Inhaltsverzeichnis Polatuzumab Vedotin 1L

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POPULATION: Global and China Extension Population, Intent-To-Treat Population
MODEL: descriptive
STUDY: GO39942
Demographic and Baseline Characteristics per Arm

	Polatuzumab Vedotin + R-CHP (N=500)	R-CHOP (N=500)	Total (N=1000)
Age (years)			
n	500	500	1000
Mean (SD)	62.60 (11.44)	62.50 (11.79)	62.55 (11.61)
Median	65	65	65
25% and 75%-ile	57.00 - 71.00	58.00 - 71.00	57.00 - 71.00
Min - Max	19.0 - 80.0	19.0 - 80.0	19.0 - 80.0
18 - 64	249 (49.8%)	242 (48.4%)	491 (49.1%)
>=65	251 (50.2%)	258 (51.6%)	509 (50.9%)
18 - 60	167 (33.4%)	158 (31.6%)	325 (32.5%)
>60	333 (66.6%)	342 (68.4%)	675 (67.5%)
Sex			
n	500	500	1000
Male	268 (53.6%)	270 (54.0%)	538 (53.8%)
Female	232 (46.4%)	230 (46.0%)	462 (46.2%)
Race			
n	500	500	1000
American Indian or Alaska Native	1 (0.2%)	2 (0.4%)	3 (0.3%)
Asian	145 (29.0%)	145 (29.0%)	290 (29.0%)
Black or African American	8 (1.6%)	8 (1.6%)	16 (1.6%)
Native Hawaiian or other Pacific Islander	0	3 (0.6%)	3 (0.3%)
White	235 (47.0%)	236 (47.2%)	471 (47.1%)
Other	6 (1.2%)	6 (1.2%)	12 (1.2%)
Unknown	105 (21.0%)	100 (20.0%)	205 (20.5%)

Ethnicity			
n	500	500	1000
Hispanic or Latino	18 (3.6%)	30 (6.0%)	48 (4.8%)
Not Hispanic or Latino	377 (75.4%)	367 (73.4%)	744 (74.4%)
Not Stated	66 (13.2%)	49 (9.8%)	115 (11.5%)
Unknown	39 (7.8%)	54 (10.8%)	93 (9.3%)
Weight (kg) at Baseline			
n	497	497	994
Mean (SD)	74.34 (19.66)	74.48 (18.44)	74.41 (19.05)
Median	72.1	73	72.95
25% and 75%-ile	60.60 - 86.00	62.00 - 84.10	61.00 - 85.00
Min - Max	38.4 - 227.9	39.8 - 191.1	38.4 - 227.9
Height (cm) at Baseline			
n	498	497	995
Mean (SD)	167.67 (10.07)	167.50 (10.17)	167.58 (10.12)
Median	167.1	168	167.6
25% and 75%-ile	160.00 - 175.00	160.00 - 175.00	160.00 - 175.00
Min - Max	144.3 - 200.0	141.3 - 200.0	141.3 - 200.0
ECOG Performance Status at Baseline			
n	500	500	1000
0	197 (39.4%)	195 (39.0%)	392 (39.2%)
1	222 (44.4%)	221 (44.2%)	443 (44.3%)
2	81 (16.2%)	82 (16.4%)	163 (16.3%)
Missing	0	2 (0.4%)	2 (0.2%)
Ann Arbor Stage			
n	500	500	1000
I	2 (0.4%)	11 (2.2%)	13 (1.3%)
II	51 (10.2%)	45 (9.0%)	96 (9.6%)
III	147 (29.4%)	136 (27.2%)	283 (28.3%)
IV	300 (60.0%)	308 (61.6%)	608 (60.8%)
Stratification - IPI Score (IxRS)			
n	500	500	1000
IPI 2	190 (38.0%)	191 (38.2%)	381 (38.1%)

IPI 3-5	310 (62.0%)	309 (61.8%)	619 (61.9%)
IPI at Screening (eCRF)			
n	500	500	1000
1	1 (0.2%)	0	1 (0.1%)
2	187 (37.4%)	187 (37.4%)	374 (37.4%)
3	199 (39.8%)	186 (37.2%)	385 (38.5%)
4	87 (17.4%)	102 (20.4%)	189 (18.9%)
5	26 (5.2%)	25 (5.0%)	51 (5.1%)
Stratification - Bulky Disease (IxRS)			
n	500	500	1000
ABSENT	290 (58.0%)	290 (58.0%)	580 (58.0%)
PRESENT	210 (42.0%)	210 (42.0%)	420 (42.0%)
Baseline Bulky Disease (eCRF)			
n	500	500	1000
Present	211 (42.2%)	218 (43.6%)	429 (42.9%)
Absent	289 (57.8%)	282 (56.4%)	571 (57.1%)
Stratification - Geographic Region (IxRS)			
n	500	500	1000
Western Europe/United States/Canada/Australia	302 (60.4%)	301 (60.2%)	603 (60.3%)
Asia	141 (28.2%)	140 (28.0%)	281 (28.1%)
Rest of World	57 (11.4%)	59 (11.8%)	116 (11.6%)
Baseline LDH			
n	500	500	1000
<= 1xULN	166 (33.2%)	169 (33.8%)	335 (33.5%)
> 1xULN	331 (66.2%)	330 (66.0%)	661 (66.1%)
Missing	3 (0.6%)	1 (0.2%)	4 (0.4%)
Bone Marrow Involvement at Diagnosis			
n	500	500	1000
INDETERMINATE	12 (2.4%)	11 (2.2%)	23 (2.3%)
NEGATIVE	393 (78.6%)	401 (80.2%)	794 (79.4%)
POSITIVE	84 (16.8%)	80 (16.0%)	164 (16.4%)
Missing	11 (2.2%)	8 (1.6%)	19 (1.9%)

No. of Extranodal Sites			
n	500	500	1000
0-1	261 (52.2%)	260 (52.0%)	521 (52.1%)
>=2	239 (47.8%)	240 (48.0%)	479 (47.9%)
Time from Diagnosis to Study Dose			
n	496	497	993
Mean (SD)	28.45 (21.13)	31.07 (34.26)	29.76 (28.48)
Median	24	26	25
25% and 75%-ile	14.00 - 35.00	15.00 - 39.00	15.00 - 36.00
Min - Max	1.0 - 195.0	1.0 - 621.0	1.0 - 621.0
<= 30 days	315 (63.0%)	316 (63.2%)	631 (63.1%)
> 30 days	181 (36.2%)	181 (36.2%)	362 (36.2%)
Missing	4 (0.8%)	3 (0.6%)	7 (0.7%)
NHL Histologic Diagnosis (eCRF)			
n	500	500	1000
DLBCL NOS, ABC, GCB	430 (86.0%)	420 (84.0%)	850 (85.0%)
HGBL, NOS, DHL/THL	44 (8.8%)	52 (10.4%)	96 (9.6%)
Other Large B-cell	26 (5.2%)	28 (5.6%)	54 (5.4%)
COO (Central Review)			
n	500	500	1000
ABC	131 (26.2%)	143 (28.6%)	274 (27.4%)
GCB	193 (38.6%)	187 (37.4%)	380 (38.0%)
UNCLASSIFIED	53 (10.6%)	60 (12.0%)	113 (11.3%)
UNKNOWN	123 (24.6%)	110 (22.0%)	233 (23.3%)
Double-Expressor Lymphoma by IHC (Central Review)			
n	500	500	1000
DEL	150 (30.0%)	163 (32.6%)	313 (31.3%)
NON DEL	253 (50.6%)	244 (48.8%)	497 (49.7%)
UNKNOWN	97 (19.4%)	93 (18.6%)	190 (19.0%)
Double/Triple-Hit Lymphoma (Central Review)			
n	500	500	1000

DH/TH+	26 (5.2%)	19 (3.8%)	45 (4.5%)
DH/TH-	341 (68.2%)	351 (70.2%)	692 (69.2%)
UNKNOWN	133 (26.6%)	130 (26.0%)	263 (26.3%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_dm.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_dm_IT_POOLED_15JUN2022_39942.xls
11MAY2023 19:03

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
MODEL: descriptive
STUDY: GO39942
Demographic and Baseline Characteristics per Arm

	Polatuzumab Vedotin + R-CHP (N=437)	R-CHOP (N=417)	Total (N=854)
Age (years)			
n	437	417	854
Mean (SD)	62.66 (11.62)	62.88 (11.55)	62.77 (11.58)
Median	65	65	65
25% and 75%-ile	58.00 - 71.00	58.00 - 71.00	58.00 - 71.00
Min - Max	19.0 - 80.0	19.0 - 80.0	19.0 - 80.0
18 - 64	213 (48.7%)	197 (47.2%)	410 (48.0%)
>=65	224 (51.3%)	220 (52.8%)	444 (52.0%)
18 - 60	140 (32.0%)	126 (30.2%)	266 (31.1%)
>60	297 (68.0%)	291 (69.8%)	588 (68.9%)
Sex			
n	437	417	854
Male	231 (52.9%)	216 (51.8%)	447 (52.3%)
Female	206 (47.1%)	201 (48.2%)	407 (47.7%)
Race			
n	437	417	854
American Indian or Alaska Native	1 (0.2%)	2 (0.5%)	3 (0.4%)
Asian	132 (30.2%)	121 (29.0%)	253 (29.6%)
Black or African American	8 (1.8%)	5 (1.2%)	13 (1.5%)
Native Hawaiian or other Pacific Islander	0	3 (0.7%)	3 (0.4%)
White	197 (45.1%)	195 (46.8%)	392 (45.9%)
Other	5 (1.1%)	3 (0.7%)	8 (0.9%)
Unknown	94 (21.5%)	88 (21.1%)	182 (21.3%)
Ethnicity			
n	437	417	854
Hispanic or Latino	12 (2.7%)	22 (5.3%)	34 (4.0%)
Not Hispanic or Latino	331 (75.7%)	304 (72.9%)	635 (74.4%)
Not Stated	59 (13.5%)	44 (10.6%)	103 (12.1%)
Unknown	35 (8.0%)	47 (11.3%)	82 (9.6%)

Weight (kg) at Baseline			
n	434	414	848
Mean (SD)	74.06 (19.73)	74.02 (18.90)	74.04 (19.32)
Median	71,05	72,39	72
25% and 75%-ile	60.50 - 85.00	61.00 - 84.00	60.55 - 84.55
Min - Max	38.4 - 227.9	39.8 - 191.1	38.4 - 227.9
Height (cm) at Baseline			
n	435	414	849
Mean (SD)	167.62 (9.95)	167.18 (10.40)	167.41 (10.17)
Median	167,2	167,1	167,2
25% and 75%-ile	160.00 - 174.50	160.00 - 175.00	160.00 - 174.70
Min - Max	144.3 - 200.0	141.3 - 200.0	141.3 - 200.0
ECOG Performance Status at Baseline			
n	437	417	854
0	174 (39.8%)	163 (39.1%)	337 (39.5%)
1	195 (44.6%)	191 (45.8%)	386 (45.2%)
2	68 (15.6%)	61 (14.6%)	129 (15.1%)
Missing	0	2 (0.5%)	2 (0.2%)
Ann Arbor Stage			
n	437	417	854
I	2 (0.5%)	11 (2.6%)	13 (1.5%)
II	48 (11.0%)	40 (9.6%)	88 (10.3%)
III	130 (29.7%)	119 (28.5%)	249 (29.2%)
IV	257 (58.8%)	247 (59.2%)	504 (59.0%)
Stratification - IPI Score (IxRS)			
n	437	417	854
IPI 2	166 (38.0%)	170 (40.8%)	336 (39.3%)
IPI 3-5	271 (62.0%)	247 (59.2%)	518 (60.7%)
IPI at Screening (eCRF)			
n	437	417	854
1	1 (0.2%)	0	1 (0.1%)
2	163 (37.3%)	168 (40.3%)	331 (38.8%)
3	181 (41.4%)	154 (36.9%)	335 (39.2%)
4	72 (16.5%)	80 (19.2%)	152 (17.8%)
5	20 (4.6%)	15 (3.6%)	35 (4.1%)
Stratification - Bulky Disease (IxRS)			
n	437	417	854
ABSENT	265 (60.6%)	260 (62.4%)	525 (61.5%)

PRESENT	172 (39.4%)	157 (37.6%)	329 (38.5%)
Baseline Bulky Disease (eCRF)			
n	437	417	854
Present	173 (39.6%)	164 (39.3%)	337 (39.5%)
Absent	264 (60.4%)	253 (60.7%)	517 (60.5%)
Stratification - Geographic Region (IxRS)			
n	437	417	854
Western Europe/United States/Canada/Australia	259 (59.3%)	252 (60.4%)	511 (59.8%)
Asia	128 (29.3%)	116 (27.8%)	244 (28.6%)
Rest of World	50 (11.4%)	49 (11.8%)	99 (11.6%)
Baseline LDH			
n	437	417	854
<= 1xULN	152 (34.8%)	153 (36.7%)	305 (35.7%)
> 1xULN	282 (64.5%)	264 (63.3%)	546 (63.9%)
Missing	3 (0.7%)	0	3 (0.4%)
Bone Marrow Involvement at Diagnosis			
n	437	417	854
INDETERMINATE	11 (2.5%)	9 (2.2%)	20 (2.3%)
NEGATIVE	344 (78.7%)	339 (81.3%)	683 (80.0%)
POSITIVE	75 (17.2%)	66 (15.8%)	141 (16.5%)
Missing	7 (1.6%)	3 (0.7%)	10 (1.2%)
No. of Extranodal Sites			
n	437	417	854
0-1	230 (52.6%)	229 (54.9%)	459 (53.7%)
>=2	207 (47.4%)	188 (45.1%)	395 (46.3%)
Time from Diagnosis to Study Dose			
n	437	417	854
Mean (SD)	28.55 (21.69)	32.08 (36.47)	30.27 (29.87)
Median	25	26	26
25% and 75%-ile	14.00 - 35.00	16.00 - 40.00	15.00 - 37.00
Min - Max	1.0 - 195.0	1.0 - 621.0	1.0 - 621.0
<= 30 days	278 (63.6%)	259 (62.1%)	537 (62.9%)
> 30 days	159 (36.4%)	158 (37.9%)	317 (37.1%)
NHL Histologic Diagnosis (eCRF)			
n	437	417	854
DLBCL NOS, ABC, GCB	378 (86.5%)	355 (85.1%)	733 (85.8%)
HGBL, NOS, DHL/THL	38 (8.7%)	39 (9.4%)	77 (9.0%)

Other Large B-cell	21 (4.8%)	23 (5.5%)	44 (5.2%)
COO (Central Review)			
n	437	417	854
ABC	124 (28.4%)	126 (30.2%)	250 (29.3%)
GCB	167 (38.2%)	151 (36.2%)	318 (37.2%)
UNCLASSIFIED	44 (10.1%)	52 (12.5%)	96 (11.2%)
UNKNOWN	102 (23.3%)	88 (21.1%)	190 (22.2%)
Double-Expressor Lymphoma by IHC (Central Review)			
n	437	417	854
DEL	127 (29.1%)	137 (32.9%)	264 (30.9%)
NON DEL	227 (51.9%)	203 (48.7%)	430 (50.4%)
UNKNOWN	83 (19.0%)	77 (18.5%)	160 (18.7%)
Double/Triple-Hit Lymphoma (Central Review)			
n	437	417	854
DH/TH+	21 (4.8%)	18 (4.3%)	39 (4.6%)
DH/TH-	301 (68.9%)	298 (71.5%)	599 (70.1%)
UNKNOWN	115 (26.3%)	101 (24.2%)	216 (25.3%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_dm.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_dm_CR_IT_POOLED_15JUN2022_39942.xls
09FEB2023 10:02

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
MODEL: descriptive
STUDY: GO39942
Demographic and Baseline Characteristics per Arm

	Polatuzumab Vedotin + R-CHP (N=381)	R-CHOP (N=364)	Total (N=745)
Age (years)			
n	381	364	745
Mean (SD)	63.01 (10.82)	62.87 (11.62)	62.94 (11.21)
Median	65	65	65
25% and 75%-ile	59.00 - 71.00	58.50 - 71.00	59.00 - 71.00
Min - Max	22.0 - 80.0	19.0 - 80.0	19.0 - 80.0
18 - 64	187 (49.1%)	171 (47.0%)	358 (48.1%)
>=65	194 (50.9%)	193 (53.0%)	387 (51.9%)
18 - 60	120 (31.5%)	107 (29.4%)	227 (30.5%)
>60	261 (68.5%)	257 (70.6%)	518 (69.5%)
Sex			
n	381	364	745
Male	203 (53.3%)	180 (49.5%)	383 (51.4%)
Female	178 (46.7%)	184 (50.5%)	362 (48.6%)
Race			
n	381	364	745
American Indian or Alaska Native	0	2 (0.5%)	2 (0.3%)
Asian	118 (31.0%)	105 (28.8%)	223 (29.9%)
Black or African American	8 (2.1%)	4 (1.1%)	12 (1.6%)
Native Hawaiian or other Pacific Islander	0	3 (0.8%)	3 (0.4%)
White	167 (43.8%)	168 (46.2%)	335 (45.0%)
Other	3 (0.8%)	3 (0.8%)	6 (0.8%)
Unknown	85 (22.3%)	79 (21.7%)	164 (22.0%)
Ethnicity			
n	381	364	745
Hispanic or Latino	10 (2.6%)	20 (5.5%)	30 (4.0%)

Not Hispanic or Latino	287 (75.3%)	259 (71.2%)	546 (73.3%)
Not Stated	52 (13.6%)	41 (11.3%)	93 (12.5%)
Unknown	32 (8.4%)	44 (12.1%)	76 (10.2%)
Weight (kg) at Baseline			
n	379	361	740
Mean (SD)	74.05 (19.92)	73.23 (19.08)	73.65 (19.51)
Median	71,2	72	71,65
25% and 75%-ile	60.30 - 85.59	60.00 - 83.00	60.00 - 84.05
Min - Max	38.4 - 227.9	39.8 - 191.1	38.4 - 227.9
Height (cm) at Baseline			
n	380	361	741
Mean (SD)	167.61 (10.00)	166.88 (10.29)	167.25 (10.14)
Median	167,1	166	167
25% and 75%-ile	160.00 - 174.20	160.00 - 174.00	160.00 - 174.00
Min - Max	144.3 - 200.0	141.3 - 200.0	141.3 - 200.0
ECOG Performance Status at Baseline			
n	381	364	745
0	152 (39.9%)	146 (40.1%)	298 (40.0%)
1	170 (44.6%)	161 (44.2%)	331 (44.4%)
2	59 (15.5%)	55 (15.1%)	114 (15.3%)
Missing	0	2 (0.5%)	2 (0.3%)
Ann Arbor Stage			
n	381	364	745
I	2 (0.5%)	11 (3.0%)	13 (1.7%)
II	44 (11.5%)	35 (9.6%)	79 (10.6%)
III	113 (29.7%)	99 (27.2%)	212 (28.5%)
IV	222 (58.3%)	219 (60.2%)	441 (59.2%)
Stratification - IPI Score (IxRS)			
n	381	364	745
IPI 2	150 (39.4%)	150 (41.2%)	300 (40.3%)
IPI 3-5	231 (60.6%)	214 (58.8%)	445 (59.7%)
IPI at Screening (eCRF)			
n	381	364	745
1	1 (0.3%)	0	1 (0.1%)
2	147 (38.6%)	147 (40.4%)	294 (39.5%)

3	156 (40.9%)	130 (35.7%)	286 (38.4%)
4	61 (16.0%)	73 (20.1%)	134 (18.0%)
5	16 (4.2%)	14 (3.8%)	30 (4.0%)
Stratification - Bulky Disease (IxRS)			
n	381	364	745
ABSENT	237 (62.2%)	238 (65.4%)	475 (63.8%)
PRESENT	144 (37.8%)	126 (34.6%)	270 (36.2%)
Baseline Bulky Disease (eCRF)			
n	381	364	745
Present	144 (37.8%)	134 (36.8%)	278 (37.3%)
Absent	237 (62.2%)	230 (63.2%)	467 (62.7%)
Stratification - Geographic Region (IxRS)			
n	381	364	745
Western Europe/United States/Canada/Australia	229 (60.1%)	221 (60.7%)	450 (60.4%)
Asia	114 (29.9%)	101 (27.7%)	215 (28.9%)
Rest of World	38 (10.0%)	42 (11.5%)	80 (10.7%)
Baseline LDH			
n	381	364	745
<= 1xULN	139 (36.5%)	138 (37.9%)	277 (37.2%)
> 1xULN	239 (62.7%)	226 (62.1%)	465 (62.4%)
Missing	3 (0.8%)	0	3 (0.4%)
Bone Marrow Involvement at Diagnosis			
n	381	364	745
INDETERMINATE	10 (2.6%)	6 (1.6%)	16 (2.1%)
NEGATIVE	301 (79.0%)	299 (82.1%)	600 (80.5%)
POSITIVE	65 (17.1%)	56 (15.4%)	121 (16.2%)
Missing	5 (1.3%)	3 (0.8%)	8 (1.1%)
No. of Extranodal Sites			
n	381	364	745
0-1	204 (53.5%)	196 (53.8%)	400 (53.7%)
>=2	177 (46.5%)	168 (46.2%)	345 (46.3%)
Time from Diagnosis to Study Dose			
n	381	364	745
Mean (SD)	28.70 (20.79)	32.41 (38.37)	30.52 (30.70)

Median	25	27	26
25% and 75%-ile	15.00 - 36.00	16.50 - 40.00	15.00 - 38.00
Min - Max	1.0 - 181.0	1.0 - 621.0	1.0 - 621.0
<= 30 days	238 (62.5%)	226 (62.1%)	464 (62.3%)
> 30 days	143 (37.5%)	138 (37.9%)	281 (37.7%)
NHL Histologic Diagnosis (eCRF)			
n	381	364	745
DLBCL NOS, ABC, GCB	329 (86.4%)	307 (84.3%)	636 (85.4%)
HGBL, NOS, DHL/THL	33 (8.7%)	36 (9.9%)	69 (9.3%)
Other Large B-cell	19 (5.0%)	21 (5.8%)	40 (5.4%)
COO (Central Review)			
n	381	364	745
ABC	115 (30.2%)	112 (30.8%)	227 (30.5%)
GCB	136 (35.7%)	134 (36.8%)	270 (36.2%)
UNCLASSIFIED	41 (10.8%)	46 (12.6%)	87 (11.7%)
UNKNOWN	89 (23.4%)	72 (19.8%)	161 (21.6%)
Double-Expressor Lymphoma by IHC (Central Review)			
n	381	364	745
DEL	114 (29.9%)	123 (33.8%)	237 (31.8%)
NON DEL	195 (51.2%)	179 (49.2%)	374 (50.2%)
UNKNOWN	72 (18.9%)	62 (17.0%)	134 (18.0%)
Double/Triple-Hit Lymphoma (Central Review)			
n	381	364	745
DH/TH+	18 (4.7%)	16 (4.4%)	34 (4.6%)
DH/TH-	261 (68.5%)	263 (72.3%)	524 (70.3%)
UNKNOWN	102 (26.8%)	85 (23.4%)	187 (25.1%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_dm.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_dm_CREOT_IT_POOLED_15JUN2022_39942.xls
02NOV2023 7:24

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: --
MODEL: descriptive
STUDY: GO39942
Randomization Stratification Factors per Arm

Stratification Factor: Bulky disease

	Polatuzumab Vedotin + R-CHP (N=500)			R-CHOP (N=500)		
	eCRF data			eCRF data		
	Absent	Present	Total	Absent	Present	Total
IxRS data						
Absent	282 (56.4%)	8 (1.6%)	290 (58.0%)	279 (55.8%)	11 (2.2%)	290 (58.0%)
Present	7 (1.4%)	203 (40.6%)	210 (42.0%)	3 (0.6%)	207 (41.4%)	210 (42.0%)
Total	289 (57.8%)	211 (42.2%)	500 (100%)	282 (56.4%)	218 (43.6%)	500 (100%)

Percentages are based on N in the column headings.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_dm_stratconc.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_dm_stratconc_IT_POOLED_15JUN2022_39942.xls
09FEB2023 10:04

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: --
MODEL: descriptive
STUDY: GO39942
Randomization Stratification Factors per Arm

Stratification Factor: Geographical region

	Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)			
	eCRF data				eCRF data			
	Asia	Rest of World	Western Europe/United States/Canada/Australia	Total	Asia	Rest of World	Western Europe/United States/Canada/Australia	Total
IxRS data								
Asia	141 (28.2%)	0	0	141 (28.2%)	140 (28.0%)	0	0	140 (28.0%)
Rest of World	0	57 (11.4%)	0	57 (11.4%)	0	59 (11.8%)	0	59 (11.8%)
Western Europe/United States/Canada/Australia	0	0	302 (60.4%)	302 (60.4%)	0	0	301 (60.2%)	301 (60.2%)
Total	141 (28.2%)	57 (11.4%)	302 (60.4%)	500 (100%)	140 (28.0%)	59 (11.8%)	301 (60.2%)	500 (100%)

Percentages are based on N in the column headings.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_dm_stratconc.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_dm_stratconc_IT_POOLED_15JUN2022_39942.xls
09FEB2023 10:04

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: --
MODEL: descriptive
STUDY: GO39942
Randomization Stratification Factors per Arm

Stratification Factor: IPI score

	Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)				
	eCRF data						eCRF data				
	1	2	3	4	5	Total	2	3	4	5	Total
IxRS data											
2	1 (0.2%)	181 (36.2%)	7 (1.4%)	1 (0.2%)	0	190 (38.0%)	184 (36.8%)	6 (1.2%)	1 (0.2%)	0	191 (38.2%)
3-5	0	6 (1.2%)	192 (38.4%)	86 (17.2%)	26 (5.2%)	310 (62.0%)	3 (0.6%)	180 (36.0%)	101 (20.2%)	25 (5.0%)	309 (61.8%)
Total	1 (0.2%)	187 (37.4%)	199 (39.8%)	87 (17.4%)	26 (5.2%)	500 (100%)	187 (37.4%)	186 (37.2%)	102 (20.4%)	25 (5.0%)	500 (100%)

Percentages are based on N in the column headings.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_dm_stratconc.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_dm_stratconc_IT_POOLED_15JUN2022_39942.xls
09FEB2023 10:04

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: --
MODEL: descriptive
STUDY: GO39942
Disposition of Patients per Arm

	Polatuzumab Vedotin + R-CHP (N=500)	R-CHOP (N=500)	Total (N=1000)
End of treatment status			
Completed	439 (87.8%)	428 (85.6%)	867 (86.7%)
Discontinued	57 (11.4%)	69 (13.8%)	126 (12.6%)
Never Treated	4 (0.8%)	3 (0.6%)	7 (0.7%)
Reason for treatment discontinuation			
n	57	69	126
Adverse event	12 (2.4%)	19 (3.8%)	31 (3.1%)
Death	12 (2.4%)	4 (0.8%)	16 (1.6%)
Other	2 (0.4%)	3 (0.6%)	5 (0.5%)
Physician decision	12 (2.4%)	15 (3.0%)	27 (2.7%)
Progressive disease	12 (2.4%)	18 (3.6%)	30 (3.0%)
Withdrawal by subject	7 (1.4%)	10 (2.0%)	17 (1.7%)
End of study status			
Discontinued	88 (17.6%)	100 (20.0%)	188 (18.8%)
Ongoing	412 (82.4%)	400 (80.0%)	812 (81.2%)
Reason for study discontinuation			
n	88	100	188
Death	68 (13.6%)	79 (15.8%)	147 (14.7%)
Lost to follow-up	4 (0.8%)	3 (0.6%)	7 (0.7%)
Other	1 (0.2%)	0	1 (0.1%)
Physician decision	3 (0.6%)	4 (0.8%)	7 (0.7%)
Withdrawal by subject	12 (2.4%)	14 (2.8%)	26 (2.6%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ds.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ds_IT_POOLED_15JUN2022_39942.xls
09FEB2023 10:05

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: --
MODEL: descriptive
STUDY: GO39942
Number of Centers/Countries/Geographical Regions with <10, >=10 Patients per Arm

	Center				Country				Geographical region			
	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients
Overall	215	100.0	1000	100.0	22	100.0	1000	100.0	3	100.0	1000	100.0
with <10 patients per arm	211	98.1	904	90.4	10	45.5	90	9.0	0	NE	NE	NE
with >=10 patients per arm	4	1.9	96	9.6	12	54.5	910	91.0	3	100.0	1000	100.0

'<10 patients' category if at least one treatment arm has <10 patients; '>=10 patients' category if all treatment arms have >=10 patients.
Geographical regions: Western Europe/United States/Canada/Australia, Asia, Rest of World.
'n': Number of centers/countries/regions; "%": Percent of centers/countries/regions compared to overall number of centers/countries/regions
'n of patients randomized': Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm)
'% randomized patients': Percent 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: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_center.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_center_IT_POOLED_15JUN2022_39942.xls
09FEB2023 10:02

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: --
MODEL: descriptive
STUDY: GO39942
Deaths and Primary Reason for Death

	Polatuzumab Vedotin + R-CHP (N=495)		R-CHOP (N=498)	
	n	%	n	%
All Deaths	69	13.9	81	16.3
Adverse event	14	2.8	11	2.2
Progressive disease	37	7.5	44	8.8
Other	18	3.6	26	5.2

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_death.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_death_SE_POOLED_15JUN2022_39942.xls
09FEB2023 10:06

POPULATION: Global and China Extension Population, Intent-To-Treat Population
STUDY: GO39942
Summary of New Anti-Lymphoma Therapy

	Polatuzumab Vedotin + R-CHP (N=500)	R-CHOP (N=500)	Total (N=1000)
Total number of patients with at least one NALT treatment	128 (25.6%)	170 (34.0%)	298 (29.8%)
Total number of NALT treatments	232	356	588
Total number of patients with at least one NALT treatment before PFS event	11 (2.2%)	21 (4.2%)	32 (3.2%)
Total number of patients with at least one NALT treatment after PFS event	81 (16.2%)	114 (22.8%)	195 (19.5%)
Total number of patients with at least one NALT treatment and without PFS event	39 (7.8%)	42 (8.4%)	81 (8.1%)
Radiotherapy			
Total number of patients with at least one treatment	49 (9.8%)	67 (13.4%)	116 (11.6%)
Total number of treatments	53	84	137
Total number of patients with pre-planned treatment	13 (2.6%)	19 (3.8%)	32 (3.2%)
Total number of patients with unplanned treatment	36 (7.2%)	48 (9.6%)	84 (8.4%)
Systemic therapy			
Total number of patients with at least one treatment	98 (19.6%)	135 (27.0%)	233 (23.3%)
Total number of treatments	181	272	453

Total number of patients received stem cell transplants	20 (4.0%)	34 (6.8%)	54 (5.4%)
Autologous transplant	20 (4.0%)	31 (6.2%)	51 (5.1%)
Allogeneic transplant	0	3 (0.6%)	3 (0.3%)
Total number of patients received CAR-T	11 (2.2%)	18 (3.6%)	29 (2.9%)
Total number of patients received platinum-based therapy	45 (9.0%)	69 (13.8%)	114 (11.4%)

NALT includes pre-planned radiotherapy.
Platinum-based therapy refers to regimens that are typically intended to proceed to consolidative transplant or cellular therapies (PBT includes R-GDP, R-ICE, R-DHAP, R-ESHAP and similar permutations).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_nalt.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_nalt_IT_POOLED_15JUN2022_39942.xls
10MAR2023 17:00

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
MODEL: Unstratified analysis
STUDY: GO39942
Duration of Follow-up by Endpoint and Arm

	Polatuzumab Vedotin + R-CHP (N=500)	R-CHOP (N=500)	Total (N=1000)
Patients with event (%)	431 (86.2%)	423 (84.6%)	854 (85.4%)
Latest contributing event			
Alive	431	423	854
Patients without event (%)	69 (13.8%)	77 (15.4%)	146 (14.6%)
Time to event (months)			
Median	39.2	38.7	39
95% CI	(38.6, 39.6)	(38.3, 39.4)	(38.5, 39.4)
25% and 75%-ile	36.3 - 42.6	36.2 - 42.6	36.2 - 42.6
Range	0 - 54	0 - 54	0 - 54

* Censored observation.
Summaries of Duration of Follow-up (median, percentiles) are based on reverse Kaplan-Meier estimates.
95% CI for median was computed using the method of Brookmeyer and Crowley.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_fu_OSDFU_IT_POOLED_15JUN2022_39942.xls
09FEB2023 10:09

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Progression-Free Survival (PFS - INV)
MODEL: Unstratified analysis
STUDY: GO39942
Duration of Follow-up by Endpoint and Arm

	Polatuzumab Vedotin + R-CHP (N=500)	R-CHOP (N=500)	Total (N=1000)
Patients with event (%)	367 (73.4%)	337 (67.4%)	704 (70.4%)
Latest contributing event			
Last Tumor Assessment	363	329	692
Randomization	4	8	12
Patients without event (%)	133 (26.6%)	163 (32.6%)	296 (29.6%)
Time to event (months)			
Median	30.7	30.6	30.7
95% CI	(30.5, 30.9)	(30.4, 30.8)	(30.5, 30.8)
25% and 75%-ile	29.3 - 41.1	29.7 - 40.1	29.6 - 40.7
Range	0 - 46	0 - 54	0 - 54

* Censored observation.
Summaries of Duration of Follow-up (median, percentiles) are based on reverse Kaplan-Meier estimates.
95% CI for median was computed using the method of Brookmeyer and Crowley.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_fu_PFSDFU_IT_POOLED_15JUN2022_39942.xls
09FEB2023 10:08

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: PRO
MODEL: Unstratified analysis
STUDY: GO39942
Duration of Follow-up by Endpoint and Arm

	Polatuzumab Vedotin + R-CHP (N=500)	R-CHOP (N=500)	Total (N=1000)
PRO Duration of Follow-up (months)			
n	494	495	989
Median	30	29.1	29.8
95% CI for Median	(29.3, 30.3)	(25.1, 29.9)	(29.0, 30.0)
25% and 75%-ile	13.3 - 31.7	9.2 - 31.0	12.3 - 31.3
Min - Max	0 - 44	0 - 54	0 - 54

Duration of Follow-up is calculated as:
Date of last PRO assessment that the patient attended - Date of Randomization + 1.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_fu_PRODFU_IT_POOLED_15JUN2022_39942.xls
09FEB2023 10:11

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: First AE
MODEL: Unstratified analysis
STUDY: GO39942
Duration of Follow-up by Endpoint and Arm

	Polatuzumab Vedotin + R-CHP (N=495)	R-CHOP (N=498)	Total (N=993)
Patients with event (%)	10 (2.0%)	7 (1.4%)	17 (1.7%)
Latest contributing event			
LAST DOSE OF STUDY TREATMENT + 90 DAYS	10	4	14
NALT	0	3	3
Patients without event (%)	485 (98.0%)	491 (98.6%)	976 (98.3%)
Time to event (months)			
Median	7.8	7.8	7.8
95% CI	(7.8, 7.9)	(7.2, 7.8)	NE
25% and 75%-ile	7.8 - 7.9	7.2 - 7.8	7.8 - 7.9
Range	0* - 8	0* - 8	0* - 8

* Censored observation.
Summaries of Duration of Follow-up (median, percentiles) are based on reverse Kaplan-Meier estimates.
95% CI for median was computed using the method of Brookmeyer and Crowley.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_fu_SAFFDFU_SE_POOLED_15JUN2022_39942.xls
09FEB2023 10:12

POPULATION: Global and China Extension Population, Safety-Evaluable Population
STUDY: GO39942
Summary of Study Drug Exposure

Cyclophosphamide

	Polatuzumab Vedotin + R-CHP (N=495)	R-CHOP (N=498)	Total (N=993)
Treatment duration (months)			
n	495	496	991
Mean (SD)	3.5 (0.6)	3.4 (0.7)	3.4 (0.7)
Median	3.5	3.5	3.5
25%-ile	3.5	3.4	3.4
75%-ile	3.6	3.5	3.6
Min - Max	0.0 - 5.5	0.0 - 8.0	0.0 - 8.0
Treatment duration (days)			
n	495	496	991
0 - 90	30 (6.1%)	38 (7.7%)	68 (6.9%)
91 - 180	465 (93.9%)	457 (92.1%)	922 (93.0%)
181 - 365	0	1 (0.2%)	1 (0.1%)
Number of Cycles Received			
n	495	496	991
Mean (SD)	5.8 (0.8)	5.7 (0.9)	5.8 (0.9)
Median	6	6	6
25%-ile	6	6	6
75%-ile	6	6	6
Min - Max	1.0 - 6.0	1.0 - 6.0	1.0 - 6.0
1-5	34 (6.9%)	43 (8.7%)	77 (7.8%)
6	461 (93.1%)	453 (91.3%)	914 (92.2%)

Relative Dose intensity (%)			
n	491	493	984
Mean (SD)	98.5 (4.0)	98.6 (4.3)	98.5 (4.1)
Median	100	100	100
25%-ile	98.2	98.2	98.2
75%-ile	100	100	100
Min - Max	63.8 - 105.9	65.4 - 108.7	63.8 - 108.7
Total cumulative dose			
n	495	496	991
Mean (SD)	7907.2 (1509.2)	7802.9 (1677.5)	7855.0 (1595.7)
Median	8010	8010	8010
25%-ile	7158	7200	7170
75%-ile	8900	8777.8	8820
Min - Max	1200.0 - 14198.0	750.0 - 14185.0	750.0 - 14198.0

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ex.sas
Output: ..541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ex_SE_POOLED_15JUN2022_39942.xls
17MAY2023 18:45

POPULATION: Global and China Extension Population, Safety-Evaluable Population
STUDY: GO39942
Summary of Study Drug Exposure

Doxorubicin

	Polatuzumab Vedotin + R-CHP (N=495)	R-CHOP (N=498)	Total (N=993)
Treatment duration (months)			
n	495	496	991
Mean (SD)	3.5 (0.6)	3.4 (0.7)	3.4 (0.7)
Median	3.5	3.5	3.5
25%-ile	3.5	3.4	3.4
75%-ile	3.6	3.5	3.6
Min - Max	0.0 - 5.5	0.0 - 8.0	0.0 - 8.0
Treatment duration (days)			
n	495	496	991
0 - 90	30 (6.1%)	38 (7.7%)	68 (6.9%)
91 - 180	465 (93.9%)	457 (92.1%)	922 (93.0%)
181 - 365	0	1 (0.2%)	1 (0.1%)
Number of Cycles Received			
n	495	496	991
Mean (SD)	5.8 (0.8)	5.7 (0.9)	5.8 (0.9)
Median	6	6	6
25%-ile	6	6	6
75%-ile	6	6	6
Min - Max	1.0 - 6.0	1.0 - 6.0	1.0 - 6.0
1-5	34 (6.9%)	43 (8.7%)	77 (7.8%)
6	461 (93.1%)	453 (91.3%)	914 (92.2%)

Relative Dose intensity (%)			
n	491	493	984
Mean (SD)	98.5 (3.9)	98.6 (4.4)	98.6 (4.2)
Median	100	100	100
25%-ile	98.4	98.4	98.4
75%-ile	100	100.4	100.1
Min - Max	65.0 - 105.9	64.4 - 108.7	64.4 - 108.7
Total cumulative dose			
n	495	496	991
Mean (SD)	527.4 (100.6)	520.5 (112.5)	523.9 (106.7)
Median	537	536	536
25%-ile	479.5	480	480
75%-ile	590.5	585	588
Min - Max	80.0 - 947.0	66.0 - 948.0	66.0 - 948.0

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ex.sas
Output: ..541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ex_SE_POOLED_15JUN2022_39942.xls
17MAY2023 18:45

POPULATION: Global and China Extension Population, Safety-Evaluable Population
STUDY: GO39942
Summary of Study Drug Exposure

Polatuzumab Vedotin

	Polatuzumab Vedotin + R-CHP (N=495)	Total (N=993)
Treatment duration (months)		
n	495	495
Mean (SD)	3.4 (0.6)	3.4 (0.6)
Median	3.5	3.5
25%-ile	3.4	3.4
75%-ile	3.6	3.6
Min - Max	0.0 - 5.5	0.0 - 5.5
Treatment duration (days)		
n	495	495
0 - 90	36 (7.3%)	36 (7.3%)
91 - 180	459 (92.7%)	459 (92.7%)
Number of Cycles Received		
n	495	495
Mean (SD)	5.8 (0.8)	5.8 (0.8)
Median	6	6
25%-ile	6	6
75%-ile	6	6
Min - Max	1.0 - 6.0	1.0 - 6.0
1-5	41 (8.3%)	41 (8.3%)
6	454 (91.7%)	454 (91.7%)

Relative Dose intensity (%)		
n	492	492
Mean (SD)	98.3 (5.0)	98.3 (5.0)
Median	99.9	99.9
25%-ile	97.8	97.8
75%-ile	100.1	100.1
Min - Max	64.4 - 111.2	64.4 - 111.2
Total cumulative dose		
n	495	495
Mean (SD)	760.3 (222.9)	760.3 (222.9)
Median	744	744
25%-ile	612	612
75%-ile	886	886
Min - Max	102.0 - 2125.0	102.0 - 2125.0

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ex.sas
Output: ..541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ex_SE_POOLED_15JUN2022_39942.xls
17MAY2023 18:45

POPULATION: Global and China Extension Population, Safety-Evaluable Population
STUDY: GO39942
Summary of Study Drug Exposure

Prednisone/Prednisolone/Methylprednisolone

	Polatuzumab Vedotin + R-CHP (N=495)	R-CHOP (N=498)	Total (N=993)
Treatment duration (months)			
n	495	498	993
Mean (SD)	3.6 (0.6)	3.5 (0.7)	3.6 (0.7)
Median	3.6	3.6	3.6
25%-ile	3.6	3.6	3.6
75%-ile	3.7	3.7	3.7
Min - Max	0.2 - 5.6	0.0 - 6.5	0.0 - 6.5
Treatment duration (days)			
n	495	498	993
0 - 90	30 (6.1%)	40 (8.0%)	70 (7.0%)
91 - 180	465 (93.9%)	457 (91.8%)	922 (92.8%)
181 - 365	0	1 (0.2%)	1 (0.1%)
Number of Cycles Received			
n	495	498	993
Mean (SD)	5.8 (0.8)	5.7 (1.0)	5.8 (0.9)
Median	6	6	6
25%-ile	6	6	6
75%-ile	6	6	6
Min - Max	1.0 - 6.0	1.0 - 6.0	1.0 - 6.0
1-5	33 (6.7%)	49 (9.8%)	82 (8.3%)
6	462 (93.3%)	449 (90.2%)	911 (91.7%)

Relative Dose intensity (%)			
n	495	498	993
Mean (SD)	98.5 (7.3)	98.5 (7.8)	98.5 (7.5)
Median	100	100	100
25%-ile	100	100	100
75%-ile	100	100	100
Min - Max	26.0 - 126.7	20.0 - 123.3	20.0 - 126.7
Total cumulative dose			
n	495	498	993
Mean (SD)	2870.3 (435.3)	2829.4 (518.3)	2849.8 (478.9)
Median	3000	3000	3000
25%-ile	3000	3000	3000
75%-ile	3000	3000	3000
Min - Max	500.0 - 3800.0	100.0 - 3700.0	100.0 - 3800.0

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ex.sas
Output: ..541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ex_SE_POOLED_15JUN2022_39942.xls
17MAY2023 18:45

POPULATION: Global and China Extension Population, Safety-Evaluable Population
STUDY: GO39942
Summary of Study Drug Exposure

Rituximab

	Polatuzumab Vedotin + R-CHP (N=495)	R-CHOP (N=498)	Total (N=993)
Treatment duration (months)			
n	495	498	993
Mean (SD)	4.8 (0.9)	4.6 (1.2)	4.7 (1.1)
Median	4.9	4.9	4.9
25%-ile	4.9	4.9	4.9
75%-ile	5.1	5.1	5.1
Min - Max	0.0 - 8.0	0.0 - 10.9	0.0 - 10.9
Treatment duration (days)			
n	495	498	993
0 - 90	32 (6.5%)	43 (8.6%)	75 (7.6%)
91 - 180	455 (91.9%)	445 (89.4%)	900 (90.6%)
181 - 365	8 (1.6%)	10 (2.0%)	18 (1.8%)
Number of Cycles Received			
n	495	498	993
Mean (SD)	7.6 (1.3)	7.5 (1.5)	7.5 (1.4)
Median	8	8	8
25%-ile	8	8	8
75%-ile	8	8	8
Min - Max	1.0 - 8.0	1.0 - 8.0	1.0 - 8.0
1-5	36 (7.3%)	47 (9.4%)	83 (8.4%)
6	9 (1.8%)	16 (3.2%)	25 (2.5%)

7	11 (2.2%)	5 (1.0%)	16 (1.6%)
8	439 (88.7%)	430 (86.3%)	869 (87.5%)
Relative Dose intensity (%)			
n	491	495	986
Mean (SD)	99.1 (3.1)	99.2 (2.6)	99.1 (2.9)
Median	100	100	100
25%-ile	98.6	98.8	98.7
75%-ile	100.1	100.1	100.1
Min - Max	63.8 - 116.0	83.7 - 108.0	63.8 - 116.0
Total cumulative dose			
n	495	498	993
Mean (SD)	5195.0 (1123.7)	5093.4 (1256.2)	5144.1 (1192.5)
Median	5295	5280	5288
25%-ile	4683.8	4680	4680
75%-ile	5909	5810	5849
Min - Max	600.0 - 9318.0	570.0 - 9452.0	570.0 - 9452.0

Clinical cut-off: 15JUN2022

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17MAY2023 18:45

POPULATION: Global and China Extension Population, Safety-Evaluable Population
STUDY: GO39942
Summary of Study Drug Exposure

Vincristine

	R-CHOP (N=498)	Total (N=993)
Treatment duration (months)		
n	496	496
Mean (SD)	3.4 (0.7)	3.4 (0.7)
Median	3.5	3.5
25%-ile	3.4	3.4
75%-ile	3.5	3.5
Min - Max	0.0 - 8.0	0.0 - 8.0
Treatment duration (days)		
n	496	496
0 - 90	49 (9.9%)	49 (9.9%)
91 - 180	446 (89.9%)	446 (89.9%)
181 - 365	1 (0.2%)	1 (0.2%)
Number of Cycles Received		
n	496	496
Mean (SD)	5.7 (1.0)	5.7 (1.0)
Median	6	6
25%-ile	6	6
75%-ile	6	6
Min - Max	1.0 - 6.0	1.0 - 6.0
1-5	54 (10.9%)	54 (10.9%)
6	442 (89.1%)	442 (89.1%)

Relative Dose intensity (%)		
n	496	496
Mean (SD)	98.6 (4.9)	98.6 (4.9)
Median	100	100
25%-ile	100	100
75%-ile	100	100
Min - Max	62.5 - 104.3	62.5 - 104.3
Total cumulative dose		
n	496	496
Mean (SD)	11.2 (2.0)	11.2 (2.0)
Median	12	12
25%-ile	12	12
75%-ile	12	12
Min - Max	1.5 - 12.0	1.5 - 12.0

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ex.sas
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17MAY2023 18:45

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: --
MODEL: descriptive
STUDY: GO39942
Number and Percentage of SAEs between randomization date and treatment start date

		Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)			
		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	6530	100.0	0	0	6258	100.0	1	<0.1

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_rndtrt1.sas
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09FEB2023 10:07

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)												R-CHOP (N=500)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	500	100.0	69	13.8	431	86.2	NE	NE	NE	NE	NE	NE	500	100.0	77	15.4	423	84.6	NE	NE	NE	NE	NE	NE	0.4502	0.88	0.64	1.22		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical studies/RO5541077/CDPT7884/GO39942/data analysis/ACE BASE/prod/program/t eff tte.sas
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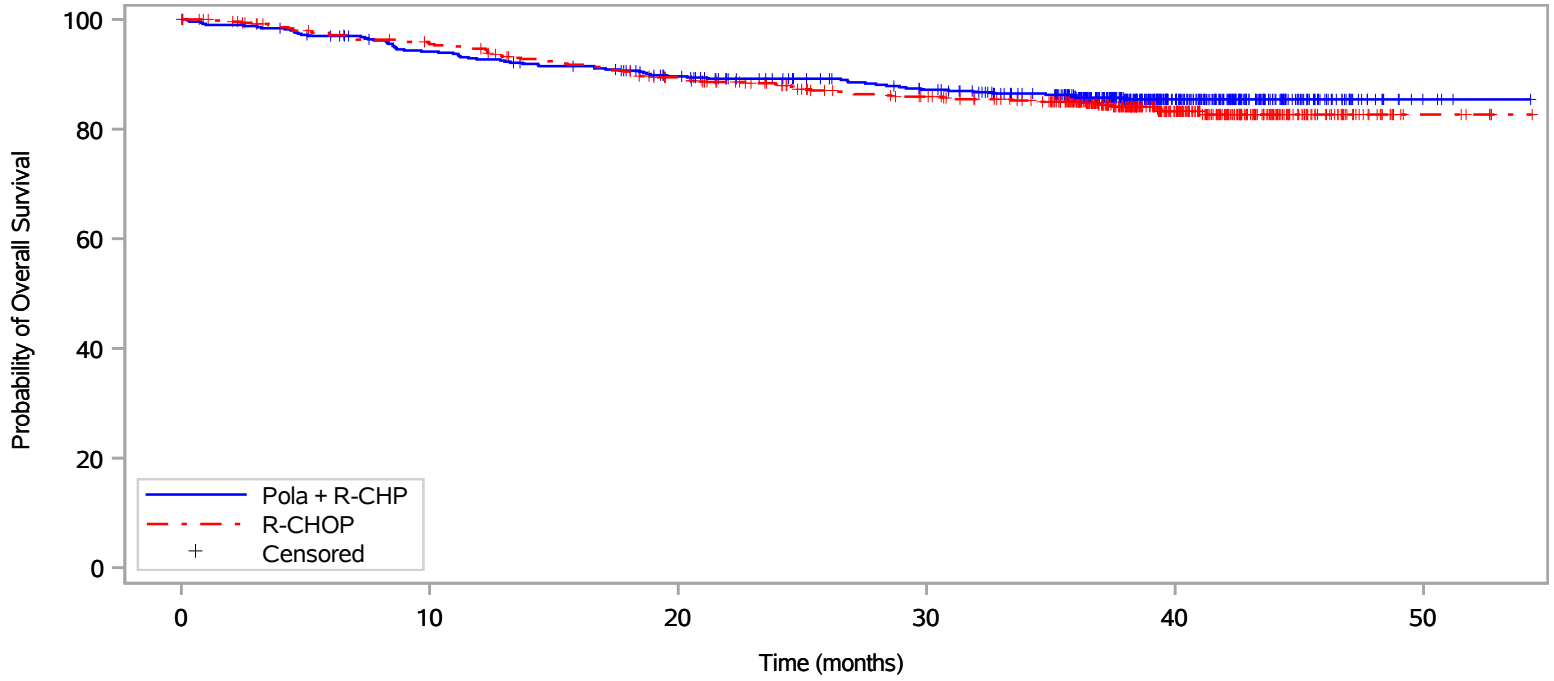
09FEB2023 20:02

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
STUDY: GO39942



Patients at risk																			
Pola + R-CHP	500	492	481	463	455	447	438	420	408	396	387	369	338	218	129	53	13	2	1
R-CHOP	500	487	473	466	458	442	433	413	401	383	376	363	329	205	124	53	18	7	1
Patients censored																			
Pola + R-CHP	0	2	4	9	9	11	16	28	39	48	51	66	95	213	302	378	418	429	430
R-CHOP	0	9	13	15	16	21	21	32	42	53	57	68	100	221	299	370	405	416	422

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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Output: ..O39942/data_analysis/ACE_FINAL_OS/prod/output/g_km_OS_IT_POOLED_15JUN2022_39942.pdf
10FEB2023 11:43

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
MODEL: Unstratified Analysis
STUDY: GO39942
Time to Event Analysis by Subgroups (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)												R-CHOP (N=500)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	Convergence Status	p-value (likelihood ratio)
All	n/a	500	100.0	69	13.8	431	86.2	NE	NE	NE	NE	NE	NE	500	100.0	77	15.4	423	84.6	NE	NE	NE	NE	NE	NE	0.4526	0.88	0.64	1.22	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	268	53.6	45	16.8	223	83.2	NE	NE	NE	NE	NE	NE	270	54.0	50	18.5	220	81.5	NE	39.3	NE	NE	NE	NE	0.5570	0.89	0.59	1.33	Convergence criterion (GCONV=1E-8) satisfied.	0.9758
	Female	232	46.4	24	10.3	208	89.7	NE	NE	NE	NE	NE	NE	230	46.0	27	11.7	203	88.3	NE	NE	NE	NE	NE	NE	0.6314	0.87	0.50	1.52	Convergence criterion (GCONV=1E-8) satisfied.	
Age	<= 60	167	33.4	16	9.6	151	90.4	NE	NE	NE	NE	NE	NE	158	31.6	20	12.7	138	87.3	NE	NE	NE	NE	NE	NE	0.3957	0.75	0.39	1.45	Convergence criterion (GCONV=1E-8) satisfied.	0.5491
	> 60	333	66.6	53	15.9	280	84.1	NE	NE	NE	NE	NE	NE	342	68.4	57	16.7	285	83.3	NE	NE	NE	NE	NE	NE	0.7529	0.94	0.65	1.37	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Western Europe/United States/Canada/Australia	302	60.4	43	14.9	257	85.1	NE	NE	NE	NE	NE	NE	301	60.2	46	15.3	255	84.7	NE	NE	NE	NE	NE	NE	0.9600	0.99	0.68	1.49	Convergence criterion (GCONV=1E-8) satisfied.	0.5997
	Asia	141	28.2	14	9.9	127	90.1	NE	NE	NE	NE	NE	NE	140	28.0	20	14.3	120	85.7	NE	NE	NE	NE	NE	NE	0.2249	0.66	0.33	1.30	Convergence criterion (GCONV=1E-8) satisfied.	
	Rest of World	57	11.4	10	17.5	47	82.5	NE	28.9	NE	NE	NE	NE	59	11.8	11	18.6	48	81.4	NE	17.2	NE	NE	NE	NE	0.7370	0.86	0.37	2.03	Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	235	47.0	37	15.7	198	84.3	NE	NE	NE	NE	NE	NE	236	47.2	33	14.0	203	86.0	NE	NE	NE	NE	NE	NE	0.6406	1.12	0.70	1.79	Convergence criterion (GCONV=1E-8) satisfied.	0.0256
	Black or African American	8	1.6	0	0.0	8	100.0	NE	NE	NE	NE	NE	NE	8	1.6	4	50.0	4	50.0	19.3	3.0	NE	NE	18.3	NE	0.0250	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	145	29.0	14	9.7	131	90.3	NE	NE	NE	NE	NE	NE	145	29.0	21	14.5	124	85.5	NE	NE	NE	NE	NE	NE	0.1829	0.63	0.32	1.26	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	7	1.4	2	28.6	5	71.4	31.9	18.9	NE	NE	31.9	NE	11	2.2	1	9.1	10	90.9	NE	12.9	NE	NE	NE	NE	0.3294	3.11	0.28	34.30	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	105	21.0	16	15.2	89	84.8	NE	NE	NE	NE	NE	NE	100	20.0	18	18.0	82	82.0	NE	39.3	NE	NE	NE	NE	0.6898	0.87	0.44	1.71	Convergence criterion (GCONV=1E-8) satisfied.	
ECOG performance status	0-1	419	83.8	53	12.6	366	87.4	NE	NE	NE	NE	NE	NE	416	83.2	57	13.7	359	86.3	NE	NE	NE	NE	NE	NE	0.6306	0.91	0.63	1.33	Convergence criterion (GCONV=1E-8) satisfied.	0.6638
	2	81	16.2	16	19.8	65	80.2	NE	14.4	NE	NE	NE	NE	82	16.4	20	24.4	62	75.6	24.7	12.6	NE	NE	NE	NE	0.4485	0.78	0.40	1.50	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0.0	0	0.0	0	0.0	NE	NE	NE	NE	NE	NE	2	0.4	0	0.0	2	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cell of origin (determined by gene expression)	ABC	131	26.2	14	10.7	117	89.3	NE	NE	NE	NE	NE	NE	143	28.6	32	22.4	111	77.6	39.3	28.7	NE	NE	NE	NE	0.0131	0.46	0.25	0.86	Convergence criterion (GCONV=1E-8) satisfied.	0.0019
	GCB	193	38.6	27	14.0	166	86.0	NE	NE	NE	NE	NE	NE	187	37.4	25	13.4	162	86.6	NE	NE	NE	NE	NE	NE	0.8796	1.04	0.61	1.80	Convergence criterion (GCONV=1E-8) satisfied.	
	Unclassified	53	10.6	11	20.8	42	79.2	NE	26.8	NE	NE	NE	NE	60	12.0	3	5.0	57	95.0	NE	NE	NE	NE	NE	NE	0.0122	4.44	1.24	15.93	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	123	24.6	17	13.8	106	86.2	NE	NE	NE	NE	NE	NE	110	22.0	17	15.5	93	84.5	NE	NE	NE	NE	NE	NE	0.6626	0.86	0.44	1.69	Convergence criterion (GCONV=1E-8) satisfied.	
IPI score at Screening	1-2	188	37.6	16	8.5	172	91.5	NE	NE	NE	NE	NE	NE	187	37.4	17	9.1	170	90.9	NE	NE	NE	NE	NE	NE	0.9002	0.96	0.48	1.89	Convergence criterion (GCONV=1E-8) satisfied.	0.3635
	3	199	39.8	24	12.1	175	87.9	NE	NE	NE	NE	NE	NE	186	37.2	32	17.2	154	82.8	NE	39.3	NE	NE	NE	NE	0.1338	0.67	0.39	1.14	Convergence criterion (GCONV=1E-8) satisfied.	
	4-5	113	22.6	29	25.7	84	74.3	32.7	26.5	NE	NE	NE	NE	127	25.4	28	22.0	99	78.0	NE	18.2	NE	NE	NE	NE	0.6168	1.14	0.68	1.92	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline Bulky Disease	Present	211	42.2	36	17.1	175	82.9	NE	NE	NE	NE	NE	NE	218	43.6	40	18.3	178	81.7	NE	39.3	NE	NE	NE	NE	0.7302	0.92	0.59	1.45	Convergence criterion (GCONV=1E-8) satisfied.	0.8085
	Absent	289	57.8	33	11.4	256	88.6	NE	NE	NE	NE	NE	NE	282	56.4	37	13.1	245	86.9	NE	NE	NE	NE	NE	NE	0.4974	0.85	0.53	1.36	Convergence criterion (GCONV=1E-8) satisfied.	
Double Expressor Lymphoma by IHC (Central Review)	DEL	150	30.0	26	17.3	124	82.7	NE	NE	NE	NE	NE	NE	163	32.6	37	22.7	126	77.3	41.0	33.4	NE	NE	NE	NE	0.3063	0.73	0.47	1.27	Convergence criterion (GCONV=1E-8) satisfied.	0.5498
	Non DEL	253	50.6	29	11.5	224	88.5	NE	NE	NE	NE	NE	NE	244	48.8	28	11.5	216	88.5	NE	NE	NE	NE	NE	NE	0.8849	0.96	0.57	1.62	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	97	19.4	14	14.4	83	85.6	NE	NE	NE	NE	NE	NE	93	18.6	12	12.9	81	87.1	NE	NE	NE	NE	NE	NE	0.7683	1.12	0.52	2.43	Convergence criterion (GCONV=1E-8) satisfied.	
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	341	68.2	49	14.4	292	85.6	NE	NE	NE	NE	NE	NE	351	70.2	56	16.0	295	84.0	NE	NE	NE	NE	NE	NE	0.5851	0.90	0.61	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.1194
	DH/TH+	26	5.2	5	19.2	21	80.8	NE	13.2	NE	NE	NE	NE	19	3.8	1	5.3	18	94.7	NE	NE	NE	NE	NE	NE	0.1810	3.89	0.45	33.32	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	133	26.6	15	11.3	118	88.7	NE	NE	NE	NE	NE	NE	130	26.0	20	15.4	110	84.6	NE	NE	NE	NE	NE	NE	0.2749	0.69	0.35	1.35	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: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_tte.sas
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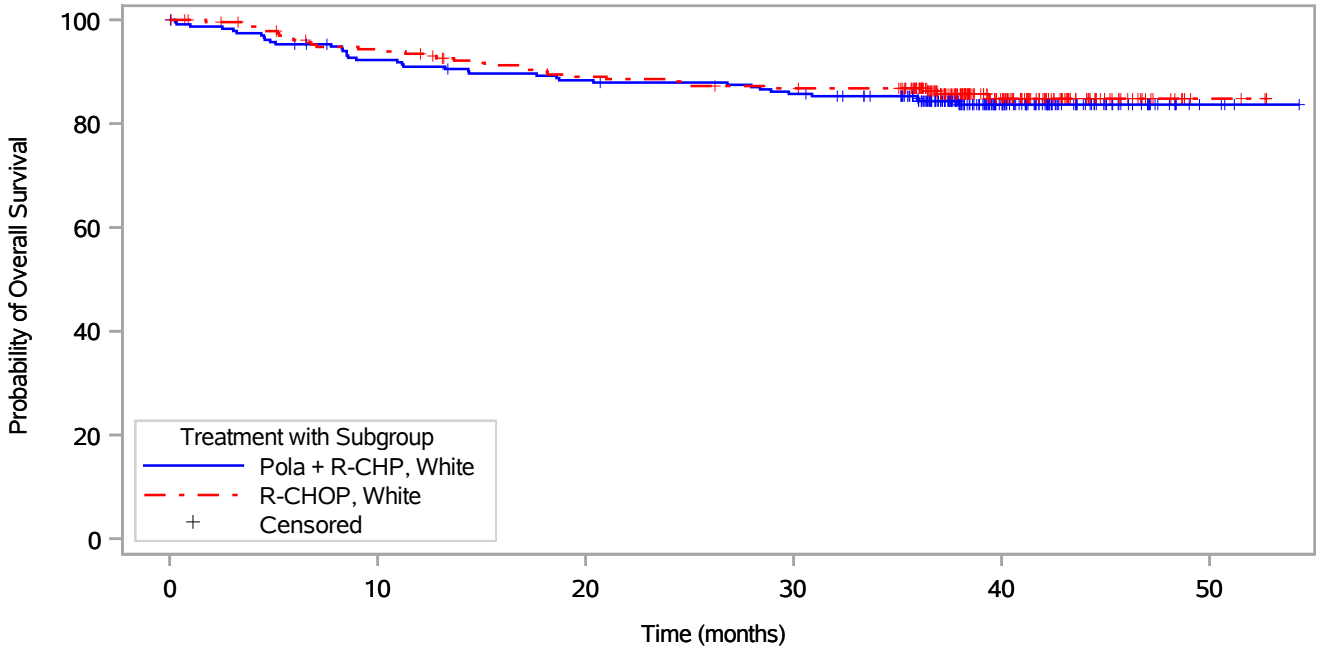
09FEB2023 20:06

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
STUDY: GO39942
Race/ethnicity



Patients at risk																			
Pola + R-CHP, White	235	230	223	213	210	206	205	201	201	200	196	192	176	106	58	27	10	2	1
R-CHOP, White	236	231	221	217	214	206	203	199	199	195	194	193	178	100	56	24	11	4	NE
Patients censored																			
Pola + R-CHP, White	0	1	1	4	4	5	5	6	6	6	6	9	24	92	140	171	188	196	197
R-CHOP, White	0	4	6	7	7	11	11	11	11	12	12	13	28	104	147	179	192	199	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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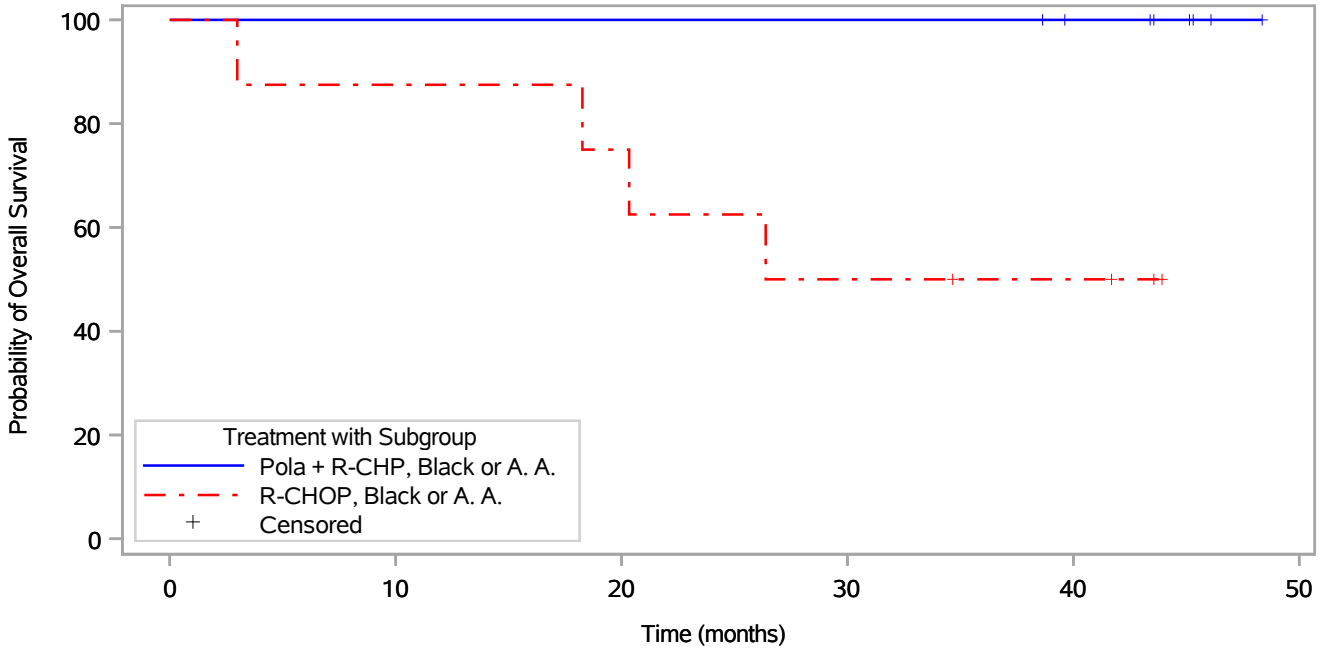
13MAR2023 19:43

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
STUDY: GO39942
Race/ethnicity



Patients at risk																	
Pola + R-CHP, Black or A. A.	8	8	8	8	8	8	8	8	8	8	8	8	8	7	6	4	1
R-CHOP, Black or A. A.	8	7	7	7	7	7	7	5	5	4	4	4	3	3	2	NE	NE
Patients censored																	
Pola + R-CHP, Black or A. A.	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	4	7
R-CHOP, Black or A. A.	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	NE	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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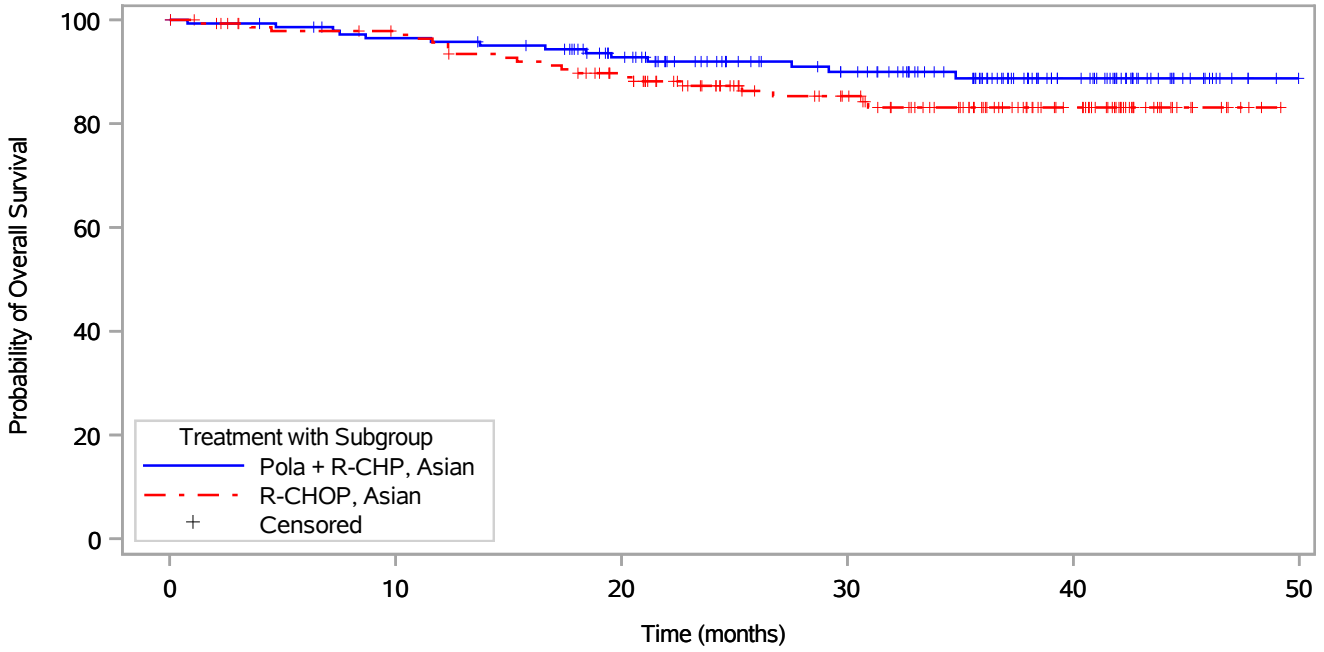
13MAR2023 19:43

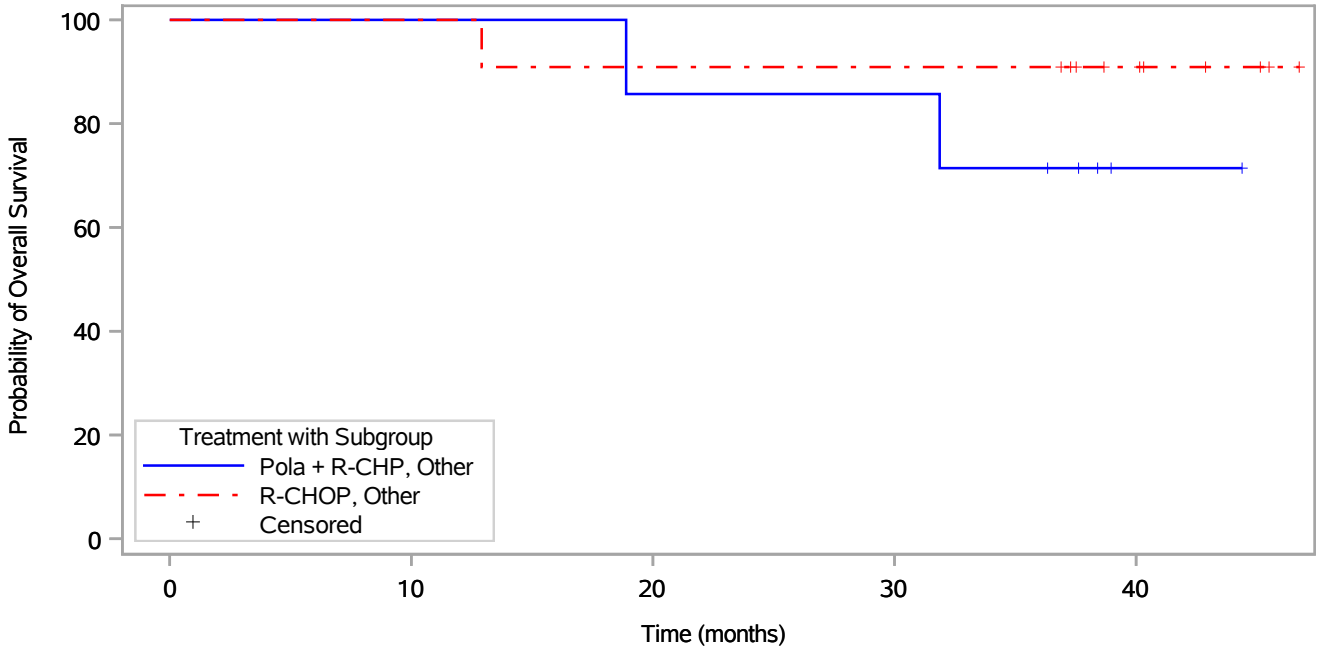
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
STUDY: GO39942
Race/ethnicity



Patients at risk																	
Pola + R-CHP, Asian	145	143	141	136	135	133	127	114	102	93	88	76	64	45	29	12	2
R-CHOP, Asian	145	139	135	134	130	125	121	108	97	85	81	69	58	43	27	9	2
Patients censored																	
Pola + R-CHP, Asian	0	1	2	4	4	5	10	21	32	41	44	56	67	86	102	119	129
R-CHOP, Asian	0	5	7	8	9	10	10	21	31	41	45	55	66	81	97	115	122

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

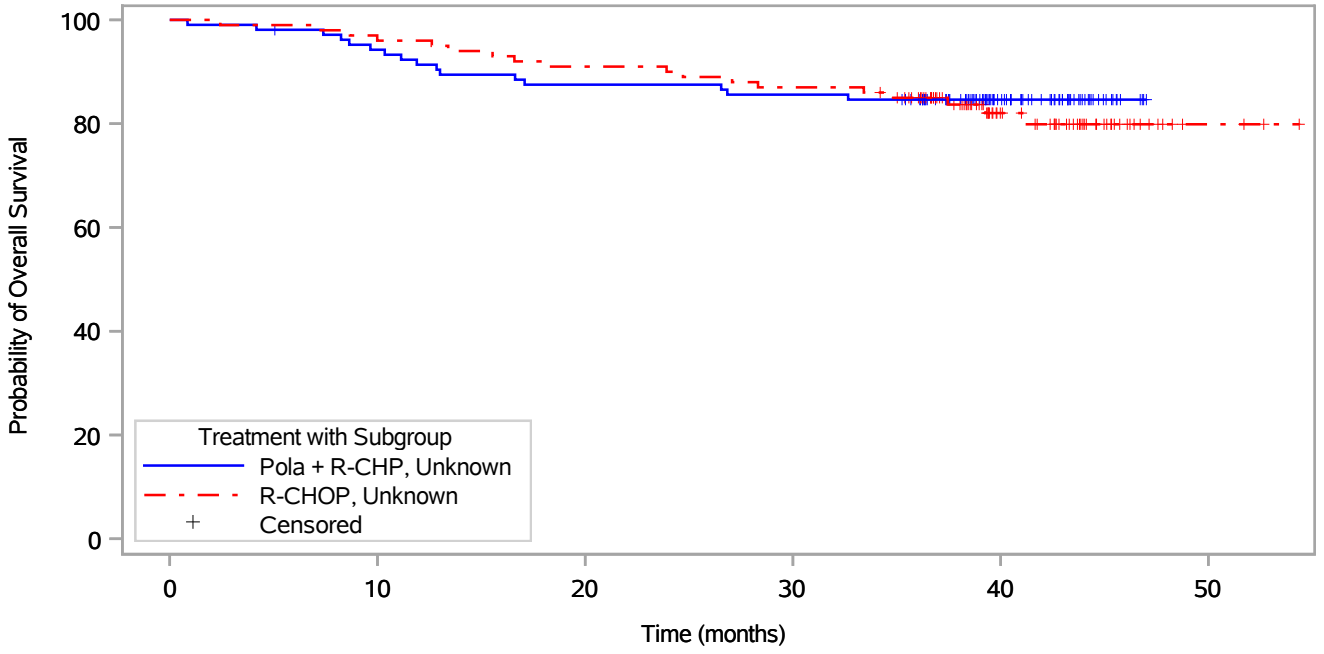
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
STUDY: GO39942
Race/ethnicity



Patients at risk																
Pola + R-CHP, Other	7	7	7	7	7	7	7	6	6	6	6	5	5	1	1	NE
R-CHOP, Other	11	11	11	11	11	10	10	10	10	10	10	10	10	6	4	3
Patients censored																
Pola + R-CHP, Other	0	0	0	0	0	0	0	0	0	0	0	0	0	4	4	NE
R-CHOP, Other	0	0	0	0	0	0	0	0	0	0	0	0	0	4	6	7

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
STUDY: GO39942
Race/ethnicity



Patients at risk																			
Pola + R-CHP, Unknown	105	104	102	99	95	93	91	91	91	89	89	88	85	59	35	10	NE	NE	NE
R-CHOP, Unknown	100	99	99	97	96	94	92	91	90	89	87	87	80	53	35	17	5	3	1
Patients censored																			
Pola + R-CHP, Unknown	0	0	1	1	1	1	1	1	1	1	1	1	4	30	54	79	NE	NE	NE
R-CHOP, Unknown	0	0	0	0	0	0	0	0	0	0	0	0	5	31	47	65	77	79	81

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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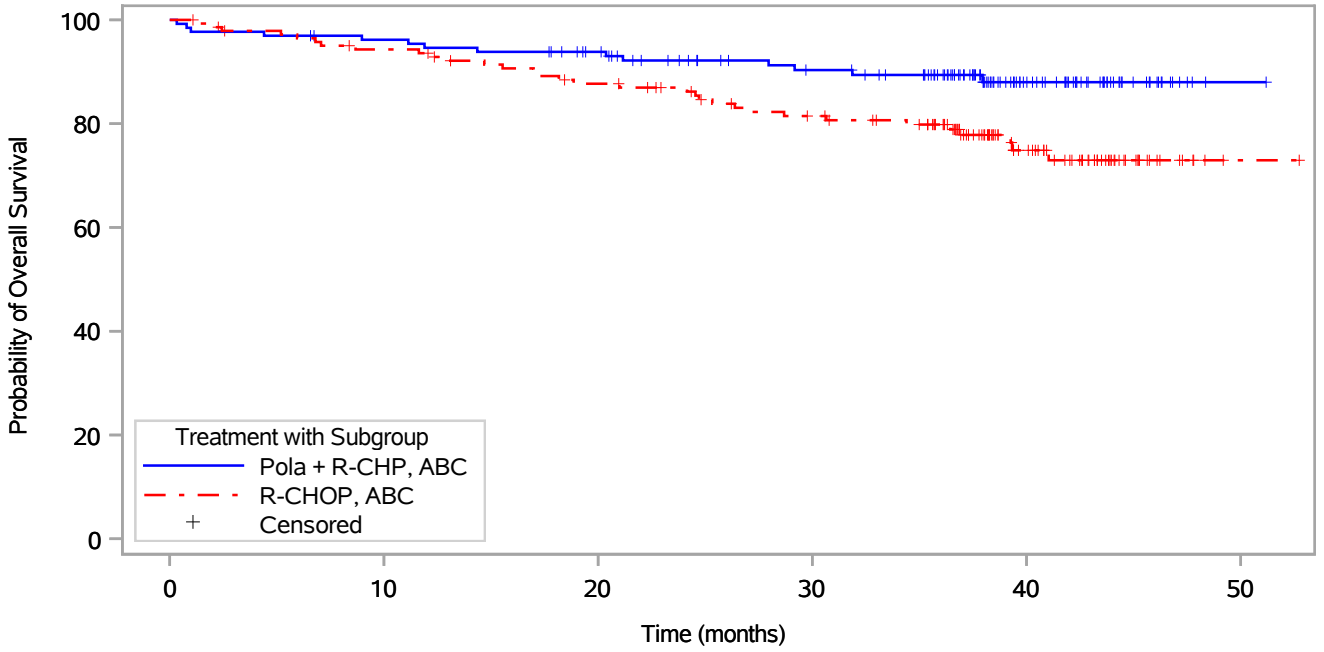
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
STUDY: GO39942
Cell of origin

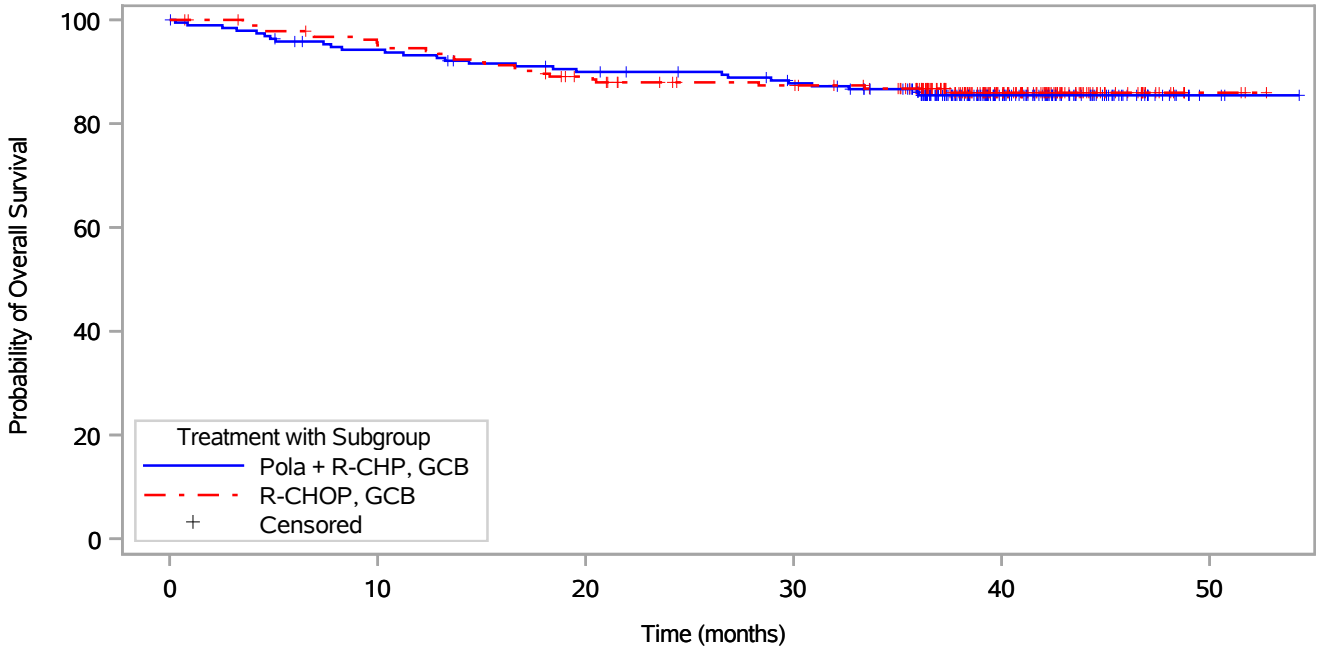


Patients at risk																		
Pola + R-CHP, ABC	131	128	127	124	122	121	119	110	105	100	97	94	84	52	34	14	2	1
R-CHOP, ABC	143	137	135	131	130	124	121	116	113	105	102	97	88	53	36	15	3	1
Patients censored																		
Pola + R-CHP, ABC	0	0	0	2	2	2	4	12	16	21	22	24	34	65	83	103	115	116
R-CHOP, ABC	0	3	3	4	4	7	7	9	12	15	16	20	28	61	75	96	108	110

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
STUDY: GO39942

Cell of origin



Patients at risk																			
Pola + R-CHP, GCB	193	189	183	178	176	171	170	166	165	162	158	154	143	94	57	26	9	1	1
R-CHOP, GCB	187	185	180	177	173	168	164	156	152	150	149	146	134	88	53	19	8	3	NE
Patients censored																			
Pola + R-CHP, GCB	0	1	2	4	4	6	6	8	9	10	12	14	24	72	109	140	157	165	165
R-CHOP, GCB	0	2	3	4	4	4	4	9	13	15	15	18	29	74	109	143	154	159	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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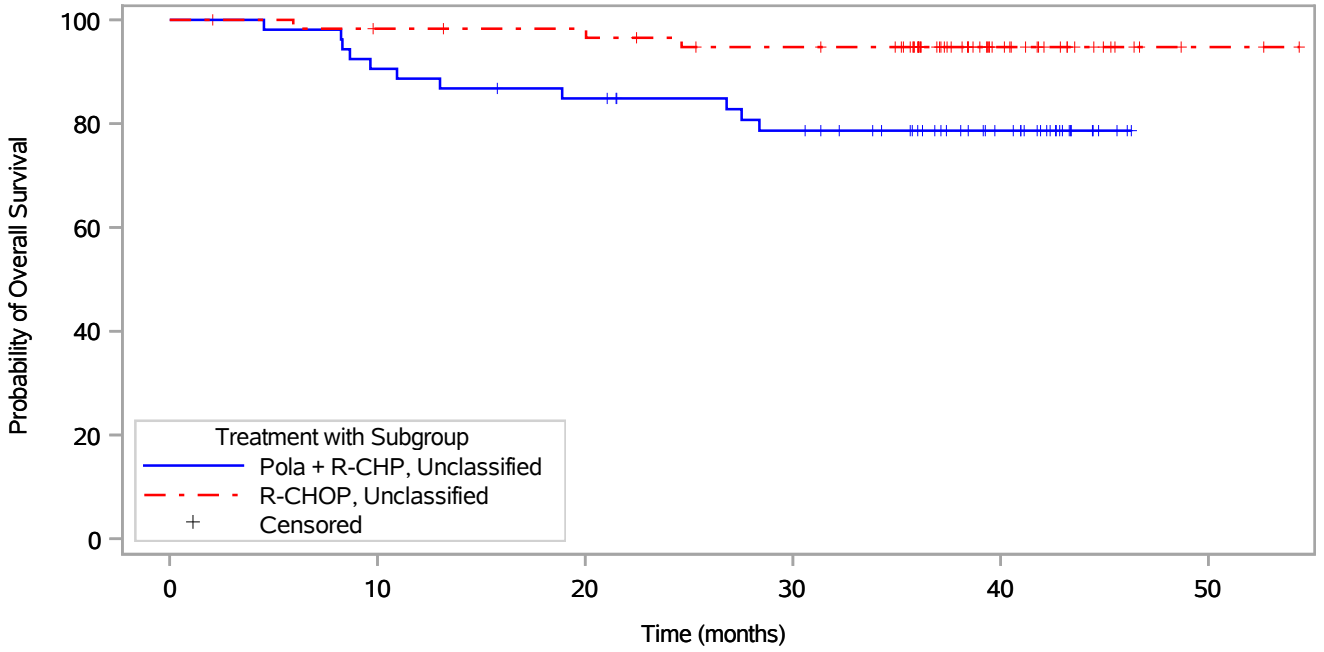
13MAR2023 19:43

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
STUDY: GO39942

Cell of origin



Patients at risk																			
Pola + R-CHP, Unclassified	53	53	52	49	47	46	45	44	41	40	38	35	31	24	15	3	NE	NE	NE
R-CHOP, Unclassified	60	59	58	58	57	56	56	55	54	52	52	51	44	25	14	7	3	2	1
Patients censored																			
Pola + R-CHP, Unclassified	0	0	0	0	0	0	1	1	4	4	4	7	11	18	27	39	NE	NE	NE
R-CHOP, Unclassified	0	1	1	1	2	3	3	3	4	5	5	6	13	32	43	50	54	55	56

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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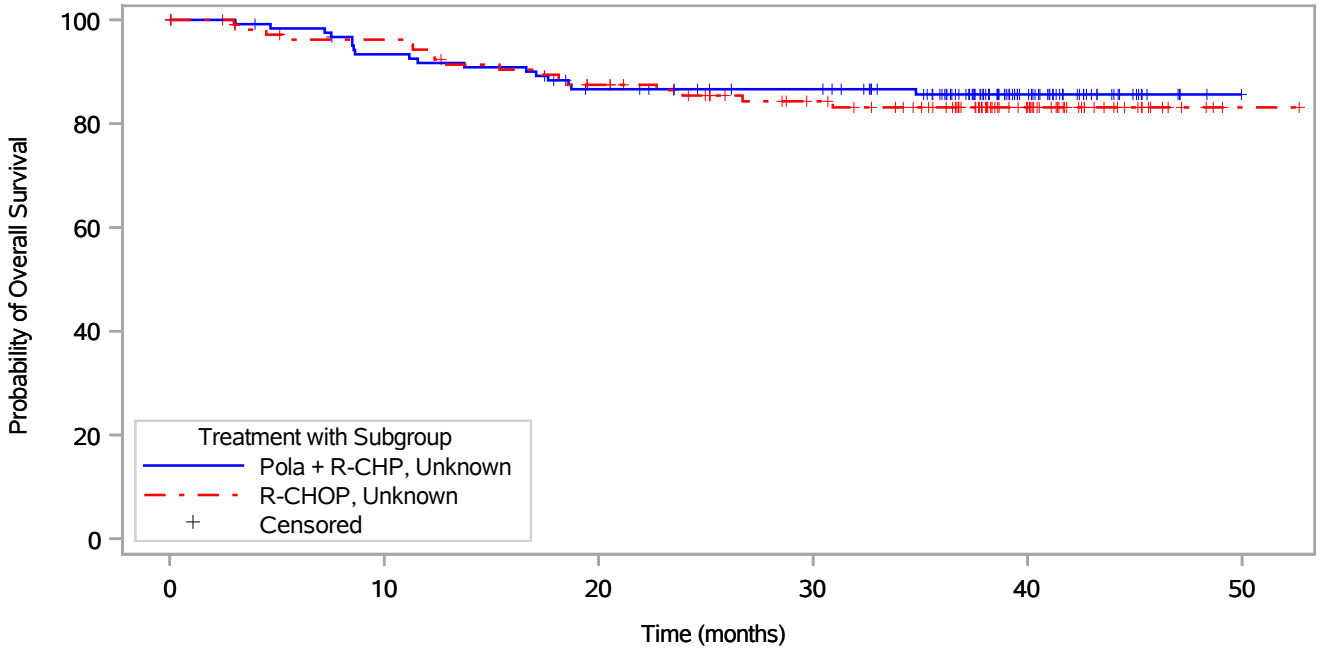
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Overall Survival
STUDY: GO39942

Cell of origin



Patients at risk																		
Pola + R-CHP, Unknown	123	122	119	112	110	109	104	100	97	94	94	86	80	48	23	10	2	NE
R-CHOP, Unknown	110	106	100	100	98	94	92	86	82	76	73	69	63	39	21	12	4	1
Patients censored																		
Pola + R-CHP, Unknown	0	1	2	3	3	3	5	7	10	13	13	21	26	58	83	96	104	NE
R-CHOP, Unknown	0	3	6	6	6	7	7	11	13	18	21	24	30	54	72	81	89	92

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..42/data_analysis/ACE_FINAL_OS/prod/output/g_km_sg1_OS_IT_POOLED_15JUN2022_39942.pdf
13MAR2023 19:43

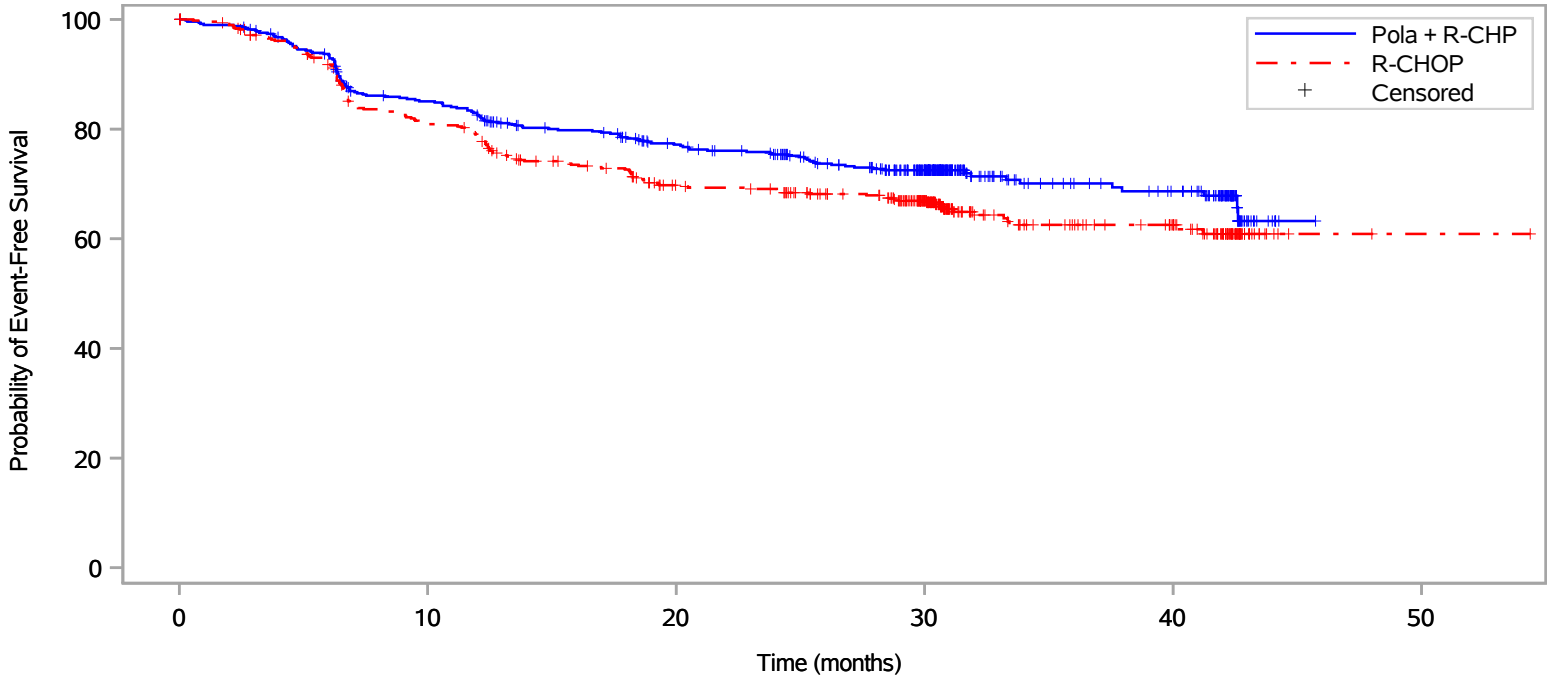
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)												R-CHOP (N=500)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	500	100.0	139	27.8	361	72.2	24.9	17.8	33.8	NE	NE	NE	500	100.0	167	33.4	333	66.6	13.2	12.0	18.5	NE	NE	NE	0.0288	0.78	0.62	0.98		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_tte_str_EFSEFF_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:36

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942



Patients at risk																			
Pola + R-CHP	500	485	459	411	395	371	359	339	329	303	247	115	101	96	66	1	NE	NE	NE
R-CHOP	500	472	441	395	375	344	333	305	302	280	229	108	94	87	59	2	2	1	1
Patients censored																			
Pola + R-CHP	0	6	10	19	20	32	37	47	53	70	123	253	265	268	297	360	NE	NE	NE
R-CHOP	0	14	19	22	23	32	36	49	51	69	115	230	241	248	274	331	332	332	332

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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10FEB2023 12:08

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
MODEL: Unstratified Analysis
STUDY: GO39942
Time to Event Analysis by Subgroups (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)												R-CHOP (N=500)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	Convergence Status	p-value (likelihood ratio)
All	n/a	500	100.0	139	27.8	361	72.2	24.9	17.8	33.8	NE	NE	NE	500	100.0	167	33.4	333	66.6	13.2	12.0	18.5	NE	NE	NE	0.0417	0.79	0.63	0.99	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	268	53.6	75	28.0	193	72.0	25.2	16.6	41.2	NE	42.6	NE	270	54.0	108	40.0	162	60.0	11.9	7.1	13.9	NE	33.3	NE	0.0031	0.64	0.48	0.86	Convergence criterion (GCONV=1E-8) satisfied.	0.0311
	Female	232	46.4	64	27.6	168	72.4	24.5	13.8	NE	NE	NE	NE	230	46.0	59	25.7	171	74.3	24.3	13.4	NE	NE	NE	NE	0.7221	1.07	0.75	1.52	Convergence criterion (GCONV=1E-8) satisfied.	
Age	<= 60	167	33.4	46	27.5	121	72.5	19.9	12.2	NE	NE	42.6	NE	158	31.6	48	30.4	110	69.6	13.2	8.2	32.0	NE	NE	NE	0.4895	0.87	0.58	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.5971
	> 60	333	66.6	93	27.9	240	72.1	25.5	17.8	37.6	NE	NE	NE	342	68.4	119	34.8	223	65.2	13.4	12.0	19.3	NE	NE	NE	0.0453	0.76	0.58	0.99	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Western Europe/United States/Canada/Australia	302	60.4	78	25.8	224	74.2	31.7	17.7	NE	NE	NE	NE	301	60.2	93	31.6	208	68.4	16.1	12.0	28.5	NE	NE	NE	0.1490	0.83	0.59	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.3744
	Asia	141	28.2	37	26.2	104	73.8	20.5	13.8	NE	NE	NE	NE	140	28.0	51	36.4	89	63.6	12.4	9.5	18.9	NE	30.7	NE	0.0418	0.63	0.42	0.99	Convergence criterion (GCONV=1E-8) satisfied.	
	Rest of World	57	11.4	24	42.1	33	57.9	17.0	6.5	28.4	42.6	28.4	NE	59	11.8	21	35.6	38	64.4	11.9	6.6	33.2	NE	33.2	NE	0.9140	1.03	0.57	1.87	Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	235	47.0	69	29.4	166	70.6	23.9	12.3	37.9	NE	NE	NE	236	47.2	72	30.5	164	69.5	18.1	11.4	30.8	NE	NE	NE	0.7018	0.94	0.67	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.0289
	Black or African American	8	1.6	0	0.0	8	100.0	NE	NE	NE	NE	NE	NE	8	1.6	4	50.0	4	50.0	5.0	2.0	NE	12.4	2.8	NE	0.0319	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	145	29.0	38	26.2	107	73.8	20.5	13.8	NE	NE	NE	NE	145	29.0	53	36.6	92	63.4	12.8	10.6	19.3	NE	30.7	NE	0.0403	0.63	0.43	0.98	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	7	1.4	4	57.1	3	42.9	6.0	4.6	NE	31.9	6.0	NE	11	2.2	4	36.4	7	63.6	6.4	2.2	NE	NE	6.4	NE	0.5454	1.53	0.38	6.16	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	105	21.0	28	26.7	77	73.3	31.7	12.8	NE	NE	42.6	NE	100	20.0	34	34.0	66	66.0	16.1	10.0	33.3	NE	NE	NE	0.3083	0.77	0.47	1.27	Convergence criterion (GCONV=1E-8) satisfied.	
ECOG performance status	0-1	419	83.8	115	27.4	304	72.6	25.5	18.4	37.6	NE	NE	NE	416	83.2	138	33.2	278	66.8	15.5	12.3	19.3	NE	NE	NE	0.0569	0.79	0.61	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.9942
	2	81	16.2	24	29.6	57	70.4	15.2	7.1	NE	NE	NE	NE	82	16.4	29	35.4	53	64.6	9.1	6.6	24.3	NE	NE	NE	0.3733	0.78	0.46	1.34	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0.0	0	0.0	0	0.0	NE	NE	NE	NE	NE	NE	2	0.4	0	0.0	2	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cell of origin (determined by gene expression)	ABC	131	26.2	28	21.4	103	78.6	33.8	24.5	NE	NE	NE	NE	143	28.6	67	46.9	76	53.1	11.9	9.1	12.5	31.2	19.3	NE	<.0001	0.38	0.24	0.59	Convergence criterion (GCONV=1E-8) satisfied.	0.0001
	GCB	193	38.6	57	29.5	136	70.5	18.5	12.1	41.2	NE	NE	NE	187	37.4	51	27.3	136	72.7	24.2	12.9	NE	NE	NE	NE	0.7128	1.07	0.74	1.57	Convergence criterion (GCONV=1E-8) satisfied.	
	Unclassified	53	10.6	17	32.1	36	67.9	22.8	10.3	NE	NE	NE	NE	60	12.0	11	18.3	49	81.7	33.3	20.0	NE	NE	NE	NE	0.1057	1.85	0.87	3.96	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	123	24.6	37	30.1	86	69.9	17.7	11.2	42.6	42.6	42.6	NE	110	22.0	38	34.5	72	65.5	12.8	6.9	22.7	NE	40.2	NE	0.3772	0.82	0.52	1.28	Convergence criterion (GCONV=1E-8) satisfied.	
IPI score at Screening	1-2	188	37.6	45	23.9	143	76.1	42.6	18.5	NE	NE	NE	NE	187	37.4	45	24.1	142	75.9	30.8	18.9	NE	NE	NE	NE	0.9827	1.00	0.66	1.52	Convergence criterion (GCONV=1E-8) satisfied.	0.0869
	3	199	39.8	48	24.1	151	75.9	33.3	20.5	NE	NE	42.6	NE	186	37.2	69	37.1	117	62.9	12.2	9.0	17.0	NE	40.2	NE	0.0032	0.58	0.40	0.84	Convergence criterion (GCONV=1E-8) satisfied.	
	4-5	113	22.6	46	40.7	67	59.3	9.7	6.7	18.0	NE	31.7	NE	127	25.4	53	41.7	74	58.3	9.6	6.6	13.4	NE	24.0	NE	0.7934	0.95	0.64	1.41	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline Bulky Disease	Present	211	42.2	72	34.1	139	65.9	12.2	8.3	23.8	NE	NE	NE	218	43.6	74	33.9	144	66.1	12.0	6.8	18.5	NE	NE	NE	0.9620	0.99	0.72	1.37	Convergence criterion (GCONV=1E-8) satisfied.	0.0602
	Absent	289	57.8	67	23.2	222	76.8	37.6	24.9	NE	NE	NE	NE	282	56.4	93	33.0	189	67.0	15.8	12.3	24.3	NE	NE	NE	0.0055	0.64	0.47	0.88	Convergence criterion (GCONV=1E-8) satisfied.	
Double Expressor Lymphoma by IHC (Central Review)	DEL	150	30.0	42	28.0	108	72.0	23.9	10.6	NE	NE	NE	NE	163	32.6	71	43.6	92	56.4	11.8	8.2	13.2	NE	33.2	NE	0.0106	0.61	0.42	0.90	Convergence criterion (GCONV=1E-8) satisfied.	0.0677
	Non DEL	253	50.6	70	27.7	183	72.3	25.3	17.3	NE	NE	NE	NE	244	48.8	65	26.6	179	73.4	24.2	12.5	NE	NE	NE	NE	0.9024	0.98	0.70	1.37	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	97	19.4	27	27.8	70	72.2	24.5	11.8	42.6	42.6	42.6	NE	93	18.6	31	33.3	62	66.7	13.7	7.1	32.0	NE	40.2	NE	0.4628	0.83	0.49	1.38	Convergence criterion (GCONV=1E-8) satisfied.	
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	341	68.2	95	27.9	246	72.1	24.5	17.7	33.8	NE	NE	NE	351	70.2	120	34.2	231	65.8	13.2	12.0	19.3	NE	NE	NE	0.0755	0.78	0.60	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.0197
	DH/TH+	26	5.2	9	34.6	17	65.4	7.5	6.3	NE	NE	25.5	NE	19	3.8	2	10.5	17	89.5	NE	10.0	NE	NE	NE	NE	0.0672	3.79	0.82	17.53	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	133	26.6	35	26.3	98	73.7	25.6	12.3	42.6	NE	42.6	NE	130	26.0	45	34.6	85	65.4	12.6	6.7	20.5	NE	40.2	NE	0.0653	0.66	0.43	1.03	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: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_tte.sas
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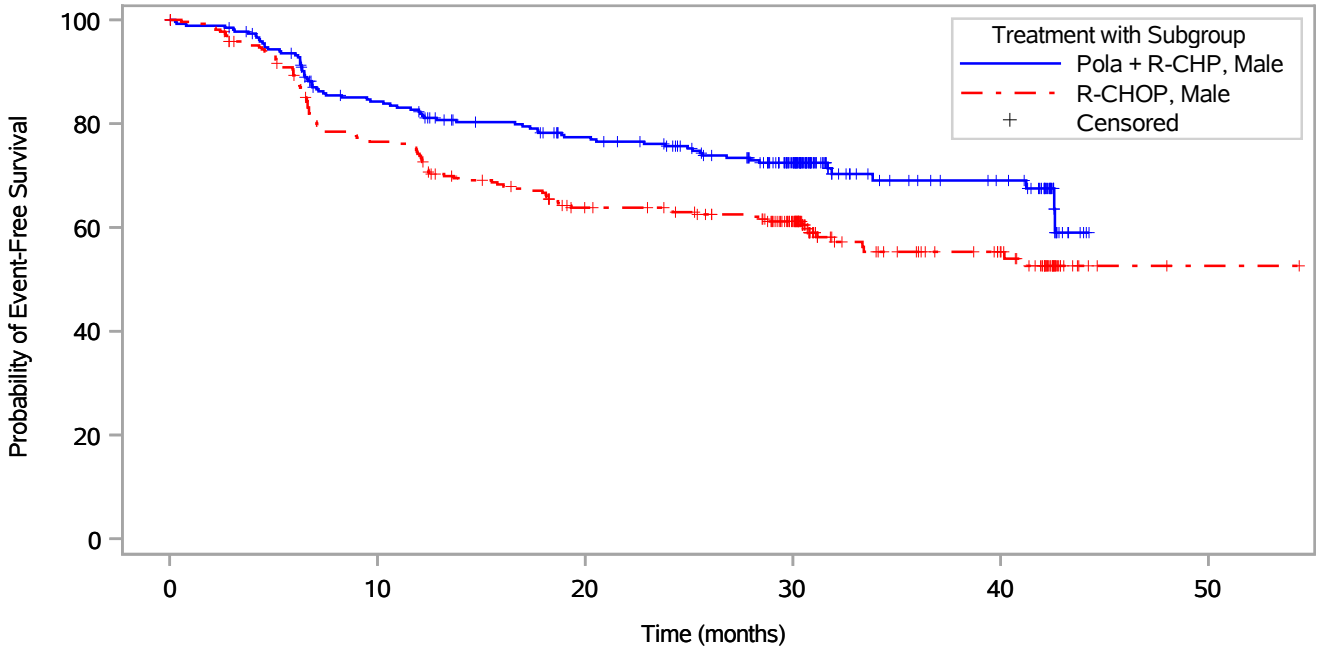
09FEB2023 20:38

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942

Sex



Patients at risk																			
Pola + R-CHP, Male	268	261	245	216	208	195	188	179	173	160	129	58	52	49	37	NE	NE	NE	NE
R-CHOP, Male	270	251	231	200	191	173	165	150	148	139	114	60	53	48	34	2	2	1	1
Patients censored																			
Pola + R-CHP, Male	0	3	6	13	14	22	24	29	33	41	70	139	144	147	158	NE	NE	NE	NE
R-CHOP, Male	0	8	11	12	12	17	19	27	29	35	57	106	111	116	128	160	161	161	161

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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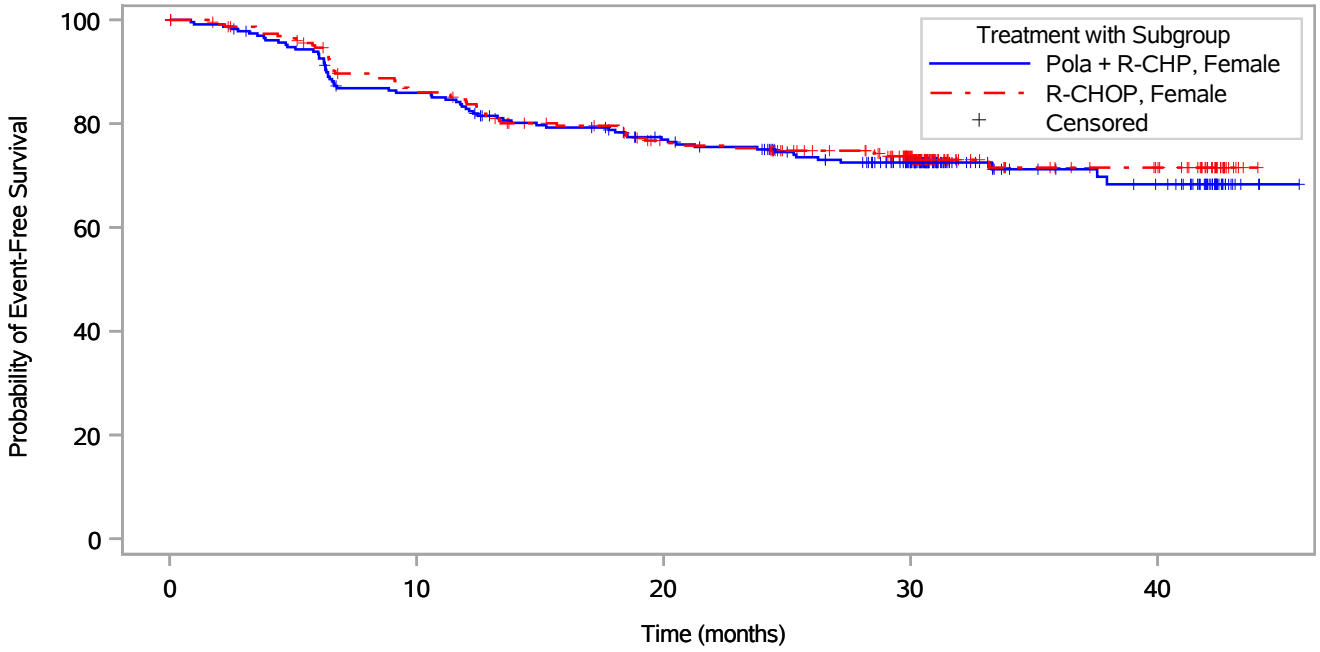
13MAR2023 19:43

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942

Sex



Patients at risk																
Pola + R-CHP, Female	232	224	214	195	187	176	171	160	156	143	118	57	49	47	29	1
R-CHOP, Female	230	221	210	195	184	171	168	155	154	141	115	48	41	39	25	NE
Patients censored																
Pola + R-CHP, Female	0	3	4	6	6	10	13	18	20	29	53	114	121	121	139	167
R-CHOP, Female	0	6	8	10	11	15	17	22	22	34	58	124	130	132	146	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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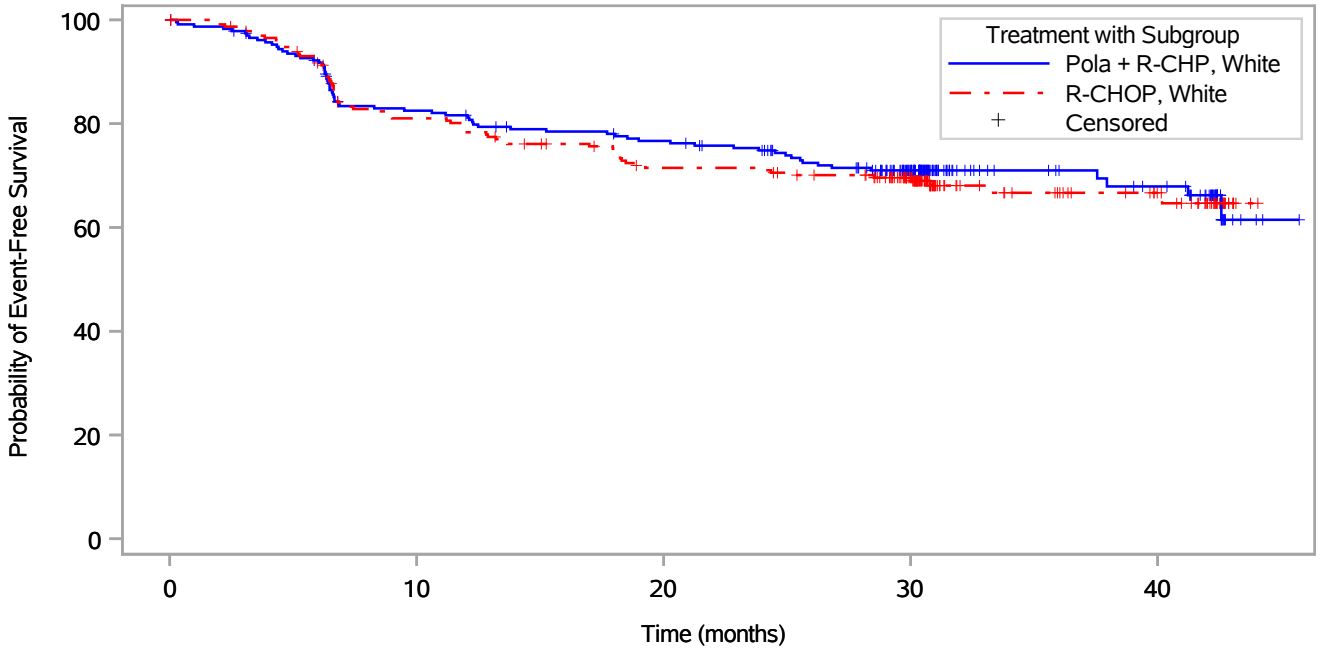
13MAR2023 19:43

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942
Race/ethnicity



Patients at risk																
Pola + R-CHP, White	235	226	211	187	183	175	172	167	161	149	117	51	47	44	33	1
R-CHOP, White	236	225	208	182	175	168	163	154	154	147	117	49	43	38	24	NE
Patients censored																
Pola + R-CHP, White	0	4	6	9	10	12	13	14	17	22	53	119	123	124	134	165
R-CHOP, White	0	6	9	12	12	14	17	18	18	22	51	117	122	127	140	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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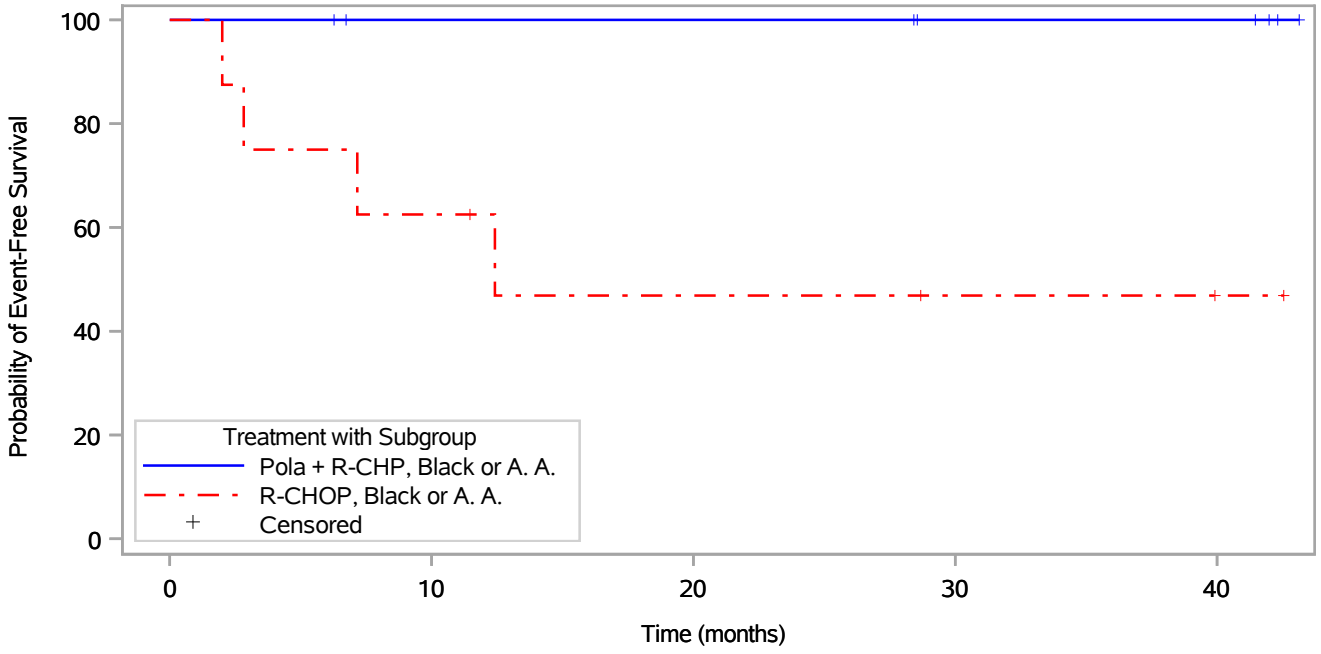
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942
Race/ethnicity



Patients at risk															
Pola + R-CHP, Black or A. A.	8	8	8	6	6	6	6	6	6	6	4	4	4	4	2
R-CHOP, Black or A. A.	8	6	6	5	4	3	3	3	3	3	2	2	2	2	1
Patients censored															
Pola + R-CHP, Black or A. A.	0	0	0	2	2	2	2	2	2	2	4	4	4	4	6
R-CHOP, Black or A. A.	0	0	0	0	1	1	1	1	1	1	2	2	2	2	3

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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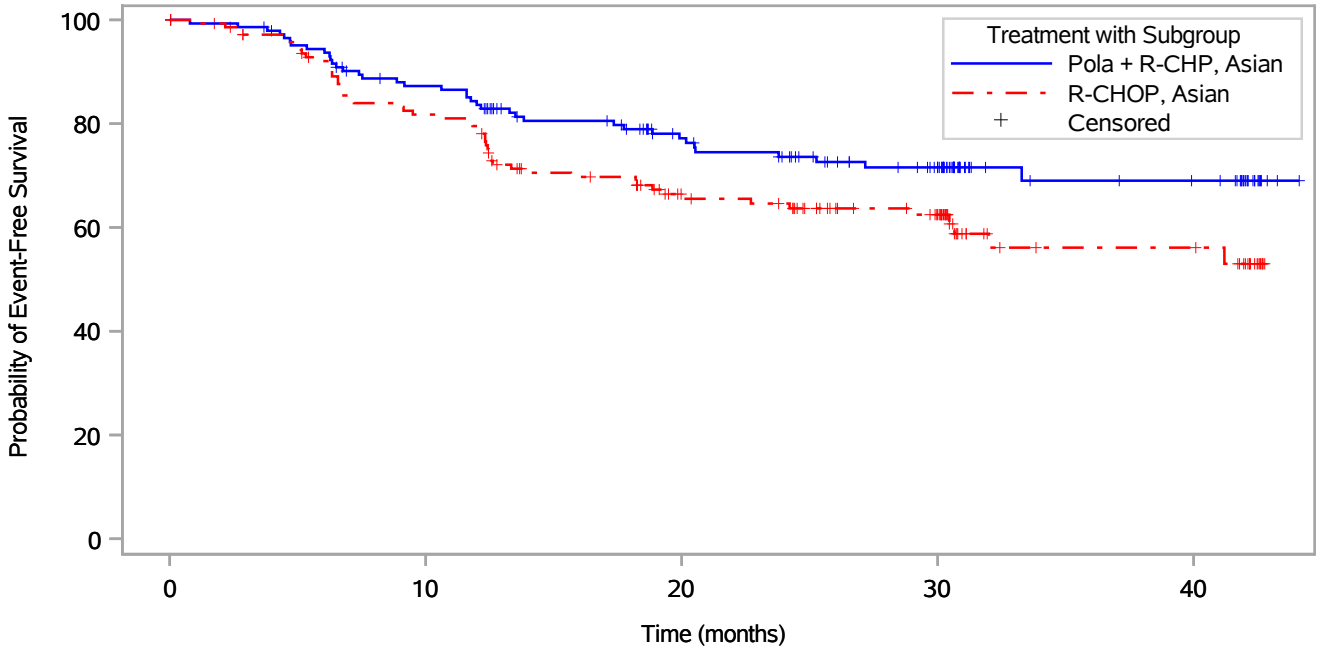
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942
Race/ethnicity



Patients at risk															
Pola + R-CHP, Asian	145	142	134	121	115	102	97	83	80	69	60	28	26	25	15
R-CHOP, Asian	145	134	125	114	108	89	87	71	69	54	48	20	19	19	14
Patients censored															
Pola + R-CHP, Asian	0	1	3	7	7	16	19	28	30	40	48	80	81	82	92
R-CHOP, Asian	0	7	9	9	9	16	17	28	29	43	48	73	74	74	78

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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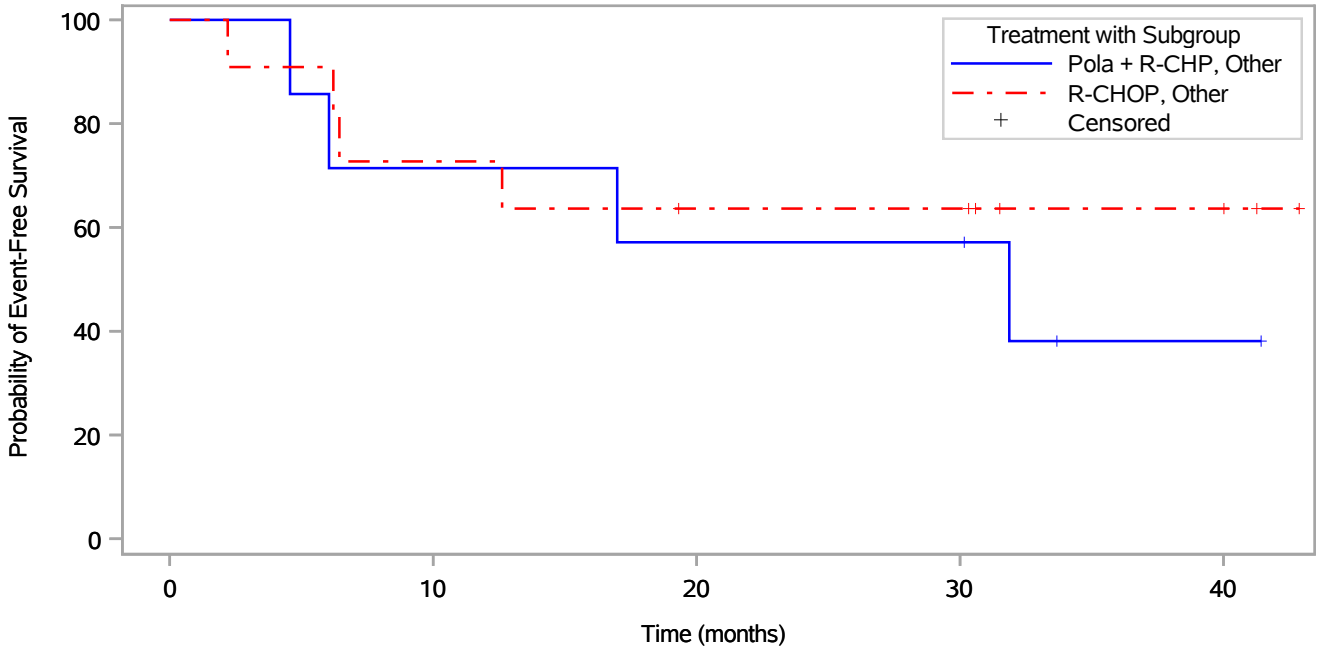
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942
Race/ethnicity



Patients at risk															
Pola + R-CHP, Other	7	7	6	5	5	5	4	4	4	4	4	2	1	1	NE
R-CHOP, Other	11	10	10	8	8	7	7	6	6	6	6	3	3	3	1
Patients censored															
Pola + R-CHP, Other	0	0	0	0	0	0	0	0	0	0	0	1	2	2	NE
R-CHOP, Other	0	0	0	0	0	0	0	1	1	1	1	4	4	4	6

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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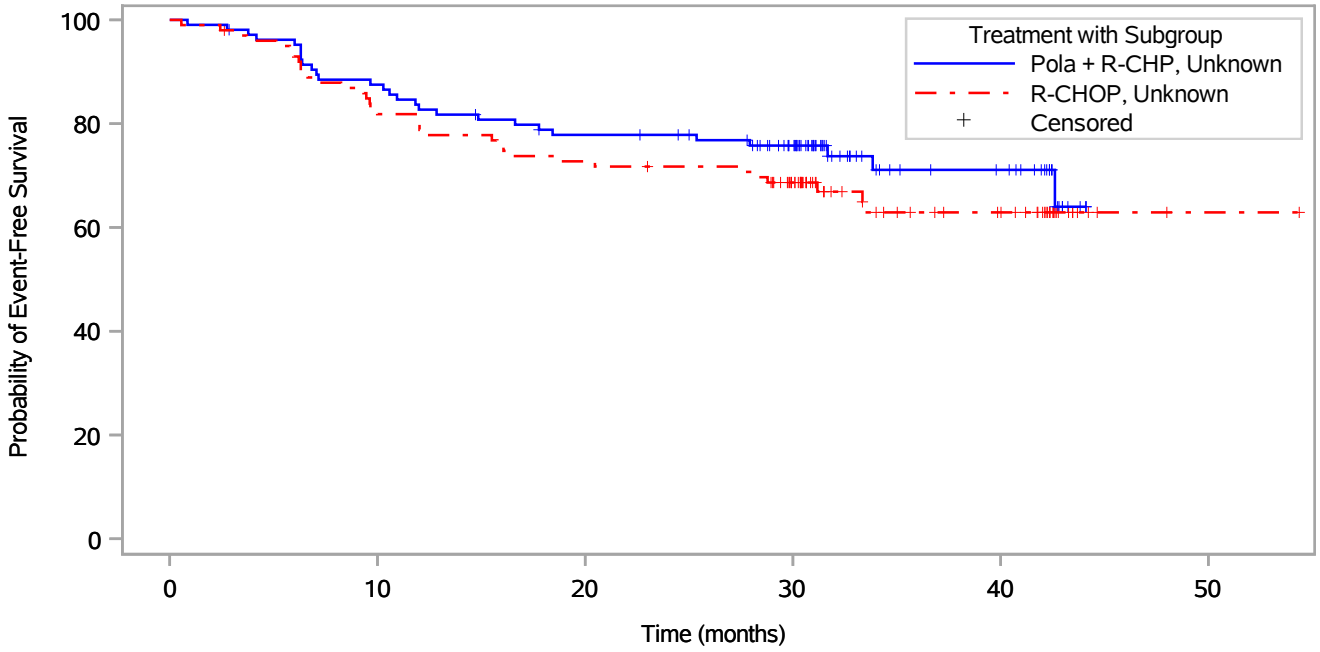
13MAR2023 19:43

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942
Race/ethnicity



Patients at risk																			
Pola + R-CHP, Unknown	105	102	100	92	86	83	80	79	78	75	62	30	23	22	16	NE	NE	NE	NE
R-CHOP, Unknown	100	97	92	86	80	77	73	71	70	70	56	34	27	25	19	2	2	1	1
Patients censored																			
Pola + R-CHP, Unknown	0	1	1	1	1	2	3	3	4	6	18	49	55	56	62	NE	NE	NE	NE
R-CHOP, Unknown	0	1	1	1	1	1	1	1	2	2	13	34	39	41	47	64	65	65	65

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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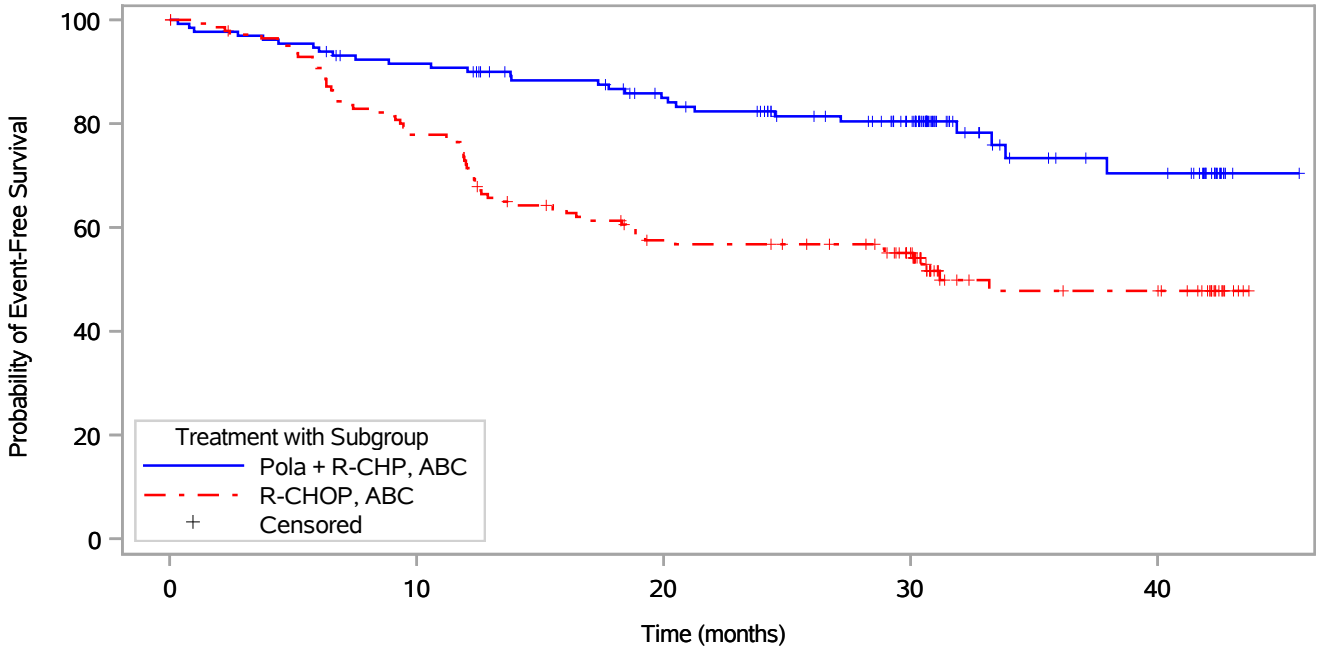
13MAR2023 19:43

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942
Cell of origin

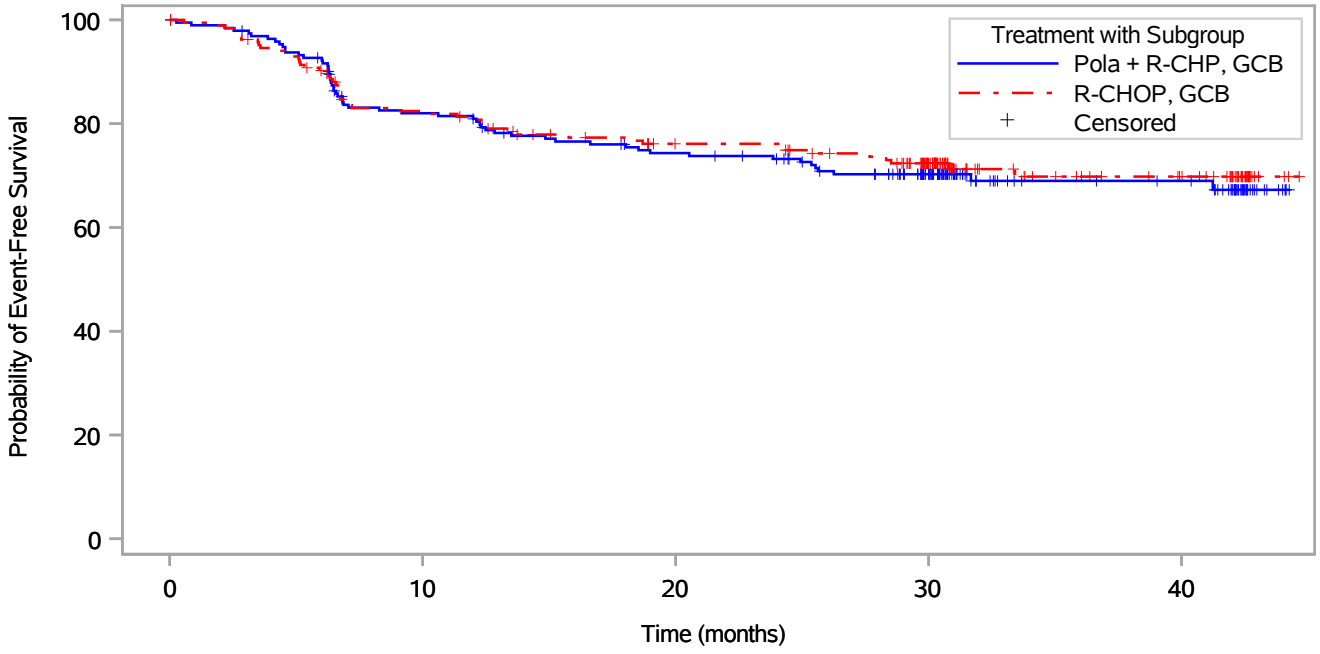


Patients at risk																
Pola + R-CHP, ABC	131	127	124	117	116	107	104	95	92	83	71	33	26	24	14	1
R-CHOP, ABC	143	136	127	115	101	88	83	74	74	70	58	24	23	22	17	NE
Patients censored																
Pola + R-CHP, ABC	0	0	0	3	3	9	10	15	17	25	36	73	78	79	89	102
R-CHOP, ABC	0	3	3	3	3	5	6	9	9	13	23	53	53	54	59	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942

Cell of origin

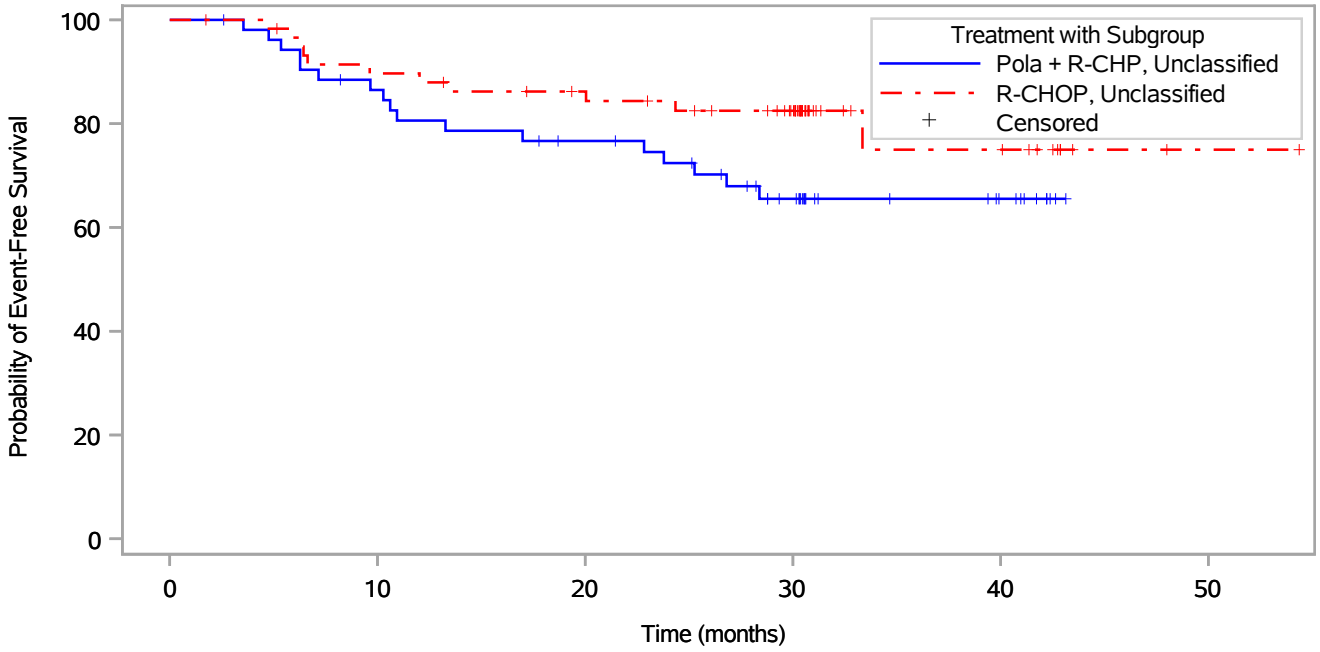


Patients at risk															
Pola + R-CHP, GCB	193	187	176	153	149	140	136	132	128	118	94	46	43	42	32
R-CHOP, GCB	187	178	164	147	144	133	130	124	124	116	92	50	43	39	28
Patients censored															
Pola + R-CHP, GCB	0	2	3	7	8	10	12	12	15	20	44	91	94	95	104
R-CHOP, GCB	0	2	5	8	9	14	16	20	20	25	46	87	93	97	108

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942

Cell of origin



Patients at risk																			
Pola + R-CHP, Unclassified	53	52	49	45	41	40	38	37	34	30	24	13	12	12	5	NE	NE	NE	NE
R-CHOP, Unclassified	60	59	56	53	52	49	48	46	45	42	37	11	10	10	7	2	2	1	1
Patients censored																			
Pola + R-CHP, Unclassified	0	1	1	2	2	2	3	4	5	7	12	23	24	24	31	NE	NE	NE	NE
R-CHOP, Unclassified	0	1	2	2	2	3	4	5	6	8	13	39	39	39	42	47	48	48	48

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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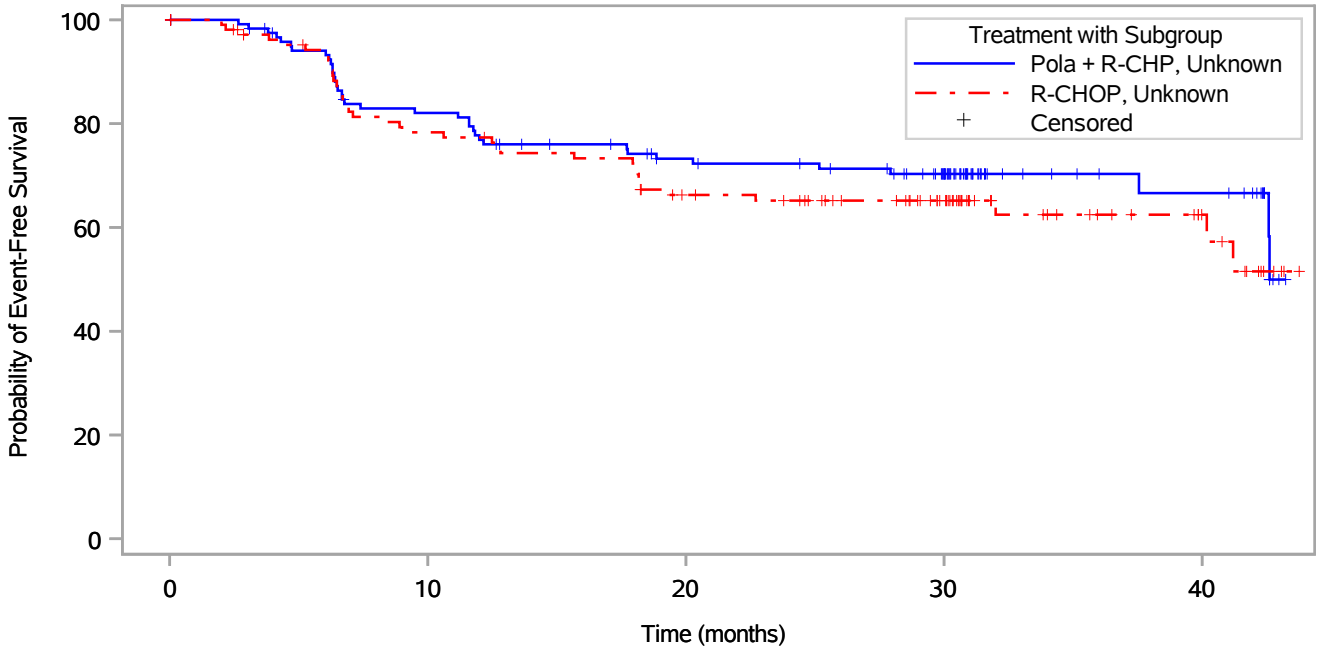
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942
Cell of origin



Patients at risk															
Pola + R-CHP, Unknown	123	119	110	96	89	84	81	75	75	72	58	23	20	18	15
R-CHOP, Unknown	110	99	94	80	78	74	72	61	59	52	42	23	18	16	7
Patients censored															
Pola + R-CHP, Unknown	0	3	6	7	7	11	12	16	16	18	31	66	69	70	73
R-CHOP, Unknown	0	8	9	9	9	10	10	15	16	23	33	51	56	58	65

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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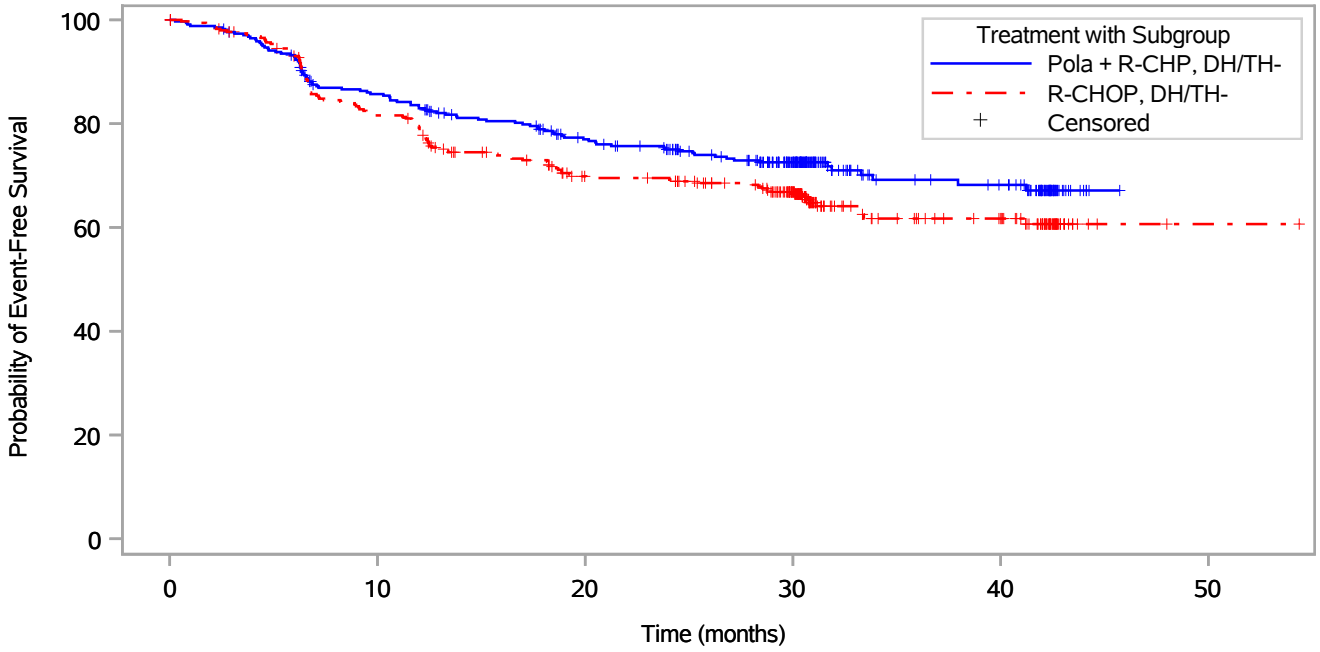
13MAR2023 19:43

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942

Double/Triple-Hit Lymphoma (Central Review)



Patients at risk																			
Pola + R-CHP, DH/TH-	341	330	314	285	273	258	248	233	224	207	163	81	72	70	45	1	NE	NE	NE
R-CHOP, DH/TH-	351	337	318	284	269	245	237	217	216	201	168	81	71	66	48	2	2	1	1
Patients censored																			
Pola + R-CHP, DH/TH-	0	3	4	11	11	19	23	29	35	47	89	169	176	177	201	245	NE	NE	NE
R-CHOP, DH/TH-	0	6	9	10	11	19	22	31	32	44	72	154	161	166	183	229	230	230	230

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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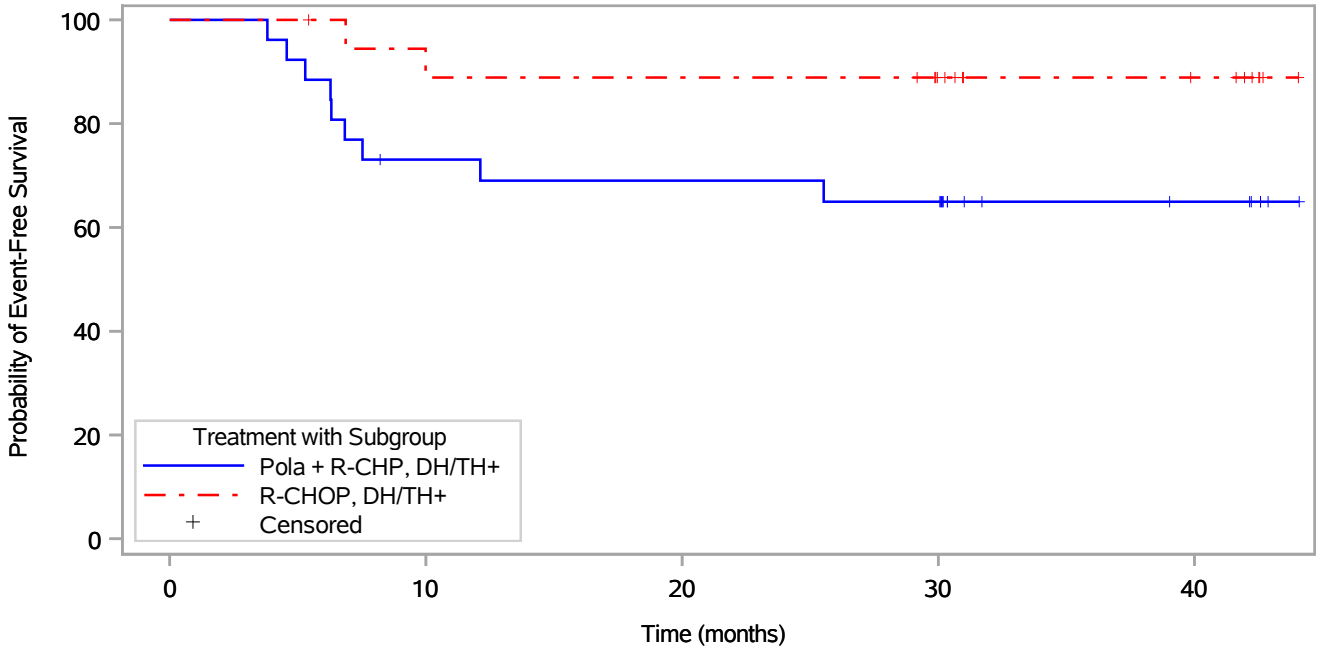
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942

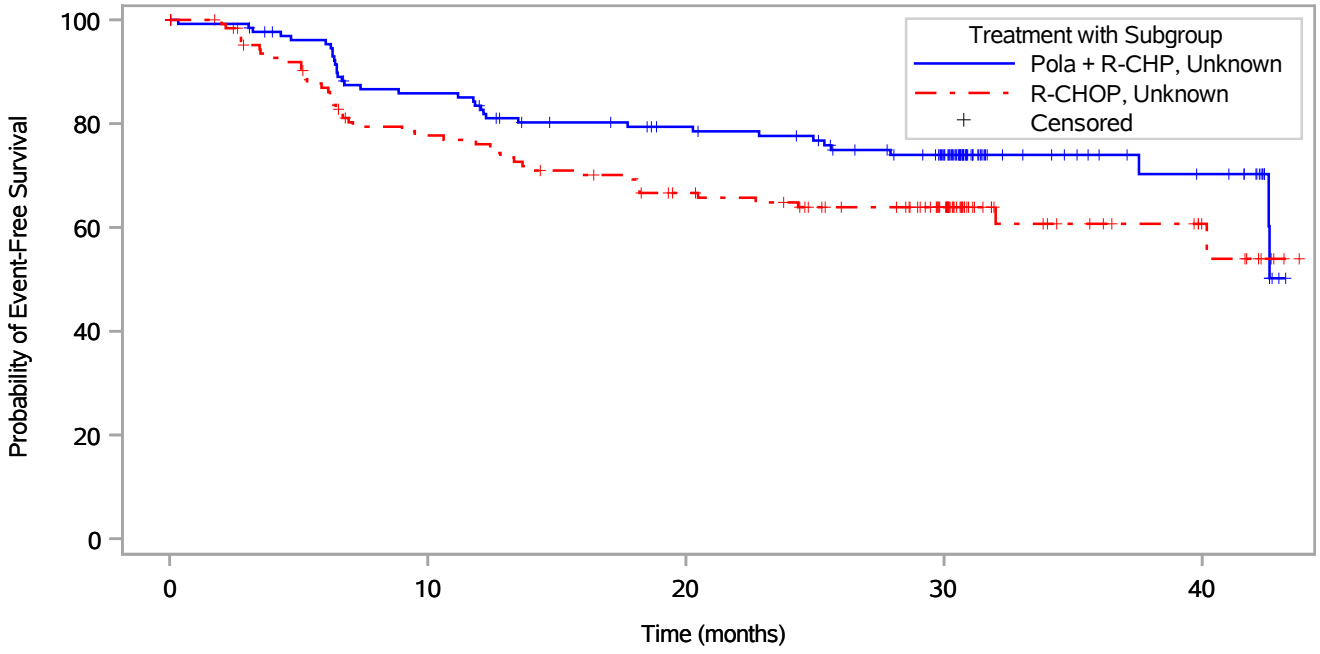
Double/Triple-Hit Lymphoma (Central Review)



Patients at risk															
Pola + R-CHP, DH/TH+	26	26	23	18	18	17	17	17	17	16	16	7	7	7	6
R-CHOP, DH/TH+	19	19	18	17	16	16	16	16	16	16	12	8	8	8	5
Patients censored															
Pola + R-CHP, DH/TH+	0	0	0	1	1	1	1	1	1	1	1	10	10	10	11
R-CHOP, DH/TH+	0	0	1	1	1	1	1	1	1	1	5	9	9	9	12

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
STUDY: GO39942
Double/Triple-Hit Lymphoma (Central Review)



Patients at risk															
Pola + R-CHP, Unknown	133	129	122	108	104	96	94	89	88	80	68	27	22	19	15
R-CHOP, Unknown	130	116	105	94	90	83	80	72	70	63	49	19	15	13	6
Patients censored															
Pola + R-CHP, Unknown	0	3	6	7	8	12	13	17	17	22	33	74	79	81	85
R-CHOP, Unknown	0	8	9	11	11	12	13	17	18	24	38	67	71	73	79

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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13MAR2023 19:43

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS - Efficacy, INV)
MODEL: descriptive
STUDY: GO39942
Overview of EFS First Contributing Event

	Polatuzumab Vedotin + R-CHP (N=500)		R-CHOP (N=500)	
	Patients		Patients	
Type of Event	Number of Patients with Event[1]	%	Number of Patients with Event[1]	%
EFS	139	27,8	167	33,4
Death	22	4,4	25	5,0
Progression Disease	104	20,8	126	25,2
NALT due to efficacy reasons	12	2,4	10	2,0
Positive biopsy	1	0,2	6	1,2

[1] Number of Patients with this Event as "first contributing event"
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_efs.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_efs_EFSEFF_IT_POOLED_15JUN2022_39942.xls
27OCT2023 17:24

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)												R-CHOP (N=500)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	500	100,0	169	33,8	331	66,2	11,6	7,1	18,5	NE	NE	NE	500	100,0	199	39,8	301	60,2	7,1	6,7	11,9	NE	41,2	NE	0,0301	0,80	0,65	0,98		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_tte.sas
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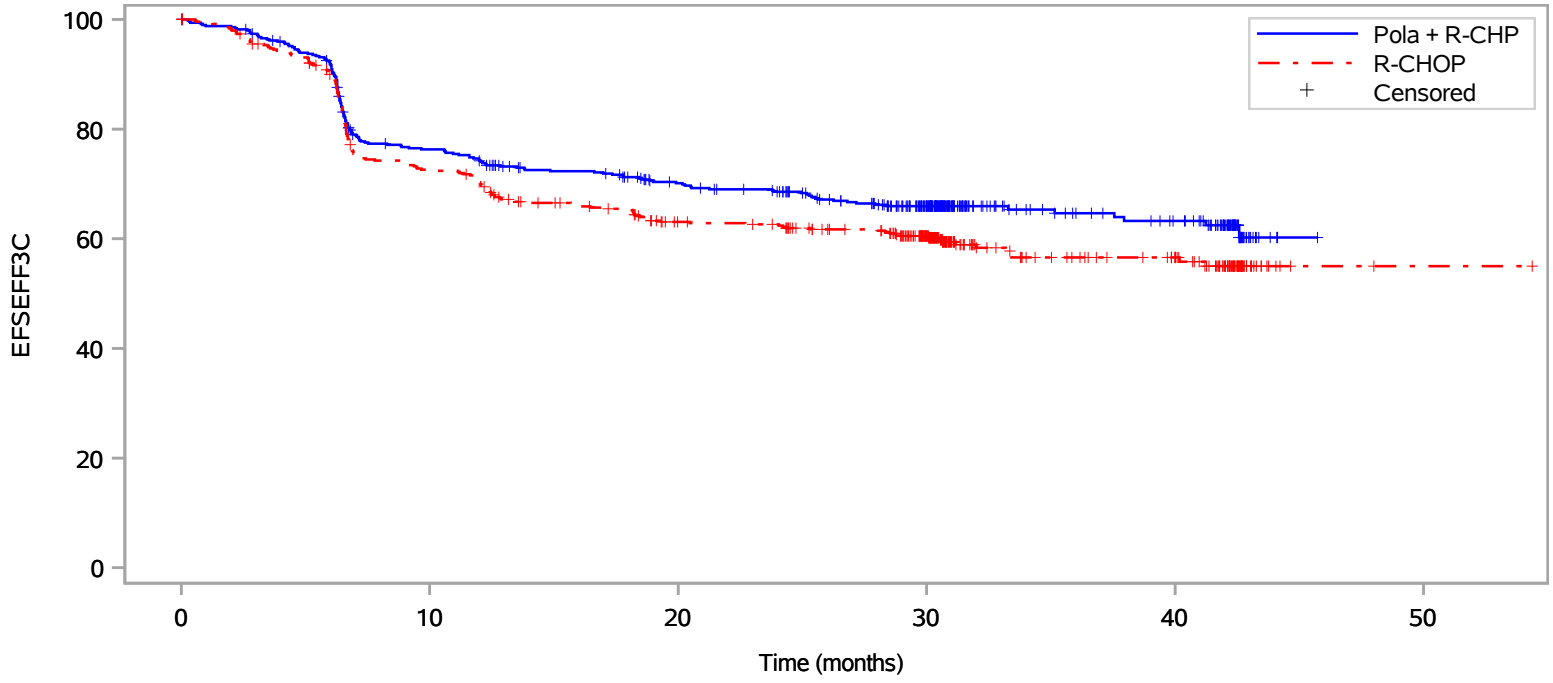
07JUL2023 8:01

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942



Patients at risk																			
Pola + R-CHP	500	481	451	369	356	337	327	309	301	278	226	107	95	90	62	1	NE	NE	NE
R-CHOP	500	468	435	357	338	312	303	279	276	258	209	100	88	82	56	2	2	1	1
Patients censored																			
Pola + R-CHP	0	6	9	17	18	28	33	42	47	62	111	230	240	243	270	330	NE	NE	NE
R-CHOP	0	10	16	17	18	26	30	42	44	58	102	206	215	221	245	299	300	300	300

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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07JUL2023 8:01

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
MODEL: Unstratified Analysis
STUDY: GO39942
Time to Event Analysis by Subgroups (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)												R-CHOP (N=500)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	Convergence Status	p-value (likelihood ratio)
All	n/a	500	100,0	169	33,8	331	66,2	11,6	7,1	18,5	NE	NE	NE	500	100,0	199	39,8	301	60,2	7,1	6,7	11,9	NE	41,2	NE	0,0496	0,81	0,66	1,00	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	268	53,6	91	34,0	177	66,0	10,9	6,2	20,5	NE	42,6	NE	270	54,0	125	46,3	145	53,7	6,7	6,5	7,1	33,4	25,3	NE	0,0045	0,68	0,52	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,0414
	Female	232	46,4	78	33,6	154	66,4	12,0	6,8	23,8	NE	NE	NE	230	46,0	74	32,2	156	67,8	12,6	9,4	24,3	NE	NE	NE	0,7837	1,05	0,76	1,44	Convergence criterion (GCONV=1E-8) satisfied.	
Age	<= 60	167	33,4	59	35,3	108	64,7	6,8	6,3	18,9	NE	NE	NE	158	31,6	63	39,9	95	60,1	6,7	6,5	9,4	NE	32,0	NE	0,3983	0,86	0,61	1,22	Convergence criterion (GCONV=1E-8) satisfied.	0,7163
	> 60	333	66,6	110	33,0	223	67,0	12,3	8,8	25,3	NE	NE	NE	342	68,4	136	39,8	206	60,2	10,9	6,7	12,5	NE	40,2	NE	0,0647	0,79	0,61	1,02	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Western Europe/United States/Canada/Australia	302	60,4	95	31,5	207	68,5	12,0	6,2	25,4	NE	NE	NE	301	60,2	114	37,9	187	62,1	9,0	6,6	12,8	NE	NE	NE	0,1457	0,82	0,62	1,07	Convergence criterion (GCONV=1E-8) satisfied.	0,2586
	Asia	141	28,2	45	31,9	96	68,1	17,3	7,6	27,2	NE	NE	NE	140	28,0	60	42,9	80	57,1	7,2	6,6	12,5	41,2	24,2	NE	0,0388	0,67	0,45	0,98	Convergence criterion (GCONV=1E-8) satisfied.	
	Rest of World	57	11,4	29	50,9	28	49,1	6,6	6,1	17,0	37,6	17,0	NE	59	11,8	25	42,4	34	57,6	6,6	6,3	18,1	NE	18,1	NE	0,6674	1,13	0,66	1,93	Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	235	47,0	87	37,0	148	63,0	6,7	6,3	18,5	NE	42,6	NE	236	47,2	83	36,9	149	63,1	6,8	6,5	12,9	NE	NE	NE	0,9805	1,00	0,73	1,35	Convergence criterion (GCONV=1E-8) satisfied.	0,0024
	Black or African American	8	1,6	0	0,0	8	100,0	NE	NE	NE	NE	NE	NE	8	1,6	5	62,5	3	37,5	4,0	2,0	12,4	9,5	2,8	NE	0,0094	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	145	29,0	46	31,7	99	68,3	13,8	8,8	27,2	NE	NE	NE	145	29,0	62	42,8	83	57,2	7,2	6,6	12,4	41,2	24,2	NE	0,0314	0,68	0,45	0,97	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	7	1,4	5	71,4	2	28,6	6,0	4,6	17,0	8,8	6,0	NE	11	2,2	4	36,4	7	63,6	6,4	2,2	NE	NE	6,6	NE	0,1961	2,33	0,62	8,73	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	105	21,0	31	29,5	74	70,5	17,8	7,2	NE	NE	NE	NE	100	20,0	41	41,0	59	59,0	11,0	6,6	20,5	NE	33,4	NE	0,1425	0,73	0,44	1,13	Convergence criterion (GCONV=1E-8) satisfied.	
ECOG performance status	0-1	419	83,8	141	33,7	278	66,3	12,1	7,0	20,2	NE	NE	NE	416	83,2	163	39,7	253	60,3	9,4	6,8	12,3	NE	40,2	NE	0,0832	0,82	0,65	1,03	Convergence criterion (GCONV=1E-8) satisfied.	0,7654
	2	81	16,2	28	34,6	53	65,4	7,2	6,4	NE	NE	NE	NE	82	16,4	34	41,5	48	58,5	6,5	5,8	9,5	NE	16,5	NE	0,2739	0,76	0,46	1,25	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	2	0,4	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cell of origin (determined by gene expression)	ABC	131	26,2	32	24,4	99	75,6	33,3	18,4	NE	NE	NE	NE	143	28,6	71	49,7	72	50,3	9,5	6,7	12,0	30,7	18,3	NE	<.0001	0,41	0,27	0,63	Convergence criterion (GCONV=1E-8) satisfied.	0,0003
	GCB	193	38,6	76	39,4	117	60,6	6,8	6,4	12,1	NE	NE	NE	187	37,4	65	34,8	122	65,2	6,8	6,8	18,7	NE	NE	NE	0,3858	1,16	0,83	1,61	Convergence criterion (GCONV=1E-8) satisfied.	
	Unclassified	53	10,6	19	35,8	34	64,2	10,6	6,4	NE	NE	28,4	NE	60	12,0	17	28,3	43	71,7	13,4	6,5	NE	NE	33,4	NE	0,4545	1,28	0,67	2,47	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	123	24,6	42	34,1	81	65,9	7,4	6,6	27,9	NE	42,6	NE	110	22,0	46	41,8	64	58,2	6,7	6,3	12,6	41,2	18,2	NE	0,1862	0,75	0,50	1,15	Convergence criterion (GCONV=1E-8) satisfied.	
IPI score at Screening	1-2	188	37,6	55	29,3	133	70,7	18,5	6,7	NE	NE	NE	NE	187	37,4	57	30,5	130	69,5	18,2	6,8	33,4	NE	NE	NE	0,8749	0,97	0,67	1,41	Convergence criterion (GCONV=1E-8) satisfied.	0,0874
	3	199	39,8	62	31,2	137	68,8	17,3	8,3	27,2	NE	NE	NE	186	37,2	85	45,7	101	54,3	6,7	6,4	11,1	40,2	24,3	NE	0,0033	0,61	0,44	0,85	Convergence criterion (GCONV=1E-8) satisfied.	
	4-5	113	22,6	52	46,0	61	54,0	6,7	6,3	9,7	37,9	23,8	NE	127	25,4	57	44,9	70	55,1	6,8	6,5	12,0	NE	18,2	NE	0,9816	1,00	0,69	1,46	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline Bulky Disease	Present	211	42,2	88	41,7	123	58,3	6,8	6,4	9,2	NE	33,3	NE	218	43,6	99	45,4	119	54,6	6,5	6,3	6,7	NE	18,2	NE	0,4108	0,89	0,66	1,18	Convergence criterion (GCONV=1E-8) satisfied.	0,4265
	Absent	289	57,8	81	28,0	208	72,0	23,9	12,8	42,6	NE	NE	NE	282	56,4	100	35,5	182	64,5	12,5	11,6	18,9	NE	NE	NE	0,0510	0,73	0,56	1,00	Convergence criterion (GCONV=1E-8) satisfied.	
Double Expressor Lymphoma by IHC (Central Review)	DEL	150	30,0	49	32,7	101	67,3	12,0	6,6	33,3	NE	NE	NE	163	32,6	78	47,9	85	52,1	7,2	6,6	11,9	33,4	18,9	NE	0,0177	0,65	0,45	0,93	Convergence criterion (GCONV=1E-8) satisfied.	0,0936
	Non DEL	253	50,6	89	35,2	164	64,8	11,8	6,9	17,9	NE	NE	NE	244	48,8	86	34,4	160	65,6	6,8	6,6	16,3	NE	NE	NE	0,8774	0,98	0,72	1,32	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	97	19,4	31	32,0	66	68,0	11,2	6,4	42,6	42,6	37,6	NE	93	18,6	37	39,8	56	60,2	7,1	6,3	18,1	NE	27,7	NE	0,3174	0,78	0,49	1,26	Convergence criterion (GCONV=1E-8) satisfied.	
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	341	68,2	118	34,6	223	65,4	10,9	6,9	18,9	NE	NE	NE	351	70,2	141	40,2	210	59,8	9,1	6,7	12,3	NE	41,2	NE	0,1707	0,84	0,66	1,08	Convergence criterion (GCONV=1E-8) satisfied.	0,1179
	DH/TH+	26	5,2	10	38,5	16	61,5	6,8	6,2	NE	NE	12,1	NE	19	3,8	4	21,1	15	78,9	NE	6,8	NE	NE	NE	NE	0,2242	2,02	0,63	6,45	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	133	26,6	41	30,8	92	69,2	12,3	6,7	NE	NE	42,6	NE	130	26,0	54	41,5	76	58,5	6,6	6,2	11,9	40,2	22,7	NE	0,0357	0,65	0,43	0,97	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: 15JUN2022

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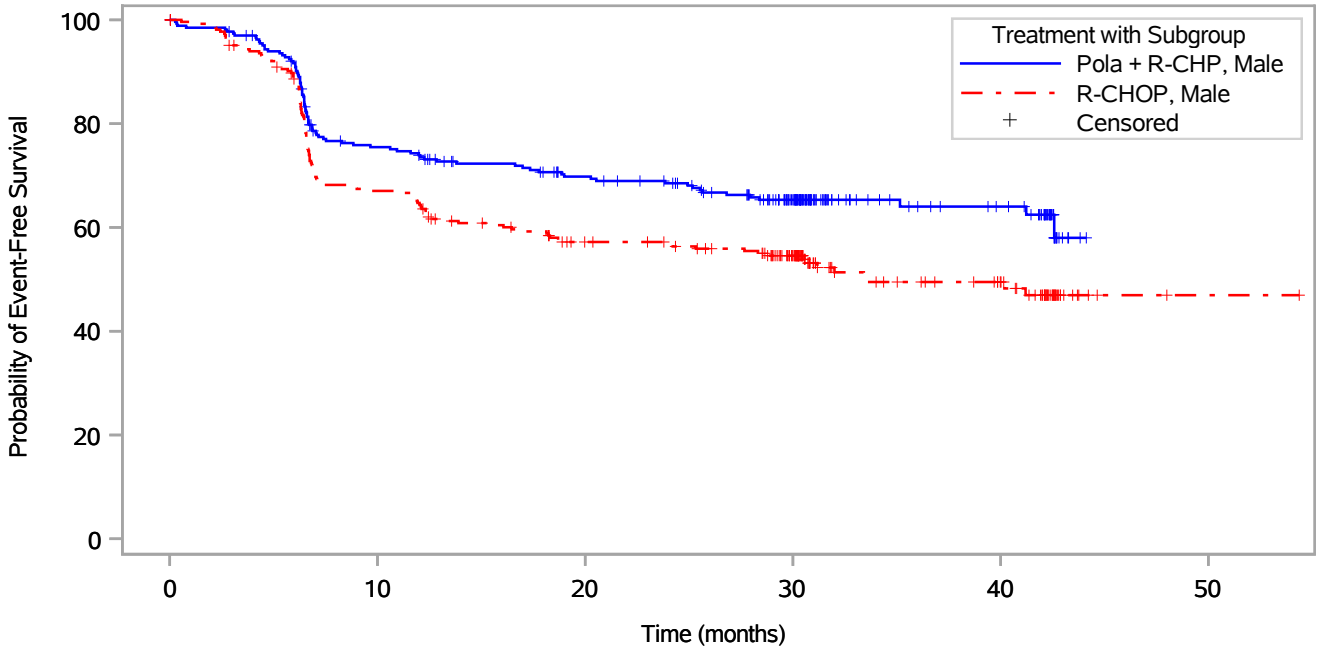
07JUL2023 8:00

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942

Sex



Patients at risk																			
Pola + R-CHP, Male	268	259	240	193	187	176	170	161	157	145	117	54	48	45	34	NE	NE	NE	NE
R-CHOP, Male	270	251	230	176	168	153	147	135	133	126	102	55	50	46	32	2	2	1	1
Patients censored																			
Pola + R-CHP, Male	0	3	6	12	13	20	22	27	30	37	63	126	131	134	144	NE	NE	NE	NE
R-CHOP, Male	0	6	10	10	10	15	17	24	26	30	51	94	97	101	113	143	144	144	144

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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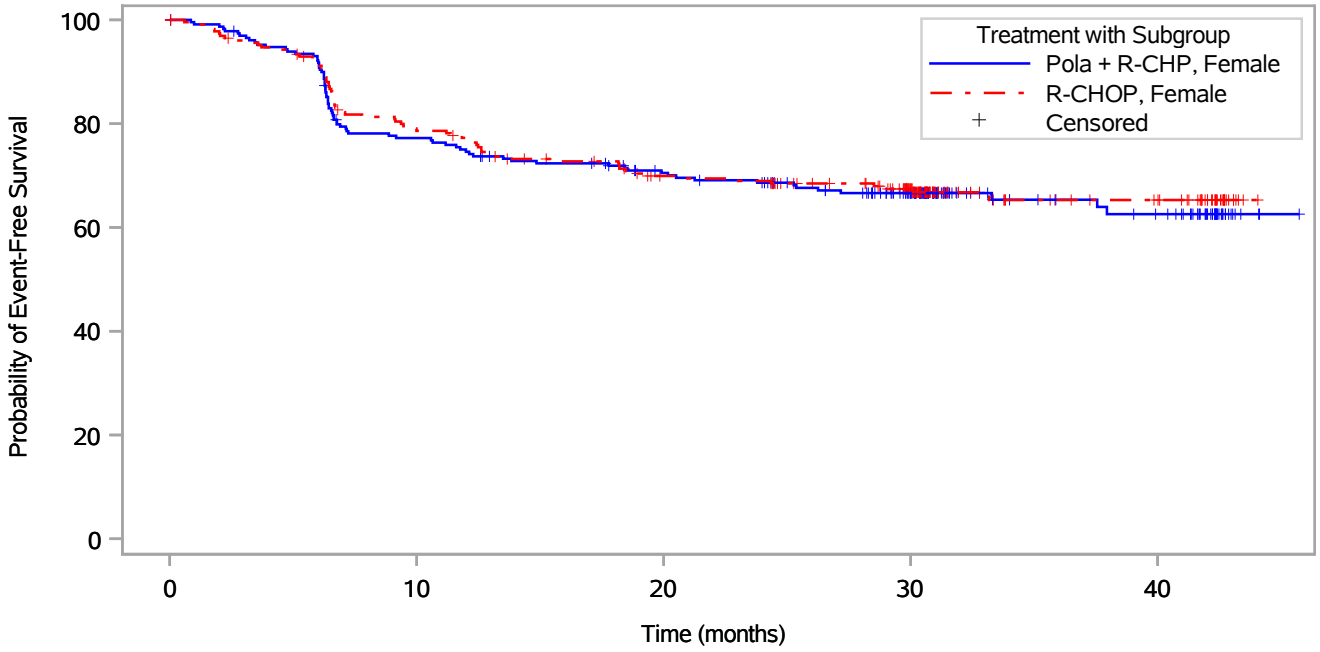
27OCT2023 17:29

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942

Sex



Patients at risk																
Pola + R-CHP, Female	232	222	211	176	169	161	157	148	144	133	109	53	47	45	28	1
R-CHOP, Female	230	217	205	181	170	159	156	144	143	132	107	45	38	36	24	NE
Patients censored																
Pola + R-CHP, Female	0	3	3	5	5	8	11	15	17	25	48	104	109	109	126	153
R-CHOP, Female	0	4	6	7	8	11	13	18	18	28	51	112	118	120	132	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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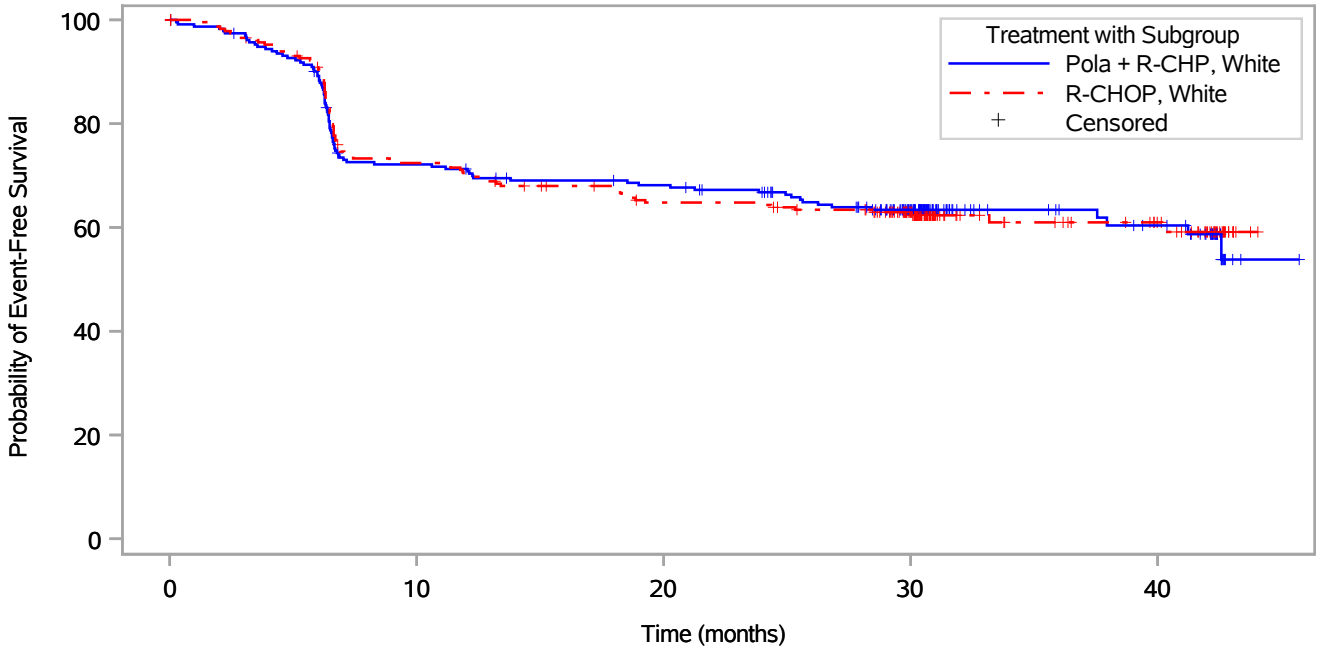
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942
Race/ethnicity



Patients at risk																
Pola + R-CHP, White	235	225	205	164	161	154	153	149	144	133	105	46	43	40	30	1
R-CHOP, White	236	223	207	165	158	152	149	141	141	135	107	46	42	38	24	NE
Patients censored																
Pola + R-CHP, White	0	4	5	7	8	10	11	12	15	20	47	106	109	110	119	147
R-CHOP, White	0	5	8	9	9	11	14	15	15	18	45	105	108	112	125	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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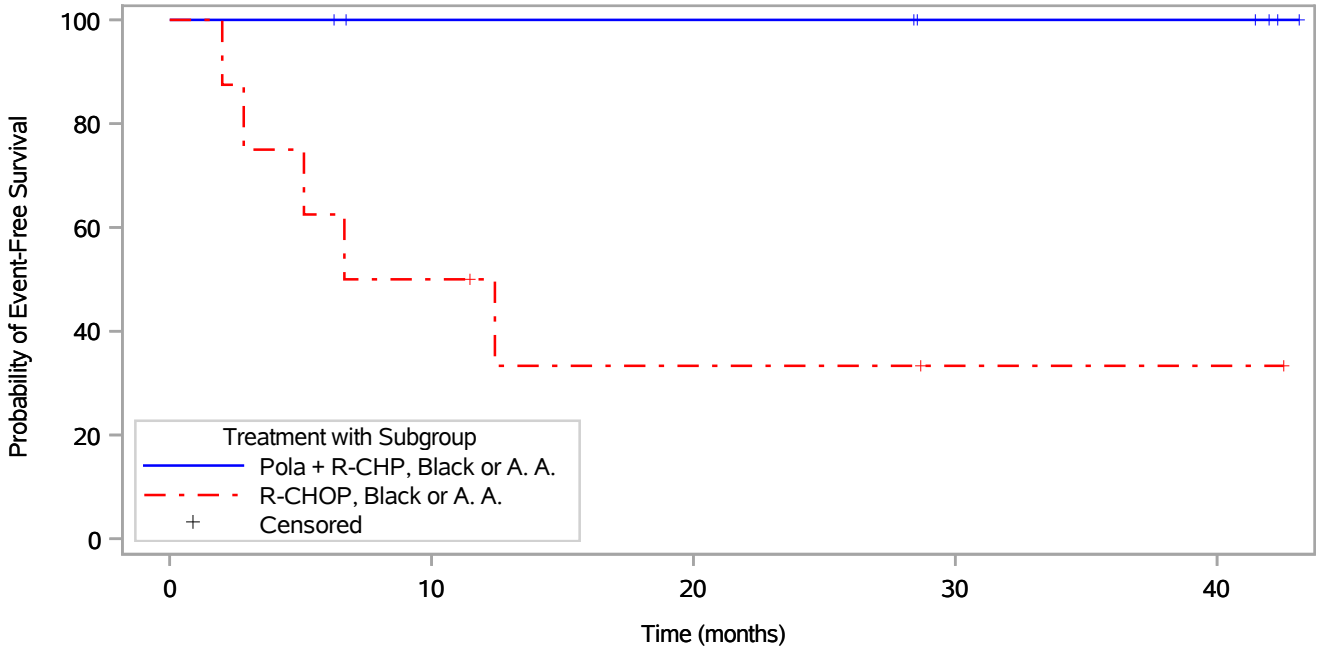
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942
Race/ethnicity



Patients at risk															
Pola + R-CHP, Black or A. A.	8	8	8	6	6	6	6	6	6	6	4	4	4	4	2
R-CHOP, Black or A. A.	8	6	5	4	3	2	2	2	2	2	1	1	1	1	1
Patients censored															
Pola + R-CHP, Black or A. A.	0	0	0	2	2	2	2	2	2	2	4	4	4	4	6
R-CHOP, Black or A. A.	0	0	0	0	1	1	1	1	1	1	2	2	2	2	2

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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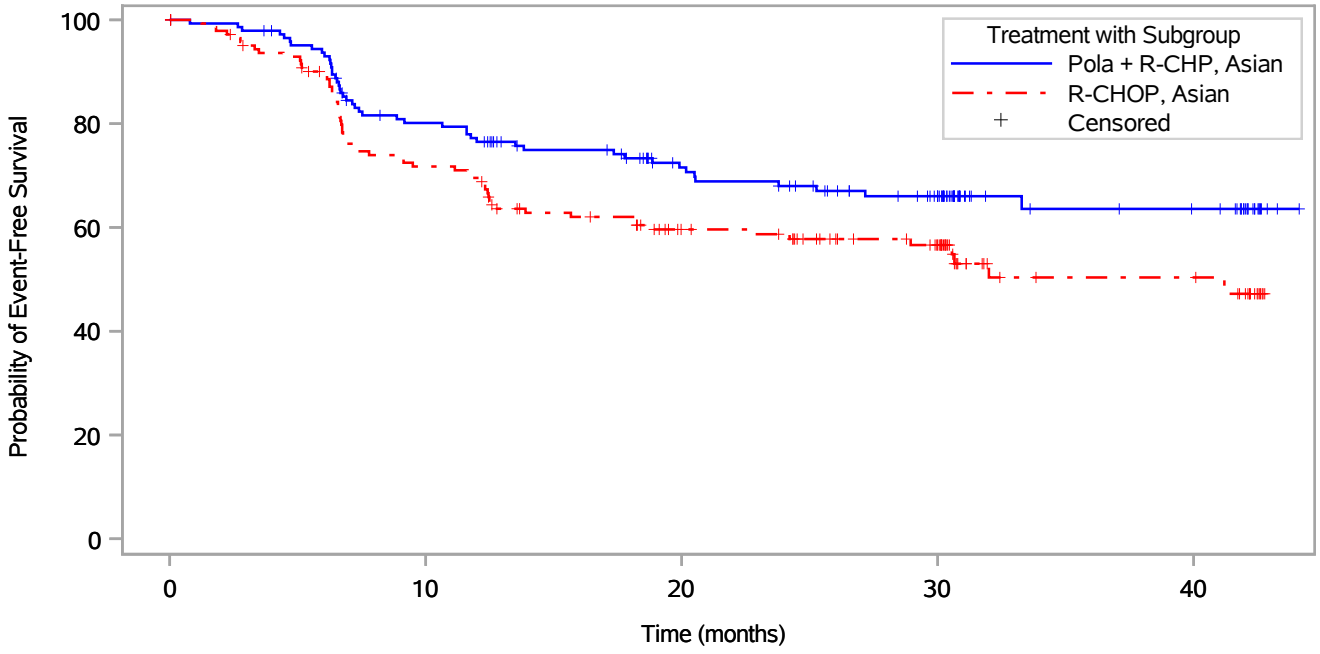
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942
Race/ethnicity

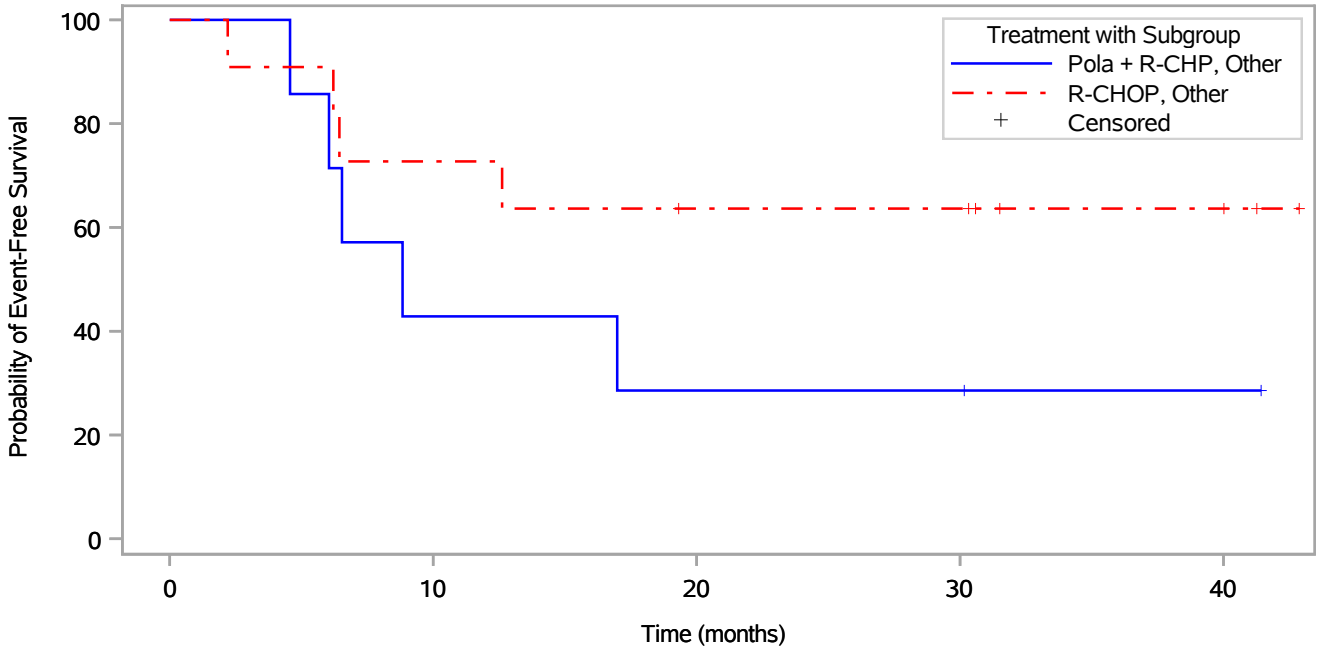


Patients at risk															
Pola + R-CHP, Asian	145	141	133	111	105	95	90	77	75	66	57	27	25	24	15
R-CHOP, Asian	145	133	122	101	95	80	78	65	63	51	45	18	17	17	13
Patients censored															
Pola + R-CHP, Asian	0	1	3	7	7	15	18	26	27	35	43	73	74	75	84
R-CHOP, Asian	0	5	8	8	8	14	15	25	26	37	42	66	67	67	70

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_km_sg1_EFSEFF3c_IT_POOLED_15JUN2022_39942.pdf
27OCT2023 17:29

