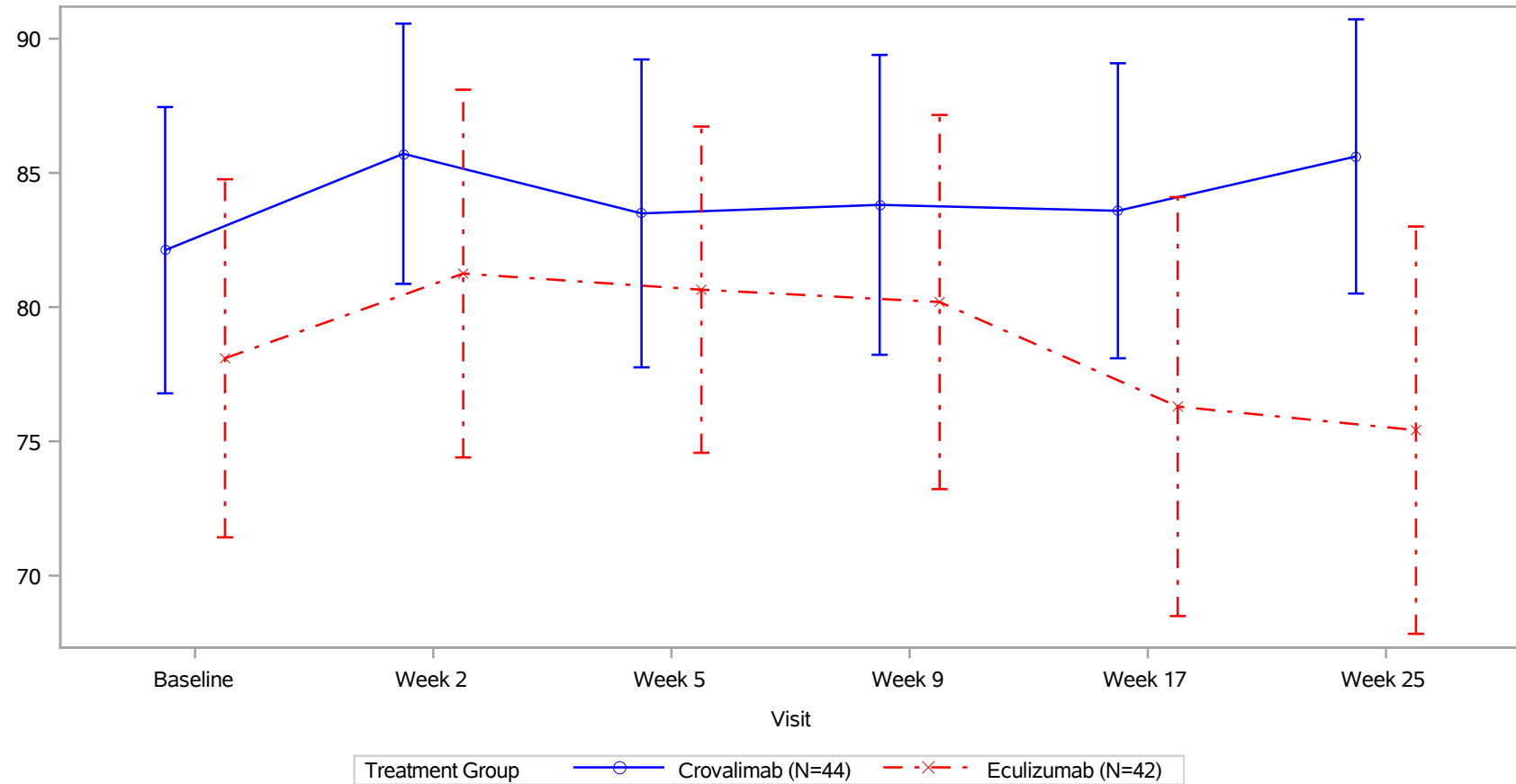
POPULATION: Primary Analysis Population
 ENDPOINT: EORTC QLQ-C30 Physical Functioning, Primary Efficacy Period
 MODEL: --
 STUDY: BO42161
 Compliance/Mean

		Crovalimab (N=44)						Eculizumab (N=42)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	44	100,0	44	100,0	82,12	17,54	42	100,0	42	100,0	78,10	21,40
Week 2	All	44	100,0	42	95,5	85,71	15,55	42	100,0	36	85,7	81,25	20,25
Week 5	All	44	100,0	42	95,5	83,49	18,40	42	100,0	41	97,6	80,65	19,25
Week 9	All	44	100,0	42	95,5	83,81	17,92	42	100,0	35	83,3	80,19	20,29
Week 17	All	44	100,0	39	88,6	83,59	16,95	41	97,6	36	87,8	76,30	23,06
Week 25	All	44	100,0	38	86,4	85,61	15,54	41	97,6	32	78,0	75,42	21,04

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP
 with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
² mean: descriptive statistics - absolute values
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_C30PHYS_PAP_31MAY2023_42161.xls
 07JUN2024 13:52

POPULATION: Primary Analysis Population
ENDPOINT: EORTC QLQ-C30 Physical Functioning, Primary Efficacy Period
STUDY: BO42161



Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/g_mean_plot.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/g_mean_plot_C30PHYS_PAP_31MAY2023_42161.pdf
07JUN2024 14:00

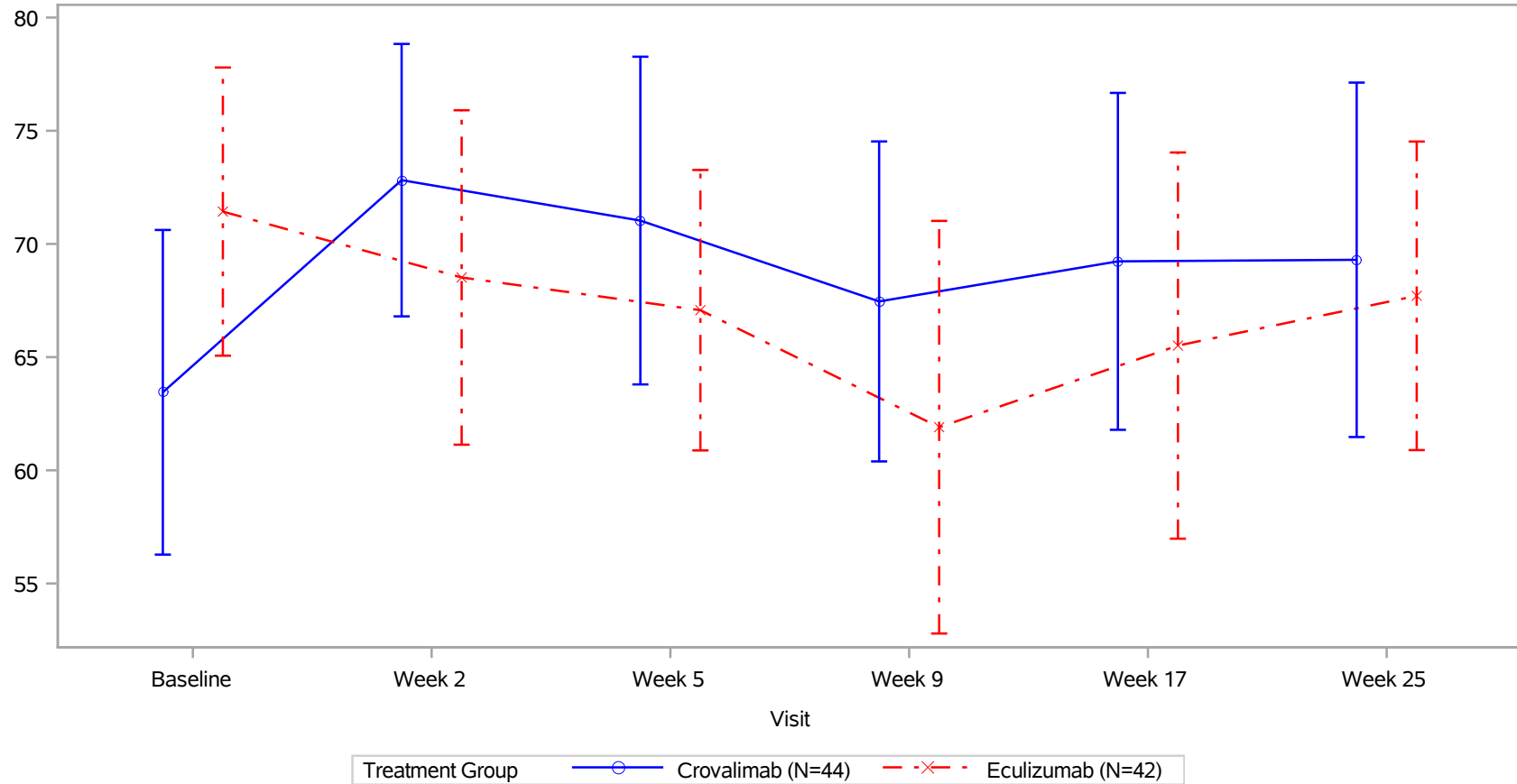
POPULATION: Primary Analysis Population
 ENDPOINT: EORTC QLQ-C30 GHS/QoL, Primary Efficacy Period
 MODEL: --
 STUDY: BO42161
 Compliance/Mean

		Crovalimab (N=44)						Eculizumab (N=42)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	44	100,0	44	100,0	63,45	23,59	42	100,0	42	100,0	71,43	20,42
Week 2	All	44	100,0	42	95,5	72,82	19,31	42	100,0	36	85,7	68,52	21,83
Week 5	All	44	100,0	42	95,5	71,03	23,23	42	100,0	41	97,6	67,07	19,63
Week 9	All	44	100,0	42	95,5	67,46	22,68	42	100,0	35	83,3	61,90	26,53
Week 17	All	44	100,0	39	88,6	69,23	22,95	41	97,6	36	87,8	65,51	25,21
Week 25	All	44	100,0	38	86,4	69,30	23,82	41	97,6	32	78,0	67,71	18,90

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP
 with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
² mean: descriptive statistics - absolute values
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_C30QOL_PAP_31MAY2023_42161.xls
 07JUN2024 13:54

POPULATION: Primary Analysis Population
ENDPOINT: EORTC QLQ-C30 GHS/QoL, Primary Efficacy Period
STUDY: BO42161



Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/g_mean_plot.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/g_mean_plot_C30QOL_PAP_31MAY2023_42161.pdf
07JUN2024 14:01

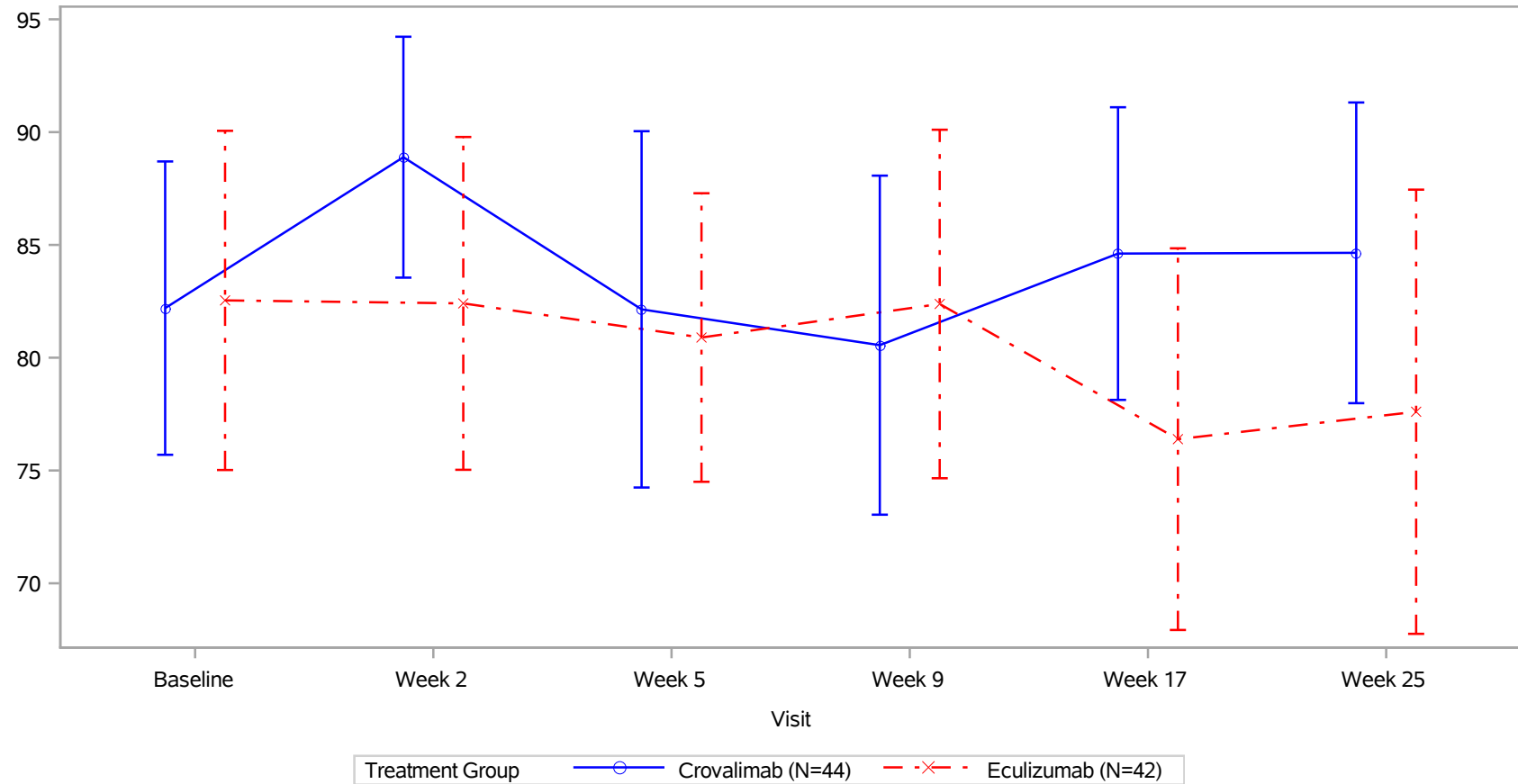
POPULATION: Primary Analysis Population
 ENDPOINT: EORTC QLQ-C30 Role Functioning, Primary Efficacy Period
 MODEL: --
 STUDY: BO42161
 Compliance/Mean

		Crovalimab (N=44)						Eculizumab (N=42)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
Visit													
All													
BASELINE	All	44	100,0	44	100,0	82,20	21,39	42	100,0	42	100,0	82,54	24,12
Week 2	All	44	100,0	42	95,5	88,89	17,13	42	100,0	36	85,7	82,41	21,80
Week 5	All	44	100,0	42	95,5	82,14	25,34	42	100,0	41	97,6	80,89	20,26
Week 9	All	44	100,0	42	95,5	80,56	24,11	42	100,0	35	83,3	82,38	22,49
Week 17	All	44	100,0	39	88,6	84,62	20,01	41	97,6	36	87,8	76,39	25,00
Week 25	All	44	100,0	38	86,4	84,65	20,28	41	97,6	32	78,0	77,60	27,31

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP
 with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
² mean: descriptive statistics - absolute values
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_C30RF_PAP_31MAY2023_42161.xls
 07JUN2024 13:55

POPULATION: Primary Analysis Population
ENDPOINT: EORTC QLQ-C30 Role Functioning, Primary Efficacy Period
STUDY: BO42161



Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/g_mean_plot.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/g_mean_plot_C30RF_PAP_31MAY2023_42161.pdf
07JUN2024 14:02

POPULATION: PRO-evaluable Population
 ENDPOINT: EORTC QLQ-C30 Responder Analysis (response criterium: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period
 MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]
 STUDY: BO42161
 Dichotomous Analysis (Efficacy)

Physical Functioning

		Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	38	100,0	4	10,5	32	100,0	2	6,3	1,79	Convergence criterion (GCONV=1E-8) satisfied.	0,31	10,32	4,5	-10,82	19,85	1,764	Algorithm converged.	0,346	9,003	0,5087	0,567	Algorithm converged.	0,111	2,892

Test for interaction based on RR (Log-binomial regression)
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_C30PHYS10_PRO_31MAY2023_42161.xls
 06JUN2024 2:19

POPULATION: PRO-evaluable Population
 ENDPOINT: EORTC QLQ-C30 Responder Analysis (response criterium: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Efficacy)

Physical Functioning

Name	Level	Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
		Patients	Patients with	Patients	Patients with	Odds Ratio		Weighted difference (Crovalimab - Eculizumab)				Relative Risk				Relative Risk											
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	38	100,0	4	10,5	32	100,0	2	6,3	1,76	Convergence criterion (GCONV=1E-8) satisfied.	0,30	10,33	4,3	-11,01	18,61	1,684	Algorithm converged.	0,330	8,604	0,5148		0,594	Algorithm converged.	0,116	3,033	
Age	<65	34	89,5	4	11,8	27	84,4	2	7,4	1,67	Convergence criterion (GCONV=1E-8) satisfied.	0,28	9,87	4,4	-13,11	20,15	1,588	Algorithm converged.	0,314	8,029	0,5602	1,0000	0,630	Algorithm converged.	0,125	3,183	
	>=65	4	10,5	0	0,0	5	15,6	0	0,0	NE	Quasi-complete separation of data points detected.	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Sex	Male	19	50,0	0	0,0	15	46,9	2	13,3	+	Quasi-complete separation of data points detected.						0,000	Algorithm converged.	0,000	NE	0,1287	NE	>999,999	Algorithm converged.	0,000	NE	
	Female	19	50,0	4	21,1	17	53,1	0	0,0	+	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	0,0244	NE	NE	Algorithm converged.	NE	NE	
Transfusion history [pRBC infusion in the last 12 months]	Yes	11	28,9	0	0,0	8	25,0	1	12,5	+	Quasi-complete separation of data points detected.						0,000	Algorithm converged.	0,000	NE	0,2850	0,0801	>999,999	Algorithm converged.	0,000	NE	
	No	27	71,1	4	14,8	24	75,0	1	4,2	4,00	Convergence criterion (GCONV=1E-8) satisfied.	0,41	38,57	10,6	-7,73	28,64	3,556	Algorithm converged.	0,426	29,657	0,1811		0,281	Algorithm converged.	0,034	2,346	
Geographic region	Japan/Rest of Asia Pacific	8	21,1	0	0,0	7	21,9	0	0,0	NE	Quasi-complete separation of data points detected.	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
	North America/Central and South America/Europe	30	78,9	4	13,3	25	78,1	2	8,0	1,77	Convergence criterion (GCONV=1E-8) satisfied.	0,30	10,57	5,3	-13,43	22,67	1,667	Algorithm converged.	0,332	8,357	0,5177		0,600	Algorithm converged.	0,120	3,008	
Aplastic anemia	Yes	13	34,2	1	7,7	13	40,6	0	0,0	+	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	0,2980	0,2849	NE	Algorithm converged.	NE	NE	
	No	25	65,8	3	12,0	19	59,4	2	10,5	1,16	Convergence criterion (GCONV=1E-8) satisfied.	0,17	7,73	1,5	-20,82	20,97	1,140	Algorithm converged.	0,211	6,159	0,8778		0,877	Algorithm converged.	0,162	4,739	
Baseline Weight Category	<100	36	94,7	4	11,1	28	87,5	1	3,6	3,37	Convergence criterion (GCONV=1E-8) satisfied.	0,36	32,02	7,5	-8,11	22,04	3,111	Algorithm converged.	0,368	26,309	0,2317		NE	0,321	Algorithm converged.	0,038	2,718
	>=100	2	5,3	0	0,0	4	12,5	1	25,0	+	Quasi-complete separation of data points detected.						0,000	Algorithm converged.	0,000	NE	0,2482	>999,999	NE	Algorithm converged.	0,000	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

POPULATION: PRO-evaluable Population

ENDPOINT: EORTC QLQ-C30 Responder Analysis (response criterium: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: BO42161

Dichotomous Analysis (Efficacy)

GHS/QoL

		Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio		Weighted difference (Crovalimab - Eculizumab)			Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	38	100,0	13	34,2	32	100,0	6	18,8	2,33	Convergence criterion (GCONV=1E-8) satisfied.	0,76	7,13	16,1	-5,14	34,92	1,880	Algorithm converged.	0,816	4,330	0,1156	0,532	Algorithm converged.	0,231	1,225

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_C30QOL10_PRO_31MAY2023_42161.xls

06JUN2024 2:17

POPULATION: PRO-evaluable Population
 ENDPOINT: EORTC QLQ-C30 Responder Analysis (response criterium: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Efficacy)

GHS/QoL

Name	Level	Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab						
		Patients		Patients with		Patients		Patients with		Odds Ratio		Weighted difference (Crovalimab - Eculizumab)						Relative Risk				Relative Risk				
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	38	100,0	13	34,2	32	100,0	6	18,8	2,25			15,5	-5,59	34,17	1,825	Algorithm converged.	0,783	4,249	0,1347		0,548	Algorithm converged.	0,235	1,276	
Age	<65	34	89,5	11	32,4	27	84,4	4	14,8	2,75			17,5	-4,53	36,55	2,184	Algorithm converged.	0,782	6,098	0,0961	0,5417	0,458	Algorithm converged.	0,164	1,279	
	>=65	4	10,5	2	50,0	5	15,6	2	40,0	1,50			10,0	-40,88	54,97	1,250	Algorithm converged.	0,292	5,348	0,7635		0,800	Algorithm converged.	0,187	3,423	
Sex	Male	19	50,0	6	31,6	15	46,9	4	26,7	1,27			4,9	-25,12	32,31	1,184	Algorithm converged.	0,407	3,448	0,7532	0,2701	0,844	Algorithm converged.	0,290	2,459	
	Female	19	50,0	7	36,8	17	53,1	2	11,8	4,37			25,1	-3,60	48,76	3,132	Algorithm converged.	0,750	13,070	0,0642		0,319	Algorithm converged.	0,077	1,333	
Transfusion history [pRBC infusion in the last 12 months]	Yes	11	28,9	2	18,2	8	25,0	1	12,5	1,56			5,7	-31,29	36,93	1,455	Algorithm converged.	0,158	13,406	0,7304	0,8120	0,688	Algorithm converged.	0,075	6,336	
	No	27	71,1	11	40,7	24	75,0	5	20,8	2,61			19,9	-5,57	41,76	1,956	Algorithm converged.	0,793	4,824	0,1134		0,511	Algorithm converged.	0,207	1,261	
Geographic region	Japan/Rest of Asia Pacific	8	21,1	1	12,5	7	21,9	1	14,3	0,86			-1,8	-40,21	34,73	0,875	Algorithm converged.	0,066	11,542	0,9194	0,5585	1,143	Algorithm converged.	0,087	15,075	
	North America/Central and South America/Europe	30	78,9	12	40,0	25	78,1	5	20,0	2,67			20,0	-4,57	40,90	2,000	Algorithm converged.	0,815	4,910	0,0956		0,500	Algorithm converged.	0,204	1,228	
Aplastic anemia	Yes	13	34,2	3	23,1	13	40,6	2	15,4	1,65			7,7	-23,01	37,04	1,500	Algorithm converged.	0,298	7,546	0,6171	0,8080	0,667	Algorithm converged.	0,133	3,354	
	No	25	65,8	10	40,0	19	59,4	4	21,1	2,50			18,9	-8,84	41,93	1,900	Algorithm converged.	0,703	5,135	0,1619		0,526	Algorithm converged.	0,195	1,423	
Baseline Weight Category	<100	36	94,7	13	36,1	28	87,5	4	14,3	3,38			21,8	-0,13	40,26	2,528	Algorithm converged.	0,924	6,912	0,0356	0,0457	0,396	Algorithm converged.	0,145	1,082	
	>=100	2	5,3	0	0,0	4	12,5	2	50,0	*	Quasi-complete separation of data points detected.					*	WARNING: Negative of Hessian not positive definite.					*	WARNING: Negative of Hessian not positive definite.			