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942
Race/ethnicity



Patients at risk															
Pola + R-CHP, Other	7	7	6	3	3	3	2	2	2	2	2	1	1	1	NE
R-CHOP, Other	11	10	10	8	8	7	7	6	6	6	6	3	3	3	1
Patients censored															
Pola + R-CHP, Other	0	0	0	0	0	0	0	0	0	0	0	1	1	1	NE
R-CHOP, Other	0	0	0	0	0	0	0	1	1	1	1	4	4	4	6

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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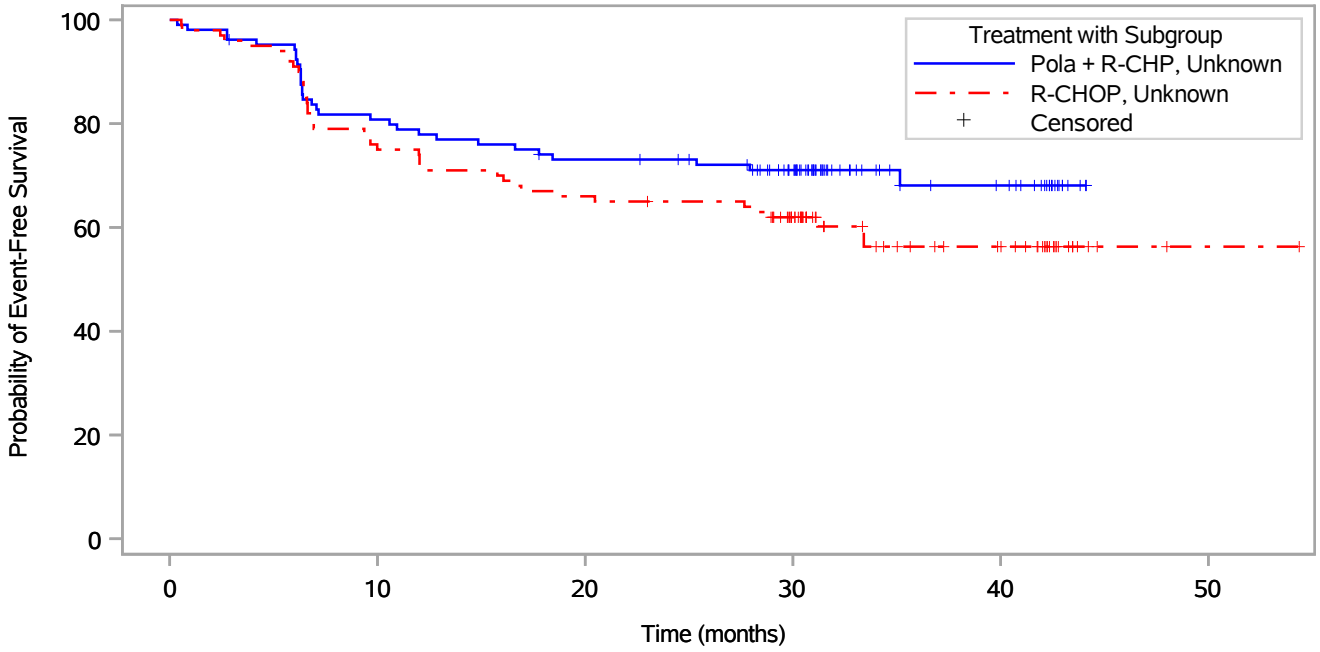
27OCT2023 17:29

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942
Race/ethnicity



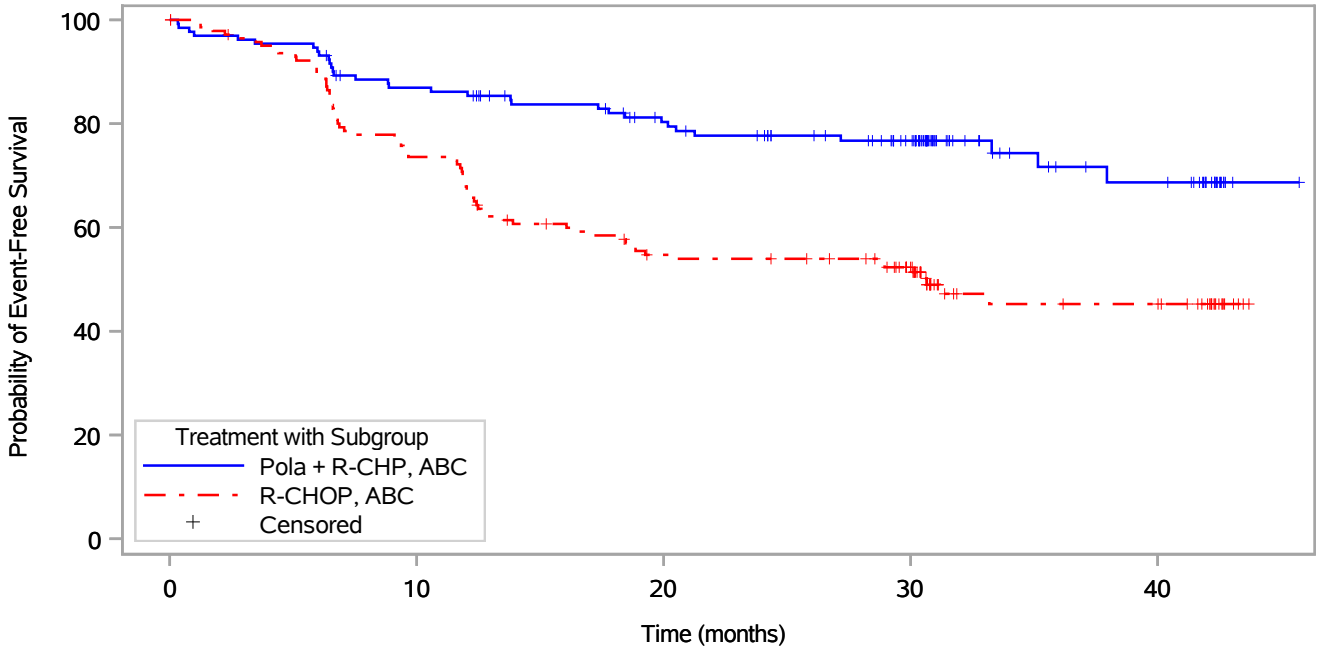
Patients at risk																			
Pola + R-CHP, Unknown	105	100	99	85	81	79	76	75	74	71	58	29	22	21	15	NE	NE	NE	NE
R-CHOP, Unknown	100	96	91	79	74	71	67	65	64	64	50	32	25	23	17	2	2	1	1
Patients censored																			
Pola + R-CHP, Unknown	0	1	1	1	1	1	2	2	3	5	17	46	52	53	59	NE	NE	NE	NE
R-CHOP, Unknown	0	0	0	0	0	0	0	0	1	1	12	29	34	36	42	57	58	58	58

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_km_sg1_EFSEFF3c_IT_POOLED_15JUN2022_39942.pdf
27OCT2023 17:29

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942

Cell of origin

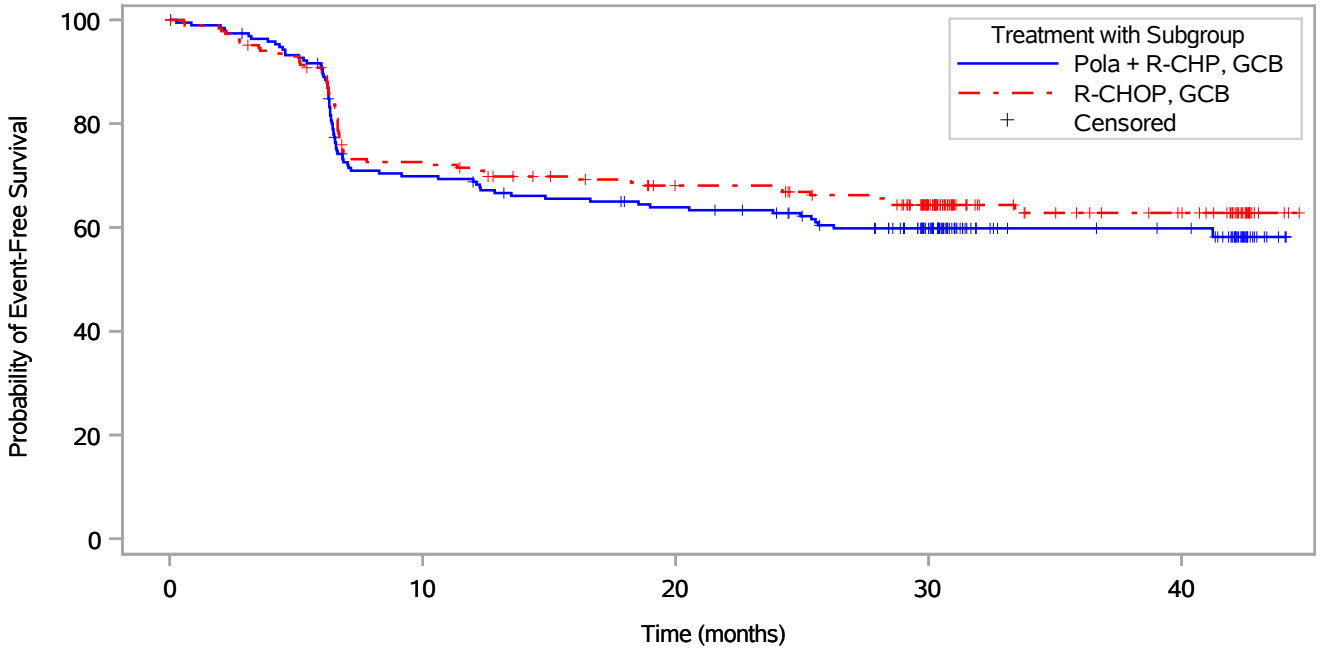


Patients at risk																
Pola + R-CHP, ABC	131	126	123	111	110	101	98	89	87	80	69	32	25	23	14	1
R-CHOP, ABC	143	135	126	109	95	83	79	71	71	68	56	24	23	22	17	NE
Patients censored																
Pola + R-CHP, ABC	0	0	0	3	3	9	10	15	16	23	33	70	75	76	85	98
R-CHOP, ABC	0	3	3	3	3	5	6	8	8	11	21	49	49	50	55	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942

Cell of origin

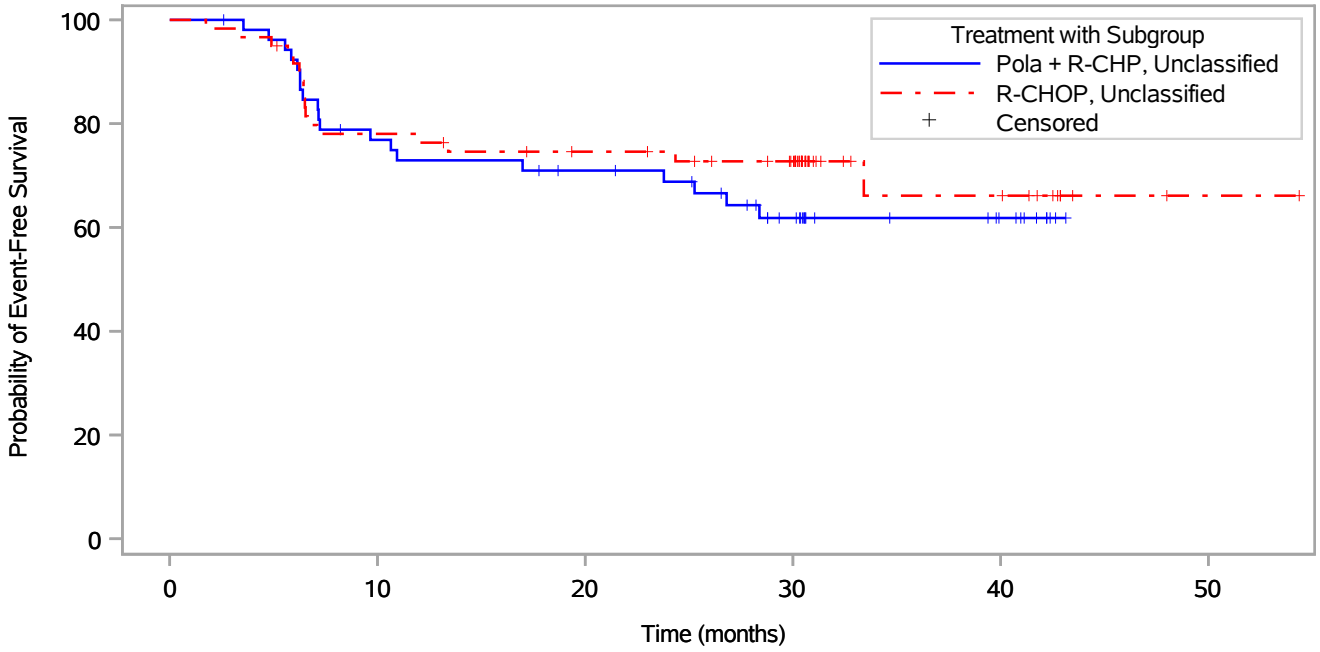


Patients at risk															
Pola + R-CHP, GCB	193	186	173	131	127	120	117	114	110	101	80	40	39	38	29
R-CHOP, GCB	187	176	165	131	128	121	118	112	112	105	81	43	37	34	25
Patients censored															
Pola + R-CHP, GCB	0	2	3	6	7	8	10	10	13	17	38	78	79	80	88
R-CHOP, GCB	0	2	5	6	7	11	13	17	17	21	42	80	85	88	97

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_km_sg1_EFSEFF3c_IT_POOLED_15JUN2022_39942.pdf
27OCT2023 17:29

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942
Cell of origin

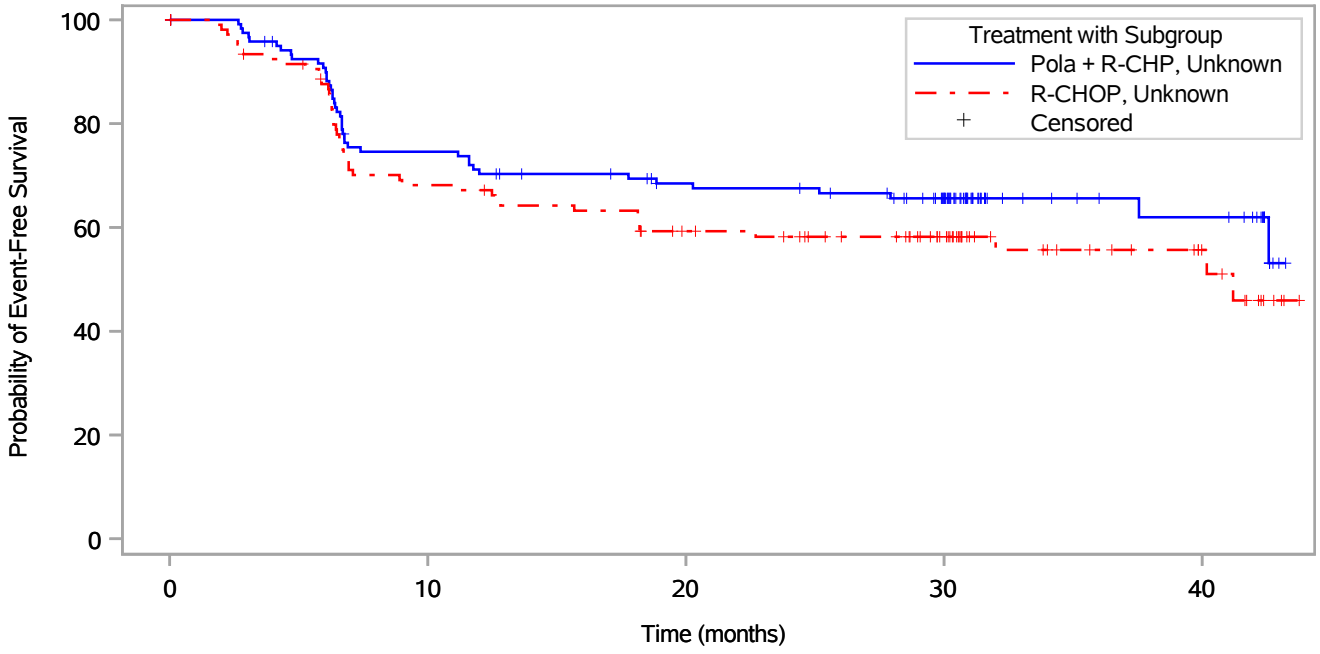


Patients at risk																			
Pola + R-CHP, Unclassified	53	52	48	40	37	37	35	34	32	28	22	13	12	12	5	NE	NE	NE	NE
R-CHOP, Unclassified	60	59	54	46	46	43	42	41	40	37	34	11	10	10	7	2	2	1	1
Patients censored																			
Pola + R-CHP, Unclassified	0	1	1	2	2	2	3	4	5	7	12	21	22	22	29	NE	NE	NE	NE
R-CHOP, Unclassified	0	0	1	1	1	2	3	4	5	7	10	33	33	33	36	41	42	42	42

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_km_sg1_EFSEFF3c_IT_POOLED_15JUN2022_39942.pdf
27OCT2023 17:29

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
STUDY: GO39942
Cell of origin



Patients at risk															
Pola + R-CHP, Unknown	123	117	107	87	82	79	77	72	72	69	55	22	19	17	14
R-CHOP, Unknown	110	98	90	71	69	65	64	55	53	48	38	22	18	16	7
Patients censored															
Pola + R-CHP, Unknown	0	3	5	6	6	9	10	13	13	15	28	61	64	65	68
R-CHOP, Unknown	0	5	7	7	7	8	8	13	14	19	29	44	48	50	57

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_km_sg1_EFSEFF3c_IT_POOLED_15JUN2022_39942.pdf
27OCT2023 17:29

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Event-Free Survival (EFS, Composite-INV)
MODEL: descriptive
STUDY: GO39942
Overview of EFSEFF First Contributing Event

	Polatuzumab Vedotin + R-CHP (N=500)	R-CHOP (N=500)
Reasons for events		
n	169	199
Death	19 (11.2%)	21 (10.6%)
EOT without CR (Composite-INV)	55 (32.5%)	55 (27.6%)
Relapse / Progression	95 (56.2%)	123 (61.8%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_evntdesc_2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_evntdesc_2_EFSEFF3c_IT_POOLED_15JUN2022_39942.xls
27OCT2023 17:25

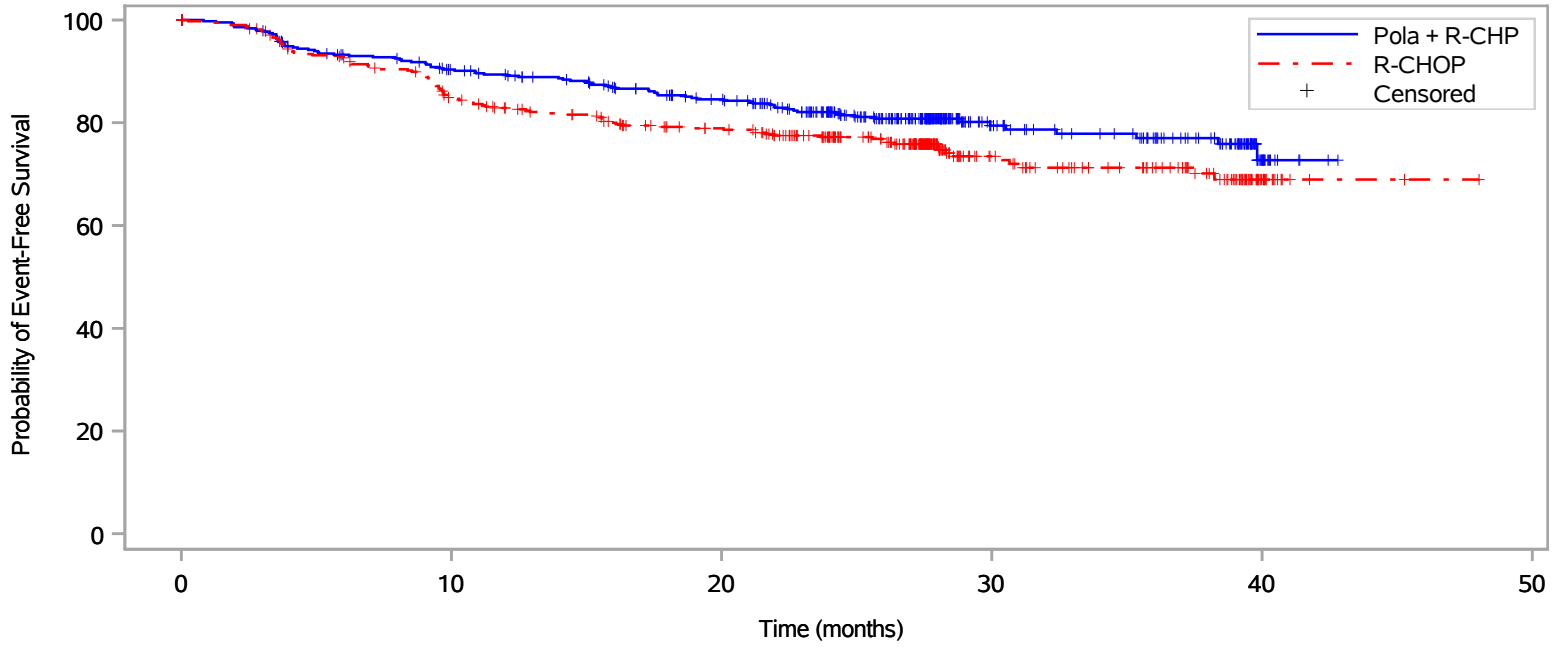
POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=437)												R-CHOP (N=417)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	437	100.0	84	19.2	353	80.8	39.8	30.5	NE	NE	NE	NE	417	100.0	103	24.7	314	75.3	28.1	18.6	38.2	NE	NE	NE	0.0304	0.73	0.54	0.97		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical studies/RO5541077/CDPT7884/GO39942/data analysis/ACE BASE/prod/program/t eff tte.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_tte_str_DFS_CR_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:17

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
STUDY: GO39942



Patients at risk																	
Pola + R-CHP	437	423	391	383	364	353	331	313	271	217	109	94	83	58	2	NE	NE
R-CHOP	417	400	376	357	321	311	288	282	245	208	101	86	75	51	2	2	1
Patients censored																	
Pola + R-CHP	0	5	17	19	28	34	45	59	93	143	249	262	272	296	351	NE	NE
R-CHOP	0	8	12	16	27	32	46	50	82	115	218	230	241	263	312	312	313

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..42/data_analysis/ACE_FINAL_OS/prod/output/g_km_DFS_CR_IT_POOLED_15JUN2022_39942.pdf
10FEB2023 11:53

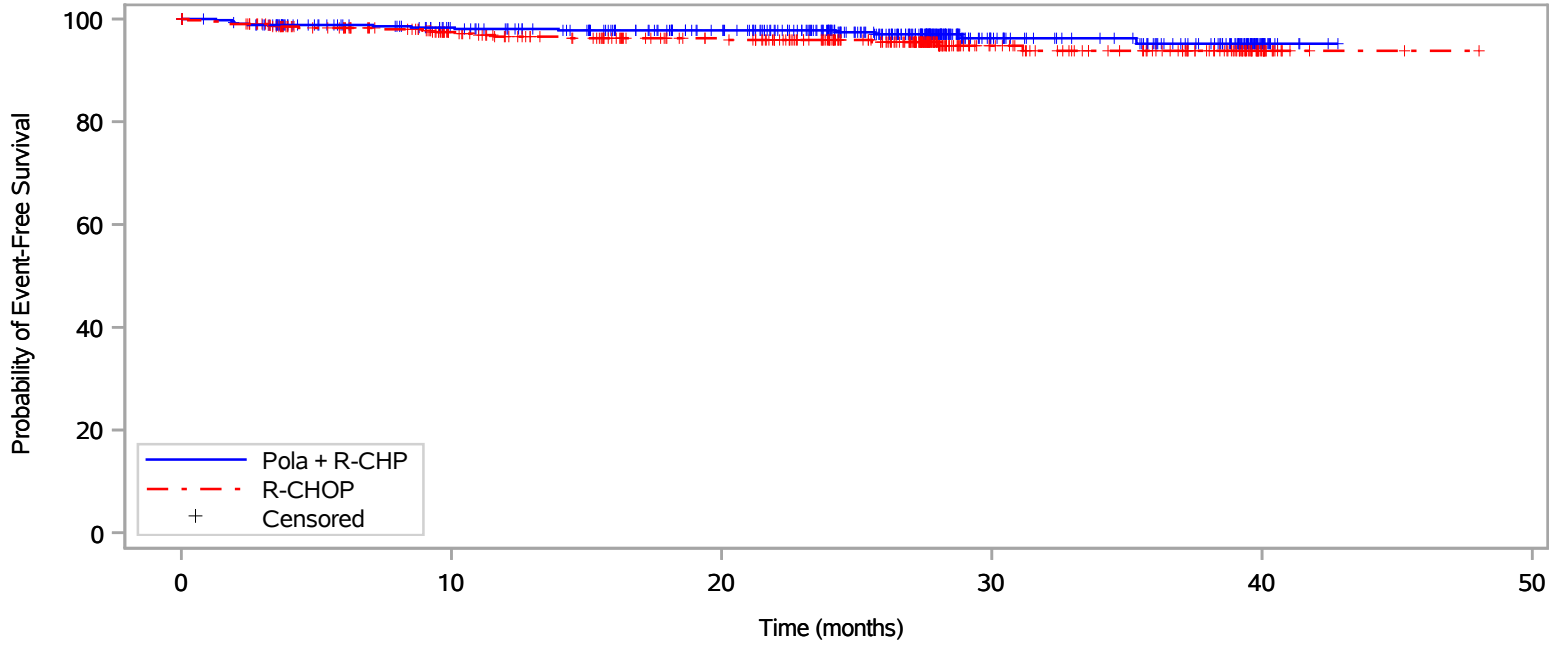
POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Time to Death (DFS from first CR(Composite-INV))
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=437)												R-CHOP (N=417)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	437	100.0	13	3.0	424	97.0	NE	NE	NE	NE	NE	NE	417	100.0	18	4.3	399	95.7	NE	NE	NE	NE	NE	NE	0.2145	0.64	0.31	1.31		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_tte_str_DFSDTH_CR_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:24

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Time to Death (DFS from first CR(Composite-INV))
STUDY: GO39942



Patients at risk																	
Pola + R-CHP	437	423	391	383	364	353	331	313	271	217	109	94	83	58	2	NE	NE
R-CHOP	417	400	376	357	321	311	288	282	245	208	101	86	75	51	2	2	1
Patients censored																	
Pola + R-CHP	0	9	41	47	65	75	97	115	157	209	316	331	341	366	422	NE	NE
R-CHOP	0	13	34	51	83	92	115	120	157	193	299	313	324	348	397	397	398

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..data_analysis/ACE_FINAL_OS/prod/output/g_km_DFSDTH_CR_IT_POOLED_15JUN2022_39942.pdf
10FEB2023 11:56

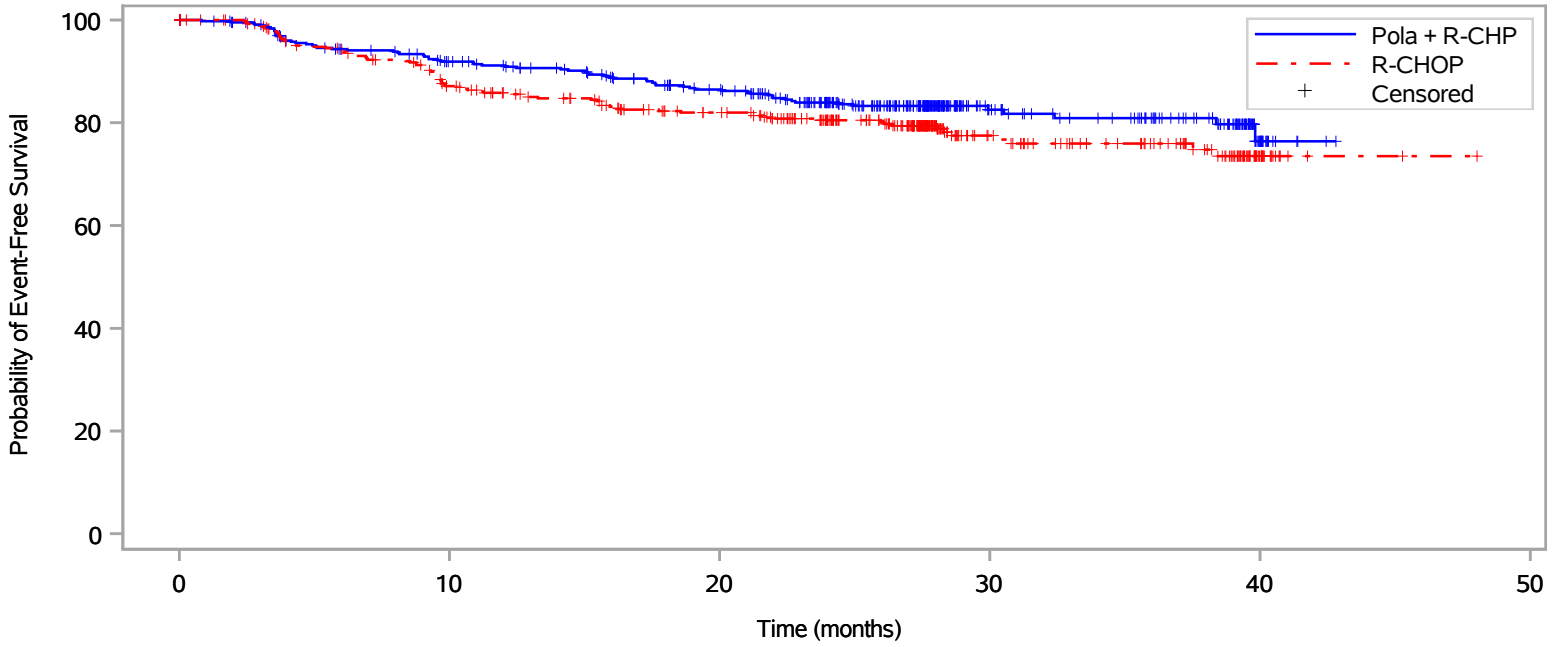
POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Time to Relapse (DFS from first CR(Composite-INV))
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=437)												R-CHOP (N=417)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	437	100.0	71	16.2	366	83.8	NE	38.4	NE	NE	NE	NE	417	100.0	85	20.4	332	79.6	37.5	28.1	NE	NE	NE	NE	0.0693	0.75	0.54	1.02		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical studies/RO5541077/CDPT7884/GO39942/data analysis/ACE BASE/prod/program/t eff tte.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_tte_str_DFSPRG_CR_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:22

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Time to Relapse (DFS from first CR(Composite-INV))
STUDY: GO39942



Patients at risk																	
Pola + R-CHP	437	423	391	383	364	353	331	313	271	217	109	94	83	58	2	NE	NE
R-CHOP	417	400	376	357	321	311	288	282	245	208	101	86	75	51	2	2	1
Patients censored																	
Pola + R-CHP	0	10	22	26	36	43	54	68	102	154	261	274	285	309	364	NE	NE
R-CHOP	0	12	19	25	40	46	60	65	97	131	235	248	259	281	330	330	331

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..data_analysis/ACE_FINAL_OS/prod/output/g_km_DFSPRG_CR_IT_POOLED_15JUN2022_39942.pdf
10FEB2023 11:55

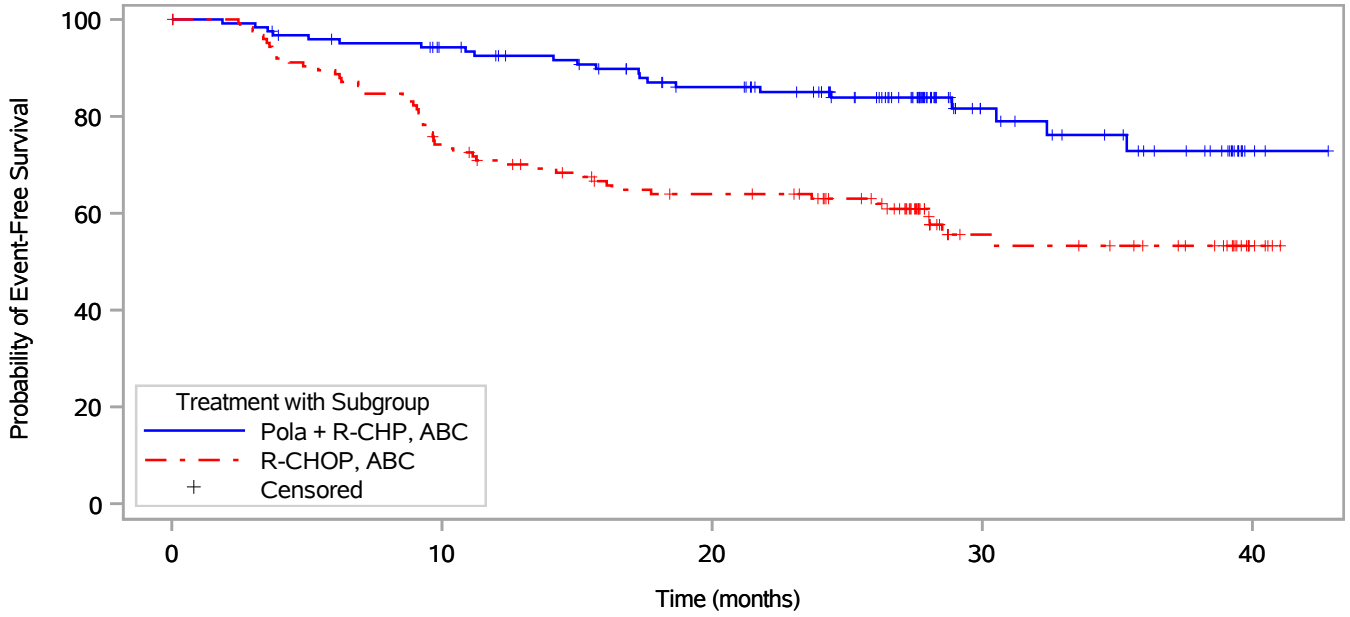
POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
MODEL: Unstratified Analysis
STUDY: GO39942
Time to Event Analysis by Subgroups (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=437)												R-CHOP (N=417)												log-rank	Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event							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	Convergence Status	p-value (likelihood ratio)
All	n/a	437	100.0	84	19.2	353	80.8	39.8	30.5	NE	NE	NE	NE	417	100.0	103	24.7	314	75.3	28.1	18.6	38.2	NE	NE	NE	0.0502	0.75	0.56	1.00	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	231	52.9	44	19.0	187	81.0	38.4	28.9	NE	NE	NE	NE	216	51.8	63	29.2	153	70.8	21.6	11.3	30.7	NE	NE	NE	0.0141	0.62	0.42	0.91	Convergence criterion (GCONV=1E-8) satisfied.	0.1423
	Female	206	47.1	40	19.4	166	80.6	NE	24.4	NE	NE	NE	NE	201	48.2	40	19.9	161	80.1	NE	26.0	NE	NE	NE	NE	0.8606	0.96	0.62	1.49	Convergence criterion (GCONV=1E-8) satisfied.	
Age	<= 60	140	32.0	20	14.3	120	85.7	NE	30.5	NE	NE	NE	NE	126	30.2	22	17.5	104	82.5	NE	26.0	NE	NE	NE	NE	0.4458	0.79	0.43	1.45	Convergence criterion (GCONV=1E-8) satisfied.	0.8528
	> 60	297	68.0	64	21.5	233	78.5	38.4	24.4	NE	NE	NE	NE	291	69.8	81	27.8	210	72.2	23.7	15.6	31.1	NE	NE	NE	0.0766	0.74	0.54	1.03	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Western Europe/United States/Canada/Australia	259	59.3	42	16.2	217	83.8	NE	35.4	NE	NE	NE	NE	252	60.4	57	22.6	195	77.4	37.5	23.7	NE	NE	NE	NE	0.0783	0.70	0.47	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.5013
	Asia	128	29.3	26	20.3	102	79.7	30.5	17.6	NE	NE	NE	NE	116	27.8	33	28.4	83	71.6	20.1	9.7	38.2	NE	38.2	NE	0.1374	0.68	0.41	1.14	Convergence criterion (GCONV=1E-8) satisfied.	
	Rest of World	50	11.4	16	32.0	34	68.0	20.1	9.7	NE	39.8	NE	NE	49	11.8	13	26.5	36	73.5	21.9	9.1	NE	NE	30.4	NE	0.8911	1.05	0.50	2.21	Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	197	45.1	37	18.8	160	81.2	39.8	35.4	NE	NE	NE	NE	195	46.8	42	21.5	153	78.5	37.5	21.3	NE	NE	NE	NE	0.4614	0.85	0.54	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.3490
	Black or African American	8	1.8	0	0.0	8	100.0	NE	NE	NE	NE	NE	NE	5	1.2	1	20.0	4	80.0	NE	9.7	NE	NE	9.7	NE	0.2207	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	132	30.2	27	20.5	105	79.5	30.5	17.6	NE	NE	NE	NE	121	29.0	34	28.1	87	71.9	20.1	9.7	38.2	NE	38.2	NE	0.1497	0.69	0.42	1.15	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	6	1.4	2	33.3	4	66.7	28.9	14.4	NE	28.9	28.9	NE	8	1.9	1	12.5	7	87.5	NE	9.8	NE	NE	NE	NE	0.4335	2.53	0.23	28.14	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	94	21.5	18	19.1	76	80.9	NE	24.9	NE	NE	NE	NE	88	21.1	25	28.4	63	71.6	26.1	12.7	NE	NE	NE	NE	0.1797	0.66	0.36	1.21	Convergence criterion (GCONV=1E-8) satisfied.	
ECOG performance status	0-1	369	84.4	71	19.2	298	80.8	39.8	29.9	NE	NE	NE	NE	354	84.9	93	26.3	261	73.7	26.4	15.6	37.5	NE	NE	NE	0.0222	0.70	0.51	0.95	Convergence criterion (GCONV=1E-8) satisfied.	0.2368
	2	68	15.6	13	19.1	55	80.9	NE	17.3	NE	NE	NE	NE	61	14.6	10	16.4	51	83.6	NE	18.6	NE	NE	NE	NE	0.7095	1.17	0.51	2.67	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0.0	0	0.0	0	0.0	NE	NE	NE	NE	NE	NE	2	0.5	0	0.0	2	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cell of origin (determined by gene expression)	ABC	124	28.4	22	17.7	102	82.3	35.4	28.9	NE	NE	NE	NE	126	30.2	51	40.5	75	59.5	9.7	9.1	15.6	NE	28.1	NE	<.0001	0.37	0.23	0.62	Convergence criterion (GCONV=1E-8) satisfied.	0.0007
	GCB	167	38.2	33	19.8	134	80.2	NE	22.0	NE	NE	NE	NE	151	36.2	24	15.9	127	84.1	NE	31.1	NE	NE	NE	NE	0.3476	1.29	0.76	2.18	Convergence criterion (GCONV=1E-8) satisfied.	
	Unclassified	44	10.1	9	20.5	35	79.5	NE	22.4	NE	NE	NE	NE	52	12.5	6	11.5	46	88.5	NE	30.7	NE	NE	NE	NE	0.2726	1.77	0.63	4.98	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	102	23.3	20	19.6	82	80.4	39.8	21.9	NE	NE	39.8	NE	88	21.1	22	25.0	66	75.0	28.3	11.6	NE	NE	38.2	NE	0.3174	0.73	0.40	1.35	Convergence criterion (GCONV=1E-8) satisfied.	
IPI score at Screening	1-2	164	37.5	24	14.6	140	85.4	NE	39.8	NE	NE	NE	NE	168	40.3	29	17.3	139	82.7	NE	28.5	NE	NE	NE	NE	0.4541	0.81	0.47	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.1940
	3	181	41.4	33	18.2	148	81.8	38.4	28.9	NE	NE	NE	NE	154	36.9	46	29.9	108	70.1	15.6	9.7	30.4	NE	NE	NE	0.0100	0.56	0.36	0.88	Convergence criterion (GCONV=1E-8) satisfied.	
	4-5	92	21.1	27	29.3	65	70.7	24.2	9.7	NE	NE	NE	NE	95	22.8	28	29.5	67	70.5	20.1	10.7	NE	NE	NE	NE	0.8403	1.06	0.62	1.79	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline Bulky Disease	Present	173	39.6	37	21.4	136	78.6	30.5	21.0	NE	NE	NE	NE	164	39.3	33	20.1	131	79.9	NE	25.6	NE	NE	NE	NE	0.7440	1.08	0.68	1.73	Convergence criterion (GCONV=1E-8) satisfied.	0.0488
	Absent	264	60.4	47	17.8	217	82.2	39.8	32.4	NE	NE	NE	NE	253	60.7	70	27.7	183	72.3	21.9	12.9	30.7	NE	NE	NE	0.0053	0.59	0.41	0.86	Convergence criterion (GCONV=1E-8) satisfied.	
Double Expressor Lymphoma by IHC (Central Review)	DEL	127	29.1	22	17.3	105	82.7	NE	30.5	NE	NE	NE	NE	137	32.9	45	32.8	92	67.2	15.6	9.4	30.7	NE	38.2	NE	0.0044	0.48	0.28	0.81	Convergence criterion (GCONV=1E-8) satisfied.	0.0232
	Non DEL	227	51.9	44	19.4	183	80.6	NE	25.7	NE	NE	NE	NE	203	48.7	37	18.2	166	81.8	NE	29.0	NE	NE	NE	NE	0.8606	1.04	0.67	1.61	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	83	19.0	18	21.7	65	78.3	29.9	15.1	NE	39.8	39.8	NE	77	18.5	21	27.3	56	72.7	21.3	10.3	NE	NE	37.5	NE	0.5738	0.84	0.44	1.57	Convergence criterion (GCONV=1E-8) satisfied.	
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	301	68.9	58	19.3	243	80.7	38.4	28.9	NE	NE	NE	NE	298	71.5	78	26.2	220	73.8	26.4	15.6	38.2	NE	NE	NE	0.0468	0.71	0.51	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.1050
	DH/TH+	21	4.8	4	19.0	17	81.0	NE	4.9	NE	NE	NE	NE	18	4.3	1	5.6	17	94.4	NE	NE	NE	NE	NE	NE	0.2370	3.46	0.39	30.99	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	115	26.3	22	19.1	93	80.9	39.8	24.9	NE	NE	39.8	NE	101	24.2	24	23.8	77	76.2	28.3	11.6	NE	NE	37.5	NE	0.3174	0.74	0.42	1.33	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: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_tte_sgl_DFS_CR_ITT_POOLED_15JUN2022_39942.xls
09FEB2023 20:19

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
STUDY: GO39942
Cell of origin



Patients at risk															
Pola + R-CHP, ABC	124	122	115	114	105	102	93	89	80	63	31	25	20	15	1
R-CHOP, ABC	126	121	111	102	85	79	72	71	66	54	24	23	19	15	NE
Patients censored															
Pola + R-CHP, ABC	0	1	4	4	10	12	16	19	27	43	74	78	82	87	101
R-CHOP, ABC	0	2	2	2	5	8	10	11	15	25	52	52	56	60	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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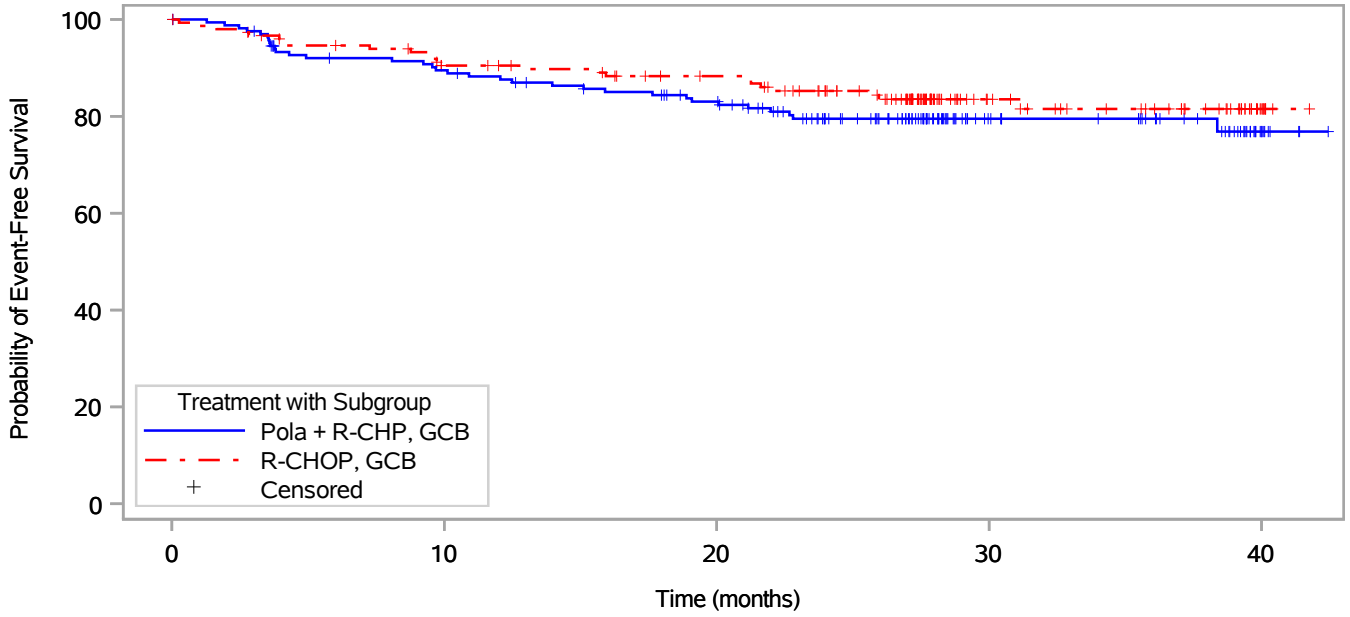
10FEB2023 11:51

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
STUDY: GO39942
Cell of origin



Patients at risk															
Pola + R-CHP, GCB	167	161	146	145	139	134	129	119	100	83	44	40	35	24	1
R-CHOP, GCB	151	144	139	135	126	124	117	116	103	88	44	36	33	22	NE
Patients censored															
Pola + R-CHP, GCB	0	2	8	8	9	11	13	20	35	52	91	95	100	110	133
R-CHOP, GCB	0	2	4	6	11	12	17	18	27	40	84	91	94	105	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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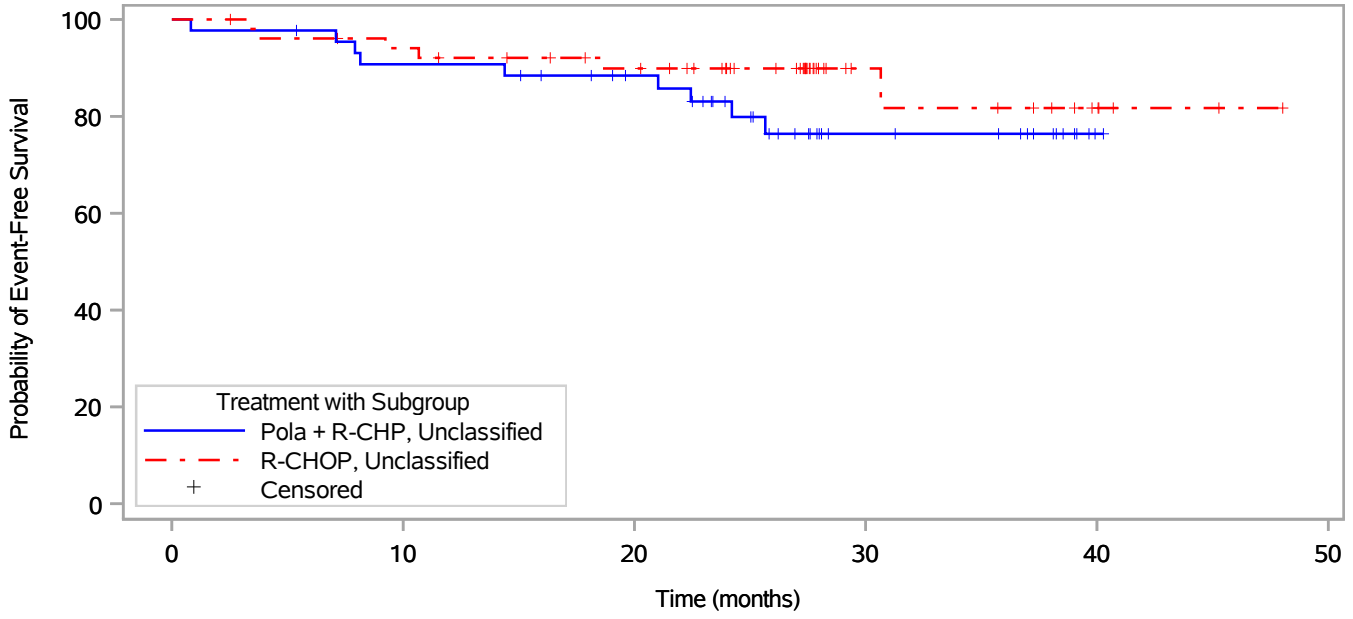
10FEB2023 11:51

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
STUDY: GO39942

Cell of origin



Patients at risk																	
Pola + R-CHP, Unclassified	44	43	42	39	39	38	36	33	26	19	13	12	11	5	NE	NE	NE
R-CHOP, Unclassified	52	51	49	48	45	44	42	40	34	31	11	10	9	7	2	2	1
Patients censored																	
Pola + R-CHP, Unclassified	0	0	1	1	1	1	3	6	11	16	22	23	24	30	NE	NE	NE
R-CHOP, Unclassified	0	1	1	2	3	4	6	7	13	16	36	36	37	39	44	44	45

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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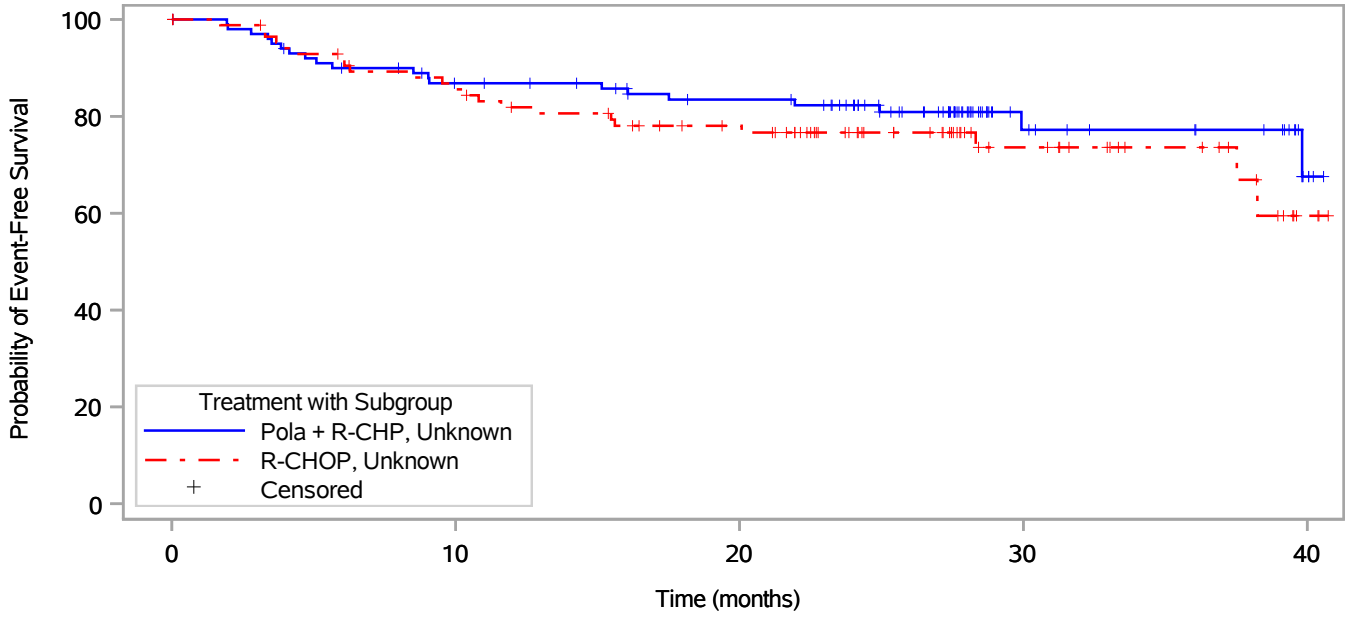
10FEB2023 11:51

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
STUDY: GO39942
Cell of origin



Patients at risk														
Pola + R-CHP, Unknown	102	97	88	85	81	79	73	72	65	52	21	17	17	14
R-CHOP, Unknown	88	84	77	72	65	64	57	55	42	35	22	17	14	7
Patients censored														
Pola + R-CHP, Unknown	0	2	4	6	8	10	13	14	20	32	62	66	66	69
R-CHOP, Unknown	0	3	5	6	8	8	13	14	27	34	46	51	54	59

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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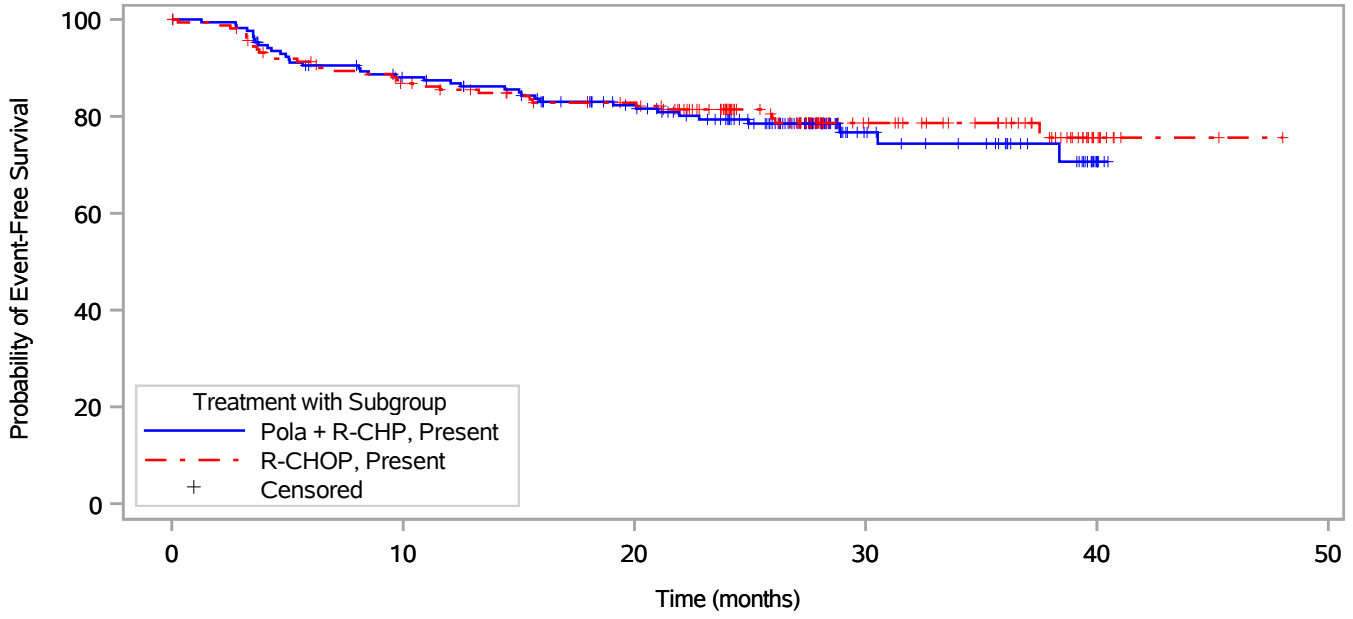
10FEB2023 11:51

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
STUDY: GO39942
Baseline Bulky Disease



Patients at risk																	
Pola + R-CHP, Present	173	167	149	145	140	135	124	112	101	77	35	30	26	19	NE	NE	NE
R-CHOP, Present	164	157	145	139	130	126	121	118	97	80	43	37	32	18	2	2	1
Patients censored																	
Pola + R-CHP, Present	0	3	8	9	12	14	21	31	39	62	103	107	111	117	NE	NE	NE
R-CHOP, Present	0	3	5	7	11	14	16	18	38	52	89	95	100	113	129	129	130

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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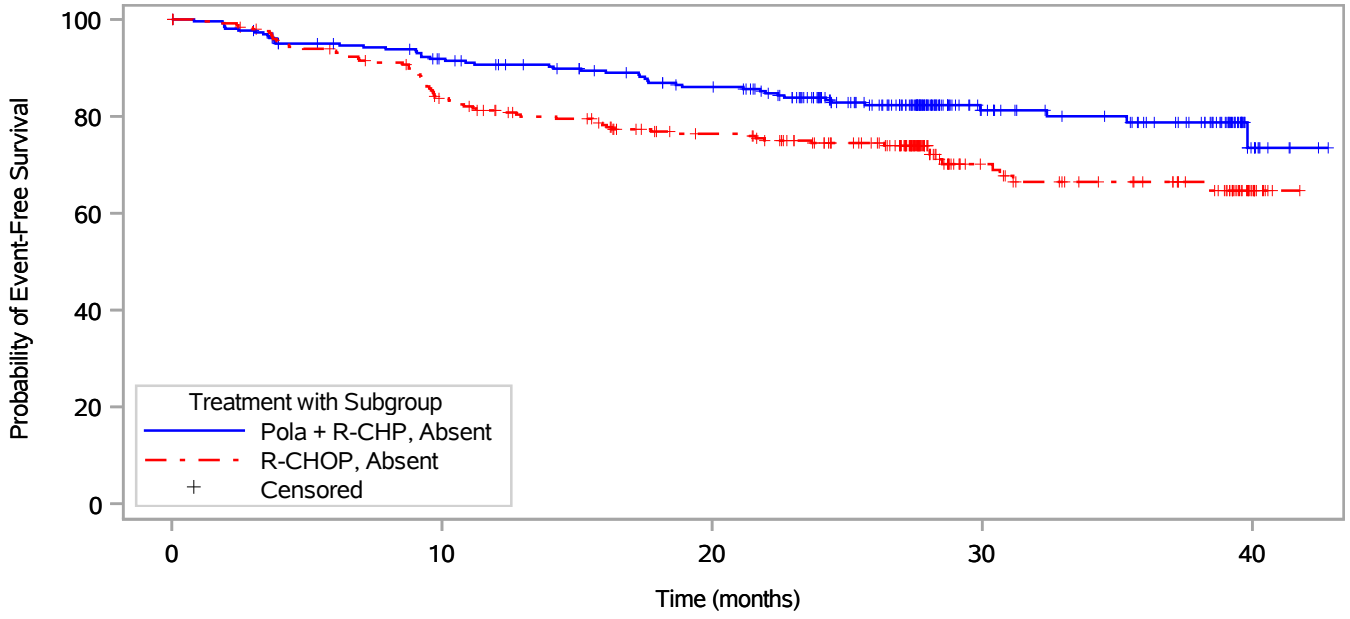
10FEB2023 11:51

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
STUDY: GO39942
Baseline Bulky Disease



Patients at risk															
Pola + R-CHP, Absent	264	256	242	238	224	218	207	201	170	140	74	64	57	39	2
R-CHOP, Absent	253	243	231	218	191	185	167	164	148	128	58	49	43	33	NE
Patients censored															
Pola + R-CHP, Absent	0	2	9	10	16	20	24	28	54	81	146	155	161	179	215
R-CHOP, Absent	0	5	7	9	16	18	30	32	44	63	129	135	141	150	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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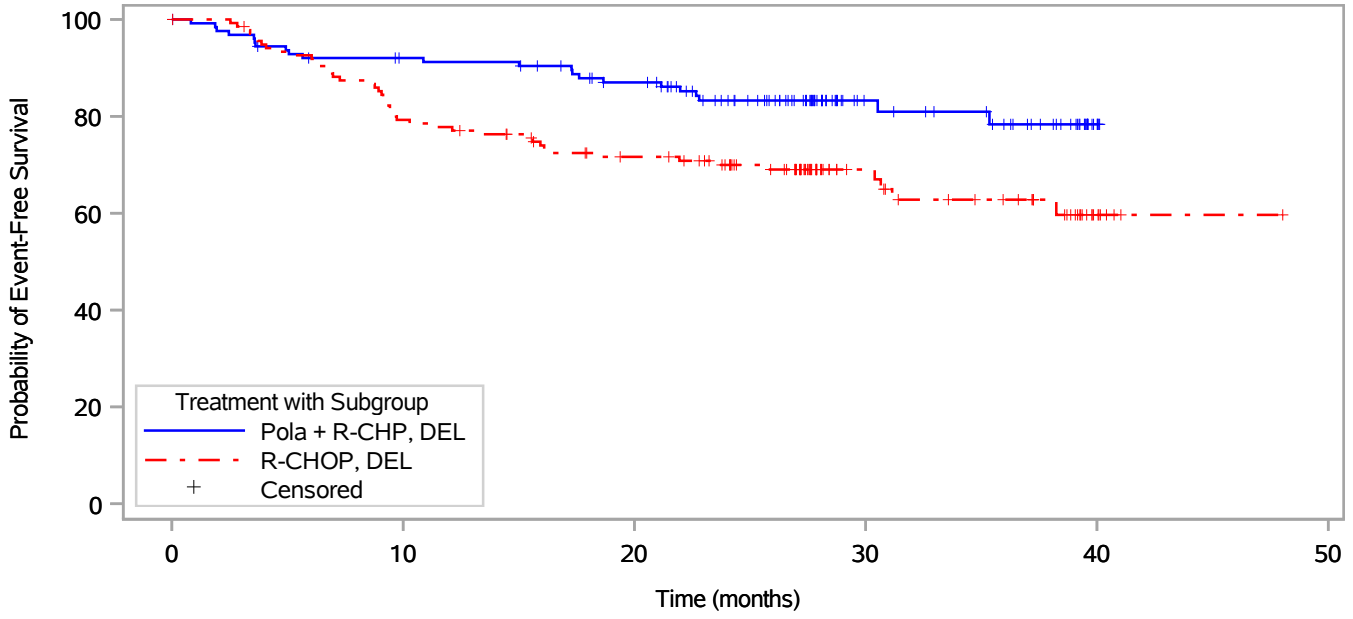
10FEB2023 11:51

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
STUDY: GO39942

Double Expressor Lymphoma by IHC (Central Review)



Patients at risk																	
Pola + R-CHP, DEL	127	122	114	114	111	111	104	98	84	69	36	32	28	19	NE	NE	NE
R-CHOP, DEL	137	134	125	115	105	100	91	89	80	66	34	28	25	16	1	1	1
Patients censored																	
Pola + R-CHP, DEL	0	1	3	3	5	5	8	13	23	38	71	74	77	86	NE	NE	NE
R-CHOP, DEL	0	1	2	2	2	5	9	10	17	30	62	65	68	76	91	91	91

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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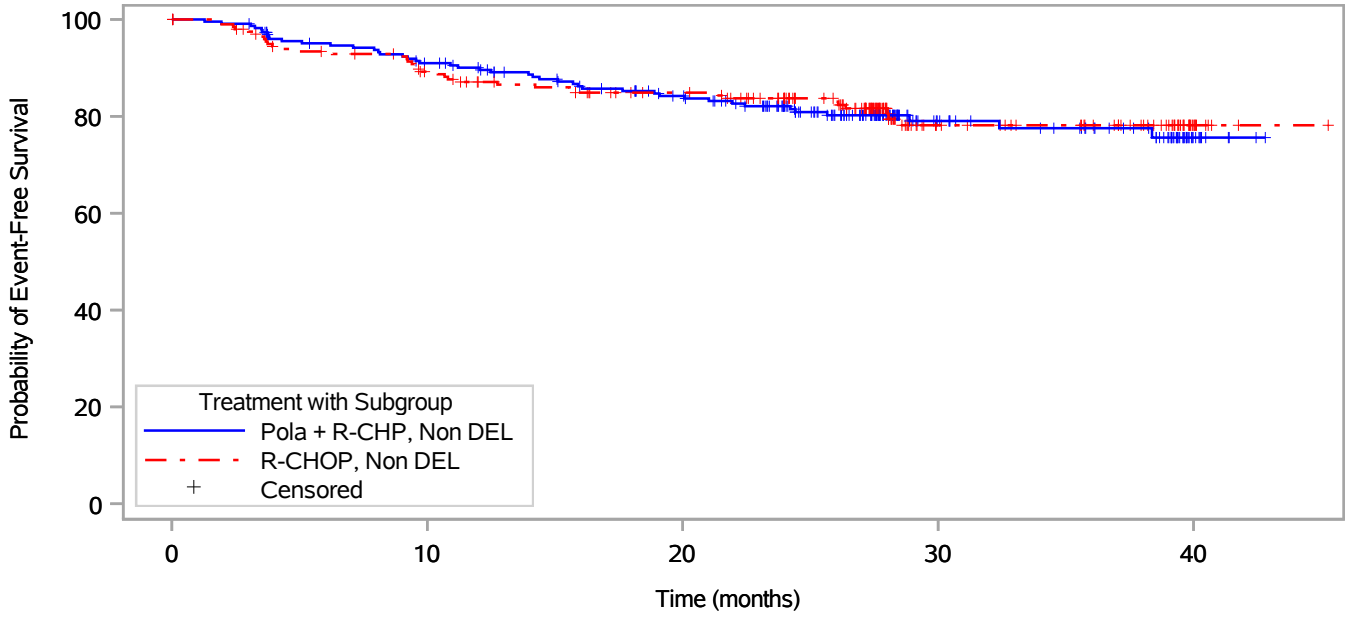
10FEB2023 11:51

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
STUDY: GO39942

Double Expressor Lymphoma by IHC (Central Review)

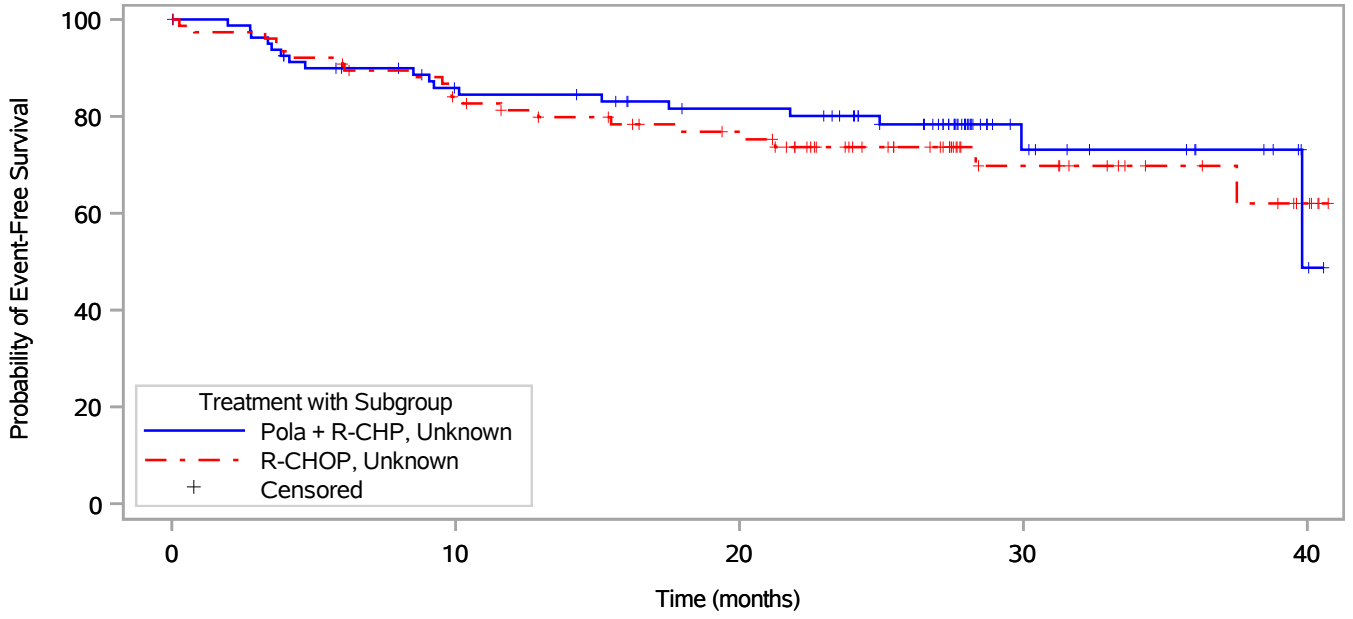


Patients at risk																
Pola + R-CHP, Non DEL	227	224	209	204	192	182	173	161	137	107	59	52	46	34	2	NE
R-CHOP, Non DEL	203	192	181	177	159	156	147	145	130	112	50	45	40	28	1	1
Patients censored																
Pola + R-CHP, Non DEL	0	1	7	7	13	18	22	31	52	79	126	132	138	149	181	NE
R-CHOP, Non DEL	0	6	9	11	19	20	27	29	42	57	116	121	126	138	165	165

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: Disease-Free Survival (DFS from first CR(Composite-INV))
STUDY: GO39942

Double Expressor Lymphoma by IHC (Central Review)



Patients at risk														
Pola + R-CHP, Unknown	83	77	68	65	61	60	54	54	50	41	14	10	9	5
R-CHOP, Unknown	77	74	70	65	57	55	50	48	35	30	17	13	10	7
Patients censored														
Pola + R-CHP, Unknown	0	3	7	9	10	11	15	15	18	26	52	56	57	61
R-CHOP, Unknown	0	1	1	3	6	7	10	11	23	28	40	44	47	49

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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10FEB2023 11:51

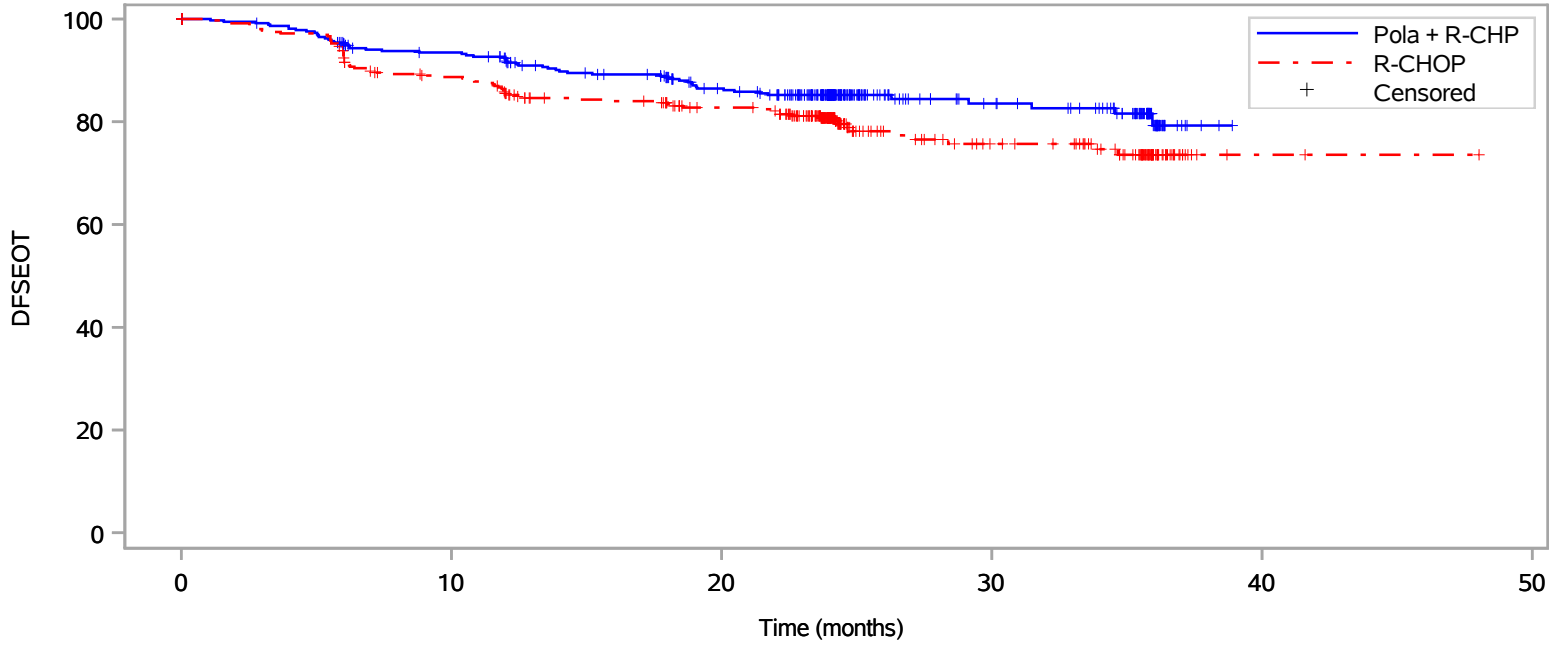
POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=381)												R-CHOP (N=364)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	381	100,0	57	15,0	324	85,0	NE	35,9	NE	NE	NE	NE	364	100,0	75	20,6	289	79,4	33,8	24,6	NE	NE	NE	NE	0,0255	0,67	0,48	0,95		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical studies/RO5541077/CDPT7884/GO39942/data analysis/ACE BASE/prod/program/t eff tte.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_tte_str_DFSEOT_CREOT_IT_POOLED_15JUN2022_39942.xls
11OCT2023 8:11

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
STUDY: GO39942



Patients at risk																	
Pola + R-CHP	381	368	350	336	327	308	295	275	192	102	94	88	33	NE	NE	NE	NE
R-CHOP	364	349	332	307	291	277	268	257	171	95	84	81	29	2	1	1	1
Patients censored																	
Pola + R-CHP	0	10	14	21	26	35	45	56	137	226	233	238	291	NE	NE	NE	NE
R-CHOP	0	7	10	18	22	32	39	47	127	197	207	210	260	287	288	288	288

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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11OCT2023 8:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Time to Death (DFS from CR at EoT (Composite-INV))
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=381)												R-CHOP (N=364)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	381	100,0	7	1,8	374	98,2	NE	NE	NE	NE	NE	NE	364	100,0	12	3,3	352	96,7	NE	NE	NE	NE	NE	NE	0,1768	0,53	0,21	1,35		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_tte.sas
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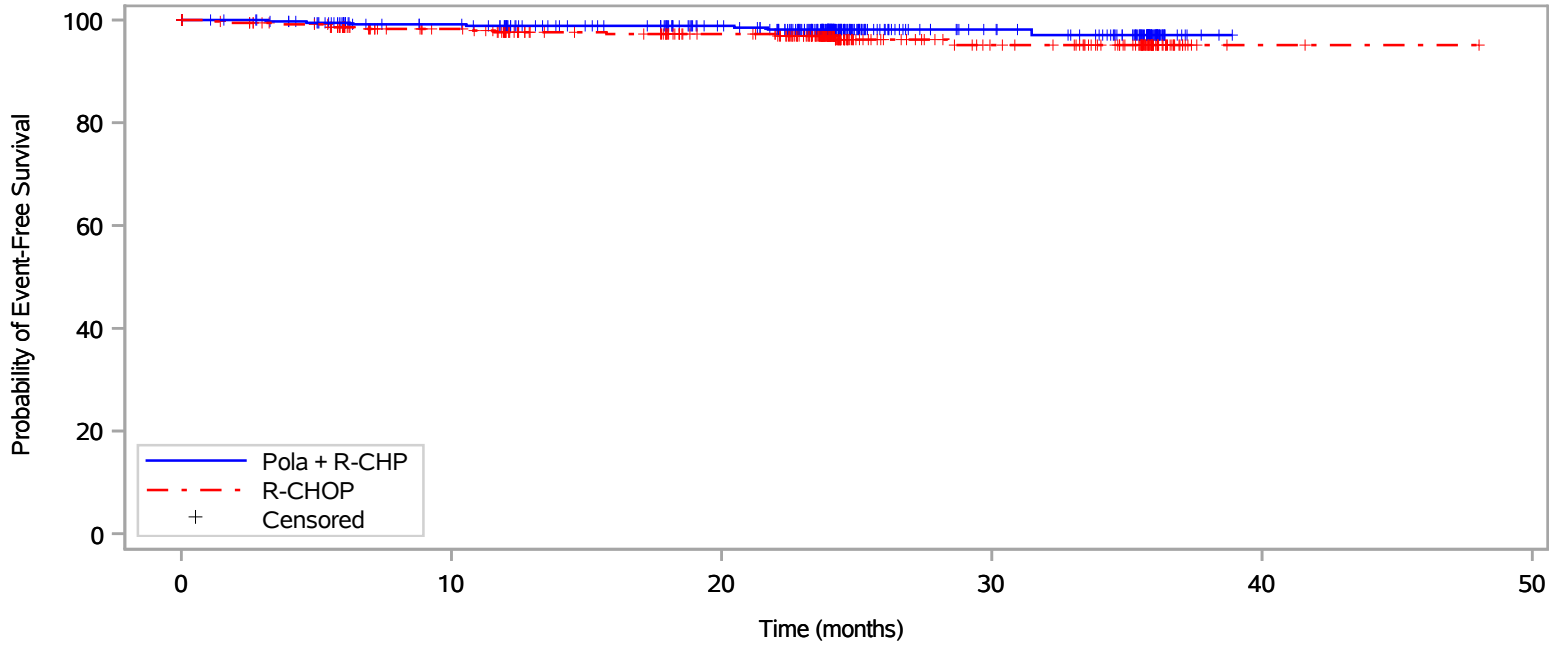
27OCT2023 17:24

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Time to Death (DFS from CR at EoT (Composite-INV))
STUDY: GO39942



Patients at risk																	
Pola + R-CHP	381	368	350	336	327	308	295	275	192	102	94	88	33	NE	NE	NE	NE
R-CHOP	364	349	332	307	291	277	268	257	171	95	84	81	29	2	1	1	1
Patients censored																	
Pola + R-CHP	0	13	29	42	50	69	82	101	183	273	281	286	341	NE	NE	NE	NE
R-CHOP	0	13	27	51	65	79	87	98	183	258	268	271	323	350	351	351	351

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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27OCT2023 17:28

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Time to Relapse (DFS from CR at EoT (Composite-INV))
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=381)												R-CHOP (N=364)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	381	100,0	50	13,1	331	86,9	NE	NE	NE	NE	NE	NE	364	100,0	63	17,3	301	82,7	NE	26,8	NE	NE	NE	NE	0,0629	0,70	0,48	1,02		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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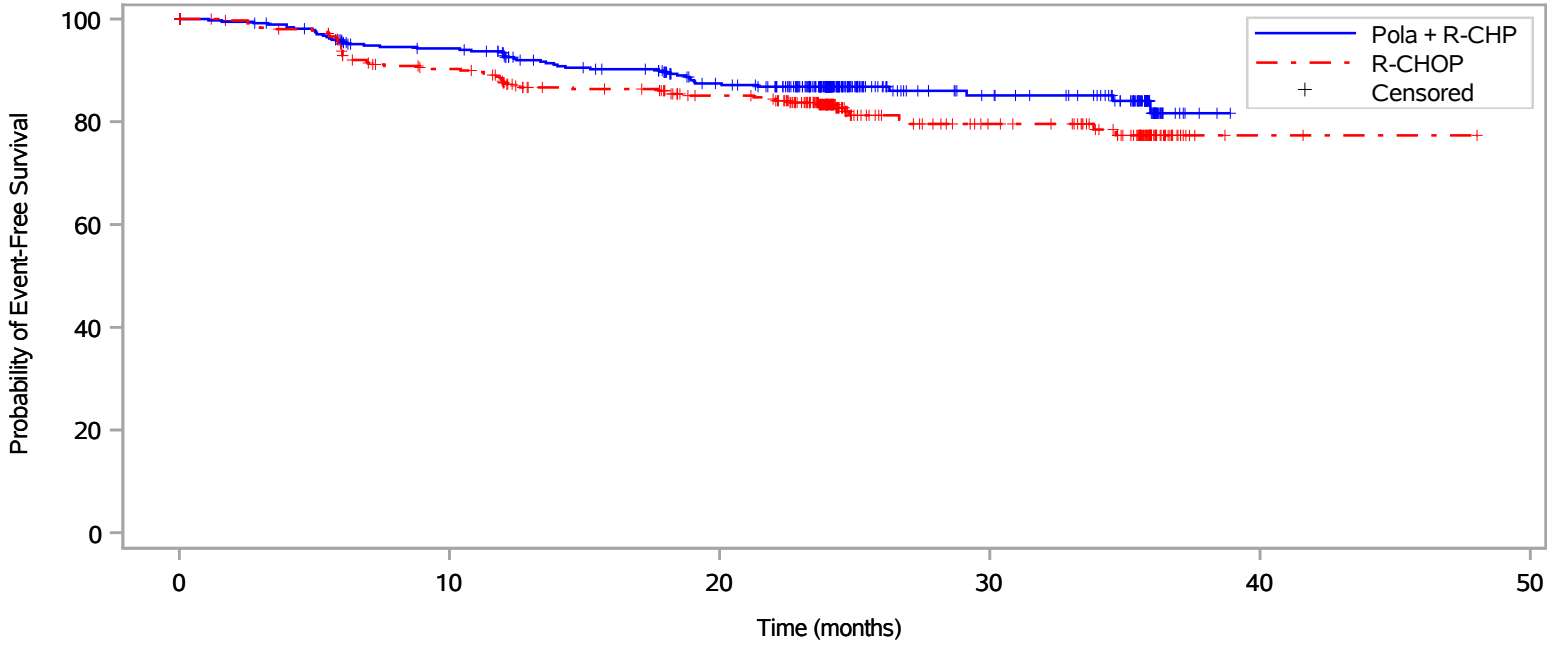
27OCT2023 17:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Time to Relapse (DFS from CR at EoT (Composite-INV))
STUDY: GO39942



Patients at risk																	
Pola + R-CHP	381	368	350	336	327	308	295	275	192	102	94	88	33	NE	NE	NE	NE
R-CHOP	364	349	332	307	291	277	268	257	171	95	84	81	29	2	1	1	1
Patients censored																	
Pola + R-CHP	0	10	16	24	30	39	49	61	143	232	239	245	298	NE	NE	NE	NE
R-CHOP	0	9	15	24	30	40	48	56	137	208	219	222	272	299	300	300	300

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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27OCT2023 17:26

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
MODEL: Unstratified Analysis
STUDY: GO39942
Time to Event Analysis by Subgroups (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=381)												R-CHOP (N=364)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	Convergence Status	p-value (likelihood ratio)
All	n/a	381	100,0	57	15,0	324	85,0	NE	35,9	NE	NE	NE	NE	364	100,0	75	20,6	289	79,4	33,8	24,6	NE	NE	NE	NE	0,0440	0,70	0,50	0,99	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	203	53,3	30	14,8	173	85,2	NE	34,6	NE	NE	NE	NE	180	49,5	42	23,3	138	76,7	24,8	22,0	NE	NE	NE	NE	0,0465	0,62	0,39	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,4723
	Female	178	46,7	27	15,2	151	84,8	NE	31,5	NE	NE	NE	NE	184	50,5	33	17,9	151	82,1	NE	26,8	NE	NE	NE	NE	0,4173	0,81	0,49	1,35	Convergence criterion (GCONV=1E-8) satisfied.	
Age	<= 60	120	31,5	14	11,7	106	88,3	NE	NE	NE	NE	NE	NE	107	29,4	16	15,0	91	85,0	NE	24,8	NE	NE	NE	NE	0,4486	0,76	0,37	1,53	Convergence criterion (GCONV=1E-8) satisfied.	0,7902
	> 60	261	68,5	43	16,5	218	83,5	NE	34,6	NE	NE	NE	NE	257	70,6	59	23,0	198	77,0	26,8	22,1	NE	NE	NE	NE	0,0619	0,69	0,47	1,02	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Western Europe/United States/Canada/Australia	229	60,1	27	11,8	202	88,2	NE	NE	NE	NE	NE	NE	221	60,7	41	18,6	180	81,4	NE	26,6	NE	NE	NE	NE	0,0603	0,63	0,39	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,7160
	Asia	114	29,9	20	17,5	94	82,5	NE	18,2	NE	NE	NE	NE	101	27,7	24	23,8	77	76,2	24,2	12,6	NE	NE	34,7	NE	0,2425	0,70	0,39	1,27	Convergence criterion (GCONV=1E-8) satisfied.	
	Rest of World	38	10,0	10	26,3	28	73,7	35,9	17,9	NE	35,9	35,9	NE	42	11,5	10	23,8	32	76,2	26,8	6,0	NE	NE	26,8	NE	0,9016	0,95	0,39	2,28	Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	167	43,8	23	13,8	144	86,2	NE	35,9	NE	NE	NE	NE	168	46,2	28	16,7	140	83,3	NE	33,8	NE	NE	NE	NE	0,4260	0,80	0,46	1,39	Convergence criterion (GCONV=1E-8) satisfied.	0,3977
	Black or African American	8	2,1	0	0,0	8	100,0	NE	NE	NE	NE	NE	NE	4	1,1	1	25,0	3	75,0	6,0	6,0	NE	NE	6,0	NE	0,1573	0,00	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	118	31,0	21	17,8	97	82,2	NE	18,2	NE	NE	NE	NE	105	28,8	25	23,8	80	76,2	24,2	11,8	NE	NE	34,7	NE	0,2430	0,71	0,40	1,27	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	3	0,8	1	33,3	2	66,7	10,4	10,4	NE	NE	10,4	NE	8	2,2	1	12,5	7	87,5	NE	6,1	NE	NE	NE	NE	0,5037	2,49	0,16	39,94	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	85	22,3	12	14,1	73	85,9	NE	29,1	NE	NE	NE	NE	79	21,7	20	25,3	59	74,7	26,6	14,6	NE	NE	NE	NE	0,0948	0,55	0,27	1,12	Convergence criterion (GCONV=1E-8) satisfied.	
ECOG performance status	0-1	322	84,5	50	15,5	272	84,5	NE	35,9	NE	NE	NE	NE	307	84,3	67	21,8	240	78,2	28,4	24,2	NE	NE	NE	NE	0,0417	0,68	0,47	0,99	Convergence criterion (GCONV=1E-8) satisfied.	0,7688
	2	59	15,5	7	11,9	52	88,1	NE	NE	NE	NE	NE	NE	55	15,1	8	14,5	47	85,5	NE	22,0	NE	NE	NE	NE	0,6263	0,78	0,28	2,15	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0,0	0	0,0	0	0,0	NE	NE	NE	NE	NE	NE	2	0,5	0	0,0	2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cell of origin (determined by gene expression)	ABC	115	30,2	16	13,9	99	86,1	NE	29,1	NE	NE	NE	NE	112	30,8	42	37,5	70	62,5	10,8	6,0	22,6	NE	24,6	NE	<.0001	0,32	0,18	0,58	Convergence criterion (GCONV=1E-8) satisfied.	0,0004
	GCB	136	35,7	21	15,4	115	84,6	NE	34,6	NE	NE	NE	NE	134	36,8	15	11,2	119	88,8	NE	NE	NE	NE	NE	NE	0,3174	1,40	0,72	2,72	Convergence criterion (GCONV=1E-8) satisfied.	
	Unclassified	41	10,8	8	19,5	33	80,5	NE	18,9	NE	NE	NE	NE	46	12,6	4	8,7	42	91,3	NE	26,6	NE	NE	NE	NE	0,1561	2,33	0,70	7,75	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	89	23,4	12	13,5	77	86,5	NE	35,9	NE	NE	NE	NE	72	19,8	14	19,4	58	80,6	33,8	24,8	NE	NE	34,7	NE	0,2647	0,65	0,30	1,40	Convergence criterion (GCONV=1E-8) satisfied.	
IPI score at Screening	1-2	148	38,8	17	11,5	131	88,5	NE	35,9	NE	NE	NE	NE	147	40,4	20	13,6	127	86,4	NE	26,6	NE	NE	NE	NE	0,5439	0,82	0,43	1,56	Convergence criterion (GCONV=1E-8) satisfied.	0,4121
	3	156	40,9	23	14,7	133	85,3	NE	34,6	NE	NE	NE	NE	130	35,7	33	25,4	97	74,6	24,3	11,9	NE	NE	NE	NE	0,0194	0,53	0,31	0,91	Convergence criterion (GCONV=1E-8) satisfied.	
	4-5	77	20,2	17	22,1	60	77,9	31,5	20,5	NE	NE	NE	NE	87	23,9	22	25,3	65	74,7	34,7	11,5	NE	NE	NE	NE	0,7235	0,89	0,47	1,68	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline Bulky Disease	Present	144	37,8	26	18,1	118	81,9	NE	26,3	NE	NE	NE	NE	134	36,8	21	15,7	113	84,3	NE	33,8	NE	NE	NE	NE	0,5007	1,22	0,69	2,17	Convergence criterion (GCONV=1E-8) satisfied.	0,0180
	Absent	237	62,2	31	13,1	206	86,9	NE	35,9	NE	NE	NE	NE	230	63,2	54	23,5	176	76,5	24,8	18,6	NE	NE	NE	NE	0,0023	0,51	0,33	0,78	Convergence criterion (GCONV=1E-8) satisfied.	
Double Expressor Lymphoma by IHC (Central Review)	DEL	114	29,9	15	13,2	99	86,8	NE	31,5	NE	NE	NE	NE	123	33,8	38	30,9	85	69,1	18,0	10,8	34,7	NE	NE	NE	0,0010	0,38	0,21	0,69	Convergence criterion (GCONV=1E-8) satisfied.	0,0051
	Non DEL	195	51,2	32	16,4	163	83,6	NE	34,6	NE	NE	NE	NE	179	49,2	25	14,0	154	86,0	NE	NE	NE	NE	NE	NE	0,5891	1,16	0,68	1,99	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	72	18,9	10	13,9	62	86,1	35,9	35,9	NE	NE	35,9	NE	62	17,0	12	19,4	50	80,6	33,8	21,3	NE	NE	NE	NE	0,5450	0,77	0,33	1,78	Convergence criterion (GCONV=1E-8) satisfied.	
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	261	68,5	41	15,7	220	84,3	NE	34,6	NE	NE	NE	NE	263	72,3	59	22,4	204	77,6	26,8	22,6	NE	NE	NE	NE	0,0552	0,68	0,46	1,01	Convergence criterion (GCONV=1E-8) satisfied.	0,4256
	DH/TH+	18	4,7	2	11,1	16	88,9	NE	19,1	NE	NE	NE	NE	16	4,4	1	6,3	15	93,8	NE	NE	NE	NE	NE	NE	0,6540	1,72	0,16	18,97	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	102	26,8	14	13,7	88	86,3	NE	35,9	NE	NE	NE	NE	85	23,4	15	17,6	70	82,4	33,8	24,8	NE	NE	33,8	NE	0,3699	0,72	0,34	1,49	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: 15JUN2022

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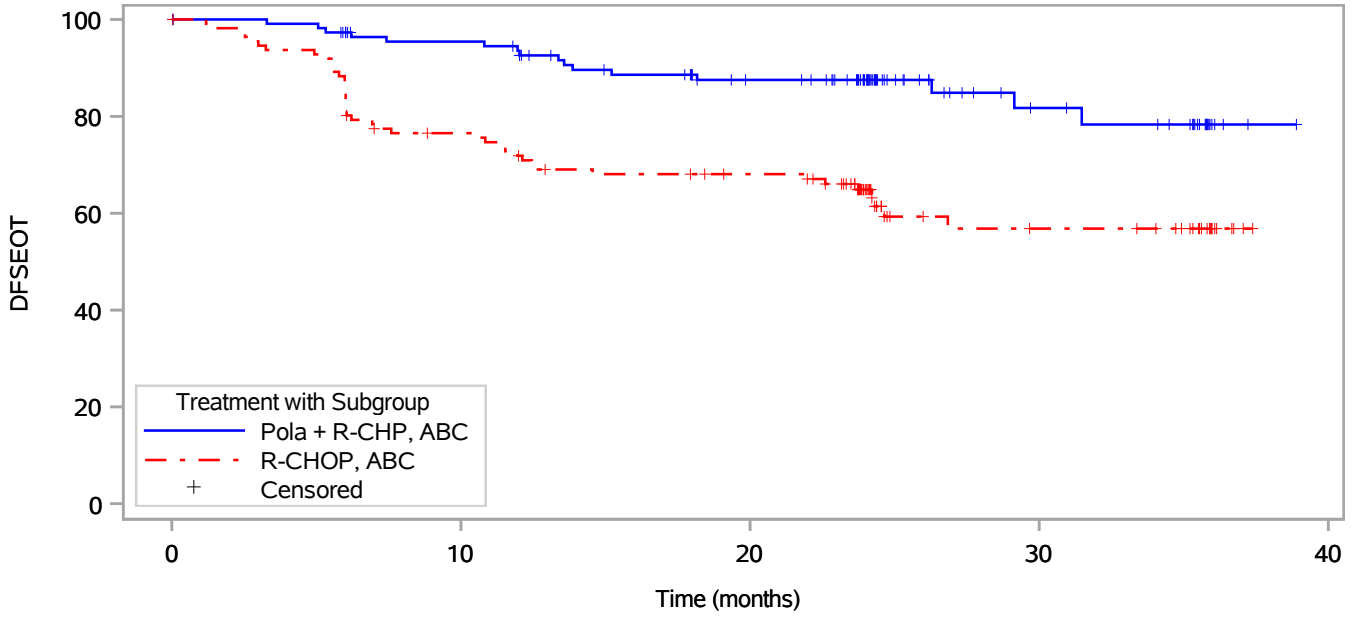
11OCT2023 8:13

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
STUDY: GO39942

Cell of origin



Patients at risk													
Pola + R-CHP, ABC	115	112	107	101	98	89	84	79	60	30	25	23	4
R-CHOP, ABC	112	105	96	82	76	71	70	68	45	23	22	22	6
Patients censored													
Pola + R-CHP, ABC	0	3	5	9	10	15	19	23	42	71	75	76	95
R-CHOP, ABC	0	1	1	4	5	6	7	9	29	47	48	48	64

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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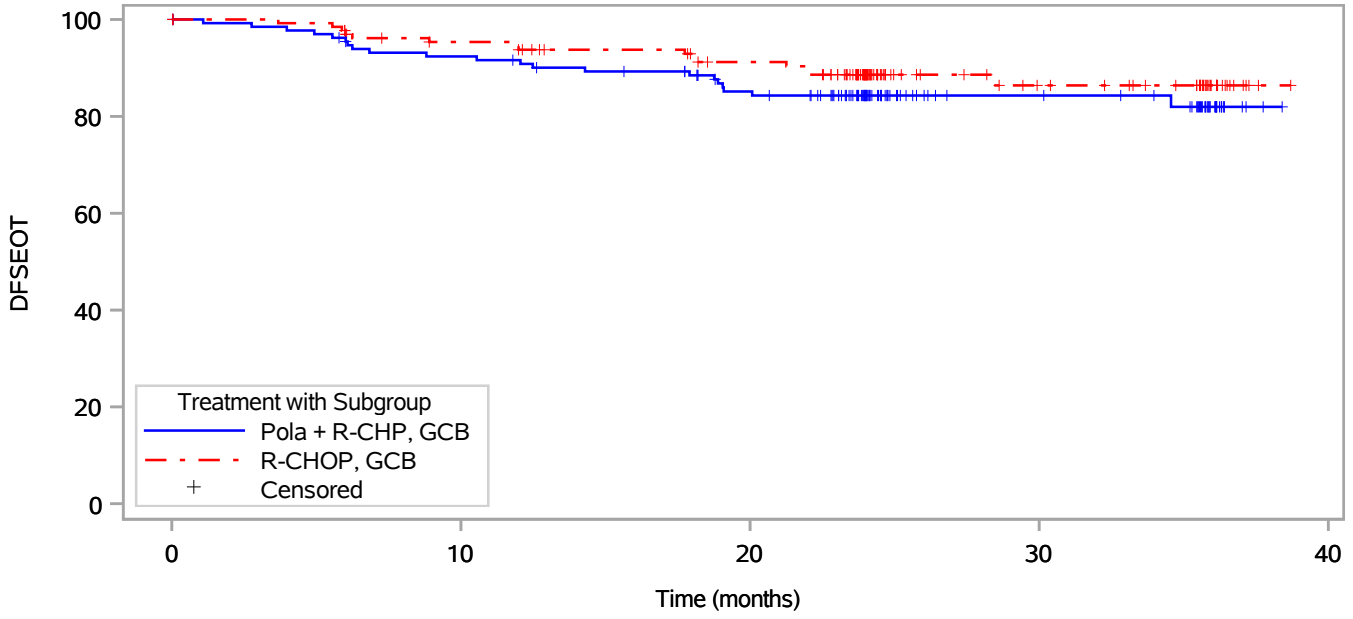
POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
STUDY: GO39942

Cell of origin



Patients at risk													
Pola + R-CHP, GCB	136	130	126	120	118	114	110	100	70	39	39	37	17
R-CHOP, GCB	134	131	126	119	116	112	109	105	71	42	36	34	14
Patients censored													
Pola + R-CHP, GCB	0	4	5	6	7	8	11	16	46	77	77	79	98
R-CHOP, GCB	0	3	5	9	10	14	16	18	49	78	83	85	105

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
STUDY: GO39942

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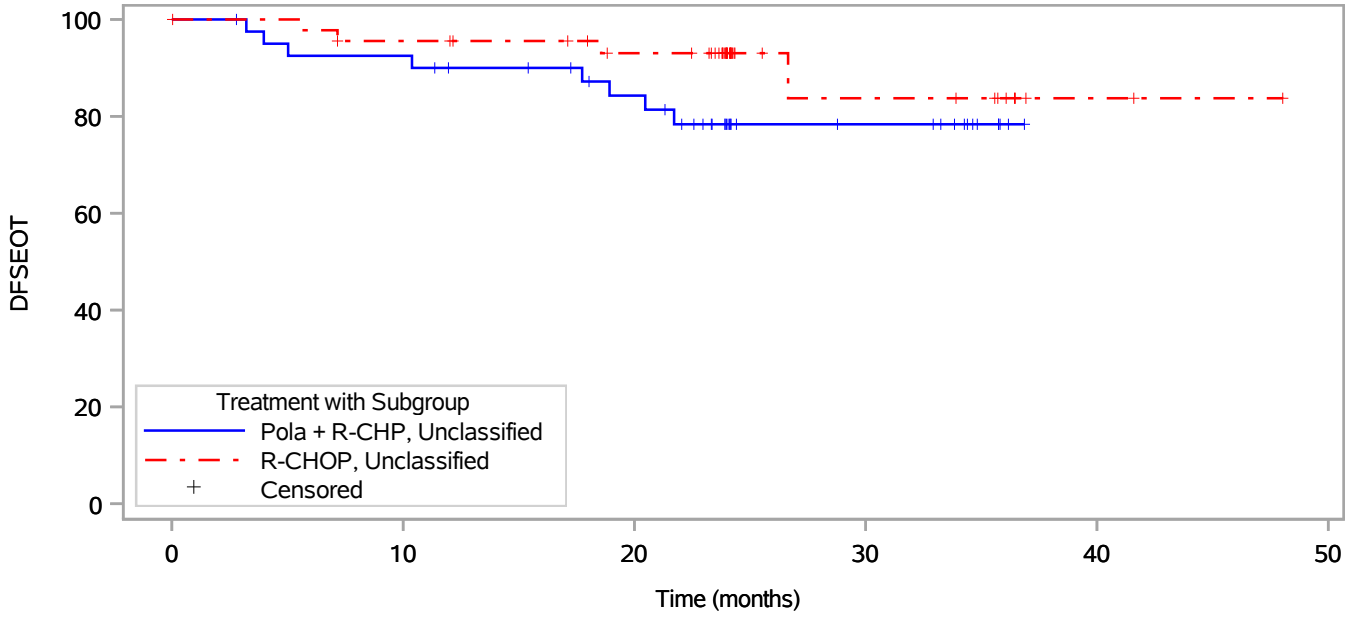

Patients at risk																	
Pola + R-CHP, Unclassified	41	40	37	37	34	34	31	28	18	13	12	11	2	NE	NE	NE	NE
R-CHOP, Unclassified	46	45	44	42	42	40	38	36	23	9	9	9	6	2	1	1	1
Patients censored																	
Pola + R-CHP, Unclassified	0	1	1	1	3	3	5	6	15	20	21	22	31	NE	NE	NE	NE
R-CHOP, Unclassified	0	1	1	2	2	4	6	7	20	33	33	33	36	40	41	41	41

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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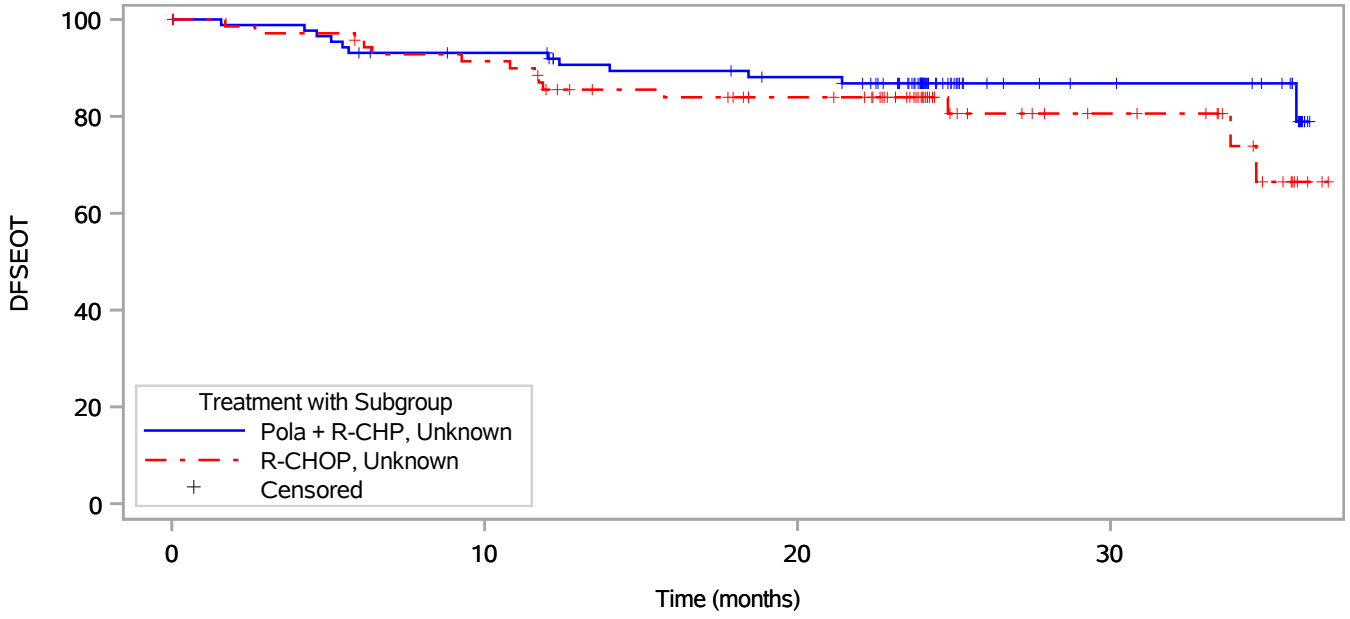
POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
STUDY: GO39942

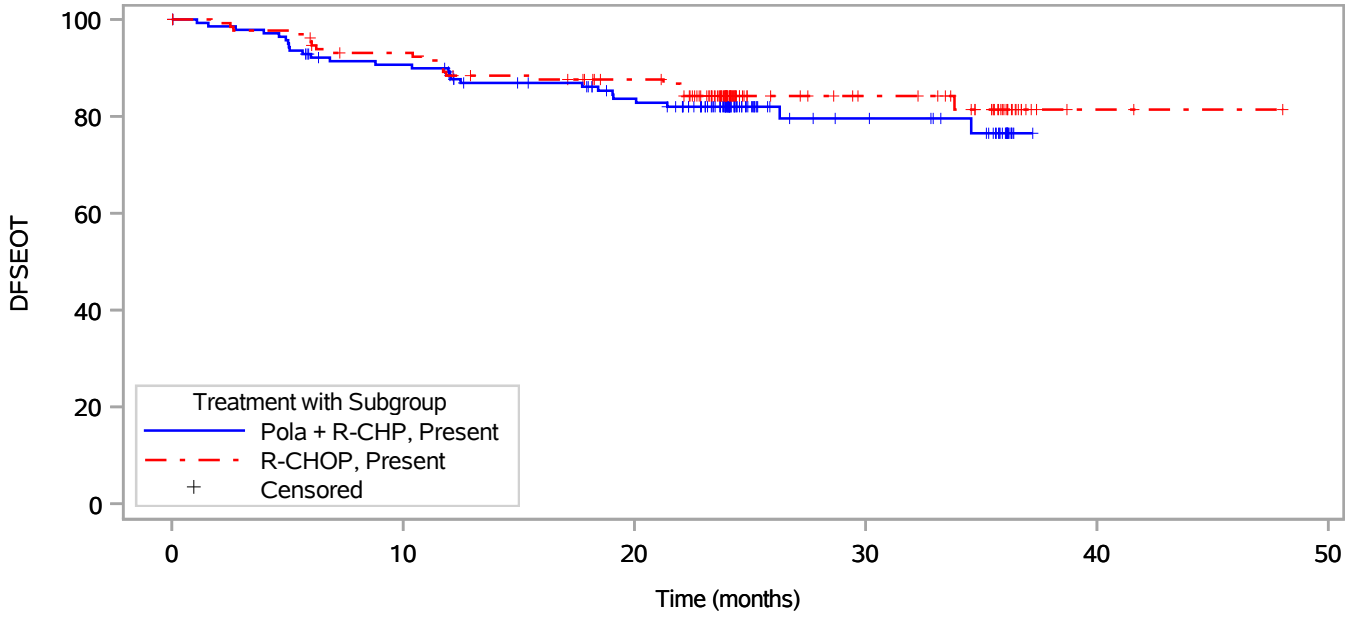
Cell of origin



Patients at risk													
Pola + R-CHP, Unknown	89	86	80	78	77	71	70	68	44	20	18	17	10
R-CHOP, Unknown	72	68	66	64	57	54	51	48	32	21	17	16	3
Patients censored													
Pola + R-CHP, Unknown	0	2	3	5	6	9	10	11	34	58	60	61	67
R-CHOP, Unknown	0	2	3	3	5	8	10	13	29	39	43	44	55

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
STUDY: GO39942
Baseline Bulky Disease



Patients at risk																	
Pola + R-CHP, Present	144	137	127	123	119	111	108	100	69	32	30	27	16	NE	NE	NE	NE
R-CHOP, Present	134	128	125	119	113	111	107	104	65	39	34	33	16	2	1	1	1
Patients censored																	
Pola + R-CHP, Present	0	4	7	8	10	15	17	21	51	87	89	92	102	NE	NE	NE	NE
R-CHOP, Present	0	3	4	6	6	8	11	14	49	75	80	81	97	111	112	112	112

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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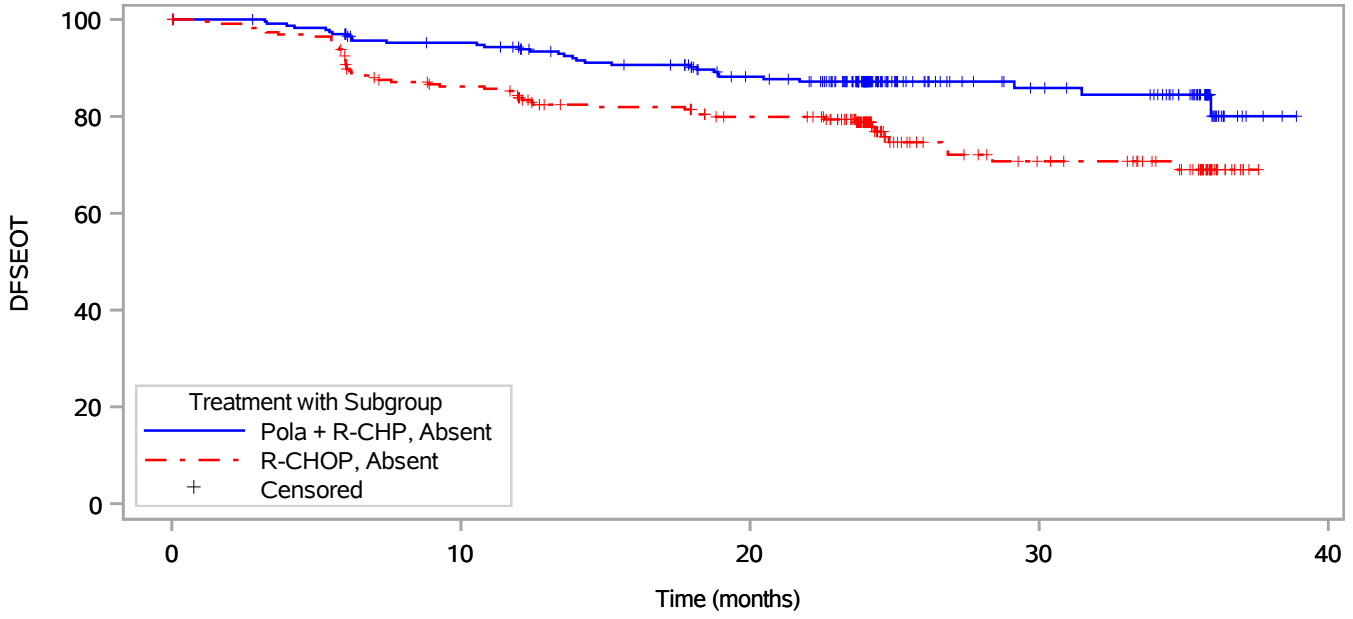
POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
STUDY: GO39942
Baseline Bulky Disease



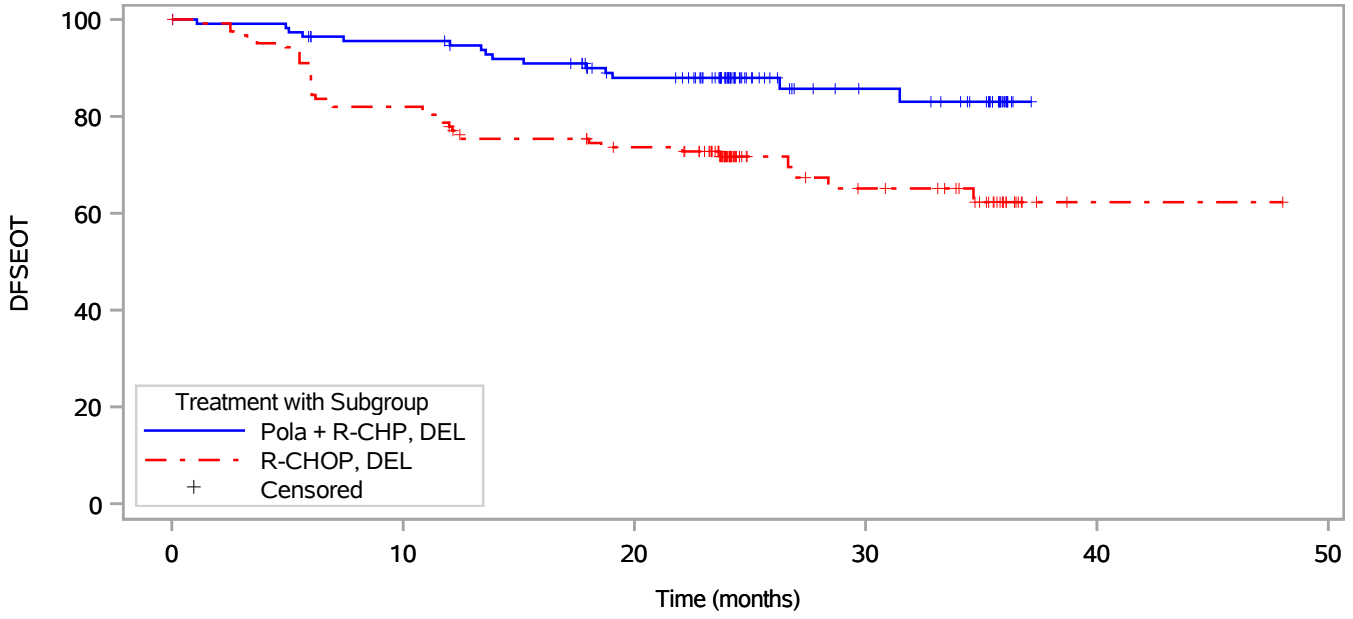
Patients at risk													
Pola + R-CHP, Absent	237	231	223	213	208	197	187	175	123	70	64	61	17
R-CHOP, Absent	230	221	207	188	178	166	161	153	106	56	50	48	13
Patients censored													
Pola + R-CHP, Absent	0	6	7	13	16	20	28	35	86	139	144	146	189
R-CHOP, Absent	0	4	6	12	16	24	28	33	78	122	127	129	163

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..alysis/ACE_FINAL_OS/prod/output/g_km_sg1_DFSEOT_CREOT_IT_POOLED_15JUN2022_39942.pdf
11OCT2023 8:16

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
STUDY: GO39942

Double Expressor Lymphoma by IHC (Central Review)



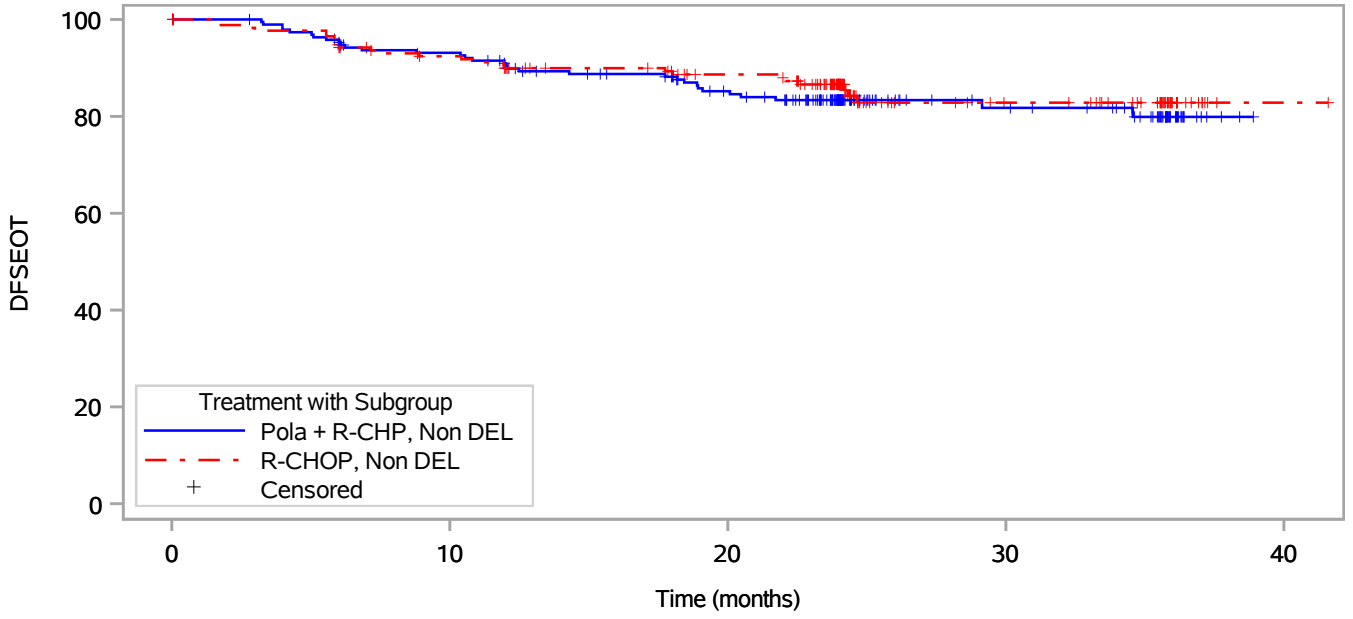
Patients at risk																	
Pola + R-CHP, DEL	114	112	108	105	104	99	91	87	65	35	32	30	10	NE	NE	NE	NE
R-CHOP, DEL	123	118	110	100	94	89	87	84	55	31	28	27	11	1	1	1	1
Patients censored																	
Pola + R-CHP, DEL	0	1	2	4	5	6	12	14	36	65	68	69	89	NE	NE	NE	NE
R-CHOP, DEL	0	1	1	1	2	4	6	7	34	56	58	59	74	84	84	84	84

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..alysis/ACE_FINAL_OS/prod/output/g_km_sg1_DFSEOT_CREOT_IT_POOLED_15JUN2022_39942.pdf
11OCT2023 8:16

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
STUDY: GO39942

Double Expressor Lymphoma by IHC (Central Review)



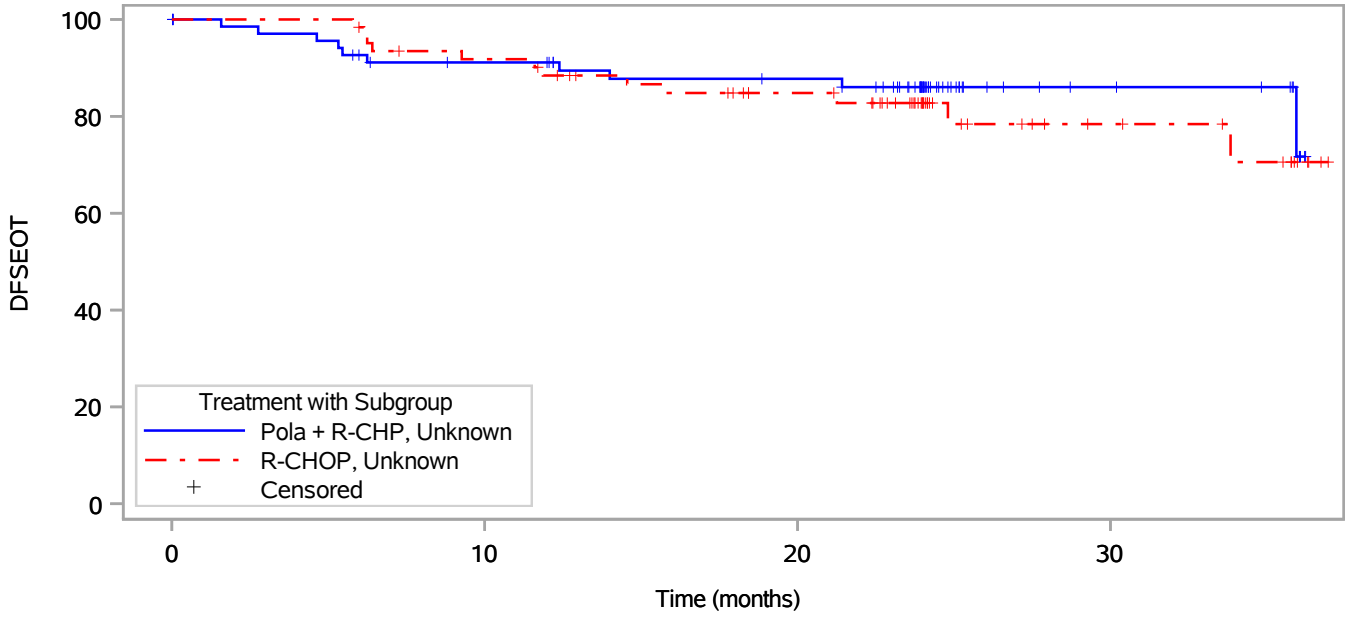
Patients at risk														
Pola + R-CHP, Non DEL	195	190	181	173	166	157	152	137	93	54	51	48	18	NE
R-CHOP, Non DEL	179	169	162	151	145	140	136	131	90	48	44	43	14	1
Patients censored														
Pola + R-CHP, Non DEL	0	5	6	9	12	17	21	29	72	111	113	116	145	NE
R-CHOP, Non DEL	0	6	8	15	17	22	25	29	67	106	110	111	140	153

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..alysis/ACE_FINAL_OS/prod/output/g_km_sg1_DFSEOT_CREOT_IT_POOLED_15JUN2022_39942.pdf
11OCT2023 8:16

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
STUDY: GO39942

Double Expressor Lymphoma by IHC (Central Review)



Patients at risk													
Pola + R-CHP, Unknown	72	66	61	58	57	52	52	51	34	13	11	10	5
R-CHOP, Unknown	62	62	60	56	52	48	45	42	26	16	12	11	4
Patients censored													
Pola + R-CHP, Unknown	0	4	6	8	9	12	12	13	29	50	52	53	57
R-CHOP, Unknown	0	0	1	2	3	6	8	11	26	35	39	40	46

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: DFS (from first CR(Composite-INV)) Rate
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=437)				R-CHOP (N=417)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	437	100.0	84	19.2	417	100.0	103	24.7	0.72		Convergence criterion (GCONV=1E-8) satisfied.	0.52	1.00	-0.054		Algorithm converged.	-0.108	0.000	0.76		Algorithm converged.	0.59	0.98	0.0466	1.31		Algorithm converged.	1.02	1.69

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_DFSFCRR_CR_IT_POOLED_15JUN2022_39942.xls
09FEB2023 19:21

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: DFS (from first CR(Composite-INV))-Death Rate
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=437)				R-CHOP (N=417)				Polatuzumab Vedotin + R-CHP vs. R-CHOP																R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	437	100.0	13	3.0	417	####	18	4.3	0.66		Convergence criterion (GCONV=1E-8) satisfied.	0.32	1.37		*	WARNING: The relative Hessian convergence criterion of 0.0340064412 is greater than the limit of 0.0001. The convergence is questionable.			0.70		Algorithm converged.	0.35	1.40	0.2400	1.43		Algorithm converged.	0.72	2.87

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical studies/RO5541077/CDPT7884/GO39942/data analysis/ACE FINAL DS/prod/output/t eff resp str DFSFCRDR CR IT POOLED 15JUN2022 39942.xls
09FEB2023 18:30

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: DFS (from first CR(Composite-INV))-Recurrence Rate
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=437)				R-CHOP (N=417)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	437	100.0	71	16.2	417	100.0	85	20.4	0.75		Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.07	-0.042		Algorithm converged.	-0.093	0.009	0.78		Algorithm converged.	0.59	1.04	0.1143	1.28		Algorithm converged.	0.97	1.70

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_DFSFCRRR_CR_IT_POOLED_15JUN2022_39942.xls
09FEB2023 19:25

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Complete Response Population (with CR, Composite-INV)
ENDPOINT: DFS (from first CR(Composite-INV)) Rate
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=437)				R-CHOP (N=417)				Polatuzumab Vedotin + R-CHP vs. R-CHOP													R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	437	100.0	84	19.2	417	100.0	103	24.7	0.73	Convergence criterion (GCONV=1E-8) satisfied.	0.52	1.00	-0.055	Algorithm converged.	-0.110	0.001	0.78	Algorithm converged.	0.60	1.00	0.0531		1.28	Algorithm converged.	1.00	1.66
Sex	Male	231	52.9	40	19.0	216	51.8	63	29.2	0.57	Convergence criterion (GCONV=1E-8) satisfied.	0.37	0.89	-0.101	Algorithm converged.	-0.180	-0.021	0.65	Algorithm converged.	0.47	0.90	0.0123	0.1278	1.53	Algorithm converged.	1.09	2.16
	Female	206	47.1	40	19.4	201	48.2	40	19.9	0.97	Convergence criterion (GCONV=1E-8) satisfied.	0.59	1.58	-0.005	Algorithm converged.	-0.082	0.072	0.98	Algorithm converged.	0.66	1.45	0.9023		1.02	Algorithm converged.	0.68	1.52
Age	>= 65	143	32.7	20	14.0	126	30.2	22	17.5	0.79	Convergence criterion (GCONV=1E-8) satisfied.	0.41	1.52	-0.031	Algorithm converged.	-0.129	0.066	0.82	Algorithm converged.	0.47	1.43	0.4782	0.9823	1.22	Algorithm converged.	0.76	2.12
	< 65	297	68.0	64	21.5	291	69.8	81	27.8	0.73	Convergence criterion (GCONV=1E-8) satisfied.	0.49	1.04	-0.063	Algorithm converged.	-0.132	0.005	0.77	Algorithm converged.	0.58	1.03	0.0773		1.28	Algorithm converged.	0.97	1.72
Geographic region	Western Europe/United States/Canada/Australia	259	59.3	40	16.2	252	60.4	57	22.6	0.66	Convergence criterion (GCONV=1E-8) satisfied.	0.43	1.03	-0.064	Algorithm converged.	-0.132	0.004	0.72	Algorithm converged.	0.52	1.00	0.0674	0.3170	1.34	Algorithm converged.	0.97	2.02
	Asia	128	29.3	22	20.3	116	27.8	33	28.4	0.64	Convergence criterion (GCONV=1E-8) satisfied.	0.36	1.16	-0.081	Algorithm converged.	-0.189	0.026	0.71	Algorithm converged.	0.46	1.12	0.1391		1.40	Algorithm converged.	0.89	2.18
	Rest of World	50	11.4	16	32.0	49	11.8	13	26.5	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.55	3.11	0.055	Algorithm converged.	-0.124	0.234	1.21	Algorithm converged.	0.65	2.23	0.5520		0.93	Algorithm converged.	0.45	1.94
Race/ethnicity	White	197	45.1	37	18.8	195	46.8	42	21.5	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.51	1.38	-0.026	Algorithm converged.	-0.107	0.052	0.87	Algorithm converged.	0.59	1.29	0.4960	0.3287	1.15	Algorithm converged.	0.77	1.70
	Black or African American	8	1.8	0	0.0	5	1.2	1	20.0	*	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	0.2059		>999.99	Algorithm converged.	0.00	NE
	Asian	132	30.2	27	20.5	121	29.0	34	28.1	0.68	Convergence criterion (GCONV=1E-8) satisfied.	0.37	1.17	-0.076	Algorithm converged.	-0.182	0.029	0.73	Algorithm converged.	0.47	1.13	0.1544		1.37	Algorithm converged.	0.88	2.14
	Other	6	1.4	2	33.3	8	1.9	1	12.5	3.90	Convergence criterion (GCONV=1E-8) satisfied.	0.24	51.90	0.208	Algorithm converged.	-0.233	0.650	2.67	Algorithm converged.	0.52	23.58	0.3459		0.38	Algorithm converged.	0.04	3.57
	Unknown	94	21.5	18	19.1	88	21.1	20	22.7	0.80	Convergence criterion (GCONV=1E-8) satisfied.	0.39	1.19	-0.093	Algorithm converged.	-0.216	0.031	0.83	Algorithm converged.	0.49	1.35	0.1428		1.48	Algorithm converged.	0.87	2.52
ECOG performance status	0-1	369	84.4	71	19.2	354	84.9	93	26.3	0.67	Convergence criterion (GCONV=1E-8) satisfied.	0.47	0.95	-0.070	Algorithm converged.	-0.131	-0.009	0.73	Algorithm converged.	0.54	0.98	0.0241	0.2484	1.37	Algorithm converged.	1.04	1.79
	2	68	15.6	13	19.1	63	14.0	10	16.0	1.22	Convergence criterion (GCONV=1E-8) satisfied.	0.49	2.99	0.027	Algorithm converged.	-0.105	0.159	1.17	Algorithm converged.	0.61	2.44	0.6873		0.96	Algorithm converged.	0.43	1.82
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cell of origin (determined by gene expression)	ABC	124	28.4	22	17.7	126	30.2	51	40.5	0.32	Convergence criterion (GCONV=1E-8) satisfied.	0.18	0.57	-0.227	Algorithm converged.	-0.336	-0.118	0.44	Algorithm converged.	0.28	0.68	<.0001	0.0585	2.28	Algorithm converged.	1.46	3.52
	GCB	167	38.2	33	19.8	151	36.2	36	23.8	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.73	2.33	0.038	Algorithm converged.	-0.045	0.122	1.24	Algorithm converged.	0.77	2.00	0.3701		0.95	Algorithm converged.	0.59	1.52
	Unclassified	44	10.1	9	20.5	52	12.5	6	11.5	1.97	Convergence criterion (GCONV=1E-8) satisfied.	0.64	6.06	0.089	Algorithm converged.	-0.058	0.237	1.77	Algorithm converged.	0.68	4.59	0.2330		0.54	Algorithm converged.	0.20	1.46
	Unknown	102	23.3	20	19.6	88	21.1	22	25.0	0.73	Convergence criterion (GCONV=1E-8) satisfied.	0.37	1.45	-0.054	Algorithm converged.	-0.173	0.065	0.78	Algorithm converged.	0.48	1.26	0.3730		1.27	Algorithm converged.	0.75	2.16
IPI score at Screening	1-2	164	37.5	24	14.6	168	40.3	29	17.3	0.82	Convergence criterion (GCONV=1E-8) satisfied.	0.46	1.48	-0.024	Algorithm converged.	-0.105	0.056	0.85	Algorithm converged.	0.52	1.38	0.5140	0.2483	1.18	Algorithm converged.	0.70	1.94
	3	181	41.4	33	18.2	154	36.9	46	29.9	0.52	Convergence criterion (GCONV=1E-8) satisfied.	0.31	0.87	-0.116	Algorithm converged.	-0.208	-0.025	0.61	Algorithm converged.	0.41	0.90	0.0153		1.64	Algorithm converged.	1.13	2.42
	4-5	92	21.1	27	29.3	95	22.8	28	29.5	0.99	Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.86	-0.001	Algorithm converged.	-0.132	0.129	1.00	Algorithm converged.	0.66	1.50	0.9850		1.00	Algorithm converged.	0.64	1.57
Baseline Bulky Disease	Present	173	39.6	37	21.4	164	39.3	33	20.1	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.64	1.83	0.013	Algorithm converged.	-0.074	0.099	1.06	Algorithm converged.	0.72	1.61	0.7751	0.0823	0.94	Algorithm converged.	0.62	1.43
	Absent	264	60.4	47	17.8	253	60.7	70	27.7	0.57	Convergence criterion (GCONV=1E-8) satisfied.	0.37	0.86	-0.093	Algorithm converged.	-0.173	-0.027	0.64	Algorithm converged.	0.46	0.89	0.0074		1.55	Algorithm converged.	1.12	2.14
Double Expressor Lymphoma by IHC (Central Review)	DEL	127	29.1	22	17.3	137	32.9	40	32.0	0.45	Convergence criterion (GCONV=1E-8) satisfied.	0.24	0.77	-0.153	Algorithm converged.	-0.258	-0.053	0.53	Algorithm converged.	0.34	0.83	0.0038	0.0181	1.85	Algorithm converged.	1.21	2.97
	Non DEL	227	51.9	44	19.4	203	48.7	37	18.2	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.66	1.75	0.012	Algorithm converged.	-0.062	0.085	1.06	Algorithm converged.	0.72	1.58	0.7587		0.94	Algorithm converged.	0.63	1.39
	Unknown	83	19.0	18	21.7	77	18.5	22	27.0	0.74	Convergence criterion (GCONV=1E-8) satisfied.	0.36	1.52	-0.052	Algorithm converged.	-0.189	0.077	0.80	Algorithm converged.	0.46	1.38	0.4254		1.24	Algorithm converged.	0.73	2.10
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	301	68.9	58	19.3	298	71.5	79	26.5	0.67	Convergence criterion (GCONV=1E-8) satisfied.	0.46	0.99	-0.069	Algorithm converged.	-0.136	-0.002	0.74	Algorithm converged.	0.55	0.99	0.0430	0.1026	1.36	Algorithm converged.	1.01	1.83
	DH/TH+	21	4.8	4	19.0	18	4.3	7	5.6	4.02	Convergence criterion (GCONV=1E-8) satisfied.	0.40	39.56	0.133	Algorithm converged.	-0.064	0.330	3.43	Algorithm converged.	0.42	27.97	0.2149		0.22	Algorithm converged.	0.04	2.38
	Unknown	115	26.3	22	19.1	101	24.2	24	23.8	0.76	Convergence criterion (GCONV=1E-8) satisfied.	0.40	1.46	-0.049	Algorithm converged.	-0.156	0.063	0.81	Algorithm converged.	0.48	1.36	0.4079		1.24	Algorithm converged.	0.76	2.03

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO55410?7/CSP?7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/BO55410?7/CSP?7884/GO39942/data_analysis/ACE_FINAL_GS/prod/output/t_eff_resp_sgl_DFSPCRR_CR_ITT_POOLED_15JUN2022_39942.xls
09FEB2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-INV) at EOT)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=381)				R-CHOP (N=364)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	381	100,0	57	15,0	364	100,0	75	20,6	0,67		Convergence criterion (GCONV=1E-8) satisfied.	0,46	0,98	-0,056		Algorithm converged.	-0,110	-0,002	0,72		Algorithm converged.	0,53	0,98	0,0408	1,39		Algorithm converged.	1,02	1,90

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_DFSEOT_CREOT_IT_POOLED_15JUN2022_39942.xls
11OCT2023 8:19

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Death Rate (DFS Form CR at EoT (Composite-INV))
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=281)				R-CHOP (N=563)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	281	100.0	7	2.5	564	100.0	32	5.7	0.39	Convergence criterion (ABSGCONV=1E-8) satisfied.	0.15	1.03	-0.03	WARNING: The relative Hessian convergence criterion of 1.0015929389 is greater than the limit of 0.0001. The convergence is questionable.	-0.06	0.00	0.44	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0.19	1.03	0.0599	2.28	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0.97	5.36

* indicates convergence problem. Result is uninterpretable.
CR is computed by stratified analysis, MH and AND by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO41077/CDPT7886/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/BO41077/CDPT7886/GO39942/data_analysis/ACE_FINAL_CS/prod/output/t_eff_resp_etv_DPSCRETO_CREDT_ST_POOLED_15JUN2022_GO39942.rtf
02NOV2023 11:25

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-INV assessments)
ENDPOINT: Recurrence Rate (DFS from CR at EoT (Composite-INV))
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=381)				R-CHOP (N=364)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	381	100,0	50	13,1	364	100,0	63	17,3	0,72		Convergence criterion (GCONV=1E-8) satisfied.	0,48	1,07	-0,047		Algorithm converged.	-0,099	0,005	0,75		Algorithm converged.	0,53	1,05	0,1037	1,33		Algorithm converged.	0,95	1,87

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_DFSCRETR_CREOT_IT_POOLED_15JUN2022_39942.xls
02NOV2023 11:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population, Patients with CR at EoT (Composite-IWP assessments)
ENDPOINT: Disease-Free Survival (DFS from CR(Composite-IWP) at EOT)
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=381)				R-CHOP (N=364)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	381	100,0	81	15,0	364	100,0	75	20,6	0,68	Convergence criterion (GCONV=1E-8) satisfied.	0,46	0,99	-0,056	Algorithm converged.	-0,111	-0,002	0,73	Algorithm converged.	0,53	0,99	0,0430		1,38	Algorithm converged.	1,01	1,86
Sex	Male	203	53,3	30	14,8	180	49,5	42	23,3	0,57	Convergence criterion (GCONV=1E-8) satisfied.	0,34	0,96	-0,086	Algorithm converged.	-0,164	-0,007	0,63	Algorithm converged.	0,41	0,97	0,0327	0,3674	1,54	Algorithm converged.	1,03	2,41
	Female	178	46,7	27	15,2	184	50,5	33	17,9	0,82	Convergence criterion (GCONV=1E-8) satisfied.	0,47	1,43	-0,028	Algorithm converged.	-0,104	0,049	0,85	Algorithm converged.	0,53	1,35	0,4798		1,18	Algorithm converged.	0,74	1,88
Age	<= 60	120	31,5	14	11,7	107	29,4	16	15,0	0,76	Convergence criterion (GCONV=1E-8) satisfied.	0,35	1,62	-0,033	Algorithm converged.	-0,122	0,056	0,78	Algorithm converged.	0,40	1,52	0,4665	0,8285	1,28	Algorithm converged.	0,66	2,50
	> 60	261	68,5	43	16,5	257	70,6	59	23,0	0,66	Convergence criterion (GCONV=1E-8) satisfied.	0,43	1,03	-0,065	Algorithm converged.	-0,133	0,004	0,72	Algorithm converged.	0,50	1,02	0,0630		1,39	Algorithm converged.	0,98	1,98
Geographic region	Western Europe/United States/Canada/Australia	229	60,1	27	11,8	221	60,7	41	18,6	0,58	Convergence criterion (GCONV=1E-8) satisfied.	0,35	0,99	-0,068	Algorithm converged.	-0,134	-0,002	0,64	Algorithm converged.	0,41	1,00	0,0455	0,4721	1,57	Algorithm converged.	1,00	2,47
	Asia	114	29,9	20	17,5	101	27,7	24	23,8	0,68	Convergence criterion (GCONV=1E-8) satisfied.	0,35	1,33	-0,062	Algorithm converged.	-0,151	0,046	0,74	Algorithm converged.	0,43	1,25	0,2604		1,55	Algorithm converged.	0,80	2,30
	Rest of World	38	10,0	10	26,3	42	11,5	10	23,8	1,16	Convergence criterion (GCONV=1E-8) satisfied.	0,42	3,15	0,025	Algorithm converged.	-0,165	0,215	1,11	Algorithm converged.	0,52	2,36	0,7973		0,96	Algorithm converged.	0,42	1,93
Race/ethnicity	White	167	43,8	23	13,8	168	46,2	28	16,7	0,80	Convergence criterion (GCONV=1E-8) satisfied.	0,44	1,45	-0,029	Algorithm converged.	-0,168	0,068	0,83	Algorithm converged.	0,50	1,37	0,4614	0,3923	1,21	Algorithm converged.	0,73	2,01
	Black or African American	8	2,1	0	0,0	4	1,1	1	25,0	*	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	0,1573		>999,99	Algorithm converged.	0,00	NE
	Asian	118	31,0	21	17,8	105	28,8	25	23,8	0,69	Convergence criterion (GCONV=1E-8) satisfied.	0,36	1,33	-0,060	Algorithm converged.	-0,167	0,047	0,75	Algorithm converged.	0,45	1,23	0,2691		1,34	Algorithm converged.	0,80	2,24
	Other	3	0,8	1	33,3	8	2,2	1	12,5	3,50	Convergence criterion (GCONV=1E-8) satisfied.	0,14	84,69	0,208	Algorithm converged.	-0,372	0,788	2,67	Algorithm converged.	0,23	30,40	0,4468		0,38	Algorithm converged.	0,03	4,21
	Unknown	85	22,3	12	14,1	79	21,7	20	25,3	0,48	Convergence criterion (GCONV=1E-8) satisfied.	0,22	1,07	-0,112	Algorithm converged.	-0,233	0,009	0,56	Algorithm converged.	0,29	1,06	0,0716		1,79	Algorithm converged.	0,94	3,41
ECOG performance status	0-1	322	84,5	66	15,5	307	84,3	67	21,8	0,66	Convergence criterion (GCONV=1E-8) satisfied.	0,44	0,99	-0,063	Algorithm converged.	-0,124	-0,002	0,71	Algorithm converged.	0,51	0,99	0,0427	0,7899	1,41	Algorithm converged.	1,01	1,96
	2	59	15,5	9	11,9	55	15,1	8	14,5	0,79	Convergence criterion (GCONV=1E-8) satisfied.	0,27	2,35	-0,027	Algorithm converged.	-0,151	0,098	0,82	Algorithm converged.	0,32	2,10	0,6730		1,23	Algorithm converged.	0,46	3,18
	Missing	0	0,0	0	0,0	2	0,5	0	0,0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cell of origin (determined by gene expression)	ABC	115	30,2	18	13,9	112	30,8	42	37,5	0,27	Convergence criterion (GCONV=1E-8) satisfied.	0,14	0,52	-0,236	Algorithm converged.	-0,346	-0,126	0,37	Algorithm converged.	0,22	0,62	<.0001	0,0003	2,70	Algorithm converged.	1,61	4,56
	GCB	134	35,7	21	15,4	134	36,8	15	11,0	1,45	Convergence criterion (GCONV=1E-8) satisfied.	0,71	2,95	0,042	Algorithm converged.	-0,038	0,121	1,38	Algorithm converged.	0,74	2,56	0,3056		0,72	Algorithm converged.	0,39	1,35
	Unclassified	41	10,8	8	19,5	46	12,6	4	8,7	2,53	Convergence criterion (GCONV=1E-8) satisfied.	0,70	9,19	0,108	Algorithm converged.	-0,038	0,254	2,24	Algorithm converged.	0,73	8,90	0,1465		0,43	Algorithm converged.	0,14	1,37
	Unknown	89	23,4	12	13,5	72	19,8	14	19,4	0,65	Convergence criterion (GCONV=1E-8) satisfied.	0,28	1,50	-0,060	Algorithm converged.	-0,175	0,056	0,69	Algorithm converged.	0,34	1,40	0,3083		1,44	Algorithm converged.	0,73	2,92
IPI score at Screening	1-2	148	38,8	17	11,5	147	40,4	20	13,6	0,82	Convergence criterion (GCONV=1E-8) satisfied.	0,41	1,64	-0,021	Algorithm converged.	-0,097	0,054	0,84	Algorithm converged.	0,46	1,55	0,5834	0,4710	1,16	Algorithm converged.	0,65	2,11
	3	156	40,9	23	14,7	130	35,7	33	25,4	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,28	0,92	-0,106	Algorithm converged.	-0,201	-0,011	0,56	Algorithm converged.	0,36	0,94	0,0242		1,72	Algorithm converged.	1,07	2,76
	4-5	77	20,2	17	22,1	87	23,9	22	25,3	0,84	Convergence criterion (GCONV=1E-8) satisfied.	0,41	1,73	-0,032	Algorithm converged.	-0,162	0,098	0,87	Algorithm converged.	0,50	1,52	0,6310		1,15	Algorithm converged.	0,64	1,99
Baseline Bulky Disease	Present	144	37,8	26	18,1	134	36,8	21	15,7	1,13	Convergence criterion (GCONV=1E-8) satisfied.	0,63	2,23	0,024	Algorithm converged.	-0,064	0,112	1,15	Algorithm converged.	0,68	1,95	0,5968	0,0300	0,87	Algorithm converged.	0,51	1,47
	Absent	237	62,2	55	13,1	230	63,2	54	23,5	0,69	Convergence criterion (GCONV=1E-8) satisfied.	0,36	0,80	-0,104	Algorithm converged.	-0,174	-0,034	0,58	Algorithm converged.	0,37	0,83	0,0038		1,79	Algorithm converged.	1,20	2,68
Double Expressor Lymphoma by IHC (Central Review)	DEL	114	29,9	15	13,2	123	33,8	38	30,9	0,34	Convergence criterion (GCONV=1E-8) satisfied.	0,17	0,66	-0,177	Algorithm converged.	-0,280	-0,075	0,43	Algorithm converged.	0,25	0,73	0,0011	0,0047	2,35	Algorithm converged.	1,37	4,03
	Non DEL	195	51,2	32	16,4	179	49,2	25	14,0	1,21	Convergence criterion (GCONV=1E-8) satisfied.	0,69	2,13	0,024	Algorithm converged.	-0,048	0,097	1,17	Algorithm converged.	0,73	1,91	0,5116		0,85	Algorithm converged.	0,53	1,38
	Unknown	72	18,9	10	13,9	62	17,0	12	19,4	0,67	Convergence criterion (GCONV=1E-8) satisfied.	0,27	1,68	-0,055	Algorithm converged.	-0,181	0,072	0,72	Algorithm converged.	0,33	1,55	0,3962		1,39	Algorithm converged.	0,65	3,00
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	261	68,5	41	15,7	263	72,3	59	22,4	0,66	Convergence criterion (GCONV=1E-8) satisfied.	0,41	1,06	-0,067	Algorithm converged.	-0,134	0,000	0,70	Algorithm converged.	0,49	1,00	0,0504	0,4158	1,43	Algorithm converged.	1,00	2,05
	DH/TH+	18	4,7	2	11,1	16	4,4	1	6,3	1,83	Convergence criterion (GCONV=1E-8) satisfied.	0,15	22,88	0,049	Algorithm converged.	-0,133	0,230	1,78	Algorithm converged.	0,18	17,80	0,6231		0,56	Algorithm converged.	0,06	5,62
	Unknown	102	26,8	14	13,7	85	23,4	15	17,6	0,74	Convergence criterion (GCONV=1E-8) satisfied.	0,34	1,64	-0,039	Algorithm converged.	-0,144	0,066	0,76	Algorithm converged.	0,40	1,52	0,4614		1,23	Algorithm converged.	0,66	2,51

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_sg1_DPSEOT_CHOP_ITT_POOLED_15JUN2022_39942.xls
27OCT2023 17:32

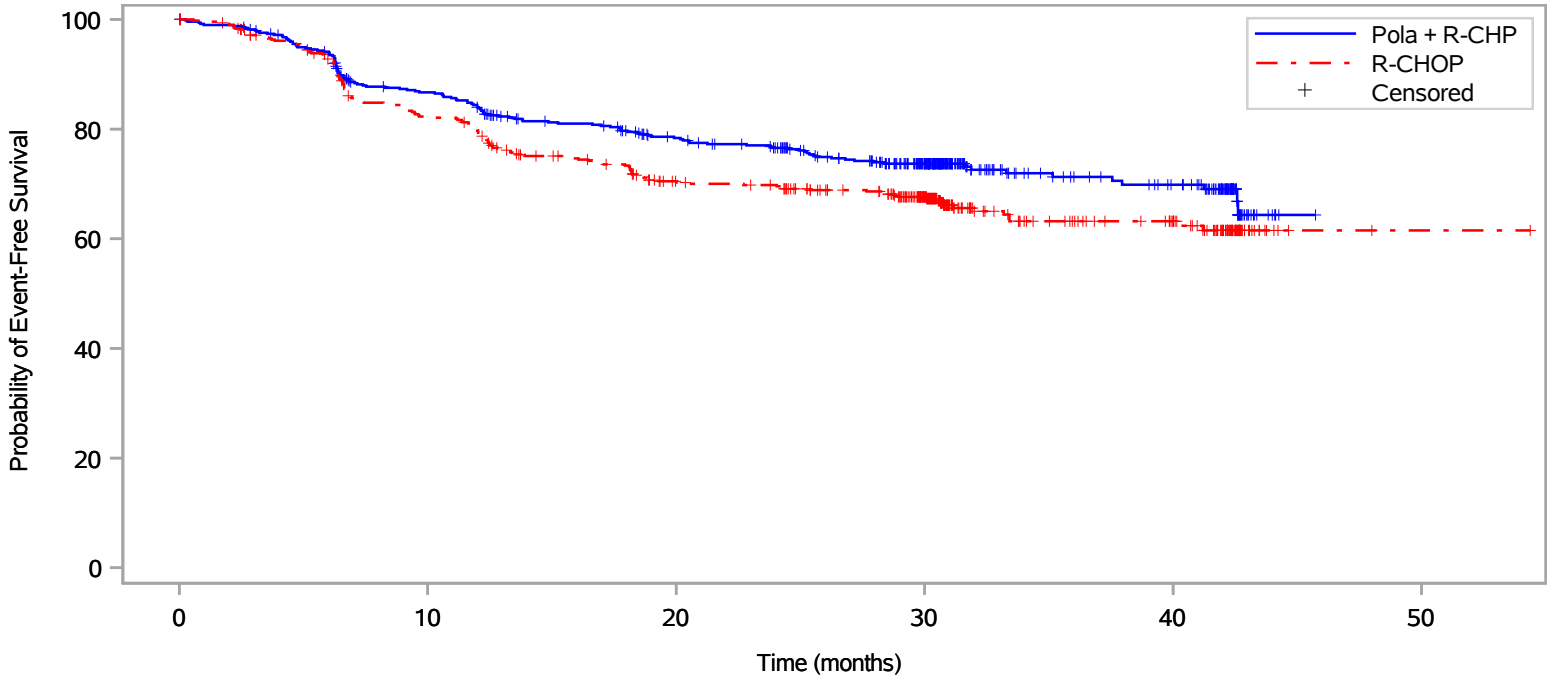
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Progression-Free Survival (PFS - INV)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)												R-CHOP (N=500)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	500	100.0	133	26.6	367	73.4	25.6	19.0	37.9	NE	NE	NE	500	100.0	163	32.6	337	67.4	15.7	12.3	18.9	NE	NE	NE	0.0176	0.76	0.60	0.95		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_tte_str_PFS_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:00

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Progression-Free Survival (PFS - INV)
STUDY: GO39942



Patients at risk																			
Pola + R-CHP	500	485	461	418	401	376	364	344	334	308	251	117	103	98	66	1	NE	NE	NE
R-CHOP	500	471	444	399	378	347	335	307	304	282	231	108	94	87	59	2	2	1	1
Patients censored																			
Pola + R-CHP	0	6	10	20	21	33	38	48	54	71	125	257	269	272	303	366	NE	NE	NE
R-CHOP	0	15	21	24	25	34	38	51	53	71	117	234	245	252	278	335	336	336	336

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..39942/data_analysis/ACE_FINAL_OS/prod/output/g_km_PFS_IT_POOLED_15JUN2022_39942.pdf
10FEB2023 11:38

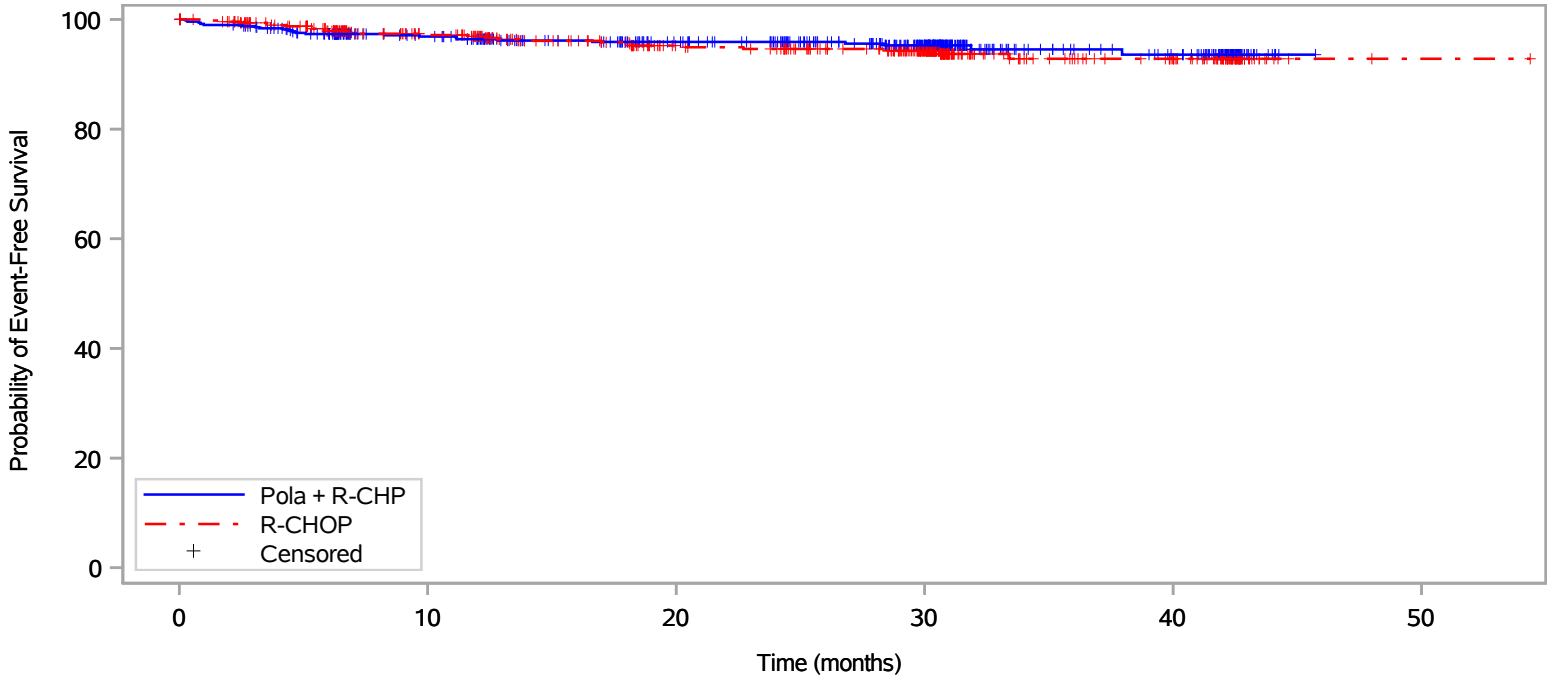
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Time to Death (PFS - Inv)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)												R-CHOP (N=500)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	500	100.0	23	4.6	477	95.4	NE	NE	NE	NE	NE	NE	500	100.0	25	5.0	475	95.0	NE	NE	NE	NE	NE	NE	0.6031	0.86	0.49	1.52		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_tte_str_PFSDTH_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:11

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Time to Death (PFS - Inv)
STUDY: GO39942



Patients at risk																			
Pola + R-CHP	500	485	461	418	401	376	364	344	334	308	251	117	103	98	66	1	NE	NE	NE
R-CHOP	500	471	444	399	378	347	335	307	304	282	231	108	94	87	59	2	2	1	1
Patients censored																			
Pola + R-CHP	0	9	26	68	82	106	117	137	147	172	228	361	375	379	411	476	NE	NE	NE
R-CHOP	0	26	46	89	108	136	147	172	174	196	246	368	381	388	416	473	474	474	474

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..42/data_analysis/ACE_FINAL_OS/prod/output/g_km_PFSDTH_IT_POOLED_15JUN2022_39942.pdf
10FEB2023 11:47

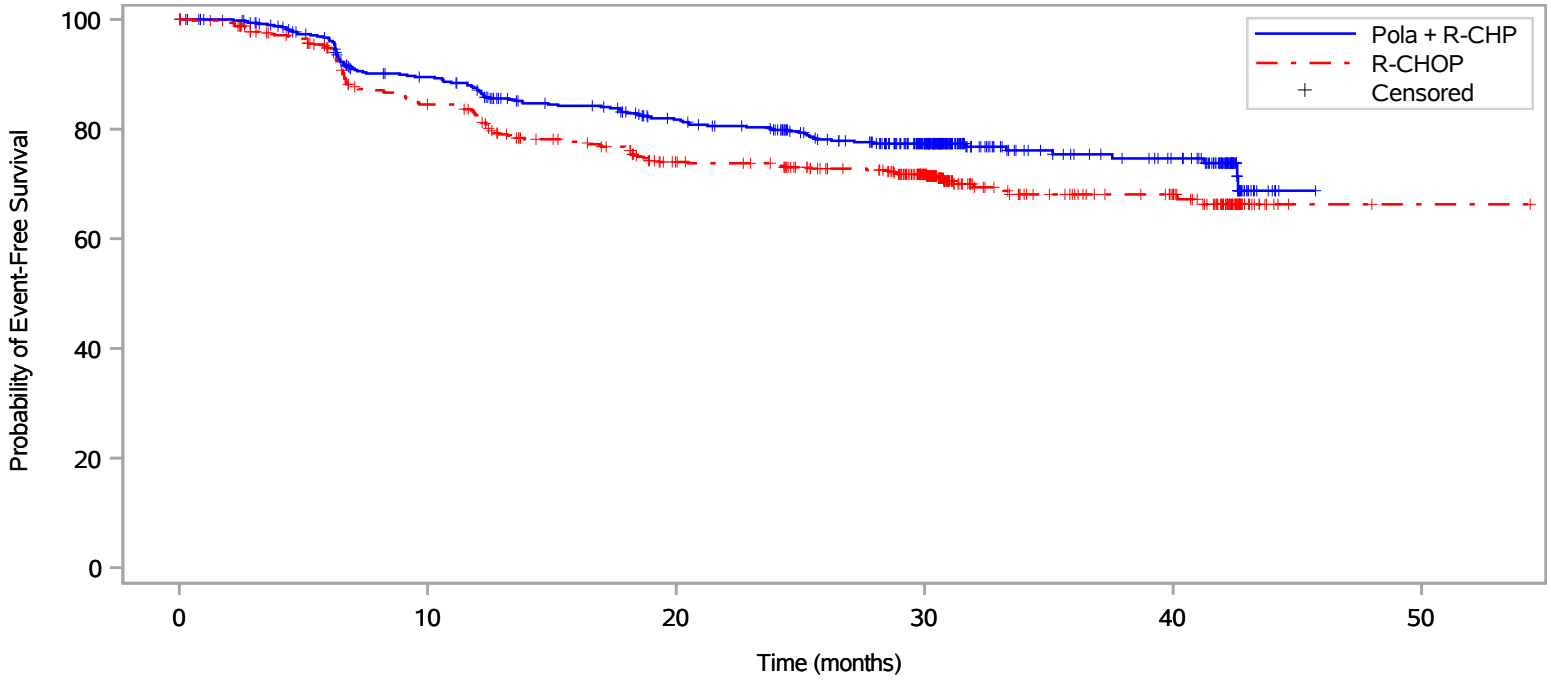
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Time to Progression/Relapse (PFS - INV)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Time to Event Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)												R-CHOP (N=500)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	500	100.0	110	22.0	390	78.0	37.6	25.4	NE	NE	NE	NE	500	100.0	138	27.6	362	72.4	18.5	13.3	30.8	NE	NE	NE	0.0181	0.74	0.57	0.95		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_tte.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_tte_str_PFSPRG_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:12

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Time to Progression/Relapse (PFS - INV)
STUDY: GO39942



Patients at risk																			
Pola + R-CHP	500	485	461	418	401	376	364	344	334	308	251	117	103	98	66	1	NE	NE	NE
R-CHOP	500	471	444	399	378	347	335	307	304	282	231	108	94	87	59	2	2	1	1
Patients censored																			
Pola + R-CHP	0	12	23	34	38	51	57	67	73	91	146	279	291	295	326	389	NE	NE	NE
R-CHOP	0	18	31	36	39	51	56	72	75	93	140	258	270	277	303	360	361	361	361

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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10FEB2023 11:49

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Progression-Free Survival (PFS - INV)
MODEL: Unstratified Analysis
STUDY: GO39942
Time to Event Analysis by Subgroups (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)												R-CHOP (N=500)												Polatuzumab Vedotin + R-CHP vs. R-CHOP					
		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	Convergence Status	p-value (likelihood ratio)
All	n/a	500	100.0	133	26.6	367	73.4	25.6	19.0	37.9	NE	NE	NE	500	100.0	163	32.6	337	67.4	15.7	12.5	18.9	NE	NE	NE	0.0257	0.77	0.61	0.97	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	268	53.6	73	27.2	195	72.8	25.6	17.3	42.6	NE	42.6	NE	270	54.0	104	38.5	166	61.5	12.1	8.9	16.5	NE	33.4	NE	0.0046	0.65	0.48	0.88	Convergence criterion (GCONV=1E-8) satisfied.	0.0820
	Female	232	46.4	60	25.9	172	74.1	26.3	18.0	NE	NE	NE	NE	230	46.0	59	25.7	171	74.3	24.3	15.7	NE	NE	NE	NE	0.9332	0.98	0.69	1.41	Convergence criterion (GCONV=1E-8) satisfied.	
Age	<= 60	167	33.4	42	25.1	125	74.9	25.2	15.2	NE	NE	42.6	NE	158	31.6	46	29.1	112	70.9	15.7	11.1	NE	NE	NE	NE	0.3474	0.82	0.54	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.7508
	> 60	333	66.6	91	27.3	242	72.7	26.3	18.5	37.9	NE	NE	NE	342	68.4	117	34.2	225	65.8	13.9	12.0	20.0	NE	NE	NE	0.0403	0.75	0.57	0.99	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Western Europe/United States/Canada/Australia	302	60.4	75	24.8	227	75.2	31.9	18.5	NE	NE	NE	NE	301	60.2	92	30.6	209	69.4	18.1	12.4	30.8	NE	NE	NE	0.1347	0.79	0.58	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.6920
	Asia	141	28.2	37	26.2	104	73.8	20.5	13.8	NE	NE	NE	NE	140	28.0	50	35.7	90	64.3	12.6	11.1	20.6	NE	30.7	NE	0.0580	0.68	0.43	1.02	Convergence criterion (GCONV=1E-8) satisfied.	
	Rest of World	57	11.4	21	36.8	36	63.2	22.8	11.2	NE	42.6	37.6	NE	59	11.8	21	35.6	38	64.4	11.9	6.6	33.2	NE	33.2	NE	0.6172	0.83	0.46	1.58	Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	235	47.0	64	27.2	171	72.8	25.6	18.0	NE	NE	NE	NE	236	47.2	70	29.7	166	70.3	18.1	11.9	33.2	NE	NE	NE	0.4821	0.89	0.63	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.0647
	Black or African American	8	1.6	0	0.0	8	100.0	NE	NE	NE	NE	NE	NE	8	1.6	4	50.0	4	50.0	7.1	2.0	NE	12.4	2.8	NE	0.0319	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Asian	145	29.0	38	26.2	107	73.8	20.5	13.8	NE	NE	NE	NE	145	29.0	51	35.2	94	64.8	12.6	11.6	20.6	NE	32.0	NE	0.0660	0.68	0.44	1.03	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	7	1.4	3	42.9	4	57.1	17.0	4.6	NE	NE	17.0	NE	11	2.2	4	36.4	7	63.6	6.4	2.2	NE	NE	6.4	NE	0.9772	0.98	0.22	4.42	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	105	21.0	28	26.7	77	73.3	31.7	12.8	NE	NE	42.6	NE	100	20.0	34	34.0	66	66.0	16.5	10.0	33.4	NE	NE	NE	0.3012	0.77	0.47	1.27	Convergence criterion (GCONV=1E-8) satisfied.	
ECOG performance status	0-1	419	83.8	110	26.3	309	73.7	27.2	20.3	41.2	NE	NE	NE	416	83.2	134	32.2	282	67.8	17.0	12.5	22.7	NE	NE	NE	0.0428	0.77	0.60	0.99	Convergence criterion (GCONV=1E-8) satisfied.	0.8834
	2	81	16.2	23	28.4	58	71.6	18.0	9.7	NE	NE	NE	NE	82	16.4	29	35.4	53	64.6	9.1	6.6	24.3	NE	NE	NE	0.2674	0.73	0.42	1.27	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	0	0.0	0	0.0	0	0.0	NE	NE	NE	NE	NE	NE	2	0.4	0	0.0	2	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Cell of origin (determined by gene expression)	ABC	131	26.2	27	20.6	104	79.4	35.2	27.2	NE	NE	NE	NE	143	28.6	66	46.2	77	53.8	11.9	9.4	12.6	33.2	20.5	NE	<.0001	0.37	0.23	0.57	Convergence criterion (GCONV=1E-8) satisfied.	<.0001
	GCB	193	38.6	53	27.5	140	72.5	24.9	12.8	NE	NE	NE	NE	187	37.4	50	26.7	137	73.3	25.3	12.5	NE	NE	NE	NE	0.9629	1.01	0.69	1.49	Convergence criterion (GCONV=1E-8) satisfied.	
	Unclassified	53	10.6	17	32.1	36	67.9	22.8	10.3	NE	NE	NE	NE	60	12.0	10	16.7	50	83.3	NE	24.3	NE	NE	NE	NE	0.0617	2.07	0.95	4.53	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	123	24.6	36	29.3	87	70.7	18.9	11.6	42.6	NE	42.6	NE	110	22.0	37	33.6	73	66.4	12.8	6.9	32.0	NE	40.2	NE	0.3485	0.80	0.51	1.27	Convergence criterion (GCONV=1E-8) satisfied.	
IPI score at Screening	1-2	188	37.6	43	22.9	145	77.1	42.6	19.9	NE	NE	NE	NE	187	37.4	44	23.5	143	76.5	31.2	18.9	NE	NE	NE	NE	0.8771	0.97	0.64	1.47	Convergence criterion (GCONV=1E-8) satisfied.	0.1552
	3	199	39.8	46	23.1	153	76.9	33.3	22.8	NE	NE	42.6	NE	186	37.2	66	35.5	120	64.5	12.5	11.2	20.0	NE	40.2	NE	0.0045	0.58	0.40	0.85	Convergence criterion (GCONV=1E-8) satisfied.	
	4-5	113	22.6	44	38.9	69	61.1	10.6	6.9	26.8	NE	35.2	NE	127	25.4	53	41.7	74	58.3	9.7	6.7	13.9	NE	24.0	NE	0.5753	0.89	0.60	1.33	Convergence criterion (GCONV=1E-8) satisfied.	
Baseline Bulky Disease	Present	211	42.2	67	31.8	144	68.2	15.2	10.9	26.3	NE	NE	NE	218	43.6	73	33.5	145	66.5	12.4	6.9	18.5	NE	NE	NE	0.6187	0.92	0.66	1.28	Convergence criterion (GCONV=1E-8) satisfied.	0.1541
	Absent	289	57.8	66	22.8	223	77.2	37.6	25.3	NE	NE	NE	NE	282	56.4	90	31.9	192	68.1	18.1	12.6	28.9	NE	NE	NE	0.0088	0.66	0.48	0.90	Convergence criterion (GCONV=1E-8) satisfied.	
Double Expressor Lymphoma by IHC (Central Review)	DEL	150	30.0	40	26.7	110	73.3	25.5	12.1	NE	NE	NE	NE	163	32.6	69	42.3	94	57.7	12.8	9.4	16.9	NE	33.2	NE	0.0082	0.59	0.40	0.88	Convergence criterion (GCONV=1E-8) satisfied.	0.0798
	Non DEL	253	50.6	66	26.1	187	73.9	26.8	18.5	NE	NE	NE	NE	244	48.8	63	25.8	181	74.2	28.5	13.4	NE	NE	NE	NE	0.7405	0.94	0.67	1.33	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	97	19.4	27	27.8	70	72.2	24.5	11.8	42.6	42.6	42.6	NE	93	18.6	31	33.3	62	66.7	13.7	7.1	32.0	NE	40.2	NE	0.4628	0.83	0.49	1.38	Convergence criterion (GCONV=1E-8) satisfied.	
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	341	68.2	89	26.1	252	73.9	27.2	19.0	NE	NE	NE	NE	351	70.2	117	33.3	234	66.7	16.1	12.1	24.0	NE	NE	NE	0.0360	0.73	0.57	0.98	Convergence criterion (GCONV=1E-8) satisfied.	0.0157
	DH/TH+	26	5.2	9	34.6	17	65.4	7.5	6.3	NE	NE	25.5	NE	19	3.8	2	10.5	17	89.5	NE	10.0	NE	NE	NE	NE	0.0672	3.79	0.82	17.53	Convergence criterion (GCONV=1E-8) satisfied.	
	Unknown	133	26.6	35	26.3	98	73.7	25.6	12.3	42.6	NE	42.6	NE	130	26.0	44	33.8	86	66.2	12.6	6.7	20.5	NE	40.2	NE	0.0812	0.67	0.43	1.05	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: 15JUN2022

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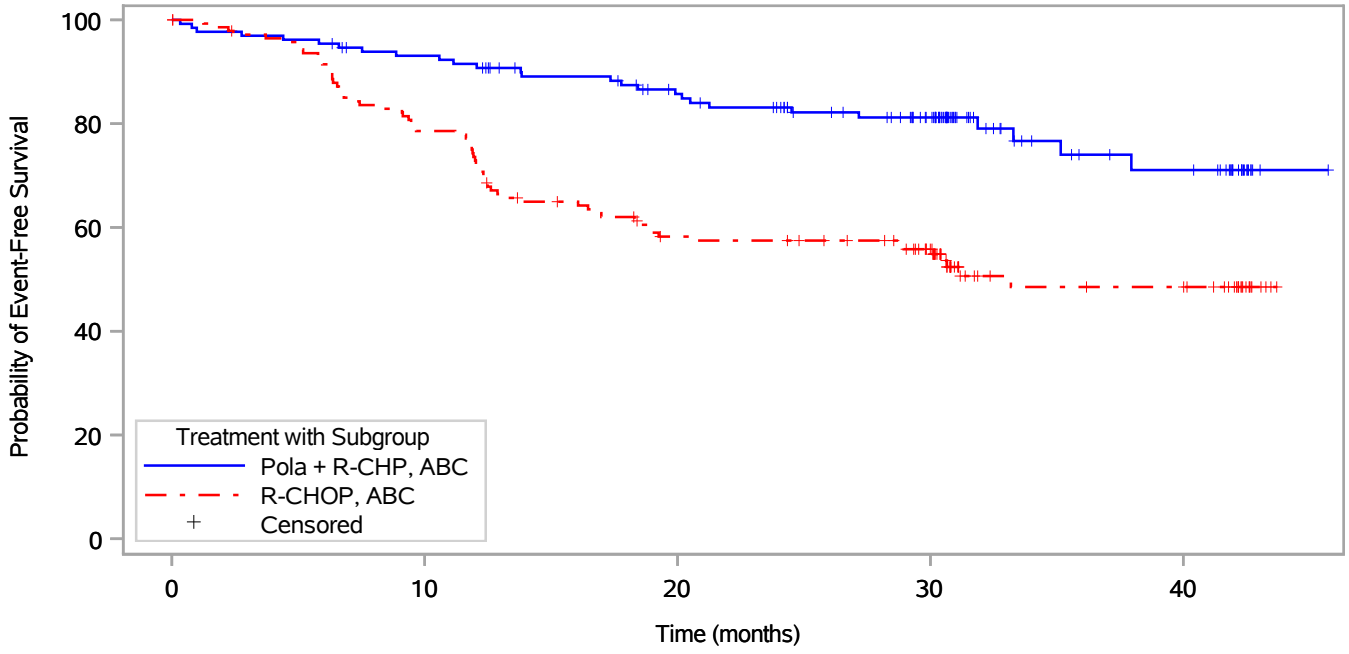
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Progression-Free Survival (PFS - INV)
STUDY: GO39942
Cell of origin



Patients at risk																
Pola + R-CHP, ABC	131	127	125	119	117	108	105	96	93	84	72	33	26	24	14	1
R-CHOP, ABC	143	136	128	116	102	89	84	75	75	71	59	24	23	22	17	NE
Patients censored																
Pola + R-CHP, ABC	0	0	0	3	3	9	10	15	17	25	36	74	79	80	90	103
R-CHOP, ABC	0	3	3	3	3	5	6	9	9	13	23	54	54	55	60	NE

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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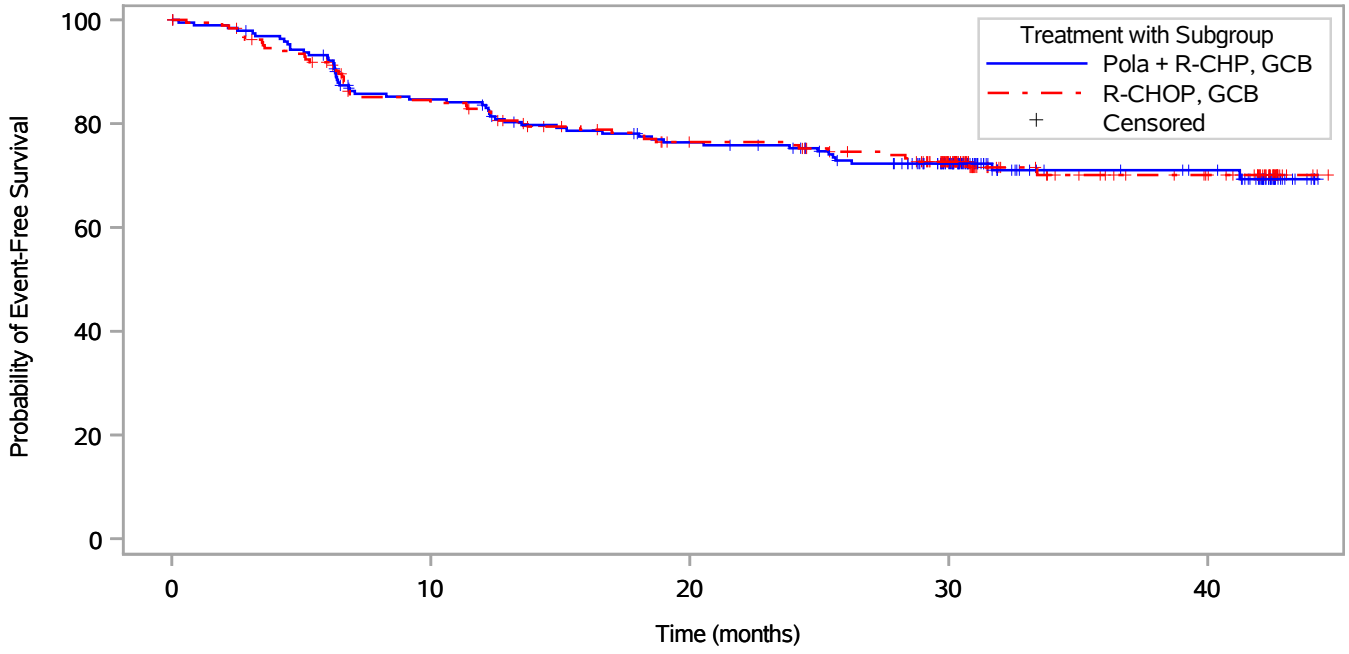
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Progression-Free Survival (PFS - INV)
STUDY: GO39942

Cell of origin



Patients at risk															
Pola + R-CHP, GCB	193	187	177	157	153	143	139	135	131	121	96	48	45	44	32
R-CHOP, GCB	187	177	166	150	146	135	131	124	124	116	92	50	43	39	28
Patients censored															
Pola + R-CHP, GCB	0	2	3	8	9	11	13	13	16	21	46	93	96	97	108
R-CHOP, GCB	0	3	6	9	10	15	17	21	21	26	47	88	94	98	109

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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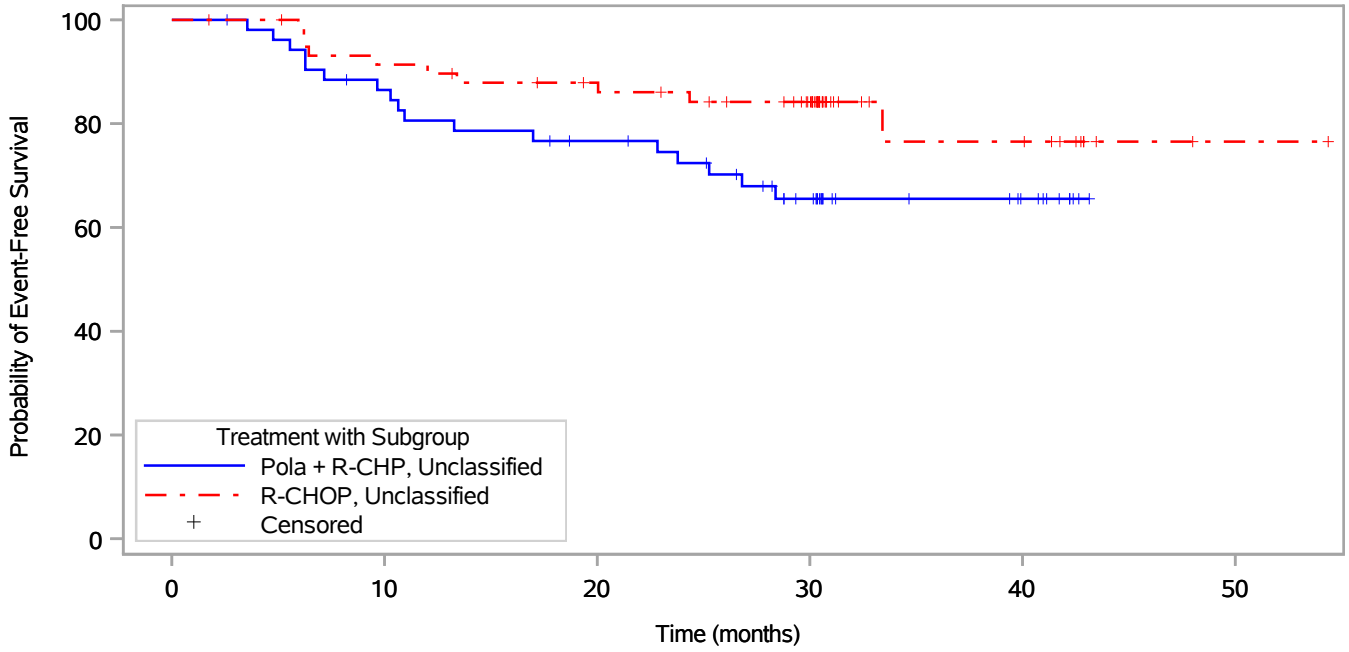
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Progression-Free Survival (PFS - INV)
STUDY: GO39942

Cell of origin



Patients at risk																			
Pola + R-CHP, Unclassified	53	52	49	45	41	40	38	37	34	30	24	13	12	12	5	NE	NE	NE	NE
R-CHOP, Unclassified	60	59	57	54	53	50	49	47	46	43	38	11	10	10	7	2	2	1	1
Patients censored																			
Pola + R-CHP, Unclassified	0	1	1	2	2	2	3	4	5	7	12	23	24	24	31	NE	NE	NE	NE
R-CHOP, Unclassified	0	1	2	2	2	3	4	5	6	8	13	40	40	40	43	48	49	49	49

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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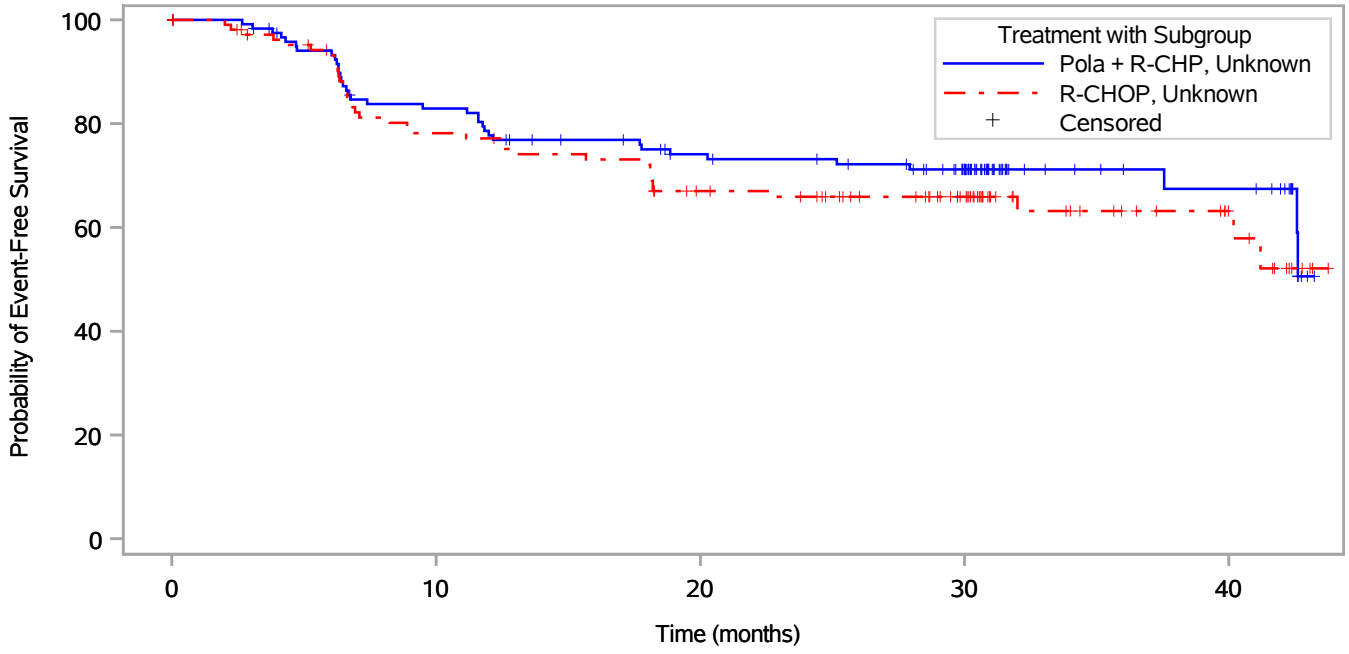
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Progression-Free Survival (PFS - INV)
STUDY: GO39942

Cell of origin



Patients at risk															
Pola + R-CHP, Unknown	123	119	110	97	90	85	82	76	76	73	59	23	20	18	15
R-CHOP, Unknown	110	99	93	79	77	73	71	61	59	52	42	23	18	16	7
Patients censored															
Pola + R-CHP, Unknown	0	3	6	7	7	11	12	16	16	18	31	67	70	71	74
R-CHOP, Unknown	0	8	10	10	10	11	11	16	17	24	34	52	57	59	66

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

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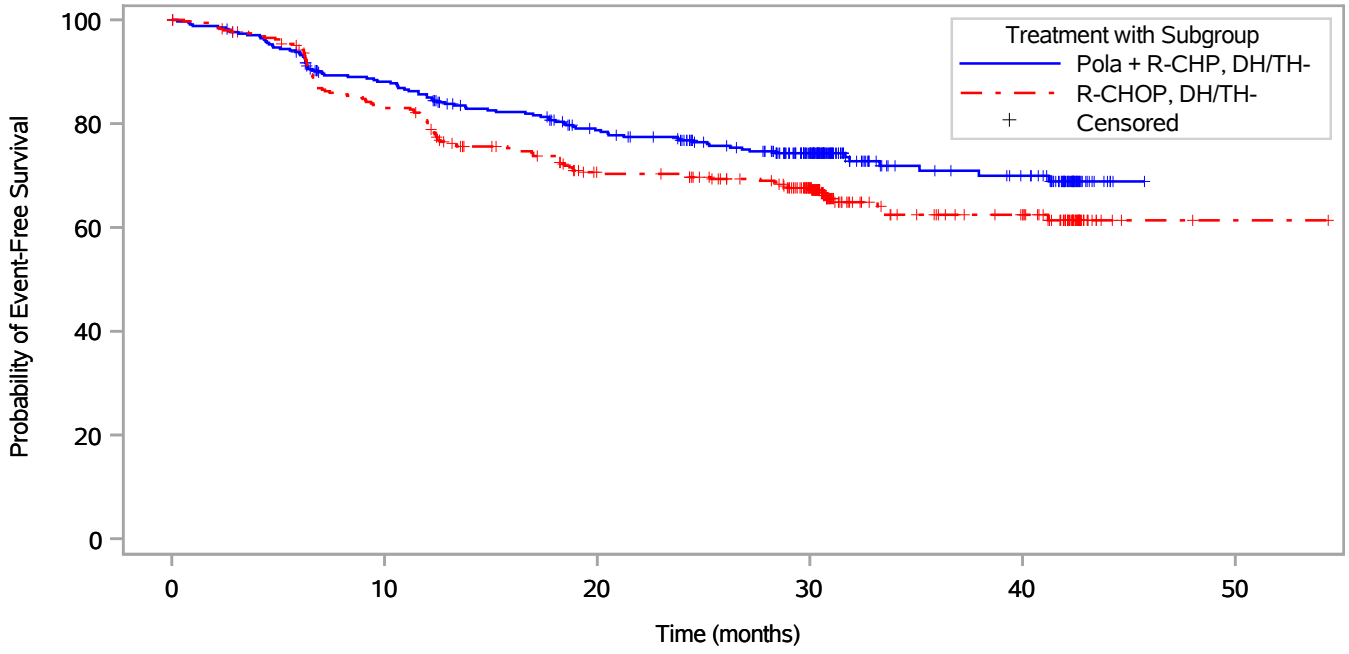
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Progression-Free Survival (PFS - INV)
STUDY: GO39942
Double/Triple-Hit Lymphoma (Central Review)



Patients at risk																			
Pola + R-CHP, DH/TH-	341	330	316	292	279	263	253	238	229	212	167	83	74	72	45	1	NE	NE	NE
R-CHOP, DH/TH-	351	337	321	288	272	248	239	219	218	203	170	81	71	66	48	2	2	1	1
Patients censored																			
Pola + R-CHP, DH/TH-	0	3	4	12	12	20	24	30	36	48	91	173	180	181	207	251	NE	NE	NE
R-CHOP, DH/TH-	0	6	10	11	12	20	23	32	33	45	73	157	164	169	186	232	233	233	233

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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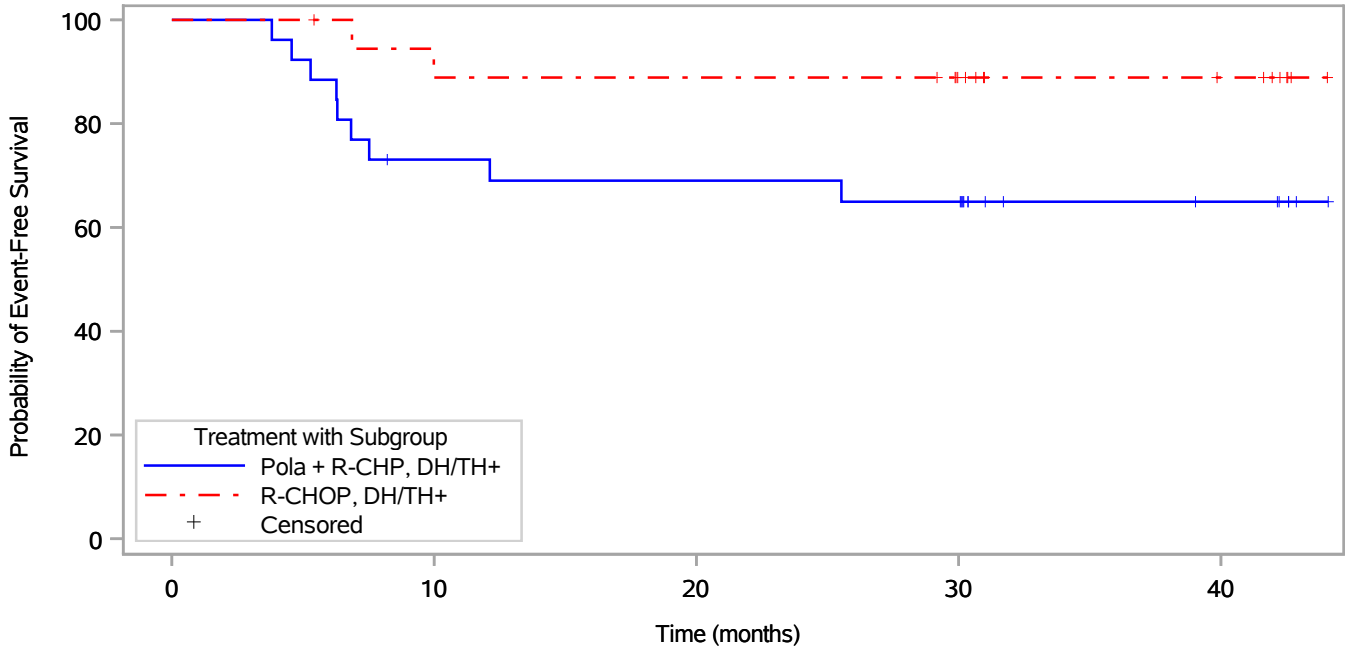
10FEB2023 11:27

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Progression-Free Survival (PFS - INV)
STUDY: GO39942
Double/Triple-Hit Lymphoma (Central Review)



Patients at risk															
Pola + R-CHP, DH/TH+	26	26	23	18	18	17	17	17	17	16	16	7	7	7	6
R-CHOP, DH/TH+	19	19	18	17	16	16	16	16	16	16	12	8	8	8	5
Patients censored															
Pola + R-CHP, DH/TH+	0	0	0	1	1	1	1	1	1	1	1	10	10	10	11
R-CHOP, DH/TH+	0	0	1	1	1	1	1	1	1	1	5	9	9	9	12

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
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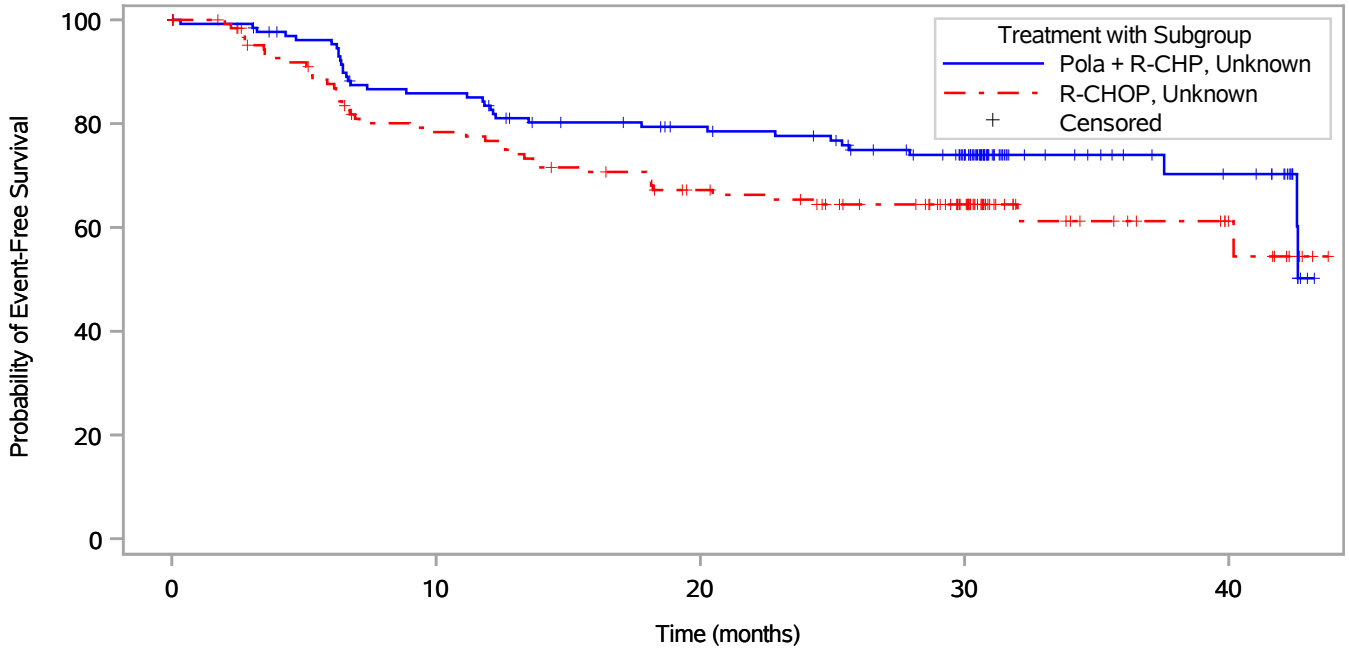
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: Progression-Free Survival (PFS - INV)
STUDY: GO39942

Double/Triple-Hit Lymphoma (Central Review)



Patients at risk															
Pola + R-CHP, Unknown	133	129	122	108	104	96	94	89	88	80	68	27	22	19	15
R-CHOP, Unknown	130	115	105	94	90	83	80	72	70	63	49	19	15	13	6
Patients censored															
Pola + R-CHP, Unknown	0	3	6	7	8	12	13	17	17	22	33	74	79	81	85
R-CHOP, Unknown	0	9	10	12	12	13	14	18	19	25	39	68	72	74	80

Pola = Polatuzumab Vedotin.
Clinical cut-off: 15JUN2022

Program: ..al_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_km.sas
Output: ..2/data_analysis/ACE_FINAL_OS/prod/output/g_km_sg1_PFS_IT_POOLED_15JUN2022_39942.pdf
10FEB2023 11:27

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Appetite loss

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	476	95.2	25.00	32.99	500	100.0	470	94.0	23.62	32.10
CYCLE 2 DAY 1	n/a	491	98.2	477	97.1	19.29	27.93	492	98.4	475	96.5	17.68	26.71
CYCLE 3 DAY 1	n/a	487	97.4	468	96.1	17.59	24.32	486	97.2	472	97.1	15.54	23.27
CYCLE 5 DAY 1	n/a	482	96.4	463	96.1	17.42	24.20	477	95.4	457	95.8	16.78	25.66
TREATMENT COMPLETION	n/a	469	93.8	448	95.5	8.78	19.75	458	91.6	426	93.0	6.89	16.15
FOLLOW-UP MONTH 6	n/a	398	79.6	347	87.2	5.57	14.59	386	77.2	326	84.5	4.40	11.89
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	5.26	14.97	338	67.6	282	83.4	4.49	13.61
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	4.18	11.69	308	61.6	275	89.3	5.45	15.55
FOLLOW-UP MONTH 24	n/a	318	63.6	286	89.9	5.24	13.38	284	56.8	250	88.0	5.47	13.41
FOLLOW-UP MONTH 36	n/a	123	24.6	95	77.2	5.96	16.11	105	21.0	64	61.0	6.77	13.52
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the table.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Cognitive functioning

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	474	94.8	85.34	20.04	500	100.0	466	93.2	86.80	17.67
CYCLE 2 DAY 1	n/a	491	98.2	477	97.1	86.65	18.68	492	98.4	473	96.1	88.34	15.56
CYCLE 3 DAY 1	n/a	487	97.4	468	96.1	86.72	17.85	486	97.2	471	96.9	88.32	16.18
CYCLE 5 DAY 1	n/a	482	96.4	462	95.9	86.62	17.69	477	95.4	459	96.2	85.40	18.98
TREATMENT COMPLETION	n/a	469	93.8	447	95.3	87.21	17.99	458	91.6	429	93.7	87.33	17.66
FOLLOW-UP MONTH 6	n/a	398	79.6	345	86.7	87.78	17.96	386	77.2	321	83.2	86.60	18.18
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	86.43	18.55	338	67.6	279	82.5	87.28	17.09
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	86.66	17.29	308	61.6	275	89.3	87.58	17.90
FOLLOW-UP MONTH 24	n/a	318	63.6	287	90.3	85.95	18.75	284	56.8	249	87.7	87.95	17.51
FOLLOW-UP MONTH 36	n/a	123	24.6	94	76.4	86.17	18.87	105	21.0	63	60.0	85.98	17.25
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the table.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Constipation

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	470	94.0	19.79	29.50	500	100.0	464	92.8	20.55	28.64
CYCLE 2 DAY 1	n/a	491	98.2	468	95.3	15.67	24.99	492	98.4	466	94.7	18.67	27.16
CYCLE 3 DAY 1	n/a	487	97.4	463	95.1	14.47	23.30	486	97.2	467	96.1	17.20	24.93
CYCLE 5 DAY 1	n/a	482	96.4	458	95.0	12.59	21.36	477	95.4	450	94.3	15.56	24.67
TREATMENT COMPLETION	n/a	469	93.8	443	94.5	9.10	19.42	458	91.6	418	91.3	7.50	17.34
FOLLOW-UP MONTH 6	n/a	398	79.6	342	85.9	8.87	17.57	386	77.2	321	83.2	9.55	20.04
FOLLOW-UP MONTH 12	n/a	373	74.6	322	86.3	11.08	20.50	338	67.6	278	82.2	8.75	18.98
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	10.83	21.10	308	61.6	275	89.3	10.06	21.50
FOLLOW-UP MONTH 24	n/a	318	63.6	287	90.3	10.69	21.09	284	56.8	250	88.0	8.67	19.83
FOLLOW-UP MONTH 36	n/a	123	24.6	95	77.2	9.12	17.83	105	21.0	63	60.0	7.41	16.33
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the table.
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Diarrhoea

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	472	94.4	9.53	20.63	500	100.0	466	93.2	8.51	18.84
CYCLE 2 DAY 1	n/a	491	98.2	477	97.1	14.54	25.07	492	98.4	473	96.1	8.67	18.98
CYCLE 3 DAY 1	n/a	487	97.4	468	96.1	10.40	19.90	486	97.2	467	96.1	8.21	18.95
CYCLE 5 DAY 1	n/a	482	96.4	462	95.9	10.53	20.23	477	95.4	459	96.2	8.71	18.99
TREATMENT COMPLETION	n/a	469	93.8	446	95.1	6.65	17.96	458	91.6	429	93.7	5.83	14.04
FOLLOW-UP MONTH 6	n/a	398	79.6	344	86.4	7.27	18.06	386	77.2	320	82.9	5.83	13.99
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	7.33	17.95	338	67.6	279	82.5	5.85	15.01
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	6.97	15.77	308	61.6	275	89.3	5.21	13.70
FOLLOW-UP MONTH 24	n/a	318	63.6	287	90.3	6.04	15.34	284	56.8	251	88.4	8.10	18.40
FOLLOW-UP MONTH 36	n/a	123	24.6	94	76.4	6.03	17.60	105	21.0	63	60.0	4.23	12.69
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the table.
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Dyspnoea

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	476	95.2	17.93	27.03	500	100.0	469	93.8	15.71	25.27
CYCLE 2 DAY 1	n/a	491	98.2	477	97.1	13.00	21.25	492	98.4	474	96.3	12.03	20.41
CYCLE 3 DAY 1	n/a	487	97.4	467	95.9	14.78	22.55	486	97.2	471	96.9	13.52	21.06
CYCLE 5 DAY 1	n/a	482	96.4	459	95.2	15.03	22.66	477	95.4	459	96.2	16.19	22.61
TREATMENT COMPLETION	n/a	469	93.8	449	95.7	13.44	22.16	458	91.6	427	93.2	10.85	18.82
FOLLOW-UP MONTH 6	n/a	398	79.6	347	87.2	12.97	20.63	386	77.2	325	84.2	10.56	18.55
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	11.56	21.60	338	67.6	281	83.1	12.57	19.52
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	11.25	20.17	308	61.6	275	89.3	12.12	20.89
FOLLOW-UP MONTH 24	n/a	318	63.6	286	89.9	12.59	21.74	284	56.8	250	88.0	12.93	20.63
FOLLOW-UP MONTH 36	n/a	123	24.6	95	77.2	12.63	24.88	105	21.0	64	61.0	16.67	20.57
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the table.
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Emotional functioning

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	474	94.8	76.81	21.56	500	100.0	467	93.4	74.92	21.84
CYCLE 2 DAY 1	n/a	491	98.2	476	96.9	83.57	18.09	492	98.4	473	96.1	83.12	18.22
CYCLE 3 DAY 1	n/a	487	97.4	468	96.1	84.19	18.00	486	97.2	471	96.9	83.16	17.98
CYCLE 5 DAY 1	n/a	482	96.4	462	95.9	84.60	18.75	477	95.4	459	96.2	82.04	19.93
TREATMENT COMPLETION	n/a	469	93.8	447	95.3	85.46	17.47	458	91.6	429	93.7	85.37	17.83
FOLLOW-UP MONTH 6	n/a	398	79.6	345	86.7	85.69	19.02	386	77.2	321	83.2	86.60	17.58
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	85.55	19.47	338	67.6	279	82.5	86.62	16.85
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	85.31	17.57	308	61.6	275	89.3	87.39	17.39
FOLLOW-UP MONTH 24	n/a	318	63.6	287	90.3	86.47	19.05	284	56.8	249	87.7	86.80	17.47
FOLLOW-UP MONTH 36	n/a	123	24.6	94	76.4	86.97	18.95	105	21.0	63	60.0	85.85	15.16
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the table.
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Fatigue

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	476	95.2	35.70	27.24	500	100.0	470	94.0	33.79	26.47
CYCLE 2 DAY 1	n/a	491	98.2	478	97.4	33.47	22.92	492	98.4	476	96.7	31.66	22.67
CYCLE 3 DAY 1	n/a	487	97.4	468	96.1	31.16	21.66	486	97.2	471	96.9	31.16	22.69
CYCLE 5 DAY 1	n/a	482	96.4	463	96.1	31.31	23.76	477	95.4	460	96.4	32.50	23.54
TREATMENT COMPLETION	n/a	469	93.8	449	95.7	24.02	21.83	458	91.6	427	93.2	24.28	20.73
FOLLOW-UP MONTH 6	n/a	398	79.6	347	87.2	20.89	21.76	386	77.2	326	84.5	20.45	19.22
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	19.75	21.13	338	67.6	282	83.4	20.11	20.70
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	18.79	20.35	308	61.6	275	89.3	20.73	21.90
FOLLOW-UP MONTH 24	n/a	318	63.6	286	89.9	19.43	20.75	284	56.8	251	88.4	19.57	19.57
FOLLOW-UP MONTH 36	n/a	123	24.6	95	77.2	19.18	19.41	105	21.0	63	60.0	22.40	22.18
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Financial difficulties

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	471	94.2	20.31	29.66	500	100.0	463	92.6	22.68	30.34
CYCLE 2 DAY 1	n/a	491	98.2	475	96.7	16.70	26.02	492	98.4	472	95.9	18.08	26.83
CYCLE 3 DAY 1	n/a	487	97.4	464	95.3	17.67	25.99	486	97.2	468	96.3	17.31	26.93
CYCLE 5 DAY 1	n/a	482	96.4	459	95.2	16.99	25.82	477	95.4	458	96.0	17.25	26.66
TREATMENT COMPLETION	n/a	469	93.8	444	94.7	16.52	25.19	458	91.6	426	93.0	14.79	25.11
FOLLOW-UP MONTH 6	n/a	398	79.6	344	86.4	12.40	21.92	386	77.2	321	83.2	14.12	22.54
FOLLOW-UP MONTH 12	n/a	373	74.6	321	86.1	9.66	19.73	338	67.6	279	82.5	12.19	22.33
FOLLOW-UP MONTH 18	n/a	343	68.6	309	90.1	9.71	20.79	308	61.6	274	89.0	9.25	20.06
FOLLOW-UP MONTH 24	n/a	318	63.6	287	90.3	8.83	19.89	284	56.8	248	87.3	8.06	19.84
FOLLOW-UP MONTH 36	n/a	123	24.6	93	75.6	8.60	18.97	105	21.0	62	59.0	11.29	21.71
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the table.
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Nausea and vomiting

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	476	95.2	7.95	17.78	500	100.0	470	94.0	5.85	14.25
CYCLE 2 DAY 1	n/a	491	98.2	478	97.4	8.30	16.36	492	98.4	477	97.0	7.34	14.65
CYCLE 3 DAY 1	n/a	487	97.4	468	96.1	8.30	15.17	486	97.2	473	97.3	6.59	14.46
CYCLE 5 DAY 1	n/a	482	96.4	463	96.1	8.24	15.27	477	95.4	459	96.2	8.02	15.55
TREATMENT COMPLETION	n/a	469	93.8	449	95.7	2.75	9.44	458	91.6	427	93.2	2.26	7.58
FOLLOW-UP MONTH 6	n/a	398	79.6	347	87.2	2.31	7.88	386	77.2	326	84.5	2.15	8.20
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	3.51	11.29	338	67.6	282	83.4	1.77	6.51
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	2.47	7.53	308	61.6	275	89.3	2.42	10.08
FOLLOW-UP MONTH 24	n/a	318	63.6	286	89.9	2.86	9.50	284	56.8	251	88.4	1.73	7.55
FOLLOW-UP MONTH 36	n/a	123	24.6	95	77.2	1.93	6.37	105	21.0	64	61.0	1.56	6.45
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the table.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Pain

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	476	95.2	29.38	30.36	500	100.0	470	94.0	27.66	30.41
CYCLE 2 DAY 1	n/a	491	98.2	478	97.4	17.26	22.15	492	98.4	477	97.0	16.21	22.46
CYCLE 3 DAY 1	n/a	487	97.4	468	96.1	15.60	21.95	486	97.2	472	97.1	15.32	21.43
CYCLE 5 DAY 1	n/a	482	96.4	464	96.3	13.65	20.42	477	95.4	459	96.2	15.58	23.02
TREATMENT COMPLETION	n/a	469	93.8	450	95.9	16.93	23.97	458	91.6	430	93.9	15.23	22.93
FOLLOW-UP MONTH 6	n/a	398	79.6	347	87.2	14.55	22.35	386	77.2	325	84.2	13.44	20.80
FOLLOW-UP MONTH 12	n/a	373	74.6	324	86.9	14.97	24.25	338	67.6	282	83.4	14.54	22.66
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	15.33	22.93	308	61.6	275	89.3	14.79	23.86
FOLLOW-UP MONTH 24	n/a	318	63.6	287	90.3	16.55	25.24	284	56.8	252	88.7	12.70	20.87
FOLLOW-UP MONTH 36	n/a	123	24.6	95	77.2	14.74	20.32	105	21.0	64	61.0	16.67	22.42
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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[2] mean: descriptive statistics - absolute values
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Physical functioning (revised)

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	475	95.0	80.39	21.96	500	100.0	470	94.0	80.68	22.50
CYCLE 2 DAY 1	n/a	491	98.2	477	97.1	80.55	19.27	492	98.4	475	96.5	82.33	18.86
CYCLE 3 DAY 1	n/a	487	97.4	468	96.1	82.56	18.60	486	97.2	472	97.1	82.40	19.49
CYCLE 5 DAY 1	n/a	482	96.4	464	96.3	82.53	18.76	477	95.4	460	96.4	81.49	19.11
TREATMENT COMPLETION	n/a	469	93.8	449	95.7	84.47	18.50	458	91.6	427	93.2	86.65	16.26
FOLLOW-UP MONTH 6	n/a	398	79.6	347	87.2	87.68	16.29	386	77.2	326	84.5	88.76	14.63
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	88.01	17.34	338	67.6	282	83.4	88.52	15.40
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	88.70	14.90	308	61.6	275	89.3	88.05	16.25
FOLLOW-UP MONTH 24	n/a	318	63.6	286	89.9	87.84	16.14	284	56.8	252	88.7	88.21	15.84
FOLLOW-UP MONTH 36	n/a	123	24.6	95	77.2	88.75	15.00	105	21.0	64	61.0	85.99	15.41
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Global health status/QoL (revised)

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	473	94.6	60.13	24.54	500	100.0	466	93.2	62.09	23.97
CYCLE 2 DAY 1	n/a	491	98.2	476	96.9	67.03	18.90	492	98.4	471	95.7	70.17	20.34
CYCLE 3 DAY 1	n/a	487	97.4	467	95.9	69.49	18.74	486	97.2	469	96.5	71.02	19.02
CYCLE 5 DAY 1	n/a	482	96.4	462	95.9	69.50	18.95	477	95.4	459	96.2	69.01	20.29
TREATMENT COMPLETION	n/a	469	93.8	447	95.3	73.42	20.15	458	91.6	428	93.4	76.11	17.22
FOLLOW-UP MONTH 6	n/a	398	79.6	345	86.7	76.86	18.60	386	77.2	320	82.9	78.65	17.91
FOLLOW-UP MONTH 12	n/a	373	74.6	322	86.3	76.99	20.10	338	67.6	278	82.2	78.15	16.48
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	77.44	17.42	308	61.6	275	89.3	79.15	16.60
FOLLOW-UP MONTH 24	n/a	318	63.6	287	90.3	77.99	18.38	284	56.8	250	88.0	78.60	18.04
FOLLOW-UP MONTH 36	n/a	123	24.6	94	76.4	73.76	21.09	105	21.0	63	60.0	76.32	18.16
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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[2] mean: descriptive statistics - absolute values
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Role functioning (revised)

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	475	95.0	70.98	33.22	500	100.0	470	94.0	72.06	31.61
CYCLE 2 DAY 1	n/a	491	98.2	476	96.9	75.11	26.46	492	98.4	476	96.7	76.47	26.72
CYCLE 3 DAY 1	n/a	487	97.4	468	96.1	77.10	25.69	486	97.2	472	97.1	77.61	26.32
CYCLE 5 DAY 1	n/a	482	96.4	464	96.3	76.94	25.85	477	95.4	459	96.2	77.02	25.90
TREATMENT COMPLETION	n/a	469	93.8	449	95.7	81.66	24.40	458	91.6	427	93.2	84.43	21.70
FOLLOW-UP MONTH 6	n/a	398	79.6	347	87.2	86.26	22.42	386	77.2	326	84.5	88.29	18.72
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	87.20	22.97	338	67.6	281	83.1	89.26	19.07
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	88.26	20.67	308	61.6	275	89.3	87.58	21.83
FOLLOW-UP MONTH 24	n/a	318	63.6	286	89.9	88.93	20.47	284	56.8	251	88.4	88.71	20.08
FOLLOW-UP MONTH 36	n/a	123	24.6	95	77.2	88.60	21.37	105	21.0	64	61.0	87.76	17.38
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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[2] mean: descriptive statistics - absolute values
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Social functioning

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	474	94.8	74.58	28.63	500	100.0	465	93.0	74.30	27.70
CYCLE 2 DAY 1	n/a	491	98.2	475	96.7	76.14	24.09	492	98.4	473	96.1	77.27	24.66
CYCLE 3 DAY 1	n/a	487	97.4	467	95.9	77.66	24.60	486	97.2	471	96.9	78.70	23.33
CYCLE 5 DAY 1	n/a	482	96.4	462	95.9	78.93	23.49	477	95.4	458	96.0	78.28	23.76
TREATMENT COMPLETION	n/a	469	93.8	446	95.1	82.85	23.60	458	91.6	429	93.7	85.16	21.25
FOLLOW-UP MONTH 6	n/a	398	79.6	345	86.7	88.94	20.31	386	77.2	321	83.2	88.21	18.41
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	89.99	19.25	338	67.6	279	82.5	90.14	17.92
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	89.92	19.73	308	61.6	275	89.3	91.09	18.08
FOLLOW-UP MONTH 24	n/a	318	63.6	287	90.3	89.66	19.90	284	56.8	249	87.7	92.10	16.33
FOLLOW-UP MONTH 36	n/a	123	24.6	94	76.4	91.84	17.58	105	21.0	63	60.0	89.15	19.44
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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[2] mean: descriptive statistics - absolute values
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EORTC QLQ-C30: Insomnia

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	475	95.0	34.67	33.48	500	100.0	469	93.8	34.90	33.37
CYCLE 2 DAY 1	n/a	491	98.2	478	97.4	25.59	29.17	492	98.4	476	96.7	24.58	28.21
CYCLE 3 DAY 1	n/a	487	97.4	466	95.7	23.32	27.04	486	97.2	468	96.3	23.29	27.01
CYCLE 5 DAY 1	n/a	482	96.4	462	95.9	22.15	26.39	477	95.4	459	96.2	22.08	27.01
TREATMENT COMPLETION	n/a	469	93.8	449	95.7	19.38	25.36	458	91.6	427	93.2	17.80	25.55
FOLLOW-UP MONTH 6	n/a	398	79.6	347	87.2	17.39	25.13	386	77.2	325	84.2	17.74	25.45
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	18.58	25.99	338	67.6	281	83.1	17.44	25.52
FOLLOW-UP MONTH 18	n/a	343	68.6	311	90.7	18.33	24.90	308	61.6	275	89.3	18.91	27.57
FOLLOW-UP MONTH 24	n/a	318	63.6	286	89.9	18.07	25.36	284	56.8	251	88.4	19.12	26.28
FOLLOW-UP MONTH 36	n/a	123	24.6	95	77.2	17.19	24.24	105	21.0	64	61.0	19.27	25.75
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
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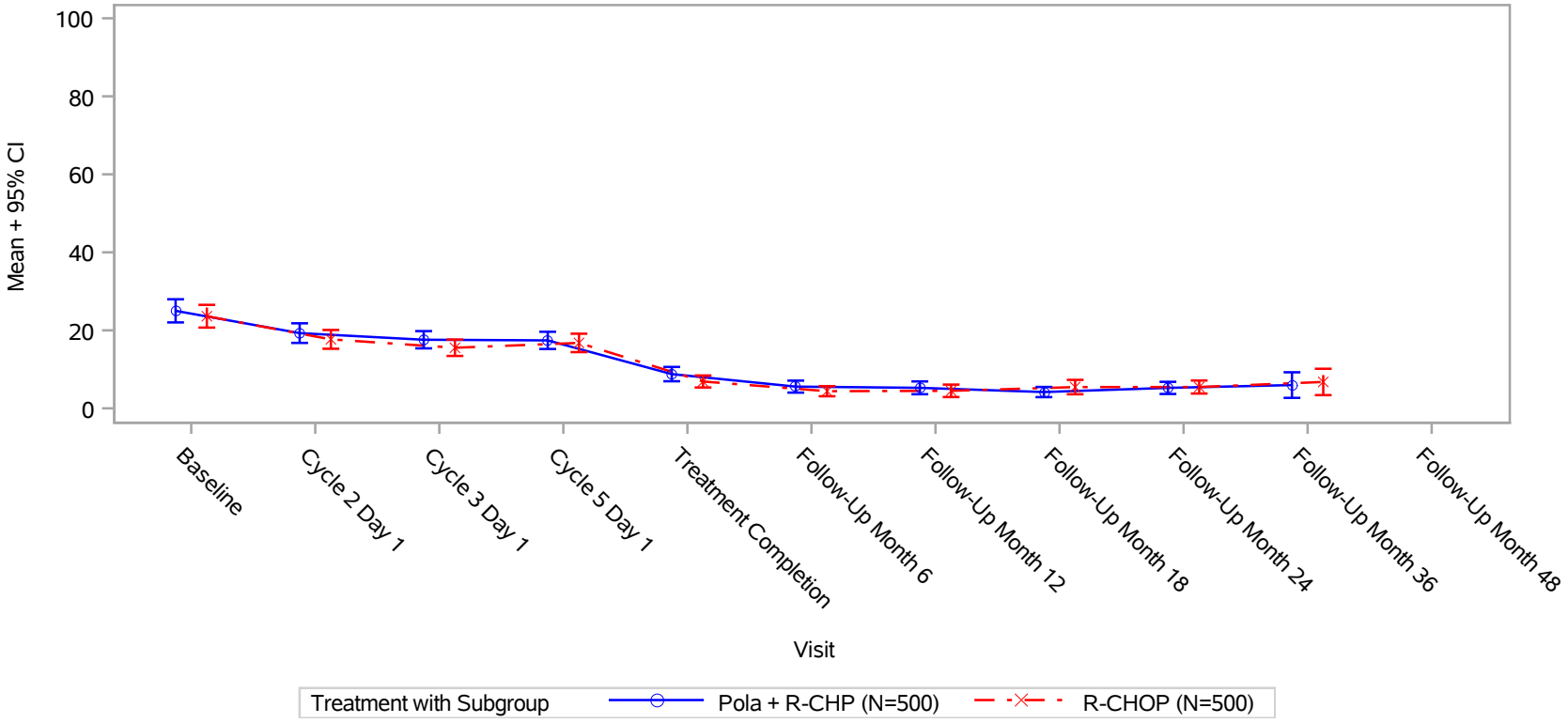
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQC30_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit
EORTC QLQ-C30: Appetite loss

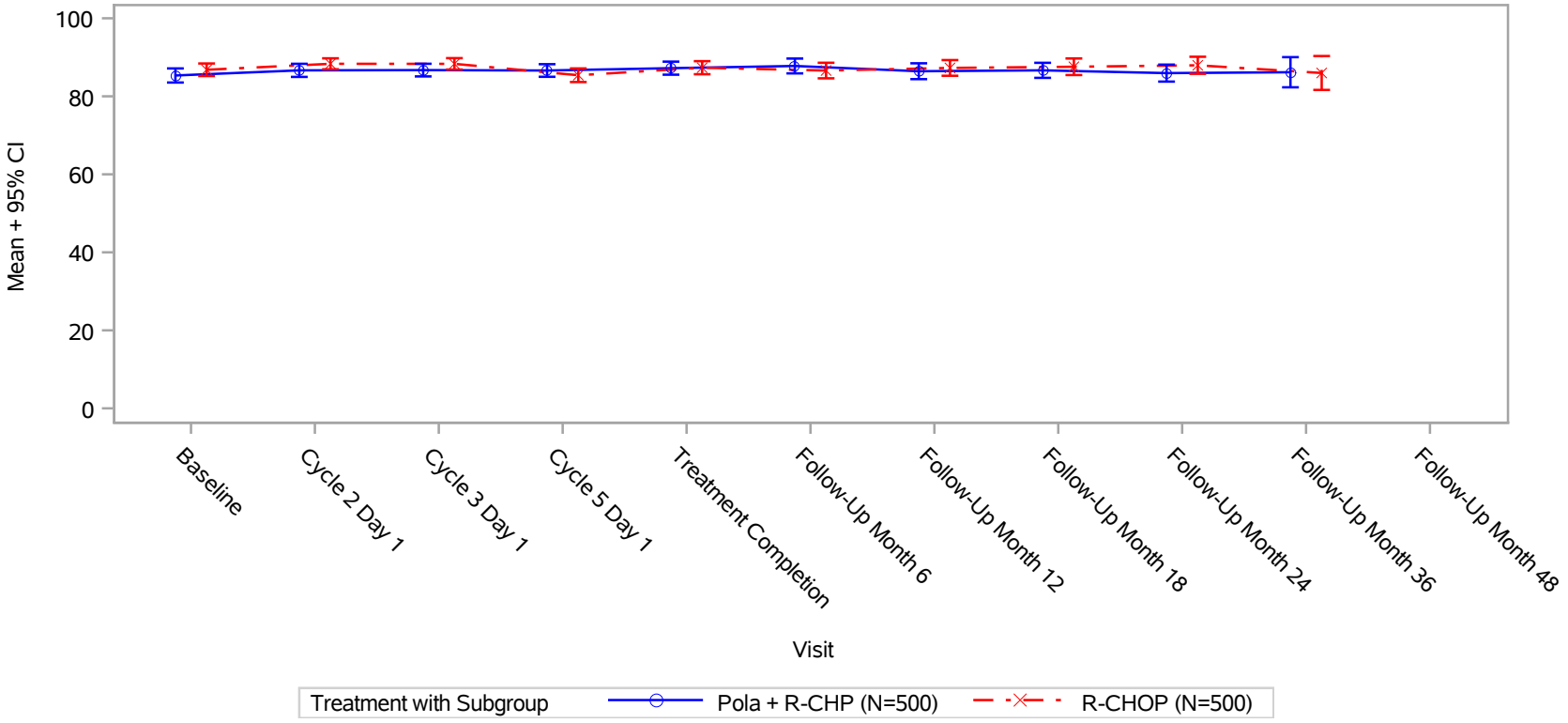


Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the plot.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit

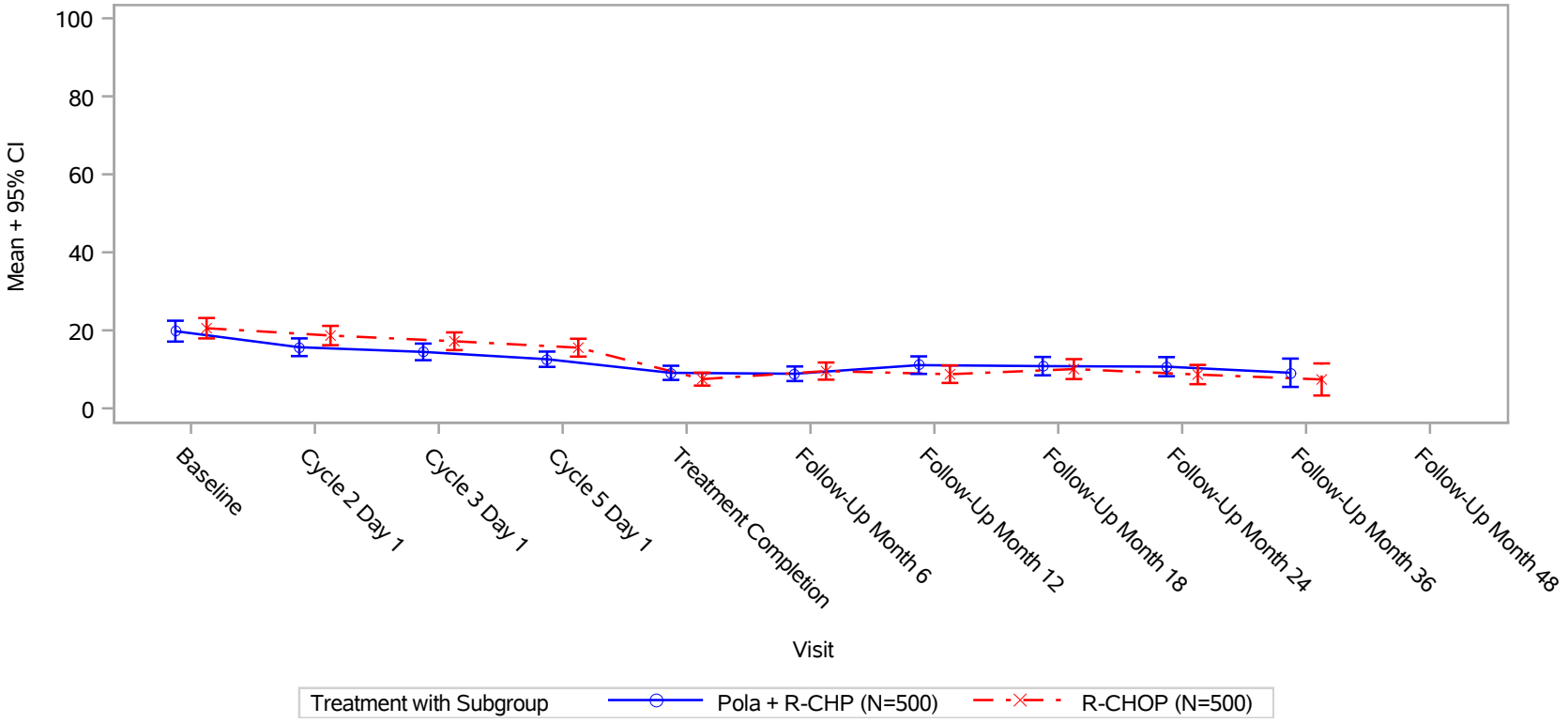
EORTC QLQ-C30: Cognitive functioning



Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the plot.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

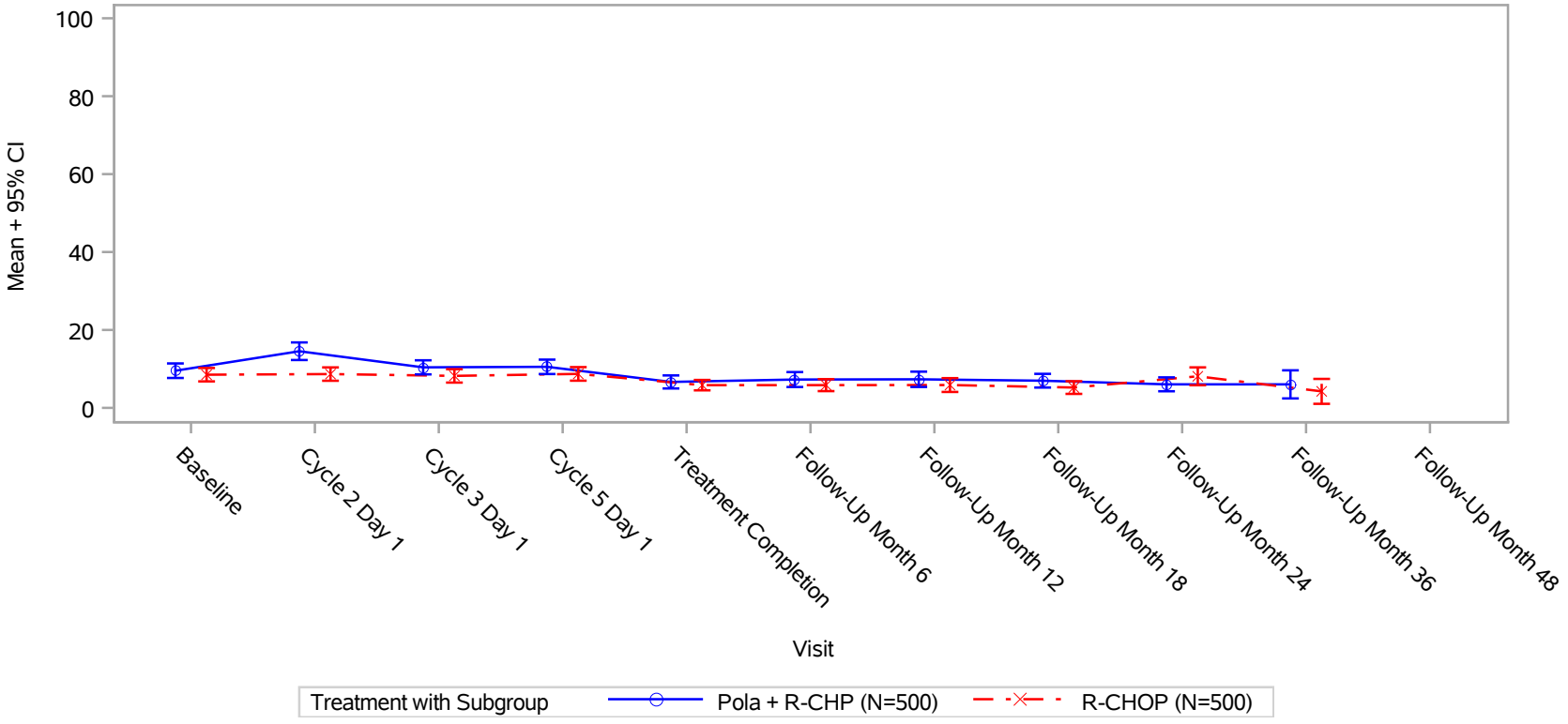
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit
EORTC QLQ-C30: Constipation



Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the plot.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

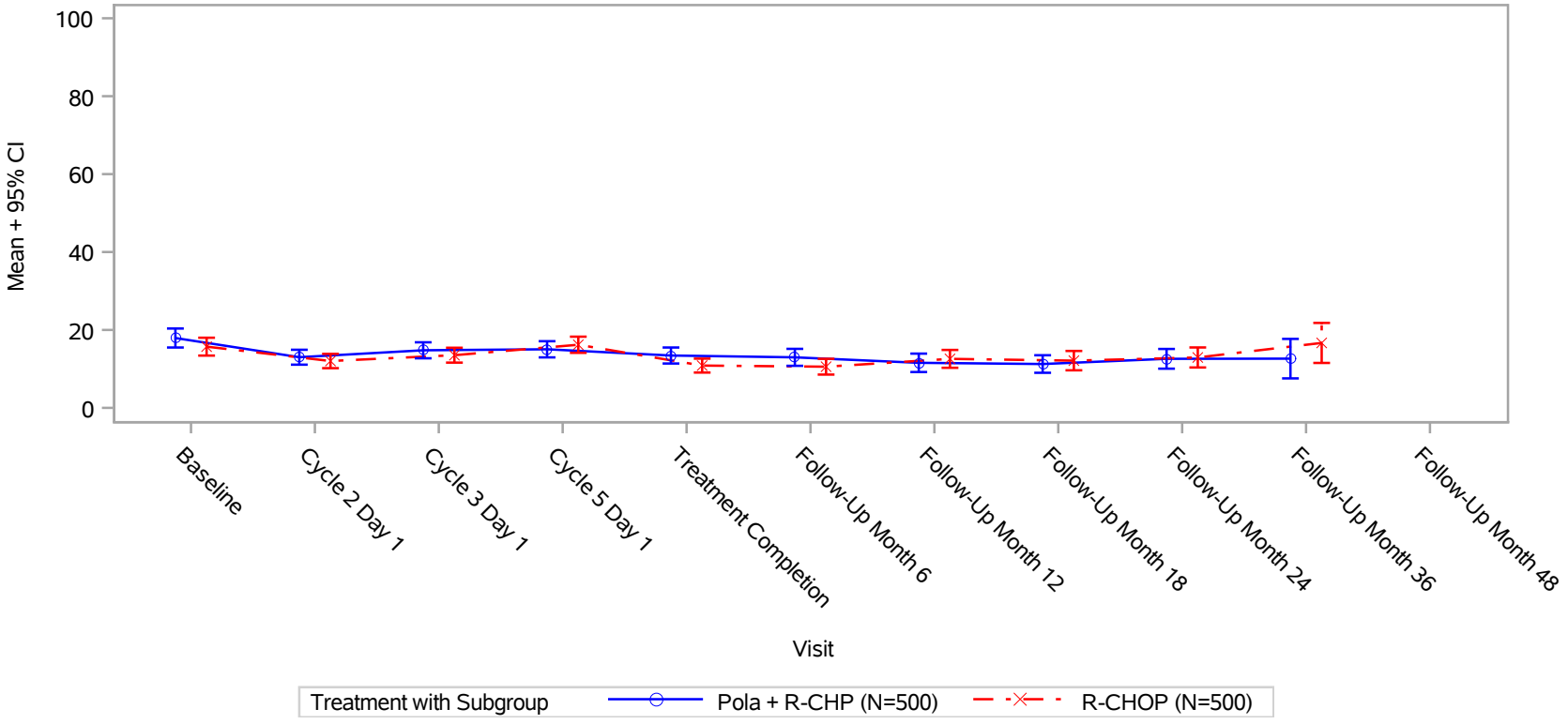
POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit
EORTC QLQ-C30: Diarrhoea



Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the plot.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit
EORTC QLQ-C30: Dyspnoea



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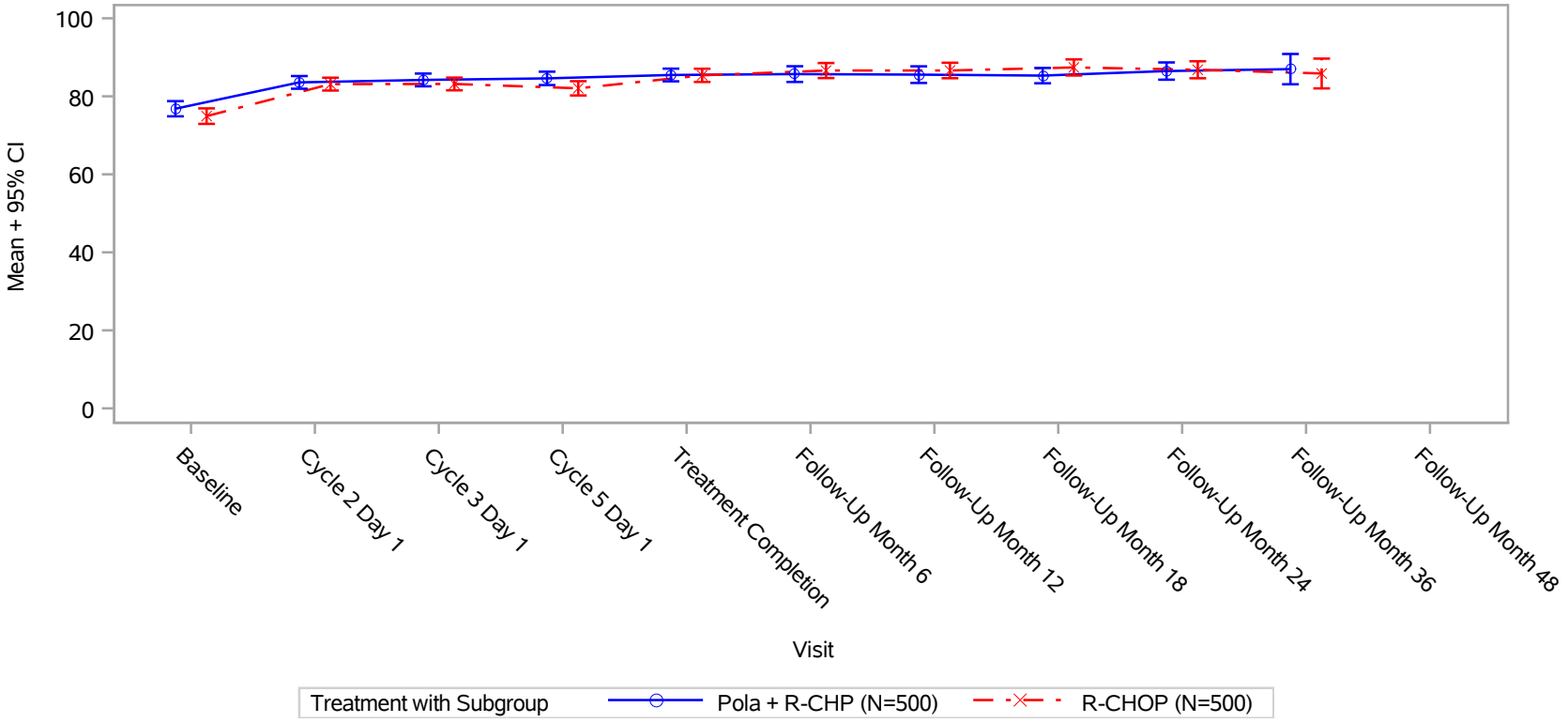
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit

EORTC QLQ-C30: Emotional functioning



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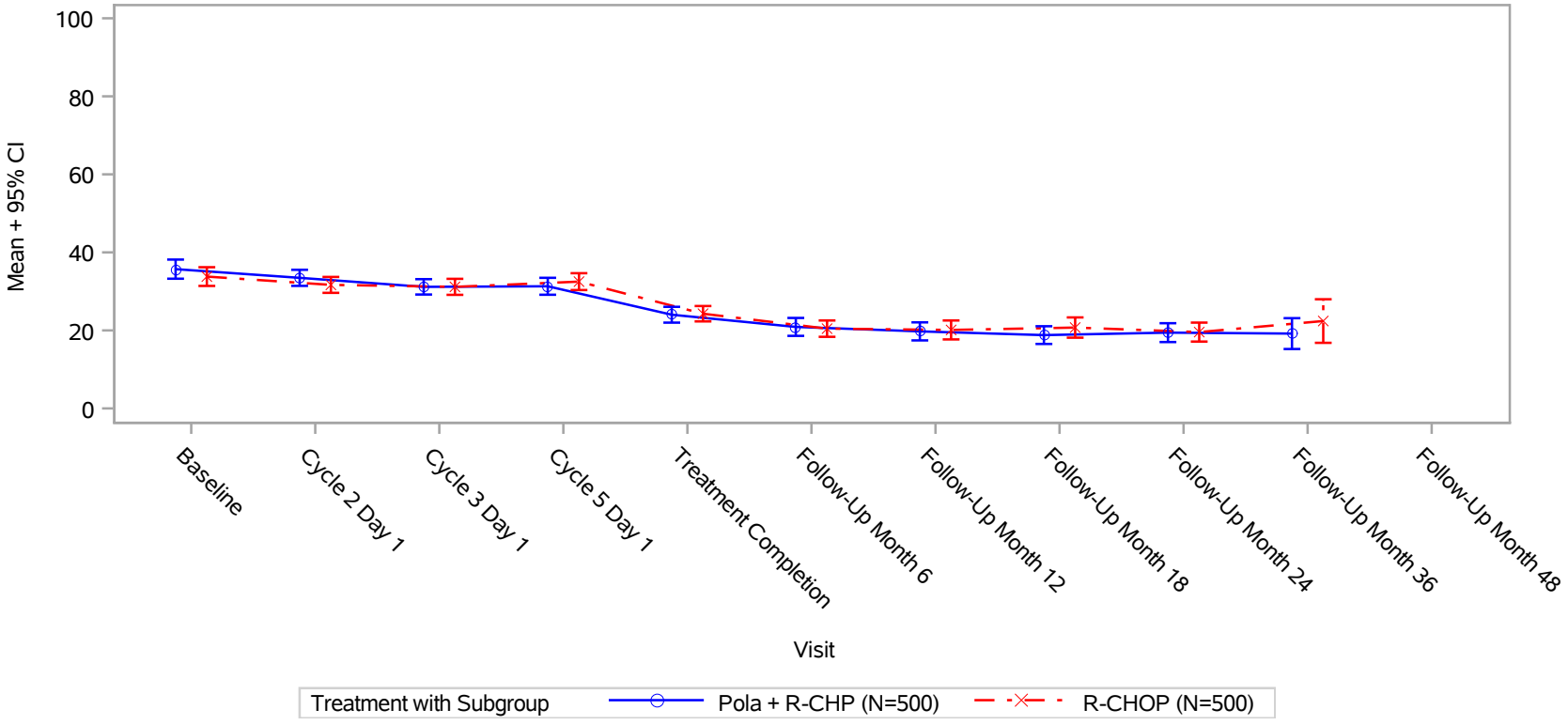
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit
EORTC QLQ-C30: Fatigue



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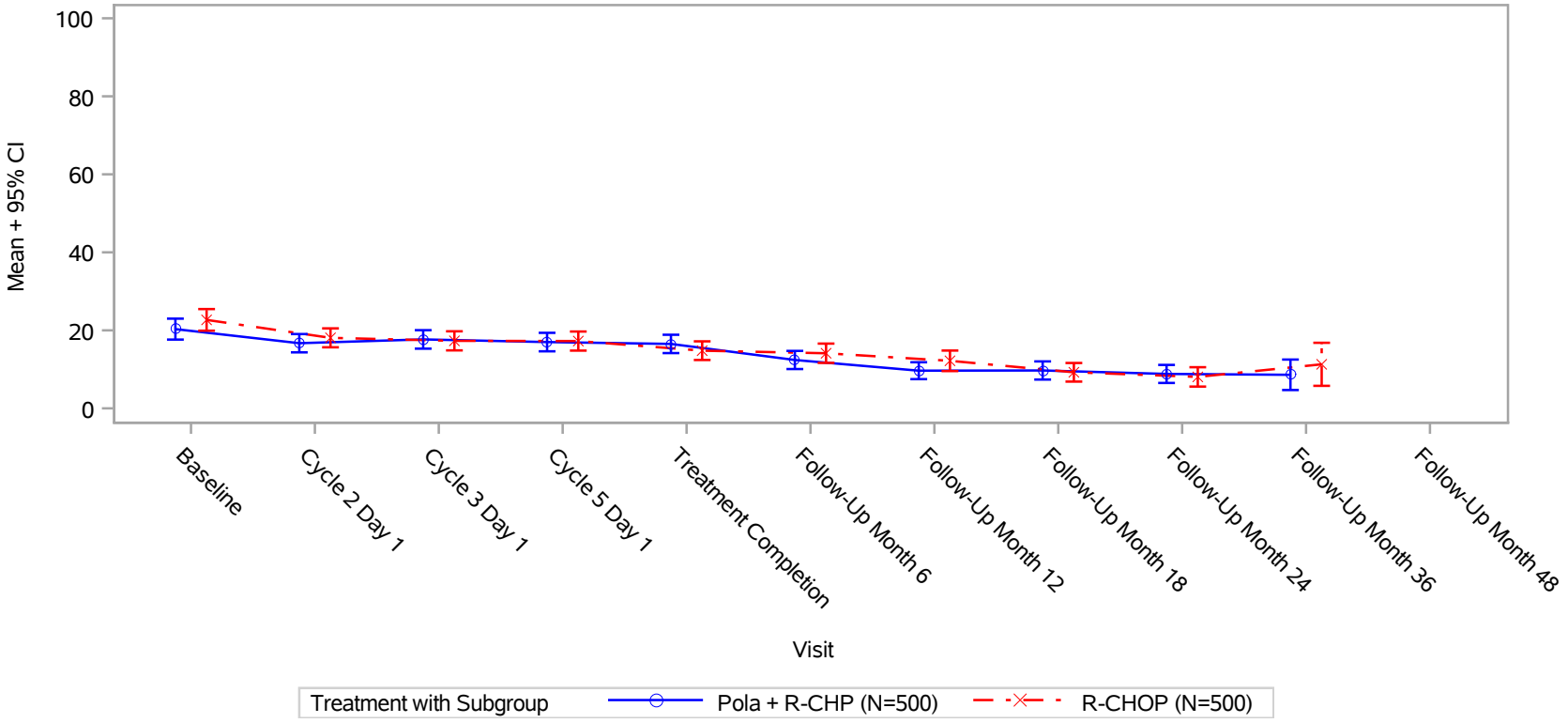
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit
EORTC QLQ-C30: Financial difficulties



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Clinical cut-off: 15JUN2022

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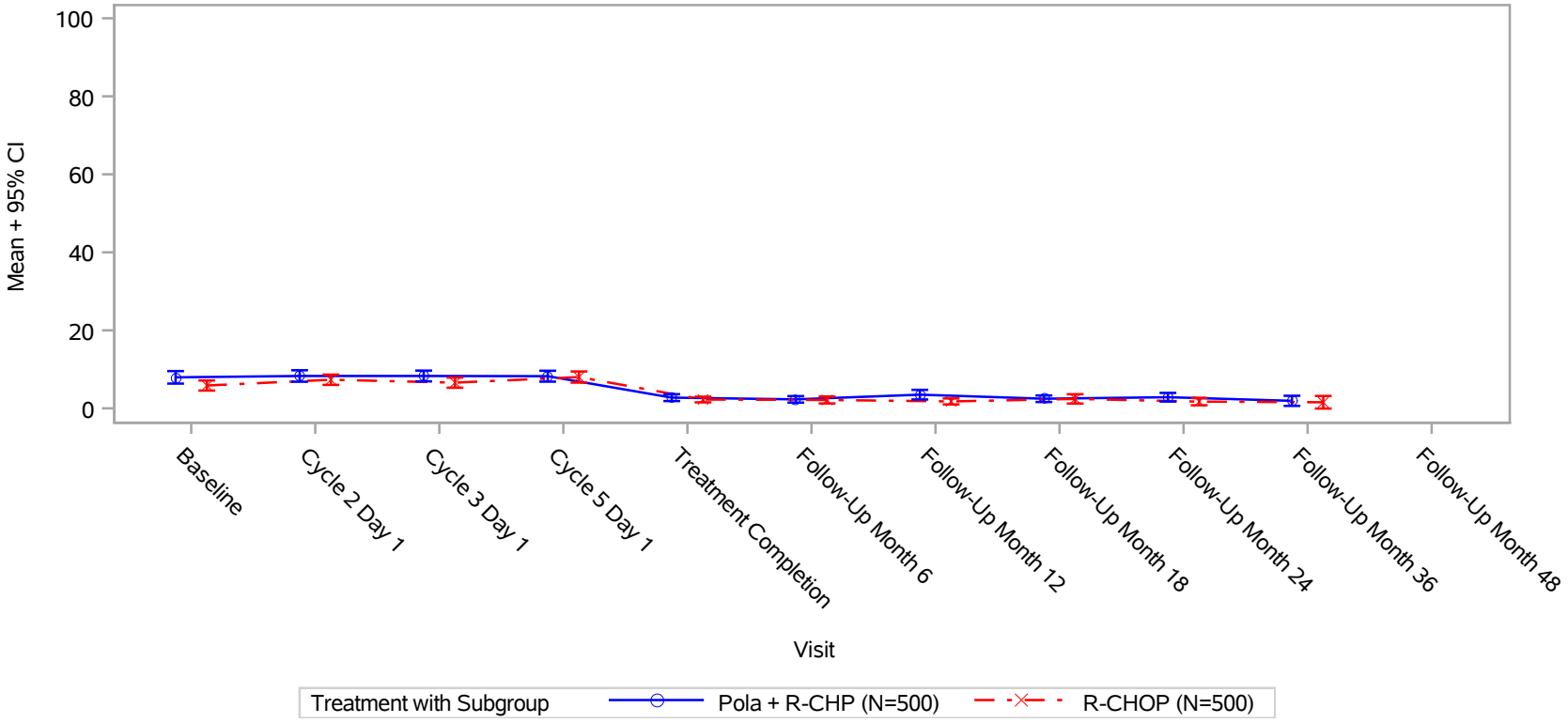
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit

EORTC QLQ-C30: Nausea and vomiting



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Clinical cut-off: 15JUN2022

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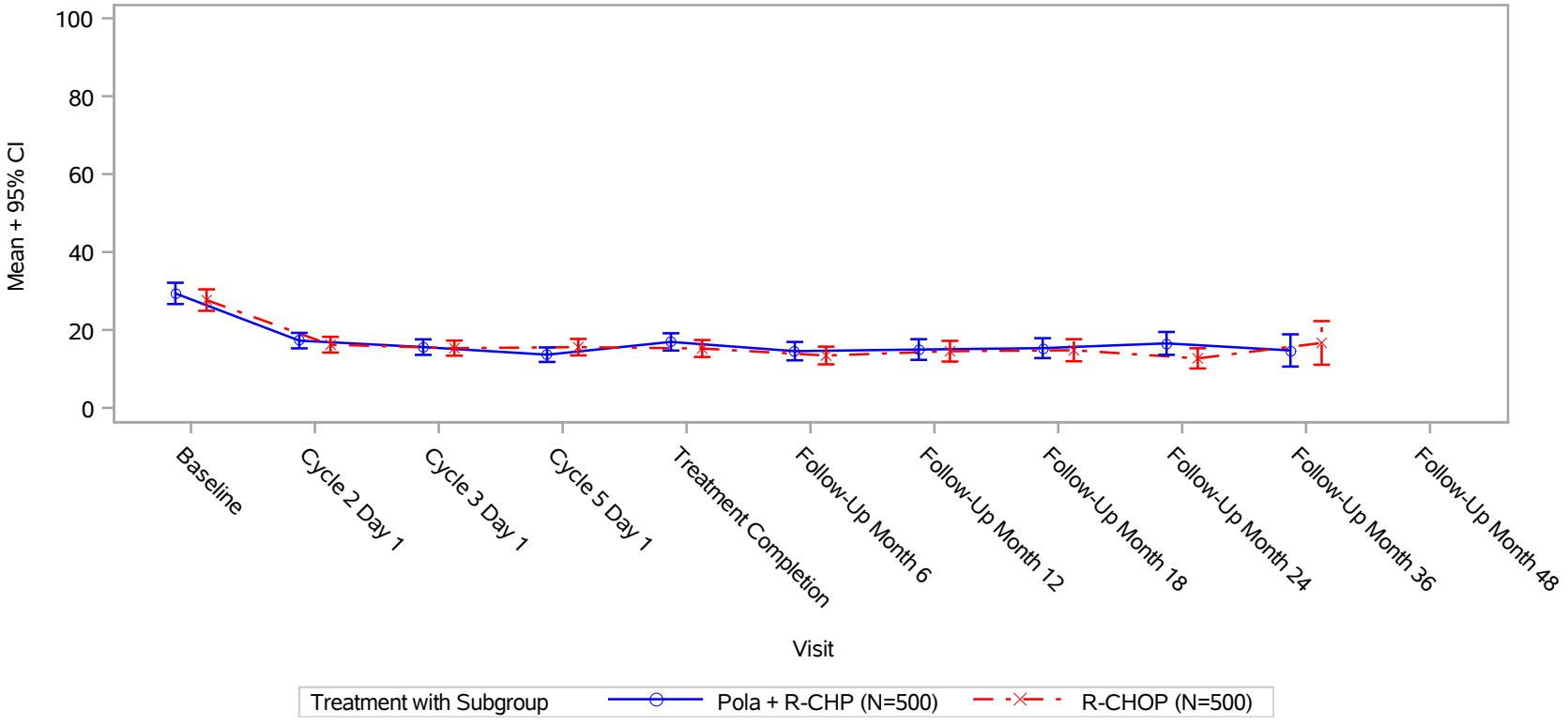
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit
EORTC QLQ-C30: Pain



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Clinical cut-off: 15JUN2022

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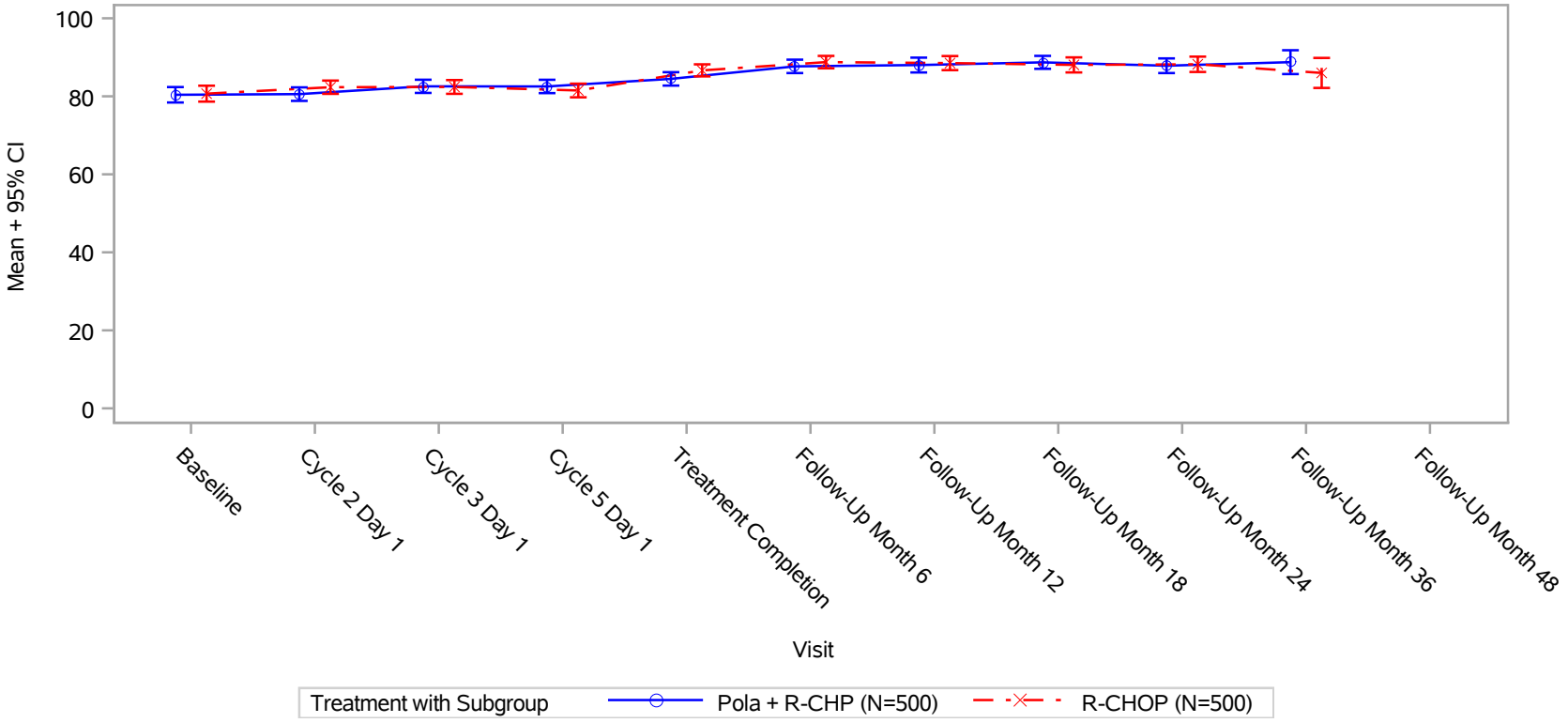
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit

EORTC QLQ-C30: Physical functioning (revised)



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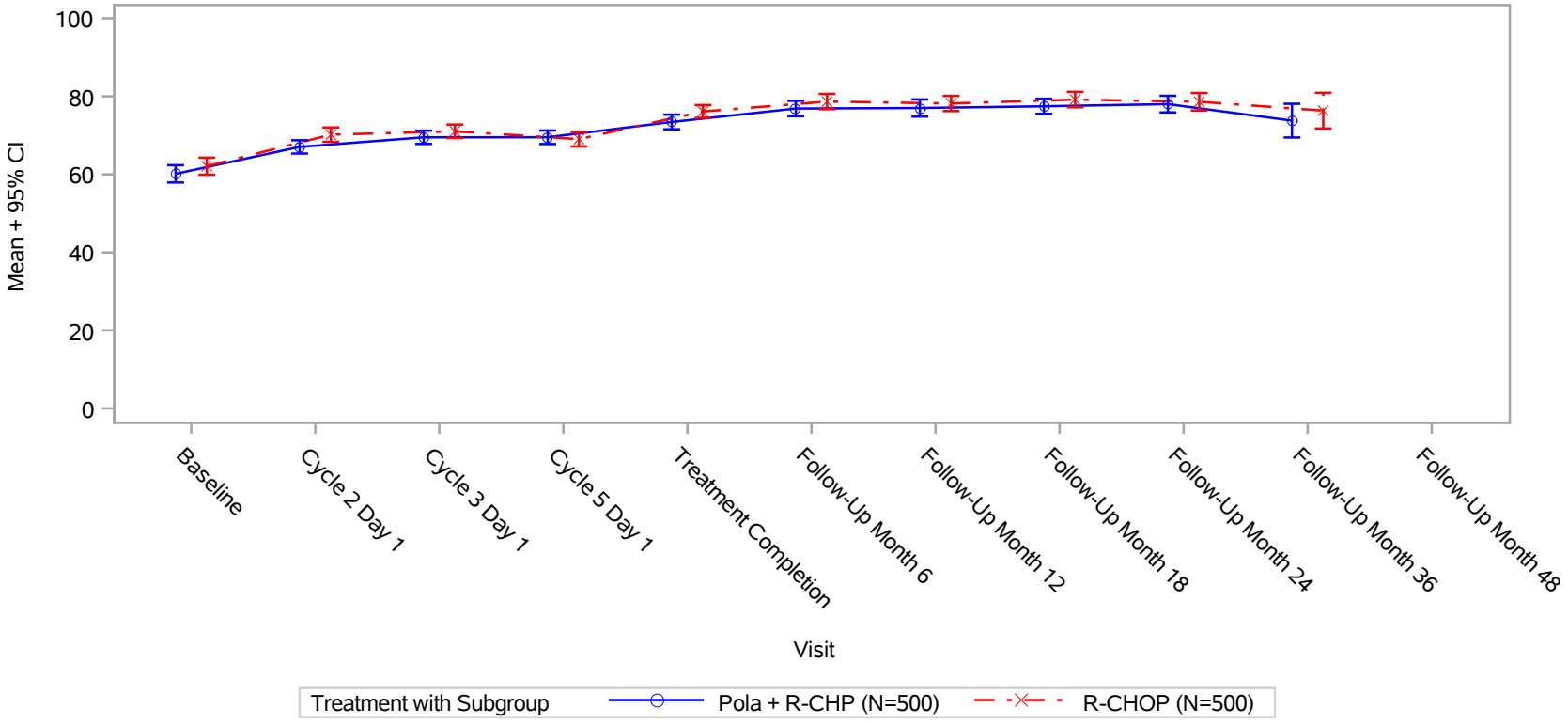
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit

EORTC QLQ-C30: Global health status/QoL (revised)



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Clinical cut-off: 15JUN2022

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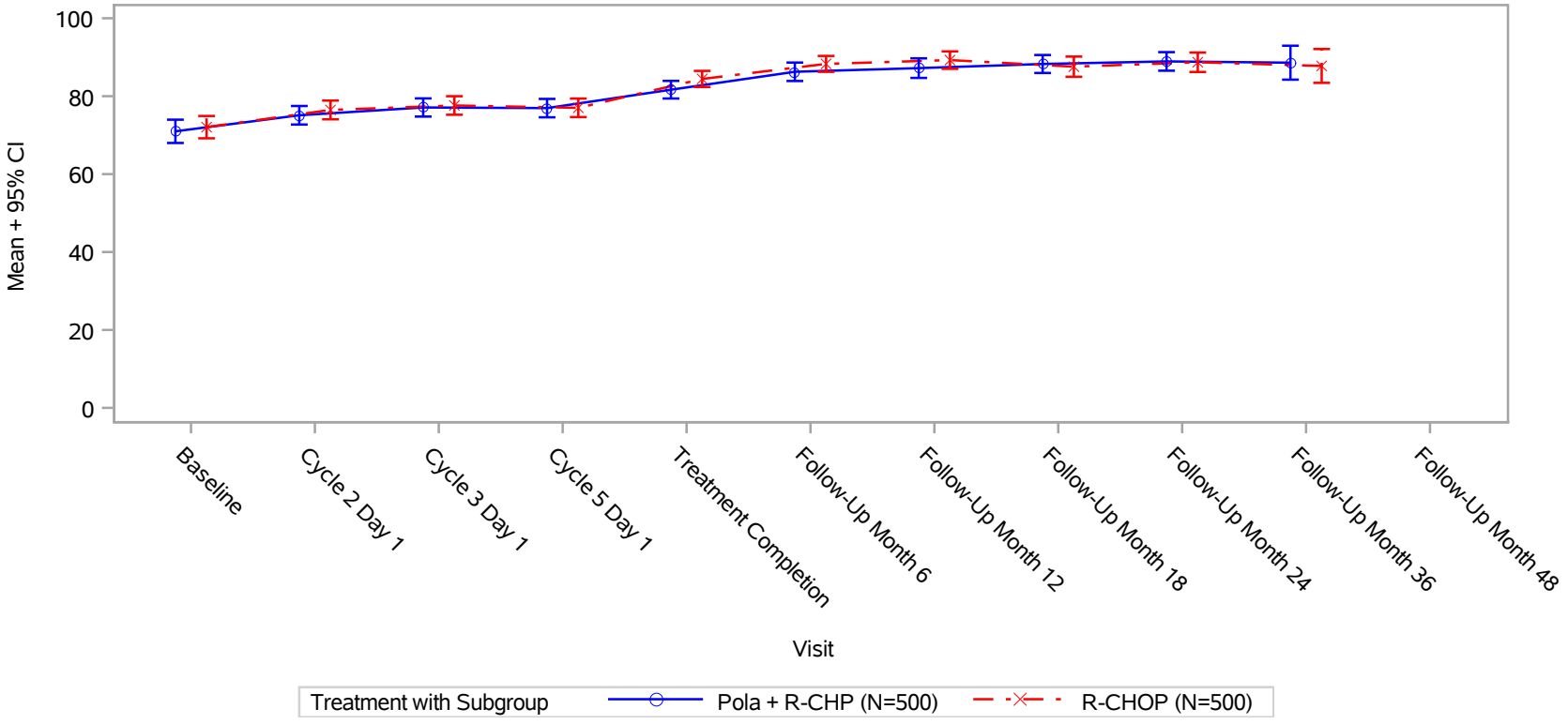
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit

EORTC QLQ-C30: Role functioning (revised)



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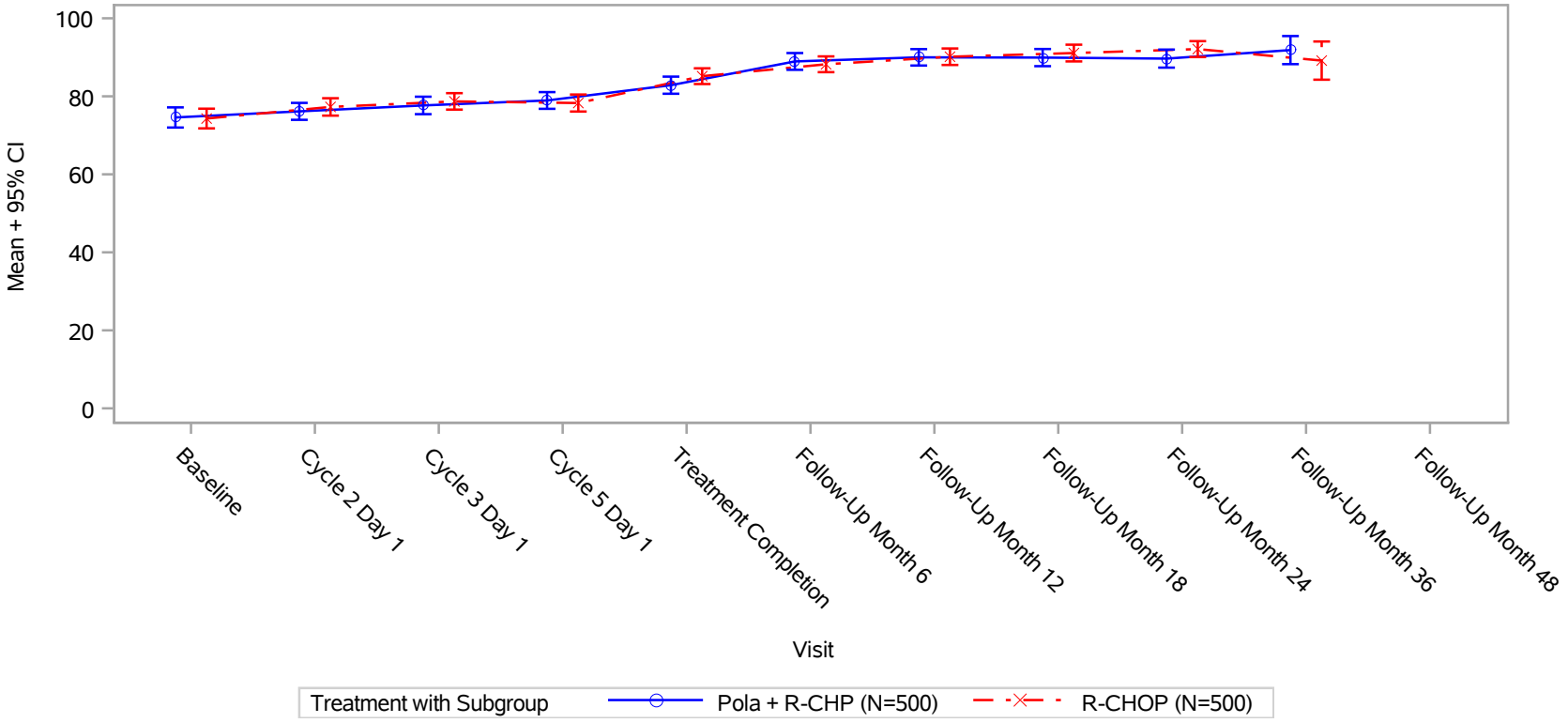
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit
EORTC QLQ-C30: Social functioning



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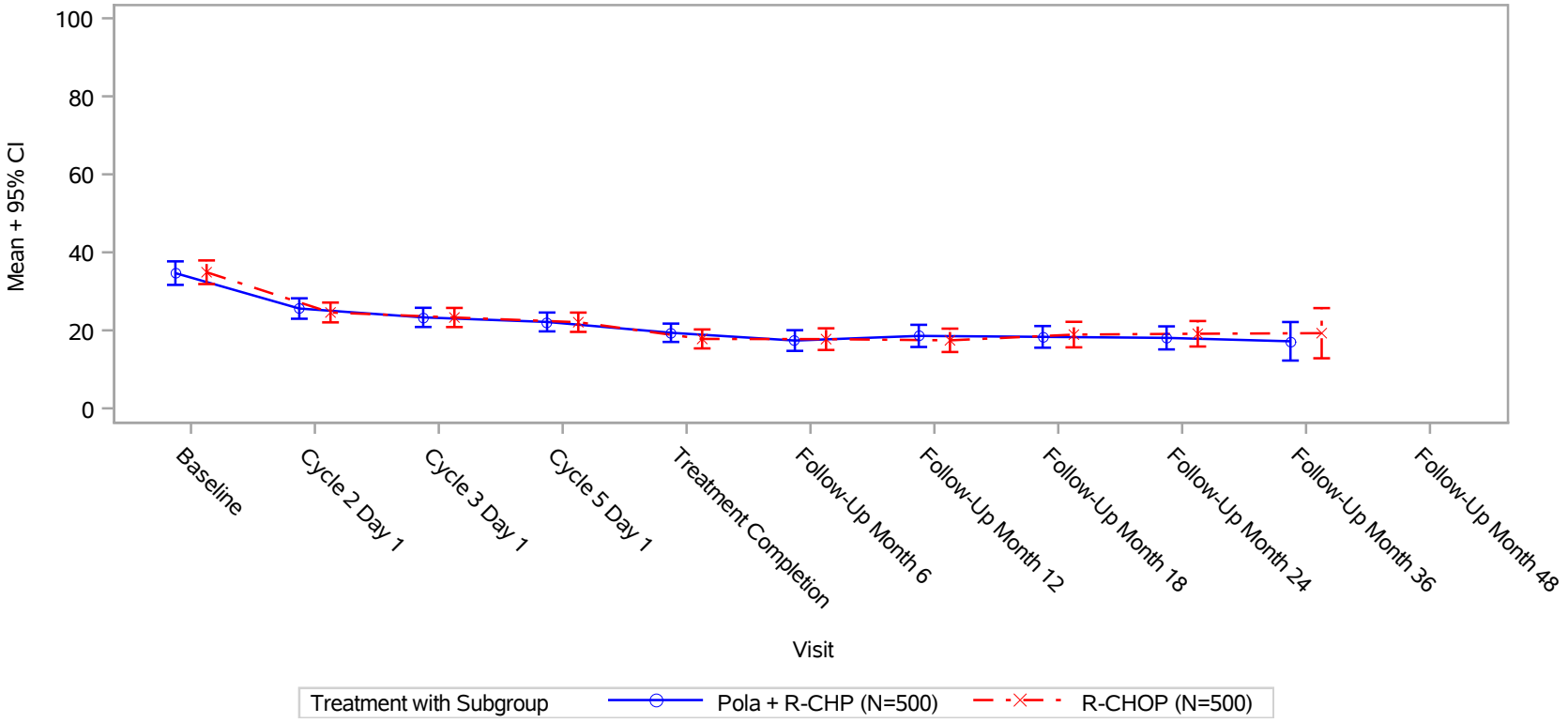
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QoL 30
STUDY: GO39942
Line Plot of Mean by Visit
EORTC QLQ-C30: Insomnia



Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the plot.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQC30_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 20:59

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Appetite loss

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	435	87.0	48	11.0	404	80.8	35	8.7	1.33		Convergence criterion (GCONV=1E-8) satisfied.	0.84	2.10	0.017		Algorithm converged.	-0.024	0.059	1.30		Algorithm converged.	0.86	1.96	0.2230	0.77		Algorithm converged.	0.51	1.17

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Cognitive functioning

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	433	86.6	98	22.6	403	80.6	101	25.1	0.87		Convergence criterion (GCONV=1E-8) satisfied.	0.63	1.20	-0.024		Algorithm converged.	-0.081	0.033	0.90		Algorithm converged.	0.71	1.14	0.4087	1.11		Algorithm converged.	0.87	1.42

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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
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13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Constipation

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	431	86.2	46	10.7	397	79.4	27	6.8	1.62		Convergence criterion (GCONV=1E-8) satisfied.	0.99	2.65	0.038		Algorithm converged.	0.000	0.076	1.57		Algorithm converged.	1.00	2.47	0.0551	0.64		Algorithm converged.	0.40	1.00

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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Diarrhoea

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	429	85.8	48	11.2	403	80.6	42	10.4	1.08		Convergence criterion (GCONV=1E-8) satisfied.	0.69	1.67	0.012		Algorithm converged.	-0.030	0.054	1.07		Algorithm converged.	0.72	1.57	0.7445	0.94		Algorithm converged.	0.64	1.39

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OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Dyspnoea

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	436	87.2	75	17.2	405	81.0	60	14.8	1.22		Convergence criterion (GCONV=1E-8) satisfied.	0.84	1.77	0.031		Algorithm converged.	-0.016	0.079	1.16		Algorithm converged.	0.85	1.57	0.2928	0.86		Algorithm converged.	0.64	1.18

* indicates convergence problem. Result is uninterpretable.
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Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Emotional functioning

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	433	86.6	45	10.4	404	80.8	33	8.2	1.28		Convergence criterion (GCONV=1E-8) satisfied.	0.80	2.06	0.015		Algorithm converged.	-0.024	0.055	1.29		Algorithm converged.	0.84	1.97	0.2979	0.78		Algorithm converged.	0.51	1.19

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
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POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Fatigue

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	436	87.2	102	23.4	404	80.8	114	28.2	0.78		Convergence criterion (GCONV=1E-8) satisfied.	0.57	1.07	-0.052		Algorithm converged.	-0.110	0.006	0.85		Algorithm converged.	0.67	1.06	0.1195	1.18		Algorithm converged.	0.94	1.48

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Financial difficulties

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	427	85.4	57	13.3	398	79.6	43	10.8	1.29		Convergence criterion (GCONV=1E-8) satisfied.	0.85	1.97	0.026		Algorithm converged.	-0.019	0.070	1.24		Algorithm converged.	0.85	1.79	0.2313	0.81		Algorithm converged.	0.56	1.17

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Nausea and vomiting

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP																R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	436	87.2	33	7.6	405	81.0	33	8.1	0.93		Convergence criterion (GCONV=1E-8) satisfied.	0.56	1.55	-0.001		Algorithm converged.	-0.034	0.031	0.94		Algorithm converged.	0.60	1.49	0.7909	1.06		Algorithm converged.	0.67	1.68

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Pain

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP																R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	437	87.4	89	20.4	407	81.4	77	18.9	1.10		Convergence criterion (GCONV=1E-8) satisfied.	0.78	1.55	0.011		Algorithm converged.	-0.042	0.064	1.08		Algorithm converged.	0.82	1.42	0.5754	0.93		Algorithm converged.	0.71	1.21

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Physical functioning (revised)

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	436	87.2	92	21.1	405	81.0	71	17.5		*	NE			0.044		Algorithm converged.	-0.009	0.097	1.20		Algorithm converged.	0.91	1.58	0.1694	0.83		Algorithm converged.	0.63	1.10

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30:Deterioration (MID=10) at EOT in Global health status/QoL (revised)

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	432	86.4	73	16.9	403	80.6	60	14.9	1.18		Convergence criterion (GCONV=1E-8) satisfied.	0.81	1.71	0.018		Algorithm converged.	-0.032	0.068	1.14		Algorithm converged.	0.84	1.56	0.3908	0.87		Algorithm converged.	0.64	1.20

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Role functioning (revised)

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	435	87.0	102	23.4	405	81.0	84	20.7	1.19		Convergence criterion (GCONV=1E-8) satisfied.	0.86	1.65	0.027		Algorithm converged.	-0.029	0.083	1.14		Algorithm converged.	0.88	1.47	0.3028	0.88		Algorithm converged.	0.68	1.13

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Social functioning

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP																R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	432	86.4	93	21.5	402	80.4	72	17.9	1.26		Convergence criterion (GCONV=1E-8) satisfied.	0.90	1.78	0.032		Algorithm converged.	-0.022	0.087	1.21		Algorithm converged.	0.92	1.59	0.1820	0.83		Algorithm converged.	0.63	1.09

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Insomnia

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	436	87.2	72	16.5	404	80.8	51	12.6	1.38		Convergence criterion (GCONV=1E-8) satisfied.	0.94	2.04	0.030		Algorithm converged.	-0.018	0.078	1.31		Algorithm converged.	0.94	1.83	0.1018	0.76		Algorithm converged.	0.55	1.06

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010ET_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:15

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Appetite loss

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	435	87.0	48	11.0	404	80.8	35	8.7	1.31	Convergence criterion (GCONV=1E-8) satisfied.	0.83	2.07	0.024	Algorithm converged.	-0.017	0.066	1.27	Algorithm converged.	0.84	1.93	0.2507		0.79	Algorithm converged.	0.52	1.19
Sex	Male	230	46.0	24	10.4	216	43.2	16	7.4	1.46	Convergence criterion (GCONV=1E-8) satisfied.	0.75	2.82	0.030	Algorithm converged.	-0.022	0.083	1.41	Algorithm converged.	0.77	2.58	0.2645	0.6498	0.71	Algorithm converged.	0.39	1.30
	Female	205	41.0	24	11.7	188	37.6	19	10.1	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.62	2.23	0.016	Algorithm converged.	-0.046	0.078	1.16	Algorithm converged.	0.64	2.03	0.6125		0.84	Algorithm converged.	0.49	1.42
Age	<= 60	150	30.0	14	9.3	129	25.8	9	7.0	1.37	Convergence criterion (GCONV=1E-8) satisfied.	0.57	3.28	0.026	Algorithm converged.	-0.040	0.080	1.34	Algorithm converged.	0.66	2.80	0.4761	0.9004	0.73	Algorithm converged.	0.32	1.67
	> 60	285	57.0	34	11.9	275	55.0	26	9.5	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.76	2.23	0.025	Algorithm converged.	-0.026	0.076	1.26	Algorithm converged.	0.78	2.03	0.3442		0.75	Algorithm converged.	0.49	1.28
Geographic region	Western Europe/United States/Canada/Australia	249	49.8	22	8.8	225	45.0	20	8.9	0.98	Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.87	-0.001	Algorithm converged.	-0.052	0.051	0.99	Algorithm converged.	0.56	1.77	0.9887	0.4146	1.01	Algorithm converged.	0.56	1.79
	Asia	133	26.6	23	14.3	128	25.6	12	9.4	1.61	Convergence criterion (GCONV=1E-8) satisfied.	0.75	3.47	0.049	Algorithm converged.	-0.029	0.127	1.52	Algorithm converged.	0.77	3.01	0.2222		0.64	Algorithm converged.	0.32	1.30
	Rest of World	53	10.6	3	13.2	51	10.2	3	5.9	2.43	Convergence criterion (GCONV=1E-8) satisfied.	0.39	9.99	0.073	Algorithm converged.	-0.038	0.185	2.25	Algorithm converged.	0.61	8.23	0.2079		0.45	Algorithm converged.	0.12	1.62
Race/ethnicity	White	252	40.4	22	10.3	184	36.8	16	8.7	1.28	Convergence criterion (GCONV=1E-8) satisfied.	0.65	2.53	0.022	Algorithm converged.	+0.037	0.081	1.25	Algorithm converged.	0.68	2.31	0.4702	NE	0.80	Algorithm converged.	0.43	1.47
	Black or African American	7	1.4	0	0.0	4	0.8	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
	Asian	137	27.4	19	13.9	133	26.6	13	9.8	1.49	Convergence criterion (GCONV=1E-8) satisfied.	0.75	3.15	0.041	Algorithm converged.	-0.036	0.118	1.42	Algorithm converged.	0.73	2.78	0.2980		0.73	Algorithm converged.	0.34	1.57
	Other	8	1.6	1	14.3	9	1.8	1	11.1	1.80	Convergence criterion (GCONV=1E-8) satisfied.	0.08	31.77	0.056	Algorithm converged.	-0.304	0.416	1.50	Algorithm converged.	0.11	19.66	0.7445		0.87	Algorithm converged.	0.05	8.73
	Unknown	83	16.0	6	7.2	74	14.8	5	6.8	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.33	3.68	0.005	Algorithm converged.	-0.075	0.085	1.07	Algorithm converged.	0.34	3.36	0.9082		0.93	Algorithm converged.	0.32	2.84
ECOG performance status	0-1	370	74.0	45	12.2	347	69.4	28	8.1	1.58	Convergence criterion (GCONV=1E-8) satisfied.	0.86	2.59	0.041	Algorithm converged.	-0.003	0.085	1.51	Algorithm converged.	0.96	2.39	0.0763	0.0710	0.64	Algorithm converged.	0.42	1.04
	2	65	13.0	3	4.6	56	11.2	6	10.7	0.40	Convergence criterion (GCONV=1E-8) satisfied.	0.10	1.69	-0.061	Algorithm converged.	+0.157	0.035	0.43	Algorithm converged.	0.12	1.48	0.2042		2.32	Algorithm converged.	0.61	8.86
	Missing	0	0.0	0	0.0	1	0.2	1	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cell of origin (determined by gene expression)	ABC	121	24.2	13	10.7	119	23.8	9	7.6	1.47	Convergence criterion (GCONV=1E-8) satisfied.	0.60	3.58	0.032	Algorithm converged.	-0.041	0.100	1.42	Algorithm converged.	0.63	3.20	0.3940	0.9018	0.73	Algorithm converged.	0.31	1.74
	GCB	165	33.0	23	13.9	151	30.2	13	8.6	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.58	2.41	0.016	Algorithm converged.	-0.052	0.084	1.16	Algorithm converged.	0.63	2.12	0.6512		0.84	Algorithm converged.	0.43	1.64
	Unclassified	47	9.4	8	17.0	52	10.4	8	15.4	1.13	Convergence criterion (GCONV=1E-8) satisfied.	0.39	3.29	0.016	Algorithm converged.	-0.129	0.162	1.11	Algorithm converged.	0.45	2.71	0.8240		0.90	Algorithm converged.	0.37	2.22
	Unknown	102	20.4	4	3.9	82	16.4	5	6.1	2.44	Convergence criterion (GCONV=1E-8) satisfied.	0.58	8.73	0.042	Algorithm converged.	-0.024	0.108	2.14	Algorithm converged.	0.59	7.83	0.2350		0.47	Algorithm converged.	0.11	1.96
IPI score at Screening	1-2	171	34.2	19	11.1	147	33.4	17	10.2	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.55	2.20	0.009	Algorithm converged.	-0.056	0.075	1.09	Algorithm converged.	0.56	2.03	0.7817	0.5408	0.82	Algorithm converged.	0.48	1.39
	3	172	34.4	20	12.8	147	29.4	11	7.5	1.81	Convergence criterion (GCONV=1E-8) satisfied.	0.80	3.88	0.053	Algorithm converged.	-0.013	0.119	1.71	Algorithm converged.	0.86	3.41	0.1215		0.69	Algorithm converged.	0.29	1.64
	4-5	92	18.4	7	7.7	90	18.0	7	7.9	0.98	Convergence criterion (GCONV=1E-8) satisfied.	0.31	2.91	-0.002	Algorithm converged.	-0.079	0.075	0.98	Algorithm converged.	0.38	2.68	0.9660		1.02	Algorithm converged.	0.37	2.83
Baseline Bulky Disease	Present	175	35.0	10	5.7	160	32.0	16	10.0	0.55	Convergence criterion (GCONV=1E-8) satisfied.	0.24	1.24	-0.043	Algorithm converged.	-0.101	0.015	0.57	Algorithm converged.	0.27	1.22	0.1427	0.0086	1.75	Algorithm converged.	0.82	3.74
	Absent	260	52.0	38	14.6	244	48.8	19	7.8	2.00	Convergence criterion (GCONV=1E-8) satisfied.	1.13	3.62	0.068	Algorithm converged.	0.014	0.123	1.86	Algorithm converged.	1.13	3.16	0.0157		0.53	Algorithm converged.	0.32	0.90
Double Expressor Lymphoma by IHC (Central Review)	DEL	129	25.8	17	13.2	134	26.8	8	6.7	2.11	Convergence criterion (GCONV=1E-8) satisfied.	0.80	6.92	0.065	Algorithm converged.	-0.008	0.137	1.86	Algorithm converged.	0.91	4.24	0.0798	0.1903	0.51	Algorithm converged.	0.24	1.10
	Non DEL	226	45.2	26	11.5	202	40.4	22	10.9	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.58	1.94	0.006	Algorithm converged.	-0.054	0.065	1.06	Algorithm converged.	0.62	1.80	0.8411		0.85	Algorithm converged.	0.52	1.40
	Unknown	80	16.0	5	6.3	68	13.6	4	5.9	1.07	Convergence criterion (GCONV=1E-8) satisfied.	0.23	4.14	0.004	Algorithm converged.	-0.073	0.081	1.06	Algorithm converged.	0.30	3.80	0.9293		0.94	Algorithm converged.	0.29	3.11
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	302	60.4	37	12.3	293	58.6	28	9.6	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.78	2.22	0.027	Algorithm converged.	-0.023	0.077	1.28	Algorithm converged.	0.81	2.04	0.2924	0.8755	0.78	Algorithm converged.	0.49	1.24
	DH/TH+	22	4.4	2	9.1	17	3.4	1	5.9	1.60	Convergence criterion (GCONV=1E-8) satisfied.	0.13	19.28	0.032	Algorithm converged.	-0.132	0.196	1.55	Algorithm converged.	0.15	15.64	0.7128		0.65	Algorithm converged.	0.06	6.56
	Unknown	111	22.2	9	8.1	94	18.8	6	6.4	1.39	Convergence criterion (GCONV=1E-8) satisfied.	0.44	3.78	0.017	Algorithm converged.	-0.054	0.088	1.27	Algorithm converged.	0.47	3.44	0.6373		0.79	Algorithm converged.	0.29	2.13

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Cognitive Functioning

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	433	86.6	95	22.0	403	80.6	101	25.1	0.85	Convergence criterion (GCONV=1E-8) satisfied.	0.64	1.20	-0.024	Algorithm converged.	-0.082	0.034	0.95	Algorithm converged.	0.71	1.27	0.4160		1.11	Algorithm converged.	0.87	1.46
Sex	Male	229	45.8	49	20.1	217	43.4	46	21.2	0.89	Convergence criterion (GCONV=1E-8) satisfied.	0.59	1.48	-0.011	Algorithm converged.	-0.086	0.064	0.95	Algorithm converged.	0.64	1.36	0.7723	0.7038	1.06	Algorithm converged.	0.73	1.53
	Female	204	40.8	52	25.5	186	37.2	55	29.6	0.81	Convergence criterion (GCONV=1E-8) satisfied.	0.52	1.27	-0.041	Algorithm converged.	-0.130	0.048	0.86	Algorithm converged.	0.62	1.19	0.3477		1.16	Algorithm converged.	0.84	1.60
Age	<= 60	149	29.8	36	24.2	131	26.2	31	23.7	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.66	1.78	0.005	Algorithm converged.	-0.095	0.105	1.02	Algorithm converged.	0.67	1.57	0.9227	0.4788	0.98	Algorithm converged.	0.64	1.49
	> 60	284	56.8	60	21.1	272	54.4	70	25.7	0.81	Convergence criterion (GCONV=1E-8) satisfied.	0.56	1.19	-0.039	Algorithm converged.	-0.110	0.032	0.85	Algorithm converged.	0.63	1.14	0.2799		1.15	Algorithm converged.	0.87	1.53
Geographic region	Western Europe/United States/Canada/Australia	247	49.4	59	23.9	223	44.6	58	26.0	0.89	Convergence criterion (GCONV=1E-8) satisfied.	0.59	1.36	-0.021	Algorithm converged.	-0.100	0.057	0.92	Algorithm converged.	0.67	1.26	0.5956	0.9468	1.09	Algorithm converged.	0.80	1.48
	Asia	133	26.6	32	24.1	128	25.6	36	28.1	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.47	1.41	-0.041	Algorithm converged.	-0.147	0.066	0.86	Algorithm converged.	0.57	1.29	0.4554		1.17	Algorithm converged.	0.78	1.76
	Rest of World	53	10.6	7	13.2	50	10.0	7	13.5	0.98	Convergence criterion (GCONV=1E-8) satisfied.	0.32	3.01	-0.003	Algorithm converged.	-0.133	0.128	0.98	Algorithm converged.	0.37	2.60	0.9699		1.02	Algorithm converged.	0.38	2.76
Race/ethnicity	White	199	39.8	45	22.6	186	37.2	38	20.4	1.14	Convergence criterion (GCONV=1E-8) satisfied.	0.70	1.85	0.022	Algorithm converged.	-0.060	0.104	1.11	Algorithm converged.	0.75	1.62	0.6032	NE	0.90	Algorithm converged.	0.62	1.32
	Black or African American	6	1.2	1	16.7	4	0.8	1	25.0	0.60	Convergence criterion (GCONV=1E-8) satisfied.	0.03	13.58	-0.083	Algorithm converged.	-0.602	0.435	0.67	Algorithm converged.	0.04	7.83	0.7595		1.50	Algorithm converged.	0.12	17.67
	Asian	137	27.4	30	23.4	133	26.6	38	28.6	0.76	Convergence criterion (GCONV=1E-8) satisfied.	0.44	1.32	-0.052	Algorithm converged.	-0.157	0.052	0.82	Algorithm converged.	0.55	1.23	0.3293		1.22	Algorithm converged.	0.82	1.83
	Other	6	1.2	0	0.0	9	1.8	3	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
	Unknown	85	17.0	20	23.5	71	14.2	24	33.8	0.60	Convergence criterion (GCONV=1E-8) satisfied.	0.30	1.22	-0.103	Algorithm converged.	-0.245	0.040	0.70	Algorithm converged.	0.42	1.17	0.1569		1.44	Algorithm converged.	0.87	2.38
ECOG performance status	0-1	368	73.6	80	22.1	346	69.2	90	26.0	0.82	Convergence criterion (GCONV=1E-8) satisfied.	0.58	1.15	-0.037	Algorithm converged.	-0.100	0.026	0.86	Algorithm converged.	0.64	1.11	0.2446	0.3056	1.17	Algorithm converged.	0.91	1.50
	2	65	13.0	15	24.6	56	11.2	11	19.6	1.36	Convergence criterion (GCONV=1E-8) satisfied.	0.56	3.18	0.050	Algorithm converged.	-0.098	0.197	1.25	Algorithm converged.	0.64	2.47	0.5142		0.82	Algorithm converged.	0.40	1.53
	Missing	0	0.0	0	0.0	1	0.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cell of origin (determined by gene expression)	ABC	119	23.8	23	19.3	116	23.2	32	27.6	0.63	Convergence criterion (GCONV=1E-8) satisfied.	0.36	1.16	-0.083	Algorithm converged.	-0.191	0.025	0.70	Algorithm converged.	0.44	1.11	0.1358	0.3243	1.43	Algorithm converged.	0.93	2.19
	GCB	166	33.2	33	21.1	152	30.4	33	21.7	0.86	Convergence criterion (GCONV=1E-8) satisfied.	0.56	1.65	-0.006	Algorithm converged.	-0.097	0.084	0.97	Algorithm converged.	0.64	1.48	0.8922		1.03	Algorithm converged.	0.68	1.57
	Unclassified	47	9.4	10	21.3	53	10.6	20	37.7	0.45	Convergence criterion (GCONV=1E-8) satisfied.	0.18	1.09	-0.165	Algorithm converged.	-0.340	0.011	0.56	Algorithm converged.	0.28	1.08	0.0745		1.77	Algorithm converged.	0.93	3.40
	Unknown	101	20.2	30	29.7	82	16.4	15	18.3	1.74	Convergence criterion (GCONV=1E-8) satisfied.	0.87	3.49	0.102	Algorithm converged.	-0.022	0.226	1.50	Algorithm converged.	0.89	2.53	0.1150		0.65	Algorithm converged.	0.33	1.26
IPI score at Screening	1-2	149	33.6	40	23.7	166	33.2	36	21.7	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.67	1.87	0.029	Algorithm converged.	-0.070	0.169	1.09	Algorithm converged.	0.73	1.62	0.6654	0.4484	0.92	Algorithm converged.	0.62	1.36
	3	171	34.2	38	22.2	149	29.8	43	28.9	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.42	1.17	-0.066	Algorithm converged.	-0.162	0.029	0.77	Algorithm converged.	0.53	1.12	0.1739		1.35	Algorithm converged.	0.89	1.84
	4-5	93	18.6	20	21.5	88	17.6	23	25.3	0.80	Convergence criterion (GCONV=1E-8) satisfied.	0.41	1.64	-0.035	Algorithm converged.	-0.158	0.088	0.85	Algorithm converged.	0.53	1.40	0.5788		1.13	Algorithm converged.	0.63	1.98
Baseline Bulky Disease	Present	176	35.2	37	21.0	160	32.0	40	25.0	0.80	Convergence criterion (GCONV=1E-8) satisfied.	0.48	1.33	-0.040	Algorithm converged.	-0.130	0.050	0.84	Algorithm converged.	0.57	1.23	0.3870	0.6491	1.19	Algorithm converged.	0.82	1.74
	Absent	257	51.4	61	23.7	243	48.6	61	25.1	0.93	Convergence criterion (GCONV=1E-8) satisfied.	0.62	1.40	-0.014	Algorithm converged.	-0.089	0.060	0.95	Algorithm converged.	0.69	1.29	0.7222		1.06	Algorithm converged.	0.78	1.44
Double Expressor Lymphoma by IHC (Central Review)	DEL	127	25.4	29	22.8	132	26.4	35	26.5	0.82	Convergence criterion (GCONV=1E-8) satisfied.	0.47	1.45	-0.037	Algorithm converged.	-0.142	0.068	0.86	Algorithm converged.	0.54	1.32	0.4932	0.7984	1.16	Algorithm converged.	0.76	1.78
	Non DEL	226	45.2	50	22.1	203	40.6	56	27.6	0.75	Convergence criterion (GCONV=1E-8) satisfied.	0.48	1.16	-0.055	Algorithm converged.	-0.137	0.027	0.80	Algorithm converged.	0.58	1.12	0.1908		1.25	Algorithm converged.	0.90	1.74
	Unknown	80	16.0	10	23.3	68	13.6	10	14.7	1.83	Convergence criterion (GCONV=1E-8) satisfied.	0.76	4.21	0.090	Algorithm converged.	-0.035	0.213	1.61	Algorithm converged.	0.83	3.23	0.1681		0.53	Algorithm converged.	0.21	1.34
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	300	60.0	66	22.0	293	58.6	73	24.9	0.85	Convergence criterion (GCONV=1E-8) satisfied.	0.58	1.24	-0.029	Algorithm converged.	-0.097	0.039	0.88	Algorithm converged.	0.64	1.18	0.4028	0.5960	1.13	Algorithm converged.	0.85	1.52
	DH/TH+	23	4.6	7	30.4	16	3.2	7	43.8	0.56	Convergence criterion (GCONV=1E-8) satisfied.	0.15	2.12	-0.133	Algorithm converged.	-0.440	0.174	0.70	Algorithm converged.	0.30	1.62	0.4060		1.64	Algorithm converged.	0.63	3.96
	Unknown	110	22.0	25	22.7	94	18.8	21	22.3	1.02	Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.98	0.004	Algorithm converged.	-0.111	0.119	1.02	Algorithm converged.	0.61	1.73	0.9476		0.98	Algorithm converged.	0.53	1.84

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Constipation

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	Interaction Test p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	431	86.2	46	10.7	397	79.4	27	6.8	1.66	Convergence criterion (GCONV=1E-8) satisfied.	1.00	2.69	0.039	Algorithm converged.	0.000	0.077	1.57	Algorithm converged.	1.00	2.47	0.0488		0.64	Algorithm converged.	0.40	1.00
Sex	Male	226	45.2	20	8.8	214	42.9	13	6.1	1.50	Convergence criterion (GCONV=1E-8) satisfied.	0.73	3.10	0.028	Algorithm converged.	-0.021	0.077	1.46	Algorithm converged.	0.74	2.85	0.2699	0.7818	0.68	Algorithm converged.	0.33	1.38
	Female	205	41.0	26	12.7	183	36.6	14	7.7	1.75	Convergence criterion (GCONV=1E-8) satisfied.	0.89	3.47	0.050	Algorithm converged.	-0.009	0.110	1.68	Algorithm converged.	0.89	3.08	0.1041		0.60	Algorithm converged.	0.33	1.12
Age	<= 60	149	29.8	9	6.0	129	25.8	4	3.1	1.77	Convergence criterion (GCONV=1E-8) satisfied.	0.50	6.03	0.023	Algorithm converged.	-0.024	0.071	1.71	Algorithm converged.	0.53	5.62	0.3542	0.8788	0.58	Algorithm converged.	0.13	1.87
	> 60	282	56.4	38	13.5	268	53.6	23	8.6	1.68	Convergence criterion (GCONV=1E-8) satisfied.	0.96	2.87	0.049	Algorithm converged.	-0.003	0.101	1.57	Algorithm converged.	0.96	2.56	0.0680		0.64	Algorithm converged.	0.39	1.04
Geographic region	Western Europe/United States/Canada/Australia	245	49.0	25	10.2	217	43.4	16	7.4	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.74	2.75	0.028	Algorithm converged.	-0.023	0.080	1.38	Algorithm converged.	0.74	2.52	0.2861	0.6604	0.73	Algorithm converged.	0.40	1.33
	Asia	133	26.6	14	10.5	128	25.6	6	4.7	2.28	Convergence criterion (GCONV=1E-8) satisfied.	0.89	6.43	0.058	Algorithm converged.	-0.005	0.122	2.22	Algorithm converged.	0.89	5.62	0.0768		0.45	Algorithm converged.	0.13	1.52
	Rest of World	53	10.6	5	13.2	52	10.4	5	9.6	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.42	4.83	0.036	Algorithm converged.	-0.085	0.157	1.37	Algorithm converged.	0.47	4.05	0.5449		0.73	Algorithm converged.	0.25	2.14
Race/ethnicity	White	197	39.4	20	10.2	182	36.4	14	7.7	1.36	Convergence criterion (GCONV=1E-8) satisfied.	0.66	2.77	0.025	Algorithm converged.	+0.033	0.082	1.32	Algorithm converged.	0.68	2.53	0.4031	0.7025	0.76	Algorithm converged.	0.39	1.46
	Black or African American	7	1.4	1	14.3	3	0.6	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	0.5127		NE	Algorithm converged.	NE	NE
	Asian	136	27.2	14	10.3	132	26.4	6	4.5	2.41	Convergence criterion (GCONV=1E-8) satisfied.	0.95	6.67	0.057	Algorithm converged.	-0.005	0.120	2.26	Algorithm converged.	0.95	5.72	0.0739		0.48	Algorithm converged.	0.17	1.34
	Other	8	1.6	1	14.3	8	1.6	1	12.5	1.80	Convergence criterion (GCONV=1E-8) satisfied.	0.07	28.12	0.042	Algorithm converged.	-0.334	0.418	1.33	Algorithm converged.	0.10	17.28	0.8317		0.79	Algorithm converged.	0.06	9.73
	Unknown	85	17.0	10	11.8	72	14.4	6	8.3	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.53	4.25	0.034	Algorithm converged.	-0.059	0.128	1.41	Algorithm converged.	0.54	3.70	0.4802		0.71	Algorithm converged.	0.27	1.85
ECOG performance status	0-1	367	73.4	36	9.8	340	68.0	22	6.5	1.53	Convergence criterion (GCONV=1E-8) satisfied.	0.90	2.73	0.033	Algorithm converged.	-0.007	0.074	1.52	Algorithm converged.	0.91	2.53	0.1063	0.8023	0.66	Algorithm converged.	0.41	1.06
	2	64	12.8	10	15.6	56	11.2	5	8.9	1.88	Convergence criterion (GCONV=1E-8) satisfied.	0.62	5.90	0.067	Algorithm converged.	+0.049	0.183	1.75	Algorithm converged.	0.64	4.83	0.2705		0.57	Algorithm converged.	0.21	1.53
	Missing	0	0.0	0	0.0	1	0.2	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE			NE		NE	NE
Cell of origin (determined by gene expression)	ABC	121	24.2	10	8.3	117	23.4	12	10.3	0.78	Convergence criterion (GCONV=1E-8) satisfied.	0.33	1.90	-0.020	Algorithm converged.	-0.094	0.054	0.81	Algorithm converged.	0.36	1.79	0.5966	0.3255	1.24	Algorithm converged.	0.56	2.74
	GCB	164	32.8	12	7.3	149	29.8	6	4.0	2.02	Convergence criterion (GCONV=1E-8) satisfied.	0.76	5.54	0.039	Algorithm converged.	-0.013	0.091	1.97	Algorithm converged.	0.77	5.03	0.1496		0.51	Algorithm converged.	0.22	1.18
	Unclassified	44	9.2	8	17.8	52	10.4	6	11.5	1.61	Convergence criterion (GCONV=1E-8) satisfied.	0.51	5.06	0.059	Algorithm converged.	-0.081	0.199	1.53	Algorithm converged.	0.54	4.32	0.4110		0.66	Algorithm converged.	0.25	1.77
	Unknown	100	20.0	16	15.8	79	15.8	3	3.8	4.45	Convergence criterion (GCONV=1E-8) satisfied.	1.25	16.04	0.112	Algorithm converged.	0.030	0.194	3.96	Algorithm converged.	1.16	13.71	0.0116		0.25	Algorithm converged.	0.06	0.84
IPI score at Screening	1-2	179	34.0	16	8.9	165	33.0	13	7.9	1.05	Convergence criterion (GCONV=1E-8) satisfied.	0.48	2.31	0.004	Algorithm converged.	-0.055	0.065	1.05	Algorithm converged.	0.51	2.16	0.9048	0.3689	0.84	Algorithm converged.	0.46	1.52
	3	148	33.6	20	13.5	145	29.0	8	5.5	2.31	Convergence criterion (GCONV=1E-8) satisfied.	0.98	5.43	0.064	Algorithm converged.	0.002	0.125	2.16	Algorithm converged.	0.98	4.75	0.0487		0.46	Algorithm converged.	0.21	1.04
	4-5	93	18.9	10	12.5	87	17.4	5	6.3	2.00	Convergence criterion (GCONV=1E-8) satisfied.	0.72	5.59	0.060	Algorithm converged.	-0.026	0.147	1.97	Algorithm converged.	0.73	4.77	0.1807		0.53	Algorithm converged.	0.21	1.34
Baseline Bulky Disease	Present	172	34.4	14	8.7	157	31.4	9	5.7	1.46	Convergence criterion (GCONV=1E-8) satisfied.	0.62	3.47	0.026	Algorithm converged.	-0.031	0.079	1.42	Algorithm converged.	0.63	3.19	0.3922	0.7684	0.70	Algorithm converged.	0.32	1.58
	Absent	258	51.6	32	12.4	240	48.0	18	7.5	1.70	Convergence criterion (GCONV=1E-8) satisfied.	0.95	3.19	0.049	Algorithm converged.	-0.004	0.101	1.65	Algorithm converged.	0.97	2.84	0.0714		0.63	Algorithm converged.	0.39	1.05
Double Expressor Lymphoma by IHC (Central Review)	DEL	130	26.0	16	12.3	133	26.6	8	6.0	1.83	Convergence criterion (GCONV=1E-8) satisfied.	0.82	4.55	0.055	Algorithm converged.	-0.015	0.126	1.82	Algorithm converged.	0.83	3.97	0.1263	0.4288	0.55	Algorithm converged.	0.25	1.22
	Non DEL	224	44.8	20	8.9	199	39.8	16	8.0	1.25	Convergence criterion (GCONV=1E-8) satisfied.	0.62	2.44	0.018	Algorithm converged.	-0.036	0.072	1.20	Algorithm converged.	0.66	2.20	0.5230		0.80	Algorithm converged.	0.44	1.44
	Unknown	77	15.4	10	13.0	65	13.0	3	3.9	3.65	Convergence criterion (GCONV=1E-8) satisfied.	0.93	17.84	0.073	Algorithm converged.	-0.007	0.153	3.36	Algorithm converged.	0.74	15.34	0.0900		0.32	Algorithm converged.	0.07	1.51
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	301	60.2	33	11.0	290	58.0	21	7.2	1.58	Convergence criterion (GCONV=1E-8) satisfied.	0.89	2.80	0.037	Algorithm converged.	-0.009	0.083	1.51	Algorithm converged.	0.90	2.53	0.1147	0.9440	0.68	Algorithm converged.	0.39	1.11
	DH/TH+	23	4.6	6	8.7	16	3.2	1	6.3	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.15	17.23	0.026	Algorithm converged.	-0.141	0.193	1.36	Algorithm converged.	0.14	14.07	0.7806		0.75	Algorithm converged.	0.07	7.87
	Unknown	107	21.4	11	10.3	91	18.2	5	5.5	1.97	Convergence criterion (GCONV=1E-8) satisfied.	0.68	5.90	0.048	Algorithm converged.	-0.026	0.122	1.87	Algorithm converged.	0.68	5.19	0.2193		0.53	Algorithm converged.	0.19	1.48

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Diarrhoea

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	429	85.8	49	11.4	403	80.6	42	10.4	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.70	1.68	0.008	Algorithm converged.	-0.015	0.050	1.07	Algorithm converged.	0.73	1.58	0.7220		0.93	Algorithm converged.	0.63	1.38
Sex	Male	227	45.4	26	11.5	217	43.4	29	13.4	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.48	1.48	-0.019	Algorithm converged.	-0.080	0.042	0.86	Algorithm converged.	0.52	1.41	0.5419	0.1499	1.17	Algorithm converged.	0.71	1.92
	Female	202	40.4	23	10.9	186	37.2	13	7.0	1.63	Convergence criterion (GCONV=1E-8) satisfied.	0.79	3.33	0.039	Algorithm converged.	-0.017	0.095	1.56	Algorithm converged.	0.81	3.00	0.1807		0.64	Algorithm converged.	0.33	1.24
Age	<= 60	148	29.6	21	14.1	131	26.2	16	12.2	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.59	2.39	0.020	Algorithm converged.	-0.060	0.095	1.16	Algorithm converged.	0.63	2.13	0.6270	0.7295	0.86	Algorithm converged.	0.47	1.59
	> 60	281	56.2	27	9.6	272	54.4	26	9.6	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.77	0.000	Algorithm converged.	-0.049	0.052	1.01	Algorithm converged.	0.60	1.68	0.9842		0.99	Algorithm converged.	0.63	1.56
Geographic region	Western Europe/United States/Canada/Australia	243	48.6	30	12.3	223	44.6	24	10.8	1.17	Convergence criterion (GCONV=1E-8) satisfied.	0.66	2.07	0.016	Algorithm converged.	-0.042	0.074	1.15	Algorithm converged.	0.69	1.91	0.5941	0.7058	0.87	Algorithm converged.	0.51	1.44
	Asia	133	26.6	13	9.8	128	25.6	11	8.6	1.23	Convergence criterion (GCONV=1E-8) satisfied.	0.50	2.68	0.012	Algorithm converged.	-0.058	0.082	1.16	Algorithm converged.	0.53	2.43	0.7412		0.86	Algorithm converged.	0.41	1.68
	Rest of World	53	10.6	5	9.4	52	10.4	7	13.5	0.67	Convergence criterion (GCONV=1E-8) satisfied.	0.20	2.26	-0.040	Algorithm converged.	-0.162	0.081	0.70	Algorithm converged.	0.24	2.07	0.5189		1.43	Algorithm converged.	0.48	4.21
Race/ethnicity	White	197	39.4	18	9.1	186	37.2	22	11.8	0.75	Convergence criterion (GCONV=1E-8) satisfied.	0.38	1.45	-0.027	Algorithm converged.	-0.089	0.035	0.77	Algorithm converged.	0.43	1.39	0.3901	NE	1.29	Algorithm converged.	0.72	2.33
	Black or African American	6	1.2	0	0.0	4	0.8	1	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
	Asian	137	27.4	13	9.5	133	26.6	12	9.0	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.46	2.41	0.005	Algorithm converged.	-0.064	0.074	1.05	Algorithm converged.	0.50	2.22	0.8953		0.93	Algorithm converged.	0.43	2.04
	Other	9	1.8	3	33.3	9	1.8	2	22.2	1.75	Convergence criterion (GCONV=1E-8) satisfied.	0.17	17.69	0.111	Algorithm converged.	-0.354	0.576	1.50	Algorithm converged.	0.26	7.93	0.6451		0.67	Algorithm converged.	0.13	3.53
	Unknown	83	16.6	15	18.1	71	14.2	6	8.5	2.30	Convergence criterion (GCONV=1E-8) satisfied.	0.87	6.53	0.096	Algorithm converged.	-0.009	0.201	2.14	Algorithm converged.	0.88	5.22	0.0839		0.47	Algorithm converged.	0.13	1.74
ECOG performance status	0-1	365	73.0	40	11.0	346	69.2	35	10.1	1.16	Convergence criterion (GCONV=1E-8) satisfied.	0.71	1.86	0.014	Algorithm converged.	-0.032	0.060	1.14	Algorithm converged.	0.74	1.74	0.5516	0.6562	0.88	Algorithm converged.	0.58	1.34
	2	64	12.8	6	9.4	56	11.2	6	10.7	0.86	Convergence criterion (GCONV=1E-8) satisfied.	0.26	2.84	-0.013	Algorithm converged.	-0.121	0.095	0.88	Algorithm converged.	0.30	2.58	0.8080		1.14	Algorithm converged.	0.33	3.94
	Missing	0	0.0	0	0.0	1	0.2	1	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cell of origin (determined by gene expression)	ABC	117	23.4	10	8.5	116	23.2	13	11.2	0.74	Convergence criterion (GCONV=1E-8) satisfied.	0.31	1.76	-0.027	Algorithm converged.	-0.103	0.050	0.76	Algorithm converged.	0.35	1.67	0.4971	0.2695	1.11	Algorithm converged.	0.60	2.07
	GCB	165	33.0	19	11.5	152	30.4	15	9.9	1.19	Convergence criterion (GCONV=1E-8) satisfied.	0.58	2.43	0.016	Algorithm converged.	-0.052	0.084	1.17	Algorithm converged.	0.62	2.21	0.6362		0.84	Algorithm converged.	0.43	1.62
	Unclassified	46	9.2	8	17.4	53	10.6	4	7.5	2.39	Convergence criterion (GCONV=1E-8) satisfied.	0.72	9.21	0.098	Algorithm converged.	-0.032	0.229	2.30	Algorithm converged.	0.74	7.16	0.1369		0.43	Algorithm converged.	0.14	1.32
	Unknown	101	20.2	11	10.9	82	16.4	10	12.2	0.88	Convergence criterion (GCONV=1E-8) satisfied.	0.35	2.19	-0.013	Algorithm converged.	-0.106	0.081	0.89	Algorithm converged.	0.40	2.01	0.7837		1.12	Algorithm converged.	0.53	2.34
IPI score at Screening	1-2	148	33.6	20	13.7	166	33.2	15	9.0	1.60	Convergence criterion (GCONV=1E-8) satisfied.	0.80	3.18	0.047	Algorithm converged.	-0.021	0.114	1.52	Algorithm converged.	0.82	2.83	0.1803	0.2120	0.66	Algorithm converged.	0.36	1.22
	3	149	33.8	16	9.5	149	29.8	20	13.4	0.67	Convergence criterion (GCONV=1E-8) satisfied.	0.34	1.36	-0.040	Algorithm converged.	-0.110	0.031	0.71	Algorithm converged.	0.38	1.31	0.2676		1.40	Algorithm converged.	0.76	2.64
	4-5	92	18.4	10	9.3	88	17.6	7	8.3	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.45	3.53	0.018	Algorithm converged.	-0.065	0.100	1.23	Algorithm converged.	0.48	3.14	0.6670		0.83	Algorithm converged.	0.32	2.16
Baseline Bulky Disease	Present	175	35.0	20	11.4	160	32.0	24	15.0	0.73	Convergence criterion (GCONV=1E-8) satisfied.	0.32	1.38	-0.036	Algorithm converged.	-0.108	0.037	0.76	Algorithm converged.	0.44	1.32	0.3344	0.0945	1.31	Algorithm converged.	0.72	2.38
	Absent	254	50.8	29	11.4	243	48.6	18	7.4	1.50	Convergence criterion (GCONV=1E-8) satisfied.	0.83	2.88	0.036	Algorithm converged.	-0.015	0.087	1.40	Algorithm converged.	0.87	2.42	0.2448		0.67	Algorithm converged.	0.38	1.18
Double Expressor Lymphoma by IHC (Central Review)	DEL	126	25.2	10	9.5	132	26.4	8	6.1	1.63	Convergence criterion (GCONV=1E-8) satisfied.	0.66	4.14	0.035	Algorithm converged.	-0.031	0.100	1.57	Algorithm converged.	0.64	3.73	0.2998	0.4089	0.64	Algorithm converged.	0.27	1.50
	Non DEL	224	44.8	31	13.8	203	40.6	27	13.3	1.05	Convergence criterion (GCONV=1E-8) satisfied.	0.60	1.82	0.005	Algorithm converged.	-0.060	0.070	1.04	Algorithm converged.	0.64	1.68	0.8710		0.96	Algorithm converged.	0.53	1.74
	Unknown	79	15.8	8	8.7	68	13.6	7	10.3	0.80	Convergence criterion (GCONV=1E-8) satisfied.	0.19	1.95	-0.040	Algorithm converged.	-0.130	0.050	0.81	Algorithm converged.	0.20	1.89	0.3830		1.33	Algorithm converged.	0.54	4.89
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	296	59.2	33	11.1	293	58.6	26	8.9	1.29	Convergence criterion (GCONV=1E-8) satisfied.	0.75	2.21	0.023	Algorithm converged.	-0.026	0.071	1.26	Algorithm converged.	0.77	2.05	0.3583	0.8357	0.80	Algorithm converged.	0.49	1.30
	DH/TH+	23	4.6	3	13.0	16	3.2	3	12.5	1.05	Convergence criterion (GCONV=1E-8) satisfied.	0.15	7.13	0.005	Algorithm converged.	-0.257	0.216	1.04	Algorithm converged.	0.20	5.53	0.9607		0.96	Algorithm converged.	0.14	5.66
	Unknown	110	22.0	13	10.9	94	18.8	14	14.9	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.31	1.60	-0.040	Algorithm converged.	-0.132	0.053	0.73	Algorithm converged.	0.34	1.53	0.3961		1.37	Algorithm converged.	0.64	2.93

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Dyspnoea

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	436	87.2	75	17.2	405	81.0	60	14.8	1.19	Convergence criterion (GCONV=1E-8) satisfied.	0.83	1.73	0.024	Algorithm converged.	-0.026	0.073	1.16	Algorithm converged.	0.85	1.59	0.2466		0.86	Algorithm converged.	0.63	1.16
Sex	Male	230	46.0	47	20.4	217	43.4	22	10.1	2.09	Convergence criterion (GCONV=1E-8) satisfied.	1.30	3.93	0.103	Algorithm converged.	0.037	0.169	2.02	Algorithm converged.	1.24	3.23	0.0029	0.0097	0.50	Algorithm converged.	0.31	0.79
	Female	206	41.2	28	13.6	188	37.6	38	20.2	0.62	Convergence criterion (GCONV=1E-8) satisfied.	0.38	1.06	-0.066	Algorithm converged.	-0.140	0.008	0.67	Algorithm converged.	0.43	1.03	0.0792		1.49	Algorithm converged.	0.95	2.32
Age	<= 60	150	30.0	20	14.7	130	26.0	18	13.8	1.07	Convergence criterion (GCONV=1E-8) satisfied.	0.55	2.10	0.008	Algorithm converged.	-0.074	0.091	1.06	Algorithm converged.	0.59	1.89	0.8451	0.4980	0.94	Algorithm converged.	0.53	1.68
	> 60	286	57.2	53	18.9	275	55.0	42	15.3	1.28	Convergence criterion (GCONV=1E-8) satisfied.	0.83	1.97	0.033	Algorithm converged.	-0.029	0.095	1.21	Algorithm converged.	0.84	1.76	0.3040		0.83	Algorithm converged.	0.57	1.19
Geographic region	Western Europe/United States/Canada/Australia	250	50.0	43	17.2	226	45.2	36	15.9	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.65	2.70	0.057	Algorithm converged.	-0.006	0.120	1.30	Algorithm converged.	0.95	2.30	0.0781	0.1060	0.67	Algorithm converged.	0.41	1.09
	Asia	133	26.6	22	16.5	128	25.6	28	21.9	0.71	Convergence criterion (GCONV=1E-8) satisfied.	0.38	1.32	-0.053	Algorithm converged.	-0.149	0.042	0.76	Algorithm converged.	0.46	1.23	0.2746		1.32	Algorithm converged.	0.82	2.12
	Rest of World	53	10.6	10	18.9	51	10.2	6	11.8	1.79	Convergence criterion (GCONV=1E-8) satisfied.	0.58	5.21	0.071	Algorithm converged.	-0.066	0.209	1.60	Algorithm converged.	0.63	4.08	0.3179		0.62	Algorithm converged.	0.24	1.59
Race/ethnicity	White	252	40.4	33	16.3	185	37.0	19	10.3	1.71	Convergence criterion (GCONV=1E-8) satisfied.	0.93	3.12	0.061	Algorithm converged.	+0.007	0.128	1.59	Algorithm converged.	0.94	2.70	0.0809	0.2168	0.63	Algorithm converged.	0.37	1.07
	Black or African American	7	1.4	2	28.6	4	0.8	1	25.0	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.07	19.63	0.036	Algorithm converged.	-0.505	0.576	1.14	Algorithm converged.	0.15	8.92	0.9029		0.88	Algorithm converged.	0.11	6.88
	Asian	137	27.4	23	16.8	133	26.6	28	21.1	0.76	Convergence criterion (GCONV=1E-8) satisfied.	0.41	1.40	-0.043	Algorithm converged.	-0.136	0.051	0.80	Algorithm converged.	0.48	1.33	0.3717		1.25	Algorithm converged.	0.76	2.04
	Other	8	1.6	2	50.0	9	1.8	2	22.2	3.30	Convergence criterion (GCONV=1E-8) satisfied.	0.37	32.97	0.278	Algorithm converged.	-0.254	0.765	2.25	Algorithm converged.	0.52	9.70	0.2851		0.46	Algorithm converged.	0.13	1.55
	Unknown	84	16.8	14	16.7	74	14.8	10	13.5	1.28	Convergence criterion (GCONV=1E-8) satisfied.	0.53	3.08	0.032	Algorithm converged.	-0.080	0.143	1.23	Algorithm converged.	0.58	2.61	0.5828		0.81	Algorithm converged.	0.38	1.71
ECOG performance status	0-1	371	74.2	66	17.8	348	69.6	51	14.7	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.85	1.88	0.031	Algorithm converged.	-0.022	0.085	1.21	Algorithm converged.	0.87	1.70	0.2556	0.4638	0.82	Algorithm converged.	0.54	1.26
	2	65	13.0	9	13.8	56	11.2	9	16.1	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.31	2.29	-0.022	Algorithm converged.	+0.150	0.105	0.86	Algorithm converged.	0.37	2.02	0.7327		1.16	Algorithm converged.	0.50	2.70
	Missing	0	0.0	0	0.0	1	0.2	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cell of origin (determined by gene expression)	ABC	121	24.2	21	17.4	119	23.8	22	18.5	0.93	Convergence criterion (GCONV=1E-8) satisfied.	0.48	1.79	-0.011	Algorithm converged.	-0.108	0.086	0.96	Algorithm converged.	0.55	1.61	0.8195	0.5558	1.07	Algorithm converged.	0.62	1.83
	GCB	166	33.2	23	17.3	151	30.2	24	15.9	1.12	Convergence criterion (GCONV=1E-8) satisfied.	0.62	2.03	0.016	Algorithm converged.	-0.066	0.098	1.10	Algorithm converged.	0.67	1.82	0.7072		0.91	Algorithm converged.	0.54	1.49
	Unclassified	47	9.4	8	8.5	53	10.6	8	15.1	0.52	Convergence criterion (GCONV=1E-8) satisfied.	0.15	1.86	-0.066	Algorithm converged.	-0.191	0.059	0.56	Algorithm converged.	0.18	1.79	0.3149		1.77	Algorithm converged.	0.57	5.52
	Unknown	102	20.4	23	22.5	82	16.4	6	7.3	3.28	Convergence criterion (GCONV=1E-8) satisfied.	1.25	8.57	0.133	Algorithm converged.	0.036	0.253	2.81	Algorithm converged.	1.16	6.83	0.0117		0.35	Algorithm converged.	0.13	0.94
IPI score at Screening	1-2	171	34.2	30	19.9	167	33.4	32	19.2	1.05	Convergence criterion (GCONV=1E-8) satisfied.	0.61	1.79	0.007	Algorithm converged.	-0.077	0.092	1.04	Algorithm converged.	0.67	1.63	0.8674	0.2570	0.96	Algorithm converged.	0.60	1.52
	3	173	34.6	27	15.9	148	29.6	22	14.9	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.57	1.95	0.007	Algorithm converged.	-0.071	0.086	1.05	Algorithm converged.	0.63	1.76	0.8540		0.95	Algorithm converged.	0.57	1.60
	4-5	92	18.4	16	15.7	90	18.0	6	6.7	2.51	Convergence criterion (GCONV=1E-8) satisfied.	0.92	6.86	0.086	Algorithm converged.	-0.004	0.175	2.26	Algorithm converged.	0.92	5.64	0.0693		0.44	Algorithm converged.	0.19	1.03
Baseline Bulky Disease	Present	175	35.0	25	14.7	161	32.2	12	8.0	1.91	Convergence criterion (GCONV=1E-8) satisfied.	0.97	3.94	0.043	Algorithm converged.	-0.026	0.113	1.66	Algorithm converged.	0.89	2.53	0.2245	0.3902	0.75	Algorithm converged.	0.39	1.45
	Absent	261	52.2	50	19.2	244	48.8	48	18.7	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.49	1.69	0.011	Algorithm converged.	-0.057	0.079	1.06	Algorithm converged.	0.74	1.53	0.7459		0.94	Algorithm converged.	0.65	1.36
Double Expressor Lymphoma by IHC (Central Review)	DEL	130	26.0	27	20.8	134	26.8	19	14.2	1.59	Convergence criterion (GCONV=1E-8) satisfied.	0.83	3.02	0.066	Algorithm converged.	-0.025	0.157	1.48	Algorithm converged.	0.84	2.59	0.1580	0.1840	0.68	Algorithm converged.	0.40	1.17
	Non DEL	226	45.2	30	13.3	203	40.6	35	17.2	0.81	Convergence criterion (GCONV=1E-8) satisfied.	0.35	1.51	-0.013	Algorithm converged.	-0.084	0.057	0.90	Algorithm converged.	0.48	1.41	0.7151		1.09	Algorithm converged.	0.71	1.66
	Unknown	80	16.0	10	15.2	68	13.6	6	8.2	1.83	Convergence criterion (GCONV=1E-8) satisfied.	0.65	5.15	0.062	Algorithm converged.	-0.042	0.169	1.70	Algorithm converged.	0.67	4.29	0.2539		0.53	Algorithm converged.	0.23	1.26
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	302	60.4	57	18.9	294	58.8	43	14.6	1.36	Convergence criterion (GCONV=1E-8) satisfied.	0.88	2.09	0.042	Algorithm converged.	-0.017	0.102	1.29	Algorithm converged.	0.90	1.85	0.1458	0.5929	0.77	Algorithm converged.	0.54	1.11
	DH/TH+	23	4.6	5	21.7	17	3.4	4	23.5	0.90	Convergence criterion (GCONV=1E-8) satisfied.	0.26	4.03	-0.018	Algorithm converged.	-0.281	0.245	0.92	Algorithm converged.	0.29	2.93	0.8947		1.05	Algorithm converged.	0.34	3.44
	Unknown	111	22.2	13	11.7	94	18.8	13	13.8	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.36	1.88	-0.021	Algorithm converged.	-0.113	0.071	0.85	Algorithm converged.	0.41	1.74	0.6506		1.16	Algorithm converged.	0.58	2.32

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Emotional Functioning

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	z-value (Cochran-Mantel-Haenszel)	Interaction Test z-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	433	86.6	45	10.4	404	80.8	33	8.2	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.81	2.09	0.022	Algorithm converged.	-0.017	0.061	1.27	Algorithm converged.	0.83	1.95	0.2689		0.79	Algorithm converged.	0.51	1.24
Sex	Male	229	45.8	23	9.4	217	43.4	16	7.4	1.34	Convergence criterion (GCONV=1E-8) satisfied.	0.68	2.62	0.022	Algorithm converged.	-0.029	0.074	1.30	Algorithm converged.	0.70	2.41	0.3969	0.9300	0.77	Algorithm converged.	0.42	1.42
	Female	204	40.8	23	11.3	187	37.4	17	9.1	1.27	Convergence criterion (GCONV=1E-8) satisfied.	0.68	2.46	0.022	Algorithm converged.	-0.038	0.082	1.24	Algorithm converged.	0.68	2.23	0.4772		0.81	Algorithm converged.	0.44	1.48
Age	<= 60	149	29.8	10	6.7	131	26.2	8	6.1	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.46	4.55	0.059	Algorithm converged.	-0.010	0.130	1.06	Algorithm converged.	0.47	3.96	0.1021	0.2136	0.56	Algorithm converged.	0.23	1.19
	> 60	284	56.8	26	9.2	273	54.6	24	8.8	1.05	Convergence criterion (GCONV=1E-8) satisfied.	0.58	1.87	0.004	Algorithm converged.	-0.044	0.051	1.04	Algorithm converged.	0.63	1.71	0.8808		0.96	Algorithm converged.	0.57	1.63
Geographic region	Western Europe/United States/Canada/Australia	247	49.4	32	13.0	224	44.8	17	7.6	1.81	Convergence criterion (GCONV=1E-8) satisfied.	0.98	3.36	0.054	Algorithm converged.	-0.001	0.106	1.71	Algorithm converged.	0.98	2.99	0.0570	0.2188	0.59	Algorithm converged.	0.31	1.09
	Asia	133	26.6	10	7.5	128	25.6	13	10.2	0.72	Convergence criterion (GCONV=1E-8) satisfied.	0.30	1.70	-0.026	Algorithm converged.	-0.095	0.043	0.74	Algorithm converged.	0.34	1.63	0.4522		1.35	Algorithm converged.	0.61	2.97
	Rest of World	53	10.6	3	5.7	52	10.4	3	5.8	0.99	Convergence criterion (GCONV=1E-8) satisfied.	0.19	5.09	-0.001	Algorithm converged.	-0.090	0.089	0.98	Algorithm converged.	0.21	4.64	0.9809		1.02	Algorithm converged.	0.22	4.62
Race/ethnicity	White	199	39.8	27	13.6	186	37.2	14	7.5	1.83	Convergence criterion (GCONV=1E-8) satisfied.	0.98	3.80	0.060	Algorithm converged.	0.000	0.121	1.80	Algorithm converged.	0.98	3.33	0.0551	NE	0.55	Algorithm converged.	0.30	1.02
	Black or African American	6	1.2	0	0.0	4	0.8	1	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Asian	137	27.4	10	7.3	133	26.6	13	9.8	0.73	Convergence criterion (GCONV=1E-8) satisfied.	0.31	1.72	-0.025	Algorithm converged.	-0.091	0.040	0.75	Algorithm converged.	0.34	1.64	0.4672		1.34	Algorithm converged.	0.61	2.93
	Other	6	1.2	0	0.0	9	1.8	3	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Unknown	85	17.0	8	9.4	72	14.4	6	8.3	1.14	Convergence criterion (GCONV=1E-8) satisfied.	0.38	3.46	0.011	Algorithm converged.	-0.078	0.100	1.13	Algorithm converged.	0.41	3.10	0.8138		0.89	Algorithm converged.	0.32	2.45
ECOG performance status	0-1	368	73.6	38	10.3	346	69.2	26	7.5	1.46	Convergence criterion (GCONV=1E-8) satisfied.	0.87	2.45	0.031	Algorithm converged.	-0.011	0.073	1.41	Algorithm converged.	0.88	2.27	0.1326	0.2744	0.71	Algorithm converged.	0.44	1.14
	2	65	13.0	6	9.2	57	11.4	7	12.3	0.73	Convergence criterion (GCONV=1E-8) satisfied.	0.23	2.30	-0.030	Algorithm converged.	+0.141	0.080	0.75	Algorithm converged.	0.27	2.11	0.5875		1.32	Algorithm converged.	0.47	3.73
	Missing	0	0.0	0	0.0	11	0.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cell of origin (determined by gene expression)	ABC	119	23.6	15	12.6	117	23.4	14	12.0	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.49	2.31	0.006	Algorithm converged.	-0.077	0.091	1.05	Algorithm converged.	0.53	2.08	0.8814	0.5737	0.93	Algorithm converged.	0.48	1.84
	GCB	166	33.2	14	8.4	152	30.4	9	5.9	1.46	Convergence criterion (GCONV=1E-8) satisfied.	0.63	3.49	0.025	Algorithm converged.	-0.031	0.082	1.42	Algorithm converged.	0.63	3.22	0.3882		0.70	Algorithm converged.	0.31	1.62
	Unclassified	47	9.4	6	12.8	53	10.6	3	5.7	2.46	Convergence criterion (GCONV=1E-8) satisfied.	0.57	10.36	0.071	Algorithm converged.	-0.043	0.185	2.28	Algorithm converged.	0.60	8.52	0.2178		0.46	Algorithm converged.	0.12	1.67
	Unknown	101	20.2	10	9.9	82	16.4	9	8.5	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.45	3.24	0.014	Algorithm converged.	-0.070	0.098	1.16	Algorithm converged.	0.46	2.91	0.7526		0.85	Algorithm converged.	0.34	2.13
IPI score at Screening	1-2	149	33.6	15	11.2	166	33.2	16	9.6	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.59	2.49	0.016	Algorithm converged.	-0.049	0.080	1.27	Algorithm converged.	0.62	2.13	0.4938	0.1402	0.84	Algorithm converged.	0.48	1.46
	3	171	34.2	20	11.7	149	29.8	8	5.4	2.35	Convergence criterion (GCONV=1E-8) satisfied.	1.00	5.47	0.043	Algorithm converged.	0.003	0.126	2.16	Algorithm converged.	0.99	4.80	0.0481		0.46	Algorithm converged.	0.21	1.04
	4-5	93	18.6	10	10.8	89	17.8	9	10.1	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.31	1.80	-0.037	Algorithm converged.	-0.117	0.043	0.86	Algorithm converged.	0.29	1.73	0.3707		1.57	Algorithm converged.	0.59	4.22
Baseline Bulky Disease	Present	176	35.2	14	8.0	160	32.0	13	8.1	0.88	Convergence criterion (GCONV=1E-8) satisfied.	0.44	2.15	-0.022	Algorithm converged.	-0.060	0.057	0.98	Algorithm converged.	0.47	2.02	0.9543	0.3748	1.02	Algorithm converged.	0.52	2.11
	Absent	257	51.4	31	12.1	244	48.8	20	8.2	1.56	Convergence criterion (GCONV=1E-8) satisfied.	0.85	2.78	0.039	Algorithm converged.	-0.014	0.091	1.47	Algorithm converged.	0.88	2.51	0.1531		0.69	Algorithm converged.	0.40	1.16
Double Expressor Lymphoma by IHC (Central Review)	DEL	127	25.4	16	12.6	132	26.4	10	7.6	1.76	Convergence criterion (GCONV=1E-8) satisfied.	0.77	4.04	0.050	Algorithm converged.	-0.023	0.123	1.66	Algorithm converged.	0.78	3.53	0.1798	0.4500	0.60	Algorithm converged.	0.28	1.28
	Non DEL	226	45.2	23	10.2	204	40.8	16	8.0	1.57	Convergence criterion (GCONV=1E-8) satisfied.	0.81	3.24	0.014	Algorithm converged.	-0.042	0.069	1.35	Algorithm converged.	0.64	2.87	0.4336		0.87	Algorithm converged.	0.48	1.56
	Unknown	80	16.0	6	7.5	68	13.6	5	7.4	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.30	3.51	0.001	Algorithm converged.	-0.083	0.086	1.02	Algorithm converged.	0.33	3.20	0.9730		0.98	Algorithm converged.	0.31	3.03
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	300	60.0	36	12.0	294	58.8	23	7.8	1.61	Convergence criterion (GCONV=1E-8) satisfied.	0.85	2.78	0.042	Algorithm converged.	-0.006	0.090	1.53	Algorithm converged.	0.93	2.52	0.0881	0.1253	0.65	Algorithm converged.	0.40	1.07
	DH/TH+	23	4.6	0	0.0	16	3.2	1	6.3	*	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	0.2305		>999.99	Algorithm converged.	0.00	NE
	Unknown	110	22.0	9	8.2	94	18.8	9	9.6	0.86	Convergence criterion (GCONV=1E-8) satisfied.	0.30	2.22	-0.014	Algorithm converged.	-0.092	0.065	0.85	Algorithm converged.	0.35	2.06	0.7277		1.17	Algorithm converged.	0.46	2.93

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Fatigue

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	Cochran-Mantel-Haenszel	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	436	87.2	100	23.4	404	80.8	114	28.2	0.78	Convergence criterion (GCONV=1E-8) satisfied.	0.57	1.06	-0.048	Algorithm converged.	-0.107	0.011	0.85	Algorithm converged.	0.66	1.09	0.1100		1.21	Algorithm converged.	0.92	1.59
Sex	Male	230	46.0	59	25.7	217	43.4	55	25.3	0.89	Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.27	-0.030	Algorithm converged.	-0.115	0.043	0.88	Algorithm converged.	0.61	1.26	0.3692	0.7479	1.17	Algorithm converged.	0.83	1.63
	Female	206	41.2	52	25.2	187	37.4	59	31.6	0.73	Convergence criterion (GCONV=1E-8) satisfied.	0.47	1.14	-0.063	Algorithm converged.	-0.152	0.026	0.80	Algorithm converged.	0.58	1.11	0.1458		1.25	Algorithm converged.	0.91	1.71
Age	<= 60	150	30.0	30	20.0	130	26.0	25	19.2	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.58	1.90	0.008	Algorithm converged.	-0.086	0.101	1.04	Algorithm converged.	0.65	1.67	0.8715	0.2877	0.86	Algorithm converged.	0.62	1.19
	> 60	286	57.2	73	25.2	274	54.8	89	32.3	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.48	1.01	-0.073	Algorithm converged.	-0.148	0.002	0.78	Algorithm converged.	0.60	1.01	0.0564		1.23	Algorithm converged.	0.93	1.68
Geographic region	Western Europe/United States/Canada/Australia	250	50.0	54	21.6	225	45.0	61	27.1	0.74	Convergence criterion (GCONV=1E-8) satisfied.	0.49	1.13	-0.055	Algorithm converged.	-0.132	0.022	0.80	Algorithm converged.	0.58	1.11	0.1416	0.8874	1.16	Algorithm converged.	0.91	1.73
	Asia	133	26.6	39	29.3	128	25.6	42	32.8	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.50	1.44	-0.035	Algorithm converged.	-0.147	0.077	0.89	Algorithm converged.	0.62	1.28	0.5432		1.12	Algorithm converged.	0.78	1.62
	Rest of World	53	10.6	9	17.0	51	10.2	11	21.6	0.76	Convergence criterion (GCONV=1E-8) satisfied.	0.28	1.98	-0.046	Algorithm converged.	-0.197	0.105	0.79	Algorithm converged.	0.36	1.74	0.5549		1.27	Algorithm converged.	0.57	2.82
Race/ethnicity	White	252	40.4	46	21.8	184	36.8	47	25.5	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.51	1.30	-0.038	Algorithm converged.	+0.123	0.047	0.85	Algorithm converged.	0.60	1.22	0.3852	0.6474	1.17	Algorithm converged.	0.82	1.68
	Black or African American	7	1.6	2	28.6	4	0.8	3	75.0	0.13	Convergence criterion (GCONV=1E-8) satisfied.	0.01	2.18	-0.464	Algorithm converged.	-1.005	0.076	0.38	Algorithm converged.	0.10	1.42	0.1581		2.62	Algorithm converged.	0.71	9.64
	Asian	137	27.4	39	28.5	133	26.6	43	32.3	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.50	1.40	-0.039	Algorithm converged.	-0.148	0.071	0.88	Algorithm converged.	0.61	1.26	0.4809		1.14	Algorithm converged.	0.79	1.63
	Other	8	1.6	1	14.3	9	1.8	2	22.2	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.05	10.01	-0.056	Algorithm converged.	-0.459	0.346	0.75	Algorithm converged.	0.09	6.53	0.7390		1.33	Algorithm converged.	0.13	13.84
	Unknown	84	16.8	13	19.2	74	14.8	19	25.7	0.68	Convergence criterion (GCONV=1E-8) satisfied.	0.32	1.45	-0.066	Algorithm converged.	-0.197	0.064	0.74	Algorithm converged.	0.41	1.33	0.3183		1.35	Algorithm converged.	0.70	2.60
ECOG performance status	0-1	371	74.2	88	24.1	347	69.4	101	29.1	0.79	Convergence criterion (GCONV=1E-8) satisfied.	0.54	1.04	-0.057	Algorithm converged.	-0.122	0.008	0.81	Algorithm converged.	0.63	1.03	0.0852	0.4156	1.24	Algorithm converged.	0.97	1.58
	2	65	13.0	10	20.0	56	11.2	10	17.9	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.46	2.67	0.021	Algorithm converged.	+0.118	0.161	1.12	Algorithm converged.	0.52	2.33	0.7655		0.89	Algorithm converged.	0.42	1.88
	Missing	0	0.0	0	0.0	1	0.2	1	100.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	
Cell of origin (determined by gene expression)	ABC	121	24.2	26	23.1	119	23.8	36	30.3	0.69	Convergence criterion (GCONV=1E-8) satisfied.	0.38	1.23	-0.071	Algorithm converged.	-0.183	0.041	0.76	Algorithm converged.	0.50	1.17	0.2116	0.8068	1.31	Algorithm converged.	0.86	2.00
	GCB	166	33.2	44	26.5	150	30.0	46	30.7	0.82	Convergence criterion (GCONV=1E-8) satisfied.	0.50	1.33	-0.042	Algorithm converged.	-0.141	0.058	0.86	Algorithm converged.	0.63	1.23	0.4122		1.16	Algorithm converged.	0.82	1.64
	Unclassified	47	9.4	13	27.7	53	10.6	16	30.2	0.79	Convergence criterion (GCONV=1E-8) satisfied.	0.33	1.91	-0.047	Algorithm converged.	-0.222	0.128	0.83	Algorithm converged.	0.45	1.60	0.6065		1.18	Algorithm converged.	0.63	2.24
	Unknown	102	20.4	18	17.6	82	16.4	16	19.5	0.88	Convergence criterion (GCONV=1E-8) satisfied.	0.45	1.86	-0.019	Algorithm converged.	-0.132	0.093	0.90	Algorithm converged.	0.49	1.69	0.7466		1.13	Algorithm converged.	0.63	2.04
IPI score at Screening	1-2	171	34.2	40	24.6	166	33.2	52	31.3	0.71	Convergence criterion (GCONV=1E-8) satisfied.	0.44	1.15	-0.068	Algorithm converged.	-0.163	0.028	0.78	Algorithm converged.	0.55	1.11	0.1669	0.9100	1.28	Algorithm converged.	0.90	1.82
	3	173	34.6	43	24.9	148	29.6	42	28.4	0.85	Convergence criterion (GCONV=1E-8) satisfied.	0.51	1.37	-0.035	Algorithm converged.	-0.132	0.062	0.88	Algorithm converged.	0.61	1.26	0.4765		1.14	Algorithm converged.	0.72	1.64
	4-5	92	18.4	17	18.5	90	18.0	20	22.2	0.79	Convergence criterion (GCONV=1E-8) satisfied.	0.38	1.64	-0.037	Algorithm converged.	-0.154	0.079	0.83	Algorithm converged.	0.47	1.48	0.5315		1.23	Algorithm converged.	0.67	2.14
Baseline Bulky Disease	Present	175	35.0	27	15.4	160	32.0	39	24.4	0.57	Convergence criterion (GCONV=1E-8) satisfied.	0.33	0.98	-0.089	Algorithm converged.	-0.175	-0.004	0.63	Algorithm converged.	0.41	0.98	0.0405	0.1361	1.58	Algorithm converged.	1.02	2.46
	Absent	261	52.2	75	28.7	244	48.8	75	30.7	0.91	Convergence criterion (GCONV=1E-8) satisfied.	0.62	1.33	-0.020	Algorithm converged.	-0.100	0.060	0.93	Algorithm converged.	0.73	1.20	0.6231		1.07	Algorithm converged.	0.80	1.45
Double Expressor Lymphoma by IHC (Central Review)	DEL	130	26.0	33	25.4	134	26.8	40	29.9	0.80	Convergence criterion (GCONV=1E-8) satisfied.	0.47	1.37	-0.045	Algorithm converged.	-0.152	0.063	0.85	Algorithm converged.	0.57	1.26	0.4182	0.9482	1.18	Algorithm converged.	0.79	1.74
	Non DEL	226	45.2	60	26.5	202	40.4	62	30.7	0.85	Convergence criterion (GCONV=1E-8) satisfied.	0.54	1.24	-0.041	Algorithm converged.	-0.127	0.044	0.86	Algorithm converged.	0.64	1.17	0.3436		1.14	Algorithm converged.	0.86	1.54
	Unknown	80	16.0	7	11.7	68	13.6	12	17.2	0.59	Convergence criterion (GCONV=1E-8) satisfied.	0.21	1.50	-0.064	Algorithm converged.	-0.178	0.050	0.66	Algorithm converged.	0.23	1.42	0.2680		1.57	Algorithm converged.	0.73	3.51
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	302	60.4	84	27.8	293	58.6	84	28.7	0.96	Convergence criterion (GCONV=1E-8) satisfied.	0.67	1.37	-0.009	Algorithm converged.	-0.081	0.064	0.97	Algorithm converged.	0.75	1.25	0.8171	0.2238	1.03	Algorithm converged.	0.80	1.33
	DH/TH+	23	4.6	5	21.7	17	3.4	7	41.2	0.40	Convergence criterion (GCONV=1E-8) satisfied.	0.10	1.58	-0.194	Algorithm converged.	-0.483	0.094	0.52	Algorithm converged.	0.20	1.38	0.1904		1.89	Algorithm converged.	0.72	4.95
	Unknown	111	22.2	13	11.7	94	18.8	23	24.5	0.61	Convergence criterion (GCONV=1E-8) satisfied.	0.19	0.86	-0.128	Algorithm converged.	-0.233	-0.023	0.66	Algorithm converged.	0.24	0.89	0.0170		2.56	Algorithm converged.	1.12	5.89

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Financial difficulties

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	427	85.4	57	13.3	398	79.6	43	10.8	1.27	Convergence criterion (GCONV=1E-8) satisfied.	0.83	1.94	0.025	Algorithm converged.	-0.019	0.070	1.26	Algorithm converged.	0.85	1.70	0.2439		0.81	Algorithm converged.	0.52	1.13
Sex	Male	226	45.2	29	12.8	216	43.2	27	12.5	1.09	Convergence criterion (GCONV=1E-8) satisfied.	0.59	1.81	0.003	Algorithm converged.	-0.059	0.065	1.03	Algorithm converged.	0.63	1.66	0.9149	0.2587	0.97	Algorithm converged.	0.60	1.58
	Female	201	40.2	28	13.9	182	36.4	16	8.8	1.68	Convergence criterion (GCONV=1E-8) satisfied.	0.88	3.22	0.051	Algorithm converged.	-0.012	0.115	1.58	Algorithm converged.	0.89	2.83	0.1157		0.63	Algorithm converged.	0.33	1.23
Age	<= 60	149	29.8	20	14.1	130	26.0	16	12.1	1.17	Convergence criterion (GCONV=1E-8) satisfied.	0.68	2.70	0.038	Algorithm converged.	-0.044	0.120	1.31	Algorithm converged.	0.73	2.37	0.3670	0.7858	0.76	Algorithm converged.	0.42	1.37
	> 60	278	55.6	33	11.9	268	53.6	23	10.1	1.21	Convergence criterion (GCONV=1E-8) satisfied.	0.70	2.06	0.018	Algorithm converged.	-0.034	0.070	1.18	Algorithm converged.	0.72	1.92	0.5028		0.85	Algorithm converged.	0.53	1.35
Geographic region	Western Europe/United States/Canada/Australia	241	48.2	30	12.4	218	43.6	22	10.1	1.21	Convergence criterion (GCONV=1E-8) satisfied.	0.68	2.15	0.019	Algorithm converged.	-0.039	0.077	1.16	Algorithm converged.	0.71	1.97	0.5257	0.9645	0.83	Algorithm converged.	0.51	1.41
	Asia	133	26.6	23	14.3	128	25.6	14	10.9	1.34	Convergence criterion (GCONV=1E-8) satisfied.	0.63	2.84	0.033	Algorithm converged.	-0.047	0.114	1.31	Algorithm converged.	0.68	2.43	0.4167		0.77	Algorithm converged.	0.42	1.46
	Rest of World	53	10.6	8	15.1	52	10.4	6	11.5	1.36	Convergence criterion (GCONV=1E-8) satisfied.	0.44	4.24	0.036	Algorithm converged.	-0.084	0.165	1.33	Algorithm converged.	0.48	3.51	0.5939		0.76	Algorithm converged.	0.28	2.05
Race/ethnicity	White	196	39.2	27	13.8	184	36.8	16	8.7	1.68	Convergence criterion (GCONV=1E-8) satisfied.	0.87	3.23	0.051	Algorithm converged.	+0.012	0.114	1.58	Algorithm converged.	0.88	2.84	0.1187	0.1053	0.63	Algorithm converged.	0.35	1.13
	Black or African American	6	1.2	1	16.7	4	0.8	2	50.0	0.20	Convergence criterion (GCONV=1E-8) satisfied.	0.01	3.66	-0.333	Algorithm converged.	-0.907	0.240	0.20	Algorithm converged.	0.04	2.54	0.2850		3.00	Algorithm converged.	0.32	23.97
	Asian	137	27.4	20	14.6	133	26.6	14	10.5	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.75	3.01	0.041	Algorithm converged.	-0.038	0.120	1.29	Algorithm converged.	0.73	2.63	0.3142		0.72	Algorithm converged.	0.38	1.40
	Other	8	1.6	1	14.3	9	1.8	5	55.6	0.16	Convergence criterion (GCONV=1E-8) satisfied.	0.01	1.98	-0.389	Algorithm converged.	-0.830	0.052	0.30	Algorithm converged.	0.05	1.97	0.1454		3.83	Algorithm converged.	0.51	21.83
	Unknown	82	16.4	8	9.8	68	13.6	9	8.8	1.12	Convergence criterion (GCONV=1E-8) satisfied.	0.37	3.39	0.009	Algorithm converged.	-0.084	0.102	1.11	Algorithm converged.	0.40	3.03	0.8455		0.91	Algorithm converged.	0.33	2.48
ECOG performance status	0-1	363	72.4	48	13.1	343	68.6	37	10.8	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.81	2.03	0.027	Algorithm converged.	-0.021	0.075	1.25	Algorithm converged.	0.84	1.87	0.2716	0.8461	0.85	Algorithm converged.	0.54	1.34
	2	64	12.8	8	12.5	54	10.8	6	11.1	1.14	Convergence criterion (GCONV=1E-8) satisfied.	0.37	3.53	0.014	Algorithm converged.	+0.103	0.138	1.12	Algorithm converged.	0.42	3.04	0.8178		0.89	Algorithm converged.	0.33	2.40
	Missing	0	0.0	0	0.0	1	0.2	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cell of origin (determined by gene expression)	ABC	117	23.6	13	11.1	115	23.0	8	7.0	1.47	Convergence criterion (GCONV=1E-8) satisfied.	0.47	4.20	0.042	Algorithm converged.	-0.032	0.111	1.40	Algorithm converged.	0.69	3.71	0.2710	0.6368	0.63	Algorithm converged.	0.27	1.45
	GCB	164	32.8	22	13.4	149	29.8	20	13.4	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.52	1.92	0.000	Algorithm converged.	-0.076	0.074	1.00	Algorithm converged.	0.57	1.74	0.9982		1.00	Algorithm converged.	0.57	1.74
	Unclassified	46	9.2	5	10.9	53	10.6	6	11.3	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.24	4.53	0.039	Algorithm converged.	-0.095	0.173	1.04	Algorithm converged.	0.40	3.71	0.5689		0.76	Algorithm converged.	0.27	2.09
	Unknown	100	20.0	16	16.0	81	16.2	9	11.1	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.58	3.42	0.039	Algorithm converged.	-0.059	0.137	1.36	Algorithm converged.	0.62	2.93	0.4446		0.74	Algorithm converged.	0.34	1.60
IPI score at Screening	1-2	168	33.6	20	11.9	169	32.6	16	9.5	1.38	Convergence criterion (GCONV=1E-8) satisfied.	0.70	2.74	0.039	Algorithm converged.	-0.036	0.105	1.33	Algorithm converged.	0.73	2.45	0.3502	0.8584	0.75	Algorithm converged.	0.43	1.32
	3	170	34.0	26	15.3	147	29.4	18	12.2	1.29	Convergence criterion (GCONV=1E-8) satisfied.	0.68	2.47	0.030	Algorithm converged.	-0.045	0.106	1.25	Algorithm converged.	0.71	2.19	0.4361		0.85	Algorithm converged.	0.48	1.46
	4-5	89	17.8	10	11.2	88	17.6	9	10.2	0.99	Convergence criterion (GCONV=1E-8) satisfied.	0.33	2.62	-0.001	Algorithm converged.	-0.090	0.089	0.99	Algorithm converged.	0.43	2.27	0.9793		1.01	Algorithm converged.	0.42	2.43
Baseline Bulky Disease	Present	172	34.4	22	12.8	156	31.2	19	12.2	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.52	2.04	0.006	Algorithm converged.	-0.065	0.078	1.05	Algorithm converged.	0.59	1.87	0.8674	0.4783	0.95	Algorithm converged.	0.54	1.68
	Absent	255	51.0	35	13.7	242	48.4	24	9.9	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.83	2.51	0.038	Algorithm converged.	-0.019	0.095	1.36	Algorithm converged.	0.87	2.26	0.1805		0.70	Algorithm converged.	0.44	1.14
Double Expressor Lymphoma by IHC (Central Review)	DEL	125	25.0	17	8.8	130	26.0	12	9.2	0.95	Convergence criterion (GCONV=1E-8) satisfied.	0.40	2.24	-0.004	Algorithm converged.	-0.075	0.066	0.95	Algorithm converged.	0.44	2.08	0.9048	0.4728	1.03	Algorithm converged.	0.48	2.22
	Non DEL	224	44.8	33	14.7	200	40.0	22	11.0	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.75	2.49	0.037	Algorithm converged.	-0.026	0.101	1.34	Algorithm converged.	0.81	2.22	0.2541		0.75	Algorithm converged.	0.45	1.24
	Unknown	78	15.6	10	14.7	68	13.6	9	13.2	1.11	Convergence criterion (GCONV=1E-8) satisfied.	0.52	3.29	0.034	Algorithm converged.	-0.081	0.150	1.26	Algorithm converged.	0.57	2.79	0.5645		0.79	Algorithm converged.	0.30	1.74
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	296	59.2	36	12.2	288	57.6	28	9.7	1.29	Convergence criterion (GCONV=1E-8) satisfied.	0.76	2.17	0.024	Algorithm converged.	-0.026	0.075	1.25	Algorithm converged.	0.78	1.99	0.3457	0.4588	0.80	Algorithm converged.	0.50	1.27
	DH/TH+	23	4.6	3	13.0	16	3.2	3	18.8	0.65	Convergence criterion (GCONV=1E-8) satisfied.	0.11	3.73	-0.057	Algorithm converged.	-0.293	0.179	0.70	Algorithm converged.	0.14	3.02	0.6315		1.44	Algorithm converged.	0.73	6.64
	Unknown	108	21.6	18	16.7	94	18.8	12	12.8	1.37	Convergence criterion (GCONV=1E-8) satisfied.	0.62	3.01	0.039	Algorithm converged.	-0.058	0.136	1.31	Algorithm converged.	0.66	2.57	0.4379		0.77	Algorithm converged.	0.39	1.53

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Nausea and vomiting

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	436	87.2	35	7.0	405	81.0	33	8.1	0.85	Convergence criterion (GCONV=1E-8) satisfied.	0.36	1.53	-0.006	Algorithm converged.	-0.042	0.031	0.85	Algorithm converged.	0.58	1.48	0.7551		1.08	Algorithm converged.	0.68	1.74
Sex	Male	230	46.0	19	8.3	217	43.4	18	8.3	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.51	1.95	0.000	Algorithm converged.	-0.051	0.051	1.00	Algorithm converged.	0.54	1.85	0.9999	0.7409	1.00	Algorithm converged.	0.54	1.84
	Female	206	41.2	14	6.8	188	37.6	15	8.0	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.39	1.79	-0.012	Algorithm converged.	-0.064	0.040	0.85	Algorithm converged.	0.42	1.72	0.6538		1.17	Algorithm converged.	0.58	2.37
Age	<= 60	150	30.0	13	8.7	130	26.0	13	10.0	0.85	Convergence criterion (GCONV=1E-8) satisfied.	0.38	1.93	-0.013	Algorithm converged.	-0.082	0.055	0.87	Algorithm converged.	0.43	1.80	0.7019	0.8298	1.13	Algorithm converged.	0.57	2.49
	> 60	286	57.2	20	7.0	275	55.0	20	7.3	0.96	Convergence criterion (GCONV=1E-8) satisfied.	0.50	1.82	-0.003	Algorithm converged.	-0.045	0.040	0.96	Algorithm converged.	0.52	1.73	0.8977		1.04	Algorithm converged.	0.57	1.89
Geographic region	Western Europe/United States/Canada/Australia	250	50.0	21	8.4	226	45.2	23	10.2	0.81	Convergence criterion (GCONV=1E-8) satisfied.	0.43	1.51	-0.018	Algorithm converged.	-0.070	0.033	0.81	Algorithm converged.	0.47	1.40	0.5043	0.4767	1.21	Algorithm converged.	0.69	2.13
	Asia	133	26.6	7	5.3	128	25.6	7	5.5	0.96	Convergence criterion (GCONV=1E-8) satisfied.	0.33	2.82	-0.002	Algorithm converged.	-0.057	0.053	0.96	Algorithm converged.	0.35	2.67	0.9414		1.04	Algorithm converged.	0.37	2.88
	Rest of World	53	10.6	5	9.4	51	10.2	3	5.9	1.67	Convergence criterion (GCONV=1E-8) satisfied.	0.38	7.37	0.036	Algorithm converged.	-0.066	0.137	1.60	Algorithm converged.	0.46	6.27	0.4989		0.62	Algorithm converged.	0.10	2.68
Race/ethnicity	White	202	40.4	16	7.9	185	37.0	18	9.7	0.80	Convergence criterion (GCONV=1E-8) satisfied.	0.36	1.62	-0.018	Algorithm converged.	-0.075	0.038	0.81	Algorithm converged.	0.43	1.53	0.5306	0.1978	1.21	Algorithm converged.	0.65	2.24
	Black or African American	7	1.4	1	14.3	4	0.8	1	25.0	0.50	Convergence criterion (GCONV=1E-8) satisfied.	0.02	11.09	-0.107	Algorithm converged.	-0.604	0.390	0.27	Algorithm converged.	0.05	6.84	0.4726		1.75	Algorithm converged.	0.12	21.68
	Asian	137	27.4	8	5.8	133	26.6	9	6.8	0.85	Convergence criterion (GCONV=1E-8) satisfied.	0.32	2.29	-0.009	Algorithm converged.	-0.067	0.049	0.86	Algorithm converged.	0.34	2.17	0.7542		1.16	Algorithm converged.	0.46	2.90
	Other	6	1.2	0	0.0	9	1.8	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	0.0721		NE	Algorithm converged.	NE	NE
	Unknown	84	16.8	6	7.1	74	14.8	5	6.8	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.31	3.63	0.004	Algorithm converged.	-0.076	0.084	1.06	Algorithm converged.	0.34	3.32	0.9244		0.95	Algorithm converged.	0.32	2.83
ECOG performance status	0-1	371	74.2	31	8.4	348	69.6	29	8.3	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.59	1.70	0.000	Algorithm converged.	-0.040	0.041	1.00	Algorithm converged.	0.62	1.62	0.9913	0.3209	1.00	Algorithm converged.	0.61	1.62
	2	65	13.0	3	4.6	56	11.2	4	7.1	0.61	Convergence criterion (GCONV=1E-8) satisfied.	0.07	2.34	-0.041	Algorithm converged.	-0.120	0.039	0.63	Algorithm converged.	0.08	2.26	0.5265		2.32	Algorithm converged.	0.44	12.30
	Missing	0	0.0	0	0.0	1	0.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cell of origin (determined by gene expression)	ABC	121	24.2	6	5.0	119	23.8	7	5.9	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.27	2.56	-0.009	Algorithm converged.	-0.067	0.048	0.86	Algorithm converged.	0.23	2.83	0.7524	0.5837	1.16	Algorithm converged.	0.41	3.43
	GCB	166	33.2	10	6.0	151	30.2	13	8.6	0.68	Convergence criterion (GCONV=1E-8) satisfied.	0.22	1.69	-0.026	Algorithm converged.	-0.083	0.032	0.70	Algorithm converged.	0.32	1.55	0.3763		1.47	Algorithm converged.	0.65	3.34
	Unclassified	47	9.4	8	17.0	53	10.6	9	17.0	0.93	Convergence criterion (GCONV=1E-8) satisfied.	0.08	1.31	-0.106	Algorithm converged.	-0.229	0.017	0.38	Algorithm converged.	0.11	1.31	0.1053		2.66	Algorithm converged.	0.77	9.25
	Unknown	102	20.4	14	13.7	82	16.4	4	4.9	3.00	Convergence criterion (GCONV=1E-8) satisfied.	0.98	9.82	0.088	Algorithm converged.	0.007	0.170	2.81	Algorithm converged.	0.98	8.07	0.0452		0.36	Algorithm converged.	0.12	1.04
IPI score at Screening	1-2	171	34.2	20	11.7	167	33.4	21	12.6	0.92	Convergence criterion (GCONV=1E-8) satisfied.	0.48	1.77	-0.009	Algorithm converged.	-0.078	0.061	0.92	Algorithm converged.	0.52	1.62	0.8048	0.9978	1.08	Algorithm converged.	0.61	1.92
	3	173	34.6	10	5.8	160	29.6	9	6.1	0.95	Convergence criterion (GCONV=1E-8) satisfied.	0.37	2.40	-0.003	Algorithm converged.	-0.055	0.049	0.95	Algorithm converged.	0.40	2.28	0.8695		1.03	Algorithm converged.	0.44	2.52
	4-5	92	18.4	5	5.4	90	18.0	3	3.3	0.86	Convergence criterion (GCONV=1E-8) satisfied.	0.20	4.98	-0.001	Algorithm converged.	-0.053	0.051	0.98	Algorithm converged.	0.26	4.72	0.9763		1.02	Algorithm converged.	0.23	4.83
Baseline Bulky Disease	Present	175	35.0	13	7.4	161	32.2	11	6.8	1.09	Convergence criterion (GCONV=1E-8) satisfied.	0.46	2.52	0.006	Algorithm converged.	-0.049	0.061	1.09	Algorithm converged.	0.50	2.36	0.8323	0.4173	0.92	Algorithm converged.	0.42	1.98
	Absent	261	52.2	20	7.7	244	48.8	23	9.4	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.44	1.58	-0.014	Algorithm converged.	-0.082	0.053	0.85	Algorithm converged.	0.48	1.52	0.5824		1.18	Algorithm converged.	0.64	2.16
Double Expressor Lymphoma by IHC (Central Review)	DEL	130	26.0	11	8.5	134	26.8	9	6.7	1.28	Convergence criterion (GCONV=1E-8) satisfied.	0.51	3.21	0.017	Algorithm converged.	-0.046	0.081	1.26	Algorithm converged.	0.54	2.94	0.5929	0.1780	0.79	Algorithm converged.	0.34	1.89
	Non DEL	226	45.2	15	6.6	203	40.6	22	10.8	0.58	Convergence criterion (GCONV=1E-8) satisfied.	0.29	1.16	-0.042	Algorithm converged.	-0.096	0.012	0.61	Algorithm converged.	0.33	1.15	0.1223		1.63	Algorithm converged.	0.87	3.06
	Unknown	80	16.0	7	8.8	68	13.6	2	2.9	3.16	Convergence criterion (GCONV=1E-8) satisfied.	0.83	15.77	0.058	Algorithm converged.	-0.016	0.133	2.97	Algorithm converged.	0.64	13.80	0.1413		0.34	Algorithm converged.	0.05	1.93
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	302	60.4	19	6.3	294	58.8	23	8.0	0.61	Convergence criterion (GCONV=1E-8) satisfied.	0.34	1.12	-0.036	Algorithm converged.	-0.079	0.008	0.64	Algorithm converged.	0.37	1.11	0.1094	0.4744	1.07	Algorithm converged.	0.92	2.73
	DH/TH+	23	4.6	2	8.7	17	3.4	1	5.9	1.52	Convergence criterion (GCONV=1E-8) satisfied.	0.13	18.31	0.028	Algorithm converged.	-0.132	0.189	1.42	Algorithm converged.	0.13	15.00	0.7416		0.69	Algorithm converged.	0.07	6.84
	Unknown	111	22.2	10	10.0	94	18.8	3	3.2	3.88	Convergence criterion (GCONV=1E-8) satisfied.	1.00	13.44	0.076	Algorithm converged.	0.008	0.144	3.39	Algorithm converged.	0.99	11.61	0.0377		0.30	Algorithm converged.	0.09	1.00

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Pain

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	437	87.4	89	20.4	407	81.4	77	18.9	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.78	1.54	0.014	Algorithm converged.	-0.019	0.048	1.08	Algorithm converged.	0.82	1.42	0.5973		0.93	Algorithm converged.	0.71	1.22
Sex	Male	231	46.2	49	19.9	218	43.6	32	14.7	1.45	Convergence criterion (GCONV=1E-8) satisfied.	0.88	2.37	0.052	Algorithm converged.	-0.017	0.122	1.36	Algorithm converged.	0.90	2.05	0.1439	0.1197	0.74	Algorithm converged.	0.49	1.13
	Female	206	41.2	40	20.9	189	37.8	45	23.8	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.34	-0.029	Algorithm converged.	-0.112	0.053	0.88	Algorithm converged.	0.61	1.27	0.4842		1.14	Algorithm converged.	0.79	1.65
Age	<= 60	150	30.0	21	14.0	132	26.4	24	18.2	0.73	Convergence criterion (GCONV=1E-8) satisfied.	0.39	1.39	-0.042	Algorithm converged.	-0.128	0.044	0.77	Algorithm converged.	0.45	1.32	0.3390	0.1410	1.03	Algorithm converged.	0.71	2.02
	> 60	287	57.4	68	23.7	275	55.0	53	19.3	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.87	1.95	0.044	Algorithm converged.	-0.024	0.112	1.23	Algorithm converged.	0.89	1.69	0.2023		0.81	Algorithm converged.	0.59	1.12
Geographic region	Western Europe/United States/Canada/Australia	251	50.2	57	22.7	227	45.4	48	21.1	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.71	1.69	0.016	Algorithm converged.	-0.059	0.091	1.07	Algorithm converged.	0.76	1.51	0.6804	0.9402	0.93	Algorithm converged.	0.66	1.31
	Asia	133	26.6	22	15.8	128	25.6	20	15.6	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.52	1.97	0.002	Algorithm converged.	-0.087	0.092	1.02	Algorithm converged.	0.58	1.77	0.9722		0.98	Algorithm converged.	0.54	1.74
	Rest of World	53	10.6	10	20.8	52	10.4	9	17.3	1.25	Convergence criterion (GCONV=1E-8) satisfied.	0.47	3.33	0.034	Algorithm converged.	-0.116	0.184	1.20	Algorithm converged.	0.54	2.65	0.6545		0.83	Algorithm converged.	0.38	1.84
Race/ethnicity	White	252	40.4	41	20.2	187	37.4	32	17.1	1.23	Convergence criterion (GCONV=1E-8) satisfied.	0.74	2.06	0.032	Algorithm converged.	+0.046	0.108	1.18	Algorithm converged.	0.78	1.80	0.4221	0.4341	0.84	Algorithm converged.	0.56	1.28
	Black or African American	7	1.4	2	28.6	4	0.8	1	25.0	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.07	19.63	0.036	Algorithm converged.	-0.505	0.576	1.14	Algorithm converged.	0.15	8.59	0.9029		0.88	Algorithm converged.	0.11	6.88
	Asian	137	27.4	23	16.8	133	26.6	22	16.5	0.97	Convergence criterion (GCONV=1E-8) satisfied.	0.51	1.84	-0.005	Algorithm converged.	-0.093	0.083	0.97	Algorithm converged.	0.57	1.67	1.019		1.03	Algorithm converged.	0.60	1.77
	Other	4	1.0	0	0.0	9	1.8	2	22.2		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	0.2308		999.99	Algorithm converged.	0.00	NE
	Unknown	85	17.0	24	28.2	74	14.8	20	27.0	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.63	2.13	0.012	Algorithm converged.	-0.127	0.151	1.04	Algorithm converged.	0.63	1.73	0.8935		0.96	Algorithm converged.	0.58	1.58
ECOG performance status	0-1	372	74.4	77	20.7	349	69.8	62	17.8	1.21	Convergence criterion (GCONV=1E-8) satisfied.	0.83	1.75	0.029	Algorithm converged.	-0.028	0.087	1.17	Algorithm converged.	0.84	1.57	0.3184	0.2480	0.86	Algorithm converged.	0.64	1.16
	2	65	13.0	13	18.3	57	11.4	14	24.6	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.28	1.66	-0.041	Algorithm converged.	-0.207	0.085	0.75	Algorithm converged.	0.38	1.49	0.4139		1.33	Algorithm converged.	0.67	2.64
	Missing	0	0.0	0	0.0	1	0.2	1	100.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cell of origin (determined by gene expression)	ABC	121	24.2	26	19.8	119	23.8	25	21.0	0.93	Convergence criterion (GCONV=1E-8) satisfied.	0.50	1.74	-0.022	Algorithm converged.	-0.114	0.059	0.96	Algorithm converged.	0.57	1.56	0.8213	0.2636	1.02	Algorithm converged.	0.64	1.63
	GCB	167	33.4	35	21.0	153	30.6	28	19.5	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.68	2.06	0.027	Algorithm converged.	-0.060	0.114	1.15	Algorithm converged.	0.73	1.79	0.5510		0.87	Algorithm converged.	0.56	1.34
	Unclassified	47	9.4	8	17.0	53	10.6	16	30.2	0.47	Convergence criterion (GCONV=1E-8) satisfied.	0.18	1.24	-0.132	Algorithm converged.	-0.295	0.032	0.56	Algorithm converged.	0.27	1.20	0.1258		1.77	Algorithm converged.	0.84	3.74
	Unknown	102	20.4	20	21.0	82	16.4	8	9.8	2.54	Convergence criterion (GCONV=1E-8) satisfied.	1.07	6.06	0.118	Algorithm converged.	0.014	0.223	2.21	Algorithm converged.	1.04	4.70	0.0357		0.40	Algorithm converged.	0.21	0.76
IPI score at Screening	1-2	171	34.2	35	20.5	168	33.6	37	22.0	0.91	Convergence criterion (GCONV=1E-8) satisfied.	0.54	1.53	-0.016	Algorithm converged.	-0.103	0.072	0.95	Algorithm converged.	0.62	1.42	0.7266	0.5786	1.08	Algorithm converged.	0.71	1.62
	3	173	34.6	30	18.5	149	29.8	24	16.1	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.66	2.11	0.026	Algorithm converged.	-0.059	0.107	1.15	Algorithm converged.	0.71	1.86	0.5733		0.87	Algorithm converged.	0.54	1.41
	4-5	93	18.6	22	23.7	90	18.0	16	17.8	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.70	2.95	0.059	Algorithm converged.	-0.058	0.176	1.33	Algorithm converged.	0.75	2.36	0.3264		0.70	Algorithm converged.	0.42	1.16
Baseline Bulky Disease	Present	176	35.2	27	15.3	162	32.4	28	17.3	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.47	1.48	-0.026	Algorithm converged.	-0.105	0.054	0.88	Algorithm converged.	0.53	1.38	0.5277	0.2439	1.17	Algorithm converged.	0.72	1.88
	Absent	261	52.2	60	23.0	245	49.0	48	19.6	1.26	Convergence criterion (GCONV=1E-8) satisfied.	0.84	1.96	0.042	Algorithm converged.	-0.030	0.113	1.21	Algorithm converged.	0.87	1.69	0.2570		0.82	Algorithm converged.	0.53	1.15
Double Expressor Lymphoma by IHC (Central Review)	DEL	130	26.0	31	23.8	134	26.8	27	20.1	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.69	2.22	0.037	Algorithm converged.	-0.063	0.137	1.18	Algorithm converged.	0.75	1.87	0.4691	0.2938	0.84	Algorithm converged.	0.54	1.33
	Non DEL	223	45.4	42	18.8	200	41.2	44	21.2	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.52	1.33	-0.030	Algorithm converged.	-0.105	0.046	0.86	Algorithm converged.	0.59	1.26	0.4423		1.16	Algorithm converged.	0.79	1.69
	Unknown	80	16.3	16	20.0	68	13.6	6	8.8	2.38	Convergence criterion (GCONV=1E-8) satisfied.	0.90	7.03	0.112	Algorithm converged.	0.001	0.250	2.27	Algorithm converged.	0.94	5.47	0.0577		0.48	Algorithm converged.	0.18	1.30
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	303	60.6	66	21.8	295	59.0	57	19.3	1.16	Convergence criterion (GCONV=1E-8) satisfied.	0.78	1.73	0.025	Algorithm converged.	-0.040	0.089	1.13	Algorithm converged.	0.82	1.53	0.4572	0.0524	0.89	Algorithm converged.	0.67	1.22
	DH/TH+	23	4.6	7	4.3	17	3.4	4	23.5	0.15	Convergence criterion (GCONV=1E-8) satisfied.	0.02	1.47	-0.192	Algorithm converged.	-0.410	0.026	0.18	Algorithm converged.	0.02	1.51	0.2754		5.43	Algorithm converged.	0.66	44.58
	Unknown	111	22.2	20	18.0	95	19.0	16	16.8	1.22	Convergence criterion (GCONV=1E-8) satisfied.	0.60	2.49	0.030	Algorithm converged.	-0.076	0.135	1.18	Algorithm converged.	0.64	2.11	0.5837		0.85	Algorithm converged.	0.47	1.52

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Physical functioning (revised)