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_sg_C30QoL1_PRO_31MAY2023_42161.xls
 06JUN2024 2:26

POPULATION: PRO-evaluable Population

ENDPOINT: EORTC QLQ-C30 Responder Analysis (response criterium: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: BO42161

Dichotomous Analysis (Efficacy)

Role Functioning

		Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab -			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	38	100,0	9	23,7	32	100,0	3	9,4	2,94	Convergence criterion (GCONV=1E-8) satisfied.	0,73	11,81	14,4	-4,91	31,08	2,525	Algorithm converged.	0,746	8,544	0,0944	0,396	Algorithm converged.	0,117	1,340

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_C30RF10_PRO_31MAY2023_42161.xls

06JUN2024 2:21

POPULATION: PRO-evaluable Population
 ENDPOINT: EORTC QLQ-C30 Responder Analysis (response criterium: improvement of at least 10 pts from BL at week 25), Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Efficacy)

Role Functioning

Name	Level	Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)				Relative Risk			Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	38	100,0	9	23,7	32	100,0	3	9,4	3,00			14,3	-3,98	31,00	2,526	Algorithm converged.	0,747	8,549	0,0965		0,396	Algorithm converged.	0,117	1,340
Age	<65	34	89,5	9	26,5	27	84,4	2	7,4	4,50			19,1	-0,83	36,55	3,574	Algorithm converged.	0,841	15,181	0,0360	0,1020	0,280	Algorithm converged.	0,066	1,189
	>=65	4	10,5	0	0,0	5	15,6	1	20,0	*	Quasi-complete separation of data points detected.					0,000	Algorithm converged.	0,000	NE	0,2636	>999,999	Algorithm converged.	0,000	NE	
Sex	Male	19	50,0	3	15,8	15	46,9	2	13,3	1,22			2,5	-24,15	26,25	1,184	Algorithm converged.	0,226	6,204	0,8395	0,2372	0,844	Algorithm converged.	0,161	4,424
	Female	19	50,0	6	31,6	17	53,1	1	5,9	7,38			25,7	-0,91	48,62	5,368	Algorithm converged.	0,717	40,200	0,0336		0,186	Algorithm converged.	0,025	1,395
Transfusion history [pRBC infusion in the last 12 months]	Yes	11	28,9	3	27,3	8	25,0	0	0,0	*	Quasi-complete separation of data points detected.					NE	Algorithm converged.	NE	NE	0,0423	0,1678	NE	Algorithm converged.	NE	NE
	No	27	71,1	6	22,2	24	75,0	3	12,5	2,00			9,7	-12,13	29,97	1,778	Algorithm converged.	0,498	6,344	0,3530		0,563	Algorithm converged.	0,158	2,007
Geographic region	Japan/Rest of Asia Pacific	8	21,1	0	0,0	7	21,9	1	14,3	*	Quasi-complete separation of data points detected.					0,000	Algorithm converged.	0,000	NE	0,2801	0,0740	>999,999	Algorithm converged.	0,000	NE
	North America/Central and South America/Europe	30	78,9	9	30,0	25	78,1	2	8,0	4,93			22,0	0,42	40,79	3,750	Algorithm converged.	0,891	15,785	0,0274		0,267	Algorithm converged.	0,063	1,122
Aplastic anemia	Yes	13	34,2	3	23,1	13	40,6	1	7,7	3,60			15,4	-14,25	43,29	3,000	Algorithm converged.	0,357	25,209	0,2658	0,8344	0,333	Algorithm converged.	0,040	2,801
	No	25	65,8	6	24,0	19	59,4	2	10,5	2,68			13,5	-10,85	34,33	2,280	Algorithm converged.	0,516	10,066	0,2235		0,439	Algorithm converged.	0,099	1,936
Baseline Weight Category	<100	36	94,7	9	25,0	28	87,5	2	7,1	4,33			17,9	-1,30	34,74	3,500	Algorithm converged.	0,821	14,927	0,0402	0,1459	0,286	Algorithm converged.	0,067	1,219
	>=100	2	5,3	0	0,0	4	12,5	1	25,0	*	Quasi-complete separation of data points detected.					0,000	Algorithm converged.	0,000	NE	0,2482	>999,999	Algorithm converged.	0,000	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_sg2_C30RF10_PRO_31MAY2023_42161.xls
06JUN2024 2:29

POPULATION: Primary Analysis Population

ENDPOINT: Questionnaire planned visits, EORTC QLQ-C30 Physical Functioning through Week 25

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: BO42161

Change from Baseline (Analysis of MMRM)

Endpoint	Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Difference between Treatments (Crovalimab - Eculizumab)					
			N		Statistics		N		Statistics		Statistics					
			With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)
Change from Baseline in EORTC QLQ-C30: Physical Functioning (revised)	All	n/a	44	44	38	0,94	2,10	42	42	32	-1,64	2,27	2,57	3,02	-3,43	8,58

[1] Patients with a value at baseline and at least one post-baseline value at Week 2,Week 5,Week 9,Week 17,Week 25.

[2] LSMeans of change from baseline to Week 25. Early Termination (ET) visit was mapped to closest regular visit.

[3] Contrasts from MMRM. Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value.

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_mmrn_str_C30PHYS_QV_PAP_31MAY2023_42161.xls

13JUN2024 13:53

POPULATION: Primary Analysis Population
 ENDPOINT: Questionnaire planned visits, EORTC QLQ-C30 GHS/QoL through Week 25
 MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]
 STUDY: B042161
 Change from Baseline (Analysis of MMRM)

Endpoint	Name	Level	Crovalimab (N=44)					Eculizumab (N=42)					Difference between Treatments (Crovalimab - Eculizumab)			
			N			Statistics		N			Statistics		Statistics			
			With baseline value	With baseline value and at least one post-baseline value [1]	With baseline value and a value at Week 25	LSMeans [2]	SE (LSMeans)	With baseline value	With baseline value and at least one post-baseline value [1]	With baseline value and a value at Week 25	LSMeans [2]	SE (LSMeans)	LSMeans [3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)
Change from Baseline in EORTC QLQ-C30: Global Health Status/QoL (revised)	All	n/a	44	44	38	3,60	2,94	42	42	32	-2,69	3,13	6,29	4,18	-2,04	14,63

[1] Patients with a value at baseline and at least one post-baseline value at Week 2, Week 5, Week 9, Week 17, Week 25.
 [2] LSMeans of change from baseline to Week 25. Early Termination (ET) visit was mapped to closest regular visit.
 [3] Contrasts from MMRM. Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_eff_mmrn.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_eff_mmrn_str_C30QOL_OV_PAP_31MAY2023_42161.xls
 13JUN2024 13:55

POPULATION: Primary Analysis Population
 ENDPOINT: Questionnaire planned visits, EORTC QLQ-C30 Role Functioning through Week 25
 MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]
 STUDY: BO42161
 Change from Baseline (Analysis of MMRM)

Endpoint	Name	Level	Crovalimab (N=44)					Eculizumab (N=42)					Difference between Treatments (Crovalimab - Eculizumab)			
			N			Statistics		N			Statistics		Statistics			
			With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)
Change from Baseline in EORTC QLQ-C30: Role Functioning (revised)	All	n/a	44	44	38	1,50	3,30	42	42	32	-4,44	3,48	5,93	4,68	-3,39	15,25

[1] Patients with a value at baseline and at least one post-baseline value at Week 2,Week 5,Week 9,Week 17,Week 25.

[2] LSMeans of change from baseline to Week 25. Early Termination (ET) visit was mapped to closest regular visit.

[3] Contrasts from MMRM. Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value.

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_mrm.aas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_mrm_str_C30RF_QV_PAP_31MAY2023_42161.xls
 13JUN2024 13:56

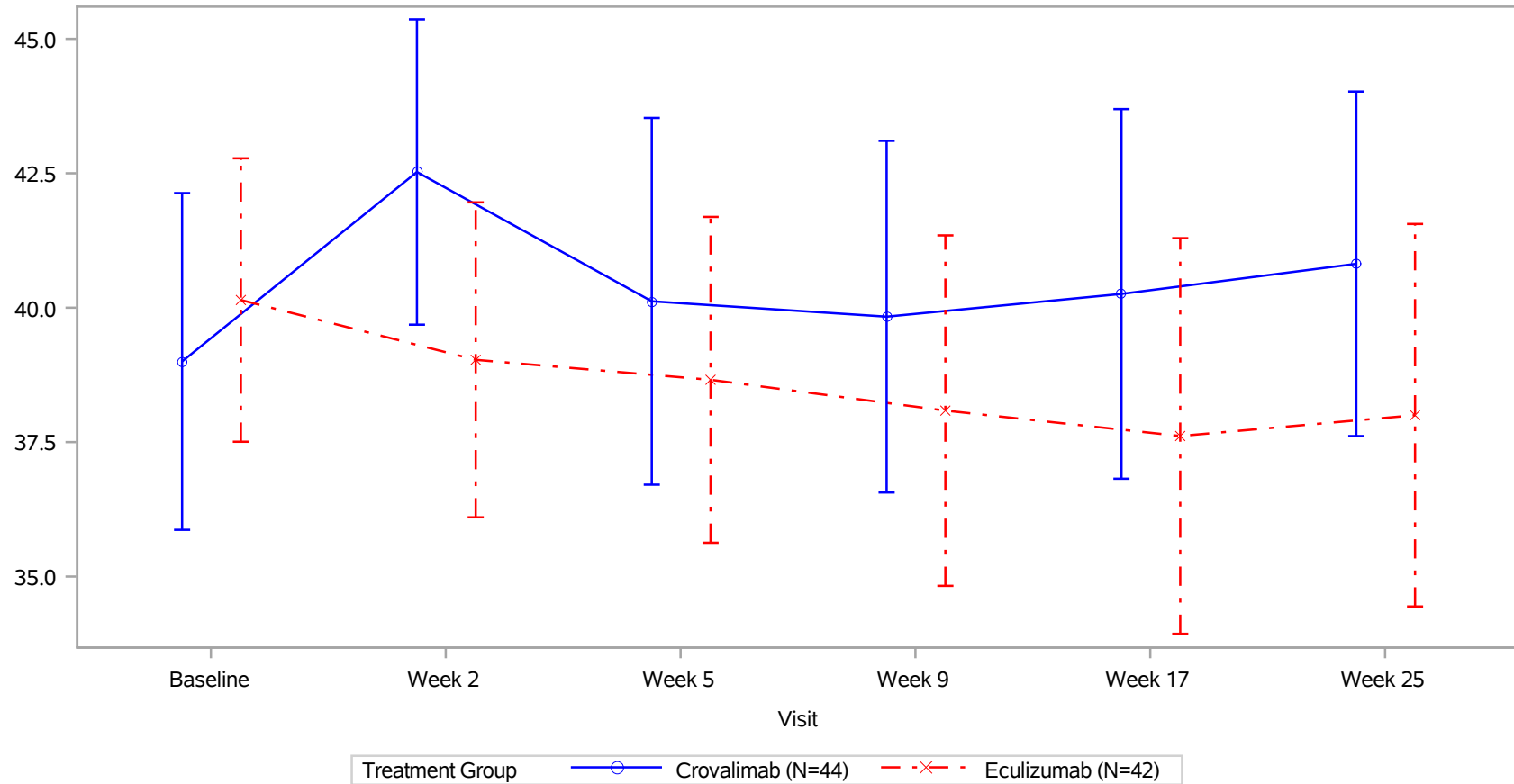
POPULATION: Efficacy Evaluable Population
 ENDPOINT: FACIT-F, Primary Efficacy Period
 MODEL: --
 STUDY: BO42161
 Compliance/Mean

		Crovalimab (N=44)						Eculizumab (N=42)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	44	100,0	44	100,0	39,00	10,30	42	100,0	42	100,0	40,14	8,46
Week 2	All	44	100,0	42	95,5	42,52	9,11	42	100,0	36	85,7	39,03	8,66
Week 5	All	44	100,0	42	95,5	40,12	10,95	42	100,0	41	97,6	38,66	9,60
Week 9	All	44	100,0	42	95,5	39,83	10,49	42	100,0	35	83,3	38,09	9,49
Week 17	All	44	100,0	39	88,6	40,26	10,60	41	97,6	36	87,8	37,61	10,87
Week 25	All	44	100,0	38	86,4	40,82	9,75	41	97,6	32	78,0	38,00	9,87

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP
 with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
² mean: descriptive statistics - absolute values
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_FAT_PAP1_31MAY2023_42161.xls
 07JUN2024 14:13

POPULATION: Efficacy Evaluable Population
ENDPOINT: FACIT-F, Primary Efficacy Period
STUDY: BO42161



Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/g_mean_plot.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/g_mean_plot_FAT_PAP1_31MAY2023_42161.pdf
07JUN2024 14:15

POPULATION: PRO-evaluable Population
 ENDPOINT: PACT-P Responder Analysis (response criterion: improvement of at least 8 pts from BL at week 25), Primary Efficacy Period
 MODEL: Stratified Analysis by Transfusion history (pRBC infusion in the last 12 months)
 STUDY: B042161
 Dichotomous Analysis (Efficacy)

Name	Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab							Eculizumab vs. Crovalimab								
	Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CI	95% Upper CI	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CI	95% Upper CI	
All	n/a	38	100,0	6	15,8	32	100,0	1	3,1	5,58	Convergence criterion (CONV=1) satisfied.	0,64	48,32	12,7	-4,21	27,67	1	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	1	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	1	1	1	1

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/B07112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/B07112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_FACT8_PRO_31MAY2023_42161.xls
 06JUN2024 2:13

POPULATION: PRO-evaluable Population
 ENDPOINT: FACIT-F Responder Analysis (response criterion: improvement of at least 8 pts from BL at week 25), Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Efficacy)

Name	Level	Crovalimab (N=38)				Eculizumab (N=32)				Odds Ratio	Crovalimab vs. Eculizumab					Eculizumab vs. Crovalimab										
		Patients		Patients with		Patients		Patients with			Odds Ratio		Weighted difference (Crovalimab - Eculizumab)			Relative Risk			Relative Risk							
		n	%	n	%	n	%	n	%		95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	38	100,0	6	15,8	32	100,0	1	3,1	5,81	Convergence criterion (GCONV=1E-8) satisfied.	0,66	51,10	12,7	-2,46	27,52	5,053	Algorithm converged.	0,641	39,806	0,0575		0,198	Algorithm converged.	0,025	1,559
Age	<65	34	89,5	6	17,6	27	84,4	1	3,7	5,57	Convergence criterion (GCONV=1E-8) satisfied.	0,63	49,45	13,9	-3,35	30,10	4,765	Algorithm converged.	0,610	37,228	0,0623	1,0000	0,210	Algorithm converged.	0,027	1,640
	>=65	4	10,5	0	0,0	5	15,6	0	0,0	NE		NE	NE				NE	NE	NE	NE		NE	NE	NE	NE	
Sex	Male	19	50,0	1	5,3	15	46,9	1	6,7	0,78	Convergence criterion (GCONV=1E-8) satisfied.	0,04	13,56	-1,4	-24,95	18,73	0,789	Algorithm converged.	0,054	11,606	0,8646	0,0701	1,267	Algorithm converged.	0,086	18,620
	Female	19	50,0	5	26,3	17	53,1	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	0,0092		NE	Algorithm converged.	NE	NE
Transfusion history [pRBC infusion in the last 12 months]	Yes	11	28,9	1	9,1	8	25,0	1	12,5	0,70	Convergence criterion (GCONV=1E-8) satisfied.	0,04	13,18	-3,4	-38,79	27,02	0,727	Algorithm converged.	0,053	9,969	0,8148	NE	1,375	Algorithm converged.	0,100	18,847
	No	27	71,1	5	18,5	24	75,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	0,0132		NE	Algorithm converged.	NE	NE
Geographic region	Japan/Rest of Asia Pacific	8	21,1	0	0,0	7	21,9	0	0,0	NE		NE	NE				NE	NE	NE	NE		NE	NE	NE	NE	
	Central and South America	30	78,9	6	20,0	25	78,1	1	4,0	6,00	Convergence criterion (GCONV=1E-8) satisfied.	0,67	53,68	16,0	-2,76	33,62	5,000	Algorithm converged.	0,644	38,816	0,0535		0,200	Algorithm converged.	0,026	1,553
Aplastic anemia	Yes	13	34,2	2	15,4	13	40,6	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	0,1242	0,3330	NE	Algorithm converged.	NE	NE
	No	25	65,8	4	16,0	19	59,4	1	5,3	3,43	Convergence criterion (GCONV=1E-8) satisfied.	0,35	33,51	10,7	-10,89	29,89	3,040	Algorithm converged.	0,369	25,038	0,2300		0,329	Algorithm converged.	0,040	2,709
Baseline Weight Category	<100	36	94,7	6	16,7	28	87,5	1	3,6	5,40	Convergence criterion (GCONV=1E-8) satisfied.	0,61	47,77	13,1	-3,56	28,60	4,667	Algorithm converged.	0,596	36,563	0,0664	NE	0,214	Algorithm converged.	0,027	1,679
	>=100	2	5,3	0	0,0	4	12,5	0	0,0	NE		NE	NE				NE	NE	NE	NE		NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_sq2_FAT8_PRO_31MAY2023_42161.xls
 06JUN2024 2:22

POPULATION: Efficacy Evaluable Population

ENDPOINT: Questionnaire planned visits, FACIT-F through Week 25

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: B042161

Change from Baseline (Analysis of MMRM)

Endpoint	Name	Level	Crovalimab (N=44)					Eculizumab (N=42)					Difference between Treatments (Crovalimab - Eculizumab)			
			N		Statistics			N		Statistics			Statistics			
			With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)
Change from Baseline in FAC070-Fatigue Subscale Score	All	n/a	44	44	38	1,07	1,26	42	42	32	-2,32	1,35	3,39	1,80	-0,21	6,98

[1] Patients with a value at baseline and at least one post-baseline value at Week 2,Week 5,Week 9,Week 17,Week 25.

[2] LSMeans of change from baseline to Week 25. Early Termination (ET) visit was mapped to closest regular visit.

[3] Contrasts from MMRM. Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value.

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_eff_mmrn_str_FAT_OV_PAP1_31MAY2023_42161.xls

13JUN2024 13:58

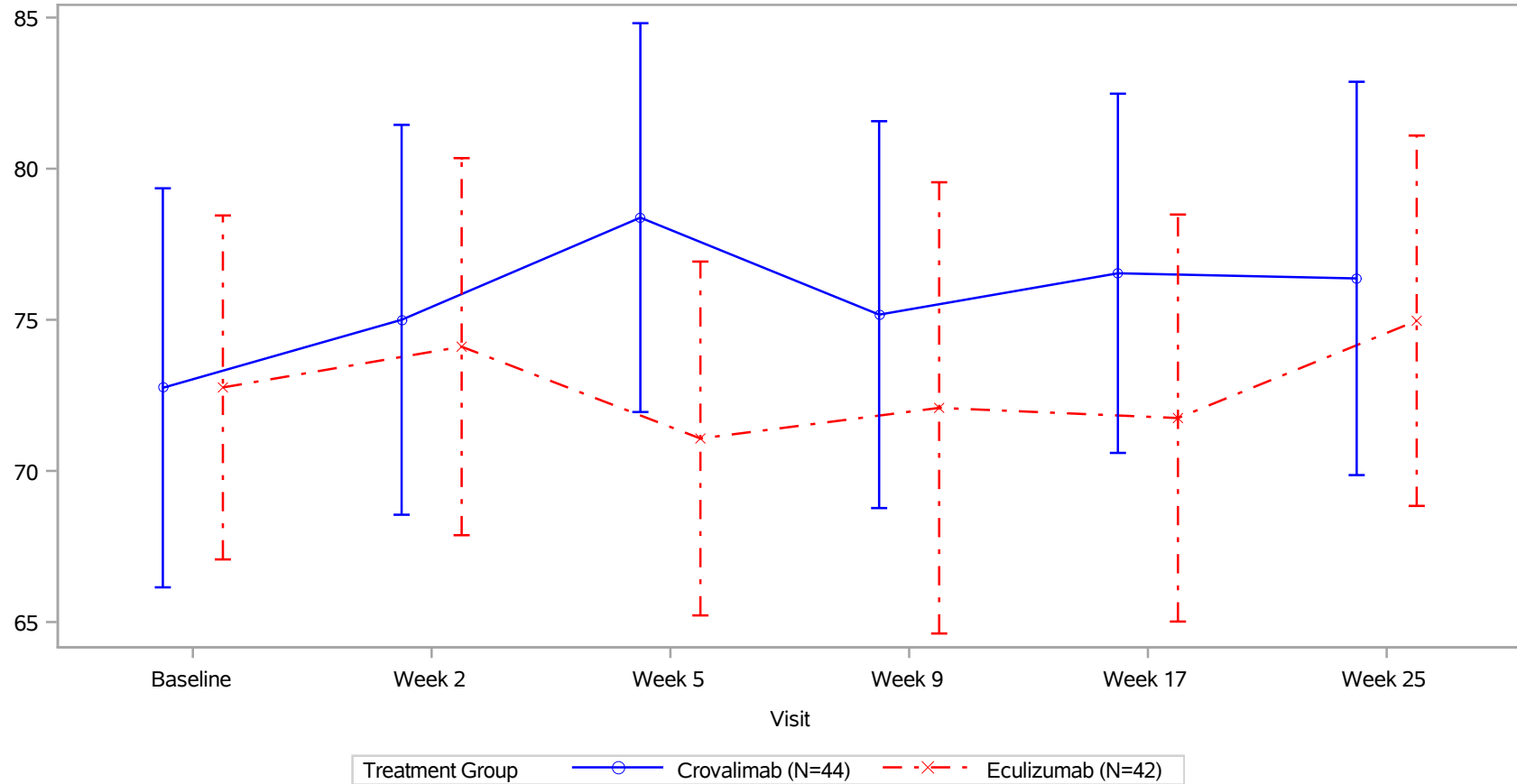
POPULATION: Primary Analysis Population
 ENDPOINT: EQ-5D-5L VAS, Primary Efficacy Period
 MODEL: --
 STUDY: BO42161
 Compliance/Mean

		Crovalimab (N=44)						Eculizumab (N=42)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)	in study ¹	%	with value ¹	%	Mean ²	SD(Mean)
All													
BASELINE	All	44	100,0	44	100,0	72,75	21,71	42	100,0	42	100,0	72,76	18,26
Week 2	All	44	100,0	42	95,5	75,00	20,70	42	100,0	36	85,7	74,11	18,44
Week 5	All	44	100,0	42	95,5	78,38	20,64	42	100,0	41	97,6	71,07	18,55
Week 9	All	44	100,0	41	93,2	75,17	20,28	42	100,0	35	83,3	72,09	21,73
Week 17	All	44	100,0	39	88,6	76,54	18,33	41	97,6	36	87,8	71,75	19,90
Week 25	All	44	100,0	38	86,4	76,37	19,80	41	97,6	32	78,0	74,97	16,99

¹ in study: number of subjects in the PAP excluding subjects who died or withdrew their ICF before the visit had happened; % based on the PAP
 with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
² mean: descriptive statistics - absolute values
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_mean.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_mean_VAS_PAP_31MAY2023_42161.xls
 07JUN2024 13:58

POPULATION: Primary Analysis Population
ENDPOINT: EQ-5D-5L VAS, Primary Efficacy Period
STUDY: BO42161



Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/g_mean_plot.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/g_mean_plot_VAS_PAP_31MAY2023_42161.pdf
07JUN2024 14:05

POPULATION: PRO-evaluable Population

ENDPOINT: EQ-5D-VAS Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: BO42161

Dichotomous Analysis (Efficacy)

		Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	38	100,0	8	21,1	32	100,0	5	15,6	1,44	Convergence criterion (GCONV=1E-8) satisfied.	0,43	4,88	5,6	-13,47	23,33	1,358	Algorithm converged.	0,493	3,740	0,5441	0,736	Algorithm converged.	0,267	2,028

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_VAS15_PRO_31MAY2023_42161.xls

06JUN2024 2:15

POPULATION: PRO-evaluable Population
 ENDPOINT: EQ-5D-VAS Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period
 MODEL: Unstratified Analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Efficacy)

Name	Level	Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio		Weighted difference (Crovalimab - Eculizumab)			Relative Risk					Relative Risk					
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	38	100,0	8	21,1	32	100,0	5	15,6	1,44			5,4	-13,54	23,05	1,347	Algorithm converged.	0,489	3,713	0,5559		0,742	Algorithm converged.	0,269	2,045
Age	<65	34	89,5	6	17,6	27	84,4	4	14,8	1,23			2,8	-17,13	21,02	1,191	Algorithm converged.	0,373	3,799	0,7646	0,5169	0,840	Algorithm converged.	0,263	2,678
	>=65	4	10,5	2	50,0	5	15,6	1	20,0	4,00			30,0	-25,01	68,64	2,500	Algorithm converged.	0,336	18,628	0,3291		0,400	Algorithm converged.	0,054	2,980
Sex	Male	19	50,0	2	10,5	15	46,9	3	20,0	0,47			-9,5	-35,78	15,09	0,526	Algorithm converged.	0,100	2,758	0,4485	0,1332	1,900	Algorithm converged.	0,363	9,955
	Female	19	50,0	6	31,6	17	53,1	2	11,8	3,46			19,8	-7,98	43,77	2,684	Algorithm converged.	0,623	11,563	0,1339		0,373	Algorithm converged.	0,086	1,605
Transfusion history [PRBC infusion in the last 12 months]	Yes	11	28,9	2	18,2	8	25,0	1	12,5	1,56			5,7	-31,29	36,93	1,455	Algorithm converged.	0,158	13,406	0,7304	0,9453	0,688	Algorithm converged.	0,075	6,336
	No	27	71,1	6	22,2	24	75,0	4	16,7	1,43			5,6	-16,87	26,61	1,333	Algorithm converged.	0,427	4,167	0,6148		0,750	Algorithm converged.	0,240	2,344
Geographic region	Japan/Rest of Asia Pacific	8	21,1	1	12,5	7	21,9	2	28,6	0,36			-16,1	-53,06	24,06	0,438	Algorithm converged.	0,050	3,853	0,4374	0,2224	2,286	Algorithm converged.	0,260	20,131
	North America/Central and South America/Europe	30	78,9	7	23,3	25	78,1	3	12,0	2,23			11,3	-10,01	30,59	1,944	Algorithm converged.	0,560	6,746	0,2615		0,514	Algorithm converged.	0,148	1,784
Aplastic anemia	Yes	13	34,2	2	15,4	13	40,6	1	7,7	2,18			7,7	-20,21	35,28	2,000	Algorithm converged.	0,206	19,437	0,5363	0,6574	0,500	Algorithm converged.	0,051	4,859
	No	25	65,8	6	24,0	19	59,4	4	21,1	1,18			2,9	-22,60	26,08	1,140	Algorithm converged.	0,374	3,479	0,8160		0,877	Algorithm converged.	0,287	2,677
Baseline Weight Category	<100	36	94,7	8	22,2	28	87,5	4	14,3	1,71			7,9	-12,22	25,97	1,556	Algorithm converged.	0,521	4,645	0,4073	0,2654	0,643	Algorithm converged.	0,215	1,920
	>=100	2	5,3	0	0,0	4	12,5	1	25,0	*						0,000	Algorithm converged.	0,000	NE	0,2482	>999,999	>999,999	Algorithm converged.	0,000	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_sg2_VAS15_PRO_31MAY2023_42161.xls
 06JUN2024 2:24

POPULATION: Primary Analysis Population
 ENDPOINT: Questionnaire planned visits, EQ-5D-5L VAS through Week 25
 MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]
 STUDY: B042161
 Change from Baseline (Analysis of MMRM)

Endpoint	Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Difference between Treatments (Crovalimab - Eculizumab)					
			N		Statistics		N		Statistics		Statistics		Statistics			
			With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	With baseline value	With baseline value and at least one post-baseline value[1]	With baseline value and a value at Week 25	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)
Change from Baseline in EQ-5D-5L: VAS Score	All	n/a	44	44	38	3,73	2,95	42	42	32	1,87	3,14	1,92	4,20	-6,49	10,33

[1] Patients with a value at baseline and at least one post-baseline value at Week 2,Week 5,Week 9,Week 17,Week 25.

[2] LSMeans of change from baseline to Week 25. Early Termination (ET) visit was mapped to closest regular visit.

[3] Contrasts from MMRM. Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value.

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_eff_mmrn.sas

Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_eff_mmrn_str_VAS_QV_PAP_31MAY2023_42161.xls

13JUN2024 14:00

POPULATION: PRO-evaluable Population

ENDPOINT: EQPNH1-Had Pain in Your Chest Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: BO42161

Dichotomous Analysis (Efficacy)

		Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab								Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	38	100,0	1	2,6	32	100,0	1	3,1	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,05	14,58	-0,3	-15,21	12,72	0,889	Algorithm converged.	0,059	13,449	0,9325	1,125	Algorithm converged.	0,074	17,022

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_ILCHEST15_PRO107_31MAY2023_42161.xls

11JUN2024 11:43

POPULATION: PRO-evaluable Population

ENDPOINT: EQPNH1-Had Problems Swallowing Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: BO42161

Dichotomous Analysis (Efficacy)

		Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab								Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	38	100,0	3	7,9	32	100,0	1	3,1	2,49	Convergence criterion (GCONV=1E-8) satisfied.	0,25	24,75	4,5	-11,06	17,39	2,494	Algorithm converged.	0,276	22,522	0,3969	0,401	Algorithm converged.	0,044	3,621

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_ILDYSPH15_PRO105_31MAY2023_42161.xls

11JUN2024 11:42

POPULATION: PRO-evaluable Population

ENDPOINT: EQPNH1-Dyspnea Score Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: BO42161

Dichotomous Analysis (Efficacy)

		Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio		Weighted difference (Crovalimab - Eculizumab)			Relative Risk					Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	38	100,0	7	18,4	32	100,0	4	12,5	1,51	Convergence criterion (GCONV=1E-8) satisfied.	0,40	5,71	5,4	-12,63	22,12	1,395	Algorithm converged.	0,455	4,277	0,5273	0,717	Algorithm converged.	0,234	2,198

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_ILDYSFN15_PRODYS_31MAY2023_42161.xls

11JUN2024 11:40

POPULATION: PRO-evaluable Population

ENDPOINT: EQPNH1-Difficulty Get/Maintain Erection Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: BO42161

Dichotomous Analysis (Efficacy)

		Crovalimab (N=15)				Eculizumab (N=14)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	15	100,0	4	26,7	14	100,0	3	21,4	1,70	Convergence criterion (GCONV=1E-8) satisfied.	0,27	10,72	8,8	-21,51	37,60	1,180	Algorithm converged.	0,375	3,718	0,5439	0,847	Algorithm converged.	0,269	2,670

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_ILERECT15_PRO108_31MAY2023_42161.xls

11JUN2024 11:47

POPULATION: PRO-evaluable Population

ENDPOINT: EQPNH1-Have You Had Headaches Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: BO42161

Dichotomous Analysis (Efficacy)

		Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab					
		Patients		Patients with		Patients		Patients with		Odds Ratio				Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	38	100,0	7	18,4	32	100,0	8	25,0	0,64	Convergence criterion (GCONV=1E-8) satisfied.	0,20	2,04	-7,4	-26,89	11,39	0,797	Algorithm converged.	0,332	1,912	0,4501	1,254	Algorithm converged.	0,523	3,008

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_ILHEAD15_PRO101_31MAY2023_42161.xls

11JUN2024 11:38

POPULATION: PRO-evaluable Population

ENDPOINT: EQPNH1-Had Pain in Your Stomach Area Responder Analysis (response criterium: improvement of at least 15 pts from BL at week 25), Primary Efficacy Period

MODEL: Stratified Analysis by Transfusion history [pRBC infusion in the last 12 months]

STUDY: BO42161

Dichotomous Analysis (Efficacy)

		Crovalimab (N=38)				Eculizumab (N=32)				Crovalimab vs. Eculizumab							Eculizumab vs. Crovalimab								
		Patients		Patients with		Patients		Patients with		Odds Ratio			Weighted difference (Crovalimab - Eculizumab)			Relative Risk				Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Weighted difference in proportion	95% Lower CL for difference in proportion	95% Upper CL for difference in proportion	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	38	100,0	4	10,5	32	100,0	4	12,5	0,83	Convergence criterion (GCONV=1E-8) satisfied.	0,19	3,56	-1,9	-19,62	13,45	0,840	Algorithm converged.	0,228	3,094	0,8033	1,190	Algorithm converged.	0,323	4,384

Test for interaction based on RR (Log-binomial regression)

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_eff_resp.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_eff_resp_str_ILSTOMACH15_PRO106_31MAY2023_42161.xls

11JUN2024 11:45

POPULATION: Primary Analysis Population

ENDPOINT: Primary Efficacy Period, Treatment Satisfaction Questionnaire for Medication-9

STUDY: BO42161

Questionnaire Visit	Crovalimab (N=44)			Eculizumab (N=42)			Hedges g (95% CI)*
	n	Mean	SD(Mean)	n	Mean	SD(Mean)	
Perceived effectiveness							
Week 13	38	73,10	16,31	35	68,10	23,27	0.251 (0.169, 0.332)
Week 25	38	77,05	19,42	30	73,15	17,14	0.211 (0.140, 0.282)
How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?							
Week 13	38	74,12	16,76	35	69,05	24,96	0.241 (0.163, 0.319)
Week 25	38	76,32	22,80	30	73,33	17,83	0.144 (0.095, 0.192)
How satisfied or dissatisfied are you with the way the medication relieves your symptoms?							
Week 13	38	71,05	20,02	35	68,10	24,04	0.134 (0.091, 0.178)
Week 25	38	77,63	19,09	30	73,33	17,83	0.232 (0.154, 0.310)
How satisfied or dissatisfied are you with the amount of time it takes the medication to start working?							
Week 13	38	74,12	18,05	35	67,14	24,42	0.327 (0.221, 0.433)
Week 25	38	77,19	19,15	30	72,78	18,30	0.235 (0.156, 0.314)
Convenience of medication							
Week 13	38	77,34	14,69	35	53,97	19,87	1.346 (0.909, 1.782)
Week 25	38	80,99	14,65	31	60,75	22,95	1.075 (0.717, 1.434)

Taking all things into account, how satisfied or dissatisfied are you with this medication?							
Week 13	38	74,12	19,64	35	75,71	16,83	-0.087 (-0.115, -0.059)
Week 25	38	80,26	18,12	30	71,67	17,59	0.481 (0.319, 0.642)

* 95% CI is calculated using Hedges g method.

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_qs_g.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_qs_g_TSQM_EF1_PAP_31MAY2023_42161.xls

16MAY2024 11:38

POPULATION: Safety Population
 ENDPOINT: Any AEs, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk							
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	44	100,0	34	77,3	42	100,0	28	66,7	1,70	Convergence criterion (GCONV=1E-8) satisfied.	0,66	4,41	0,106	Algorithm converged.	-0,083	0,295	1,16	Algorithm converged.	0,89	1,51	0,2789		0,86	Algorithm converged.	0,66	1,13
Age	<65	39	88,6	30	76,9	35	83,3	25	71,4	1,33	Convergence criterion (GCONV=1E-8) satisfied.	0,47	3,79	0,055	Algorithm converged.	-0,145	0,255	1,08	Algorithm converged.	0,82	1,41	0,5920	0,2612	0,93	Algorithm converged.	0,71	1,22
	>=65	5	11,4	4	80,0	7	16,7	3	42,9	5,33	Convergence criterion (GCONV=1E-8) satisfied.	0,38	75,77	0,371	Algorithm converged.	-0,136	0,879	1,87	Algorithm converged.	0,71	4,88	0,2031		0,54	Algorithm converged.	0,20	1,40
Sex	Male	20	45,5	15	75,0	21	50,0	16	76,2	0,94	Convergence criterion (GCONV=1E-8) satisfied.	0,23	3,90	-0,012	Algorithm converged.	-0,275	0,251	0,98	Algorithm converged.	0,69	1,39	0,9293	0,2118	1,02	Algorithm converged.	0,72	1,44
	Female	24	54,5	19	79,2	21	50,0	12	57,1	2,85	Convergence criterion (GCONV=1E-8) satisfied.	0,77	10,57	0,220	Algorithm converged.	-0,047	0,487	1,39	Algorithm converged.	0,91	2,12	0,1313		0,72	Algorithm converged.	0,47	1,10
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	9	75,0	10	23,8	6	60,0	2,00	Convergence criterion (GCONV=1E-8) satisfied.	0,32	12,33	0,150	Algorithm converged.	-0,240	0,540	1,25	Algorithm converged.	0,68	2,28	0,4678	0,7783	0,80	Algorithm converged.	0,44	1,46
	No	32	72,7	25	78,1	32	76,2	22	68,8	1,62	Convergence criterion (GCONV=1E-8) satisfied.	0,53	4,99	0,094	Algorithm converged.	-0,121	0,309	1,14	Algorithm converged.	0,84	1,53	0,3988		0,88	Algorithm converged.	0,65	1,18
Geographic region	Japan/Rest of Asia Pacific	8	18,2	7	87,5	7	16,7	6	85,7	1,17	Convergence criterion (GCONV=1E-8) satisfied.	0,06	22,94	0,018	Algorithm converged.	-0,328	0,364	1,02	Algorithm converged.	0,68	1,52	0,9195	0,5599	0,98	Algorithm converged.	0,66	1,46
	North America/Central and South America/Europe	36	81,8	27	75,0	35	83,3	22	62,9	1,77	Convergence criterion (GCONV=1E-8) satisfied.	0,64	4,91	0,121	Algorithm converged.	-0,092	0,335	1,19	Algorithm converged.	0,87	1,64	0,2747		0,84	Algorithm converged.	0,61	1,15

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_AE_SE1_31MAY2023_42161.xls
 23APR2024 20:38

POPULATION: Safety Population
 ENDPOINT: AEs Grade >= 3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab								
		Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk						
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	44	100,0	8	18,2	42	100,0	1	2,4	9,11	Convergence criterion (GCONV=1E-8) satisfied.	1,09	76,39	0,158	Algorithm converged.	0,035	0,281	7,636	Algorithm converged.	0,998	58,459	0,0503		0,131	Algorithm converged.	0,017	1,002	
Age	<65	39	88,6	7	17,9	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 1.9072270231 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	>=65	5	11,4	1	20,0	7	16,7	1	14,3	1,50	Convergence criterion (GCONV=1E-8) satisfied.	0,07	31,57	0,057	Algorithm converged.	-0,379	0,493	1,400	Algorithm converged.	0,112	17,453	0,7938		0,714	Algorithm converged.	0,057	8,905	
Sex	Male	20	45,5	4	20,0	21	50,0	1	4,8	5,00	Convergence criterion (GCONV=1E-8) satisfied.	0,51	49,27	0,152	Algorithm converged.	-0,045	0,350	4,200	Algorithm converged.	0,512	34,435	0,1813	0,2831	0,238	Algorithm converged.	0,029	1,952	
	Female	24	54,5	4	16,7	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 1.9423173446 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	3	25,0	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	0,3771	NE	Algorithm converged.	NE	NE
	No	32	72,7	5	15,6	32	76,2	1	3,1	5,74	Convergence criterion (GCONV=1E-8) satisfied.	0,63	52,23	0,125	Algorithm converged.	-0,015	0,265	5,000	Algorithm converged.	0,618	40,439	0,1313		0,200	Algorithm converged.	0,025	1,618	
Geographic region	Japan/Rest of Asia Pacific	8	18,2	3	37,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	0,3600	NE	Algorithm converged.	NE	NE
	North America/Central and South America/Europe	36	81,8	5	13,9	35	83,3	1	2,9	5,48	Convergence criterion (GCONV=1E-8) satisfied.	0,61	49,57	0,110	Algorithm converged.	-0,015	0,236	4,861	Algorithm converged.	0,598	39,538	0,1392		0,206	Algorithm converged.	0,025	1,673	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_GE3_SE1_31MAY2023_42161.xls
 23MAY2024 22:43

POPULATION: Safety Population
 ENDPOINT: AEs Grade 3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	44	100,0	7	15,9	42	100,0	1	2,4	7,76	Convergence criterion (GCONV=1E-8) satisfied.	0,91	66,05	0,135	Algorithm converged.	0,018	0,253	6,68	Algorithm converged.	0,86	52,02	0,0697		0,15	Algorithm converged.	0,02	1,17
Age	<65	39	88,6	6	15,4	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 2.0903851153 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	>=65	5	11,4	1	20,0	7	16,7	1	14,3	1,50	Convergence criterion (GCONV=1E-8) satisfied.	0,07	31,57	0,057	Algorithm converged.	-0,379	0,493	1,40	Algorithm converged.	0,11	17,45	0,7938		0,71	Algorithm converged.	0,06	8,90
Sex	Male	20	45,5	3	15,0	21	50,0	1	4,8	3,53	Convergence criterion (GCONV=1E-8) satisfied.	0,34	37,14	0,102	Algorithm converged.	-0,079	0,283	3,15	Algorithm converged.	0,36	27,83	0,3020	0,2374	0,32	Algorithm converged.	0,04	2,80
	Female	24	54,5	4	16,7	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 1.9423173446 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	3	25,0	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	0,3365	NE	Algorithm converged.	NE	NE
	No	32	72,7	4	12,5	32	76,2	1	3,1	4,43	Convergence criterion (GCONV=1E-8) satisfied.	0,47	42,02	0,094	Algorithm converged.	-0,036	0,223	4,00	Algorithm converged.	0,47	33,86	0,2033		0,25	Algorithm converged.	0,03	2,12
Geographic region	Japan/Rest of Asia Pacific	8	18,2	3	37,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	0,3195	NE	Algorithm converged.	NE	NE
	North America/Central and South America/Europe	36	81,8	4	11,1	35	83,3	1	2,9	4,25	Convergence criterion (GCONV=1E-8) satisfied.	0,45	40,08	0,083	Algorithm converged.	-0,034	0,199	3,89	Algorithm converged.	0,46	33,10	0,2138		0,26	Algorithm converged.	0,03	2,19

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_G3_SE1_31MAY2023_42161.xls
 23APR2024 20:43

POPULATION: Safety Population
 ENDPOINT: AEs Grade 4, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab										
		Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL			
All	n/a	44	100,0	1	2,3	42	100,0	0	0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Age	<65	39	88,6	1	2,6	35	83,3	0	0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 7.2864437275 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	>=65	5	11,4	0	0,0	7	16,7	0	0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		
Sex	Male	20	45,5	1	5,0	21	50,0	0	0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Female	24	54,5	0	0,0	21	50,0	0	0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	0	0,0	10	23,8	0	0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		
	No	32	72,7	1	3,1	32	76,2	0	0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Geographic region	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		
	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 7.4354133187 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_G4_SE1_31MAY2023_42161.xls
 23APR2024 20:45

POPULATION: Safety Population
 ENDPOINT: AEs Grade 5 (AEs leading to death), Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
		n	%	n	%	n	%	n	%
All	n/a	44	100,0	0	0	42	100,0	0	0
Age	<65	39	88,6	0	0	35	83,3	0	0
	>=65	5	11,4	0	0	7	16,7	0	0
Sex	Male	20	45,5	0	0	21	50,0	0	0
	Female	24	54,5	0	0	21	50,0	0	0
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	0	0	10	23,8	0	0
	No	32	72,7	0	0	32	76,2	0	0
Geographic region	Japan/Rest of Asia Pacific	8	18,2	0	0	7	16,7	0	0
	North America/ Central and South America/ Europe	36	81,8	0	0	35	83,3	0	0

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_G5_SE1_31MAY2023_42161.xls
 23APR2024 20:47

POPULATION: Safety Population
 ENDPOINT: Any SAEs, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab						
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk						
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	44	100,0	6	13,6	42	100,0	1	2,4	6,47	Convergence criterion (GCONV=1E-8) satisfied.	0,74	56,27	0,113	Algorithm converged.	0,001	0,224	5,73	Algorithm converged.	0,72	45,59	0,0991		0,17	Algorithm converged.	0,02	1,39
Age	<65	39	88,6	4	10,3	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	>=65	5	11,4	2	40,0	7	16,7	1	14,3	4,00	Convergence criterion (GCONV=1E-8) satisfied.	0,25	63,95	0,257	Algorithm converged.	-0,244	0,759	2,80	Algorithm converged.	0,34	23,06	0,3385		0,36	Algorithm converged.	0,04	2,94
Sex	Male	20	45,5	3	15,0	21	50,0	1	4,8	3,53	Convergence criterion (GCONV=1E-8) satisfied.	0,34	37,14	0,102	Algorithm converged.	-0,079	0,283	3,15	Algorithm converged.	0,36	27,83	0,3020	0,2892	0,32	Algorithm converged.	0,04	2,80
	Female	24	54,5	3	12,5	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	3	25,0	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 1.4822914344 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	0,2871	NE	Algorithm converged.	NE	NE
	No	32	72,7	3	9,4	32	76,2	1	3,1	3,21	Convergence criterion (GCONV=1E-8) satisfied.	0,32	32,60	0,063	Algorithm converged.	-0,055	0,180	3,00	Algorithm converged.	0,33	27,33	0,3298		0,33	Algorithm converged.	0,04	3,04
Geographic region	Japan/Rest of Asia Pacific	8	18,2	4	50,0	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	0,1671	NE	Algorithm converged.	NE	NE

	North America/ Central and South America/ Europe	36	81,8	2	5,6	35	83,3	1	2,9	2,00	Convergence criterion (GCONV=1E-8) satisfied.	0,17	23,11	0,027	Algorithm converged.	-0,066	0,120	1,94	Algorithm converged.	0,18	20,49	0,5800		0,51	Algorithm converged.	0,05	5,42
--	--	----	------	---	-----	----	------	---	-----	------	--	------	-------	-------	-------------------------	--------	-------	------	-------------------------	------	-------	--------	--	------	-------------------------	------	------

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sq_SAE_SE1_31MAY2023_42161.xls
 23APR2024 20:40

POPULATION: Safety Population
 ENDPOINT: AEs leading to treatment discontinuation, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	0	0	42	100,0	0	0
Age	<65	39	88,6	0	0	35	83,3	0	0
	>=65	5	11,4	0	0	7	16,7	0	0
Sex	Male	20	45,5	0	0	21	50,0	0	0
	Female	24	54,5	0	0	21	50,0	0	0
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	0	0	10	23,8	0	0
	No	32	72,7	0	0	32	76,2	0	0
Geographic region	Japan/Rest of Asia Pacific	8	18,2	0	0	7	16,7	0	0
	North America/ Central and South America/ Europe	36	81,8	0	0	35	83,3	0	0

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_DIS_SE1_31MAY2023_42161.xls
 23APR2024 20:48

POPULATION: Safety Population
 ENDPPOINT: Any AEs
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Age

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab												Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		<65	39	88,6	4	10,3	35	83,3	1	2,9	3,89	Convergence criterion (GCONV=1E-8) satisfied.	0,41	36,56	0,074	Algorithm converged.	-0,036	0,184	3,59	Algorithm converged.	0,42	30,61	0,2425		-	0,28	Algorithm converged.	0,03	2,38
Blood and lymphatic system disorders		>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Blood and lymphatic system disorders	Extravascular haemolysis	<65	39	88,6	1	2,6	35	83,3	1	2,9	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,05	14,86	-0,003	Algorithm converged.	-0,077	0,071	0,90	Algorithm converged.	0,06	13,82	0,9382		-	1,11	Algorithm converged.	0,07	17,15
Blood and lymphatic system disorders	Extravascular haemolysis	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	<65	39	88,6	2	5,1	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Blood and lymphatic system disorders	Pancytopenia	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Pancytopenia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Cardiac disorders		<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Cardiac disorders		>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Cardiac disorders	Palpitations	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Cardiac disorders	Palpitations	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Eye disorders		<65	39	88,6	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	
Eye disorders		>=65	5	11,4	0	0,0	7	16,7	1	14,3	*	Quasi-complete separation of data points detected.			*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE	
Eye disorders	Lacrimation increased	<65	39	88,6	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	
Eye disorders	Lacrimation increased	>=65	5	11,4	0	0,0	7	16,7	1	14,3	*	Quasi-complete separation of data points detected.			*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0,00	Algorithm converged.	0,00	NE	1,0000		>999,99	Algorithm converged.	0,00	NE	
Gastrointestinal disorders		<65	39	88,6	7	17,9	35	83,3	5	14,3	1,31	Convergence criterion (GCONV=1E-8) satisfied.	0,38	4,59	0,037	Algorithm converged.	-0,131	0,204	1,26	Algorithm converged.	0,44	3,60	0,6709		-	0,80	Algorithm converged.	0,28	2,28
Gastrointestinal disorders		>=65	5	11,4	1	20,0	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Gastrointestinal disorders	Abdominal pain	<65	39	88,6	1	2,6	35	83,3	1	2,9	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,05	14,86	-0,003	Algorithm converged.	-0,077	0,071	0,90	Algorithm converged.	0,06	13,82	0,9382		-	1,11	Algorithm converged.	0,07	17,15