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	436	87.2	95	21.8	405	81.0	71	17.5	1.26	Convergence criterion (GCONV=1E-8) satisfied.	0.88	1.78	0.036	Algorithm converged.	-0.018	0.089	1.20	Algorithm converged.	0.91	1.59	0.1909		0.83	Algorithm converged.	0.62	1.14
Sex	Male	230	46.0	52	22.6	217	43.4	30	13.8	1.80	Convergence criterion (GCONV=1E-8) satisfied.	1.11	2.98	0.088	Algorithm converged.	0.017	0.159	1.64	Algorithm converged.	1.04	2.66	0.0169	0.0339	0.61	Algorithm converged.	0.41	0.90
	Female	206	41.2	40	19.4	188	37.6	41	21.8	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.41	-0.024	Algorithm converged.	-0.104	0.056	0.88	Algorithm converged.	0.60	1.31	0.5568		1.13	Algorithm converged.	0.74	1.68
Age	<= 60	150	30.0	19	12.7	130	26.0	22	16.9	0.71	Convergence criterion (GCONV=1E-8) satisfied.	0.37	1.38	-0.043	Algorithm converged.	-0.126	0.041	0.75	Algorithm converged.	0.42	1.32	0.3159	0.0506	1.34	Algorithm converged.	0.75	2.38
	> 60	286	57.2	73	25.5	275	55.0	49	17.8	1.38	Convergence criterion (GCONV=1E-8) satisfied.	1.00	2.38	0.077	Algorithm converged.	0.009	0.145	1.43	Algorithm converged.	1.04	1.98	0.0271		0.75	Algorithm converged.	0.53	0.86
Geographic region	Western Europe/United States/Canada/Australia	250	50.0	53	21.2	226	45.2	37	16.4	1.37	Convergence criterion (GCONV=1E-8) satisfied.	0.90	2.19	0.048	Algorithm converged.	-0.022	0.116	1.26	Algorithm converged.	0.89	1.80	0.1796	0.5058	0.77	Algorithm converged.	0.51	1.15
	Asia	133	26.6	28	19.3	128	25.6	26	20.3	0.93	Convergence criterion (GCONV=1E-8) satisfied.	0.52	1.75	-0.008	Algorithm converged.	-0.105	0.089	0.96	Algorithm converged.	0.59	1.57	0.8772		1.24	Algorithm converged.	0.64	1.68
	Rest of World	53	10.6	13	24.5	51	10.2	8	15.7	1.75	Convergence criterion (GCONV=1E-8) satisfied.	0.66	4.66	0.088	Algorithm converged.	-0.064	0.241	1.56	Algorithm converged.	0.71	3.43	0.2639		0.64	Algorithm converged.	0.29	1.42
Race/ethnicity	White	252	40.4	45	22.2	185	37.0	27	14.6	1.68	Convergence criterion (GCONV=1E-8) satisfied.	0.99	2.84	0.077	Algorithm converged.	0.000	0.154	1.53	Algorithm converged.	0.99	2.35	0.0527	0.4582	0.66	Algorithm converged.	0.42	1.03
	Black or African American	7	1.6	2	28.6	4	0.8	1	25.0	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.07	19.63	0.036	Algorithm converged.	-0.505	0.576	1.14	Algorithm converged.	0.15	8.59	0.9029		0.88	Algorithm converged.	0.11	6.88
	Asian	137	27.4	28	19.0	133	26.6	28	21.1	0.88	Convergence criterion (GCONV=1E-8) satisfied.	0.48	1.60	-0.021	Algorithm converged.	-0.116	0.075	0.90	Algorithm converged.	0.56	1.43	0.6336		1.11	Algorithm converged.	0.69	1.79
	Other	8	1.6	1	14.3	9	1.8	1	11.1	1.60	Convergence criterion (GCONV=1E-8) satisfied.	0.08	31.77	0.056	Algorithm converged.	-0.304	0.416	1.50	Algorithm converged.	0.11	19.66	0.7445		0.67	Algorithm converged.	0.05	8.73
	Unknown	84	16.8	19	21.4	74	14.8	14	18.3	1.17	Convergence criterion (GCONV=1E-8) satisfied.	0.54	2.55	0.025	Algorithm converged.	-0.100	0.150	1.13	Algorithm converged.	0.61	2.12	0.6962		0.84	Algorithm converged.	0.47	1.49
ECOG performance status	0-1	371	74.2	78	21.0	348	69.6	60	17.2	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.85	1.89	0.041	Algorithm converged.	-0.017	0.099	1.24	Algorithm converged.	0.91	1.67	0.1664	0.6288	0.83	Algorithm converged.	0.61	1.14
	2	65	13.0	13	20.0	56	11.2	11	19.6	1.02	Convergence criterion (GCONV=1E-8) satisfied.	0.42	2.51	0.004	Algorithm converged.	+0.139	0.148	1.02	Algorithm converged.	0.52	2.03	0.9610		0.98	Algorithm converged.	0.48	2.02
	Missing	0	0.0	0	0.0	1	0.2	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cell of origin (determined by gene expression)	ABC	121	24.1	20	16.5	119	23.8	21	17.6	0.96	Convergence criterion (GCONV=1E-8) satisfied.	0.47	1.81	-0.011	Algorithm converged.	-0.106	0.084	0.96	Algorithm converged.	0.54	1.64	0.8164	0.4578	1.07	Algorithm converged.	0.61	1.84
	GCB	166	33.2	41	24.7	151	30.2	23	15.2	1.28	Convergence criterion (GCONV=1E-8) satisfied.	0.83	2.36	0.055	Algorithm converged.	-0.036	0.146	1.22	Algorithm converged.	0.84	1.82	0.2397		0.76	Algorithm converged.	0.51	1.14
	Unclassified	47	9.4	9	19.1	53	10.6	8	15.1	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.47	3.79	0.041	Algorithm converged.	-0.108	0.189	1.27	Algorithm converged.	0.53	3.02	0.5919		0.79	Algorithm converged.	0.30	1.88
	Unknown	102	20.4	25	21.6	82	16.4	13	15.9	1.46	Convergence criterion (GCONV=1E-8) satisfied.	0.68	3.11	0.057	Algorithm converged.	-0.055	0.169	1.36	Algorithm converged.	0.71	2.63	0.3276		0.74	Algorithm converged.	0.40	1.37
IPI score at Screening	1-2	171	34.2	40	23.4	167	33.4	40	24.0	0.97	Convergence criterion (GCONV=1E-8) satisfied.	0.59	1.69	-0.006	Algorithm converged.	-0.096	0.085	0.98	Algorithm converged.	0.67	1.43	0.9027	0.2680	1.02	Algorithm converged.	0.70	1.50
	3	173	34.6	31	17.9	148	29.6	19	12.8	1.48	Convergence criterion (GCONV=1E-8) satisfied.	0.80	2.75	0.051	Algorithm converged.	-0.028	0.129	1.40	Algorithm converged.	0.82	2.39	0.2115		0.73	Algorithm converged.	0.42	1.26
	4-5	92	18.4	21	22.8	90	18.0	12	13.3	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.58	4.19	0.045	Algorithm converged.	-0.016	0.206	1.31	Algorithm converged.	0.80	3.27	0.0973		0.59	Algorithm converged.	0.31	1.11
Baseline Bulky Disease	Present	175	35.0	35	20.0	161	32.2	31	19.3	1.05	Convergence criterion (GCONV=1E-8) satisfied.	0.62	1.80	0.007	Algorithm converged.	-0.078	0.092	1.04	Algorithm converged.	0.67	1.62	0.8638	0.3885	0.96	Algorithm converged.	0.62	1.48
	Absent	261	52.2	57	21.8	244	48.8	40	16.4	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.91	2.23	0.054	Algorithm converged.	-0.014	0.123	1.33	Algorithm converged.	0.97	1.92	0.1209		0.75	Algorithm converged.	0.52	1.08
Double Expressor Lymphoma by IHC (Central Review)	DEL	130	26.0	31	23.8	134	26.8	23	17.2	1.51	Convergence criterion (GCONV=1E-8) satisfied.	0.83	2.76	0.067	Algorithm converged.	-0.030	0.164	1.39	Algorithm converged.	0.84	2.29	0.1782	0.3870	0.73	Algorithm converged.	0.44	1.21
	Non DEL	226	45.2	46	20.4	203	40.6	35	19.2	1.07	Convergence criterion (GCONV=1E-8) satisfied.	0.67	1.73	0.011	Algorithm converged.	-0.064	0.087	1.06	Algorithm converged.	0.72	1.57	0.7670		0.84	Algorithm converged.	0.64	1.08
	Unknown	80	16.0	10	12.5	68	13.6	9	13.2	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.42	3.71	0.055	Algorithm converged.	-0.062	0.173	1.02	Algorithm converged.	0.48	3.03	0.9680		0.73	Algorithm converged.	0.33	1.51
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	302	60.4	69	22.8	294	58.8	48	16.7	1.48	Convergence criterion (GCONV=1E-8) satisfied.	0.98	2.23	0.062	Algorithm converged.	-0.002	0.126	1.37	Algorithm converged.	0.99	1.91	0.0585	0.1705	0.73	Algorithm converged.	0.52	1.01
	DH/TH+	23	4.6	4	17.4	17	3.4	5	29.4	0.51	Convergence criterion (GCONV=1E-8) satisfied.	0.11	2.27	-0.120	Algorithm converged.	-0.386	0.146	0.56	Algorithm converged.	0.19	1.68	0.3742		1.69	Algorithm converged.	0.57	5.07
	Unknown	111	22.2	19	17.1	94	18.8	17	18.1	0.94	Convergence criterion (GCONV=1E-8) satisfied.	0.45	1.92	-0.010	Algorithm converged.	-0.114	0.095	0.95	Algorithm converged.	0.52	1.73	0.8563		1.06	Algorithm converged.	0.58	1.93

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ECOG Q&Q-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

ECOG Q&Q-C30:Deterioration (MID=10) at EOT in Global health status/QoL (revised)

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	432	86.4	70	16.2	403	80.6	60	14.9	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.80	1.69	0.020	Algorithm converged.	-0.029	0.070	1.13	Algorithm converged.	0.83	1.52	0.4280		0.88	Algorithm converged.	0.66	1.16
Sex	Male	228	45.6	41	18.0	217	43.4	35	16.1	1.14	Convergence criterion (GCONV=1E-8) satisfied.	0.69	1.87	0.019	Algorithm converged.	-0.051	0.088	1.13	Algorithm converged.	0.74	1.69	0.6029	0.8878	0.88	Algorithm converged.	0.53	1.39
	Female	204	40.8	32	15.7	186	37.2	25	13.4	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.68	2.11	0.022	Algorithm converged.	-0.047	0.092	1.17	Algorithm converged.	0.72	1.83	0.5312		0.86	Algorithm converged.	0.53	1.38
Age	<= 60	149	29.8	15	10.1	131	26.2	14	10.7	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.47	2.15	0.001	Algorithm converged.	-0.072	0.073	1.00	Algorithm converged.	0.51	1.95	0.9890	0.6630	1.00	Algorithm converged.	0.51	1.96
	> 60	283	56.6	57	20.1	272	54.4	46	16.9	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.83	1.90	0.032	Algorithm converged.	-0.032	0.097	1.19	Algorithm converged.	0.84	1.69	0.3284		0.84	Algorithm converged.	0.53	1.34
Geographic region	Western Europe/United States/Canada/Australia	246	49.2	44	17.9	223	44.6	30	13.5	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.85	2.32	0.046	Algorithm converged.	-0.021	0.111	1.35	Algorithm converged.	0.87	2.06	0.1869	0.5068	0.73	Algorithm converged.	0.40	1.33
	Asia	133	26.6	18	13.5	128	25.6	20	15.6	0.85	Convergence criterion (GCONV=1E-8) satisfied.	0.42	1.68	-0.021	Algorithm converged.	-0.107	0.065	0.87	Algorithm converged.	0.48	1.52	0.6327		1.15	Algorithm converged.	0.64	2.08
	Rest of World	53	10.6	13	22.8	52	10.4	10	19.2	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.42	2.86	0.015	Algorithm converged.	-0.138	0.168	1.08	Algorithm converged.	0.50	2.32	0.8403		0.93	Algorithm converged.	0.43	1.99
Race/ethnicity	White	198	39.6	38	19.2	186	37.2	29	15.6	1.29	Convergence criterion (GCONV=1E-8) satisfied.	0.76	2.19	0.036	Algorithm converged.	+0.040	0.112	1.23	Algorithm converged.	0.79	1.91	0.3535	0.4635	0.81	Algorithm converged.	0.52	1.26
	Black or African American	6	1.2	1	16.7	4	0.8	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	0.4142		NE	Algorithm converged.	NE	NE
	Asian	137	27.4	18	13.1	133	26.6	22	16.5	0.76	Convergence criterion (GCONV=1E-8) satisfied.	0.39	1.50	-0.036	Algorithm converged.	-0.119	0.051	0.79	Algorithm converged.	0.45	1.41	0.4323		1.24	Algorithm converged.	0.71	2.24
	Other	8	1.6	1	14.3	9	1.8	2	22.2	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.05	10.01	-0.056	Algorithm converged.	-0.453	0.346	0.75	Algorithm converged.	0.09	6.53	0.7990		1.07	Algorithm converged.	0.13	11.64
	Unknown	85	17.0	13	17.8	71	14.2	7	9.9	1.86	Convergence criterion (GCONV=1E-8) satisfied.	0.75	5.11	0.078	Algorithm converged.	-0.029	0.185	1.79	Algorithm converged.	0.77	4.13	0.1654		0.56	Algorithm converged.	0.24	1.29
ECOG performance status	0-1	367	73.4	66	18.1	345	69.0	49	14.2	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.85	1.98	0.038	Algorithm converged.	-0.016	0.092	1.27	Algorithm converged.	0.90	1.78	0.1716	0.1349	0.79	Algorithm converged.	0.54	1.16
	2	65	13.0	9	10.8	57	11.4	10	17.5	0.93	Convergence criterion (GCONV=1E-8) satisfied.	0.35	1.60	-0.068	Algorithm converged.	+0.182	0.056	0.81	Algorithm converged.	0.23	1.51	0.2838		1.61	Algorithm converged.	0.48	4.30
	Missing	0	0.0	0	0.0	1	0.2	1	100.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cell of origin (determined by gene expression)	ABC	119	23.8	20	16.8	117	23.4	17	14.5	1.16	Convergence criterion (GCONV=1E-8) satisfied.	0.58	2.40	0.023	Algorithm converged.	-0.070	0.111	1.16	Algorithm converged.	0.64	2.11	0.6311	0.4050	0.88	Algorithm converged.	0.48	1.57
	GCB	166	33.2	27	16.3	151	30.2	27	17.9	0.89	Convergence criterion (GCONV=1E-8) satisfied.	0.50	1.60	-0.016	Algorithm converged.	-0.099	0.067	0.92	Algorithm converged.	0.56	1.49	0.7022		1.10	Algorithm converged.	0.63	1.78
	Unclassified	47	9.4	13	27.7	53	10.6	7	13.2	2.01	Convergence criterion (GCONV=1E-8) satisfied.	0.71	5.70	0.100	Algorithm converged.	-0.050	0.250	1.77	Algorithm converged.	0.75	4.20	0.1875		0.56	Algorithm converged.	0.24	1.34
	Unknown	100	20.0	10	10.0	82	16.4	9	11.0	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.55	3.46	0.040	Algorithm converged.	-0.057	0.136	1.37	Algorithm converged.	0.61	2.91	0.4256		0.73	Algorithm converged.	0.34	1.56
IPI score at Screening	1-2	168	33.6	26	14.3	166	33.2	25	15.1	0.96	Convergence criterion (GCONV=1E-8) satisfied.	0.51	1.72	-0.008	Algorithm converged.	-0.084	0.068	0.85	Algorithm converged.	0.57	1.53	0.8417	0.3303	1.03	Algorithm converged.	0.63	1.72
	3	171	34.2	33	19.1	149	29.8	27	18.1	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.61	1.90	0.012	Algorithm converged.	-0.074	0.097	1.06	Algorithm converged.	0.67	1.68	0.7881		0.84	Algorithm converged.	0.52	1.44
	4-5	93	18.6	10	17.2	88	17.6	8	9.1	2.08	Convergence criterion (GCONV=1E-8) satisfied.	0.84	5.13	0.081	Algorithm converged.	-0.016	0.179	1.89	Algorithm converged.	0.89	4.26	0.1087		0.53	Algorithm converged.	0.24	1.13
Baseline Bulky Disease	Present	175	35.0	24	13.7	160	32.0	23	14.4	0.95	Convergence criterion (GCONV=1E-8) satisfied.	0.52	1.75	-0.027	Algorithm converged.	-0.081	0.068	0.95	Algorithm converged.	0.54	1.62	0.8625	0.4178	1.05	Algorithm converged.	0.62	1.78
	Absent	257	51.4	40	15.7	243	48.6	37	15.2	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.82	2.10	0.038	Algorithm converged.	-0.028	0.104	1.25	Algorithm converged.	0.87	1.83	0.2580		0.80	Algorithm converged.	0.54	1.18
Double Expressor Lymphoma by IHC (Central Review)	DEL	127	25.4	20	20.0	132	26.4	15	11.4	2.01	Convergence criterion (GCONV=1E-8) satisfied.	1.01	4.00	0.091	Algorithm converged.	0.002	0.180	1.80	Algorithm converged.	1.00	3.24	0.0451	0.0358	0.58	Algorithm converged.	0.31	1.08
	Non DEL	226	45.2	39	17.3	203	40.6	41	20.2	0.85	Convergence criterion (GCONV=1E-8) satisfied.	0.51	1.34	-0.029	Algorithm converged.	-0.103	0.045	0.85	Algorithm converged.	0.58	1.27	0.4350		1.17	Algorithm converged.	0.72	1.74
	Unknown	79	15.8	8	10.1	68	13.6	4	5.9	1.80	Convergence criterion (GCONV=1E-8) satisfied.	0.52	6.27	0.042	Algorithm converged.	-0.044	0.129	1.72	Algorithm converged.	0.54	5.47	0.3504		0.59	Algorithm converged.	0.19	1.84
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	300	60.0	50	18.3	293	58.6	46	15.7	1.21	Convergence criterion (GCONV=1E-8) satisfied.	0.78	1.85	0.026	Algorithm converged.	-0.034	0.087	1.17	Algorithm converged.	0.82	1.67	0.3941	0.9916	0.86	Algorithm converged.	0.60	1.22
	DH/TH+	23	4.6	5	21.7	16	3.2	3	18.8	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.24	5.96	0.030	Algorithm converged.	-0.225	0.285	1.16	Algorithm converged.	0.32	4.16	0.8224		0.86	Algorithm converged.	0.24	3.11
	Unknown	109	21.8	15	11.9	94	18.8	11	11.7	1.02	Convergence criterion (GCONV=1E-8) satisfied.	0.43	2.40	0.002	Algorithm converged.	-0.087	0.091	1.02	Algorithm converged.	0.48	2.17	0.9607		0.98	Algorithm converged.	0.46	2.09

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Role functioning (revised)

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	435	87.0	100	23.0	405	81.0	84	20.7	1.17	Convergence criterion (GCONV=1E-8) satisfied.	0.84	1.62	0.027	Algorithm converged.	-0.029	0.083	1.15	Algorithm converged.	0.88	1.49	0.2455		0.88	Algorithm converged.	0.67	1.14
Sex	Male	230	46.0	53	23.0	217	43.4	36	16.6	1.58	Convergence criterion (GCONV=1E-8) satisfied.	0.99	2.52	0.073	Algorithm converged.	-0.001	0.147	1.44	Algorithm converged.	0.99	2.10	0.0549	0.0700	0.69	Algorithm converged.	0.48	1.00
	Female	205	41.0	47	22.9	188	37.6	48	25.5	0.87	Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.38	-0.026	Algorithm converged.	-0.111	0.059	0.90	Algorithm converged.	0.63	1.27	0.5473		1.11	Algorithm converged.	0.78	1.58
Age	<= 60	150	30.0	20	14.0	130	26.0	20	15.4	1.05	Convergence criterion (GCONV=1E-8) satisfied.	0.55	2.00	0.006	Algorithm converged.	-0.079	0.091	1.04	Algorithm converged.	0.66	1.70	0.8891	0.4980	0.96	Algorithm converged.	0.59	1.56
	> 60	285	57.0	79	27.4	275	55.0	64	23.3	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.85	1.82	0.041	Algorithm converged.	-0.031	0.113	1.18	Algorithm converged.	0.88	1.57	0.2658		0.85	Algorithm converged.	0.64	1.13
Geographic region	Western Europe/United States/Canada/Australia	249	49.8	57	22.9	226	45.2	43	19.0	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.77	1.85	0.030	Algorithm converged.	-0.044	0.104	1.15	Algorithm converged.	0.81	1.63	0.4361	0.7883	0.87	Algorithm converged.	0.61	1.23
	Asia	133	26.6	32	24.1	128	25.6	30	23.4	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.83	0.006	Algorithm converged.	-0.097	0.109	1.02	Algorithm converged.	0.66	1.53	0.9062		0.97	Algorithm converged.	0.63	1.50
	Rest of World	53	10.6	13	24.5	51	10.2	9	17.6	1.52	Convergence criterion (GCONV=1E-8) satisfied.	0.58	3.94	0.069	Algorithm converged.	-0.087	0.225	1.39	Algorithm converged.	0.65	2.97	0.3909		0.72	Algorithm converged.	0.34	1.54
Race/ethnicity	White	202	40.4	47	23.3	185	37.0	34	18.4	1.35	Convergence criterion (GCONV=1E-8) satisfied.	0.82	2.21	0.049	Algorithm converged.	-0.032	0.130	1.27	Algorithm converged.	0.85	1.88	0.2382	0.8103	0.76	Algorithm converged.	0.53	1.11
	Black or African American	7	1.4	1	14.3	4	0.8	1	25.0	0.50	Convergence criterion (GCONV=1E-8) satisfied.	0.03	11.09	-0.107	Algorithm converged.	-0.604	0.390	0.27	Algorithm converged.	0.05	6.84	0.6726		1.79	Algorithm converged.	0.11	21.60
	Asian	137	27.4	33	24.1	133	26.6	32	24.1	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.57	1.75	0.000	Algorithm converged.	-0.102	0.102	1.00	Algorithm converged.	0.66	1.53	0.9958		1.00	Algorithm converged.	0.65	1.54
	Other	8	1.6	1	14.3	9	1.8	1	11.1	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.08	31.77	0.056	Algorithm converged.	-0.304	0.416	1.50	Algorithm converged.	0.11	19.86	0.7445		0.67	Algorithm converged.	0.05	8.73
	Unknown	83	16.6	20	24.1	74	14.8	16	21.6	1.13	Convergence criterion (GCONV=1E-8) satisfied.	0.54	2.43	0.025	Algorithm converged.	-0.107	0.156	1.11	Algorithm converged.	0.63	1.93	0.7136		0.91	Algorithm converged.	0.52	1.60
ECOG performance status	0-1	370	74.0	90	24.3	348	69.6	73	21.0	1.23	Convergence criterion (GCONV=1E-8) satisfied.	0.86	1.77	0.039	Algorithm converged.	-0.023	0.101	1.16	Algorithm converged.	0.90	1.51	0.2166	0.4650	0.84	Algorithm converged.	0.64	1.11
	2	65	13.0	10	15.4	56	11.2	10	17.9	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.32	2.18	-0.025	Algorithm converged.	-0.158	0.108	0.86	Algorithm converged.	0.39	1.92	0.7162		1.16	Algorithm converged.	0.52	2.58
	Missing	0	0.0	0	0.0	1	0.2	1	100.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	
Cell of origin (determined by gene expression)	ABC	121	24.2	26	21.5	119	23.8	31	26.1	0.78	Convergence criterion (GCONV=1E-8) satisfied.	0.43	1.41	-0.046	Algorithm converged.	-0.153	0.061	0.82	Algorithm converged.	0.52	1.30	0.4070	0.3358	1.21	Algorithm converged.	0.77	1.91
	GCB	165	33.0	42	25.5	151	30.2	31	20.5	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.78	2.24	0.049	Algorithm converged.	-0.043	0.142	1.24	Algorithm converged.	0.82	1.86	0.3202		0.81	Algorithm converged.	0.54	1.22
	Unclassified	47	9.4	10	21.3	53	10.6	8	15.1	1.52	Convergence criterion (GCONV=1E-8) satisfied.	0.54	4.24	0.060	Algorithm converged.	-0.090	0.211	1.43	Algorithm converged.	0.61	3.27	0.4242		0.71	Algorithm converged.	0.31	1.60
	Unknown	102	20.4	24	23.5	82	16.4	14	17.1	1.48	Convergence criterion (GCONV=1E-8) satisfied.	0.65	3.32	0.065	Algorithm converged.	-0.051	0.181	1.38	Algorithm converged.	0.76	2.49	0.2836		0.73	Algorithm converged.	0.43	1.24
IPI score at Screening	1-2	171	34.2	43	25.1	167	33.4	41	24.6	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.63	1.69	0.006	Algorithm converged.	-0.086	0.098	1.02	Algorithm converged.	0.71	1.48	0.8984	0.7280	0.98	Algorithm converged.	0.67	1.42
	3	173	34.6	39	22.5	148	29.6	35	16.9	1.38	Convergence criterion (GCONV=1E-8) satisfied.	0.76	2.43	0.051	Algorithm converged.	-0.036	0.137	1.30	Algorithm converged.	0.83	2.05	0.2567		0.77	Algorithm converged.	0.49	1.24
	4-5	93	18.6	21	23.1	90	18.0	18	20.2	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.59	2.44	0.031	Algorithm converged.	-0.089	0.150	1.15	Algorithm converged.	0.68	2.00	0.6157		0.87	Algorithm converged.	0.50	1.53
Baseline Bulky Disease	Present	174	34.8	35	20.1	161	32.2	33	19.3	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.62	1.81	0.009	Algorithm converged.	-0.077	0.094	1.04	Algorithm converged.	0.68	1.61	0.8424	0.6520	0.96	Algorithm converged.	0.62	1.48
	Absent	261	52.2	67	25.7	244	48.8	51	21.7	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.82	1.88	0.039	Algorithm converged.	-0.035	0.114	1.18	Algorithm converged.	0.88	1.62	0.2975		0.85	Algorithm converged.	0.62	1.16
Double Expressor Lymphoma by IHC (Central Review)	DEL	130	26.0	29	22.3	134	26.8	24	17.9	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.72	2.41	0.044	Algorithm converged.	-0.053	0.141	1.25	Algorithm converged.	0.77	2.02	0.3735	0.6083	0.89	Algorithm converged.	0.49	1.62
	Non DEL	225	45.0	58	25.8	203	40.6	49	24.1	1.09	Convergence criterion (GCONV=1E-8) satisfied.	0.70	1.69	0.016	Algorithm converged.	-0.066	0.098	1.07	Algorithm converged.	0.77	1.48	0.6360		0.94	Algorithm converged.	0.67	1.34
	Unknown	80	16.0	13	16.3	68	13.6	11	16.2	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.51	2.01	0.026	Algorithm converged.	-0.097	0.148	1.16	Algorithm converged.	0.57	2.36	0.6829		0.93	Algorithm converged.	0.43	1.79
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	301	60.2	74	24.6	294	58.8	63	21.4	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.82	1.75	0.032	Algorithm converged.	-0.036	0.099	1.15	Algorithm converged.	0.85	1.54	0.3410	0.5030	0.87	Algorithm converged.	0.65	1.17
	DH/TH+	23	4.6	7	30.4	17	3.4	3	17.6	2.04	Convergence criterion (GCONV=1E-8) satisfied.	0.44	9.44	0.128	Algorithm converged.	-0.133	0.389	1.72	Algorithm converged.	0.52	5.72	0.3616		0.58	Algorithm converged.	0.17	1.92
	Unknown	111	22.2	21	18.9	94	18.8	18	19.1	0.99	Convergence criterion (GCONV=1E-8) satisfied.	0.48	1.98	-0.002	Algorithm converged.	-0.110	0.106	0.99	Algorithm converged.	0.56	1.74	0.9667		1.01	Algorithm converged.	0.57	1.78

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Social Functioning

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	Interaction Test p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	432	86.4	95	21.9	402	80.4	72	17.9	1.26	Convergence criterion (GCONV=1E-8) satisfied.	0.88	1.77	0.036	Algorithm converged.	-0.018	0.091	1.20	Algorithm converged.	0.91	1.58	0.1906		0.83	Algorithm converged.	0.62	1.16
Sex	Male	228	45.6	46	20.2	217	43.4	36	16.6	1.27	Convergence criterion (GCONV=1E-8) satisfied.	0.78	2.06	0.036	Algorithm converged.	-0.036	0.108	1.22	Algorithm converged.	0.82	1.80	0.3365	0.9245	0.82	Algorithm converged.	0.53	1.26
	Female	204	40.8	49	23.9	185	37.0	36	19.5	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.78	2.02	0.036	Algorithm converged.	-0.045	0.117	1.18	Algorithm converged.	0.80	1.74	0.3905		0.84	Algorithm converged.	0.57	1.24
Age	<= 60	148	29.6	26	18.5	131	26.2	23	17.6	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.60	2.02	0.014	Algorithm converged.	-0.077	0.105	1.06	Algorithm converged.	0.65	1.77	0.7484	0.5989	0.83	Algorithm converged.	0.54	1.53
	> 60	284	56.8	69	22.3	271	54.2	49	18.1	1.34	Convergence criterion (GCONV=1E-8) satisfied.	0.88	2.04	0.048	Algorithm converged.	-0.019	0.115	1.27	Algorithm converged.	0.91	1.76	0.1616		0.75	Algorithm converged.	0.57	1.26
Geographic region	Western Europe/United States/Canada/Australia	246	49.2	55	22.4	222	44.4	34	15.3	1.59	Convergence criterion (GCONV=1E-8) satisfied.	0.99	2.55	0.070	Algorithm converged.	0.000	0.141	1.40	Algorithm converged.	0.99	2.11	0.0526	0.1878	0.69	Algorithm converged.	0.47	1.01
	Asia	133	26.6	30	22.6	128	25.6	26	20.3	1.14	Convergence criterion (GCONV=1E-8) satisfied.	0.63	2.07	0.022	Algorithm converged.	-0.077	0.122	1.11	Algorithm converged.	0.70	1.77	0.6595		0.90	Algorithm converged.	0.57	1.43
	Rest of World	53	10.6	8	15.1	50	10.0	12	23.1	0.59	Convergence criterion (GCONV=1E-8) satisfied.	0.22	1.60	-0.080	Algorithm converged.	-0.230	0.070	0.69	Algorithm converged.	0.28	1.67	0.3009		1.53	Algorithm converged.	0.68	3.43
Race/ethnicity	White	199	39.8	42	21.1	186	37.2	35	18.8	1.15	Convergence criterion (GCONV=1E-8) satisfied.	0.70	1.90	0.023	Algorithm converged.	+0.057	0.103	1.12	Algorithm converged.	0.75	1.68	0.5753	NE	0.80	Algorithm converged.	0.60	1.33
	Black or African American	6	1.2	0	0.0	4	0.8	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
	Asian	137	27.4	31	22.6	133	26.6	27	20.3	1.15	Convergence criterion (GCONV=1E-8) satisfied.	0.64	2.05	0.023	Algorithm converged.	-0.075	0.121	1.11	Algorithm converged.	0.71	1.74	0.6422		0.93	Algorithm converged.	0.57	1.52
	Other	6	1.2	2	33.3	9	1.8	1	11.1	4.80	Convergence criterion (GCONV=1E-8) satisfied.	0.37	58.56	0.222	Algorithm converged.	-0.207	0.651	3.00	Algorithm converged.	0.34	26.13	0.3369		0.83	Algorithm converged.	0.04	2.51
	Unknown	84	16.8	18	21.4	70	14.0	9	12.9	1.83	Convergence criterion (GCONV=1E-8) satisfied.	0.77	4.42	0.086	Algorithm converged.	-0.032	0.203	1.67	Algorithm converged.	0.80	3.47	0.1652		0.61	Algorithm converged.	0.23	1.29
ECOG performance status	0-1	367	73.4	80	21.8	346	69.2	61	17.6	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.86	1.89	0.042	Algorithm converged.	-0.017	0.101	1.24	Algorithm converged.	0.90	1.67	0.1626	0.7752	0.83	Algorithm converged.	0.61	1.14
	2	65	13.0	13	20.0	55	11.0	10	18.2	1.12	Convergence criterion (GCONV=1E-8) satisfied.	0.45	2.81	0.018	Algorithm converged.	+0.123	0.159	1.10	Algorithm converged.	0.52	2.33	0.8018		0.91	Algorithm converged.	0.43	1.92
	Missing	0	0.0	0	0.0	1	0.2	1	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cell of origin (determined by gene expression)	ABC	119	23.8	27	22.7	117	23.4	31	17.9	1.36	Convergence criterion (GCONV=1E-8) satisfied.	0.71	2.54	0.047	Algorithm converged.	-0.055	0.150	1.26	Algorithm converged.	0.76	2.11	0.3667	0.9997	0.79	Algorithm converged.	0.48	1.32
	GCB	166	33.2	33	23.3	151	30.2	28	18.5	1.23	Convergence criterion (GCONV=1E-8) satisfied.	0.78	2.33	0.050	Algorithm converged.	-0.040	0.139	1.27	Algorithm converged.	0.82	1.93	0.2812		0.79	Algorithm converged.	0.51	1.22
	Unclassified	47	9.4	10	21.3	53	10.6	9	17.0	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.49	3.60	0.043	Algorithm converged.	-0.112	0.198	1.25	Algorithm converged.	0.56	2.82	0.5869		0.80	Algorithm converged.	0.30	1.79
	Unknown	100	20.0	17	17.0	81	16.2	14	17.3	0.98	Convergence criterion (GCONV=1E-8) satisfied.	0.45	2.13	-0.003	Algorithm converged.	-0.113	0.106	0.98	Algorithm converged.	0.52	1.83	0.9568		1.02	Algorithm converged.	0.53	1.94
IPI score at Screening	1-2	169	33.8	30	17.8	166	33.2	32	19.3	0.90	Convergence criterion (GCONV=1E-8) satisfied.	0.52	1.57	-0.015	Algorithm converged.	-0.098	0.068	0.82	Algorithm converged.	0.54	1.44	0.7186	0.3381	1.09	Algorithm converged.	0.69	1.72
	3	170	34.0	41	24.1	148	29.6	25	16.9	1.56	Convergence criterion (GCONV=1E-8) satisfied.	0.90	2.72	0.072	Algorithm converged.	-0.016	0.160	1.43	Algorithm converged.	0.91	2.23	0.1138		0.75	Algorithm converged.	0.49	1.64
	4-5	93	18.6	20	23.7	88	17.6	15	17.7	1.33	Convergence criterion (GCONV=1E-8) satisfied.	0.52	3.14	0.066	Algorithm converged.	-0.051	0.183	1.30	Algorithm converged.	0.77	2.52	0.2717		0.73	Algorithm converged.	0.40	1.35
Baseline Bulky Disease	Present	176	35.2	31	17.6	158	31.6	33	19.6	0.88	Convergence criterion (GCONV=1E-8) satisfied.	0.52	1.52	-0.020	Algorithm converged.	-0.104	0.064	0.90	Algorithm converged.	0.57	1.41	0.6382	0.1040	1.11	Algorithm converged.	0.72	1.73
	Absent	256	51.2	62	24.2	244	48.8	40	16.4	1.50	Convergence criterion (GCONV=1E-8) satisfied.	1.02	2.46	0.074	Algorithm converged.	0.004	0.145	1.44	Algorithm converged.	1.03	2.05	0.0406		0.69	Algorithm converged.	0.48	0.98
Double Expressor Lymphoma by IHC (Central Review)	DEL	127	25.4	33	26.0	131	26.2	21	16.0	1.84	Convergence criterion (GCONV=1E-8) satisfied.	1.00	3.39	0.100	Algorithm converged.	0.001	0.198	1.62	Algorithm converged.	0.99	2.64	0.0489	0.1983	0.62	Algorithm converged.	0.38	1.01
	Non DEL	226	45.2	51	22.6	203	40.6	42	20.7	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.70	1.77	0.019	Algorithm converged.	-0.059	0.097	1.09	Algorithm converged.	0.76	1.57	0.6380		0.93	Algorithm converged.	0.64	1.36
	Unknown	79	15.8	10	11.4	68	13.6	9	13.2	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.31	2.26	-0.018	Algorithm converged.	-0.125	0.089	0.86	Algorithm converged.	0.38	2.04	0.7348		1.10	Algorithm converged.	0.40	2.74
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	300	60.0	73	24.3	292	58.4	48	16.4	1.63	Convergence criterion (GCONV=1E-8) satisfied.	1.09	2.45	0.079	Algorithm converged.	0.014	0.143	1.48	Algorithm converged.	1.07	2.05	0.0173	0.1429	0.68	Algorithm converged.	0.49	0.94
	DH/TH+	23	4.6	6	26.1	16	3.2	5	37.5	0.59	Convergence criterion (GCONV=1E-8) satisfied.	0.15	2.33	-0.114	Algorithm converged.	-0.412	0.183	0.70	Algorithm converged.	0.27	1.77	0.4536		1.44	Algorithm converged.	0.54	3.66
	Unknown	109	21.8	16	12.8	94	18.8	19	19.1	0.62	Convergence criterion (GCONV=1E-8) satisfied.	0.29	1.33	-0.063	Algorithm converged.	-0.164	0.038	0.67	Algorithm converged.	0.35	1.27	0.2201		1.49	Algorithm converged.	0.79	2.83

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

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13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at EOT
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at EOT in Insomnia

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP													R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	436	87.2	70	16.1	404	80.8	51	12.6	1.37	Convergence criterion (GCONV=1E-8) satisfied.	0.93	2.02	0.039	Algorithm converged.	-0.009	0.086	1.31	Algorithm converged.	0.94	1.82	0.1113		0.76	Algorithm converged.	0.53	1.07
Sex	Male	230	46.0	29	12.6	217	43.4	24	11.1	1.15	Convergence criterion (GCONV=1E-8) satisfied.	0.62	1.99	0.011	Algorithm converged.	-0.048	0.071	1.10	Algorithm converged.	0.64	1.84	0.7139	0.3890	0.91	Algorithm converged.	0.54	1.52
	Female	206	41.2	44	21.4	187	37.4	27	14.4	1.61	Convergence criterion (GCONV=1E-8) satisfied.	0.95	2.72	0.069	Algorithm converged.	-0.006	0.145	1.48	Algorithm converged.	0.96	2.23	0.0753		0.68	Algorithm converged.	0.44	1.05
Age	<= 60	150	30.0	19	12.7	130	26.0	18	13.8	0.85	Convergence criterion (GCONV=1E-8) satisfied.	0.40	1.71	-0.018	Algorithm converged.	-0.097	0.061	0.87	Algorithm converged.	0.47	1.57	0.6459	0.1116	1.13	Algorithm converged.	0.63	2.02
	> 60	286	57.2	52	18.2	274	54.8	33	12.0	1.70	Convergence criterion (GCONV=1E-8) satisfied.	1.06	2.72	0.068	Algorithm converged.	0.009	0.128	1.37	Algorithm converged.	1.05	2.34	0.0227		0.64	Algorithm converged.	0.43	0.95
Geographic region	Western Europe/United States/Canada/Australia	250	50.0	48	19.2	225	45.0	35	15.6	1.28	Convergence criterion (GCONV=1E-8) satisfied.	0.80	2.08	0.036	Algorithm converged.	-0.032	0.104	1.23	Algorithm converged.	0.83	1.84	0.2969	0.7050	0.81	Algorithm converged.	0.54	1.20
	Asia	133	26.6	14	10.5	128	25.6	11	8.6	1.23	Convergence criterion (GCONV=1E-8) satisfied.	0.53	2.87	0.019	Algorithm converged.	-0.052	0.091	1.22	Algorithm converged.	0.58	2.62	0.5966		0.82	Algorithm converged.	0.33	1.73
	Rest of World	53	10.6	10	18.9	51	10.2	5	9.8	2.14	Convergence criterion (GCONV=1E-8) satisfied.	0.68	6.77	0.091	Algorithm converged.	-0.043	0.224	1.92	Algorithm converged.	0.71	5.24	0.1909		0.52	Algorithm converged.	0.19	1.42
Race/ethnicity	White	252	40.4	37	18.3	185	37.0	24	13.2	1.50	Convergence criterion (GCONV=1E-8) satisfied.	0.86	2.63	0.053	Algorithm converged.	+0.019	0.125	1.41	Algorithm converged.	0.88	2.27	0.1501	0.2893	0.71	Algorithm converged.	0.44	1.14
	Black or African American	7	1.6	3	42.9	4	0.8	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	0.1432		NE	Algorithm converged.	NE	NE
	Asian	137	27.4	14	10.2	133	26.6	11	8.3	1.26	Convergence criterion (GCONV=1E-8) satisfied.	0.55	2.89	0.019	Algorithm converged.	-0.050	0.089	1.24	Algorithm converged.	0.58	2.62	0.5815		0.81	Algorithm converged.	0.32	1.74
	Other	6	1.6	1	16.7	9	1.8	3	33.3	0.40	Convergence criterion (GCONV=1E-8) satisfied.	0.03	5.15	-0.167	Algorithm converged.	-0.595	0.260	0.50	Algorithm converged.	0.07	3.75	0.4897		2.50	Algorithm converged.	0.27	14.58
	Unknown	84	16.0	17	20.2	73	14.6	13	17.8	1.17	Convergence criterion (GCONV=1E-8) satisfied.	0.53	2.61	0.024	Algorithm converged.	-0.099	0.147	1.14	Algorithm converged.	0.59	2.19	0.7002		0.86	Algorithm converged.	0.46	1.69
ECOG performance status	0-1	371	74.2	61	16.4	348	69.6	43	12.4	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.91	2.13	0.041	Algorithm converged.	-0.010	0.091	1.32	Algorithm converged.	0.93	1.91	0.1168	0.7715	0.75	Algorithm converged.	0.52	1.08
	2	65	13.0	11	16.9	55	11.0	8	14.5	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.44	3.22	0.024	Algorithm converged.	+0.107	0.154	1.16	Algorithm converged.	0.52	2.63	0.7233		0.86	Algorithm converged.	0.37	1.98
	Missing	0	0.0	0	0.0	1	0.2	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cell of origin (determined by gene expression)	ABC	121	24.1	20	20.7	118	23.6	18	15.3	1.45	Convergence criterion (GCONV=1E-8) satisfied.	0.74	2.82	0.054	Algorithm converged.	-0.043	0.151	1.35	Algorithm converged.	0.78	2.30	0.2776	0.5257	0.74	Algorithm converged.	0.41	1.34
	GCB	166	33.2	23	15.7	151	30.2	17	11.3	1.46	Convergence criterion (GCONV=1E-8) satisfied.	0.76	2.82	0.044	Algorithm converged.	-0.031	0.119	1.32	Algorithm converged.	0.79	2.40	0.2532		0.72	Algorithm converged.	0.41	1.27
	Unclassified	47	9.4	7	14.9	53	10.6	10	18.9	0.75	Convergence criterion (GCONV=1E-8) satisfied.	0.26	2.17	-0.040	Algorithm converged.	-0.186	0.107	0.79	Algorithm converged.	0.33	1.91	0.5983		1.27	Algorithm converged.	0.52	3.09
	Unknown	102	20.4	14	13.7	82	16.4	6	7.3	2.02	Convergence criterion (GCONV=1E-8) satisfied.	0.74	5.50	0.064	Algorithm converged.	-0.023	0.151	1.88	Algorithm converged.	0.75	4.67	0.1460		0.53	Algorithm converged.	0.21	1.34
IPI score at Screening	1-2	171	34.2	30	17.5	167	33.4	21	12.6	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.81	2.71	0.050	Algorithm converged.	-0.026	0.126	1.40	Algorithm converged.	0.83	2.34	0.2065	0.9420	0.72	Algorithm converged.	0.43	1.20
	3	173	34.6	29	16.8	148	29.6	19	12.8	1.37	Convergence criterion (GCONV=1E-8) satisfied.	0.71	2.56	0.039	Algorithm converged.	-0.038	0.117	1.31	Algorithm converged.	0.76	2.23	0.3269		0.77	Algorithm converged.	0.45	1.34
	4-5	92	18.4	10	14.1	89	17.8	11	12.5	1.13	Convergence criterion (GCONV=1E-8) satisfied.	0.40	2.76	0.018	Algorithm converged.	-0.081	0.119	1.16	Algorithm converged.	0.54	2.43	0.7283		0.87	Algorithm converged.	0.41	1.83
Baseline Bulky Disease	Present	175	35.0	18	10.7	160	32.0	25	15.6	0.62	Convergence criterion (GCONV=1E-8) satisfied.	0.32	1.18	-0.053	Algorithm converged.	-0.125	0.019	0.66	Algorithm converged.	0.37	1.16	0.1455	0.0025	1.52	Algorithm converged.	0.84	2.68
	Absent	261	52.2	54	20.7	244	48.8	26	10.7	2.10	Convergence criterion (GCONV=1E-8) satisfied.	1.32	3.42	0.100	Algorithm converged.	0.038	0.163	1.94	Algorithm converged.	1.28	3.00	0.0020		0.52	Algorithm converged.	0.33	0.79
Double Expressor Lymphoma by IHC (Central Review)	DEL	130	26.0	20	15.4	134	26.8	11	8.2	2.03	Convergence criterion (GCONV=1E-8) satisfied.	0.85	6.43	0.072	Algorithm converged.	-0.006	0.149	1.87	Algorithm converged.	0.94	3.74	0.0787	0.1007	0.53	Algorithm converged.	0.27	1.07
	Non DEL	226	45.2	40	17.7	202	40.4	37	18.3	0.96	Convergence criterion (GCONV=1E-8) satisfied.	0.50	1.57	-0.006	Algorithm converged.	-0.079	0.067	0.97	Algorithm converged.	0.64	1.47	0.8680		1.03	Algorithm converged.	0.65	1.64
	Unknown	80	16.0	10	13.2	68	13.6	3	4.4	3.80	Convergence criterion (GCONV=1E-8) satisfied.	1.03	14.16	0.106	Algorithm converged.	0.014	0.199	3.40	Algorithm converged.	1.08	11.51	0.0340		0.23	Algorithm converged.	0.05	1.05
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	302	60.4	54	17.9	293	58.6	40	13.7	1.38	Convergence criterion (GCONV=1E-8) satisfied.	0.88	2.15	0.042	Algorithm converged.	-0.016	0.101	1.31	Algorithm converged.	0.90	1.91	0.1577	0.6251	0.76	Algorithm converged.	0.52	1.11
	DH/TH+	23	4.6	4	13.0	17	3.4	1	5.9	2.40	Convergence criterion (GCONV=1E-8) satisfied.	0.23	25.33	0.072	Algorithm converged.	-0.106	0.249	2.22	Algorithm converged.	0.25	19.51	0.4812		0.45	Algorithm converged.	0.05	3.87
	Unknown	111	22.2	15	13.5	94	18.8	10	10.6	1.31	Convergence criterion (GCONV=1E-8) satisfied.	0.56	3.08	0.029	Algorithm converged.	-0.080	0.138	1.27	Algorithm converged.	0.60	2.69	0.5318		0.76	Algorithm converged.	0.37	1.63

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO55410?7/CSP?7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/BO55410?7/CSP?7884/GO39942/data_analysis/ACE_FINAL_GS/prod/output/t_eff_resp_sgl_QC3010ET_?? POOLED_15JUN2022_39942.xls
13MAR2023 19:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Appetite loss

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=502)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	275	55.0	22	8.0	241	48.2	11	4.6	1.70		Convergence criterion (GCONV=1E-8) satisfied.	0.80	3.59		*	WARNING: The relative Hessian convergence criterion of 0.0876826052 is greater than the limit of 0.0001. The convergence is questionable.			1.66		Algorithm converged.	0.83	3.34	0.1626	0.60		Algorithm converged.	0.30	1.21

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CD97884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CD97884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010PU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Cognitive functioning

		Polatuzumab Vedotin + R-CHP (N=555)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	275	55.0	68	24.7	237	47.4	56	23.6	1.05		Convergence criterion (GCONV=1E-8) satisfied.	0.68	1.59	0.009		Algorithm converged.	-0.064	0.082	1.03		Algorithm converged.	0.74	1.39	0.8881	0.97		Algorithm converged.	0.72	1.32

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Constipation

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	274	54.8	32	11.7	240	48.0	17	7.1	1.68		Convergence criterion (GCONV=1E-8) satisfied.	0.91	3.10	0.048		Algorithm converged.	-0.001	0.096	1.61		Algorithm converged.	0.93	2.80	0.0972	2.62		Algorithm converged.	0.95	1.84

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Diarrhoea

		Polatuzumab Vedotin + R-CHP (N=570)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	272	54.4	27	9.9	230	47.8	28	12.1	0.77	Convergence criterion (GCONV=1E-8) satisfied.	0.44	1.34	-0.024	Algorithm converged.	-0.078	0.029	0.84	Algorithm converged.	0.51	1.37	0.3499	1.19	Algorithm converged.	0.73	1.95

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Dyspnoea

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	275	55.0	39	14.2	241	48.2	44	18.3		*	NE			-0.038		Algorithm converged.	-0.101	0.026	0.77		Algorithm converged.	0.53	1.14	0.1847	1.30		Algorithm converged.	0.88	1.93

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Emotional functioning

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	275	55.0	29	10.5	237	47.4	20	8.4	1.23	Convergence criterion (GCONV=1E-8) satisfied.	0.67	2.24	0.037	Algorithm converged.	-0.030	0.068	1.26	Algorithm converged.	0.73	2.18	0.3069	0.80	Algorithm converged.	0.46	1.37

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Fatigue

		Polatuzumab Vedotin + R-CHP (N=555)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP											R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	275	55.0	55	20.0	240	48.4	46	19.8	0.99	Convergence criterion (GCONV=1E-8) satisfied.	0.64	1.53	-0.001	Algorithm converged.	-0.078	0.055	1.01	Algorithm converged.	0.72	1.42	0.9491	0.99	Algorithm converged.	0.70	1.38

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Financial difficulties

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP													R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	274	54.8	18	6.6	236	46.9	14	6.0	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.50	2.22	0.007	Algorithm converged.	-0.024	0.038	1.02	Algorithm converged.	0.52	1.99	0.8841	0.98	Algorithm converged.	0.50	1.92

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Nausea and vomiting

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=502)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	275	55.0	17	6.2	242	48.4	8	3.3	1.84		Convergence criterion (GCONV=1E-8) satisfied.	0.78	4.36		*	WARNING: The relative Hessian convergence criterion of 0.0006360284 is greater than the limit of 0.0001. The convergence is questionable.			1.88		Algorithm converged.	0.83	4.28	0.1579	0.53		Algorithm converged.	0.23	1.22

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CD97884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CD97884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010PU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Pain

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP													R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	274	55.2	52	18.8	240	48.4	26	10.7	1.92	Convergence criterion (GCONV=1E-8) satisfied.	1.16	3.19	0.079	Algorithm converged.	0.018	0.140	1.80	Algorithm converged.	1.16	2.79	0.0107	0.56	Algorithm converged.	0.36	0.86

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Physical functioning (revised)

		Polatuzumab Vedotin + R-CHP (N=569)				R-CHOP (N=560)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	275	55.0	44	16.0	265	48.4	37	15.2	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.69	1.71	0.001	Algorithm converged.	-0.081	0.083	1.06	Algorithm converged.	0.71	1.59	0.8200	0.94	Algorithm converged.	0.63	1.40

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30:Deterioration (MID=10) at FU24 in Global health status/QoL (revised)

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=502)				Polatuzumab Vedotin + R-CHP vs. R-CHOP										R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					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 (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	274	54.8	41	15.0	238	47.4	31	13.0	1.17	Convergence criterion (GCONV=1E-8) satisfied.	0.71	1.94	0.013	Algorithm converged.	-0.048	0.072	1.10	Algorithm converged.	0.73	1.79	0.5447	0.86	Algorithm converged.	0.56	1.33

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Role functioning (revised)

		Polatuzumab Vedotin + R-CHP (N=555)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	275	55.0	45	16.4	240	48.4	34	14.2	1.15	Convergence criterion (GCONV=1E-8) satisfied.	0.71	1.86	0.007	Algorithm converged.	-0.054	0.068	1.13	Algorithm converged.	0.74	1.68	0.5721	0.85	Algorithm converged.	0.60	1.32

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Social functioning

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=502)				Polatuzumab Vedotin + R-CHP vs. R-CHOP													R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	275	55.0	33	12.0	236	47.2	24	10.2	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.67	2.07	0.020	Algorithm converged.	-0.026	0.076	1.18	Algorithm converged.	0.71	1.99	0.5585	0.87	Algorithm converged.	0.53	1.42

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EORTC QLQ-C30: Deterioration (MID=10) at FU Month 24
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

EORTC QLQ-C30: Deterioration (MID=10) at FU24 in Insomnia

		Polatuzumab Vedotin + R-CHP (N=570)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP													R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	275	55.0	32	11.6	240	48.0	34	14.2		*	NE			-0.026		Algorithm converged.	-0.084	0.029	0.78		Algorithm converged.	0.50	1.23	0.2039	1.28		Algorithm converged.	0.82	1.98

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_QC3010FU_ITT_POOLED_15JUN2022_39942.xls
13MAR2023 19:18

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ESAVI (Jul-CY2): Intercurrence (ANlb2d) at FU Month 24
MODEL: Unstratified Analysis
STUDY: ADS5941
Subcutaneous Analysis by Subgroups (Efficacy)

| | | Evaluableness Hamilton (v1.0-CRF (Weight) | | | | ITT/ESAF (Weight) | | | | Evaluableness Hamilton (v1.0-CRF (Weight) | | | |

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EASOI (pg-CR): Intersection (MIA=10) at FU Month 24
MODEL: Unstratified Analysis
STUDY: GS03782
Dichotomous Analysis by Subgroups (Efficacy)

EASOI (pg-CR): Intersection (MIA=10) at FU24 in Overview Population

		Fruquintinib Naïve (n=348) (Mono)				Fruzaci (Mono)				Fruquintinib Naïve (n=348) vs. n=348												Fruzaci vs. Fruquintinib Naïve (n=348)			
		Variable		Variable with Event		Patients		Variable with Event		Odds Ratio	Convergence Reason	95% Lower Bound	95% Upper Bound	Absolute Risk	Convergence Reason	95% Lower Bound	95% Upper Bound	Relative Risk	Convergence Reason	95% Lower Bound	95% Upper Bound	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower Bound	95% Upper Bound
Name	Level	N	%	n	%	n	N	n	%																		
All	n/a	348	69.0	83	23.7	174	348	44	25.3	0.909	Convergence criteria (GCONV=0) satisfied.	0.72	1.14	0.011	Algorithm converged.	-0.043	0.065	0.96	Algorithm converged.	0.73	1.26	0.772		0.92	Algorithm converged.	0.72	1.18
Sex	Male	183	68.9	53	29.1	116	348	30	17.9	1.818	Convergence criteria (GCONV=0) satisfied.	0.93	3.55	0.107	Algorithm converged.	-0.042	0.256	0.63	Algorithm converged.	0.35	1.14	0.1565	0.2771	0.63	Algorithm converged.	0.33	1.19
	Female	165	69.1	30	18.2	165	348	14	8.5	1.000	Convergence criteria (GCONV=0) satisfied.	0.53	1.91	0.000	Algorithm converged.	-0.113	0.113	0.00	Algorithm converged.	0.34	2.93	0.9999		0.00	Algorithm converged.	0.00	0.00
Age	< 65	172	68.6	43	25.0	87	348	22	25.3	0.988	Convergence criteria (GCONV=0) satisfied.	0.62	1.57	0.000	Algorithm converged.	-0.116	0.116	0.00	Algorithm converged.	0.64	1.53	0.9499		0.00	Algorithm converged.	0.00	0.00
	>= 65	176	69.4	40	22.7	87	348	22	25.3	0.872	Convergence criteria (GCONV=0) satisfied.	0.55	1.39	-0.026	Algorithm converged.	-0.154	0.102	-0.10	Algorithm converged.	0.41	1.85	0.7283		-0.10	Algorithm converged.	-0.42	0.22
Geographic region	Western Europe/United States/Canada/Australia	270	66.4	62	23.0	132	348	34	25.8	0.711	Convergence criteria (GCONV=0) satisfied.	0.43	1.18	0.022	Algorithm converged.	-0.070	0.115	0.16	Algorithm converged.	0.73	1.19	0.444	0.4133	0.40	Algorithm converged.	0.42	1.15
	Asia	78	79.5	21	26.9	42	348	10	23.8	1.183	Convergence criteria (GCONV=0) satisfied.	0.49	2.86	-0.034	Algorithm converged.	-0.179	0.110	-0.08	Algorithm converged.	0.26	2.67	0.8241		-0.08	Algorithm converged.	-0.52	0.28
	Rest of World	0	0.0	0	0.0	0	348	0	0.0	0.000	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00
Risk-tolerability	White	319	69.4	83	26.0	159	348	44	27.7	0.909	Convergence criteria (GCONV=0) satisfied.	0.63	1.31	-0.000	Algorithm converged.	-0.111	0.0998	0.00	Algorithm converged.	0.61	1.35	0.9999	.nan	0.00	Algorithm converged.	0.00	0.00
	Black or African American	3	0.0	0	0.0	3	348	0	0.0	0.000	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00
	Asian	26	0.0	0	0.0	12	348	0	0.0	0.000	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00
	Other	0	0.0	0	0.0	0	348	0	0.0	.	Complete separation of data exists (detected).	0.00	0.00	0.000	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0.000	0.000	0.00	WARNING: Detection of Hessian not positive definite.	0.00	0.00	1.0000		0.00	WARNING: Detection of Hessian not positive definite.	0.00	0.00
	Unknown	0	0.0	0	0.0	0	348	0	0.0	.	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00
ECOG performance status	0-1	309	67.6	69	22.3	155	348	34	21.9	1.024	Convergence criteria (GCONV=0) satisfied.	0.65	1.59	0.004	Algorithm converged.	-0.064	0.0731	0.06	Algorithm converged.	0.36	1.03	0.7885		0.06	Algorithm converged.	-0.37	0.50
	2	39	87.2	14	35.9	19	348	10	52.6	0.500	Convergence criteria (GCONV=0) satisfied.	0.23	1.10	-0.167	Algorithm converged.	-0.314	0.0000	-0.32	Algorithm converged.	0.14	1.81	0.0837		-0.32	Algorithm converged.	-0.63	0.00
	Missing	0	0.0	0	0.0	0	348	0	0.0	.	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		n/a	n/a	n/a	n/a
Cell of origin - Intermediate for meta-analysis	GEC	77	73.2	21	29.1	52	348	11	25.0	1.227	Convergence criteria (GCONV=0) satisfied.	0.63	2.33	0.041	Algorithm converged.	-0.131	0.213	0.16	Algorithm converged.	0.51	2.93	0.6521	0.3325	0.91	Algorithm converged.	0.52	1.59
	CCR	213	69.4	49	23.0	104	348	23	22.1	1.047	Convergence criteria (GCONV=0) satisfied.	0.63	1.82	-0.009	Algorithm converged.	-0.127	0.107	-0.04	Algorithm converged.	0.53	2.07	0.8257		-0.04	Algorithm converged.	-0.32	0.24
	Colorectum	58	0.0	13	22.4	18	348	9	50.0	0.333	Convergence criteria (GCONV=0) satisfied.	0.03	0.92	-0.255	Algorithm converged.	-0.384	0.0000	-0.51	Algorithm converged.	0.21	0.53	0.0007		-0.51	Algorithm converged.	-0.72	-0.29
	Others	0	0.0	0	0.0	0	348	0	0.0	.	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00
Yes	n/a	0	0.0	0	0.0	0	348	0	0.0	.	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00
Oligometastatic Disease	n/a	0	0.0	0	0.0	0	348	0	0.0	.	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00
Double Expressor Lymphoma by IHC (Clinical Review)	Yes	0	0.0	0	0.0	0	348	0	0.0	.	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00
	Non-DEL	0	0.0	0	0.0	0	348	0	0.0	.	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00
	Unknown	0	0.0	0	0.0	0	348	0	0.0	.	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00
Double/Triple-Hit Lymphoma (Clinical Review)	Yes	0	0.0	0	0.0	0	348	0	0.0	.	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00
	No/Unk	0	0.0	0	0.0	0	348	0	0.0	.	Convergence criteria (GCONV=0) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	1.0000		0.00	Algorithm converged.	0.00	0.00

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BGB161077/GSFY7884/GS03782/data_analysis/ADE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/BGB161077/GSFY7884/GS03782/data_analysis/ADE_FINAL_DS/prod/output/t_eff_resp_eql_QCUT1FU_ITT_POOLED_15JUN2022_095421.rtf
13MAR2023 19:27

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ASAUC (Log-CS): Intersection (MCS=20) at FU Month 24
MODEL: Unstratified Analysis
STUDY: GS39342
Subsequence Analysis by Subgroups (Efficacy)

ASAUC (Log-CS): Intersection (MCS=20) at FU24 in Overlapping

		Proportionate Number 0-1-INF (Wilson)				Primary Efficacy				Proportionate Number 0-1-INF (Wilson)														Proportionate Number 0-1-INF (Wilson)					
		Variable		Variable with Event		Estimate		Variance with Event		Odds Ratio	Odds Ratio													Relative Risk					
Name	Level	N	%	n	%	n	N	n	%	Odds Ratio	Convergence Reason	95% Lower Limit	95% Upper Limit	Absolute Risk	Convergence Reason	95% Lower Limit	95% Upper Limit	Relative Risk	Convergence Reason	95% Lower Limit	95% Upper Limit	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (Simulated value)	Relative Risk	Convergence Reason	95% Lower Limit	95% Upper Limit
All	Yes	153	39.8	61	15.7	153	153	61	7.1	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.52	0.93	0.066	Algorithm converged.	0.044	0.089	0.0	Algorithm converged.	0.00	0.00	0.07		0.00	Algorithm converged.	0.00	0.00
	No	231	60.2	97	25.0	231	231	97	7.1	0.0																	
Sex	Male	181	47.1	73	18.8	181	181	73	7.1	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.53	0.92	0.065	Algorithm converged.	0.044	0.088	0.0	Algorithm converged.	0.00	0.00	0.9949	0.9952	0.00	Algorithm converged.	0.00	0.00
	Female	203	52.9	85	21.9	203	203	85	6.9	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.53	0.93	0.065	Algorithm converged.	0.043	0.090	0.0	Algorithm converged.	0.00	0.00	0.9949		0.00	Algorithm converged.	0.00	0.00
Age	< 65	157	40.8	63	16.2	157	157	63	7.1	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.52	0.92	0.065	Algorithm converged.	0.043	0.088	0.0	Algorithm converged.	0.00	0.00	0.9952	0.9952	0.00	Algorithm converged.	0.00	0.00
	>= 65	227	59.2	95	24.5	227	227	95	7.1	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.53	0.93	0.065	Algorithm converged.	0.044	0.089	0.0	Algorithm converged.	0.00	0.00	0.9952		0.00	Algorithm converged.	0.00	0.00
Geographic region	Western Europe/United States/Canada/Australia	215	56.2	85	21.7	192	215	77	6.4	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.62	0.97	0.053	Algorithm converged.	0.029	0.051	0.0	Algorithm converged.	0.00	0.00	0.0382	0.8815	0.00	Algorithm converged.	0.00	0.00
	Asia	168	43.8	73	18.6	153	168	69	7.8	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.49	0.93	0.083	Algorithm converged.	0.052	0.098	0.0	Algorithm converged.	0.00	0.00	0.0382		0.00	Algorithm converged.	0.00	0.00
	Rest of World	0	0.0	0	0.0	0	0	0	0.0	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Algorithm converged.	0.0	0.0	0.0	Algorithm converged.	0.0	0.0	0.0382		0.0	Algorithm converged.	0.0	0.0
Race/ethnicity	White	215	56.2	85	21.7	192	215	77	6.4	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.62	0.97	0.053	Algorithm converged.	0.029	0.051	0.0	Algorithm converged.	0.00	0.00	0.0382	0.8815	0.00	Algorithm converged.	0.00	0.00
	Black or African American	0	0.0	0	0.0	0	0	0	0.0	0.0		0.0	0.0	0.0		0.0	0.0	0.0		0.0	0.0	0.0		0.0		0.0	0.0
	Asian	168	43.8	73	18.8	153	168	69	7.8	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.49	0.93	0.083	Algorithm converged.	0.052	0.098	0.0	Algorithm converged.	0.00	0.00	0.0382		0.00	Algorithm converged.	0.00	0.00
	Other	0	0.0	0	0.0	0	0	0	0.0	0.0	Complete separation of data points detected.	0.0	0.0	0.0	Algorithm converged.	0.0	0.0	0.0	WARNING: Detection of Hessian non-sensitive deficits.	0.0	0.0	0.0		0.0	WARNING: Detection of Hessian non-sensitive deficits.	0.0	0.0
	Unknown	0	0.0	0	0.0	0	0	0	0.0	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Algorithm converged.	0.0	0.0	0.0	Algorithm converged.	0.0	0.0	0.0		0.0	Algorithm converged.	0.0	0.0
ECOG performance status	0-1	153	39.8	61	15.7	153	153	61	7.1	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.52	0.93	0.066	Algorithm converged.	0.044	0.089	0.0	Algorithm converged.	0.00	0.00	0.0382	0.9358	0.00	Algorithm converged.	0.00	0.00
	2	231	60.2	97	25.0	231	231	97	7.1	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.53	0.93	0.065	Algorithm converged.	0.044	0.089	0.0	Algorithm converged.	0.00	0.00	0.0382		0.00	Algorithm converged.	0.00	0.00
	Missing	0	0.0	0	0.0	0	0	0	0.0	0.0		0.0	0.0	0.0		0.0	0.0	0.0		0.0	0.0	0.0		0.0		0.0	0.0
Cell of origin - Determined by Sponsor	SCC	39	10.2	11	2.8	39	39	11	8.2	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.52	0.98	0.080	Algorithm converged.	0.033	0.126	0.0	Algorithm converged.	0.00	0.00	0.1720		0.00	Algorithm converged.	0.00	0.00
	Non-SCC	345	89.8	135	34.9	345	345	135	7.1	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.52	0.92	0.065	Algorithm converged.	0.043	0.087	0.0	Algorithm converged.	0.00	0.00	0.9949		0.00	Algorithm converged.	0.00	0.00
	Unclassified	0	0.0	0	0.0	0	0	0	0.0	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Algorithm converged.	0.0	0.0	0.0	Algorithm converged.	0.0	0.0	0.0		0.0	Algorithm converged.	0.0	0.0
	Missing	0	0.0	0	0.0	0	0	0	0.0	0.0	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 2.5207152457 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.						Algorithm converged.	
CNS mets at Screening	Yes	153	39.8	61	15.7	153	153	61	7.1	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.52	0.93	0.066	Algorithm converged.	0.044	0.089	0.0	Algorithm converged.	0.00	0.00	0.0382	0.9358	0.00	Algorithm converged.	0.00	0.00
	No	231	60.2	97	25.0	231	231	97	7.1	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.53	0.93	0.065	Algorithm converged.	0.044	0.089	0.0	Algorithm converged.	0.00	0.00	0.0382		0.00	Algorithm converged.	0.00	0.00
	Missing	0	0.0	0	0.0	0	0	0	0.0	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Algorithm converged.	0.0	0.0	0.0	Algorithm converged.	0.0	0.0	0.0		0.0	Algorithm converged.	0.0	0.0
Baseline Bone Disease	Present	39	10.2	11	2.8	39	39	11	8.2	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.52	0.98	0.080	Algorithm converged.	0.033	0.126	0.0	Algorithm converged.	0.00	0.00	0.1720	0.8888	0.00	Algorithm converged.	0.00	0.00
	Absent	345	89.8	135	34.9	345	345	135	7.1	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.52	0.93	0.065	Algorithm converged.	0.044	0.089	0.0	Algorithm converged.	0.00	0.00	0.0382		0.00	Algorithm converged.	0.00	0.00
Docetaxel Exposure (Lymphoma by IHC Ethnic) Review	YES	27	17.6	7	4.6	27	153	7	4.6	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.52	0.11	0.033	Algorithm converged.	0.008	0.069	0.0	Algorithm converged.	0.00	0.00	0.4859	0.4869	0.00	Algorithm converged.	0.00	0.00
	Non-YES	126	28.6	54	14.1	126	153	54	8.6	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.53	0.93	0.083	Algorithm converged.	0.057	0.109	0.0	Algorithm converged.	0.00	0.00	0.4859		0.00	Algorithm converged.	0.00	0.00
	Unknown	0	0.0	0	0.0	0	0	0	0.0	0.0	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 2.5851526535 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.						Algorithm converged.	
Docetaxel/Prednisone Lymphoma (Central Review)	YES/TP	27	18.2	7	4.7	27	148	7	4.7	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.79	0.18	0.047	Algorithm converged.	0.000	0.000	0.0	Algorithm converged.	0.00	0.00	0.1720	0.1720	0.00	Algorithm converged.	0.00	0.00
	NO/TP	121	81.8	54	36.5	121	148	54	7.1	0.0	Quasi-complete separation of data points detected.				WARNING: Error in computing the risk function or derivatives on the returned results.				Algorithm converged.						Algorithm converged.	
	Unknown	0	0.0	0	0.0	0	0	0	0.0	0.0	Convergence criterion (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Algorithm converged.	0.0	0.0	0.0	Algorithm converged.	0.0	0.0	0.0		0.0	Algorithm converged.	0.0	0.0

Test for interaction based on Wu (Log-binomial regression)
Quasi-complete separation of data points detected. Result is uninterpretable.
Clinical cut-off: 31JAN2020

Program: root/clinical_studies/BOS341577/CSPF7884/GS39342/data_analysis/SAS_BASE/prod/program/t_ef3_resp.sas
Output: root/clinical_studies/BOS341577/CSPF7884/GS39342/data_analysis/SAS_FINAL_OS/prod/output/t_ef3_resp_sql_QC20210FU_ITT_POOLED_15JUN2020_09942.rtf
17MAR2023 19:27

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDOCORE: ESHOC (JQ-CR): Intracoronion (MCS=10) at FU Month 24
MODEL: Unstratified Analysis
STUDY: ESTUDY
Dichotomous Analysis by Subgroups (Efficacy)

ESHOC (JQ-CR): Intracoronion (MCS=10) at FU24 in Placebo

| | | Proportionwise Newton (n=3-20) (Wilson) | | | | Primer (Wilson) | | | | Proportionwise Newton (n=3-20) | | | | | | Proportionwise Newton (n=3-20) | | | | | |

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ASAUC (µg/ml·hr): Intravascular (AUC0-24) at PY Month 24
MODEL: Unstratified Analysis
STUDY: ASTRIA
Subcutaneous Analysis by Subgroups (Efficacy)

ASAUC (µg/ml·hr): Intravascular (AUC0-24) at PY24 in Primary

		Pralsetinemab Naïve (n=348) (Ref)				Pralsetinemab Naïve (n=348) (Ref)				Pralsetinemab Naïve (n=348) vs. n=1,044								Pralsetinemab Naïve (n=348) vs. Pralsetinemab Naïve (n=348)							
		Variable		Variable with Event		Patients		Variable with Event		Odds Ratio	Odds Ratio			Absolute Risk Difference				Relative Risk						Relative Risk			
Name	Level	N	%	n	%	N	n	%	95% CI		Convergence Reason	95% Lower Limit	95% Upper Limit	Absolute Risk	Convergence Reason	95% Lower Limit	95% Upper Limit	Relative Risk	Convergence Reason	95% Lower Limit	95% Upper Limit	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower Limit	95% Upper Limit
All	n/a	348	100.0	76	21.8	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.04	0.04	-0.001	Algorithm converged.	-0.05	0.049	0.98	Algorithm converged.	0.71	1.35			0.98	Algorithm converged.	0.71	1.35
Sex	Male	181	52.0	39	21.5	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.04	0.07	0.004	Algorithm converged.	-0.05	0.06	1.02	Algorithm converged.	0.65	1.61	0.9382	0.9382	1.02	Algorithm converged.	0.65	1.61
	Female	167	48.0	37	22.2	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.04	0.04	-0.004	Algorithm converged.	-0.06	0.05	0.96	Algorithm converged.	0.64	1.44			0.96	Algorithm converged.	0.64	1.44
Age	< 65	174	50.0	38	21.8	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.04	0.04	-0.001	Algorithm converged.	-0.06	0.06	0.98	Algorithm converged.	0.66	1.46	0.9283	0.9283	0.98	Algorithm converged.	0.66	1.46
	>= 65	174	50.0	38	21.8	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.04	0.04	-0.001	Algorithm converged.	-0.06	0.06	0.98	Algorithm converged.	0.66	1.46			0.98	Algorithm converged.	0.66	1.46
Geographic region	Western Europe/United States/Canada/Australia	272	78.2	22	12.8	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.02	0.02	-0.001	Algorithm converged.	-0.07	0.05	0.98	Algorithm converged.	0.57	1.17	0.4368	0.4368	1.01	Algorithm converged.	0.72	1.43
	Asia	76	21.8	54	71.1	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.03	0.03	0.000	Convergence criteria (GCONV=1E-8) satisfied.	-0.07	0.08	1.00	Algorithm converged.	0.66	1.51			1.00	Algorithm converged.	0.66	1.51
	Rest of World	0	0.0	0	0.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.00	0.00	0.00	Algorithm converged.	0.00	0.00			0.00	Algorithm converged.	0.00	0.00
Race/ethnicity	White	318	91.4	69	21.7	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.04	0.05	-0.000	Algorithm converged.	-0.06	0.06	1.00	Algorithm converged.	0.61	1.64	0.9855	0.9855	1.00	Algorithm converged.	0.61	1.64
	Black or African American	30	8.6	7	23.3	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.13	0.17	0.015	Algorithm converged.	-0.20	0.23	1.07	Algorithm converged.	0.46	2.49			1.07	Algorithm converged.	0.46	2.49
	Asian	12	3.5	12	100.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	0.00	147.49	0.000	Algorithm converged.	0.00	1.00	0.00	Algorithm converged.	0.00	47.89	0.5763		0.00	Algorithm converged.	0.00	0.47
	Unknown	28	8.0	28	100.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.00	0.00	0.00	Algorithm converged.	0.00	0.00	0.0000		0.00	Algorithm converged.	0.00	0.00
		0	0.0	0	0.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.00	0.00	0.00	Algorithm converged.	0.00	0.00			0.00	Algorithm converged.	0.00	0.00
ECOG performance status	0-1	309	87.6	69	22.3	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.08	0.006	Algorithm converged.	-0.07	0.09	1.03	Algorithm converged.	0.66	1.61	0.8455	0.8455	1.03	Algorithm converged.	0.66	1.61
	2	44	12.4	7	15.9	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.03	0.10	0.040	Algorithm converged.	-0.14	0.22	1.26	Algorithm converged.	0.56	2.84			1.26	Algorithm converged.	0.56	2.84
	Missing	0	0.0	0	0.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			NA	NA	NA	NA
Cell of origin - Investigator Assessment	GCC	77	17.0	11	14.3	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.10	0.06	-0.035	Algorithm converged.	-0.21	0.11	0.66	Algorithm converged.	0.31	1.41	0.3316		0.66	Algorithm converged.	0.31	1.41
	SCN	271	83.4	65	24.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	0.02	0.07	0.022	Algorithm converged.	-0.03	0.08	1.09	Algorithm converged.	0.82	2.03	0.3241		1.09	Algorithm converged.	0.82	2.03
	Contraction	28	8.6	4	14.3	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.09	0.09	-0.035	Algorithm converged.	-0.26	0.14	0.66	Algorithm converged.	0.21	2.03	0.5253		0.66	Algorithm converged.	0.21	2.03
	Unknown	172	53.0	10	5.8	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	0.03	0.08	0.029	Algorithm converged.	-0.06	0.11	1.14	Algorithm converged.	0.55	2.33	0.2859		1.14	Algorithm converged.	0.55	2.33
Tie issue at Screening	0-1	323	92.8	71	22.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.07	0.002	Algorithm converged.	-0.07	0.07	1.01	Algorithm converged.	0.67	1.51	0.9358		1.01	Algorithm converged.	0.67	1.51
	2	25	7.2	5	20.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.03	0.10	0.018	Algorithm converged.	-0.17	0.21	0.92	Algorithm converged.	0.31	2.73			0.92	Algorithm converged.	0.31	2.73
	Missing	0	0.0	0	0.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			NA	NA	NA	NA
Baseline Body Surface	Category	348	100.0	76	21.8	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.04	0.04	-0.001	Algorithm converged.	-0.06	0.06	0.98	Algorithm converged.	0.66	1.46	0.9283	0.9283	0.98	Algorithm converged.	0.66	1.46
	Missing	0	0.0	0	0.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			NA	NA	NA	NA
Double-Expressor Lymphoma by IHC (Central Review)	Yes	35	11.0	11	34.4	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	0.03	0.27	0.157	Algorithm converged.	-0.03	0.33	1.59	Algorithm converged.	0.93	2.71	0.1015		1.59	Algorithm converged.	0.93	2.71
	Non-DEL	313	89.0	65	20.8	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.03	0.03	-0.009	Algorithm converged.	-0.09	0.06	0.90	Algorithm converged.	0.65	1.25	0.5358		0.90	Algorithm converged.	0.65	1.25
	Unknown	0	0.0	0	0.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.00	0.00	0.00	Algorithm converged.	0.00	0.00			0.00	Algorithm converged.	0.00	0.00
Double/Triple-Hit Lymphoma (Central Review)	Yes	37	10.6	10	27.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	0.01	0.25	0.127	Algorithm converged.	-0.07	0.32	1.46	Algorithm converged.	0.77	2.77	0.3208		1.46	Algorithm converged.	0.77	2.77
	No/DEL	311	89.4	66	21.2	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	-0.03	0.03	-0.006	Algorithm converged.	-0.08	0.06	0.93	Algorithm converged.	0.67	1.29			0.93	Algorithm converged.	0.67	1.29
	Unknown	0	0.0	0	0.0	348	76	21.8	16.0		Convergence criteria (GCONV=1E-8) satisfied.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA			NA	NA	NA	NA

Test for interaction based on RR (log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/ROCHI4177/CSP07884/S039982/data_analysis/ADE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/ROCHI4177/CSP07884/S039982/data_analysis/ADE_FINAL_DS/prod/output/t_eff_resp_sql_QCPOINT_IT_POOLED_15JUN2022_095421.rtf
13MAR2023 19:27

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ASACC (QLQ-C30: Intersection (MCSs)) at FU Month 24
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

ASACC (QLQ-C30): Intersection (MCSs)) at FU24 in Revised Population

| | | Proportional Hazards (c-stat (Harrell)) | | | | Primary Analysis | | | | Proportionality Testing (c-stat vs. c-stat) | | | | | Proportionality Testing (c-stat vs. c-stat) | | | | |

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ECOG (2y)-CSC: Intersection (MCS=10) at FU Month 24
MODEL: Unstratified Analysis
STUDY: GO39942
Subsetwise Analysis by Subgroups (Efficacy)

EGGFC (2y)-CSC: Intersection (MCS=10) at FU24 vs Ratings

| | | Proportionwise Numbers (n/N=%) (Model) | | | | Primary (Model) | | | | Proportionwise Numbers (n/N=%) | | | |

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ASAUC (µg/ml·hr): Intensification (M3toD1) at FU Month 24
MODEL: Unstratified Analysis
STUDY: ASCO362
Subsequence Analysis by Subgroups (Efficacy)

ASAUC (µg/ml·hr): Intensification (M3toD1) at FU24 in Financial Difficulties

| | | Full-Framework Updates (v3.0-CAP (Active)) | | | | Primary (Active) | | | | Full-Framework Updates (v3.0-CAP (Active)) | | | |

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ESAVI (Jul-CY): Intercurrence (MCE=30) at FU Month 24
MODEL: Unstratified Analysis
STUDY: ADS9362
Dichotomous Analysis by Subgroups (Efficacy)

ESAVI (Jul-CY): Intercurrence (MCE=30) at FU Month 24 Events and controls

		Kruskal-Wallis (C-P-GW) (Model)				Fisher (Model)				Kruskal-Wallis (C-P-GW)						Kruskal-Wallis (C-P-GW)								Kruskal-Wallis (C-P-GW)					
		Variable		Variable with Event		Exhaustive		Variable with Event		Odds Ratio																			
Name	Level	N	%	n	%	n	N	n	%		Convergence Reason	95% Lower Limit	95% Upper Limit	Absolute Risk		Convergence Reason	95% Lower Limit	95% Upper Limit	Relative Risk		Convergence Reason	95% Lower Limit	95% Upper Limit	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (Simulated value)	Relative Risk		Convergence Reason	95% Lower Limit	95% Upper Limit
All	n/a	1014	100.0	111	9.2	1014	1014	111	9.2	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.062	0.153	0.0908		Algorithm converged.	0.058	0.0997	1.00		Algorithm converged.	0.61	0.99	0.1256			0.72		Algorithm converged.	0.53	0.99
Sex	Male	493	48.6	53	8.7	493	1014	53	8.7	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.063	0.182	0.0953		Algorithm converged.	0.054	0.1054	1.00		Algorithm converged.	0.41	0.99	0.7707	0.6882	0.93		Algorithm converged.	0.53	0.99
	Female	521	51.4	58	9.5	521	1014	58	9.5	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.063	0.182	0.0953		Algorithm converged.	0.054	0.1054	1.00		Algorithm converged.	0.41	0.99	0.7707		0.93		Algorithm converged.	0.53	0.99
Age	< 65	875	86.3	97	9.2	875	1014	97	9.2	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.062	0.162	0.0881		Algorithm converged.	0.054	0.1021	1.00		Algorithm converged.	0.40	0.99	0.4859	0.3482	0.91		Algorithm converged.	0.53	0.99
	>= 65	139	13.7	14	9.4	139	1014	14	9.4	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.062	0.162	0.0881		Algorithm converged.	0.054	0.1021	1.00		Algorithm converged.	0.40	0.99	0.4859		0.91		Algorithm converged.	0.53	0.99
Geographic region	Western Europe/United States/Canada/Australia	172	16.6	1	0.6	172	1014	1	0.6	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.000	0.032	0.0058		Algorithm converged.	0.000	0.0321	1.00		Algorithm converged.	0.00	0.79	0.1326	0.1028	0.71		Algorithm converged.	0.00	1.00
	Korea	208	19.9	8	3.8	208	1014	8	3.8	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.040	0.183	0.0721		Algorithm converged.	0.032	0.1441	0.66		Algorithm converged.	0.26	0.99	0.3863		0.64		Algorithm converged.	0.32	0.99
	Rest of World	634	63.5	102	16.1	634	1014	102	16.1	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.131	0.261	0.1672		Algorithm converged.	0.107	0.2127	2.76		Algorithm converged.	1.41	5.41	0.0027		2.61		Algorithm converged.	1.71	3.98
Race/ethnicity	White	918	91.0	97	8.6	918	1014	97	8.6	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.051	0.151	0.0845		Algorithm converged.	0.046	0.0965	1.00		Algorithm converged.	0.41	0.99	0.4859	NE	0.92		Algorithm converged.	0.49	0.99
	Black or African American	7	0.7	0	0.0	7	1014	0	0.0	0.000	Convergence criterion (GCONV=1E-6) satisfied.	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE			NE		NE	NE
	Asian	79	7.8	14	17.7	79	1014	14	17.7	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.000	0.000	0.0000		Algorithm converged.	0.000	0.0000	0.00		Algorithm converged.	0.00	0.00	0.0000		0.00		Algorithm converged.	0.00	0.00
	Other	10	1.0	0	0.0	10	1014	0	0.0	0.000	Complete separation of data points detected.	0.0	0.307	0.0000		ERROR: The mean parameter is either invalid or at a limit of its space for some observations.					WARNING: Detection of Hessian non-sensitive definite.							WARNING: Detection of Hessian non-sensitive definite.		
	Unknown	19	1.9	0	0.0	19	1014	0	0.0	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.0	0.169	0.0000		Algorithm converged.	0.000	0.1688	0.00		Algorithm converged.	0.00	0.00	0.0000		0.00		Algorithm converged.	0.00	0.00
		1	0.1	0	0.0	1	1014	0	0.0	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.0	0.975	0.0000		Algorithm converged.	0.000	0.9750	0.00		Algorithm converged.	0.00	0.00	0.0000		0.00		Algorithm converged.	0.00	0.00
With pertinent risks	Yes	909	89.6	101	8.6	909	1014	101	8.6	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.051	0.151	0.0855		Algorithm converged.	0.046	0.0977	1.00		Algorithm converged.	0.41	0.99	0.4859	0.3482	0.92		Algorithm converged.	0.49	0.99
	No	105	10.4	10	9.5	105	1014	10	9.5	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.037	0.163	0.0952		Algorithm converged.	0.034	0.1633	1.00		Algorithm converged.	0.14	2.03	0.4859		0.91		Algorithm converged.	0.03	2.04
	Missing	0	0.0	0	0.0	0	1014	0	0.0	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE			NE		NE	NE
Call of origin (Questions to make assessment)	SAC	77	13.2	1	1.3	77	1014	1	1.3	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.11	4.58	0.000		Algorithm converged.	0.11	3.21	0.78		Algorithm converged.	0.11	3.21	0.7868	0.2268	1.00		Algorithm converged.	0.11	3.21
	SCM	1013	86.8	90	8.9	1013	1014	90	8.9	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.062	0.153	0.0908		Algorithm converged.	0.058	0.0997	1.00		Algorithm converged.	0.61	0.99	0.1256		0.72		Algorithm converged.	0.53	0.99
	Contractions	29	2.5	1	3.4	29	1014	1	3.4	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.000	0.098	0.0345		Algorithm converged.	0.000	0.0980	0.39		Algorithm converged.	0.05	2.91	0.4859		0.37		Algorithm converged.	0.03	2.04
	Cervical	14	1.2	0	0.0	14	1014	0	0.0	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.000	0.233	0.0000		Algorithm converged.	0.000	0.2330	0.00		Algorithm converged.	0.00	0.00	0.0000		0.00		Algorithm converged.	0.00	0.00
		1	0.1	0	0.0	1	1014	0	0.0	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.0	0.975	0.0000		Algorithm converged.	0.000	0.9750	0.00		Algorithm converged.	0.00	0.00	0.0000		0.00		Algorithm converged.	0.00	0.00
Pre-knee or Screening	1-2	1013	99.9	111	9.2	1013	1014	111	9.2	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.062	0.153	0.0908		Algorithm converged.	0.058	0.0997	1.00		Algorithm converged.	0.61	0.99	0.1256	0.0958	0.72		Algorithm converged.	0.53	0.99
	3-7	1014	99.8	9	0.9	1014	1014	9	0.9	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.000	0.062	0.0010		Algorithm converged.	0.000	0.0621	0.01		Algorithm converged.	0.00	0.07	0.0000		0.01		Algorithm converged.	0.00	0.04
	8-14	1014	99.8	9	0.9	1014	1014	9	0.9	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.000	0.062	0.0010		Algorithm converged.	0.000	0.0621	0.01		Algorithm converged.	0.00	0.07	0.0000		0.01		Algorithm converged.	0.00	0.04
	15+	1013	99.8	9	0.9	1013	1014	9	0.9	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.000	0.062	0.0010		Algorithm converged.	0.000	0.0621	0.01		Algorithm converged.	0.00	0.07	0.0000		0.01		Algorithm converged.	0.00	0.04
		1	0.1	0	0.0	1	1014	0	0.0	0.000	Quasi-complete separation of data points detected.					ERROR: Error in computing new list therefore try derivatives or obs intersect function.															
		1	0.1	0	0.0	1	1014	0	0.0	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.000	0.975	0.0000		Algorithm converged.	0.000	0.9750	0.00		Algorithm converged.	0.00	0.00	0.0000		0.00		Algorithm converged.	0.00	0.00
Absolute Eosin Increase	Increase	909	89.6	101	8.6	909	1014	101	8.6	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.051	0.151	0.0855		Algorithm converged.	0.046	0.0977	1.00		Algorithm converged.	0.41	0.99	0.4859	0.3482	0.92		Algorithm converged.	0.49	0.99
	Decrease	105	10.4	10	9.5	105	1014	10	9.5	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.037	0.163	0.0952		Algorithm converged.	0.034	0.1633	1.00		Algorithm converged.	0.14	2.03	0.4859		0.91		Algorithm converged.	0.03	2.04
		0	0.0	0	0.0	0	1014	0	0.0	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE			NE		NE	NE
Double Expressor Lymphoma by IHC (Clinical Review)	DEL	93	17.2	1	1.1	93	1014	1	1.1	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.00	44.31	0.007		Algorithm converged.	0.00	44.31	0.39		Algorithm converged.	0.00	44.31	0.3173	0.2173	0.33		Algorithm converged.	0.00	5.75
	Non-DEL	1014	100.0	110	9.2	1014	1014	110	9.2	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.062	0.153	0.0908		Algorithm converged.	0.058	0.0997	1.00		Algorithm converged.	0.61	0.99	0.1256		0.72		Algorithm converged.	0.53	0.99
	Unknown	7	0.7	0	0.0	7	1014	0	0.0	0.000	Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 3.9555474749 is greater than the limit of 0.0001. The convergence is questionable.					Algorithm converged.	NE	NE	0.1333		NE		Algorithm converged.	NE	NE
Double/Triple-Hit Lymphoma (Clinical Review)	DH/TH+	106	68.6	11	8.6	160	1014	11	8.6	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.42	4.29	0.069		Algorithm converged.	0.421	3.106	1.00		Algorithm converged.	0.15	3.05	0.9884	0.9401	0.61		Algorithm converged.	0.23	1.53
	DH/TH-	93	3.0	0	0.7	160	1014	0	0.0	0.000	Quasi-complete separation of data points detected.					WARNING: The relative Hessian convergence criterion of 3.7901754749 is greater than the limit of 0.0001. The convergence is questionable.					Algorithm converged.	NE	NE	0.1333		NE		Algorithm converged.	NE	NE
	Unknown	775	14.0	0	0.7	160	1014	0	0.0	0.000	Convergence criterion (GCONV=1E-6) satisfied.	0.00	27.84	0.008		Algorithm converged.	0.000	0.2322	0.00		Algorithm converged.	0.00	26.21	0.3173		0.00		Algorithm converged.	0.00	0.00

Test for interaction based on Wu (Log-binomial regression)
Quasi-complete separation of data points. Results is untrustworthy.
Clinical sur-refs (ALTERNATIVE)

Program: root/clinical_studies/ADS9362/CSPF7884/GS39942/data_analysis/SAS_BASE/prod/program/t_e06_resp.sas
Output: root/clinical_studies/ADS9362/CSPF7884/GS39942/data_analysis/SAS_FINAL_OS/prod/output/t_e06_resp_sql_QCD3C0PD_ST_POOLED_15JUN2022_095422.rtf
15MAR2023 18:27

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ESAVI (Jul-CIA): Intussusception (MedDRA) as PT Month 24
MODEL: Unstratified Analysis
STUDY: A2059241
Risk/Outcome Analysis by Subgroups (Efficacy)

ESAVI (Jul-CIA): Intussusception (MedDRA) as PT26 on Pair

		Relationship Number 0-5=CHF (Model)				P-CHIF (Model)				Relationship Number 0-5=CHF vs. 6-CHIF																Relationship Number 6-9=CHF vs. 0-CHIF			
		Variable		Variable with Risk		Estimate		Variable with Risk		Odds Ratio	Odds Ratio			Absolute Risk				Relative Risk								Relative Risk			
Name	Level	N	%	n	%		N	n	%	OddR Ratio	Convergence Reason	95% Lower Limit	95% Upper Limit	Absolute Risk	Convergence Reason	95% Lower Limit	95% Upper Limit	Relative Risk	Convergence Reason	95% Lower Limit	95% Upper Limit	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower Limit	95% Upper Limit
Sex		232	100.0	23	9.9		232	23	9.9																				
	Male	103	44.4	13	12.6	0.27	103	13	12.6	1.318	Convergence criteria (GCONV=1E-8) satisfied.	0.72	2.79	0.021	Algorithm converged.	0.262	0.918	0.34	Algorithm converged.	0.15	0.75	0.7507	0.1988	0.34	Algorithm converged.	0.15	0.75
	Female	129	55.6	10	7.8	0.00	129	10	7.8	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.53	2.71	0.015	Algorithm converged.	0.183	0.655	0.24	Algorithm converged.	0.11	0.54	0.7507		0.24	Algorithm converged.	0.11	0.54
Age		232	100.0	23	9.9		232	23	9.9																				
	6 - 23	232	100.0	23	9.9	0.00	232	23	9.9	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.68	16.32	0.099	Algorithm converged.	0.366	0.268	0.27	Algorithm converged.	0.14	0.51	0.0000	0.5486	0.27	Algorithm converged.	0.14	0.51
	24 - 35	232	100.0	23	9.9	0.00	232	23	9.9	1.000	Convergence criteria (GCONV=1E-8) satisfied.	1.60	37.68	0.230	Algorithm converged.	0.366	0.268	0.63	Algorithm converged.	0.14	0.51	0.0000		0.63	Algorithm converged.	0.14	0.51
Geographic region	Western Europe/United States/Canada/Australia	219	94.4	22	10.0		219	22	10.0		Convergence criteria (GCONV=1E-8) satisfied.	1.32	6.67	0.118	Algorithm converged.	0.039	0.265	0.33	Algorithm converged.	0.15	0.73	0.7507	0.4029	0.49	Algorithm converged.	0.22	1.10
	Asia	13	5.6	1	7.7	0.00	13	1	7.7	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.03	2.90	0.077	Algorithm converged.	0.010	0.606	0.96	Algorithm converged.	0.06	6.37	0.7507		1.92	Algorithm converged.	0.12	30.84
	Rest of World	0	0.0	0	0.0	0.00	0	0	0.0	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	0.7507		0.00	Algorithm converged.	0.00	0.00
Risk/Infinity	White	219	94.4	22	10.0	0.00	219	22	10.0	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.63	6.00	0.111	Algorithm converged.	0.031	0.000	0.31	Algorithm converged.	0.14	0.69	0.0000	NE	0.46	Algorithm converged.	0.21	1.04
	Black or African American	13	5.6	1	7.7	0.00	13	1	7.7			00	NE	00		00	NE	00		00	NE	00		00		00	NE
	Asian	13	5.6	1	7.7	0.00	13	1	7.7	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.03	2.90	0.077	Algorithm converged.	0.010	0.606	0.96	Algorithm converged.	0.06	6.37	0.7507		1.92	Algorithm converged.	0.12	30.84
	Other	0.4		0	100.0	0.0	0	0	0.0	Quasi-complete separation of data points detected.		888dh. The mean parameter is either invalid or at a limit of its range for some observations.			888dh. The mean parameter is either invalid or at a limit of its range for some observations.					888dh. The mean parameter is either invalid or at a limit of its range for some observations.							
	Unknown	13	5.6	1	7.7	0.00	13	1	7.7	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.03	2.90	0.077	Algorithm converged.	0.010	0.606	0.96	Algorithm converged.	0.06	6.37	0.7507		1.92	Algorithm converged.	0.12	30.84
Prior Pertussal Status	Yes	232	100.0	23	9.9		232	23	9.9																				
	No	0	0.0	0	0.0	0.00	0	0	0.0	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	0.7507	0.5486	0.00	Algorithm converged.	0.00	0.00
	Missing	0	0.0	0	0.0	0.00	0	0	0.0	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	0.7507	0.5486	0.00	Algorithm converged.	0.00	0.00
												00	00	00		00	00	00		00	00	00		00		00	00
Dwell of Antigen (Assessment or mass assessment)	<5C	0	13.0	13	18.6	0.0	70	13	18.6	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.69	4.43	0.186	Algorithm converged.	0.065	0.528	0.37	Algorithm converged.	0.15	0.7	0.2464	0.7357	0.69	Algorithm converged.	0.3	1.58
	>5C	232	100.0	23	9.9		232	23	9.9	1.000	Convergence criteria (GCONV=1E-8) satisfied.	1.13	5.92	0.099	Algorithm converged.	0.032	0.304	0.27	Algorithm converged.	0.13	0.56	0.7507		0.55	Algorithm converged.	0.23	1.31
	Unknown	0	0.0	0	0.0	0.00	0	0	0.0	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	0.7507		0.00	Algorithm converged.	0.00	0.00
CDC Area of Residence	Urban	232	100.0	23	9.9		232	23	9.9																				
	Suburban	232	100.0	23	9.9	0.00	232	23	9.9	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.68	16.32	0.099	Algorithm converged.	0.366	0.268	0.27	Algorithm converged.	0.14	0.51	0.0000	0.5486	0.27	Algorithm converged.	0.14	0.51
	Rural	232	100.0	23	9.9	0.00	232	23	9.9	1.000	Convergence criteria (GCONV=1E-8) satisfied.	1.60	37.68	0.230	Algorithm converged.	0.366	0.268	0.63	Algorithm converged.	0.14	0.51	0.0000		0.63	Algorithm converged.	0.14	0.51
Baseline Body Stimmin	Stimmin	232	100.0	23	9.9		232	23	9.9																				
	Absent	232	100.0	23	9.9	0.00	232	23	9.9	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.68	16.32	0.099	Algorithm converged.	0.366	0.268	0.27	Algorithm converged.	0.14	0.51	0.0000	0.5486	0.27	Algorithm converged.	0.14	0.51
Double Expression Lymphoma by IHC (Genetic Review)	YES	27	17.0	13	18.6	0.0	70	13	18.6	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.69	4.43	0.186	Algorithm converged.	0.065	0.528	0.37	Algorithm converged.	0.15	0.7	0.2464	0.7357	0.69	Algorithm converged.	0.3	1.58
	Non-YES	232	28.0	23	9.9	0.00	232	23	9.9	1.000	Convergence criteria (GCONV=1E-8) satisfied.	1.13	5.92	0.099	Algorithm converged.	0.032	0.304	0.27	Algorithm converged.	0.13	0.56	0.7507		0.55	Algorithm converged.	0.23	1.31
	Unknown	0	0.0	0	0.0	0.00	0	0	0.0	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	0.7507		0.00	Algorithm converged.	0.00	0.00
Double/Triple-Hit Lymphoma (Genetic Review)	YES/DH-	27	88.0	23	20.9	0.0	70	13	18.6	1.000	Convergence criteria (GCONV=1E-8) satisfied.	1.13	6.39	0.186	Algorithm converged.	0.065	0.528	0.37	Algorithm converged.	0.15	0.7	0.2464	0.7357	0.69	Algorithm converged.	0.3	1.58
	Non-YES/DH-	232	0.0	0	0.0	0.00	232	23	9.9	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	0.7507		0.00	Algorithm converged.	0.00	0.00
	Unknown	0	0.0	0	0.0	0.00	0	0	0.0	1.000	Convergence criteria (GCONV=1E-8) satisfied.	0.00	0.00	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	0.7507		0.00	Algorithm converged.	0.00	0.00

Test for interaction based on RR (Log-binomial regression)
* Indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JAN2023

Program: /cvn/clinical_studies/B2051A1077/CSP07884/GS39582/data_analysis/ADE_BASE/prod/program/t_eff_resp.sas
Output: /cvn/clinical_studies/B2051A1077/CSP07884/GS39582/data_analysis/ADE_FINAL/02prod/output/t_eff_resp_sql_QC0610FG_17_FOOLSE_15JAN2023_09h42.rtf
17MAR2023 19:27

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ASAUC (µg/ml·hr): Intracranial (MCA:ICA) at FU Month 24
MODEL: Unstratified Analysis
STUDY: ASTA3A2
Dichotomous Analysis by Subgroups (Efficacy)

ASAUC (µg/ml·hr): Intracranial (MCA:ICA) at FU Month 24 (Protocol Participants Completed)

| | | Protocol-Model Version 2.0 (08 JAN 2021) | | | | Primary Analysis | | | | Protocol-Model Version 4.0 (08 JAN 20.. | | | |

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ASACC (JAJ-CD): Intercurrence (MCE=10) at FU Month 24
MODEL: Unstratified Analysis
STUDY: ASCC562
Dichotomous Analysis by Subgroups (Efficacy)

ASACC (JAJ-CD) Intercurrence (MCE=10) at FU24 in Global Health strata(Col Legend)

		Relationship Matrix (n=348 (Model))				Global (Model)				Relationship Matrix (n=348 vs. n=348)														Global (n=Relationship Matrix) (n=348)		
		Variable ==		Variable with Event		Reference		Variable with Event		Odds Ratio	Odds Ratio			Absolute Risk Difference				Relative Risk						Relative Risk		
Name	Level	N	%	n	%	n	N	n	%		Convergence Reason	95% Lower Limit	95% Upper Limit	Absolute Risk	Convergence Reason	95% Lower Limit	95% Upper Limit	Relative Risk	Convergence Reason	95% Lower Limit	95% Upper Limit	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower Limit	95% Upper Limit
All	n/a	348	100.0	23	15.0	348	348	23	15.0	1.000	Convergence criteria (GCONV=1E-6) satisfied.	-0.70	0.94	0.059	Algorithm converged.	-0.041	0.159	1.00	Algorithm converged.	0.53	3.13	0.4224		0.97	Algorithm converged.	0.52	3.03
Sex	Male	161	46.3	11	14.7	187	348	13	7.0	2.1000	Convergence criteria (GCONV=1E-6) satisfied.	-0.52	0.72	0.051	Algorithm converged.	-0.082	0.184	1.00	Algorithm converged.	0.43	3.55	0.7509	0.6282	0.93	Algorithm converged.	0.43	3.15
	Female	187	53.7	12	15.5	161	348	10	6.2	2.1000	Convergence criteria (GCONV=1E-6) satisfied.	-0.53	0.73	0.065	Algorithm converged.	-0.061	0.191	1.00	Algorithm converged.	0.49	2.93	0.7509		1.04	Algorithm converged.	0.49	2.24
Age	< 60	17	4.9	1	10.0	17	348	1	5.9	0.000	Convergence criteria (GCONV=1E-6) satisfied.	-0.93	0.61	0.040	Algorithm converged.	-0.171	0.251	1.00	Algorithm converged.	0.06	8.11	0.5867		0.59	Algorithm converged.	0.06	5.64
	>= 60	331	95.1	22	11.6	331	348	22	6.6	1.000	Convergence criteria (GCONV=1E-6) satisfied.	-0.52	0.72	0.059	Algorithm converged.	-0.041	0.159	1.00	Algorithm converged.	0.53	3.13	0.4224		0.97	Algorithm converged.	0.52	3.03
Geographic region	Western Europe/United States/Canada/Australia	171	49.1	21	12.3	332	348	19	11.7	7.13	Convergence criteria (GCONV=1E-6) satisfied.	0.62	3.37	0.223	Algorithm converged.	0.049	0.396	1.28	Algorithm converged.	0.99	2.13	0.5269	0.9604	0.40	Algorithm converged.	0.47	1.13
	Asia	64	18.4	0	18.8	16	348	3	17.6	1.000	Convergence criteria (GCONV=1E-6) satisfied.	0.43	2.92	0.023	Convergence criteria (GCONV=1E-6) satisfied.	-0.165	0.211	1.00	Algorithm converged.	0.46	2.19	0.8414		0.93	Algorithm converged.	0.43	2.00
	Rest of World	113	32.5	2	1.8	113	348	2	1.8	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.51	3.81	0.032	Algorithm converged.	-0.151	0.215	1.00	Algorithm converged.	0.11	1.73	0.0019		0.11	Algorithm converged.	0.11	1.14
Risk/ethnicity	White	318	91.4	21	14.6	318	348	21	14.6	1.000	Convergence criteria (GCONV=1E-6) satisfied.	0.63	3.43	0.228	Algorithm converged.	0.053	0.403	1.00	Algorithm converged.	0.96	2.09	0.4170	0.9995	0.40	Algorithm converged.	0.46	1.09
	Black or African American	30	8.6	2	7.7	30	348	2	7.7	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0		0.0	Algorithm converged.	0.0	0.0
	Other	12	3.5	0	11.5	12	348	0	11.5	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.00	1.39	51.000	Algorithm converged.	-0.137	0.212	1.00	Algorithm converged.	0.00	2.11	0.9719		0.00	Algorithm converged.	0.00	2.11
	Other	2	0.6	0	50.0	2	348	0	25.0	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.00	147.49	0.250	Algorithm converged.	-0.063	1.063	0.00	Algorithm converged.	0.00	17.89	0.5763		0.00	Algorithm converged.	0.00	8.47
	Unknown	4	1.1	0	0.0	4	348	0	0.0	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0		0.0	Algorithm converged.	0.0	0.0
ECOG performance status	0-1	309	88.8	20	14.6	309	348	20	14.6	1.000	Convergence criteria (GCONV=1E-6) satisfied.	0.65	4.05	0.255	Algorithm converged.	0.016	0.493	1.00	Algorithm converged.	0.96	2.07	0.3259	0.9258	0.42	Algorithm converged.	0.43	0.99
	2	37	10.6	3	8.1	37	348	3	8.1	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.63	1.59	13.000	Algorithm converged.	-0.114	0.251	1.00	Algorithm converged.	0.14	2.03	0.9719		0.00	Algorithm converged.	0.00	2.03
	Missing	2	0.6	0	0.0	2	348	0	0.0	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0		0.0	Algorithm converged.	0.0	0.0
Cell of origin - Determined by BMSK assessment	SCC	77	17.2	11	15.7	77	348	11	15.7	1.000	Convergence criteria (GCONV=1E-6) satisfied.	0.62	2.60	0.000	Algorithm converged.	-0.119	0.119	1.00	Algorithm converged.	0.51	2.11	0.9719	0.7358	0.41	Algorithm converged.	0.42	1.43
	Non-SCC	271	82.8	12	14.8	271	348	12	14.8	1.000	Convergence criteria (GCONV=1E-6) satisfied.	0.52	4.91	0.000	Algorithm converged.	-0.065	0.065	1.00	Algorithm converged.	0.52	2.43	0.9719		0.41	Algorithm converged.	0.42	1.79
	Indeterminate	28	8.0	0	10.7	28	348	0	10.7	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.53	6.81	0.000	Algorithm converged.	-0.103	0.103	1.00	Algorithm converged.	0.00	2.43	0.9719		0.00	Algorithm converged.	0.00	2.43
	Missing	172	49.4	10	11.6	172	348	10	7.0	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.63	4.66	0.058	Algorithm converged.	-0.063	0.063	1.00	Algorithm converged.	0.53	2.03	0.9719		0.43	Algorithm converged.	0.43	1.14
Oil since at screening	0-3	309	88.8	20	14.6	309	348	20	14.6	1.000	Convergence criteria (GCONV=1E-6) satisfied.	0.65	4.05	0.255	Algorithm converged.	-0.016	0.493	1.00	Algorithm converged.	0.96	2.07	0.3259	0.9258	0.42	Algorithm converged.	0.43	0.99
	4-7	37	10.6	3	11.4	40	348	3	10.0	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.63	2.20	13.000	Algorithm converged.	-0.122	0.251	1.00	Algorithm converged.	0.41	2.03	0.9719		0.00	Algorithm converged.	0.00	2.03
	Missing	2	0.6	0	0.0	2	348	0	0.0	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0		0.0	Algorithm converged.	0.0	0.0
Absolute Polio Burden	Unknown	309	88.8	20	14.6	309	348	20	14.6	1.000	Convergence criteria (GCONV=1E-6) satisfied.	0.65	4.05	0.255	Algorithm converged.	-0.016	0.493	1.00	Algorithm converged.	0.96	2.07	0.3259	0.9258	0.42	Algorithm converged.	0.43	0.99
	Missing	39	11.2	3	7.7	39	348	3	7.7	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.63	2.59	13.000	Algorithm converged.	-0.114	0.251	1.00	Algorithm converged.	0.14	2.03	0.9719		0.00	Algorithm converged.	0.00	2.03
Double Expressor Lymphoma by IHC (Clinical Review)	DEL	35	10.0	3	10.7	35	348	3	10.7	1.000	Convergence criteria (GCONV=1E-6) satisfied.	0.53	2.90	0.000	Algorithm converged.	-0.081	0.081	1.00	Algorithm converged.	0.33	2.11	0.9719	0.9258	0.41	Algorithm converged.	0.33	1.71
	Non-DEL	313	89.9	20	14.0	313	348	20	14.0	1.000	Convergence criteria (GCONV=1E-6) satisfied.	0.53	2.07	0.000	Algorithm converged.	-0.065	0.065	1.00	Algorithm converged.	0.43	2.03	0.9719		0.43	Algorithm converged.	0.43	1.43
	Unknown	0	0.0	0	0.0	0	348	0	0.0	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0		0.0	Algorithm converged.	0.0	0.0
Double/Triple-Hit Lymphoma (Clinical Review)	DH/TH	37	10.6	3	10.7	37	348	3	10.7	1.000	Convergence criteria (GCONV=1E-6) satisfied.	0.53	2.60	0.000	Algorithm converged.	-0.081	0.081	1.00	Algorithm converged.	0.33	2.11	0.9719	0.9258	0.41	Algorithm converged.	0.33	1.71
	Non-DH/TH	311	89.4	20	14.0	311	348	20	14.0	1.000	Convergence criteria (GCONV=1E-6) satisfied.	0.53	2.07	0.000	Algorithm converged.	-0.065	0.065	1.00	Algorithm converged.	0.43	2.03	0.9719		0.43	Algorithm converged.	0.43	1.43
	Unknown	0	0.0	0	0.0	0	348	0	0.0	0.000	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0	Convergence criteria (GCONV=1E-6) satisfied.	0.0	0.0	0.0		0.0	Algorithm converged.	0.0	0.0

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO35410/CSP/TFL/GS199582/data_analysis/ADE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/BO35410/CSP/TFL/GS199582/data_analysis/ADE_FINAL_DS/prod/output/t_eff_resp_sql_QC01DFC_TF_FOLLSE_15JUN2022_095422.rtf
13MAR2023 19:27

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ASAUC (µg/ml·hr): Intravitreous (AUC0-672) at FU Month 24
MODEL: Unstratified Analysis
STUDY: GO39942
Subcohorts Analysis by Subgroups (Efficacy)

ASAUC (µg/ml·hr): Intravitreous (AUC0-672) at FU Month 24 Data Description (updated)

		Pre-Screening Baseline (>=-168 Hours)				Primary Analysis				Univariate Analysis (>=-168 hr, <=168)								Multivariate Analysis (>=-168 hr, <=168)								Bivariate Plot			
		Variable		Variable with Visit		Patients		Variable with Visit		Odds Ratio																			
Name	Level	N	%	n	%	n	N	n	%		Convergence Reason	95% Lower Limit	95% Upper Limit	Absolute Risk		Convergence Reason	95% Lower Limit	95% Upper Limit	Relative Risk		Convergence Reason	95% Lower Limit	95% Upper Limit	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (Likelihood ratio)	Relative Risk		Convergence Reason	95% Lower Limit	95% Upper Limit
All	n/a	313	100.0	23	15.4	313	313	23	15.4	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.999	1.002	0.000		Algorithm converged.	0.000	0.000			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
Sex	Male	183	58.5	13	14.8	183	183	13	14.8	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.999	1.002	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.9803	0.00		Algorithm converged.	0.00	0.00
	Female	130	41.5	10	16.1	130	130	10	16.1	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.999	1.002	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.9803	0.00		Algorithm converged.	0.00	0.00
Age	< 65	172	54.9	13	12.8	172	172	13	12.8	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.999	1.002	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.9803	0.00		Algorithm converged.	0.00	0.00
	>= 65	141	45.0	10	18.4	141	141	10	18.4	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.999	1.002	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
Geographic region	Western Europe/United States/Canada/Australia	272	86.9	22	17.6	272	272	22	17.6	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.72	0.98	0.000		Algorithm converged.	0.000	0.000			Algorithm converged.	0.00	0.00		0.3713	0.00		Algorithm converged.	0.00	0.00
	Asia	41	13.1	1	10.3	41	41	1	10.3	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.99	0.000		Algorithm converged.	0.000	0.000			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
	Rest of World	0	0.0	0	0.0	0	0	0	0.0	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.99	0.000		Algorithm converged.	0.000	0.000			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
Race/ethnicity	White	308	97.8	23	14.9	308	308	23	14.9	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.5000	0.00		Algorithm converged.	0.00	0.00
	Black or African American	0	0.0	0	0.0	0	0	0	0.0			0.0	0.0																	
	Asian	5	1.6	0	0.0	5	5	0	0.0	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	1.89	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
	Other	2	0.6	0	0.0	2	2	0	0.0	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.00	167.49	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
	Unknown	0	0.0	0	0.0	0	0	0	0.0	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
		0	0.0	0	0.0	0	0	0	0.0			0.0	0.0																	
ECOG performance status	0-1	309	97.8	23	15.4	309	309	23	15.4	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.5000	0.00		Algorithm converged.	0.00	0.00
	2	7	2.2	0	0.0	7	7	0	0.0	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.98	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
	Missing	0	0.0	0	0.0	0	0	0	0.0			NA	NA	NA		NA	NA	NA	NA		NA	NA	NA	NA		NA		NA	NA	NA
Cell of origin (Determined by BRAF mutation)	SSC	71	17.2	3	11.8	71	71	3	11.8	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.72	1.93	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.2387	0.00		Algorithm converged.	0.00	0.00
	SCM	113	36.4	23	19.8	251	251	23	19.8	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.000	0.000			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
	Conjunctiva	39	9.6	23	59.0	62	62	23	59.0	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.000	0.000			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
	Unknown	73	22.8	23	31.5	251	251	23	31.5	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.98	0.000		Algorithm converged.	0.000	0.000			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
Tissue of Origin	Skin	113	36.4	23	20.4	251	251	23	20.4	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	1.97	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.9803	0.00		Algorithm converged.	0.00	0.00
	Conjunctiva	39	9.6	23	59.0	62	62	23	59.0	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.000	0.000			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
	Unknown	73	22.8	23	31.5	251	251	23	31.5	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.98	0.000		Algorithm converged.	0.000	0.000			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
		0	0.0	0	0.0	0	0	0	0.0			0.0	0.0																	
Baseline Sum Diameter	Missing	313	100.0	23	15.4	313	313	23	15.4	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.5000	0.00		Algorithm converged.	0.00	0.00
	Present	0	0.0	0	0.0	0	0	0	0.0	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00			0.00		Algorithm converged.	0.00	0.00
Double Expressor Lymphoma by IHC (Central Review)	Yes	31	17.2	3	14.1	31	31	3	14.1	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	2.71	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.7171	0.00		Algorithm converged.	0.00	0.00
	Non-DEL	149	82.8	23	18.0	177	177	23	18.0	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.5000	0.00		Algorithm converged.	0.00	0.00
	Unknown	133	9.4	23	13.5	133	133	23	13.5	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.5000	0.00		Algorithm converged.	0.00	0.00
Double/Triple-Hit Lymphoma (Central Review)	Yes	31	17.2	3	14.1	31	31	3	14.1	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	2.71	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.7171	0.00		Algorithm converged.	0.00	0.00
	No/DEL	149	82.8	23	18.0	177	177	23	18.0	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.5000	0.00		Algorithm converged.	0.00	0.00
	Unknown	133	9.4	23	13.5	133	133	23	13.5	1.000	Convergence criterion (GCONV=1E-6) satisfied.	0.97	0.97	0.000		Algorithm converged.	0.00	0.00			Algorithm converged.	0.00	0.00		0.5000	0.00		Algorithm converged.	0.00	0.00

Test for interaction based on RR (log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO39416/CSR/TFL/GO39942/data_analysis/ADE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/BO39416/CSR/TFL/GO39942/data_analysis/ADE_FINAL_DS/prod/output/t_eff_resp_sql_QC01DFC_TF_POOLED_15JUN2022_09942.rtf
13MAR2023 19:27

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ASACC (Jul-CY): Intercurrence (ACE=2+3) at FU Month 24
MODEL: Unstratified Analysis
STUDY: GS03782
Dichotomous Analysis by Subgroups (Efficacy)

ASACC (Jul-CY): Intercurrence (ACE=2+3) at FU24 in Total Population

		Primewald Hankin 0-D-GEE (Wald)				Fisher (Exact)				Primewald Hankin 0-D-GEE vs. 0-GEE												0-GEE vs. Primewald Hankin 0-D-GEE			
		Variable		Variable with Event		Patients		Variable with Event														Relative Risk			
Name	Level	N	%	n	%	n	N	n	%	Odds Ratio	Convergence Reason	95% Lower Bound	95% Upper Bound	Absolute Risk	Convergence Reason	95% Lower Bound	95% Upper Bound	Relative Risk	Convergence Reason	95% Lower Bound	95% Upper Bound	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower Bound	95% Upper Bound
All	n/a	1014	100.0	153	15.1	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.939	0.113	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.00	0.00			0.00	Algorithm converged.	0.00	0.00
Sex	Male	483	47.6	73	15.1	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.939	0.239	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.00	0.00	0.9999	0.9999	0.00	Algorithm converged.	0.00	0.00
	Female	531	52.4	80	15.1	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.939	0.239	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.00	0.00	0.9999		0.00	Algorithm converged.	0.00	0.00
Age	< 65	172	16.9	26	15.1	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.939	0.431	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.00	0.00	0.9999	0.9999	0.00	Algorithm converged.	0.00	0.00
	>= 65	842	83.0	127	15.1	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.939	0.239	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.00	0.00	0.9999		0.00	Algorithm converged.	0.00	0.00
Geographic region	Western Europe/United States/Canada/Australia	233	22.9	23	9.9	1014	1014	153	15.1	0.6	Convergence criteria (GCONV=1E-6) satisfied.	0.82	5.76	0.055	Algorithm converged.	0.022	0.031	0.66	Algorithm converged.	0.37	0.19	0.1169	0.0672	0.66	Algorithm converged.	0.32	1.13
	Korea	208	19.8	28	13.5	1014	1014	153	15.1	0.88	Convergence criteria (GCONV=1E-6) satisfied.	0.56	0.363	0.028	Algorithm converged.	0.028	0.028	0.90	Algorithm converged.	0.48	0.25	0.8819		0.90	Algorithm converged.	0.52	1.56
	Rest of World	573	56.5	102	17.8	1014	1014	153	15.1	1.2	Convergence criteria (GCONV=1E-6) satisfied.	0.71	1.68	0.028	Algorithm converged.	0.028	0.028	1.18	Algorithm converged.	0.64	0.33	0.4211		1.18	Algorithm converged.	0.73	1.91
Risk/ethnicity	White	719	70.9	111	15.4	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.939	0.211	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.00	0.00	0.9999	NE	0.00	Algorithm converged.	0.00	0.00
	Black or African American	33	3.3	5	15.2	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
	Asian	262	25.8	37	14.1	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.939	0.239	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.00	0.00	0.9999		0.00	Algorithm converged.	0.00	0.00
	Other	10	0.9	0	0.0	1014	1014	153	15.1	0.00	Complete separation of data points detected.	0.00	31.007	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	0.9999		0.00	Algorithm converged.	0.00	0.00
	Unknown	10	0.9	0	0.0	1014	1014	153	15.1	0.00	Complete separation of data points detected.	0.00	31.007	0.000	Algorithm converged.	0.000	0.000	0.00	Algorithm converged.	0.00	0.00	0.9999		0.00	Algorithm converged.	0.00	0.00
ECOG performance status	0-1	972	95.9	147	15.1	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.939	0.239	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.00	0.00	0.9999		0.00	Algorithm converged.	0.00	0.00
	2	42	4.1	6	14.3	1014	1014	153	15.1	0.9	Convergence criteria (GCONV=1E-6) satisfied.	0.40	5.93	0.000	Algorithm converged.	0.000	0.000	0.94	Algorithm converged.	0.34	0.17	0.9219		0.94	Algorithm converged.	0.41	2.14
	Missing	0	0.0	0	n/a	1014	1014	153	15.1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cell of origin - Derivations by data exploration	SCC	71	13.2	9	11.8	92	92	7	10.0	0.8	Convergence criteria (GCONV=1E-6) satisfied.	0.41	5.93	0.000	Algorithm converged.	0.000	0.000	0.79	Algorithm converged.	0.31	0.17	0.7315	0.4202	0.81	Algorithm converged.	0.32	1.93
	ADK	1013	86.8	149	14.8	1014	1014	153	15.1	0.8	Convergence criteria (GCONV=1E-6) satisfied.	0.73	6.60	0.000	Algorithm converged.	0.000	0.000	0.98	Algorithm converged.	0.73	0.37	0.9380		0.98	Algorithm converged.	0.37	2.59
	Surcomatoid	28	2.4	4	14.3	92	92	7	10.0	0.8	Convergence criteria (GCONV=1E-6) satisfied.	0.23	5.93	0.000	Algorithm converged.	0.000	0.000	0.79	Algorithm converged.	0.21	0.09	0.6955		0.81	Algorithm converged.	0.22	2.93
	Unknown	71	13.2	9	11.8	92	92	7	10.0	0.8	Convergence criteria (GCONV=1E-6) satisfied.	0.41	5.93	0.000	Algorithm converged.	0.000	0.000	0.79	Algorithm converged.	0.31	0.17	0.7315		0.81	Algorithm converged.	0.32	1.93
Tit since st Screening	0-3	1013	99.9	153	15.1	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.939	0.239	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.00	0.00	0.9999	0.9999	0.00	Algorithm converged.	0.00	0.00
	4-7	1014	99.9	153	15.1	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.93	6.38	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.47	0.23	0.9999		0.00	Algorithm converged.	0.47	2.13
	>7	1014	99.9	153	15.1	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.93	14.98	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.00	0.00	0.9999		0.00	Algorithm converged.	0.00	0.00
	Missing	0	0.0	0	n/a	1014	1014	153	15.1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Baseline Body Surface	<1.8sqm	972	95.9	147	15.1	1014	1014	153	15.1	1.0000	Convergence criteria (GCONV=1E-6) satisfied.	0.93	0.239	0.000	Algorithm converged.	0.000	0.000	1.00	Algorithm converged.	0.00	0.00	0.9999	0.9999	0.00	Algorithm converged.	0.00	0.00
	>=1.8sqm	42	4.1	6	14.3	1014	1014	153	15.1	0.9	Convergence criteria (GCONV=1E-6) satisfied.	0.40	5.93	0.000	Algorithm converged.	0.000	0.000	0.94	Algorithm converged.	0.34	0.17	0.9219		0.94	Algorithm converged.	0.41	2.14
Double Expressor Lymphoma by IHC (Clinical Review)	Yes	71	14.8	7	9.9	92	92	7	8.7	0.7	Convergence criteria (GCONV=1E-6) satisfied.	0.73	6.73	0.000	Algorithm converged.	0.000	0.000	0.67	Algorithm converged.	0.31	0.15	0.5188	0.3058	0.69	Algorithm converged.	0.19	1.91
	Non-DEL	409	85.2	63	15.4	92	92	7	10.0	0.8	Convergence criteria (GCONV=1E-6) satisfied.	0.32	5.93	0.000	Algorithm converged.	0.000	0.000	0.79	Algorithm converged.	0.21	0.09	0.6955		0.81	Algorithm converged.	0.22	2.93
	Unknown	534	52.6	83	15.5	92	92	7	10.0	0.8	Convergence criteria (GCONV=1E-6) satisfied.	0.41	5.93	0.000	Algorithm converged.	0.000	0.000	0.79	Algorithm converged.	0.31	0.17	0.7315		0.81	Algorithm converged.	0.32	1.93
Double/Triple-Hit Lymphoma (Clinical Review)	Yes	71	14.8	7	9.9	92	92	7	8.7	0.7	Convergence criteria (GCONV=1E-6) satisfied.	0.73	6.73	0.000	Algorithm converged.	0.000	0.000	0.67	Algorithm converged.	0.31	0.15	0.5188	0.3058	0.69	Algorithm converged.	0.19	1.91
	Non-DEL	409	85.2	63	15.4	92	92	7	10.0	0.8	Convergence criteria (GCONV=1E-6) satisfied.	0.32	5.93	0.000	Algorithm converged.	0.000	0.000	0.79	Algorithm converged.	0.21	0.09	0.6955		0.81	Algorithm converged.	0.22	2.93
	Unknown	534	52.6	83	15.5	92	92	7	10.0	0.8	Convergence criteria (GCONV=1E-6) satisfied.	0.41	5.93	0.000	Algorithm converged.	0.000	0.000	0.79	Algorithm converged.	0.31	0.17	0.7315		0.81	Algorithm converged.	0.32	1.93

Test for interaction based on RR (log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO39167/CSP07884/GS39782/data_analysis/ADE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/BO39167/CSP07884/GS39782/data_analysis/ADE_FINAL_DS/prod/output/t_eff_resp_sql_QC01SFC_TF_FOLLS_15JUN2022_39942.rtf
13MAR2023 19:27

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: ESAVI (Jul-CIA): Intensification (AE2nJ1) at FU Month 24
MODEL: Unstratified Analysis
DATASET: ADSCR2
Subcutaneous Analysis by Subgroups (Efficacy)

ESAVI (Jul-CIA): Intensification (AE2nJ1) at FU24 in Overall Population

		Proportionate Newton (n=3-GEE (Binom)				Primary (Binom)				Proportionate Newton (n=3-GEE vs. n=3-GEE																Proportionate Newton (n=3-GEE vs. Proportionate Newton (n=3-GEE			
		Variable		Variable with Event		Estimate		Variable with Event		Odds Ratio	Odds Ratio			Absolute Risk				Relative Risk								Relative Risk			
Name	Level	N	%	n	%	n	%	n	%		Convergence Reason	95% Lower Bound	95% Upper Bound		Convergence Reason	95% Lower Bound	95% Upper Bound		Convergence Reason	95% Lower Bound	95% Upper Bound	p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower Bound	95% Upper Bound
All	Arm	1737	100.0	121	11.6	1737	100.0	121	11.6	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00			1.00	Algorithm converged.	0.00	0.00
Sex	Male	1021	58.8	73	7.1	1021	58.8	73	7.1	1.02	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.02	-0.003	Algorithm converged.	-0.023	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900	0.9850	1.02	Algorithm converged.	0.00	0.00
	Female	716	41.2	48	6.7	716	41.2	48	6.7	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.76	-0.003	Algorithm converged.	-0.016	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
Age	18 - 40	1737	100.0	121	6.9	1737	100.0	121	6.9	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900	0.9850	1.00	Algorithm converged.	0.00	0.00
	41 - 60	1737	100.0	121	11.6	1737	100.0	121	11.6	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
Geographic region	Western Europe/United States/Canada/Australia	219	91.6	20	11.6	192	91.6	20	11.7	0.91	Convergence criteria (GCONV=1E-8) satisfied.	0.52	1.13	-0.081	Algorithm converged.	-0.137	0.000	0.00	Algorithm converged.	0.00	0.00	0.1310	0.9920	1.52	Algorithm converged.	0.00	0.00
	Asia	158	10.0	16	10.1	158	10.0	16	10.1	0.88	Convergence criteria (GCONV=1E-8) satisfied.	0.49	0.98	-0.064	Algorithm converged.	-0.060	0.000	0.00	Algorithm converged.	0.00	0.00	0.1310		0.88	Algorithm converged.	0.00	0.00
	Rest of World	1	0.1	0	0.0	1	0.1	0	0.0	0.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
Risk/ethnicity	White	219	91.6	20	11.6	192	91.6	20	10.4	0.91	Convergence criteria (GCONV=1E-8) satisfied.	0.52	1.13	-0.081	Algorithm converged.	-0.137	0.000	0.00	Algorithm converged.	0.00	0.00	0.1310		1.52	Algorithm converged.	0.00	0.00
	Black or African American	2	0.1	0	0.0	2	0.1	0	0.0	0.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900	1.000	1.00	Algorithm converged.	0.00	0.00
	Asian	158	10.0	16	10.1	158	10.0	16	10.1	0.88	Convergence criteria (GCONV=1E-8) satisfied.	0.49	0.98	-0.064	Algorithm converged.	-0.060	0.000	0.00	Algorithm converged.	0.00	0.00	0.1310		0.88	Algorithm converged.	0.00	0.00
	Other	1	0.1	0	0.0	1	0.1	0	0.0	0.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
	Other	1.4	0	0	000.0	0	0.0	0	00.0	Quasi-complete separation of data points detected.		ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			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.			
	Unknown	1737	100.0	121	6.9	1737	100.0	121	6.9	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
Prior daily/weekly status	Yes	1737	100.0	121	11.6	1737	100.0	121	11.6	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900	0.9850	1.00	Algorithm converged.	0.00	0.00
	No	1737	100.0	121	6.9	1737	100.0	121	6.9	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
	Missing	1737	100.0	121	6.9	1737	100.0	121	6.9	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
Call-up origin (assessment or mass vaccination)	SAC	1	57.1	1	11.8	85	57.1	1	27.3	0.00	Convergence criteria (GCONV=1E-8) satisfied.	0.27	1.15	-0.093	Algorithm converged.	-0.321	0.000	0.00	Algorithm converged.	0.00	0.00	0.1310	0.9310	1.00	Algorithm converged.	0.00	0.00
	SIA	219	91.6	20	9.1	192	91.6	20	10.5	0.91	Convergence criteria (GCONV=1E-8) satisfied.	0.52	1.08	-0.081	Algorithm converged.	-0.140	0.000	0.00	Algorithm converged.	0.00	0.00	0.2500		1.52	Algorithm converged.	0.00	0.00
	Unstratified	158	0.0	16	0.0	158	0.0	16	10.1	0.88	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.03	-0.064	Algorithm converged.	-0.060	0.000	0.00	Algorithm converged.	0.00	0.00	0.1310		0.88	Algorithm converged.	0.00	0.00
	Outside	158	10.0	16	10.1	158	0.0	16	0.0	0.88	Convergence criteria (GCONV=1E-8) satisfied.	0.53	0.91	-0.087	Algorithm converged.	-0.060	0.000	0.00	Algorithm converged.	0.00	0.00	0.1310		0.88	Algorithm converged.	0.00	0.00
CIA since 1st Dilution	Yes	1737	100.0	121	6.9	1737	100.0	121	6.9	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900	0.9850	1.00	Algorithm converged.	0.00	0.00
	No	1737	100.0	121	6.9	1737	100.0	121	6.9	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
	Missing	1737	100.0	121	6.9	1737	100.0	121	6.9	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
Baseline Body Stature	Stunted	1737	100.0	121	6.9	1737	100.0	121	6.9	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900	0.9850	1.00	Algorithm converged.	0.00	0.00
	Normal	1737	100.0	121	6.9	1737	100.0	121	6.9	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
Double Expression Lymphoma by IHC (Overall Review)	YES	27	17.6	3	8.2	27	17.6	3	7.0	0.00	Convergence criteria (GCONV=1E-8) satisfied.	0.57	0.74	-0.057	Algorithm converged.	-0.072	0.000	0.00	Algorithm converged.	0.00	0.00	0.2220	0.8420	0.00	Algorithm converged.	0.00	0.00
	Non-YES	1710	98.2	118	11.6	1710	98.2	118	11.6	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	0.92	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
	Indeter	1.4	0.1	0	000.0	0	0.0	0	00.0	Convergence criteria (GCONV=1E-8) satisfied.		ERROR: Error in computing the log-likelihood or its gradient function.															
	Unknown	1737	100.0	121	6.9	1737	100.0	121	6.9	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00
Double/Triple-Hit Lymphoma (Overall Review)	NO/DH-	1710	98.2	21	10.5	1710	98.2	21	10.5	0.91	Convergence criteria (GCONV=1E-8) satisfied.	0.52	1.23	-0.087	Algorithm converged.	-0.118	0.000	0.00	Algorithm converged.	0.00	0.00	0.1310	0.9360	1.00	Algorithm converged.	0.00	0.00
	DH/TH+	27	1.4	0	0.0	27	1.4	0	0.0	0.00	Convergence criteria (GCONV=1E-8) satisfied.		ERROR: Error in computing the log-likelihood or its gradient function.														
	Unknown	1737	100.0	121	6.9	1737	100.0	121	6.9	1.00	Convergence criteria (GCONV=1E-8) satisfied.	0.53	1.04	-0.002	Algorithm converged.	-0.041	0.0000	0.00	Algorithm converged.	0.00	0.00	0.7900		1.00	Algorithm converged.	0.00	0.00

Test for interaction based on RR (Log-binomial regression)
* Indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 31JAN2023

Program: root/clinical_studies/BGB16167/CSR/TFL/GCP/BGB16167_data_analysis/ADS_R&RS/prod/program/t_eff_resp.sas
Output: root/clinical_studies/BGB16167/CSR/TFL/GCP/BGB16167_data_analysis/ADS_FINAL_DS/prod/output/t_eff_resp_sp1_QC0610FG_IT_POOLED_31JAN2023_095432.rtf
13MAR2023 19:27

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Appetite loss

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	470	0	NE	NE	469	469	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	469	462	-3.46	1.25	462	462	452	-4.85	1.26	1.39	1.73	-2.01	4.79	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	466	456	-5.07	1.12	454	454	445	-6.85	1.13	1.78	1.54	-1.25	4.81	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	458	442	-4.38	1.21	437	437	425	-5.56	1.22	1.19	1.68	-2.11	4.48	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	458	440	-13.59	0.92	457	457	423	-15.22	0.93	1.62	1.25	-0.83	4.08	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	382	335	-16.99	0.77	368	368	314	-18.30	0.79	1.31	1.04	-0.74	3.36	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	359	312	-16.99	0.84	324	324	272	-18.08	0.90	1.09	1.17	-1.22	3.39	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	330	299	-18.13	0.82	294	294	265	-17.05	0.86	-1.08	1.13	-3.30	1.14	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	307	275	-16.93	0.84	271	271	241	-17.08	0.89	0.15	1.16	-2.14	2.44	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	92	-16.29	1.34	100	100	62	-16.99	1.59	0.70	2.05	-3.34	4.73	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Cognitive functioning

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	469	0	NE	NE	469	465	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	468	461	1.13	0.71	462	458	447	2.14	0.71	-1.01	0.92	-2.82	0.80	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	465	455	1.31	0.74	454	450	442	2.08	0.75	-0.77	0.97	-2.68	1.14	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	457	441	0.93	0.82	437	433	424	-0.41	0.83	1.35	1.10	-0.81	3.50	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	457	438	1.29	0.84	457	453	422	0.36	0.84	0.93	1.12	-1.26	3.13	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	381	332	2.01	0.89	368	365	307	0.82	0.91	1.19	1.21	-1.18	3.56	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	358	312	0.98	0.93	324	321	267	1.99	0.98	-1.01	1.29	-3.54	1.52	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	329	298	1.58	0.90	294	292	265	1.67	0.94	-0.09	1.23	-2.51	2.33	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	306	275	0.50	0.95	271	269	237	1.75	1.00	-1.25	1.32	-3.84	1.34	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	91	0.64	1.64	100	99	60	0.07	1.98	0.56	2.54	-4.45	5.58	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Constipation

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	464	0	NE	NE	469	463	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	463	452	-4.44	1.16	462	456	443	-1.61	1.17	-2.83	1.58	-5.93	0.27	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	460	449	-5.65	1.12	454	448	439	-3.24	1.13	-2.40	1.52	-5.39	0.58	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	452	437	-7.27	1.09	437	431	416	-5.13	1.11	-2.14	1.48	-5.05	0.77	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	453	436	-10.70	0.91	457	451	416	-11.81	0.92	1.12	1.21	-1.25	3.49	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	377	328	-11.32	0.98	368	364	306	-11.23	1.00	-0.09	1.32	-2.68	2.49	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	354	309	-8.69	1.07	324	321	266	-11.80	1.12	3.11	1.47	0.22	6.00	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	326	296	-9.31	1.15	294	291	262	-10.43	1.21	1.12	1.60	-2.01	4.26	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	303	274	-9.68	1.13	271	269	240	-12.53	1.18	2.84	1.56	-0.22	5.91	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	92	-9.93	1.57	100	99	60	-11.85	1.89	1.92	2.41	-2.83	6.67	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Diarrhoea

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	466	0	NE	NE	469	465	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	465	458	6.17	1.05	462	458	447	0.20	1.06	5.97	1.44	3.15	8.80	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	462	452	1.75	0.94	454	450	440	-0.14	0.94	1.89	1.27	-0.60	4.39	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	454	438	1.98	0.93	437	433	424	0.24	0.95	1.74	1.27	-0.75	4.24	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	454	434	-1.57	0.83	457	453	422	-2.00	0.83	0.43	1.11	-1.74	2.61	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	378	328	-1.06	0.90	368	365	306	-1.99	0.92	0.93	1.23	-1.48	3.34	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	355	310	-1.14	0.92	324	321	267	-2.77	0.98	1.63	1.29	-0.90	4.17	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	326	296	-1.91	0.89	294	292	265	-3.04	0.94	1.12	1.23	-1.29	3.54	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	303	272	-2.11	1.00	271	269	239	-0.40	1.06	-1.71	1.41	-4.48	1.06	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	117	89	-0.42	1.60	100	99	60	-2.48	1.93	2.05	2.47	-2.82	6.93	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Dyspnoea

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	470	0	NE	NE	469	468	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	469	462	-4.03	0.94	462	461	451	-4.01	0.94	-0.02	1.24	-2.45	2.41	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	466	455	-2.06	1.01	454	453	444	-2.66	1.02	0.61	1.35	-2.03	3.25	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	458	438	-1.42	1.10	437	436	426	0.12	1.11	-1.54	1.48	-4.44	1.36	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	458	441	-3.26	1.03	457	456	424	-4.60	1.04	1.33	1.37	-1.36	4.03	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	382	335	-3.95	1.04	368	367	312	-5.21	1.07	1.26	1.41	-1.51	4.03	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	359	312	-4.75	1.14	324	323	270	-2.99	1.20	-1.77	1.57	-4.85	1.32	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	330	299	-6.29	1.13	294	293	265	-3.64	1.18	-2.65	1.55	-5.69	0.39	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	307	275	-5.34	1.15	271	270	241	-2.82	1.21	-2.53	1.59	-5.65	0.59	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	92	-2.80	1.99	100	100	62	-3.39	2.38	0.59	3.07	-5.46	6.64	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Emotional functioning

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	469	0	NE	NE	469	466	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	468	460	7.84	0.74	462	459	448	8.24	0.74	-0.40	0.96	-2.27	1.48	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	465	455	8.37	0.79	454	451	443	7.97	0.79	0.40	1.04	-1.63	2.44	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	457	441	8.56	0.84	437	434	425	7.00	0.85	1.56	1.12	-0.64	3.75	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	457	438	9.41	0.82	457	454	423	9.16	0.82	0.25	1.09	-1.88	2.39	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	381	332	9.03	0.89	368	365	307	11.40	0.92	-2.37	1.21	-4.75	0.01	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	358	312	9.43	0.92	324	321	267	12.12	0.97	-2.69	1.27	-5.19	-0.19	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	329	298	9.34	0.89	294	292	265	12.34	0.93	-3.00	1.22	-5.40	-0.60	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	306	275	10.35	0.95	271	269	237	12.45	1.00	-2.10	1.31	-4.67	0.47	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	91	10.20	1.46	100	99	60	11.85	1.74	-1.65	2.24	-6.06	2.76	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Fatigue

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	470	0	NE	NE	469	469	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	469	463	-1.23	0.98	462	462	453	-2.61	0.98	1.38	1.27	-1.12	3.88	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	466	456	-3.36	1.03	454	454	445	-2.71	1.04	-0.65	1.36	-3.33	2.02	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	458	442	-2.74	1.12	437	437	427	-1.10	1.13	-1.64	1.50	-4.57	1.30	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	458	441	-10.24	1.04	457	457	423	-7.81	1.05	-2.42	1.38	-5.14	0.29	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	382	335	-13.20	1.07	368	368	314	-13.00	1.09	-0.20	1.44	-3.02	2.62	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	359	312	-14.03	1.13	324	324	272	-13.33	1.18	-0.70	1.54	-3.73	2.33	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	330	299	-15.30	1.14	294	294	265	-13.22	1.18	-2.08	1.55	-5.13	0.96	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	307	275	-14.78	1.13	271	271	242	-14.82	1.18	0.05	1.54	-2.97	3.07	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	92	-14.03	1.78	100	100	61	-14.74	2.11	0.71	2.71	-4.64	6.05	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Financial difficulties

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	466	0	NE	NE	469	462	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	465	456	-4.36	1.03	462	455	444	-3.47	1.04	-0.89	1.37	-3.58	1.79	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	462	450	-3.43	1.07	454	447	440	-4.35	1.08	0.92	1.43	-1.88	3.73	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	454	437	-3.70	1.09	437	430	420	-4.02	1.10	0.33	1.46	-2.53	3.19	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	454	431	-4.03	1.10	457	450	417	-6.36	1.11	2.33	1.47	-0.56	5.21	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	378	329	-8.42	1.09	368	363	305	-8.76	1.12	0.34	1.47	-2.54	3.23	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	356	308	-11.20	1.09	324	319	266	-9.21	1.15	-1.99	1.49	-4.92	0.94	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	327	295	-10.56	1.11	294	290	262	-11.62	1.16	1.06	1.51	-1.91	4.03	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	304	274	-10.87	1.13	271	267	234	-12.83	1.20	1.95	1.55	-1.09	5.00	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	117	89	-10.25	1.87	100	98	59	-11.52	2.26	1.26	2.88	-4.43	6.95	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Nausea and vomiting

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	470	0	NE	NE	469	469	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	469	463	1.87	0.72	462	462	453	1.12	0.72	0.75	1.00	-1.21	2.71	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	466	456	1.77	0.69	454	454	446	0.30	0.70	1.47	0.96	-0.42	3.36	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	458	442	2.06	0.73	437	437	427	1.73	0.74	0.32	1.02	-1.68	2.32	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	458	441	-3.73	0.47	457	457	424	-3.47	0.48	-0.26	0.64	-1.52	0.99	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	382	335	-4.09	0.45	368	368	314	-4.20	0.46	0.11	0.61	-1.08	1.31	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	359	312	-3.05	0.53	324	324	272	-4.73	0.56	1.68	0.75	0.22	3.15	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	330	299	-4.09	0.52	294	294	265	-3.97	0.55	-0.12	0.73	-1.56	1.31	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	307	275	-3.66	0.54	271	271	242	-4.78	0.57	1.12	0.75	-0.35	2.59	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	92	-2.68	0.71	100	100	62	-3.89	0.85	1.21	1.08	-0.93	3.34	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Pain

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	470	0	NE	NE	469	469	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	469	463	-11.37	1.00	462	462	453	-11.99	1.00	0.61	1.31	-1.96	3.19	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	466	456	-12.86	1.02	454	454	446	-12.58	1.02	-0.28	1.34	-2.92	2.35	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	458	443	-14.49	1.03	437	437	427	-12.41	1.04	-2.08	1.37	-4.77	0.61	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	458	442	-11.27	1.16	457	457	426	-11.71	1.17	0.44	1.56	-2.63	3.51	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	382	335	-13.07	1.15	368	368	313	-14.30	1.18	1.23	1.56	-1.83	4.30	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	359	313	-12.89	1.28	324	324	272	-13.62	1.34	0.73	1.77	-2.75	4.21	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	330	299	-13.34	1.28	294	294	265	-13.58	1.34	0.24	1.77	-3.24	3.72	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	307	276	-12.35	1.27	271	271	242	-16.07	1.32	3.71	1.75	0.27	7.15	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	92	-12.93	1.78	100	100	62	-11.80	2.10	-1.14	2.70	-6.46	4.19	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Physical functioning (revised)

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	470	0	NE	NE	469	469	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	469	462	-0.53	0.74	462	462	453	1.08	0.74	-1.61	0.95	-3.47	0.25	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	466	456	1.24	0.84	454	454	445	0.55	0.84	0.69	1.10	-1.48	2.85	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	458	443	0.51	0.88	437	437	427	-0.53	0.89	1.04	1.17	-1.25	3.34	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	458	441	2.49	0.87	457	457	424	3.71	0.88	-1.22	1.15	-3.49	1.04	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	382	335	4.91	0.87	368	368	314	6.77	0.88	-1.87	1.15	-4.13	0.40	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	359	312	5.13	0.95	324	324	272	6.51	0.99	-1.38	1.30	-3.93	1.17	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	330	299	5.94	0.88	294	294	265	6.20	0.91	-0.26	1.18	-2.58	2.06	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	307	275	5.14	0.90	271	271	243	6.31	0.93	-1.18	1.21	-3.56	1.20	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	92	4.10	1.26	100	100	62	4.81	1.46	-0.71	1.88	-4.40	2.99	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Global health status/QoL (revised)

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	468	0	NE	NE	469	465	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	467	459	5.34	0.87	462	458	446	7.59	0.87	-2.25	1.14	-4.49	0.00	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	464	453	7.76	0.91	454	450	441	8.03	0.91	-0.27	1.20	-2.62	2.07	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	456	440	7.50	0.96	437	433	424	6.55	0.97	0.95	1.28	-1.55	3.46	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	456	437	11.16	0.95	457	453	422	11.82	0.96	-0.66	1.27	-3.15	1.83	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	381	332	14.29	0.98	368	364	305	15.75	1.00	-1.46	1.32	-4.05	1.13	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	357	310	14.30	1.05	324	320	265	15.12	1.11	-0.82	1.45	-3.67	2.02	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	328	298	15.16	0.98	294	291	265	15.88	1.01	-0.72	1.32	-3.32	1.88	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	305	274	15.45	1.07	271	268	238	15.31	1.13	0.15	1.48	-2.76	3.06	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	91	14.50	1.62	100	99	60	15.67	1.92	-1.17	2.47	-6.04	3.71	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Role functioning (revised)

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	469	0	NE	NE	469	469	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	468	460	2.99	1.12	462	462	453	4.19	1.12	-1.20	1.49	-4.13	1.72	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	465	455	4.82	1.17	454	454	446	4.30	1.18	0.52	1.57	-2.55	3.60	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	457	442	3.79	1.23	437	437	427	3.81	1.24	-0.02	1.65	-3.26	3.21	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	457	440	9.03	1.17	457	457	424	10.05	1.18	-1.02	1.56	-4.08	2.04	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	381	334	12.65	1.15	368	368	314	15.34	1.17	-2.69	1.54	-5.72	0.34	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	359	312	13.50	1.22	324	324	271	15.92	1.28	-2.41	1.68	-5.72	0.89	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	330	299	14.93	1.23	294	294	265	14.54	1.28	0.39	1.68	-2.91	3.69	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	307	275	15.60	1.21	271	271	242	15.85	1.26	-0.26	1.65	-3.50	2.98	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	92	14.30	1.86	100	100	62	16.26	2.22	-1.97	2.84	-7.56	3.63	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Social functioning

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	469	0	NE	NE	469	464	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	468	459	1.83	1.06	462	457	446	2.73	1.07	-0.90	1.41	-3.67	1.87	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	465	454	3.22	1.10	454	449	442	3.62	1.10	-0.40	1.46	-3.27	2.46	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	457	441	3.42	1.12	437	432	422	3.29	1.13	0.13	1.50	-2.81	3.07	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	457	437	7.84	1.12	457	452	421	8.52	1.14	-0.68	1.51	-3.64	2.27	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	381	332	13.39	1.09	368	364	306	13.22	1.13	0.18	1.48	-2.72	3.08	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	358	312	14.56	1.07	324	320	266	14.70	1.12	-0.14	1.46	-2.99	2.72	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	329	298	14.22	1.13	294	291	264	15.25	1.18	-1.03	1.54	-4.05	1.99	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	306	275	14.07	1.10	271	268	236	16.43	1.16	-2.35	1.50	-5.30	0.59	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	91	14.58	1.73	100	99	60	14.32	2.07	0.26	2.64	-4.95	5.47	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30
ENDPOINT: EORTC QoL 30
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EORTC QoL 30 (Analysis of MMRM)

EORTC QLQ-C30: Insomnia

			Polatuzumab Vedotin + R-CHP (N=470)					R-CHOP (N=469)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	470	470	0	NE	NE	469	468	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 2 Day 1	All	n/a	469	469	463	-9.70	1.26	462	461	453	-10.79	1.27	1.09	1.67	-2.18	4.37	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 3 Day 1	All	n/a	466	466	454	-11.65	1.27	454	453	442	-11.57	1.27	-0.08	1.67	-3.37	3.21	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Cycle 5 Day 1	All	n/a	458	458	441	-12.75	1.26	437	436	426	-12.65	1.27	-0.10	1.67	-3.38	3.19	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Treatment Comp Or Early Discon	All	n/a	458	458	441	-15.31	1.24	457	456	423	-16.23	1.26	0.92	1.65	-2.31	4.15	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 6	All	n/a	382	382	335	-17.30	1.33	368	368	313	-17.05	1.36	-0.24	1.79	-3.77	3.28	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 12	All	n/a	359	359	312	-16.34	1.40	324	324	271	-16.97	1.46	0.64	1.92	-3.13	4.41	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 18	All	n/a	330	330	299	-17.42	1.39	294	294	265	-16.49	1.44	-0.93	1.90	-4.65	2.79	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 24	All	n/a	307	307	275	-17.64	1.46	271	271	242	-16.82	1.53	-0.82	2.02	-4.78	3.14	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 36	All	n/a	119	119	92	-17.47	2.14	100	100	62	-17.24	2.54	-0.24	3.25	-6.64	6.17	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EORTC QLQ-C30	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQC30_QLQC30pop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:44

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: FACT-G NTX
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

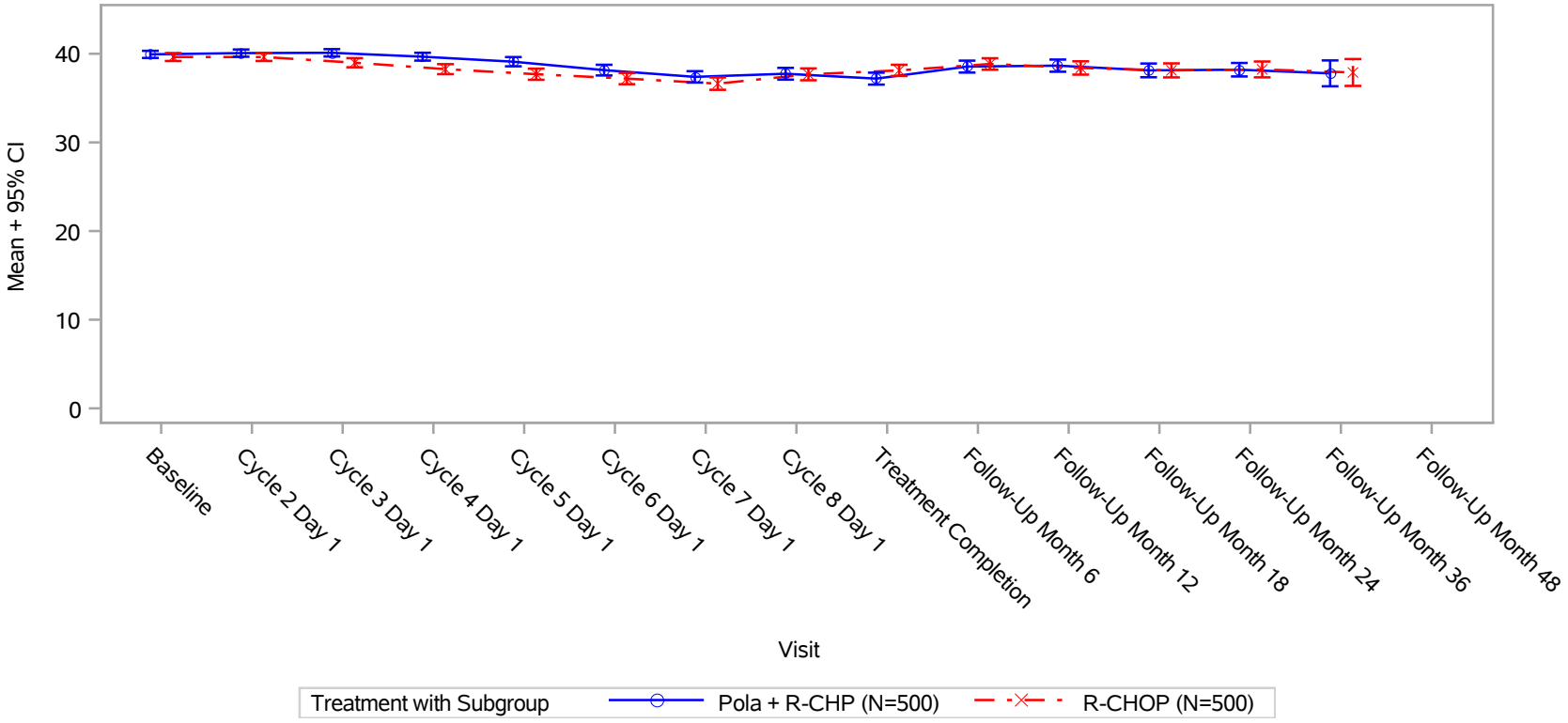
FACT-GOG-NTX: Neurotoxicity subscale (NtxS)

		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		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	n/a	500	100.0	471	94.2	39.93	4.46	500	100.0	466	93.2	39.63	4.89
CYCLE 2 DAY 1	n/a	491	98.2	478	97.4	40.07	4.53	492	98.4	473	96.1	39.63	4.93
CYCLE 3 DAY 1	n/a	487	97.4	468	96.1	40.11	4.55	486	97.2	470	96.7	38.99	5.70
CYCLE 4 DAY 1	n/a	484	96.8	472	97.5	39.67	4.89	478	95.6	457	95.6	38.26	6.12
CYCLE 5 DAY 1	n/a	482	96.4	466	96.7	39.10	5.74	471	94.2	455	96.6	37.69	6.83
CYCLE 6 DAY 1	n/a	468	93.6	456	97.4	38.15	6.56	458	91.6	447	97.6	37.20	6.85
CYCLE 7 DAY 1	n/a	457	91.4	444	97.2	37.39	6.88	444	88.8	431	97.1	36.63	7.37
CYCLE 8 DAY 1	n/a	451	90.2	439	97.3	37.74	7.08	444	88.8	435	98.0	37.68	7.09
TREATMENT COMPLETION	n/a	449	89.8	433	96.4	37.19	7.13	434	86.8	417	96.1	38.12	6.59
FOLLOW-UP MONTH 6	n/a	398	79.6	348	87.4	38.55	6.38	386	77.2	325	84.2	38.84	5.93
FOLLOW-UP MONTH 12	n/a	373	74.6	322	86.3	38.66	6.26	338	67.6	280	82.8	38.40	6.37
FOLLOW-UP MONTH 18	n/a	343	68.6	310	90.4	38.12	6.93	308	61.6	274	89.0	38.12	6.64
FOLLOW-UP MONTH 24	n/a	318	63.6	287	90.3	38.20	6.54	284	56.8	251	88.4	38.23	7.19
FOLLOW-UP MONTH 36	n/a	123	24.6	93	75.6	37.79	7.08	105	21.0	64	61.0	37.89	6.06
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the table.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_PFGNTX_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:53

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: FACT-G NTX
STUDY: GO39942
Line Plot of Mean by Visit
FACT-GOG-NTX: Neurotoxicity subscale (NtxS)



Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the plot.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: .._analysis/ACE_FINAL_OS/prod/output/g_mean_plot_PFGNTX_IT_POOLED_15JUN2022_39942.pdf
13MAR2023 19:52

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: FACT-GOG-NTX: Deterioration (MID=7) at EOT in Neurotoxicity subscale (NtxS)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	415	83.0	91	21.9	393	78.6	60	15.3	1.57		Convergence criterion (GCONV=1E-8) satisfied.	1.09	2.26	0.058		Algorithm converged.	0.007	0.110	1.43		Algorithm converged.	1.07	1.92	0.0146	0.70		Algorithm converged.	0.52	0.93

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Only Patients with a value at Baseline and EOT are included in analysis.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_DPFGNTXET_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:17

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: FACT-GOG-NTX: Deterioration (MID=7) at EOT in Neurotoxicity subscale (NtxS)
MODEL: Unstratified Analysis
97007: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	415	83.0	91	21.9	393	78.6	60	15.3	1.56	Convergence criterion (GCONV=1E-8) satisfied.	1.08	2.23	0.067	Algorithm converged.	0.013	0.120	1.44	Algorithm converged.	1.07	1.93			0.70	Algorithm converged.	0.52	0.94
Sex	Male	219	43.8	47	21.5	207	41.4	33	15.9	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.88	2.36	0.055	Algorithm converged.	-0.019	0.129	1.35	Algorithm converged.	0.92	2.01			0.74	Algorithm converged.	0.50	1.11
	Female	196	39.2	44	22.4	186	37.2	27	14.5	1.70	Convergence criterion (GCONV=1E-8) satisfied.	1.01	2.89	0.079	Algorithm converged.	0.002	0.157	1.55	Algorithm converged.	1.00	2.39			0.63	Algorithm converged.	0.42	1.00
Age	>= 65	143	28.6	26	18.2	123	24.6	16	13.0	1.48	Convergence criterion (GCONV=1E-8) satisfied.	0.76	2.92	0.052	Algorithm converged.	-0.035	0.139	1.46	Algorithm converged.	0.79	2.68			0.8884		0.73	Algorithm converged.	0.48	1.27
	> 60	272	54.4	65	23.9	270	54.0	44	16.3	1.61	Convergence criterion (GCONV=1E-8) satisfied.	1.03	2.47	0.076	Algorithm converged.	0.009	0.143	1.47	Algorithm converged.	1.04	2.07			0.68	Algorithm converged.	0.48	0.94
Geographic region	Western Europe/United States/Canada/Australia	241	48.2	65	27.0	223	44.6	41	18.4	1.66	Convergence criterion (GCONV=1E-8) satisfied.	1.05	2.55	0.086	Algorithm converged.	0.010	0.162	1.47	Algorithm converged.	1.04	2.07			0.7400		0.68	Algorithm converged.	0.48	0.96
	Asia	123	24.6	14	11.4	119	23.8	12	10.1	1.23	Convergence criterion (GCONV=1E-8) satisfied.	0.53	2.59	0.013	Algorithm converged.	-0.065	0.091	1.13	Algorithm converged.	0.54	2.34			0.7449		0.82	Algorithm converged.	0.42	1.84
	Rest of World	51	10.2	12	23.5	51	10.2	7	13.7	1.93	Convergence criterion (GCONV=1E-8) satisfied.	0.69	5.40	0.098	Algorithm converged.	-0.052	0.248	1.71	Algorithm converged.	0.73	4.00			0.2057		0.58	Algorithm converged.	0.25	1.34
Race/ethnicity	White	197	39.4	59	29.9	186	37.2	32	17.2	2.06	Convergence criterion (GCONV=1E-8) satisfied.	1.26	3.35	0.127	Algorithm converged.	0.044	0.211	1.74	Algorithm converged.	1.19	2.55			0.0034		0.57	Algorithm converged.	0.39	0.84
	Black or African American	8	1.6	2	25.0	2	0.4	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	Algorithm converged.	NE	NE			0.4533		NE	Algorithm converged.	NE	NE
	Asian	127	25.4	14	11.0	126	24.8	13	10.3	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.48	2.35	0.005	Algorithm converged.	-0.071	0.080	1.05	Algorithm converged.	0.52	2.13			0.8905		0.95	Algorithm converged.	0.47	1.94
	Other	5	1.0	2	40.0	8	1.6	2	25.0	2.00	Convergence criterion (GCONV=1E-8) satisfied.	0.19	22.06	0.150	Algorithm converged.	-0.374	0.674	1.69	Algorithm converged.	0.32	8.01			0.5839		0.63	Algorithm converged.	0.10	3.13
	Unknown	78	15.6	14	17.9	73	14.6	13	17.8	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.44	2.32	0.001	Algorithm converged.	-0.121	0.124	1.01	Algorithm converged.	0.51	2.00			0.9821		0.99	Algorithm converged.	0.50	1.97
ECOG performance status	0-1	352	70.4	79	22.4	338	67.6	53	15.7	1.56	Convergence criterion (GCONV=1E-8) satisfied.	1.06	2.29	0.068	Algorithm converged.	0.009	0.126	1.43	Algorithm converged.	1.05	1.96			0.0241		0.70	Algorithm converged.	0.53	0.94
	2	63	12.6	12	19.0	54	10.8	7	13.0	1.66	Convergence criterion (GCONV=1E-8) satisfied.	0.57	4.35	0.061	Algorithm converged.	-0.071	0.193	1.42	Algorithm converged.	0.62	3.43			0.3753		0.69	Algorithm converged.	0.28	1.64
	Missing	0	0.0	0	0.0	1	0.2	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE			NE		NE	NE
Cell of origin (determined by gene expression)	ABC	115	23.0	18	15.7	116	23.2	15	14.4	0.95	Convergence criterion (GCONV=1E-8) satisfied.	0.47	1.91	-0.007	Algorithm converged.	-0.102	0.087	0.94	Algorithm converged.	0.53	1.73			0.8805		1.05	Algorithm converged.	0.58	1.89
	GCB	142	32.4	43	26.3	145	29.0	21	14.5	2.13	Convergence criterion (GCONV=1E-8) satisfied.	1.25	3.81	0.121	Algorithm converged.	0.032	0.210	1.83	Algorithm converged.	1.14	2.94			0.0095		0.55	Algorithm converged.	0.34	0.87
	Unclassified	45	9.0	7	20.0	49	9.8	11	22.4	0.86	Convergence criterion (GCONV=1E-8) satisfied.	0.32	2.33	-0.024	Algorithm converged.	-0.190	0.140	0.84	Algorithm converged.	0.41	1.69			0.7731		1.13	Algorithm converged.	0.51	2.49
	Unknown	93	18.6	21	22.8	83	16.6	9	10.8	2.46	Convergence criterion (GCONV=1E-8) satisfied.	1.01	5.59	0.117	Algorithm converged.	0.009	0.226	2.08	Algorithm converged.	1.01	4.29			0.0393		0.48	Algorithm converged.	0.23	0.96
IPI score at Screening	1-2	163	32.6	34	20.9	159	31.8	27	17.0	1.29	Convergence criterion (GCONV=1E-8) satisfied.	0.76	2.26	0.039	Algorithm converged.	-0.047	0.124	1.23	Algorithm converged.	0.78	1.94			0.3754		0.907	0.82	0.52	1.28
	3	165	33.0	37	22.4	144	28.8	16	11.1	2.01	Convergence criterion (GCONV=1E-8) satisfied.	1.22	4.37	0.113	Algorithm converged.	0.031	0.195	2.02	Algorithm converged.	1.17	3.47			0.0084		0.50	Algorithm converged.	0.29	0.85
	4-5	87	17.4	20	23.0	90	18.0	17	18.9	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.62	2.65	0.041	Algorithm converged.	-0.079	0.163	1.22	Algorithm converged.	0.68	2.18			0.5037		0.82	Algorithm converged.	0.46	1.46
Baseline Bulky Disease	Present	170	34.0	38	22.4	156	31.2	28	17.9	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.76	2.27	0.044	Algorithm converged.	-0.043	0.131	1.25	Algorithm converged.	0.80	1.93			0.3236		0.805	0.82	0.52	1.29
	Absent	245	49.0	53	21.6	237	47.4	32	13.5	1.73	Convergence criterion (GCONV=1E-8) satisfied.	1.09	2.86	0.081	Algorithm converged.	0.014	0.149	1.60	Algorithm converged.	1.07	2.39			0.0193		0.62	Algorithm converged.	0.42	0.93
Double Expressor Lymphoma by IHC (Central Review)	DEL	121	24.2	24	19.8	128	25.6	16	12.5	1.70	Convergence criterion (GCONV=1E-8) satisfied.	0.87	3.45	0.073	Algorithm converged.	-0.018	0.165	1.58	Algorithm converged.	0.89	2.84			0.1158	0.3186	0.63	Algorithm converged.	0.35	1.14
	Non DEL	221	44.2	40	20.8	198	39.6	37	18.7	1.14	Convergence criterion (GCONV=1E-8) satisfied.	0.72	1.85	0.021	Algorithm converged.	-0.055	0.098	1.11	Algorithm converged.	0.76	1.64			0.5858		0.92	Algorithm converged.	0.62	1.32
	Unknown	73	14.6	27	28.9	67	13.4	7	10.4	3.40	Convergence criterion (GCONV=1E-8) satisfied.	1.36	9.80	0.183	Algorithm converged.	0.056	0.310	2.73	Algorithm converged.	1.25	6.04			0.0070		0.36	Algorithm converged.	0.17	0.80
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	289	57.8	61	21.1	285	57.0	45	15.8	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.95	2.18	0.053	Algorithm converged.	-0.010	0.116	1.34	Algorithm converged.	0.94	1.89			0.1010	0.7304	0.75	Algorithm converged.	0.53	1.06
	DH/TH+	22	4.4	6	27.3	16	3.2	4	25.0	1.16	Convergence criterion (GCONV=1E-8) satisfied.	0.26	4.89	0.023	Algorithm converged.	-0.259	0.305	1.09	Algorithm converged.	0.37	3.24			0.8768		0.92	Algorithm converged.	0.31	2.72
	Unknown	104	20.8	24	23.1	92	18.4	11	12.0	2.01	Convergence criterion (GCONV=1E-8) satisfied.	1.02	4.81	0.111	Algorithm converged.	0.007	0.216	1.93	Algorithm converged.	1.00	3.72			0.0430		0.52	Algorithm converged.	0.27	1.00

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Only Patients with a value at Baseline and EOT are included in analysis.
ETTY is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_GS/prod/output/t_eff_resp_sgl_DSFSNTHAT_ITT_POOLED_15JUN2022_39942.xls
09FEB2023 20:23

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: FACT-GOG-NTX: Deterioration (MID=7) at FU Month 24 in Neurotoxicity subscale (NtxS)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	272	54.4	44	16.2	237	47.4	37	15.6	1.05		Convergence criterion (GCONV=1E-8) satisfied.	0.65	1.69	-0.010		Algorithm converged.	-0.074	0.054	1.07		Algorithm converged.	0.72	1.60	0.8476	0.93		Algorithm converged.	0.63	1.39

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Only Patients with a value at Baseline and Follow-up Month 24 are included in analysis.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_DPFGNTXFU_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:19

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: FACT-GOG-NTX: Intoxication (NIDs=7) at PP Month 24 in Neurotoxicity subscale (Bad)
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

		Pelarexenab Ventolin + N-CHP (N=501)				N-CHP (N=501)				Pelarexenab Ventolin + N-CHP vs. N-CHP										N-CHP vs. Pelarexenab Ventolin + N-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (stratified ratios)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	272	30,5	83	15,2	265	47,1	97	19,4	1,03	Convergence criterion (GCONV=1E-6) satisfied.	0,80	1,48	0,004	Algorithm converged.	-0,038	0,045	1,01	Algorithm converged.	0,93	0,93	0,6422		0,97	Algorithm converged.	0,93	1,02
Sex	Male	140	28,0	39	13,9	134	22,1	49	17,9	0,73	Convergence criterion (GCONV=1E-6) satisfied.	0,37	1,42	-0,039	Algorithm converged.	-0,130	0,053	0,73	Algorithm converged.	0,43	1,24	0,0833		0,80	Algorithm converged.	0,57	2,35
	Female	132	26,4	44	16,5	131	21,5	48	18,0	1,24	Convergence criterion (GCONV=1E-6) satisfied.	0,73	2,45	0,045	Algorithm converged.	-0,039	0,162	1,24	Algorithm converged.	0,79	2,61	0,2718		0,92	Algorithm converged.	0,63	1,34
Age	18- 40	86	17,2	25	14,7	76	12,5	5	8,2	1,25	Convergence criterion (GCONV=1E-6) satisfied.	0,43	3,72	0,052	Algorithm converged.	-0,039	0,326	1,23	Algorithm converged.	0,53	4,24	0,6839		0,93	Algorithm converged.	0,56	2,79
	> 40	186	36,8	59	15,7	188	31,	53	18,9	1,02	Convergence criterion (GCONV=1E-6) satisfied.	0,59	1,76	0,002	Algorithm converged.	-0,084	0,089	1,01	Algorithm converged.	0,61	1,68	0,9565		0,96	Algorithm converged.	0,61	1,53
Geographic region	Europe, Europe/United States/Canada/Australia	149	30,8	39	22,0	139	30,6	33	14,9	1,85	Convergence criterion (GCONV=1E-6) satisfied.	0,93	2,93	0,074	Algorithm converged.	-0,026	0,185	1,30	Algorithm converged.	0,94	2,61	0,0838	0,0111	0,98	Algorithm converged.	0,63	1,54
	Japan	48	10,0	5	8,7	50	10,1	10	18,9	0,47	Convergence criterion (GCONV=1E-6) satisfied.	0,09	2,42	-0,134	Algorithm converged.	-0,253	-0,015	0,47	Algorithm converged.	0,10	2,93	0,4087		0,13	Algorithm converged.	0,03	5,54
	Rest of World	87	17,9	39	9,1	76	8,2	7	12,8	0,29	Convergence criterion (GCONV=1E-6) satisfied.	0,03	2,16	-0,071	Algorithm converged.	-0,211	0,084	0,43	Algorithm converged.	0,05	2,14	0,2952		0,07	Algorithm converged.	0,03	10,13
Race/ethnicity	White	137	27,6	27	19,7	134	29,1	20	15,0	1,32	Convergence criterion (GCONV=1E-6) satisfied.	0,64	2,66	0,059	Algorithm converged.	-0,054	0,210	1,22	Algorithm converged.	0,73	2,16	0,4183	80	0,80	Algorithm converged.	0,38	1,26
	Black or African American	3	4,7	1	33,3	3	6,7	1	0,0	98		98	98	98		98	98	98		98	98			98		98	98
	Asian	98	19,6	5	5,1	93	11,1	10	18,3	0,29	Convergence criterion (GCONV=1E-6) satisfied.	0,06	0,95	-0,124	Algorithm converged.	-0,230	-0,057	0,03	Algorithm converged.	0,11	0,98	0,0203		0,09	Algorithm converged.	0,01	0,53
	Other	2	0,0	0	100,0	2	0,0	0	25,0		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				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.		
	Unknown	60	12,0	8	13,3	62	10,5	6	11,5	1,33	Convergence criterion (GCONV=1E-6) satisfied.	0,41	4,29	0,049	Algorithm converged.	-0,091	0,189	1,60	Algorithm converged.	0,50	3,41	0,5363		0,77	Algorithm converged.	0,27	2,22
ECOG performance status	0-1	230	29,1	66	14,3	222	40,1	81	19,1	1,07	Convergence criterion (GCONV=1E-6) satisfied.	0,80	1,87	0,023	Algorithm converged.	-0,035	0,077	1,03	Algorithm converged.	0,83	1,69	0,7965	0,7554	0,96	Algorithm converged.	0,71	1,29
	2	40	8,0	6	15,0	38	7,9	6	17,1	0,89	Convergence criterion (GCONV=1E-6) satisfied.	0,29	2,93	-0,022	Algorithm converged.	-0,198	0,165	0,84	Algorithm converged.	0,32	2,47	0,8019		0,92	Algorithm converged.	0,32	3,22
	Missing	2	0,0	0	0,0	1	0,0	0	0,0	98		98	98	98		98	98	98		98	98			98		98	98
Cell of origin (determined by gene expression)	NEC	74	15,9	12	16,2	78	11,6	13	16,0	1,24	Convergence criterion (GCONV=1E-6) satisfied.	0,41	2,73	0,060	Algorithm converged.	-0,116	0,132	1,09	Algorithm converged.	0,47	2,51	0,9134	0,8666	0,96	Algorithm converged.	0,29	2,12
	GCB	113	23,4	17	15,0	97	18,0	17	17,5	0,83	Convergence criterion (GCONV=1E-6) satisfied.	0,43	1,78	-0,022	Algorithm converged.	-0,123	0,073	0,91	Algorithm converged.	0,63	1,62	0,5859		0,93	Algorithm converged.	0,63	2,12
	Unclassified	29	6,0	6	20,7	26	8,0	6	23,1	0,69	Convergence criterion (GCONV=1E-6) satisfied.	0,14	3,32	-0,054	Algorithm converged.	-0,236	0,126	0,74	Algorithm converged.	0,32	2,13	0,5771		0,85	Algorithm converged.	0,42	4,53
	Unknown	65	13,4	11	17,0	67	8,3	5	6,0	2,23	Convergence criterion (GCONV=1E-6) satisfied.	0,84	20,17	0,107	Algorithm converged.	0,010	0,241	2,01	Algorithm converged.	0,93	15,73	0,0541		0,97	Algorithm converged.	0,89	1,13
IPI score at Screening	0-2	198	21,2	33	16,7	210	26,1	37	16,2	0,79	Convergence criterion (GCONV=1E-6) satisfied.	0,45	1,42	-0,041	Algorithm converged.	-0,131	0,060	0,77	Algorithm converged.	0,43	1,51	0,4888	0,8765	0,93	Algorithm converged.	0,64	2,02
	3-5	113	22,1	21	18,6	88	14,2	12	13,6	1,52	Convergence criterion (GCONV=1E-6) satisfied.	0,61	2,87	0,059	Algorithm converged.	-0,048	0,166	1,24	Algorithm converged.	0,59	2,61	0,6859		0,93	Algorithm converged.	0,62	2,52
	N/A	53	10,4	7	13,2	52	10,4	8	14,8	1,18	Convergence criterion (GCONV=1E-6) satisfied.	0,41	3,32	0,022	Algorithm converged.	-0,117	0,160	1,10	Algorithm converged.	0,49	2,79	0,7883		0,97	Algorithm converged.	0,72	2,25
Baseline Baltz Disease	Present	139	28,0	37	16,7	95	19,0	19	14,6	1,23	Convergence criterion (GCONV=1E-6) satisfied.	0,68	2,23	0,060	Algorithm converged.	-0,038	0,157	1,07	Algorithm converged.	0,72	1,89	0,8717	0,8577	0,96	Algorithm converged.	0,63	1,80
	Absent	148	30,0	21	14,2	106	27,1	23	15,1	1,27	Convergence criterion (GCONV=1E-6) satisfied.	0,67	2,38	0,060	Algorithm converged.	-0,037	0,088	1,08	Algorithm converged.	0,71	1,78	0,8383		0,95	Algorithm converged.	0,71	1,60
Double Expressor Lymphoma by IHC (Central Review)	DEL	82	16,4	14	19,5	79	15,1	11	14,1	1,48	Convergence criterion (GCONV=1E-6) satisfied.	0,64	3,42	0,056	Algorithm converged.	-0,026	0,175	1,18	Algorithm converged.	0,69	2,79	0,5624	0,2533	0,93	Algorithm converged.	0,38	1,68
	Non-DEL	145	29,0	23	15,9	108	29,1	24	15,0	0,83	Convergence criterion (GCONV=1E-6) satisfied.	0,43	1,52	-0,032	Algorithm converged.	-0,123	0,053	0,83	Algorithm converged.	0,52	1,63	0,4903		0,93	Algorithm converged.	0,53	2,02
	Unknown	55	9,0	5	13,0	52	9,0	5	9,6	1,54	Convergence criterion (GCONV=1E-6) satisfied.	0,50	20,47	0,082	Algorithm converged.	-0,072	0,172	1,60	Algorithm converged.	0,58	8,67	0,5434		0,93	Algorithm converged.	0,22	4,56
Double/Triple-Hit Lymphoma (Central Review)	DH/TH	138	27,5	20	15,	137	34,	20	15,	0,77	Convergence criterion (GCONV=1E-6) satisfied.	0,45	1,34	-0,091	Algorithm converged.	-0,177	0,000	0,82	Algorithm converged.	0,51	1,27	0,3550	0,2035	0,91	Algorithm converged.	0,5	1,35
	DH/TH	19	3,0	3	20,	13	2,1	1	7,	5,00	Convergence criterion (GCONV=1E-6) satisfied.	0,27	93,08	0,162	Algorithm converged.	-0,126	0,371	2,82	Algorithm converged.	0,31	25,64	0,3021		0,59	Algorithm converged.	0,05	7,28
	Unknown	69	13,8	12	17,	55	10,	6	9,	2,27	Convergence criterion (GCONV=1E-6) satisfied.	0,92	12,40	0,116	Algorithm converged.	0,039	0,222	2,66	Algorithm converged.	0,99	8,94	0,0606		0,92	Algorithm converged.	0,31	2,14

Test for interaction based on MH (log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Only Patients with a value at Baseline and Follow-up Month 24 are included in analysis.
ETTY is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: sas6/clinical_studies/BO39431?7/CSFT?84/GO39942/data_analysis/ACE_BASE/prod/programs/t_eff_resp.sas
Output: sas6/clinical_studies/BO39431?7/CSFT?84/GO39942/data_analysis/ACE_FINAL GE/prod/output?: eff resp mg1 UPPERTEXT: IT POOLED 15JUN2022 39942.ala
09FEB2023 20:26

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX
ENDPOINT: FACT-G NTX
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in FACT-G NTX (Analysis of MMRM)

FACT-GOG-NTX: Neurotoxicity subscale (NtxS)

			Polatuzumab Vedotin + R-CHP (N=466)					R-CHOP (N=465)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	466	466	0	NE	NE	465	465	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Cycle 2 Day 1	All	n/a	465	465	457	0.21	0.18	458	458	446	-0.07	0.18	0.28	0.23	-0.18	0.74	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Cycle 3 Day 1	All	n/a	462	462	451	0.17	0.21	449	449	442	-0.76	0.21	0.93	0.28	0.38	1.47	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Cycle 4 Day 1	All	n/a	462	462	452	-0.38	0.23	442	442	428	-1.57	0.23	1.19	0.30	0.59	1.79	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Cycle 5 Day 1	All	n/a	454	454	441	-0.94	0.27	432	432	424	-2.14	0.27	1.20	0.36	0.50	1.91	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Cycle 6 Day 1	All	n/a	442	442	432	-1.85	0.29	426	426	421	-2.82	0.29	0.97	0.40	0.19	1.75	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Cycle 7 Day 1	All	n/a	429	429	419	-2.50	0.31	409	409	399	-3.29	0.32	0.79	0.43	-0.05	1.63	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Cycle 8 Day 1	All	n/a	419	419	409	-2.29	0.32	403	403	397	-2.37	0.32	0.07	0.43	-0.77	0.92	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Treatment Comp Or Early Discon	All	n/a	454	454	440	-2.72	0.30	453	453	433	-1.80	0.30	-0.92	0.41	-1.71	-0.12	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Follow-Up Month 6	All	n/a	379	379	332	-1.29	0.28	363	363	308	-1.07	0.28	-0.21	0.38	-0.96	0.53	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Follow-Up Month 12	All	n/a	356	356	308	-1.32	0.30	319	319	267	-1.08	0.31	-0.24	0.41	-1.05	0.58	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Follow-Up Month 18	All	n/a	326	326	294	-1.68	0.32	289	289	262	-1.42	0.33	-0.26	0.45	-1.14	0.62	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Follow-Up Month 24	All	n/a	303	303	272	-1.45	0.33	266	266	237	-1.31	0.35	-0.14	0.47	-1.06	0.77	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Follow-Up Month 36	All	n/a	119	119	90	-1.99	0.53	97	97	61	-1.39	0.62	-0.59	0.81	-2.19	1.00	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-G NTX	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_PFGNTX_FACTGpop_IT_POOLED_15JUN2022_39942.xls
13MAR2023 19:51

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: FACT-LYM Subscale
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

FACT-LYM: Lymphoma subscale (LYMS)

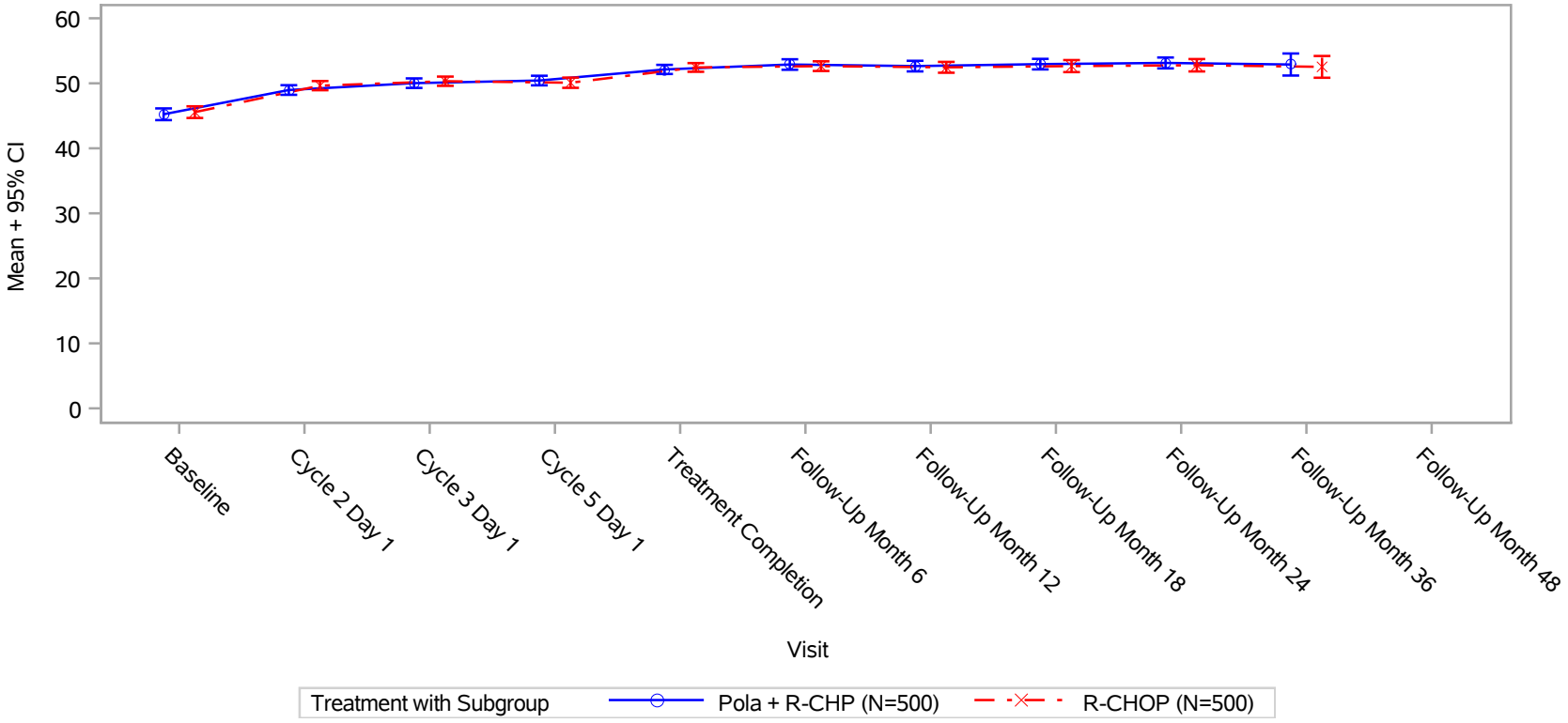
		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	Mean[2]	SD(Mean)	in study[1]	%	with value[1]	%	Mean[2]	SD(Mean)
All													
BASELINE	n/a	500	100.0	469	93.8	45.24	9.94	500	100.0	465	93.0	45.56	9.85
CYCLE 2 DAY 1	n/a	491	98.2	477	97.1	48.97	8.24	492	98.4	475	96.5	49.64	7.82
CYCLE 3 DAY 1	n/a	487	97.4	471	96.7	50.02	8.11	486	97.2	471	96.9	50.32	7.88
CYCLE 5 DAY 1	n/a	482	96.4	462	95.9	50.43	8.07	477	95.4	458	96.0	50.09	8.56
TREATMENT COMPLETION	n/a	469	93.8	448	95.5	52.13	7.56	458	91.6	426	93.0	52.44	7.03
FOLLOW-UP MONTH 6	n/a	398	79.6	346	86.9	52.89	7.64	386	77.2	326	84.5	52.64	6.81
FOLLOW-UP MONTH 12	n/a	373	74.6	323	86.6	52.65	7.47	338	67.6	280	82.8	52.46	7.09
FOLLOW-UP MONTH 18	n/a	343	68.6	310	90.4	52.95	7.26	308	61.6	273	88.6	52.65	7.78
FOLLOW-UP MONTH 24	n/a	318	63.6	284	89.3	53.13	7.17	284	56.8	255	89.8	52.78	7.72
FOLLOW-UP MONTH 36	n/a	123	24.6	94	76.4	52.89	8.27	105	21.0	66	62.9	52.53	6.81
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	0	NE	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the table.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_PLYMS_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:54

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: FACT-LYM Subscale
STUDY: GO39942
Line Plot of Mean by Visit

FACT-LYM: Lymphoma subscale (LYMS)



Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the plot.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..a_analysis/ACE_FINAL_OS/prod/output/g_mean_plot_PLYMS_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 21:00

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: FACT-LYM: Deterioration (MID=9) at EOT in Lymphoma subscale (LYMS)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP																R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	428	85.6	10	2.3	400	80.0	13	3.3	0.72		Convergence criterion (GCONV=1E-8) satisfied.	0.31	1.66	-0.009		Algorithm converged.	-0.032	0.014	0.72		Algorithm converged.	0.32	1.63	0.4423	1.38		Algorithm converged.	0.61	3.11