Gastrointestinal disorders	Abdominal pain	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE										
Gastrointestinal disorders	Diarrhoea	<65	39	88,6	2	5,1	35	83,3	1	2,9	1,84		0,16	21,20	0,023		Algorithm converged.	-0,066	0,111	1,79		Algorithm converged.	0,17	18,95	0,6266		-	0,56		Algorithm converged.	0,05	5,88						
Gastrointestinal disorders	Diarrhoea	>=65	5	11,4	1	20,0	7	16,7	0	0,0	*						Quasi-complete separation of data points detected.				NE	Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE							
Gastrointestinal disorders	Dyspepsia	<65	39	88,6	1	2,6	35	83,3	0	0,0	*						Quasi-complete separation of data points detected.				NE	Algorithm converged.	NE	NE	NE		-	NE		Algorithm converged.	NE	NE						
Gastrointestinal disorders	Dyspepsia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE							
Gastrointestinal disorders	Gastroesophageal reflux disease	<65	39	88,6	0	0,0	35	83,3	1	2,9	*						Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.						0,00	Algorithm converged.	0,00	NE	0,9999		>999,9	Algorithm converged.	0,00	NE	
Gastrointestinal disorders	Gastroesophageal reflux disease	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE						
Gastrointestinal disorders	Nausea	<65	39	88,6	3	7,7	35	83,3	2	5,7	1,37		0,22	8,75	0,020		Convergence criterion (GCONV=1E-8) satisfied.					Algorithm converged.	-0,094	0,133	1,35		0,24	7,59	0,7363		-	0,74		Algorithm converged.	0,13	4,19		
Gastrointestinal disorders	Nausea	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Gastrointestinal disorders	Odynophagia	<65	39	88,6	1	2,6	35	83,3	1	2,9	0,89		0,05	14,86	-0,003		Convergence criterion (GCONV=1E-8) satisfied.					Algorithm converged.	-0,077	0,071	0,90		0,06	13,82	0,9382		-	1,11		Algorithm converged.	0,07	17,15		
Gastrointestinal disorders	Odynophagia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Gastrointestinal disorders	Stomatitis	<65	39	88,6	1	2,6	35	83,3	0	0,0	*						Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 7.2864437209 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE		-	NE		Algorithm converged.	NE	NE
Gastrointestinal disorders	Stomatitis	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Gastrointestinal disorders	Vomiting	<65	39	88,6	1	2,6	35	83,3	1	2,9	0,89		0,05	14,86	-0,003		Convergence criterion (GCONV=1E-8) satisfied.					Algorithm converged.	-0,077	0,071	0,90		0,06	13,82	0,9382		-	1,11		Algorithm converged.	0,07	17,15		
Gastrointestinal disorders	Vomiting	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
General disorders and administration site conditions		<65	39	88,6	9	23,1	35	83,3	7	20,0	1,20		0,39	3,66	0,031		Convergence criterion (GCONV=1E-8) satisfied.					Algorithm converged.	-0,156	0,218	1,15		0,48	2,77	0,7488		-	0,87		Algorithm converged.	0,36	2,08		
General disorders and administration site conditions		>=65	5	11,4	3	60,0	7	16,7	1	14,3	9,00		0,56	143,86	0,457		Convergence criterion (GCONV=1E-8) satisfied.					Algorithm converged.	-0,044	0,959	4,20		0,60	29,54	0,1493		0,24		Algorithm converged.	0,03	1,67			
General disorders and administration site conditions	Asthenia	<65	39	88,6	3	7,7	35	83,3	2	5,7	1,37		0,22	8,75	0,020		Convergence criterion (GCONV=1E-8) satisfied.					Algorithm converged.	-0,094	0,133	1,35		0,24	7,59	0,7363		-	0,74		Algorithm converged.	0,13	4,19		
General disorders and administration site conditions	Asthenia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
General disorders and administration site conditions	Chest pain	<65	39	88,6	0	0,0	35	83,3	1	2,9	*						Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0,00	Algorithm converged.	0,00	NE	0,9999		-	>999,9	Algorithm converged.	0,00	NE	
General disorders and administration site conditions	Chest pain	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
General disorders and administration site conditions	Fatigue	<65	39	88,6	1	2,6	35	83,3	2	5,7	0,43		0,04	5,01	-0,032		Convergence criterion (GCONV=1E-8) satisfied.					Algorithm converged.	-0,123	0,060	0,45		0,04	4,74	0,5051		-	2,23		Algorithm converged.	0,21	23,52		

Injury, poisoning and procedural complications	Thermal burn	<65	39	88,6	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 8.329780699 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,9	9	Algorithm converged.	0,00	NE	
Injury, poisoning and procedural complications	Thermal burn	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Investigations		<65	39	88,6	0	0,0	35	83,3	2	5,7	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 5.0458638341 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,9	9	Algorithm converged.	0,00	NE	
Investigations		>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Investigations	Alanine aminotransferase increased	<65	39	88,6	0	0,0	35	83,3	2	5,7	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 5.0458638341 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,9	9	Algorithm converged.	0,00	NE	
Investigations	Alanine aminotransferase increased	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Metabolism and nutrition disorders		<65	39	88,6	1	2,6	35	83,3	2	5,7	0,43	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,123	0,060	0,45	Algorithm converged.	0,04	4,74	0,5051	-	2,23	Algorithm converged.	0,21	23,52
Metabolism and nutrition disorders		>=65	5	11,4	0	0,0	7	16,7	1	14,3	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,9	9	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Glucose tolerance impaired	<65	39	88,6	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 8.3297807067 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,9	9	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Glucose tolerance impaired	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Metabolism and nutrition disorders	Hyperkalaemia	<65	39	88,6	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Metabolism and nutrition disorders	Hyperkalaemia	>=65	5	11,4	0	0,0	7	16,7	1	14,3	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,9	9	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Hypokalaemia	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	NE	
Metabolism and nutrition disorders	Hypokalaemia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Metabolism and nutrition disorders	Iron deficiency	<65	39	88,6	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 8.329780699 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,9	9	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Iron deficiency	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Musculoskeletal and connective tissue disorders		<65	39	88,6	5	12,8	35	83,3	5	14,3	0,88	Convergence criterion (GCONV=1E-8) satisfied.	Algorithm converged.	-0,171	0,142	0,90	Algorithm converged.	0,28	2,84	0,8540	-	1,11	Algorithm converged.	0,35	3,53
Musculoskeletal and connective tissue disorders		>=65	5	11,4	2	40,0	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	NE	

Musculoskeletal and connective tissue disorders	Arthralgia	<65	39	88,6	2	5,1	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.							ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Arthralgia	>=65	5	11,4	1	20,0	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.							ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Back pain	<65	39	88,6	0	0,0	35	83,3	2	5,7	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 5.0458638388 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,9	Algorithm converged.	0,00	NE
Musculoskeletal and connective tissue disorders	Back pain	>=65	5	11,4	1	20,0	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.							ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Coccydynia	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 7.2864437209 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Coccydynia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Muscle spasms	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.							ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Muscle spasms	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Myalgia	<65	39	88,6	1	2,6	35	83,3	2	5,7	0,43		Convergence criterion (GCONV=1E-8) satisfied.	0,04	5,01	-0,032			Algorithm converged.	-0,123	0,060	0,45		Algorithm converged.	0,04	4,74	0,5051	-	2,23	Algorithm converged.	0,21	23,52
Musculoskeletal and connective tissue disorders	Myalgia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Neck pain	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.							ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Neck pain	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Spinal pain	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.							ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Spinal pain	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	<65	39	88,6	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.							ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,9	Algorithm converged.	0,00	NE
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Nervous system disorders		<65	39	88,6	5	12,8	35	83,3	1	2,9	5,00		Convergence criterion (GCONV=1E-8) satisfied.	0,55	45,08	0,100			Algorithm converged.	-0,019	0,218	4,49		Algorithm converged.	0,55	36,57	0,1608	-	0,22	Algorithm converged.	0,03	1,82
Nervous system disorders		>=65	5	11,4	0	0,0	7	16,7	2	28,6	*	Quasi-complete separation of data points detected.							ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,9	Algorithm converged.	0,00	NE
Nervous system disorders	Cervicobrachial syndrome	<65	39	88,6	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 8.329780699 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,9	Algorithm converged.	0,00	NE

Reproductive system and breast disorders	Menstruation irregular	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 7.2864437209 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Reproductive system and breast disorders	Menstruation irregular	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE								NE						NE	NE	NE	NE	NE	NE	NE	NE	
Reproductive system and breast disorders	Premature menopause	<65	39	88,6	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.							ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,99	Algorithm converged.	0,00	NE
Reproductive system and breast disorders	Premature menopause	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE								NE						NE	NE	NE	NE	NE	NE	NE		
Reproductive system and breast disorders	Vaginal discharge	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 7.2864437342 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Reproductive system and breast disorders	Vaginal discharge	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE								NE						NE	NE	NE	NE	NE	NE	NE		
Respiratory, thoracic and mediastinal disorders		<65	39	88,6	1	2,6	35	83,3	4	11,4	0,20	Convergence criterion (GCONV=1E-8) satisfied.	0,02	1,92	-0,089				Algorithm converged.	-0,205	0,028	0,22			Algorithm converged.	0,03	1,91	0,1717	-	4,46	Algorithm converged.	0,52	38,01
Respiratory, thoracic and mediastinal disorders		>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE								NE						NE	NE	NE	NE	NE	NE	NE		
Respiratory, thoracic and mediastinal disorders	Cough	<65	39	88,6	1	2,6	35	83,3	1	2,9	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,05	14,86	-0,003				Algorithm converged.	-0,077	0,071	0,90			Algorithm converged.	0,06	13,82	0,9382	-	1,11	Algorithm converged.	0,07	17,15
Respiratory, thoracic and mediastinal disorders	Cough	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE								NE						NE	NE	NE	NE	NE	NE	NE		
Respiratory, thoracic and mediastinal disorders	Dysphonia	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 7.2864437275 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Dysphonia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE								NE						NE	NE	NE	NE	NE	NE	NE		
Respiratory, thoracic and mediastinal disorders	Dyspnoea	<65	39	88,6	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 8.329780699 is greater than the limit of 0.0001. The convergence is questionable.					0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,99	Algorithm converged.	0,00	NE
Respiratory, thoracic and mediastinal disorders	Dyspnoea	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE								NE						NE	NE	NE	NE	NE	NE	NE		
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	<65	39	88,6	0	0,0	35	83,3	2	5,7	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 5.0458638388 is greater than the limit of 0.0001. The convergence is questionable.					0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,99	Algorithm converged.	0,00	NE
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE								NE						NE	NE	NE	NE	NE	NE	NE		
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	<65	39	88,6	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.							WARNING: The relative Hessian convergence criterion of 8.329780699 is greater than the limit of 0.0001. The convergence is questionable.					0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,99	Algorithm converged.	0,00	NE

Vascular disorders		<65	39	88,6	2	5,1	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.						NE	Algorithm converged.					-	NE	Algorithm converged.	NE	NE
Vascular disorders		>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE			NE	NE	NE	NE		NE	NE	NE	NE	NE	
Vascular disorders	Hypertension	<65	39	88,6	2	5,1	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.						NE	Algorithm converged.					-	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypertension	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE			NE	NE	NE	NE		NE	NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_AE_SE1_31MAY2023_42161.xls
 24APR2024 5:54

POPULATION: Safety Population
 ENDPPOINT: Any AEs
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

All

			Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab																			
			Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Eculizumab vs. Crovalimab								
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
Blood and lymphatic system disorders		n/a	44	100,0	4	9,1	42	100,0	1	2,4	4,10	Convergence criterion (GCONV=1E-8) satisfied.	0,44	38,29	0,067	Algorithm converged.	-0,030	0,164	3,82	Algorithm converged.	0,44	32,78	0,2220		NE	0,26	Algorithm converged.	0,03	2,25	
Blood and lymphatic system disorders	Extravascular haemolysis	n/a	44	100,0	1	2,3	42	100,0	1	2,4	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,75	-0,001	Algorithm converged.	-0,065	0,063	0,95	Algorithm converged.	0,06	14,77	0,9734		NE	1,05	Algorithm converged.	0,07	16,21	
Blood and lymphatic system disorders	Neutropenia	n/a	44	100,0	2	4,5	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 5.1032936995 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Pancytopenia	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE
Cardiac disorders		n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Palpitations	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE
Eye disorders		n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 8.9456063823 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999		NE	>999.9	Algorithm converged.	0,00	NE

Eye disorders	Lacrimation increased	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.9456063823 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
Gastrointestinal disorders		n/a	44	100,0	8	18,2	42	100,0	5	11,9	1,64	Convergence criterion (GCONV=1E-8) satisfied.	0,49	5,50	0,063	Algorithm converged.	-0,087	0,213	1,53	Algorithm converged.	0,54	4,30	0,4223	NE	0,65	Algorithm converged.	0,23	1,84
Gastrointestinal disorders	Abdominal pain	n/a	44	100,0	1	2,3	42	100,0	1	2,4	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,75	-0,001	Algorithm converged.	-0,065	0,063	0,95	Algorithm converged.	0,06	14,77	0,9734	NE	1,05	Algorithm converged.	0,07	16,21
Gastrointestinal disorders	Diarrhoea	n/a	44	100,0	3	6,8	42	100,0	1	2,4	3,00	Convergence criterion (GCONV=1E-8) satisfied.	0,30	30,04	0,044	Algorithm converged.	-0,043	0,132	2,86	Algorithm converged.	0,31	26,45	0,3537	NE	0,35	Algorithm converged.	0,04	3,23
Gastrointestinal disorders	Dyspepsia	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Gastroesophageal reflux disease	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.945606366 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
Gastrointestinal disorders	Nausea	n/a	44	100,0	3	6,8	42	100,0	2	4,8	1,46	Convergence criterion (GCONV=1E-8) satisfied.	0,23	9,23	0,021	Algorithm converged.	-0,078	0,119	1,43	Algorithm converged.	0,25	8,15	0,6857	NE	0,70	Algorithm converged.	0,12	3,97
Gastrointestinal disorders	Odynophagia	n/a	44	100,0	1	2,3	42	100,0	1	2,4	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,75	-0,001	Algorithm converged.	-0,065	0,063	0,95	Algorithm converged.	0,06	14,77	0,9734	NE	1,05	Algorithm converged.	0,07	16,21
Gastrointestinal disorders	Stomatitis	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Gastrointestinal disorders	Vomiting	n/a	44	100,0	1	2,3	42	100,0	1	2,4	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,75	-0,001	Algorithm converged.	-0,065	0,063	0,95	Algorithm converged.	0,06	14,77	0,9734	NE	1,05	Algorithm converged.	0,07	16,21
General disorders and administration site conditions		n/a	44	100,0	12	27,3	42	100,0	8	19,0	1,59	Convergence criterion (GCONV=1E-8) satisfied.	0,58	4,40	0,082	Algorithm converged.	-0,095	0,260	1,43	Algorithm converged.	0,65	3,15	0,3722	NE	0,70	Algorithm converged.	0,32	1,54
General disorders and administration site conditions	Asthenia	n/a	44	100,0	3	6,8	42	100,0	2	4,8	1,46	Convergence criterion (GCONV=1E-8) satisfied.	0,23	9,23	0,021	Algorithm converged.	-0,078	0,119	1,43	Algorithm converged.	0,25	8,15	0,6857	NE	0,70	Algorithm converged.	0,12	3,97

General disorders and administration site conditions	Chest pain	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.9456063741 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
General disorders and administration site conditions	Fatigue	n/a	44	100,0	2	4,5	42	100,0	2	4,8	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,13	7,09	-0,002	Algorithm converged.	-0,091	0,087	0,95	Algorithm converged.	0,14	6,47	0,9620	NE	1,05	Algorithm converged.	0,15	7,10
General disorders and administration site conditions	Injection site reaction	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE			
General disorders and administration site conditions	Malaise	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.9456063578 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
General disorders and administration site conditions	Oedema	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE				
General disorders and administration site conditions	Oedema peripheral	n/a	44	100,0	3	6,8	42	100,0	1	2,4	3,00	Convergence criterion (GCONV=1E-8) satisfied.	0,30	30,04	0,044	Algorithm converged.	-0,043	0,132	2,86	Algorithm converged.	0,31	26,45	0,3537	NE	0,35	Algorithm converged.	0,04	3,23
General disorders and administration site conditions	Pain	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.9456063823 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
General disorders and administration site conditions	Peripheral swelling	n/a	44	100,0	2	4,5	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 5.1032936995 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE			
General disorders and administration site conditions	Fyrexia	n/a	44	100,0	7	15,9	42	100,0	1	2,4	7,76	Convergence criterion (GCONV=1E-8) satisfied.	0,91	66,05	0,135	Algorithm converged.	0,018	0,253	6,68	Algorithm converged.	0,86	52,02	0,0697	NE	0,15	Algorithm converged.	0,02	1,17

Hepatobiliary disorders		n/a	44	100,0	5	11,4	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE						
Hepatobiliary disorders	Biliary colic	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE						
Hepatobiliary disorders	Cholelithiasis	n/a	44	100,0	2	4,5	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE						
Hepatobiliary disorders	Hyperbilirubinaemia	n/a	44	100,0	2	4,5	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE						
Immune system disorders		n/a	44	100,0	10	22,7	42	100,0	1	2,4	12,05	Convergence criterion (GCONV=1E-8) satisfied.	1,47	98,92	0,203				Algorithm converged.	0,071	0,336	9,55			Algorithm converged.	1,28	71,36	0,0279	NE	0,10	Algorithm converged.	0,01	0,78
Immune system disorders	Hypersensitivity	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE						
Immune system disorders	Immunisation reaction	n/a	44	100,0	2	4,5	42	100,0	1	2,4	1,95	Convergence criterion (GCONV=1E-8) satisfied.	0,17	22,37	0,022				Algorithm converged.	-0,055	0,099	1,91			Algorithm converged.	0,18	20,28	0,5917	NE	0,52	Algorithm converged.	0,05	5,56
Immune system disorders	Type III immune complex mediated reaction	n/a	44	100,0	7	15,9	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE						
Infections and infestations		n/a	44	100,0	18	40,9	42	100,0	15	35,7	1,25	Convergence criterion (GCONV=1E-8) satisfied.	0,52	2,98	0,052				Algorithm converged.	-0,153	0,257	1,15			Algorithm converged.	0,67	1,96	0,6216	NE	0,87	Algorithm converged.	0,51	1,50
Infections and infestations	Abscess jaw	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,9	Algorithm converged.	0,00	NE						
Infections and infestations	COVID-19	n/a	44	100,0	6	13,6	42	100,0	7	16,7	0,79	Convergence criterion (GCONV=1E-8) satisfied.	0,24	2,58	-0,030				Algorithm converged.	-0,182	0,121	0,82			Algorithm converged.	0,30	2,24	0,6956	NE	1,22	Algorithm converged.	0,45	3,34

Infections and infestations	Cellulitis	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Infections and infestations	Conjunctivitis	n/a	44	100,0	1	2,3	42	100,0	1	2,4	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,75	-0,001			0,95	Algorithm converged.	0,06	14,77	0,9734		NE	1,05	Algorithm converged.	0,07	16,21
Infections and infestations	Cystitis	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	0,9999		NE	>999.99	Algorithm converged.	0,00	NE
Infections and infestations	Diverticulitis	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Infections and infestations	Folliculitis	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	0,9999		NE	>999.99	Algorithm converged.	0,00	NE
Infections and infestations	Influenza	n/a	44	100,0	2	4,5	42	100,0	3	7,1	0,62	Convergence criterion (GCONV=1E-8) satisfied.	0,10	3,90	-0,026			0,64	Algorithm converged.	-0,125	0,073	0,64		NE	1,57	Algorithm converged.	0,28	8,94
Infections and infestations	Nasopharyngitis	n/a	44	100,0	2	4,5	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Infections and infestations	Oral candidiasis	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Infections and infestations	Pneumonia	n/a	44	100,0	2	4,5	42	100,0	1	2,4	1,95	Convergence criterion (GCONV=1E-8) satisfied.	0,17	22,37	0,022			1,91	Algorithm converged.	-0,055	0,099	1,91		NE	0,52	Algorithm converged.	0,05	5,56
Infections and infestations	Pyelonephritis	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	0,9999		NE	>999.99	Algorithm converged.	0,00	NE

Infections and infestations	Respiratory syncytial virus infection	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Infections and infestations	Respiratory tract infection	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Infections and infestations	Sinusitis	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.9456063823 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE			
Infections and infestations	Upper respiratory tract infection	n/a	44	100,0	3	6,8	42	100,0	1	2,4	3,00	Convergence criterion (GCONV=1E-8) satisfied.	0,30	30,04	0,044	Algorithm converged.	-0,043	0,132	2,86	0,31	26,45	0,3537	NE	0,35	Algorithm converged.	0,04	3,23
Infections and infestations	Urinary tract infection	n/a	44	100,0	2	4,5	42	100,0	3	7,1	0,62	Convergence criterion (GCONV=1E-8) satisfied.	0,10	3,90	-0,026	Algorithm converged.	-0,125	0,073	0,64	0,11	3,62	0,6104	NE	1,57	Algorithm converged.	0,28	8,94
Infections and infestations	Vaginal infection	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Infections and infestations	Viral infection	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Injury, poisoning and procedural complications		n/a	44	100,0	11	25,0	42	100,0	3	7,1	4,33	Convergence criterion (GCONV=1E-8) satisfied.	1,11	16,85	0,179	Algorithm converged.	0,029	0,328	3,50	1,05	11,67	0,0415	NE	0,29	Algorithm converged.	0,09	0,95
Injury, poisoning and procedural complications	Arthropod bite	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Injury, poisoning and procedural complications	Fall	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.9456063741 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE			
Injury, poisoning and procedural complications	Febrile nonhaemolytic transfusion reaction	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			

Injury, poisoning and procedural complications	Head injury	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 8.9456063741 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Injury, poisoning and procedural complications	Infusion related reaction	n/a	44	100,0	6	13,6	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 2.3956760731 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injection related reaction	n/a	44	100,0	3	6,8	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 3.8177365884 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injury	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 8.9456063741 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE
Injury, poisoning and procedural complications	Joint injury	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Skin laceration	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Thermal burn	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 8.9456063578 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE

Musculoskeletal and connective tissue disorders	Arthralgia	n/a	44	100,0	3	6,8	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 3.8177365955 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Musculoskeletal and connective tissue disorders	Back pain	n/a	44	100,0	1	2,3	42	100,0	2	4,8	0,47	Convergence criterion (GCONV=1E-8) satisfied.	0,04	5,33	-0,025	Algorithm converged.	-0,103	0,053	0,48	Algorithm converged.	0,04	5,07	0,5395	NE	2,10	Algorithm converged.	0,20	22,26
Musculoskeletal and connective tissue disorders	Coccydynia	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Musculoskeletal and connective tissue disorders	Muscle spasms	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Musculoskeletal and connective tissue disorders	Myalgia	n/a	44	100,0	1	2,3	42	100,0	2	4,8	0,47	Convergence criterion (GCONV=1E-8) satisfied.	0,04	5,33	-0,025	Algorithm converged.	-0,103	0,053	0,48	Algorithm converged.	0,04	5,07	0,5395	NE	2,10	Algorithm converged.	0,20	22,26
Musculoskeletal and connective tissue disorders	Neck pain	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Musculoskeletal and connective tissue disorders	Spinal pain	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.9456063741 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
Nervous system disorders		n/a	44	100,0	5	11,4	42	100,0	3	7,1	1,67	Convergence criterion (GCONV=1E-8) satisfied.	0,37	7,46	0,042	Algorithm converged.	-0,080	0,164	1,59	Algorithm converged.	0,41	6,25	0,5057	NE	0,63	Algorithm converged.	0,16	2,47
Nervous system disorders	Cervicobrachial syndrome	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.9456063823 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
Nervous system disorders	Headache	n/a	44	100,0	5	11,4	42	100,0	1	2,4	5,26	Convergence criterion (GCONV=1E-8) satisfied.	0,59	47,03	0,090	Algorithm converged.	-0,015	0,194	4,77	Algorithm converged.	0,58	39,17	0,1456	NE	0,21	Algorithm converged.	0,03	1,72

Reproductive system and breast disorders	Premature menopause	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE			
Reproductive system and breast disorders	Vaginal discharge	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Respiratory, thoracic and mediastinal disorders		n/a	44	100,0	1	2,3	42	100,0	4	9,5	0,22	Convergence criterion (GCONV=1E-8) satisfied.	0,02	2,06	-0,073				Algorithm converged.	-0,172	0,027	0,24	Algorithm converged.	0,03	2,05	0,1915	NE	4,19	Algorithm converged.	0,49	35,98
Respiratory, thoracic and mediastinal disorders	Cough	n/a	44	100,0	1	2,3	42	100,0	1	2,4	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,75	-0,001				Algorithm converged.	-0,065	0,063	0,95	Algorithm converged.	0,06	14,77	0,9734	NE	1,05	Algorithm converged.	0,07	16,21
Respiratory, thoracic and mediastinal disorders	Dysphonia	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Dyspnoea	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE			
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	n/a	44	100,0	0	0,0	42	100,0	2	4,8	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE			
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE			

Respiratory, thoracic and mediastinal disorders	Wheezing	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.													WARNING: The relative Hessian convergence criterion of 8.9456063823 is greater than the limit of 0.0001. The convergence is questionable.						0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE				
Skin and subcutaneous tissue disorders		n/a	44	100,0	8	18,2	42	100,0	1	2,4	9,11	Convergence criterion (GCONV=1E-8) satisfied.	1,09	76,39	0,158										Algorithm converged.	0,035	0,281	7,64	Algorithm converged.	1,00	58,46	0,0503	NE	0,13	Algorithm converged.	0,02	1,00							
Skin and subcutaneous tissue disorders	Ecchymosis	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.													WARNING: The relative Hessian convergence criterion of 8.9456063823 is greater than the limit of 0.0001. The convergence is questionable.							0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999.99	Algorithm converged.	0,00	NE			
Skin and subcutaneous tissue disorders	Erythema	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.													ERROR: Error in computing the link function, its derivatives, or the variance function.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Skin and subcutaneous tissue disorders	Papule	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.													ERROR: Error in computing the link function, its derivatives, or the variance function.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Skin and subcutaneous tissue disorders	Petechiae	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.													ERROR: Error in computing the link function, its derivatives, or the variance function.							NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Skin and subcutaneous tissue disorders	Pruritus	n/a	44	100,0	2	4,5	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.													WARNING: The relative Hessian convergence criterion of 5.1032936995 is greater than the limit of 0.0001. The convergence is questionable.										NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Rash	n/a	44	100,0	3	6,8	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.													WARNING: The relative Hessian convergence criterion of 3.817736592 is greater than the limit of 0.0001. The convergence is questionable.										NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Skin and subcutaneous tissue disorders	Skin exfoliation	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders		n/a	44	100,0	2	4,5	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 5.1032936995 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypertension	n/a	44	100,0	2	4,5	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 5.1032936995 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_AE_SE1_31MAY2023_42161.xls
 24APR2024 5:54

POPULATION: Safety Population
 ENDPOINT: Any AEs
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Transfusion history [pRBC infusion in the last 12 months]

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab										
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk										
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
Blood and lymphatic system disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE	
Blood and lymphatic system disorders		No	32	72,7	4	12,5	32	76,2	1	3,1	4,43	Convergence criterion (GCONV=1E-8) satisfied.	0,47	42,02	0,094	Algorithm converged.	-0,036	0,223	4,00	Algorithm converged.	0,47	33,86	0,2033			0,25	Algorithm converged.	0,03	2,12	
Blood and lymphatic system disorders	Extravascular haemolysis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE		
Blood and lymphatic system disorders	Extravascular haemolysis	No	32	72,7	1	3,1	32	76,2	1	3,1	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,71	0,000	Algorithm converged.	-0,085	0,085	1,00	Algorithm converged.	0,07	15,30	1,0000			1,00	Algorithm converged.	0,07	15,30	
Blood and lymphatic system disorders	Neutropenia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE		
Blood and lymphatic system disorders	Neutropenia	No	32	72,7	2	6,3	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 4.25196428 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Pancytopenia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE		
Blood and lymphatic system disorders	Pancytopenia	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Cardiac disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE		
Cardiac disorders		No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Cardiac disorders	Palpitations	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE		
Cardiac disorders	Palpitations	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Eye disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE		
Eye disorders		No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999		>999,9	Algorithm converged.	0,00	NE	
Eye disorders	Lacrimation increased	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE		
Eye disorders	Lacrimation increased	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999		>999,9	Algorithm converged.	0,00	NE	

Gastrointestinal disorders		Yes	12	27,3	4	33,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE			
Gastrointestinal disorders		No	32	72,7	4	12,5	32	76,2	5	15,6	0,77	Convergence criterion (GCONV=1E-8) satisfied.	0,19	3,18	-0,031		Algorithm converged.	-0,201	0,139	0,80	Algorithm converged.	0,24	2,71	0,7200		1,25	Algorithm converged.	0,37	4,23			
Gastrointestinal disorders	Abdominal pain	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE						NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE			
Gastrointestinal disorders	Abdominal pain	No	32	72,7	1	3,1	32	76,2	1	3,1	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,71	0,000		Algorithm converged.	-0,085	0,085	1,00	Algorithm converged.	0,07	15,30	1,0000		1,00	Algorithm converged.	0,07	15,30			
Gastrointestinal disorders	Diarrhoea	Yes	12	27,3	2	16,7	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE		
Gastrointestinal disorders	Diarrhoea	No	32	72,7	1	3,1	32	76,2	1	3,1	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,71	0,000		Algorithm converged.	-0,085	0,085	1,00	Algorithm converged.	0,07	15,30	1,0000		1,00	Algorithm converged.	0,07	15,30			
Gastrointestinal disorders	Dyspepsia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE						NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE			
Gastrointestinal disorders	Dyspepsia	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.							ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Gastrointestinal disorders	Gastroesophageal reflux disease	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE						NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE			
Gastrointestinal disorders	Gastroesophageal reflux disease	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 7.0164094161 is greater than the limit of 0.0001. The convergence is questionable.				0,00	Algorithm converged.	0,00	NE	0,9999		>999.9	Algorithm converged.	0,00	NE	
Gastrointestinal disorders	Nausea	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.							ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	
Gastrointestinal disorders	Nausea	No	32	72,7	2	6,3	32	76,2	2	6,3	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,13	7,57	0,000		Algorithm converged.	-0,119	0,119	1,00	Algorithm converged.	0,15	6,67	1,0000		1,00	Algorithm converged.	0,15	6,67			
Gastrointestinal disorders	Odynophagia	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.							ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	
Gastrointestinal disorders	Odynophagia	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.								ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999		>999.9	Algorithm converged.	0,00	NE
Gastrointestinal disorders	Stomatitis	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.								ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Stomatitis	No	32	72,7	0	0,0	32	76,2	0	0,0	NE						NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE			
Gastrointestinal disorders	Vomiting	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE						NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE		
Gastrointestinal disorders	Vomiting	No	32	72,7	1	3,1	32	76,2	1	3,1	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,71	0,000		Algorithm converged.	-0,085	0,085	1,00	Algorithm converged.	0,07	15,30	1,0000		1,00	Algorithm converged.	0,07	15,30			
General disorders and administration site conditions		Yes	12	27,3	3	25,0	10	23,8	2	20,0	1,33	Convergence criterion (GCONV=1E-8) satisfied.	0,18	10,12	0,050		Algorithm converged.	-0,299	0,399	1,25	Algorithm converged.	0,26	6,07	0,7820		-	0,80	Algorithm converged.	0,16	3,88		

General disorders and administration site conditions		No	32	72,7	9	28,1	32	76,2	6	18,8	1,70	Convergence criterion (GCONV=1E-8) satisfied.	0,52	5,49	0,094	Algorithm converged.	-0,113	0,300	1,50	Algorithm converged.	0,60	3,72	0,3822	0,67	Algorithm converged.	0,27	1,66	
General disorders and administration site conditions	Asthenia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Asthenia	No	32	72,7	3	9,4	32	76,2	2	6,3	1,55	Convergence criterion (GCONV=1E-8) satisfied.	0,24	9,97	0,031	Algorithm converged.	-0,100	0,163	1,50	Algorithm converged.	0,27	8,38	0,6442	0,67	Algorithm converged.	0,12	3,73	
General disorders and administration site conditions	Chest pain	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Chest pain	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 7.0164094097 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE
General disorders and administration site conditions	Fatigue	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Fatigue	No	32	72,7	1	3,1	32	76,2	2	6,3	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,04	5,62	-0,031	Algorithm converged.	-0,135	0,072	0,50	Algorithm converged.	0,05	5,24	0,5632	2,00	Algorithm converged.	0,19	20,97	
General disorders and administration site conditions	Injection site reaction	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Injection site reaction	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Malaise	Yes	12	27,3	0	0,0	10	23,8	1	10,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE
General disorders and administration site conditions	Malaise	No	32	72,7	0	0,0	32	76,2	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Oedema	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Oedema	No	32	72,7	0	0,0	32	76,2	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Oedema peripheral	Yes	12	27,3	1	8,3	10	23,8	1	10,0	0,82	Convergence criterion (GCONV=1E-8) satisfied.	0,04	15,00	-0,017	Algorithm converged.	-0,260	0,226	0,83	Algorithm converged.	0,06	11,70	0,8924	-1,20	Algorithm converged.	0,09	16,84	
General disorders and administration site conditions	Oedema peripheral	No	32	72,7	2	6,3	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Pain	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Pain	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 7.0164094097 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE

Immune system disorders	Immunisation reaction	No	32	72,7	2	6,3	32	76,2	1	3,1	2,07		Convergence criterion (GCONV=1E-8) satisfied.	0,18	24,01	0,031	Algorithm converged.	-0,072	0,135	2,00	Algorithm converged.	0,19	20,97	0,5632		0,50	Algorithm converged.	0,05	5,24			
Immune system disorders	Type III immune complex mediated reaction	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*		Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.		NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE		
Immune system disorders	Type III immune complex mediated reaction	No	32	72,7	6	18,8	32	76,2	0	0,0	*		Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 2.0721976333 is greater than the limit of 0.0001. The convergence is questionable.		NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE			
Infections and infestations		Yes	12	27,3	6	50,0	10	23,8	4	40,0	1,50		Convergence criterion (GCONV=1E-8) satisfied.	0,27	8,19	0,100	Algorithm converged.	-0,315	0,515	1,25	Algorithm converged.	0,48	3,22	0,6441	0,8158	0,80	Algorithm converged.	0,31	2,06			
Infections and infestations		No	32	72,7	12	37,5	32	76,2	11	34,4	1,15		Convergence criterion (GCONV=1E-8) satisfied.	0,41	3,18	0,031	Algorithm converged.	-0,204	0,266	1,09	Algorithm converged.	0,57	2,10	0,7946		0,92	Algorithm converged.	0,48	1,77			
Infections and infestations	Abscess jaw	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Infections and infestations	Abscess jaw	No	32	72,7	0	0,0	32	76,2	1	3,1	*		Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999		>999.9	9	Algorithm converged.	0,00	NE	
Infections and infestations	COVID-19	Yes	12	27,3	1	8,3	10	23,8	2	20,0	0,36		Convergence criterion (GCONV=1E-8) satisfied.	0,03	4,74	-0,117	Algorithm converged.	-0,410	0,176	0,42	Algorithm converged.	0,04	3,95	0,4455		-	2,40	Algorithm converged.	0,25	22,75		
Infections and infestations	COVID-19	No	32	72,7	5	15,6	32	76,2	5	15,6	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,26	3,86	0,000	Algorithm converged.	-0,178	0,178	1,00	Algorithm converged.	0,32	3,12	1,0000		1,00	Algorithm converged.	0,32	3,12			
Infections and infestations	Cellulitis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Infections and infestations	Cellulitis	No	32	72,7	1	3,1	32	76,2	0	0,0	*		Quasi-complete separation of data points detected.					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE		
Infections and infestations	Conjunctivitis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Infections and infestations	Conjunctivitis	No	32	72,7	1	3,1	32	76,2	1	3,1	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,71	0,000	Algorithm converged.	-0,085	0,085	1,00	Algorithm converged.	0,07	15,30	1,0000		1,00	Algorithm converged.	0,07	15,30			
Infections and infestations	Cystitis	Yes	12	27,3	0	0,0	10	23,8	1	10,0	*		Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999		-	>999.9	9	Algorithm converged.	0,00	NE
Infections and infestations	Cystitis	No	32	72,7	0	0,0	32	76,2	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Infections and infestations	Diverticulitis	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*		Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE	
Infections and infestations	Diverticulitis	No	32	72,7	0	0,0	32	76,2	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		
Infections and infestations	Folliculitis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	
Infections and infestations	Folliculitis	No	32	72,7	0	0,0	32	76,2	1	3,1	*		Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999		>999.9	9	Algorithm converged.	0,00	NE	
Infections and infestations	Influenza	Yes	12	27,3	2	16,7	10	23,8	0	0,0	*		Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE	

Infections and infestations	Influenza	No	32	72,7	0	0,0	32	76,2	3	9,4	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE		
Infections and infestations	Nasopharyngitis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Infections and infestations	Nasopharyngitis	No	32	72,7	2	6,3	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Infections and infestations	Oral candidiasis	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Oral candidiasis	No	32	72,7	0	0,0	32	76,2	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Pneumonia	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Pneumonia	No	32	72,7	1	3,1	32	76,2	1	3,1	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,71	0,000	Algorithm converged.	-0,085	0,085	1,00	Algorithm converged.	0,07	15,30	1,0000	1,00	Algorithm converged.	0,07	15,30	
Infections and infestations	Eyelonephritis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Infections and infestations	Eyelonephritis	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE		
Infections and infestations	Respiratory syncytial virus infection	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Infections and infestations	Respiratory syncytial virus infection	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Infections and infestations	Respiratory tract infection	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Respiratory tract infection	No	32	72,7	0	0,0	32	76,2	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Sinusitis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Infections and infestations	Sinusitis	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE		
Infections and infestations	Upper respiratory tract infection	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Infections and infestations	Upper respiratory tract infection	No	32	72,7	3	9,4	32	76,2	1	3,1	3,21	Convergence criterion (GCONV=1E-8) satisfied.	0,32	32,60	0,063	Algorithm converged.	-0,055	0,180	3,00	Algorithm converged.	0,33	27,33	0,3298	0,33	Algorithm converged.	0,04	3,04	
Infections and infestations	Urinary tract infection	Yes	12	27,3	2	16,7	10	23,8	2	20,0	0,80	Convergence criterion (GCONV=1E-8) satisfied.	0,09	7,00	-0,033	Algorithm converged.	-0,359	0,292	0,83	Algorithm converged.	0,14	4,90	0,8401	-	1,20	Algorithm converged.	0,20	7,05

Metabolism and nutrition disorders		No	32	72,7	0	0,0	32	76,2	3	9,4	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Glucose tolerance impaired	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE	-	NE	NE	NE	NE
Metabolism and nutrition disorders	Glucose tolerance impaired	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Hyperkalaemia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE	-	NE	NE	NE	NE
Metabolism and nutrition disorders	Hyperkalaemia	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE	
Metabolism and nutrition disorders	Hypokalaemia	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Metabolism and nutrition disorders	Hypokalaemia	No	32	72,7	0	0,0	32	76,2	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE	-	NE	NE	NE	NE
Metabolism and nutrition disorders	Iron deficiency	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE	-	NE	NE	NE	NE
Metabolism and nutrition disorders	Iron deficiency	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE	
Musculoskeletal and connective tissue disorders		Yes	12	27,3	2	16,7	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders		No	32	72,7	5	15,6	32	76,2	5	15,6	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,26	3,86	0,000	Algorithm converged.	-0,178	0,178	1,00	Algorithm converged.	0,32	3,12	1,0000	1,00	Algorithm converged.	0,32	3,12	
Musculoskeletal and connective tissue disorders	Arthralgia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE	-	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Arthralgia	No	32	72,7	3	9,4	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Back pain	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Back pain	No	32	72,7	0	0,0	32	76,2	2	6,3	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE	

Musculoskeletal and connective tissue disorders	Coccydynia	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	
Musculoskeletal and connective tissue disorders	Coccydynia	No	32	72,7	0	0,0	32	76,2	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Muscle spasms	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Musculoskeletal and connective tissue disorders	Muscle spasms	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Musculoskeletal and connective tissue disorders	Myalgia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Musculoskeletal and connective tissue disorders	Myalgia	No	32	72,7	1	3,1	32	76,2	2	6,3	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,04	5,62	-0,031	Algorithm converged.	-0,135	0,072	0,50	Algorithm converged.	0,05	5,24	0,5632			2,00	Algorithm converged.	0,19	20,97		
Musculoskeletal and connective tissue disorders	Neck pain	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Musculoskeletal and connective tissue disorders	Neck pain	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Musculoskeletal and connective tissue disorders	Spinal pain	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Musculoskeletal and connective tissue disorders	Spinal pain	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 7.0164094097 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE		
Nervous system disorders		Yes	12	27,3	3	25,0	10	23,8	1	10,0	3,00	Convergence criterion (GCONV=1E-8) satisfied.	0,26	34,57	0,150	Algorithm converged.	-0,158	0,458	2,50	Algorithm converged.	0,31	20,45	0,3929			-	0,40	Algorithm converged.	0,05	3,27	
Nervous system disorders		No	32	72,7	2	6,3	32	76,2	2	6,3	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,13	7,57	0,000	Algorithm converged.	-0,119	0,119	1,00	Algorithm converged.	0,15	6,67	1,0000			1,00	Algorithm converged.	0,15	6,67		
Nervous system disorders	Cervicobrachial syndrome	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Nervous system disorders	Cervicobrachial syndrome	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE		
Nervous system disorders	Headache	Yes	12	27,3	3	25,0	10	23,8	1	10,0	3,00	Convergence criterion (GCONV=1E-8) satisfied.	0,26	34,57	0,150	Algorithm converged.	-0,158	0,458	2,50	Algorithm converged.	0,31	20,45	0,3929			-	0,40	Algorithm converged.	0,05	3,27	

Nervous system disorders	Headache	No	32	72,7	2	6,3	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 4.2519642839 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE		NE	Algorithm converged.	NE	NE
Nervous system disorders	Transient ischaemic attack	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE						NE			NE	NE	NE	NE	NE		NE	NE	NE	NE	
Nervous system disorders	Transient ischaemic attack	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE	
Psychiatric disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE						NE			NE	NE	NE	NE	NE		NE	NE	NE	NE	
Psychiatric disorders		No	32	72,7	1	3,1	32	76,2	1	3,1	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,71	0,000	Algorithm converged.	-0,085	0,085	1,00	Algorithm converged.	0,07	15,30	1,0000		1,00	Algorithm converged.	0,07	15,30		
Psychiatric disorders	Anxiety	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE						NE			NE	NE	NE	NE	NE		NE	NE	NE	NE	
Psychiatric disorders	Anxiety	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
Psychiatric disorders	Insomnia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE						NE			NE	NE	NE	NE	NE		NE	NE	NE	NE	
Psychiatric disorders	Insomnia	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE	
Renal and urinary disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE						NE			NE	NE	NE	NE	NE		NE	NE	NE	NE	
Renal and urinary disorders		No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders	Haemoglobinuria	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE						NE			NE	NE	NE	NE	NE		NE	NE	NE	NE	
Renal and urinary disorders	Haemoglobinuria	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
Reproductive system and breast disorders		Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE		NE	NE	NE	NE
Reproductive system and breast disorders		No	32	72,7	1	3,1	32	76,2	1	3,1	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,71	0,000	Algorithm converged.	-0,085	0,085	1,00	Algorithm converged.	0,07	15,30	1,0000		1,00	Algorithm converged.	0,07	15,30		
Reproductive system and breast disorders	Cervical dysplasia	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE		NE	NE	NE	NE
Reproductive system and breast disorders	Cervical dysplasia	No	32	72,7	0	0,0	32	76,2	0	0,0	NE						NE			NE	NE	NE	NE	NE		NE	NE	NE	NE	
Reproductive system and breast disorders	Menstruation irregular	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.					ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE		NE	NE	NE	NE

Skin and subcutaneous tissue disorders	Fruritus	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Fruritus	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Rash	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE		-	NE	NE	NE	NE
Skin and subcutaneous tissue disorders	Rash	No	32	72,7	3	9,4	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Skin exfoliation	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE				NE	NE	NE	NE		-	NE	NE	NE	NE
Skin and subcutaneous tissue disorders	Skin exfoliation	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Vascular disorders		Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Vascular disorders		No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Vascular disorders	Hypertension	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypertension	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.							NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_AE_SE1_31MAY2023_42161.xls
 24APR2024 5:54

POPULATION: Safety Population
 ENDPPOINT: Any AEs
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Geographic region			Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab									
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patient		Patients with		Patient		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk									
			n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL				
Blood and lymphatic system disorders		Japan/Rest of Asia Pacific	8	18,2	2	25,0	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders		North America/Central and South America/Europe	36	81,8	2	5,6	35	83,3	1	2,9	2,00	Convergence criterion (GCONV=1E-8) satisfied.	0,17	23,11	0,027	Algorithm converged.	-0,066	0,120	1,94	Algorithm converged.	0,18	20,49	0,5800		0,51	Algorithm converged.	0,05	5,42			
Blood and lymphatic system disorders	Extravascular haemolysis	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravascular haemolysis	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE		
Blood and lymphatic system disorders	Neutropenia	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE		
Blood and lymphatic system disorders	Neutropenia	North America/Central and South America/Europe	36	81,8	2	5,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 4.4971381018 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Pancytopenia	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Pancytopenia	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE		
Cardiac disorders		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE		
Cardiac disorders		North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Cardiac disorders	Palpitations	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE		
Cardiac disorders	Palpitations	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Eye disorders		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE		
Eye disorders		North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE	
Eye disorders	Lacrimation increased	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE		

General disorders and administration site conditions	Oedema peripheral	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	
General disorders and administration site conditions	Oedema peripheral	North America/ Central and South America/ Europe	36	81,8	2	5,6	35	83,3	1	2,9	2,00	Convergence criterion (GCONV=1E-8) satisfied.	0,17	23,11	0,027			Algorithm converged.	-0,066	0,120	1,94								0,51	Algorithm converged.	0,05	5,42
General disorders and administration site conditions	Pain	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
General disorders and administration site conditions	Pain	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	0,9999		>999.93	Algorithm converged.	0,00	NE	
General disorders and administration site conditions	Peripheral swelling	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
General disorders and administration site conditions	Peripheral swelling	North America/ Central and South America/ Europe	36	81,8	2	5,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 4.4971381018 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
General disorders and administration site conditions	Pyrexia	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 2.3217503965 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
General disorders and administration site conditions	Pyrexia	North America/ Central and South America/ Europe	36	81,8	6	16,7	35	83,3	1	2,9	6,80	Convergence criterion (GCONV=1E-8) satisfied.	0,77	59,74	0,138			Algorithm converged.	0,004	0,272	5,83								0,17	Algorithm converged.	0,02	1,35
Hepatobiliary disorders		Japan/Rest of Asia Pacific	8	18,2	2	25,0	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Hepatobiliary disorders		North America/ Central and South America/ Europe	36	81,8	3	8,3	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.						WARNING: The relative Hessian convergence criterion of 3.3804331287 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Hepatobiliary disorders	Biliary colic	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Hepatobiliary disorders	Biliary colic	North America/ Central and South America/ Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Hepatobiliary disorders	Cholelithiasis	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Hepatobiliary disorders	Cholelithiasis	North America/ Central and South America/ Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Hepatobiliary disorders	Hyperbilirubinemia	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Hepatobiliary disorders	Hyperbilirubinemia	North America/ Central and South America/ Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.						ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	

Immune system disorders		Japan/Rest of Asia Pacific	8	18,2	3	37,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	
Immune system disorders		North America/Central and South America/Europe	36	81,8	7	19,4	35	83,3	1	2,9	8,21	Convergence criterion (GCONV=1E-8) satisfied.	0,95	70,67	0,166		Algorithm converged.	0,025	0,306	6,81	Algorithm converged.	0,88	52,49	0,0658		0,15	Algorithm converged.	0,02	1,13	
Immune system disorders	Hypersensitivity	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Immune system disorders	Hypersensitivity	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Immune system disorders	Immunisation reaction	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Immune system disorders	Immunisation reaction	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	1	2,9	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,16	-0,001		Algorithm converged.	-0,078	0,076	0,97	Algorithm converged.	0,06	14,94	0,9839		1,03	Algorithm converged.	0,07	15,81	
Immune system disorders	Type III immune complex mediated reaction	Japan/Rest of Asia Pacific	8	18,2	2	25,0	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Immune system disorders	Type III immune complex mediated reaction	North America/Central and South America/Europe	36	81,8	5	13,9	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 2.4119532673 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Infections and infestations		Japan/Rest of Asia Pacific	8	18,2	3	37,5	7	16,7	2	28,6	1,50	Convergence criterion (GCONV=1E-8) satisfied.	0,17	13,22	0,089		Algorithm converged.	-0,385	0,563	1,31	Algorithm converged.	0,30	5,73	0,7176		-	0,76	Algorithm converged.	0,17	3,33
Infections and infestations		North America/Central and South America/Europe	36	81,8	15	41,7	35	83,3	13	37,1	1,21	Convergence criterion (GCONV=1E-8) satisfied.	0,47	3,14	0,045		Algorithm converged.	-0,182	0,272	1,12	Algorithm converged.	0,63	2,00	0,6972		0,89	Algorithm converged.	0,50	1,59	
Infections and infestations	Abscess jaw	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Infections and infestations	Abscess jaw	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 7.6992016995 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999		>999.9	9	Algorithm converged.	0,00	NE
Infections and infestations	COVID-19	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Infections and infestations	COVID-19	North America/Central and South America/Europe	36	81,8	5	13,9	35	83,3	7	20,0	0,65	Convergence criterion (GCONV=1E-8) satisfied.	0,18	2,27	-0,061		Algorithm converged.	-0,235	0,113	0,69	Algorithm converged.	0,24	1,98	0,4957		1,44	Algorithm converged.	0,50	4,11	
Infections and infestations	Cellulitis	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Infections and infestations	Cellulitis	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Infections and infestations	Conjunctivitis	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE

Injury, poisoning and procedural complications	Febrile nonhaemolytic transfusion reaction	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Injury, poisoning and procedural complications	Febrile nonhaemolytic transfusion reaction	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Head injury	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Injury, poisoning and procedural complications	Head injury	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 7.6992016995 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE	NE	NE
Injury, poisoning and procedural complications	Infusion related reaction	Japan/Rest of Asia Pacific	8	18,2	2	25,0	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Infusion related reaction	North America/Central and South America/Europe	36	81,8	4	11,1	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 2.7842464146 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injection related reaction	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injection related reaction	North America/Central and South America/Europe	36	81,8	2	5,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.4971380977 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injury	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Injury, poisoning and procedural complications	Injury	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 7.6992016995 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE	NE	NE
Injury, poisoning and procedural complications	Joint injury	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Injury, poisoning and procedural complications	Joint injury	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Skin laceration	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Skin laceration	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Thermal burn	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE