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Only Patients with a value at Baseline and EOT are included in analysis.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_DPLYMSET_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:03

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: FACT-LYM: Deterioration (MID=9) at EOT in Lymphoma subscale (LYMS)
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														Relative Risk					
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference										Relative Risk					
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk D	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	Interaction Test p-value (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	438	87.6	66	13.2	468	93.6	33	6.6	2.1	0.73	Convergence criterion (GCONV=1E-8) satisfied.	0.85	5.45	-0.019	Algorithm converged.	-0.043	0.005	0.79	Algorithm converged.	0.53	1.16			0.4240	Algorithm converged.	0.86	5.14
Sex	Male	229	87.7	4	1.8	215	93.5	9	4.2	0.42																			
	Female	209	86.4	8	3.8	183	92.9	4	2.2	1.78	Convergence criterion (GCONV=1E-8) satisfied.	0.58	4.94	0.024	Algorithm converged.	-0.023	0.058	1.27	Algorithm converged.	0.93	4.71			0.6247	Algorithm converged.	0.91	3.49
Age	<= 60	147	29.4	1	0.7	169	33.8	7	1.4	0.43	Convergence criterion (GCONV=1E-8) satisfied.	0.04	4.64	-0.009	Algorithm converged.	-0.034	0.016	0.49	Algorithm converged.	0.05	4.79			0.4879	0.4628	0.49	24.64
	> 60	381	76.2	5	1.3	371	74.2	12	3.2	0.78	Convergence criterion (GCONV=1E-8) satisfied.	0.30	1.93	-0.009	Algorithm converged.	-0.040	0.023	0.75	Algorithm converged.	0.33	1.67			0.5908		0.67	3.03
Geographic region	Western Europe/United States/Canada/Australia	236	88.1	7	2.1	227	84.7	9	2.7	0.79	Convergence criterion (GCONV=1E-8) satisfied.	0.30	2.02	-0.006	Algorithm converged.	-0.036	0.025	0.79	Algorithm converged.	0.32	1.96			0.6434	0.5855	0.80	4.00
	Asia	130	72.6	7	3.8	158	87.8	8	4.7	0.47	Convergence criterion (GCONV=1E-8) satisfied.	0.15	1.52	-0.054	Algorithm converged.	-0.153	0.045	0.48	Algorithm converged.	0.16	1.46			0.2427		0.50	1.69
	Rest of World	72	100.0	2	2.8	83	100.0	3	3.6	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.17	22.54	0.014	Algorithm converged.	-0.044	0.092	1.39	Algorithm converged.	0.14	20.56			0.5847		0.93	5.64
Race/ethnicity	White	140	38.1	7	2.5	467	94.6	7	2.7	0.92	Convergence criterion (GCONV=1E-8) satisfied.	0.34	3.03	-0.003	Algorithm converged.	-0.043	0.035	0.93	Algorithm converged.	0.27	3.16			0.8939	0.7647	1.00	3.75
	Black or African American	1	1.4	0	0.0	1	0.8	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE			NE		NE	NE
	Asian	130	73.4	7	3.8	158	87.8	8	4.7	0.47	Convergence criterion (GCONV=1E-8) satisfied.	0.15	1.52	-0.054	Algorithm converged.	-0.153	0.045	0.48	Algorithm converged.	0.16	1.46			0.2427		0.50	1.69
	Other	7	77.8	0	0.0	8	88.9	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	NE					0.4140		>999.99	NE
	Unknown	60	14.3	2	2.5	75	14.0	1	1.4	1.79	Convergence criterion (GCONV=1E-8) satisfied.	0.16	20.03	0.014	Algorithm converged.	-0.033	0.061	1.70	Algorithm converged.	0.16	19.16			0.4329		0.93	6.66
ECOG performance status	0-1	366	73.4	6	2.5	385	68.8	12	3.5	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.24	1.67	-0.016	Algorithm converged.	-0.053	0.016	0.70	Algorithm converged.	0.30	1.66			0.4248	0.8645	1.83	3.73
	2	69	12.9	4	5.6	56	11.0	1	1.8	0.30	Convergence criterion (GCONV=1E-8) satisfied.	0.04	14.79	-0.060	Algorithm converged.	-0.248	0.045	0.30	Algorithm converged.	0.04	14.40			0.3459		0.07	17.63
	Missing	3	5.6	0	0.0	3	9.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE			NE		NE	NE
Cell of origin (determined by gene expression)	ABC	122	24.4	8	3.3	117	23.4	3	1.7	1.87	Convergence criterion (GCONV=1E-8) satisfied.	0.39	10.04	0.014	Algorithm converged.	-0.024	0.054	1.93	Algorithm converged.	0.34	10.34			0.4103	0.4071	0.93	2.73
	GCB	160	32.0	4	2.5	153	30.6	2	1.3	0.43	Convergence criterion (GCONV=1E-8) satisfied.	0.07	2.23	-0.016	Algorithm converged.	-0.044	0.009	0.43	Algorithm converged.	0.10	2.20			0.4688		1.58	5.44
	Unclassified	46	9.2	1	2.2	32	10.0	3	5.9	0.36	Convergence criterion (GCONV=1E-8) satisfied.	0.04	3.54	-0.037	Algorithm converged.	-0.114	0.040	0.37	Algorithm converged.	0.04	3.43			0.3410		2.71	25.12
	Unknown	101	20.2	3	3.0	89	16.0	2	2.3	0.99	Convergence criterion (GCONV=1E-8) satisfied.	0.09	4.58	-0.015	Algorithm converged.	-0.094	0.064	0.89	Algorithm converged.	0.08	4.09			0.4307		0.93	27.82
IPI score at Screening	1-2	166	32.6	4	2.4	164	32.8	5	3.0	0.80	Convergence criterion (GCONV=1E-8) satisfied.	0.21	3.01	-0.006	Algorithm converged.	-0.061	0.028	0.80	Algorithm converged.	0.22	2.93			0.7257	0.7123	1.23	4.57
	3	173	34.3	4	2.3	167	33.4	6	3.4	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.24	3.01	-0.004	Algorithm converged.	-0.043	0.026	0.84	Algorithm converged.	0.23	2.91			0.8081		1.24	3.84
	4-5	93	18.3	7	7.5	87	17.3	3	3.4	2.21	Convergence criterion (GCONV=1E-8) satisfied.	0.61	7.93	0.023	Algorithm converged.	-0.046	0.092	2.32	Algorithm converged.	0.03	7.01			0.2004		2.13	22.93
Baseline Bulky Disease	Present	172	34.4	5	1.7	162	32.4	4	2.5	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.19	3.18	-0.027	Algorithm converged.	-0.098	0.024	0.72	Algorithm converged.	0.19	3.11			0.4446	0.9734	1.42	4.23
	Absent	266	53.2	7	2.7	306	67.6	8	3.0	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.24	1.97	-0.015	Algorithm converged.	-0.062	0.031	0.70	Algorithm converged.	0.27	1.93			0.5137		0.92	3.47
Double Expressor Lymphoma by IHC (Central Review)	DEL	128	25.6	6	4.7	120	24.0	3	1.5	3.17	Convergence criterion (GCONV=1E-8) satisfied.	0.83	14.01	0.030	Algorithm converged.	-0.031	0.074	3.07	Algorithm converged.	0.43	14.93			0.1495	0.0446	0.33	1.64
	Non DEL	220	44.0	4	1.8	253	50.6	10	3.9	0.45	Convergence criterion (GCONV=1E-8) satisfied.	0.13	1.51	-0.021	Algorithm converged.	-0.053	0.011	0.46	Algorithm converged.	0.14	1.52			0.1842		0.47	1.53
	Unknown	70	15.1	0	0.0	69	13.2	3	4.5	*	Quasi-complete separation of data points detected.	*	*	*	ERROR: Error in computing the link function, its derivatives, or the variance function.			0.00	NE					0.0578		>999.99	NE
Double/Triple-Hit Lymphoma (Central Review)	DE/TE-	294	58.8	10	3.4	290	58.0	7	2.4	1.42	Convergence criterion (GCONV=1E-8) satisfied.	0.53	3.79	0.014	Algorithm converged.	-0.027	0.057	1.41	Algorithm converged.	0.53	3.69			0.4728	0.1418	0.77	1.84
	DE/TE+	30	6.0	0	0.0	34	7.0	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	NE					0.2300		>999.99	NE
	Unknown	114	22.8	0	0.0	94	18.8	4	5.3	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: The relative Hessian convergence criterion of 5.6259681493 is greater than the limit of 0.0001. The convergence is questionable.			0.00	NE					0.0141		>999.99	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Only Patients with a value at Baseline and EOT are included in analysis.
ETTU is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_sgl_DPLYMSBY_ITT_POOLED_15JUN2022_39942.xls
09FEB2023 20:10

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: PACT-LYM: Deterioration (WIDOW) at FU Month 24 in Lymphoma subscale (LYMS)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (Pola01)				R-CHOP (Ref001)				Odds Ratio				Polatuzumab Vedotin + R-CHP vs. R-CHOP										R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event						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 (Cochran-Mantel-Haenszel)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	270	54.0	[redacted]	[redacted]	240	48.0	[redacted]	[redacted]	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.87	1.93	[redacted]	WARNING: The relative Hessian convergence criterion of 1.0217947894 is greater than the limit of 0.0001. The convergence is questionable.	[redacted]	[redacted]	[redacted]	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	[redacted]	[redacted]	[redacted]	[redacted]	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	[redacted]	[redacted]

* indicates convergence problem. Result is uninterpretable.
CR is computed by stratified analysis, MH and AND by adjusted analysis
Only Patients with a value at Baseline and Follow-up Month 24 are included in analysis.
ETT1 is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO554107/CSPT788/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/BO554107/CSPT788/GO39942/data_analysis/ACE_FINAL_CS/prod/output/t_eff_resp_ety_DPLYMXFU_IT_FOOLME_15JUN2022_39942.rtf
09FEB2023 20:06

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: FACT-LYM: Deterioration (MID=9) at FU Month 24 in Lymphoma subscale (LYMS)
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

| | | Polatuzumab Vedotin + R-CHP (N=500) | | | | R-CHOP (N=500) | | | | Polatuzumab Vedotin + R-CHP vs. R-CHOP | | | |

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale
ENDPOINT: FACT-LYM Subscale
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in FACT-LYM Subscale (Analysis of MMRM)

FACT-LYM: Lymphoma subscale (LYMS)

			Polatuzumab Vedotin + R-CHP (N=464)					R-CHOP (N=463)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)				
			N			Statistics		N			Statistics		Statistics				
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	464	464	0	NE	NE	463	463	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale	adjusted
Cycle 2 Day 1	All	n/a	463	463	453	3.38	0.31	457	457	447	3.98	0.31	-0.60	0.40	-1.39	0.19	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale	adjusted
Cycle 3 Day 1	All	n/a	460	460	451	4.43	0.34	448	448	439	4.38	0.34	0.06	0.45	-0.83	0.94	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale	adjusted
Cycle 5 Day 1	All	n/a	452	452	435	4.51	0.36	431	431	421	4.25	0.37	0.25	0.48	-0.69	1.20	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale	adjusted
Treatment Comp Or Early Discon	All	n/a	452	452	433	6.51	0.35	452	452	418	6.07	0.35	0.43	0.46	-0.47	1.34	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale	adjusted
Follow-Up Month 6	All	n/a	378	378	329	7.07	0.35	364	364	311	6.76	0.35	0.31	0.46	-0.59	1.21	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale	adjusted
Follow-Up Month 12	All	n/a	354	354	309	6.96	0.37	320	320	266	6.89	0.39	0.07	0.51	-0.93	1.07	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale	adjusted
Follow-Up Month 18	All	n/a	325	325	294	7.36	0.39	290	290	260	6.98	0.40	0.38	0.53	-0.66	1.41	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale	adjusted
Follow-Up Month 24	All	n/a	302	302	270	7.42	0.39	267	267	242	7.29	0.40	0.14	0.53	-0.90	1.18	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale	adjusted
Follow-Up Month 36	All	n/a	119	119	90	6.78	0.58	96	96	63	7.28	0.67	-0.50	0.87	-2.21	1.21	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale	adjusted
Follow-Up Month 48	All	n/a	0	0	0	NE	NE	1	1	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for FACT-Lymphoma Subscale	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits)
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_PLYMS_FACTLpop_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:47

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EQ-5D-5L HEALTH STATE (VAS)
MODEL: descriptive
STUDY: GO39942
Compliance/Mean

EQ-5D-5L: Your Health Today (VAS)

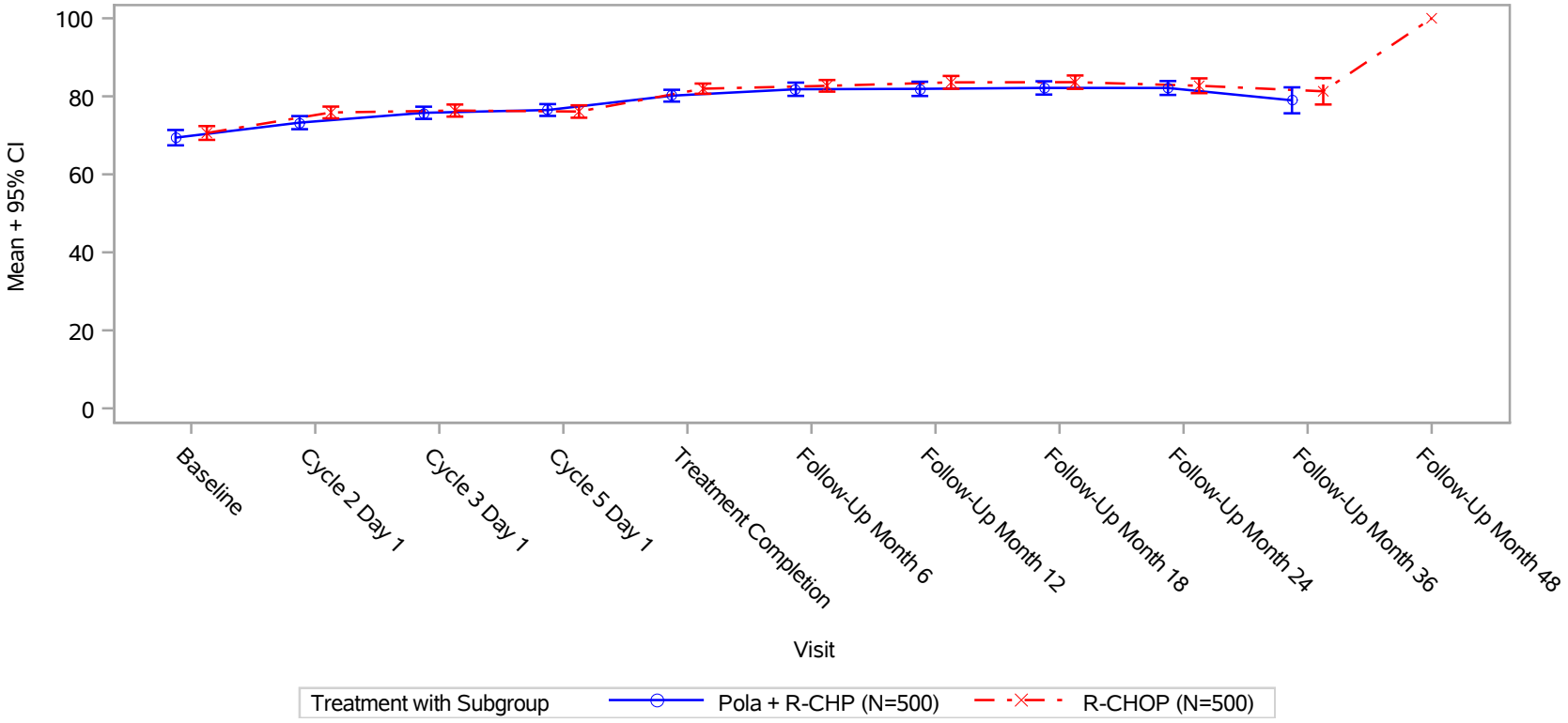
		Polatuzumab Vedotin + R-CHP (N=500)						R-CHOP (N=500)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	Mean[2]	SD(Mean)	in study[1]	%	with value[1]	%	Mean[2]	SD(Mean)
All													
BASELINE	n/a	500	100.0	463	92.6	69.40	21.53	500	100.0	465	93.0	70.60	19.40
CYCLE 2 DAY 1	n/a	491	98.2	466	94.9	73.25	18.48	492	98.4	470	95.5	75.85	16.63
CYCLE 3 DAY 1	n/a	487	97.4	467	95.9	75.77	17.17	486	97.2	466	95.9	76.34	17.01
CYCLE 5 DAY 1	n/a	482	96.4	456	94.6	76.48	16.46	477	95.4	455	95.4	76.10	17.26
TREATMENT COMPLETION	n/a	469	93.8	445	94.9	80.16	16.22	458	91.6	421	91.9	81.95	13.70
FOLLOW-UP MONTH 6	n/a	398	79.6	333	83.7	81.81	15.81	386	77.2	318	82.4	82.69	13.50
FOLLOW-UP MONTH 12	n/a	373	74.6	310	83.1	81.91	16.34	338	67.6	272	80.5	83.58	13.77
FOLLOW-UP MONTH 18	n/a	343	68.6	304	88.6	82.15	15.09	308	61.6	265	86.0	83.62	14.18
FOLLOW-UP MONTH 24	n/a	318	63.6	273	85.8	82.13	14.94	284	56.8	251	88.4	82.70	15.22
FOLLOW-UP MONTH 36	n/a	123	24.6	104	84.6	78.97	17.10	105	21.0	77	73.3	81.29	14.93
FOLLOW-UP MONTH 48	n/a	0	NE	0	NE	NE	NE	1	0.2	1	100.0	100.00	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
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
Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the table.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_mean_EQ5DVAS_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:57

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EQ-5D-5L HEALTH STATE (VAS)
STUDY: GO39942
Line Plot of Mean by Visit

EQ-5D-5L: Your Health Today (VAS)



Baseline is defined as the last assessment prior to the first dose of study treatment. Only scheduled assessments are included in the plot.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: ..ies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/g_mean_plot.sas
Output: ..analysis/ACE_FINAL_OS/prod/output/g_mean_plot_EQ5DVAS_IT_POOLED_15JUN2022_39942.pdf
09FEB2023 21:02

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EQ-5D-5L: Deterioration (MID=15) at EOT in Health State (VAS)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP																R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	421	84.2	37	8.8	395	79.0	32	8.1	1.09		Convergence criterion (GCONV=1E-8) satisfied.	0.66	1.79	-0.001		Algorithm converged.	-0.041	0.039	1.09		Algorithm converged.	0.69	1.71	0.7312	0.92		Algorithm converged.	0.59	1.44

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Only Patients with a value at Baseline and EOT are included in analysis.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_DEQVASET_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:31

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EQ-5D-5L Deterioration (MID=15) at EOT in Health State (VAS)
MODEL: Unstratified Analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=550)				R-CHOP (N=550)				Polatuzumab Vedotin + R-CHP vs. R-CHOP												R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	421	84.2	37	8.8	395	79.0	32	8.1	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.67	1.79	0.007	Algorithm converged.	-0.031	0.045	1.04	Algorithm converged.	0.69	1.71	0.7245		0.92	Algorithm converged.	0.59	1.45
Sex	Male	223	44.6	16	7.2	213	42.6	20	9.4	0.75	Convergence criterion (GCONV=1E-8) satisfied.	0.38	1.48	-0.022	Algorithm converged.	-0.074	0.030	0.74	Algorithm converged.	0.41	1.43	0.4015	0.1114	1.31	Algorithm converged.	0.70	2.46
	Female	198	39.6	21	10.6	182	36.4	12	6.6	1.68	Convergence criterion (GCONV=1E-8) satisfied.	0.83	3.52	0.040	Algorithm converged.	-0.016	0.096	1.61	Algorithm converged.	0.81	3.18	0.1658		0.62	Algorithm converged.	0.31	1.23
Age	>= 60	146	29.2	10	6.8	126	25.2	7	5.6	1.25	Convergence criterion (GCONV=1E-8) satisfied.	0.46	3.39	0.013	Algorithm converged.	-0.044	0.070	1.23	Algorithm converged.	0.48	3.14	0.6604	0.7768	0.91	Algorithm converged.	0.32	2.57
	> 60	275	55.0	27	9.8	269	53.8	25	9.3	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.60	1.88	0.005	Algorithm converged.	-0.044	0.055	1.06	Algorithm converged.	0.63	1.77	0.8354		0.95	Algorithm converged.	0.56	1.59
Geographic region	Western Europe/United States/Canada/Australia	238	47.6	10	7.1	221	44.2	22	10.0	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.30	1.35	-0.028	Algorithm converged.	-0.079	0.023	0.72	Algorithm converged.	0.39	1.32	0.2805	0.1195	1.30	Algorithm converged.	0.76	2.56
	Asia	131	26.2	10	9.2	124	24.8	6	4.8	1.88	Convergence criterion (GCONV=1E-8) satisfied.	0.72	5.46	0.043	Algorithm converged.	-0.019	0.105	1.89	Algorithm converged.	0.73	4.89	0.1790		0.53	Algorithm converged.	0.20	1.34
	Rest of World	52	10.4	8	15.4	50	10.0	4	8.0	2.09	Convergence criterion (GCONV=1E-8) satisfied.	0.59	7.44	0.074	Algorithm converged.	-0.050	0.197	1.92	Algorithm converged.	0.62	5.99	0.2495		0.53	Algorithm converged.	0.13	1.62
Race/ethnicity	White	194	38.8	16	8.2	182	36.4	15	8.2	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.48	2.09	0.000	Algorithm converged.	-0.056	0.056	1.00	Algorithm converged.	0.51	1.96	0.9984	0.4744	1.00	Algorithm converged.	0.52	1.91
	Black or African American	7	1.4	2	28.6	4	0.8	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	0.2598		NE	Algorithm converged.	NE	NE
	Asian	130	27.0	10	8.9	128	25.6	7	5.5	1.69	Convergence criterion (GCONV=1E-8) satisfied.	0.64	4.43	0.036	Algorithm converged.	-0.028	0.098	1.63	Algorithm converged.	0.66	4.00	0.2853		0.62	Algorithm converged.	0.25	1.54
	Other	5	1.0	1	20.0	9	1.8	1	11.1	2.58	Convergence criterion (GCONV=1E-8) satisfied.	0.30	41.05	0.089	Algorithm converged.	-0.317	0.495	1.89	Algorithm converged.	0.14	22.99	0.6608		0.58	Algorithm converged.	0.04	7.09
	Unknown	80	16.0	6	7.5	72	14.4	9	12.5	0.57	Convergence criterion (GCONV=1E-8) satisfied.	0.19	1.68	-0.050	Algorithm converged.	-0.146	0.046	0.60	Algorithm converged.	0.22	1.60	0.3034		1.47	Algorithm converged.	0.62	4.45
ECOG performance status	0-1	358	71.6	30	8.4	342	68.4	27	7.9	1.07	Convergence criterion (GCONV=1E-8) satisfied.	0.62	1.84	0.005	Algorithm converged.	-0.036	0.045	1.06	Algorithm converged.	0.64	1.75	0.8146	0.8891	0.94	Algorithm converged.	0.57	1.54
	2	63	12.6	7	11.1	52	10.4	5	9.6	1.17	Convergence criterion (GCONV=1E-8) satisfied.	0.32	3.95	0.015	Algorithm converged.	-0.097	0.127	1.12	Algorithm converged.	0.39	3.43	0.7440		0.87	Algorithm converged.	0.22	2.51
	Missing	0	0.0	0	0.0	1	0.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cell of origin (determined by gene expression)	ABC	113	22.6	10	10.6	114	22.8	11	9.6	1.13	Convergence criterion (GCONV=1E-8) satisfied.	0.47	2.64	0.010	Algorithm converged.	-0.069	0.088	1.16	Algorithm converged.	0.51	2.39	0.8090	0.1870	0.91	Algorithm converged.	0.42	1.97
	GCB	162	32.4	8	5.6	150	30.0	14	9.3	0.57	Convergence criterion (GCONV=1E-8) satisfied.	0.24	1.36	-0.038	Algorithm converged.	-0.096	0.021	0.60	Algorithm converged.	0.27	1.33	0.2027		1.48	Algorithm converged.	0.75	3.73
	Unclassified	47	9.4	5	10.8	51	10.2	2	3.9	2.80	Convergence criterion (GCONV=1E-8) satisfied.	0.56	15.82	0.067	Algorithm converged.	-0.036	0.170	2.77	Algorithm converged.	0.55	13.92	0.1994		0.37	Algorithm converged.	0.08	1.84
	Unknown	99	19.8	11	11.1	80	16.0	5	6.3	1.87	Convergence criterion (GCONV=1E-8) satisfied.	0.62	5.64	0.049	Algorithm converged.	-0.033	0.130	1.78	Algorithm converged.	0.64	4.91	0.2584		0.56	Algorithm converged.	0.20	1.52
IPI score at Screening	1-2	164	32.8	11	6.7	163	32.6	10	6.1	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.45	2.67	0.006	Algorithm converged.	-0.047	0.059	1.04	Algorithm converged.	0.48	2.50	0.8331	0.9647	0.92	Algorithm converged.	0.40	2.08
	3	166	33.2	15	9.0	145	29.0	13	9.0	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.48	2.20	0.001	Algorithm converged.	-0.063	0.064	1.01	Algorithm converged.	0.50	2.05	0.9827		0.99	Algorithm converged.	0.49	2.02
	4-5	91	18.2	11	12.1	87	17.4	9	10.3	1.19	Convergence criterion (GCONV=1E-8) satisfied.	0.47	3.03	0.017	Algorithm converged.	-0.075	0.110	1.17	Algorithm converged.	0.51	2.68	0.7138		0.86	Algorithm converged.	0.37	1.96
Baseline Bulky Disease	Present	166	33.2	8	4.8	158	31.6	13	8.2	0.48	Convergence criterion (GCONV=1E-8) satisfied.	0.20	1.17	-0.047	Algorithm converged.	-0.103	0.009	0.51	Algorithm converged.	0.22	1.16	0.1020	0.0230	1.97	Algorithm converged.	0.88	4.52
	Absent	255	51.0	29	11.4	237	47.4	17	7.2	1.66	Convergence criterion (GCONV=1E-8) satisfied.	0.89	3.11	0.042	Algorithm converged.	-0.009	0.093	1.53	Algorithm converged.	0.89	2.81	0.1102		0.63	Algorithm converged.	0.36	1.14
Double Expressor Lymphoma by IHC (Central Review)	DEL	124	24.8	9	7.3	130	26.0	10	7.7	0.96	Convergence criterion (GCONV=1E-8) satisfied.	0.37	2.39	-0.004	Algorithm converged.	-0.069	0.060	0.94	Algorithm converged.	0.40	2.24	0.8956	0.9706	1.06	Algorithm converged.	0.45	2.52
	Non DEL	220	44.0	18	8.2	200	40.0	17	8.5	0.96	Convergence criterion (GCONV=1E-8) satisfied.	0.48	1.92	-0.003	Algorithm converged.	-0.056	0.050	0.94	Algorithm converged.	0.51	1.82	0.9063		1.04	Algorithm converged.	0.55	1.96
	Unknown	77	15.4	10	13.0	65	13.0	5	7.7	1.79	Convergence criterion (GCONV=1E-8) satisfied.	0.58	5.54	0.053	Algorithm converged.	-0.046	0.152	1.69	Algorithm converged.	0.61	4.69	0.3082		0.59	Algorithm converged.	0.22	1.65
Double/Triple-Hit Lymphoma (Central Review)	DH/TH-	290	58.0	27	9.3	290	58.0	23	7.9	1.19	Convergence criterion (GCONV=1E-8) satisfied.	0.67	2.13	0.014	Algorithm converged.	-0.032	0.059	1.17	Algorithm converged.	0.69	2.00	0.5543	0.1554	0.85	Algorithm converged.	0.50	1.46
	DH/TH+	22	4.4	1	0.0	15	3.0	1	6.7	*	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	0.2259		>999.99	Algorithm converged.	0.00	NE
	Unknown	109	21.8	10	9.2	95	18.0	8	8.4	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.38	2.74	0.003	Algorithm converged.	-0.077	0.083	1.03	Algorithm converged.	0.43	2.53	0.9444		0.97	Algorithm converged.	0.49	2.35

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Only Patients with a value at Baseline and EOT are included in analysis.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO55410?7/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/BO55410?7/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_sgl_DEQVASET_ITT_POOLED_15JUN2022_39942.xls
09FEB2023 20:37

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EQ-5D-5L: Deterioration (MID=15) at FU Month 24 in Health State (VAS)
MODEL: Stratified Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Dichotomous Analysis (Efficacy)

		Polatuzumab Vedotin + R-CHP (N=500)				R-CHOP (N=500)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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 (Cochran-Mantel-Haenszel)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	254	50.8	27	10.6	237	47.4	10	4.2	2.66		Convergence criterion (GCONV=1E-8) satisfied.	1.26	5.62		*	WARNING: The relative Hessian convergence criterion of 0.0763004843 is greater than the limit of 0.0001. The convergence is questionable.			2.56		Algorithm converged.	1.27	5.17	0.0080	0.39		Algorithm converged.	0.19	0.79

* indicates convergence problem. Result is uninterpretable.
OR is computed by stratified analysis, RR and ARD by adjusted analysis
Only Patients with a value at Baseline and Follow-up Month 24 are included in analysis.
ETTV is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_eff_resp.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_eff_resp_str_DEQVASFU_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:33

POPULATION: Global and China Extension Population, Intent-To-Treat Population
ENDPOINT: EQ-5D-5L: Determination (MCID=0.05) at FU Month 24 in Health State (VAS)
MODEL: Unstratified Analysis
SUBSET: ADSUBS2
Dichotomous Analysis by Subgroups (Efficacy)

		Relationship Tablets + Acupat (Q=300)				Acupat (Q=300)				Relationship Tablets + Acupat vs. Acupat										Acupat vs. Relationship Tablets + Acupat			
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk							
Name	Level	N	%	n	%	N	%	n	%	Odds Ratio	Convergence Message	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Message	95% Lower CL	95% Upper CL	Relative Risk	Convergence Message	Interaction Test p-value (Likelihood-Ratio)	Interaction Test p-value (Likelihood-Wald)	Relative Risk	Convergence Message	95% Lower CL	95% Upper CL
All	Yes	250	50.8	33	13.2	247	47.4	12	4.9	2.93	Convergence criterion (GCONV=1E-6) satisfied.	0.69	5.71	0.082	Algorithm converged.	0.033	0.132	2.69	Algorithm converged.			2.69	Algorithm converged.	1.46	4.95
Sex	Male	127	50.8	16	12.6	131	51.2	5	3.8	3.63	Convergence criterion (GCONV=1E-6) satisfied.	0.93	13.65	0.088	Algorithm converged.	0.035	0.140	3.33	Algorithm converged.		0.0519	3.33	Algorithm converged.	1.46	7.59
	Female	123	52.0	17	13.8	116	52.2	7	6.0	2.68	Convergence criterion (GCONV=1E-6) satisfied.	0.82	8.67	0.078	Algorithm converged.	0.031	0.126	2.24	Algorithm converged.			2.24	Algorithm converged.	1.03	7.03
Age	18-39	59	49.2	10	16.9	58	44.8	4	6.9	3.04	Convergence criterion (GCONV=1E-6) satisfied.	0.65	8.67	0.081	Algorithm converged.	-0.045	0.192	3.19	Algorithm converged.		0.0625	3.19	Algorithm converged.	0.92	7.76
	40-60	191	54.5	23	12.0	189	52.9	8	4.2	2.87	Convergence criterion (GCONV=1E-6) satisfied.	0.93	8.93	0.083	Algorithm converged.	0.033	0.134	2.72	Algorithm converged.		0.0519	2.72	Algorithm converged.	1.32	5.61
Geographic region	Western Europe/United States/Canada/Australia	150	50.0	33	22.0	150	50.0	12	8.0	3.14	Convergence criterion (GCONV=1E-6) satisfied.	1.57	6.27	0.120	Algorithm converged.	-0.026	0.265	2.75	Algorithm converged.		0.1106	2.75	Algorithm converged.	1.46	5.18
	Asia	100	51.0	0	0.0	97	50.5	0	0.0	0.00	Convergence criterion (GCONV=1E-6) satisfied.	0.00	76.83	0.010	Algorithm converged.	-0.044	0.227	0.00	Algorithm converged.			0.00	Algorithm converged.	0.00	0.00
	Rest of World	0	0.0	0	0.0	0	0.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Fekete-Szwayer criterion of 2.765/3871911 is greater than the limit of 0.0001. The convergence is questionable.							0.0	0.0			0.0	0.0
Race/ethnicity	White	229	50.8	30	13.1	226	50.2	9	3.9	3.47	Convergence criterion (GCONV=1E-6) satisfied.	1.53	8.17	0.093	Algorithm converged.	0.039	0.146	3.33	Algorithm converged.		0.0519	3.33	Algorithm converged.	1.69	6.56
	Black or African American	0	0.0	0	0.0	0	0.0	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
	Other	21	53.8	3	14.3	21	53.8	3	14.3	6.43	Convergence criterion (GCONV=1E-6) satisfied.	0.96	22.33	0.231	Algorithm converged.	0.019	0.309	6.12	Algorithm converged.		0.0625	6.12	Algorithm converged.	0.29	5.04
	Trans	0	0.0	0	100.0	0	0.0	0	0.0		Complete separation of data points detected.				WARNING: Error in computing the link function, its derivatives, or the variance function.				WARNING: The mean parameter is either invalid or at a limit of its range for some observations.				WARNING: The mean parameter is either invalid or at a limit of its range for some observations.		
	Unknown	0	50.8	0	0.0	0	50.2	0	0.0	0.00	Convergence criterion (GCONV=1E-6) satisfied.	0.00	0.00	<0.001	Algorithm converged.	<0.001	0.000	0.00	Algorithm converged.		0.0519	0.00	Algorithm converged.	0.00	0.00
ECOG performance status	0-1	217	49.9	27	11.7	217	49.9	9	3.9	3.43	Convergence criterion (GCONV=1E-6) satisfied.	1.65	13.17	0.088	Algorithm converged.	0.037	0.139	3.37	Algorithm converged.		0.0519	3.37	Algorithm converged.	1.69	6.70
	2	33	51.6	6	18.2	30	46.9	3	9.4	2.03	Convergence criterion (GCONV=1E-6) satisfied.	0.61	7.23	<0.001	Algorithm converged.	-0.113	0.060	1.93	Algorithm converged.		0.1611	1.93	Algorithm converged.	0.61	7.11
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE
Cell of origin (determined by gene expression)	GBC	71	52.2	8	9.9	69	51.9	3	3.7	2.91	Convergence criterion (GCONV=1E-6) satisfied.	0.69	9.11	0.063	Algorithm converged.	-0.041	0.167	1.91	Algorithm converged.		0.1519	1.91	Algorithm converged.	0.52	1.78
	ABC	102	50.0	16	9.8	97	50.0	3	3.1	3.23	Convergence criterion (GCONV=1E-6) satisfied.	0.91	12.57	0.067	Algorithm converged.	0.023	0.154	3.13	Algorithm converged.		0.0519	3.13	Algorithm converged.	0.92	7.11
	Unclassified	77	51.9	11	17.1	81	51.9	3	3.7	4.69	Convergence criterion (GCONV=1E-6) satisfied.	1.33	20.67	0.134	Algorithm converged.	-0.017	0.218	4.62	Algorithm converged.		0.0519	4.62	Algorithm converged.	1.33	16.01
	Unknown	0	51.9	0	0.0	0	0.0	0	0.0	0.00	Convergence criterion (GCONV=1E-6) satisfied.	0.00	60.47	0.000	Algorithm converged.	-0.013	0.173	0.00	Algorithm converged.		0.0519	0.00	Algorithm converged.	0.00	1.84
IPI score at Screening	Low	103	50.8	12	11.7	99	50.3	4	4.0	2.93	Convergence criterion (GCONV=1E-6) satisfied.	0.82	8.39	0.076	Algorithm converged.	-0.039	0.191	2.69	Algorithm converged.		0.0519	2.69	Algorithm converged.	0.88	5.23
	Int	104	51.0	15	14.4	104	51.0	4	3.8	4.04	Convergence criterion (GCONV=1E-6) satisfied.	1.12	14.58	0.104	Algorithm converged.	0.020	0.188	3.87	Algorithm converged.		0.0519	3.87	Algorithm converged.	1.32	11.35
	High	43	51.2	6	14.0	44	51.2	3	7.0	2.03	Convergence criterion (GCONV=1E-6) satisfied.	0.53	7.80	0.069	Algorithm converged.	-0.045	0.183	2.00	Algorithm converged.		0.1611	2.00	Algorithm converged.	0.53	7.55
Baseline Bulky Disease	Present	118	50.0	16	13.6	118	50.0	4	3.4	3.97	Convergence criterion (GCONV=1E-6) satisfied.	1.32	11.92	0.102	Algorithm converged.	-0.016	0.220	3.77	Algorithm converged.		0.0625	3.77	Algorithm converged.	1.32	10.78
	Absent	132	51.9	17	12.9	129	51.9	4	3.1	3.92	Convergence criterion (GCONV=1E-6) satisfied.	1.32	11.63	0.098	Algorithm converged.	0.019	0.180	3.59	Algorithm converged.		0.0519	3.59	Algorithm converged.	1.32	9.76
Double Expressor Lymphoma by IHC (Cheiron Review)	DEL	73	50.8	7	9.6	71	50.4	2	2.8	3.51	Convergence criterion (GCONV=1E-6) satisfied.	0.73	16.87	0.069	Algorithm converged.	-0.041	0.180	3.43	Algorithm converged.		0.1611	3.43	Algorithm converged.	0.79	14.93
	Non DEL	177	50.9	26	14.7	176	50.9	6	3.4	4.69	Convergence criterion (GCONV=1E-6) satisfied.	1.91	19.45	0.118	Algorithm converged.	0.045	0.191	4.31	Algorithm converged.		0.0625	4.31	Algorithm converged.	1.91	9.74
	Unknown	0	0.0	0	0.0	0	0.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Error in computing the link function, its derivatives, or the variance function.										
Double/Triple-Hit Lymphoma (Clinical Review)	DH/TH+	113	50.9	16	14.2	113	50.9	4	3.5	4.29	Convergence criterion (GCONV=1E-6) satisfied.	1.23	15.89	0.107	Algorithm converged.	0.037	0.210	3.99	Algorithm converged.		0.0625	3.99	Algorithm converged.	1.46	10.93
	DH/TH-	137	51.1	17	12.4	134	51.1	4	3.0	3.92	Convergence criterion (GCONV=1E-6) satisfied.	1.32	11.63	0.098	Algorithm converged.	0.019	0.180	3.59	Algorithm converged.		0.0519	3.59	Algorithm converged.	1.32	9.76
	Unknown	0	51.1	0	0.0	0	51.1	0	0.0	0.00	Quasi-complete separation of data points detected.	0.00	16.87	0.000	WARNING: Error in computing the link function, its derivatives, or the variance function.	-0.036	0.178	0.00	Algorithm converged.		0.0519	0.00	Algorithm converged.	0.00	1.84

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Only Patients with a value at Baseline and Follow-up Month 24 are included in analysis.
ETT= is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/MOUNTAIN777/CSPT7882/SS39842/data_analysis/ADE_BASE/prod/program/t_efficacy.sas
Output: root/clinical_studies/MOUNTAIN777/CSPT7882/SS39842/data_analysis/ADE_FINAL_OS/prod/output/t_efficacy_eq5_VAS24FU_ITT_POOLED_15JUN2022_09842.ale
08FEB2023 20:09

POPULATION: Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EQ-5D-5L (VAS)
ENDPOINT: EQ-5D-5L HEALTH STATE (VAS)
MODEL: Adjusted Analysis by IPI score, Bulky disease, Geographical region
STUDY: GO39942
Change from Baseline in EQ-5D-5L HEALTH STATE (VAS) (Analysis of MMRM)

EQ-5D-5L: Your Health Today (VAS)

			Polatuzumab Vedotin + R-CHP (N=458)					R-CHOP (N=464)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All	n/a	458	458	0	NE	NE	464	464	0	NE	NE	NE	NE	NE	NE	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EQ-5D-5L (VAS)	adjusted
Cycle 2 Day 1	All	n/a	457	457	438	3.25	0.73	457	457	442	4.98	0.72	-1.73	0.94	-3.58	0.12	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EQ-5D-5L (VAS)	adjusted
Cycle 3 Day 1	All	n/a	454	454	441	5.58	0.76	448	448	435	5.24	0.76	0.34	0.99	-1.60	2.28	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EQ-5D-5L (VAS)	adjusted
Cycle 5 Day 1	All	n/a	446	446	423	6.03	0.79	431	431	417	5.46	0.79	0.57	1.04	-1.47	2.62	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EQ-5D-5L (VAS)	adjusted
Treatment Comp Or Early Discon	All	n/a	447	447	426	9.44	0.77	453	453	414	10.08	0.77	-0.64	1.01	-2.62	1.34	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EQ-5D-5L (VAS)	adjusted
Follow-Up Month 6	All	n/a	371	371	313	10.69	0.80	364	364	303	11.66	0.80	-0.98	1.05	-3.05	1.09	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EQ-5D-5L (VAS)	adjusted
Follow-Up Month 12	All	n/a	348	348	292	10.11	0.85	320	320	262	12.76	0.88	-2.64	1.15	-4.90	-0.39	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EQ-5D-5L (VAS)	adjusted
Follow-Up Month 18	All	n/a	319	319	284	11.05	0.83	290	290	251	12.63	0.85	-1.58	1.11	-3.76	0.60	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EQ-5D-5L (VAS)	adjusted
Follow-Up Month 24	All	n/a	296	296	254	10.91	0.86	267	267	237	12.21	0.87	-1.30	1.15	-3.55	0.95	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EQ-5D-5L (VAS)	adjusted
Follow-Up Month 36	All	n/a	115	115	98	9.13	1.18	97	97	72	11.35	1.31	-2.22	1.72	-5.60	1.16	Global and China Extension Population, Intent-To-Treat Population, PRO-Evaluable for EQ-5D-5L (VAS)	adjusted

[1] Patients with a value at baseline and a post-baseline value at the respective visit.
[2] LSMeans of change from baseline from MMRM (including all available records from all scheduled visits but visit FOLLOW-UP MONTH 48)
Visit FOLLOW-UP MONTH 48 including only one patient randomized to R-CHOP in study GO39942 caused a model estimation problem and was hence excluded. The excluded VAS score was 100.
[3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_BASE/prod/program/t_pro_mmrm2.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_pro_mmrm2_adj_EQ5DVAS_VASEVAL_IT_POOLED_15JUN2022_39942.xls
09FEB2023 20:51

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	485	98.0	498	100.0	491	98.6	0.69	Convergence criterion (GCONV=1E-8) satisfied.	0.26	1.83	-0.006	Algorithm converged.	-0.022	0.010	0.99	Algorithm converged.	0.98	1.01	0.4557		1.01	Algorithm converged.	0.99	1.02
Sex	Male	265	53.5	258	97.4	269	54.0	265	98.5	0.56	Convergence criterion (GCONV=1E-8) satisfied.	0.16	1.92	-0.012	Algorithm converged.	-0.036	0.013	0.99	Algorithm converged.	0.96	1.01	0.3491	0.4732	1.01	Algorithm converged.	0.99	1.04
	Female	230	46.5	227	98.7	229	46.0	226	98.7	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.20	5.03	0.000	Algorithm converged.	-0.021	0.021	1.00	Algorithm converged.	0.98	1.02	0.9957		1.00	Algorithm converged.	0.98	1.02
Age	<= 60	167	33.7	162	97.0	157	31.5	155	98.7	0.42	Convergence criterion (GCONV=1E-8) satisfied.	0.08	2.18	-0.017	Algorithm converged.	-0.048	0.014	0.98	Algorithm converged.	0.95	1.01	0.2821	0.3651	1.02	Algorithm converged.	0.99	1.05
	> 60	328	66.3	323	98.5	341	68.5	336	98.5	0.96	Convergence criterion (GCONV=1E-8) satisfied.	0.28	3.35	-0.001	Algorithm converged.	-0.019	0.018	1.00	Algorithm converged.	0.98	1.02	0.9508		1.00	Algorithm converged.	0.98	1.02
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	295	99.0	300	60.2	298	99.3	0.66	Convergence criterion (GCONV=1E-8) satisfied.	0.11	3.98	-0.003	Algorithm converged.	-0.018	0.011	1.00	Algorithm converged.	0.98	1.01	0.6482	0.7654	1.00	Algorithm converged.	0.99	1.02
	Asia	140	28.3	139	99.3	139	27.9	138	99.3	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.06	16.26	0.000	Algorithm converged.	-0.029	0.029	1.00	Algorithm converged.	0.98	1.02	0.9959		1.00	Algorithm converged.	0.98	1.02
	Rest of World	57	11.5	51	89.5	59	11.8	55	93.2	0.62	Convergence criterion (GCONV=1E-8) satisfied.	0.16	2.32	-0.037	Algorithm converged.	-0.140	0.065	0.96	Algorithm converged.	0.86	1.07	0.4749		1.04	Algorithm converged.	0.93	1.17
IPI score at Screening	1-2	187	37.8	183	97.9	187	37.6	185	98.9	0.49	Convergence criterion (GCONV=1E-8) satisfied.	0.09	2.73	-0.011	Algorithm converged.	-0.036	0.015	0.99	Algorithm converged.	0.96	1.02	0.4109	0.6184	1.01	Algorithm converged.	0.99	1.04
	3	196	39.6	191	97.4	186	37.3	183	98.4	0.63	Convergence criterion (GCONV=1E-8) satisfied.	0.15	2.66	-0.009	Algorithm converged.	-0.038	0.019	0.99	Algorithm converged.	0.96	1.02	0.5199		1.01	Algorithm converged.	0.98	1.04
	4-5	112	22.6	111	99.1	125	25.1	123	98.4	1.80	Convergence criterion (GCONV=1E-8) satisfied.	0.16	20.18	0.007	Algorithm converged.	-0.023	0.035	1.01	Algorithm converged.	0.98	1.04	0.6216		0.99	Algorithm converged.	0.97	1.02

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_AE_SE_POOLED_15JUN2022_39942.xls
08FEB2023 14:17

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 3-5
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	310	62.6	498	100.0	302	60.6	1.09	Convergence criterion (GCONV=1E-8) satisfied.	0.84	1.40	0.020	Algorithm converged.	-0.041	0.080	1.03	Algorithm converged.	0.94	1.14	0.5205		0.97	Algorithm converged.	0.88	1.07
Sex	Male	265	53.5	161	60.8	269	54.0	155	57.6	1.14	Convergence criterion (GCONV=1E-8) satisfied.	0.81	1.61	0.031	Algorithm converged.	-0.052	0.115	1.05	Algorithm converged.	0.92	1.21	0.4615	0.6609	0.95	Algorithm converged.	0.82	1.09
	Female	230	46.5	149	64.8	229	46.0	147	64.2	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.70	1.50	0.006	Algorithm converged.	-0.082	0.093	1.01	Algorithm converged.	0.88	1.16	0.8949		0.99	Algorithm converged.	0.87	1.13
Age	<= 60	167	33.7	98	58.7	157	31.5	85	54.1	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.77	1.87	0.045	Algorithm converged.	-0.063	0.153	1.08	Algorithm converged.	0.89	1.31	0.4112	0.5673	0.92	Algorithm converged.	0.76	1.12
	> 60	328	66.3	212	64.6	341	68.5	217	63.6	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.76	1.43	0.010	Algorithm converged.	-0.063	0.083	1.02	Algorithm converged.	0.91	1.14	0.7878		0.98	Algorithm converged.	0.88	1.10
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	172	57.7	304	60.2	170	56.7	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.75	1.44	0.011	Algorithm converged.	-0.069	0.090	1.02	Algorithm converged.	0.89	1.17	0.7950	0.4123	0.98	Algorithm converged.	0.85	1.13
	Asia	140	28.3	105	75.0	139	27.9	94	67.6	1.44	Convergence criterion (GCONV=1E-8) satisfied.	0.85	2.42	0.074	Algorithm converged.	-0.022	0.180	1.11	Algorithm converged.	0.95	1.29	0.1751		0.90	Algorithm converged.	0.78	1.03
	Rest of World	57	11.5	33	57.9	55	11.8	38	64.4	0.76	Convergence criterion (GCONV=1E-8) satisfied.	0.36	1.61	-0.065	Algorithm converged.	-0.242	0.112	0.90	Algorithm converged.	0.67	1.20	0.4736		1.11	Algorithm converged.	0.83	1.49
IPI score at Screening	1-2	187	37.8	112	59.9	187	37.6	105	56.1	1.17	Convergence criterion (GCONV=1E-8) satisfied.	0.77	1.76	0.037	Algorithm converged.	-0.063	0.137	1.07	Algorithm converged.	0.90	1.27	0.4637	0.1859	0.94	Algorithm converged.	0.79	1.11
	3	196	39.6	113	57.7	186	37.3	115	61.8	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.56	1.27	-0.042	Algorithm converged.	-0.140	0.057	0.93	Algorithm converged.	0.79	1.10	0.4056		1.07	Algorithm converged.	0.91	1.26
	4-5	112	22.6	85	75.9	125	25.1	82	65.6	1.63	Convergence criterion (GCONV=1E-8) satisfied.	0.93	2.92	0.103	Algorithm converged.	-0.012	0.218	1.16	Algorithm converged.	0.98	1.36	0.0822		0.86	Algorithm converged.	0.73	1.02

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Only AEs of highest severity are counted.
Test for interaction based on RR (Log-binomial regression)
* indicates a convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_WGR35AE_SE_POOLED_15JUN2022_39942.xls
08FEB2023 14:19

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	139	28.1	498	100.0	127	25.5	1.14	Convergence criterion (GCONV=1E-8) satisfied.	0.86	1.51	0.026	Algorithm converged.	-0.029	0.081	1.10	Algorithm converged.	0.90	1.35	0.3592		0.91	Algorithm converged.	0.74	1.12
Sex	Male	265	53.5	76	28.7	269	54.0	66	24.5	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.84	1.82	0.041	Algorithm converged.	-0.033	0.116	1.17	Algorithm converged.	0.88	1.55	0.2784	0.5428	0.86	Algorithm converged.	0.64	1.14
	Female	230	46.5	63	27.4	229	46.0	61	26.6	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.69	1.57	0.008	Algorithm converged.	-0.074	0.089	1.03	Algorithm converged.	0.76	1.39	0.8567		0.97	Algorithm converged.	0.72	1.31
Age	<= 60	167	33.7	49	29.3	157	31.5	47	29.9	0.97	Convergence criterion (GCONV=1E-8) satisfied.	0.60	1.57	-0.006	Algorithm converged.	-0.105	0.094	0.98	Algorithm converged.	0.70	1.37	0.9067	0.4150	1.02	Algorithm converged.	0.73	1.43
	> 60	328	66.3	90	27.4	341	68.5	80	23.5	1.23	Convergence criterion (GCONV=1E-8) satisfied.	0.87	1.75	0.040	Algorithm converged.	-0.026	0.106	1.17	Algorithm converged.	0.90	1.52	0.2381		0.86	Algorithm converged.	0.66	1.11
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	95	31.9	300	60.2	84	28.0	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.85	1.71	0.039	Algorithm converged.	-0.038	0.112	1.14	Algorithm converged.	0.89	1.46	0.3011	0.6288	0.88	Algorithm converged.	0.69	1.12
	Asia	140	28.3	31	22.1	139	27.9	33	23.7	0.91	Convergence criterion (GCONV=1E-8) satisfied.	0.52	1.60	-0.016	Algorithm converged.	-0.115	0.083	0.93	Algorithm converged.	0.61	1.43	0.7510		1.07	Algorithm converged.	0.70	1.63
	Rest of World	57	11.5	13	22.8	59	11.8	10	16.9	1.45	Convergence criterion (GCONV=1E-8) satisfied.	0.58	3.63	0.059	Algorithm converged.	-0.086	0.204	1.35	Algorithm converged.	0.64	2.82	0.4315		0.74	Algorithm converged.	0.35	1.56
IPI score at Screening	1-2	187	37.8	62	33.2	187	37.6	49	26.2	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.89	2.18	0.070	Algorithm converged.	-0.023	0.162	1.27	Algorithm converged.	0.92	1.73	0.1432	0.1966	0.78	Algorithm converged.	0.58	1.06
	3	196	39.6	46	23.5	186	37.3	51	27.4	0.81	Convergence criterion (GCONV=1E-8) satisfied.	0.51	1.29	-0.039	Algorithm converged.	-0.127	0.048	0.86	Algorithm converged.	0.61	1.21	0.3760		1.17	Algorithm converged.	0.83	1.65
	4-5	112	22.6	31	27.7	125	25.1	27	21.6	1.39	Convergence criterion (GCONV=1E-8) satisfied.	0.77	2.52	0.061	Algorithm converged.	-0.049	0.171	1.28	Algorithm converged.	0.82	2.01	0.2785		0.78	Algorithm converged.	0.50	1.22

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Only AEs of highest severity are counted.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_WGR3AE_SE_POOLED_15JUN2022_39942.xls
08FEB2023 14:20

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	157	31.7	498	100.0	165	33.1	0.94	Convergence criterion (GCONV=1E-8) satisfied.	0.72	1.22	-0.014	Algorithm converged.	-0.072	0.044	0.96	Algorithm converged.	0.80	1.15	0.6339		1.04	Algorithm converged.	0.87	1.23
Sex	Male	265	53.5	79	29.8	269	54.0	80	29.7	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.69	1.45	0.001	Algorithm converged.	-0.077	0.078	1.00	Algorithm converged.	0.77	1.30	0.9856	0.6127	1.00	Algorithm converged.	0.77	1.29
	Female	230	46.5	78	33.9	229	46.0	85	37.1	0.87	Convergence criterion (GCONV=1E-8) satisfied.	0.59	1.27	-0.032	Algorithm converged.	-0.128	0.055	0.91	Algorithm converged.	0.71	1.17	0.4735		1.09	Algorithm converged.	0.86	1.40
Age	<= 60	167	33.7	45	26.9	157	31.5	38	24.2	1.16	Convergence criterion (GCONV=1E-8) satisfied.	0.70	1.90	0.027	Algorithm converged.	-0.068	0.122	1.11	Algorithm converged.	0.77	1.62	0.5726	0.3695	0.90	Algorithm converged.	0.62	1.30
	> 60	328	66.3	112	34.1	341	68.5	127	37.2	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.64	1.20	-0.031	Algorithm converged.	-0.104	0.042	0.92	Algorithm converged.	0.75	1.12	0.4033		1.09	Algorithm converged.	0.89	1.34
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	68	22.8	300	60.2	81	27.0	0.80	Convergence criterion (GCONV=1E-8) satisfied.	0.55	1.16	-0.042	Algorithm converged.	-0.113	0.027	0.85	Algorithm converged.	0.64	1.12	0.2384	0.0920	1.18	Algorithm converged.	0.89	1.57
	Asia	140	28.3	72	51.4	139	27.9	60	43.2	1.39	Convergence criterion (GCONV=1E-8) satisfied.	0.87	2.23	0.083	Algorithm converged.	-0.024	0.199	1.19	Algorithm converged.	0.93	1.53	0.1690		0.84	Algorithm converged.	0.65	1.08
	Rest of World	57	11.5	17	29.8	59	11.8	24	40.7	0.62	Convergence criterion (GCONV=1E-8) satisfied.	0.29	1.34	-0.108	Algorithm converged.	-0.281	0.064	0.73	Algorithm converged.	0.44	1.21	0.2270		1.38	Algorithm converged.	0.82	2.26
IPI score at Screening	1-2	187	37.8	43	23.0	187	37.6	55	29.4	0.72	Convergence criterion (GCONV=1E-8) satisfied.	0.45	1.14	-0.064	Algorithm converged.	-0.153	0.025	0.78	Algorithm converged.	0.55	1.10	0.1604	0.2310	1.28	Algorithm converged.	0.91	1.80
	3	196	39.6	63	32.1	186	37.3	61	32.8	0.97	Convergence criterion (GCONV=1E-8) satisfied.	0.63	1.49	-0.007	Algorithm converged.	-0.100	0.087	0.98	Algorithm converged.	0.73	1.31	0.8916		1.02	Algorithm converged.	0.76	1.36
	4-5	112	22.6	51	45.5	125	25.1	49	39.2	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.77	2.17	0.063	Algorithm converged.	-0.062	0.189	1.16	Algorithm converged.	0.86	1.56	0.3241		0.88	Algorithm converged.	0.64	1.16

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Only AEs of highest severity are counted.
Test for interaction based on RR (Log-binomial regression)
* indicates a convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_WGR4AE_SE_POOLED_15JUN2022_39942.xls
08FEB2023 14:22

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 5 (AEs leading to Death)
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	14	2.8	498	100.0	10	2.0	1.42	Convergence criterion (GCONV=1E-8) satisfied.	0.62	3.23	0.008	Algorithm converged.	-0.011	0.027	1.41	Algorithm converged.	0.63	3.14	0.4025		0.71	Algorithm converged.	0.32	1.58
Sex	Male	265	53.5	6	2.3	269	54.0	9	3.3	0.67	Convergence criterion (GCONV=1E-8) satisfied.	0.23	1.91	-0.011	Algorithm converged.	-0.039	0.013	0.68	Algorithm converged.	0.24	1.87	0.4526	0.0131	1.48	Algorithm converged.	0.53	4.09
	Female	230	46.5	8	3.5	229	46.0	1	0.4	8.21	Convergence criterion (GCONV=1E-8) satisfied.	1.02	66.21	0.030	Algorithm converged.	0.005	0.054	7.97	Algorithm converged.	1.00	63.17	0.0495		0.13	Algorithm converged.	0.02	1.00
Age	<= 60	167	33.7	4	2.4	157	31.5	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	0.0321	NE	Algorithm converged.	NE	NE
	> 60	328	66.3	10	3.0	341	68.5	10	2.9	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.43	2.53	0.005	Algorithm converged.	-0.025	0.027	1.04	Algorithm converged.	0.44	2.46	0.9297		0.96	Algorithm converged.	0.41	2.26
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	9	3.0	302	60.6	5	1.7	1.84	Convergence criterion (GCONV=1E-8) satisfied.	0.61	5.55	0.014	Algorithm converged.	-0.011	0.038	1.81	Algorithm converged.	0.62	5.34	0.2813	0.4214	0.55	Algorithm converged.	0.19	1.63
	Asia	140	28.3	2	1.4	139	27.9	3	2.2	0.65	Convergence criterion (GCONV=1E-8) satisfied.	0.10	4.21	-0.007	Algorithm converged.	-0.037	0.023	0.65	Algorithm converged.	0.10	4.05	0.5736		0.56	Algorithm converged.	0.05	5.46
	Rest of World	57	11.5	3	5.3	58	11.6	2	3.4	0.76	Convergence criterion (GCONV=1E-8) satisfied.	0.14	3.56	-0.025	Algorithm converged.	-0.102	0.071	0.78	Algorithm converged.	0.18	3.32	0.7325		1.26	Algorithm converged.	0.30	5.50
IPI score at Screening	1-2	187	37.8	7	3.7	187	37.5	1	0.5	7.23	Convergence criterion (GCONV=1E-8) satisfied.	0.88	59.37	0.032	Algorithm converged.	0.003	0.061	7.00	Algorithm converged.	0.87	56.34	0.0674	0.0733	0.14	Algorithm converged.	0.02	1.15
	3	196	39.6	4	2.0	184	37.2	3	1.6	1.27	Convergence criterion (GCONV=1E-8) satisfied.	0.28	5.72	0.004	Algorithm converged.	-0.023	0.031	1.27	Algorithm converged.	0.29	5.58	0.7559		0.79	Algorithm converged.	0.18	3.48
	4-5	112	22.6	3	2.7	125	25.1	6	4.8	0.55	Convergence criterion (GCONV=1E-8) satisfied.	0.13	2.24	-0.025	Algorithm converged.	-0.069	0.027	0.56	Algorithm converged.	0.14	2.18	0.4013		1.79	Algorithm converged.	0.46	7.00

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Only AEs of highest severity are counted.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO55410777/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/BO55410777/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_wgf_WGRSAE_SE_POOLED_15JUN2022_39942.xls
08FEB2023 14:24

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	170	34.3	498	100.0	155	31.1	1.16	Convergence criterion (GCONV=1E-8) satisfied.	0.89	1.51	0.032	Algorithm converged.	-0.026	0.091	1.10	Algorithm converged.	0.92	1.32	0.2902		0.91	Algorithm converged.	0.76	1.08
Sex	Male	265	53.5	94	35.5	269	54.0	90	33.5	1.09	Convergence criterion (GCONV=1E-8) satisfied.	0.77	1.56	0.020	Algorithm converged.	-0.060	0.101	1.06	Algorithm converged.	0.84	1.34	0.6244	0.6123	0.94	Algorithm converged.	0.75	1.19
	Female	230	46.5	76	33.0	229	46.0	65	28.4	1.25	Convergence criterion (GCONV=1E-8) satisfied.	0.84	1.85	0.047	Algorithm converged.	-0.038	0.131	1.16	Algorithm converged.	0.88	1.53	0.2804		0.86	Algorithm converged.	0.65	1.13
Age	<= 60	167	33.7	46	27.5	157	31.5	44	28.0	0.98	Convergence criterion (GCONV=1E-8) satisfied.	0.60	1.59	-0.005	Algorithm converged.	-0.102	0.093	0.98	Algorithm converged.	0.68	1.40	0.9231	0.4224	1.02	Algorithm converged.	0.72	1.45
	> 60	328	66.3	124	37.8	341	68.5	111	32.6	1.26	Convergence criterion (GCONV=1E-8) satisfied.	0.92	1.73	0.053	Algorithm converged.	-0.020	0.125	1.16	Algorithm converged.	0.94	1.43	0.1554		0.86	Algorithm converged.	0.70	1.06
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	102	34.2	300	60.2	88	29.3	1.25	Convergence criterion (GCONV=1E-8) satisfied.	0.89	1.77	0.049	Algorithm converged.	-0.028	0.123	1.17	Algorithm converged.	0.92	1.48	0.1996	0.7694	0.86	Algorithm converged.	0.68	1.08
	Asia	140	28.3	46	32.9	139	27.9	45	32.4	1.02	Convergence criterion (GCONV=1E-8) satisfied.	0.62	1.69	0.005	Algorithm converged.	-0.105	0.115	1.01	Algorithm converged.	0.72	1.42	0.9314		0.99	Algorithm converged.	0.70	1.38
	Rest of World	57	11.5	22	38.6	59	11.8	22	37.3	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.50	2.24	0.013	Algorithm converged.	-0.164	0.190	1.04	Algorithm converged.	0.65	1.68	0.8846		0.97	Algorithm converged.	0.61	1.54
IPI score at Screening	1-2	187	37.8	61	32.6	187	37.6	43	23.0	1.62	Convergence criterion (GCONV=1E-8) satisfied.	1.03	2.56	0.096	Algorithm converged.	0.006	0.187	1.42	Algorithm converged.	1.02	1.98	0.0399	0.1130	0.76	Algorithm converged.	0.51	0.98
	3	196	39.6	59	30.1	186	37.3	63	33.9	0.84	Convergence criterion (GCONV=1E-8) satisfied.	0.55	1.29	-0.038	Algorithm converged.	-0.131	0.056	0.89	Algorithm converged.	0.66	1.19	0.4300		1.13	Algorithm converged.	0.84	1.51
	4-5	112	22.6	50	44.6	125	25.1	49	39.2	1.25	Convergence criterion (GCONV=1E-8) satisfied.	0.75	2.10	0.054	Algorithm converged.	-0.071	0.180	1.14	Algorithm converged.	0.84	1.54	0.3962		0.88	Algorithm converged.	0.65	1.19

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_SAE_SE_POOLED_15JUN2022_39942.xls
08FEB2023 14:26

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs leading to any Study Treatment Discontinuation
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	30	6.1	498	100.0	30	6.0	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.60	1.70	0.000	Algorithm converged.	-0.029	0.030	1.01	Algorithm converged.	0.62	1.64	0.9807		0.99	Algorithm converged.	0.61	1.62
Sex	Male	265	53.5	16	6.0	269	54.0	13	4.8	1.27	Convergence criterion (GCONV=1E-8) satisfied.	0.60	2.69	0.012	Algorithm converged.	-0.026	0.051	1.25	Algorithm converged.	0.61	2.55	0.5399	0.4015	0.80	Algorithm converged.	0.39	1.63
	Female	230	46.5	14	6.1	229	46.0	17	7.4	0.81	Convergence criterion (GCONV=1E-8) satisfied.	0.39	1.68	-0.013	Algorithm converged.	-0.099	0.033	0.82	Algorithm converged.	0.41	1.62	0.5691		1.22	Algorithm converged.	0.62	2.42
Age	<= 60	167	33.7	5	3.0	157	31.5	8	5.1	0.57	Convergence criterion (GCONV=1E-8) satisfied.	0.18	1.80	-0.021	Algorithm converged.	-0.064	0.022	0.59	Algorithm converged.	0.20	1.76	0.3416	0.2584	1.70	Algorithm converged.	0.57	5.08
	> 60	328	66.3	25	7.6	341	68.5	22	6.5	1.20	Convergence criterion (GCONV=1E-8) satisfied.	0.66	2.17	0.012	Algorithm converged.	-0.027	0.050	1.18	Algorithm converged.	0.68	2.05	0.5543		0.85	Algorithm converged.	0.49	1.47
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	18	6.0	309	60.2	18	6.0	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.51	1.98	0.000	Algorithm converged.	-0.038	0.039	1.01	Algorithm converged.	0.53	1.90	0.9835	0.5932	0.99	Algorithm converged.	0.53	1.87
	Asia	140	28.3	8	5.7	139	27.9	10	7.2	0.78	Convergence criterion (GCONV=1E-8) satisfied.	0.30	2.04	-0.015	Algorithm converged.	-0.072	0.043	0.79	Algorithm converged.	0.32	1.91	0.6158		1.26	Algorithm converged.	0.51	3.10
	Rest of World	57	11.5	4	7.0	59	11.8	2	3.4	2.15	Convergence criterion (GCONV=1E-8) satisfied.	0.38	12.23	0.038	Algorithm converged.	-0.045	0.117	2.07	Algorithm converged.	0.39	10.86	0.3897		0.48	Algorithm converged.	0.09	2.54
IPI score at Screening	1-2	187	37.8	8	4.3	187	37.6	9	4.8	0.88	Convergence criterion (GCONV=1E-8) satisfied.	0.33	2.34	-0.008	Algorithm converged.	-0.048	0.037	0.89	Algorithm converged.	0.35	2.25	0.8041	0.7091	1.12	Algorithm converged.	0.44	2.85
	3	196	39.6	10	5.1	186	37.3	11	5.9	0.86	Convergence criterion (GCONV=1E-8) satisfied.	0.35	2.06	-0.008	Algorithm converged.	-0.054	0.038	0.86	Algorithm converged.	0.38	1.98	0.7281		1.16	Algorithm converged.	0.50	2.67
	4-5	112	22.6	12	10.7	125	25.1	10	8.0	1.38	Convergence criterion (GCONV=1E-8) satisfied.	0.57	3.33	0.027	Algorithm converged.	-0.047	0.102	1.34	Algorithm converged.	0.60	2.98	0.4738		0.75	Algorithm converged.	0.34	1.66

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_WDSTAE_SE_POOLED_15JUN2022_39942.xls
08FEB2023 14:27

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STOUT: ds20662
Dichotomous Analysis by Subgroups (Safety)

All

			Ertugliflozin Tablets 5 mg/Day (N=495)			Placebo (N=495)			Odds Ratio	Ertugliflozin Tablets 5 mg/Day vs. Placebo				Ertugliflozin Tablets 5 mg/Day vs. Placebo						Placebo vs. Ertugliflozin Tablets 5 mg			
			Patients	Patients with Event		Patients	Patients with Event			Absolute Risk Difference				Relative Risk						Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	Odds Ratio	Convergence Result	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Result	95% Lower CL	95% Upper CL	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL	p-value (MLE)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		n/a	495	100.0	281	56.8	495	100.0	258	51.6	1.22	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	1.30	0.052	Algorithm converged.	-0.032	0.111	1.10	Algorithm converged.	0.98	1.23	0.1172	NE	0.91	Algorithm converged.	0.83	1.00
Blood and lymphatic system disorders	Anaemia nutritional	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Anaemia	n/a	495	100.0	164	33.1	495	100.0	146	29.3	1.18	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	1.56	0.038	Algorithm converged.	-0.018	0.094	1.13	Algorithm converged.	0.94	1.34	0.1951	NE	0.88	Algorithm converged.	0.74	1.04
Blood and lymphatic system disorders	Aplasia pure red cell	n/a	495	100.0	1	0.2	495	100.0	1	0.2	1.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	14.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Blood and lymphatic system disorders	Cytopenia	n/a	495	100.0	1	0.2	495	100.0	1	0.2	1.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	14.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Blood and lymphatic system disorders	Erythrocytosis	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	n/a	495	100.0	1	0.2	495	100.0	2	0.4	0.50	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	5.55	-0.002	Algorithm converged.	-0.004	0.000	0.50	Algorithm converged.	0.06	5.53	0.5743	NE	1.99	Algorithm converged.	0.16	21.65
Blood and lymphatic system disorders	Febrile neutropenia	n/a	495	100.0	66	13.3	495	100.0	39	7.9	1.81	Convergence criterion (NCOA8+1E-8) satisfied.	1.10	2.75	0.055	Algorithm converged.	0.023	0.093	1.71	Algorithm converged.	1.17	2.46	0.0055	NE	0.59	Algorithm converged.	0.40	0.86
Blood and lymphatic system disorders	Granulocytopenia	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Hypofibrinogenaemia	n/a	495	100.0	1	0.2	495	100.0	1	0.2	1.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	14.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Blood and lymphatic system disorders	Increased tendency to bruising	n/a	495	100.0	1	0.2	495	100.0	1	0.2	1.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	14.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Blood and lymphatic system disorders	Iron deficiency anaemia	n/a	495	100.0	0	0.0	495	100.0	2	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Leukocytosis	n/a	495	100.0	1	0.2	495	100.0	4	0.8	0.25	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	2.84	-0.004	Algorithm converged.	-0.009	0.001	0.25	Algorithm converged.	0.01	2.24	0.2143	NE	1.98	Algorithm converged.	0.40	35.45
Blood and lymphatic system disorders	Leukopenia	n/a	495	100.0	44	8.9	495	100.0	49	9.8	0.88	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	1.37	-0.010	Algorithm converged.	-0.046	0.025	0.90	Algorithm converged.	0.61	1.33	0.4675	NE	1.11	Algorithm converged.	0.75	1.62
Blood and lymphatic system disorders	Lymph node pain	n/a	495	100.0	1	0.2	495	100.0	2	0.4	0.50	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	5.55	-0.002	Algorithm converged.	-0.009	0.005	0.50	Algorithm converged.	0.05	5.53	0.5743	NE	1.99	Algorithm converged.	0.16	21.65
Blood and lymphatic system disorders	Lymphadenopathy	n/a	495	100.0	3	0.6	495	100.0	1	0.2	3.03	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	28.43	0.004	Algorithm converged.	-0.004	0.013	3.03	Algorithm converged.	0.34	26.94	0.3381	NE	0.33	Algorithm converged.	0.03	3.13
Blood and lymphatic system disorders	Lymphopenia	n/a	495	100.0	12	2.4	495	100.0	16	3.2	0.73	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	1.46	-0.008	Algorithm converged.	-0.038	0.013	0.77	Algorithm converged.	0.36	1.54	0.4645	NE	1.35	Algorithm converged.	0.42	2.77
Blood and lymphatic system disorders	Myelosuppression	n/a	495	100.0	4	0.8	495	100.0	1	0.2	4.05	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	36.99	0.006	Algorithm converged.	-0.003	0.013	4.02	Algorithm converged.	0.45	35.84	0.2122	NE	0.25	Algorithm converged.	0.02	2.22
Blood and lymphatic system disorders	Neutropenia	n/a	495	100.0	140	28.3	495	100.0	152	30.5	0.88	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	1.14	-0.022	Algorithm converged.	-0.079	0.034	0.93	Algorithm converged.	0.76	1.13	0.4380	NE	1.08	Algorithm converged.	0.80	1.33
Blood and lymphatic system disorders	Neutrophilia	n/a	495	100.0	1	0.2	495	100.0	3	0.6	0.33	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	9.89	-0.004	Algorithm converged.	-0.009	0.001	0.34	Algorithm converged.	0.04	3.01	0.3433	NE	2.98	Algorithm converged.	0.34	28.57
Blood and lymphatic system disorders	Pancytopenia	n/a	495	100.0	1	0.2	495	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	Splenic infarction	n/a	495	100.0	1	0.2	495	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	Thrombocytosenia	n/a	495	100.0	46	9.3	495	100.0	47	9.4	0.98	Convergence criterion (NCOA8+1E-8) satisfied.	0.66	1.45	-0.001	Algorithm converged.	-0.038	0.035	0.99	Algorithm converged.	0.67	1.45	0.9276	NE	1.02	Algorithm converged.	0.69	1.50
Cardiac disorders		n/a	495	100.0	60	8.1	495	100.0	62	12.4	0.92	Convergence criterion (NCOA8+1E-8) satisfied.	0.81	0.99	-0.044	Algorithm converged.	-0.085	-0.004	0.93	Algorithm converged.	0.86	0.99	0.0248	NE	1.54	Algorithm converged.	1.04	2.20
Cardiac disorders	Acute myocardial infarction	n/a	495	100.0	1	0.2	495	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	Acute vascular insufficiency	n/a	495	100.0	2	0.4	495	100.0	0	0.0	5.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	22.40	0.002	Algorithm converged.	-0.002	0.009	5.01	Algorithm converged.	0.22	22.38	0.0000	NE	0.00	Algorithm converged.	0.00	NE
Cardiac disorders	Arrhythmia	n/a	495	100.0	0	0.0	495	100.0	2	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	n/a	495	100.0	11	2.2	495	100.0	8	1.6	1.39	Convergence criterion (NCOA8+1E-8) satisfied.	0.59	3.40	-0.008	Algorithm converged.	-0.053	0.037	1.38	Algorithm converged.	0.59	3.24	0.4773	NE	0.72	Algorithm converged.	0.30	1.73
Cardiac disorders	Atrial flutter	n/a	495	100.0	1	0.2	495	100.0	1	0.2	1.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	14.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Cardiac disorders	Atrioventricular block	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block complete	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block first degree	n/a	495	100.0	2	0.4	495	100.0	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
Cardiac disorders	Bradycardia	n/a	495	100.0	2	0.4	495	100.0	1	0.2	2.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	2.73	-0.004	Algorithm converged.	-0.004	0.012	2.00	Algorithm converged.	0.18	2.68	0.3173	NE	1.99	Algorithm converged.	0.37	10.84
Cardiac disorders	Cardiac disorder	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Cardiac dysfunction	n/a	495	100.0	1	0.2	495	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Cardiac failure	n/a	495	100.0	2	0.4	495	100.0	2	0.4	1.01	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	7.03	0.000	Algorithm converged.	-0.008	0.010	1.01	Algorithm converged.	0.14	7.11	0.9953	NE	0.99	Algorithm converged.	0.14	7.03
Cardiac disorders	Cardiac failure congestive	n/a	495	100.0	1	0.2	495	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Congestion	n/a	495	100.0	1	0.2	495	100.0	2	0.4	0.50	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	5.55	-0.002	Algorithm converged.	-0.009	0.005	0.50	Algorithm converged.	0.05	5.53	0.5743	NE	1.99	Algorithm converged.	0.16	21.65
Cardiac disorders	Coronary artery disease	n/a	495	100.0	1	0.2	495	100.0	2	0.4	0.50	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	5.55	-0.002	Algorithm converged.	-0.009	0.005	0.50	Algorithm converged.	0.05	5.53	0.5743	NE	1.99	Algorithm converged.	0.16	21.65
Cardiac disorders	Cyanosis	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Dilatation ventricular	n/a	495	100.0	1	0.2	495	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Diastolic dysfunction	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Dysfunction	n/a	495	100.0	2	0.4	495	100.0	3	0.6	0.67	Convergence criterion (NCOA8+1E-8) satisfied.	0.01	4.00	-0.002	Algorithm converged.	-0.011	0.007	0.67	Algorithm converged.	0.11	4.00	0.6609	NE	1.49	Algorithm converged.	0.20	8.86
Cardiac disorders	Myocardial infarction	n/a	495	100.0	1	0.2	495	100.0	1	0.2	1.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	14.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Cardiac disorders	Palpitations	n/a	495	100.0	2	0.4	495	100.0	9	1.8	0.22	Convergence criterion (NCOA8+1E-8) satisfied.	0.05	1.04	-0.014	Algorithm converged.	-0.087	-0.021	0.23	Algorithm converged.	0.05	1.03	0.0547	NE	4.47	Algorithm converged.	0.97	20.65
Cardiac disorders	Ventricular hypertrophy	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Ventricular tachycardia	n/a	495	100.0	1	0.2	495	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	Ventricular tachycardia paroxysmal	n/a	495	100.0	1	0.2	495	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Ventricular extrasystoles	n/a	495	100.0	1	0.2	495	100.0	2	0.4	0.50	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	5.55	-0.002	Algorithm converged.	-0.009	0.005	0.50	Algorithm converged.	0.05	5.53	0.5743	NE	1.99	Algorithm converged.	0.16	21.65
Congenital, familial and genetic disorders		n/a	495	100.0	3	0.6	495	100.0	2	0.4	1.51	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	29.67	0.004	Algorithm converged.	-0.004	0.013	1.51	Algorithm converged.	0.33	28.32	0.3382	NE	0.33	Algorithm converged.	0.02	3.13
Congenital, familial and genetic disorders	Aplasia	n/a	495	100.0	1	0.2	495	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	Dacryocystocele	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Congenital, familial and genetic disorders	Disseminated superficial actinic poikilodermatitis	n/a	495	100.0	1	0.2	495	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	Pyloric stenosis	n/a	495	100.0	1	0.2	495	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	495	100.0	31	6.3	495	100.0	23	4.6	1.38	Convergence criterion (NCOA8+1E-8) satisfied.	0.79	2.40	0.014	Algorithm converged.	-0.002	0.045	1.38	Algorithm converged.	0.90	2.09	0.2554	NE	0.74	Algorithm converged.	0.44	1.23
Ear and labyrinth disorders	Deafness	n/a	495	100.0	1	0.2	495	100.0	2	0.4	0.50	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	5.55	-0.002	Algorithm converged.	-0.009	0.005	0.50	Algorithm converged.	0.05	5.53	0.5743	NE	1.99	Algorithm converged.	0.16	21.65
Ear and labyrinth disorders	Deafness unilateral	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Ear congestion	n/a	495	100.0	1	0.2	495	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	Ear discomfort	n/a	495	100.0	1	0.2	495	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	Ear disorder	n/a	495	100.0	1	0.2	495	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	Ear pain	n/a	495	100.0	5	1.0	495	100.0	5	1.0	1.01	Convergence criterion (NCOA8+1E-8) satisfied.	0.24	3.93	0.000	Algorithm converged.	-0.012	0.012	1.01	Algorithm converged.	0.24	4.01	0.9923	NE	0.99	Algorithm converged.	0.23	3.43
Ear and labyrinth disorders	Ear pruritus	n/a	495	100.0	1	0.2	495	100.0	0	0.0	3.03	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	28.43	0.004	Algorithm converged.	-0.004	0.013	3.03	Algorithm converged.	0.34	26.94	0.3433	NE	0.33	Algorithm converged.	0.03	3.13
Ear and labyrinth disorders	Hypoacusis	n/a	495	100.0	2	0.4	495	100.0	2	0.4	1.01	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	9.89	0.000	Algorithm converged.	-0.007	0.013	1.01	Algorithm converged.	0.11	9.89	0.9954	NE	0.99	Algorithm converged.	0.11	9.89
Ear and labyrinth disorders	Meniere's disease	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Mixed deafness	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Presbycusis ear	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Vertigo	n/a	495	100.0	13	2.6	495	100.0	6	1.2	2.21	Convergence criterion (NCOA8+1E-8) satisfied.	0.83	5.47	0.014	Algorithm converged.	-0.003	0.031	2.19	Algorithm converged.	0.86	5.63	0.1111	NE	0.45	Algorithm converged.	0.10	1.23
Ear and labyrinth disorders	Tympanic membrane perforation	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Vertigo	n/a	495	100.0	8	1.6	495	100.0	3	0.6	2.71	Convergence criterion (NCOA8+1E-8) satisfied.	0.71	10.39	0.010	Algorithm converged.	-0.002	0.023	2.69	Algorithm converged.	0.72	10.27	0.1432	NE	0.27	Algorithm converged.	0.10	1.64
Endocrine disorders		n/a	495	100.0	1	1.0	495	100.0	6	0.8	0.16	Convergence criterion (NCOA8+1E-8) satisfied.	0.04	4.77	0.002	Algorithm converged.	-0.003	0.014	1.01	Algorithm converged.	0.24	4.66	0.7317	NE	0.24	Algorithm converged.	0.02	2.57
Endocrine disorders	Adrenal insufficiency	n/a	495	100.0	1	0.2	495	100.0	1	0.2	1.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	14.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Endocrine disorders	Diabetes insipidus	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Endocrine disorders	Glucocorticoid deficiency	n/a	495	100.0	1	0.2	495	100.0	1	0.2	1.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	14.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Endocrine disorders	Hypothyroidism	n/a	495	100.0	1	0.2	495	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
Endocrine disorders	Hypothyroidism	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Endocrine disorders	Thyroiditis	n/a	495	100.0	2	0.4	495	100.0	3	0.6	0.67	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	9.89	-0.004	Algorithm converged.	-0.009	0.001	0.67	Algorithm converged.	0.08	5.52	0.7343	NE	1.98	Algorithm converged.	0.15	3.03
Endocrine disorders	Withdrawal syndrome steroid withdrawal syndrome	n/a	495	100.0	1	0.2	495	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
Eye disorders		n/a	495	100.0	61	12.7	495	100.0	48	9.8	1.24	Convergence criterion (NCOA8+1E-8) satisfied.	0.80	1.92	0.029	Algorithm converged.	-0.018	0.064	1.23	Algorithm converged.	0.84	1.79	0.2137	NE	0.81	Algorithm converged.	0.56	1.14
Eye disorders	Angle closure glaucoma	n/a	495	100.0	1	0.2	495	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
Eye disorders	Asthenopia	n/a	495	100.0	1	0.2	495	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
Eye disorders	Blepharitis	n/a	495	100.0	1	0.2	495	100.0	1	0.2	1.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	14.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Eye disorders	Blindness	n/a	495	100.0	2	0.4	495	100.0	1	0.2	2.00	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	28.20	0.002	Algorithm converged.	-0.002	0.009	2.00	Algorithm converged.	0.22	27.92	0.1693	NE	1.99	Algorithm converged.	0.37	10.84
Eye disorders	Cataract	n/a	495	100.0	4	0.8	495	100.0	1	0.2	4.05	Convergence criterion (NCOA8+1E-8) satisfied.	0.00	36.99	0.006	Algorithm converged.	-0.003	0.013	4.02	Algorithm converged.	0.45	35.84	0.2122	NE	0.25	Algorithm converged.	0.02	2.22
Eye disorders	Chalazion	n/a	495	100.0	0	0.0	495	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Eye disorders	Conjunctival haemorrhage	n/a	495	100.0	1	0.2	495	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
Eye disorders	Conjunctival hyperaemia	n/a	495	100.0	0	0.0

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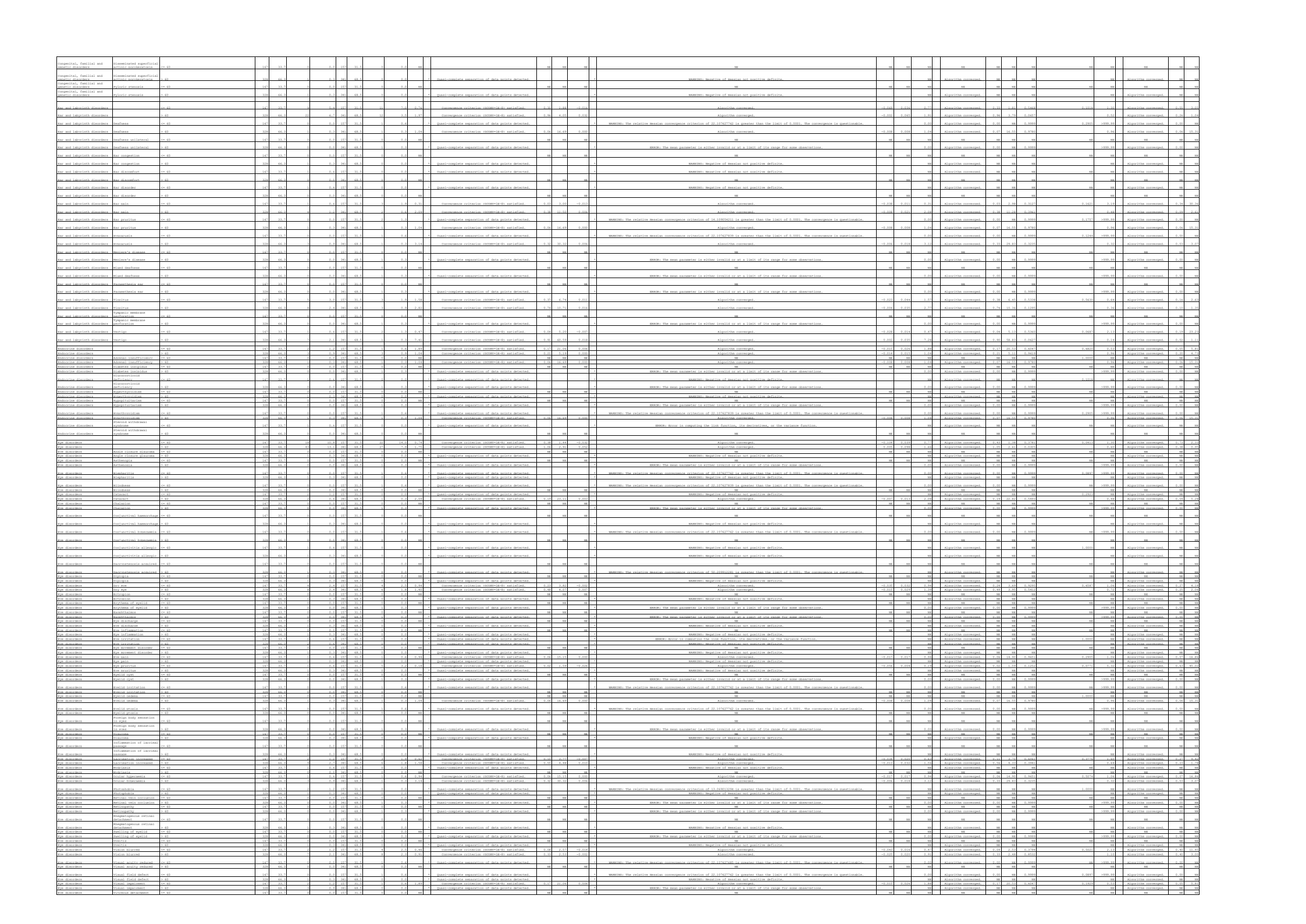
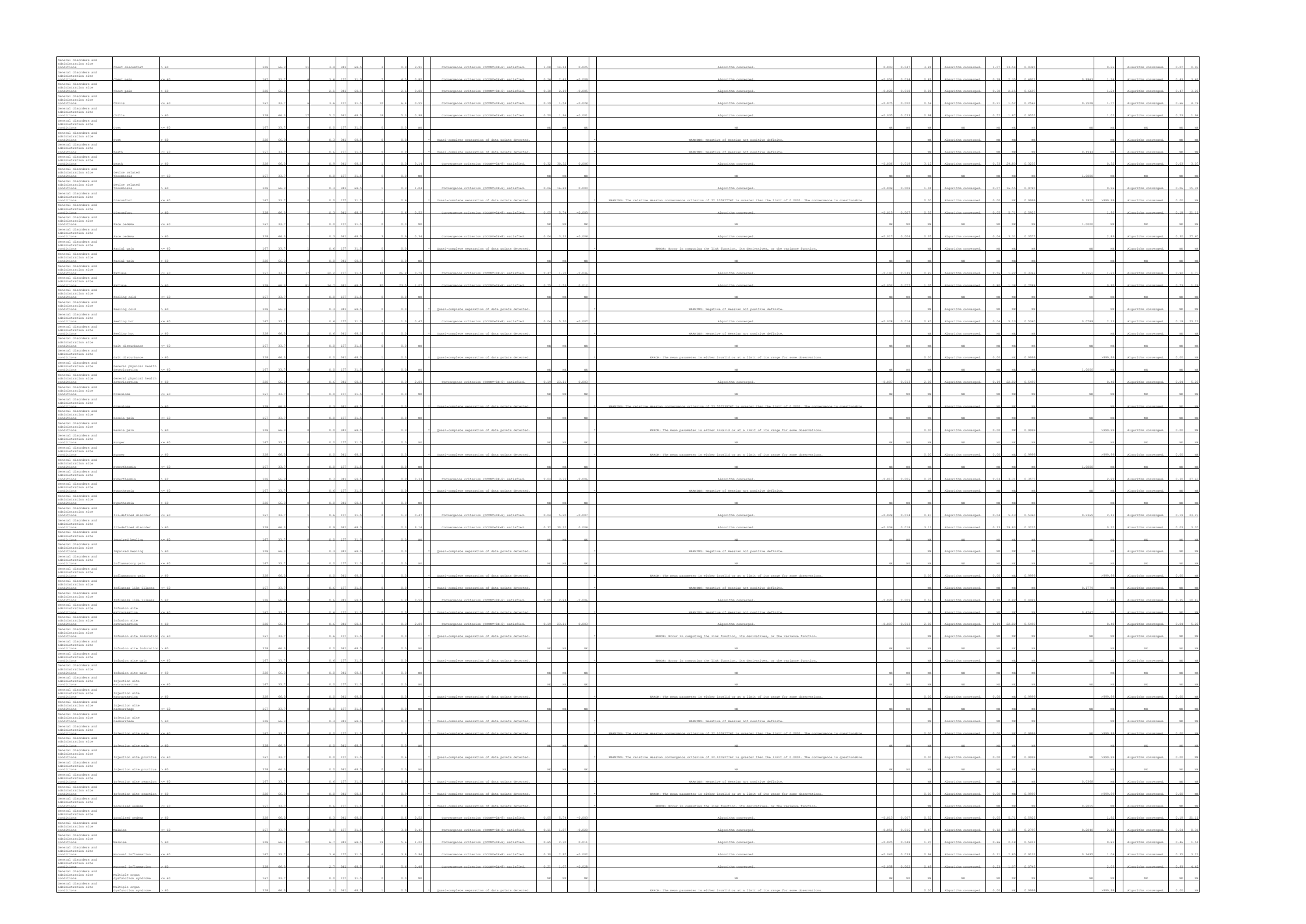
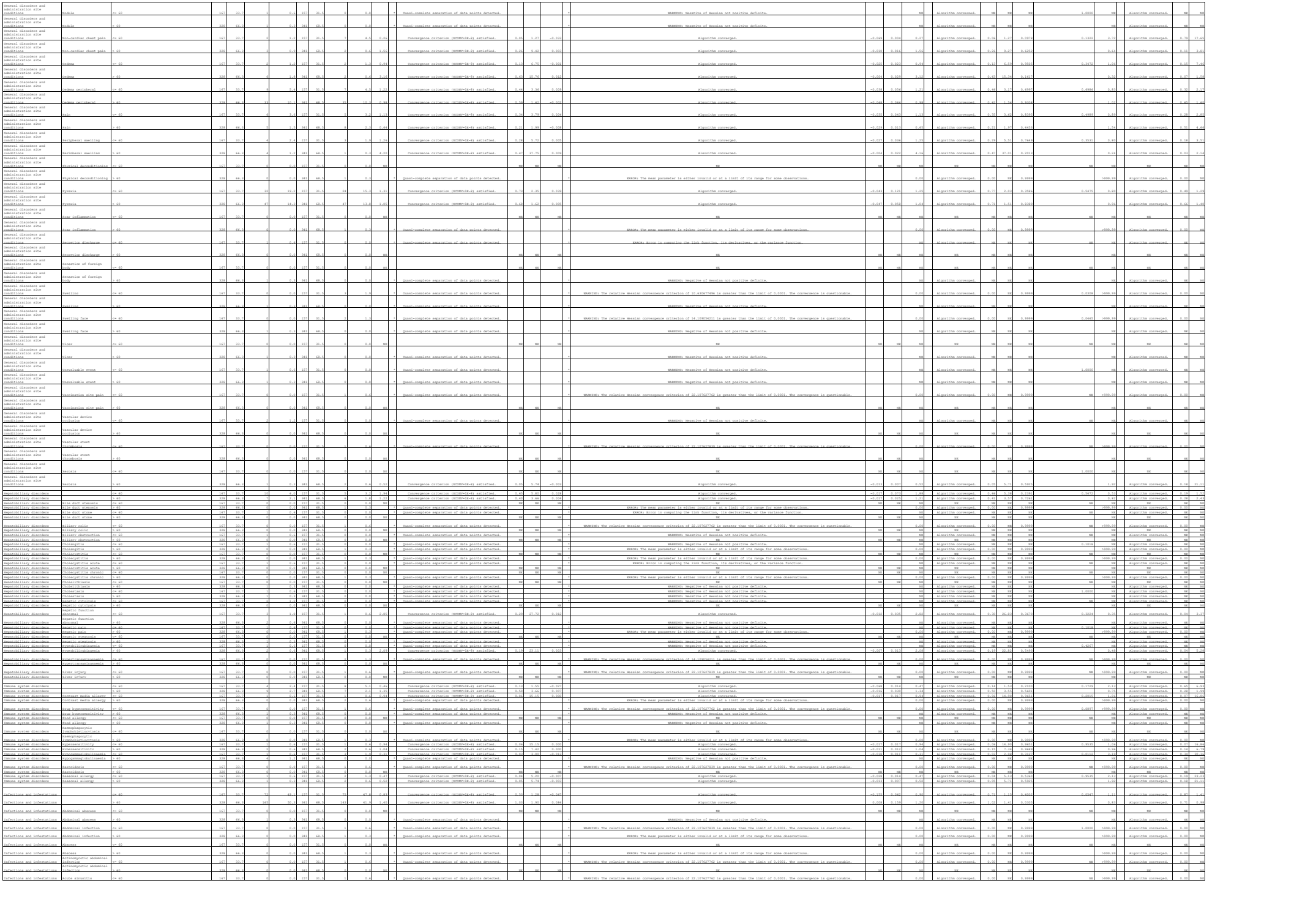
POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
ANOVT: SOZ09862
Dichotomous Analysis by Subgroups (Safety)

Age

			Intervention Therapy + R-CHP (N=XXX)				R-CHP (N=XXX)				Intervention Therapy + R-CHP vs. R-CHP										R-CHP vs. Intervention Therapy + R-CHP			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	N	%	n	%	N	%	n	%	Convergence Result	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Result	95% Lower CL	95% Upper CL	Relative Risk	Convergence Result	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		<= 40	167	33.7	69	52.7	157	31.2	49	43.9	1.42	Convergence criterion (ECOSS=1E-8) satisfied.	0.92	2.20	0.097	Algorithm converged.	-0.091	0.195	1.31	Algorithm converged.	0.46	1.11	0.1183	0.3625	0.63	Algorithm converged.	0.44	1.06
Blood and lymphatic system disorders		> 40	328	66.3	123	68.8	345	68.5	189	65.4	1.16	Convergence criterion (ECOSS=1E-8) satisfied.	0.69	1.96	0.034	Algorithm converged.	-0.044	0.035	1.06	Algorithm converged.	0.94	1.19	0.3723		0.94	Algorithm converged.	0.83	1.07
Blood and lymphatic system disorders	Agranulocytosis	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Agranulocytosis	> 40	328	66.3	0	0.0	345	68.5	1	0.3					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	0.9999		>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Anaemia	<= 40	167	33.7	46	27.5	157	31.2	37	23.6	1.24	Convergence criterion (ECOSS=1E-8) satisfied.	0.75	2.04	0.040	Algorithm converged.	-0.050	0.130	1.17	Algorithm converged.	0.86	1.73	0.4137	0.9633	0.84	Algorithm converged.	0.59	1.24
Blood and lymphatic system disorders	Anaemia	> 40	328	66.3	118	36.0	345	68.5	109	32.0	1.16	Convergence criterion (ECOSS=1E-8) satisfied.	0.87	1.60	0.040	Algorithm converged.	-0.032	0.103	1.13	Algorithm converged.	0.94	1.39	0.2736		0.84	Algorithm converged.	0.72	1.10
Blood and lymphatic system disorders	Aplasia pure red cell	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Aplasia pure red cell	> 40	328	66.3	1	0.3	345	68.5	3	0.9	3.04	Convergence criterion (ECOSS=1E-8) satisfied.	0.06	14.65	0.606	Algorithm converged.	-0.008	0.006	1.64	Algorithm converged.	0.07	14.33	0.9780		0.94	Algorithm converged.	0.06	15.31
Blood and lymphatic system disorders	Cytopenia	<= 40	167	33.7	1	0.6	157	31.2	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.		0.00	Algorithm converged.	NE	NE	0.9999		1.1016	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Cytopenia	> 40	328	66.3	0	0.0	345	68.5	1	0.3					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	0.9999		>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Erythraemia	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Erythraemia	> 40	328	66.3	0	0.0	345	68.5	1	0.3					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	0.9999		>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	<= 40	167	33.7	0	0.0	157	31.2	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 bone marrow aplasia	> 40	328	66.3	1	0.3	345	68.5	2	0.6	2.02	Convergence criterion (ECOSS=1E-8) satisfied.	0.05	5.74	-0.003	Algorithm converged.	-0.010	0.003	0.52	Algorithm converged.	0.05	5.33	0.5425		1.02	Algorithm converged.	0.04	23.13
Blood and lymphatic system disorders	Febrile neutropenia	<= 40	167	33.7	14	8.4	157	31.2	12	7.6	1.11	Convergence criterion (ECOSS=1E-8) satisfied.	0.49	2.47	0.007	Algorithm converged.	-0.050	0.063	1.13	Algorithm converged.	0.52	2.36	0.8044	0.1731	0.91	Algorithm converged.	0.46	1.81
Blood and lymphatic system disorders	Febrile neutropenia	> 40	328	66.3	52	16.0	345	68.5	23	7.9	1.13	Convergence criterion (ECOSS=1E-8) satisfied.	1.05	2.68	0.074	Algorithm converged.	0.000	0.049	2.00	Algorithm converged.	1.00	3.11	0.0503		0.94	Algorithm converged.	0.80	2.79
Blood and lymphatic system disorders	Granulocytopenia	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Granulocytopenia	> 40	328	66.3	0	0.0	345	68.5	1	0.3					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	0.9999		>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Hypofibrinogenaemia	<= 40	167	33.7	1	0.6	157	31.2	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.		0.00	Algorithm converged.	NE	NE	0.9999		1.1016	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Hypofibrinogenaemia	> 40	328	66.3	0	0.0	345	68.5	1	0.3					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	0.9999		>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Increased tendency to bruise	<= 40	167	33.7	0	0.0	157	31.2	1	0.6					Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.107627485 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
Blood and lymphatic system disorders	Increased tendency to bruise	> 40	328	66.3	1	0.3	345	68.5	0	0.0					Quasi-complete separation of data points detected.				ERROR: Negative of Hessian not positive definite.		0.00	Algorithm converged.	NE	NE	0.9999		>999.99	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Iron deficiency anaemia	<= 40	167	33.7	0	0.0	157	31.2	2	1.3					Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.109054211 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	Iron deficiency anaemia	> 40	328	66.3	0	0.0	345	68.5	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Leukocytosis	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Leukocytosis	> 40	328	66.3	1	0.3	345	68.5	4	1.2	0.24	Convergence criterion (ECOSS=1E-8) satisfied.	0.03	2.02	-0.009	Algorithm converged.	-0.020	0.002	0.24	Algorithm converged.	0.03	2.22	0.2270		0.83	Algorithm converged.	0.43	34.24
Blood and lymphatic system disorders	Leukopenia	<= 40	167	33.7	14	9.6	157	31.2	8	5.7	1.74	Convergence criterion (ECOSS=1E-8) satisfied.	0.75	4.07	0.038	Algorithm converged.	-0.003	0.090	1.47	Algorithm converged.	0.76	2.87	0.2009	0.0681	0.65	Algorithm converged.	0.27	1.23
Blood and lymphatic system disorders	Leukopenia	> 40	328	66.3	29	8.5	345	68.5	43	11.7	0.76	Convergence criterion (ECOSS=1E-8) satisfied.	0.42	1.37	-0.032	Algorithm converged.	-0.078	0.014	0.77	Algorithm converged.	0.46	1.13	0.1743		1.27	Algorithm converged.	0.87	2.17
Blood and lymphatic system disorders	Lymph node pain	<= 40	167	33.7	1	0.6	157	31.2	0	0.0					Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.		0.00	Algorithm converged.	NE	NE	0.9944		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Lymph node pain	> 40	328	66.3	0	0.0	345	68.5	2	0.6					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		>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Lymphadenopathy	<= 40	167	33.7	1	0.6	157	31.2	0	0.0					Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.		0.00	Algorithm converged.	NE	NE	0.4249		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Lymphadenopathy	> 40	328	66.3	2	0.6	345	68.5	3	0.9	2.08	Convergence criterion (ECOSS=1E-8) satisfied.	0.33	23.13	0.003	Algorithm converged.	-0.007	0.013	2.00	Algorithm converged.	0.33	22.82	0.5493		0.86	Algorithm converged.	0.06	5.20
Blood and lymphatic system disorders	Lymphopenia	<= 40	167	33.7	2	1.2	157	31.2	3	1.9	0.92	Convergence criterion (ECOSS=1E-8) satisfied.	0.15	4.77	-0.007	Algorithm converged.	-0.038	0.005	0.43	Algorithm converged.	0.15	3.79	0.4361	0.9058	1.45	Algorithm converged.	0.27	9.44
Blood and lymphatic system disorders	Lymphopenia	> 40	328	66.3	10	3.0	345	68.5	13	3.8	0.79	Convergence criterion (ECOSS=1E-8) satisfied.	0.34	1.84	-0.008	Algorithm converged.	-0.045	0.020	0.80	Algorithm converged.	0.34	1.82	0.5880		1.21	Algorithm converged.	0.52	2.83
Blood and lymphatic system disorders	Myelosuppression	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	> 40	328	66.3	4	1.2	345	68.5	1	0.3	0.23	Convergence criterion (ECOSS=1E-8) satisfied.	0.47	97.55	0.004	Algorithm converged.	-0.004	0.022	4.14	Algorithm converged.	0.47	97.01	0.2013		0.24	Algorithm converged.	0.02	2.14
Blood and lymphatic system disorders	Neutropenia	<= 40	167	33.7	43	25.7	157	31.2	37	23.6	1.13	Convergence criterion (ECOSS=1E-8) satisfied.	0.69	1.87	0.022	Algorithm converged.	-0.073	0.116	1.09	Algorithm converged.	0.75	1.62	0.6495	0.9280	0.92	Algorithm converged.	0.62	1.34
Blood and lymphatic system disorders	Neutropenia	> 40	328	66.3	97	29.6	345	68.5	115	33.3	1.23	Convergence criterion (ECOSS=1E-8) satisfied.	0.92	1.64	0.040	Algorithm converged.	-0.010	0.039	1.06	Algorithm converged.	0.95	1.19	0.2487		1.16	Algorithm converged.	0.92	1.47
Blood and lymphatic system disorders	Neutrophilia	<= 40	167	33.7	1	0.6	157	31.2	2	1.3	0.47	Convergence criterion (ECOSS=1E-8) satisfied.	0.04	5.00	-0.007	Algorithm converged.	-0.039	0.014	0.47	Algorithm converged.	0.04	5.23	0.5340	0.4241	1.13	Algorithm converged.	0.19	23.23
Blood and lymphatic system disorders	Neutrophilia	> 40	328	66.3	0	0.0	345	68.5	1	0.3					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	0.9999		>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Pancytopenia	<= 40	167	33.7	0	0.0	157	31.2	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	> 40	328	66.3	1	0.3	345	68.5	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.		0.00	Algorithm converged.	NE	NE	0.9999		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Splenic infarction	<= 40	167	33.7	0	0.0	157	31.2	1	0.6					Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.		0.00	Algorithm converged.	NE	NE	0.9944		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Splenic infarction	> 40	328	66.3	0	0.0	345	68.5	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Thrombocytosis	<= 40	167	33.7	10	6.9	157	31.2	12	7.6	0.77	Convergence criterion (ECOSS=1E-8) satisfied.	0.32	1.84	-0.017	Algorithm converged.	-0.072	0.038	0.79	Algorithm converged.	0.35	1.74	0.5550	0.5071	1.28	Algorithm converged.	0.57	2.87
Blood and lymphatic system disorders	Thrombocytosis	> 40	328	66.3	24	11.0	345	68.5	20	10.2	1.05	Convergence criterion (ECOSS=1E-8) satisfied.	0.60	1.73	0.007	Algorithm converged.	-0.040	0.054	1.07	Algorithm converged.	0.65	1.69	0.7652		0.93	Algorithm converged.	0.60	1.44
Cardiac disorders		<= 40	167	33.7	9	5.4	157	31.2	17	10.8	0.47	Convergence criterion (ECOSS=1E-8) satisfied.	0.20	1.09	-0.054	Algorithm converged.	-0.114	0.007	0.49	Algorithm converged.	0.23	1.04	0.0788	0.4178	0.21	Algorithm converged.	0.02	4.27
Cardiac disorders		> 40	328	66.3	31	9.5	345	68.5	43	12.5	0.69	Convergence criterion (ECOSS=1E-8) satisfied.	0.43	1.09	-0.031	Algorithm converged.	-0.085	0.023	0.72	Algorithm converged.	0.47	1.09	0.1284		1.05	Algorithm converged.	0.72	2.19
Cardiac disorders	Acute myocardial infarction	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Acute myocardial infarction	> 40	328	66.3	1	0.3	345	68.5	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.		0.00	Algorithm converged.	NE	NE	0.9999		NE	Algorithm converged.	NE	NE
Cardiac disorders	Angina pectoris	<= 40	167	33.7	0	0.0	157	31.2	1	0.6					Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.107627742 is greater than the limit of 0.0001. The convergence is questionable.		0.00	Algorithm converged.	0.00	NE	0.9999	0.9940	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Angina pectoris	> 40	328	66.3	2	0.6	345	68.5	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.		0.00	Algorithm converged.	NE	NE	0.9999		NE	Algorithm converged.	NE	NE
Cardiac disorders	Arrhythmia	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Arrhythmia	> 40	328	66.3	0	0.0	345	68.5	2	0.6					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		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	<= 40	167	33.7	3	1.8	157	31.2	5	3.2	0.54	Convergence criterion (ECOSS=1E-8) satisfied.	0.11	2.61	-0.017	Algorithm converged.	-0.064	0.014	0.56	Algorithm converged.	0.11	2.84	0.4833	0.6334	0.58	Algorithm converged.	0.19	1.78
Cardiac disorders	Atrial fibrillation	> 40	328	66.3	3	0.9	345	68.5	9	2.6	0.34	Convergence criterion (ECOSS=1E-8) satisfied.	0.09	1.22	-0.037	Algorithm converged.	-0.097	0.023	0.39	Algorithm converged.	0.08	1.23	0.1093		0.85	Algorithm converged.	0.70	10.53
Cardiac disorders	Atrial flutter	<= 40	167	33.7	1	0.6	157	31.2	1	0.6	1.04	Convergence criterion (ECOSS=1E-8) satisfied.	0.06	16.55	0.000	Algorithm converged.	-0.017	0.017	1.04	Algorithm converged.	0.06	16.30	0.9453		0.96	Algorithm converged.	0.06	14.92
Cardiac disorders	Atrial flutter	> 40	328	66.3	0	0.0	345	68.5	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrioventricular block	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrioventricular block	> 40	328	66.3	0	0.0	345	68.5	1	0.3					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	0.9999		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block complete	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	> 40	328	66.3	0	0.0	345	68.5	1	0.3					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	0.9999		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block first degree	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrioventricular block first degree	> 40	328	66.3	2	0.6	345	68.5	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.		0.00	Algorithm converged.	NE	NE	0.9999		NE	Algorithm converged.	NE	NE
Cardiac disorders	Bradycardia	<= 40	167	33.7	0	0.0	157	31.2	1	0.6					Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.107627742 is greater than the limit of 0.0001. The convergence is questionable.		0.00	Algorithm converged.	0.00	NE	0.9999	0.9224	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Bradycardia	> 40	328	66.3	7	2.0	345	68.5	2	0.6	3.29	Convergence criterion (ECOSS=1E-8) satisfied.	0.63	4.60	-0.009	Algorithm converged.	-0.024	0.001	0.31	Algorithm converged.	0.63	4.60	0.0881	0.0881	3.24	Algorithm converged.	0.63	4.60
Cardiac disorders	Cardiac disorder	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Cardiac disorder	> 40	328	66.3	1	0.3	345	68.5	1	0.3					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	0.9999		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Cardiac dysfunction	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Cardiac dysfunction	> 40	328	66.3	1	0.3	345	68.5	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.		0.00	Algorithm converged.	NE	NE	0.9999		NE	Algorithm converged.	NE	NE
Cardiac disorders	Cardiac failure	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Cardiac failure	> 40	328	66.3	2	0.6	345	68.5	2	0.6	1.04	Convergence criterion (ECOSS=1E-8) satisfied.	0.15	7.40	0.000	Algorithm converged.	-0.011	0.013	1.04	Algorithm converged.	0.15	7.24	0.9489		0.96	Algorithm converged.	0.14	6.73
Cardiac disorders	Cardiac failure congestive	<= 40	167	33.7	1	0.6	157	31.2	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.		0.00	Algorithm converged.	NE	NE	0.9944		NE	Algorithm converged.	NE	NE
Cardiac disorders	Cardiac failure congestive	> 40	328	66.3	0	0.0	345	68.5	2	0.6					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		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Cardiomyopathy	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Cardiomyopathy	> 40	328	66.3	1	0.3	345	68.5	2	0.6	2.02	Convergence criterion (ECOSS=1E-8) satisfied.	0.05	5.74	-0.003	Algorithm converged.	-0.010	0.003	0.52	Algorithm converged.	0.05	5.71	0.5325		1.02	Algorithm converged.	0.04	23.13
Cardiac disorders	Cardiomyopathy failure	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Cardiomyopathy failure	> 40	328	66.3	1	0.3	345	68.5	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.		0.00	Algorithm converged.	NE	NE	0.9999		NE	Algorithm converged.	NE	NE
Cardiac disorders	Chromotropic dysfunction	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Chromotropic dysfunction	> 40	328	66.3	0	0.0	345	68.5	1	0.3					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	0.9999		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Left ventricular dysfunction	<= 40	167	33.7	0	0.0	157	31.2	1	0.6					Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.107627485 is greater than the limit of 0.0001. The convergence is questionable.		0.00	Algorithm converged.	0.00	NE	0.9999	0.2597	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Left ventricular dysfunction	> 40	328	66.3	2	0.6	345	68.5	2	0.6	1.04	Convergence criterion (ECOSS=1E-8) satisfied.	0.15	7.40	0.000	Algorithm converged.	-0.011	0.013	1.04	Algorithm converged.	0.15	7.24	0.9489		0.96	Algorithm converged.	0.14	6.73
Cardiac disorders	Myocardial infarction	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Myocardial infarction	> 40	328	66.3	1	0.3	345	68.5	3	0.9	3.04	Convergence criterion (ECOSS=1E-8) satisfied.	0.06	14.65	0.606	Algorithm converged.	-0.008	0.006	1.64	Algorithm converged.	0.07	14.33	0.9780		0.94	Algorithm converged.	0.06	15.31
Cardiac disorders	Palpitations	<= 40	167	33.7	3	1.8	157	31.2	1	0.6	0.17	Convergence criterion (ECOSS=1E-8) satisfied.	0.03	2.60	-0.013	Algorithm converged.	-0.068	0.013	0.18	Algorithm converged.	0.03	2.58	0.3127	0.7573	0.18	Algorithm converged.	0.03	20.36
Cardiac disorders	Palpitations	> 40	328	66.3	1	0.3	345	68.5	6	1.8	0.17	Convergence criterion (ECOSS=1E-8) satisfied.	0.02	1.43	-0.016	Algorithm converged.	-0.049	0.001	0.17	Algorithm converged.	0.02	1.43	0.1057		0.17	Algorithm converged.	0.02	87.65
Cardiac disorders	Ventricular diffusion	<= 40	167	33.7	0	0.0	157	31.2	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Ventricular diffusion	> 40	328	66.3	0	0.0	345	68.5	1	0.3					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	0.9999		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Pericarditis	<= 40	167	33.7	1	0.6	157	31.2	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.		0.00	Algorithm converged.	NE	NE	0.9944		NE	Algorithm converged.	NE	NE
Cardiac disorders	Pericarditis	> 40	328	66.3	0	0.0	345	68.5	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	<= 40	167	33.7	0	0.0	157	31.2	1	0.6					Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.107627485 is greater than the limit of 0.0001. The convergence is questionable.		0.00	Algorithm converged.	0.00	NE	0.9999	1.0000	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Sinus bradycardia	> 40	328	66.3	0	0.0	345	68.5	2	0.6					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







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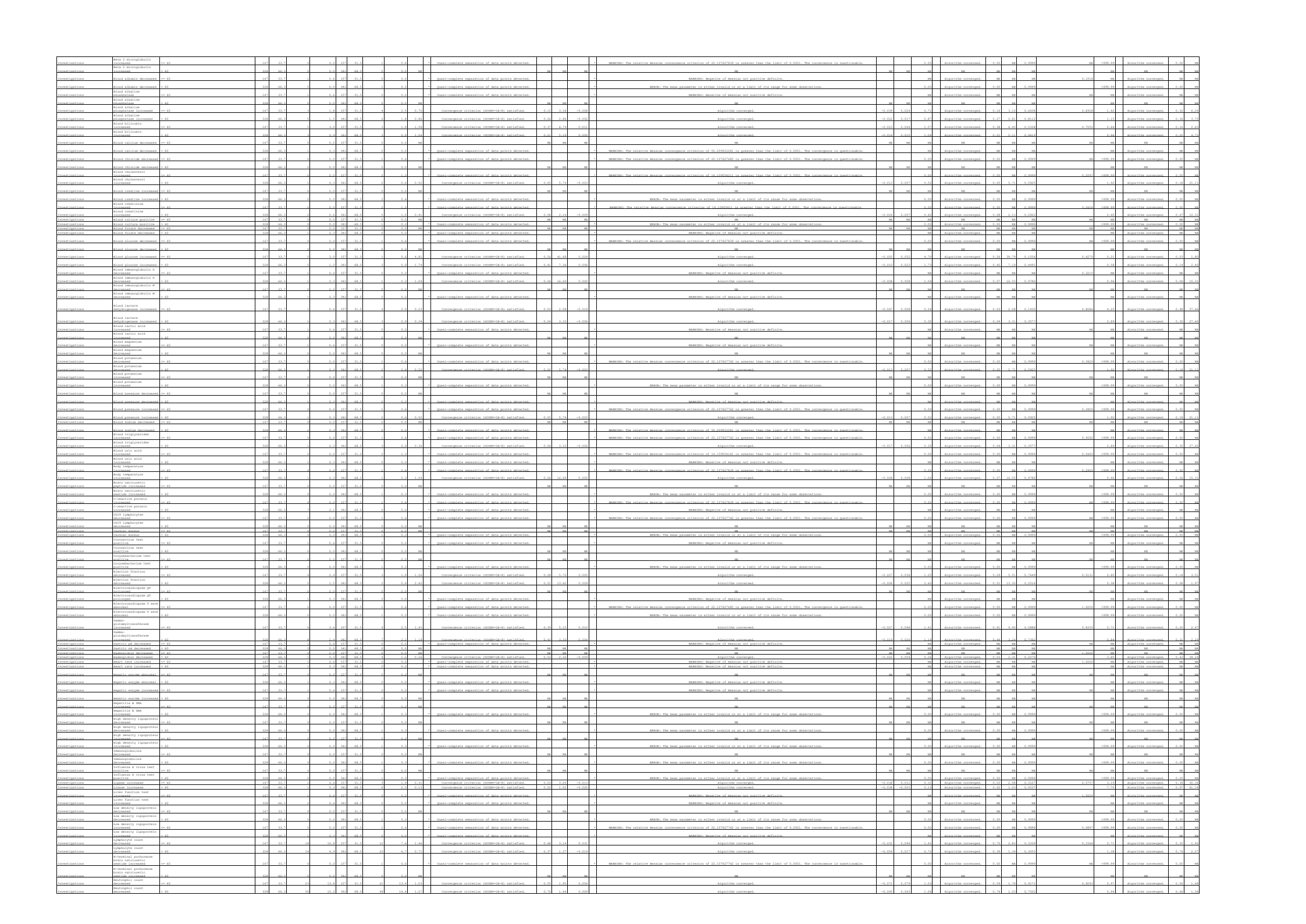

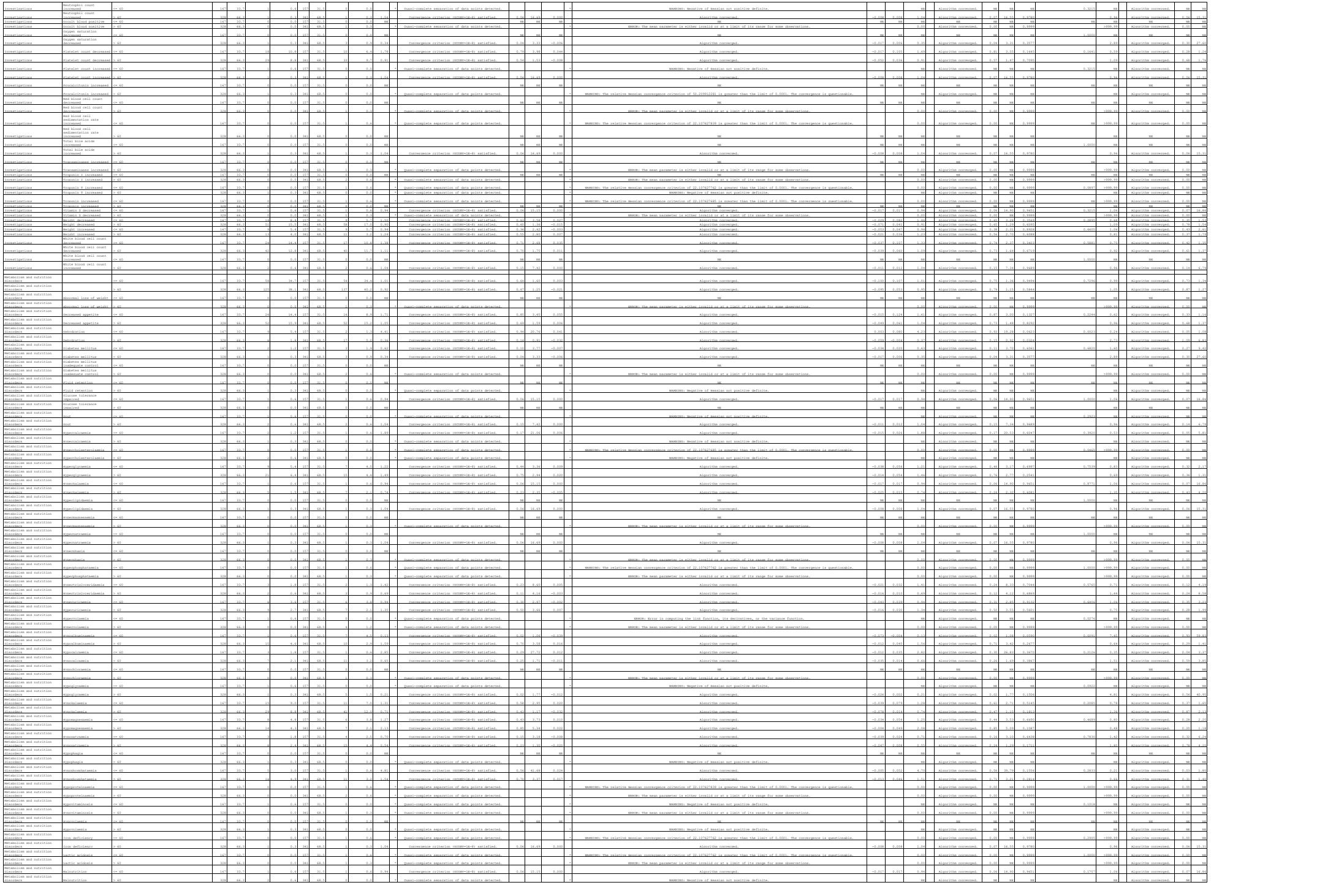

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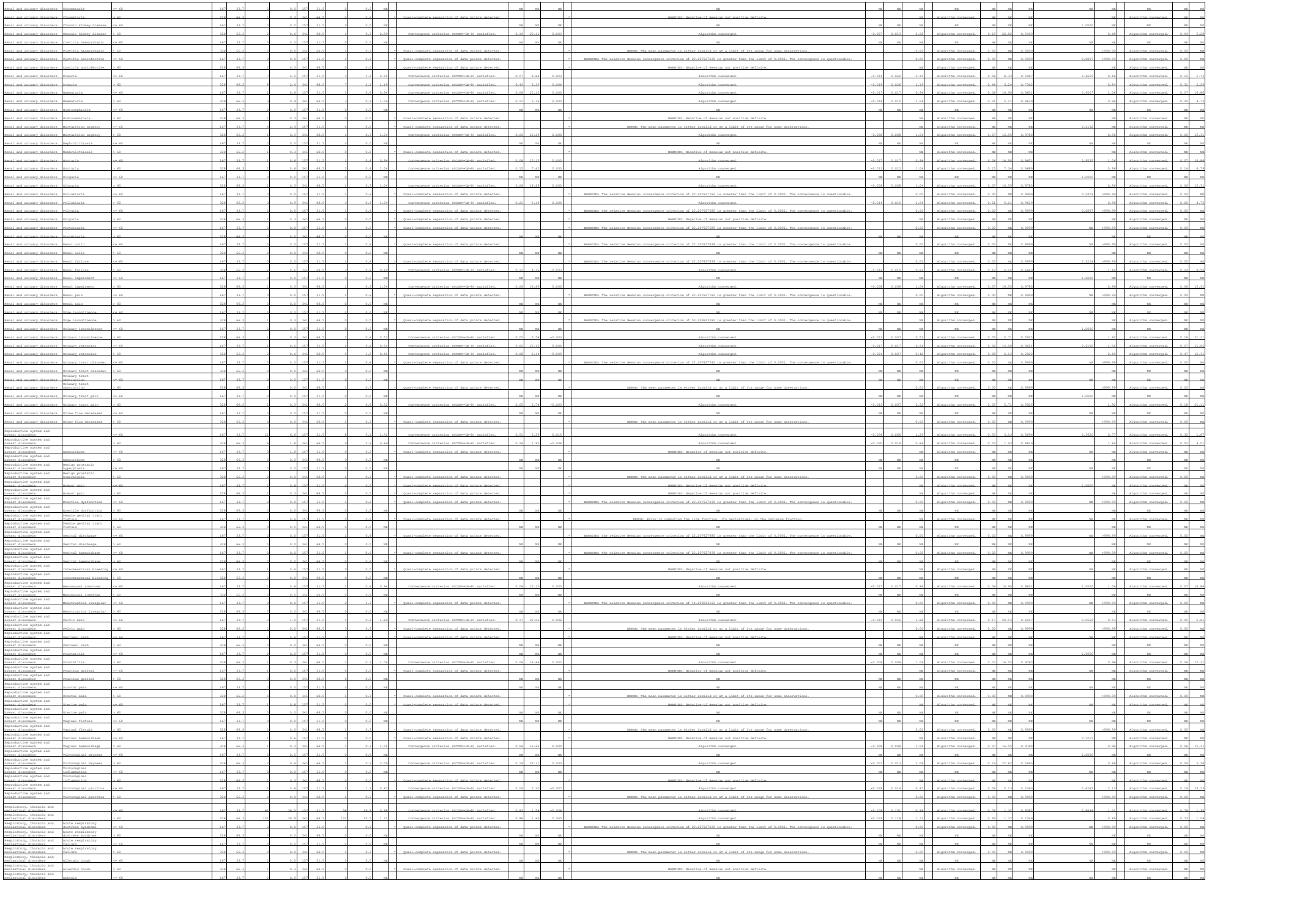

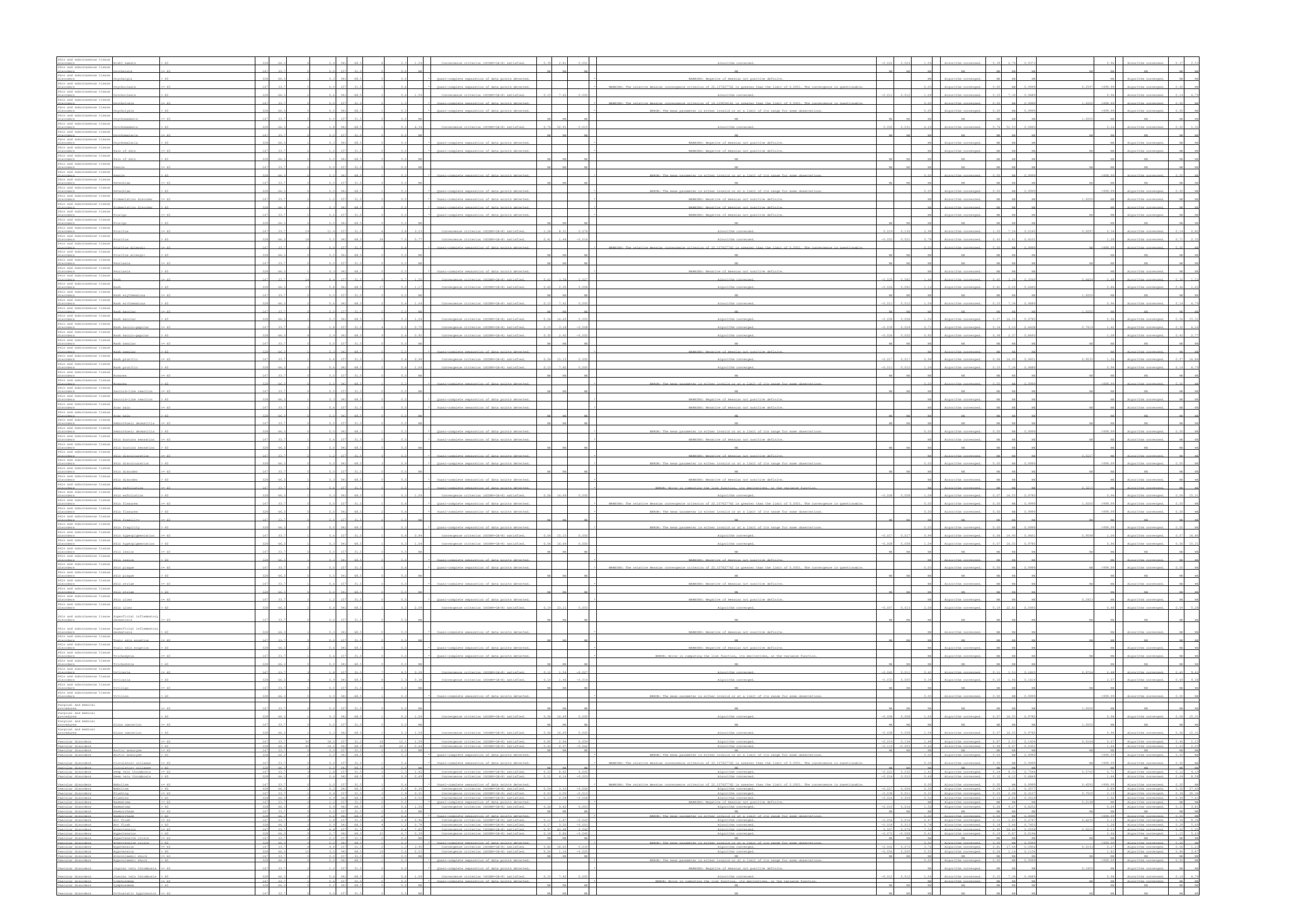

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Any AEs
MODEL: Unstratified Analysis
STRUT: SS39962
Dichotomous Analysis by Subgroups (Safety)

ZPG score at Screening

			Pulsatronab Tablets + N-CNP (N=187)				N-CNP (N=188)				Pulsatronab Tablets + N-CNP vs. N-CNP												N-CNP vs. Pulsatronab Tablets + N-CNP			
			Patients		Patients with Event		Patients		Patients with Event		Absolute Risk Difference												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	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		1-2	187	37.8	101	54.0	187	37.4	93	49.7	1.19	Convergence criterion (ncons<1E-6) satisfied.	0.73	1.78	0.041	Algorithm converged.	-0.056	0.145	1.08	Algorithm converged.	0.48	1.12	0.4881	0.5392	0.92	Algorithm converged.	0.74	1.14
Blood and lymphatic system disorders		3	196	39.6	104	53.1	188	37.4	85	45.2	1.34	Convergence criterion (ncons<1E-6) satisfied.	0.79	1.90	0.079	Algorithm converged.	-0.056	0.145	1.41	Algorithm converged.	0.96	1.19	0.4881		1.18	Algorithm converged.	0.79	1.17
Blood and lymphatic system disorders		4-5	112	22.6	74	67.9	125	25.1	70	56.0	1.64	Convergence criterion (ncons<1E-6) satisfied.	0.98	2.82	0.119	Algorithm converged.	-0.056	0.145	1.21	Algorithm converged.	0.96	1.48	0.0611		1.21	Algorithm converged.	0.99	1.01
Blood and lymphatic system disorders	Agranulocytosis	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Agranulocytosis	3	196	39.6	0	0.0	188	37.4	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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	Agranulocytosis	4-5	112	22.6	0	0.0	125	25.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Anemia	1-2	187	37.8	52	27.8	187	37.4	51	27.3	1.03	Convergence criterion (ncons<1E-6) satisfied.	0.69	1.54	0.005	Algorithm converged.	-0.096	0.086	1.02	Algorithm converged.	0.79	1.40	0.9079	0.7004	1.02	Algorithm converged.	0.73	1.39
Blood and lymphatic system disorders	Anemia	3	196	39.6	65	33.2	188	37.4	50	26.9	1.35	Convergence criterion (ncons<1E-6) satisfied.	0.87	2.10	0.063	Algorithm converged.	-0.096	0.086	1.23	Algorithm converged.	0.96	1.48	0.1803		1.23	Algorithm converged.	0.93	1.10
Blood and lymphatic system disorders	Anemia	4-5	112	22.6	47	42.0	125	25.1	45	36.0	1.28	Convergence criterion (ncons<1E-6) satisfied.	0.75	2.15	0.060	Algorithm converged.	-0.096	0.086	1.17	Algorithm converged.	0.85	1.55	0.3476		1.16	Algorithm converged.	0.82	1.16
Blood and lymphatic system disorders	Aplasia pure red cell	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	1.0000		NE	NE	NE	NE
Blood and lymphatic system disorders	Aplasia pure red cell	3	196	39.6	0	0.0	188	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Aplasia pure red cell	4-5	112	22.6	1	0.9	125	25.1	1	0.8	1.12	Convergence criterion (ncons<1E-6) satisfied.	0.07	18.07	0.001	Algorithm converged.	-0.030	0.024	1.13	Algorithm converged.	0.07	17.63	0.9278		1.13	Algorithm converged.	0.06	14.16
Blood and lymphatic system disorders	Cytopenia	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Cytopenia	3	196	39.6	1	0.5	188	37.4	1	0.5	1.05	Convergence criterion (ncons<1E-6) satisfied.	0.06	15.28	0.000	Algorithm converged.	-0.030	0.024	0.97	Algorithm converged.	0.06	15.24	0.9704		1.05	Algorithm converged.	0.07	16.72
Blood and lymphatic system disorders	Cytopenia	4-5	112	22.6	0	0.0	125	25.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Erythrocytosis	1-2	187	37.8	0	0.0	187	37.4	1	0.5		Quasi-complete separation of data points detected.				KNOWN: 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	Erythrocytosis	3	196	39.6	0	0.0	188	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Erythrocytosis	4-5	112	22.6	0	0.0	125	25.1	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 bone marrow aplasia	1-2	187	37.8	0	0.0	187	37.4	1	0.5		Quasi-complete separation of data points detected.				KNOWN: 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	Febrile bone marrow aplasia	3	196	39.6	0	0.0	188	37.4	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 bone marrow aplasia	4-5	112	22.6	1	0.9	125	25.1	1	0.8	1.12	Convergence criterion (ncons<1E-6) satisfied.	0.07	18.07	0.001	Algorithm converged.	-0.030	0.024	1.13	Algorithm converged.	0.07	17.63	0.9278		1.13	Algorithm converged.	0.06	14.16
Blood and lymphatic system disorders	Febrile neutropenia	1-2	187	37.8	21	11.2	187	37.4	12	6.4	1.84	Convergence criterion (ncons<1E-6) satisfied.	0.88	3.85	0.048	Algorithm converged.	-0.030	0.103	1.75	Algorithm converged.	0.99	3.41	0.1044	0.6210	1.75	Algorithm converged.	0.29	1.11
Blood and lymphatic system disorders	Febrile neutropenia	3	196	39.6	25	12.8	188	37.4	17	9.1	1.45	Convergence criterion (ncons<1E-6) satisfied.	0.76	2.78	0.036	Algorithm converged.	-0.030	0.093	1.40	Algorithm converged.	0.79	2.51	0.2421		1.41	Algorithm converged.	0.40	1.26
Blood and lymphatic system disorders	Febrile neutropenia	4-5	112	22.6	20	17.9	125	25.1	10	8.0	2.55	Convergence criterion (ncons<1E-6) satisfied.	1.13	5.80	0.099	Algorithm converged.	0.043	0.183	2.24	Algorithm converged.	1.05	4.94	0.0277		2.24	Algorithm converged.	0.84	0.84
Blood and lymphatic system disorders	Granulocytopenia	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Granulocytopenia	3	196	39.6	0	0.0	188	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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	Granulocytopenia	4-5	112	22.6	0	0.0	125	25.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Hypofibrinogenemia	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Hypofibrinogenemia	3	196	39.6	1	0.5	188	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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	Hypofibrinogenemia	4-5	112	22.6	0	0.0	125	25.1	1	0.8	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 14.31412847 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
Blood and lymphatic system disorders	Increased tendency to bruise	1-2	187	37.8	0	0.0	187	37.4	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	3	196	39.6	0	0.0	188	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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	Increased tendency to bruise	4-5	112	22.6	1	0.9	125	25.1	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 18.71248136 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	Iron deficiency anaemia	1-2	187	37.8	0	0.0	187	37.4	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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	Iron deficiency anaemia	3	196	39.6	0	0.0	188	37.4	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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	Iron deficiency anaemia	4-5	112	22.6	0	0.0	125	25.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Leukocytosis	1-2	187	37.8	1	0.6	187	37.4	2	1.1	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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	Leukocytosis	3	196	39.6	1	0.5	188	37.4	2	1.1	0.47	Convergence criterion (ncons<1E-6) satisfied.	0.04	5.20	-0.006	Algorithm converged.	-0.024	0.012	0.47	Algorithm converged.	0.04	5.18	0.5411		0.47	Algorithm converged.	0.04	22.01
Blood and lymphatic system disorders	Leukocytosis	4-5	112	22.6	0	0.0	125	25.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Leukopenia	1-2	187	37.8	12	6.4	187	37.4	10	8.0	0.79	Convergence criterion (ncons<1E-6) satisfied.	0.34	1.77	-0.016	Algorithm converged.	-0.064	0.034	0.80	Algorithm converged.	0.38	1.66	0.5489	0.2489	0.80	Algorithm converged.	0.40	2.60
Blood and lymphatic system disorders	Leukopenia	3	196	39.6	17	8.7	188	37.4	23	12.2	0.67	Convergence criterion (ncons<1E-6) satisfied.	0.35	1.30	-0.037	Algorithm converged.	-0.064	0.023	0.73	Algorithm converged.	0.38	1.27	0.2413		0.73	Algorithm converged.	0.73	2.50
Blood and lymphatic system disorders	Leukopenia	4-5	112	22.6	15	13.4	125	25.1	11	8.8	1.60	Convergence criterion (ncons<1E-6) satisfied.	0.73	3.47	0.046	Algorithm converged.	-0.034	0.134	1.52	Algorithm converged.	0.73	3.17	0.2625		1.46	Algorithm converged.	0.32	1.37
Blood and lymphatic system disorders	Lymph node pain	1-2	187	37.8	1	0.5	187	37.4	1	0.5	1.00	Convergence criterion (ncons<1E-6) satisfied.	0.06	16.11	0.000	Algorithm converged.	-0.033	0.033	1.00	Algorithm converged.	0.06	15.87	1.0000	0.5811	1.00	Algorithm converged.	0.06	15.8
Blood and lymphatic system disorders	Lymph node pain	3	196	39.6	0	0.0	188	37.4	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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	Lymph node pain	4-5	112	22.6	0	0.0	125	25.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Lymphadenopathy	1-2	187	37.8	1	0.6	187	37.4	2	1.1	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE	0.2981	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Lymphadenopathy	3	196	39.6	1	0.5	188	37.4	1	0.5	0.95	Convergence criterion (ncons<1E-6) satisfied.	0.06	15.28	0.000	Algorithm converged.	-0.033	0.033	0.95	Algorithm converged.	0.06	15.24	0.9704		1.05	Algorithm converged.	0.07	16.72
Blood and lymphatic system disorders	Lymphadenopathy	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 18.71248136 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	Lymphocytosis	1-2	187	37.8	5	2.7	187	37.4	3	1.7	0.71	Convergence criterion (ncons<1E-6) satisfied.	0.20	2.37	-0.011	Algorithm converged.	-0.046	0.029	0.71	Algorithm converged.	0.20	2.21	0.5593	0.1541	0.80	Algorithm converged.	0.40	4.32
Blood and lymphatic system disorders	Lymphocytosis	3	196	39.6	1	0.5	188	37.4	3	1.7	0.31	Convergence criterion (ncons<1E-6) satisfied.	0.03	1.60	-0.022	Algorithm converged.	-0.047	0.004	0.33	Algorithm converged.	0.04	1.61	0.1274		0.47	Algorithm converged.	0.04	44.68
Blood and lymphatic system disorders	Lymphopenia	4-5	112	22.6	6	5.4	125	25.1	4	3.2	1.75	Convergence criterion (ncons<1E-6) satisfied.	0.47	6.20	0.022	Algorithm converged.	-0.030	0.073	1.47	Algorithm converged.	0.46	5.78	0.4153		0.80	Algorithm converged.	0.17	2.04
Blood and lymphatic system disorders	Myelosuppression	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	0.2567	NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	3	196	39.6	3	1.5	188	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Myelosuppression	4-5	112	22.6	1	0.9	125	25.1	1	0.8	1.12	Convergence criterion (ncons<1E-6) satisfied.	0.07	18.07	0.001	Algorithm converged.	-0.030	0.024	1.13	Algorithm converged.	0.07	17.63	0.9278		1.13	Algorithm converged.	0.06	14.16
Blood and lymphatic system disorders	Neutropenia	1-2	187	37.8	43	23.0	187	37.4	50	26.7	0.83	Convergence criterion (ncons<1E-6) satisfied.	0.53	1.30	-0.034	Algorithm converged.	-0.099	0.031	0.84	Algorithm converged.	0.54	1.31	0.4892	0.9114	0.84	Algorithm converged.	0.63	1.54
Blood and lymphatic system disorders	Neutropenia	3	196	39.6	52	26.5	188	37.4	53	28.5	0.90	Convergence criterion (ncons<1E-6) satisfied.	0.58	1.40	-0.026	Algorithm converged.	-0.099	0.045	0.93	Algorithm converged.	0.67	1.29	0.4674		1.07	Algorithm converged.	0.78	1.49
Blood and lymphatic system disorders	Neutropenia	4-5	112	22.6	23	20.5	125	25.1	44	35.2	0.48	Convergence criterion (ncons<1E-6) satisfied.	0.28	0.84	-0.054	Algorithm converged.	-0.099	0.045	0.58	Algorithm converged.	0.70	1.45	0.9514		1.05	Algorithm converged.	0.73	1.43
Blood and lymphatic system disorders	Neutrophilia	1-2	187	37.8	1	0.5	187	37.4	1	0.5	1.00	Convergence criterion (ncons<1E-6) satisfied.	0.06	16.11	0.000	Algorithm converged.	-0.033	0.033	1.00	Algorithm converged.	0.06	15.87	1.0000	0.6245	1.00	Algorithm converged.	0.06	15.87
Blood and lymphatic system disorders	Neutrophilia	3	196	39.6	0	0.0	188	37.4	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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	Neutrophilia	4-5	112	22.6	0	0.0	125	25.1	1	0.8	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 14.31412847 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
Blood and lymphatic system disorders	Pancytopenia	1-2	187	37.8	0	0.0	187	37.4	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	3	196	39.6	0	0.0	188	37.4	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	4-5	112	22.6	1	0.9	125	25.1	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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	Splenic infarction	1-2	187	37.8	1	0.5	187	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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	Splenic infarction	3	196	39.6	0	0.0	188	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Splenic infarction	4-5	112	22.6	0	0.0	125	25.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Thrombocytosis	1-2	187	37.8	10	5.3	187	37.4	16	8.6	0.60	Convergence criterion (ncons<1E-6) satisfied.	0.27	1.37	-0.032	Algorithm converged.	-0.084	0.019	0.61	Algorithm converged.	0.29	1.29	0.2277	0.3775	0.60	Algorithm converged.	0.73	3.43
Blood and lymphatic system disorders	Thrombocytosis	3	196	39.6	24	12.2	188	37.4	20	10.6	1.16	Convergence criterion (ncons<1E-6) satisfied.	0.62	2.16	0.016	Algorithm converged.	-0.084	0.019	1.15	Algorithm converged.	0.66	1.99	0.6481		1.06	Algorithm converged.	0.70	1.53
Blood and lymphatic system disorders	Thrombocytopenia	4-5	112	22.6	12	10.7	125	25.1	11	8.8	1.24	Convergence criterion (ncons<1E-6) satisfied.	0.53	2.94	0.014	Algorithm converged.	-0.057	0.085	1.23	Algorithm converged.	0.54	2.83	0.6397		1.02	Algorithm converged.	0.90	1.79
Cardiac disorders		1-2	187	37.8	13	7.0	187	37.4	18	9.6	0.73	Convergence criterion (ncons<1E-6) satisfied.	0.33	1.60	-0.027	Algorithm converged.	-0.083	0.029	0.73	Algorithm converged.	0.34	1.61	0.3514	0.0059	0.68	Algorithm converged.	0.73	2.74
Cardiac disorders		3	196	39.6	11	5.6	188	37.4	32	17.0	0.29	Convergence criterion (ncons<1E-6) satisfied.	0.14	0.59	-0.114	Algorithm converged.	-0.170	-0.057	0.33	Algorithm converged.	0.17	0.63	0.0002		0.47	Algorithm converged.	0.19	1.06
Cardiac disorders		4-5	112	22.6	16	14.3	125	25.1	32	25.6	0.47	Convergence criterion (ncons<1E-6) satisfied.	0.24	0.90	-0.067	Algorithm converged.	-0.168	0.035	0.56	Algorithm converged.	0.25	1.26	0.0083		0.67	Algorithm converged.	0.29	1.52
Cardiac disorders	Acute myocardial infarction	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Acute myocardial infarction	3	196	39.6	0	0.0	188	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Acute myocardial infarction	4-5	112	22.6	1	0.9	125	25.1	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	0.9999		NE	Algorithm converged.	0.00	NE
Cardiac disorders	Angina pectoris	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Angina pectoris	3	196	39.6	2	1.0	188	37.4	1	0.5	1.95	Convergence criterion (ncons<1E-6) satisfied.	0.17	21.93	0.005	Algorithm converged.	-0.034	0.043	1.47	Algorithm converged.	0.17	20.75	0.5960		1.95	Algorithm converged.	0.03	0.03
Cardiac disorders	Angina pectoris	4-5	112	22.6	0	0.0	125	25.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Arrhythmia	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Arrhythmia	3	196	39.6	0	0.0	188	37.4	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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
Cardiac disorders	Arrhythmia	4-5	112	22.6	2	0.6	125	25.1	1	0.8	1.12	Convergence criterion (ncons<1E-6) satisfied.	0.07	18.07	0.001	WARNING: The relative Hessian convergence criterion of 14.31412847 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
Cardiac disorders	Atrial fibrillation	1-2	187	37.8	3	1.6	187	37.4	1	0.5	3.00	Convergence criterion (ncons<1E-6) satisfied.	0.31	4.61	-0.000	Algorithm converged.	-0.029	0.014	3.00	Algorithm converged.	0.31	4.58	0.0449	0.5449	3.00	Algorithm converged.	0.31	4.58
Cardiac disorders	Atrial fibrillation	3	196	39.6	1	0.5	188	37.4	4	2.1	0.23	Convergence criterion (ncons<1E-6) satisfied.	0.03	2.03	-0.014	Algorithm converged.	-0.080	0.007	0.23	Algorithm converged.	0.03	2.03	0.1963		0.23	Algorithm converged.	0.03	37.37
Cardiac disorders	Atrial fibrillation	4-5	112	22.6	2	1.8	125	25.1	3	2.4	0.73	Convergence criterion (ncons<1E-6) satisfied.	0.11	4.67	0.000	Algorithm converged.	-0.073	0.043	0.73	Algorithm converged.	0.11	4.64	0.7313		0.73	Algorithm converged.	0.11	4.64
Cardiac disorders	Atrial flutter	1-2	187	37.8	1	0.5	187	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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
Cardiac disorders	Atrial flutter	3	196	39.6	1	0.5	188	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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
Cardiac disorders	Atrial flutter	4-5	112	22.6	0	0.0	125	25.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block	3	196	39.6	0	0.0	188	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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
Cardiac disorders	Atrioventricular block complete	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	3	196	39.6	0	0.0	188	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	4-5	112	22.6	0	0.0	125	25.1	1	0.8	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 14.31412847 is greater

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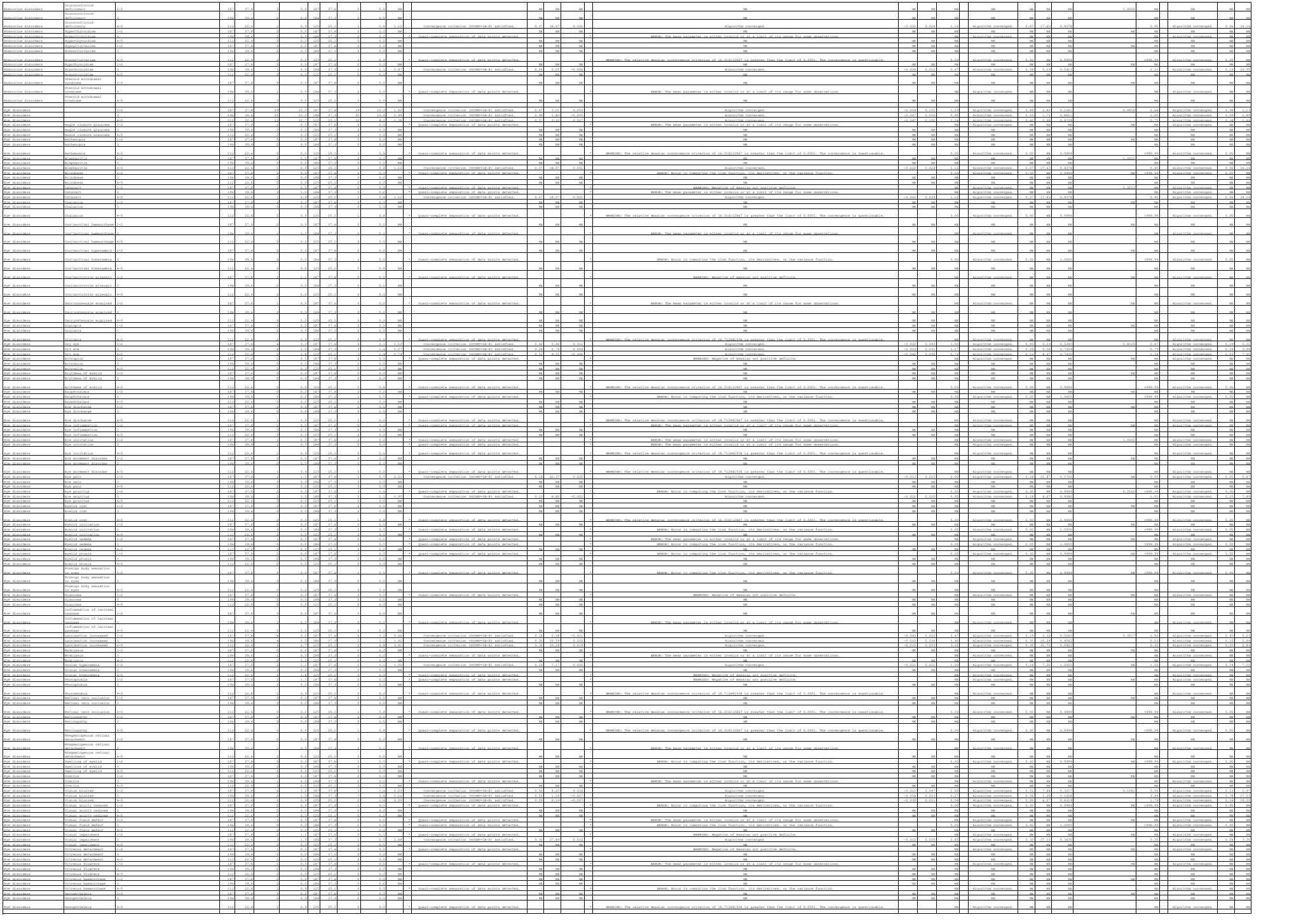

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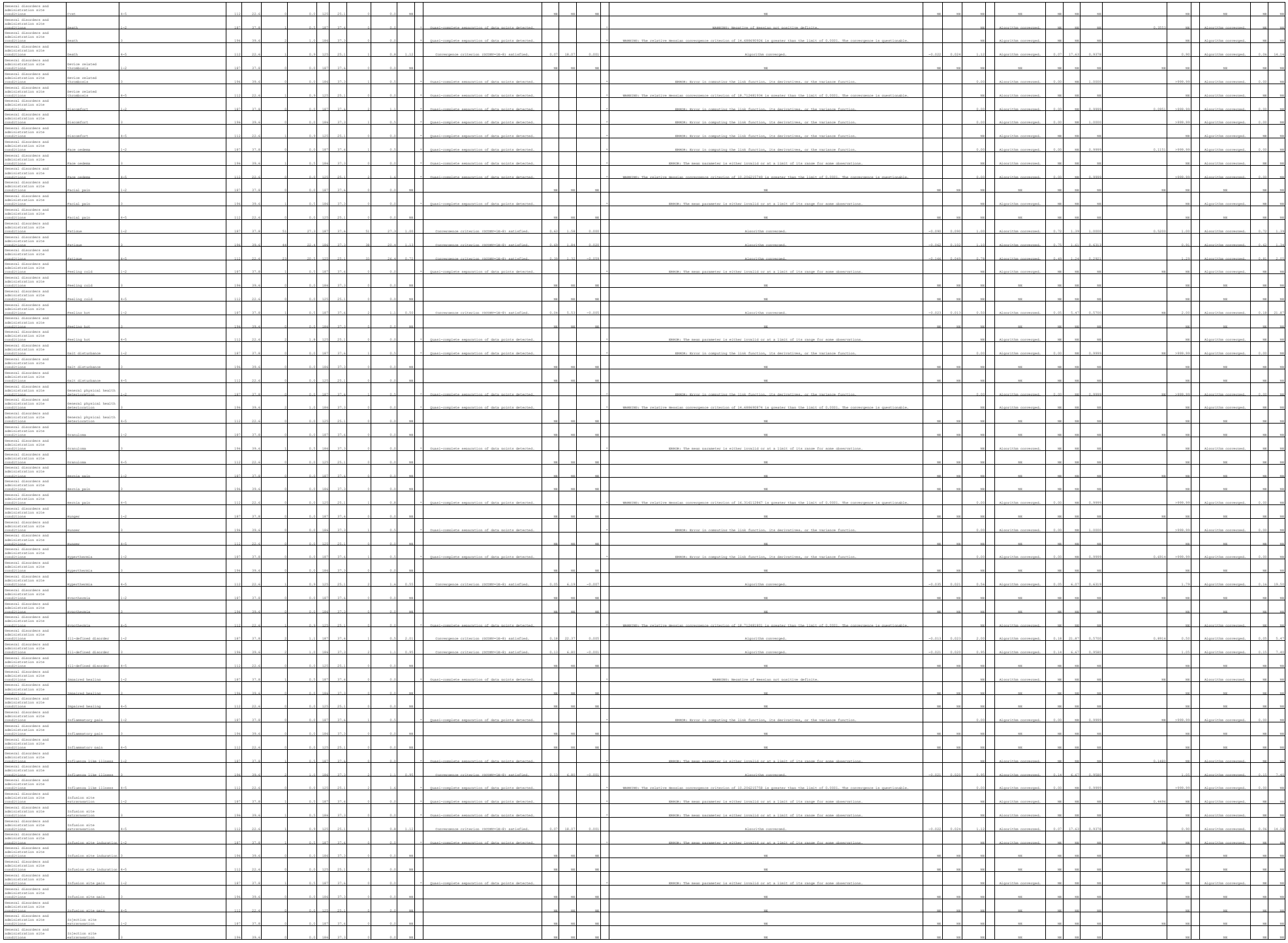

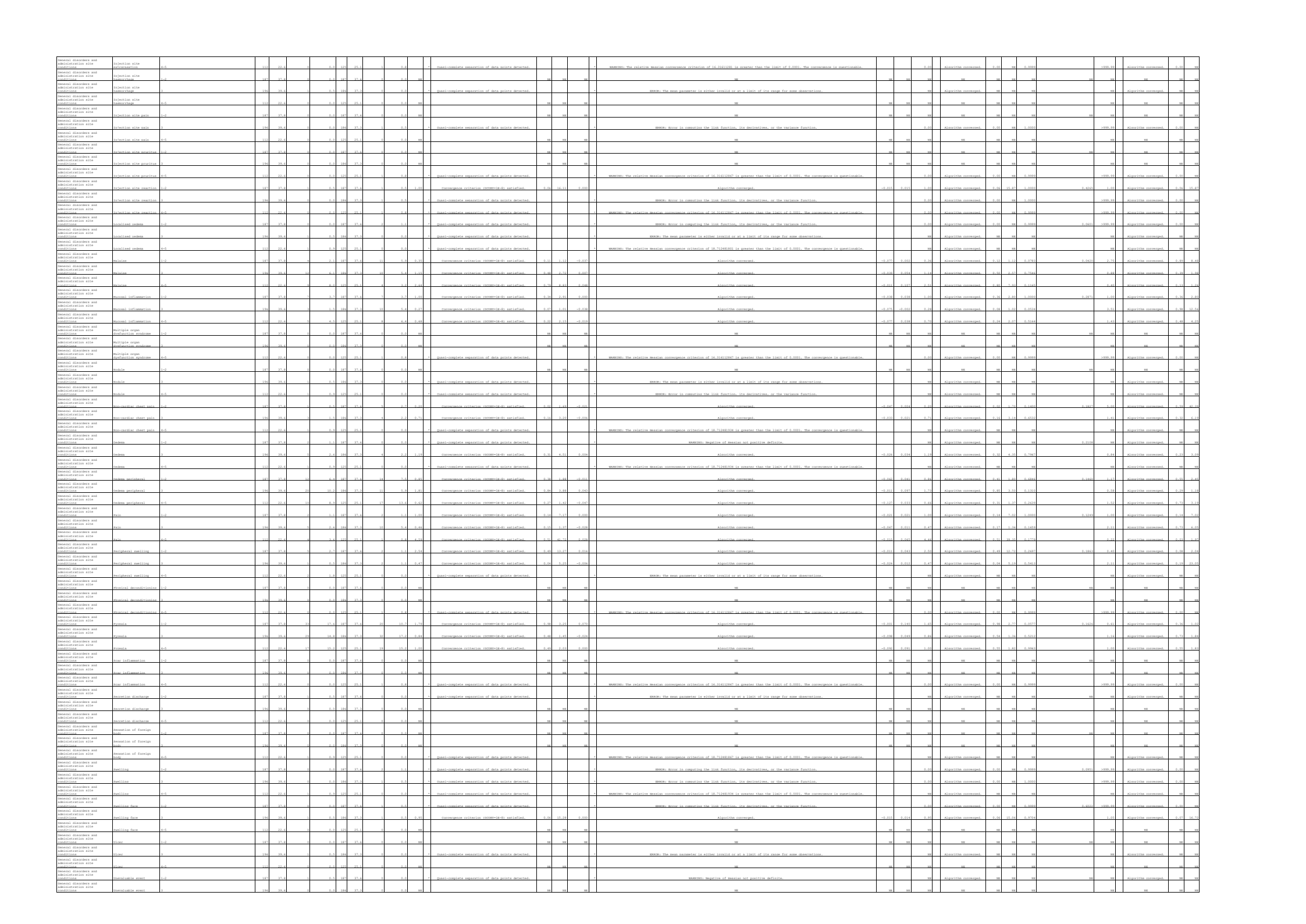

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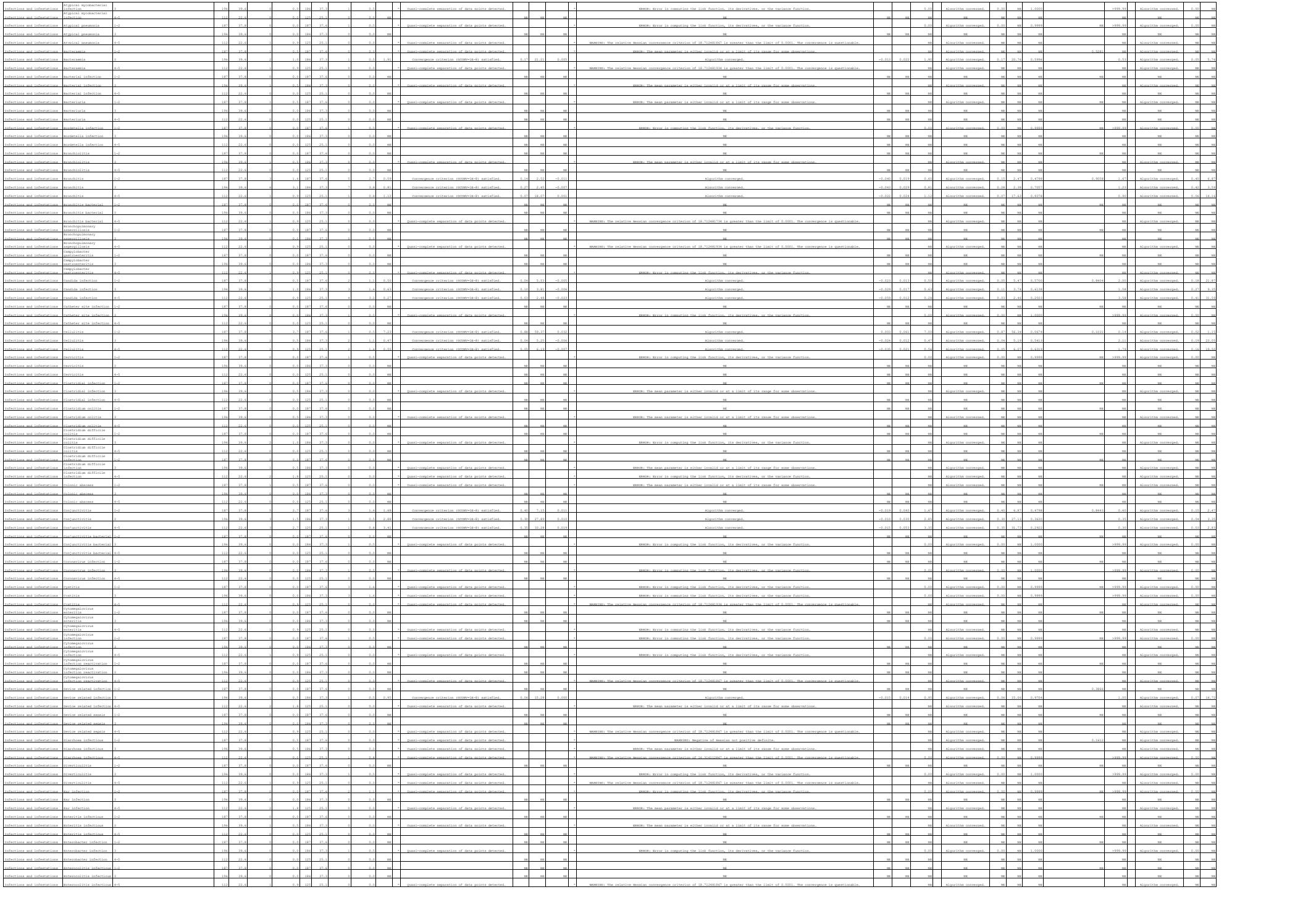

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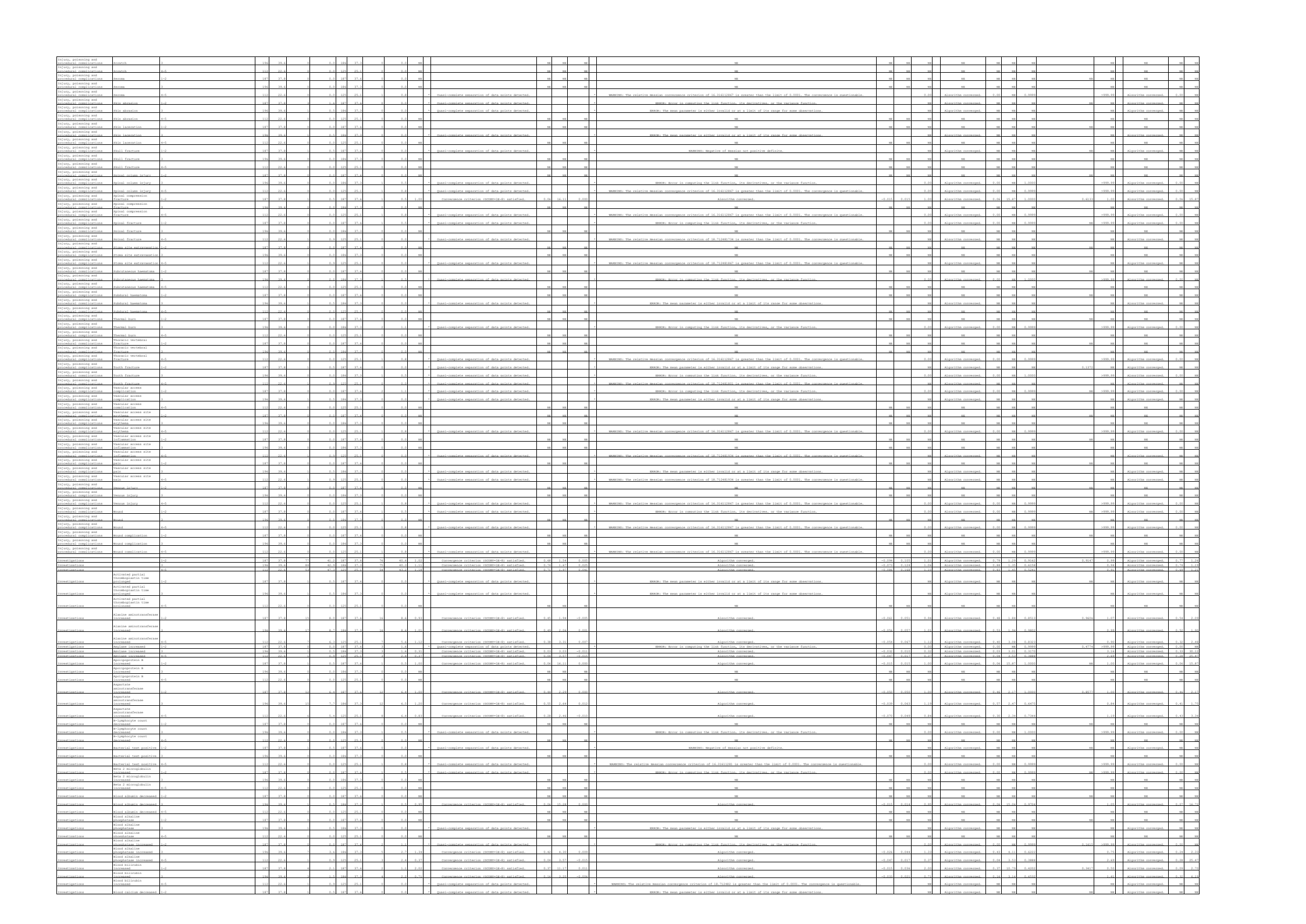

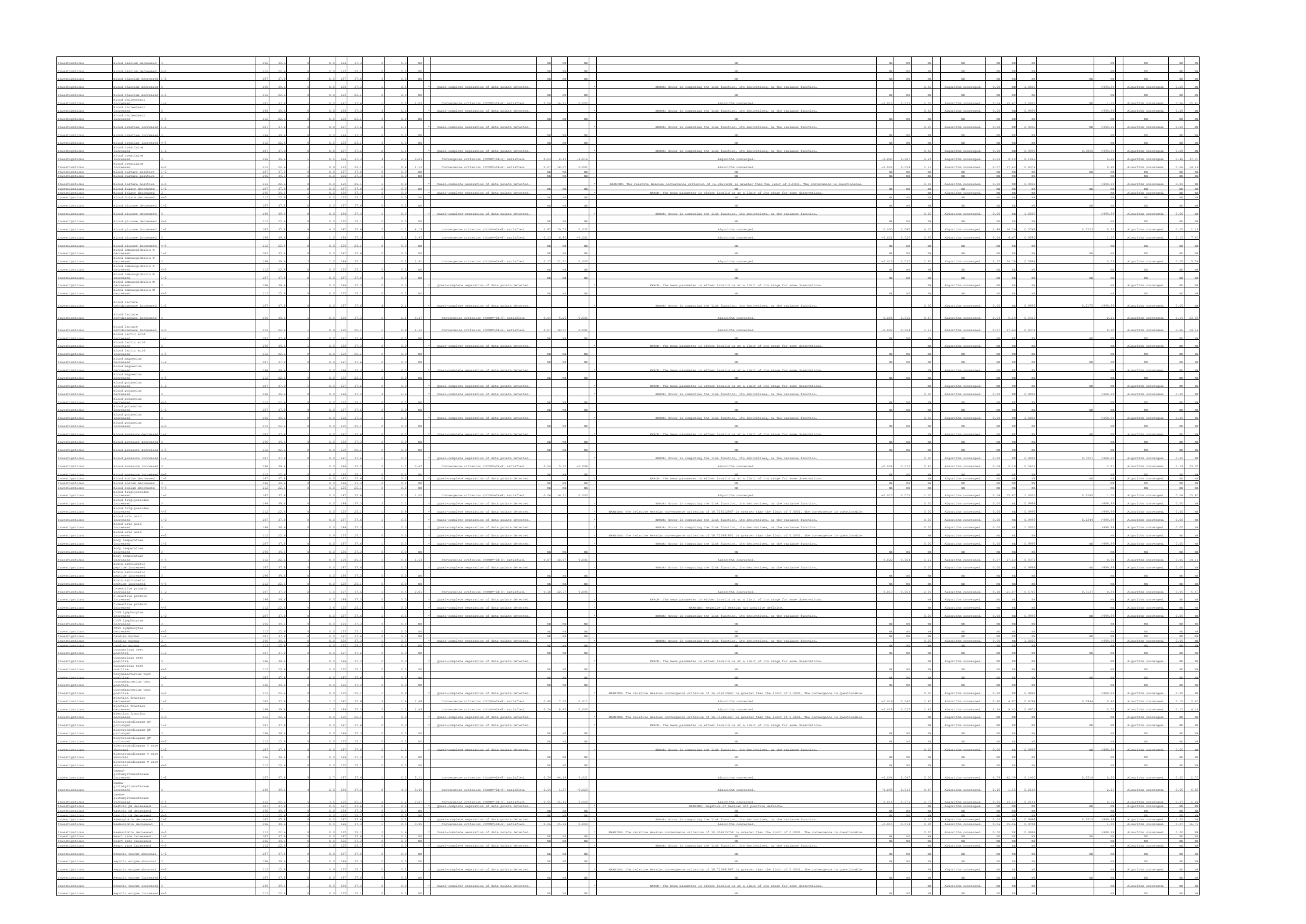

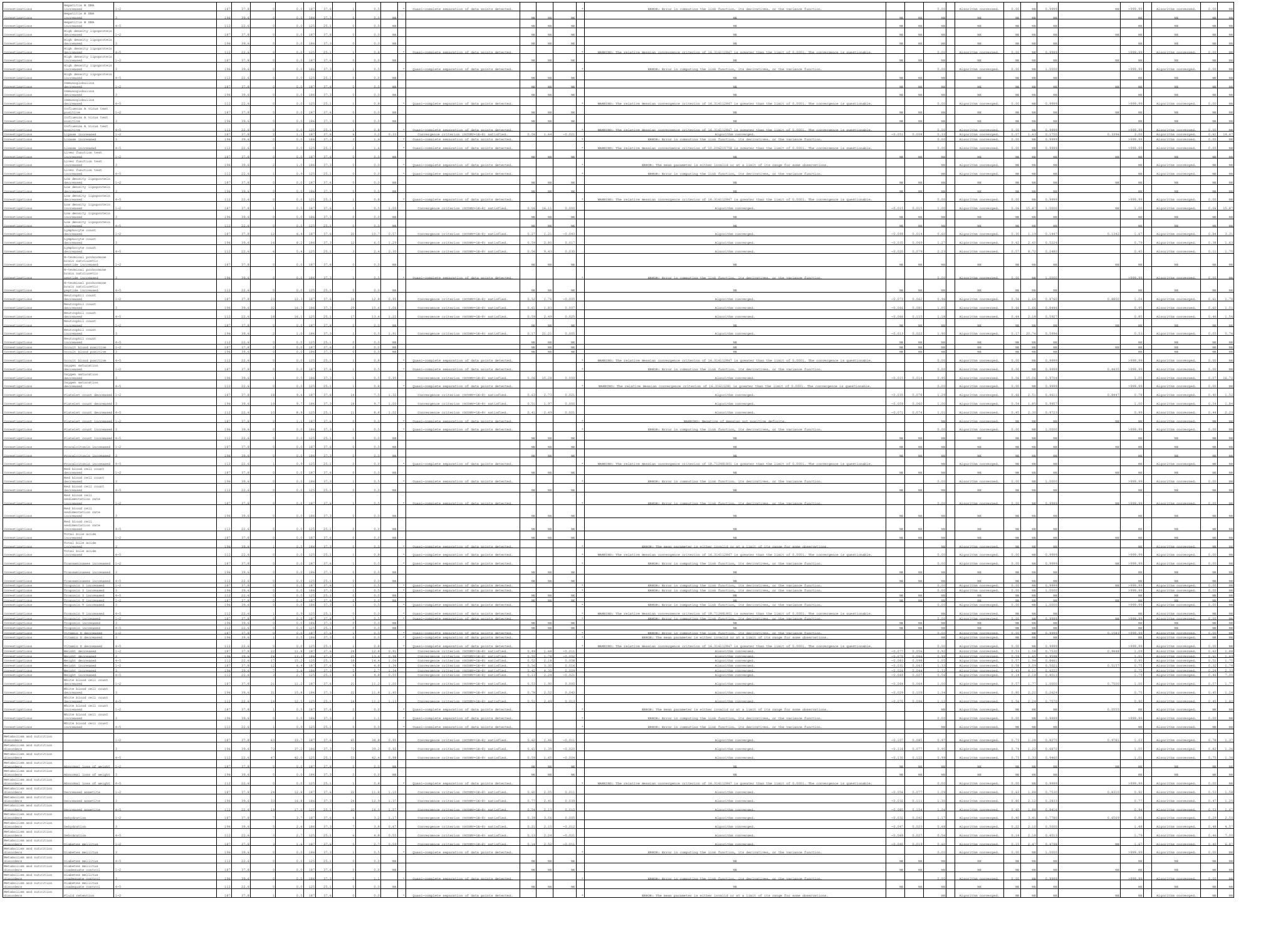

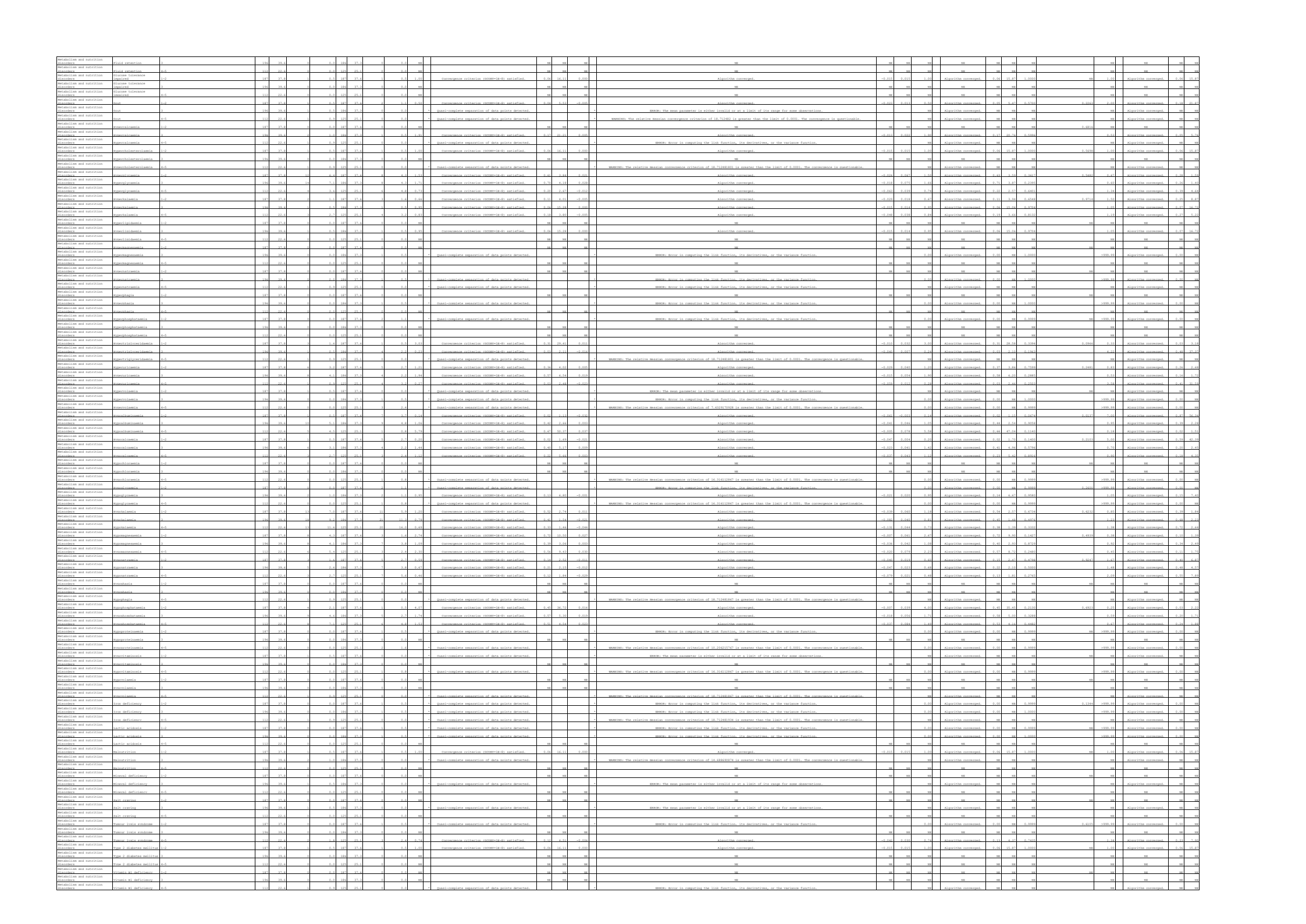

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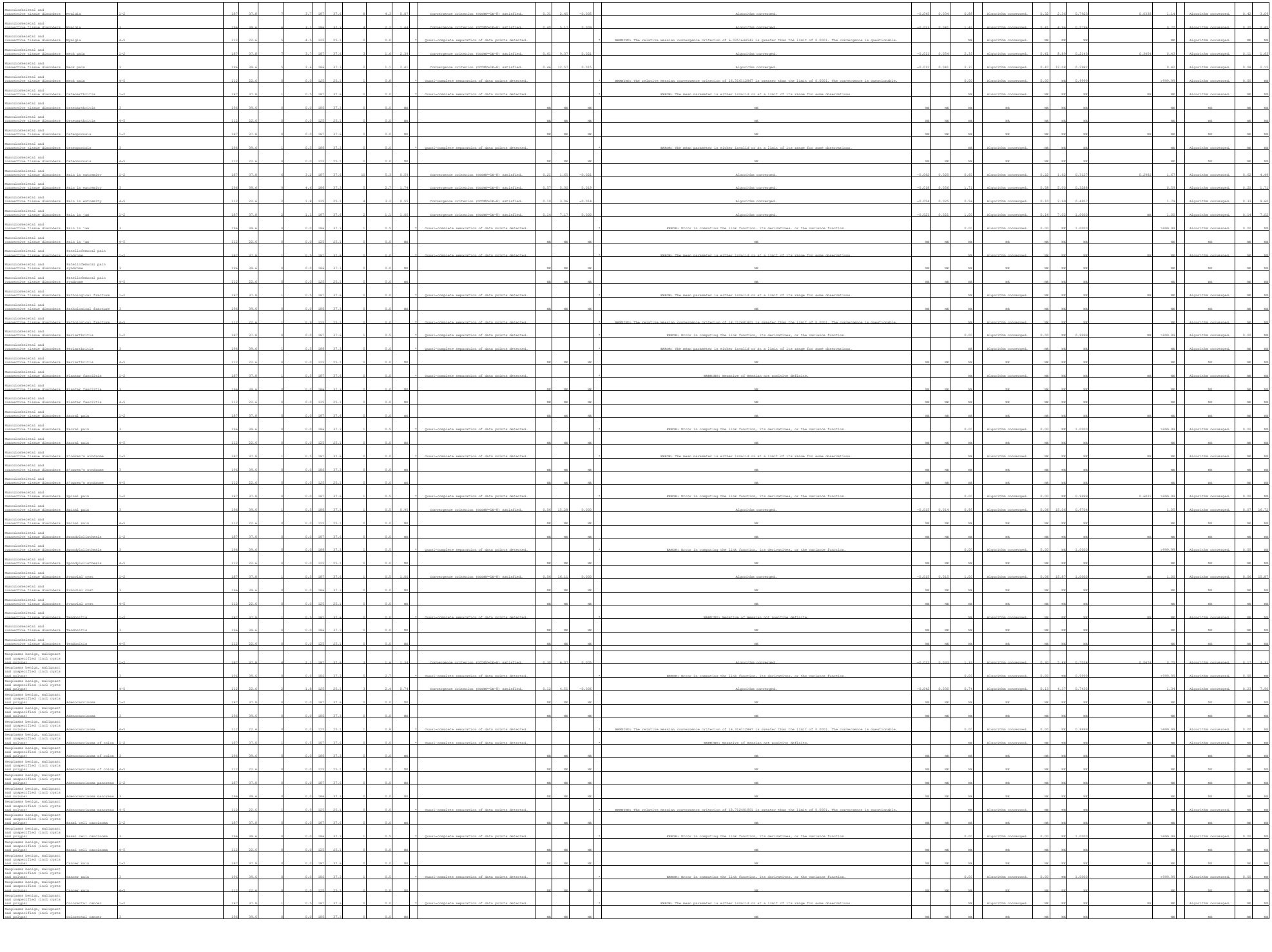

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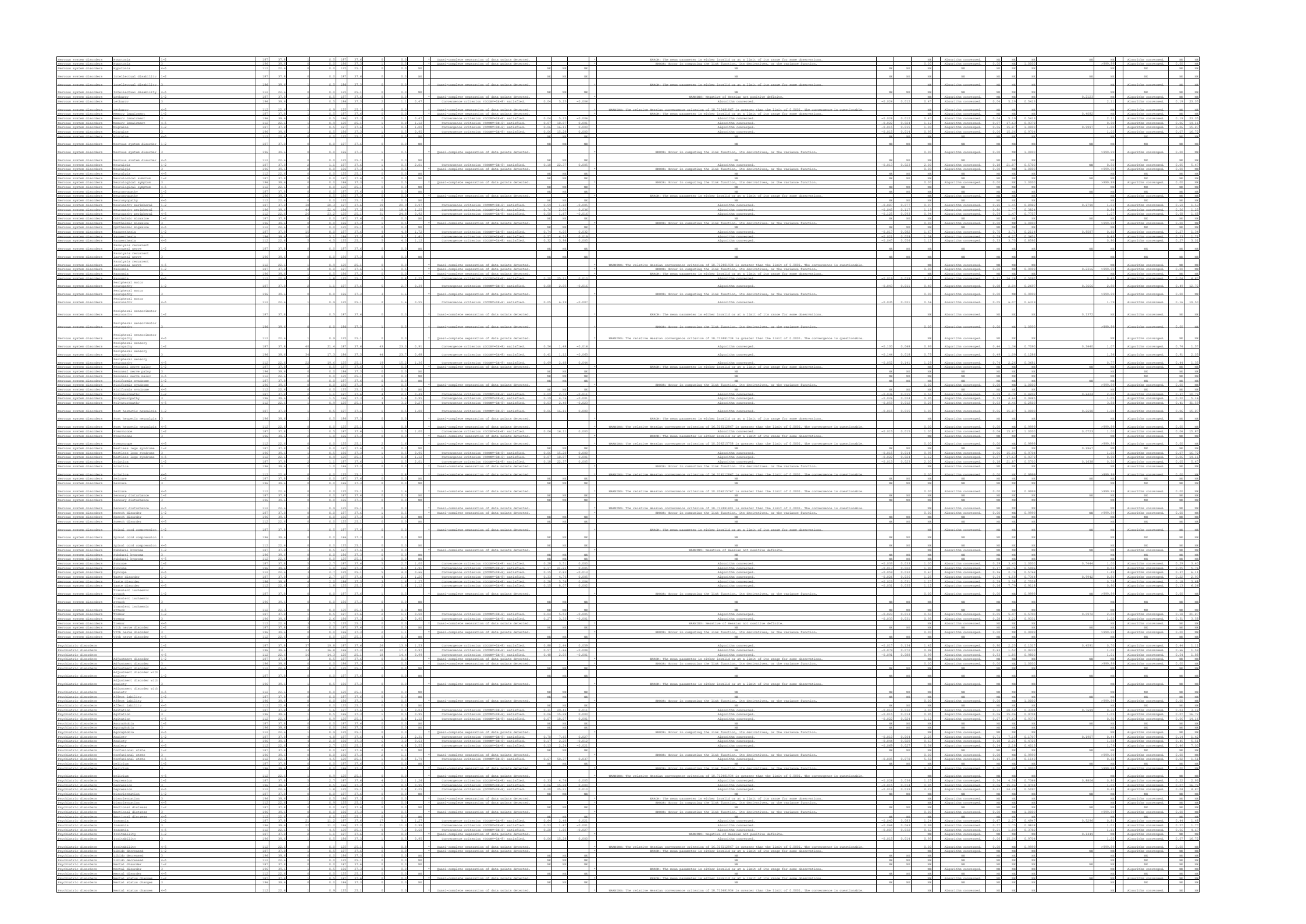