Injury, poisoning and procedural complications	Thermal burn	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 7.6992016995 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE					
Investigations		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	2	28,6	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE					
Investigations		North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Investigations	Alanine aminotransferase increased	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	2	28,6	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE					
Investigations	Alanine aminotransferase increased	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Metabolism and nutrition disorders		Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	1	14,3	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,04	16,85	-0,018	Algorithm converged.	-0,364	0,328	0,88	Algorithm converged.	0,07	11,54	0,9192	-	1,14	Algorithm converged.	0,09	15,08
Metabolism and nutrition disorders		North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	2	5,7	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE					
Metabolism and nutrition disorders	Glucose tolerance impaired	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Metabolism and nutrition disorders	Glucose tolerance impaired	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE					
Metabolism and nutrition disorders	Hyperkalaemia	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	1	14,3	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0,00	Algorithm converged.	0,00	NE	1,0000	>999.99	Algorithm converged.	0,00	NE					
Metabolism and nutrition disorders	Hyperkalaemia	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Metabolism and nutrition disorders	Hypokalaemia	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE				
Metabolism and nutrition disorders	Hypokalaemia	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Metabolism and nutrition disorders	Iron deficiency	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE					
Metabolism and nutrition disorders	Iron deficiency	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 7.6992016995 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE					
Musculoskeletal and connective tissue disorders		Japan/Rest of Asia Pacific	8	18,2	3	37,5	7	16,7	1	14,3	3,60	Convergence criterion (GCONV=1E-8) satisfied.	0,28	46,36	0,232	Algorithm converged.	-0,192	0,656	2,62	Algorithm converged.	0,35	19,85	0,3498	-	0,38	Algorithm converged.	0,05	2,88

Reproductive system and breast disorders		Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 2.3217503965 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE			
Reproductive system and breast disorders		North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	1	2,9	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,16	-0,001	Algorithm converged.	-0,078	0,076	0,97	Algorithm converged.	0,06	14,94	0,9839	1,03	Algorithm converged.	0,07	15,81
Reproductive system and breast disorders	Cervical dysplasia	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 2.3217503965 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE			
Reproductive system and breast disorders	Cervical dysplasia	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Reproductive system and breast disorders	Menstruation irregular	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 2.3217503965 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE			
Reproductive system and breast disorders	Menstruation irregular	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Reproductive system and breast disorders	Premature menopause	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	NE	NE	
Reproductive system and breast disorders	Premature menopause	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	>999.9	9	Algorithm converged.	0,00	NE			
Reproductive system and breast disorders	Vaginal discharge	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	NE		
Reproductive system and breast disorders	Vaginal discharge	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Respiratory, thoracic and mediastinal disorders		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	NE		
Respiratory, thoracic and mediastinal disorders		North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	4	11,4	0,22	Convergence criterion (GCONV=1E-8) satisfied.	0,02	2,09	-0,087	Algorithm converged.	-0,205	0,032	0,24	Algorithm converged.	0,03	2,07	0,1954	4,11	Algorithm converged.	0,48	35,02
Respiratory, thoracic and mediastinal disorders	Cough	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	NE	NE	
Respiratory, thoracic and mediastinal disorders	Cough	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	1	2,9	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,16	-0,001	Algorithm converged.	-0,078	0,076	0,97	Algorithm converged.	0,06	14,94	0,9839	1,03	Algorithm converged.	0,07	15,81
Respiratory, thoracic and mediastinal disorders	Dysphonia	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	NE	NE	

Respiratory, thoracic and mediastinal disorders	Dysphonia	North America/ Central and South America/ Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE			
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE			
Respiratory, thoracic and mediastinal disorders	Dyspnoea	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 7.6992016995 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE			
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE			
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	2	5,7	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE			
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE			
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 7.6992016995 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE			
Respiratory, thoracic and mediastinal disorders	Wheezing	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE			
Respiratory, thoracic and mediastinal disorders	Wheezing	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 7.6992016995 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE			
Skin and subcutaneous tissue disorders		Japan/Rest of Asia Pacific	8	18,2	3	37,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE		
Skin and subcutaneous tissue disorders		North America/ Central and South America/ Europe	36	81,8	5	13,9	35	83,3	1	2,9	5,48	Convergence criterion (GCONV=1E-8) satisfied.	0,61	49,57	0,110	Algorithm converged.	-0,015	0,236	4,86		0,60	39,54	0,1392	0,21	Algorithm converged.	0,03	1,67
Skin and subcutaneous tissue disorders	Ecchymosis	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE			
Skin and subcutaneous tissue disorders	Ecchymosis	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 7.6992016995 is greater than the limit of 0.0001. The convergence is questionable.	0,00	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE			
Skin and subcutaneous tissue disorders	Erythema	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE			
Skin and subcutaneous tissue disorders	Erythema	North America/ Central and South America/ Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 7.4354133187 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE		

Skin and subcutaneous tissue disorders	Papule	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.								ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	
Skin and subcutaneous tissue disorders	Papule	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE														NE	NE	NE	NE							
Skin and subcutaneous tissue disorders	Petechiae	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE														NE	NE	NE	NE							
Skin and subcutaneous tissue disorders	Petechiae	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.								ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE						
Skin and subcutaneous tissue disorders	Pruritus	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.								ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	
Skin and subcutaneous tissue disorders	Pruritus	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.								ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE						
Skin and subcutaneous tissue disorders	Rash	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE														NE	NE	NE	NE							
Skin and subcutaneous tissue disorders	Rash	North America/Central and South America/Europe	36	81,8	3	8,3	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.								WARNING: The relative Hessian convergence criterion of 3.3804331287 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE						
Skin and subcutaneous tissue disorders	Skin exfoliation	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.								ERROR: Error in computing the link function, its derivatives, or the variance function.					NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	
Skin and subcutaneous tissue disorders	Skin exfoliation	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE														NE	NE	NE	NE							
Vascular disorders		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE														NE	NE	NE	NE							
Vascular disorders		North America/Central and South America/Europe	36	81,8	2	5,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.								WARNING: The relative Hessian convergence criterion of 4.4971380977 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE						
Vascular disorders	Hypertension	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE														NE	NE	NE	NE							
Vascular disorders	Hypertension	North America/Central and South America/Europe	36	81,8	2	5,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.								WARNING: The relative Hessian convergence criterion of 4.4971380977 is greater than the limit of 0.0001. The convergence is questionable.					NE	Algorithm converged.	NE	NE	NE						

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_se_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_se_raw_soc_sq_AE_SE1_31MAY2023_42161.xls
 24APR2024 5:54

POPULATION: Safety Population
 ENDPPOINT: Any AEs
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Sex			Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab								
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk							
			n	%	n	%	n	%	n	%	Odds Rati o	Convergence Reason	95% Lower CL	95% Upper CL	Absolu te Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relati ve Risk	Convergence Reason	95% Lower CL	95% Upper CL	p- value (Wald)	Interaction Test p-value (likelihood ratio)	Relati ve Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		Male	20	45,5	3	15,0	21	50,0	1	4,8	3,53	Convergence criterion (GCONV=1E-8) satisfied.	0,34	37,14	0,102	Algorithm converged.	-0,079	0,283	3,15	Algorithm converged.	0,36	27,83	0,3020		-	0,32	Algorithm converged.	0,04	2,80
Blood and lymphatic system disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravascular haemolysis	Male	20	45,5	1	5,0	21	50,0	1	4,8	1,05	Convergence criterion (GCONV=1E-8) satisfied.	0,06	18,05	0,002	Algorithm converged.	-0,130	0,134	1,05	Algorithm converged.	0,07	15,68	0,9718		-	0,95	Algorithm converged.	0,06	14,22
Blood and lymphatic system disorders	Extravascular haemolysis	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Pancytopenia	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Pancytopenia	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE
Cardiac disorders		Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE
Cardiac disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Cardiac disorders	Palpitations	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE
Cardiac disorders	Palpitations	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Eye disorders		Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	1,0000			>999,9	Algorithm converged.	0,00	NE
Eye disorders		Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE

Eye disorders	Lacrimation increased	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.							0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE				
Eye disorders	Lacrimation increased	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE		NE	NE	NE	NE	NE			
Gastrointestinal disorders		Male	20	45,5	2	10,0	21	50,0	4	19,0	0,47	Convergence criterion (GCONV=1E-8) satisfied.	0,08	2,92	-0,090					Algorithm converged.	-0,304	0,123	0,53	Algorithm converged.	0,11	2,56	0,4250	-	1,90	Algorithm converged.	0,39	9,28
Gastrointestinal disorders		Female	24	54,5	6	25,0	21	50,0	1	4,8	6,67	Convergence criterion (GCONV=1E-8) satisfied.	0,73	60,81	0,202					Algorithm converged.	0,007	0,398	5,25	Algorithm converged.	0,69	40,15	0,1101		0,19	Algorithm converged.	0,02	1,46
Gastrointestinal disorders	Abdominal pain	Male	20	45,5	1	5,0	21	50,0	1	4,8	1,05	Convergence criterion (GCONV=1E-8) satisfied.	0,06	18,05	0,002					Algorithm converged.	-0,130	0,134	1,05	Algorithm converged.	0,07	15,68	0,9718	-	0,95	Algorithm converged.	0,06	14,22
Gastrointestinal disorders	Abdominal pain	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	
Gastrointestinal disorders	Diarrhoea	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.								NE	NE	NE	NE		-	NE	Algorithm converged.	NE	NE	NE	NE	
Gastrointestinal disorders	Diarrhoea	Female	24	54,5	2	8,3	21	50,0	1	4,8	1,82	Convergence criterion (GCONV=1E-8) satisfied.	0,15	21,62	0,036					Algorithm converged.	-0,108	0,179	1,75	Algorithm converged.	0,17	17,95	0,6375		0,57	Algorithm converged.	0,06	5,86
Gastrointestinal disorders	Dyspepsia	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE		-	NE	NE	NE	NE	NE	NE	
Gastrointestinal disorders	Dyspepsia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.								NE	NE	NE	NE		-	NE	Algorithm converged.	NE	NE	NE	NE	
Gastrointestinal disorders	Gastroesophageal reflux disease	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.								0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE	NE	NE	
Gastrointestinal disorders	Gastroesophageal reflux disease	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE		-	NE	NE	NE	NE	NE	NE	
Gastrointestinal disorders	Nausea	Male	20	45,5	0	0,0	21	50,0	2	9,5	*	Quasi-complete separation of data points detected.								0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,99	Algorithm converged.	0,00	NE	NE	NE	
Gastrointestinal disorders	Nausea	Female	24	54,5	3	12,5	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.								NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE	NE	NE
Gastrointestinal disorders	Odynophagia	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.								0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE	NE	NE	
Gastrointestinal disorders	Odynophagia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.								NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE	NE	NE
Gastrointestinal disorders	Stomatitis	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE		-	NE	NE	NE	NE	NE	NE	
Gastrointestinal disorders	Stomatitis	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.								NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE	NE	NE
Gastrointestinal disorders	Vomiting	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.								0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE	NE	NE	NE

Gastrointestinal disorders	Vomiting	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE							
General disorders and administration site conditions		Male	20	45,5	5	25,0	21	50,0	4	19,0	1,42	Convergence criterion (GCONV=1E-8) satisfied.		0,32	6,27	0,060	Algorithm converged.	-0,194	0,313	1,31	Algorithm converged.	0,41	4,20	0,6469	-	0,76	Algorithm converged.	0,24	2,44	
General disorders and administration site conditions		Female	24	54,5	7	29,2	21	50,0	4	19,0	1,75	Convergence criterion (GCONV=1E-8) satisfied.		0,43	7,10	0,101	Algorithm converged.	-0,146	0,349	1,53	Algorithm converged.	0,52	4,51	0,4393		0,65	Algorithm converged.	0,22	1,92	
General disorders and administration site conditions	Asthenia	Male	20	45,5	1	5,0	21	50,0	1	4,8	1,05	Convergence criterion (GCONV=1E-8) satisfied.		0,06	18,05	0,002	Algorithm converged.	-0,130	0,134	1,05	Algorithm converged.	0,07	15,68	0,9718		0,95	Algorithm converged.	0,06	14,22	
General disorders and administration site conditions	Asthenia	Female	24	54,5	2	8,3	21	50,0	1	4,8	1,82	Convergence criterion (GCONV=1E-8) satisfied.		0,15	21,62	0,036	Algorithm converged.	-0,108	0,179	1,75	Algorithm converged.	0,17	17,95	0,6375		0,57	Algorithm converged.	0,06	5,86	
General disorders and administration site conditions	Chest pain	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Chest pain	Female	24	54,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	1,0000			>999.99			Algorithm converged.	0,00	NE
General disorders and administration site conditions	Fatigue	Male	20	45,5	1	5,0	21	50,0	1	4,8	1,05	Convergence criterion (GCONV=1E-8) satisfied.		0,06	18,05	0,002	Algorithm converged.	-0,130	0,134	1,05	Algorithm converged.	0,07	15,68	0,9718		0,95	Algorithm converged.	0,06	14,22	
General disorders and administration site conditions	Fatigue	Female	24	54,5	1	4,2	21	50,0	1	4,8	0,87	Convergence criterion (GCONV=1E-8) satisfied.		0,05	14,82	-0,006	Algorithm converged.	-0,127	0,115	0,88	Algorithm converged.	0,06	13,14	0,9230		1,14	Algorithm converged.	0,08	17,16	
General disorders and administration site conditions	Injection site reaction	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Injection site reaction	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630852 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Malaise	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Malaise	Female	24	54,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	1,0000			>999.99			Algorithm converged.	0,00	NE
General disorders and administration site conditions	Oedema	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Oedema	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Oedema peripheral	Male	20	45,5	2	10,0	21	50,0	1	4,8	2,22	Convergence criterion (GCONV=1E-8) satisfied.		0,19	26,63	0,052	Algorithm converged.	-0,108	0,212	2,10	Algorithm converged.	0,21	21,39	0,5310		0,48	Algorithm converged.	0,05	4,85	

Immune system disorders		Male	20	45,5	4	20,0	21	50,0	1	4,8	5,00	Convergence criterion (GCONV=1E-8) satisfied.	0,51	49,27	0,152	Algorithm converged.	-0,045	0,350	4,20	Algorithm converged.	0,51	34,44	0,1813	-	0,24	Algorithm converged.	0,03	1,95
Immune system disorders		Female	24	54,5	6	25,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				NE				Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Immune system disorders	Hypersensitivity	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	-	NE	NE	NE	NE
Immune system disorders	Hypersensitivity	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				NE				Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Immune system disorders	Immunisation reaction	Male	20	45,5	1	5,0	21	50,0	1	4,8	1,05	Convergence criterion (GCONV=1E-8) satisfied.	0,06	18,05	0,002	Algorithm converged.	-0,130	0,134	1,05	Algorithm converged.	0,07	15,68	0,9718	-	0,95	Algorithm converged.	0,06	14,22
Immune system disorders	Immunisation reaction	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				NE				Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Immune system disorders	Type III immune complex mediated reaction	Male	20	45,5	3	15,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				NE				Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Immune system disorders	Type III immune complex mediated reaction	Female	24	54,5	4	16,7	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				NE				Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations		Male	20	45,5	7	35,0	21	50,0	9	42,9	0,72	Convergence criterion (GCONV=1E-8) satisfied.	0,20	2,53	-0,079	Algorithm converged.	-0,376	0,219	0,82	Algorithm converged.	0,38	1,77	0,6085	0,2266	1,22	Algorithm converged.	0,56	2,66
Infections and infestations		Female	24	54,5	11	45,8	21	50,0	6	28,6	2,12	Convergence criterion (GCONV=1E-8) satisfied.	0,61	7,32	0,173	Algorithm converged.	-0,105	0,450	1,60	Algorithm converged.	0,72	3,58	0,2493	0,62		Algorithm converged.	0,28	1,39
Infections and infestations	Abscess jaw	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	-	NE	NE	NE	NE
Infections and infestations	Abscess jaw	Female	24	54,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.				NE		0,00		Algorithm converged.	0,00	NE	1,0000	>999.99		Algorithm converged.	0,00	NE
Infections and infestations	COVID-19	Male	20	45,5	4	20,0	21	50,0	4	19,0	1,06	Convergence criterion (GCONV=1E-8) satisfied.	0,23	4,98	0,010	Algorithm converged.	-0,233	0,252	1,05	Algorithm converged.	0,30	3,64	0,9387	-	0,95	Algorithm converged.	0,27	3,30
Infections and infestations	COVID-19	Female	24	54,5	2	8,3	21	50,0	3	14,3	0,55	Convergence criterion (GCONV=1E-8) satisfied.	0,08	3,63	-0,060	Algorithm converged.	-0,246	0,127	0,58	Algorithm converged.	0,11	3,16	0,5321	1,71		Algorithm converged.	0,32	9,30
Infections and infestations	Cellulitis	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				NE				Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Cellulitis	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	-	NE	NE	NE	NE

Infections and infestations	Conjunctivitis	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Conjunctivitis	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Cystitis	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Infections and infestations	Cystitis	Female	24	54,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Diverticulitis	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Infections and infestations	Diverticulitis	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Folliculitis	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Folliculitis	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Infections and infestations	Influenza	Male	20	45,5	0	0,0	21	50,0	2	9,5	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Influenza	Female	24	54,5	2	8,3	21	50,0	1	4,8	1,82	Convergence criterion (GCONV=1E-8) satisfied.	0,15	21,62	0,036			Algorithm converged.	-0,108	0,179	1,75			0,57	Algorithm converged.	0,06	5,86
Infections and infestations	Nasopharyngitis	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Infections and infestations	Nasopharyngitis	Female	24	54,5	2	8,3	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Oral candidiasis	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Oral candidiasis	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Infections and infestations	Pneumonia	Male	20	45,5	1	5,0	21	50,0	1	4,8	1,05	Convergence criterion (GCONV=1E-8) satisfied.	0,06	18,05	0,002			Algorithm converged.	-0,130	0,134	1,05			0,95	Algorithm converged.	0,06	14,22
Infections and infestations	Pneumonia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Pyelonephritis	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.						0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Pyelonephritis	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Infections and infestations	Respiratory syncytial virus infection	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE	-	NE	NE	NE	NE

Infections and infestations	Respiratory syncytial virus infection	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630852 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Infections and infestations	Respiratory tract infection	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Infections and infestations	Respiratory tract infection	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Infections and infestations	Sinusitis	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	-	>999.99	Algorithm converged.	0,00	NE				
Infections and infestations	Sinusitis	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Infections and infestations	Upper respiratory tract infection	Male	20	45,5	3	15,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 2.48302529 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Infections and infestations	Upper respiratory tract infection	Female	24	54,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	-	>999.99	Algorithm converged.	0,00	NE				
Infections and infestations	Urinary tract infection	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	-	>999.99	Algorithm converged.	0,00	NE				
Infections and infestations	Urinary tract infection	Female	24	54,5	2	8,3	21	50,0	2	9,5	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,11	6,73	-0,012	Algorithm converged.	-0,179	0,155	0,88	Algorithm converged.	0,13	5,68	0,8887	1,14	Algorithm converged.	0,18	7,42	
Infections and infestations	Vaginal infection	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Infections and infestations	Vaginal infection	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Infections and infestations	Viral infection	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				
Infections and infestations	Viral infection	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				
Injury, poisoning and procedural complications		Male	20	45,5	4	20,0	21	50,0	2	9,5	2,37	Convergence criterion (GCONV=1E-8) satisfied.	0,38	14,70	0,105	Algorithm converged.	-0,111	0,320	2,10	Algorithm converged.	0,43	10,23	0,3583	-	0,48	Algorithm converged.	0,10	2,32
Injury, poisoning and procedural complications		Female	24	54,5	7	29,2	21	50,0	1	4,8	8,24	Convergence criterion (GCONV=1E-8) satisfied.	0,92	73,79	0,244	Algorithm converged.	0,041	0,447	6,12	Algorithm converged.	0,82	45,79	0,0774	0,16	Algorithm converged.	0,02	1,22	
Injury, poisoning and procedural complications	Arthropod bite	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE				

Injury, poisoning and procedural complications	Arthropod bite	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE					NE	NE	NE				NE	NE	NE	NE		
Injury, poisoning and procedural complications	Fall	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.					0,00		Algorithm converged.	0,00	NE	1,0000	-	>999.99	Algorithm converged.	0,00	NE
Injury, poisoning and procedural complications	Fall	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE					NE	NE	NE				NE	NE	NE	NE		
Injury, poisoning and procedural complications	Febrile nonhaemolytic transfusion reaction	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE					NE	NE	NE				-	NE	NE	NE	NE	
Injury, poisoning and procedural complications	Febrile nonhaemolytic transfusion reaction	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.					NE		Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Head injury	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE					NE	NE	NE				-	NE	NE	NE	NE	
Injury, poisoning and procedural complications	Head injury	Female	24	54,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.					0,00		Algorithm converged.	0,00	NE	1,0000	-	>999.99	Algorithm converged.	0,00	NE
Injury, poisoning and procedural complications	Infusion related reaction	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.					NE		Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Infusion related reaction	Female	24	54,5	5	20,8	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.					NE		Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injection related reaction	Male	20	45,5	2	10,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.					NE		Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injection related reaction	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.					NE		Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Injury	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.					0,00		Algorithm converged.	0,00	NE	1,0000	-	>999.99	Algorithm converged.	0,00	NE
Injury, poisoning and procedural complications	Injury	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE					NE	NE	NE				NE	NE	NE	NE		
Injury, poisoning and procedural complications	Joint injury	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.					NE		Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Joint injury	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE					NE	NE	NE				NE	NE	NE	NE		
Injury, poisoning and procedural complications	Skin laceration	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.					NE		Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Skin laceration	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE					NE	NE	NE				NE	NE	NE	NE		

Injury, poisoning and procedural complications	Thermal burn	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE				
Injury, poisoning and procedural complications	Thermal burn	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE				
Investigations		Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE				
Investigations		Female	24	54,5	0	0,0	21	50,0	2	9,5	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,99	Algorithm converged.	0,00	NE				
Investigations	Alanine aminotransferase increased	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE				
Investigations	Alanine aminotransferase increased	Female	24	54,5	0	0,0	21	50,0	2	9,5	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,99	Algorithm converged.	0,00	NE				
Metabolism and nutrition disorders		Male	20	45,5	0	0,0	21	50,0	3	14,3	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	-	>999,99	Algorithm converged.	0,00	NE				
Metabolism and nutrition disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE				
Metabolism and nutrition disorders	Glucose tolerance impaired	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE				
Metabolism and nutrition disorders	Glucose tolerance impaired	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE				
Metabolism and nutrition disorders	Hyperkalaemia	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE				
Metabolism and nutrition disorders	Hyperkalaemia	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE				
Metabolism and nutrition disorders	Hypokalaemia	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE				
Metabolism and nutrition disorders	Hypokalaemia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE				
Metabolism and nutrition disorders	Iron deficiency	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE				
Metabolism and nutrition disorders	Iron deficiency	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE				
Musculoskeletal and connective tissue disorders		Male	20	45,5	3	15,0	21	50,0	4	19,0	0,75	Convergence criterion (GCONV=1E-8) satisfied.	0,15	3,87	-0,040	Algorithm converged.	-0,270	0,189	0,79	Algorithm converged.	0,20	3,09	0,7318	-	1,27	Algorithm converged.	0,32	4,98
Musculoskeletal and connective tissue disorders		Female	24	54,5	4	16,7	21	50,0	1	4,8	4,00	Convergence criterion (GCONV=1E-8) satisfied.	0,41	39,00	0,119	Algorithm converged.	-0,056	0,294	3,50	Algorithm converged.	0,42	28,91	0,2449	-	0,29	Algorithm converged.	0,03	2,36
Musculoskeletal and connective tissue disorders	Arthralgia	Male	20	45,5	2	10,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE	NE			

Musculoskeletal and connective tissue disorders	Arthralgia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE						
Musculoskeletal and connective tissue disorders	Back pain	Male	20	45,5	1	5,0	21	50,0	2	9,5	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,04	5,99	-0,045	Algorithm converged.	-0,203	0,113	0,53	Algorithm converged.	0,05	5,35	0,5864	-	1,90	Algorithm converged.	0,19	19,40	
Musculoskeletal and connective tissue disorders	Back pain	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Musculoskeletal and connective tissue disorders	Coccydynia	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Musculoskeletal and connective tissue disorders	Coccydynia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	
Musculoskeletal and connective tissue disorders	Muscle spasms	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Musculoskeletal and connective tissue disorders	Muscle spasms	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Myalgia	Male	20	45,5	0	0,0	21	50,0	2	9,5	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999	-	>999.9	9	Algorithm converged.	0,00	NE	NE	NE	NE	
Musculoskeletal and connective tissue disorders	Myalgia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Neck pain	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Neck pain	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Spinal pain	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Musculoskeletal and connective tissue disorders	Spinal pain	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	Female	24	54,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	-	>999.9	9	Algorithm converged.	0,00	NE	NE	NE	NE	NE

Nervous system disorders		Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.											ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE	
Nervous system disorders		Female	24	54,5	5	20,8	21	50,0	2	9,5	2,50	Convergence criterion (GCONV=1E-8) satisfied.	0,43	14,51	0,113								Algorithm converged.	-0,092	0,318	2,19	Algorithm converged.	0,47	10,12	0,3165		0,46	Algorithm converged.	0,10	2,11		
Nervous system disorders	Cervicobrachial syndrome	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE							NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Nervous system disorders	Cervicobrachial syndrome	Female	24	54,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.											ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE	
Nervous system disorders	Headache	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE							NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Nervous system disorders	Headache	Female	24	54,5	5	20,8	21	50,0	1	4,8	5,26	Convergence criterion (GCONV=1E-8) satisfied.	0,56	49,29	0,161								Algorithm converged.	-0,026	0,347	4,37	Algorithm converged.	0,55	34,52	0,1614		0,23	Algorithm converged.	0,03	1,80		
Nervous system disorders	Transient ischaemic attack	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.											ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE	
Nervous system disorders	Transient ischaemic attack	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE							NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Psychiatric disorders		Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.											ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE	
Psychiatric disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.											ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Psychiatric disorders	Anxiety	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE							NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Psychiatric disorders	Anxiety	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.											ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Psychiatric disorders	Insomnia	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.											ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE	
Psychiatric disorders	Insomnia	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE							NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Renal and urinary disorders		Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE							NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.											WARNING: The relative Hessian convergence criterion of 4.9884630852 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Renal and urinary disorders	Haemoglobinuria	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE							NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders	Haemoglobinuria	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.											WARNING: The relative Hessian convergence criterion of 4.9884630852 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	

Skin and subcutaneous tissue disorders	Petechiae	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 5.235088947 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Petechiae	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Skin and subcutaneous tissue disorders	Pruritus	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Skin and subcutaneous tissue disorders	Pruritus	Female	24	54,5	2	8,3	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 3.0442264216 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Rash	Male	20	45,5	2	10,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Rash	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Skin exfoliation	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Skin and subcutaneous tissue disorders	Skin exfoliation	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Vascular disorders		Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Vascular disorders		Female	24	54,5	2	8,3	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 3.0442264187 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypertension	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Vascular disorders	Hypertension	Female	24	54,5	2	8,3	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 3.0442264187 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_AE_SE1_31MAY2023_42161.xls
24APR2024 5:54

POPULATION: Safety Population
 ENDPOINT: AEs Grade >= 3
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Age		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab										
		Patient		Patients with		Patient		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk								
MedDRA System	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL		
Blood and lymphatic system disorders		<65	39	88,6	3	7,7	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 3.2998393231 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders		>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Extravascular haemolysis	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 7.2864437275 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravascular haemolysis	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	<65	39	88,6	2	5,1	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Hepatobiliary disorders		<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	
Hepatobiliary disorders	Hyperbilirubinaemia	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hyperbilirubinaemia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	

POPULATION: Safety Population
 ENDPPOINT: AEs Grade >= 3
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

All

		Crovalimab (N=44)						Eculizumab (N=42)						Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
		Patients			Patients with			Patients			Patients with			Odds Ratio				Absolute Risk Difference				Relative Risk						Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL			
Blood and lymphatic system disorders		n/a	44	100,0	3	6,8	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 3.817736592 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Extravascular haemolysis	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Neutropenia	n/a	44	100,0	2	4,5	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 5.1032936995 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Hepatobiliary disorders		n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Hepatobiliary disorders	Hyperbilirubinaemia	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Immune system disorders		n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Immune system disorders	Hypersensitivity	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Immune system disorders	Type III immune complex mediated reaction	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 8.4461744379 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	NE	Algorithm converged.	NE	NE	
Infections and infestations		n/a	44	100,0	1	2,3	42	100,0	1	2,4	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,75	-0,001	Algorithm converged.	-0,065	0,063	0,95	Algorithm converged.	0,06	14,77	0,9734		NE	1,05	Algorithm converged.	0,07	16,21		
Infections and infestations	Pneumonia	n/a	44	100,0	1	2,3	42	100,0	1	2,4	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,75	-0,001	Algorithm converged.	-0,065	0,063	0,95	Algorithm converged.	0,06	14,77	0,9734		NE	1,05	Algorithm converged.	0,07	16,21		
Infections and infestations	Pyelonephritis	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 8.9456063823 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999		NE	>999,9	Algorithm converged.	0,00	NE		

Infections and infestations	Urinary tract infection	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications		n/a	44	100,0	0	0,0	42	100,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Injury, poisoning and procedural complications	Skin laceration	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Metabolism and nutrition disorders		n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Metabolism and nutrition disorders	Hypokalaemia	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders		n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.4461744379 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypertension	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 8.4461744379 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_GE3_SE1_31MAY2023_42161.xls
 24APR2024 6:00

POPULATION: Safety Population
 ENDPOINT: AEs Grade >= 3
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

Transfusion history [pRBC infusion in the last 12 months]

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab									
		Patient		Patients with		Patient		Patients with		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk									
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE
Blood and lymphatic system disorders		No	32	72,7	3	9,4	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 3.2077155496 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravascular haemolysis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE	
Blood and lymphatic system disorders	Extravascular haemolysis	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	No	32	72,7	2	6,3	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 4.25196428 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE	
Hepatobiliary disorders		No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hyperbilirubin aemia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE	
Hepatobiliary disorders	Hyperbilirubin aemia	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Immune system disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		-	NE	NE	NE	NE	

Immune system disorders		No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Immune system disorders	Hypersensitivity	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	
Immune system disorders	Hypersensitivity	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	
Immune system disorders	Type III immune complex mediated reaction	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Immune system disorders	Type III immune complex mediated reaction	No	32	72,7	0	0,0	32	76,2	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations		Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations		No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE	
Infections and infestations	Pneumonia	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Pneumonia	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE	
Infections and infestations	Pyelonephritis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	
Infections and infestations	Pyelonephritis	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE	
Infections and infestations	Urinary tract infection	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	-	NE	Algorithm converged.	NE	NE

Infections and infestations	Urinary tract infection	No	32	72,7	0	0,0	32	76,2	0	0,0	NE					NE	NE	NE	NE					NE	NE	NE	NE	
Injury, poisoning and procedural complications		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE					NE	NE	NE	NE					NE	NE	NE	NE	
Injury, poisoning and procedural complications		No	32	72,7	0	0,0	32	76,2	0	0,0	NE					NE	NE	NE	NE					NE	NE	NE	NE	
Injury, poisoning and procedural complications	Skin laceration	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE					NE	NE	NE	NE					NE	NE	NE	NE	
Injury, poisoning and procedural complications	Skin laceration	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.												Algorithm converged.	NE	NE	NE	NE
Metabolism and nutrition disorders		Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.												Algorithm converged.	NE	NE	NE	NE
Metabolism and nutrition disorders		No	32	72,7	0	0,0	32	76,2	0	0,0	NE					NE	NE	NE	NE					NE	NE	NE	NE	
Metabolism and nutrition disorders	Hypokalaemia	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.												Algorithm converged.	NE	NE	NE	NE
Metabolism and nutrition disorders	Hypokalaemia	No	32	72,7	0	0,0	32	76,2	0	0,0	NE					NE	NE	NE	NE					NE	NE	NE	NE	
Vascular disorders		Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.												Algorithm converged.	NE	NE	NE	NE
Vascular disorders		No	32	72,7	0	0,0	32	76,2	0	0,0	NE					NE	NE	NE	NE					NE	NE	NE	NE	
Vascular disorders	Hypertension	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.												Algorithm converged.	NE	NE	NE	NE
Vascular disorders	Hypertension	No	32	72,7	0	0,0	32	76,2	0	0,0	NE					NE	NE	NE	NE					NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_GE3_SE1_31MAY2023_42161.xls
 24APR2024 6:00

POPULATION: Safety Population
 ENDPPOINT: AEs Grade >= 3
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab						
			Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk						
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders		North America/Central and South America/Europe	36	81,8	2	5,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4,4971381018 is greater than the limit of 0,0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravascular haemolysis	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravascular haemolysis	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	North America/Central and South America/Europe	36	81,8	2	5,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4,4971381018 is greater than the limit of 0,0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Hepatobiliary disorders	Hyperbilirubinaemia	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hyperbilirubinaemia	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Immune system disorders		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Immune system disorders		North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE

Metabolism and nutrition disorders		North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Metabolism and nutrition disorders	Hypokalaemia	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Metabolism and nutrition disorders	Hypokalaemia	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Vascular disorders		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	NE
Vascular disorders		North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Vascular disorders	Hypertension	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	NE
Vascular disorders	Hypertension	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_GE3_SE1_31MAY2023_42161.xls
24APR2024 6:00

POPULATION: Safety Population
 ENDPOINT: AEs Grade >= 3
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Sex		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab																		
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk			Eculizumab vs. Crovalimab									
MedDRA System	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		Male	20	45,5	2	10,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravasacular haemolysis	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravasacular haemolysis	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Hepatobiliary disorders	Hyperbilirubinaemia	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hyperbilirubinaemia	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Immune system disorders		Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Immune system disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Immune system disorders	Hypersensitivity	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Immune system disorders	Hypersensitivity	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE

Immune system disorders	Type III immune complex mediated reaction	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE													
Immune system disorders	Type III immune complex mediated reaction	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.															ERROR: Error in computing the link function, its derivatives, or the variance function.	Algorithm converged.	NE	NE	NE		Algorithm converged.	NE	NE				
Infections and infestations		Male	20	45,5	1	5,0	21	50,0	1	4,8	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,06	18,05	0,002											Algorithm converged.	-0,130	0,134	1,05	Algorithm converged.	0,07	15,68	0,9718	-	0,95	Algorithm converged.	0,06	14,22
Infections and infestations		Female	24	54,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Pneumonia	Male	20	45,5	1	5,0	21	50,0	1	4,8	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,06	18,05	0,002											Algorithm converged.	-0,130	0,134	1,05	Algorithm converged.	0,07	15,68	0,9718	-	0,95	Algorithm converged.	0,06	14,22
Infections and infestations	Pneumonia	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Pyelonephritis	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.															Algorithm converged.	0,00		NE	1,0000	-	>999.99	Algorithm converged.	0,00		NE		
Infections and infestations	Pyelonephritis	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Urinary tract infection	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Infections and infestations	Urinary tract infection	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.															Algorithm converged.			NE						NE	Algorithm converged.		
Injury, poisoning and procedural complications		Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications		Female	24	54,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Skin laceration	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.															Algorithm converged.			NE						NE	Algorithm converged.		
Injury, poisoning and procedural complications	Skin laceration	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	
Metabolism and nutrition disorders		Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.															Algorithm converged.			NE						NE	Algorithm converged.		
Metabolism and nutrition disorders	Hypokalaemia	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Metabolism and nutrition disorders	Hypokalaemia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.															Algorithm converged.			NE						NE	Algorithm converged.		
Vascular disorders		Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Vascular disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.															Algorithm converged.			NE						NE	Algorithm converged.		
Vascular disorders	Hypertension	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE										NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Vascular disorders	Hypertension	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.															Algorithm converged.			NE						NE	Algorithm converged.		

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_GE3_SE1_31MAY2023_42161.xls
24APR2024 6:00

Hepatobiliary disorders	Hyperbilirubinaemia	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE			
Hepatobiliary disorders	Hyperbilirubinaemia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Immune system disorders		<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 7.2864437342 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE			
Immune system disorders		>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Immune system disorders	Hypersensitivity	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 7.2864437342 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE			
Immune system disorders	Hypersensitivity	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Immune system disorders	Type III immune complex mediated reaction	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	WARNING: The relative Hessian convergence criterion of 7.2864437342 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE			
Immune system disorders	Type III immune complex mediated reaction	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Infections and infestations		<65	39	88,6	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE			
Infections and infestations		>=65	5	11,4	1	20,0	7	16,7	1	14,3	1,50	Convergence criterion (GCONV=1E-8) satisfied.	0,07	31,57	0,057	Algorithm converged.	-0,379	0,493	1,40	0,11	17,45	0,7938	0,71	Algorithm converged.	0,06	8,90
Infections and infestations	Pneumonia	<65	39	88,6	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	NE		
Infections and infestations	Pneumonia	>=65	5	11,4	1	20,0	7	16,7	1	14,3	1,50	Convergence criterion (GCONV=1E-8) satisfied.	0,07	31,57	0,057	Algorithm converged.	-0,379	0,493	1,40	0,11	17,45	0,7938	0,71	Algorithm converged.	0,06	8,90
Infections and infestations	Pyelonephritis	<65	39	88,6	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	NE		

Vascular disorders		>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE		
Vascular disorders	Hypertension	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 7.2864437342 is greater than the limit of 0.0001. The convergence is questionable.					Algorithm converged.	NE	NE	NE	NE
Vascular disorders	Hypertension	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE		

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sq_G3_SE1_31MAY2023_42161.xls
 24APR2024 5:58

POPULATION: Safety Population
 ENDPOINT: AEs Grade 3
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

All

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk							
MedDRA System	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		n/a	44	100,0	2	4,5	42	100,0	0	0,0	*				WARNING: The relative Hessian convergence criterion of 5,1032936995 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravascular haemolysis	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		n/a	44	100,0	1	2,3	42	100,0	0	0,0	*				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hyperbilirubinaemia	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Immune system disorders		n/a	44	100,0	1	2,3	42	100,0	0	0,0	*				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Immune system disorders	Hypersensitivity	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Immune system disorders	Type III immune complex mediated reaction	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*				WARNING: The relative Hessian convergence criterion of 8,4461744379 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations		n/a	44	100,0	1	2,3	42	100,0	1	2,4	0,95	0,06	15,75	-0,001	Algorithm converged.	-0,065	0,063	0,95	Algorithm converged.	0,06	14,77	0,9734	NE	1,05	Algorithm converged.	0,07	16,21
Infections and infestations	Pneumonia	n/a	44	100,0	1	2,3	42	100,0	1	2,4	0,95	0,06	15,75	-0,001	Algorithm converged.	-0,065	0,063	0,95	Algorithm converged.	0,06	14,77	0,9734	NE	1,05	Algorithm converged.	0,07	16,21

POPULATION: Safety Population
 ENDPOINT: AEs Grade 3
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Transfusion history [pRBC infusion in the last 12 months]

		Crossover (N=44)				Eculizumab (N=42)				Crossover vs. Eculizumab										Eculizumab vs. Crossover								
		Patient		Patients with		Patient		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk								
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolu te Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relati ve Risk	Convergence Reason	95% Lower CL	95% Upper CL	p- value (Wald)	Interac tion Test p-value (likeli hood ratio)	Relati ve Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Blood and lymphatic system disorders		No	32	72,7	2	6,3	32	76,2	0	0,0	*				Quasi-complete separation of data points detected.	*									NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravascular haemolysis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Blood and lymphatic system disorders	Extravascular haemolysis	No	32	72,7	1	3,1	32	76,2	0	0,0	*				Quasi-complete separation of data points detected.	*									NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	No	32	72,7	1	3,1	32	76,2	0	0,0	*				Quasi-complete separation of data points detected.	*									NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Hepatobiliary disorders		No	32	72,7	1	3,1	32	76,2	0	0,0	*				Quasi-complete separation of data points detected.	*									NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hyperbilirubinaemia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Hepatobiliary disorders	Hyperbilirubinaemia	No	32	72,7	1	3,1	32	76,2	0	0,0	*				Quasi-complete separation of data points detected.	*									NE	Algorithm converged.	NE	NE
Immune system disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Immune system disorders		No	32	72,7	1	3,1	32	76,2	0	0,0	*				Quasi-complete separation of data points detected.	*									NE	Algorithm converged.	NE	NE
Immune system disorders	Hypersensitivity	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Immune system disorders	Hypersensitivity	No	32	72,7	1	3,1	32	76,2	0	0,0	*				Quasi-complete separation of data points detected.	*									NE	Algorithm converged.	NE	NE
Immune system disorders	Type III immune complex mediated reaction	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*				Quasi-complete separation of data points detected.	*									NE	Algorithm converged.	NE	NE
Immune system disorders	Type III immune complex mediated reaction	No	32	72,7	0	0,0	32	76,2	0	0,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	

POPULATION: Safety Population
 ENDPOINT: AEs Grade 3
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

MedDRA System Organ Class	MedDRA Preferred Term	Level	Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab												Eculizumab vs. Crovalimab					
			Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk					
			n	%	n	%	n	%	n	%	Odds Rati o	Convergence Reason	95% Lowe r CL	95% Upper CL	Absolu te Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Upper CL	p- value (Wald)	Interaction Test p-value (likelihood ratio)	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Upper CL
Blood and lymphatic system disorders		Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders		North America/ Central and South America/ Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Blood and lymphatic system disorders	Extravascular haemolysis	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravascular haemolysis	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE		-	NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	North America/ Central and South America/ Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	
Hepatobiliary disorders		Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
Hepatobiliary disorders	Hyperbilirubina emia	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.						NE	Algorithm converged.	NE	NE	NE		-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hyperbilirubina emia	North America/ Central and South America/ Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
Immune system disorders		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE			NE	NE	NE	NE	NE		-	NE	NE	NE	NE

Immune system disorders		North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE		
Immune system disorders	Hypersensitivity	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE		
Immune system disorders	Hypersensitivity	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE		
Immune system disorders	Type III immune complex mediated reaction	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE		
Immune system disorders	Type III immune complex mediated reaction	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE		
Infections and infestations		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE		
Infections and infestations		North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	1	2,9	0,97	Convergence criterion (GCONV=1E-8) satisfied.		0,06	16,16	-0,001		Algorithm converged.	-0,078	0,076	0,97	Algorithm converged.	0,06	14,94	0,9839		1,03	Algorithm converged.	0,07	15,81
Infections and infestations	Pneumonia	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE		
Infections and infestations	Pneumonia	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	1	2,9	0,97	Convergence criterion (GCONV=1E-8) satisfied.		0,06	16,16	-0,001		Algorithm converged.	-0,078	0,076	0,97	Algorithm converged.	0,06	14,94	0,9839		1,03	Algorithm converged.	0,07	15,81
Infections and infestations	Pyelonephritis	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE		
Infections and infestations	Pyelonephritis	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				0,00	Algorithm converged.	0,00	NE	0,9999			>999.99	Algorithm converged.	0,00	NE		
Infections and infestations	Urinary tract infection	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE		
Infections and infestations	Urinary tract infection	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE		
Injury, poisoning and procedural complications		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE		
Injury, poisoning and procedural complications		North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	NE		
Injury, poisoning and procedural complications	Skin laceration	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE		

POPULATION: Safety Population
 ENDPOINT: AEs Grade 3
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Sex

			Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab												Eculizumab vs. Crovalimab						
			Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk			Relative Risk									
MedDRA System	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravasacular haemolysis	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Extravasacular haemolysis	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Hepatobiliary disorders	Hyperbilirubinaemia	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hyperbilirubinaemia	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Immune system disorders		Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Immune system disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Immune system disorders	Hypersensitivity	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	

POPULATION: Safety Population
 ENDPPOINT: AEs Grade 4
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

Age			Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab									
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patient		Patients with		Patient		Patients with		Odds Ratio		Absolute Risk Difference			Relative Risk					Relative Risk									
			n	%	n	%	n	%	n	%	Odds Rati o	Convergence Reason	95% Lowe r CL	95% Uppe r CL	Absolu te Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL	p- value (Wald)	Interaction Test p-value (likelihood ratio)	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL		
Blood and lymphatic system disorders		<65	39	88,6	1	2,6	35	83,3	0	0	*				WARNING: The relative Hessian convergence criterion of 7.2864437275 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE			-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders		>=65	5	11,4	0	0,0	7	16,7	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	<65	39	88,6	1	2,6	35	83,3	0	0	*				WARNING: The relative Hessian convergence criterion of 7.2864437275 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE			-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	>=65	5	11,4	0	0,0	7	16,7	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE				NE	NE	NE	NE	

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_G4_SE1_31MAY2023_42161.xls
 24APR2024 6:02

POPULATION: Safety Population
 ENDPPOINT: AEs Grade 4
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

All

			Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
			Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Rati o	Convergence Reason	95% Lowe r CL	95% Uppe r CL	Absolu te Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL	p- value (Wald)	Interaction Test p-value (likelihood ratio)	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL
Blood and lymphatic system disorders		n/a	44	100,0	1	2,3	42	100,0	0	0	*	Quasi- complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	n/a	44	100,0	1	2,3	42	100,0	0	0	*	Quasi- complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_G4_SE1_31MAY2023_42161.xls
 24APR2024 6:02

POPULATION: Safety Population
 ENDPPOINT: AEs Grade 4
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

Transfusion history [pRBC infusion in the last 12 months]

			Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab								
			Patient		Patients with		Patient		Patients with		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk								
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Rati o	Convergence Reason	95% Lowe r CL	95% Uppe r CL	Absolu te Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL	p- value (Wald)	Interaction Test p-value (likelihood ratio)	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL	
Blood and lymphatic system disorders		Yes	12	27,3	0	0,0	10	23,8	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	NE
Blood and lymphatic system disorders		No	32	72,7	1	3,1	32	76,2	0	0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	Yes	12	27,3	0	0,0	10	23,8	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	No	32	72,7	1	3,1	32	76,2	0	0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_G4_SE1_31MAY2023_42161.xls
 24APR2024 6:02

POPULATION: Safety Population
 ENDPOINT: AEs Grade 4
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab							
			Patient		Patients with		Patient		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Rati o	Convergence Reason	95% Lowe r CL	95% Upe r CL	Absolu te Risk	Convergence Reason	95% Lowe r CL	95% Upe r CL	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Upe r CL	p- value (Wald)	Interaction Test p-value (likelihood ratio)	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Upe r CL	
Blood and lymphatic system disorders		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-		NE	NE	NE	NE
Blood and lymphatic system disorders		North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 7.4354133187 is greater than the limit of 0.0001. The convergence is questionable.		NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-		NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 7.4354133187 is greater than the limit of 0.0001. The convergence is questionable.		NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_G4_SE1_31MAY2023_42161.xls
 24APR2024 6:02

POPULATION: Safety Population
 ENDPPOINT: AEs Grade 4
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

Sex

			Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
MedDRA System Organ Class	MedDRA Preferred Term	Level	Patient		Patients with		Patient		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk							
			n	%	n	%	n	%	n	%	Odds Rati o	Convergence Reason	95% Lowe r CL	95% Uppe r CL	Absolu te Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL	p- value (Wald)	Interaction Test p-value (likelihood ratio)	Relati ve Risk	Convergence Reason	95% Lowe r CL	95% Uppe r CL
Blood and lymphatic system disorders		Male	20	45,5	1	5,0	21	50,0	0	0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders		Female	24	54,5	0	0,0	21	50,0	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	Male	20	45,5	1	5,0	21	50,0	0	0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Female	24	54,5	0	0,0	21	50,0	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sq_G4_SE1_31MAY2023_42161.xls
 24APR2024 6:02

POPULATION: Safety Population
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_G5_SE1_31MAY2023_42161.xls
21MAY2024 14:52

POPULATION: Safety Population
 ENDPOINT: Any SAEs
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Age

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab									
		Patient		Patients with		Patient		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk									
MedDRA System	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				* questionable.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders		>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				* questionable.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
General disorders and administration site conditions		<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				* questionable.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
General disorders and administration site conditions	Pyrexia	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.				* questionable.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE

Reproductive system and breast disorders	Cervical dysplasia	<65	39	88,6	1	2,6	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 7.2864437209 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Reproductive system and breast disorders	Cervical dysplasia	>=65	5	11,4	0	0,0	7	16,7	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sq_SAE_SE1_31MAY2023_42161.xls
 24APR2024 5:56

POPULATION: Safety Population
 ENDPOINT: Any SAEs
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

All

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab								
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk								
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Fyrexia	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hyperbilirubinaemia	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations		n/a	44	100,0	3	6,8	42	100,0	1	2,4	3,00	Convergence criterion (GCONV=1E-8) satisfied.	0,30	30,04	0,044	Algorithm converged.	-0,043	0,132	2,86	Algorithm converged.	0,31	26,45	0,3537	NE	0,35	Algorithm converged.	0,04	3,23
Infections and infestations	Nasopharyngitis	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Infections and infestations	Pneumonia	n/a	44	100,0	1	2,3	42	100,0	1	2,4	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,75	-0,001	Algorithm converged.	-0,065	0,063	0,95	Algorithm converged.	0,06	14,77	0,9734	NE	1,05	Algorithm converged.	0,07	16,21
Infections and infestations	Eyelonephritis	n/a	44	100,0	0	0,0	42	100,0	1	2,4	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 8.9456063823 is greater than the limit of 0.0001. The convergence is questionable.			0,00	Algorithm converged.	0,00	NE	0,9999	NE	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Urinary tract infection	n/a	44	100,0	1	2,3	42	100,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