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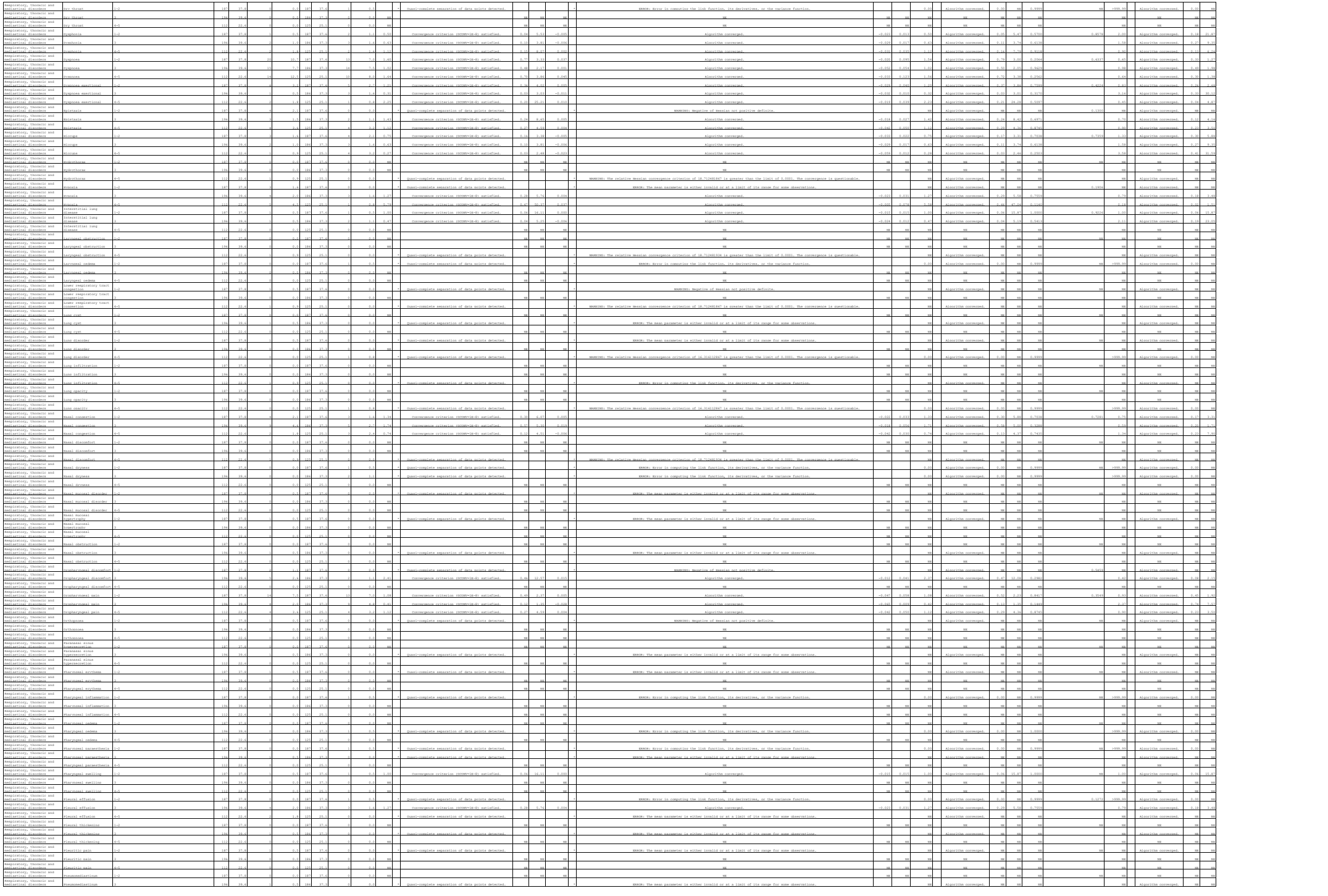

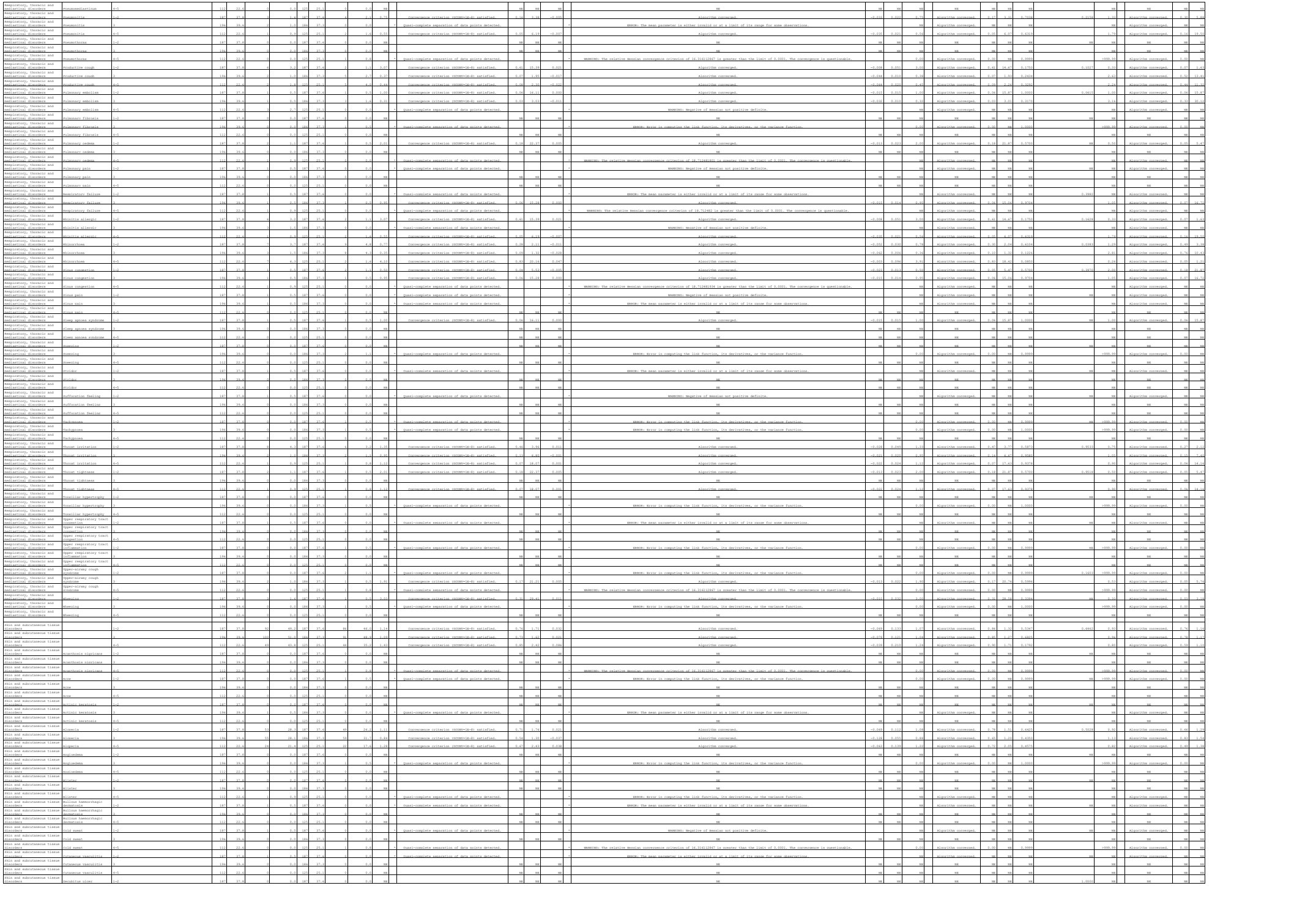

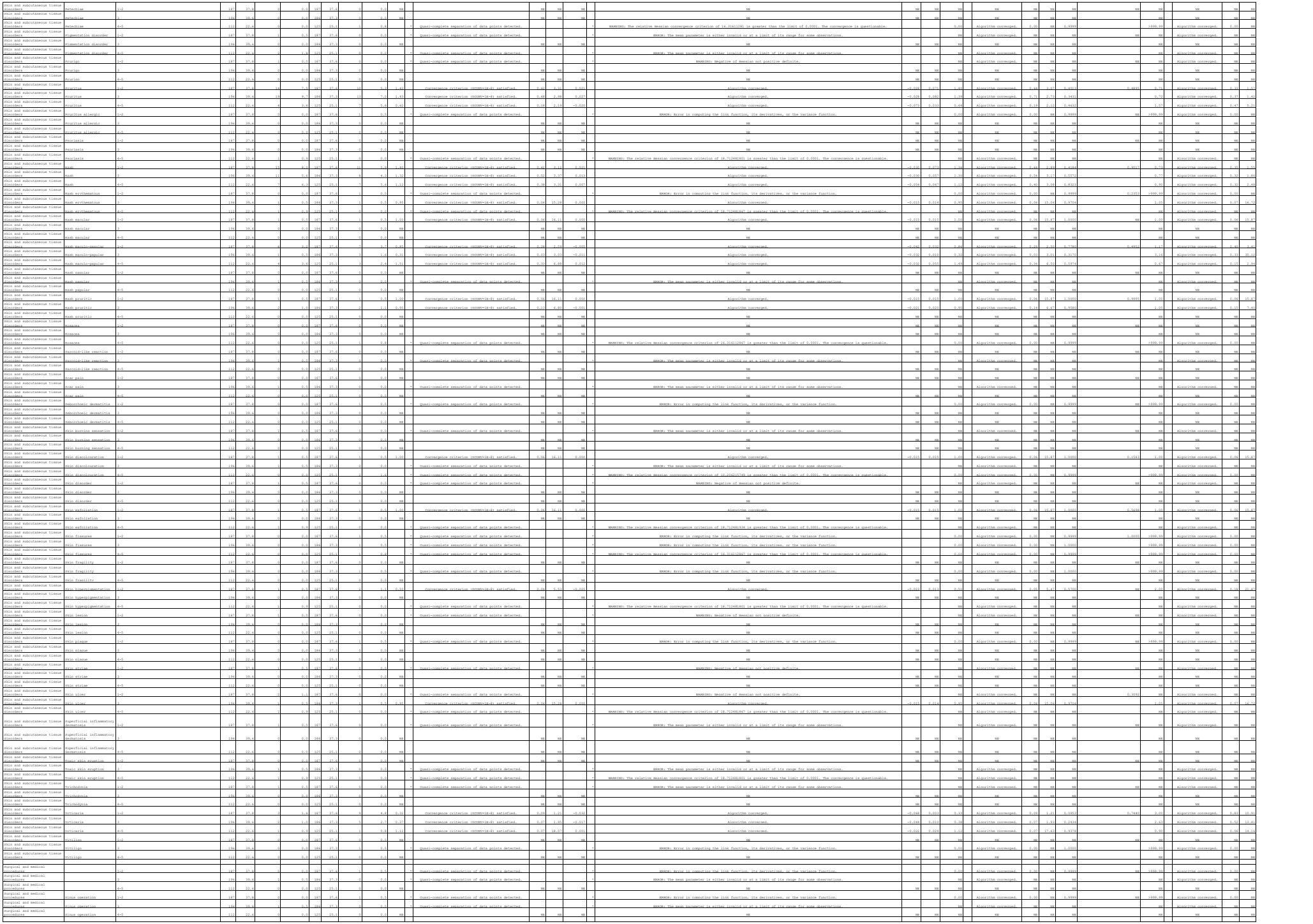

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Any AEs
MODEL: Unstratified Analysis
STUDY: BG39862
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Bictarvimab Tebotru + B-Cmp (N=493)				B-Cmp (N=496)				Bictarvimab Tebotru + B-Cmp vs. B-Cmp										B-Cmp vs. Bictarvimab Tebotru + B-Cmp			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Cohort	n	%	n	%	n	%	n	%	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		Western Europe/United States/Canada/Australia	298	60.4	149	50.0	300	49.2	141	47.0	1.13	Convergence criterion (ZCONV*1E-8) satisfied.	0.82	1.55	0.030	Algorithm converged.	-0.051	0.110	1.06	Algorithm converged.	0.46	1.23	0.4632	0.6711	0.94	Algorithm converged.	0.80	1.11
Blood and lymphatic system disorders		Asia	140	28.4	93	70.5	139	27.4	84	60.4	1.58	Convergence criterion (ZCONV*1E-8) satisfied.	0.98	2.55	0.101	Algorithm converged.	-0.059	0.263	1.17	Algorithm converged.	0.98	1.39	0.0728		0.85	Algorithm converged.	0.72	1.00
Blood and lymphatic system disorders		Rest of World	57	11.5	33	57.9	57	11.3	23	55.9	1.08	Convergence criterion (ZCONV*1E-8) satisfied.	0.52	2.26	0.020	Algorithm converged.	-0.161	0.200	1.04	Algorithm converged.	0.75	1.43	0.8315		0.97	Algorithm converged.	0.70	1.33
Blood and lymphatic system disorders	Agranulocytosis	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	1	0.3		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Agranulocytosis	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Agranulocytosis	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Anemia	Western Europe/United States/Canada/Australia	298	60.2	88	29.5	300	60.5	74	24.7	1.24	Convergence criterion (ZCONV*1E-8) satisfied.	0.89	1.85	0.048	Algorithm converged.	-0.043	0.140	1.21	Algorithm converged.	0.96	1.59	0.1821	0.9854	0.84	Algorithm converged.	0.69	1.04
Blood and lymphatic system disorders	Anemia	Asia	140	28.4	62	44.3	139	27.4	56	40.3	1.18	Convergence criterion (ZCONV*1E-8) satisfied.	0.73	1.92	0.040	Algorithm converged.	-0.076	0.155	1.13	Algorithm converged.	0.98	1.45	0.4997		0.91	Algorithm converged.	0.63	1.30
Blood and lymphatic system disorders	Anemia	Rest of World	57	11.5	14	24.6	57	11.3	16	27.1	0.88	Convergence criterion (ZCONV*1E-8) satisfied.	0.38	2.01	-0.024	Algorithm converged.	-0.185	0.136	0.91	Algorithm converged.	0.48	1.69	0.7334		1.10	Algorithm converged.	0.60	2.00
Blood and lymphatic system disorders	Aplasia pure red cell	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	1	0.3	1.01	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.009	0.009	1.01	Algorithm converged.	0.06	16.02	0.9962	1.0000	0.99	Algorithm converged.	0.06	15.81
Blood and lymphatic system disorders	Aplasia pure red cell	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Aplasia pure red cell	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Cytopenia	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 44.806790292 is greater than the limit of 0.0001. The convergence is questionable.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Cytopenia	Asia	140	28.4	0	0.0	139	27.4	1	0.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 19.480043492 is greater than the limit of 0.0001. The convergence is questionable.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Cytopenia	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Erythropenia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Erythropenia	Asia	140	28.4	0	0.0	139	27.4	1	0.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 19.480043296 is greater than the limit of 0.0001. The convergence is questionable.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Erythropenia	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	2	0.7	0.50	Convergence criterion (ZCONV*1E-8) satisfied.	0.05	5.04	-0.001	Algorithm converged.	-0.005	0.002	0.50	Algorithm converged.	0.05	5.02	0.5743	NE	1.98	Algorithm converged.	0.10	21.73
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile neutropenia	Western Europe/United States/Canada/Australia	298	60.2	41	13.8	300	60.5	19	6.3	2.34	Convergence criterion (ZCONV*1E-8) satisfied.	1.33	4.13	0.074	Algorithm converged.	0.030	0.122	2.19	Algorithm converged.	1.24	4.41	0.0224	0.3032	0.44	Algorithm converged.	0.27	0.73
Blood and lymphatic system disorders	Febrile neutropenia	Asia	140	28.4	17	12.1	139	27.4	15	10.8	1.14	Convergence criterion (ZCONV*1E-8) satisfied.	0.55	2.36	0.014	Algorithm converged.	-0.061	0.089	1.13	Algorithm converged.	0.59	2.16	0.7234		0.84	Algorithm converged.	0.46	1.71
Blood and lymphatic system disorders	Febrile neutropenia	Rest of World	57	11.5	8	14.0	57	11.3	5	8.8	1.76	Convergence criterion (ZCONV*1E-8) satisfied.	0.54	5.75	0.052	Algorithm converged.	-0.059	0.170	1.60	Algorithm converged.	0.56	5.74	0.3483		0.65	Algorithm converged.	0.24	1.74
Blood and lymphatic system disorders	Granulocytopenia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Granulocytopenia	Asia	140	28.4	0	0.0	139	27.4	1	0.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 19.480043228 is greater than the limit of 0.0001. The convergence is questionable.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Granulocytopenia	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Hypofibrinogenemia	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	1	0.3	1.01	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.009	0.009	1.01	Algorithm converged.	0.06	16.02	0.9962	1.0000	0.99	Algorithm converged.	0.06	15.81
Blood and lymphatic system disorders	Hypofibrinogenemia	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Hypofibrinogenemia	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Increased tendency to bruise	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	1	0.3	1.01	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.009	0.009	1.01	Algorithm converged.	0.06	16.02	0.9962	1.0000	0.99	Algorithm converged.	0.06	15.81
Blood and lymphatic system disorders	Increased tendency to bruise	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Increased tendency to bruise	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Iron deficiency anaemia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	2	0.7		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Iron deficiency anaemia	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Iron deficiency anaemia	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Leukocytosis	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	3	1.0		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Leukocytosis	Asia	140	28.4	1	0.7	139	27.4	3	2.2	0.33	Convergence criterion (ZCONV*1E-8) satisfied.	0.04	14.63	0.000	Algorithm converged.	-0.020	0.020	0.33	Algorithm converged.	0.04	12.32	0.9957		1.01	Algorithm converged.	0.04	10.91
Blood and lymphatic system disorders	Leukocytosis	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Leukopenia	Western Europe/United States/Canada/Australia	298	60.2	3	1.0	300	60.5	13	4.3	0.23	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	1.43	-0.011	Algorithm converged.	-0.043	0.017	0.71	Algorithm converged.	0.30	1.41	0.3963	0.7823	1.41	Algorithm converged.	0.42	3.21
Blood and lymphatic system disorders	Leukopenia	Asia	140	28.4	22	22.5	139	27.4	31	22.3	1.05	Convergence criterion (ZCONV*1E-8) satisfied.	0.53	1.46	-0.009	Algorithm converged.	-0.109	0.091	0.96	Algorithm converged.	0.65	1.47	0.8417		1.04	Algorithm converged.	0.68	1.59
Blood and lymphatic system disorders	Leukopenia	Rest of World	57	11.5	3	5.3	57	11.3	5	8.1	0.64	Convergence criterion (ZCONV*1E-8) satisfied.	0.15	2.77	0.032	Algorithm converged.	-0.073	0.041	1.66	Algorithm converged.	0.20	4.32	0.9604		0.21	Algorithm converged.	0.21	4.03
Blood and lymphatic system disorders	Lymph node pain	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	3	1.0	0.33	Convergence criterion (ZCONV*1E-8) satisfied.	0.03	3.04	-0.020	Algorithm converged.	-0.022	0.002	0.33	Algorithm converged.	0.03	3.02	0.5743	NE	1.98	Algorithm converged.	0.10	21.73
Blood and lymphatic system disorders	Lymph node pain	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Lymph node pain	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Lymphadenopathy	Western Europe/United States/Canada/Australia	298	60.2	3	1.0	300	60.5	1	0.3	3.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.31	29.93	0.007	Algorithm converged.	-0.006	0.020	3.02	Algorithm converged.	0.31	29.67	3.3272	NE	9.23	Algorithm converged.	0.97	9.43
Blood and lymphatic system disorders	Lymphadenopathy	Asia	140	28.4	0	0.0	139	27.4	1	0.7	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Lymphadenopathy	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Lymphocytosis	Western Europe/United States/Canada/Australia	298	60.2	8	2.7	300	60.5	13	4.3	0.61	Convergence criterion (ZCONV*1E-8) satisfied.	0.25	1.49	-0.014	Algorithm converged.	-0.046	0.017	0.62	Algorithm converged.	0.26	1.47	0.2767	0.6825	1.25	Algorithm converged.	0.69	2.64
Blood and lymphatic system disorders	Lymphocytosis	Asia	140	28.4	4	2.9	139	27.4	3	2.2	1.33	Convergence criterion (ZCONV*1E-8) satisfied.	0.30	6.01	0.007	Algorithm converged.	-0.030	0.044	1.33	Algorithm converged.	0.30	5.91	0.7280		0.76	Algorithm converged.	0.17	3.34
Blood and lymphatic system disorders	Lymphopenia	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	Asia	140	28.4	4	2.9	139	27.4	1	0.7	4.06	Convergence criterion (ZCONV*1E-8) satisfied.	0.40	36.78	0.021	Algorithm converged.	-0.010	0.052	3.97	Algorithm converged.	0.45	25.09	0.2147		0.25	Algorithm converged.	0.02	2.22
Blood and lymphatic system disorders	Myelosuppression	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	Western Europe/United States/Canada/Australia	298	60.2	72	24.2	300	60.5	82	28.7	0.79	Convergence criterion (ZCONV*1E-8) satisfied.	0.55	1.14	-0.042	Algorithm converged.	-0.159	0.033	0.84	Algorithm converged.	0.55	1.13	0.1868	0.9424	1.33	Algorithm converged.	0.93	1.92
Blood and lymphatic system disorders	Neutropenia	Asia	140	28.4	47	32.4	139	27.4	41	29.5	1.03	Convergence criterion (ZCONV*1E-8) satisfied.	0.70	2.00	0.041	Algorithm converged.	-0.098	0.100	1.14	Algorithm converged.	0.80	1.41	0.4647		0.88	Algorithm converged.	0.62	1.24
Blood and lymphatic system disorders	Neutropenia	Rest of World	57	11.5	23	40.4	57	11.3	29	42.4	0.92	Convergence criterion (ZCONV*1E-8) satisfied.	0.44	1.90	-0.028	Algorithm converged.	-0.198	0.169	0.92	Algorithm converged.	0.45	1.87	0.8252		1.05	Algorithm converged.	0.68	1.62
Blood and lymphatic system disorders	Neutrophilia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	2	0.7		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Neutrophilia	Asia	140	28.4	1	0.7	139	27.4	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Neutrophilia	Rest of World	57	11.5	0	0.0	57	11.3	1	1.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 10.546148611 is greater than the limit of 0.0001. The convergence is questionable.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Pancytopenia	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 44.806790292 is greater than the limit of 0.0001. The convergence is questionable.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Pancytopenia	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Pancytopenia	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Splenic infarction	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Splenic infarction	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Splenic infarction	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Thrombocytosenia	Western Europe/United States/Canada/Australia	298	60.2	15	5.0	300	60.5	25	8.7	0.74	Convergence criterion (ZCONV*1E-8) satisfied.	0.37	1.48	-0.014	Algorithm converged.	-0.056	0.031	0.74	Algorithm converged.	0.36	1.45	0.3969	0.9841	1.32	Algorithm converged.	0.69	2.54
Blood and lymphatic system disorders	Thrombocytosenia	Asia	140	28.4	24	17.1	139	27.4	18	12.9	1.38	Convergence criterion (ZCONV*1E-8) satisfied.	0.73	2.75	0.042	Algorithm converged.	-0.042	0.165	1.32	Algorithm converged.	0.79	2.65	0.3295		0.74	Algorithm converged.	0.43	1.53
Blood and lymphatic system disorders	Thrombocytopenia	Rest of World	57	11.5	7	12.3	57	11.3	9	15.3	0.78	Convergence criterion (ZCONV*1E-8) satisfied.	0.27	2.35	-0.030	Algorithm converged.	-0.193	0.085	0.81	Algorithm converged.	0.28	2.33	0.6435		1.24	Algorithm converged.	0.50	3.11
Cardiac disorders		Western Europe/United States/Canada/Australia	298	60.2	29	9.7	300	60.5	44	14.7	0.65	Convergence criterion (ZCONV*1E-8) satisfied.	0.39	1.07	-0.049	Algorithm converged.	-0.103	0.007	0.66	Algorithm converged.	0.45	1.03	0.0690	0.7447	1.55	Algorithm converged.	0.97	2.59
Cardiac disorders		Asia	140	28.4	8	5.7	139	27.4	15	10.8	0.52	Convergence criterion (ZCONV*1E-8) satisfied.	0.21	1.33	-0.051	Algorithm converged.	-0.193	0.014	0.53	Algorithm converged.	0.23	1.21	0.1313		1.83	Algorithm converged.	0.63	4.33
Cardiac disorders		Rest of World	57	11.5	3	5.3	57	11.3	3	5.1	1.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.20	5.39	0.002	Algorithm converged.	-0.079	0.083	1.03	Algorithm converged.	0.25	4.32	0.9614		0.97	Algorithm converged.	0.25	3.83
Cardiac disorders	Acute myocardial infarction	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 44.806790292 is greater than the limit of 0.0001. The convergence is questionable.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Acute myocardial infarction	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Acute myocardial infarction	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Angina pectoris	Western Europe/United States/Canada/Australia	298	60.2	2	0.7	300	60.5	0	0.0		Convergence criterion (ZCONV*1E-8) satisfied.	0.14	22.40	0.003	Algorithm converged.	-0.006	0.013	2.02	Algorithm converged.	0.14	22.04	5.0469	NE	0.56	Algorithm converged.	0.03	5.49
Cardiac disorders	Angina pectoris	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Angina pectoris	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Arrhythmia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	2	0.7		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Arrhythmia	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Arrhythmia	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrial fibrillation	Western Europe/United States/Canada/Australia	298	60.2	4	1.3	300	60.5	6	2.0	0.67	Convergence criterion (ZCONV*1E-8) satisfied.	0.19	2.39	-0.007	Algorithm converged.	-0.029	0.016	0.67	Algorithm converged.	0.19	2.40	0.5234	0.5849	1.93	Algorithm converged.	0.42	5.25
Cardiac disorders	Atrial fibrillation	Asia	140	28.4	0	0.0	139	27.4	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 9.2384695421 is greater than the limit of 0.0001. The convergence is questionable.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0		Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial flutter	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0	3.03	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.009	0.009	1.01	Algorithm converged.	0.06	16.02	0.9962	1.0000	0.99	Algorithm converged.	0.06	15.81
Cardiac disorders	Atrial flutter	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrial flutter	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	2	0.7		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	1	0.3		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block complete	Asia	140	28.4	0	0.0	139	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	Rest of World	57	11.5	0	0.0	57	11.3	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block first degree	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 44.806790292 is greater than the limit of 0.0001. The convergence is questionable.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block first degree	Asia	140	28.4	1	0.7	139	27.4	0	0.0		Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.					0.02	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block first degree	Rest of World	57	11.5	0	0.0	57	11.3

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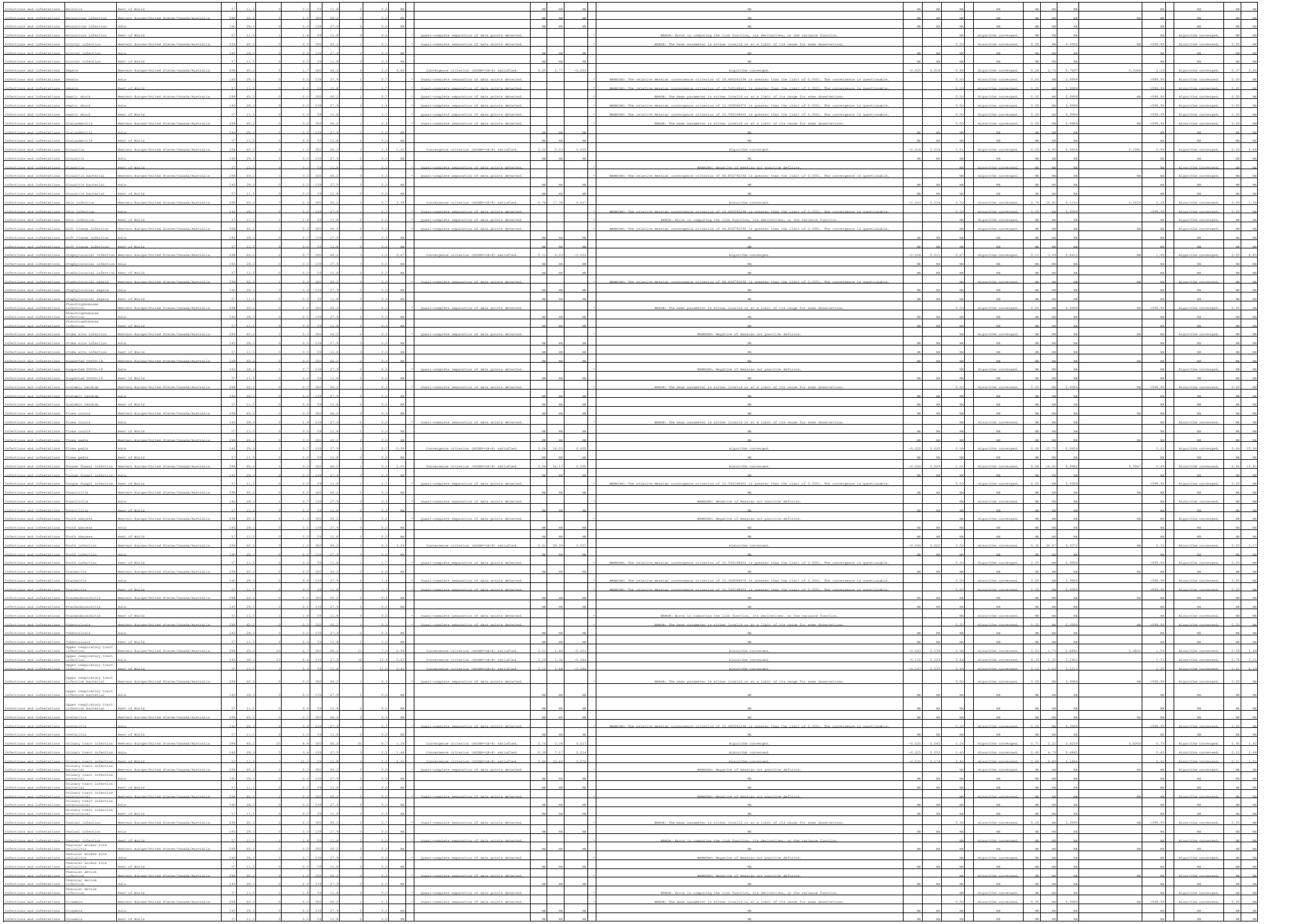

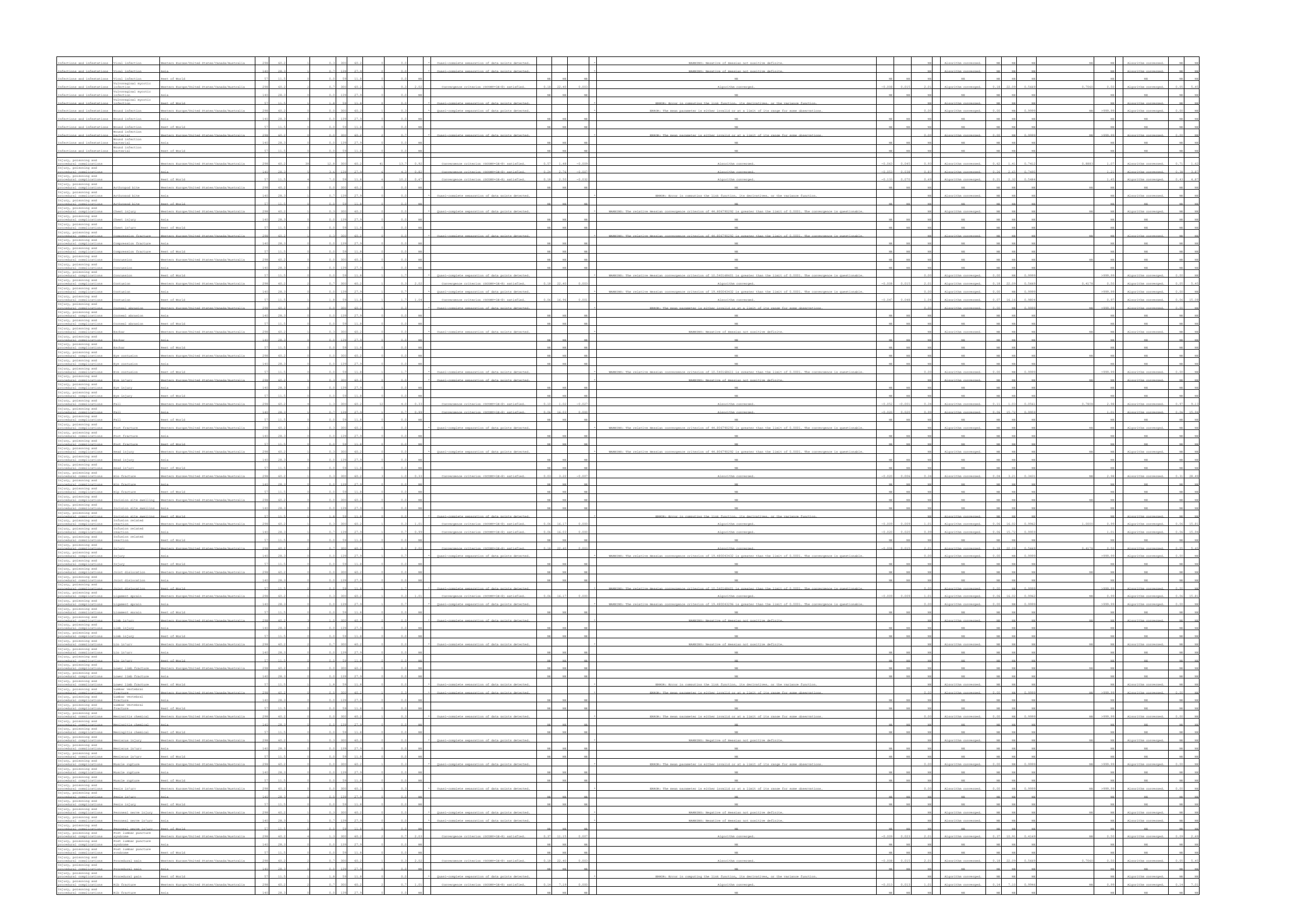

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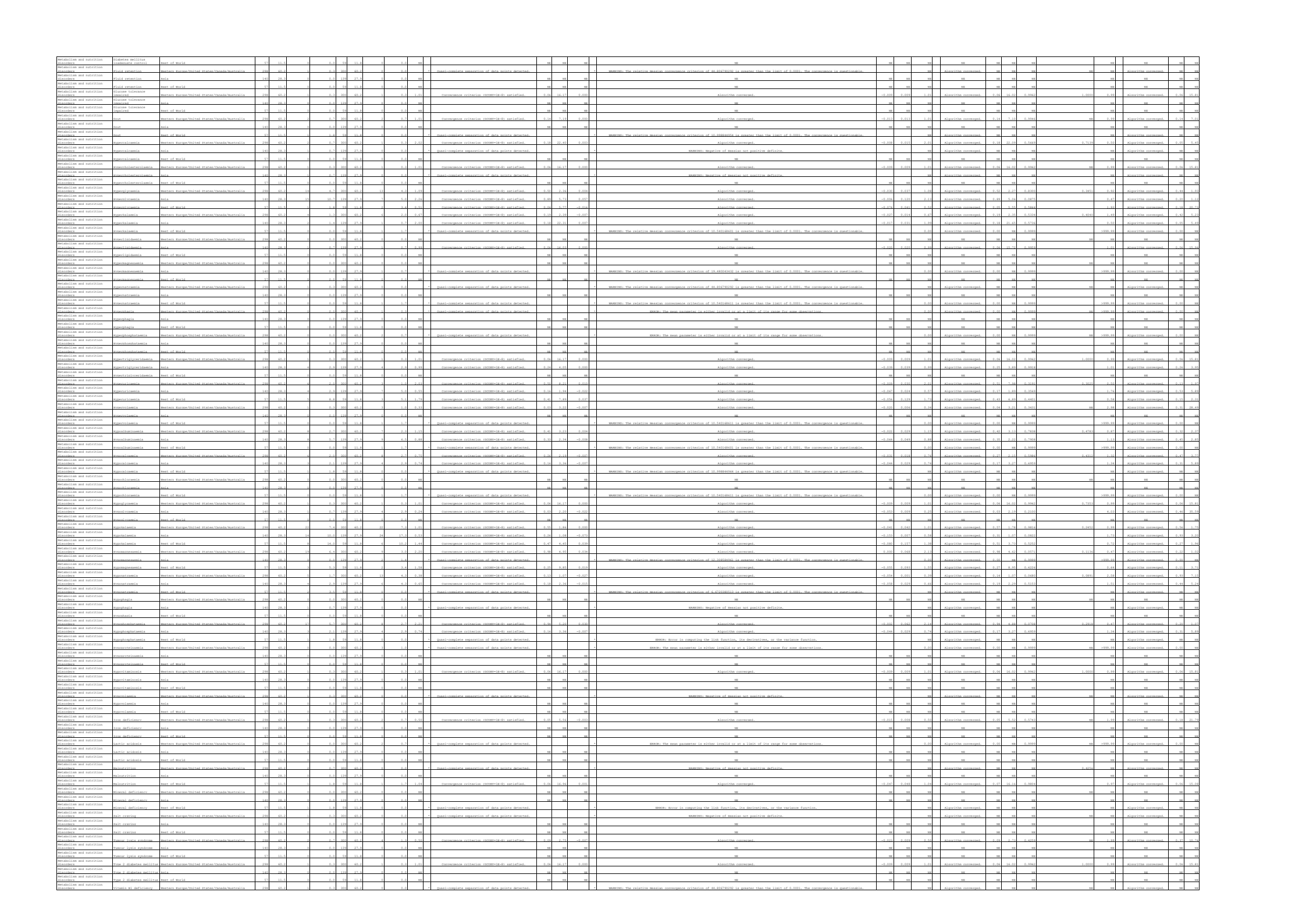

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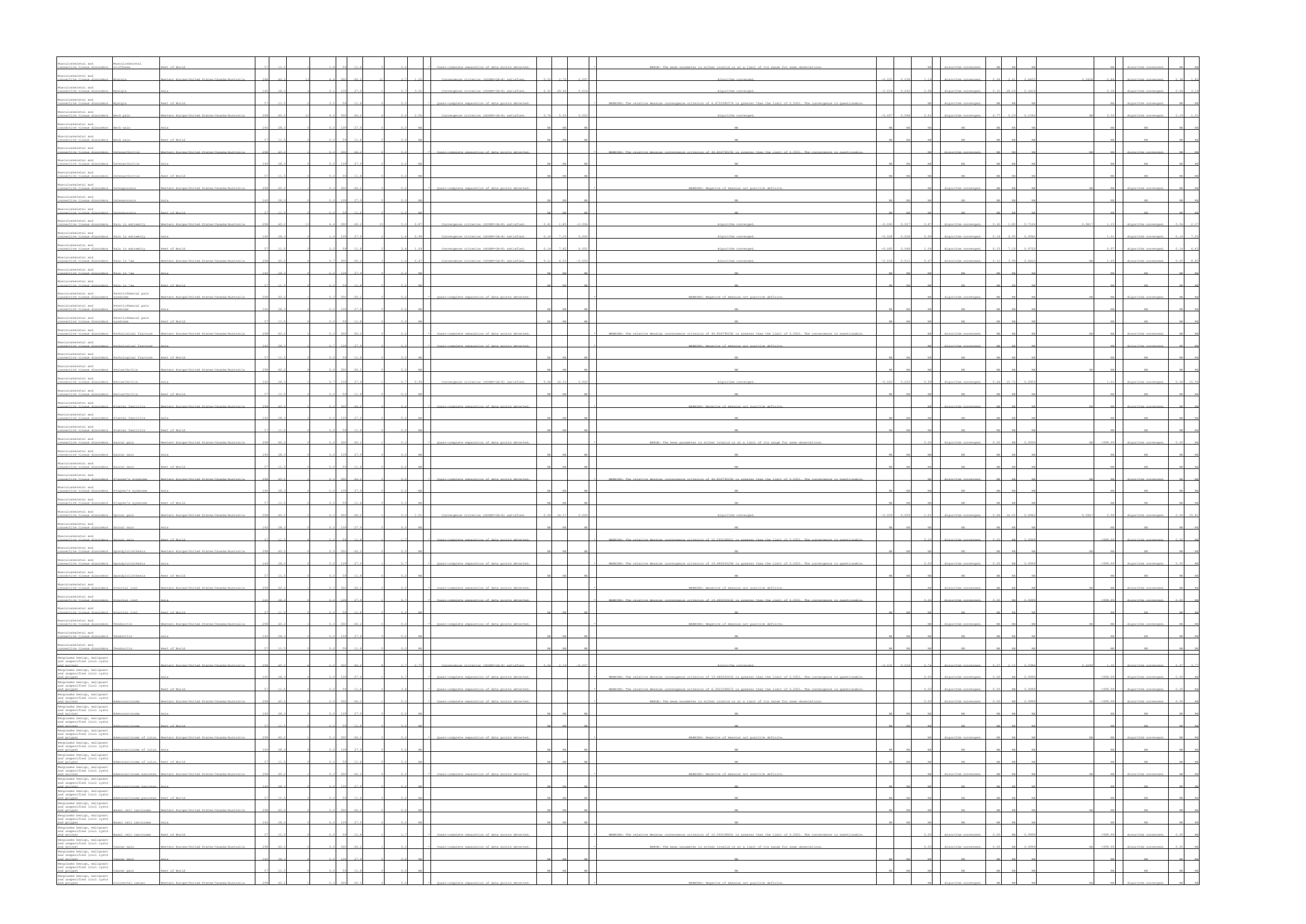

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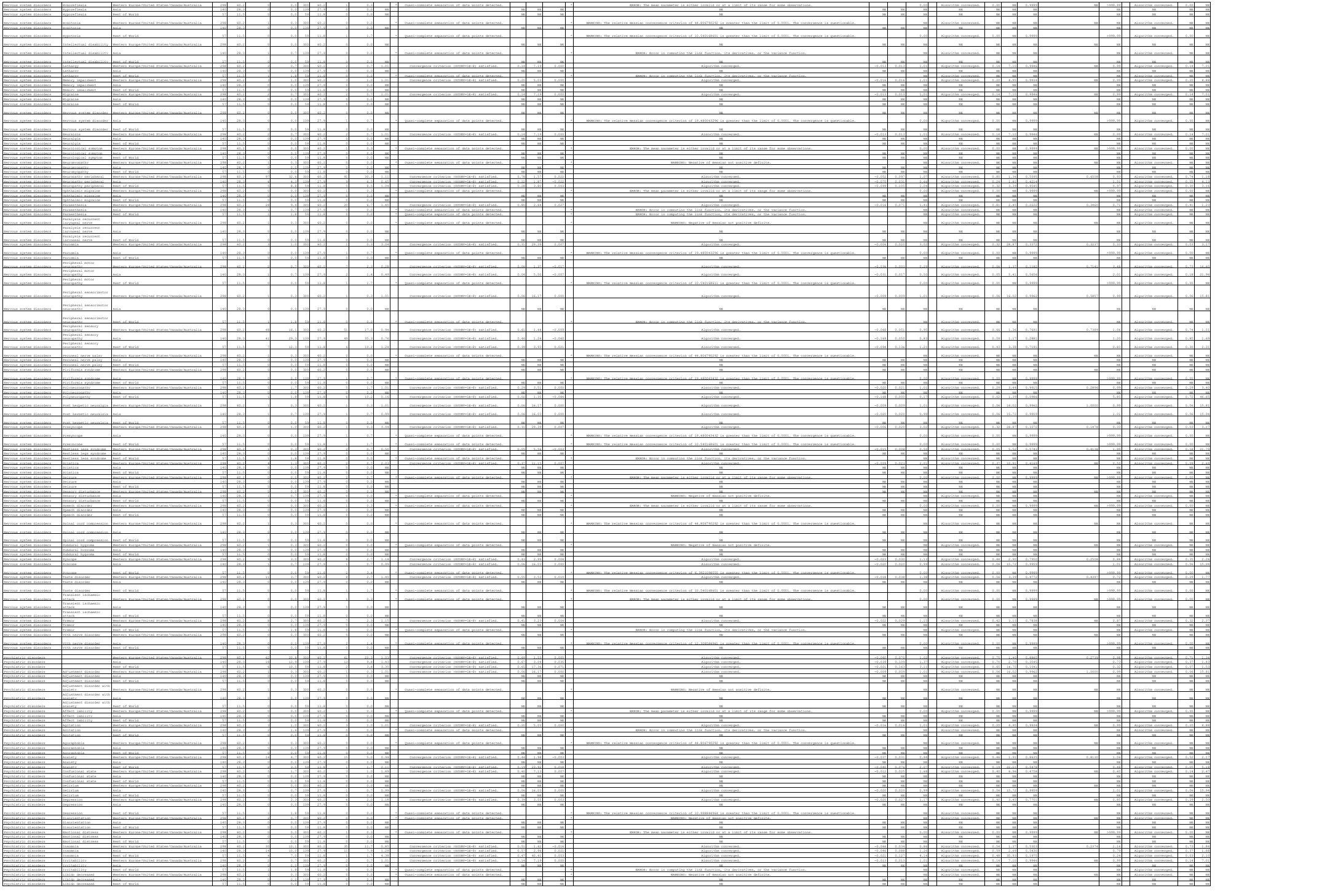

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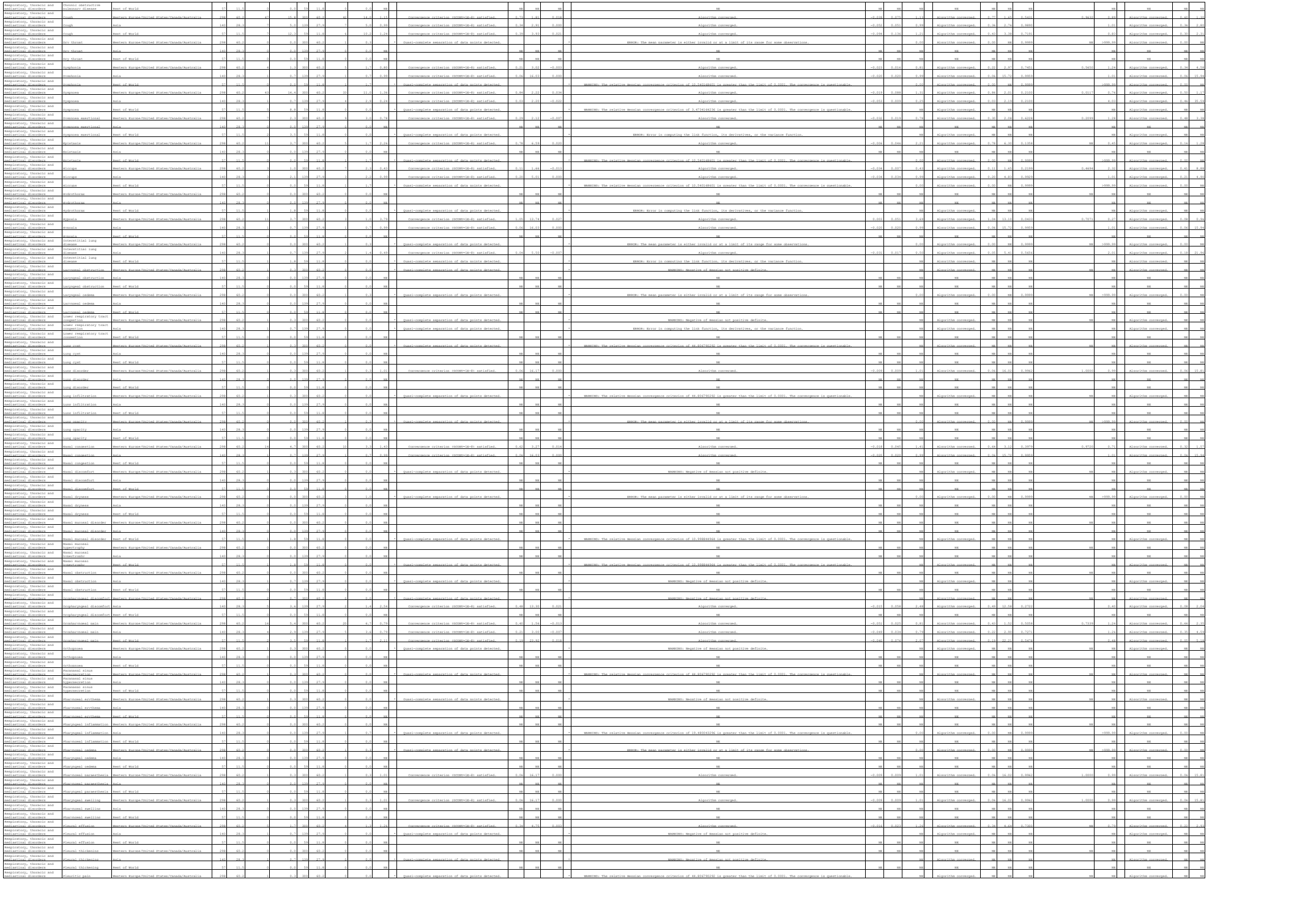

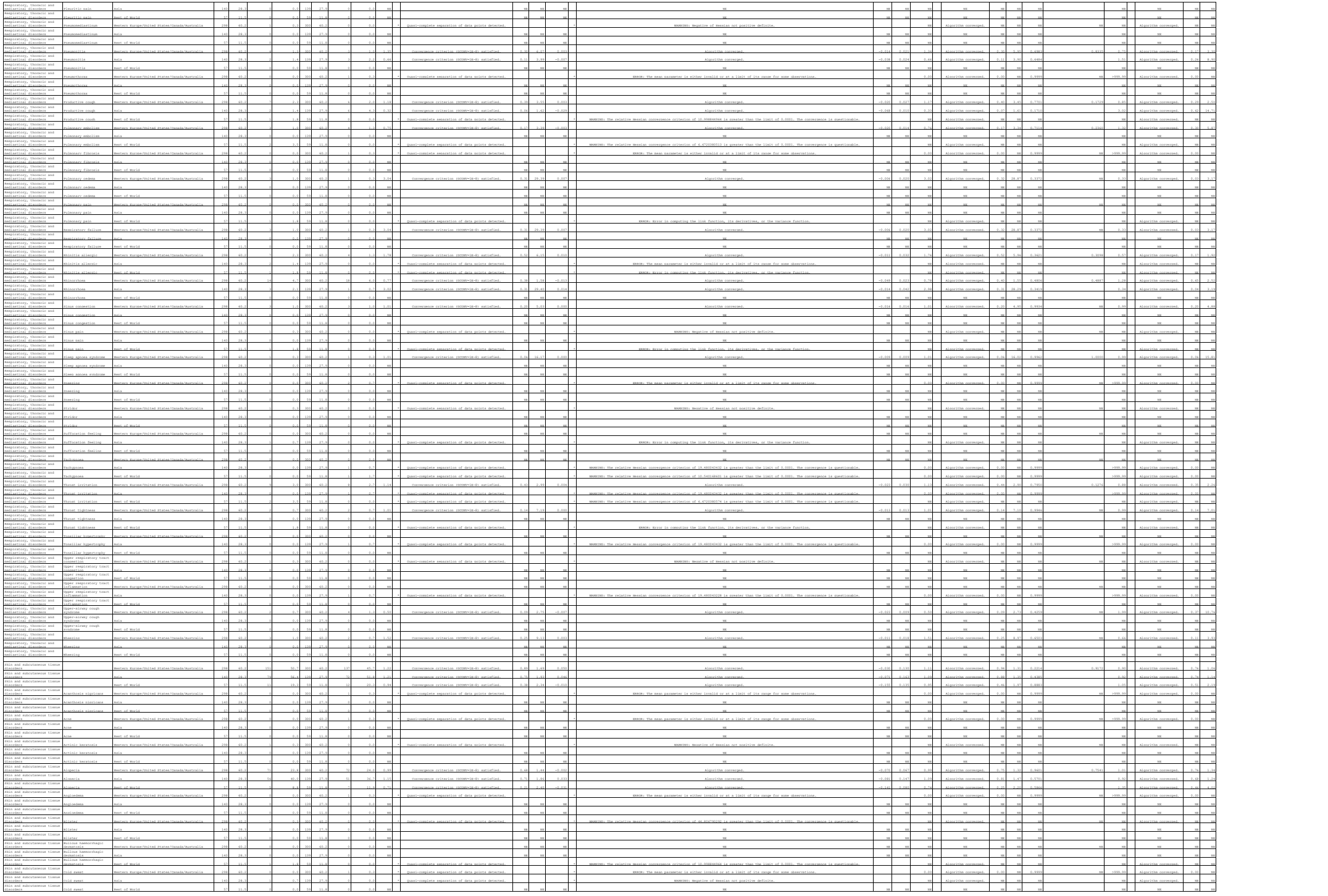

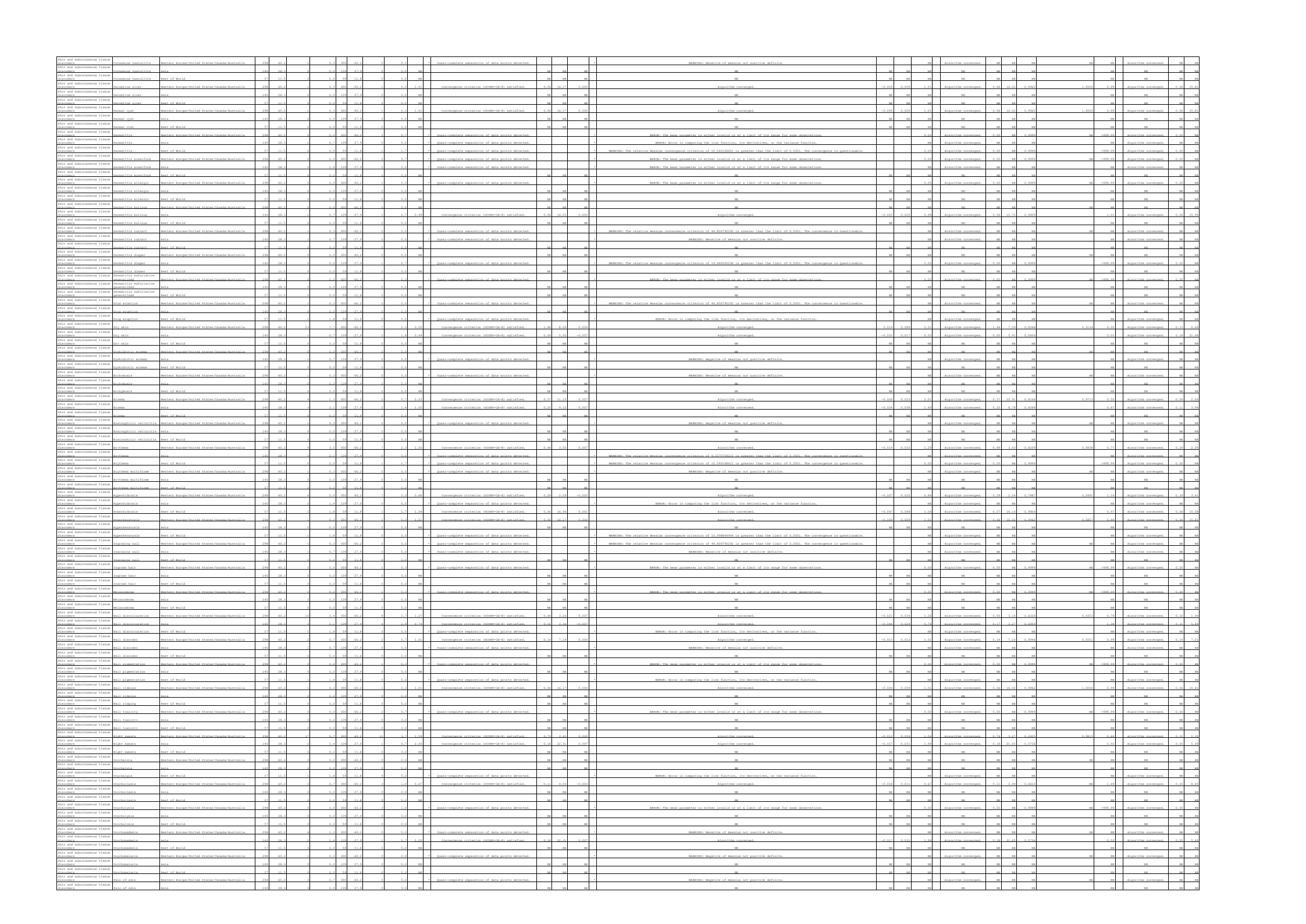

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Any AEs
MODEL: Unstratified Analysis
STUDY: BGB9942
Dichotomous Analysis by Subgroups (Safety)

Sex

| | | | Zotatravimab Tablets + B-cell (N=245) | | | | B-cell (N=245) | | | | Zotatravimab Tablets + B-cell vs. B-cell | | | |

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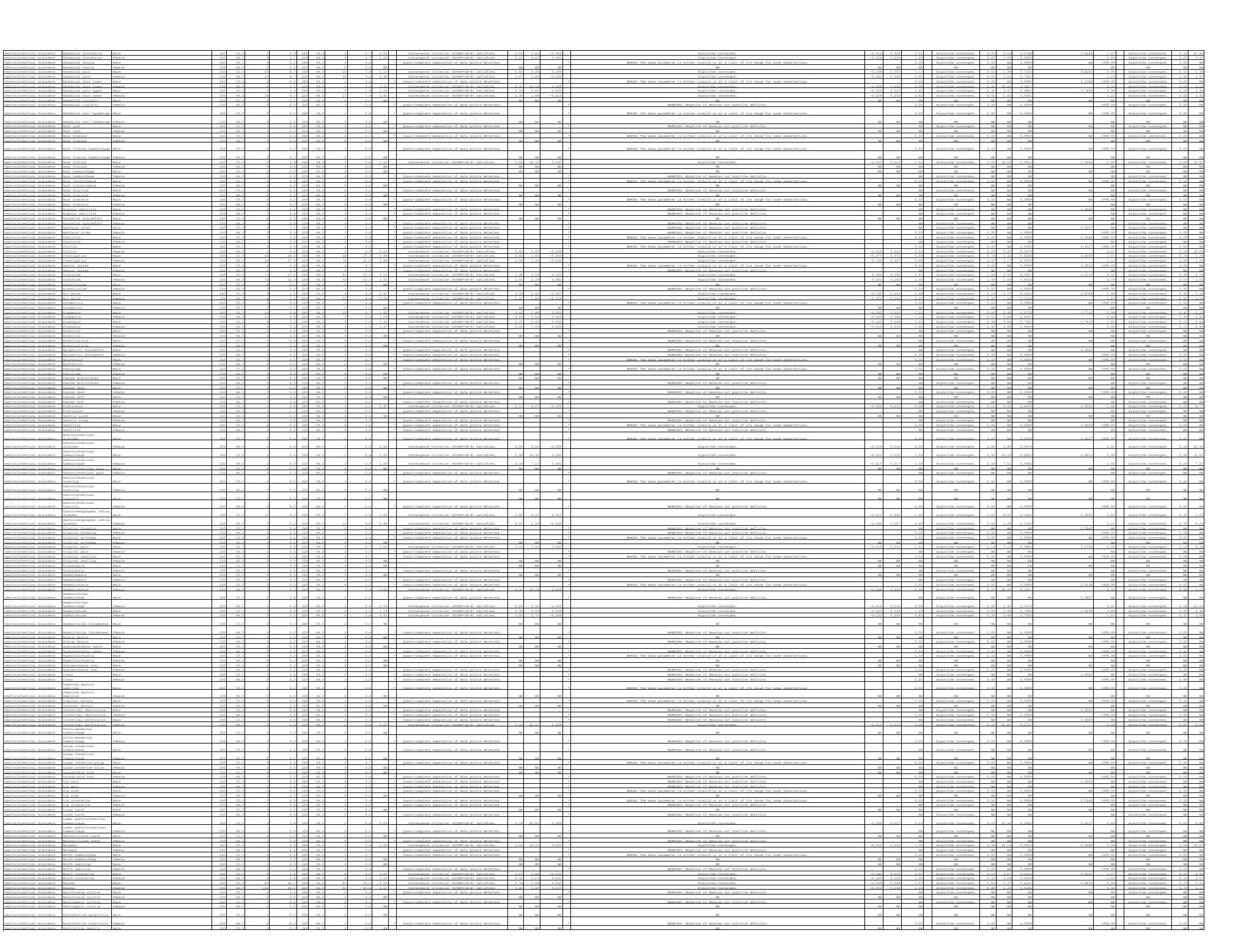

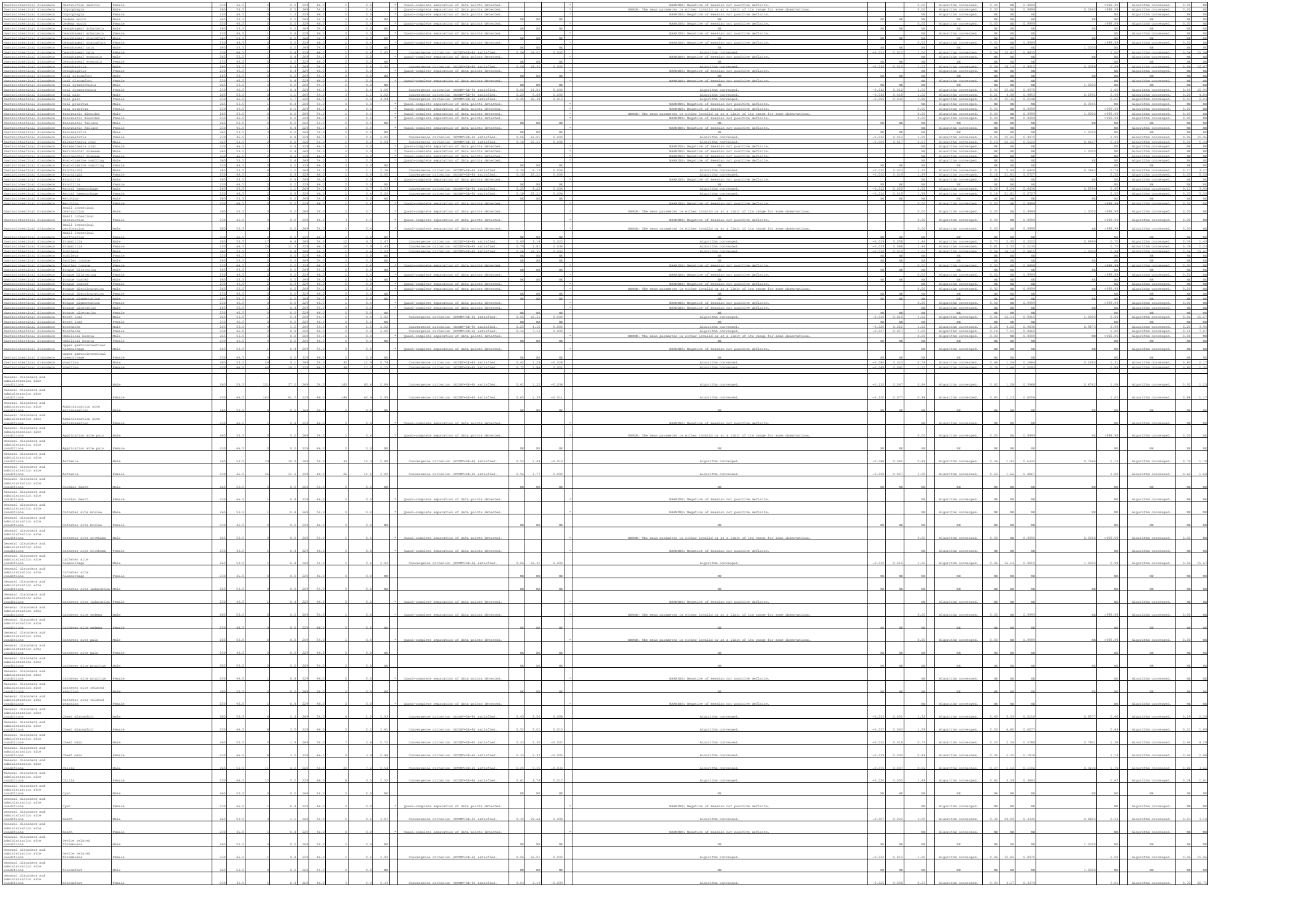

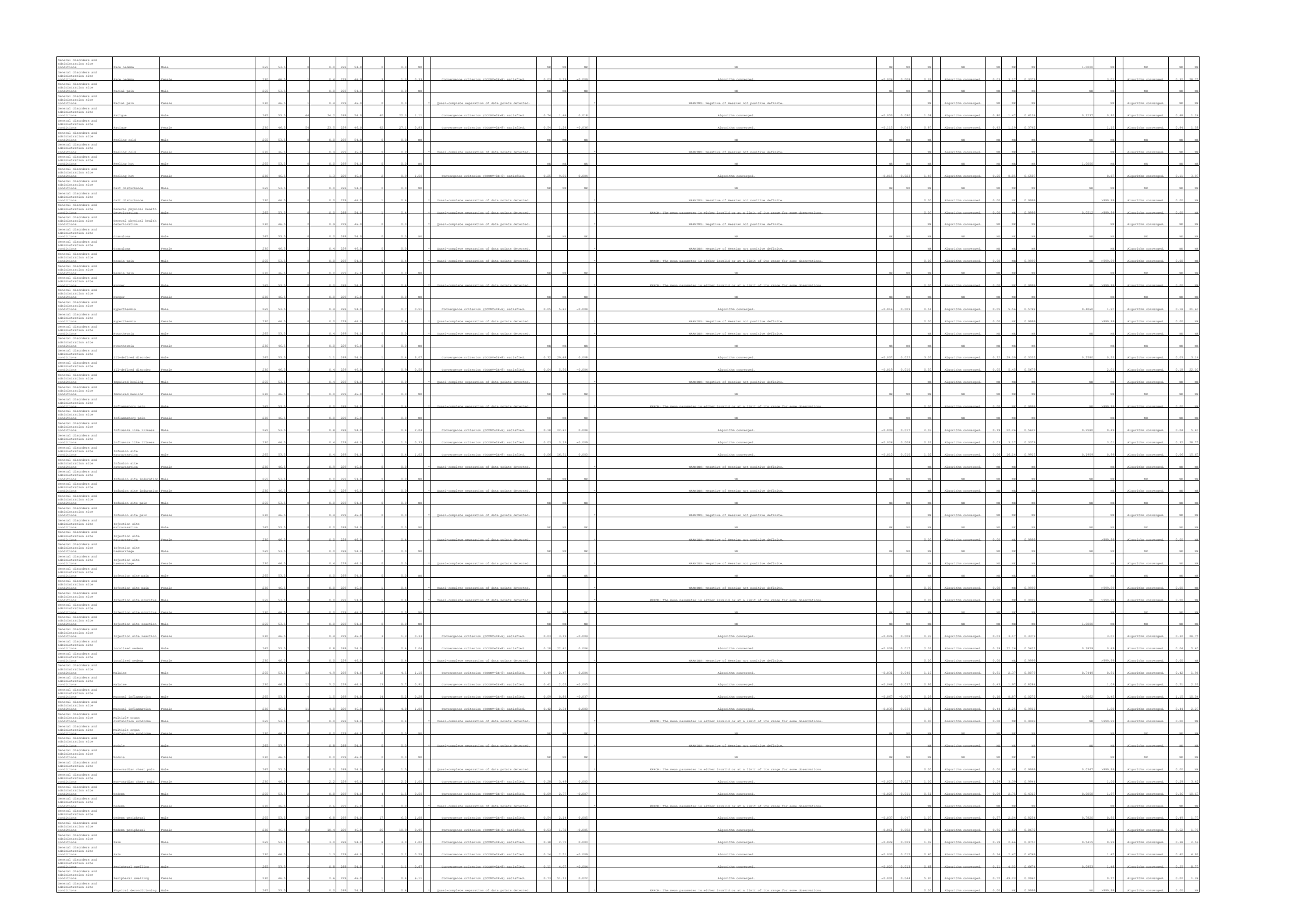

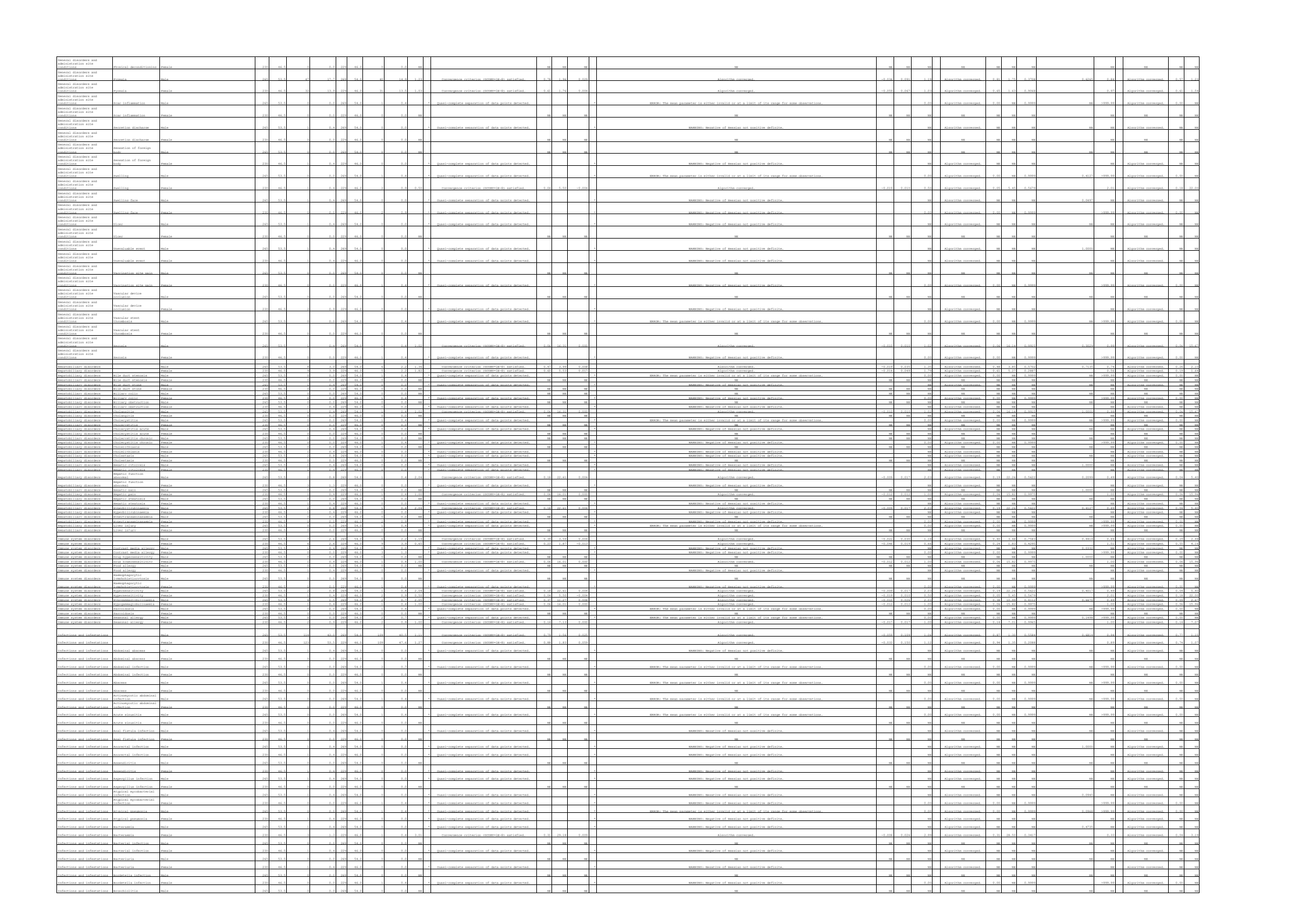

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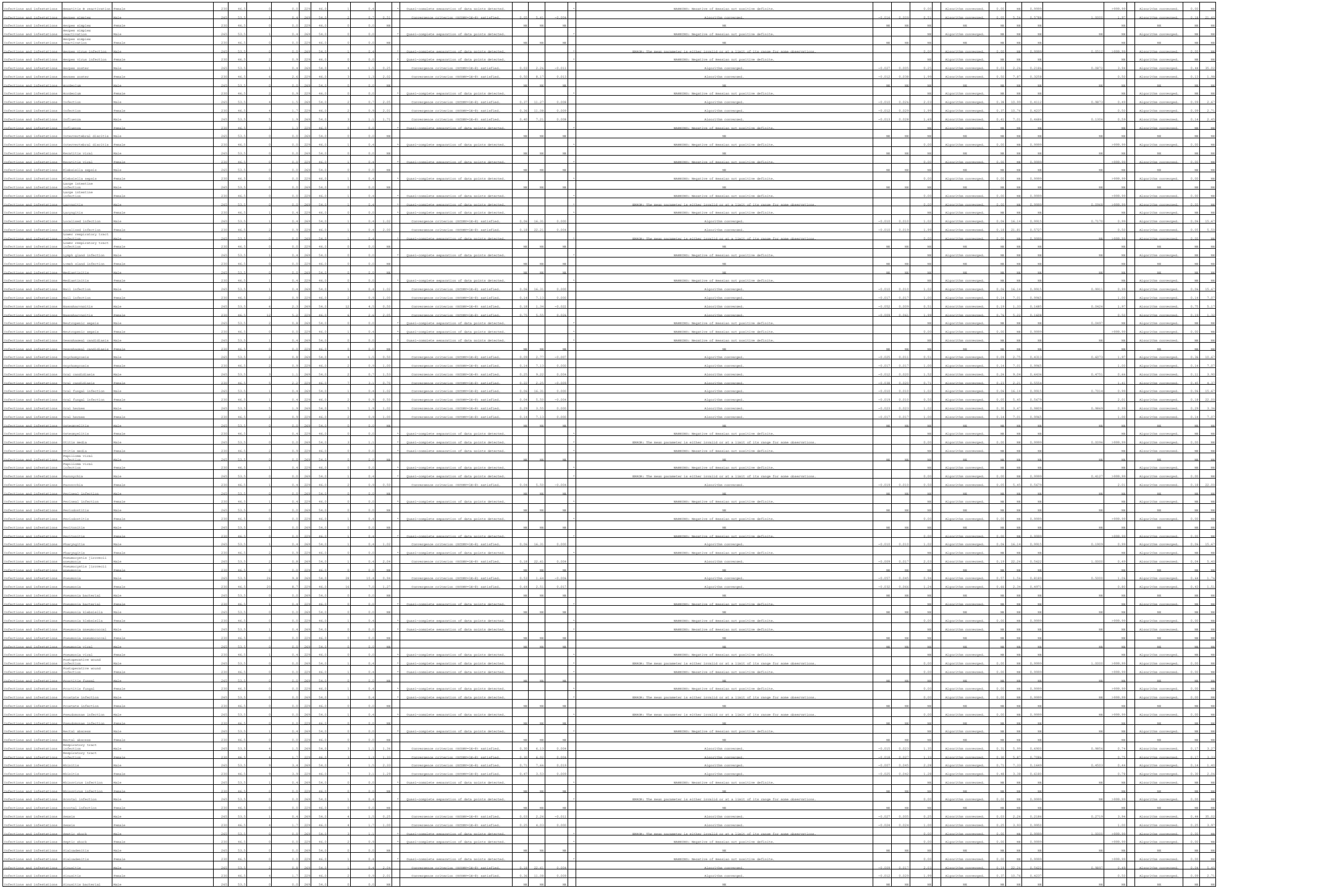

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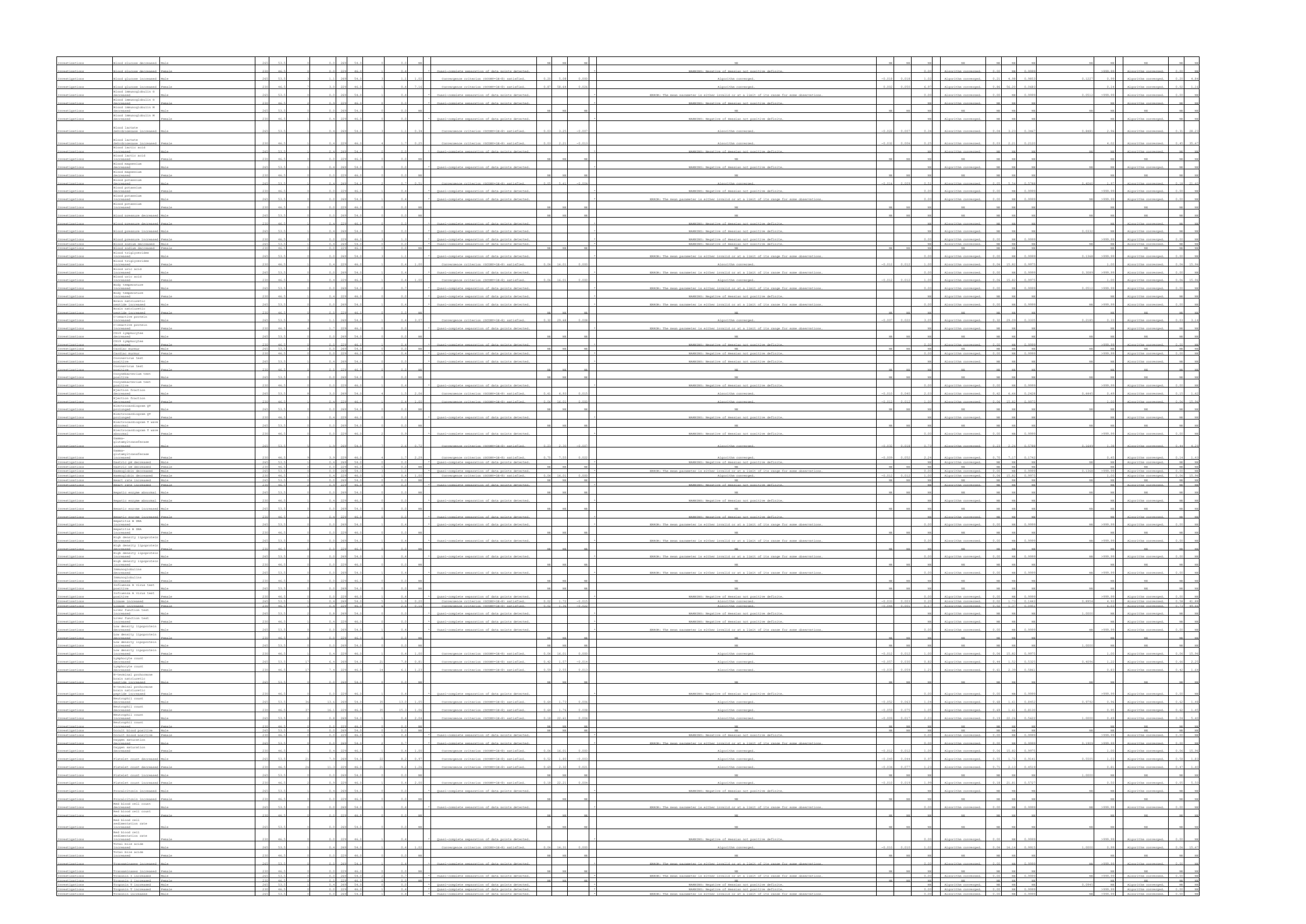

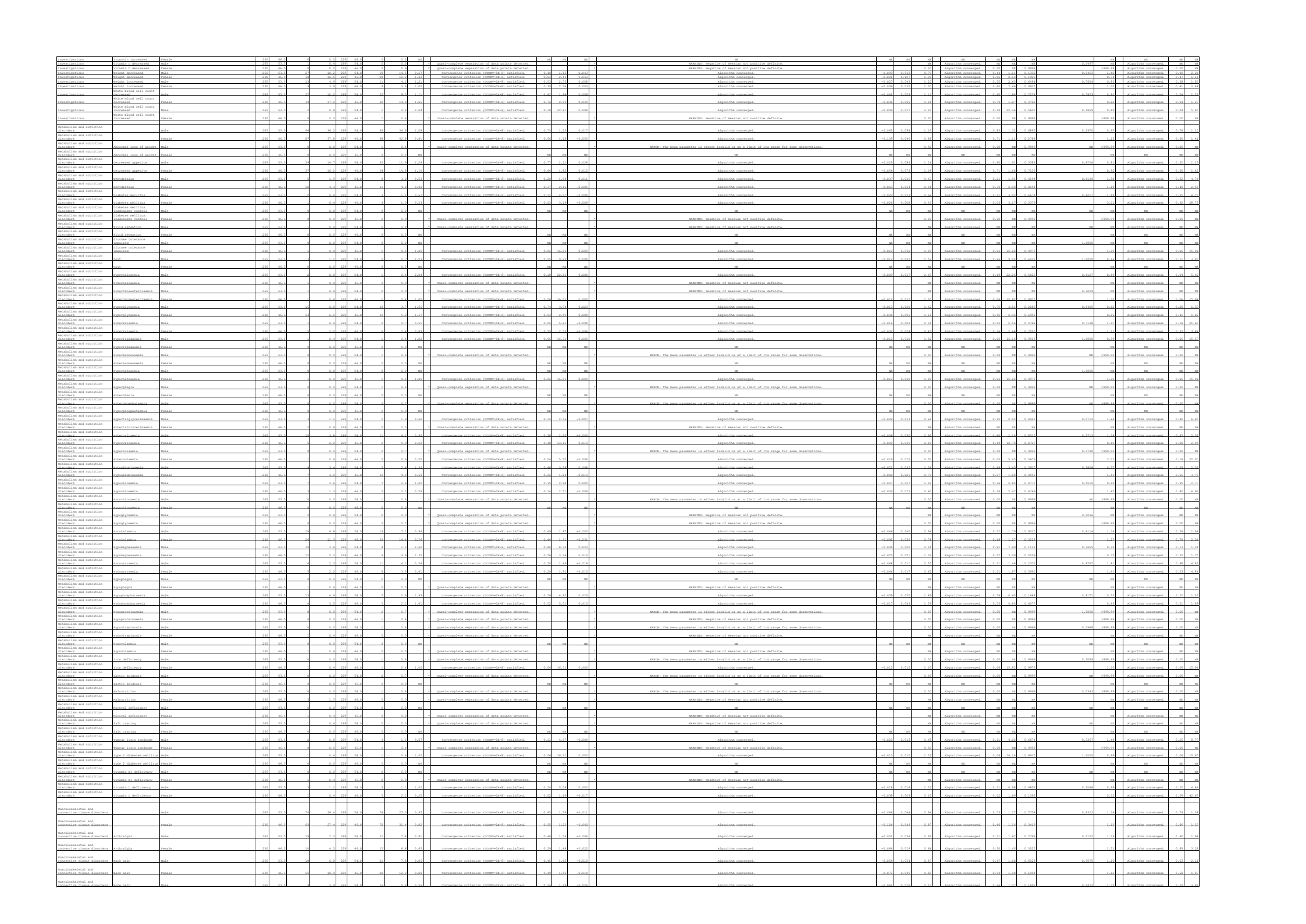

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Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to HAUT, whichever is earlier.
Test for interaction based on RR (log-binomial regression)
* indicates convergence problem. Result is untestgeratable.
Clinical cut-off: 15JN2022

Program: root/clinical_studies/BOS541077/CDPT7896/bo39942/data_analysis/ACE_FINAL_DS/prod/program/t_ae_soc_soc.sas
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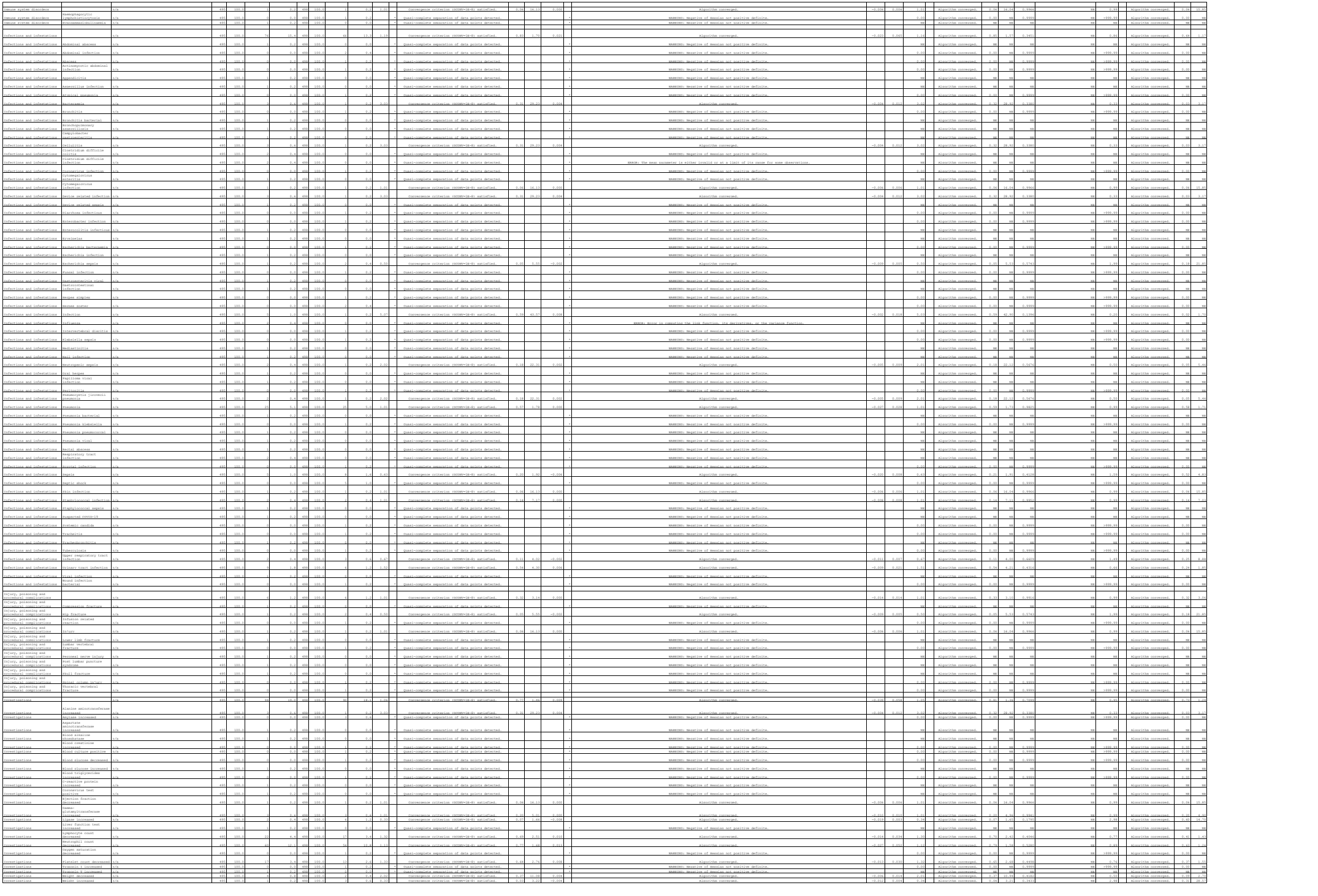
08FEB2023 17:30

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 3-5
MODEL: Unstratified Analysis
STUDY: BI39862
Dichotomous Analysis by Subgroups (Safety)

all

			Bulevirumab Velotris + R-CHP (N=495)				R-CHP (N=496)				Bulevirumab Velotris + R-CHP vs. R-CHP										R-CHP vs. Bulevirumab Velotris + R-CHP			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio						Absolute Risk Difference				Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Result	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Result	95% Lower CL	95% Upper CL	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		n/a	495	100.0	169	40.0	496	100.0	191	38.4	1.07	Convergence criterion (GCONV=1E-6) satisfied.	0.83	1.38	0.016	Algorithm converged.	-0.046	0.077	1.04	Algorithm converged.	0.88	1.22	0.5451	NE	0.96	Algorithm converged.	0.82	1.12
Blood and lymphatic system disorders	Anaemia NOS	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Blood and lymphatic system disorders	Anaemia	n/a	495	100.0	54	11.3	496	100.0	48	9.6	1.20	Convergence criterion (GCONV=1E-6) satisfied.	0.80	1.80	0.017	Algorithm converged.	-0.031	0.065	1.17	Algorithm converged.	0.86	1.60	0.3896	NE	0.85	Algorithm converged.	0.59	1.23
Blood and lymphatic system disorders	Aplasia pure red cell	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.00	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Blood and lymphatic system disorders	Cytopenia	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Blood and lymphatic system disorders	Febrile bone marrow aplasia	n/a	495	100.0	1	0.2	496	100.0	2	0.4	0.50	Convergence criterion (GCONV=1E-6) satisfied.	0.03	5.90	-0.002	Algorithm converged.	-0.008	0.003	0.50	Algorithm converged.	0.05	5.03	0.5743	NE	1.99	Algorithm converged.	0.19	21.01
Blood and lymphatic system disorders	Febrile neutropenia	n/a	495	100.0	64	12.9	496	100.0	38	7.7	1.80	Convergence criterion (GCONV=1E-6) satisfied.	1.18	2.76	0.051	Algorithm converged.	0.019	0.083	1.67	Algorithm converged.	1.14	2.46	0.0068	NE	0.59	Algorithm converged.	0.40	0.86
Blood and lymphatic system disorders	Hypofibrinogenaemia	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Blood and lymphatic system disorders	Leukopenia	n/a	495	100.0	20	4.1	496	100.0	27	7.4	0.80	Convergence criterion (GCONV=1E-6) satisfied.	0.49	1.30	-0.014	Algorithm converged.	-0.045	0.017	0.82	Algorithm converged.	0.61	1.10	0.3908	NE	1.23	Algorithm converged.	0.77	1.95
Blood and lymphatic system disorders	Lymphopenia	n/a	495	100.0	8	1.6	496	100.0	10	2.0	0.80	Convergence criterion (GCONV=1E-6) satisfied.	0.31	2.05	-0.004	Algorithm converged.	-0.031	0.013	0.80	Algorithm converged.	0.32	2.02	0.6442	NE	1.24	Algorithm converged.	0.49	3.10
Blood and lymphatic system disorders	Myelosuppression	n/a	495	100.0	4	0.8	496	100.0	1	0.2	4.05	Convergence criterion (GCONV=1E-6) satisfied.	0.45	36.49	0.006	Algorithm converged.	-0.009	0.043	4.01	Algorithm converged.	0.45	35.85	0.2123	NE	3.95	Algorithm converged.	0.34	2.24
Blood and lymphatic system disorders	Neutropenia	n/a	495	100.0	127	25.7	496	100.0	140	28.1	0.88	Convergence criterion (GCONV=1E-6) satisfied.	0.67	1.17	-0.025	Algorithm converged.	-0.080	0.031	0.87	Algorithm converged.	0.74	1.03	0.9432	NE	1.10	Algorithm converged.	0.80	1.50
Blood and lymphatic system disorders	Pancytopenia	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Blood and lymphatic system disorders	Thrombocytosenia	n/a	495	100.0	16	3.2	496	100.0	20	4.0	0.80	Convergence criterion (GCONV=1E-6) satisfied.	0.41	1.56	-0.008	Algorithm converged.	-0.035	0.011	0.80	Algorithm converged.	0.42	1.53	0.5088	NE	1.24	Algorithm converged.	0.60	2.57
Cardiac disorders		n/a	495	100.0	6	1.2	496	100.0	8	1.6	0.75	Convergence criterion (GCONV=1E-6) satisfied.	0.26	2.18	-0.004	Algorithm converged.	-0.028	0.011	0.74	Algorithm converged.	0.28	2.01	0.5895	NE	1.33	Algorithm converged.	0.44	3.79
Cardiac disorders	Atrial fibrillation	n/a	495	100.0	1	0.2	496	100.0	2	0.4	0.50	Convergence criterion (GCONV=1E-6) satisfied.	0.03	5.53	-0.002	Algorithm converged.	-0.008	0.003	0.50	Algorithm converged.	0.05	5.12	0.5743	NE	1.99	Algorithm converged.	0.19	20.63
Cardiac disorders	Atrioventricular block complete	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Cardiac disorders	Cardiac failure congestive	n/a	495	100.0	3	0.6	496	100.0	2	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Cardiac disorders	Cardiopulmonary failure	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Cardiac disorders	Left ventricular dysfunction	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.004	0.004	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Cardiac disorders	Myocardial infarction	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Cardiac disorders	Sinus bradycardia	n/a	495	100.0	2	0.4	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Cardiac disorders	Sinus tachycardia	n/a	495	100.0	2	0.4	496	100.0	1	0.2	2.02	Convergence criterion (GCONV=1E-6) satisfied.	0.19	22.33	0.002	Algorithm converged.	-0.003	0.007	2.01	Algorithm converged.	0.19	22.12	0.5471	NE	4.00	Algorithm converged.	0.35	5.44
Cardiac disorders	Tachycardia	n/a	495	100.0	0	0.0	496	100.0	2	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Congenital, familial and genetic disorders		n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Congenital, familial and genetic disorders	Pyloric stenosis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Ear and labyrinth disorders		n/a	495	100.0	0	0.0	496	100.0	2	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Ear and labyrinth disorders	Deafness	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Ear and labyrinth disorders	Hypoacusis	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Eye disorders		n/a	495	100.0	3	0.6	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 21.431437574 is greater than the limit of 0.0001. The convergence is questionable.							NE	NE				
Eye disorders	Angle closure glaucoma	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Eye disorders	Cataract	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Eye disorders	Rhegmatogenous retinal detachment	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Gastrointestinal disorders		n/a	495	100.0	45	9.1	496	100.0	36	7.4	1.21	Convergence criterion (GCONV=1E-6) satisfied.	0.77	1.90	0.013	Algorithm converged.	-0.020	0.049	1.17	Algorithm converged.	0.79	1.83	0.4047	NE	0.84	Algorithm converged.	0.56	1.27
Gastrointestinal disorders	Abdominal distension	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Gastrointestinal pain	Abdominal pain	n/a	495	100.0	4	0.8	496	100.0	5	1.0	0.77	Convergence criterion (GCONV=1E-6) satisfied.	0.21	2.80	-0.004	Algorithm converged.	-0.031	0.023	0.80	Algorithm converged.	0.23	2.77	0.7174	NE	1.24	Algorithm converged.	0.32	4.78
Gastrointestinal disorders	Abdominal pain upper	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Gastrointestinal disorders	Anal fistula	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.004	0.004	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Anal stenosis	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Gastrointestinal disorders	Colitis	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.004	0.004	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Constipation	n/a	495	100.0	5	1.0	496	100.0	3	0.6	1.67	Convergence criterion (GCONV=1E-6) satisfied.	0.50	42.07	0.004	Algorithm converged.	-0.006	0.014	1.67	Algorithm converged.	0.50	42.04	0.1360	NE	2.78	Algorithm converged.	0.42	7.36
Gastrointestinal disorders	Diarrhoea	n/a	495	100.0	14	2.8	496	100.0	8	1.6	1.75	Convergence criterion (GCONV=1E-6) satisfied.	1.05	5.01	0.020	Algorithm converged.	0.005	0.041	2.50	Algorithm converged.	1.03	5.14	0.0018	NE	1.41	Algorithm converged.	0.69	1.63
Gastrointestinal disorders	Dyspepsia	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Gastrointestinal disorders	Enteritis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Gastrointestinal disorders	Gastrointestinal discomfort	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Gastrointestinal disorders	Gastric ulcer	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Gastrointestinal disorders	Gastrointestinal haemorrhage	n/a	495	100.0	2	0.4	496	100.0	3	0.6	0.67	Convergence criterion (GCONV=1E-6) satisfied.	0.11	4.00	-0.004	Algorithm converged.	-0.031	0.023	0.67	Algorithm converged.	0.11	4.00	0.6409	NE	1.49	Algorithm converged.	0.21	9.80
Gastrointestinal disorders	Gastrooesophageal reflux disease	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Gastrointestinal disorders	Haematochezia	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Gastrointestinal disorders	Haemorrhoids	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Gastrointestinal disorders	Haemorrhoids	n/a	495	100.0	1	0.2	496	100.0	2	0.4	0.50	Convergence criterion (GCONV=1E-6) satisfied.	0.03	5.90	-0.002	Algorithm converged.	-0.008	0.003	0.50	Algorithm converged.	0.05	5.03	0.5743	NE	1.99	Algorithm converged.	0.19	21.01
Gastrointestinal disorders	Impaired gastric emptying	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Gastrointestinal disorders	Intestinal obstruction	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.004	0.004	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Intestinal perforation	n/a	495	100.0	3	0.6	496	100.0	1	0.2	3.03	Convergence criterion (GCONV=1E-6) satisfied.	0.32	29.23	0.004	Algorithm converged.	-0.004	0.012	3.02	Algorithm converged.	0.32	28.92	0.2383	NE	3.02	Algorithm converged.	0.32	9.11
Gastrointestinal disorders	Intra-abdominal haemorrhage	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Gastrointestinal disorders	Large intestinal haemorrhage	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Gastrointestinal disorders	Nausea	n/a	495	100.0	17	3.4	496	100.0	12	2.4	1.42	Convergence criterion (GCONV=1E-6) satisfied.	0.69	2.93	0.009	Algorithm converged.	-0.004	0.023	1.42	Algorithm converged.	0.69	2.92	0.3451	NE	1.42	Algorithm converged.	0.69	2.92
Gastrointestinal disorders	Necrotising colitis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Gastrointestinal disorders	Neutropenic colitis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Gastrointestinal disorders	Obstruction gastric	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Gastrointestinal disorders	Pancreatic disorder	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Gastrointestinal disorders	Pancreatitis	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.004	0.004	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Small intestinal obstruction	n/a	495	100.0	0	0.0	496	100.0	3	1.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Gastrointestinal disorders	Small intestinal perforation	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Gastrointestinal disorders	Stomatitis	n/a	495	100.0	3	0.6	496	100.0	1	0.2	3.03	Convergence criterion (GCONV=1E-6) satisfied.	0.32	29.23	0.004	Algorithm converged.	-0.004	0.012	3.02	Algorithm converged.	0.32	28.92	0.2383	NE	3.02	Algorithm converged.	0.32	9.11
Gastrointestinal disorders	Subileus	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.004	0.004	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Subileus loop	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.004	0.004	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Gastrointestinal disorders	Vomiting	n/a	495	100.0	5	1.0	496	100.0	3	0.6	1.68	Convergence criterion (GCONV=1E-6) satisfied.	0.40	7.08	0.004	Algorithm converged.	-0.007	0.015	1.67	Algorithm converged.	0.40	6.95	0.4774	NE	0.84	Algorithm converged.	0.19	2.49
General disorders and administration site conditions		n/a	495	100.0	30	6.1	496	100.0	28	5.6	1.07	Convergence criterion (GCONV=1E-6) satisfied.	0.66	2.00	0.008	Algorithm converged.	-0.036	0.057	1.07	Algorithm converged.	0.74	1.61	0.5867	NE	0.94	Algorithm converged.	0.52	1.64
General disorders and administration site conditions	Asthenia	n/a	495	100.0	7	1.4	496	100.0	2	0.4	3.56	Convergence criterion (GCONV=1E-6) satisfied.	0.74	17.30	0.016	Algorithm converged.	-0.002	0.022	3.53	Algorithm converged.	0.79	16.87	0.1153	NE	0.28	Algorithm converged.	0.06	1.26
General disorders and administration site conditions	Cardiac death	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
General disorders and administration site conditions	Catheter site haemorrhage	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
General disorders and administration site conditions	Chest discomfort	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
General disorders and administration site conditions	Chest pain	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.004	0.004	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
General disorders and administration site conditions	Chills	n/a	495	100.0	3	0.6	496	100.0	4	0.8	0.76	Convergence criterion (GCONV=1E-6) satisfied.	0.17	3.44	-0.002	Algorithm converged.	-0.020	0.007	0.75	Algorithm converged.	0.18	3.41	0.5743	NE	1.99	Algorithm converged.	0.19	21.01
General disorders and administration site conditions	Death	n/a	495	100.0	4	0.8	496	100.0	1	0.2	4.05	Convergence criterion (GCONV=1E-6) satisfied.	0.45	36.49	0.006	Algorithm converged.	-0.009	0.043	4.01	Algorithm converged.	0.45	35.85	0.2123	NE	3.95	Algorithm converged.	0.34	2.24
General disorders and administration site conditions	Device related thrombosis	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
General disorders and administration site conditions	Fatigue	n/a	495	100.0	5	1.0	496	100.0	11	2.2	0.45	Convergence criterion (GCONV=1E-6) satisfied.	0.16	1.31	-0.012	Algorithm converged.	-0.028	0.004	0.46	Algorithm converged.	0.16	1.31	0.1441	NE	2.19	Algorithm converged.	0.77	4.23
General disorders and administration site conditions	General physical health deterioration	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
General disorders and administration site conditions	Ill-defined disorder	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
General disorders and administration site conditions	Infusion site extravasation	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
General disorders and administration site conditions	Injection site extravasation	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
General disorders and administration site conditions	Malaise	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
General disorders and administration site conditions	Mucosal inflammation	n/a	495	100.0	2	0.4	496	100.0	1	0.2	2.02	Convergence criterion (GCONV=1E-6) satisfied.	0.18	22.33	0.002	Algorithm converged.	-0.005	0.009	2.01	Algorithm converged.	0.18	22.12	0.5474	NE	4.00	Algorithm converged.	0.35	5.44
General disorders and administration site conditions	Multiple organ dysfunction syndrome	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
General disorders and administration site conditions	Oedema	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
General disorders and administration site conditions	Oedema peripheral	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.13	0.000	Algorithm converged.	-0.004	0.004	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
General disorders and administration site conditions	Pain	n/a	495	100.0	3	0.6	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 21.431437574 is greater than the limit of 0.0001. The convergence is questionable.							NE	NE				
General disorders and administration site conditions	Pyrexia	n/a	495	100.0	5	1.0	496	100.0	1	0.2	5.07	Convergence criterion (GCONV=1E-6) satisfied.	0.64	43.05	0.008	Algorithm converged.	-0.006	0.019	5.01	Algorithm converged.	0.59	42.84	0.1396	NE	0.25	Algorithm converged.	0.02	1.70
General disorders and administration site conditions	Ulcer	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
General disorders and administration site conditions	Vascular stent thrombosis	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Hepatobiliary disorders		n/a	495	100.0	2	0.4	496	100.0	4	0.8	0.50	Convergence criterion (GCONV=1E-6) satisfied.	0.07	3.64	-0.002	Algorithm converged.	-0.020	0.008	0.50	Algorithm converged.	0.07	3.64	0.7114	NE	1.32	Algorithm converged.	0.30	5.83
Hepatobiliary disorders	Bile duct stenosis	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Hepatobiliary disorders	Biliary obstruction	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Hepatobiliary disorders	Cholecystitis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Hepatobiliary disorders	Cholecystitis acute	n/a	495	100.0	2	0.4	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Hepatobiliary disorders	Cholelithiasis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	NE				
Hepatobiliary disorders	Hepatic function abnormal	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999.99				
Hepatobiliary disorders	Hepatomegaly	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.							NE	>999



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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 3-5
MODEL: Unstratified Analysis
STUDY: BG399662
Dichotomous Analysis by Subgroups (Safety)

Age

			Bofanglustat Tablets + N-Corr (N=493)				N-Corr (N=496)				Bofanglustat Tablets + N-CRP vs. N-Corr										N-Corr vs. Bofanglustat Tablets + N-CRP			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	N	%	n	%	N	%	n	%	Convergence Remark	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Remark	95% Lower CL	95% Upper CL	Relative Risk	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Remark	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		<= 40	147	33.7	51	30.5	157	31.7	47	29.9	1.03	Convergence criterion (ZCONV*1E-8) satisfied.	0.66	1.60	0.036	Algorithm converged.	-0.096	0.168	1.02	Algorithm converged.	0.76	1.52	0.9561	0.8376	0.98	Algorithm converged.	0.72	1.34
Blood and lymphatic system disorders		> 40	328	66.3	147	68.8	341	68.8	144	42.2	1.11	Convergence criterion (ZCONV*1E-8) satisfied.	0.80	1.55	0.029	Algorithm converged.	-0.068	0.165	1.03	Algorithm converged.	0.88	1.23	0.4356		0.94	Algorithm converged.	0.79	1.14
Blood and lymphatic system disorders	Agranulocytosis	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Agranulocytosis	> 40	328	66.3	0	0.0	341	68.8	1	0.3					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.						0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Anaemia	<= 40	147	33.7	14	8.4	157	31.7	7	4.5	1.94	Convergence criterion (ZCONV*1E-8) satisfied.	0.77	4.88	0.036	Algorithm converged.	-0.016	0.080	1.43	Algorithm converged.	0.76	4.04	0.1405	0.2405	0.53	Algorithm converged.	0.22	1.26
Blood and lymphatic system disorders	Anaemia	> 40	328	66.3	62	12.6	341	68.8	41	12.0	1.07	Convergence criterion (ZCONV*1E-8) satisfied.	0.68	1.70	0.006	Algorithm converged.	-0.042	0.068	1.05	Algorithm converged.	0.71	1.59	0.7593		0.94	Algorithm converged.	0.63	1.40
Blood and lymphatic system disorders	Aplasia pure red cell	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Aplasia pure red cell	> 40	328	66.3	1	0.3	341	68.8	1	0.3	1.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.65	0.000	Algorithm converged.	-0.008	0.008	1.04	Algorithm converged.	0.07	16.03	0.9780		0.94	Algorithm converged.	0.06	15.31
Blood and lymphatic system disorders	Cytopenia	<= 40	147	33.7	1	0.6	157	31.7	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Cytopenia	> 40	328	66.3	0	0.0	341	68.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	> 40	328	66.3	1	0.3	341	68.8	2	0.6	0.52	Convergence criterion (ZCONV*1E-8) satisfied.	0.05	5.74	-0.003	Algorithm converged.	-0.009	0.003	0.52	Algorithm converged.	0.05	5.31	0.5425		1.32	Algorithm converged.	0.10	23.13
Blood and lymphatic system disorders	Febrile neutropenia	<= 40	147	33.7	14	8.4	157	31.7	12	7.6	1.11	Convergence criterion (ZCONV*1E-8) satisfied.	0.49	2.87	0.007	Algorithm converged.	-0.030	0.043	1.13	Algorithm converged.	0.52	2.39	0.8044	0.1745	0.91	Algorithm converged.	0.44	1.93
Blood and lymphatic system disorders	Febrile neutropenia	> 40	328	66.3	50	10.2	341	68.8	26	7.6	1.18	Convergence criterion (ZCONV*1E-8) satisfied.	1.00	3.99	0.074	Algorithm converged.	0.008	0.144	1.22	Algorithm converged.	1.08	3.13	0.0225		0.93	Algorithm converged.	0.82	0.78
Blood and lymphatic system disorders	Hypofibrinogenaemia	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Hypofibrinogenaemia	> 40	328	66.3	0	0.0	341	68.8	1	0.3		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	0.9999		>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Leukopenia	<= 40	147	33.7	7	4.2	157	31.7	7	4.5	0.94	Convergence criterion (ZCONV*1E-8) satisfied.	0.33	2.74	-0.031	Algorithm converged.	-0.087	0.042	0.94	Algorithm converged.	0.34	2.62	0.9065	0.7764	1.05	Algorithm converged.	0.30	2.86
Blood and lymphatic system disorders	Leukopenia	> 40	328	66.3	23	7.0	341	68.8	30	8.8	0.78	Convergence criterion (ZCONV*1E-8) satisfied.	0.44	1.38	-0.018	Algorithm converged.	-0.055	0.022	0.80	Algorithm converged.	0.47	1.34	0.3461		1.25	Algorithm converged.	0.74	2.11
Blood and lymphatic system disorders	Lymphocytosis	<= 40	147	33.7	0	0.0	157	31.7	3	1.9		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 10.6326777486 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	0.0276	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Lymphocytosis	> 40	328	66.3	8	2.4	341	68.8	7	2.1	1.15	Convergence criterion (ZCONV*1E-8) satisfied.	0.43	3.00	0.004	Algorithm converged.	-0.036	0.065	1.14	Algorithm converged.	0.46	2.84	0.7362		0.84	Algorithm converged.	0.36	2.24
Blood and lymphatic system disorders	Myelosuppression	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	1.0000	NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	> 40	328	66.3	4	1.2	341	68.8	1	0.3	4.23	Convergence criterion (ZCONV*1E-8) satisfied.	0.47	37.75	0.004	Algorithm converged.	-0.006	0.022	4.14	Algorithm converged.	0.47	37.01	0.2013		0.24	Algorithm converged.	0.02	2.14
Blood and lymphatic system disorders	Neutropenia	<= 40	147	33.7	34	23.4	157	31.7	33	21.0	1.03	Convergence criterion (ZCONV*1E-8) satisfied.	0.61	1.76	0.005	Algorithm converged.	-0.086	0.093	1.03	Algorithm converged.	0.67	1.64	0.9065	0.5447	0.98	Algorithm converged.	0.64	1.48
Blood and lymphatic system disorders	Neutropenia	> 40	328	66.3	93	27.7	341	68.8	107	31.4	0.83	Convergence criterion (ZCONV*1E-8) satisfied.	0.63	1.07	-0.034	Algorithm converged.	-0.109	0.022	0.84	Algorithm converged.	0.70	1.03	0.0682		1.13	Algorithm converged.	0.89	1.42
Blood and lymphatic system disorders	Pancytopenia	<= 40	147	33.7	0	0.0	157	31.7	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	> 40	328	66.3	1	0.3	341	68.8	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Thrombocytopenia	<= 40	147	33.7	2	1.2	157	31.7	5	3.2	0.37	Convergence criterion (ZCONV*1E-8) satisfied.	0.07	1.82	-0.026	Algorithm converged.	-0.092	0.013	0.38	Algorithm converged.	0.07	1.81	0.2382	0.2764	0.66	Algorithm converged.	0.52	13.51
Blood and lymphatic system disorders	Thrombocytopenia	> 40	328	66.3	14	4.3	341	68.8	15	4.4	0.93	Convergence criterion (ZCONV*1E-8) satisfied.	0.44	2.04	-0.001	Algorithm converged.	-0.030	0.020	0.97	Algorithm converged.	0.48	1.98	0.9335		1.03	Algorithm converged.	0.51	2.10
Cardiac disorders		<= 40	147	33.7	1	0.6	157	31.7	1	0.6	0.94	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	15.05	0.000	Algorithm converged.	-0.057	0.057	0.94	Algorithm converged.	0.06	14.66	0.9653	0.8771	1.04	Algorithm converged.	0.07	16.80
Cardiac disorders		> 40	328	66.3	7	1.7	341	68.8	7	2.1	0.74	Convergence criterion (ZCONV*1E-8) satisfied.	0.29	2.05	-0.005	Algorithm converged.	-0.033	0.013	0.73	Algorithm converged.	0.24	2.00	0.4083		1.28	Algorithm converged.	0.49	3.42
Cardiac disorders	Atrial fibrillation	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	1.0000	NE	NE	NE	NE
Cardiac disorders	Atrial fibrillation	> 40	328	66.3	1	0.3	341	68.8	2	0.6	0.52	Convergence criterion (ZCONV*1E-8) satisfied.	0.05	5.74	-0.003	Algorithm converged.	-0.009	0.003	0.52	Algorithm converged.	0.05	5.31	0.5425		1.32	Algorithm converged.	0.10	23.13
Cardiac disorders	Atrioventricular block complete	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	> 40	328	66.3	0	0.0	341	68.8	1	0.3		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	0.9999		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Cardiac failure congestive	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Cardiac failure congestive	> 40	328	66.3	1	0.3	341	68.8	2	0.6		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		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Cardiopulmonary failure	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Cardiopulmonary failure	> 40	328	66.3	1	0.3	341	68.8	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
Cardiac disorders	Left ventricular dysfunction	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	> 40	328	66.3	1	0.3	341	68.8	1	0.3	1.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.65	0.000	Algorithm converged.	-0.008	0.008	1.04	Algorithm converged.	0.07	16.03	0.9780		0.94	Algorithm converged.	0.06	15.31
Cardiac disorders	Myocardial infarction	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Myocardial infarction	> 40	328	66.3	1	0.3	341	68.8	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
Cardiac disorders	Sinus bradycardia	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	> 40	328	66.3	1	0.3	341	68.8	2	0.6	0.52	Convergence criterion (ZCONV*1E-8) satisfied.	0.05	5.74	-0.003	Algorithm converged.	-0.009	0.003	0.52	Algorithm converged.	0.05	5.31	0.5425		1.32	Algorithm converged.	0.10	23.13
Cardiac disorders	Sinus tachycardia	<= 40	147	33.7	1	0.6	157	31.7	1	0.6	0.94	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	15.05	0.000	Algorithm converged.	-0.057	0.057	0.94	Algorithm converged.	0.06	14.66	0.9653	0.8955	1.04	Algorithm converged.	0.07	16.80
Cardiac disorders	Sinus tachycardia	> 40	328	66.3	1	0.3	341	68.8	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
Cardiac disorders	Tachycardia	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Tachycardia	> 40	328	66.3	0	0.0	341	68.8	2	0.6		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		>999.99	Algorithm converged.	0.00	NE
Congenital, familial and genetic disorders		<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Congenital, familial and genetic disorders		> 40	328	66.3	1	0.3	341	68.8	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
Congenital, familial and genetic disorders	Pyloric atresia	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Congenital, familial and genetic disorders	Pyloric atresia	> 40	328	66.3	1	0.3	341	68.8	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
Ear and labyrinth disorders		<= 40	147	33.7	0	0.0	157	31.7	1	0.6		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.107627839 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	1.0000	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders		> 40	328	66.3	0	0.0	341	68.8	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.			0.00	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Deafness	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Ear and labyrinth disorders	Deafness	> 40	328	66.3	0	0.0	341	68.8	1	0.3		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	0.9999		>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Hypoacusis	<= 40	147	33.7	0	0.0	157	31.7	1	0.6		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.107627839 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
Ear and labyrinth disorders	Hypoacusis	> 40	328	66.3	0	0.0	341	68.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders		<= 40	147	33.7	1	0.6	157	31.7	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	NE	NE	NE
Eye disorders		> 40	328	66.3	2	0.6	341	68.8	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
Eye disorders	Acute closure glaucoma	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Acute closure glaucoma	> 40	328	66.3	1	0.3	341	68.8	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
Eye disorders	Cataract	<= 40	147	33.7	1	0.6	157	31.7	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	NE	NE	NE
Eye disorders	Cataract	> 40	328	66.3	1	0.3	341	68.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	> 40	328	66.3	1	0.3	341	68.8	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
Gastrointestinal disorders		<= 40	147	33.7	4	1.6	157	31.7	11	7.0	0.24	Convergence criterion (ZCONV*1E-8) satisfied.	0.07	0.80	-0.014	Algorithm converged.	-0.060	0.018	0.23	Algorithm converged.	0.07	0.77	0.0460	0.2218	0.33	Algorithm converged.	0.10	1.10
Gastrointestinal disorders		> 40	328	66.3	34	11.5	341	68.8	27	7.9	1.43	Convergence criterion (ZCONV*1E-8) satisfied.	0.87	2.40	0.031	Algorithm converged.	-0.014	0.079	1.39	Algorithm converged.	0.94	2.23	0.1782		0.72	Algorithm converged.	0.40	1.14
Gastrointestinal disorders	Abdominal distension	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Abdominal distension	> 40	328	66.3	0	0.0	341	68.8	1	0.3		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	0.9999		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Abdominal pain	<= 40	147	33.7	2	1.2	157	31.7	4	2.5	0.46	Convergence criterion (ZCONV*1E-8) satisfied.	0.08	2.72	-0.016	Algorithm converged.	-0.061	0.014	0.47	Algorithm converged.	0.08	2.61	0.2764	0.7563	0.13	Algorithm converged.	0.02	11.45
Gastrointestinal disorders	Abdominal pain	> 40	328	66.3	2	0.6	341	68.8	4	1.2	0.49	Convergence criterion (ZCONV*1E-8) satisfied.	0.09	4.00	-0.003	Algorithm converged.	-0.018	0.010	0.49	Algorithm converged.	0.09	3.91	0.6617		0.64	Algorithm converged.	0.09	4.56
Gastrointestinal disorders	Abdominal pain upper	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Abdominal pain upper	> 40	328	66.3	0	0.0	341	68.8	1	0.3		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	0.9999		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Anal fistula	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	1.0000	NE	NE	NE	NE
Gastrointestinal disorders	Anal fistula	> 40	328	66.3	1	0.3	341	68.8	1	0.3	1.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.65	0.000	Algorithm converged.	-0.008	0.008	1.04	Algorithm converged.	0.07	16.03	0.9780		0.94	Algorithm converged.	0.06	15.31
Gastrointestinal disorders	Anal stenosis	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Anal stenosis	> 40	328	66.3	0	0.0	341	68.8	1	0.3		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	0.9999		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Ascites	<= 40	147	33.7	1	0.6	157	31.7	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	NE	NE	NE
Gastrointestinal disorders	Ascites	> 40	328	66.3	1	0.3	341	68.8	0	0.0		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	0.9547	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Constipation	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Constipation	> 40	328	66.3	1	0.3	341	68.8	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
Gastrointestinal disorders	Diarrhoea	<= 40	147	33.7	15	10.2	157	31.7	15	9.6	1.07	Convergence criterion (ZCONV*1E-8) satisfied.	0.52	2.19	0.006	Algorithm converged.	-0.028	0.042	1.06	Algorithm converged.	0.53	2.14	0.8452		0.98	Algorithm converged.	0.57	1.71
Gastrointestinal disorders	Diarrhoea	> 40	328	66.3	55	16.8	341	68.8	46	13.5	1.24	Convergence criterion (ZCONV*1E-8) satisfied.	0.84	1.83	0.028	Algorithm converged.	-0.003	0.063	1.17	Algorithm converged.	0.96	1.69	0.1172		1.15	Algorithm converged.	0.92	1.44
Gastrointestinal disorders	Dysphagia	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Dysphagia	> 40	328	66.3	3	0.9	341	68.8	2	0.6	1.52	Convergence criterion (ZCONV*1E-8) satisfied.	0.29	7.96	0.003	Algorithm converged.	-0.004	0.012	1.51	Algorithm converged.	0.30	7.74	0.4469		0.84	Algorithm converged.	0.21	10.78
Gastrointestinal disorders	Dyspepsia	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Dyspepsia	> 40	328	66.3	1	0.3	341	68.8	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
Gastrointestinal disorders	Enteritis	<= 40	147	33.7	1	0.6	157	31.7	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	NE	NE	NE
Gastrointestinal disorders	Enteritis	> 40	328	66.3	1	0.3	341	68.8	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
Gastrointestinal disorders	Epigastric discomfort	<= 40	147	33.7	1	0.6	157	31.7	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	NE	NE	NE
Gastrointestinal disorders	Epigastric discomfort	> 40	328	66.3	0	0.0	341	68.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Gastric ulcer	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Gastric ulcer	> 40	328	66.3	1	0.3	341	68.8	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
Gastrointestinal disorders	Gastrointestinal haemorrhage	<= 40	147	33.7	0	0.0	157	31.7	3	0.6		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.107627839 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	0.9547	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	> 40	328	66.3	2	0.6	341	68.8	2	0.6	1.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.15	7.40	0.000	Algorithm converged.	-0.041	0.041	1.04	Algorithm converged.	0.15	7.19	0.9893		0.96	Algorithm converged.	0.14	6.79
Gastrointestinal disorders	Gastrooesophageal reflux disease	<= 40	147	33.7	0	0.0	157	31.7	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE	NE

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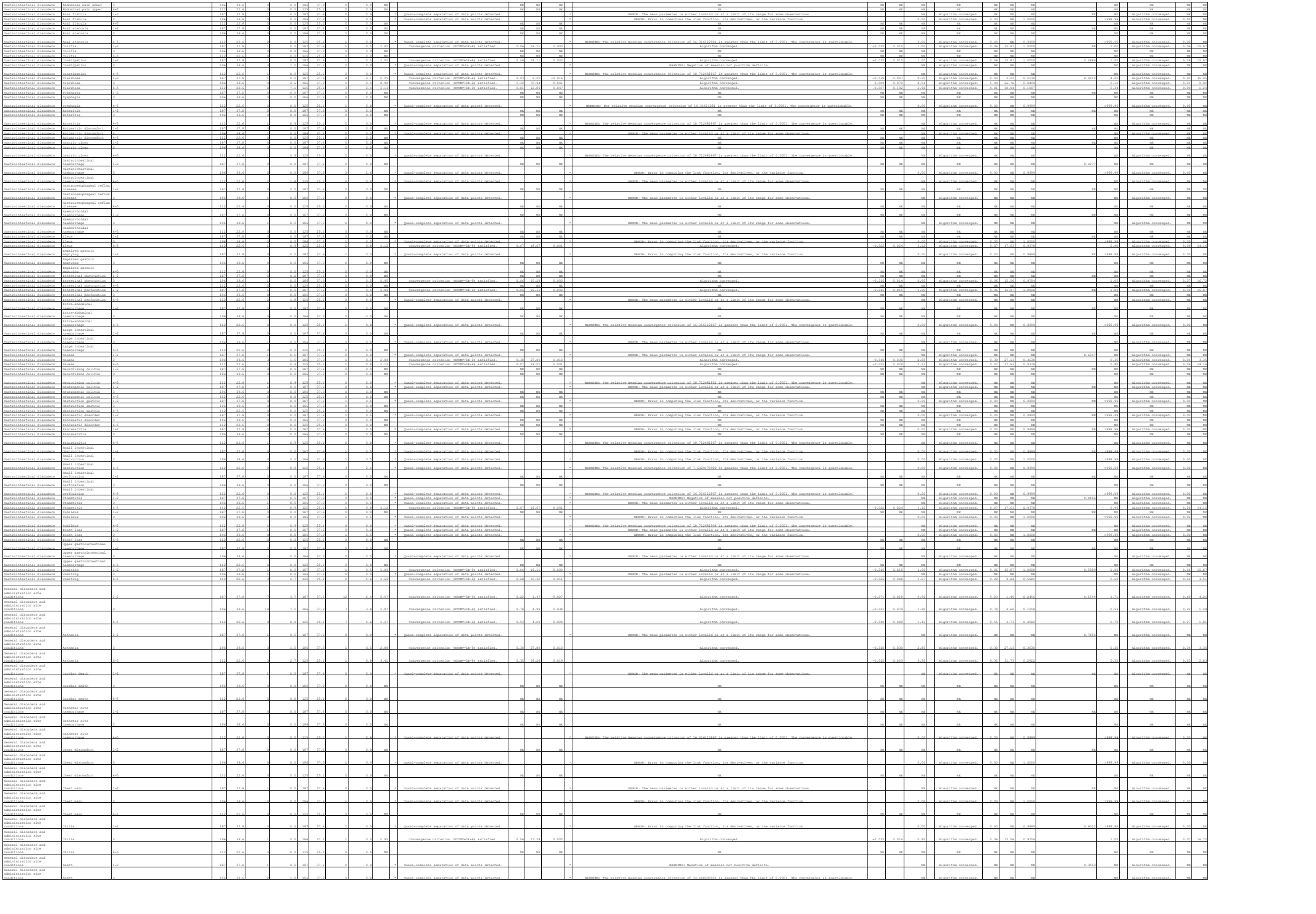
POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDCOINT: AEs Grade 3-5
MODEL: Unstratified Analysis
STOCT: 20159962
Dichotomous Analysis by Subgroups (Safety)

ZPG score at Screening

| | | | Pulsatorum Vaccine + B-CHP (N=493) | | | | B-CHP (N=498) | | | | Pulsatorum Vaccine + B-CHP vs. B-CHP | | | |



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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 3-5
MODEL: Unstratified Analysis
STUDY: BG39862
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Bintrafusp Alpha + M-CSF (N=453)				M-CSF (N=150)				Bintrafusp Alpha + M-CSF vs. M-CSF										M-CSF vs. Bintrafusp Alpha + M-CSF			
			Patients		Patients with Event		Patients		Patients with Event		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	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		Western Europe/United States/Canada/Australia	298	60.2	113	37.6	300	49.2	156	35.3	1.15	Convergence criterion (ZCONV*18-8) satisfied.	0.73	1.76	0.021	Algorithm converged.	-0.091	0.105	1.06	Algorithm converged.	0.86	1.11	0.5477	0.8152	0.96	Algorithm converged.	0.74	1.14
Blood and lymphatic system disorders		Asia	140	28.3	61	43.6	135	27.4	57	41.0	1.11	Convergence criterion (ZCONV*18-8) satisfied.	0.69	1.79	0.026	Algorithm converged.	-0.092	0.145	1.06	Algorithm converged.	0.81	1.40	0.6458		0.94	Algorithm converged.	0.72	1.24
Blood and lymphatic system disorders		Rest of World	57	11.5	25	43.9	15	11.4	28	47.5	0.84	Convergence criterion (ZCONV*18-8) satisfied.	0.42	1.68	-0.036	Algorithm converged.	-0.203	0.145	0.92	Algorithm converged.	0.62	1.38	0.6978		1.08	Algorithm converged.	0.73	1.61
Blood and lymphatic system disorders	Agranulocytosis	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	49.2	1	0.3		Quasi-complete separation of data points detected.	NE	NE	NE	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
Blood and lymphatic system disorders	Agranulocytosis	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Agranulocytosis	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Anemia	Western Europe/United States/Canada/Australia	298	60.2	36	12.1	300	49.2	20	7.3	1.74	Convergence criterion (ZCONV*18-8) satisfied.	1.00	3.03	0.047	Algorithm converged.	0.006	0.089	1.47	Algorithm converged.	0.98	2.23	0.0555	0.1021	1.64	Algorithm converged.	0.97	1.65
Blood and lymphatic system disorders	Anemia	Asia	140	28.3	12	8.6	135	27.4	16	12.9	0.63	Convergence criterion (ZCONV*18-8) satisfied.	0.29	1.36	-0.044	Algorithm converged.	-0.159	0.065	0.66	Algorithm converged.	0.33	1.33	0.2421		1.51	Algorithm converged.	0.76	3.00
Blood and lymphatic system disorders	Anemia	Rest of World	57	11.5	8	14.0	15	11.4	8	13.6	1.04	Convergence criterion (ZCONV*18-8) satisfied.	0.36	2.99	0.005	Algorithm converged.	-0.191	0.191	1.04	Algorithm converged.	0.42	2.57	0.9408		0.97	Algorithm converged.	0.39	2.40
Blood and lymphatic system disorders	Aplasia pure red cell	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	49.2	1	0.3	1.01	Convergence criterion (ZCONV*18-8) satisfied.	0.06	16.15	0.000	Algorithm converged.	-0.009	0.009	1.01	Algorithm converged.	0.06	16.03	0.9962	1.0000	0.99	Algorithm converged.	0.06	15.81
Blood and lymphatic system disorders	Aplasia pure red cell	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Aplasia pure red cell	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Cytopenia	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	49.2	0	0.0		Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 44.806790292 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	Cytopenia	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Cytopenia	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	49.2	2	0.7	0.30	Convergence criterion (ZCONV*18-8) satisfied.	0.03	5.66	-0.021	Algorithm converged.	-0.093	0.049	0.30	Algorithm converged.	0.06	3.03	0.5743		0.99	Algorithm converged.	0.06	15.73
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile neutropenia	Western Europe/United States/Canada/Australia	298	60.2	40	12.4	300	49.2	14	4.3	2.28	Convergence criterion (ZCONV*18-8) satisfied.	1.23	4.24	0.071	Algorithm converged.	0.020	0.122	2.13	Algorithm converged.	1.26	3.93	0.0044	0.4097	2.87	Algorithm converged.	0.99	8.80
Blood and lymphatic system disorders	Febrile neutropenia	Asia	140	28.3	17	12.1	135	27.4	14	10.1	1.23	Convergence criterion (ZCONV*18-8) satisfied.	0.55	2.80	0.021	Algorithm converged.	-0.051	0.093	1.21	Algorithm converged.	0.66	2.23	0.5825		1.21	Algorithm converged.	0.61	1.54
Blood and lymphatic system disorders	Febrile neutropenia	Rest of World	57	11.5	7	12.3	15	11.4	5	8.5	1.51	Convergence criterion (ZCONV*18-8) satisfied.	0.45	5.07	0.038	Algorithm converged.	-0.073	0.149	1.43	Algorithm converged.	0.49	4.21	0.5041		1.45	Algorithm converged.	0.23	2.05
Blood and lymphatic system disorders	Hypofibrinogenemia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	49.2	1	0.3		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	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Hypofibrinogenemia	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Hypofibrinogenemia	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Leukopenia	Western Europe/United States/Canada/Australia	298	60.2	4	1.3	300	49.2	10	3.2	0.38	Convergence criterion (ZCONV*18-8) satisfied.	0.11	1.27	-0.026	Algorithm converged.	-0.086	0.034	0.40	Algorithm converged.	0.13	1.27	0.1206	0.2681	0.48	Algorithm converged.	0.79	7.83
Blood and lymphatic system disorders	Leukopenia	Asia	140	28.3	24	17.1	135	27.4	25	18.0	0.94	Convergence criterion (ZCONV*18-8) satisfied.	0.51	1.72	-0.008	Algorithm converged.	-0.086	0.063	0.95	Algorithm converged.	0.57	1.56	0.8533		1.05	Algorithm converged.	0.63	1.74
Blood and lymphatic system disorders	Leukopenia	Rest of World	57	11.5	2	3.5	15	11.4	2	3.4	1.04	Convergence criterion (ZCONV*18-8) satisfied.	0.14	7.62	0.001	Algorithm converged.	-0.081	0.083	1.04	Algorithm converged.	0.15	7.12	0.9720		0.97	Algorithm converged.	0.14	6.63
Blood and lymphatic system disorders	Lymphocytosis	Western Europe/United States/Canada/Australia	298	60.2	4	1.3	300	49.2	2	0.7	0.44	Convergence criterion (ZCONV*18-8) satisfied.	0.11	1.84	-0.017	Algorithm converged.	-0.081	0.027	0.47	Algorithm converged.	0.14	1.44	0.1767	0.1571	0.23	Algorithm converged.	0.79	7.16
Blood and lymphatic system disorders	Lymphocytosis	Asia	140	28.3	4	2.9	135	27.4	4	2.7	0.91	Convergence criterion (ZCONV*18-8) satisfied.	0.45	36.79	0.001	Algorithm converged.	-0.056	0.053	0.97	Algorithm converged.	0.45	35.05	0.2147		0.91	Algorithm converged.	0.64	7.22
Blood and lymphatic system disorders	Lymphopenia	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	49.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	Asia	140	28.3	4	2.9	135	27.4	3	2.2	0.91	Convergence criterion (ZCONV*18-8) satisfied.	0.45	36.79	0.001	Algorithm converged.	-0.056	0.053	0.97	Algorithm converged.	0.45	35.05	0.2147		0.91	Algorithm converged.	0.64	7.22
Blood and lymphatic system disorders	Myelosuppression	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	Western Europe/United States/Canada/Australia	298	60.2	64	21.5	300	49.2	78	26.0	0.77	Convergence criterion (ZCONV*18-8) satisfied.	0.51	1.15	-0.043	Algorithm converged.	-0.117	0.030	0.82	Algorithm converged.	0.61	1.09	0.1453	0.4043	1.23	Algorithm converged.	0.82	1.64
Blood and lymphatic system disorders	Neutropenia	Asia	140	28.3	42	30.0	135	27.4	37	26.6	1.18	Convergence criterion (ZCONV*18-8) satisfied.	0.71	1.95	0.034	Algorithm converged.	-0.032	0.139	1.13	Algorithm converged.	0.78	1.64	0.5314		0.93	Algorithm converged.	0.61	1.23
Blood and lymphatic system disorders	Neutropenia	Rest of World	57	11.5	21	36.8	15	11.4	24	40.7	0.85	Convergence criterion (ZCONV*18-8) satisfied.	0.41	1.80	-0.036	Algorithm converged.	-0.204	0.136	0.91	Algorithm converged.	0.57	1.43	0.6722		1.11	Algorithm converged.	0.72	1.73
Blood and lymphatic system disorders	Pancytopenia	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	49.2	0	0.0		Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 44.806790292 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	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Pancytopenia	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Thrombocytosis	Western Europe/United States/Canada/Australia	298	60.2	7	2.3	300	49.2	10	3.3	0.70	Convergence criterion (ZCONV*18-8) satisfied.	0.26	1.86	-0.010	Algorithm converged.	-0.034	0.017	0.79	Algorithm converged.	0.27	1.83	0.4714	0.8991	1.41	Algorithm converged.	0.53	3.69
Blood and lymphatic system disorders	Thrombocytosis	Asia	140	28.3	5	3.6	135	27.4	6	4.3	0.82	Convergence criterion (ZCONV*18-8) satisfied.	0.24	2.79	-0.007	Algorithm converged.	-0.053	0.038	0.83	Algorithm converged.	0.26	2.63	0.7485		1.21	Algorithm converged.	0.38	3.87
Blood and lymphatic system disorders	Thrombocytosis	Rest of World	57	11.5	4	7.0	15	11.4	4	6.8	1.04	Convergence criterion (ZCONV*18-8) satisfied.	0.27	4.04	0.002	Algorithm converged.	-0.081	0.085	1.04	Algorithm converged.	0.27	3.94	0.9687		0.97	Algorithm converged.	0.23	3.69
Cardiac disorders		Western Europe/United States/Canada/Australia	298	60.2	5	1.7	300	49.2	3	1.0	1.73	Convergence criterion (ZCONV*18-8) satisfied.	0.42	7.07	0.006	Algorithm converged.	-0.059	0.070	1.61	Algorithm converged.	0.58	4.46	0.9917	0.4883	0.99	Algorithm converged.	0.23	3.46
Cardiac disorders		Asia	140	28.3	3	2.1	135	27.4	2	1.5	1.43	Convergence criterion (ZCONV*18-8) satisfied.	0.26	7.85	0.007	Algorithm converged.	-0.064	0.077	1.52	Algorithm converged.	0.32	7.24	0.7451		1.47	Algorithm converged.	0.29	7.45
Cardiac disorders		Rest of World	57	11.5	0	0.0	15	11.4	1	1.7		Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 10.546148401 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	Atrial fibrillation	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	49.2	1	0.3	1.01	Convergence criterion (ZCONV*18-8) satisfied.	0.06	16.15	0.000	Algorithm converged.	-0.009	0.009	1.01	Algorithm converged.	0.06	16.03	0.9962	NE	0.99	Algorithm converged.	0.06	15.81
Cardiac disorders	Atrial fibrillation	Asia	140	28.3	0	0.0	135	27.4	0	0.0		Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 19.480043432 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	Atrial fibrillation	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	49.2	1	0.3		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	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block complete	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Cardiac failure congestive	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	49.2	2	0.7		Quasi-complete separation of data points detected.	NE	NE	NE	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
Cardiac disorders	Cardiac failure congestive	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Cardiac failure congestive	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Cardiomyopathy failure	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	49.2	0	0.0		Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 44.806790292 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Cardiomyopathy failure	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Cardiopulmonary failure	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	49.2	1	0.3	1.01	Convergence criterion (ZCONV*18-8) satisfied.	0.06	16.15	0.000	Algorithm converged.	-0.009	0.009	1.01	Algorithm converged.	0.06	16.03	0.9962	1.0000	0.99	Algorithm converged.	0.06	15.81
Cardiac disorders	Left ventricular dysfunction	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Myocardial infarction	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	49.2	0	0.0		Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Myocardial infarction	Asia	140	28.3	1	0.7	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Myocardial infarction	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	49.2	1	0.3		Quasi-complete separation of data points detected.	NE	NE	NE	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
Cardiac disorders	Sinus bradycardia	Asia	140	28.3	0	0.0	135	27.4	1	0.7		Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 19.480043432 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	Sinus bradycardia	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Sinus tachycardia	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	49.2	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	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Sinus tachycardia	Asia	140	28.3	1	0.7	135	27.4	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	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Sinus tachycardia	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Tachycardia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	49.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Tachycardia	Asia	140	28.3	0	0.0	135	27.4	1	0.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 19.480043432 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9885		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Tachycardia	Rest of World	57	11.5	0	0.0	15	11.4	1	1.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 10.546148401 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9885		>999.99	Algorithm converged.	0.00	NE
Congenital, familial and genetic disorders		Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	49.2	0	0.0		Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Congenital, familial and genetic disorders		Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Congenital, familial and genetic disorders		Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Congenital, familial and genetic disorders	Pyloric stenosis	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	49.2	0	0.0		Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Congenital, familial and genetic disorders	Pyloric stenosis	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Congenital, familial and genetic disorders	Pyloric stenosis	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders		Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	49.2	2	0.7		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	0.9885	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders		Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders		Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders	Deafness	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	49.2	1	0.3		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	0.9885	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Deafness	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders	Deafness	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders	Hypoacusis	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	49.2	1	0.3		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	0.9885	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Hypoacusis	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders	Hypoacusis	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders		Western Europe/United States/Canada/Australia	298	60.2	1	0.4	300	49.2	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
Eye disorders		Asia	140	28.3	2	1.4	135	27.4	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
Eye disorders		Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Angle closure glaucoma	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	49.2	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
Eye disorders	Angle closure glaucoma	Asia	140	28.3	0	0.0	135	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Angle closure glaucoma	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Cataract	Western Europe/United States/Canada/Australia	298	60.2	2	0.7	300	49.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Cataract	Asia	140	28.3	1	0.7	135	27.4	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
Eye disorders	Cataract	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	49.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	Asia	140	28.3	1	0.7	135	27.4	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
Eye disorders	Rhegmatogenous retinal detachment	Rest of World	57	11.5	0	0.0	15	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders		Western

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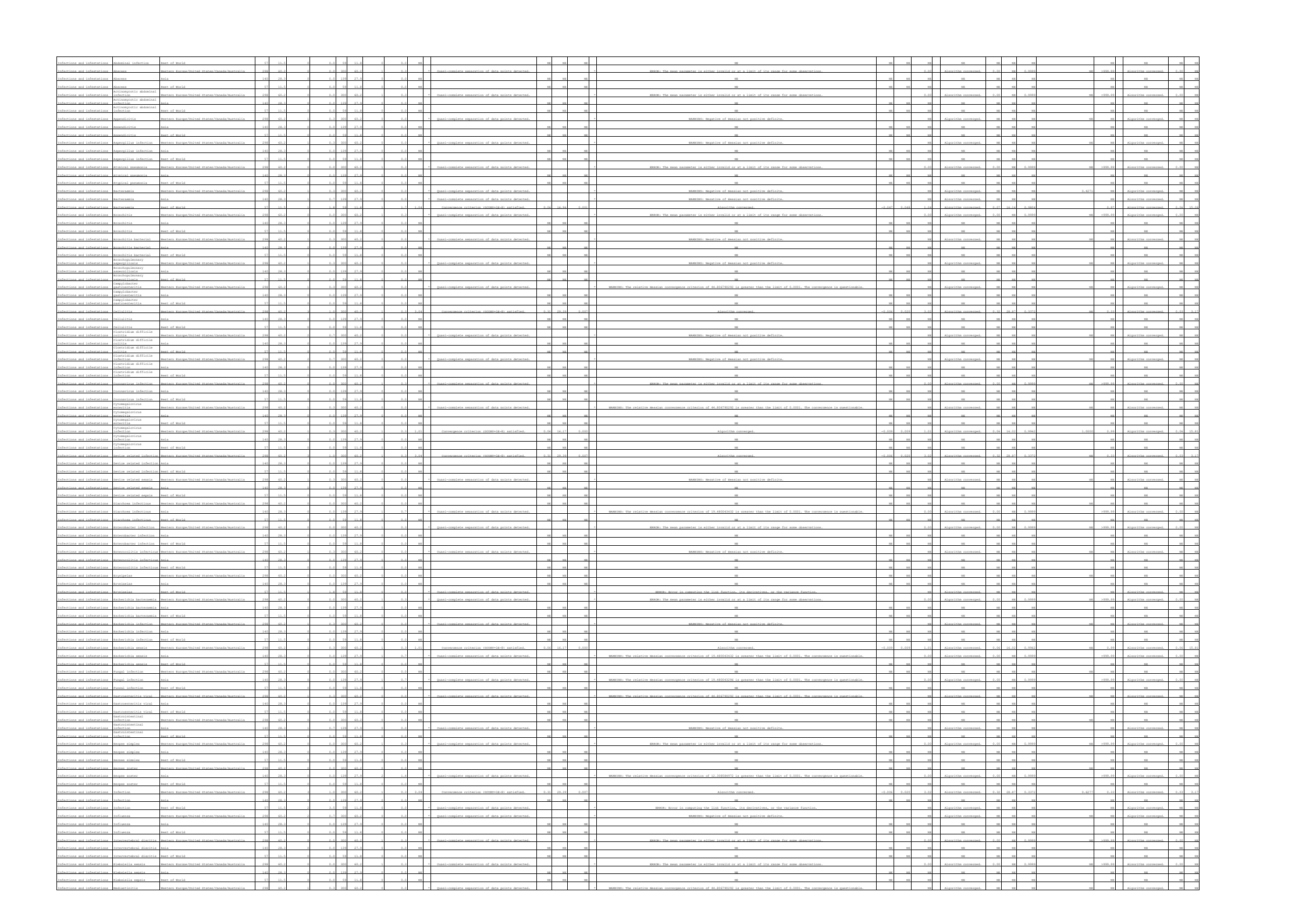

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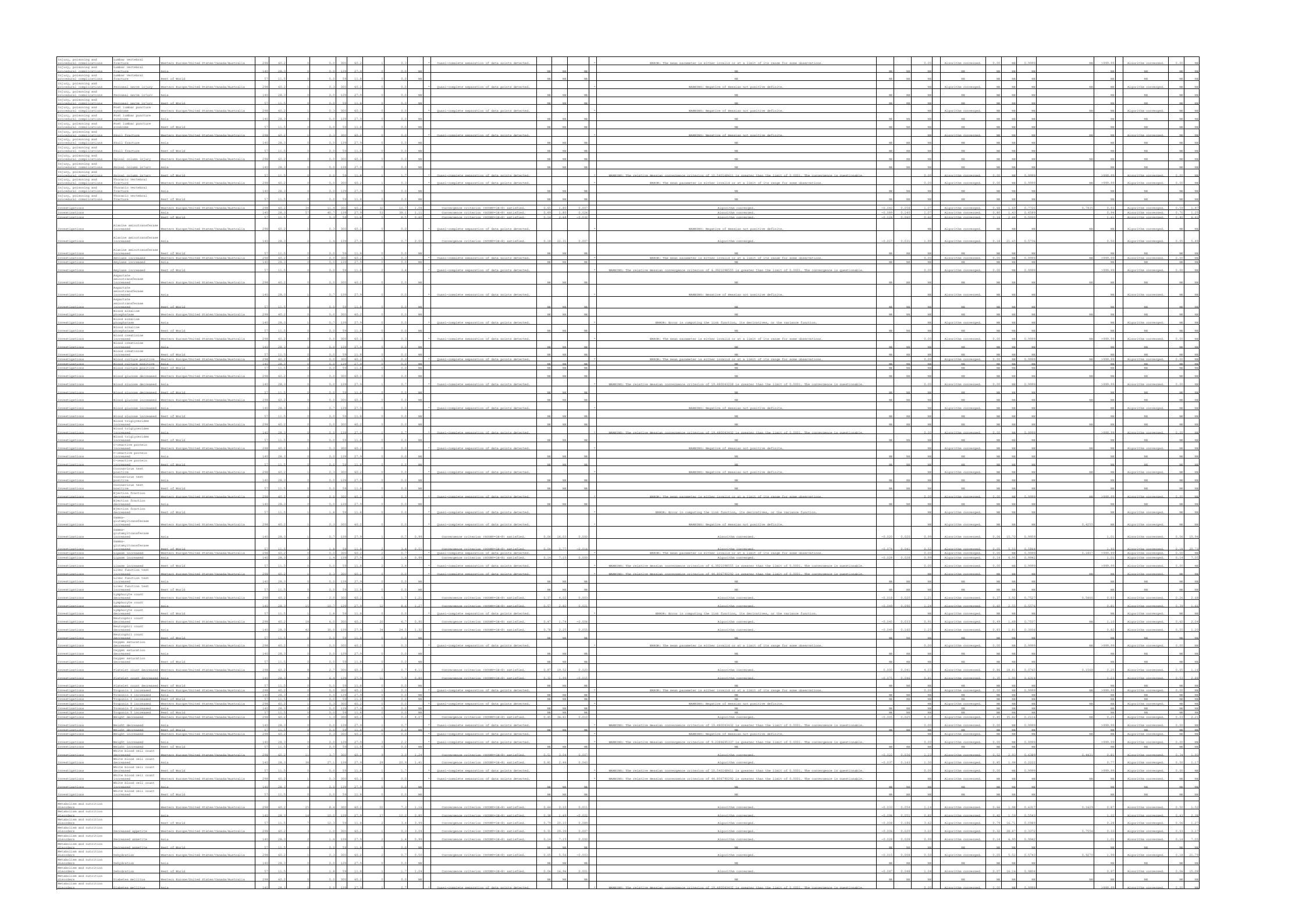

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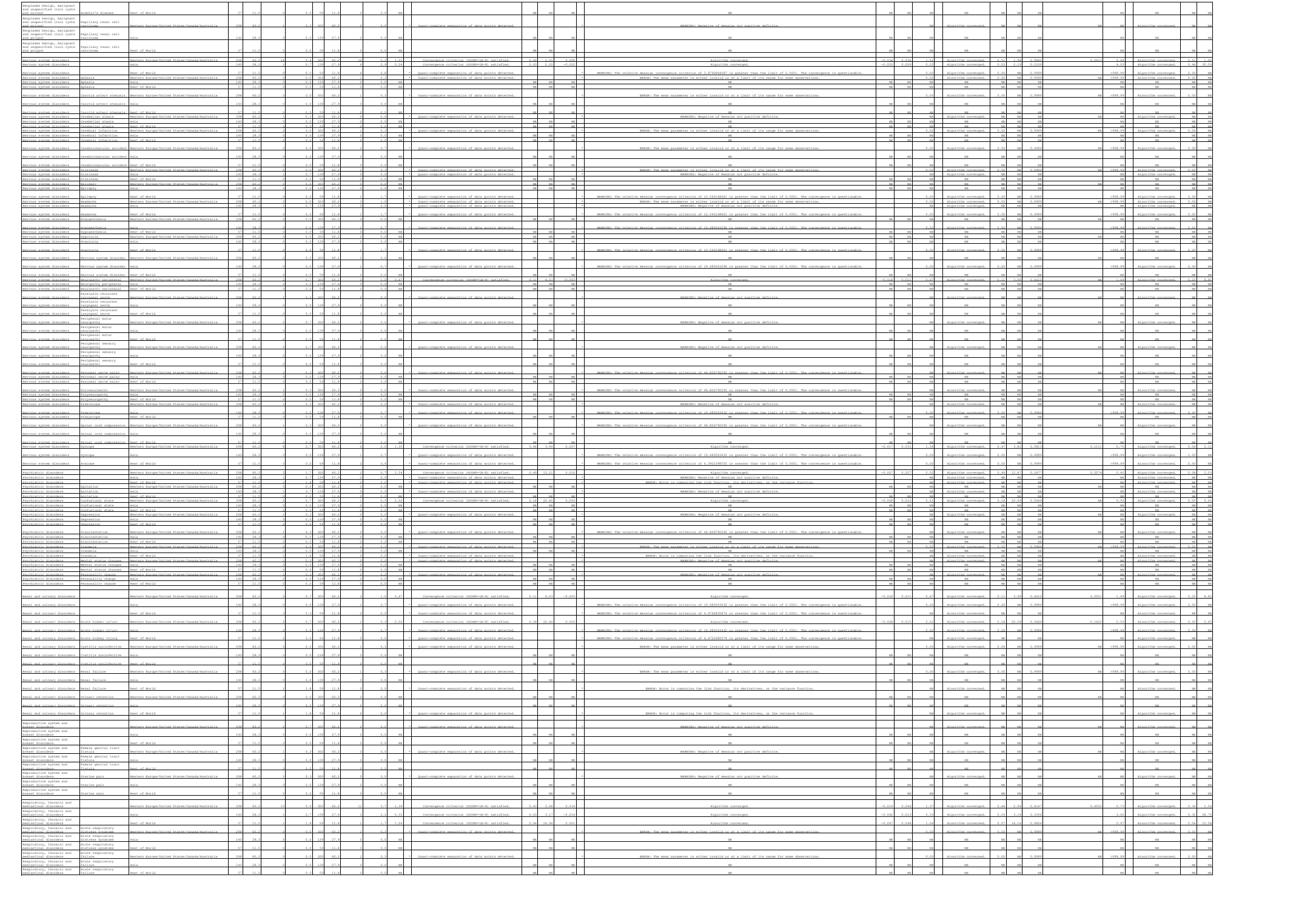

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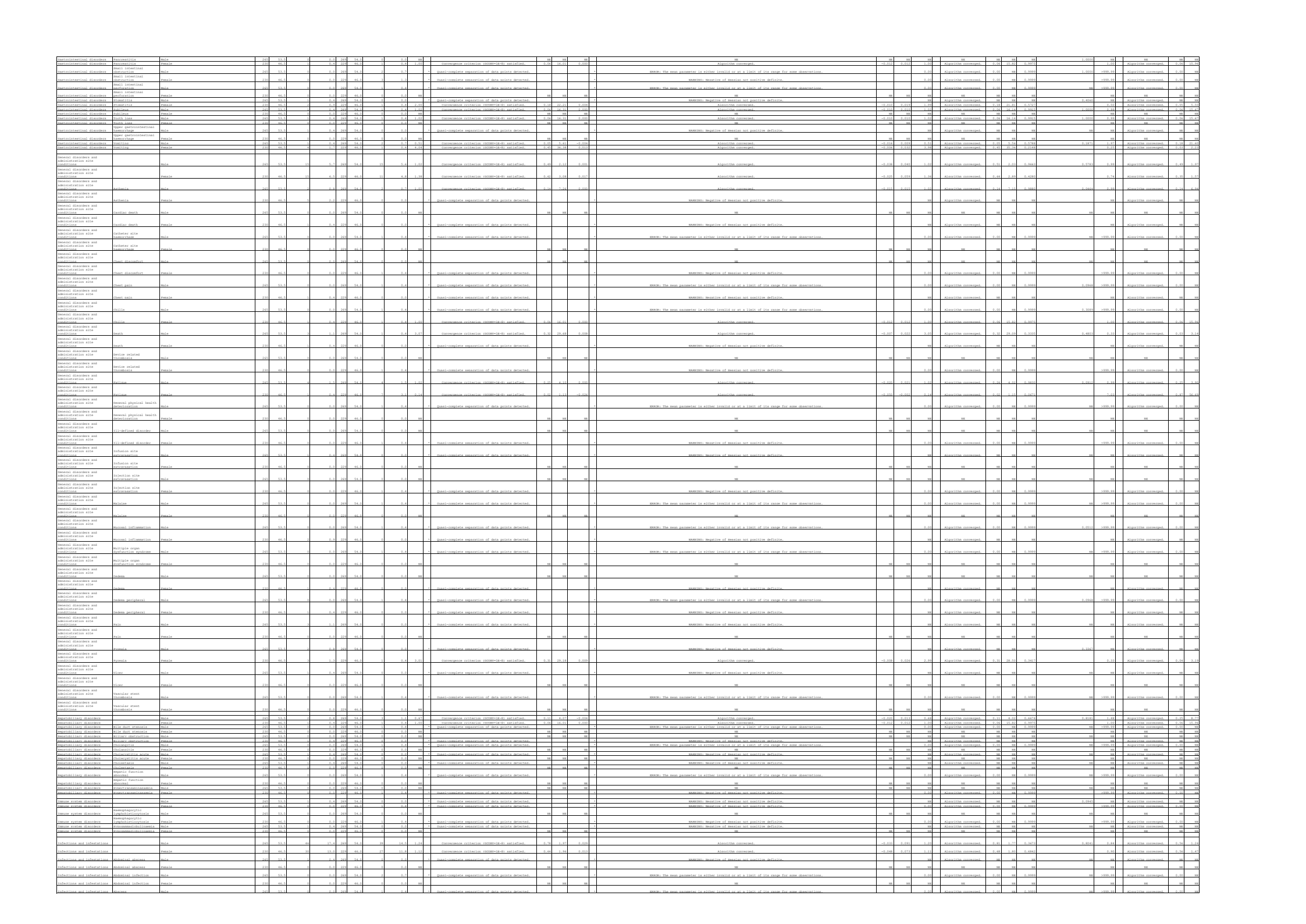
POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 3-5
MODEL: Unstratified Analysis
STRUT: HLT0962
Dichotomous Analysis by Subgroups (Safety)

Sex

			Pulsatorumab Vedotin + N-CHP (N=265)				N-CHP (N=265)				Pulsatorumab Vedotin + N-CHP vs. N-CHP																		N-CHP vs. Pulsatorumab Vedotin + N-CHP			
			Patients		Patients with Event		Patients		Patients with Event		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	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	245	53.9	103	38.5	265	54.0	97	36.1	1.11	Convergence criterion (ZCONV*1E-8) satisfied.	0.79	1.58	0.024	Algorithm converged.	-0.056	0.105	1.07	Algorithm converged.	0.66	1.13	0.5414	0.7596	0.96	Algorithm converged.	0.79	1.17
Blood and lymphatic system disorders		Female	230	46.9	94	40.7	265	46.0	84	41.0	1.03	Convergence criterion (ZCONV*1E-8) satisfied.	0.73	1.45	0.007	Algorithm converged.	-0.083	0.097	1.02	Algorithm converged.	0.86	1.24	0.8853		0.98	Algorithm converged.	0.79	1.24
Blood and lymphatic system disorders	Agranulocytosis	Male	245	53.5	0	0.0	265	54.0	1	0.4		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
Blood and lymphatic system disorders	Agranulocytosis	Female	230	46.5	0	0.0	265	46.0	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	Male	245	53.5	23	8.7	265	54.0	21	7.8	1.12	Convergence criterion (ZCONV*1E-8) satisfied.	0.61	2.08	0.009	Algorithm converged.	-0.038	0.093	1.11	Algorithm converged.	0.64	1.94	0.7149	0.9154	0.96	Algorithm converged.	0.72	1.56
Blood and lymphatic system disorders	Anaemia	Female	230	46.5	33	14.3	265	46.0	27	11.8	1.25	Convergence criterion (ZCONV*1E-8) satisfied.	0.73	2.16	0.024	Algorithm converged.	-0.036	0.087	1.21	Algorithm converged.	0.74	1.96	0.4175		0.82	Algorithm converged.	0.71	1.32
Blood and lymphatic system disorders	Aplasia pure red cell	Male	245	53.5	0	0.0	265	54.0	1	0.4		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	0.9969	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Aplasia pure red cell	Female	230	46.5	1	0.4	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Cytopenia	Male	245	53.5	0	0.0	265	54.0	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	Cytopenia	Female	230	46.5	1	0.4	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Male	245	53.5	1	0.4	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	0.9957	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Female	230	46.5	0	0.0	265	46.0	2	0.9		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Febrile neutropenia	Male	245	53.5	38	14.3	265	54.0	20	7.4	2.08	Convergence criterion (ZCONV*1E-8) satisfied.	1.16	3.85	0.049	Algorithm converged.	0.006	0.103	1.93	Algorithm converged.	1.11	3.23	0.0123	0.4549	0.93	Algorithm converged.	0.70	0.97
Blood and lymphatic system disorders	Febrile neutropenia	Female	230	46.5	24	10.4	265	46.0	18	7.9	1.49	Convergence criterion (ZCONV*1E-8) satisfied.	0.79	2.85	0.034	Algorithm converged.	-0.009	0.088	1.49	Algorithm converged.	0.91	2.55	0.2135		0.70	Algorithm converged.	0.50	1.23
Blood and lymphatic system disorders	Hypofibrinogenaemia	Male	245	53.5	0	0.0	265	54.0	1	0.4		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
Blood and lymphatic system disorders	Hypofibrinogenaemia	Female	230	46.5	0	0.0	265	46.0	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	Leukopenia	Male	245	53.5	12	4.5	265	54.0	21	7.8	0.58	Convergence criterion (ZCONV*1E-8) satisfied.	0.27	1.24	-0.033	Algorithm converged.	-0.073	0.008	0.59	Algorithm converged.	0.28	1.15	0.1251	0.1490	1.32	Algorithm converged.	0.87	3.43
Blood and lymphatic system disorders	Leukopenia	Female	230	46.5	18	7.8	265	46.0	14	7.0	1.13	Convergence criterion (ZCONV*1E-8) satisfied.	0.55	2.29	0.008	Algorithm converged.	-0.045	0.093	1.12	Algorithm converged.	0.58	2.14	0.7316		0.85	Algorithm converged.	0.47	1.73
Blood and lymphatic system disorders	Lymphopenia	Male	245	53.5	6	2.3	265	54.0	5	1.9	1.22	Convergence criterion (ZCONV*1E-8) satisfied.	0.37	4.04	0.004	Algorithm converged.	-0.035	0.043	1.22	Algorithm converged.	0.38	3.84	0.7420	0.2414	0.82	Algorithm converged.	0.20	3.46
Blood and lymphatic system disorders	Lymphopenia	Female	230	46.5	2	0.9	265	46.0	5	2.0	0.45	Convergence criterion (ZCONV*1E-8) satisfied.	0.09	2.26	-0.011	Algorithm converged.	-0.036	0.013	0.44	Algorithm converged.	0.09	2.03	0.2482		0.51	Algorithm converged.	0.09	12.84
Blood and lymphatic system disorders	Myelosuppression	Male	245	53.5	2	0.8	265	54.0	1	0.4	2.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.18	22.81	0.004	Algorithm converged.	-0.009	0.017	2.01	Algorithm converged.	0.19	22.24	0.5422	0.2790	5.45	Algorithm converged.	0.54	5.49
Blood and lymphatic system disorders	Myelosuppression	Female	230	46.5	2	0.9	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Male	245	53.5	63	23.8	265	54.0	73	27.1	0.84	Convergence criterion (ZCONV*1E-8) satisfied.	0.57	1.24	-0.034	Algorithm converged.	-0.107	0.040	0.84	Algorithm converged.	0.65	1.07	0.2731	0.6948	1.14	Algorithm converged.	0.80	1.63
Blood and lymphatic system disorders	Neutropenia	Female	230	46.5	64	27.8	265	46.0	67	29.2	0.93	Convergence criterion (ZCONV*1E-8) satisfied.	0.65	1.40	-0.016	Algorithm converged.	-0.095	0.063	0.93	Algorithm converged.	0.75	1.23	0.7382		1.05	Algorithm converged.	0.79	1.49
Blood and lymphatic system disorders	Pancytopenia	Male	245	53.5	1	0.4	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Pancytopenia	Female	230	46.5	0	0.0	265	46.0	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	Thrombocytopenia	Male	245	53.5	6	2.3	265	54.0	8	3.2	0.67	Convergence criterion (ZCONV*1E-8) satisfied.	0.23	1.91	-0.011	Algorithm converged.	-0.036	0.017	0.68	Algorithm converged.	0.26	1.67	0.4524	0.4647	1.48	Algorithm converged.	0.53	4.09
Blood and lymphatic system disorders	Thrombocytopenia	Female	230	46.5	10	4.3	265	46.0	11	4.8	0.90	Convergence criterion (ZCONV*1E-8) satisfied.	0.37	2.16	-0.005	Algorithm converged.	-0.061	0.024	0.91	Algorithm converged.	0.56	2.02	0.8154		1.10	Algorithm converged.	0.49	2.50
Cardiac disorders		Male	245	53.5	2	0.8	265	54.0	8	1.9	0.41	Convergence criterion (ZCONV*1E-8) satisfied.	0.08	2.08	-0.011	Algorithm converged.	-0.060	0.004	0.41	Algorithm converged.	0.08	2.07	0.2758	0.2810	0.44	Algorithm converged.	0.09	12.50
Cardiac disorders		Female	230	46.5	4	1.7	265	46.0	7	2.6	1.14	Convergence criterion (ZCONV*1E-8) satisfied.	0.32	4.03	0.004	Algorithm converged.	-0.039	0.047	1.13	Algorithm converged.	0.34	3.77	0.7084		0.73	Algorithm converged.	0.23	2.32
Cardiac disorders	Atrial fibrillation	Male	245	53.5	2	0.8	265	54.0	2	0.7	1.13	Convergence criterion (ZCONV*1E-8) satisfied.	0.16	7.89	0.004	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	0.9511	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	Female	230	46.5	1	0.4	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Atrioventricular block complete	Male	245	53.5	0	0.0	265	54.0	1	0.4		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
Cardiac disorders	Atrioventricular block complete	Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Cardiac failure congestive	Male	245	53.5	0	0.0	265	54.0	2	0.7		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	0.9997		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Cardiac failure congestive	Female	230	46.5	0	0.0	265	46.0	1	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Cardiopulmonary failure	Male	245	53.5	1	0.4	265	54.0	1	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Cardiopulmonary failure	Female	230	46.5	0	0.0	265	46.0	1	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	Male	245	53.5	1	0.4	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	0.9941	NE	Algorithm converged.	NE	NE
Cardiac disorders	Left ventricular dysfunction	Female	230	46.5	0	0.0	265	46.0	1	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Myocardial infarction	Male	245	53.5	0	0.0	265	54.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Myocardial infarction	Female	230	46.5	1	0.4	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Sinus bradycardia	Male	245	53.5	0	0.0	265	54.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	Female	230	46.5	0	0.0	265	46.0	1	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Sinus tachycardia	Male	245	53.5	0	0.0	265	54.0	1	0.4		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	0.9511	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Sinus tachycardia	Female	230	46.5	2	0.9	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Tachycardia	Male	245	53.5	2	0.8	265	54.0	1	0.4		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			1.00	Algorithm converged.	0.09	11.09	0.1998		>999.99	Algorithm converged.	0.09	11.09
Cardiac disorders	Tachycardia	Female	230	46.5	0	0.0	265	46.0	1	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Congenital, familial and genetic disorders		Male	245	53.5	1	0.4	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Congenital, familial and genetic disorders		Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Congenital, familial and genetic disorders	Pyloric atenosis	Male	245	53.5	1	0.4	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Congenital, familial and genetic disorders	Pyloric atenosis	Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Ear and labyrinth disorders		Male	245	53.5	0	0.0	265	54.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Ear and labyrinth disorders		Female	230	46.5	0	0.0	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Deafness	Male	245	53.5	0	0.0	265	54.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Ear and labyrinth disorders	Deafness	Female	230	46.5	0	0.0	265	46.0	1	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Hypoacusis	Male	245	53.5	0	0.0	265	54.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Ear and labyrinth disorders	Hypoacusis	Female	230	46.5	0	0.0	265	46.0	1	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Eye disorders		Male	245	53.5	2	0.8	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	0.9955	NE	Algorithm converged.	NE	NE
Eye disorders		Female	230	46.5	1	0.4	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Acute closure glaucoma	Male	245	53.5	0	0.0	265	54.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Acute closure glaucoma	Female	230	46.5	1	0.4	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Cataract	Male	245	53.5	1	0.4	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Cataract	Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	Male	245	53.5	1	0.4	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders		Male	245	53.5	27	10.2	265	54.0	10	3.6	2.92	Convergence criterion (ZCONV*1E-8) satisfied.	1.43	6.00	0.064	Algorithm converged.	0.027	0.101	2.77	Algorithm converged.	1.83	4.19	0.0021	0.9613	3.13	Algorithm converged.	1.47	6.67
Gastrointestinal disorders		Female	230	46.5	18	7.8	265	46.0	23	10.0	0.76	Convergence criterion (ZCONV*1E-8) satisfied.	0.40	1.46	-0.026	Algorithm converged.	-0.074	0.020	0.78	Algorithm converged.	0.43	1.40	0.4643		1.04	Algorithm converged.	0.70	2.03
Gastrointestinal disorders	Abdominal distension	Male	245	53.5	0	0.0	265	54.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Abdominal distension	Female	230	46.5	2	0.9	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	>999.99	Algorithm converged.	NE	NE
Gastrointestinal disorders	Abdominal pain	Male	245	53.5	2	0.8	265	54.0	4	1.1	0.47	Convergence criterion (ZCONV*1E-8) satisfied.	0.11	4.02	-0.024	Algorithm converged.	-0.060	0.013	0.48	Algorithm converged.	0.11	4.02	0.4674	0.8043	1.48	Algorithm converged.	0.33	9.73
Gastrointestinal disorders	Abdominal pain	Female	230	46.5	4	1.7	265	46.0	7	2.6	0.65	Convergence criterion (ZCONV*1E-8) satisfied.	0.20	2.10	-0.020	Algorithm converged.	-0.058	0.018	0.65	Algorithm converged.	0.22	1.91	0.5107		0.91	Algorithm converged.	0.27	3.15
Gastrointestinal disorders	Abdominal pain upper	Male	245	53.5	0	0.0	265	54.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Abdominal pain upper	Female	230	46.5	1	0.4	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	>999.99	Algorithm converged.	NE	NE
Gastrointestinal disorders	Anal fistula	Male	245	53.5	1	0.4	265	54.0	1	0.4	1.02	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.85	0.000	Algorithm converged.	-0.048	0.050	1.02	Algorithm converged.	0.06	16.14	0.9815	1.0000	0.96	Algorithm converged.	0.06	15.47
Gastrointestinal disorders	Anal fistula	Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Anal stenosis	Male	245	53.5	0	0.0	265	54.0	1	0.4		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
Gastrointestinal disorders	Anal stenosis	Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Colitis	Male	245	53.5	2	0.8	265	54.0	1	0.4	2.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.18	22.81	0.004	Algorithm converged.	-0.009	0.017	2.01	Algorithm converged.	0.19	22.24	0.5422	0.2790	5.45	Algorithm converged.	0.54	5.49
Gastrointestinal disorders	Colitis	Female	230	46.5	1	0.4	265	46.0	0	0.0	1.06	Convergence criterion (ZCONV*1E-8) satisfied.	0.04	16.07	0.000	Algorithm converged.	-0.046	0.051	1.05	Algorithm converged.	0.04	15.64	0.9737		1.04	Algorithm converged.	0.06	15.56
Gastrointestinal disorders	Constipation	Male	245	53.5	4	1.6	265	54.0	2	0.7	2.01	Convergence criterion (ZCONV*1E-8) satisfied.	0.36	11.16	0.013	Algorithm converged.	-0.002	0.028	1.98	Algorithm converged.	0.38	10.42	0.2419	0.9861	2.72	Algorithm converged.	0.48	15.42
Gastrointestinal disorders	Constipation	Female	230	46.5	1	0.4	265	46.0	1	0.4	1.02	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.85	0.000	Algorithm converged.	-0.048	0.050	1.02	Algorithm converged.	0.06	16.14	0.9815	1.0000	0.96	Algorithm converged.	0.06	15.47
Gastrointestinal disorders	Diarrhoea	Female	230	46.5	10	4.3	265	46.0	7	2.6	1.64	Convergence criterion (ZCONV*1E-8) satisfied.	0.63	4.28	0.017	Algorithm converged.	-0.009	0.043	1.62	Algorithm converged.	0.66	4.07	0.4406		1.32	Algorithm converged.	0.57	3.06
Gastrointestinal disorders	Dysphagia	Male	245	53.5	0	0.0	265	54.0	1	0.4		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
Gastrointestinal disorders	Dysphagia	Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Enteritis	Male	245	53.5	1	0.4	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Enteritis	Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Epigastric discomfort	Male	245	53.5	1	0.4	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Epigastric discomfort	Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Gastric ulcer	Male	245	53.5	0	0.0	265	54.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Gastric ulcer	Female	230	46.5	1	0.4	265	46.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	Male	245	53.5	0	0.0	265	54.0	1	0.4		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	0.9738	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	Female	230	46.5	2	0.9	265	46.0	2	0.9	1.00	Convergence criterion (ZCONV*1E-8) satisfied.	0.14	7.10	0.000	Algorithm converged.	-0.057	0.057	1.00	Algorithm converged.	0.14	7.03	0.9963		1.00	Algorithm converged.	0.14	7.07
Gastrointestinal disorders	Gastrooesophageal reflux disease	Male	245	53.5	1	0.4	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Gastrooesophageal reflux disease	Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Haemorrhoidal haemorrhage	Male	245	53.5	1	0.4	265	54.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Haemorrhoidal haemorrhage	Female	230	46.5	0	0.0	265	46.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE



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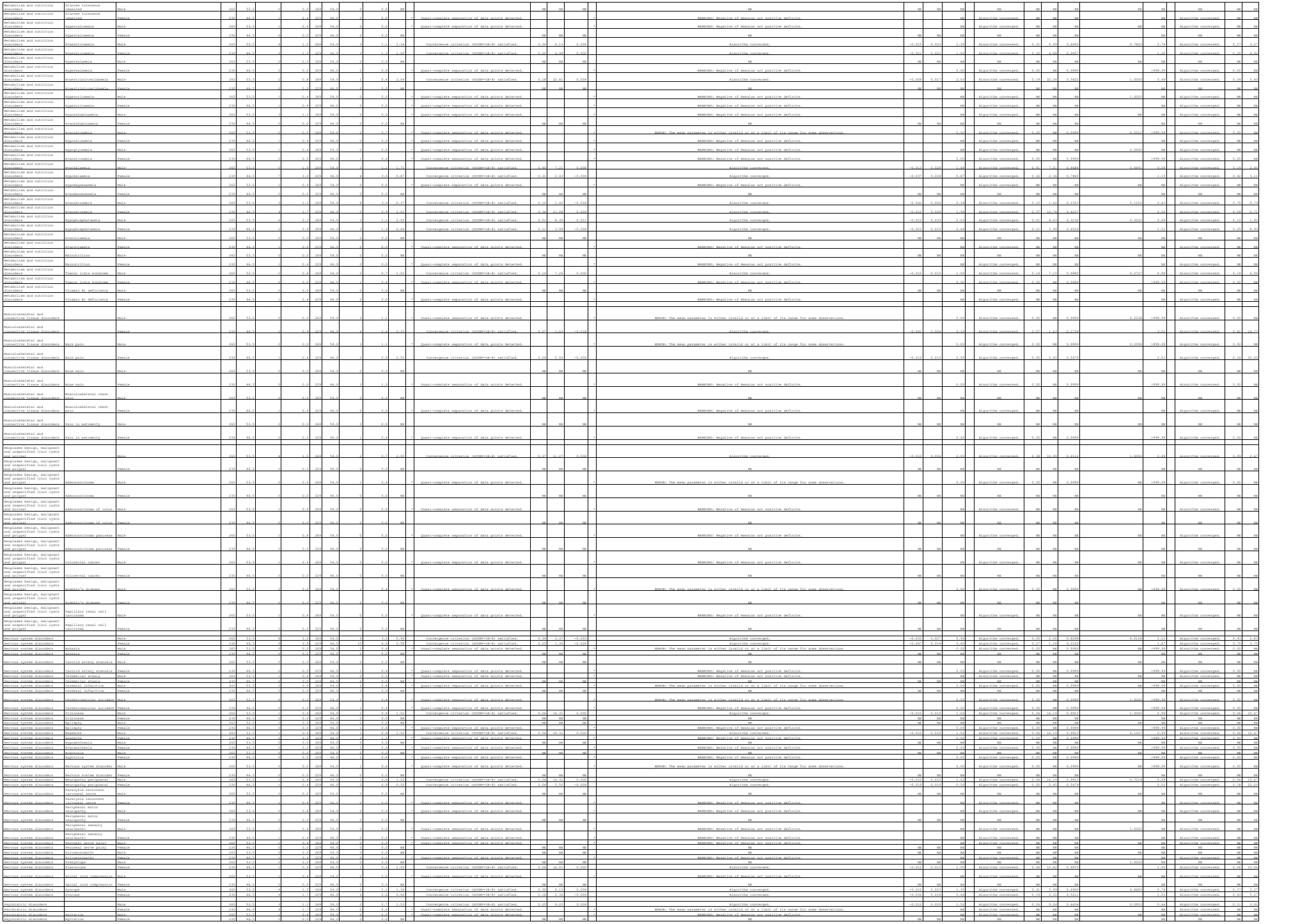

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified Analysis
STUDY: BG39862
Dichotomous Analysis by Subgroups (Safety)

All

			Pulsatile Tablets + R-CHOP (N=495)				R-CHOP (N=496)				Pulsatile Tablets + R-CHOP vs. R-CHOP																		R-CHOP vs. Pulsatile Tablets + R-CHOP			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio							Absolute Risk Difference						Relative Risk						Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Result	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Result	95% Lower CL	95% Upper CL	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		n/a	495	100.0	93	18.8	496	100.0	74	15.9	1.16	Convergence criterion (HCONV=1E-8) satisfied.	0.83	1.62	0.029	Algorithm converged.	-0.060	0.060	1.13	Algorithm converged.	0.96	1.49	0.3743	NE	0.96	Algorithm converged.	0.67	1.14
Blood and lymphatic system disorders	Anaemia	n/a	495	100.0	47	9.5	496	100.0	47	9.4	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.71	1.70	0.011	Algorithm converged.	-0.060	0.060	1.11	Algorithm converged.	0.76	1.45	0.9063	NE	0.98	Algorithm converged.	0.81	1.24
Blood and lymphatic system disorders	Febrile bone marrow aplasia	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Blood and lymphatic system disorders	Febrile neutropenia	n/a	495	100.0	28	5.7	496	100.0	27	5.4	1.04	Convergence criterion (HCONV=1E-8) satisfied.	1.00	2.90	0.039	Algorithm converged.	0.000	0.079	1.07	Algorithm converged.	1.00	2.73	0.0211	NE	0.98	Algorithm converged.	0.77	0.92
Blood and lymphatic system disorders	Hypofibrinogenaemia	n/a	495	100.0	1	0.2	496	100.0	5	0.9	0.20	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.22	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.02	NE
Blood and lymphatic system disorders	Leukaemia	n/a	495	100.0	12	2.3	496	100.0	20	4.0	0.56	Convergence criterion (HCONV=1E-8) satisfied.	0.26	1.15	-0.016	Algorithm converged.	-0.040	0.008	0.57	Algorithm converged.	0.27	1.16	0.1097	NE	1.81	Algorithm converged.	0.92	3.73
Blood and lymphatic system disorders	Lymphopenia	n/a	495	100.0	7	1.4	496	100.0	7	1.4	0.98	Convergence criterion (HCONV=1E-8) satisfied.	0.33	2.95	-0.000	Algorithm converged.	-0.024	0.023	0.99	Algorithm converged.	0.34	2.85	0.9867	NE	1.01	Algorithm converged.	0.33	3.13
Blood and lymphatic system disorders	Myelosuppression	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Blood and lymphatic system disorders	Neutropenia	n/a	495	100.0	39	7.9	496	100.0	43	8.6	0.90	Convergence criterion (HCONV=1E-8) satisfied.	0.58	1.43	-0.006	Algorithm converged.	-0.060	0.047	0.91	Algorithm converged.	0.60	1.38	0.6854	NE	1.10	Algorithm converged.	0.73	1.62
Blood and lymphatic system disorders	Pancytopenia	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Thrombocytopenia	n/a	495	100.0	14	2.8	496	100.0	10	2.0	1.39	Convergence criterion (HCONV=1E-8) satisfied.	0.65	2.89	-0.008	Algorithm converged.	-0.049	0.033	1.19	Algorithm converged.	0.67	2.64	0.4731	NE	1.42	Algorithm converged.	0.58	3.74
Cardiac disorders		n/a	495	100.0	1	1.0	496	100.0	1	1.0	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Cardiac disorders	Atrial fibrillation	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Cardiac disorders	Cardiac failure congestive	n/a	495	100.0	2	0.4	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.50	Algorithm converged.	0.05	NE	0.9999	NE	>999.99	Algorithm converged.	0.05	NE
Cardiac disorders	Cardiopulmonary failure	n/a	495	100.0	1	0.2	496	100.0	1	0.2		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	Left ventricular dysfunction	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Cardiac disorders	Myocardial infarction	n/a	495	100.0	1	0.2	496	100.0	1	0.2		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	Sinus bradycardia	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Sinus tachycardia	n/a	495	100.0	4	0.8	496	100.0	1	0.2	0.25	Convergence criterion (HCONV=1E-8) satisfied.	0.03	22.30	0.000	Algorithm converged.	-0.020	0.000	0.25	Algorithm converged.	0.03	22.12	0.5674	NE	0.25	Algorithm converged.	0.03	NE
Cardiac disorders	Tachycardia	n/a	495	100.0	0	0.0	496	100.0	2	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Congenital, familial and genetic disorders		n/a	495	100.0	1	0.2	496	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	Fibrolic steatosis	n/a	495	100.0	1	0.2	496	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	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.50	Algorithm converged.	0.05	NE	0.9999	NE	>999.99	Algorithm converged.	0.05	NE
Ear and labyrinth disorders	Hypoacusis	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.50	Algorithm converged.	0.05	NE	0.9999	NE	>999.99	Algorithm converged.	0.05	NE
Eye disorders		n/a	495	100.0	2	0.4	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 21.431637574 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Angle closure glaucoma	n/a	495	100.0	1	0.2	496	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
Eye disorders	Cataract	n/a	495	100.0	1	0.2	496	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
Eye disorders	Rhegmatogenous retinal detachment	n/a	495	100.0	1	0.2	496	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	495	100.0	40	8.1	496	100.0	13	2.6	3.15	Convergence criterion (HCONV=1E-8) satisfied.	1.81	5.47	0.053	Convergence criterion (HCONV=1E-8) satisfied.	0.011	0.095	3.13	Algorithm converged.	2.16	4.54	8.2581	NE	3.13	Algorithm converged.	1.63	6.03
Gastrointestinal disorders	Abdominal distension	n/a	495	100.0	5	1.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.20	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Abdominal pain	n/a	495	100.0	7	1.4	496	100.0	1	0.2	0.14	Convergence criterion (HCONV=1E-8) satisfied.	0.01	1.06	-0.016	Quasi-complete separation of data points detected.			0.14	Algorithm converged.	0.01	1.04	0.0743	NE	0.14	Algorithm converged.	0.01	1.04
Gastrointestinal disorders	Abdominal pain upper	n/a	495	100.0	2	0.4	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.50	Algorithm converged.	0.05	NE	0.9999	NE	>999.99	Algorithm converged.	0.05	NE
Gastrointestinal disorders	Anal fistula	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Anal stenosis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Colitis	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Colitis ischaemic	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Diarrhoea	n/a	495	100.0	14	2.8	496	100.0	5	1.0	2.84	Convergence criterion (HCONV=1E-8) satisfied.	1.05	8.07	0.018	Convergence criterion (HCONV=1E-8) satisfied.	0.003	0.033	2.80	Algorithm converged.	1.09	7.21	3.8243	NE	2.80	Algorithm converged.	1.09	7.21
Gastrointestinal disorders	Diverticulum	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Enterocolitis	n/a	495	100.0	1	0.2	496	100.0	1	0.2		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	Enterocolitis haemorrhagic	n/a	495	100.0	1	0.2	496	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	Gastrointestinal haemorrhage	n/a	495	100.0	2	0.4	496	100.0	1	0.2	0.50	Convergence criterion (HCONV=1E-8) satisfied.	0.05	5.05	-0.000	Algorithm converged.	-0.030	0.010	0.50	Algorithm converged.	0.05	5.03	0.5743	NE	0.50	Algorithm converged.	0.05	21.84
Gastrointestinal disorders	Gastrooesophageal reflux disease	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Haemorrhoidal haemorrhage	n/a	495	100.0	1	0.2	496	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	Ileus	n/a	495	100.0	5	1.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.20	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Impaired gastric emptying	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Intestinal obstruction	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Intestinal perforation	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Large intestinal haemorrhage	n/a	495	100.0	1	0.2	496	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	495	100.0	5	1.0	496	100.0	2	0.4	2.53	Convergence criterion (HCONV=1E-8) satisfied.	0.49	13.05	0.006	Algorithm converged.	-0.006	0.016	2.52	Algorithm converged.	0.49	12.90	0.7609	NE	2.52	Algorithm converged.	0.58	7.04
Gastrointestinal disorders	Neutropenic colitis	n/a	495	100.0	2	0.4	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.50	Algorithm converged.	0.05	NE	0.9999	NE	>999.99	Algorithm converged.	0.05	NE
Gastrointestinal disorders	Pancreatitis	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Small intestinal obstruction	n/a	495	100.0	0	0.0	496	100.0	1	1.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Small intestinal perforation	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Stomatitis	n/a	495	100.0	4	0.8	496	100.0	1	0.2	0.25	Convergence criterion (HCONV=1E-8) satisfied.	0.03	22.30	0.000	Convergence criterion (HCONV=1E-8) satisfied.	-0.020	0.000	0.25	Algorithm converged.	0.03	22.12	0.5674	NE	0.25	Algorithm converged.	0.03	NE
Gastrointestinal disorders	Subileus	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Tooth loss	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	n/a	495	100.0	1	0.2	496	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	Vomiting	n/a	495	100.0	5	1.0	496	100.0	2	0.4	2.53	Convergence criterion (HCONV=1E-8) satisfied.	0.49	13.05	0.006	Convergence criterion (HCONV=1E-8) satisfied.	-0.007	0.019	2.52	Algorithm converged.	0.49	12.90	0.7609	NE	2.52	Algorithm converged.	0.58	7.04
General disorders and administration site conditions		n/a	495	100.0	34	6.9	496	100.0	24	4.8	1.41	Convergence criterion (HCONV=1E-8) satisfied.	0.86	2.85	0.020	Algorithm converged.	-0.006	0.047	1.41	Algorithm converged.	0.88	2.30	0.9629	NE	1.40	Algorithm converged.	0.87	2.27
General disorders and administration site conditions	Asthenia	n/a	495	100.0	7	1.4	496	100.0	2	0.4	3.54	Convergence criterion (HCONV=1E-8) satisfied.	0.74	17.00	0.016	Algorithm converged.	-0.002	0.022	3.52	Algorithm converged.	0.74	16.87	0.1153	NE	3.28	Algorithm converged.	0.06	1.36
General disorders and administration site conditions	Catheter site haemorrhage	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
General disorders and administration site conditions	Chest discomfort	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
General disorders and administration site conditions	Chest pain	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
General disorders and administration site conditions	Chills	n/a	495	100.0	2	0.4	496	100.0	1	0.2	0.50	Convergence criterion (HCONV=1E-8) satisfied.	0.05	5.03	-0.000	Algorithm converged.	-0.030	0.009	0.50	Algorithm converged.	0.05	5.03	0.5743	NE	0.50	Algorithm converged.	0.05	21.84
General disorders and administration site conditions	Device related thrombosis	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			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	495	100.0	11	2.2	496	100.0	15	3.0	0.73	Convergence criterion (HCONV=1E-8) satisfied.	0.34	1.55	-0.010	Algorithm converged.	-0.028	0.004	0.74	Algorithm converged.	0.34	1.55	0.1441	NE	0.73	Algorithm converged.	0.77	4.25
General disorders and administration site conditions	General physical health deterioration	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
General disorders and administration site conditions	Ill-defined disorder	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
General disorders and administration site conditions	Infusion site extravasation	n/a	495	100.0	1	0.2	496	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 extravasation	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
General disorders and administration site conditions	Malaise	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
General disorders and administration site conditions	Mucosal inflammation	n/a	495	100.0	2	0.4	496	100.0	1	0.2	2.02	Convergence criterion (HCONV=1E-8) satisfied.	0.18	22.30	0.000	Algorithm converged.	-0.020	0.059	2.01	Algorithm converged.	0.18	22.12	0.5674	NE	2.01	Algorithm converged.	0.03	5.44
General disorders and administration site conditions	Oedema	n/a	495	100.0	1	0.2	496	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	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV=1E-8) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9964	NE	0.99	Algorithm converged.	0.06	15.85
General disorders and administration site conditions	Pain	n/a	495	100.0	2	0.4	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 21.431637574 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	495	100.0	9	1.8	496	100.0	2	0.4	4.65	Convergence criterion (HCONV=1E-8) satisfied.	0.85	26.00	0.056	Algorithm converged.	-0.006	0.037	4.50	Algorithm converged.	0.85	25.80	0.2123	NE	4.50	Algorithm converged.	0.93	2.22
General disorders and administration site conditions	Ulcer	n/a	495	100.0	1	0.2	496	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	Vascular stent thrombosis	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Hepatobiliary disorders		n/a	495	100.0	4	0.8	496	100.0	1	0.2	0.25	Convergence criterion (HCONV=1E-8) satisfied.	0.03	2.73	-0.000	Algorithm converged.	-0.030	0.000	0.25	Algorithm converged.	0.03	2.71	0.4243	NE	0.25	Algorithm converged.	0.07	19.45
Hepatobiliary disorders	Bile duct stenosis	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Hepatobiliary disorders	Biliary dysfunction	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Hepatobiliary disorders	Cholangitis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Hepatobiliary disorders	Cholestasis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Hepatobiliary disorders	Hepatic function abnormal	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Hepatobiliary disorders	Hypertransaminasaemia	n/a	495	100.0	2	0.4	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.50	Algorithm converged.	0.05	NE	0.9999	NE	>999.99	Algorithm converged.	0.05	NE
Immune system disorders		n/a	495	100.0	3	0.6	496	100.0	1	0.2	3.03	Convergence criterion (HCONV=1E-8) satisfied.	0.32	16.47	0.008	Algorithm converged.	-0.004	0.020	3.01	Algorithm converged.	0.34	16.42	0.9964	NE	3.01	Algorithm converged.	0.34	15.43
Immune system disorders	Haemophagocytic lymphohistiocytosis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARN

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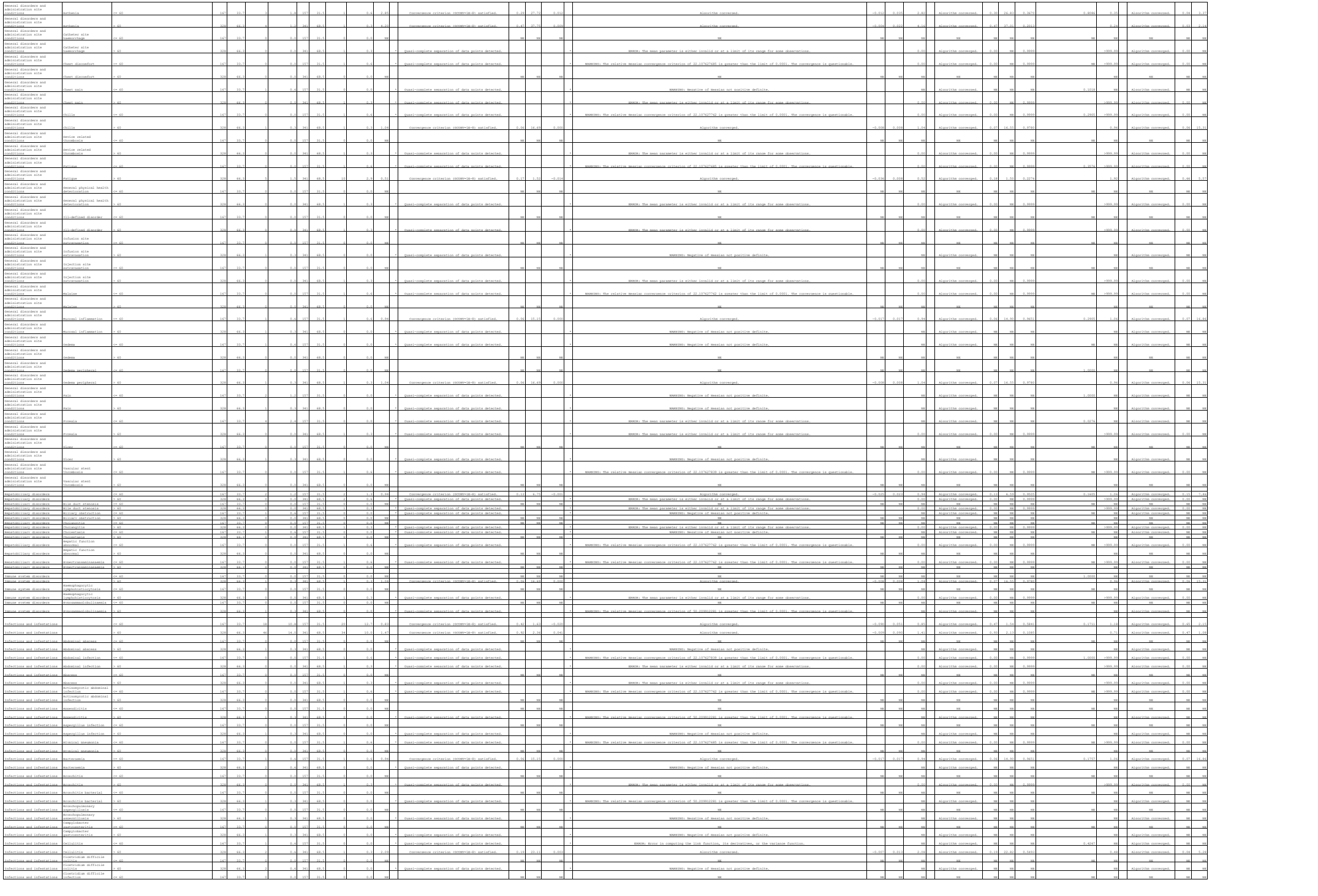
POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified Analysis
STOUT: 20190422
Dichotomous Analysis by Subgroups (Safety)

Age

			Ociltaroxab Tablets + N-CBP (N=197)		Placebo (N=196)		Ociltaroxab Tablets + N-CBP vs. N-CBP														Ociltaroxab Tablets + N-CBP vs. N-CBP			
			Patients	Patients with Event	Patients	Patients with Event	Odds Ratio					Absolute Risk Difference					Relative Risk					Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	Odds Ratio	Convergence Result	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Result	95% Lower CL	95% Upper CL	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		>= 60	147	33.7	34	14.4	107	31.1	27	17.2	0.81	Convergence criterion (NCOMP=1E-8) satisfied.	0.44	1.47	-0.026	Algorithm converged.	-0.098	0.053	0.44	Algorithm converged.	0.65	1.38	0.4854	0.1515	1.05	Algorithm converged.	0.72	1.54
Blood and lymphatic system disorders		< 60	328	66.3	93	19.8	761	68.1	54	15.2	1.37	Convergence criterion (NCOMP=1E-8) satisfied.	0.93	2.00	0.048	Algorithm converged.	-0.043	0.140	1.41	Algorithm converged.	0.93	1.93	0.1211		1.37	Algorithm converged.	0.91	1.63
Blood and lymphatic system disorders	Anaemia	>= 60	147	33.7	12	7.9	107	31.1	7	4.5	1.66	Convergence criterion (NCOMP=1E-8) satisfied.	0.66	4.20	0.027	Algorithm converged.	-0.010	0.076	1.41	Algorithm converged.	0.85	3.49	0.3620	0.4690	1.62	Algorithm converged.	0.91	1.54
Blood and lymphatic system disorders	Anaemia	< 60	328	66.3	93	12.5	761	68.1	65	11.7	1.08	Convergence criterion (NCOMP=1E-8) satisfied.	0.80	1.71	0.008	Algorithm converged.	-0.042	0.067	1.41	Algorithm converged.	0.91	1.60	0.7601		1.04	Algorithm converged.	0.92	1.41
Blood and lymphatic system disorders	Febrile bone marrow aplasia	>= 60	147	33.7	1	0.9	107	31.1	1	0.8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	< 60	328	66.3	1	0.3	761	68.1	1	0.3	1.04	Convergence criterion (NCOMP=1E-8) satisfied.	0.06	16.89	0.000	Algorithm converged.	-0.008	0.008	1.41	Algorithm converged.	0.07	16.55	0.9780		0.96	Algorithm converged.	0.06	15.31
Blood and lymphatic system disorders	Febrile neutropenia	>= 60	147	33.7	4	4.8	107	31.1	4	5.7	0.82	Convergence criterion (NCOMP=1E-8) satisfied.	0.20	3.35	-0.008	Algorithm converged.	-0.068	0.049	0.44	Algorithm converged.	0.24	2.91	0.7663	0.9777	1.05	Algorithm converged.	0.43	3.64
Blood and lymphatic system disorders	Febrile neutropenia	< 60	328	66.3	38	11.6	761	68.1	18	5.3	2.35	Convergence criterion (NCOMP=1E-8) satisfied.	1.33	4.25	0.060	Algorithm converged.	0.022	0.105	2.13	Algorithm converged.	1.28	3.77	0.0043		2.46	Algorithm converged.	1.27	3.78
Blood and lymphatic system disorders	Hypofibrinogenaemia	>= 60	147	33.7	0	0.0	107	31.1	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	Hypofibrinogenaemia	< 60	328	66.3	1	0.3	761	68.1	1	0.3	*	Quasi-complete separation of data points detected.	*	*	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	*	*	0.41	*	*	*	>999.99	*	*	*	*	*
Blood and lymphatic system disorders	Leukopenia	>= 60	147	33.7	4	2.4	107	31.1	4	2.6	0.86	Convergence criterion (NCOMP=1E-8) satisfied.	0.21	3.49	-0.006	Algorithm converged.	-0.068	0.045	0.44	Algorithm converged.	0.24	3.03	0.9691	0.9814	1.06	Algorithm converged.	0.41	4.14
Blood and lymphatic system disorders	Leukopenia	< 60	328	66.3	7	2.1	761	68.1	33	4.7	0.45	Convergence criterion (NCOMP=1E-8) satisfied.	0.18	1.09	-0.026	Algorithm converged.	-0.055	0.002	0.41	Algorithm converged.	0.15	1.33	0.0777		0.25	Algorithm converged.	0.92	5.27
Blood and lymphatic system disorders	Lymphopenia	>= 60	147	33.7	1	0.0	107	31.1	1	1.9	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: The relative Hessian convergence criterion of 10.630477486 is greater than the limit of 0.0001. The convergence is questionable.	*	*	0.00	Algorithm converged.	0.00	NE	0.9999	0.6280	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Lymphopenia	< 60	328	66.3	4	1.2	761	68.1	4	0.4	2.83	Convergence criterion (NCOMP=1E-8) satisfied.	0.66	9.85	0.000	Algorithm converged.	-0.010	0.020	1.54	Algorithm converged.	0.46	5.46	0.4681		2.46	Algorithm converged.	0.19	2.24
Blood and lymphatic system disorders	Myelosuppression	>= 60	147	33.7	0	0.0	107	31.1	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	Myelosuppression	< 60	328	66.3	1	0.3	761	68.1	1	0.3	1.04	Convergence criterion (NCOMP=1E-8) satisfied.	0.06	16.89	0.000	Algorithm converged.	-0.008	0.008	1.41	Algorithm converged.	0.07	16.55	0.9780		0.96	Algorithm converged.	0.06	15.31
Blood and lymphatic system disorders	Neutropenia	>= 60	147	33.7	14	8.4	107	31.1	10	10.2	0.81	Convergence criterion (NCOMP=1E-8) satisfied.	0.38	1.71	-0.016	Algorithm converged.	-0.085	0.040	0.42	Algorithm converged.	0.48	1.43	0.5754	0.7250	1.20	Algorithm converged.	0.62	2.43
Blood and lymphatic system disorders	Neutropenia	< 60	328	66.3	23	7.6	761	68.1	23	7.9	0.96	Convergence criterion (NCOMP=1E-8) satisfied.	0.54	1.69	-0.006	Algorithm converged.	-0.046	0.028	0.96	Algorithm converged.	0.63	1.43	0.8804		1.04	Algorithm converged.	0.62	1.73
Blood and lymphatic system disorders	Pancytopenia	>= 60	147	33.7	0	0.0	107	31.1	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	Pancytopenia	< 60	328	66.3	0	0.0	761	68.1	0	0.0	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: Negative of hessian not positive definite.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Thrombocytopenia	>= 60	147	33.7	3	1.2	107	31.1	3	1.9	0.62	Convergence criterion (NCOMP=1E-8) satisfied.	0.22	3.77	-0.007	Algorithm converged.	-0.094	0.020	0.43	Algorithm converged.	0.31	3.73	0.4041	0.8740	1.63	Algorithm converged.	0.21	9.42
Blood and lymphatic system disorders	Thrombocytopenia	< 60	328	66.3	7	1.5	761	68.1	7	2.1	0.74	Convergence criterion (NCOMP=1E-8) satisfied.	0.23	2.05	-0.005	Algorithm converged.	-0.065	0.013	0.74	Algorithm converged.	0.24	2.33	0.4081		1.25	Algorithm converged.	0.42	4.24
Cardiac disorders		>= 60	147	33.7	1	0.6	107	31.1	1	0.6	0.96	Convergence criterion (NCOMP=1E-8) satisfied.	0.06	15.60	0.000	Algorithm converged.	-0.007	0.013	0.96	Algorithm converged.	0.06	14.93	0.9653	0.9480	1.06	Algorithm converged.	0.07	16.93
Cardiac disorders		< 60	328	66.3	5	1.5	761	68.1	5	1.5	0.99	Convergence criterion (NCOMP=1E-8) satisfied.	0.30	3.23	0.000	Algorithm converged.	-0.028	0.028	1.00	Algorithm converged.	0.29	3.42	0.9939		1.00	Algorithm converged.	0.29	3.45
Cardiac disorders	Atrial fibrillation	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrial fibrillation	< 60	328	66.3	1	0.3	761	68.1	1	0.3	1.04	Convergence criterion (NCOMP=1E-8) satisfied.	0.06	16.89	0.000	Algorithm converged.	-0.008	0.008	1.41	Algorithm converged.	0.07	16.55	0.9780		0.96	Algorithm converged.	0.06	15.31
Cardiac disorders	Cardiac failure congestive	>= 60	147	33.7	0	0.0	107	31.1	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 congestive	< 60	328	66.3	1	0.3	761	68.1	1	0.3	*	Quasi-complete separation of data points detected.	*	*	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	*	*	0.41	*	*	*	>999.99	*	*	*	*	*
Cardiac disorders	Cardiomyopathy failure	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Cardiomyopathy failure	< 60	328	66.3	0	0.0	761	68.1	0	0.0	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: Negative of hessian not positive definite.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	< 60	328	66.3	1	0.3	761	68.1	1	0.3	1.04	Convergence criterion (NCOMP=1E-8) satisfied.	0.06	16.89	0.000	Algorithm converged.	-0.008	0.008	1.41	Algorithm converged.	0.07	16.55	0.9780		0.96	Algorithm converged.	0.06	15.31
Cardiac disorders	Myocardial infarction	>= 60	147	33.7	0	0.0	107	31.1	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	< 60	328	66.3	0	0.0	761	68.1	0	0.0	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: Negative of hessian not positive definite.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	< 60	328	66.3	1	0.3	761	68.1	1	0.3	*	Quasi-complete separation of data points detected.	*	*	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	*	*	0.41	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Sinus tachycardia	>= 60	147	33.7	1	0.6	107	31.1	1	0.9	0.64	Convergence criterion (NCOMP=1E-8) satisfied.	0.04	10.77	0.000	Algorithm converged.	-0.057	0.031	0.64	Algorithm converged.	0.04	11.02	0.9802	0.2900	1.16	Algorithm converged.	0.08	16.81
Cardiac disorders	Sinus tachycardia	< 60	328	66.3	0	0.0	761	68.1	0	0.0	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: Negative of hessian not positive definite.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Tachycardia	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Tachycardia	< 60	328	66.3	0	0.0	761	68.1	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.	*	*	0.41	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Congenital, familial and genetic disorders		>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Congenital, familial and genetic disorders		< 60	328	66.3	1	0.3	761	68.1	1	0.3	*	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
Congenital, familial and genetic disorders	Pyloric atresia	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Congenital, familial and genetic disorders	Pyloric atresia	< 60	328	66.3	1	0.3	761	68.1	1	0.3	*	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
Ear and labyrinth disorders		>= 60	147	33.7	0	0.0	107	31.1	0	0.6	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: The relative Hessian convergence criterion of 22.107627939 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		< 60	328	66.3	0	0.0	761	68.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Ear and labyrinth disorders	Hypoacusis	>= 60	147	33.7	0	0.0	107	31.1	0	0.6	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: The relative Hessian convergence criterion of 22.107627939 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	Hypoacusis	< 60	328	66.3	0	0.0	761	68.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders		>= 60	147	33.7	0	0.0	107	31.1	0	0.0	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: Negative of hessian not positive definite.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Abnormal sensation eye	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Abnormal sensation eye	< 60	328	66.3	0	0.0	761	68.1	0	0.0	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: Negative of hessian not positive definite.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Cataract	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Cataract	< 60	328	66.3	0	0.0	761	68.1	0	0.0	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: Negative of hessian not positive definite.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	< 60	328	66.3	0	0.0	761	68.1	0	0.0	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: Negative of hessian not positive definite.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders		>= 60	147	33.7	8	5.4	107	31.1	6	5.7	0.94	Convergence criterion (NCOMP=1E-8) satisfied.	0.34	2.62	-0.010	Algorithm converged.	-0.093	0.047	0.94	Algorithm converged.	0.38	2.33	0.8923	0.4630	1.06	Algorithm converged.	0.43	2.63
Gastrointestinal disorders		< 60	328	66.3	19	6.1	761	68.1	45	6.1	1.00	Convergence criterion (NCOMP=1E-8) satisfied.	0.59	2.00	0.000	Algorithm converged.	-0.031	0.031	1.00	Algorithm converged.	0.61	1.64	0.9939		1.00	Algorithm converged.	0.61	1.64
Gastrointestinal disorders	Abdominal distension	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Abdominal distension	< 60	328	66.3	1	0.3	761	68.1	1	0.3	*	Quasi-complete separation of data points detected.	*	*	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	*	*	0.41	*	*	*	>999.99	*	*	*	*	*
Gastrointestinal disorders	Abdominal pain	>= 60	147	33.7	3	1.2	107	31.1	3	2.8	0.45	Convergence criterion (NCOMP=1E-8) satisfied.	0.08	2.47	-0.014	Algorithm converged.	-0.068	0.013	0.47	Algorithm converged.	0.09	2.43	0.2324	0.7560	0.43	Algorithm converged.	0.08	11.43
Gastrointestinal disorders	Abdominal pain	< 60	328	66.3	3	0.9	761	68.1	9	1.2	0.69	Convergence criterion (NCOMP=1E-8) satisfied.	0.17	2.80	-0.003	Algorithm converged.	-0.043	0.011	0.69	Algorithm converged.	0.17	2.76	0.4803		0.59	Algorithm converged.	0.14	2.50
Gastrointestinal disorders	Abdominal pain upper	>= 60	147	33.7	0	0.0	107	31.1	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	< 60	328	66.3	0	0.0	761	68.1	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.	*	*	0.41	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Anal fistula	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Anal fistula	< 60	328	66.3	1	0.3	761	68.1	1	0.3	1.04	Convergence criterion (NCOMP=1E-8) satisfied.	0.06	16.89	0.000	Algorithm converged.	-0.008	0.008	1.41	Algorithm converged.	0.07	16.55	0.9780		0.96	Algorithm converged.	0.06	15.31
Gastrointestinal disorders	Anal stenosis	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Anal stenosis	< 60	328	66.3	1	0.3	761	68.1	1	0.3	*	Quasi-complete separation of data points detected.	*	*	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	*	*	0.41	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Ascites	>= 60	147	33.7	1	0.6	107	31.1	1	0.9	0.64	Convergence criterion (NCOMP=1E-8) satisfied.	0.04	10.77	0.000	Algorithm converged.	-0.057	0.031	0.64	Algorithm converged.	0.04	11.02	0.9802	0.2900	1.16	Algorithm converged.	0.08	16.81
Gastrointestinal disorders	Ascites	< 60	328	66.3	0	0.0	761	68.1	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.	*	*	0.41	*	*	*	>999.99	*	*	*	*	*
Gastrointestinal disorders	Colitis	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Colitis	< 60	328	66.3	1	0.3	761	68.1	1	0.3	*	Quasi-complete separation of data points detected.	*	*	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	*	*	0.41	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Constipation	>= 60	147	33.7	3	2.0	107	31.1	2	1.9	1.07	Convergence criterion (NCOMP=1E-8) satisfied.	0.17	6.69	0.000	Algorithm converged.	-0.057	0.057	1.07	Algorithm converged.	0.17	6.73	0.9431	1.0000	1.00	Algorithm converged.	0.15	7.13
Gastrointestinal disorders	Constipation	< 60	328	66.3	4	1.2	761	68.1	11	1.4	0.85	Convergence criterion (NCOMP=1E-8) satisfied.	0.27	2.69	-0.003	Algorithm converged.	-0.057	0.028	0.85	Algorithm converged.	0.32	2.26	0.7172		0.93	Algorithm converged.	0.34	2.53
Gastrointestinal disorders	Diarrhoea	>= 60	147	33.7	5	3.4	107	31.1	4	3.8	0.89	Convergence criterion (NCOMP=1E-8) satisfied.	0.24	3.29	-0.004	Algorithm converged.	-0.085	0.057	0.89	Algorithm converged.	0.34	2.33	0.7454	0.5041	0.96	Algorithm converged.	0.34	2.59
Gastrointestinal disorders	Diarrhoea	< 60	328	66.3	7	2.1	761	68.1	17	2.2	0.95	Convergence criterion (NCOMP=1E-8) satisfied.	0.38	2.39	-0.003	Algorithm converged.	-0.057	0.028	0.95	Algorithm converged.	0.40	2.26	0.8459		0.96	Algorithm converged.	0.40	2.30
Gastrointestinal disorders	Dyspepsia	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Dyspepsia	< 60	328	66.3	1	0.3	761	68.1	1	0.3	*	Quasi-complete separation of data points detected.	*	*	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	*	*	0.41	Algorithm converged.	0.00	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Enteritis	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Enteritis	< 60	328	66.3	0	0.0	761	68.1	0	0.0	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: Negative of hessian not positive definite.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Eosinophilic discomfort	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: Negative of hessian not positive definite.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Eosinophilic discomfort	< 60	328	66.3	0	0.0	761	68.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Haematochezia	>= 60	147	33.7	0	0.0	107	31.1	0	0.6	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: The relative Hessian convergence criterion of 22.107627939 is greater than the limit of 0.0001. The convergence is questionable.	*	*	0.00	Algorithm converged.	0.00	NE	0.9999	0.2900	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Haematochezia	< 60	328	66.3	1	0.3	761	68.1	1	0.3	1.04	Convergence criterion (NCOMP=1E-8) satisfied.	0.06	16.89	0.000	Algorithm converged.	-0.008	0.008	1.41	Algorithm converged.	0.07	16.55	0.9780		0.96	Algorithm converged.	0.06	15.31
Gastrointestinal disorders	Haematochezia reflux disease	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Haematochezia reflux disease	< 60	328	66.3	1	0.3	761	68.1	1	0.3	*	Quasi-complete separation of data points detected.	*	*	*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	*	*	0.41	*	*	*	>999.99	*	*	*	*	*
Gastrointestinal disorders	Haemorrhoidal haemorrhage	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Haemorrhoidal haemorrhage	< 60	328	66.3	1	0.3	761	68.1	1	0.3	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: The relative Hessian convergence criterion of 50.209912281 is greater than the limit of 0.0001. The convergence is questionable.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Ileus	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Ileus	< 60	328	66.3	0	0.0	761	68.1	0	0.0	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: Negative of hessian not positive definite.	*	*	NE	Algorithm converged.	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Impaired gastric emptying	>= 60	147	33.7	0	0.0	107	31.1	0	0.6	*	Quasi-complete separation of data points detected.	*	*	*	WARNING: The relative Hessian convergence criterion of 22.107627939 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	Impaired gastric emptying	< 60	328	66.3	0	0.0	761	68.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Intestinal obstruction	>= 60	147	33.7	0	0.0	107	31.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Intestinal obstruction	< 60	328	66.3	1	0.3	761	68.1	1	0.3	1.04	Convergence criterion (NCOMP=1E-8) satisfied.	0.06	16.89	0.000	Algorithm converged.	-0.008	0.008	1.41	Algorithm converged.	0.07	16.55	0.9780		0.96	Algorithm converged.	0.06	15.31
Gastrointestinal disorders	Intestinal perforation	>= 60	147	33.7	0	0.0	107	31.1	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
Gastrointestinal disorders	Intestinal perforation	< 60	328	66.3	0	0.0	761	68.1



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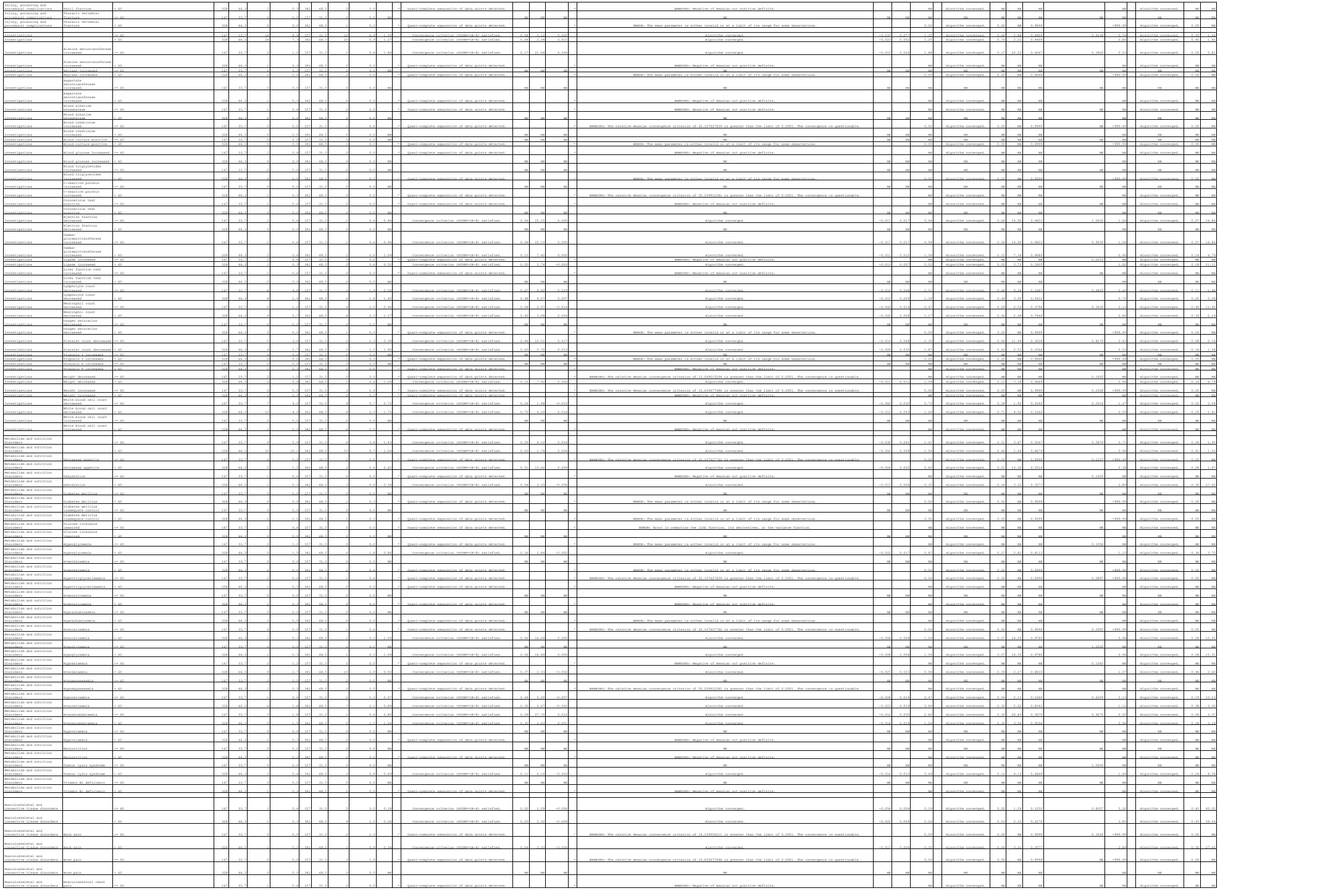

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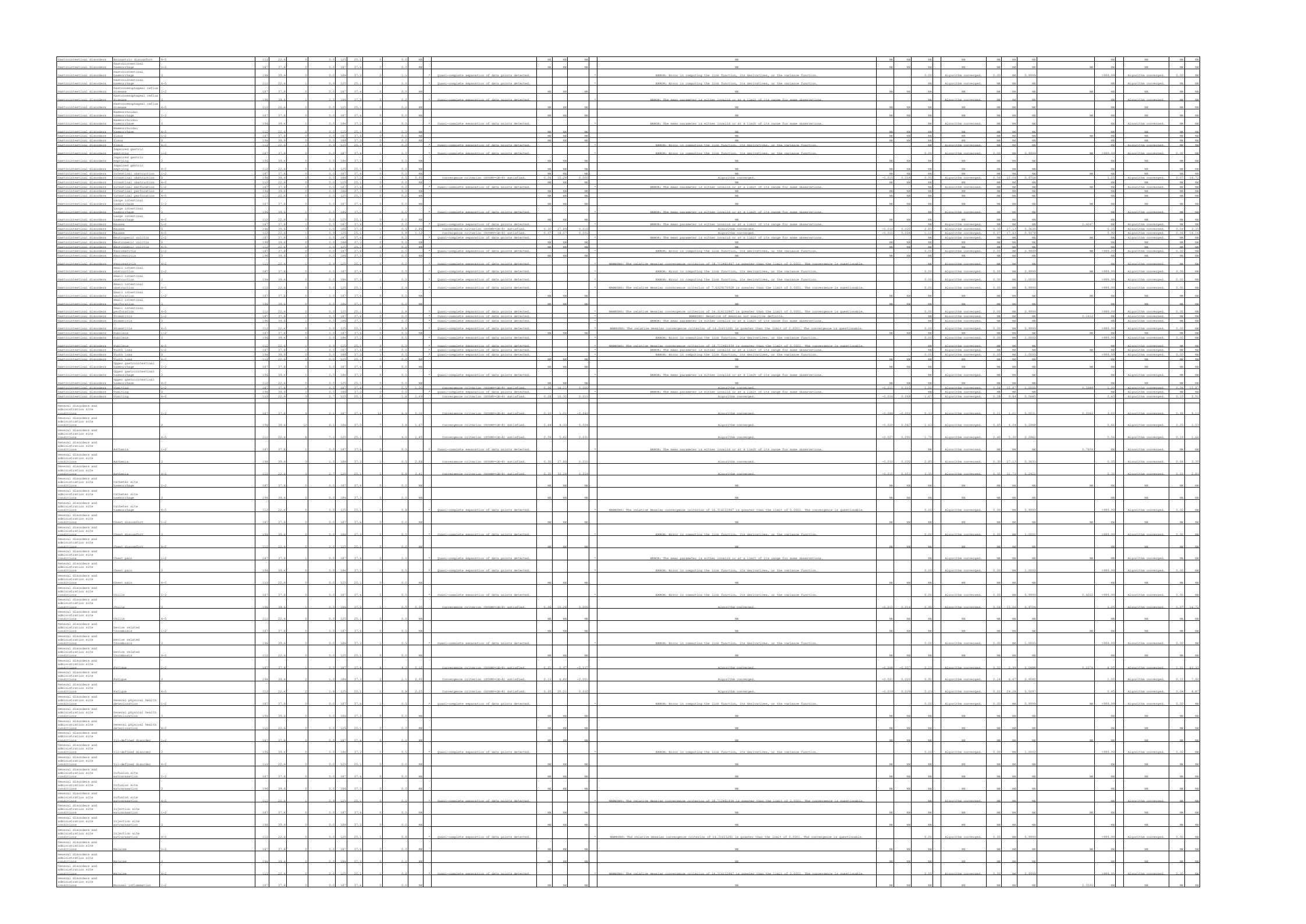
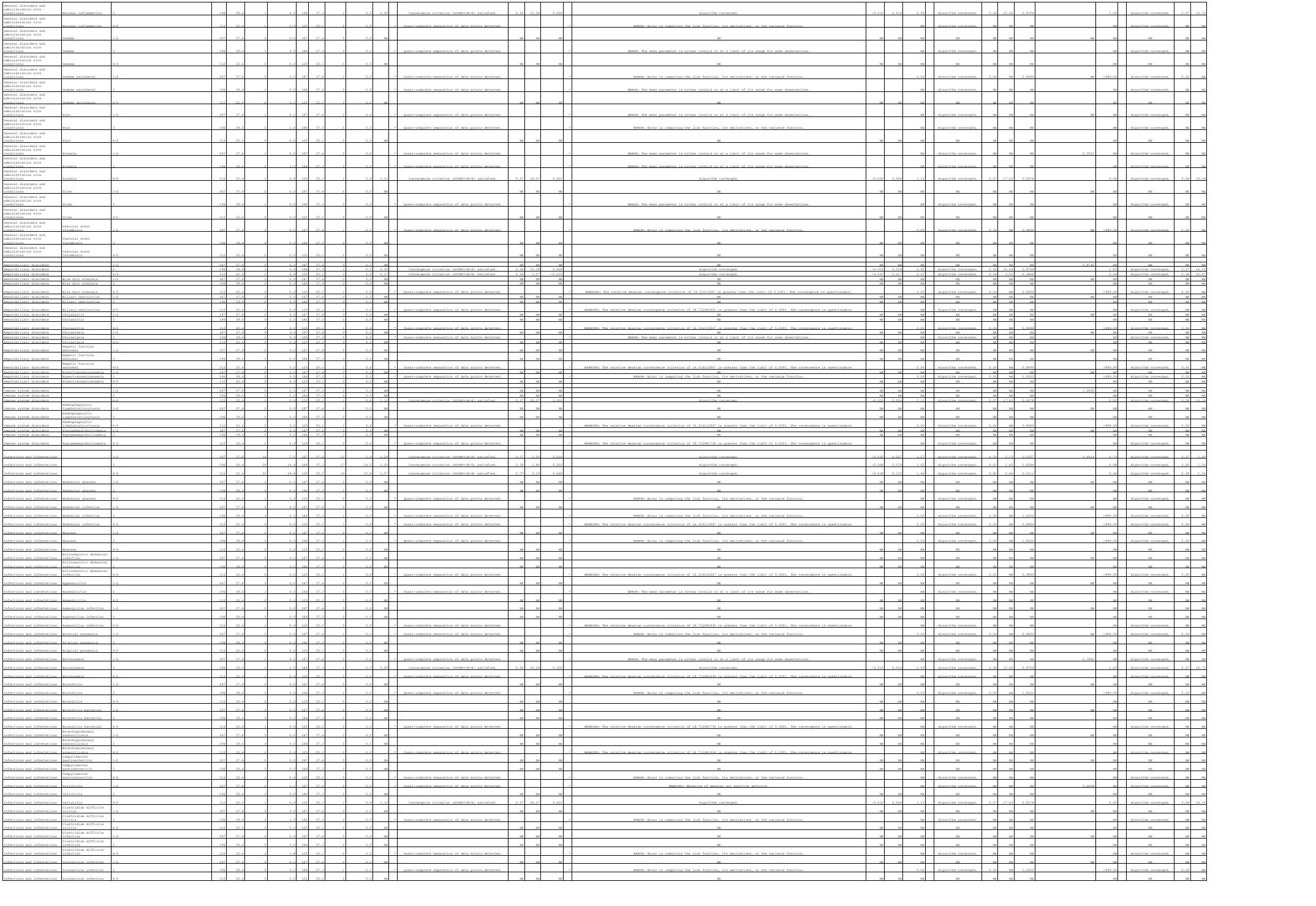
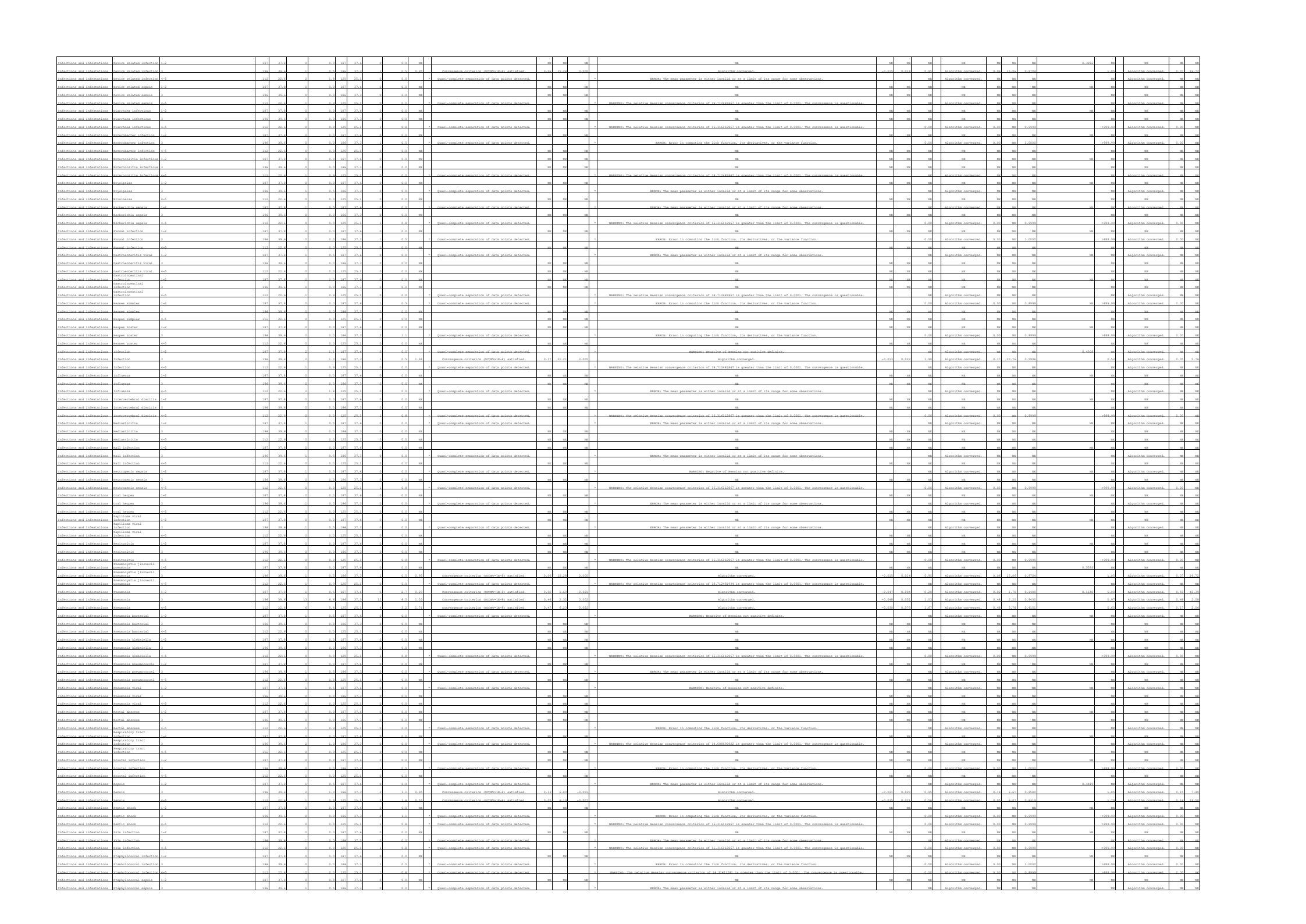
POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified Analysis
STOUT: 20190822
Dichotomous Analysis by Subgroups (Safety)

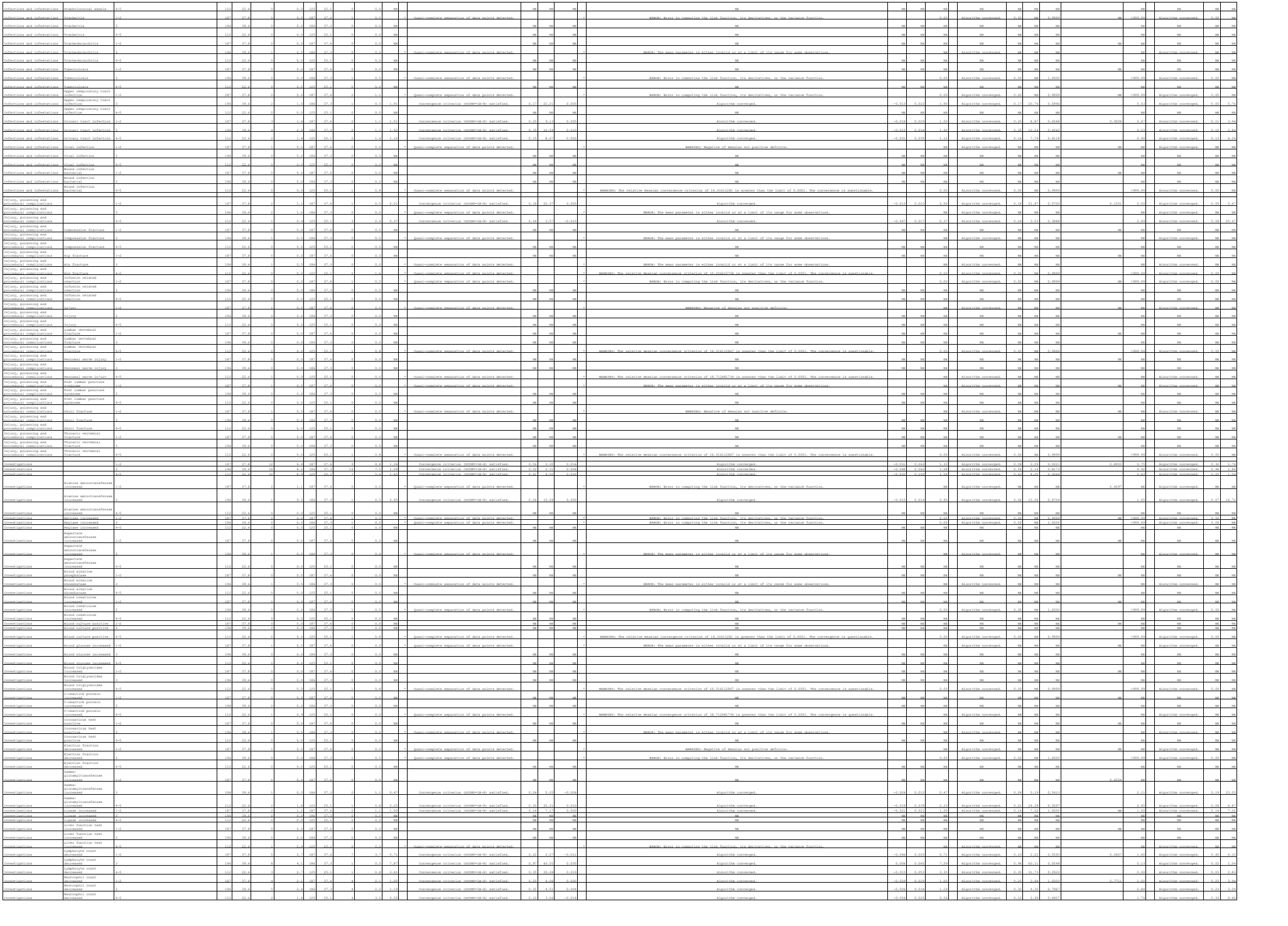
ZPG score at Screening

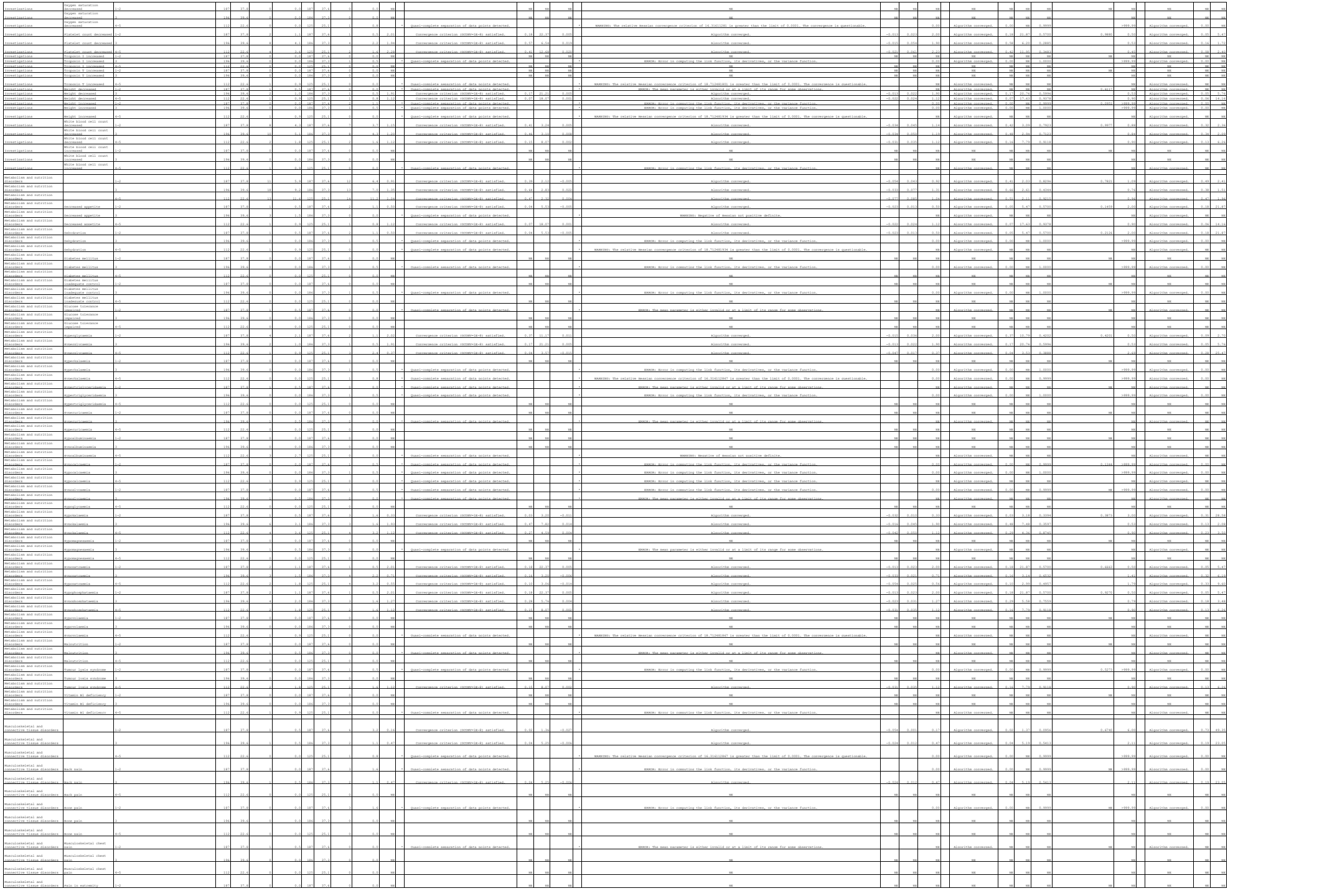
			Pembrolizumab Cohort 1 N=187 (N=191)				K-Cmor (N=193)				Pembrolizumab Cohort 1 N=187 vs. K-Cmor										K-Cmor vs. Pembrolizumab Cohort 1 N=187			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference				Relative Risk				Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	N	%	n	%	N	%	n	%	Convergence Result	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Result	95% Lower CL	95% Upper CL	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		1-2	187	37.8	30	16.0	187	27.4	29	15.5	1.04																
Blood and lymphatic system disorders		3	196	39.4	30	14.8	196	27.6	29	15.6	0.94																
Blood and lymphatic system disorders		4-5	112	22.6	30	26.8	125	25.6	20	16.8	1.81																
Blood and lymphatic system disorders	Anaemia	1-2	187	37.8	33	5.3	187	27.4	11	5.9	0.90																
Blood and lymphatic system disorders	Anaemia	3	196	39.4	33	11.2	196	27.6	14	8.6	1.34																
Blood and lymphatic system disorders	Anaemia	4-5	112	22.6	33	18.9	125	25.6	20	16.8	1.21																
Blood and lymphatic system disorders	Febrile bone marrow aplasia	1-2	187	37.8	1	0.5	187	27.4	1	0.5																	
Blood and lymphatic system disorders	Febrile bone marrow aplasia	3	196	39.4	1	0.5	196	27.6	1	0.5	NE	NE	NE														
Blood and lymphatic system disorders	Febrile bone marrow aplasia	4-5	112	22.6	1	0.9	125	25.6	1	0.8					Quasi-complete separation of data points detected.				WARNING: The relative mean convergence criterion of 18.72482 is greater than the limit of 0.0001. The convergence is questionable.							
Blood and lymphatic system disorders	Febrile neutropenia	1-2	187	37.8	15	8.0	187	27.4	8	4.3	1.95				Convergence criterion (ncon=16-8) satisfied.	0.65	4.55	0.037	Algorithm converged.	-0.065	0.586	1.47	Algorithm converged.	0.91	4.33	0.1395		0.73	5.10	1.23
Blood and lymphatic system disorders	Febrile neutropenia	3	196	39.4	15	8.2	196	27.6	11	5.8	1.41				Convergence criterion (ncon=16-8) satisfied.	0.46	4.19	0.084	Algorithm converged.	-0.049	0.676	1.39	Algorithm converged.	0.96	4.90	0.0838		0.72	5.04	1.24
Blood and lymphatic system disorders	Febrile neutropenia	4-5	112	22.6	15	13.4	125	25.6	8	6.4	2.26				Convergence criterion (ncon=16-8) satisfied.	0.96	9.96	0.078	Algorithm converged.	-0.096	0.540	2.09	Algorithm converged.	0.92	4.73	0.0772		0.48	3.38	1.05
Blood and lymphatic system disorders	Hypofibrinogenaemia	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Hypofibrinogenaemia	3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Hypofibrinogenaemia	4-5	112	22.6	0	0.0	125	25.6	1	0.8					Quasi-complete separation of data points detected.				WARNING: The relative mean convergence criterion of 16.31411947 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
Blood and lymphatic system disorders	Leukopenia	1-2	187	37.8	3	1.6	187	27.4	1	0.5	3.05				Convergence criterion (ncon=16-8) satisfied.	0.48	1.47	0.022	Algorithm converged.	-0.036	0.065	0.14	Algorithm converged.	1.08	3.63	0.0643		0.256	1.22	0.84	11.54
Blood and lymphatic system disorders	Leukopenia	3	196	39.4	4	2.0	196	27.6	1	0.8	3.03				Convergence criterion (ncon=16-8) satisfied.	0.23	1.85	<0.01	Algorithm converged.	-0.091	0.013	0.19	Algorithm converged.	1.16	3.93	0.0223			1.85	0.92	6.20
Blood and lymphatic system disorders	Leukopenia	4-5	112	22.6	4	3.6	125	25.6	1	0.8	3.03				Convergence criterion (ncon=16-8) satisfied.	0.23	6.89	0.031	Algorithm converged.	-0.091	0.013	1.49	Algorithm converged.	1.24	6.93	0.0574			3.87	0.93	2.94
Blood and lymphatic system disorders	Lymphocytosis	1-2	187	37.8	2	1.1	187	27.4	1	0.5	2.15				Convergence criterion (ncon=16-8) satisfied.	0.09	2.73	<0.01	Algorithm converged.	-0.096	0.013	0.19	Algorithm converged.	1.08	2.73	0.4202		0.2116	2.05	0.71	10.73
Blood and lymphatic system disorders	Lymphocytosis	3	196	39.4	2	0.5	196	27.6	1	0.5	1.13				Convergence criterion (ncon=16-8) satisfied.	0.04	5.65	<0.01	Algorithm converged.	-0.096	0.013	0.47	Algorithm converged.	1.04	5.65	0.5614			1.13	0.14	23.04
Blood and lymphatic system disorders	Lymphocytosis	4-5	112	22.6	3	2.7	125	25.6	1	0.8	3.41				Convergence criterion (ncon=16-8) satisfied.	0.25	12.08	0.016	Algorithm converged.	-0.093	0.013	2.35	Algorithm converged.	1.25	21.73	0.2923			3.35	0.92	2.83
Blood and lymphatic system disorders	Myelosuppression	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	3	196	39.4	1	0.5	196	27.6	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.							
Blood and lymphatic system disorders	Myelosuppression	4-5	112	22.6	1	0.9	125	25.6	1	0.8					Quasi-complete separation of data points detected.				WARNING: The relative mean convergence criterion of 16.31411947 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
Blood and lymphatic system disorders	Neutropenia	1-2	187	37.8	14	7.5	187	27.4	13	9.6	0.76				Convergence criterion (ncon=16-8) satisfied.	0.23	1.58	<0.001	Algorithm converged.	-0.076	0.020	0.78	Algorithm converged.	0.80	3.22	0.4611		0.8206	1.28	0.66	2.53
Blood and lymphatic system disorders	Neutropenia	3	196	39.4	14	7.1	196	27.6	13	7.0	1.02				Convergence criterion (ncon=16-8) satisfied.	0.47	2.24	0.000	Algorithm converged.	-0.050	0.653	1.02	Algorithm converged.	0.88	2.12	0.9531			0.98	0.47	2.03
Blood and lymphatic system disorders	Neutropenia	4-5	112	22.6	11	9.8	125	25.6	13	9.6	1.03				Convergence criterion (ncon=16-8) satisfied.	0.43	2.45	0.000	Algorithm converged.	-0.073	0.078	1.02	Algorithm converged.	0.47	2.23	0.9541			0.96	0.45	2.13
Blood and lymphatic system disorders	Pancytopenia	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Pancytopenia	3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Pancytopenia	4-5	112	22.6	0	0.0	125	25.6	1	0.8					Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.							
Blood and lymphatic system disorders	Thrombocytopenia	1-2	187	37.8	2	1.1	187	27.4	1	1.6	0.66				Convergence criterion (ncon=16-8) satisfied.	0.31	4.03	<0.001	Algorithm converged.	-0.020	0.016	0.47	Algorithm converged.	0.31	3.94	0.4548		0.4870	1.02	0.25	9.47
Blood and lymphatic system disorders	Thrombocytopenia	3	196	39.4	4	2.0	196	27.6	1	1.6	1.27				Convergence criterion (ncon=16-8) satisfied.	0.26	5.74	0.004	Algorithm converged.	-0.020	0.031	1.07	Algorithm converged.	0.28	5.78	0.7553			0.79	0.10	3.46
Blood and lymphatic system disorders	Thrombocytopenia	4-5	112	22.6	3	2.7	125	25.6	1	0.8	3.27				Convergence criterion (ncon=16-8) satisfied.	0.21	2.69	<0.001	Algorithm converged.	-0.093	0.013	2.35	Algorithm converged.	1.25	21.73	0.2923			3.35	0.92	11.54
Cardiac disorders		1-2	187	37.8	3	1.6	187	27.4	1	0.5	3.05				Convergence criterion (ncon=16-8) satisfied.	0.31	29.41	0.011	Algorithm converged.	-0.093	0.013	2.35	Algorithm converged.	1.31	28.59	0.1091		0.1620	3.35	0.92	3.13
Cardiac disorders		3	196	39.4	3	1.5	196	27.6	1	0.5	3.03				Convergence criterion (ncon=16-8) satisfied.	0.13	4.76	<0.001	Algorithm converged.	-0.093	0.013	2.35	Algorithm converged.	1.25	21.73	0.2923			3.35	0.92	14.74
Cardiac disorders		4-5	112	22.6	0	0.0	125	25.6	1	1.6					Quasi-complete separation of data points detected.				WARNING: The relative mean convergence criterion of 23.20215758 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9996		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrial fibrillation	3	196	39.4	1	0.5	196	27.6	0	0.0	0.96	15.28	0.000		Convergence criterion (ncon=16-8) satisfied.	0.14	15.28	0.000	Algorithm converged.	-0.050	0.014	0.48	Algorithm converged.	1.04	15.28	0.9706			1.00	0.07	14.74
Cardiac disorders	Atrial fibrillation	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Cardiac failure congestive	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Cardiac failure congestive	3	196	39.4	1	0.5	196	27.6	0	1.1					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
Cardiac disorders	Cardiac failure congestive	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Cardiopulmonary failure	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Cardiopulmonary failure	3	196	39.4	1	0.5	196	27.6	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.							
Cardiac disorders	Cardiopulmonary failure	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	1-2	187	37.8	1	0.5	187	27.4	1	0.5					Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.							
Cardiac disorders	Left ventricular dysfunction	3	196	39.4	1	0.5	196	27.6	1	0.5	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	4-5	112	22.6	0	0.0	125	25.6	1	0.8					Quasi-complete separation of data points detected.				WARNING: The relative mean convergence criterion of 16.31411281 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
Cardiac disorders	Myocardial infarction	1-2	187	37.8	0	0.0	187	27.4	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of mean not positive definite.							
Cardiac disorders	Myocardial infarction	3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Myocardial infarction	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	4-5	112	22.6	1	0.9	125	25.6	1	0.8					Quasi-complete separation of data points detected.				WARNING: The relative mean convergence criterion of 16.31411947 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
Cardiac disorders	Sinus tachycardia	1-2	187	37.8	1	0.5	187	27.4	1	0.5	1.03				Convergence criterion (ncon=16-8) satisfied.	0.03	16.11	0.000	Algorithm converged.	-0.093	0.013	2.35	Algorithm converged.	1.04	15.87	1.0000		0.6200	1.00	0.06	15.87
Cardiac disorders	Sinus tachycardia	3	196	39.4	1	0.5	196	27.6	1	0.5					Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.							
Cardiac disorders	Sinus tachycardia	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Tachycardia	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Tachycardia	3	196	39.4	0	0.0	196	27.6	0	0.0					Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.							
Cardiac disorders	Tachycardia	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Congenital, familial and genetic disorders		1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Congenital, familial and genetic disorders		3	196	39.4	0	0.0	196	27.6	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.							
Congenital, familial and genetic disorders		4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Congenital, familial and genetic disorders	Pyloric stenosis	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Congenital, familial and genetic disorders	Pyloric stenosis	3	196	39.4	0	0.0	196	27.6	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.							
Congenital, familial and genetic disorders	Pyloric stenosis	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders		1-2	187	37.8	0	0.0	187	27.4	0	0.0					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
Ear and labyrinth disorders		3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders		4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders	Vertigo	1-2	187	37.8	0	0.0	187	27.4	0	0.0					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
Ear and labyrinth disorders	Vertigo	3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders	Vertigo	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders		1-2	187	37.8	1	0.5	187	27.4	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of hessian not positive definite.							
Eye disorders		3	196	39.4	1	0.5	196	27.6	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.							
Eye disorders		4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Angle closure glaucoma	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Angle closure glaucoma	3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Angle closure glaucoma	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Cataract	1-2	187	37.8	1	0.5	187	27.4	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of hessian not positive definite.							
Eye disorders	Cataract	3	196	39.4	1	0.5	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Cataract	4-5	112	22.6	1	0.9	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	1-2	187	37.8	1	0.5	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	3	196	39.4	1	0.5	196	27.6	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.							
Eye disorders	Rhegmatogenous retinal detachment	4-5	112	22.6	1	0.9	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders		1-2	187	37.8	8	4.3	187	27.4	10	5.3	0.79				Convergence criterion (ncon=16-8) satisfied.	0.33	2.07	<0.01	Algorithm converged.	-0.066	0.011	0.49	Algorithm converged.	0.80	3.66	0.4294		0.2456	1.25	0.70	2.14
Gastrointestinal disorders		3	196	39.4	14	10.7	196	27.6	10	5.1	2.11				Convergence criterion (ncon=16-8) satisfied.	0.97	4.61	0.000	Algorithm converged.	-0.066	0.011	1.34	Algorithm converged.	0.96	5.13	0.0634			2.10	0.96	4.59
Gastrointestinal disorders		4-5	112	22.6	11	9.8	125	25.6	10	8.0	1.21				Convergence criterion (ncon=16-8) satisfied.	0.57	2.57	0.003	Algorithm converged.	-0.066	0.011	0.49	Algorithm converged.	0.80	3.66	0.7448			1.23	0.57	2.65
Gastrointestinal disorders	Abdominal distension	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Abdominal distension	3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Abdominal distension	4-5	112	22.6	0	0.0	125	25.6	1	0.8					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		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Abdominal pain	1-2	187	37.8	3	1.6	187	27.4	2	1.0	1.64				Convergence criterion (ncon=16-8) satisfied.	0.31	8.69	0.011	Algorithm converged.	-0.093	0.013	2.35	Algorithm converged.	1.25	21.73	0.2923		0.7824	1.64	0.31	8.69
Gastrointestinal disorders	Abdominal pain	3	196	39.4	3	1.5	196	27.6	2	1.1	1.35				Convergence criterion (ncon=16-8) satisfied.	0.11	6.89	<0.001	Algorithm converged.	-0.093	0.013	2.35	Algorithm converged.	1.24	6.91	0.9681			1.35	0.33	7.49
Gastrointestinal disorders	Abdominal pain	4-5	112	22.6	3	2.7	125	25.6	2	1.6	1.53				Convergence criterion (ncon=16-8) satisfied.	0.31	1.10	<0.001	Algorithm converged.	-0.093	0.013	2.35	Algorithm converged.	1.25	21.73	0.2923			1.53	0.31	19.56
Gastrointestinal disorders	Abdominal pain upper	1-2	187	37.8	0	0.0	187	27.4	0	0.0					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
Gastrointestinal disorders	Abdominal pain upper	3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Abdominal pain upper	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Anal fistula	1-2	187	37.8	0	0.0	187	27.4	0	0.0					Quasi-complete separation of data points detected.				WARNING: Negative of hessian not positive definite.							
Gastrointestinal disorders	Anal fistula	3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Anal fistula	4-5	112	22.6	0	0.0	125	25.6	1	0.8					Quasi-complete separation of data points detected.				WARNING: Error in computing the link function, its derivatives, or the variance function.							
Gastrointestinal disorders	Anal stenosis	1-2	187	37.8	0	0.0	187	27.4	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Anal stenosis	3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Anal stenosis	4-5	112	22.6	0	0.0	125	25.6	1	0.8					Quasi-complete separation of data points detected.				WARNING: The relative mean convergence criterion of 16.31411281 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	Colitis	1-2	187	37.8	1	0.5	187	27.4	0	0.0	0.96	14.11	0.000		Convergence criterion (ncon=16-8) satisfied.	0.14	14.11	0.000	Algorithm converged.	-0.093	0.013	2.35	Algorithm converged.	1.04	14.11	0.9706			1.00	0.07	13.61
Gastrointestinal disorders	Colitis	3	196	39.4	0	0.0	196	27.6	0	0.0	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Colitis	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Constipation	1-2	187	37.8	3	1.6	187	27.4	3	1.6	1.03				Convergence criterion (ncon=16-8) satisfied.	0.04	14.11	0.000	Algorithm converged.	-0.066	0.011	1.49	Algorithm converged.	1.04	14.11	1.0000			1.03	0.21	14.11
Gastrointestinal disorders	Constipation	3	196	39.4	3	1.5	196	27.6	3	1.6					Quasi-complete separation of data points detected.				WARNING: Negative of hessian not positive definite.							
Gastrointestinal disorders	Constipation	4-5	112	22.6	0	0.0	125	25.6	1	0.8	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Diarrhoea	1-2	187	37.8	4	2.1	187	27.4	5	2.6	0.81				Convergence criterion (ncon=16-8) satisfied.	0.23	2.83	<0.01	Algorithm converged.	-0.039	0.007	0.25	Algorithm converged.	0.81	4.23	0.2139		0.0212	1.25	0.70	2.25
Gastrointestinal disorders	Diarrhoea	3	196	39.4	9	4.6	196	27.6	5

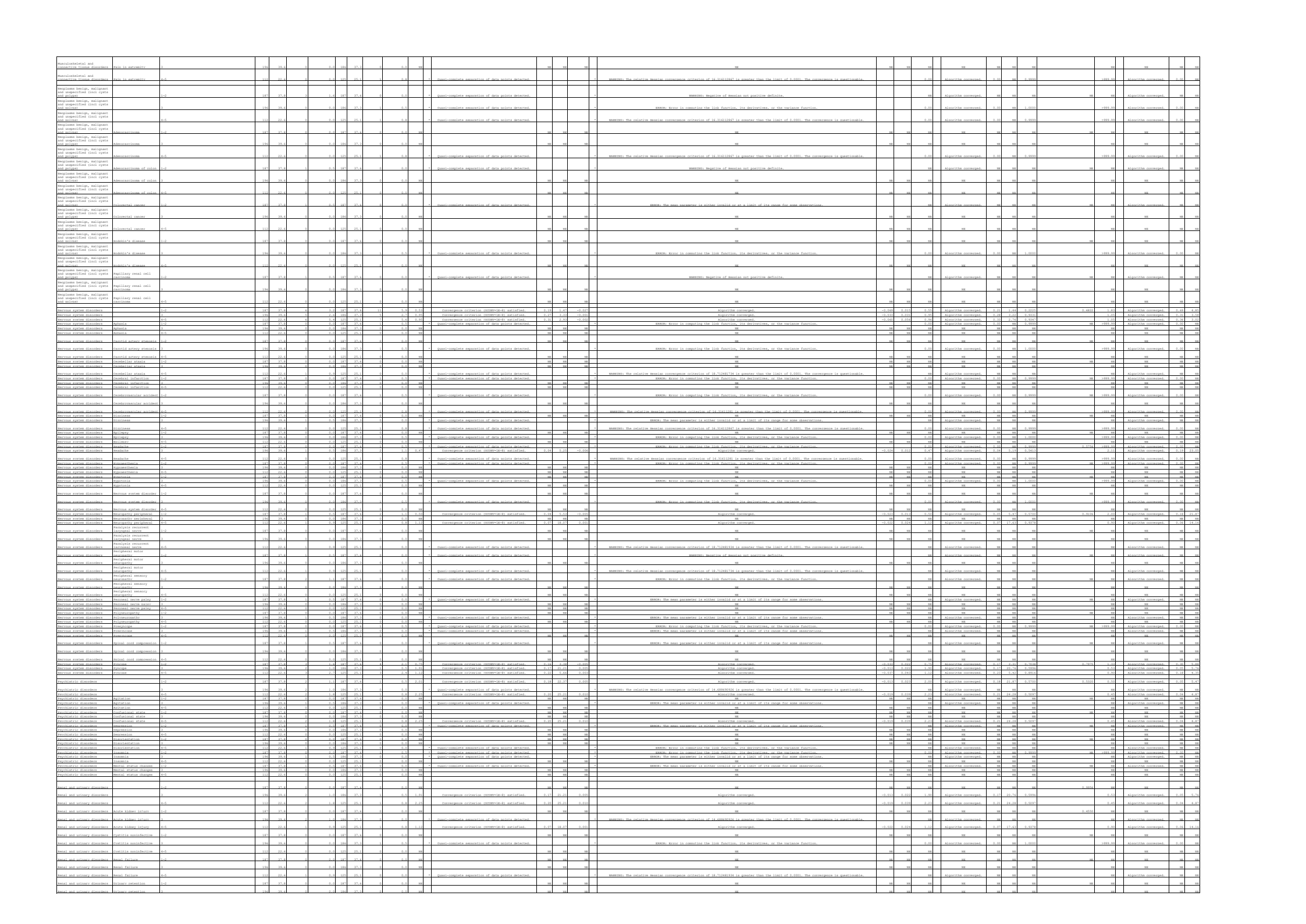












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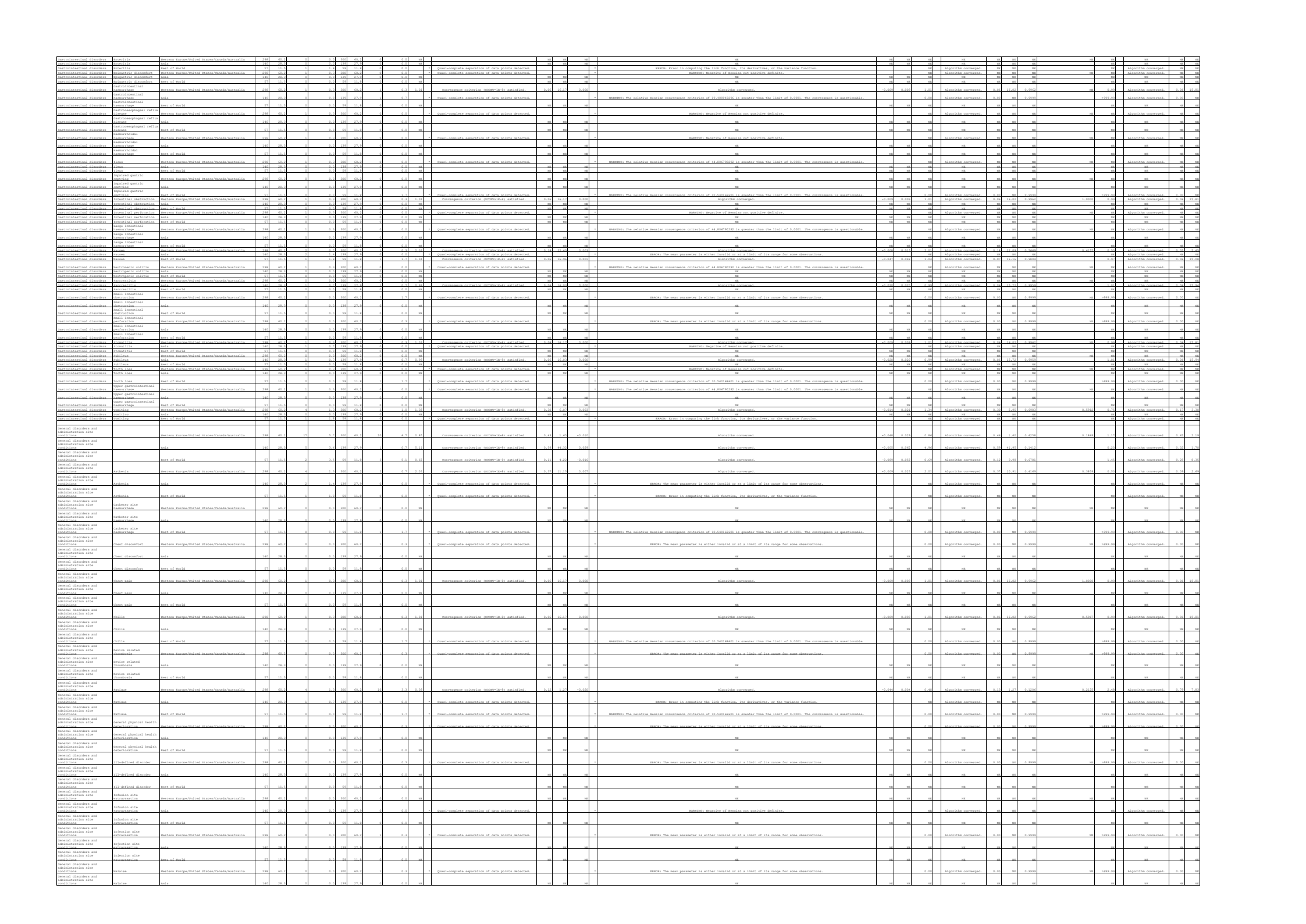
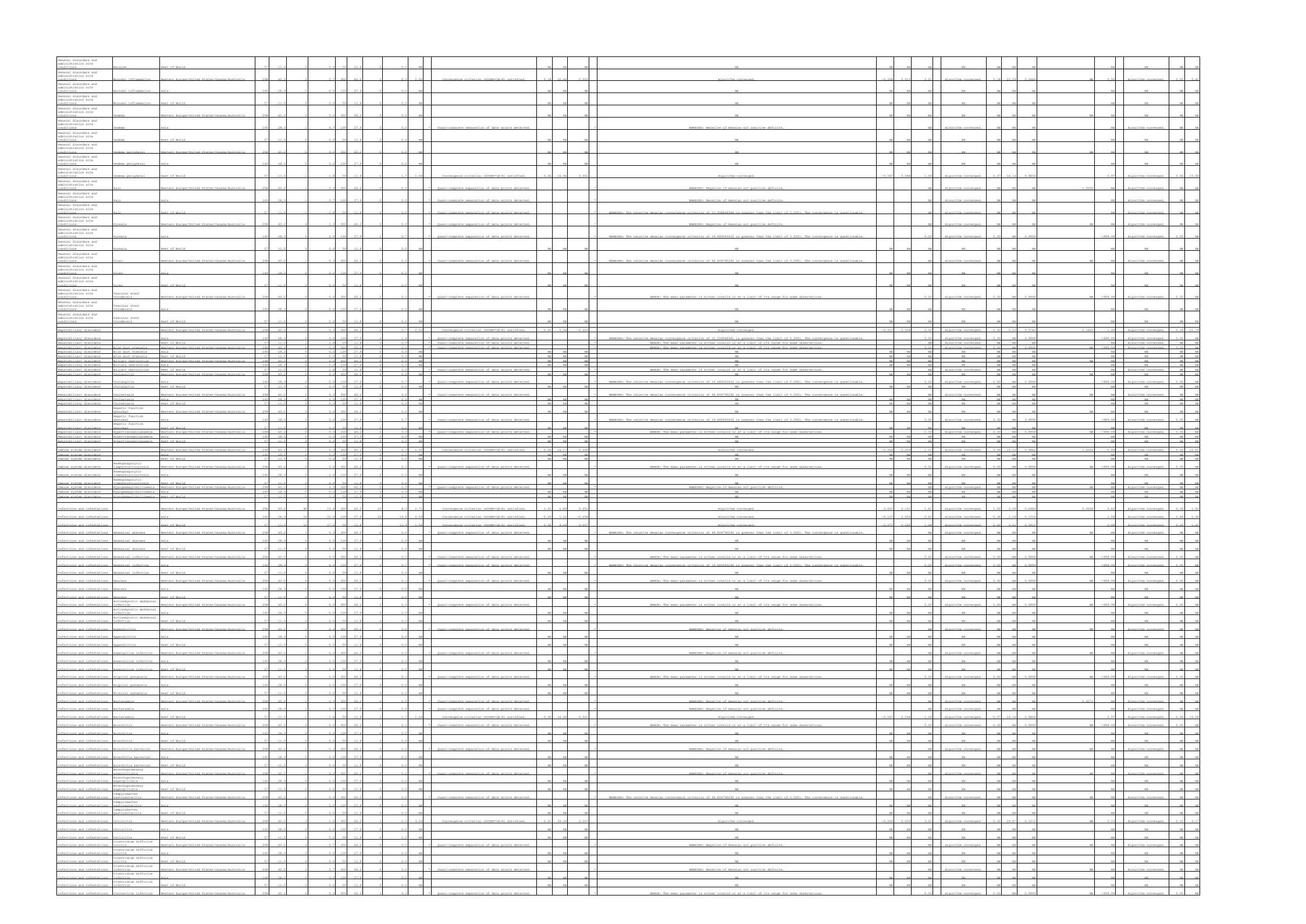
POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified Analysis
STUDY: BG39862
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Bictarvimab Vedotin + B-Cell (N=XXX)				B-Cell (N=XXX)				Bictarvimab Vedotin + B-CHP vs. B-Cell										Bictarvimab Vedotin + B-CHP vs. B-Cell							
			Patients		Patients with Event		Patients		Patients with Event		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		Western Europe/United States/Canada/Australia	298	60.2	98	22.1	300	60.2	47	15.7	1.53	Convergence criterion (HCONV<1E-8) satisfied.	1.03	2.32	0.064	Algorithm converged.	0.002	0.127	1.41	Algorithm converged.	1.06	1.88	0.0497	0.0415	0.71	Algorithm converged.	0.52	0.99
Blood and lymphatic system disorders		Asia	140	28.3	33	10.7	140	27.4	24	18.5	0.50	Convergence criterion (HCONV<1E-8) satisfied.	0.27	1.00	-0.078	Algorithm converged.	-0.169	0.003	0.61	Algorithm converged.	0.36	1.04	0.0651		0.58	Algorithm converged.	0.34	1.04
Blood and lymphatic system disorders		Rest of World	57	11.5	8	14.0	55	11.4	7	11.9	1.21	Convergence criterion (HCONV<1E-8) satisfied.	0.41	3.60	0.020	Algorithm converged.	-0.150	0.166	1.18	Algorithm converged.	0.46	3.00	0.7281		1.05	Algorithm converged.	0.31	2.16
Blood and lymphatic system disorders	Anaemia	Western Europe/United States/Canada/Australia	298	60.2	33	11.7	300	60.2	22	7.3	1.68	Convergence criterion (HCONV<1E-8) satisfied.	0.96	2.98	0.044	Algorithm converged.	-0.002	0.091	1.61	Algorithm converged.	0.96	2.66	0.0691	0.0849	1.62	Algorithm converged.	0.98	1.04
Blood and lymphatic system disorders	Anaemia	Asia	140	28.3	11	7.9	140	27.4	18	12.9	0.57	Convergence criterion (HCONV<1E-8) satisfied.	0.26	1.26	-0.051	Algorithm converged.	-0.152	0.001	0.61	Algorithm converged.	0.36	1.04	0.1693		1.06	Algorithm converged.	0.91	3.76
Blood and lymphatic system disorders	Anaemia	Rest of World	57	11.5	7	12.3	55	11.4	7	11.9	1.04	Convergence criterion (HCONV<1E-8) satisfied.	0.34	3.18	0.004	Algorithm converged.	-0.114	0.123	1.04	Algorithm converged.	0.36	2.74	0.9451		0.97	Algorithm converged.	0.34	2.58
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Western Europe/United States/Canada/Australia	298	60.2	3	0.8	300	60.2	1	0.3	1.04	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.17	0.005	Algorithm converged.	-0.009	0.009	1.41	Algorithm converged.	0.04	14.66	0.9861	1.0000	0.98	Algorithm converged.	0.06	15.64
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Asia	140	28.3	1	0.0	140	27.4	1	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Rest of World	57	11.5	2	0.0	55	11.4	2	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Febrile neutropenia	Western Europe/United States/Canada/Australia	298	60.2	32	9.4	300	60.2	12	4.0	2.48	Convergence criterion (HCONV<1E-8) satisfied.	1.26	4.90	0.054	Algorithm converged.	0.016	0.096	2.35	Algorithm converged.	1.26	4.33	0.0104	0.1207	2.40	Algorithm converged.	0.21	0.82
Blood and lymphatic system disorders	Febrile neutropenia	Asia	140	28.3	15	8.6	140	27.4	13	9.4	0.91	Convergence criterion (HCONV<1E-8) satisfied.	0.45	2.07	-0.008	Algorithm converged.	-0.095	0.065	0.91	Algorithm converged.	0.46	1.84	0.8139		1.06	Algorithm converged.	0.39	2.14
Blood and lymphatic system disorders	Febrile neutropenia	Rest of World	57	11.5	5	10.5	55	11.4	4	3.4	3.05	Convergence criterion (HCONV<1E-8) satisfied.	0.65	17.26	0.071	Algorithm converged.	-0.095	0.163	3.11	Algorithm converged.	0.65	14.73	0.1541		3.22	Algorithm converged.	0.37	1.52
Blood and lymphatic system disorders	Hypofibrinogenaemia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0.00		NE	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Hypofibrinogenaemia	Asia	140	28.3	0	0.0	140	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Hypofibrinogenaemia	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Leukopenia	Western Europe/United States/Canada/Australia	298	60.2	6	2.0	300	60.2	1	0.3	6.00	Convergence criterion (HCONV<1E-8) satisfied.	0.67	1.49	0.017	Algorithm converged.	-0.006	0.040	5.91	Algorithm converged.	0.83	5.45	0.1783	0.2811	5.98	Algorithm converged.	0.81	15.49
Blood and lymphatic system disorders	Leukopenia	Asia	140	28.3	8	5.7	140	27.4	14	10.1	0.56	Convergence criterion (HCONV<1E-8) satisfied.	0.22	1.43	-0.048	Algorithm converged.	-0.165	0.022	0.57	Algorithm converged.	0.25	1.31	0.1841		1.76	Algorithm converged.	0.74	4.03
Blood and lymphatic system disorders	Leukopenia	Rest of World	57	11.5	1	1.8	55	11.4	1	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 10.9988446954 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Lymphocytosis	Western Europe/United States/Canada/Australia	298	60.2	1	1.0	300	60.2	5	2.0	0.50	Convergence criterion (HCONV<1E-8) satisfied.	0.12	2.01	-0.010	Algorithm converged.	-0.095	0.010	0.50	Algorithm converged.	0.13	1.93	0.3284	0.2707	1.95	Algorithm converged.	0.52	7.34
Blood and lymphatic system disorders	Lymphocytosis	Asia	140	28.3	1	2.1	140	27.4	1	0.7	3.00	Convergence criterion (HCONV<1E-8) satisfied.	0.21	23.60	0.014	Algorithm converged.	-0.064	0.092	2.98	Algorithm converged.	0.31	28.93	0.4618		3.18	Algorithm converged.	0.04	3.14
Blood and lymphatic system disorders	Lymphopenia	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Myelosuppression	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Blood and lymphatic system disorders	Myelosuppression	Asia	140	28.3	1	0.7	140	27.4	1	0.7	0.99	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.01	0.000	Algorithm converged.	-0.093	0.093	0.99	Algorithm converged.	0.06	15.73	0.9954		1.01	Algorithm converged.	0.06	15.94
Blood and lymphatic system disorders	Myelosuppression	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Neutropenia	Western Europe/United States/Canada/Australia	298	60.2	28	9.4	300	60.2	31	10.0	0.93	Convergence criterion (HCONV<1E-8) satisfied.	0.54	1.60	-0.006	Algorithm converged.	-0.093	0.081	0.94	Algorithm converged.	0.56	1.53	0.8030	0.9200	0.95	Algorithm converged.	0.62	1.74
Blood and lymphatic system disorders	Neutropenia	Asia	140	28.3	7	5.0	140	27.4	9	6.5	0.76	Convergence criterion (HCONV<1E-8) satisfied.	0.28	2.10	-0.031	Algorithm converged.	-0.180	0.082	0.77	Algorithm converged.	0.30	2.02	0.5971		1.25	Algorithm converged.	0.52	3.24
Blood and lymphatic system disorders	Neutropenia	Rest of World	57	11.5	4	7.0	55	11.4	3	4.8	1.06	Convergence criterion (HCONV<1E-8) satisfied.	0.22	4.26	0.006	Algorithm converged.	-0.090	0.090	1.04	Algorithm converged.	0.27	3.94	0.9597		0.97	Algorithm converged.	0.23	3.68
Blood and lymphatic system disorders	Pancytopenia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 44.804796293 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Pancytopenia	Asia	140	28.3	0	0.0	140	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Pancytopenia	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Thrombocytopenia	Western Europe/United States/Canada/Australia	298	60.2	4	1.3	300	60.2	6	2.0	0.67	Convergence criterion (HCONV<1E-8) satisfied.	0.19	2.39	-0.007	Algorithm converged.	-0.087	0.054	0.67	Algorithm converged.	0.19	2.35	0.5334	0.9086	1.45	Algorithm converged.	0.42	5.23
Blood and lymphatic system disorders	Thrombocytopenia	Asia	140	28.3	4	1.4	140	27.4	4	1.4	0.98	Convergence criterion (HCONV<1E-8) satisfied.	0.24	7.05	0.000	Algorithm converged.	-0.099	0.099	0.99	Algorithm converged.	0.24	6.91	0.9941		1.01	Algorithm converged.	0.31	7.06
Blood and lymphatic system disorders	Thrombocytopenia	Rest of World	57	11.5	1	1.8	55	11.4	4	3.4	0.51	Convergence criterion (HCONV<1E-8) satisfied.	0.05	5.03	-0.016	Algorithm converged.	-0.074	0.041	0.53	Algorithm converged.	0.06	4.64	0.5863		0.52	Algorithm converged.	0.14	20.17
Cardiac disorders		Western Europe/United States/Canada/Australia	298	60.2	5	1.7	300	60.2	3	1.0	1.69	Convergence criterion (HCONV<1E-8) satisfied.	0.40	7.14	0.007	Algorithm converged.	-0.053	0.067	1.68	Algorithm converged.	0.40	6.94	0.4753	0.3240	1.60	Algorithm converged.	0.19	7.43
Cardiac disorders		Asia	140	28.3	4	2.9	140	27.4	2	1.4	2.15	Convergence criterion (HCONV<1E-8) satisfied.	0.39	11.91	0.015	Algorithm converged.	-0.047	0.078	2.13	Algorithm converged.	0.43	10.57	0.3003		2.10	Algorithm converged.	0.47	9.43
Cardiac disorders		Rest of World	57	11.5	0	0.0	55	11.4	1	1.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 10.5451484655 is greater than the limit of 0.0001. The convergence is questionable.	0.00		NE	Algorithm converged.	0.00	NE	0.9994		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	3	1.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Atrial fibrillation	Asia	140	28.3	0	0.0	140	27.4	1	0.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 19.480364343 is greater than the limit of 0.0001. The convergence is questionable.	0.00		NE	Algorithm converged.	0.00	NE	0.9994		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Cardiac failure congestive	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	2	0.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0.00		NE	Algorithm converged.	0.00	NE	0.9994	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Cardiac failure congestive	Asia	140	28.3	0	0.0	140	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Cardiac failure congestive	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Cardiomyopathy failure	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 44.804796293 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Cardiopulmonary failure	Asia	140	28.3	0	0.0	140	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Cardiopulmonary failure	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Left ventricular dysfunction	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	Algorithm converged.	-0.000	0.000	1.41	Algorithm converged.	0.06	14.01	0.9943	1.0000	0.99	Algorithm converged.	0.06	15.41
Cardiac disorders	Left ventricular dysfunction	Asia	140	28.3	0	0.0	140	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Left ventricular dysfunction	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Myocardial infarction	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Myocardial infarction	Asia	140	28.3	0	0.0	140	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Myocardial infarction	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Sinus bradycardia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Cardiac disorders	Sinus bradycardia	Asia	140	28.3	0	0.0	140	27.4	1	0.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 19.480364343 is greater than the limit of 0.0001. The convergence is questionable.	0.00		NE	Algorithm converged.	0.00	NE	0.9994		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Sinus bradycardia	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Sinus tachycardia	Western Europe/United States/Canada/Australia	298	60.2	2	0.7	300	60.2	0	0.0	5.00	Convergence criterion (HCONV<1E-8) satisfied.	0.24	16.67	0.020	Algorithm converged.	-0.018	0.058	4.97	Algorithm converged.	0.24	16.23	0.9963		5.09	Algorithm converged.	0.24	16.23
Cardiac disorders	Sinus tachycardia	Asia	140	28.3	2	0.7	140	27.4	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: Error in computing the 11th function, its derivatives, or the variance function.	NE	NE	NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Cardiac disorders	Sinus tachycardia	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Tachycardia	Western Europe/United States/Canada/Australia	298	60.2	2	0.7	300	60.2	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Cardiac disorders	Tachycardia	Asia	140	28.3	2	0.9	140	27.4	1	0.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 19.480364343 is greater than the limit of 0.0001. The convergence is questionable.	0.00		NE	Algorithm converged.	0.00	NE	0.9994		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Tachycardia	Rest of World	57	11.5	0	0.0	55	11.4	1	1.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 10.5451484655 is greater than the limit of 0.0001. The convergence is questionable.	0.00		NE	Algorithm converged.	0.00	NE	0.9994		>999.99	Algorithm converged.	0.00	NE
Congenital, familial and genetic disorders		Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Congenital, familial and genetic disorders		Asia	140	28.3	0	0.0	140	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Congenital, familial and genetic disorders		Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Congenital, familial and genetic disorders	Pyloric stenosis	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Congenital, familial and genetic disorders	Pyloric stenosis	Asia	140	28.3	0	0.0	140	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Congenital, familial and genetic disorders	Pyloric stenosis	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Ear and labyrinth disorders		Western Europe/United States/Canada/Australia	298	60.2	2	0.9	300	60.2	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0.00		NE	Algorithm converged.	0.00	NE	0.9994	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders		Asia	140	28.3	2	0.9	140	27.4	1	0.7	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Ear and labyrinth disorders		Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Ear and labyrinth disorders	Hypoacusis	Western Europe/United States/Canada/Australia	298	60.2	2	0.9	300	60.2	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	0.00		NE	Algorithm converged.	0.00	NE	0.9994	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Hypoacusis	Asia	140	28.3	2	0.9	140	27.4	1	0.7	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Ear and labyrinth disorders	Hypoacusis	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Eye disorders		Western Europe/United States/Canada/Australia	298	60.2	3	0.9	300	60.2	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders		Asia	140	28.3	2	1.4	140	27.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders		Rest of World	57	11.5	1	1.8	55	11.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Angle closure glaucoma	Western Europe/United States/Canada/Australia	298	60.2	2	0.7	300	60.2	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Angle closure glaucoma	Asia	140	28.3	1	0.7	140	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Eye disorders	Angle closure glaucoma	Rest of World	57	11.5	1	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Eye disorders	Cataract	Western Europe/United States/Canada/Australia	298	60.2	2	0.7	300	60.2	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Cataract	Asia	140	28.3	2	0.7	140	27.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Eye disorders	Cataract	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Eye disorders	Rhegmatogenous retinal detachment	Western Europe/United States/Canada/Australia	298	60.2	2	0.9	300	60.2	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Eye disorders	Rhegmatogenous retinal detachment	Asia	140	28.3	1	0.7	140	27.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	Rest of World	57	11.5	1	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders		Western Europe/United States/Canada/Australia	298	60.2	19	6.4	300	60.2	2	0.7	9.14	Convergence criterion (HCONV<1E-8) satisfied.	2.04	40.97	0.057	Algorithm converged.	0.017	0.097	9.11	Algorithm converged.	2.04	40.71	0.0037	0.1894	9.17	Algorithm converged.	1.97	42.71
Gastrointestinal disorders		Asia	140	28.3	14	9.9	140	27.4	1	0.7	15.00	Convergence criterion (HCONV<1E-8) satisfied.	1.91	117.91	0.092	Convergence criterion (HCONV<1E-8) satisfied.	0.004	0.180	14.93	Algorithm converged.	1.91	116.74	0.0010		14.99	Algorithm converged.	1.91	117.74
Gastrointestinal disorders		Rest of World	57	11.5	7	12.3	55	11.4	1	1.7	7.64	Convergence criterion (HCONV<1E-8) satisfied.	0.91	64.11	0.106	Convergence criterion (HCONV<1E-8) satisfied.	0.013	0.199	7.41	Algorithm converged.	0.91	60.23	0.0063		7.51	Algorithm converged.	0.91	61.23
Gastrointestinal disorders	Abdominal distension	Western Europe/United States/Canada/Australia	298	60.2	3	1.0	300	60.2	1	0.3	3.03	Convergence criterion (HCONV<1E-8) satisfied.	0.31	29.73	0.007	Algorithm converged.	-0.004	0.018	3.01	Algorithm converged.	0.31	29.31	0.3181		3.01	Algorithm converged.	0.31	29.31
Gastrointestinal disorders	Abdominal distension	Asia	140	28.3	0	0.0	140	27.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	>999.99	Algorithm converged.	NE	NE
Gastrointestinal disorders	Abdominal distension	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Abdominal pain	Western Europe/United States/Canada/Australia	298	60.2	5	1.0	300	60.2	2	0.7	2.53	Convergence criterion (HCONV<1E-8) satisfied.	0.23	2.01	-0.010	Algorithm converged.	-0.029	0.013	2.52	Algorithm converged.	0.23	1.93	0.3284	0.2201	1.95	Algorithm converged.	0.52	7.34
Gastrointestinal disorders	Abdominal pain	Asia	140	28.3	0	0.0	140	27.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 19.480364228 is greater than the limit of 0.0001. The convergence is questionable.	0.00		NE	Algorithm converged.	0.00	NE	0.9994		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Abdominal pain	Rest of World	57	11.5	0	0.0	55	11.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 10.9988446954 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Abdominal pain upper	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	>999.99	Algorithm converged.	NE	NE
Gastrointestinal disorders	Abdominal pain upper	Asia	140	28.3	0





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* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/mo5541077/CDP7884/mo39942/data_analysis/ACK_FINAL_DS/prod/program/t_ae_raw_soc.sas
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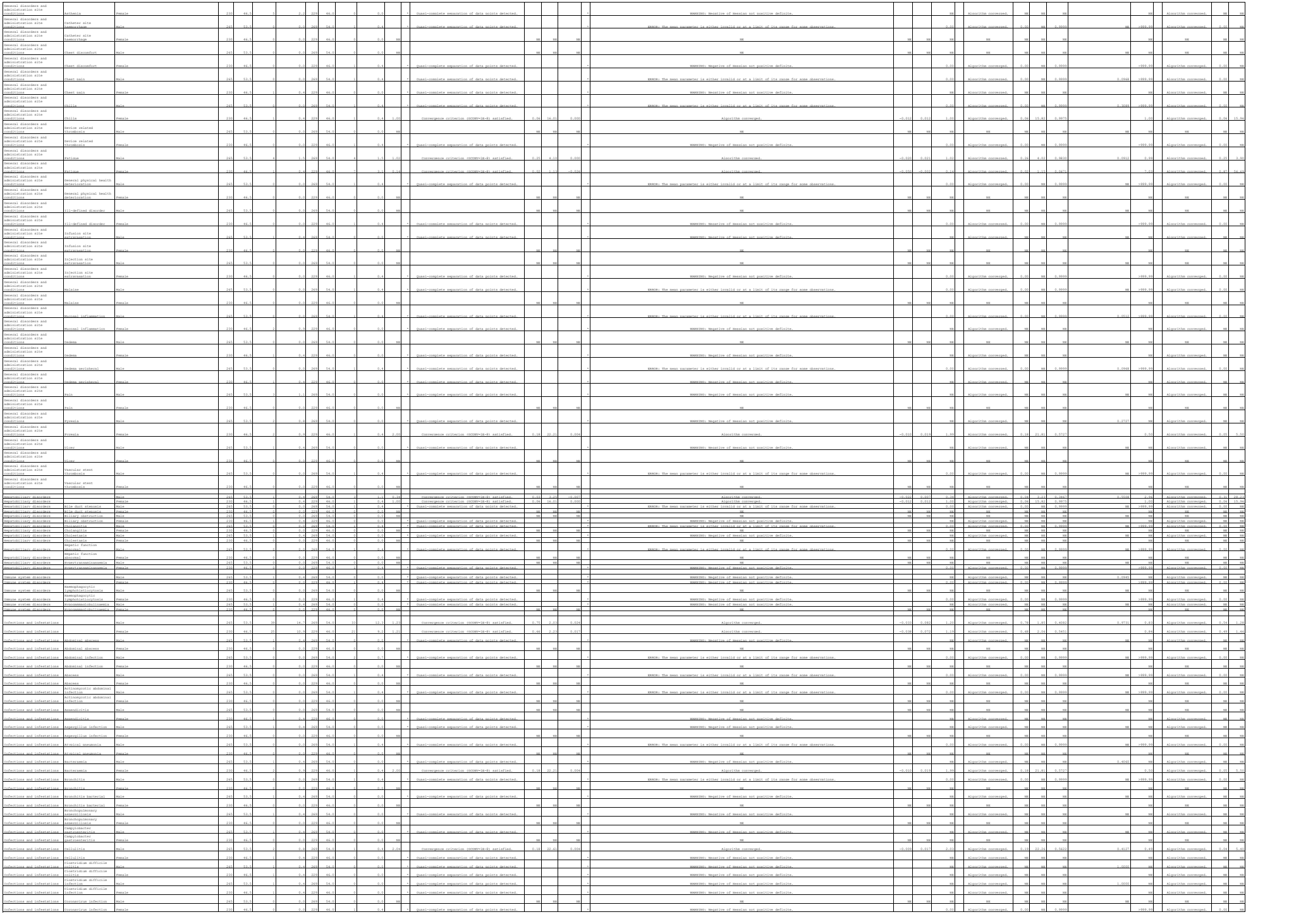
08MAR2023 18:19

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 3
MODEL: Unstratified Analysis
STRUC: SS39862
Dichotomous Analysis by Subgroups (Safety)

Prep

			Ociliroseph Tablets + R-Cop (N=245)				R-Cop (N=230)				Ociliroseph Tablets + R-CHP vs. R-Cop							R-Cop vs. Ociliroseph Tablets + R-CHP			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference			Relative Risk				Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Result	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Result	95% Lower CL	95% Upper CL	Relative Risk	Convergence Result	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		Male	245	53.9	93	18.9	265	54.2	39	14.5	1.38	Convergence criterion (GCONV=1E-8) satisfied.	0.84	2.32	0.040	Algorithm converged.	-0.053	0.133	1.24	Algorithm converged.	0.47	1.47	0.2154	0.3804	0.78	Algorithm converged.	0.53	1.14
Blood and lymphatic system disorders		Female	230	46.9	85	17.6	265	54.2	46	17.5	0.98	Convergence criterion (GCONV=1E-8) satisfied.	0.63	1.51	-0.000	Algorithm converged.	-0.078	0.065	1.00	Algorithm converged.	0.47	1.48	0.9824		1.00	Algorithm converged.	0.67	1.50
Blood and lymphatic system disorders	Anaemia	Male	245	53.9	33	8.9	265	54.2	20	7.4	1.13	Convergence criterion (GCONV=1E-8) satisfied.	0.60	2.10	0.006	Algorithm converged.	-0.037	0.064	1.12	Algorithm converged.	0.46	2.00	0.7101	0.9514	1.06	Algorithm converged.	0.52	1.42
Blood and lymphatic system disorders	Anaemia	Female	230	46.9	57	13.5	265	54.2	37	11.8	1.17	Convergence criterion (GCONV=1E-8) satisfied.	0.67	2.02	0.017	Algorithm converged.	-0.044	0.078	1.14	Algorithm converged.	0.71	1.83	0.5867		1.07	Algorithm converged.	0.74	1.42
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Male	245	53.9	1	0.4	265	54.2	1	0.3		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	0.5940	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Female	230	46.9	1	0.9	265	54.2	1	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			2.00	Algorithm converged.	0.66	NE	0.9999	>999.99	2.00	Algorithm converged.	0.70	NE
Blood and lymphatic system disorders	Febrile neutropenia	Male	245	53.9	44	9.8	265	54.2	24	9.0	1.12	Convergence criterion (GCONV=1E-8) satisfied.	0.66	2.03	0.038	Algorithm converged.	-0.045	0.085	1.11	Algorithm converged.	0.46	2.66	0.7811	0.8847	1.04	Algorithm converged.	0.51	1.13
Blood and lymphatic system disorders	Febrile neutropenia	Female	230	46.9	55	8.7	265	54.2	31	6.8	1.28	Convergence criterion (GCONV=1E-8) satisfied.	0.88	4.03	0.038	Algorithm converged.	-0.045	0.085	1.41	Algorithm converged.	0.88	3.45	0.1024		1.35	Algorithm converged.	0.97	1.13
Blood and lymphatic system disorders	Hypofibrinogenaemia	Male	245	53.9	1	0.9	265	54.2	1	0.4		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	0.00	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Hypofibrinogenaemia	Female	230	46.9	1	0.9	265	54.2	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Leukopenia	Male	245	53.9	23	2.3	265	54.2	10	3.7	0.62	Convergence criterion (GCONV=1E-8) satisfied.	0.29	1.48	-0.016	Algorithm converged.	-0.149	0.043	0.63	Algorithm converged.	0.26	1.43	0.3001	0.7856	1.46	Algorithm converged.	0.81	4.44
Blood and lymphatic system disorders	Leukopenia	Female	230	46.9	10	2.2	265	54.2	11	4.4	0.49	Convergence criterion (GCONV=1E-8) satisfied.	0.16	1.45	-0.020	Algorithm converged.	-0.094	0.041	0.50	Algorithm converged.	0.17	1.43	0.1462		2.01	Algorithm converged.	0.72	5.72
Blood and lymphatic system disorders	Lymphopenia	Male	245	53.9	5	1.9	265	54.2	4	1.5	1.27	Convergence criterion (GCONV=1E-8) satisfied.	0.34	4.85	0.006	Algorithm converged.	-0.038	0.050	1.27	Algorithm converged.	0.34	4.73	0.7206	0.2686	0.79	Algorithm converged.	0.21	2.99
Blood and lymphatic system disorders	Lymphopenia	Female	230	46.9	3	0.4	265	54.2	1	1.3	0.33	Convergence criterion (GCONV=1E-8) satisfied.	0.03	3.19	-0.008	Algorithm converged.	-0.094	0.068	0.19	Algorithm converged.	0.03	3.17	0.3078		0.21	Algorithm converged.	0.32	28.72
Blood and lymphatic system disorders	Myelosuppression	Male	245	53.9	1	0.4	265	54.2	1	0.4	1.02	Convergence criterion (GCONV=1E-8) satisfied.	0.06	16.25	0.000	Algorithm converged.	-0.045	0.045	1.02	Algorithm converged.	0.06	16.14	0.9815	1.0000	0.98	Algorithm converged.	0.06	15.42
Blood and lymphatic system disorders	Myelosuppression	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Male	245	53.9	22	8.2	265	54.2	23	8.6	0.97	Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.79	-0.006	Algorithm converged.	-0.095	0.060	0.97	Algorithm converged.	0.55	1.73	0.9178	0.7470	1.03	Algorithm converged.	0.59	1.80
Blood and lymphatic system disorders	Neutropenia	Female	230	46.9	17	7.4	265	54.2	26	9.7	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.42	1.64	-0.016	Algorithm converged.	-0.095	0.036	0.87	Algorithm converged.	0.46	1.63	0.5973		1.18	Algorithm converged.	0.64	2.20
Blood and lymphatic system disorders	Pancytopenia	Male	245	53.9	1	0.4	265	54.2	1	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	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Thrombocytopenia	Male	245	53.9	3	1.1	265	54.2	4	1.5	0.74	Convergence criterion (GCONV=1E-8) satisfied.	0.17	3.40	-0.006	Algorithm converged.	-0.093	0.053	0.76	Algorithm converged.	0.17	3.37	0.7192	0.4601	1.31	Algorithm converged.	0.32	5.83
Blood and lymphatic system disorders	Thrombocytopenia	Female	230	46.9	6	1.7	265	54.2	6	2.6	0.66	Convergence criterion (GCONV=1E-8) satisfied.	0.24	2.06	-0.009	Algorithm converged.	-0.096	0.053	0.66	Algorithm converged.	0.24	2.02	0.5211		1.51	Algorithm converged.	0.42	5.27
Cardiac disorders		Male	245	53.9	2	0.8	265	54.2	3	1.1	0.82	Convergence criterion (GCONV=1E-8) satisfied.	0.11	4.87	-0.004	Algorithm converged.	-0.085	0.053	0.82	Algorithm converged.	0.11	4.83	0.8474	0.5650	1.45	Algorithm converged.	0.23	9.73
Cardiac disorders		Female	230	46.9	4	1.7	265	54.2	3	1.3	1.23	Convergence criterion (GCONV=1E-8) satisfied.	0.25	6.03	0.008	Convergence criterion (GCONV=1E-8) satisfied.	-0.049	0.067	1.23	Algorithm converged.	0.25	6.00	0.7283		2.23	Algorithm converged.	0.27	18.52
Cardiac disorders	Atrial fibrillation	Male	245	53.9	0	0.0	265	54.2	1	0.4		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	0.00	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	Female	230	46.9	0	0.0	265	54.2	1	0.8		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 congestive	Male	245	53.9	1	0.4	265	54.2	2	0.7		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	0.00	Algorithm converged.	0.00	NE
Cardiac disorders	Cardiac failure congestive	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Cardiomyopathy failure	Male	245	53.9	1	0.4	265	54.2	1	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	Cardiomyopathy failure	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Left ventricular dysfunction	Male	245	53.9	1	0.4	265	54.2	1	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	0.0940	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Left ventricular dysfunction	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Myocardial infarction	Male	245	53.9	0	0.0	265	54.2	1	0.3	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Myocardial infarction	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Sinus bradycardia	Male	245	53.9	1	0.4	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Sinus bradycardia	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Sinus tachycardia	Male	245	53.9	1	0.4	265	54.2	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	Sinus tachycardia	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Tachycardia	Male	245	53.9	1	0.4	265	54.2	1	0.4		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			1.00	Algorithm converged.	0.00	NE	0.9999	>999.99	1.00	Algorithm converged.	0.00	NE
Cardiac disorders	Tachycardia	Female	230	46.9	0	0.0	265	54.2	1	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	>999.99	NE	Algorithm converged.	NE	NE
Congenital, familial and genetic disorders		Male	245	53.9	1	0.4	265	54.2	1	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		Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Congenital, familial and genetic disorders	Pyloric stenosis	Male	245	53.9	1	0.4	265	54.2	1	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	Pyloric stenosis	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Ear and labyrinth disorders		Male	245	53.9	1	0.0	265	54.2	1	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Ear and labyrinth disorders		Female	230	46.9	1	0.0	265	54.2	1	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	>999.99	0.00	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Hypoacusis	Male	245	53.9	1	0.0	265	54.2	1	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Ear and labyrinth disorders	Hypoacusis	Female	230	46.9	1	0.0	265	54.2	1	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	>999.99	0.00	Algorithm converged.	0.00	NE
Eye disorders		Male	245	53.9	1	0.0	265	54.2	1	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
Eye disorders		Female	230	46.9	1	0.0	265	54.2	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	0.0000	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Acute closure glaucoma	Male	245	53.9	0	0.0	265	54.2	1	0.3	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Acute closure glaucoma	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Cataract	Male	245	53.9	1	0.4	265	54.2	1	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
Eye disorders	Cataract	Female	230	46.9	0	0.0	265	54.2	1	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	Male	245	53.9	1	0.4	265	54.2	1	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
Eye disorders	Rhegmatogenous retinal detachment	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders		Male	245	53.9	24	8.2	265	54.2	14	5.2	1.61	Convergence criterion (GCONV=1E-8) satisfied.	0.82	3.26	0.030	Algorithm converged.	-0.055	0.082	1.54	Algorithm converged.	0.92	3.23	0.0893	0.1227	0.57	Algorithm converged.	0.30	1.09
Gastrointestinal disorders		Female	230	46.9	16	7.0	265	54.2	13	4.9	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.67	3.05	0.021	Convergence criterion (GCONV=1E-8) satisfied.	-0.047	0.089	1.42	Algorithm converged.	0.67	3.02	0.3257		0.70	Algorithm converged.	0.33	1.52
Gastrointestinal disorders	Abdominal distension	Male	245	53.9	0	0.0	265	54.2	1	0.3	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Abdominal distension	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Abdominal pain	Male	245	53.9	3	0.4	265	54.2	1	1.1	0.47	Convergence criterion (GCONV=1E-8) satisfied.	0.05	4.67	-0.024	Algorithm converged.	-0.149	0.013	0.48	Algorithm converged.	0.05	4.65	0.4674	0.4046	1.48	Algorithm converged.	0.20	8.13
Gastrointestinal disorders	Abdominal pain	Female	230	46.9	4	1.7	265	54.2	2	0.8	2.17	Convergence criterion (GCONV=1E-8) satisfied.	0.38	12.37	0.009	Convergence criterion (GCONV=1E-8) satisfied.	-0.040	0.058	2.13	Algorithm converged.	0.38	12.03	0.3178		2.73	Algorithm converged.	0.61	12.19
Gastrointestinal disorders	Abdominal pain upper	Male	245	53.9	0	0.0	265	54.2	1	0.3	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Abdominal pain upper	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Anal fistula	Male	245	53.9	1	0.4	265	54.2	1	0.4	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.06	16.01	0.000	Algorithm converged.	-0.045	0.045	1.00	Algorithm converged.	0.06	15.94	0.9911	1.0000	0.98	Algorithm converged.	0.06	15.49
Gastrointestinal disorders	Anal fistula	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Anal stenosis	Male	245	53.9	0	0.0	265	54.2	1	0.4	NE		NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	Algorithm converged.	NE	NE	NE	>999.99	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Anal stenosis	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Ascites	Male	245	53.9	1	0.4	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	0.0000	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Colitis	Female	230	46.9	1	0.4	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Constipation	Male	245	53.9	4	1.4	265	54.2	2	0.8	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.24	4.20	0.000	Convergence criterion (GCONV=1E-8) satisfied.	-0.040	0.040	1.00	Algorithm converged.	0.24	4.17	0.9971	0.1220	1.75	Algorithm converged.	0.39	7.78
Gastrointestinal disorders	Constipation	Female	230	46.9	1	0.4	265	54.2	1	0.4	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.06	16.01	0.000	Algorithm converged.	-0.045	0.045	1.00	Algorithm converged.	0.06	15.94	0.9971		1.00	Algorithm converged.	0.06	15.49
Gastrointestinal disorders	Diarrhoea	Male	245	53.9	7	2.4	265	54.2	4	1.5	1.58	Convergence criterion (GCONV=1E-8) satisfied.	0.47	5.33	0.009	Convergence criterion (GCONV=1E-8) satisfied.	-0.031	0.049	1.57	Algorithm converged.	0.47	5.30	0.4712	0.0881	2.12	Algorithm converged.	0.72	6.23
Gastrointestinal disorders	Diarrhoea	Female	230	46.9	10	4.4	265	54.2	3	1.1	4.06	Convergence criterion (GCONV=1E-8) satisfied.	1.15	14.31	0.033	Convergence criterion (GCONV=1E-8) satisfied.	-0.016	0.083	4.00	Algorithm converged.	1.15	13.83	0.0315		3.70	Algorithm converged.	1.08	12.68
Gastrointestinal disorders	Dyspepsia	Male	245	53.9	1	0.0	265	54.2	1	0.4		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	0.00	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Dyspepsia	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Enteritis	Male	245	53.9	1	0.4	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Enteritis	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Faecaloma	Male	245	53.9	1	0.4	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Faecaloma	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Faecal incontinence	Male	245	53.9	1	0.4	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Faecal incontinence	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Gastritis	Male	245	53.9	1	0.4	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Gastritis	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	Male	245	53.9	1	0.4	265	54.2	0	0.0	NE		NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.	NE	NE	NE	Algorithm converged.	NE	NE	0.0940	>999.99	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	Female	230	46.9	1	0.4	265	54.2	1	0.4	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.06	16.01	0.000	Algorithm converged.	-0.045	0.045	1.00	Algorithm converged.	0.06	15.94	0.9971		1.00	Algorithm converged.	0.06	15.49
Gastrointestinal disorders	Gastrooesophageal reflux disease	Male	245	53.9	1	0.4	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Gastrooesophageal reflux disease	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Haemorrhoidal haemorrhage	Male	245	53.9	1	0.4	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Haemorrhoidal haemorrhage	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Ileus	Male	245	53.9	1	0.4	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Ileus	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Impaired gastric emptying	Male	245	53.9	1	0.0	265	54.2	1	0.4		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	0.00	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Impaired gastric emptying	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Intestinal obstruction	Male	245	53.9	1	0.4	265	54.2	1	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	Intestinal obstruction	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	0.0000	>999.99	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Intestinal perforation	Male	245	53.9	0	0.0	265	54.2	1	0.3	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Intestinal perforation	Female	230	46.9	0	0.0	265	54.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Large intestinal haemorrhage	Male	245	53.9	1	0.4	265	54.2	0	0.0		Quas



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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified Analysis
ANOX: BO39942
Dichotomous Analysis by Subgroups (Safety)

All

			Pulvinerumab Vehicle + B-Cov (N=493)				B-Cov (N=496)				Pulvinerumab Vehicle + B-Cov vs. B-Cov																		B-Cov vs. Pulvinerumab Vehicle + B-Cov			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio								Absolute Risk Difference										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	495	100.0	169	22.6	496	100.0	112	22.5	0.97	Convergence criterion (NCONV=1E-6) satisfied.	0.72	1.31	-0.006	Algorithm converged.	-0.056	0.045	0.96	Algorithm converged.	0.79	1.24	0.8588		1.02	Algorithm converged.	0.81	1.29
Blood and lymphatic system disorders	Anaemia	n/a	495	100.0	3	0.6	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.			0.99		999.99	Algorithm converged.	999.99	NE
Blood and lymphatic system disorders	Anaemia	n/a	495	100.0	3	0.6	496	100.0	1	0.2	3.02	Convergence criterion (NCONV=1E-6) satisfied.	0.32	29.16	0.004	Algorithm converged.	-0.004	0.012	3.02	Algorithm converged.	0.32	28.47	0.3380		3.02	Algorithm converged.	0.03	3.17
Blood and lymphatic system disorders	Aplasia pure red cell	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.00	Convergence criterion (NCONV=1E-6) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.01	0.9944		1.00	Algorithm converged.	0.06	15.85
Blood and lymphatic system disorders	Cytopenia	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.				Algorithm converged.			NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Febrile neutropenia	n/a	495	100.0	14	2.8	496	100.0	10	2.0	1.42	Convergence criterion (NCONV=1E-6) satisfied.	0.59	3.43	0.014	Algorithm converged.	-0.009	0.045	1.42	Algorithm converged.	0.73	2.80	0.4185		1.41	Algorithm converged.	0.49	1.27
Blood and lymphatic system disorders	Leukopenia	n/a	495	100.0	19	3.8	496	100.0	17	3.4	1.13	Convergence criterion (NCONV=1E-6) satisfied.	0.58	2.20	0.004	Algorithm converged.	-0.035	0.026	1.12	Algorithm converged.	0.63	2.16	0.7205		1.12	Algorithm converged.	0.47	1.49
Blood and lymphatic system disorders	Lymphopenia	n/a	495	100.0	2	0.4	496	100.0	3	0.6	0.67	Convergence criterion (NCONV=1E-6) satisfied.	0.11	4.02	-0.002	Algorithm converged.	-0.031	0.027	0.67	Algorithm converged.	0.11	4.00	0.6629		1.93	Algorithm converged.	0.25	5.88
Blood and lymphatic system disorders	Myelosuppression	n/a	495	100.0	0	0.0	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 21.631667499 is greater than the limit of 0.0001. The convergence is questionable.							NE		NE		NE	NE
Blood and lymphatic system disorders	Neutropenia	n/a	495	100.0	88	17.8	496	100.0	80	19.5	0.88	Convergence criterion (NCONV=1E-6) satisfied.	0.65	1.20	-0.017	Algorithm converged.	-0.085	0.031	0.91	Algorithm converged.	0.73	1.14	0.4917		1.16	Algorithm converged.	0.84	1.62
Blood and lymphatic system disorders	Thrombocytopenia	n/a	495	100.0	9	1.8	496	100.0	10	2.0	0.90	Convergence criterion (NCONV=1E-6) satisfied.	0.36	2.24	-0.002	Algorithm converged.	-0.039	0.035	0.90	Algorithm converged.	0.47	2.21	0.8272		1.10	Algorithm converged.	0.45	2.69
Cardiac disorders		n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders		n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Deafness	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders		n/a	495	100.0	4	0.8	496	100.0	7	1.4	0.57	Convergence criterion (NCONV=1E-6) satisfied.	0.17	1.90	-0.006	Algorithm converged.	-0.024	0.007	0.57	Algorithm converged.	0.17	1.90	0.3747		1.70	Algorithm converged.	0.51	1.90
Gastrointestinal disorders	Constipation	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Gastric ulcer	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.00	Convergence criterion (NCONV=1E-6) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.01	0.9944		1.00	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Ileus	n/a	495	100.0	0	0.0	496	100.0	2	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Intestinal perforation	n/a	495	100.0	1	0.2	496	100.0	3	0.6	0.33	Convergence criterion (NCONV=1E-6) satisfied.	0.03	3.42	0.002	Algorithm converged.	-0.004	0.002	0.33	Algorithm converged.	0.03	3.42	0.3304		0.33	Algorithm converged.	0.06	1.83
Gastrointestinal disorders	Intra-abdominal haemorrhage	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Necrotising colitis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Obstruction gastric	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Pancreatic disorder	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Stomatitis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Pyrexia	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Cholecystitis acute	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Infections and infestations		n/a	495	100.0	6	1.2	496	100.0	6	1.2	1.00	Convergence criterion (NCONV=1E-6) satisfied.	0.32	3.14	0.000	Algorithm converged.	-0.024	0.024	1.00	Algorithm converged.	0.33	3.10	0.9916		1.00	Algorithm converged.	0.32	3.06
Infections and infestations	Cytomegalovirus enteritis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Cytomegalovirus infection	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.00	Convergence criterion (NCONV=1E-6) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.01	0.9944		1.00	Algorithm converged.	0.06	15.85
Infections and infestations	Escherichia bacteraemia	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Infections and infestations	Escherichia infection	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Escherichia sepsis	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Infections and infestations	Klebsiella sepsis	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Infections and infestations	Neutropenic sepsis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Pneumonia	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.00	Convergence criterion (NCONV=1E-6) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.01	0.9944		1.00	Algorithm converged.	0.06	15.85
Infections and infestations	Sepsis	n/a	495	100.0	0	0.0	496	100.0	3	0.6		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Infections and infestations	Staphylococcal infection	n/a	495	100.0	2	0.4	496	100.0	0	0.0		Quasi-complete separation of data points detected.				ERROR: Error in computing the risk function, its derivatives, or the variance function.			NE				NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Systemic candida	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Injury, poisoning and procedural complications		n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.00	Convergence criterion (NCONV=1E-6) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.01	0.9944		1.00	Algorithm converged.	0.06	15.85
Injury, poisoning and procedural complications	Lower limb fracture	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Spinal column injury	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Investigations		n/a	495	100.0	54	11.3	496	100.0	60	12.0	0.93	Convergence criterion (NCONV=1E-6) satisfied.	0.62	1.37	-0.007	Algorithm converged.	-0.067	0.032	0.94	Algorithm converged.	0.67	1.32	0.7185		1.05	Algorithm converged.	0.74	1.50
Investigations	Amylase increased	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Investigations	Blood glucose decreased	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Investigations	Glucose increased	n/a	495	100.0	0	0.0	496	100.0	4	0.8		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Investigations	Lymphocyte count decreased	n/a	495	100.0	6	1.2	496	100.0	8	1.6	0.75	Convergence criterion (NCONV=1E-6) satisfied.	0.26	2.18	-0.004	Algorithm converged.	-0.024	0.016	0.75	Algorithm converged.	0.28	2.04	0.5995		1.31	Algorithm converged.	0.44	2.79
Investigations	Neutrophil count decreased	n/a	495	100.0	49	9.9	496	100.0	42	8.4	1.19	Convergence criterion (NCONV=1E-6) satisfied.	0.77	1.84	0.015	Algorithm converged.	-0.021	0.052	1.17	Algorithm converged.	0.79	1.74	0.4242		0.85	Algorithm converged.	0.58	1.24
Investigations	Platelet count decreased	n/a	495	100.0	3	0.6	496	100.0	4	1.2	0.50	Convergence criterion (NCONV=1E-6) satisfied.	0.11	2.21	-0.004	Algorithm converged.	-0.024	0.004	0.50	Algorithm converged.	0.11	2.20	0.3292		1.95	Algorithm converged.	0.50	7.90
Investigations	White blood cell count decreased	n/a	495	100.0	29	5.9	496	100.0	22	4.4	1.35	Convergence criterion (NCONV=1E-6) satisfied.	0.79	2.29	0.015	Algorithm converged.	-0.015	0.062	1.33	Algorithm converged.	0.77	2.29	0.1600		0.73	Algorithm converged.	0.49	1.09
Metabolism and nutrition disorders		n/a	495	100.0	4	0.8	496	100.0	2	0.4	2.00	Convergence criterion (NCONV=1E-6) satisfied.	0.37	11.08	0.004	Algorithm converged.	-0.008	0.016	2.00	Algorithm converged.	0.37	10.94	0.4182		0.50	Algorithm converged.	0.09	2.79
Metabolism and nutrition disorders	Hypercalcaemia	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Metabolism and nutrition disorders	Hypertriglyceridaemia	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Metabolism and nutrition disorders	Hyperuricaemia	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Metabolism and nutrition disorders	Hypokalaemia	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.00	Convergence criterion (NCONV=1E-6) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.01	0.9944		1.00	Algorithm converged.	0.06	15.85
Metabolism and nutrition disorders	Hyponatraemia	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenocarcinoma pancreas	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Nervous system disorders		n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Nervous system disorders	Stroke	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Psychiatric disorders		n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Psychiatric disorders	Personality change	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Renal and urinary disorders		n/a	495	100.0	2	0.4	496	100.0	2	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Renal and urinary disorders	Acute kidney injury	n/a	495	100.0	2	0.4	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Renal and urinary disorders	Renal failure	n/a	495	100.0	2	0.4	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Respiratory, thoracic and mediastinal disorders		n/a	495	100.0	2	0.4	496	100.0	3	0.6	0.67	Convergence criterion (NCONV=1E-6) satisfied.	0.11	4.02	-0.002	Algorithm converged.	-0.031	0.027	0.67	Algorithm converged.	0.11	4.00	0.6629		1.93	Algorithm converged.	0.25	5.88
Respiratory, thoracic and mediastinal disorders	Acute respiratory distress syndrome	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Respiratory, thoracic and mediastinal disorders	Dyspnoea	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.00	Convergence criterion (NCONV=1E-6) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.01	0.9944		1.00	Algorithm converged.	0.06	15.85
Respiratory, thoracic and mediastinal disorders	Lung disorder	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE				NE		NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.00	Convergence criterion (NCONV=1E-6) satisfied.	0.06	16.10	0.000	Algorithm converged.	-0.004	0.004	1.00	Algorithm converged.	0.06	16.01	0.9944		1.00	Algorithm converged.	0.06	15.85
Vascular disorders		n/a	495	100.0	2	0.4	496	100.0	2	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE
Vascular disorders	Hypotension	n/a	495	100.0	2	0.4	496	100.0	2	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00				0.9999		999.99	Algorithm converged.	0.00	NE

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to WASH, whichever is earlier.
Only AEs of highest severity are counted.
Test for interaction based on RR (log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO5541077/CDP57896/BO39942/data_analysis/ACE_FINAL_DH/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/BO5541077/CDP57896/BO39942/data_analysis/ACE_FINAL_DH/prod/output/t_ae_raw_soc_ag2_WSHKAE_SE_POOLED_15JUN2022_39942.rtf
SEP26A2023 18:33

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified Analysis
ANOVA: SS39962
Dichotomous Analysis by Subgroups (Safety)

Age

			Pralsetinib Yeskita + R-CHP (N=315)				R-CHP (N=316)				Pralsetinib Yeskita + R-CHP vs. R-CHP												R-CHP vs. Pralsetinib Yeskita + R-CHP			
			Patients		Patients with Event		Patients		Patients with Event		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		<= 40	167	33.7	27	16.2	157	31.1	20	12.7	1.32	convergence criterion (ZCONV*1E-8) satisfied.	0.71	2.45	0.034	Algorithm converged.	-0.041	0.111	1.27	Algorithm converged.	0.79	2.17	0.3831	0.2965	0.79	Algorithm converged.	0.44	1.35
Blood and lymphatic system disorders		> 40	328	66.3	82	25.0	341	68.9	92	27.0	0.90	convergence criterion (ZCONV*1E-8) satisfied.	0.68	1.18	-0.020	Algorithm converged.	-0.088	0.047	0.93	Algorithm converged.	0.79	1.10	0.5599		1.08	Algorithm converged.	0.84	1.39
Blood and lymphatic system disorders	Agranulocytosis	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Agranulocytosis	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Anaemia	<= 40	167	33.7	2	1.2	157	31.1	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	0.2015		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Anaemia	> 40	328	66.3	1	0.3	341	68.9	1	0.3	1.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.66	0.000	Algorithm converged.	-0.008	0.008	1.04	Algorithm converged.	0.07	16.05	0.9790		0.96	Algorithm converged.	0.06	15.31
Blood and lymphatic system disorders	Aplasia pure red cell	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	1.0000		NE	NE	NE	NE
Blood and lymphatic system disorders	Aplasia pure red cell	> 40	328	66.3	1	0.3	341	68.9	1	0.3	1.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.66	0.000	Algorithm converged.	-0.008	0.008	1.04	Algorithm converged.	0.07	16.05	0.9790		0.96	Algorithm converged.	0.06	15.31
Blood and lymphatic system disorders	Cytopenia	<= 40	167	33.7	1	0.6	157	31.1	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
Blood and lymphatic system disorders	Cytopenia	> 40	328	66.3	0	0.0	341	68.9	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 bone marrow aplasia	<= 40	167	33.7	0	0.0	157	31.1	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 bone marrow aplasia	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Febrile neutropenia	<= 40	167	33.7	6	3.6	157	31.1	3	1.9	1.91	convergence criterion (ZCONV*1E-8) satisfied.	0.47	7.78	0.017	Algorithm converged.	-0.039	0.065	1.88	Algorithm converged.	0.48	7.28	0.3659	0.8910	0.53	Algorithm converged.	0.14	2.09
Blood and lymphatic system disorders	Febrile neutropenia	> 40	328	66.3	12	3.7	341	68.9	8	2.3	1.58	convergence criterion (ZCONV*1E-8) satisfied.	0.66	3.80	0.013	Algorithm converged.	-0.019	0.045	1.56	Algorithm converged.	0.65	3.77	0.3233		0.66	Algorithm converged.	0.27	1.55
Blood and lymphatic system disorders	Leukaemia	<= 40	167	33.7	3	1.8	157	31.1	3	1.9	0.94	convergence criterion (ZCONV*1E-8) satisfied.	0.19	4.55	-0.001	Algorithm converged.	-0.035	0.026	0.94	Algorithm converged.	0.19	4.69	0.9092	0.7963	1.05	Algorithm converged.	0.22	5.19
Blood and lymphatic system disorders	Leukaemia	> 40	328	66.3	14	4.3	341	68.9	14	4.1	1.06	Convergence criterion (ZCONV*1E-8) satisfied.	0.49	2.40	0.004	Algorithm converged.	-0.049	0.059	1.11	Algorithm converged.	0.49	2.49	0.8298		0.89	Algorithm converged.	0.46	1.76
Blood and lymphatic system disorders	Lymphopenia	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	1.0000		NE	NE	NE	NE
Blood and lymphatic system disorders	Lymphopenia	> 40	328	66.3	2	0.6	341	68.9	3	0.9	0.68	Convergence criterion (ZCONV*1E-8) satisfied.	0.11	4.14	-0.003	Algorithm converged.	-0.036	0.030	0.69	Algorithm converged.	0.12	4.12	0.6849		1.46	Algorithm converged.	0.24	8.58
Blood and lymphatic system disorders	Myelosuppression	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	> 40	328	66.3	3	0.9	341	68.9	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	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	<= 40	167	33.7	22	13.2	157	31.1	17	10.8	1.25	Convergence criterion (ZCONV*1E-8) satisfied.	0.64	2.45	0.021	Algorithm converged.	-0.047	0.094	1.22	Algorithm converged.	0.65	2.28	0.5178	0.2874	0.82	Algorithm converged.	0.45	1.49
Blood and lymphatic system disorders	Neutropenia	> 40	328	66.3	64	20.1	341	68.9	80	22.5	0.82	Convergence criterion (ZCONV*1E-8) satisfied.	0.57	1.18	-0.031	Algorithm converged.	-0.096	0.029	0.84	Algorithm converged.	0.66	1.14	0.2971		1.17	Algorithm converged.	0.87	1.56
Blood and lymphatic system disorders	Thrombocytosenia	<= 40	167	33.7	0	0.0	157	31.1	2	1.3		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.10905411 is greater than the limit of 0.0001; The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	0.0827	9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Thrombocytosenia	> 40	328	66.3	8	2.2	341	68.9	8	2.2	1.43	Convergence criterion (ZCONV*1E-8) satisfied.	0.45	3.68	0.004	Algorithm converged.	-0.049	0.064	1.13	Algorithm converged.	0.44	3.64	0.7480		0.91	Algorithm converged.	0.33	2.48
Cardiac disorders		<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders		> 40	328	66.3	0	0.0	341	68.9	0	0.0	NE		NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	0.9999		9999.99	Algorithm converged.	NE	NE
Cardiac disorders	Atrial fibrillation	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrial fibrillation	> 40	328	66.3	1	0.3	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders		<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders		> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Deafness	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders	Deafness	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders		<= 40	167	33.7	2	0.0	157	31.1	2	1.2		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.13967411 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	0.1364	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders		> 40	328	66.3	4	1.0	341	68.9	0	1.0	0.89	Convergence criterion (ZCONV*1E-8) satisfied.	0.03	3.07	-0.009	Algorithm converged.	-0.069	0.051	0.83	Algorithm converged.	0.07	3.07	0.7821		0.93	Algorithm converged.	0.03	4.44
Gastrointestinal disorders	Constipation	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Constipation	> 40	328	66.3	1	0.3	341	68.9	0	0.0	NE		NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Gastric ulcer	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Gastric ulcer	> 40	328	66.3	1	0.3	341	68.9	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
Gastrointestinal disorders	Gastrointestinal haemorrhage	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	1.0000		NE	NE	NE	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	> 40	328	66.3	1	0.3	341	68.9	1	0.3	1.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.66	0.000	Algorithm converged.	-0.008	0.008	1.04	Algorithm converged.	0.07	16.05	0.9790		0.96	Algorithm converged.	0.06	15.31
Gastrointestinal disorders	Ileus	<= 40	167	33.7	0	0.0	157	31.1	2	1.3		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.10905411 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999		9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Ileus	> 40	328	66.3	0	0.0	341	68.9	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Intestinal perforation	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	1.0000		NE	NE	NE	NE
Gastrointestinal disorders	Intestinal perforation	> 40	328	66.3	1	0.3	341	68.9	1	0.3	1.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.66	0.000	Algorithm converged.	-0.008	0.008	1.04	Algorithm converged.	0.07	16.05	0.9790		0.96	Algorithm converged.	0.06	15.31
Gastrointestinal disorders	Intra-abdominal haemorrhage	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Intra-abdominal haemorrhage	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Necrotising colitis	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Necrotising colitis	> 40	328	66.3	1	0.3	341	68.9	0	0.0	NE		NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Obstruction gastric	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Obstruction gastric	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Pancreatic disorder	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Pancreatic disorder	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Stomatitis	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Stomatitis	> 40	328	66.3	1	0.3	341	68.9	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
General disorders and administration site conditions		<= 40	167	33.7	0	0.0	157	31.1	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		> 40	328	66.3	1	0.3	341	68.9	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
General disorders and administration site conditions	Pyrexia	<= 40	167	33.7	0	0.0	157	31.1	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	Pyrexia	> 40	328	66.3	1	0.3	341	68.9	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
Hepatobiliary disorders		<= 40	167	33.7	1	0.6	157	31.1	0	0.0	NE		NE	NE	NE	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		> 40	328	66.3	0	0.0	341	68.9	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Hepatobiliary disorders	Cholecystitis acute	<= 40	167	33.7	1	0.6	157	31.1	0	0.0	NE		NE	NE	NE	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	Cholecystitis acute	> 40	328	66.3	0	0.0	341	68.9	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations		<= 40	167	33.7	2	1.2	157	31.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	0.4935		NE	Algorithm converged.	NE	NE
Infections and infestations		> 40	328	66.3	4	1.0	341	68.9	6	1.8	0.69	Convergence criterion (ZCONV*1E-8) satisfied.	0.19	2.47	-0.009	Algorithm converged.	-0.064	0.031	0.69	Algorithm converged.	0.20	2.41	0.5672		1.45	Algorithm converged.	0.41	5.27
Infections and infestations	Cytomegalovirus enteritis	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Cytomegalovirus enteritis	> 40	328	66.3	1	0.3	341	68.9	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
Infections and infestations	Cytomegalovirus infection	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	1.0000		NE	NE	NE	NE
Infections and infestations	Cytomegalovirus infection	> 40	328	66.3	1	0.3	341	68.9	1	0.3	1.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.66	0.000	Algorithm converged.	-0.008	0.008	1.04	Algorithm converged.	0.07	16.05	0.9790		0.96	Algorithm converged.	0.06	15.31
Infections and infestations	Escherichia bacteraemia	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Escherichia bacteraemia	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Infections and infestations	Escherichia infection	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Escherichia infection	> 40	328	66.3	1	0.3	341	68.9	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 50.20991295 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	Escherichia sepsis	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Escherichia sepsis	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Infections and infestations	Klebsiella sepsis	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Klebsiella sepsis	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Infections and infestations	Neurosepsis	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Neurosepsis	> 40	328	66.3	1	0.3	341	68.9	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
Infections and infestations	Pneumonia	<= 40	167	33.7	1	0.6	157	31.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	0.1018		NE	Algorithm converged.	NE	NE
Infections and infestations	Pneumonia	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Infections and infestations	Sepsis	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Sepsis	> 40	328	66.3	0	0.0	341	68.9	2	0.6		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		9999.99	Algorithm converged.	0.00	NE
Infections and infestations	Staphylococcal infection	<= 40	167	33.7	1	0.6	157	31.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	1.0000		NE	Algorithm converged.	NE	NE
Infections and infestations	Staphylococcal infection	> 40	328	66.3	1	0.3	341	68.9	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 50.20991296 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	Systemic candida	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Systemic candida	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Injury, poisoning and procedural complications		<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	1.0000		NE	NE	NE	NE
Injury, poisoning and procedural complications		> 40	328	66.3	1	0.3	341	68.9	1	0.3	1.04	Convergence criterion (ZCONV*1E-8) satisfied.	0.06	16.66	0.000	Algorithm converged.	-0.008	0.008	1.04	Algorithm converged.	0.07	16.05	0.9790		0.96	Algorithm converged.	0.06	15.31
Injury, poisoning and procedural complications	Lower limb fracture	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Injury, poisoning and procedural complications	Lower limb fracture	> 40	328	66.3	1	0.3	341	68.9	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
Injury, poisoning and procedural complications	Spinal column injury	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Injury, poisoning and procedural complications	Spinal column injury	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Investigations		<= 40	167	33.7	16	9.6	157	31.1	18	11.5	0.82	Convergence criterion (ZCONV*1E-8) satisfied.	0.40	1.67	-0.019	Algorithm converged.	-0.086	0.048	0.84	Algorithm converged.	0.40	1.69	0.5808	0.4597	1.20	Algorithm converged.	0.43	2.24
Investigations		> 40	328	66.3	40	12.2	341	68.9	42	12.3	0.98	Convergence criterion (ZCONV*1E-8) satisfied.	0.62	1.53	-0.001	Algorithm converged.	-0.061	0.040	0.99	Algorithm converged.	0.62	1.52	0.9618		1.01	Algorithm converged.	0.47	1.52
Investigations	Amylase increased	<= 40	167	33.7	0	0.0	157	31.1	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Investigations	Amylase increased	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99	Algorithm converged.	0.00	NE
Investigations	Blood glucose decreased	<= 40	167	33.7	0	0.0	157	31.1	1	0.6		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.10742729 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999		9999.99	Algorithm converged.	0.00	NE
Investigations	Blood glucose decreased	> 40	328	66.3	0	0.0	341	68.9	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Investigations	Lipase increased	<= 40	167	33.7	0	0.0	157	31.1	1	0.6		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.10742727 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	0.1003	9999.99	Algorithm converged.	0.00	NE
Investigations	Lipase increased	> 40	328	66.3	0	0.0	341	68.9	1	0.3		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	0.9999		9999.99

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified Analysis
STUDY: BG39862
Dichotomous Analysis by Subgroups (Safety)

ZPG score at Screening

			Pulrorusenb Vedrtx + B-Cmr (N=193)				B-Cmr (N=193)				Pulrorusenb Vedrtx + B-Cmr vs. B-Cmr																Pulrorusenb Vedrtx + B-Cmr vs. B-Cmr			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	N	%	n	%	N	%	n	%	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 (Global Odd Ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		1-2	187	37.8	31	16.6	187	37.4	37	19.8	0.81	Convergence criterion (GCONV=1E-6) satisfied.	0.49	1.36	-0.032	Algorithm converged.	-0.101	0.040	0.84	Algorithm converged.	0.58	1.24	0.4222	0.4263	1.10	Algorithm converged.	0.77	1.64
Blood and lymphatic system disorders		3	196	39.6	43	21.9	196	37.8	40	21.0	1.06	Convergence criterion (GCONV=1E-6) satisfied.	0.69	1.67	0.009	Algorithm converged.	-0.078	0.097	1.04	Algorithm converged.	0.76	1.43	0.8182		0.98	Algorithm converged.	0.67	1.43
Blood and lymphatic system disorders		4-5	112	22.6	35	31.3	125	25.0	25	20.0	1.17	Convergence criterion (GCONV=1E-6) satisfied.	0.67	2.04	0.031	Algorithm converged.	-0.084	0.160	1.12	Algorithm converged.	0.79	1.67	0.5840		0.98	Algorithm converged.	0.69	1.33
Blood and lymphatic system disorders	Agranulocytosis	1-2	187	37.8	0	0.0	187	37.4	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	Agranulocytosis	3	196	39.6	0	0.0	196	37.8	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	1.0000	9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Agranulocytosis	4-5	112	22.6	0	0.0	125	25.0	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	Anemia	1-2	187	37.8	1	0.5	187	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	0.1167	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Anemia	3	196	39.6	2	1.0	196	37.8	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 14.689690874 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	Anemia	4-5	112	22.6	0	0.0	125	25.0	1	0.8	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 16.314012847 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Aplasia pure red cell	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	1.0000	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Aplasia pure red cell	3	196	39.6	0	0.0	196	37.8	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	Aplasia pure red cell	4-5	112	22.6	1	0.9	125	25.0	1	0.8	1.12	Convergence criterion (GCONV=1E-6) satisfied.	0.07	18.07	0.001	Algorithm converged.	-0.035	0.049	1.12	Algorithm converged.	0.07	17.65	0.9378		0.96	Algorithm converged.	0.06	14.14
Blood and lymphatic system disorders	Cytopenia	1-2	187	37.8	0	0.0	187	37.4	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	Cytopenia	3	196	39.6	1	0.5	196	37.8	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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	Cytopenia	4-5	112	22.6	0	0.0	125	25.0	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 bone marrow aplasia	1-2	187	37.8	0	0.0	187	37.4	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 bone marrow aplasia	3	196	39.6	0	0.0	196	37.8	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	Febrile bone marrow aplasia	4-5	112	22.6	0	0.0	125	25.0	1	0.8		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314111281 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Febrile neutropenia	1-2	187	37.8	4	2.2	187	37.4	4	2.1	1.02	Convergence criterion (GCONV=1E-6) satisfied.	0.40	5.44	0.011	Algorithm converged.	-0.090	0.949	1.50	Algorithm converged.	0.43	5.23	0.5245	0.9875	0.67	Algorithm converged.	0.19	2.32
Blood and lymphatic system disorders	Febrile neutropenia	3	196	39.6	9	4.6	196	37.8	5	2.7	1.74	Convergence criterion (GCONV=1E-6) satisfied.	0.67	6.46	0.019	Algorithm converged.	-0.008	0.056	1.71	Algorithm converged.	0.68	6.26	0.3288		0.85	Algorithm converged.	0.20	3.71
Blood and lymphatic system disorders	Febrile neutropenia	4-5	112	22.6	3	2.7	125	25.0	2	1.6	1.69	Convergence criterion (GCONV=1E-6) satisfied.	0.28	10.30	0.011	Algorithm converged.	-0.006	0.046	1.67	Algorithm converged.	0.28	9.96	0.5495		0.85	Algorithm converged.	0.10	2.51
Blood and lymphatic system disorders	Leukopenia	1-2	187	37.8	3	1.6	187	37.4	2	1.1	1.51	Convergence criterion (GCONV=1E-6) satisfied.	0.25	9.13	0.005	Algorithm converged.	-0.008	0.029	1.50	Algorithm converged.	0.25	8.97	0.6548	0.1597	0.67	Algorithm converged.	0.11	3.94
Blood and lymphatic system disorders	Leukopenia	3	196	39.6	5	2.6	196	37.8	9	4.8	0.53	Convergence criterion (GCONV=1E-6) satisfied.	0.17	1.65	-0.023	Algorithm converged.	-0.061	0.015	0.53	Algorithm converged.	0.18	1.56	0.2430		1.95	Algorithm converged.	0.45	5.54
Blood and lymphatic system disorders	Leukopenia	4-5	112	22.6	11	9.8	125	25.0	8	6.4	1.61	Convergence criterion (GCONV=1E-6) satisfied.	0.71	6.65	0.034	Algorithm converged.	-0.004	0.137	2.00	Algorithm converged.	0.74	5.95	0.1444		0.85	Algorithm converged.	0.19	3.28
Blood and lymphatic system disorders	Lymphopenia	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Lymphopenia	3	196	39.6	0	0.0	196	37.8	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	1.0000	9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Lymphopenia	4-5	112	22.6	2	1.8	125	25.0	0	0.0	0.05	Convergence criterion (GCONV=1E-6) satisfied.	0.00	25.21	0.018	Algorithm converged.	-0.059	0.039	2.23	Algorithm converged.	0.23	24.28	0.5097		0.85	Algorithm converged.	0.04	4.87
Blood and lymphatic system disorders	Neutropenia	1-2	187	37.8	0	0.0	187	37.4	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	3	196	39.6	2	1.0	196	37.8	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 14.689490677 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	Neutropenia	4-5	112	22.6	1	0.9	125	25.0	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 16.712441801 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	Neutropenia	1-2	187	37.8	24	12.9	187	37.4	32	17.1	0.74	Convergence criterion (GCONV=1E-6) satisfied.	0.41	1.37	-0.032	Algorithm converged.	-0.105	0.041	0.81	Algorithm converged.	0.55	1.01	0.3927	0.8046	1.25	Algorithm converged.	0.76	1.98
Blood and lymphatic system disorders	Neutropenia	3	196	39.6	34	18.4	196	37.8	34	18.2	1.01	Convergence criterion (GCONV=1E-6) satisfied.	0.62	1.65	0.001	Algorithm converged.	-0.077	0.079	1.00	Algorithm converged.	0.66	1.51	0.9823		1.00	Algorithm converged.	0.65	1.52
Blood and lymphatic system disorders	Neutropenia	4-5	112	22.6	24	22.2	125	25.0	31	24.8	0.92	Convergence criterion (GCONV=1E-6) satisfied.	0.53	1.63	-0.014	Algorithm converged.	-0.165	0.093	0.94	Algorithm converged.	0.63	1.47	0.7757		1.17	Algorithm converged.	0.68	1.68
Blood and lymphatic system disorders	Thrombocytopenia	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Thrombocytopenia	3	196	39.6	5	2.6	196	37.8	2	1.1	2.41	Convergence criterion (GCONV=1E-6) satisfied.	0.44	12.57	0.013	Algorithm converged.	-0.022	0.061	2.37	Algorithm converged.	0.47	12.06	0.2982		0.85	Algorithm converged.	0.08	2.15
Blood and lymphatic system disorders	Thrombocytopenia	4-5	112	22.6	4	3.6	125	25.0	1	0.8	4.00	Convergence criterion (GCONV=1E-6) satisfied.	0.43	37.40	0.028	Algorithm converged.	-0.001	0.064	4.40	Algorithm converged.	0.47	9.04	0.8433		1.17	Algorithm converged.	0.31	4.57
Cardiac disorders		1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders		3	196	39.6	0	0.0	196	37.8	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	1.0000	9999.99	Algorithm converged.	0.00	NE
Cardiac disorders		4-5	112	22.6	0	0.0	125	25.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrial fibrillation	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrial fibrillation	3	196	39.6	0	0.0	196	37.8	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	1.0000	9999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	4-5	112	22.6	0	0.0	125	25.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Ear and labyrinth disorders		1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Ear and labyrinth disorders		3	196	39.6	0	0.0	196	37.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Ear and labyrinth disorders		4-5	112	22.6	0	0.0	125	25.0	1	0.8		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 16.314012847 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Deafness	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Ear and labyrinth disorders	Deafness	3	196	39.6	0	0.0	196	37.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Ear and labyrinth disorders	Deafness	4-5	112	22.6	0	0.0	125	25.0	1	0.8		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 16.314012847 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders		1-2	187	37.8	0	0.0	187	37.4	3	1.6		Quasi-complete separation of data points detected.				KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	0.9999	0.3053	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders		3	196	39.6	3	1.5	196	37.8	2	1.1	1.41	Quasi-complete separation of data points detected.	0.23	8.61	0.004	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders		4-5	112	22.6	4	3.6	125	25.0	3	2.4	1.54	Convergence criterion (GCONV=1E-6) satisfied.	0.31	12.69	0.020	Algorithm converged.	-0.021	0.061	2.23	Algorithm converged.	0.27	11.07	0.4883		0.85	Algorithm converged.	0.09	2.40
Gastrointestinal disorders	Constipation	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Constipation	3	196	39.6	1	0.5	196	37.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Constipation	4-5	112	22.6	1	0.9	125	25.0	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 18.712481867 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	Gastric ulcer	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Gastric ulcer	3	196	39.6	0	0.0	196	37.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Gastric ulcer	4-5	112	22.6	1	0.9	125	25.0	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 18.712481867 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	Gastrointestinal haemorrhage	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	3	196	39.6	0	0.0	196	37.8	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	1.0000	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	4-5	112	22.6	1	0.9	125	25.0	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 18.712481867 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	Ileus	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	1.0000	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Ileus	3	196	39.6	0	0.0	196	37.8	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	1.0000	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Ileus	4-5	112	22.6	0	0.0	125	25.0	1	0.8	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 16.314012847 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Intestinal perforation	1-2	187	37.8	0	0.0	187	37.4	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Intestinal perforation	3	196	39.6	0	0.0	196	37.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Intestinal perforation	4-5	112	22.6	1	0.9	125	25.0	1	0.8	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 18.712481867 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	Intra-abdominal haemorrhage	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Intra-abdominal haemorrhage	3	196	39.6	0	0.0	196	37.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Intra-abdominal haemorrhage	4-5	112	22.6	0	0.0	125	25.0	1	0.8	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 16.314012847 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Necrotising colitis	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Necrotising colitis	3	196	39.6	0	0.0	196	37.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Necrotising colitis	4-5	112	22.6	0	0.0	125	25.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Obstruction gastric	1-2	187	37.8	0	0.0	187	37.4	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Obstruction gastric	3	196	39.6	0	0.0	196	37.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Obstruction gastric	4-5	112	22.6	0	0.0	125	25.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Pancreatic disorder	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Pancreatic disorder	3	196	39.6	0	0.0	196	37.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Pancreatic disorder	4-5	112	22.6	0	0.0	125	25.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Proctalgia	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Proctalgia	3	196	39.6	0	0.0	196	37.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Proctalgia	4-5	112	22.6	1	0.9	125	25.0	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: 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		1-2	187	37.8	1	0.5	187	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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		3	196	39.6	0	0.0	196	37.8	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		4-5	112	22.6	0	0.0	125	25.0	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	Pyrexia	1-2	187	37.8	1	0.5	187	37.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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	Pyrexia	3	196	39.6	0	0.0	196	37.8	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	Pyrexia	4-5	112	22.6	0	0.0	125	25.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Hepatobiliary disorders		1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Hepatobiliary disorders		3	196	39.6	1	0.5	196	37.8	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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
Hepatobiliary disorders		4-5	112	22.6	1	0.9	125	25.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Hepatobiliary disorders	Cholecystitis acute	1-2	187	37.8	0	0.0	187	37.4	1	0.5	NE	Quasi-complete separation of data points detected.	NE	NE	NE	KNOWN: Error in computing the link function, its derivatives, or the variance function.			0.00	Algorithm converged.	0.00	NE	0.9999	9999.99	Algorithm converged.	0.00	NE
Hepatobiliary disorders	Cholecystitis acute	3	196	39.6	0	0.0	196	37.8	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Hepatobiliary disorders	Cholecystitis acute	4-5	112	22.6	0	0.0	125	25.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations		1-2	187	37.8	1	0.5	187	37.4	1	0.5	1.00	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.33	0.000	Algorithm converged.	-0.031	0.031	1.00	Algorithm converged.	0.06	15.87	1.0000	0.9916	1.00	Algorithm converged.	0.06	15.87
Infections and infestations		3	196	39.6	2	1.0	196	37.8	2	1.1	0.95	Convergence criterion (GCONV=1E-6) satisfied.	0.13	6.90	-0.001	Algorithm converged.	-0.031	0.029	0.95	Algorithm converged.	0.13	6.67	0.9580		1.00	Algorithm converged.	0.15	7.49
Infections and infestations		4-5	112	22.6	3	2.7	125	25.0	3	2.4	1.16	Convergence criterion (GCONV=1E-6) satisfied.	0.23	5.80	0.003	Algorithm converged.	-0.029	0.043	1.10	Algorithm converged.	0.26	4.90	0.8214		0.85	Algorithm converged.	0.14	4.35
Infections and infestations	Cytomegalovirus infection	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Cytomegalovirus infection	3	196	39.6	0	0.0	196

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified Analysis
STUDY: BG39862
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Futibrutinib Ynbrita + R-CHP (N=493)				R-CHP (N=496)				Futibrutinib Ynbrita + R-CHP vs. R-CHP										R-CHP vs. Futibrutinib Ynbrita + R-CHP			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk				Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Cavrel	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		Western Europe/United States/Canada/Australia	298	60.4	46	15.4	300	49.2	59	19.7	0.75	Convergence criterion (HCONV<1E-8) satisfied.	0.49	1.16	-0.043	Algorithm converged.	-0.101	0.015	0.76	Algorithm converged.	0.53	1.11	0.1757	0.0593	1.27	Algorithm converged.	0.90	1.81
Blood and lymphatic system disorders		Asia	140	28.4	44	32.6	139	27.0	32	23.0	1.64	Convergence criterion (HCONV<1E-8) satisfied.	0.98	2.76	0.096	Algorithm converged.	-0.066	0.257	1.43	Algorithm converged.	0.87	2.41	0.1724		1.70	Algorithm converged.	0.68	1.22
Blood and lymphatic system disorders		Rest of World	57	11.5	17	29.8	58	11.4	21	35.6	0.77	Convergence criterion (HCONV<1E-8) satisfied.	0.35	1.68	-0.058	Algorithm converged.	-0.258	0.113	0.84	Algorithm converged.	0.50	1.40	0.5096		1.18	Algorithm converged.	0.71	2.02
Blood and lymphatic system disorders	Agranulocytosis	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	1	0.3		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	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Agranulocytosis	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Agranulocytosis	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Anemia	Western Europe/United States/Canada/Australia	298	60.4	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 44.854790292 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	0.4271		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Anemia	Asia	140	28.4	1	0.7	139	27.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Anemia	Rest of World	57	11.5	1	1.8	58	11.4	1	1.7	1.04	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.96	0.001	Algorithm converged.	-0.065	0.068	1.04	Algorithm converged.	0.07	16.16	0.9804		1.07	Algorithm converged.	0.06	15.08
Blood and lymphatic system disorders	Aplasia pure red cell	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	1	0.3	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Algorithm converged.	-0.065	0.065	1.01	Algorithm converged.	0.06	16.02	0.9942	1.0000	1.00	Algorithm converged.	0.06	15.81
Blood and lymphatic system disorders	Aplasia pure red cell	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Aplasia pure red cell	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Cytopenia	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 44.854790292 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	Cytopenia	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Cytopenia	Rest of World	57	11.5	0	0.0	58	11.4	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 bone marrow aplasia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	1	0.3		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	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Rest of World	57	11.5	0	0.0	58	11.4	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	Western Europe/United States/Canada/Australia	298	60.2	12	4.0	300	60.5	7	2.3	1.76	Convergence criterion (HCONV<1E-8) satisfied.	0.68	4.55	0.017	Algorithm converged.	-0.031	0.065	1.71	Algorithm converged.	0.69	4.30	0.2441	0.1682	0.58	Algorithm converged.	0.23	1.45
Blood and lymphatic system disorders	Febrile neutropenia	Asia	140	28.4	9	6.4	139	27.0	3	2.2	3.11	Convergence criterion (HCONV<1E-8) satisfied.	0.85	44.96	0.042	Algorithm converged.	-0.005	0.089	4.36	Algorithm converged.	0.86	44.85	0.1412		2.90	Algorithm converged.	0.90	9.73
Blood and lymphatic system disorders	Febrile neutropenia	Rest of World	57	11.5	1	1.8	58	11.4	3	5.1	0.33	Convergence criterion (HCONV<1E-8) satisfied.	0.03	3.05	-0.033	Algorithm converged.	-0.099	0.032	0.35	Algorithm converged.	0.04	3.00	0.3504		0.35	Algorithm converged.	0.04	27.05
Blood and lymphatic system disorders	Leukopenia	Western Europe/United States/Canada/Australia	298	60.2	2	0.7	300	60.5	4	1.3	0.55	Convergence criterion (HCONV<1E-8) satisfied.	0.09	2.75	-0.007	Algorithm converged.	-0.093	0.009	0.50	Algorithm converged.	0.08	2.73	0.4259	0.4018	1.85	Algorithm converged.	0.37	10.74
Blood and lymphatic system disorders	Leukopenia	Asia	140	28.4	14	11.4	139	27.0	11	7.9	1.55	Convergence criterion (HCONV<1E-8) satisfied.	0.67	3.56	0.035	Algorithm converged.	-0.036	0.106	1.44	Algorithm converged.	0.70	3.00	0.3244		0.65	Algorithm converged.	0.33	1.44
Blood and lymphatic system disorders	Leukopenia	Rest of World	57	11.5	1	1.8	58	11.4	2	3.4	0.55	Convergence criterion (HCONV<1E-8) satisfied.	0.05	5.71	-0.016	Algorithm converged.	-0.074	0.041	0.52	Algorithm converged.	0.05	5.05	0.5844		0.53	Algorithm converged.	0.18	20.72
Blood and lymphatic system disorders	Lymphopenia	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	2	1.0	0.33	Convergence criterion (HCONV<1E-8) satisfied.	0.03	3.22	-0.007	Algorithm converged.	-0.065	0.006	0.34	Algorithm converged.	0.04	3.21	0.3431	0.3292	2.95	Algorithm converged.	0.31	28.49
Blood and lymphatic system disorders	Lymphopenia	Asia	140	28.4	1	0.7	139	27.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Lymphopenia	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	Asia	140	28.4	3	2.1	139	27.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 9.1573729238 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	Myelosuppression	Rest of World	57	11.5	0	0.0	58	11.4	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	Western Europe/United States/Canada/Australia	298	60.2	34	12.1	300	60.5	49	16.3	0.70	Convergence criterion (HCONV<1E-8) satisfied.	0.44	1.10	-0.041	Algorithm converged.	-0.098	0.013	0.74	Algorithm converged.	0.55	1.01	0.1397	0.2230	1.35	Algorithm converged.	0.91	2.02
Blood and lymphatic system disorders	Neutropenia	Asia	140	28.4	35	25.0	139	27.0	28	20.1	1.32	Convergence criterion (HCONV<1E-8) satisfied.	0.75	2.32	0.049	Algorithm converged.	-0.045	0.140	1.24	Algorithm converged.	0.80	1.92	0.3339		0.95	Algorithm converged.	0.52	1.25
Blood and lymphatic system disorders	Neutropenia	Rest of World	57	11.5	17	29.8	58	11.4	20	33.9	0.81	Convergence criterion (HCONV<1E-8) satisfied.	0.36	1.83	-0.041	Algorithm converged.	-0.203	0.123	0.88	Algorithm converged.	0.47	1.62	0.6394		1.15	Algorithm converged.	0.43	1.94
Blood and lymphatic system disorders	Thrombocytopenia	Western Europe/United States/Canada/Australia	298	60.2	3	1.0	300	60.5	4	1.3	0.75	Convergence criterion (HCONV<1E-8) satisfied.	0.17	3.35	-0.010	Algorithm converged.	-0.080	0.015	0.76	Algorithm converged.	0.17	3.34	0.7114	0.7792	1.30	Algorithm converged.	0.30	5.87
Blood and lymphatic system disorders	Thrombocytopenia	Asia	140	28.4	3	2.1	139	27.0	4	2.9	0.74	Convergence criterion (HCONV<1E-8) satisfied.	0.16	3.36	-0.027	Algorithm converged.	-0.084	0.029	0.74	Algorithm converged.	0.17	3.27	0.4959		1.36	Algorithm converged.	0.31	5.99
Blood and lymphatic system disorders	Thrombocytopenia	Rest of World	57	11.5	2	3.4	58	11.4	3	5.1	0.68	Convergence criterion (HCONV<1E-8) satisfied.	0.07	6.87	0.016	Algorithm converged.	-0.061	0.093	1.50	Algorithm converged.	0.27	8.90	0.4206		2.60	Algorithm converged.	0.11	3.71
Cardiac disorders		Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	1	0.3		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	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders		Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders		Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrial fibrillation	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	1	0.3		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	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrial fibrillation	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders		Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	1	0.3		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	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders		Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders		Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders	Deafness	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	1	0.3		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	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Deafness	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Ear and labyrinth disorders	Deafness	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders		Western Europe/United States/Canada/Australia	298	60.2	4	1.3	300	60.5	1	0.3	4.07	Convergence criterion (HCONV<1E-8) satisfied.	0.45	36.83	0.010	Algorithm converged.	-0.009	0.029	4.03	Algorithm converged.	0.45	35.83	0.2114	0.3069	4.03	Algorithm converged.	0.03	3.21
Gastrointestinal disorders		Asia	140	28.4	0	0.0	139	27.0	1	0.7		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 19.480043432 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		Rest of World	57	11.5	0	0.0	58	11.4	5	8.5		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 2.320439852 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	Constipation	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 44.854790292 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	Constipation	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Constipation	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Gastric ulcer	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	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
Gastrointestinal disorders	Gastric ulcer	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Gastric ulcer	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	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
Gastrointestinal disorders	Gastrointestinal haemorrhage	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Ileus	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 10.540148401 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	Ileus	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Ileus	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Intestinal perforation	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 6.2921158572 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	Intestinal perforation	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Intestinal perforation	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Intra-abdominal haemorrhage	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Intra-abdominal haemorrhage	Asia	140	28.4	0	0.0	139	27.0	1	0.7		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 19.480043432 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	Intra-abdominal haemorrhage	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Necrotising colitis	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	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
Gastrointestinal disorders	Necrotising colitis	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Necrotising colitis	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Obstruction gastric	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	1	0.3		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	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Obstruction gastric	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Obstruction gastric	Rest of World	57	11.5	0	0.0	58	11.4	1	1.7		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 10.540148401 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	Pancreatic disorder	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.5	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Pancreatic disorder	Asia	140	28.4	0	0.0	139	27.0	1	0.7	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Pancreatic disorder	Rest of World	57	11.5	0	0.0	58	11.4	1	1.7		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 10.540148401 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	Stomatitis	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 44.854790292 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	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Stomatitis	Rest of World	57	11.5	0	0.0	58	11.4	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		Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	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
General disorders and administration site conditions		Asia	140	28.4	0	0.0	139	27.0	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		Rest of World	57	11.5	0	0.0	58	11.4	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	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	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
General disorders and administration site conditions	Pyrexia	Asia	140	28.4	0	0.0	139	27.0	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	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Hepatobiliary disorders		Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	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
Hepatobiliary disorders		Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Hepatobiliary disorders		Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Hepatobiliary disorders	Cholecystitis acute	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	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
Hepatobiliary disorders	Cholecystitis acute	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Hepatobiliary disorders	Cholecystitis acute	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations		Western Europe/United States/Canada/Australia	298	60.2	4	2.0	300	60.5	6	2.0	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.31	3.15	0.000	Algorithm converged.	-0.065	0.067	1.01	Algorithm converged.	0.33	3.09	0.9907		0.99	Algorithm converged.	0.30	3.24
Infections and infestations		Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations		Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Cytomegalovirus infection	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	0	0.0		Quasi-complete separation of data points detected.				WARNING: The relative Wexalan convergence criterion of 44.854790292 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	Cytomegalovirus enteritis	Asia	140	28.4	0	0.0	139	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Cytomegalovirus enteritis	Rest of World	57	11.5	0	0.0	58	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Cytomegalovirus infection	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.5	1	0.3	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Algorithm converged.	-0.065	0.065	1.01	Algorithm converged.	0.06	16.02	0.9942	1.0000	1.00	Algor

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Respiratory, thoracic and mediastinal disorders		Asia	140	28.3	0	0.0	100	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		
Respiratory, thoracic and mediastinal disorders		Rest of World	57	11.5	0	0.0	50	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		
Respiratory, thoracic and mediastinal disorders	Acute respiratory distress syndrome	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	68.2	1	0.3	-	*	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	0.9999	NE	9999.99	Algorithm converged.	0.00	NE									
Respiratory, thoracic and mediastinal disorders	Acute respiratory distress syndrome	Asia	140	28.3	0	0.0	100	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		
Respiratory, thoracic and mediastinal disorders	Acute respiratory distress syndrome	Rest of World	57	11.5	0	0.0	50	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	68.2	1	0.3	1.00		Convergence criterion (HCONV<1E-6) satisfied.	0.00	14.17	0.000		Algorithm converged.	-2.000	0.000	1.00	Algorithm converged.	0.00	14.17	0.8182	1.0000	0.00	Algorithm converged.	0.00	16.81									
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Asia	140	28.3	0	0.0	100	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Rest of World	57	11.5	0	0.0	50	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		
Respiratory, thoracic and mediastinal disorders	Lung disorder	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	68.2	0	0.0	-	*	Quasi-complete separation of data points detected.				*	WARNING: Hessian of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE									
Respiratory, thoracic and mediastinal disorders	Lung disorder	Asia	140	28.3	0	0.0	100	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		
Respiratory, thoracic and mediastinal disorders	Lung disorder	Rest of World	57	11.5	0	0.0	50	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	68.2	1	0.3	1.00		Convergence criterion (HCONV<1E-6) satisfied.	0.00	14.17	0.000		Algorithm converged.	-2.000	0.000	1.00	Algorithm converged.	0.00	14.17	0.8182	1.0000	0.00	Algorithm converged.	0.00	16.81									
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Asia	140	28.3	0	0.0	100	27.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Rest of World	57	11.5	0	0.0	50	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		
Vascular disorders		Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	68.2	1	0.3	-	*	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	0.9999	NE	9999.99	Algorithm converged.	0.00	NE									
Vascular disorders		Asia	140	28.3	0	0.0	100	27.4	1	0.7	-	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 19.480634432 is greater than the limit of 0.001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999		9999.99	Algorithm converged.	0.00	NE									
Vascular disorders		Rest of World	57	11.5	0	0.0	50	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		
Vascular disorders	Hypotension	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	68.2	1	0.3	-	*	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	0.9999	NE	9999.99	Algorithm converged.	0.00	NE									
Vascular disorders	Hypotension	Asia	140	28.3	0	0.0	100	27.4	1	0.7	-	*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 19.480634432 is greater than the limit of 0.001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999		9999.99	Algorithm converged.	0.00	NE									
Vascular disorders	Hypotension	Rest of World	57	11.5	0	0.0	50	11.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE																		

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NAAT, whichever is earlier.
Only AEs of highest severity are counted.
Test for interaction based on RR (log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/MO554107/CSP07884/MO39942/data_analysis/ACE_FINAL_DS/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/MO554107/CSP07884/MO39942/data_analysis/ACE_FINAL_DS/prod/output/t_ae_raw_soc_agd_RSW4WAR_RE_POOLED_15JUN2022_39942.xls
08FEB2023 16:33

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 4
MODEL: Unstratified Analysis
STUDY: BG39862
Dichotomous Analysis by Subgroups (Safety)

Sex

			Pulrotrexnib Vedotin + B-Cell (N=265)				B-Cell (N=265)				Pulrotrexnib Vedotin + B-Cell vs. B-Cell															B-Cell vs. Pulrotrexnib Vedotin + B-Cell			
			Patients		Patients with Event		Patients		Patients with Event		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		Male	245	53.9	53	20.6	265	54.4	58	21.6	0.93	Convergence criterion (ECOG#=1&=0) satisfied.	0.61	1.39	-0.014	Algorithm converged.	-0.086	0.057	0.93	Algorithm converged.	0.67	1.29	0.6548	0.4513	1.08	Algorithm converged.	0.77	1.55
Blood and lymphatic system disorders		Female	230	46.5	54	24.3	265	45.6	54	23.6	1.04	Convergence criterion (ECOG#=1&=0) satisfied.	0.68	1.60	0.008	Algorithm converged.	-0.070	0.086	1.04	Algorithm converged.	0.75	1.45	0.8474		0.97	Algorithm converged.	0.70	1.34
Blood and lymphatic system disorders	Agranulocytosis	Male	245	53.5	0	0.0	265	54.4	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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	<9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Agranulocytosis	Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Blood and lymphatic system disorders	Anaemia	Male	245	53.5	1	0.4	265	54.4	1	0.4	1.02	Convergence criterion (ECOG#=1&=0) satisfied.	0.06	16.16	0.000	Algorithm converged.	-0.010	0.010	1.02	Algorithm converged.	0.06	16.14	0.9915	0.1909	0.98	Algorithm converged.	0.06	15.47
Blood and lymphatic system disorders	Anaemia	Female	230	46.5	2	0.9	265	45.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Aplasia pure red cell	Male	245	53.5	0	0.0	265	54.4	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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	0.0969	<9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Aplasia pure red cell	Female	230	46.5	1	0.4	265	45.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Cytopenia	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Blood and lymphatic system disorders	Cytopenia	Female	230	46.5	1	0.4	265	45.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Febrile neutropenia	Male	245	53.5	12	4.5	265	54.4	4	1.5	3.14	Convergence criterion (ECOG#=1&=0) satisfied.	1.00	9.87	0.030	Algorithm converged.	0.000	0.059	3.00	Algorithm converged.	0.99	9.05	0.0511	0.0997	3.03	Algorithm converged.	0.11	1.00
Blood and lymphatic system disorders	Febrile neutropenia	Female	230	46.5	6	2.6	265	45.6	7	3.1	0.85	Convergence criterion (ECOG#=1&=0) satisfied.	0.28	2.57	-0.004	Algorithm converged.	-0.035	0.026	0.85	Algorithm converged.	0.29	2.50	0.7726		1.17	Algorithm converged.	0.40	3.43
Blood and lymphatic system disorders	Leukaemia	Male	245	53.5	6	2.2	265	54.4	11	4.1	0.54	Convergence criterion (ECOG#=1&=0) satisfied.	0.20	1.49	-0.018	Algorithm converged.	-0.048	0.011	0.55	Algorithm converged.	0.23	1.28	0.2272	0.8441	1.81	Algorithm converged.	0.68	4.81
Blood and lymphatic system disorders	Leukaemia	Female	230	46.5	12	5.2	265	45.6	6	2.4	2.23	Convergence criterion (ECOG#=1&=0) satisfied.	0.83	5.96	0.030	Algorithm converged.	-0.006	0.067	2.14	Algorithm converged.	0.83	5.36	0.1126		0.96	Algorithm converged.	0.18	1.22
Blood and lymphatic system disorders	Lymphopenia	Male	245	53.5	1	0.4	265	54.4	1	0.4	1.02	Convergence criterion (ECOG#=1&=0) satisfied.	0.06	16.16	0.000	Algorithm converged.	-0.010	0.010	1.02	Algorithm converged.	0.06	16.14	0.9915	0.7014	0.98	Algorithm converged.	0.06	15.47
Blood and lymphatic system disorders	Lymphopenia	Female	230	46.5	1	0.4	265	45.6	2	0.9	0.52	Convergence criterion (ECOG#=1&=0) satisfied.	0.05	5.60	-0.004	Algorithm converged.	-0.035	0.026	0.51	Algorithm converged.	0.05	5.45	0.5679		2.01	Algorithm converged.	0.18	22.50
Blood and lymphatic system disorders	Myelosuppression	Male	245	53.5	1	0.4	265	54.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	1.0000	NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Myelosuppression	Female	230	46.5	2	0.9	265	45.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Blood and lymphatic system disorders	Neutropenia	Male	245	53.5	41	15.5	265	54.4	50	18.4	0.80	Convergence criterion (ECOG#=1&=0) satisfied.	0.51	1.26	-0.031	Algorithm converged.	-0.095	0.032	0.83	Algorithm converged.	0.65	1.05	0.1995	0.5003	1.05	Algorithm converged.	0.82	1.75
Blood and lymphatic system disorders	Neutropenia	Female	230	46.5	47	20.4	265	45.6	47	22.5	0.99	Convergence criterion (ECOG#=1&=0) satisfied.	0.63	1.57	-0.001	Algorithm converged.	-0.070	0.072	1.00	Algorithm converged.	0.69	1.45	0.9811		1.00	Algorithm converged.	0.70	1.44
Blood and lymphatic system disorders	Thrombocytopenia	Male	245	53.5	3	1.1	265	54.4	5	1.9	0.63	Convergence criterion (ECOG#=1&=0) satisfied.	0.14	2.76	-0.007	Algorithm converged.	-0.058	0.032	0.61	Algorithm converged.	0.15	2.52	0.4841	0.4494	1.66	Algorithm converged.	0.40	6.80
Blood and lymphatic system disorders	Thrombocytopenia	Female	230	46.5	6	2.6	265	45.6	9	3.4	0.66	Convergence criterion (ECOG#=1&=0) satisfied.	0.24	2.00	-0.004	Algorithm converged.	-0.046	0.029	0.69	Algorithm converged.	0.27	1.84	0.7681		1.44	Algorithm converged.	0.24	7.72
Cardiac disorders		Male	245	53.5	0	0.0	265	54.4	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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	<9999.99	Algorithm converged.	0.00	NE
Cardiac disorders		Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Cardiac disorders	Atrial fibrillation	Male	245	53.5	0	0.0	265	54.4	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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	<9999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Ear and labyrinth disorders		Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Ear and labyrinth disorders		Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Ear and labyrinth disorders	Deafness	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Ear and labyrinth disorders	Deafness	Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders		Male	245	53.5	2	0.8	265	54.4	1	0.4	2.04	Convergence criterion (ECOG#=1&=0) satisfied.	0.18	22.80	0.004	Algorithm converged.	-0.009	0.017	2.03	Algorithm converged.	0.19	22.05	0.5622	0.1983	5.00	Algorithm converged.	0.04	5.40
Gastrointestinal disorders		Female	230	46.5	2	0.9	265	45.6	6	2.6	0.33	Convergence criterion (ECOG#=1&=0) satisfied.	0.07	1.63	-0.018	Algorithm converged.	-0.081	0.026	0.33	Algorithm converged.	0.07	1.62	0.1739		3.03	Algorithm converged.	0.41	14.77
Gastrointestinal disorders	Constipation	Male	245	53.5	1	0.4	265	54.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Constipation	Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Gastrointestinal disorders	Gastric ulcer	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Gastrointestinal disorders	Gastric ulcer	Female	230	46.5	1	0.4	265	45.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Gastrointestinal disorders	Gastrointestinal haemorrhage	Female	230	46.5	1	0.4	265	45.6	1	0.4	1.00	Convergence criterion (ECOG#=1&=0) satisfied.	0.06	16.06	0.000	Algorithm converged.	-0.010	0.010	1.00	Algorithm converged.	0.06	15.92	0.9975		1.00	Algorithm converged.	0.06	15.94
Gastrointestinal disorders	Ileus	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Ileus	Female	230	46.5	0	0.0	265	45.6	2	0.9	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Intestinal perforation	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	1.0000	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Intestinal perforation	Female	230	46.5	1	0.4	265	45.6	1	0.4	1.00	Convergence criterion (ECOG#=1&=0) satisfied.	0.06	16.06	0.000	Algorithm converged.	-0.010	0.010	1.00	Algorithm converged.	0.06	15.92	0.9975		1.00	Algorithm converged.	0.06	15.94
Gastrointestinal disorders	Intra-abdominal haemorrhage	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Gastrointestinal disorders	Intra-abdominal haemorrhage	Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Necrotising colitis	Male	245	53.5	1	0.4	265	54.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Necrotising colitis	Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Gastrointestinal disorders	Obstruction gastric	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Gastrointestinal disorders	Obstruction gastric	Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Pancreatic disorder	Male	245	53.5	0	0.0	265	54.4	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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	<9999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Pancreatic disorder	Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Gastrointestinal disorders	Stomatitis	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Gastrointestinal disorders	Stomatitis	Female	230	46.5	1	0.4	265	45.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
General disorders and administration site conditions		Female	230	46.5	1	0.4	265	45.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Pyrexia	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
General disorders and administration site conditions	Pyrexia	Female	230	46.5	1	0.4	265	45.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		Male	245	53.5	1	0.4	265	54.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Hepatobiliary disorders		Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Hepatobiliary disorders	Cholecystitis acute	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Hepatobiliary disorders	Cholecystitis acute	Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Infections and infestations		Male	245	53.5	5	1.9	265	54.4	3	1.1	1.65	Convergence criterion (ECOG#=1&=0) satisfied.	0.41	44.91	0.015	Algorithm converged.	-0.001	0.031	5.08	Algorithm converged.	0.80	43.17	0.1349	0.8149	0.30	Algorithm converged.	0.03	1.48
Infections and infestations		Female	230	46.5	1	0.4	265	45.6	5	2.2	0.20	Convergence criterion (ECOG#=1&=0) satisfied.	0.03	1.65	-0.011	Algorithm converged.	-0.038	0.007	0.20	Algorithm converged.	0.04	1.61	0.1232		0.99	Algorithm converged.	0.69	46.45
Infections and infestations	Cytomegalovirus colitis	Male	245	53.5	1	0.4	265	54.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Cytomegalovirus colitis	Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Infections and infestations	Cytomegalovirus infection	Male	245	53.5	1	0.4	265	54.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Cytomegalovirus infection	Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Infections and infestations	Escherichia bacteraemia	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Infections and infestations	Escherichia bacteraemia	Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Infections and infestations	Escherichia infection	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Infections and infestations	Escherichia infection	Female	230	46.5	1	0.4	265	45.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Escherichia sepsis	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Infections and infestations	Escherichia sepsis	Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Infections and infestations	Klebsiella sepsis	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Infections and infestations	Klebsiella sepsis	Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Infections and infestations	Neutropenic sepsis	Male	245	53.5	1	0.4	265	54.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Neutropenic sepsis	Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Infections and infestations	Pneumonia	Male	245	53.5	1	0.4	265	54.4	1	0.4	1.02	Convergence criterion (ECOG#=1&=0) satisfied.	0.06	16.16	0.000	Algorithm converged.	-0.010	0.010	1.02	Algorithm converged.	0.06	16.14	0.9915	1.0000	0.98	Algorithm converged.	0.06	15.47
Infections and infestations	Pneumonia	Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Infections and infestations	Sepsis	Male	245	53.5	0	0.0	265	54.4	1	0.4	NE	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	1.0000	<9999.99	Algorithm converged.	0.00	NE
Infections and infestations	Sepsis	Female	230	46.5	0	0.0	265	45.6	2	0.9	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Infections and infestations	Staphylococcal infection	Male	245	53.5	1	0.4	265	54.4	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	1.0000	NE	Algorithm converged.	NE	NE
Infections and infestations	Staphylococcal infection	Female	230	46.5	1	0.4	265	45.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Systemic candida	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Infections and infestations	Systemic candida	Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Injury, poisoning and procedural complications		Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Injury, poisoning and procedural complications		Female	230	46.5	1	0.4	265	45.6	1	0.4	1.00	Convergence criterion (ECOG#=1&=0) satisfied.	0.06	16.06	0.000	Algorithm converged.	-0.010	0.010	1.00	Algorithm converged.	0.06	15.92	0.9975		1.00	Algorithm converged.	0.06	15.94
Injury, poisoning and procedural complications	Lower limb fracture	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Injury, poisoning and procedural complications	Lower limb fracture	Female	230	46.5	1	0.4	265	45.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications	Spinal column injury	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Injury, poisoning and procedural complications	Spinal column injury	Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Investigations		Male	245	53.5	29	10.9	265	54.4	27	10.0	1.10	Convergence criterion (ECOG#=1&=0) satisfied.	0.63	1.90	0.009	Algorithm converged.	-0.043	0.061	1.09	Algorithm converged.	0.68	1.73	0.7326	0.4044	0.90	Algorithm converged.	0.54	1.51
Investigations		Female	230	46.5	27	11.7	265	45.6	33	14.4	0.73	Convergence criterion (ECOG#=1&=0) satisfied.	0.41	1.31	-0.027	Algorithm converged.	-0.095	0.030	0.81	Algorithm converged.	0.47	1.37	0.3971		1.23	Algorithm converged.	0.74	1.97
Investigations	Amylase increased	Male	245	53.5	0	0.0	265	54.4	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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	<9999.99	Algorithm converged.	0.00	NE
Investigations	Amylase increased	Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Investigations	Blood glucose decreased	Male	245	53.5	0	0.0	265	54.4	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Investigations	Blood glucose decreased	Female	230	46.5	0	0.0	265	45.6	1	0.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999		<9999.99	Algorithm converged.	0.00	NE
Investigations	Lipase increased	Male	245	53.5	0	0.0	265	54.4	2	0.8	NE	Quasi-complete separation of data points detected.	NE	NE	NE	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	1.0000	<9999.99	Algorithm converged.	0.00	NE
Investigations	Lipase increased	Female	230	46.5	0	0.0	265	45.6	0	0.0	NE		NE	NE	NE				NE				NE		NE			
Investigations	Lymphocyte count decreased	Male	245	53.5	4	1.5	265	54.4	4	1.5	1.02	Convergence criterion (ECOG#=1&=0) satisfied.	0.25	4.15	0.000	Algorithm converged.	-0.035	0.031	1.02	Algorithm converged.	0.33	4.02	0.9830	0.5164	0.99	Algorithm converged.	0.25	3.96
Investigations	Lymphocyte count decreased	Female	230	46.5	3	0.9	265	45.6	8	1.7	0.49	Convergence criterion (ECOG#=1&=0) satisfied.	0.09	2.59	-0.004	Algorithm converged.	-0.049	0.041	0.50	Algorithm converged.	0.09	2.45	0.4179		2.01	Algorithm converged.	0.43	10.84
Investigations	Neutr

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 5 (AEs leading to Death)
MODEL: Unstratified Analysis
STUDY: BO39942
Dichotomous Analysis by Subgroups (Safety)

All

			Relatlizumab Velebrk + B-CHW (N=495)				B-CHW (N=496)				Relatlizumab Velebrk + B-CHW vs. B-CHW														B-CHW vs. Relatlizumab Velebrk + B-CHW			
			Patients		Patients with Event		Patients		Patients with Event		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		n/a	495	100.0	1	0.2	496	100.0	1	0.2	*	Quasi-complete separation of data points detected.			*	WARNING: Negative of Hessian not positive definite.				Algorithm converged.	0.01	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block complete	n/a	495	100.0	1	0.2	496	100.0	1	0.2	*	Quasi-complete separation of data points detected.			*	WARNING: Negative of Hessian not positive definite.				Algorithm converged.	0.01	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders		n/a	495	100.0	1	0.2	496	100.0	3	0.6	*	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	Intestinal perforation	n/a	495	100.0	1	0.2	496	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	495	100.0	5	1.0	496	100.0	2	0.4	2.53	Convergence criterion (RCONV=1E-8) satisfied.	0.48	13.30	0.006	Algorithm converged.	-0.006	0.016	2.52	Algorithm converged.	0.48	12.90	0.2489	NE	0.80	Algorithm converged.	0.08	2.04
General disorders and administration site conditions	Cardiac death	n/a	495	100.0	1	0.2	496	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	Death	n/a	495	100.0	4	0.8	496	100.0	1	0.2	4.05	Convergence criterion (RCONV=1E-8) satisfied.	0.45	36.35	0.006	Algorithm converged.	-0.003	0.015	4.02	Algorithm converged.	0.45	35.88	0.2123	NE	0.25	Algorithm converged.	0.03	2.22
General disorders and administration site conditions	Multiple organ dysfunction syndrome	n/a	495	100.0	1	0.2	496	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	>999.99	Algorithm converged.	NE	NE
Infections and infestations		n/a	495	100.0	6	1.2	496	100.0	1	0.2	6.03	Convergence criterion (RCONV=1E-8) satisfied.	0.72	50.57	0.010	Algorithm converged.	-0.002	0.022	5.98	Algorithm converged.	0.73	48.97	0.0844	NE	0.50	Algorithm converged.	0.06	4.00
Infections and infestations	Pneumonia	n/a	495	100.0	4	0.8	496	100.0	1	0.2	4.05	Convergence criterion (RCONV=1E-8) satisfied.	0.45	36.35	0.006	Algorithm converged.	-0.003	0.015	4.02	Algorithm converged.	0.45	35.88	0.2123	NE	0.25	Algorithm converged.	0.03	2.22
Infections and infestations	Sepsis	n/a	495	100.0	2	0.4	496	100.0	1	0.2	2.02	Convergence criterion (RCONV=1E-8) satisfied.	0.18	22.57	0.002	Algorithm converged.	-0.004	0.008	2.01	Algorithm converged.	0.18	22.45	0.4964	NE	0.50	Algorithm converged.	0.06	4.00
Infections and infestations	Septic shock	n/a	495	100.0	2	0.4	496	100.0	1	0.2	*	Quasi-complete separation of data points detected.			*	WARNING: Negative of Hessian not positive definite.			2.01	Algorithm converged.	0.18	22.45	0.4964	NE	0.50	Algorithm converged.	0.06	4.00
Infections and infestations	Suspected COVID-19	n/a	495	100.0	1	0.2	496	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	495	100.0	1	0.2	496	100.0	1	0.2	*	Quasi-complete separation of data points detected.			*	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.01	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Injury, poisoning and procedural complications	Injury	n/a	495	100.0	1	0.2	496	100.0	1	0.2	*	Quasi-complete separation of data points detected.			*	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.01	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Renal and urinary disorders		n/a	495	100.0	1	0.2	496	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	Acute kidney injury	n/a	495	100.0	1	0.2	496	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	495	100.0	1	0.2	496	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 failure	n/a	495	100.0	1	0.2	496	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