POPULATION: Safety Population
 ENDPOINT: Any SAEs
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Transfusion history (pRBC infusion in the last 12 months)

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab								
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk								
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Blood and lymphatic system disorders		No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		No	32	72,7	0	0,0	32	76,2	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
General disorders and administration site conditions	Pyrexia	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Pyrexia	No	32	72,7	0	0,0	32	76,2	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Hepatobiliary disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Hepatobiliary disorders		No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hyperbilirubinaemia	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Hepatobiliary disorders	Hyperbilirubinaemia	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations		Yes	12	27,3	2	16,7	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations		No	32	72,7	1	3,1	32	76,2	1	3,1	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,71	0,000	Algorithm converged.	-0,085	0,085	1,00	Algorithm converged.	0,07	15,30	1,0000		1,00	Algorithm converged.	0,07	15,30
Infections and infestations	Nasopharyngitis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	

Infections and infestations	Nasopharyngitis	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Pneumonia	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Pneumonia	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	NE	Algorithm converged.	0,00	NE
Infections and infestations	Pyelonephritis	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Infections and infestations	Pyelonephritis	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	NE	Algorithm converged.	0,00	NE
Infections and infestations	Urinary tract infection	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Infections and infestations	Urinary tract infection	No	32	72,7	0	0,0	32	76,2	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Injury, poisoning and procedural complications		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Injury, poisoning and procedural complications		No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Skin laceration	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Injury, poisoning and procedural complications	Skin laceration	No	32	72,7	1	3,1	32	76,2	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Nervous system disorders		Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Nervous system disorders		No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	NE	Algorithm converged.	0,00	NE
Nervous system disorders	Transient ischaemic attack	Yes	12	27,3	0	0,0	10	23,8	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
Nervous system disorders	Transient ischaemic attack	No	32	72,7	0	0,0	32	76,2	1	3,1	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	NE	Algorithm converged.	0,00	NE
Reproductive system and breast disorders		Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Reproductive system and breast disorders		No	32	72,7	0	0,0	32	76,2	0	0,0	NE		NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE

Reproductive system and breast disorders	Cervical dysplasia	Yes	12	27,3	1	8,3	10	23,8	0	0,0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Reproductive system and breast disorders	Cervical dysplasia	No	32	72,7	0	0,0	32	76,2	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/R07112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/R07112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_SAE_SE1_31MAY2023_42161.xls
 24APR2024 5:56

POPULATION: Safety Population
 ENDFPOINT: Any SAEs
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab											Eculizumab vs. Crovalimab							
			Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk				Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-		NE	NE	NE	NE
Blood and lymphatic system disorders		North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 7.4354133187 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-		NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 7.4354133187 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE			NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 2.3217503965 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	-		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	
General disorders and administration site conditions	Pyrexia	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 2.3217503965 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	-		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Pyrexia	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	
Hepatobiliary disorders		Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-		NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			NE	NE	NE	NE	
Hepatobiliary disorders	Hyperbilirubinaemia	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	-		NE	Algorithm converged.	NE	NE

Nervous system disorders		North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.								ERROR: The mean parameter is either invalid or at a limit of its range for some observations.								0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE	
Nervous system disorders	Transient ischaemic attack	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE														
Nervous system disorders	Transient ischaemic attack	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	1	2,9	*	Quasi-complete separation of data points detected.								ERROR: The mean parameter is either invalid or at a limit of its range for some observations.								0,00	Algorithm converged.	0,00	NE	0,9999	>999.99	Algorithm converged.	0,00	NE	
Reproductive system and breast disorders		Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.								WARNING: The relative Hessian convergence criterion of 2.3217503965 is greater than the limit of 0.0001. The convergence is questionable.								NE	Algorithm converged.	NE	NE	NE					
Reproductive system and breast disorders		North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE														
Reproductive system and breast disorders	Cervical dysplasia	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0,0	*	Quasi-complete separation of data points detected.								WARNING: The relative Hessian convergence criterion of 2.3217503965 is greater than the limit of 0.0001. The convergence is questionable.								NE	Algorithm converged.	NE	NE	NE					
Reproductive system and breast disorders	Cervical dysplasia	North America/Central and South America/Europe	36	81,8	0	0,0	35	83,3	0	0,0	NE		NE	NE	NE					NE	NE	NE	NE														

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_I/prod/output/t_ae_raw_soc_sg_SAE_SE1_31MAY2023_42161.xls
 24APR2024 5:56

POPULATION: Safety Population
 ENDPOINT: Any SAEs
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Sex

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab									
		Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
MedDRA System	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
Blood and lymphatic system disorders		Male	20	45,5	1	5,0	21	50,0	0	0,0	+	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders		Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Blood and lymphatic system disorders	Neutropenia	Male	20	45,5	1	5,0	21	50,0	0	0,0	+	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
General disorders and administration site conditions		Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
General disorders and administration site conditions		Female	24	54,5	1	4,2	21	50,0	0	0,0	+	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Pyrexia	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE	
General disorders and administration site conditions	Pyrexia	Female	24	54,5	1	4,2	21	50,0	0	0,0	+	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.				NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		Male	20	45,5	1	5,0	21	50,0	0	0,0	+	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Hepatobiliary disorders	Hyperbilirubinaemia	Male	20	45,5	1	5,0	21	50,0	0	0,0	+	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				NE	Algorithm converged.	NE	NE	NE	-	NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Hyperbilirubinaemia	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	

Infections and infestations		Male	20	45,5	1	5,0	21	50,0	1	4,8	1,05	Convergence criterion (GCONV=1E-8) satisfied.	0,06	18,05	0,002	Algorithm converged.	-0,130	0,134	1,05	Algorithm converged.	0,07	15,68	0,9718	-	0,95	Algorithm converged.	0,06	14,22
Infections and infestations		Female	24	54,5	2	8,3	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 3.0442264187 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Nasopharyngitis	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Infections and infestations	Nasopharyngitis	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Pneumonia	Male	20	45,5	1	5,0	21	50,0	1	4,8	1,05	Convergence criterion (GCONV=1E-8) satisfied.	0,06	18,05	0,002	Algorithm converged.	-0,130	0,134	1,05	Algorithm converged.	0,07	15,68	0,9718	-	0,95	Algorithm converged.	0,06	14,22
Infections and infestations	Pneumonia	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Eyelonephritis	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE
Infections and infestations	Eyelonephritis	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Urinary tract infection	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Urinary tract infection	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications		Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications		Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Injury, poisoning and procedural complications	Skin laceration	Male	20	45,5	1	5,0	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Skin laceration	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Nervous system disorders		Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE
Nervous system disorders		Female	24	54,5	0	0,0	21	50,0	0	0,0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE

Nervous system disorders	Transient ischaemic attack	Male	20	45,5	0	0,0	21	50,0	1	4,8	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	0,00	Algorithm converged.	0,00	NE	1,0000	-	>999,99	Algorithm converged.	0,00	NE
Nervous system disorders	Transient ischaemic attack	Female	24	54,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Reproductive system and breast disorders		Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Reproductive system and breast disorders		Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Reproductive system and breast disorders	Cervical dysplasia	Male	20	45,5	0	0,0	21	50,0	0	0,0	NE			NE	NE	NE	NE	NE	NE	-	NE	NE	NE	NE
Reproductive system and breast disorders	Cervical dysplasia	Female	24	54,5	1	4,2	21	50,0	0	0,0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 4.9884630898 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_soc.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_soc_sg_SAE_SE1_31MAY2023_42161.xls
 24APR2024 5:56

POPULATION: Safety Population
ENDPOINT: Adverse event leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_soc_descriptive.sas
Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_soc_descriptive_sg_WDAE_SE1_31MAY2023_42161.xls
21MAY2024 14:43

POPULATION: Safety Population
 ENDPOINT: DILI, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	0	0	42	100,0	0	0
Age	<65	39	88,6	0	0	35	83,3	0	0
	>=65	5	11,4	0	0	7	16,7	0	0
Sex	Male	20	45,5	0	0	21	50,0	0	0
	Female	24	54,5	0	0	21	50,0	0	0
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	0	0	10	23,8	0	0
	No	32	72,7	0	0	32	76,2	0	0
Geographic region	Japan/Rest of Asia Pacific	8	18,2	0	0	7	16,7	0	0
	North America/ Central and South America/ Europe	36	81,8	0	0	35	83,3	0	0

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_DILI_SE1_31MAY2023_42161.xls
 23APR2024 20:57

POPULATION: Safety Population
 ENDPOINT: Type III hypersensitivity reactions Grade >=3, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab								
		Patients		Patients with		Patients		Patients with		Odds Ratio		Absolute Risk Difference				Relative Risk				Relative Risk								
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	
All	n/a	44	100,0	1	2,3	42	100,0	0	0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 8.4461744379 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Age	<65	39	88,6	1	2,6	35	83,3	0	0	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 7.2864437342 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	>=65	5	11,4	0	0,0	7	16,7	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Sex	Male	20	45,5	0	0,0	21	50,0	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
	Female	24	54,5	1	4,2	21	50,0	0	0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	1	8,3	10	23,8	0	0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	No	32	72,7	0	0,0	32	76,2	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Geographic region	Japan/Rest of Asia Pacific	8	18,2	0	0,0	7	16,7	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
	North America/Central and South America/Europe	36	81,8	1	2,8	35	83,3	0	0	*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

POPULATION: Safety Population

ENDPOINT: Serious Type III hypersensitivity reactions, Primary Safety Period

MODEL: Unstratified analysis

STUDY: BO42161

Dichotomous Analysis by Subgroups (Safety)

	Level	Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name		n	%	n	%	n	%	n	%
All	n/a	44	100,0	0	0	42	100,0	0	0
Age	<65	39	88,6	0	0	35	83,3	0	0
	>=65	5	11,4	0	0	7	16,7	0	0
Sex	Male	20	45,5	0	0	21	50,0	0	0
	Female	24	54,5	0	0	21	50,0	0	0
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	0	0	10	23,8	0	0
	No	32	72,7	0	0	32	76,2	0	0
Geographic region	Japan/Rest of Asia Pacific	8	18,2	0	0	7	16,7	0	0
	North America/ Central and South America/ Europe	36	81,8	0	0	35	83,3	0	0

Test for interaction based on RR (Log-binomial regression)

* indicates convergence problem. Result is uninterpretable.

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_H3S_SE1_31MAY2023_42161.xls

23APR2024 20:59

POPULATION: Safety Population
 ENDPOINT: Hypersensitivity reactions other than Type III hypersensitivity, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	44	100,0	4	9,1	42	100,0	0	0	*	Quasi-complete separation of data points detected.			*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Age	<65	39	88,6	4	10,3	35	83,3	0	0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 2.7111195922 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
	>=65	5	11,4	0	0,0	7	16,7	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
Sex	Male	20	45,5	2	10,0	21	50,0	0	0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	1,0000	NE	Algorithm converged.	NE	NE
	Female	24	54,5	2	8,3	21	50,0	0	0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 3.0442264244 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	0	0,0	10	23,8	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	
	No	32	72,7	4	12,5	32	76,2	0	0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE

Geographic region	Japan/Rest of Asia Pacific	8	18,2	1	12,5	7	16,7	0	0	*	Quasi-complete separation of data points detected.	*	ERROR: Error in computing the link function, its derivatives, or the variance function.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	North America/ Central and South America/ Europe	36	81,8	3	8,3	35	83,3	0	0	*	Quasi-complete separation of data points detected.	*	WARNING: The relative Hessian convergence criterion of 3.3804331287 is greater than the limit of 0.0001. The convergence is questionable.	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sq_HR_SE1_31MAY2023_42161.xls
 23APR2024 20:56

POPULATION: Safety Population
 ENDPOINT: Type III hypersensitivity reactions, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference				Relative Risk			Relative Risk							
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	44	100,0	7	15,9	42	100,0	0	0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Age	<65	39	88,6	7	17,9	35	83,3	0	0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	>=65	5	11,4	0	0,0	7	16,7	0	0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Sex	Male	20	45,5	3	15,0	21	50,0	0	0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Female	24	54,5	4	16,7	21	50,0	0	0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 1.9423173446 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	1	8,3	10	23,8	0	0	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	No	32	72,7	6	18,8	32	76,2	0	0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 2.0721976333 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Geographic region	Japan/Rest of Asia Pacific	8	18,2	2	25,0	7	16,7	0	0	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	North America/Central and South America/Europe	36	81,8	5	13,9	35	83,3	0	0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 2.4119532673 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

POPULATION: Safety Population
 ENDPOINT: Infections, including meningococcal meningitis, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab										
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk										
		n	%	n	%	n	%	n	%	Odds Ratio	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL				
All	n/a	44	100,0	18	40,9	42	100,0	15	35,7	1,25				Convergence criterion (GCONV=1E-8) satisfied.	0,52	2,98	0,052	Algorithm converged.	-0,153	0,257	1,15	Algorithm converged.	0,67	1,96	0,6216		0,87	Algorithm converged.	0,51	1,50
Age	<65	39	88,6	15	38,5	35	83,3	14	40,0	0,94				Convergence criterion (GCONV=1E-8) satisfied.	0,37	2,39	-0,015	Algorithm converged.	-0,238	0,207	0,96	Algorithm converged.	0,55	1,70	0,8923	0,1041	1,04	Algorithm converged.	0,59	1,83
	>=65	5	11,4	3	60,0	7	16,7	1	14,3	9,00				Convergence criterion (GCONV=1E-8) satisfied.	0,56	143,86	0,457	Algorithm converged.	-0,044	0,959	4,20	Algorithm converged.	0,60	29,54	0,1493		0,24	Algorithm converged.	0,03	1,67
Sex	Male	20	45,5	7	35,0	21	50,0	9	42,9	0,72				Convergence criterion (GCONV=1E-8) satisfied.	0,20	2,53	-0,079	Algorithm converged.	-0,376	0,219	0,82	Algorithm converged.	0,38	1,77	0,6085	0,2266	1,22	Algorithm converged.	0,56	2,66
	Female	24	54,5	11	45,8	21	50,0	6	28,6	2,12				Convergence criterion (GCONV=1E-8) satisfied.	0,61	7,32	0,173	Algorithm converged.	-0,105	0,450	1,60	Algorithm converged.	0,72	3,58	0,2493		0,62	Algorithm converged.	0,28	1,39
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	6	50,0	10	23,8	4	40,0	1,50				Convergence criterion (GCONV=1E-8) satisfied.	0,27	8,19	0,100	Algorithm converged.	-0,315	0,515	1,25	Algorithm converged.	0,48	3,22	0,6441	0,8158	0,80	Algorithm converged.	0,31	2,06
	No	32	72,7	12	37,5	32	76,2	11	34,4	1,15				Convergence criterion (GCONV=1E-8) satisfied.	0,41	3,18	0,031	Algorithm converged.	-0,204	0,266	1,09	Algorithm converged.	0,57	2,10	0,7946		0,92	Algorithm converged.	0,48	1,77
Geographic region	Japan/Rest of Asia Pacific	8	18,2	3	37,5	7	16,7	2	28,6	1,50				Convergence criterion (GCONV=1E-8) satisfied.	0,17	13,22	0,089	Algorithm converged.	-0,385	0,563	1,31	Algorithm converged.	0,30	5,73	0,7176	0,8448	0,76	Algorithm converged.	0,17	3,33
	North America/Central and South America/Europe	36	81,8	15	41,7	35	83,3	13	37,1	1,21				Convergence criterion (GCONV=1E-8) satisfied.	0,47	3,14	0,045	Algorithm converged.	-0,182	0,272	1,12	Algorithm converged.	0,63	2,00	0,6972		0,89	Algorithm converged.	0,50	1,59

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_INFEC_SEI_31MAY2023_42161.xls
 23APR2024 20:54

POPULATION: Safety Population
 ENDPOINT: Infusion-related reactions, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: B042161
 Dichotomous Analysis by Subgroups (Safety)

Name	Level	Crovalimab (N=44)				Eculizumab (N=42)				Crovalimab vs. Eculizumab										Eculizumab vs. Crovalimab							
		Patients		Patients with		Patients		Patients with		Odds Ratio			Absolute Risk Difference			Relative Risk				Relative Risk							
		n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	44	100,0	6	13,6	42	100,0	0	0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 2.3956760731 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Age	<65	39	88,6	5	12,8	35	83,3	0	0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 2.3427330039 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	>=65	5	11,4	1	20,0	7	16,7	0	0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Sex	Male	20	45,5	1	5,0	21	50,0	0	0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	Female	24	54,5	5	20,8	21	50,0	0	0	*	Quasi-complete separation of data points detected.			*	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	2	16,7	10	23,8	0	0	*	Quasi-complete separation of data points detected.			*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
	No	32	72,7	4	12,5	32	76,2	0	0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 2.6522859843 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Geographic region	Japan/Rest of Asia Pacific	8	18,2	2	25,0	7	16,7	0	0	*	Quasi-complete separation of data points detected.			*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE

POPULATION: Safety Population
 ENDPOINT: Suspected transmission of an infectious agent by the study drug, Primary Safety Period
 MODEL: Unstratified analysis
 STUDY: BO42161
 Dichotomous Analysis by Subgroups (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	0	0	42	100,0	0	0
Age	<65	39	88,6	0	0	35	83,3	0	0
	>=65	5	11,4	0	0	7	16,7	0	0
Sex	Male	20	45,5	0	0	21	50,0	0	0
	Female	24	54,5	0	0	21	50,0	0	0
Transfusion history [pRBC infusion in the last 12 months]	Yes	12	27,3	0	0	10	23,8	0	0
	No	32	72,7	0	0	32	76,2	0	0
Geographic region	Japan/Rest of Asia Pacific	8	18,2	0	0	7	16,7	0	0
	North America/ Central and South America/ Europe	36	81,8	0	0	35	83,3	0	0

Test for interaction based on RR (Log-binomial regression)
 * indicates convergence problem. Result is uninterpretable.
 Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_sg_REL_SE1_31MAY2023_42161.xls
 23APR2024 20:49

POPULATION: Safety Population
 ENDPOINT: Primary Safety Period
 MODEL: --
 STUDY: B042161
 Outcome of Adverse Events

Endpoint Grade	Crovalimab (N=44)												Eculizumab (N=42)																		
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN	MISSING	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN	MISSING					
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%					
Any AEs	All	127	118	92,9	0	0,0	8	6,3	0	0,0	1	0,8	0	0,0	0	0,0	67	58	86,6	0	0,0	1	1,5	0	0,0	8	11,9	0	0,0	0	0,0
	1	66	60	90,9	0	0,0	5	7,6	0	0,0	1	1,5	0	0,0	0	0,0	41	34	82,9	0	0,0	0	0,0	0	0,0	7	17,1	0	0,0	0	0,0
	2	50	48	96,0	0	0,0	2	4,0	0	0,0	0	0,0	0	0,0	0	0,0	24	22	91,7	0	0,0	1	4,2	0	0,0	1	4,2	0	0,0	0	0,0
	3	10	9	90,0	0	0,0	1	10,0	0	0,0	0	0,0	0	0,0	0	0,0	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	4	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Any SAEs	All	8	8	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	3	3	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	2	3	3	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	3	4	4	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	4	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Any AESI	All	45	44	97,8	0	0,0	1	2,2	0	0,0	0	0,0	0	0,0	21	21	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	1	19	18	94,7	0	0,0	1	5,3	0	0,0	0	0,0	0	0,0	8	8	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	2	22	22	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	11	11	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
	3	4	4	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_ae_resolved.aas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_ae_resolved_SE1_SF1_31MAY2023_42161.xls
 21MAY2024 20:14

POPULATION: Safety Population
 ENDPOINT: Primary Safety Period
 MODEL: --
 STUDY: B042161
 Outcome of Adverse Events

Endpoint Grade	Crovalimab (N=44)												Eculizumab (N=42)																								
	Total	RECOVERED/RESOLVED			RECOVERED/RESOLVED WITH SEQUELAE			NOT RECOVERED/NOT RESOLVED			FATAL			RECOVERING/RESOLVING			UNKNOWN	MISSING	Total	RECOVERED/RESOLVED			RECOVERED/RESOLVED WITH SEQUELAE			NOT RECOVERED/NOT RESOLVED			FATAL			RECOVERING/RESOLVING			UNKNOWN	MISSING	
	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
Type III hypersensitivity reaction																																					
All	7	7	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
1	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
2	4	4	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Type III hypersensitivity reactions Grade >=3																																					
All	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
3	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Serious Type III hypersensitivity reaction																																					
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
DILI																																					
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Suspected transmission of an infectious agent by the study drug																																					
All	0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Injection-site reactions																																					
All	5	4	80,0	0	0,0	1	20,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
1	5	4	80,0	0	0,0	1	20,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Infusion-related reactions																																					
All	6	6	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
1	5	5	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
2	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
Infections, including meningococcal meningitis																																					
All	26	26	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	21	21	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	
1	7	7	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	8	8	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	
2	17	17	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	11	11	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	
3	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	2	2	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	
Hypersensitivity reactions other than Type III Hypersensitivity																																					
All	5	4	80,0	0	0,0	1	20,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
1	4	3	75,0	0	0,0	1	25,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0
2	1	1	100,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/program/t_ae_resolved.sas
 Output: root/clinical_studies/RO7112689/CDT70115/B042161/data_analysis/ACE_CSR_1/prod/output/t_ae_resolved_AEST_SE1_SP1_31MAY2023_42161.xls
 21MAY2024 20:16

POPULATION: Safety Population
ENDPOINT: Any AEs, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	39	88,6	42	100,0	30	71,4

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/R07112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
Output: root/clinical_studies/R07112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_AE_SE1_31MAY2023_42161.xls
20MAY2024 12:55

POPULATION: Safety Population
ENDPOINT: AEs Grade >= 3, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	10	22,7	42	100,0	9	21,4

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_GE3_SE1_31MAY2023_42161.xls
 20MAY2024 12:57

POPULATION: Safety Population
ENDPOINT: AEs Grade 3, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	7	15,9	42	100,0	8	19,0

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/R07112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/R07112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_G3_SE1_31MAY2023_42161.xls
 20MAY2024 13:02

POPULATION: Safety Population
ENDPOINT: AEs Grade 4, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	2	4,5	42	100,0	1	2,4

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/R07112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/R07112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_G4_SE1_31MAY2023_42161.xls
 20MAY2024 13:04

POPULATION: Safety Population

ENDPOINT: AEs Grade 5 (AEs leading to death), Crovalimab Safety Period

MODEL: Unstratified analysis

STUDY: BO42161

Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	1	2,3	42	100,0	0	0

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/R07112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas

Output: root/clinical_studies/R07112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_G5_SE1_31MAY2023_42161.xls

20MAY2024 13:05

POPULATION: Safety Population
ENDPOINT: Any SAEs, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	10	22,7	42	100,0	4	9,5

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_SAE_SE1_31MAY2023_42161.xls
 20MAY2024 12:56

POPULATION: Safety Population
ENDPOINT: AEs leading to treatment discontinuation, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	0	0	42	100,0	1	2,4

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_DIS_SE1_31MAY2023_42161.xls
 20MAY2024 13:07

POPULATION: Safety Population
ENDPOINT:DILI, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	0	0	42	100,0	0	0

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_DILI_SE1_31MAY2023_42161.xls
 20MAY2024 13:15

POPULATION: Safety Population
ENDPOINT: Type III hypersensitivity reactions Grade >=3, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	1	2,3	42	100,0	3	7,1

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_H3G3_SE1_31MAY2023_42161.xls
 20MAY2024 13:00

POPULATION: Safety Population
ENDPOINT: Serious Type III hypersensitivity reactions, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	0	0	42	100,0	1	2,4

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_H3S_SE1_31MAY2023_42161.xls
 20MAY2024 13:01

POPULATION: Safety Population
ENDPOINT: Type III hypersensitivity reactions, Crovalimab Safety Period
MODEL: Unstratified analysis
STUDY: BO42161
Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	7	15,9	42	100,0	8	19,0

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas
 Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_HYP3_SE1_31MAY2023_42161.xls
 20MAY2024 12:58

POPULATION: Safety Population

ENDPOINT: Suspected transmission of an infectious agent by the study drug, Crovalimab Safety Period

MODEL: Unstratified analysis

STUDY: BO42161

Dichotomous Analysis (Safety)

		Crovalimab (N=44)				Eculizumab (N=42)			
		Patients		Patients with Event		Patients		Patients with Event	
Name	Level	n	%	n	%	n	%	n	%
All	n/a	44	100,0	0	0	42	100,0	0	0

Clinical cut-off: 31MAY2023

Program: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/program/t_ae_raw_descriptive.sas

Output: root/clinical_studies/RO7112689/CDT70115/BO42161/data_analysis/ACE_CSR_1/prod/output/t_ae_raw_descriptive_REL_SE1_31MAY2023_42161.xls

20MAY2024 13:08