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to HAT, whichever is earlier.
Only AEs of highest severity are counted.
Test for interaction based on RR (log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: /cust/clinical_studies/BO554107/CSP57884/BO39942/data_analysis/ACE_FINAL_DS/prod/program/t_ae_raw_aoc.sas
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08FEB2023 18:43

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 5 (AEs leading to Death)
MODEL: Unstratified Analysis
STUDY: BO39942
Dichotomous Analysis by Subgroups (Safety)

Age

			Pulsatilla Vedotin + B-CHP (N=335)				B-CHP (N=336)				Pulsatilla Vedotin + B-CHP vs. B-CHP												B-CHP vs. Pulsatilla Vedotin + B-CHP			
			Patients		Patients with Event		Patients		Patients with Event		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		>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Cardiac disorders		< 40	328	66.3	1	0.3	361	68.9	1	0.3		* Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	0.95	NE	0.9999		>999.99	Algorithm converged.	0.05	NE
Cardiac disorders	Atrioventricular block complete	>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Cardiac disorders	Atrioventricular block complete	< 40	328	66.3	1	0.3	361	68.9	1	0.3		* Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	0.95	NE	0.9999		>999.99	Algorithm converged.	0.05	NE
Gastrointestinal disorders		>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Gastrointestinal disorders		< 40	328	66.3	1	0.3	361	68.9	1	0.3		* 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
Gastrointestinal disorders	Intestinal perforation	>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Gastrointestinal disorders	Intestinal perforation	< 40	328	66.3	1	0.3	361	68.9	1	0.3		* 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
General disorders and administration site conditions		>= 40	167	33.7	1	0.6	167	31.1	1	0.6		* Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	0.4383	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		< 40	328	66.3	4	1.2	361	68.9	3	0.8	1.59	Convergence criterion (HCONV=1E-6) satisfied.	0.34	11.50	0.004	Algorithm converged.	-0.004	0.001	2.08	Algorithm converged.	0.94	11.36	0.3941		0.48	Algorithm converged.	0.09	2.41
General disorders and administration site conditions	Cardiac death	>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
General disorders and administration site conditions	Cardiac death	< 40	328	66.3	1	0.3	361	68.9	1	0.3		* 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
General disorders and administration site conditions	Death	>= 40	167	33.7	1	0.6	167	31.1	1	0.6		* Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	0.4944	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Death	< 40	328	66.3	3	0.9	361	68.9	1	0.3	3.16	Convergence criterion (HCONV=1E-6) satisfied.	0.32	30.93	0.006	Algorithm converged.	-0.006	0.018	3.12	Algorithm converged.	0.93	29.93	0.3235		0.32	Algorithm converged.	0.03	3.07
General disorders and administration site conditions	Multiple organ dysfunction syndrome	>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
General disorders and administration site conditions	Multiple organ dysfunction syndrome	< 40	328	66.3	0	0.0	361	68.9	1	0.3		* Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	0.95	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Infections and infestations		>= 40	167	33.7	3	1.8	167	31.1	1	0.6		* Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	0.0245	NE	Algorithm converged.	NE	NE
Infections and infestations		< 40	328	66.3	3	0.9	361	68.9	5	1.4	0.63	Convergence criterion (HCONV=1E-6) satisfied.	0.13	2.98	-0.006	Algorithm converged.	-0.006	0.006	0.52	Algorithm converged.	0.13	2.86	0.3519		1.55	Algorithm converged.	0.49	7.43
Infections and infestations	Pneumonia	>= 40	167	33.7	2	1.2	167	31.1	1	0.6		* Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	0.1025	NE	Algorithm converged.	NE	NE
Infections and infestations	Pneumonia	< 40	328	66.3	2	0.6	361	68.9	3	0.8	0.69	Convergence criterion (HCONV=1E-6) satisfied.	0.11	4.16	-0.003	Algorithm converged.	-0.006	0.002	0.49	Algorithm converged.	0.11	4.12	0.4869		1.44	Algorithm converged.	0.24	8.58
Infections and infestations	Sepsis	>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	1.0000	NE		NE	NE
Infections and infestations	Sepsis	< 40	328	66.3	1	0.3	361	68.9	1	0.3	1.06	Convergence criterion (HCONV=1E-6) satisfied.	0.06	16.69	0.000	Algorithm converged.	-0.006	0.006	1.04	Algorithm converged.	0.07	16.35	0.9765		0.96	Algorithm converged.	0.06	15.31
Infections and infestations	Septic shock	>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Infections and infestations	Septic shock	< 40	328	66.3	1	0.3	361	68.9	1	0.3		* Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	0.95	NE	0.9999		>999.99	Algorithm converged.	0.05	NE
Infections and infestations	Suspected COVID-19	>= 40	167	33.7	1	0.6	167	31.1	1	0.6		* 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	Suspected COVID-19	< 40	328	66.3	1	0.3	361	68.9	1	0.3	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Injury, poisoning and procedural complications		>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Injury, poisoning and procedural complications		< 40	328	66.3	1	0.3	361	68.9	1	0.3		* Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	0.95	NE	0.9999		>999.99	Algorithm converged.	0.05	NE
Injury, poisoning and procedural complications	Injury	>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Injury, poisoning and procedural complications	Injury	< 40	328	66.3	1	0.3	361	68.9	1	0.3		* Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	0.95	NE	0.9999		>999.99	Algorithm converged.	0.05	NE
Renal and urinary disorders		>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Renal and urinary disorders		< 40	328	66.3	1	0.3	361	68.9	1	0.3		* 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
Renal and urinary disorders	Acute kidney injury	>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Renal and urinary disorders	Acute kidney injury	< 40	328	66.3	1	0.3	361	68.9	1	0.3		* 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		>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Respiratory, thoracic and mediastinal disorders		< 40	328	66.3	1	0.3	361	68.9	1	0.3		* 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	Respiratory failure	>= 40	167	33.7	1	0.6	167	31.1	1	0.6	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory failure	< 40	328	66.3	1	0.3	361	68.9	1	0.3		* 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

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to HALT, whichever is earlier.
Only AEs of highest severity are counted.
Test for interaction based on RR (log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO5541077/CSP57884/bo39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/BO5541077/CSP57884/bo39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_soc_ap2_WSKSAE_RE_POOLED_15JUN2022_39942.rtf
08FEB2023 18:43

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 5 (AEs leading to Death)
MODEL: Unstratified Analysis
STUDY: BI39942
Dichotomous Analysis by Subgroups (Safety)

ZPG score at Screening

			Pulsatilla Vedrita + B-CHP (N=495)				B-CHP (N=495)				Pulsatilla Vedrita + B-CHP vs. B-CHP																Pulsatilla Vedrita + B-CHP			
			Patients		Patients with Event		Patients		Patients with Event		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		1-2	187	37.8	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders		3	196	39.6	1	0.5	196	37.2	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders		4-5	112	22.6	1	0.9	125	25.1	1	0.8		* Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314112847 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block complete	1-2	187	37.8	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	3	196	39.6	1	0.5	196	37.2	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	4-5	112	22.6	1	0.9	125	25.1	1	0.8		* Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314112847 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders		1-2	187	37.8	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders		3	196	39.6	1	0.5	196	37.2	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders		4-5	112	22.6	1	0.9	125	25.1	1	0.8		* Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	0.05	NE	NE		NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Intestinal perforation	1-2	187	37.8	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Intestinal perforation	3	196	39.6	1	0.5	196	37.2	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Intestinal perforation	4-5	112	22.6	1	0.9	125	25.1	1	0.8		* Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	0.05	NE	NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		1-2	187	37.8	1	1.1	187	37.4	1	0.5		* Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	0.1177	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		3	196	39.6	1	1.0	196	37.2	1	0.5		* Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.698690926 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		4-5	112	22.6	1	0.9	125	25.1	1	0.8	1.43	Convergence criterion (GCONV=1E-6) satisfied.	0.09	6.59	-0.000	Algorithm converged.	-0.095	0.064	0.91	Algorithm converged.	0.05	6.47	0.8369		1.15	Algorithm converged.	0.14	18.66
General disorders and administration site conditions	Cardiac death	1-2	187	37.8	1	0.5	187	37.4	1	0.5		* 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	Cardiac death	3	196	39.6	1	0.5	196	37.2	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Cardiac death	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Death	1-2	187	37.8	1	0.5	187	37.4	1	0.5		* Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	0.3553	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Death	3	196	39.6	1	1.0	196	37.2	1	0.5		* Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.698690926 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	Death	4-5	112	22.6	1	0.9	125	25.1	1	0.8	1.13	Convergence criterion (GCONV=1E-6) satisfied.	0.07	18.07	0.000	Algorithm converged.	-0.095	0.064	1.12	Algorithm converged.	0.07	17.40	0.9378		0.95	Algorithm converged.	0.06	14.14
General disorders and administration site conditions	Multiple organ dysfunction syndrome	1-2	187	37.8	0	0.0	187	37.4	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	Multiple organ dysfunction syndrome	3	196	39.6	0	0.0	196	37.2	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	Multiple organ dysfunction syndrome	4-5	112	22.6	0	0.0	125	25.1	1	0.8		* Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314112847 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Infections and infestations		1-2	187	37.8	4	2.1	187	37.4	1	0.5	4.67	Convergence criterion (GCONV=1E-6) satisfied.	0.45	36.75	0.016	Algorithm converged.	-0.095	0.064	4.00	Algorithm converged.	0.45	35.45	0.2130	0.1845	0.25	Algorithm converged.	0.03	2.22
Infections and infestations		3	196	39.6	3	1.5	196	37.2	1	1.6	3.01	Convergence criterion (GCONV=1E-6) satisfied.	0.30	7.03	-0.011	Algorithm converged.	-0.095	0.064	0.32	Algorithm converged.	0.03	3.01	0.3570		3.16	Algorithm converged.	0.33	30.12
Infections and infestations		4-5	112	22.6	1	0.9	125	25.1	1	1.6	0.03	Convergence criterion (GCONV=1E-6) satisfied.	0.00	4.19	-0.000	Algorithm converged.	-0.095	0.064	0.54	Algorithm converged.	0.05	4.07	0.6319		1.79	Algorithm converged.	0.16	19.50
Infections and infestations	Pneumonia	1-2	187	37.8	3	1.5	187	37.4	1	0.5	3.01	Convergence criterion (GCONV=1E-6) satisfied.	0.30	29.85	0.011	Algorithm converged.	-0.095	0.064	3.00	Algorithm converged.	0.03	28.56	0.3384	0.2225	0.33	Algorithm converged.	0.03	3.18
Infections and infestations	Pneumonia	3	196	39.6	1	0.5	196	37.2	1	0.5	0.95	Convergence criterion (GCONV=1E-6) satisfied.	0.06	15.04	0.000	Algorithm converged.	-0.095	0.064	0.95	Algorithm converged.	0.05	15.76	0.9704		1.05	Algorithm converged.	0.07	14.72
Infections and infestations	Pneumonia	4-5	112	22.6	0	0.0	125	25.1	1	0.8		* Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314112847 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Infections and infestations	Sepsis	1-2	187	37.8	0	0.0	187	37.4	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Sepsis	3	196	39.6	1	0.5	196	37.2	1	0.5		* Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	0.05	NE	1.0000		>999.99	Algorithm converged.	0.00	NE
Infections and infestations	Sepsis	4-5	112	22.6	1	0.9	125	25.1	1	0.8		* Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.713482 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	0.05	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Septic shock	1-2	187	37.8	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Septic shock	3	196	39.6	1	0.5	196	37.2	1	0.5		* Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.				Algorithm converged.	0.05	NE	1.0000		>999.99	Algorithm converged.	0.00	NE
Infections and infestations	Septic shock	4-5	112	22.6	1	0.9	125	25.1	1	0.8		* Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314112847 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Infections and infestations	Suspected COVID-19	1-2	187	37.8	1	0.5	187	37.4	1	0.5		* 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	Suspected COVID-19	3	196	39.6	0	0.0	196	37.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Suspected COVID-19	4-5	112	22.6	0	0.0	125	25.1	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		1-2	187	37.8	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications		3	196	39.6	1	0.5	196	37.2	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications		4-5	112	22.6	1	0.9	125	25.1	1	0.8		* Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314112847 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Injury, poisoning and procedural complications	Injury	1-2	187	37.8	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Injury	3	196	39.6	1	0.5	196	37.2	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Injury, poisoning and procedural complications	Injury	4-5	112	22.6	1	0.9	125	25.1	1	0.8		* Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314112847 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Renal and urinary disorders		1-2	187	37.8	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders		3	196	39.6	1	0.5	196	37.2	1	0.5		* Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	0.05	NE	NE		NE	Algorithm converged.	NE	NE
Renal and urinary disorders		4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders	Acute kidney injury	1-2	187	37.8	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders	Acute kidney injury	3	196	39.6	1	0.5	196	37.2	1	0.5		* Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	0.05	NE	NE		NE	Algorithm converged.	NE	NE
Renal and urinary disorders	Acute kidney injury	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders		1-2	187	37.8	1	0.5	187	37.4	1	0.5		* Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	0.05	NE	NE		NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders		3	196	39.6	1	0.5	196	37.2	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders		4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory failure	1-2	187	37.8	1	0.5	187	37.4	1	0.5		* Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				Algorithm converged.	0.05	NE	NE		NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory failure	3	196	39.6	1	0.5	196	37.2	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory failure	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to HALT, whichever is earlier.
Only AEs of highest severity are counted.
Test for interaction based on RR (log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/mc0541077/CDF57894/bi39942/data_analysis/ACE_FINAL_DB/prod/program/t_ae_raw_soc.sas
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08FEB2023 18:43

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 5 (AEs leading to Death)
MODEL: Unstratified Analysis
STUDY: BG39942
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Pulrotuxmab Vedotin + B-CHP (N=496)				B-CHP (N=498)				Pulrotuxmab Vedotin + B-CHP vs. B-CHP																B-CHP vs. Pulrotuxmab Vedotin + B-CHP			
			Patients		Patients with Event		Patients		Patients with Event		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)	Interacting Text (p-value likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Cardiac disorders		Western Europe/United States/Canada/Australia	298	60.2	3	0.6	300	60.2	1	0.2		* 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
Cardiac disorders		Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders		Rest of World	57	11.5	0	0.0	55	11.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	Western Europe/United States/Canada/Australia	298	60.2	3	0.6	300	60.2	1	0.2		* 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
Cardiac disorders	Atrioventricular block complete	Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	Rest of World	57	11.5	0	0.0	55	11.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders		Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	0	0.0		* Quasi-complete separation of data points detected.				WARNING: The relative Weaisn convergence criterion of 44.8047902392 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE		>999.99	Algorithm converged.	NE	NE
Gastrointestinal disorders		Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders		Rest of World	57	11.5	0	0.0	55	11.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Intestinal perforation	Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	0	0.0		* Quasi-complete separation of data points detected.				WARNING: The relative Weaisn convergence criterion of 44.8047902392 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE		>999.99	Algorithm converged.	NE	NE
Gastrointestinal disorders	Intestinal perforation	Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Intestinal perforation	Rest of World	57	11.5	0	0.0	55	11.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
General disorders and administration site conditions		Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	0	0.0		* Quasi-complete separation of data points detected.				WARNING: Negative of Weaisn not positive definite.			NE	Algorithm converged.	NE	NE	NE	0.4078	NE	Algorithm converged.	NE	NE
General disorders and administration site conditions		Asia	140	28.3	1	0.7	135	27.0	1	0.7	0.96	Convergence criterion (NCONV=1E-8) satisfied.	0.06	14.53	0.000	Algorithm converged.	-0.060	0.061	0.99	Algorithm converged.	0.06	15.72	0.9959		1.03	Algorithm converged.	0.06	15.94
General disorders and administration site conditions		Rest of World	57	11.5	2	3.5	55	11.0	1	1.7	2.11	Convergence criterion (NCONV=1E-8) satisfied.	0.18	23.93	0.018	Algorithm converged.	-0.040	0.076	2.07	Algorithm converged.	0.18	22.21	0.5474		0.48	Algorithm converged.	0.03	5.14
General disorders and administration site conditions	Cardiac death	Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	0	0.0		* Quasi-complete separation of data points detected.				WARNING: The relative Weaisn convergence criterion of 44.8047902392 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE		>999.99	Algorithm converged.	NE	NE
General disorders and administration site conditions	Cardiac death	Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
General disorders and administration site conditions	Cardiac death	Rest of World	57	11.5	0	0.0	55	11.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
General disorders and administration site conditions	Death	Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	0	0.0		* Quasi-complete separation of data points detected.				WARNING: Negative of Weaisn not positive definite.			NE	Algorithm converged.	NE	NE	NE		>999.99	Algorithm converged.	NE	NE
General disorders and administration site conditions	Death	Asia	140	28.3	1	0.7	135	27.0	1	0.7	0.96	Convergence criterion (NCONV=1E-8) satisfied.	0.06	14.53	0.000	Algorithm converged.	-0.060	0.061	0.99	Algorithm converged.	0.06	15.72	0.9959		1.03	Algorithm converged.	0.06	15.94
General disorders and administration site conditions	Death	Rest of World	57	11.5	2	3.5	55	11.0	1	1.7	2.11	* Quasi-complete separation of data points detected.				WARNING: The relative Weaisn convergence criterion of 6.6723398513 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE		>999.99	Algorithm converged.	NE	NE
General disorders and administration site conditions	Multiple organ dysfunction syndrome	Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	0	0.0		* Quasi-complete separation of data points detected.				WARNING: Negative of Weaisn not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Multiple organ dysfunction syndrome	Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
General disorders and administration site conditions	Multiple organ dysfunction syndrome	Rest of World	57	11.5	0	0.0	55	11.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Infections and infestations		Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	1	0.2	1.00	Convergence criterion (NCONV=1E-8) satisfied.	0.06	7.10	0.000	Algorithm converged.	-0.020	0.020	1.00	Algorithm converged.	0.06	6.90	0.4758		0.99	Algorithm converged.	0.14	2.47
Infections and infestations		Asia	140	28.3	1	0.7	135	27.0	1	0.7	0.96	Convergence criterion (NCONV=1E-8) satisfied.	0.06	14.53	0.000	Algorithm converged.	-0.060	0.061	0.99	Algorithm converged.	0.06	15.72	0.9959		1.03	Algorithm converged.	0.06	15.94
Infections and infestations		Rest of World	57	11.5	3	5.3	55	11.0	2	3.6	1.49	Convergence criterion (NCONV=1E-8) satisfied.	0.25	34.41	0.211	Algorithm converged.	-0.030	0.090	1.48	Algorithm converged.	0.25	35.82	0.2116		1.029	Algorithm converged.	0.05	9.21
Infections and infestations	Pneumonia	Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	1	0.2	1.00	Convergence criterion (NCONV=1E-8) satisfied.	0.06	7.10	0.000	Algorithm converged.	-0.020	0.020	1.00	Algorithm converged.	0.06	6.90	0.4758		0.99	Algorithm converged.	0.14	2.47
Infections and infestations	Pneumonia	Asia	140	28.3	1	0.7	135	27.0	1	0.7	0.96	Convergence criterion (NCONV=1E-8) satisfied.	0.06	14.53	0.000	Algorithm converged.	-0.060	0.061	0.99	Algorithm converged.	0.06	15.72	0.9959		1.03	Algorithm converged.	0.06	15.94
Infections and infestations	Pneumonia	Rest of World	57	11.5	2	3.5	55	11.0	1	1.7	2.11	* Quasi-complete separation of data points detected.				WARNING: The relative Weaisn convergence criterion of 6.6723398513 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE		>999.99	Algorithm converged.	NE	NE
Infections and infestations	Sepsis	Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	1	0.2	1.00	Convergence criterion (NCONV=1E-8) satisfied.	0.06	7.10	0.000	Algorithm converged.	-0.020	0.020	1.00	Algorithm converged.	0.06	6.90	0.4758		0.99	Algorithm converged.	0.14	2.47
Infections and infestations	Sepsis	Asia	140	28.3	1	0.7	135	27.0	1	0.7	0.96	Convergence criterion (NCONV=1E-8) satisfied.	0.06	14.53	0.000	Algorithm converged.	-0.060	0.061	0.99	Algorithm converged.	0.06	15.72	0.9959		1.03	Algorithm converged.	0.06	15.94
Infections and infestations	Sepsis	Rest of World	57	11.5	3	5.3	55	11.0	2	3.6	1.49	* Quasi-complete separation of data points detected.				WARNING: The relative Weaisn convergence criterion of 6.6723398513 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE		>999.99	Algorithm converged.	NE	NE
Infections and infestations	Septic shock	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.2		* 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	Septic shock	Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Septic shock	Rest of World	57	11.5	0	0.0	55	11.0	1	1.7		* Quasi-complete separation of data points detected.				WARNING: The relative Weaisn convergence criterion of 10.540168405 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
Infections and infestations	Suspected COVID-19	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.2		* 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	Suspected COVID-19	Asia	140	28.3	1	0.7	135	27.0	1	0.7	0.96	Convergence criterion (NCONV=1E-8) satisfied.	0.06	14.53	0.000	Algorithm converged.	-0.060	0.061	0.99	Algorithm converged.	0.06	15.72	0.9959		1.03	Algorithm converged.	0.06	15.94
Infections and infestations	Suspected COVID-19	Rest of World	57	11.5	3	5.3	55	11.0	2	3.6	1.49	* Quasi-complete separation of data points detected.				WARNING: The relative Weaisn convergence criterion of 6.6723398513 is greater than the limit of 0.0001. The convergence is questionable.				Algorithm converged.	NE	NE	NE		>999.99	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications		Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	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.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Injury, poisoning and procedural complications		Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Injury, poisoning and procedural complications		Rest of World	57	11.5	0	0.0	55	11.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Injury, poisoning and procedural complications	Injury	Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	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.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Injury, poisoning and procedural complications	Injury	Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Injury, poisoning and procedural complications	Injury	Rest of World	57	11.5	0	0.0	55	11.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Renal and urinary disorders		Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	0	0.0		* Quasi-complete separation of data points detected.				WARNING: Negative of Weaisn not positive definite.			NE	Algorithm converged.	NE	NE	NE	0.4078	NE	Algorithm converged.	NE	NE
Renal and urinary disorders		Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Renal and urinary disorders		Rest of World	57	11.5	1	1.8	55	11.0	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
Renal and urinary disorders	Acute kidney injury	Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Renal and urinary disorders	Acute kidney injury	Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Renal and urinary disorders	Acute kidney injury	Rest of World	57	11.5	1	1.8	55	11.0	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
Respiratory, thoracic and mediastinal disorders		Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	0	0.0		* Quasi-complete separation of data points detected.				WARNING: Negative of Weaisn not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders		Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders		Rest of World	57	11.5	0	0.0	55	11.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Western Europe/United States/Canada/Australia	298	60.2	1	0.2	300	60.2	0	0.0		* Quasi-complete separation of data points detected.				WARNING: Negative of Weaisn not positive definite.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Asia	140	28.3	0	0.0	135	27.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Rest of World	57	11.5	0	0.0	55	11.0	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE		NE	NE	NE		NE	NE	NE	NE

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to HALT, whichever is earlier.
Only AEs of highest severity are counted.
Test for interaction based on RR (log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JAN2022

Program: root/clinical_studies/BG541077/CDPT7886/BG39942/data_analysis/ACR_FINAL_DB/prod/program/t_ae_xaw_aoc.sas
Output: root/clinical_studies/BG541077/CDPT7886/BG39942/data_analysis/ACR_FINAL_DB/prod/output/t_ae_xaw_aoc_ag2_WHOEAE_SE_POOLED_15JAN2022_39942.rtf
SEP04A2023 18:43

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs Grade 5 (AEs leading to Death)
MODEL: Unstratified Analysis
STUDY: BO39942
Dichotomous Analysis by Subgroups (Safety)

Sex

			Pirtobrutinib Vebrit + B-CHP (N=495)				B-CHOP (N=495)				Pirtobrutinib Vebrit + B-CHP vs. B-CHOP												B-CHOP vs. Pirtobrutinib Vebrit + B-CHP			
			Patients		Patients with Event		Patients		Patients with Event		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		Male	245	53.9	1	0.4	260	54.4	1	0.4	NE																			
Cardiac disorders		Female	230	46.5	1	0.4	235	46.0	1	0.4	NE																			
Cardiac disorders	Atrioventricular block complete	Male	245	53.9	1	0.4	260	54.4	1	0.4		* Quasi-complete separation of data points detected.					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					Algorithm converged.	0.04	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block complete	Female	230	46.5	1	0.4	235	46.0	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders		Male	245	53.9	1	0.4	260	54.4	1	0.4		* Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.					Algorithm converged.	0.04	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders		Female	230	46.5	1	0.4	235	46.0	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Intestinal perforation	Male	245	53.9	1	0.4	260	54.4	1	0.4		* Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.					Algorithm converged.	0.04	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Intestinal perforation	Female	230	46.5	1	0.4	235	46.0	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE
General disorders and administration site conditions		Male	245	53.9	1	1.1	260	54.4	2	0.7	1.53	Convergence criterion (GCONV=1E-8) satisfied.	0.05	9.03	0.006		Algorithm converged.	-0.010	0.021	1.52		Algorithm converged.	0.04	8.66	0.6436	0.2019	0.64	Algorithm converged.	0.13	3.90
General disorders and administration site conditions		Female	230	46.5	1	0.4	235	46.0	1	0.4		* Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.					Algorithm converged.	0.04	NE	NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Cardiac death	Male	245	53.9	1	0.4	260	54.4	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE
General disorders and administration site conditions	Cardiac death	Female	230	46.5	1	0.4	235	46.0	1	0.4		* Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.					Algorithm converged.	0.04	NE	NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Death	Male	245	53.9	1	1.1	260	54.4	2	0.4	1.67	Convergence criterion (GCONV=1E-8) satisfied.	0.05	29.68	0.006		Algorithm converged.	-0.007	0.020	3.05		Algorithm converged.	0.04	29.68	0.3305	0.4803	0.03	Algorithm converged.	0.03	3.14
General disorders and administration site conditions	Death	Female	230	46.5	1	0.4	235	46.0	1	0.4		* Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.					Algorithm converged.	0.04	NE	NE		NE	Algorithm converged.	NE	NE
General disorders and administration site conditions	Multiple organ dysfunction syndrome	Male	245	53.9	1	0.4	260	54.4	1	0.4		* Quasi-complete separation of data points detected.					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					Algorithm converged.	0.04	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
General disorders and administration site conditions	Multiple organ dysfunction syndrome	Female	230	46.5	1	0.4	235	46.0	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations		Male	245	53.9	1	0.4	260	54.4	5	1.9	5.45	Convergence criterion (GCONV=1E-8) satisfied.	0.58	2.89	<0.001		Algorithm converged.	-0.008	0.036	0.41		Algorithm converged.	0.04	2.87	0.2768	0.0721	2.86	Algorithm converged.	0.48	12.58
Infections and infestations		Female	230	46.5	4	1.7	235	46.0	1	0.4	4.66	Convergence criterion (GCONV=1E-8) satisfied.	0.45	34.38	0.012		Algorithm converged.	-0.006	0.050	3.96		Algorithm converged.	0.03	35.36	0.2148		0.03	Algorithm converged.	0.03	2.23
Infections and infestations	Pneumonia	Male	245	53.9	2	0.8	260	54.4	4	0.7	1.66	Convergence criterion (GCONV=1E-8) satisfied.	0.21	7.69	0.006		Algorithm converged.	-0.006	0.029	1.06		Algorithm converged.	0.03	7.67	0.9880	0.4856	0.03	Algorithm converged.	0.14	4.94
Infections and infestations	Pneumonia	Female	230	46.5	2	0.9	235	46.0	1	0.4	3.00	Convergence criterion (GCONV=1E-8) satisfied.	0.24	22.23	0.004		Algorithm converged.	-0.006	0.044	1.94		Algorithm converged.	0.04	21.91	0.5727		0.05	Algorithm converged.	0.05	5.50
Infections and infestations	Sepsis	Male	245	53.9	1	0.4	260	54.4	1	0.4		* Quasi-complete separation of data points detected.					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					Algorithm converged.	0.04	NE	0.9999	0.0968	>999.99	Algorithm converged.	0.00	NE
Infections and infestations	Sepsis	Female	230	46.5	1	0.4	235	46.0	1	0.4		* Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.					Algorithm converged.	0.04	NE	NE		NE	Algorithm converged.	NE	NE
Infections and infestations	Septic shock	Male	245	53.9	1	0.4	260	54.4	2	0.7		* Quasi-complete separation of data points detected.					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					Algorithm converged.	0.04	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Infections and infestations	Septic shock	Female	230	46.5	1	0.4	235	46.0	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE
Infections and infestations	Suspected COVID-19	Male	245	53.9	1	0.4	260	54.4	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE
Infections and infestations	Suspected COVID-19	Female	230	46.5	1	0.4	235	46.0	1	0.4		* Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.					Algorithm converged.	0.04	NE	NE		NE	Algorithm converged.	NE	NE
Injury, poisoning and procedural complications		Male	245	53.9	1	0.4	260	54.4	1	0.4		* Quasi-complete separation of data points detected.					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					Algorithm converged.	0.04	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Injury, poisoning and procedural complications		Female	230	46.5	1	0.4	235	46.0	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE
Injury, poisoning and procedural complications	Injury	Male	245	53.9	1	0.4	260	54.4	1	0.4		* Quasi-complete separation of data points detected.					ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					Algorithm converged.	0.04	NE	0.9999		>999.99	Algorithm converged.	0.00	NE
Injury, poisoning and procedural complications	Injury	Female	230	46.5	1	0.4	235	46.0	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE
Renal and urinary disorders		Male	245	53.9	1	0.4	260	54.4	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders		Female	230	46.5	1	0.4	235	46.0	1	0.4		* Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.					Algorithm converged.	0.04	NE	NE		NE	Algorithm converged.	NE	NE
Renal and urinary disorders	Acute kidney injury	Male	245	53.9	1	0.4	260	54.4	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE
Renal and urinary disorders	Acute kidney injury	Female	230	46.5	1	0.4	235	46.0	1	0.4		* Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.					Algorithm converged.	0.04	NE	NE		NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders		Male	245	53.9	1	0.4	260	54.4	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders		Female	230	46.5	1	0.4	235	46.0	1	0.4		* Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.					Algorithm converged.	0.04	NE	NE		NE	Algorithm converged.	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Male	245	53.9	1	0.4	260	54.4	1	0.4	NE		NE	NE	NE		NE	NE	NE	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Female	230	46.5	1	0.4	235	46.0	1	0.4		* Quasi-complete separation of data points detected.					WARNING: Negative of Hessian not positive definite.					Algorithm converged.	0.04	NE	NE		NE	Algorithm converged.	NE	NE

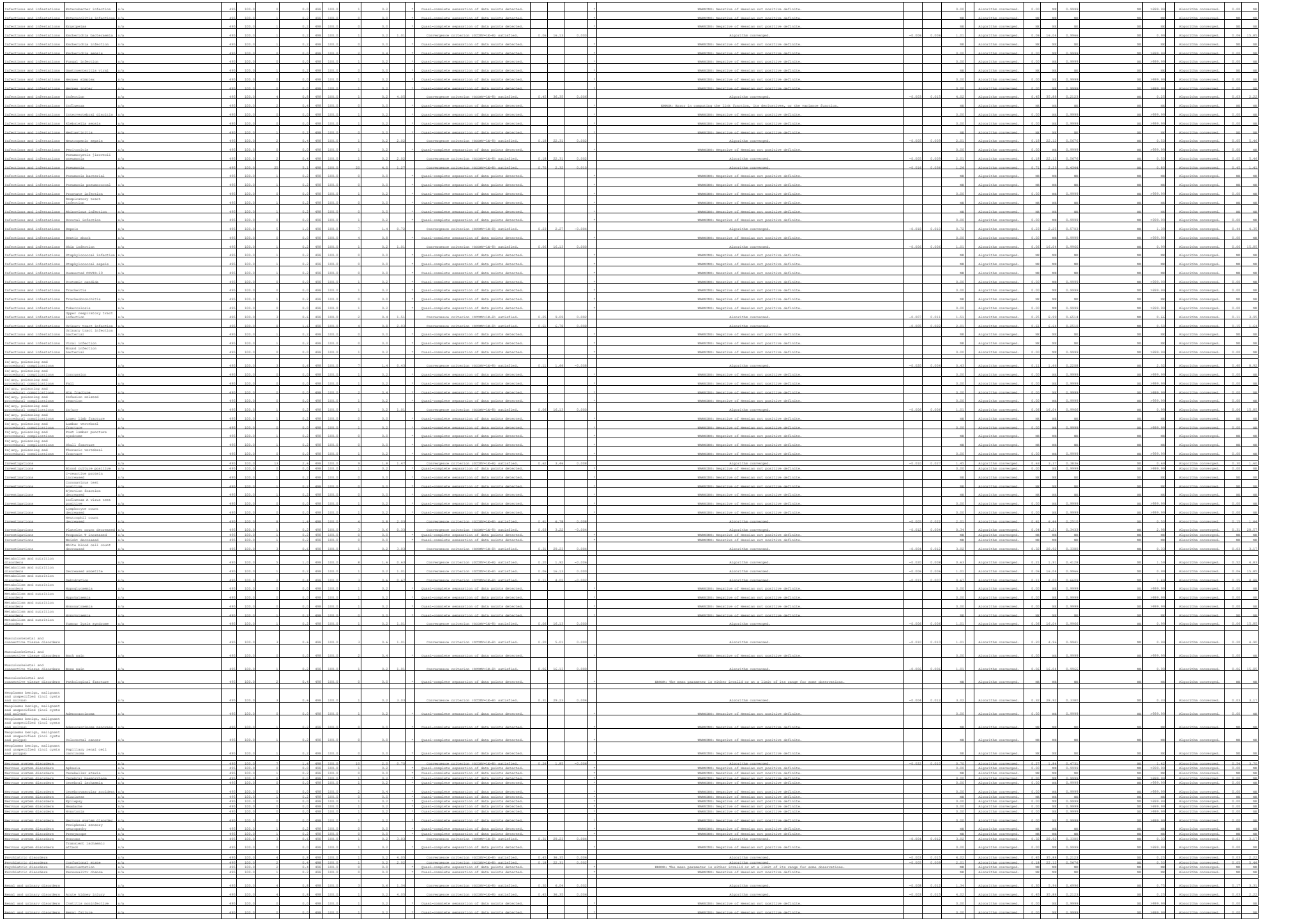
Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to HALT, whichever is earlier.
Only AEs of highest severity are counted.
Test for interaction based on RR (log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO5541077/CSP07884/bo39942/data_analysis/ACK_FINAL_OS/prod/program/t_ae_raw_soc.sas
Output: root/clinical_studies/BO5541077/CSP07884/bo39942/data_analysis/ACK_FINAL_OS/prod/output/t_ae_raw_soc_sp2_WORKSAE_RR_POOLED_15JUN2022_39942.xls
08FEB2023 18:43

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Any SOAEs
MODEL: Unstratified Analysis
ATOOT: SOJ0962
Dichotomous Analysis by Subgroups (Safety)

All

			Pulsatorsomab Vedotin + N-Cmpr (N=496)				N-Cmpr (N=496)				Pulsatorsomab Vedotin + N-CMP vs. N-Cmpr											Pulsatorsomab Vedotin + N-CMP vs. N-Cmpr					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio							Absolute Risk Difference				Relative Risk					
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Result	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Result	95% Lower CL	95% Upper CL	Relative Risk	Convergence Result	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		n/a	495	100.0	59	11.9	496	100.0	45	9.0	1.38	Convergence criterion (HCONV<1E-8) satisfied.	0.89	2.02	0.029	Algorithm converged.	-0.011	0.067	1.32	Algorithm converged.	0.96	1.80	0.1676	NE	0.77	Algorithm converged.	0.52	1.12
Blood and lymphatic system disorders	Anaemia	n/a	495	100.0	9	1.8	496	100.0	5	1.0	1.81	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			1.80	Algorithm converged.	0.96	NE	0.9994	NE	>999.99	Algorithm converged.	0.56	NE
Blood and lymphatic system disorders	Anaemia	n/a	495	100.0	9	1.8	496	100.0	8	1.6	1.14	Convergence criterion (HCONV<1E-8) satisfied.	0.45	2.90	-0.006	Algorithm converged.	-0.040	0.028	0.43	Algorithm converged.	0.24	1.91	0.4126	NE	1.58	Algorithm converged.	0.52	4.83
Blood and lymphatic system disorders	Febrile bone marrow aplasia	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9961	NE	1.00	Algorithm converged.	0.06	15.85
Blood and lymphatic system disorders	Febrile neutropenia	n/a	495	100.0	47	9.5	496	100.0	31	6.2	1.58	Convergence criterion (HCONV<1E-8) satisfied.	0.98	2.55	0.033	Algorithm converged.	-0.001	0.068	1.53	Algorithm converged.	0.98	2.39	0.0576	NE	1.54	Algorithm converged.	0.99	1.01
Blood and lymphatic system disorders	Leukopenia	n/a	495	100.0	5	0.9	496	100.0	2	0.4	2.53	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			2.52	Algorithm converged.	0.96	NE	0.9999	NE	>999.99	Algorithm converged.	0.70	NE
Blood and lymphatic system disorders	Pancytopenia	n/a	495	100.0	4	0.8	496	100.0	3	0.6	1.34	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	Neutropenia	n/a	495	100.0	6	1.2	496	100.0	1	0.2	6.07	Convergence criterion (HCONV<1E-8) satisfied.	0.73	2.38	-0.006	Algorithm converged.	-0.016	0.005	0.43	Algorithm converged.	0.19	2.35	0.5341	NE	5.40	Algorithm converged.	0.61	5.23
Blood and lymphatic system disorders	Thrombocytopenia	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9961	NE	1.00	Algorithm converged.	0.06	15.85
Cardiac disorders		n/a	495	100.0	14	2.8	496	100.0	10	2.0	1.40	Convergence criterion (HCONV<1E-8) satisfied.	0.57	3.47	-0.014	Algorithm converged.	-0.047	0.017	0.71	Algorithm converged.	0.33	1.57	0.7171	NE	0.68	Algorithm converged.	0.32	1.54
Cardiac disorders	Atrial fibrillation	n/a	495	100.0	3	0.6	496	100.0	1	0.2	3.03	Convergence criterion (HCONV<1E-8) satisfied.	0.31	3.23	-0.004	Algorithm converged.	-0.013	0.004	0.34	Algorithm converged.	0.04	3.23	0.3433	NE	2.98	Algorithm converged.	0.31	29.13
Cardiac disorders	Atrial flutter	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Convergence criterion (HCONV<1E-8) satisfied.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9961	NE	1.00	Algorithm converged.	0.06	15.85
Cardiac disorders	Atrioventricular block complete	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Cardiac disorders	Cardiac failure congestive	n/a	495	100.0	1	0.2	496	100.0	2	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.49	Algorithm converged.	0.05	NE	0.9999	NE	>999.99	Algorithm converged.	0.05	NE
Cardiac disorders	Left ventricular dysfunction	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Cardiac disorders	Myocardial infarction	n/a	495	100.0	1	0.2	496	100.0	1	0.2		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	Mitral valve incompetence	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Cardiac disorders	Sinus tachycardia	n/a	495	100.0	1	0.2	496	100.0	1	0.2		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	Tachycardia	n/a	495	100.0	2	0.4	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.49	Algorithm converged.	0.05	NE	0.9999	NE	>999.99	Algorithm converged.	0.05	NE
Eye disorders		n/a	495	100.0	2	0.4	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.49	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders		n/a	495	100.0	32	6.5	496	100.0	17	3.4	1.93	Convergence criterion (HCONV<1E-8) satisfied.	0.99	3.68	0.031	Convergence criterion (HCONV<1E-8) satisfied.	-0.001	0.064	1.91	Algorithm converged.	0.10	3.65	0.0727	NE	1.87	Algorithm converged.	0.92	3.87
Gastrointestinal disorders	Abdominal distension	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Gastrointestinal disorders	Abdominal pain	n/a	495	100.0	3	0.6	496	100.0	3	0.6	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.21	4.03	-0.010	Algorithm converged.	-0.051	0.027	0.67	Algorithm converged.	0.21	4.03	0.6603	NE	1.01	Algorithm converged.	0.21	4.83
Gastrointestinal disorders	Anal fistula	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Convergence criterion (HCONV<1E-8) satisfied.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9961	NE	1.00	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Anal stenosis	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Gastrointestinal disorders	Ascites	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Convergence criterion (HCONV<1E-8) satisfied.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9961	NE	1.00	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Constipation	n/a	495	100.0	4	0.8	496	100.0	4	0.8	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.24	4.24	0.000	Convergence criterion (HCONV<1E-8) satisfied.	-0.024	0.024	1.01	Algorithm converged.	0.24	4.24	0.9961	NE	1.01	Algorithm converged.	0.24	4.24
Gastrointestinal disorders	Diarrhoea	n/a	495	100.0	11	2.2	496	100.0	5	1.0	2.22	Convergence criterion (HCONV<1E-8) satisfied.	0.77	6.40	0.012	Convergence criterion (HCONV<1E-8) satisfied.	-0.009	0.033	2.20	Algorithm converged.	0.22	22.06	0.3043	NE	2.19	Algorithm converged.	0.77	6.23
Gastrointestinal disorders	Duodenitis	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Gastrointestinal disorders	Enteritis	n/a	495	100.0	2	0.4	496	100.0	1	0.2	2.03	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.49	Algorithm converged.	0.05	NE	0.9999	NE	>999.99	Algorithm converged.	0.05	NE
Gastrointestinal disorders	Enterocolitis	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Gastrointestinal disorders	Enterocolitis haemorrhagic	n/a	495	100.0	1	0.2	496	100.0	1	0.2		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	Gastritis	n/a	495	100.0	2	0.4	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.49	Algorithm converged.	0.05	NE	0.9999	NE	>999.99	Algorithm converged.	0.05	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Gastrointestinal disorders	Gastrointestinal obstruction	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Gastrointestinal disorders	Gastrointestinal perforation	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Gastrointestinal disorders	Gastritis	n/a	495	100.0	3	0.6	496	100.0	2	0.4	1.52	Convergence criterion (HCONV<1E-8) satisfied.	0.18	22.61	0.000	Convergence criterion (HCONV<1E-8) satisfied.	-0.000	0.000	1.52	Algorithm converged.	0.18	22.61	0.5676	NE	0.00	Algorithm converged.	0.00	0.00
Gastrointestinal disorders	Gingivitis	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Convergence criterion (HCONV<1E-8) satisfied.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9961	NE	1.00	Algorithm converged.	0.06	15.85
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	n/a	495	100.0	2	0.4	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.49	Algorithm converged.	NE	NE	NE	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Vomiting	n/a	495	100.0	7	1.4	496	100.0	3	0.6	2.34	Convergence criterion (HCONV<1E-8) satisfied.	0.60	13.07	0.008	Convergence criterion (HCONV<1E-8) satisfied.	-0.004	0.019	2.33	Algorithm converged.	0.60	12.90	0.2489	NE	2.40	Algorithm converged.	0.68	7.26
General disorders and administration site conditions		n/a	495	100.0	38	5.7	496	100.0	26	4.8	1.18	Convergence criterion (HCONV<1E-8) satisfied.	0.68	2.07	0.008	Algorithm converged.	-0.019	0.044	1.17	Algorithm converged.	0.49	2.80	0.5542	NE	0.85	Algorithm converged.	0.52	1.43
General disorders and administration site conditions	Administration site extravasation	n/a	495	100.0	1	0.2	496	100.0	1	0.2		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	495	100.0	2	0.4	496	100.0	1	0.2	2.03	Convergence criterion (HCONV<1E-8) satisfied.	0.18	22.61	0.000	Algorithm converged.	-0.000	0.000	2.03	Algorithm converged.	0.18	22.61	0.5676	NE	0.00	Algorithm converged.	0.01	5.44
General disorders and administration site conditions	Cardiac death	n/a	495	100.0	1	0.2	496	100.0	1	0.2		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	Catheter site haemorrhage	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
General disorders and administration site conditions	Chest pain	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Convergence criterion (HCONV<1E-8) satisfied.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9961	NE	1.00	Algorithm converged.	0.06	15.85
General disorders and administration site conditions	Chills	n/a	495	100.0	1	0.2	496	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	Death	n/a	495	100.0	4	0.8	496	100.0	1	0.2	4.05	Convergence criterion (HCONV<1E-8) satisfied.	0.45	36.35	0.004	Algorithm converged.	-0.003	0.011	4.02	Algorithm converged.	0.45	35.96	0.3123	NE	3.99	Algorithm converged.	0.50	2.22
General disorders and administration site conditions	Fatigue	n/a	495	100.0	2	0.4	496	100.0	1	0.2	2.03	Convergence criterion (HCONV<1E-8) satisfied.	0.18	5.63	-0.002	Algorithm converged.	-0.008	0.003	2.02	Algorithm converged.	0.05	5.53	0.5743	NE	1.99	Algorithm converged.	0.18	21.85
General disorders and administration site conditions	General physical health deterioration	n/a	495	100.0	2	0.4	496	100.0	1	0.2	2.03	Convergence criterion (HCONV<1E-8) satisfied.	0.18	22.61	0.000	Algorithm converged.	-0.000	0.000	2.03	Algorithm converged.	0.18	22.61	0.5676	NE	0.00	Algorithm converged.	0.00	5.44
General disorders and administration site conditions	Hypothermia	n/a	495	100.0	2	0.4	496	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	Ill-defined disorder	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
General disorders and administration site conditions	Infusion site extravasation	n/a	495	100.0	1	0.2	496	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	495	100.0	1	0.2	496	100.0	2	0.4	0.50	Convergence criterion (HCONV<1E-8) satisfied.	0.05	5.03	-0.002	Algorithm converged.	-0.008	0.003	0.50	Algorithm converged.	0.05	5.03	0.5743	NE	1.99	Algorithm converged.	0.18	21.85
General disorders and administration site conditions	Mucosal inflammation	n/a	495	100.0	2	0.4	496	100.0	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	Multiple organ dysfunction syndrome	n/a	495	100.0	1	0.2	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
General disorders and administration site conditions	Non-cardiac chest pain	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9961	NE	1.00	Algorithm converged.	0.06	15.85
General disorders and administration site conditions	Oedema peripheral	n/a	495	100.0	1	0.2	496	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	495	100.0	9	1.8	496	100.0	12	2.4	0.75	Convergence criterion (HCONV<1E-8) satisfied.	0.31	1.80	-0.004	Algorithm converged.	-0.028	0.010	0.75	Algorithm converged.	0.30	1.77	0.5197	NE	0.83	Algorithm converged.	0.32	2.14
General disorders and administration site conditions	Ulcer	n/a	495	100.0	1	0.2	496	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	Vascular stent thrombosis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Hepatobiliary disorders		n/a	495	100.0	2	0.4	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.20	5.03	0.000	Algorithm converged.	-0.010	0.010	1.01	Algorithm converged.	0.20	4.94	0.9941	NE	0.99	Algorithm converged.	0.20	4.93
Hepatobiliary disorders	Bile duct stenosis	n/a	495	100.0	0	0.0	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Hepatobiliary disorders	Bile duct stone	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Hepatobiliary disorders	Biliary obstruction	n/a	495	100.0	2	0.4	496	100.0	1	0.2		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	Cholecystitis	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Convergence criterion (HCONV<1E-8) satisfied.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9961	NE	1.00	Algorithm converged.	0.06	15.85
Hepatobiliary disorders	Cholecystitis acute	n/a	495	100.0	2	0.4	496	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.49	Algorithm converged.	0.05	NE	0.9999	NE	>999.99	Algorithm converged.	0.05	NE
Hepatobiliary disorders	Cholelithiasis	n/a	495	100.0	2	0.4	496	100.0	1	0.2		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	Biliary injury	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Infections and infestations		n/a	495	100.0	70	14.1	496	100.0	53	10.6	1.38	Convergence criterion (HCONV<1E-8) satisfied.	0.94	2.02	0.030	Algorithm converged.	-0.004	0.074	1.33	Algorithm converged.	0.95	1.84	0.0955	NE	0.73	Algorithm converged.	0.52	1.03
Infections and infestations	Abdominal infection	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Infections and infestations	Arteriovenous shunt infection	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Infections and infestations	Appendicitis	n/a	495	100.0	1	0.2	496	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	Aspergillus infection	n/a	495	100.0	1	0.2	496	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	Atypical pneumonia	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9961	NE	1.00	Algorithm converged.	0.06	15.85
Infections and infestations	Bacteraemia	n/a	495	100.0	4	0.8	496	100.0	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
Infections and infestations	Bronchitis	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Infections and infestations	Bronchopulmonary aspergillosis	n/a	495	100.0	1	0.2	496	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	Campylobacter gastroenteritis	n/a	495	100.0	1	0.2	496	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	Cellulitis	n/a	495	100.0	2	0.4	496	100.0	1	0.2	2.03	Convergence criterion (HCONV<1E-8) satisfied.	0.18	22.61	0.000	Algorithm converged.	-0.000	0.000	2.03	Algorithm converged.	0.18	22.61	0.5676	NE	0.00	Algorithm converged.	0.00	5.44
Infections and infestations	Clostridium difficile colitis	n/a	495	100.0	3	0.6	496	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	Clostridium difficile infection	n/a	495	100.0	1	0.2	496	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	Coronavirus infection	n/a	495	100.0	1	0.2	496	100.0	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.99	Algorithm converged.	0.06	NE	0.9999	NE	>999.99	Algorithm converged.	0.06	NE
Infections and infestations	Cytomegalovirus colitis	n/a	495	100.0	1	0.2	496	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	Cytomegalovirus infection	n/a	495	100.0	1	0.2	496	100.0	1	0.2	1.01	Convergence criterion (HCONV<1E-8) satisfied.	0.06	16.15	0.000	Algorithm converged.	-0.006	0.006	1.01	Algorithm converged.	0.06	16.04	0.9961	NE	1.00	Algorithm converged.	0.06	15.85
Infections and infestations	Device related infection	n/a	495	100.0	2	0.4	496	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	Device related sepsis	n/a	495	100.0	1	0.2	496	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



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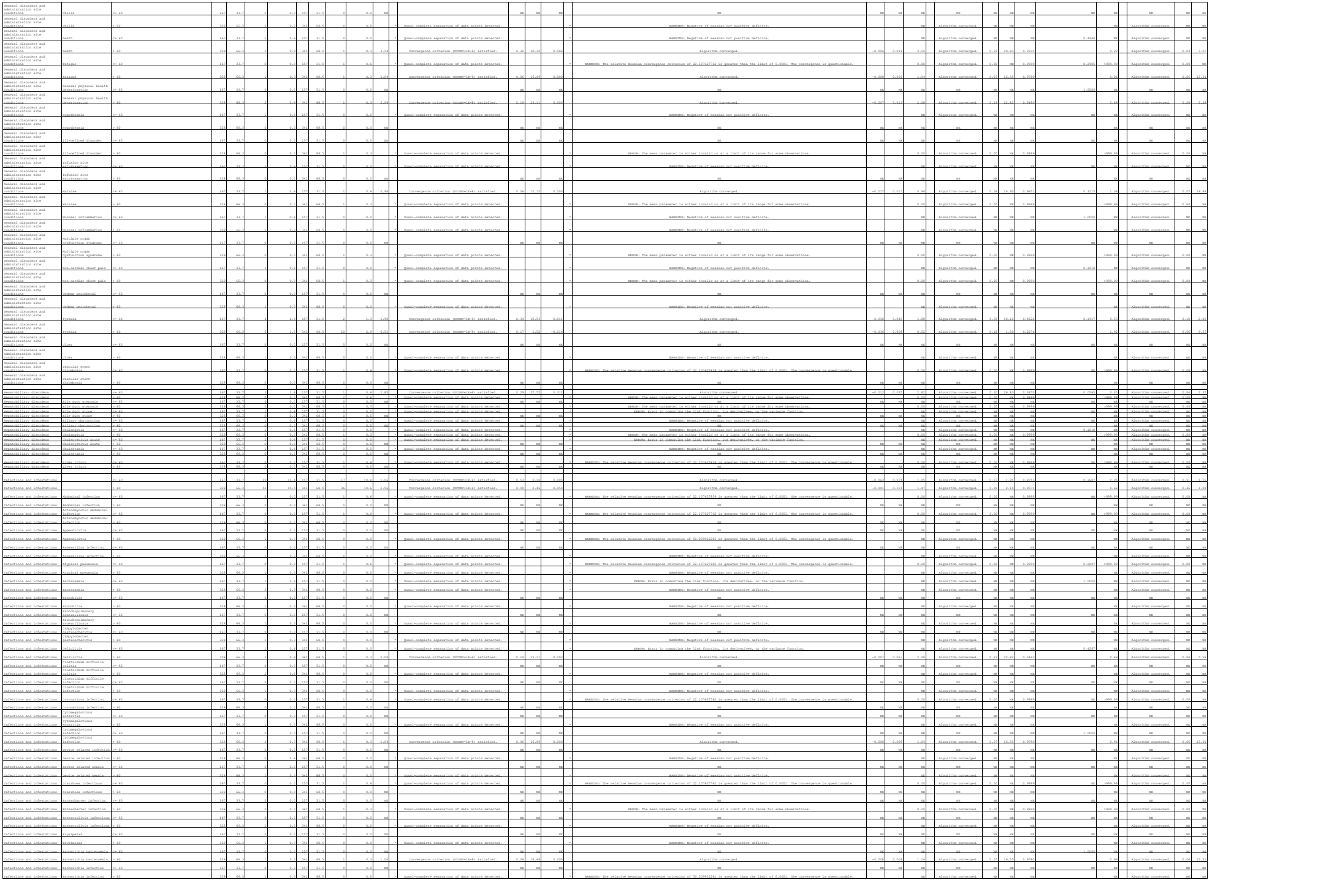
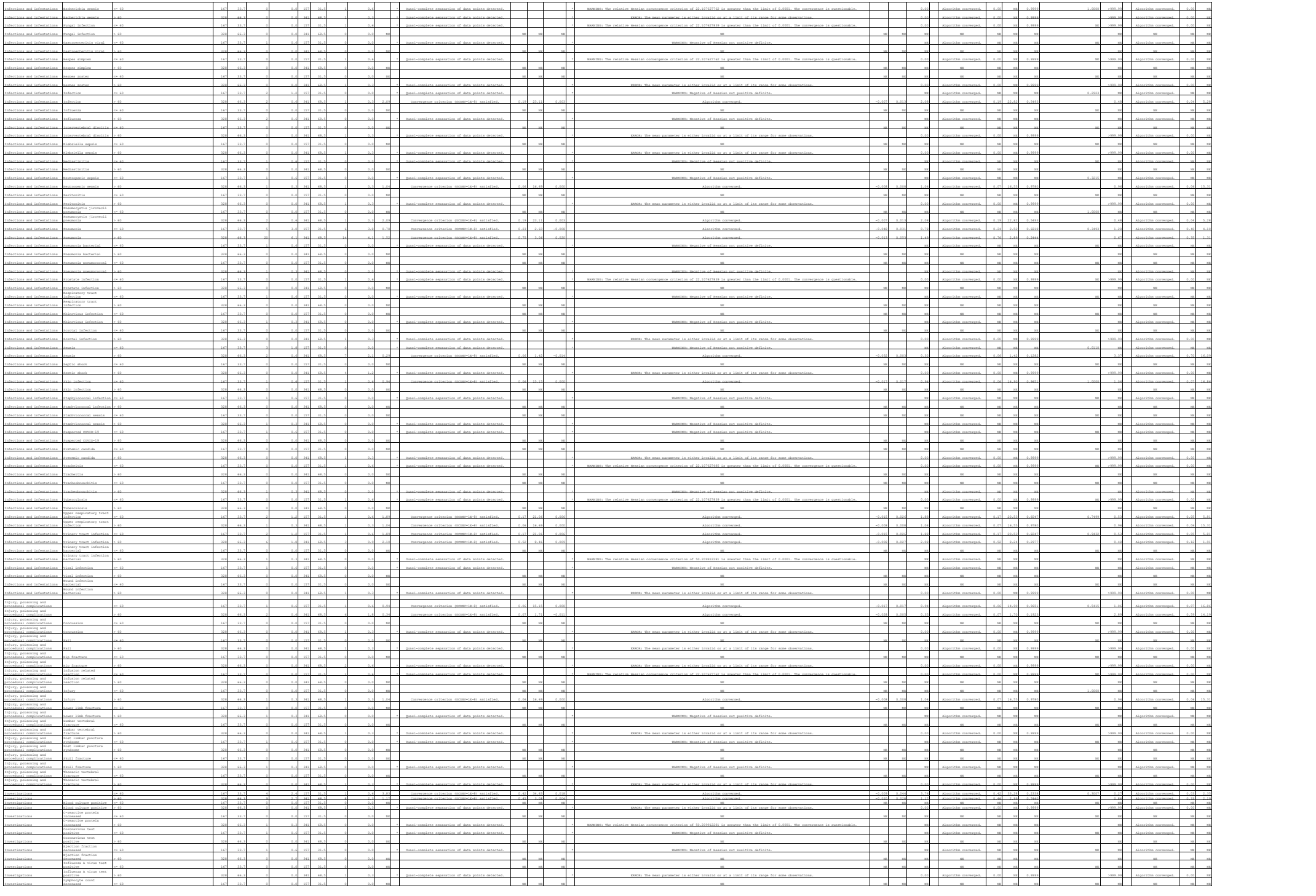
POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Any SAEs
MODEL: Unstratified Analysis
STUDY: BG39862
Dichotomous Analysis by Subgroups (Safety)

Age

			Pulkstenbank Vedrick v A-CAR (n=151)				A-CAR (n=151)				Pulkstenbank Vedrick v A-CAR vs. A-CAR																		A-CAR vs. Pulkstenbank Vedrick v A-CAR			
			Patients		Patients with Event		Patients		Patients with Event		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		<= 40	147	33.7	11	7.5	151	31.1	11	7.3	0.97	Convergence criterion (NCONV=1E-8) satisfied.	0.33	3.13	0.026	Algorithm converged.	-0.056	0.065	1.37	Algorithm converged.	0.45	2.97	0.4047	0.8849	0.97	Algorithm converged.	0.31	1.53
Blood and lymphatic system disorders		> 40	328	66.3	42	12.8	341	68.9	34	10.0	1.32	Convergence criterion (NCONV=1E-8) satisfied.	0.82	2.19	0.028	Algorithm converged.	-0.006	0.074	1.43	Algorithm converged.	0.94	3.97	0.2431		0.78	Algorithm converged.	0.51	1.19
Blood and lymphatic system disorders	Agranulocytosis	<= 40	147	33.7	1	0.9	151	31.1	1	0.9	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Agranulocytosis	> 40	328	66.3	3	0.9	341	68.9	1	0.3	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0.60	Algorithm converged.	0.06	NE	0.9999		>999.99	Algorithm converged.	0.02	NE
Blood and lymphatic system disorders	Anaemia	<= 40	147	33.7	9	2.4	151	31.1	2	1.3	1.90	Convergence criterion (NCONV=1E-8) satisfied.	0.39	10.15	0.031	Algorithm converged.	-0.018	0.080	1.46	Algorithm converged.	0.26	10.12	0.4621	0.9558	1.53	Algorithm converged.	0.33	2.84
Blood and lymphatic system disorders	Anaemia	> 40	328	66.3	6	0.9	341	68.9	4	1.8	2.17	Convergence criterion (NCONV=1E-8) satisfied.	0.62	1.49	<0.001	Algorithm converged.	-0.010	0.065	1.17	Algorithm converged.	0.66	3.43	0.1023		1.77	Algorithm converged.	0.76	47.64
Blood and lymphatic system disorders	Febrile bone marrow aplasia	<= 40	147	33.7	1	0.9	151	31.1	1	0.9	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	> 40	328	66.3	1	0.3	341	68.9	1	0.3	1.04	Convergence criterion (NCONV=1E-8) satisfied.	0.06	16.99	0.000	Algorithm converged.	-0.006	0.006	1.14	Algorithm converged.	0.06	16.93	0.9780		1.04	Algorithm converged.	0.06	15.33
Blood and lymphatic system disorders	Febrile neutropenia	<= 40	147	33.7	11	7.5	151	31.1	10	6.4	1.24	Convergence criterion (NCONV=1E-8) satisfied.	0.53	2.90	0.014	Algorithm converged.	-0.042	0.070	1.12	Algorithm converged.	0.35	2.71	0.6209	0.5310	1.22	Algorithm converged.	0.57	1.83
Blood and lymphatic system disorders	Febrile neutropenia	> 40	328	66.3	24	10.4	341	68.9	21	6.2	1.76	Convergence criterion (NCONV=1E-8) satisfied.	1.00	3.11	0.040	Algorithm converged.	0.000	0.080	1.43	Algorithm converged.	1.00	3.84	0.0504		1.55	Algorithm converged.	1.00	1.00
Blood and lymphatic system disorders	Leukopenia	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Leukopenia	> 40	328	66.3	2	0.6	341	68.9	2	0.6	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0.20	Algorithm converged.	0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Blood and lymphatic system disorders	Myelosuppression	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Myelosuppression	> 40	328	66.3	4	1.2	341	68.9	3	0.9	*	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.40	Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.04	NE
Blood and lymphatic system disorders	Neutropenia	<= 40	147	33.7	0	0.0	151	31.1	1	0.6	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.107627742 is greater than the limit of 0.0001. The convergence is questionable.			0.20	Algorithm converged.	0.00	NE	0.9999	0.2770	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Neutropenia	> 40	328	66.3	4	1.2	341	68.9	5	1.5	1.83	Convergence criterion (NCONV=1E-8) satisfied.	0.49	3.49	<0.001	Algorithm converged.	-0.006	0.043	0.83	Algorithm converged.	0.26	3.63	0.7821		1.25	Algorithm converged.	0.33	4.44
Blood and lymphatic system disorders	Thrombocytopenia	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Blood and lymphatic system disorders	Thrombocytopenia	> 40	328	66.3	1	0.3	341	68.9	1	0.3	1.04	Convergence criterion (NCONV=1E-8) satisfied.	0.06	16.99	0.000	Algorithm converged.	-0.006	0.006	1.14	Algorithm converged.	0.06	16.93	0.9780		1.04	Algorithm converged.	0.06	15.33
Cardiac disorders		<= 40	147	33.7	3	1.2	151	31.1	3	0.6	1.83	Convergence criterion (NCONV=1E-8) satisfied.	0.37	21.64	0.008	Algorithm converged.	-0.033	0.065	1.19	Algorithm converged.	0.13	20.93	0.6637	0.3290	1.83	Algorithm converged.	0.32	9.83
Cardiac disorders		> 40	328	66.3	5	1.5	341	68.9	5	1.5	2.11	Convergence criterion (NCONV=1E-8) satisfied.	0.61	7.30	0.022	Algorithm converged.	-0.006	0.043	0.83	Algorithm converged.	0.25	7.18	0.5032		2.10	Algorithm converged.	0.53	8.26
Cardiac disorders	Atrial fibrillation	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Atrial fibrillation	> 40	328	66.3	2	0.6	341	68.9	2	0.6	2.04	Convergence criterion (NCONV=1E-8) satisfied.	0.28	14.87	<0.001	Algorithm converged.	-0.013	0.055	0.78	Algorithm converged.	0.04	NE	0.9577		2.04	Algorithm converged.	0.28	27.49
Cardiac disorders	Atrial flutter	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Atrial flutter	> 40	328	66.3	1	0.3	341	68.9	1	0.3	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Atrioventricular block complete	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Atrioventricular block complete	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0.20	Algorithm converged.	0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Cardiac disorders	Cardiac failure congestive	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Cardiac failure congestive	> 40	328	66.3	2	0.6	341	68.9	2	0.6	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0.20	Algorithm converged.	0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Cardiac disorders	Left ventricular dysfunction	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Left ventricular dysfunction	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0.20	Algorithm converged.	0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Cardiac disorders	Myocardial infarction	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Myocardial infarction	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Cardiac disorders	Sinus bradycardia	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Sinus bradycardia	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0.20	Algorithm converged.	0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Cardiac disorders	Sinus tachycardia	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Sinus tachycardia	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Cardiac disorders	Tachycardia	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Cardiac disorders	Tachycardia	> 40	328	66.3	3	0.9	341	68.9	3	0.9	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0.60	Algorithm converged.	0.06	NE	0.9999		>999.99	Algorithm converged.	0.02	NE
Eye disorders		<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Eye disorders		> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Eye disorders	Rhegmatogenous retinal detachment	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Eye disorders	Rhegmatogenous retinal detachment	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Gastrointestinal disorders		<= 40	147	33.7	4	2.4	151	31.1	8	5.1	0.49	Convergence criterion (NCONV=1E-8) satisfied.	0.14	2.05	<0.001	Algorithm converged.	-0.060	0.020	0.73	Algorithm converged.	0.25	1.99	0.5083	0.2750	0.42	Algorithm converged.	0.12	1.52
Gastrointestinal disorders		> 40	328	66.3	10	3.0	341	68.9	15	4.4	0.65	Convergence criterion (NCONV=1E-8) satisfied.	0.33	2.00	0.023	Algorithm converged.	-0.031	0.006	0.87	Algorithm converged.	0.15	1.93	0.4872		0.65	Algorithm converged.	0.33	1.32
Gastrointestinal disorders	Abdominal distension	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Abdominal distension	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0.20	Algorithm converged.	0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Abdominal pain	<= 40	147	33.7	0	0.0	151	31.1	1	1.3	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.109654211 is greater than the limit of 0.0001. The convergence is questionable.			0.40	Algorithm converged.	0.05	NE	0.9999	0.0784	>999.99	Algorithm converged.	0.03	NE
Gastrointestinal disorders	Abdominal pain	> 40	328	66.3	2	0.6	341	68.9	1	0.3	0.49	Convergence criterion (NCONV=1E-8) satisfied.	0.04	23.62	0.000	Algorithm converged.	-0.007	0.013	0.28	Algorithm converged.	0.03	22.83	0.5433		0.49	Algorithm converged.	0.04	5.24
Gastrointestinal disorders	Anal fistula	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Anal fistula	> 40	328	66.3	1	0.3	341	68.9	1	0.3	1.04	Convergence criterion (NCONV=1E-8) satisfied.	0.06	16.99	0.000	Algorithm converged.	-0.006	0.006	1.14	Algorithm converged.	0.06	16.93	0.9780		1.04	Algorithm converged.	0.06	15.33
Gastrointestinal disorders	Anal stenosis	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Anal stenosis	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Gastrointestinal disorders	Colitis	<= 40	147	33.7	1	0.6	151	31.1	1	0.6	*	Quasi-complete separation 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	Colitis	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	Quasi-complete separation 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	Constipation	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Constipation	> 40	328	66.3	1	0.3	341	68.9	1	0.3	0.96	Convergence criterion (NCONV=1E-8) satisfied.	0.06	14.00	0.000	Algorithm converged.	-0.006	0.006	1.14	Algorithm converged.	0.06	13.95	0.9780		0.96	Algorithm converged.	0.06	14.10
Gastrointestinal disorders	Diarrhoea	<= 40	147	33.7	1	0.6	151	31.1	1	0.6	0.96	Convergence criterion (NCONV=1E-8) satisfied.	0.06	14.00	0.000	Algorithm converged.	-0.006	0.006	1.14	Algorithm converged.	0.06	13.95	0.9624	0.5861	0.96	Algorithm converged.	0.06	14.10
Gastrointestinal disorders	Diarrhoea	> 40	328	66.3	7	2.1	341	68.9	6	1.8	0.93	Convergence criterion (NCONV=1E-8) satisfied.	0.31	14.00	0.000	Algorithm converged.	0.000	0.043	0.83	Algorithm converged.	0.04	13.64	0.1048		0.93	Algorithm converged.	0.31	3.84
Gastrointestinal disorders	Epigastric discomfort	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Epigastric discomfort	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Gastrointestinal disorders	Faeces discoloured	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Faeces discoloured	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Gastrointestinal disorders	Gastric ulcer	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Gastric ulcer	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Gastrointestinal disorders	Gastrointestinal haemorrhage	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.107627939 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	0.2599	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	> 40	328	66.3	2	0.6	341	68.9	2	0.6	1.04	Convergence criterion (NCONV=1E-8) satisfied.	0.15	7.65	0.000	Algorithm converged.	-0.031	0.031	1.00	Algorithm converged.	0.15	7.54	0.9699		1.04	Algorithm converged.	0.15	6.73
Gastrointestinal disorders	Haemorrhoidal haemorrhage	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Haemorrhoidal haemorrhage	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 30.209812291 is greater than the limit of 0.0001. The convergence is questionable.			0.20	Algorithm converged.	0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Ileus	<= 40	147	33.7	0	0.0	151	31.1	1	1.3	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.109654211 is greater than the limit of 0.0001. The convergence is questionable.			0.40	Algorithm converged.	0.05	NE	0.9999	0.0646	>999.99	Algorithm converged.	0.03	NE
Gastrointestinal disorders	Ileus	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Gastrointestinal disorders	Impaired gastric emptying	<= 40	147	33.7	0	0.0	151	31.1	1	0.6	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.107627939 is greater than the limit of 0.0001. The convergence is questionable.			0.40	Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.03	NE
Gastrointestinal disorders	Impaired gastric emptying	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Gastrointestinal disorders	Intestinal obstruction	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Intestinal obstruction	> 40	328	66.3	1	0.3	341	68.9	1	0.3	0.96	Convergence criterion (NCONV=1E-8) satisfied.	0.06	14.00	0.000	Algorithm converged.	-0.006	0.006	1.14	Algorithm converged.	0.06	13.95	0.9780		0.96	Algorithm converged.	0.06	14.10
Gastrointestinal disorders	Intestinal perforation	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Intestinal perforation	> 40	328	66.3	1	0.3	341	68.9	1	0.3	0.96	Convergence criterion (NCONV=1E-8) satisfied.	0.06	14.00	0.000	Algorithm converged.	-0.006	0.006	1.14	Algorithm converged.	0.06	13.95	0.9780		0.96	Algorithm converged.	0.06	14.10
Gastrointestinal disorders	Oesophagitis	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Oesophagitis	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Gastrointestinal disorders	Rectal haemorrhage	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Rectal haemorrhage	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Gastrointestinal disorders	Small intestinal obstruction	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Small intestinal obstruction	> 40	328	66.3	2	0.6	341	68.9	2	0.6	1.04	Convergence criterion (NCONV=1E-8) satisfied.	0.15	7.65	0.000	Algorithm converged.	-0.031	0.031	1.00	Algorithm converged.	0.15	7.54	0.9699		1.04	Algorithm converged.	0.15	6.73
Gastrointestinal disorders	Small intestinal perforation	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Small intestinal perforation	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			0.20	Algorithm converged.	0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Stomatitis	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Stomatitis	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Gastrointestinal disorders	Subileus	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Subileus	> 40	328	66.3	1	0.3	341	68.9	1	0.3	0.96	Convergence criterion (NCONV=1E-8) satisfied.	0.06	14.00	0.000	Algorithm converged.	-0.006	0.006	1.14	Algorithm converged.	0.06	13.95	0.9780		0.96	Algorithm converged.	0.06	14.10
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	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
Gastrointestinal disorders	Vomiting	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Gastrointestinal disorders	Vomiting	> 40	328	66.3	4	1.2	341	68.9	3	0.9	0.98	Convergence criterion (NCONV=1E-8) satisfied.	0.26	11.03	0.000	Algorithm converged.	-0.004	0.037	0.89	Algorithm converged.	0.09	11.00	0.9413		0.98	Algorithm converged.	0.26	2.14
General disorders and administration site conditions		<= 40	147	33.7	10	7.2	151	31.1	5	3.2	0.35	Convergence criterion (NCONV=1E-8) satisfied.	0.41	4.49	0.040	Algorithm converged.	-0.059	0.086	2.24	Algorithm converged.	0.81	4.24	0.1183	0.1137	0.46	Algorithm converged.	0.14	1.22
General disorders and administration site conditions		> 40	328	66.3	15	4.9	341	68.9	13	5.6	0.87	Convergence criterion (NCONV=1E-8) satisfied.	0.44	1.73	<0.001	Algorithm converged.	-0.043	0.063	0.64	Algorithm converged.	0.46	1.67	0.6873		1.14	Algorithm converged.	0.60	2.13
General disorders and administration site conditions	Administration site extravasation	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
General disorders and administration site conditions	Administration site extravasation	> 40	328	66.3	1	0.3	341	68.9	1	0.3	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 30.209812291 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	Asthenia	<= 40	147	33.7	2	1.2	151	31.1	1	0.6	1.89	Convergence criterion (NCONV=1E-8) satisfied.	0.17	21.04	0.008	Algorithm converged.	-0.033	0.039	1.49	Algorithm converged.	0.17	20.93	0.6047	1.0000	0.33	Algorithm converged.	0.02	5.84
General disorders and administration site conditions	Asthenia	> 40	328	66.3	0	0.0	341	68.9	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
General disorders and administration site conditions	Cardiac death	<= 40	147	33.7	0	0.0	151	31.1	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
General disorders and administ





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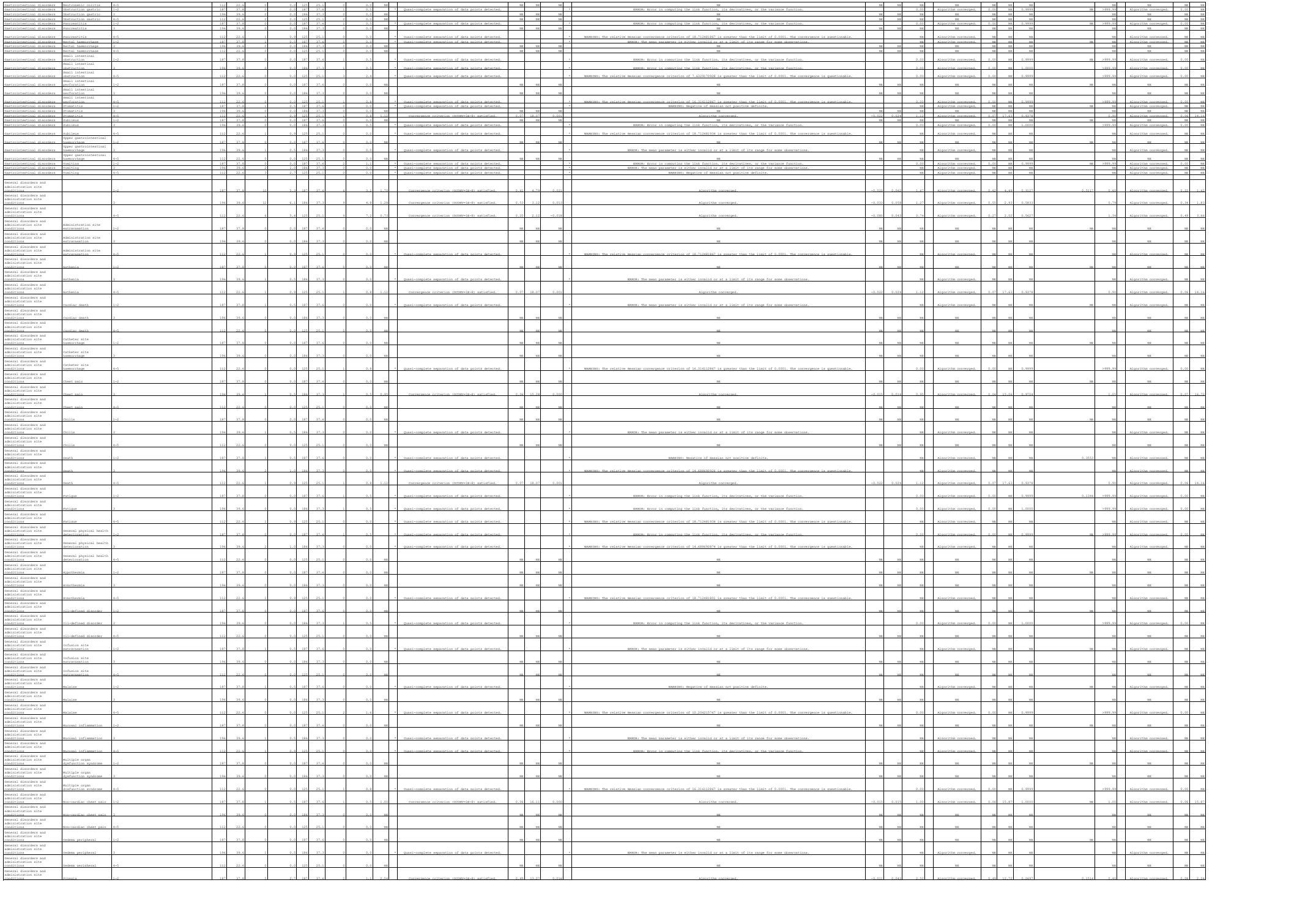
POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Any SAEs
MODEL: Unstratified Analysis
ATOXT: HLT0982
Dichotomous Analysis by Subgroups (Safety)

EPG score at Screening

			Pembrolizumab Yuanfu + N-Chemo (N=335)				N-Chemo (N=336)				Pembrolizumab Yuanfu + N-CRT vs. N-Chemo										Pembrolizumab Yuanfu + N-CRT vs. N-Chemo					
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference						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		1-2	187	37.6	10	5.4	187	37.4	16	8.6	0.61	Convergence criterion (ncons<16-8) satisfied.	0.27	1.39	-0.040	Algorithm converged.	-0.093	0.006	1.45	Algorithm converged.	0.65	3.23	0.1221	0.5924	0.63	Algorithm converged.	0.26	1.53
Blood and lymphatic system disorders		3	196	39.4	24	12.2	186	37.1	19	10.2	1.23	Convergence criterion (ncons<16-8) satisfied.	0.65	2.35	0.020	Algorithm converged.	-0.043	0.083	1.41	Algorithm converged.	0.98	2.11	0.5911		1.20	Algorithm converged.	0.67	1.43
Blood and lymphatic system disorders		4-5	112	22.6	16	14.3	125	25.1	16	12.8	1.14	Convergence criterion (ncons<16-8) satisfied.	0.54	2.39	0.015	Algorithm converged.	-0.052	0.083	1.12	Algorithm converged.	0.59	2.13	0.7981		1.12	Algorithm converged.	0.67	1.73
Blood and lymphatic system disorders	Agranulocytosis	1-2	187	37.6	2	0.9	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Agranulocytosis	3	196	39.4	2	0.9	186	37.1	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.41	Algorithm converged.	0.06	NE	1.0000		>999.99	Algorithm converged.	0.02	NE
Blood and lymphatic system disorders	Agranulocytosis	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Anemia	1-2	187	37.6	12	6.4	187	37.4	7	3.7	1.82	Convergence criterion (ncons<16-8) satisfied.	0.73	4.55	0.027	Algorithm converged.	-0.048	0.103	1.73	Algorithm converged.	0.94	3.18	0.0731		1.72	Algorithm converged.	0.93	3.19
Blood and lymphatic system disorders	Anemia	3	196	39.4	13	6.6	186	37.1	7	3.8	1.83	Convergence criterion (ncons<16-8) satisfied.	0.73	4.59	0.028	Algorithm converged.	-0.048	0.103	1.73	Algorithm converged.	0.94	3.18	0.0731		1.72	Algorithm converged.	0.93	3.19
Blood and lymphatic system disorders	Anemia	4-5	112	22.6	11	9.8	125	25.1	11	8.8	1.11	Convergence criterion (ncons<16-8) satisfied.	0.53	2.33	0.010	Algorithm converged.	-0.048	0.103	1.11	Algorithm converged.	0.56	2.19	0.7983		1.10	Algorithm converged.	0.67	1.81
Blood and lymphatic system disorders	Febrile bone marrow aplasia	1-2	187	37.6	2	0.9	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	3	196	39.4	2	0.9	186	37.1	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.41	Algorithm converged.	0.06	NE	1.0000		>999.99	Algorithm converged.	0.02	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile neutropenia	1-2	187	37.6	16	8.6	187	37.4	8	4.3	2.05	Convergence criterion (ncons<16-8) satisfied.	0.87	5.05	0.042	Algorithm converged.	-0.007	0.080	2.00	Algorithm converged.	1.00	4.34	0.0493	0.7220	2.02	Algorithm converged.	0.99	4.12
Blood and lymphatic system disorders	Febrile neutropenia	3	196	39.4	18	9.2	186	37.1	8	7.0	1.35	Convergence criterion (ncons<16-8) satisfied.	0.64	2.85	0.022	Algorithm converged.	-0.030	0.077	1.31	Algorithm converged.	0.80	2.21	0.4349		1.31	Algorithm converged.	0.80	1.52
Blood and lymphatic system disorders	Febrile neutropenia	4-5	112	22.6	12	11.4	125	25.1	12	8.0	1.61	Convergence criterion (ncons<16-8) satisfied.	0.65	3.99	0.034	Algorithm converged.	-0.048	0.103	1.47	Algorithm converged.	0.66	3.16	0.3621		1.45	Algorithm converged.	0.71	1.52
Blood and lymphatic system disorders	Leukopenia	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Leukopenia	3	196	39.4	1	0.5	186	37.1	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.39	Algorithm converged.	0.05	NE	1.0000		>999.99	Algorithm converged.	0.01	NE
Blood and lymphatic system disorders	Leukopenia	4-5	112	22.6	1	0.9	125	25.1	1	0.8	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314112907 is greater than the limit of 0.0001. The convergence is questionable.			0.39	Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Blood and lymphatic system disorders	Myelosuppression	1-2	187	37.6	2	0.9	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	3	196	39.4	2	0.9	186	37.1	1	0.5	*	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	Myelosuppression	4-5	112	22.6	1	0.9	125	25.1	1	0.8	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 18.712481801 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	1-2	187	37.6	2	1.1	187	37.4	1	0.5	2.01	Convergence criterion (ncons<16-8) satisfied.	0.18	22.37	0.005	Algorithm converged.	-0.013	0.023	2.00	Algorithm converged.	0.18	21.97	0.5706	0.4249	2.02	Algorithm converged.	0.02	5.43
Blood and lymphatic system disorders	Neutropenia	3	196	39.4	2	0.5	186	37.1	1	0.5	0.95	Convergence criterion (ncons<16-8) satisfied.	0.06	15.06	0.000	Algorithm converged.	-0.013	0.013	0.95	Algorithm converged.	0.06	15.06	0.9704		1.05	Algorithm converged.	0.07	16.72
Blood and lymphatic system disorders	Neutropenia	4-5	112	22.6	3	2.7	125	25.1	3	2.4	1.13	Convergence criterion (ncons<16-8) satisfied.	0.23	5.49	-0.020	Algorithm converged.	-0.093	0.023	1.09	Algorithm converged.	0.26	4.63	0.9021		1.08	Algorithm converged.	0.24	31.14
Blood and lymphatic system disorders	Thrombocytopenia	1-2	187	37.6	2	0.9	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Blood and lymphatic system disorders	Thrombocytopenia	3	196	39.4	2	0.9	186	37.1	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.39	Algorithm converged.	0.05	NE	1.0000		>999.99	Algorithm converged.	0.01	NE
Blood and lymphatic system disorders	Thrombocytopenia	4-5	112	22.6	1	0.9	125	25.1	1	0.8	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 18.721249324 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
Cardiac disorders		1-2	187	37.6	2	1.1	187	37.4	1	0.5	2.01	Convergence criterion (ncons<16-8) satisfied.	0.18	22.37	0.005	Algorithm converged.	-0.013	0.023	2.00	Algorithm converged.	0.18	21.97	0.5706	0.4249	2.02	Algorithm converged.	0.02	5.43
Cardiac disorders		3	196	39.4	2	1.1	186	37.1	1	0.5	0.97	Convergence criterion (ncons<16-8) satisfied.	0.07	13.80	-0.017	Algorithm converged.	-0.049	0.015	0.98	Algorithm converged.	0.07	13.43	0.9838		1.03	Algorithm converged.	0.07	13.44
Cardiac disorders		4-5	112	22.6	1	0.9	125	25.1	1	0.8	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 20.224215758 is greater than the limit of 0.0001. The convergence is questionable.			0.40	Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.02	NE
Cardiac disorders	Atrial fibrillation	1-2	187	37.6	2	0.9	187	37.4	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.41	Algorithm converged.	0.06	NE	1.0000	0.7201	>999.99	Algorithm converged.	0.02	NE
Cardiac disorders	Atrial fibrillation	3	196	39.4	3	1.5	186	37.1	2	1.1	0.97	Convergence criterion (ncons<16-8) satisfied.	0.24	3.93	-0.008	Algorithm converged.	-0.049	0.032	0.98	Algorithm converged.	0.24	3.93	0.9813		1.03	Algorithm converged.	0.24	3.94
Cardiac disorders	Atrial fibrillation	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrial flutter	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrial flutter	3	196	39.4	1	0.5	186	37.1	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.41	Algorithm converged.	0.06	NE	1.0000		>999.99	Algorithm converged.	0.02	NE
Cardiac disorders	Atrial flutter	4-5	112	22.6	1	0.9	125	25.1	1	0.8	*	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
Cardiac disorders	Atrioventricular block complete	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	3	196	39.4	1	0.5	186	37.1	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	4-5	112	22.6	1	0.9	125	25.1	1	0.8	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314112907 is greater than the limit of 0.0001. The convergence is questionable.			0.40	Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.02	NE
Cardiac disorders	Cardiac failure congestive	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Cardiac failure congestive	3	196	39.4	1	0.5	186	37.1	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.41	Algorithm converged.	0.06	NE	1.0000		>999.99	Algorithm converged.	0.02	NE
Cardiac disorders	Cardiac failure congestive	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	3	196	39.4	1	0.5	186	37.1	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.41	Algorithm converged.	0.06	NE	1.0000		>999.99	Algorithm converged.	0.02	NE
Cardiac disorders	Left ventricular dysfunction	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Myocardial infarction	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Myocardial infarction	3	196	39.4	1	0.5	186	37.1	1	0.5	*	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
Cardiac disorders	Myocardial infarction	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	3	196	39.4	1	0.5	186	37.1	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	4-5	112	22.6	1	0.9	125	25.1	1	0.8	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314112907 is greater than the limit of 0.0001. The convergence is questionable.			0.40	Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.02	NE
Cardiac disorders	Sinus tachycardia	1-2	187	37.6	1	0.5	187	37.4	1	0.5	*	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
Cardiac disorders	Sinus tachycardia	3	196	39.4	1	0.5	186	37.1	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Sinus tachycardia	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Tachycardia	1-2	187	37.6	2	1.1	187	37.4	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.41	Algorithm converged.	0.06	NE	1.0000		>999.99	Algorithm converged.	0.02	NE
Cardiac disorders	Tachycardia	3	196	39.4	2	1.1	186	37.1	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.41	Algorithm converged.	0.06	NE	1.0000		>999.99	Algorithm converged.	0.02	NE
Cardiac disorders	Tachycardia	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders		1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders		3	196	39.4	1	0.5	186	37.1	1	0.5	*	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
Eye disorders		4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	3	196	39.4	1	0.5	186	37.1	1	0.5	*	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
Eye disorders	Rhegmatogenous retinal detachment	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders		1-2	187	37.6	8	4.3	187	37.4	4	2.1	2.03	Convergence criterion (ncons<16-8) satisfied.	0.61	6.80	0.022	Algorithm converged.	-0.007	0.045	1.94	Algorithm converged.	0.66	5.65	0.2431	0.2252	1.85	Algorithm converged.	0.55	6.24
Gastrointestinal disorders		3	196	39.4	10	4.9	186	37.1	4	2.1	2.37	Convergence criterion (ncons<16-8) satisfied.	0.82	6.87	0.028	Algorithm converged.	-0.007	0.045	2.26	Algorithm converged.	0.82	6.24	0.1156		2.24	Algorithm converged.	0.79	6.34
Gastrointestinal disorders		4-5	112	22.6	7	6.4	125	25.1	7	5.6	1.32	Convergence criterion (ncons<16-8) satisfied.	0.54	4.60	0.010	Algorithm converged.	-0.041	0.103	1.27	Algorithm converged.	0.54	4.01	0.5653		1.25	Algorithm converged.	0.24	1.24
Gastrointestinal disorders	Abdominal distension	1-2	187	37.6	2	1.1	187	37.4	1	0.5	2.01	Convergence criterion (ncons<16-8) satisfied.	0.18	22.37	0.005	Algorithm converged.	-0.013	0.023	2.00	Algorithm converged.	0.18	21.97	0.5706	0.4249	2.02	Algorithm converged.	0.02	5.43
Gastrointestinal disorders	Abdominal distension	3	196	39.4	2	0.5	186	37.1	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.39	Algorithm converged.	0.05	NE	1.0000		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Abdominal distension	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Abdominal pain	1-2	187	37.6	2	0.9	187	37.4	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.41	Algorithm converged.	0.06	NE	1.0000	0.5681	>999.99	Algorithm converged.	0.02	NE
Gastrointestinal disorders	Abdominal pain	3	196	39.4	3	1.5	186	37.1	1	0.5	2.92	Convergence criterion (ncons<16-8) satisfied.	0.33	25.89	0.008	Algorithm converged.	-0.033	0.016	2.92	Algorithm converged.	0.33	25.89	0.3274		2.92	Algorithm converged.	0.33	25.89
Gastrointestinal disorders	Abdominal pain	4-5	112	22.6	1	0.9	125	25.1	1	0.8	1.13	Convergence criterion (ncons<16-8) satisfied.	0.07	18.07	0.000	Algorithm converged.	-0.033	0.016	1.13	Algorithm converged.	0.07	17.67	0.9374		1.13	Algorithm converged.	0.07	17.67
Gastrointestinal disorders	Anal fistula	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Anal fistula	3	196	39.4	1	0.5	186	37.1	1	0.5	*	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	Anal fistula	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Anal stenosis	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Anal stenosis	3	196	39.4	1	0.5	186	37.1	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Anal stenosis	4-5	112	22.6	1	0.9	125	25.1	1	0.8	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.314112985 is greater than the limit of 0.0001. The convergence is questionable.			0.40	Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.02	NE
Gastrointestinal disorders	Colitis	1-2	187	37.6	2	0.9	187	37.4	1	0.5	2.03	Convergence criterion (ncons<16-8) satisfied.	0.18	22.69	0.005	Algorithm converged.	-0.013	0.023	2.02	Algorithm converged.	0.18	22.29	0.5693		2.04	Algorithm converged.	0.02	5.47
Gastrointestinal disorders	Colitis	3	196	39.4	2	0.9	186	37.1	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.41	Algorithm converged.	0.06	NE	1.0000		>999.99	Algorithm converged.	0.02	NE
Gastrointestinal disorders	Colitis	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Constipation	1-2	187	37.6	1	0.5	187	37.4	1	0.5	*	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
Gastrointestinal disorders	Constipation	3	196	39.4	1	0.5	186	37.1	1	0.5	*	Quasi-complete separation of data points detected.				ERROR: Error in computing the link function, its derivatives, or the variance function.			0.41	Algorithm converged.	0.06	NE	1.0000		>999.99	Algorithm converged.	0.02	NE
Gastrointestinal disorders	Constipation	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Diarrhoea	1-2	187	37.6	3	1.1	187	37.4	1	0.5	2.01	Convergence criterion (ncons<16-8) satisfied.	0.18	22.37	0.005	Algorithm converged.	-0.013	0.023	2.00	Algorithm converged.	0.18	21.97	0.5706	0.4250	2.02	Algorithm converged.	0.02	5.43
Gastrointestinal disorders	Diarrhoea	3	196	39.4	3	1.5	186	37.1	1	0.5	2.92	Convergence criterion (ncons<16-8) satisfied.	0.33	25.89	0.008	Algorithm converged.	-0.033	0.016	2.92	Algorithm converged.	0.33	25.89	0.3274	0.1750	2.92	Algorithm converged.	0.33	25.89
Gastrointestinal disorders	Diarrhoea	4-5	112	22.6	1	0.9	125	25.1	1	0.8	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 5.292238593 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	Dysgeusia discomfort	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Dysgeusia discomfort	3	196	39.4	1	0.5	186	37.1	1	0.5	*	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	Dysgeusia discomfort	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Nausea aggravated	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Nausea aggravated	3	196	39.4	1	0.5	186	37.1	1	0.5	*	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	Nausea aggravated	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Oesophageal stenosis	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Oesophageal stenosis	3	196	39.4	1	0.5	186	37.1	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Oesophageal stenosis	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Oral mucosal erythema	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Oral mucosal erythema	3	196	39.4	1	0.5	186	37.1	1	0.5	*	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	Oral mucosal erythema	4-5	112	22.6	1	0.9	125	25.1	1	0.8	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Pancreatitis	1-2	187	37.6	1	0.5	187	37.4	1	0.5	NE		NE	NE	NE	NE	NE	NE	NE	NE



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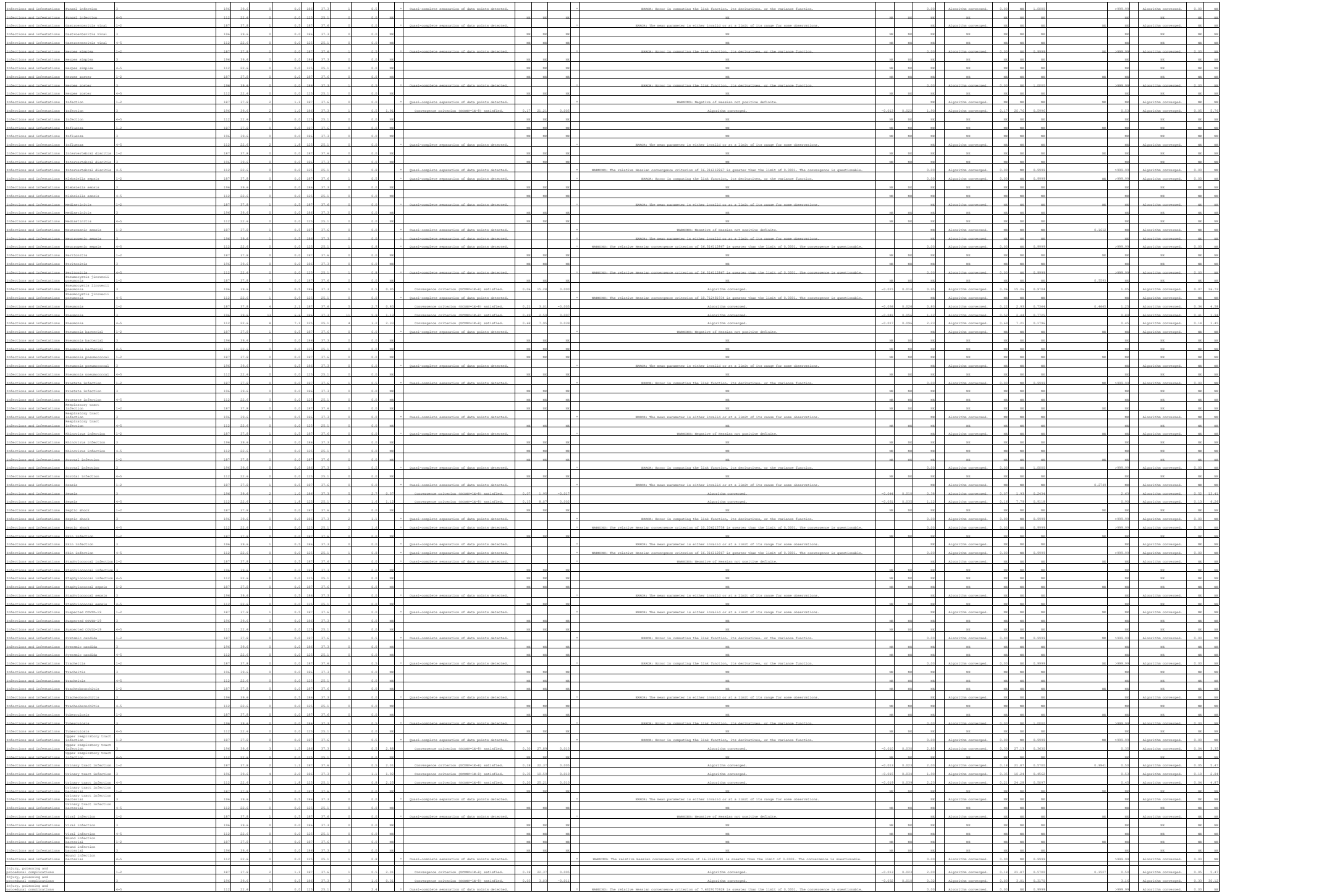

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENCOUNT: Any EAEs
MODEL: Destratified Analysis
STUDY: BCZ0962
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Ociliroxumab Vedrolimab + R-CHP (n=305)				R-CHP (n=305)				Ociliroxumab Vedrolimab + R-CHP vs. R-CHP																R-CHP vs. Ociliroxumab Vedrolimab + R-CHP			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio							Absolute Risk Difference									Relative Risk				
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Risk 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		Western Europe/United States/Canada/Australia	298	60.2	33	11.1	305	63.2	20	6.7	1.66	Convergence criterion (ECOG#=1E-8) satisfied.	1.03	3.01	0.051	Algorithm converged.	0.002	0.097	1.74	Algorithm converged.	1.04	2.98	0.0347	0.2224	0.57	Algorithm converged.	0.34	0.94
Blood and lymphatic system disorders		Asia	140	28.3	10	10.7	140	27.6	15	10.8	0.98	Convergence criterion (ECOG#=1E-8) satisfied.	0.47	2.10	-0.000	Algorithm converged.	-0.093	0.093	0.99	Algorithm converged.	0.46	2.09	0.9824		0.91	Algorithm converged.	0.51	1.58
Blood and lymphatic system disorders		Rest of World	57	11.5	8	14.0	55	11.6	10	16.9	0.80	Convergence criterion (ECOG#=1E-8) satisfied.	0.29	2.20	-0.029	Algorithm converged.	-0.160	0.100	0.83	Algorithm converged.	0.26	1.99	0.6651		1.21	Algorithm converged.	0.51	2.83
Blood and lymphatic system disorders	Agranulocytosis	Western Europe/United States/Canada/Australia	298	60.2	3	0.9	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observation.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Agranulocytosis	Asia	140	28.3	1	0.9	140	27.6	1	0.8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Agranulocytosis	Rest of World	57	11.5	1	0.9	55	11.6	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	Anemia	Western Europe/United States/Canada/Australia	298	60.2	18	6.0	305	60.7	3	0.9	6.66	Convergence criterion (ECOG#=1E-8) satisfied.	2.06	29.35	0.050	Algorithm converged.	0.024	0.076	5.43	Algorithm converged.	2.04	28.97	0.0073	0.1880	0.22	Algorithm converged.	0.07	0.73
Blood and lymphatic system disorders	Anemia	Asia	140	28.3	10	7.1	140	27.6	3	2.2	3.30	Convergence criterion (ECOG#=1E-8) satisfied.	0.93	13.15	0.049	Algorithm converged.	-0.040	0.053	3.13	Algorithm converged.	0.93	13.16	0.0554		3.22	Algorithm converged.	0.92	28.72
Blood and lymphatic system disorders	Anemia	Rest of World	57	11.5	7	12.2	55	11.6	1	4.8	2.65	Convergence criterion (ECOG#=1E-8) satisfied.	0.33	27.37	0.054	Algorithm converged.	-0.029	0.163	1.81	Algorithm converged.	0.32	21.91	0.2201		1.86	Algorithm converged.	0.40	33.56
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Western Europe/United States/Canada/Australia	298	60.2	3	0.9	305	60.7	1	0.3	3.01	Convergence criterion (ECOG#=1E-8) satisfied.	0.30	14.13	0.006	Algorithm converged.	-0.009	0.015	1.01	Algorithm converged.	0.30	14.03	0.9962	1.0000	3.00	Algorithm converged.	0.09	15.83
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Asia	140	28.3	0	0.0	140	27.6	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	Febrile bone marrow aplasia	Rest of World	57	11.5	0	0.0	55	11.6	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	Febrile neutropenia	Western Europe/United States/Canada/Australia	298	60.2	30	10.1	305	60.7	17	5.7	1.85	Convergence criterion (ECOG#=1E-8) satisfied.	1.05	3.46	0.044	Algorithm converged.	0.005	0.083	1.79	Algorithm converged.	1.05	3.15	0.0492	0.5106	0.56	Algorithm converged.	0.32	1.00
Blood and lymphatic system disorders	Febrile neutropenia	Asia	140	28.3	10	7.1	140	27.6	10	7.2	0.99	Convergence criterion (ECOG#=1E-8) satisfied.	0.40	2.46	-0.002	Algorithm converged.	-0.081	0.060	0.99	Algorithm converged.	0.43	2.31	0.9667		1.01	Algorithm converged.	0.42	2.34
Blood and lymphatic system disorders	Febrile neutropenia	Rest of World	57	11.5	7	12.2	55	11.6	4	6.8	1.62	Convergence criterion (ECOG#=1E-8) satisfied.	0.33	8.97	0.054	Algorithm converged.	-0.095	0.160	1.81	Algorithm converged.	0.34	9.36	0.3210		1.83	Algorithm converged.	0.37	1.78
Blood and lymphatic system disorders	Leukopenia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observation.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Leukopenia	Asia	140	28.3	0	0.0	140	27.6	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	Leukopenia	Rest of World	57	11.5	0	0.0	55	11.6	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	Myelosuppression	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	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	Myelosuppression	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observation.	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	Rest of World	57	11.5	0	0.0	55	11.6	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	Neutropenia	Western Europe/United States/Canada/Australia	298	60.2	3	1.0	305	60.7	1	0.3	3.04	Convergence criterion (ECOG#=1E-8) satisfied.	0.31	29.89	0.007	Algorithm converged.	-0.006	0.020	2.99	Algorithm converged.	0.30	28.87	0.3272	0.0762	3.23	Algorithm converged.	0.92	3.11
Blood and lymphatic system disorders	Neutropenia	Asia	140	28.3	1	0.7	140	27.6	1	1.4	0.49	Convergence criterion (ECOG#=1E-8) satisfied.	0.04	5.60	-0.007	Algorithm converged.	-0.091	0.017	0.50	Algorithm converged.	0.05	5.43	0.5656		0.51	Algorithm converged.	0.10	21.92
Blood and lymphatic system disorders	Neutropenia	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 4.7624271686 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Thrombocytopenia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	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	Asia	140	28.3	0	0.0	140	27.6	1	0.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 19.480043296 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Blood and lymphatic system disorders	Thrombocytopenia	Rest of World	57	11.5	1	1.8	55	11.6	0	0.0	NE	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
Cardiac disorders		Western Europe/United States/Canada/Australia	298	60.2	5	1.7	305	60.7	2	0.7	2.45	Convergence criterion (ECOG#=1E-8) satisfied.	0.24	2.53	-0.007	Algorithm converged.	-0.059	0.010	0.45	Algorithm converged.	0.15	0.53	0.4873	0.5577	1.44	Algorithm converged.	0.40	6.83
Cardiac disorders		Asia	140	28.3	2	1.4	140	27.6	2	1.4	0.99	Convergence criterion (ECOG#=1E-8) satisfied.	0.10	2.00	-0.000	Algorithm converged.	-0.053	0.053	0.99	Algorithm converged.	0.10	2.00	0.9999		0.99	Algorithm converged.	0.24	35.16
Cardiac disorders		Rest of World	57	11.5	0	0.0	55	11.6	1	1.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 10.540148605 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	Western Europe/United States/Canada/Australia	298	60.2	3	0.9	305	60.7	1	0.3	3.01	Convergence criterion (ECOG#=1E-8) satisfied.	0.30	14.13	0.006	Algorithm converged.	-0.009	0.015	1.01	Algorithm converged.	0.30	14.03	0.9962	1.0000	3.00	Algorithm converged.	0.09	15.83
Cardiac disorders	Atrial fibrillation	Asia	140	28.3	0	0.0	140	27.6	1	1.4	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 12.368584472 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrial fibrillation	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrial flutter	Western Europe/United States/Canada/Australia	298	60.2	2	0.7	305	60.7	0	0.0	5.11	Convergence criterion (ECOG#=1E-8) satisfied.	0.24	107.97	0.020	Algorithm converged.	-0.007	0.047	1.99	Algorithm converged.	0.24	104.92	0.3662	0.1609	3.00	Algorithm converged.	0.08	107.49
Cardiac disorders	Atrial flutter	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrial flutter	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observation.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Atrioventricular block complete	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	Rest of World	57	11.5	0	0.0	55	11.6	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 congestive	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observation.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Cardiac failure congestive	Asia	140	28.3	0	0.0	140	27.6	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 congestive	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 19.480043296 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Left ventricular dysfunction	Rest of World	57	11.5	0	0.0	55	11.6	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	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Myocardial infarction	Asia	140	28.3	0	0.0	140	27.6	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	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Sinus bradycardia	Asia	140	28.3	0	0.0	140	27.6	1	0.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 19.480043432 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Sinus bradycardia	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Sinus tachycardia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	NE	Algorithm converged.	NE	NE
Cardiac disorders	Sinus tachycardia	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	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
Cardiac disorders	Sinus tachycardia	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Tachycardia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observation.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	1.0000	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Tachycardia	Asia	140	28.3	0	0.0	140	27.6	1	0.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 19.480043432 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Cardiac disorders	Tachycardia	Rest of World	57	11.5	0	0.0	55	11.6	1	1.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 10.540148605 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Eye disorders		Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders		Asia	140	28.3	0	0.0	140	27.6	1	0.7	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	NE	Algorithm converged.	NE	NE
Eye disorders		Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Abnormal sensation in eye	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	NE	Algorithm converged.	NE	NE
Eye disorders	Abnormal sensation in eye	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Abnormal sensation in eye	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders		Western Europe/United States/Canada/Australia	298	60.2	19	7.0	305	60.7	15	5.0	1.44	Convergence criterion (ECOG#=1E-8) satisfied.	0.73	2.87	0.020	Algorithm converged.	-0.009	0.049	1.41	Algorithm converged.	0.74	2.68	0.2951	0.5609	0.71	Algorithm converged.	0.37	1.39
Gastrointestinal disorders		Asia	140	28.3	6	4.3	140	27.6	8	6.4	0.66	Convergence criterion (ECOG#=1E-8) satisfied.	0.21	2.10	-0.020	Algorithm converged.	-0.068	0.027	0.69	Algorithm converged.	0.21	2.09	0.5632		0.68	Algorithm converged.	0.29	2.44
Gastrointestinal disorders		Rest of World	57	11.5	3	5.3	55	11.6	2	3.7	1.47	Convergence criterion (ECOG#=1E-8) satisfied.	0.23	9.57	0.016	Algorithm converged.	-0.110	0.142	1.46	Algorithm converged.	0.23	9.29	0.5434		1.47	Algorithm converged.	0.43	5.04
Gastrointestinal disorders	Abdominal distension	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	ERROR: The mean parameter is either invalid or at a limit of its range for some observation.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Abdominal distension	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Abdominal distension	Rest of World	57	11.5	0	0.0	55	11.6	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	Western Europe/United States/Canada/Australia	298	60.2	5	1.7	305	60.7	2	0.7	2.45	Convergence criterion (ECOG#=1E-8) satisfied.	0.24	2.53	-0.007	Algorithm converged.	-0.059	0.010	0.45	Algorithm converged.	0.15	0.53	0.4873	0.5577	1.44	Algorithm converged.	0.40	6.83
Gastrointestinal disorders	Abdominal pain	Asia	140	28.3	2	1.4	140	27.6	2	1.4	0.99	Convergence criterion (ECOG#=1E-8) satisfied.	0.10	2.00	-0.000	Algorithm converged.	-0.053	0.053	0.99	Algorithm converged.	0.10	2.00	0.9999		0.99	Algorithm converged.	0.24	35.16
Gastrointestinal disorders	Abdominal pain	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 10.998844964 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Anal fistula	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Anal fistula	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Anal fistula	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Anal stenosis	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 19.480043296 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	>999.99	Algorithm converged.	0.00	NE
Gastrointestinal disorders	Anal stenosis	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Anal stenosis	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Colitis	Western Europe/United States/Canada/Australia	298	60.2	3	1.0	305	60.7	0	0.0	7.11	Convergence criterion (ECOG#=1E-8) satisfied.	0.37	136.56	0.020	Algorithm converged.	-0.007	0.047	1.99	Algorithm converged.	0.36	110.61	0.3662	0.1609	3.00	Algorithm converged.	0.08	107.49
Gastrointestinal disorders	Colitis	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Colitis	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Constipation	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Constipation	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Constipation	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Diarrhoea	Western Europe/United States/Canada/Australia	298	60.2	14	4.7	305	60.7	9	3.0	1.58	Convergence criterion (ECOG#=1E-8) satisfied.	0.69	3.61	0.017	Algorithm converged.	-0.007	0.041	1.57	Algorithm converged.	0.69	3.57	0.1744	0.5766	0.57	Algorithm converged.	0.27	1.21
Gastrointestinal disorders	Diarrhoea	Asia	140	28.3	3	2.1	140	27.6	4	2.9	0.73	Convergence criterion (ECOG#=1E-8) satisfied.	0.16	3.34	-0.007	Algorithm converged.	-0.053	0.039	0.73	Algorithm converged.	0.16	3.34	0.6772		0.72	Algorithm converged.	0.19	2.73
Gastrointestinal disorders	Diarrhoea	Rest of World	57	11.5	1	1.8	55	11.6	1	1.7	1.04	Convergence criterion (ECOG#=1E-8) satisfied.	0.06	18.20	0.001	Algorithm converged.	-0.095	0.097	1.04	Algorithm converged.	0.06	17.94	0.9731		1.04	Algorithm converged.	0.06	17.94
Gastrointestinal disorders	Dyspeptic discomfort	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: Negative of Hessian not positive definite.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Dyspeptic discomfort	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Dyspeptic discomfort	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Faecal discoloured	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	305	60.7	1	0.3	NE	Quasi-complete separation of data points detected.	NE	NE	NE	WARNING: The relative Hessian convergence criterion of 44.804746292 is greater than the limit of 0.0001. The convergence is questionable.	NE	NE	0.00	Algorithm converged.	0.00	NE	0.9999	NE	NE	Algorithm converged.	NE	NE
Gastrointestinal disorders	Faecal discoloured	Asia	140	28.3	0	0.0	140	27.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Faecal discoloured	Rest of World	57	11.5	0	0.0	55	11.6	0	0.0	NE	NE	NE	NE	NE	NE	NE	N

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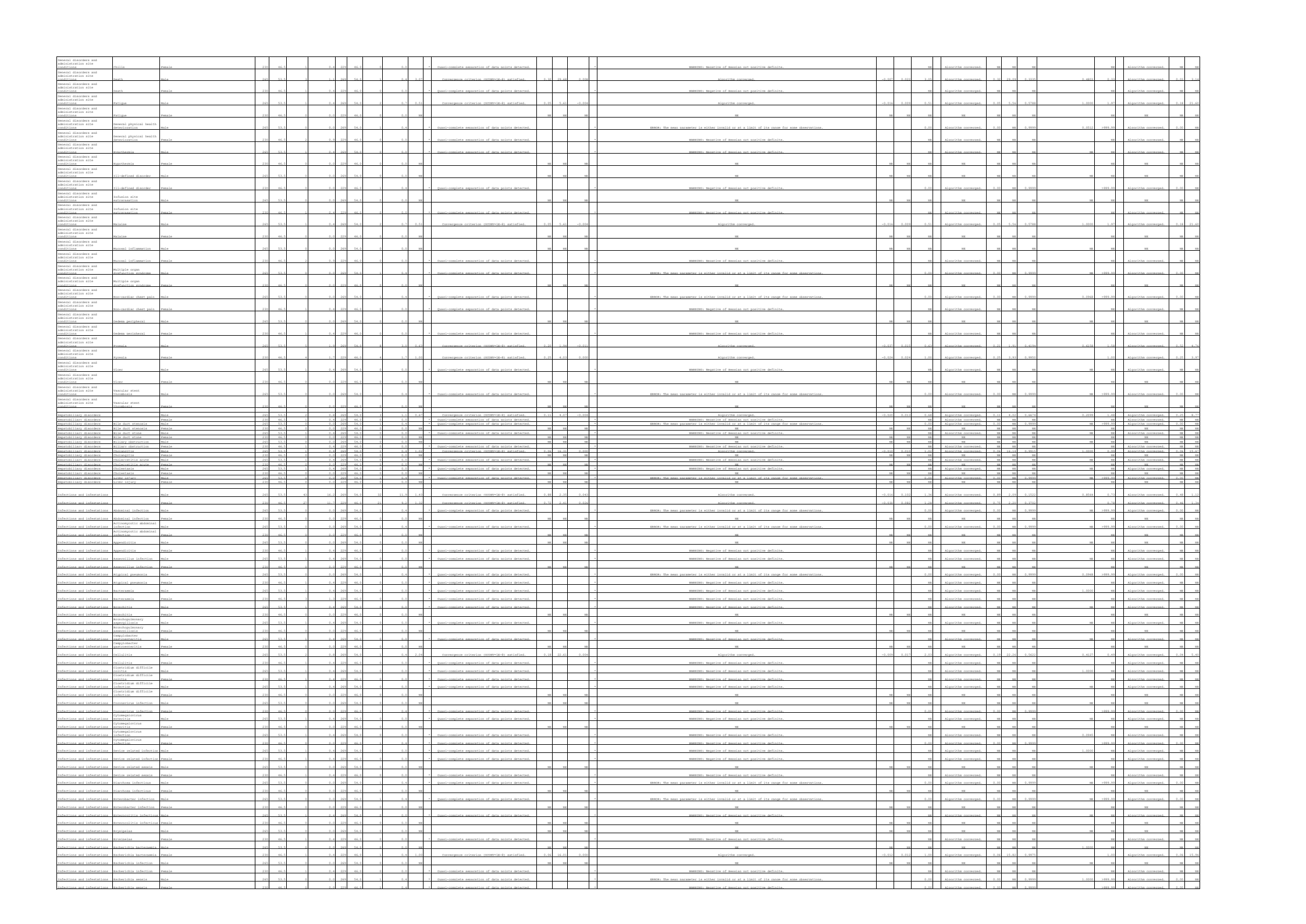
POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Any SAEs
MODEL: Unstratified Analysis
STUDY: BG39862
Dichotomous Analysis by Subgroups (Safety)

Sex

			Active+Placebo Pooled (N=1,000)				A-Cohort (N=500)				Active+Placebo Pooled vs A-Cohort														A-Cohort vs. Active+Placebo Pooled (N=1,000)				
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio							Absolute Risk Difference					Relative Risk							
MedDRA System Organ Class	MedDRA Preferred Term	Level	N	%	n	%	N	%	n	%	Odds Ratio	Convergence Result	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Result	95% Lower CL	95% Upper CL	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk	Convergence Result	95% Lower CL	95% Upper CL
Blood and lymphatic system disorders		Male	245	53.9	33	10.9	245	54.1	24	9.7	1.15	Convergence criterion (ECOSW=1E-8) satisfied.	0.66	2.01	0.011	Algorithm converged.	-0.040	0.065	1.13	Algorithm converged.	0.66	1.97	0.6274	0.4367	0.88	Algorithm converged.	0.53	1.44
Blood and lymphatic system disorders		Female	230	46.5	33	12.9	255	46.1	19	8.3	1.58	Convergence criterion (ECOSW=1E-8) satisfied.	0.87	2.90	0.049	Algorithm converged.	-0.014	0.095	1.42	Algorithm converged.	0.98	2.63	0.1252		1.24	Algorithm converged.	0.96	1.14
Blood and lymphatic system disorders	Agranulocytosis	Male	245	53.5	2	0.9	245	54.1	1	0.4		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.01	NE	0.9999	NE	>999.99	Algorithm converged.	0.01	NE
Blood and lymphatic system disorders	Agranulocytosis	Female	230	46.5	2	0.9	255	46.1	2	0.8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	Anaemia	Male	245	53.5	4	1.6	245	54.1	4	1.6	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.23	2.26	-0.011	Algorithm converged.	-0.049	0.025	0.99	Algorithm converged.	0.26	3.84	0.2716	0.2716	1.04	Algorithm converged.	0.44	95.04
Blood and lymphatic system disorders	Anaemia	Female	230	46.5	4	1.7	255	46.1	4	1.6	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.23	4.33	0.006	Algorithm converged.	-0.034	0.046	1.01	Algorithm converged.	0.26	3.93	0.9951		1.00	Algorithm converged.	0.31	3.97
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Male	245	53.5	2	0.8	245	54.1	2	0.8		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	0.5840	NE	NE	NE	NE
Blood and lymphatic system disorders	Febrile bone marrow aplasia	Female	230	46.5	0	0.0	255	46.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Blood and lymphatic system disorders	Febrile neutropenia	Male	245	53.5	15	5.8	245	54.1	17	6.9	1.41	Convergence criterion (ECOSW=1E-8) satisfied.	0.85	2.35	0.030	Algorithm converged.	-0.015	0.081	1.15	Algorithm converged.	0.86	2.33	0.1421	0.5010	1.16	Algorithm converged.	0.91	1.14
Blood and lymphatic system disorders	Febrile neutropenia	Female	230	46.5	15	6.1	255	46.1	14	6.1	1.04	Convergence criterion (ECOSW=1E-8) satisfied.	0.75	3.11	0.030	Algorithm converged.	-0.018	0.079	1.14	Algorithm converged.	0.78	2.85	0.2272		1.07	Algorithm converged.	0.91	1.29
Blood and lymphatic system disorders	Leukopenia	Male	245	53.5	0	0.0	245	54.1	0	0.4		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.01	NE	0.9999	1.0000	>999.99	Algorithm converged.	0.01	NE
Blood and lymphatic system disorders	Leukopenia	Female	230	46.5	0	0.0	255	46.1	0	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Blood and lymphatic system disorders	Myelosuppression	Male	245	53.5	0	0.0	245	54.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	1.0000	NE	NE	NE	NE
Blood and lymphatic system disorders	Myelosuppression	Female	230	46.5	0	0.0	255	46.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.		NE	NE	NE	NE
Blood and lymphatic system disorders	Neutropenia	Male	245	53.5	1	0.4	245	54.1	1	0.4	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.05	7.05	-0.000	Algorithm converged.	-0.025	0.020	0.99	Algorithm converged.	0.06	3.33	0.9467	0.4297	1.00	Algorithm converged.	0.31	28.23
Blood and lymphatic system disorders	Neutropenia	Female	230	46.5	1	1.2	255	46.1	1	1.2	1.05	Convergence criterion (ECOSW=1E-8) satisfied.	0.05	4.89	0.004	Algorithm converged.	-0.021	0.043	1.01	Algorithm converged.	0.06	4.89	0.9957		1.00	Algorithm converged.	0.20	4.94
Blood and lymphatic system disorders	Thrombocytopenia	Male	245	53.5	1	0.4	245	54.1	1	0.4	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.04	16.01	0.000	Algorithm converged.	-0.030	0.010	1.02	Algorithm converged.	0.04	14.14	0.9915	1.0000	1.00	Algorithm converged.	0.06	15.61
Blood and lymphatic system disorders	Thrombocytopenia	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders		Male	245	53.5	5	1.9	245	54.1	5	1.9	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.28	3.53	-0.010	Algorithm converged.	-0.039	0.040	1.00	Algorithm converged.	0.30	3.37	0.9433	0.3890	0.83	Algorithm converged.	0.32	45.49
Cardiac disorders		Female	230	46.5	5	1.9	255	46.1	2	0.8	2.31	Convergence criterion (ECOSW=1E-8) satisfied.	0.41	12.97	0.011	Algorithm converged.	-0.013	0.035	1.02	Algorithm converged.	0.41	12.77	0.1147		1.17	Algorithm converged.	0.42	4.91
Cardiac disorders	Atrial fibrillation	Male	245	53.5	2	0.8	245	54.1	2	0.7	1.00	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.01	NE	0.9999	1.0000	>999.99	Algorithm converged.	0.01	NE
Cardiac disorders	Atrial fibrillation	Female	230	46.5	1	0.4	255	46.1	1	0.4	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.04	16.01	0.000	Algorithm converged.	-0.031	0.010	1.02	Algorithm converged.	0.04	14.14	0.9915		1.00	Algorithm converged.	0.06	15.61
Cardiac disorders	Atrial flutter	Male	245	53.5	2	0.8	245	54.1	2	0.8	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.05	15.97	0.000	Algorithm converged.	-0.030	0.010	1.02	Algorithm converged.	0.05	14.13	0.9915	1.0000	1.00	Algorithm converged.	0.06	15.61
Cardiac disorders	Atrial flutter	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Atrioventricular block complete	Male	245	53.5	0	0.0	245	54.1	0	0.4		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.01	NE	0.9999	NE	>999.99	Algorithm converged.	0.01	NE
Cardiac disorders	Atrioventricular block complete	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Cardiac failure congestive	Male	245	53.5	0	0.0	245	54.1	0	0.7		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.01	NE	0.9999	NE	>999.99	Algorithm converged.	0.01	NE
Cardiac disorders	Cardiac failure congestive	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	Male	245	53.5	0	0.0	245	54.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Cardiac disorders	Left ventricular dysfunction	Female	230	46.5	0	0.0	255	46.1	0	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999	NE	>999.99	Algorithm converged.	0.01	NE
Cardiac disorders	Myocardial infarction	Male	245	53.5	0	0.0	245	54.1	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	Female	230	46.5	1	0.4	255	46.1	1	0.4	1.00	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	NE	NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	Male	245	53.5	0	0.0	245	54.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Sinus bradycardia	Female	230	46.5	1	0.4	255	46.1	1	0.4	1.00	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999	NE	>999.99	Algorithm converged.	0.01	NE
Cardiac disorders	Sinus tachycardia	Male	245	53.5	0	0.0	245	54.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cardiac disorders	Sinus tachycardia	Female	230	46.5	1	0.4	255	46.1	1	0.4	1.00	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	NE	NE	NE	NE	NE
Cardiac disorders	Tachycardia	Male	245	53.5	1	0.4	245	54.1	1	0.4	1.00	Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.01	NE	0.9999	1.0000	>999.99	Algorithm converged.	0.01	NE
Cardiac disorders	Tachycardia	Female	230	46.5	0	0.0	255	46.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Eye disorders		Male	245	53.5	0	0.4	245	54.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	NE	NE	NE	NE	NE
Eye disorders		Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	Male	245	53.5	0	0.4	245	54.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	NE	NE	NE	NE	NE
Eye disorders	Rhegmatogenous retinal detachment	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders		Male	245	53.5	14	4.9	245	54.1	9	3.3	1.51	Convergence criterion (ECOSW=1E-8) satisfied.	0.93	4.77	0.039	Algorithm converged.	-0.000	0.072	2.23	Algorithm converged.	0.93	5.44	0.0751	0.0660	0.49	Algorithm converged.	0.23	1.58
Gastrointestinal disorders		Female	230	46.5	10	3.7	255	46.1	14	5.4	0.71	Convergence criterion (ECOSW=1E-8) satisfied.	0.33	1.47	-0.023	Algorithm converged.	-0.066	0.019	0.77	Algorithm converged.	0.34	1.63	0.4841		1.15	Algorithm converged.	0.52	2.71
Gastrointestinal disorders	Abdominal distension	Male	245	53.5	0	0.0	245	54.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Abdominal distension	Female	230	46.5	0	0.0	255	46.1	0	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Abdominal pain	Male	245	53.5	2	0.8	245	54.1	2	0.7	0.91	Convergence criterion (ECOSW=1E-8) satisfied.	0.05	7.05	-0.000	Algorithm converged.	-0.025	0.020	0.99	Algorithm converged.	0.06	3.33	0.9467	0.4297	1.00	Algorithm converged.	0.31	28.23
Gastrointestinal disorders	Abdominal pain	Female	230	46.5	1	0.4	255	46.1	1	0.4	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.04	16.01	0.000	Algorithm converged.	-0.031	0.010	1.02	Algorithm converged.	0.04	14.14	0.9915		1.00	Algorithm converged.	0.06	15.61
Gastrointestinal disorders	Anal fistula	Male	245	53.5	0	0.4	245	54.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Anal fistula	Female	230	46.5	1	0.4	255	46.1	1	0.4	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.04	16.01	0.000	Algorithm converged.	-0.031	0.010	1.02	Algorithm converged.	0.04	14.14	0.9915	1.0000	1.00	Algorithm converged.	0.06	15.61
Gastrointestinal disorders	Anal stenosis	Male	245	53.5	0	0.0	245	54.1	0	0.4		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.01	NE	0.9999	NE	>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Anal stenosis	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Colitis	Male	245	53.5	1	0.4	245	54.1	1	0.4	1.00	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	1.0000	NE	NE	NE	NE
Gastrointestinal disorders	Colitis	Female	230	46.5	1	0.4	255	46.1	1	0.4	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.04	16.01	0.000	Algorithm converged.	-0.031	0.010	1.02	Algorithm converged.	0.04	15.32	0.9957		1.00	Algorithm converged.	0.06	15.61
Gastrointestinal disorders	Constipation	Male	245	53.5	1	0.4	245	54.1	1	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	1.0040	NE	NE	NE	NE
Gastrointestinal disorders	Constipation	Female	230	46.5	0	0.0	255	46.1	0	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Diarrhoea	Male	245	53.5	5	1.9	245	54.1	2	0.8	0.43	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999	0.1728	>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Diarrhoea	Female	230	46.5	4	2.4	255	46.1	3	0.9	2.64	Convergence criterion (ECOSW=1E-8) satisfied.	0.65	10.69	0.011	Algorithm converged.	-0.007	0.041	2.58	Algorithm converged.	0.65	10.14	0.1771		2.03	Algorithm converged.	0.97	1.43
Gastrointestinal disorders	Duodenitis	Male	245	53.5	1	0.4	245	54.1	1	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	NE	NE	NE	NE	NE
Gastrointestinal disorders	Duodenitis	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Duodenitis haemorrhagic	Male	245	53.5	0	0.0	245	54.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	NE	NE	NE	NE	NE
Gastrointestinal disorders	Duodenitis haemorrhagic	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Enteritis	Male	245	53.5	0	0.0	245	54.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Enteritis	Female	230	46.5	0	0.0	255	46.1	0	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Gastritis	Male	245	53.5	1	0.4	245	54.1	1	0.4	1.00	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	1.0000	NE	NE	NE	NE
Gastrointestinal disorders	Gastritis	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Gastritis haemorrhagic	Male	245	53.5	0	0.0	245	54.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Gastritis haemorrhagic	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Gastrointestinal haemorrhage	Male	245	53.5	2	0.8	245	54.1	2	0.8	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.05	15.97	0.000	Algorithm converged.	-0.030	0.010	1.02	Algorithm converged.	0.05	14.13	0.9915	1.0000	1.00	Algorithm converged.	0.06	15.61
Gastrointestinal disorders	Gastrointestinal haemorrhage	Female	230	46.5	0	0.0	255	46.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Gastrointestinal perforation	Male	245	53.5	1	0.4	245	54.1	1	0.4	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.04	16.01	0.000	Algorithm converged.	-0.031	0.010	1.02	Algorithm converged.	0.04	14.14	0.9915		1.00	Algorithm converged.	0.06	15.61
Gastrointestinal disorders	Gastrointestinal perforation	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Gastrointestinal stenosis	Male	245	53.5	0	0.0	245	54.1	0	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Gastrointestinal stenosis	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Haemorrhoids	Male	245	53.5	0	0.0	245	54.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Haemorrhoids	Female	230	46.5	0	0.0	255	46.1	0	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Ileus	Male	245	53.5	1	0.4	245	54.1	1	0.4	1.00	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	1.0040	NE	NE	NE	NE
Gastrointestinal disorders	Ileus	Female	230	46.5	0	0.0	255	46.1	0	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Impaired gastric emptying	Male	245	53.5	0	0.0	245	54.1	0	0.4		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.01	NE	0.9999	NE	>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Impaired gastric emptying	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Intestinal obstruction	Male	245	53.5	0	0.4	245	54.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	1.0040	NE	NE	NE	NE
Gastrointestinal disorders	Intestinal obstruction	Female	230	46.5	0	0.0	255	46.1	0	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Intestinal perforation	Male	245	53.5	0	0.4	245	54.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	1.4040	NE	NE	NE	NE
Gastrointestinal disorders	Intestinal perforation	Female	230	46.5	1	0.4	255	46.1	1	0.4	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.14	22.21	0.000	Algorithm converged.	-0.043	0.014	1.02	Algorithm converged.	0.14	21.72	0.9727		1.00	Algorithm converged.	0.19	5.22
Gastrointestinal disorders	Intra-abdominal haemorrhage	Male	245	53.5	0	0.0	245	54.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Intra-abdominal haemorrhage	Female	230	46.5	0	0.0	255	46.1	0	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Nausea	Male	245	53.5	1	0.4	245	54.1	1	0.4	1.00	Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	1.0047	NE	NE	NE	NE
Gastrointestinal disorders	Nausea	Female	230	46.5	3	1.2	255	46.1	3	1.2	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.21	4.69	0.000	Algorithm converged.	-0.033	0.033	1.00	Algorithm converged.	0.21	4.66	0.9967	0.2047	1.00	Algorithm converged.	0.27	4.73
Gastrointestinal disorders	Necrotising colitis	Male	245	53.5	0	0.4	245	54.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	NE	NE	NE	NE	NE
Gastrointestinal disorders	Necrotising colitis	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Neutropenic colitis	Male	245	53.5	0	0.4	245	54.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	NE	NE	NE	NE	NE
Gastrointestinal disorders	Neutropenic colitis	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Obstruction gastric	Male	245	53.5	0	0.0	245	54.1	0	0.4		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Obstruction gastric	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Gastrointestinal disorders	Pancreatitis	Male	245	53.5	0	0.0	245	54.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	1.0000	NE	NE	NE	NE
Gastrointestinal disorders	Pancreatitis	Female	230	46.5	1	0.4	255	46.1	1	0.4	1.00	Convergence criterion (ECOSW=1E-8) satisfied.	0.04	16.01	0.000	Algorithm converged.	-0.031	0.010	1.02	Algorithm converged.	0.04	15.32	0.9957		1.00	Algorithm converged.	0.06	15.61
Gastrointestinal disorders	Rectal haemorrhage	Male	245	53.5	0	0.0	245	54.1	0	0.0		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					NE	NE	Algorithm converged.	NE	NE	NE	NE	NE
Gastrointestinal disorders	Rectal haemorrhage	Female	230	46.5	0	0.0	255	46.1	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	Small intestinal haemorrhage	Male	245	53.5	0	0.0	245	54.1	0	0.7		Quasi-complete separation of data points detected.				ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					0.01	NE	0.9999	1.0000	>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Small intestinal obstruction	Female	230	46.5	0	0.0	255	46.1	0	1.3		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.					0.01	NE	0.9999		>999.99	Algorithm converged.	0.01	NE
Gastrointestinal disorders	Small intestinal perforation	Male	245	53.5	0	0.0	245	54.1	0	0.4		Quasi-complete separation of data points detected.				ERROR: The mean parameter



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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs leading to any Study Treatment Discontinuation
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

All

			Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		n/a	495	100.0	3	0.6	498	100.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	n/a	495	100.0	2	0.4	498	100.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	n/a	495	100.0	1	0.2	498	100.0	0	0.0
Cardiac disorders		n/a	495	100.0	0	0.0	498	100.0	1	0.2
Cardiac disorders	Left ventricular dysfunction	n/a	495	100.0	0	0.0	498	100.0	1	0.2
Gastrointestinal disorders		n/a	495	100.0	2	0.4	498	100.0	3	0.6
Gastrointestinal disorders	Intestinal obstruction	n/a	495	100.0	0	0.0	498	100.0	1	0.2
Gastrointestinal disorders	Intestinal perforation	n/a	495	100.0	1	0.2	498	100.0	0	0.0
Gastrointestinal disorders	Intra-abdominal haemorrhage	n/a	495	100.0	0	0.0	498	100.0	1	0.2
Gastrointestinal disorders	Nausea	n/a	495	100.0	0	0.0	498	100.0	1	0.2
Gastrointestinal disorders	Necrotising colitis	n/a	495	100.0	1	0.2	498	100.0	0	0.0
General disorders and administration site conditions		n/a	495	100.0	5	1.0	498	100.0	1	0.2
General disorders and administration site conditions	Cardiac death	n/a	495	100.0	1	0.2	498	100.0	0	0.0
General disorders and administration site conditions	Death	n/a	495	100.0	3	0.6	498	100.0	1	0.2
General disorders and administration site conditions	Fatigue	n/a	495	100.0	1	0.2	498	100.0	0	0.0
Infections and infestations		n/a	495	100.0	9	1.8	498	100.0	12	2.4
Infections and infestations	Intervertebral discitis	n/a	495	100.0	0	0.0	498	100.0	1	0.2
Infections and infestations	Peritonitis	n/a	495	100.0	0	0.0	498	100.0	1	0.2
Infections and infestations	Pneumonia	n/a	495	100.0	7	1.4	498	100.0	8	1.6
Infections and infestations	Prostate infection	n/a	495	100.0	0	0.0	498	100.0	1	0.2
Infections and infestations	Sepsis	n/a	495	100.0	1	0.2	498	100.0	1	0.2
Infections and infestations	Suspected COVID-19	n/a	495	100.0	1	0.2	498	100.0	0	0.0
Investigations		n/a	495	100.0	0	0.0	498	100.0	1	0.2
Investigations	Ejection fraction decreased	n/a	495	100.0	0	0.0	498	100.0	1	0.2
Nervous system disorders		n/a	495	100.0	3	0.6	498	100.0	10	2.0
Nervous system disorders	Cerebral infarction	n/a	495	100.0	0	0.0	498	100.0	1	0.2
Nervous system disorders	Hypoaesthesia	n/a	495	100.0	0	0.0	498	100.0	1	0.2
Nervous system disorders	Neuropathy peripheral	n/a	495	100.0	1	0.2	498	100.0	4	0.8
Nervous system disorders	Peripheral motor neuropathy	n/a	495	100.0	0	0.0	498	100.0	2	0.4
Nervous system disorders	Peripheral sensorimotor neuropathy	n/a	495	100.0	1	0.2	498	100.0	1	0.2
Nervous system disorders	Peripheral sensory neuropathy	n/a	495	100.0	0	0.0	498	100.0	1	0.2
Nervous system disorders	Polyneuropathy	n/a	495	100.0	1	0.2	498	100.0	0	0.0
Renal and urinary disorders		n/a	495	100.0	1	0.2	498	100.0	1	0.2
Renal and urinary disorders	Acute kidney injury	n/a	495	100.0	1	0.2	498	100.0	1	0.2
Respiratory, thoracic and mediastinal disorders		n/a	495	100.0	7	1.4	498	100.0	1	0.2
Respiratory, thoracic and mediastinal disorders	Dyspnoea	n/a	495	100.0	1	0.2	498	100.0	1	0.2
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	n/a	495	100.0	1	0.2	498	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	n/a	495	100.0	3	0.6	498	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	n/a	495	100.0	1	0.2	498	100.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	n/a	495	100.0	1	0.2	498	100.0	0	0.0

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Clinical cut-off: 15JUN2022

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs leading to any Study Treatment Discontinuation
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

Age

			Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Blood and lymphatic system disorders		> 60	328	66.3	3	0.9	341	68.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Blood and lymphatic system disorders	Neutropenia	> 60	328	66.3	2	0.6	341	68.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	> 60	328	66.3	1	0.3	341	68.5	0	0.0
Cardiac disorders		<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Cardiac disorders		> 60	328	66.3	0	0.0	341	68.5	1	0.3
Cardiac disorders	Left ventricular dysfunction	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Cardiac disorders	Left ventricular dysfunction	> 60	328	66.3	0	0.0	341	68.5	1	0.3
Gastrointestinal disorders		<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Gastrointestinal disorders		> 60	328	66.3	2	0.6	341	68.5	3	0.9
Gastrointestinal disorders	Intestinal obstruction	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Gastrointestinal disorders	Intestinal obstruction	> 60	328	66.3	0	0.0	341	68.5	1	0.3
Gastrointestinal disorders	Intestinal perforation	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Gastrointestinal disorders	Intestinal perforation	> 60	328	66.3	1	0.3	341	68.5	0	0.0
Gastrointestinal disorders	Intra-abdominal haemorrhage	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Gastrointestinal disorders	Intra-abdominal haemorrhage	> 60	328	66.3	0	0.0	341	68.5	1	0.3
Gastrointestinal disorders	Nausea	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Gastrointestinal disorders	Nausea	> 60	328	66.3	0	0.0	341	68.5	1	0.3
Gastrointestinal disorders	Necrotising colitis	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Gastrointestinal disorders	Necrotising colitis	> 60	328	66.3	1	0.3	341	68.5	0	0.0
General disorders and administration site conditions		<= 60	167	33.7	1	0.6	157	31.5	0	0.0
General disorders and administration site conditions		> 60	328	66.3	4	1.2	341	68.5	1	0.3
General disorders and administration site conditions	Cardiac death	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
General disorders and administration site conditions	Cardiac death	> 60	328	66.3	1	0.3	341	68.5	0	0.0
General disorders and administration site conditions	Death	<= 60	167	33.7	1	0.6	157	31.5	0	0.0
General disorders and administration site conditions	Death	> 60	328	66.3	2	0.6	341	68.5	1	0.3
General disorders and administration site conditions	Fatigue	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
General disorders and administration site conditions	Fatigue	> 60	328	66.3	1	0.3	341	68.5	0	0.0
Infections and infestations		<= 60	167	33.7	3	1.8	157	31.5	5	3.2
Infections and infestations		> 60	328	66.3	6	1.8	341	68.5	7	2.1
Infections and infestations	Intervertebral discitis	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Infections and infestations	Intervertebral discitis	> 60	328	66.3	0	0.0	341	68.5	1	0.3
Infections and infestations	Peritonitis	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Infections and infestations	Peritonitis	> 60	328	66.3	0	0.0	341	68.5	1	0.3
Infections and infestations	Pneumonia	<= 60	167	33.7	2	1.2	157	31.5	4	2.5
Infections and infestations	Pneumonia	> 60	328	66.3	5	1.5	341	68.5	4	1.2
Infections and infestations	Prostate infection	<= 60	167	33.7	0	0.0	157	31.5	1	0.6
Infections and infestations	Prostate infection	> 60	328	66.3	0	0.0	341	68.5	0	0.0
Infections and infestations	Sepsis	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Infections and infestations	Sepsis	> 60	328	66.3	1	0.3	341	68.5	1	0.3
Infections and infestations	Suspected COVID-19	<= 60	167	33.7	1	0.6	157	31.5	0	0.0
Infections and infestations	Suspected COVID-19	> 60	328	66.3	0	0.0	341	68.5	0	0.0
Investigations		<= 60	167	33.7	0	0.0	157	31.5	1	0.6
Investigations		> 60	328	66.3	0	0.0	341	68.5	0	0.0
Investigations	Ejection fraction decreased	<= 60	167	33.7	0	0.0	157	31.5	1	0.6
Investigations	Ejection fraction decreased	> 60	328	66.3	0	0.0	341	68.5	0	0.0
Nervous system disorders		<= 60	167	33.7	0	0.0	157	31.5	1	0.6
Nervous system disorders		> 60	328	66.3	3	0.9	341	68.5	9	2.6
Nervous system disorders	Cerebral infarction	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Nervous system disorders	Cerebral infarction	> 60	328	66.3	0	0.0	341	68.5	1	0.3
Nervous system disorders	Hypoaesthesia	<= 60	167	33.7	0	0.0	157	31.5	0	0.0

Nervous system disorders	Hypoaesthesia	> 60	328	66.3	0	0.0	341	68.5	1	0.3
Nervous system disorders	Neuropathy peripheral	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Nervous system disorders	Neuropathy peripheral	> 60	328	66.3	1	0.3	341	68.5	4	1.2
Nervous system disorders	Peripheral motor neuropathy	<= 60	167	33.7	0	0.0	157	31.5	1	0.6
Nervous system disorders	Peripheral motor neuropathy	> 60	328	66.3	0	0.0	341	68.5	1	0.3
Nervous system disorders	Peripheral sensorimotor neuropathy	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Nervous system disorders	Peripheral sensorimotor neuropathy	> 60	328	66.3	1	0.3	341	68.5	1	0.3
Nervous system disorders	Peripheral sensory neuropathy	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Nervous system disorders	Peripheral sensory neuropathy	> 60	328	66.3	0	0.0	341	68.5	1	0.3
Nervous system disorders	Polyneuropathy	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Nervous system disorders	Polyneuropathy	> 60	328	66.3	1	0.3	341	68.5	0	0.0
Renal and urinary disorders		<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Renal and urinary disorders		> 60	328	66.3	1	0.3	341	68.5	1	0.3
Renal and urinary disorders	Acute kidney injury	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Renal and urinary disorders	Acute kidney injury	> 60	328	66.3	1	0.3	341	68.5	1	0.3
Respiratory, thoracic and mediastinal disorders		<= 60	167	33.7	1	0.6	157	31.5	1	0.6
Respiratory, thoracic and mediastinal disorders		> 60	328	66.3	6	1.8	341	68.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	<= 60	167	33.7	0	0.0	157	31.5	1	0.6
Respiratory, thoracic and mediastinal disorders	Dyspnoea	> 60	328	66.3	1	0.3	341	68.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	> 60	328	66.3	1	0.3	341	68.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	<= 60	167	33.7	1	0.6	157	31.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	> 60	328	66.3	2	0.6	341	68.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	> 60	328	66.3	1	0.3	341	68.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	<= 60	167	33.7	0	0.0	157	31.5	0	0.0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	> 60	328	66.3	1	0.3	341	68.5	0	0.0

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Clinical cut-off: 15JUN2022

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs leading to any Study Treatment Discontinuation
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

IPI score at Screening

			Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		1-2	187	37.8	0	0.0	187	37.6	0	0.0
Blood and lymphatic system disorders		3	196	39.6	1	0.5	186	37.3	0	0.0
Blood and lymphatic system disorders		4-5	112	22.6	2	1.8	125	25.1	0	0.0
Blood and lymphatic system disorders	Neutropenia	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Blood and lymphatic system disorders	Neutropenia	3	196	39.6	0	0.0	186	37.3	0	0.0
Blood and lymphatic system disorders	Neutropenia	4-5	112	22.6	2	1.8	125	25.1	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	3	196	39.6	1	0.5	186	37.3	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Cardiac disorders		1-2	187	37.8	0	0.0	187	37.6	0	0.0
Cardiac disorders		3	196	39.6	0	0.0	186	37.3	0	0.0
Cardiac disorders		4-5	112	22.6	0	0.0	125	25.1	1	0.8
Cardiac disorders	Left ventricular dysfunction	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Cardiac disorders	Left ventricular dysfunction	3	196	39.6	0	0.0	186	37.3	0	0.0
Cardiac disorders	Left ventricular dysfunction	4-5	112	22.6	0	0.0	125	25.1	1	0.8
Gastrointestinal disorders		1-2	187	37.8	0	0.0	187	37.6	0	0.0
Gastrointestinal disorders		3	196	39.6	0	0.0	186	37.3	2	1.1
Gastrointestinal disorders		4-5	112	22.6	2	1.8	125	25.1	1	0.8
Gastrointestinal disorders	Intestinal obstruction	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Gastrointestinal disorders	Intestinal obstruction	3	196	39.6	0	0.0	186	37.3	1	0.5
Gastrointestinal disorders	Intestinal obstruction	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Gastrointestinal disorders	Intestinal perforation	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Gastrointestinal disorders	Intestinal perforation	3	196	39.6	0	0.0	186	37.3	0	0.0
Gastrointestinal disorders	Intestinal perforation	4-5	112	22.6	1	0.9	125	25.1	0	0.0
Gastrointestinal disorders	Intra-abdominal haemorrhage	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Gastrointestinal disorders	Intra-abdominal haemorrhage	3	196	39.6	0	0.0	186	37.3	0	0.0
Gastrointestinal disorders	Intra-abdominal haemorrhage	4-5	112	22.6	0	0.0	125	25.1	1	0.8
Gastrointestinal disorders	Nausea	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Gastrointestinal disorders	Nausea	3	196	39.6	0	0.0	186	37.3	1	0.5
Gastrointestinal disorders	Nausea	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Gastrointestinal disorders	Necrotising colitis	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Gastrointestinal disorders	Necrotising colitis	3	196	39.6	0	0.0	186	37.3	0	0.0
Gastrointestinal disorders	Necrotising colitis	4-5	112	22.6	1	0.9	125	25.1	0	0.0
General disorders and administration site conditions		1-2	187	37.8	2	1.1	187	37.6	0	0.0
General disorders and administration site conditions		3	196	39.6	1	0.5	186	37.3	0	0.0
General disorders and administration site conditions		4-5	112	22.6	2	1.8	125	25.1	1	0.8
General disorders and administration site conditions	Cardiac death	1-2	187	37.8	1	0.5	187	37.6	0	0.0
General disorders and administration site conditions	Cardiac death	3	196	39.6	0	0.0	186	37.3	0	0.0
General disorders and administration site conditions	Cardiac death	4-5	112	22.6	0	0.0	125	25.1	0	0.0
General disorders and administration site conditions	Death	1-2	187	37.8	1	0.5	187	37.6	0	0.0
General disorders and administration site conditions	Death	3	196	39.6	1	0.5	186	37.3	0	0.0
General disorders and administration site conditions	Death	4-5	112	22.6	1	0.9	125	25.1	1	0.8
General disorders and administration site conditions	Fatigue	1-2	187	37.8	0	0.0	187	37.6	0	0.0
General disorders and administration site conditions	Fatigue	3	196	39.6	0	0.0	186	37.3	0	0.0
General disorders and administration site conditions	Fatigue	4-5	112	22.6	1	0.9	125	25.1	0	0.0
Infections and infestations		1-2	187	37.8	3	1.6	187	37.6	3	1.6
Infections and infestations		3	196	39.6	4	2.0	186	37.3	5	2.7
Infections and infestations		4-5	112	22.6	2	1.8	125	25.1	4	3.2
Infections and infestations	Intervertebral discitis	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Infections and infestations	Intervertebral discitis	3	196	39.6	0	0.0	186	37.3	0	0.0
Infections and infestations	Intervertebral discitis	4-5	112	22.6	0	0.0	125	25.1	1	0.8
Infections and infestations	Peritonitis	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Infections and infestations	Peritonitis	3	196	39.6	0	0.0	186	37.3	0	0.0
Infections and infestations	Peritonitis	4-5	112	22.6	0	0.0	125	25.1	1	0.8
Infections and infestations	Pneumonia	1-2	187	37.8	2	1.1	187	37.6	2	1.1

Infections and infestations	Pneumonia	3	196	39.6	4	2.0	186	37.3	4	2.2
Infections and infestations	Pneumonia	4-5	112	22.6	1	0.9	125	25.1	2	1.6
Infections and infestations	Prostate infection	1-2	187	37.8	0	0.0	187	37.6	1	0.5
Infections and infestations	Prostate infection	3	196	39.6	0	0.0	186	37.3	0	0.0
Infections and infestations	Prostate infection	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Infections and infestations	Sepsis	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Infections and infestations	Sepsis	3	196	39.6	0	0.0	186	37.3	1	0.5
Infections and infestations	Sepsis	4-5	112	22.6	1	0.9	125	25.1	0	0.0
Infections and infestations	Suspected COVID-19	1-2	187	37.8	1	0.5	187	37.6	0	0.0
Infections and infestations	Suspected COVID-19	3	196	39.6	0	0.0	186	37.3	0	0.0
Infections and infestations	Suspected COVID-19	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Investigations		1-2	187	37.8	0	0.0	187	37.6	0	0.0
Investigations		3	196	39.6	0	0.0	186	37.3	1	0.5
Investigations		4-5	112	22.6	0	0.0	125	25.1	0	0.0
Investigations	Ejection fraction decreased	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Investigations	Ejection fraction decreased	3	196	39.6	0	0.0	186	37.3	1	0.5
Investigations	Ejection fraction decreased	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Nervous system disorders		1-2	187	37.8	0	0.0	187	37.6	6	3.2
Nervous system disorders		3	196	39.6	1	0.5	186	37.3	2	1.1
Nervous system disorders		4-5	112	22.6	2	1.8	125	25.1	2	1.6
Nervous system disorders	Cerebral infarction	1-2	187	37.8	0	0.0	187	37.6	1	0.5
Nervous system disorders	Cerebral infarction	3	196	39.6	0	0.0	186	37.3	0	0.0
Nervous system disorders	Cerebral infarction	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Nervous system disorders	Hypoaesthesia	1-2	187	37.8	0	0.0	187	37.6	1	0.5
Nervous system disorders	Hypoaesthesia	3	196	39.6	0	0.0	186	37.3	0	0.0
Nervous system disorders	Hypoaesthesia	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Nervous system disorders	Neuropathy peripheral	1-2	187	37.8	0	0.0	187	37.6	2	1.1
Nervous system disorders	Neuropathy peripheral	3	196	39.6	0	0.0	186	37.3	1	0.5
Nervous system disorders	Neuropathy peripheral	4-5	112	22.6	1	0.9	125	25.1	1	0.8
Nervous system disorders	Peripheral motor neuropathy	1-2	187	37.8	0	0.0	187	37.6	2	1.1
Nervous system disorders	Peripheral motor neuropathy	3	196	39.6	0	0.0	186	37.3	0	0.0
Nervous system disorders	Peripheral motor neuropathy	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Nervous system disorders	Peripheral sensorimotor neuropathy	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Nervous system disorders	Peripheral sensorimotor neuropathy	3	196	39.6	0	0.0	186	37.3	1	0.5
Nervous system disorders	Peripheral sensorimotor neuropathy	4-5	112	22.6	1	0.9	125	25.1	0	0.0
Nervous system disorders	Peripheral sensory neuropathy	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Nervous system disorders	Peripheral sensory neuropathy	3	196	39.6	0	0.0	186	37.3	0	0.0
Nervous system disorders	Peripheral sensory neuropathy	4-5	112	22.6	0	0.0	125	25.1	1	0.8
Nervous system disorders	Polyneuropathy	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Nervous system disorders	Polyneuropathy	3	196	39.6	1	0.5	186	37.3	0	0.0
Nervous system disorders	Polyneuropathy	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Renal and urinary disorders		1-2	187	37.8	0	0.0	187	37.6	0	0.0
Renal and urinary disorders		3	196	39.6	1	0.5	186	37.3	0	0.0
Renal and urinary disorders		4-5	112	22.6	0	0.0	125	25.1	1	0.8
Renal and urinary disorders	Acute kidney injury	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Renal and urinary disorders	Acute kidney injury	3	196	39.6	1	0.5	186	37.3	0	0.0
Renal and urinary disorders	Acute kidney injury	4-5	112	22.6	0	0.0	125	25.1	1	0.8
Respiratory, thoracic and mediastinal disorders		1-2	187	37.8	3	1.6	187	37.6	0	0.0
Respiratory, thoracic and mediastinal disorders		3	196	39.6	2	1.0	186	37.3	1	0.5
Respiratory, thoracic and mediastinal disorders		4-5	112	22.6	2	1.8	125	25.1	0	0.0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	3	196	39.6	0	0.0	186	37.3	1	0.5
Respiratory, thoracic and mediastinal disorders	Dyspnoea	4-5	112	22.6	1	0.9	125	25.1	0	0.0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	1-2	187	37.8	0	0.0	187	37.6	0	0.0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	3	196	39.6	1	0.5	186	37.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	1-2	187	37.8	1	0.5	187	37.6	0	0.0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	3	196	39.6	1	0.5	186	37.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	4-5	112	22.6	1	0.9	125	25.1	0	0.0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	1-2	187	37.8	1	0.5	187	37.6	0	0.0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	3	196	39.6	0	0.0	186	37.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	4-5	112	22.6	0	0.0	125	25.1	0	0.0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	1-2	187	37.8	1	0.5	187	37.6	0	0.0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	3	196	39.6	0	0.0	186	37.3	0	0.0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	4-5	112	22.6	0	0.0	125	25.1	0	0.0

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Clinical cut-off: 15JUN2022

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs leading to any Study Treatment Discontinuation
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	0	0.0
Blood and lymphatic system disorders		Asia	140	28.3	2	1.4	139	27.9	0	0.0
Blood and lymphatic system disorders		Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Blood and lymphatic system disorders	Neutropenia	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	0	0.0
Blood and lymphatic system disorders	Neutropenia	Asia	140	28.3	1	0.7	139	27.9	0	0.0
Blood and lymphatic system disorders	Neutropenia	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Asia	140	28.3	1	0.7	139	27.9	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Cardiac disorders		Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3
Cardiac disorders		Asia	140	28.3	0	0.0	139	27.9	0	0.0
Cardiac disorders		Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Cardiac disorders	Left ventricular dysfunction	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3
Cardiac disorders	Left ventricular dysfunction	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Cardiac disorders	Left ventricular dysfunction	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Gastrointestinal disorders		Western Europe/United States/Canada/Australia	298	60.2	2	0.7	300	60.2	1	0.3
Gastrointestinal disorders		Asia	140	28.3	0	0.0	139	27.9	1	0.7
Gastrointestinal disorders		Rest of World	57	11.5	0	0.0	59	11.8	1	1.7
Gastrointestinal disorders	Intestinal obstruction	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3
Gastrointestinal disorders	Intestinal obstruction	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Gastrointestinal disorders	Intestinal obstruction	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Gastrointestinal disorders	Intestinal perforation	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	0	0.0
Gastrointestinal disorders	Intestinal perforation	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Gastrointestinal disorders	Intestinal perforation	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Gastrointestinal disorders	Intra-abdominal haemorrhage	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0
Gastrointestinal disorders	Intra-abdominal haemorrhage	Asia	140	28.3	0	0.0	139	27.9	1	0.7
Gastrointestinal disorders	Intra-abdominal haemorrhage	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Gastrointestinal disorders	Nausea	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0
Gastrointestinal disorders	Nausea	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Gastrointestinal disorders	Nausea	Rest of World	57	11.5	0	0.0	59	11.8	1	1.7
Gastrointestinal disorders	Necrotising colitis	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	0	0.0
Gastrointestinal disorders	Necrotising colitis	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Gastrointestinal disorders	Necrotising colitis	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
General disorders and administration site conditions		Western Europe/United States/Canada/Australia	298	60.2	3	1.0	300	60.2	0	0.0
General disorders and administration site conditions		Asia	140	28.3	1	0.7	139	27.9	1	0.7
General disorders and administration site conditions		Rest of World	57	11.5	1	1.8	59	11.8	0	0.0
General disorders and administration site conditions	Cardiac death	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	0	0.0
General disorders and administration site conditions	Cardiac death	Asia	140	28.3	0	0.0	139	27.9	0	0.0
General disorders and administration site conditions	Cardiac death	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
General disorders and administration site conditions	Death	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	0	0.0
General disorders and administration site conditions	Death	Asia	140	28.3	1	0.7	139	27.9	1	0.7
General disorders and administration site conditions	Death	Rest of World	57	11.5	1	1.8	59	11.8	0	0.0
General disorders and administration site conditions	Fatigue	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	0	0.0
General disorders and administration site conditions	Fatigue	Asia	140	28.3	0	0.0	139	27.9	0	0.0
General disorders and administration site conditions	Fatigue	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Infections and infestations		Western Europe/United States/Canada/Australia	298	60.2	4	1.3	300	60.2	6	2.0
Infections and infestations		Asia	140	28.3	4	2.9	139	27.9	5	3.6
Infections and infestations		Rest of World	57	11.5	1	1.8	59	11.8	1	1.7
Infections and infestations	Intervertebral discitis	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3
Infections and infestations	Intervertebral discitis	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Infections and infestations	Intervertebral discitis	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Infections and infestations	Peritonitis	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3
Infections and infestations	Peritonitis	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Infections and infestations	Peritonitis	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Infections and infestations	Pneumonia	Western Europe/United States/Canada/Australia	298	60.2	3	1.0	300	60.2	2	0.7

Infections and infestations	Pneumonia	Asia	140	28.3	3	2.1	139	27.9	5	3.6
Infections and infestations	Pneumonia	Rest of World	57	11.5	1	1.8	59	11.8	1	1.7
Infections and infestations	Prostate infection	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3
Infections and infestations	Prostate infection	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Infections and infestations	Prostate infection	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Infections and infestations	Sepsis	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	1	0.3
Infections and infestations	Sepsis	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Infections and infestations	Sepsis	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Infections and infestations	Suspected COVID-19	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0
Infections and infestations	Suspected COVID-19	Asia	140	28.3	1	0.7	139	27.9	0	0.0
Infections and infestations	Suspected COVID-19	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Investigations		Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3
Investigations		Asia	140	28.3	0	0.0	139	27.9	0	0.0
Investigations		Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Investigations	Ejection fraction decreased	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3
Investigations	Ejection fraction decreased	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Investigations	Ejection fraction decreased	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Nervous system disorders		Western Europe/United States/Canada/Australia	298	60.2	3	1.0	300	60.2	8	2.7
Nervous system disorders		Asia	140	28.3	0	0.0	139	27.9	2	1.4
Nervous system disorders		Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Nervous system disorders	Cerebral infarction	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3
Nervous system disorders	Cerebral infarction	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Nervous system disorders	Cerebral infarction	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Nervous system disorders	Hypoaesthesia	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0
Nervous system disorders	Hypoaesthesia	Asia	140	28.3	0	0.0	139	27.9	1	0.7
Nervous system disorders	Hypoaesthesia	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Nervous system disorders	Neuropathy peripheral	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	3	1.0
Nervous system disorders	Neuropathy peripheral	Asia	140	28.3	0	0.0	139	27.9	1	0.7
Nervous system disorders	Neuropathy peripheral	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Nervous system disorders	Peripheral motor neuropathy	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	2	0.7
Nervous system disorders	Peripheral motor neuropathy	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Nervous system disorders	Peripheral motor neuropathy	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Nervous system disorders	Peripheral sensorimotor neuropathy	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	1	0.3
Nervous system disorders	Peripheral sensorimotor neuropathy	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Nervous system disorders	Peripheral sensorimotor neuropathy	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Nervous system disorders	Peripheral sensory neuropathy	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	1	0.3
Nervous system disorders	Peripheral sensory neuropathy	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Nervous system disorders	Peripheral sensory neuropathy	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Nervous system disorders	Polyneuropathy	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	0	0.0
Nervous system disorders	Polyneuropathy	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Nervous system disorders	Polyneuropathy	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Renal and urinary disorders		Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0
Renal and urinary disorders		Asia	140	28.3	0	0.0	139	27.9	1	0.7
Renal and urinary disorders		Rest of World	57	11.5	1	1.8	59	11.8	0	0.0
Renal and urinary disorders	Acute kidney injury	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0
Renal and urinary disorders	Acute kidney injury	Asia	140	28.3	0	0.0	139	27.9	1	0.7
Renal and urinary disorders	Acute kidney injury	Rest of World	57	11.5	1	1.8	59	11.8	0	0.0
Respiratory, thoracic and mediastinal disorders		Western Europe/United States/Canada/Australia	298	60.2	5	1.7	300	60.2	1	0.3
Respiratory, thoracic and mediastinal disorders		Asia	140	28.3	1	0.7	139	27.9	0	0.0
Respiratory, thoracic and mediastinal disorders		Rest of World	57	11.5	1	1.8	59	11.8	0	0.0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	1	0.3
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Western Europe/United States/Canada/Australia	298	60.2	0	0.0	300	60.2	0	0.0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Rest of World	57	11.5	1	1.8	59	11.8	0	0.0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Western Europe/United States/Canada/Australia	298	60.2	2	0.7	300	60.2	0	0.0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Asia	140	28.3	1	0.7	139	27.9	0	0.0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	0	0.0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	0	0.0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Asia	140	28.3	0	0.0	139	27.9	0	0.0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Rest of World	57	11.5	0	0.0	59	11.8	0	0.0

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Clinical cut-off: 15JUN2022

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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: AEs leading to any Study Treatment Discontinuation
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

Sex

			Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
Blood and lymphatic system disorders		Male	265	53.5	0	0.0	269	54.0	0	0.0
Blood and lymphatic system disorders		Female	230	46.5	3	1.3	229	46.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	Male	265	53.5	0	0.0	269	54.0	0	0.0
Blood and lymphatic system disorders	Neutropenia	Female	230	46.5	2	0.9	229	46.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Male	265	53.5	0	0.0	269	54.0	0	0.0
Blood and lymphatic system disorders	Thrombocytopenia	Female	230	46.5	1	0.4	229	46.0	0	0.0
Cardiac disorders		Male	265	53.5	0	0.0	269	54.0	0	0.0
Cardiac disorders		Female	230	46.5	0	0.0	229	46.0	1	0.4
Cardiac disorders	Left ventricular dysfunction	Male	265	53.5	0	0.0	269	54.0	0	0.0
Cardiac disorders	Left ventricular dysfunction	Female	230	46.5	0	0.0	229	46.0	1	0.4
Gastrointestinal disorders		Male	265	53.5	2	0.8	269	54.0	0	0.0
Gastrointestinal disorders		Female	230	46.5	0	0.0	229	46.0	3	1.3
Gastrointestinal disorders	Intestinal obstruction	Male	265	53.5	0	0.0	269	54.0	0	0.0
Gastrointestinal disorders	Intestinal obstruction	Female	230	46.5	0	0.0	229	46.0	1	0.4
Gastrointestinal disorders	Intestinal perforation	Male	265	53.5	1	0.4	269	54.0	0	0.0
Gastrointestinal disorders	Intestinal perforation	Female	230	46.5	0	0.0	229	46.0	0	0.0
Gastrointestinal disorders	Intra-abdominal haemorrhage	Male	265	53.5	0	0.0	269	54.0	0	0.0
Gastrointestinal disorders	Intra-abdominal haemorrhage	Female	230	46.5	0	0.0	229	46.0	1	0.4
Gastrointestinal disorders	Nausea	Male	265	53.5	0	0.0	269	54.0	0	0.0
Gastrointestinal disorders	Nausea	Female	230	46.5	0	0.0	229	46.0	1	0.4
Gastrointestinal disorders	Necrotising colitis	Male	265	53.5	1	0.4	269	54.0	0	0.0
Gastrointestinal disorders	Necrotising colitis	Female	230	46.5	0	0.0	229	46.0	0	0.0
General disorders and administration site conditions		Male	265	53.5	4	1.5	269	54.0	1	0.4
General disorders and administration site conditions		Female	230	46.5	1	0.4	229	46.0	0	0.0
General disorders and administration site conditions	Cardiac death	Male	265	53.5	0	0.0	269	54.0	0	0.0
General disorders and administration site conditions	Cardiac death	Female	230	46.5	1	0.4	229	46.0	0	0.0
General disorders and administration site conditions	Death	Male	265	53.5	3	1.1	269	54.0	1	0.4
General disorders and administration site conditions	Death	Female	230	46.5	0	0.0	229	46.0	0	0.0
General disorders and administration site conditions	Fatigue	Male	265	53.5	1	0.4	269	54.0	0	0.0
General disorders and administration site conditions	Fatigue	Female	230	46.5	0	0.0	229	46.0	0	0.0
Infections and infestations		Male	265	53.5	4	1.5	269	54.0	7	2.6
Infections and infestations		Female	230	46.5	5	2.2	229	46.0	5	2.2
Infections and infestations	Intervertebral discitis	Male	265	53.5	0	0.0	269	54.0	0	0.0
Infections and infestations	Intervertebral discitis	Female	230	46.5	0	0.0	229	46.0	1	0.4
Infections and infestations	Peritonitis	Male	265	53.5	0	0.0	269	54.0	0	0.0
Infections and infestations	Peritonitis	Female	230	46.5	0	0.0	229	46.0	1	0.4
Infections and infestations	Pneumonia	Male	265	53.5	4	1.5	269	54.0	5	1.9
Infections and infestations	Pneumonia	Female	230	46.5	3	1.3	229	46.0	3	1.3
Infections and infestations	Prostate infection	Male	265	53.5	0	0.0	269	54.0	1	0.4
Infections and infestations	Prostate infection	Female	230	46.5	0	0.0	229	46.0	0	0.0
Infections and infestations	Sepsis	Male	265	53.5	0	0.0	269	54.0	1	0.4
Infections and infestations	Sepsis	Female	230	46.5	1	0.4	229	46.0	0	0.0
Infections and infestations	Suspected COVID-19	Male	265	53.5	0	0.0	269	54.0	0	0.0
Infections and infestations	Suspected COVID-19	Female	230	46.5	1	0.4	229	46.0	0	0.0
Investigations		Male	265	53.5	0	0.0	269	54.0	0	0.0
Investigations		Female	230	46.5	0	0.0	229	46.0	1	0.4
Investigations	Ejection fraction decreased	Male	265	53.5	0	0.0	269	54.0	0	0.0
Investigations	Ejection fraction decreased	Female	230	46.5	0	0.0	229	46.0	1	0.4
Nervous system disorders		Male	265	53.5	3	1.1	269	54.0	4	1.5
Nervous system disorders		Female	230	46.5	0	0.0	229	46.0	6	2.6
Nervous system disorders	Cerebral infarction	Male	265	53.5	0	0.0	269	54.0	1	0.4
Nervous system disorders	Cerebral infarction	Female	230	46.5	0	0.0	229	46.0	0	0.0
Nervous system disorders	Hypoaesthesia	Male	265	53.5	0	0.0	269	54.0	0	0.0

Nervous system disorders	Hypoaesthesia	Female	230	46.5	0	0.0	229	46.0	1	0.4
Nervous system disorders	Neuropathy peripheral	Male	265	53.5	1	0.4	269	54.0	1	0.4
Nervous system disorders	Neuropathy peripheral	Female	230	46.5	0	0.0	229	46.0	3	1.3
Nervous system disorders	Peripheral motor neuropathy	Male	265	53.5	0	0.0	269	54.0	0	0.0
Nervous system disorders	Peripheral motor neuropathy	Female	230	46.5	0	0.0	229	46.0	2	0.9
Nervous system disorders	Peripheral sensorimotor neuropathy	Male	265	53.5	1	0.4	269	54.0	1	0.4
Nervous system disorders	Peripheral sensorimotor neuropathy	Female	230	46.5	0	0.0	229	46.0	0	0.0
Nervous system disorders	Peripheral sensory neuropathy	Male	265	53.5	0	0.0	269	54.0	1	0.4
Nervous system disorders	Peripheral sensory neuropathy	Female	230	46.5	0	0.0	229	46.0	0	0.0
Nervous system disorders	Polyneuropathy	Male	265	53.5	1	0.4	269	54.0	0	0.0
Nervous system disorders	Polyneuropathy	Female	230	46.5	0	0.0	229	46.0	0	0.0
Renal and urinary disorders		Male	265	53.5	0	0.0	269	54.0	1	0.4
Renal and urinary disorders		Female	230	46.5	1	0.4	229	46.0	0	0.0
Renal and urinary disorders	Acute kidney injury	Male	265	53.5	0	0.0	269	54.0	1	0.4
Renal and urinary disorders	Acute kidney injury	Female	230	46.5	1	0.4	229	46.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Male	265	53.5	3	1.1	269	54.0	0	0.0
Respiratory, thoracic and mediastinal disorders		Female	230	46.5	4	1.7	229	46.0	1	0.4
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Male	265	53.5	1	0.4	269	54.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Female	230	46.5	0	0.0	229	46.0	1	0.4
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Male	265	53.5	1	0.4	269	54.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	Female	230	46.5	0	0.0	229	46.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Male	265	53.5	1	0.4	269	54.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	Female	230	46.5	2	0.9	229	46.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	Male	265	53.5	0	0.0	269	54.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	Female	230	46.5	1	0.4	229	46.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Male	265	53.5	0	0.0	269	54.0	0	0.0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	Female	230	46.5	1	0.4	229	46.0	0	0.0

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_soc_descriptive.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_soc_descriptive_sg2_WDSTAE_SE_POOLED_15JUN2022_39942.xls
08FEB2023 19:04

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: DILI (potential drug-induced liver injury)
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 Overall (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	495	100.0	3	0.6	498	100.0	3	0.6	0.99	Convergence criterion (GCONV=1E-6) satisfied.	0.20	4.92	-0.0045	Algorithm converged.	-0.612	0.604	0.98	Algorithm converged.	0.20	4.83	0.9833		0.99	Algorithm converged.	0.21	28.47
Sex	Male	245	49.5	3	0.6	253	50.8	3	1.2	0.99	Convergence criterion (GCONV=1E-6) satisfied.	0.20	4.95	-0.0057	Algorithm converged.	-0.622	0.607	0.98	Algorithm converged.	0.20	4.87	0.9847	1.0000	0.99	Algorithm converged.	0.21	28.27
	Female	250	50.5	0	0.0	245	49.2	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
Age	>= 60	167	33.7	2	0.8	157	31.5	2	1.3	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 14.108054211 is greater than the limit of 0.0001. The convergence is questionable.			0.80		0.00	NE	0.9999	0.1757	>999.99			0.00	NE
	< 60	328	66.3	1	0.3	341	68.5	1	0.3	1.04	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.86	0.0045	Algorithm converged.	-0.608	0.864	1.04	Algorithm converged.	0.07	16.45	0.9780		0.96	Algorithm converged.	0.06	15.31
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	3	1.0	302	60.6	2	0.7	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	NE	NE		NE	NE
	Asia	140	28.3	0	0.0	139	27.9	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE		NE		NE	NE
		140	28.3	1	0.7	139	27.9	2	1.4	0.49	Convergence criterion (GCONV=1E-6) satisfied.	0.04	5.50	-0.007	Algorithm converged.	-0.031	0.017	0.50	Algorithm converged.	0.05	5.41	0.5454		2.01	Algorithm converged.	0.18	22.34
	Rest of World	57	11.5	0	0.0	58	11.6	1	1.7	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 30.540248401 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
IPI score at Screening	1-2	187	37.8	0	0.0	187	37.6	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	0.4551	NE		NE	NE
	3	194	39.2	1	0.5	184	37.0	1	0.5	0.93	Convergence criterion (GCONV=1E-6) satisfied.	0.04	15.26	0.0003	Algorithm converged.	-0.015	0.016	0.93	Algorithm converged.	0.04	15.04	0.9724		1.03	Algorithm converged.	0.07	14.73
	4-5	113	22.8	1	0.9	125	25.1	2	1.6	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 10.204215767 is greater than the limit of 0.0001. The convergence is questionable.			0.93	Algorithm converged.	0.05	NE	0.9999		>999.99	Algorithm converged.	0.00	NE

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO55410?7/CSP?7884/GO39942/data_analysis/ACE_FINAL_CS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/BO55410?7/CSP?7884/GO39942/data_analysis/ACE_FINAL_CS/prod/output/t_ae_raw_eg2_DILI_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:06

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: SILI (potential drug-induced liver injury) Grade 3-5
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 Overall (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	495	100.0	1	0.2	498	100.0	2	0.4	0.50	Convergence criterion (GCONV=1E-6) satisfied.	0.04	5.64	-0.0005	Algorithm converged.	-0.009	0.008	0.95	Algorithm converged.	0.05	5.63	0.9743		1.98	Algorithm converged.	0.19	33.49
Sex	Male	245	49.5	1	0.4	253	50.8	2	0.7	0.51	Convergence criterion (GCONV=1E-6) satisfied.	0.04	5.61	-0.0007	Algorithm converged.	-0.014	0.005	0.93	Algorithm converged.	0.05	5.62	0.9749	1.0000	1.97	Algorithm converged.	0.19	33.49
	Female	250	50.5	0	0.0	245	49.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Age	<= 60	167	33.7	0	0.0	157	31.5	1	0.6	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.1076277627 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	0.2905	>999.99	Algorithm converged.	0.00	NE
	> 60	328	66.3	1	0.3	341	68.5	1	0.3	1.04	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.85	0.0005	Algorithm converged.	-0.008	0.008	1.04	Algorithm converged.	0.07	16.85	0.9780		0.96	Algorithm converged.	0.06	15.31
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	300	60.2	2	0.7	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Asia	140	28.3	1	0.7	139	27.9	1	0.7	0.99	Convergence criterion (GCONV=1E-6) satisfied.	0.06	16.01	0.0005	Algorithm converged.	-0.020	0.021	0.93	Algorithm converged.	0.06	15.73	0.9953		1.01	Algorithm converged.	0.06	15.94
	Rest of World	57	11.5	0	0.0	59	11.8	1	1.7	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 30.5492484001 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
IPI score at Screening	1-2	167	33.7	0	0.0	167	33.5	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	3	184	38.0	1	0.5	182	37.3	2	1.1	*	Quasi-complete separation of data points detected.				ERROR: The Hess 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
	4-5	112	22.6	1	0.9	109	25.1	2	1.8	*	Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 10.2042157567 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

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO55410?7/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/BO55410?7/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_ag2_DILIGK35_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:08

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Serious ILI (potential drug-induced liver injury)
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 (2-Sided)	Interaction Test p-value (Likelihood Ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	495	100.0	0	0	498	100.0	1	0.2		Quasi-complete separation of data points detected.				WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9980		>999.99	Algorithm converged.	0.00	NE
Sex	Male	245	49.5	0	0	253	50.8	1	0.4		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	0.9990		>999.99	Algorithm converged.	0.00	NE
	Female	250	50.5	0	0	245	49.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Age	<= 60	167	33.7	0	0	167	33.5	1	0.6		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 22.1076278239 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9998	1.0000	>999.99	Algorithm converged.	0.00	NE
	> 60	328	66.3	0	0	331	66.5	1	0.3		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	0.9980		>999.99	Algorithm converged.	0.00	NE
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	0	0	300	60.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	Asia	140	28.3	0	0	139	27.9	1	0.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 19.6850432228 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9990		>999.99	Algorithm converged.	0.00	NE
	Rest of World	57	11.5	0	0	59	11.8	1	1.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 10.5402168401 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9980		>999.99	Algorithm converged.	0.00	NE
IPI score at Screening	1-2	187	37.8	0	0	187	37.5	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	3	192	38.8	0	0	189	37.9	1	0.5		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	1.0000		>999.99	Algorithm converged.	0.00	NE
	4-5	116	22.6	0	0	122	25.1	1	0.8		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 16.3145132867 is greater than the limit of 0.0001. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9980		>999.99	Algorithm converged.	0.00	NE

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to HALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO55410?7/CDPT7884/GO39942/data_analysis/ACE_FINAL_DS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/BO55410?7/CDPT7884/GO39942/data_analysis/ACE_FINAL_DS/prod/output/t_ae_raw_sg2_DILIS_HR_POOLED_15JUN2022_39942.xls
08FEB2023 15:09

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Hepatic Toxicity
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	74	14.9	498	100.0	54	10.8	1.45	Convergence criterion (GCONV=1E-8) satisfied.	0.99	2.10	0.041	Algorithm converged.	-0.001	0.083	1.38	Algorithm converged.	0.99	1.91	0.0550		0.73	Algorithm converged.	0.52	1.01
Sex	Male	265	53.5	33	12.5	269	54.0	28	10.4	1.22	Convergence criterion (GCONV=1E-8) satisfied.	0.72	2.09	0.028	Algorithm converged.	-0.034	0.074	1.20	Algorithm converged.	0.74	1.92	0.4586	0.4174	0.84	Algorithm converged.	0.52	1.34
	Female	230	46.5	41	17.8	229	46.0	26	11.4	1.69	Convergence criterion (GCONV=1E-8) satisfied.	1.00	2.88	0.065	Algorithm converged.	0.000	0.129	1.57	Algorithm converged.	1.00	2.48	0.0525		0.64	Algorithm converged.	0.40	1.00
Age	<= 60	167	33.7	32	19.2	157	31.5	30	19.1	1.00	Convergence criterion (GCONV=1E-8) satisfied.	0.58	1.75	0.001	Algorithm converged.	-0.085	0.086	1.00	Algorithm converged.	0.64	1.57	0.9903	0.0732	1.00	Algorithm converged.	0.64	1.56
	> 60	328	66.3	42	12.8	341	68.5	24	7.0	1.94	Convergence criterion (GCONV=1E-8) satisfied.	1.15	3.28	0.058	Algorithm converged.	0.012	0.103	1.82	Algorithm converged.	1.13	2.93	0.0141		0.55	Algorithm converged.	0.34	0.89
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	21	7.0	309	60.2	19	6.3	1.12	Convergence criterion (GCONV=1E-8) satisfied.	0.59	2.13	0.007	Algorithm converged.	-0.038	0.047	1.11	Algorithm converged.	0.81	2.03	0.7270	0.2195	0.90	Algorithm converged.	0.49	1.64
	Asia	140	28.3	45	32.1	139	27.9	33	23.7	1.52	Convergence criterion (GCONV=1E-8) satisfied.	0.90	2.58	0.084	Algorithm converged.	-0.021	0.189	1.35	Algorithm converged.	0.92	1.99	0.1210		0.74	Algorithm converged.	0.50	1.08
	Rest of World	57	11.5	8	14.0	59	11.8	2	3.4	4.65	Convergence criterion (GCONV=1E-8) satisfied.	0.94	22.95	0.108	Algorithm converged.	0.005	0.208	4.14	Algorithm converged.	0.92	18.67	0.0645		0.24	Algorithm converged.	0.05	1.09
IPI score at Screening	1-2	187	37.8	25	13.4	187	37.6	19	10.2	1.36	Convergence criterion (GCONV=1E-8) satisfied.	0.72	2.57	0.032	Algorithm converged.	-0.033	0.097	1.32	Algorithm converged.	0.76	2.31	0.3377	0.9845	0.76	Algorithm converged.	0.43	1.33
	3	196	39.6	34	17.3	186	37.3	23	12.4	1.49	Convergence criterion (GCONV=1E-8) satisfied.	0.84	2.64	0.050	Algorithm converged.	-0.021	0.121	1.40	Algorithm converged.	0.86	2.29	0.1754		0.71	Algorithm converged.	0.44	1.16
	4-5	112	22.6	15	13.4	125	25.1	12	9.6	1.46	Convergence criterion (GCONV=1E-8) satisfied.	0.65	3.26	0.038	Algorithm converged.	-0.044	0.119	1.40	Algorithm converged.	0.68	2.85	0.3614		0.72	Algorithm converged.	0.35	1.47

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_HEPT_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:33

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Hepatic Toxicity Grade 3-5
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polatuzumab Vedotin + R-CHP (N=435)				R-CHOP (N=428)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	435	100.0	8	1.8	428	100.0	5	1.2	1.62	Convergence criterion (GCONV=1E-8) satisfied.	0.53	4.96	0.006	Algorithm converged.	-0.008	0.020	1.61	Algorithm converged.	0.53	4.89	0.4208		0.62	Algorithm converged.	0.20	1.93
Sex	Male	269	61.8	4	1.5	260	54.0	1	0.4	4.11	Convergence criterion (GCONV=1E-8) satisfied.	0.46	36.99	0.011	Algorithm converged.	-0.005	0.028	4.08	Algorithm converged.	0.46	36.59	0.2067	0.2580	0.25	Algorithm converged.	0.03	2.12
	Female	236	46.5	4	1.7	220	46.0	4	1.7	1.05	Convergence criterion (GCONV=1E-8) satisfied.	0.25	4.03	0.000	Algorithm converged.	-0.044	0.024	1.05	Algorithm converged.	0.25	3.97	0.9550		1.05	Algorithm converged.	0.25	3.97
Age	<= 60	167	33.7	5	3.0	157	31.5	3	1.9	1.58	Convergence criterion (GCONV=1E-8) satisfied.	0.37	6.74	0.015	Algorithm converged.	-0.023	0.044	1.57	Algorithm converged.	0.38	6.45	0.5339	0.9967	0.64	Algorithm converged.	0.16	2.63
	> 60	328	66.3	3	0.9	341	68.5	2	0.6	1.56	Convergence criterion (GCONV=1E-8) satisfied.	0.26	9.42	0.003	Algorithm converged.	-0.036	0.016	1.56	Algorithm converged.	0.26	9.37	0.6252		0.64	Algorithm converged.	0.11	3.83
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	4	1.3	302	60.2	1	0.3	4.07	Convergence criterion (GCONV=1E-8) satisfied.	0.45	36.61	0.010	Algorithm converged.	-0.003	0.025	4.03	Algorithm converged.	0.45	35.82	0.2114	0.4156	0.25	Algorithm converged.	0.03	2.21
	Asia	140	28.3	3	2.1	130	27.9	2	1.5	1.50	Convergence criterion (GCONV=1E-8) satisfied.	0.25	9.12	0.007	Algorithm converged.	-0.024	0.038	1.49	Algorithm converged.	0.25	8.78	0.6599		0.67	Algorithm converged.	0.11	3.96
	Rest of World	57	11.5	1	1.8	52	11.8	2	3.8	0.51	Convergence criterion (GCONV=1E-8) satisfied.	0.04	5.77	-0.016	Algorithm converged.	-0.074	0.041	0.52	Algorithm converged.	0.05	5.55	0.5864		1.93	Algorithm converged.	0.18	20.73
IPI score at Screening	1-2	187	37.8	2	1.1	187	37.6	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	0.3071	NE	Algorithm converged.	NE	NE
	3	196	39.6	3	1.5	186	37.3	3	1.6	0.95	Convergence criterion (GCONV=1E-8) satisfied.	0.19	4.76	-0.003	Algorithm converged.	-0.028	0.024	0.95	Algorithm converged.	0.19	4.69	0.9487		1.05	Algorithm converged.	0.21	5.12
	4-5	112	22.6	3	2.7	125	25.1	2	1.6	1.69	Convergence criterion (GCONV=1E-8) satisfied.	0.28	10.32	0.011	Algorithm converged.	-0.026	0.048	1.67	Algorithm converged.	0.28	9.84	0.5685		0.60	Algorithm converged.	0.10	3.51

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to HALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_HEPTGR35_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:35

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Serious Hepatic Toxicity
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 Overall (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	495	100.0	1	0.2	498	100.0	1	0.2	1.01	Convergence criterion (GCONV=1E-6) satisfied	0.06	16.11	0.000	Algorithm converged.	-0.006	0.006	1.00	Algorithm converged	0.06	16.06	0.9969		0.99	Algorithm converged	0.06	15.87
Sex	Male	295	59.6	1	0.4	293	58.8	1	0.4	1.01	Convergence criterion (GCONV=1E-6) satisfied	0.06	16.01	0.000	Algorithm converged.	-0.010	0.010	1.00	Algorithm converged	0.06	16.14	0.9973	1.0000	0.99	Algorithm converged	0.06	15.47
	Female	200	40.4	0	0.0	205	41.2	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Age	>= 60	167	33.7	1	0.6	167	33.5	1	0.6	0.99	Convergence criterion (GCONV=1E-6) satisfied	0.06	15.95	0.000	Algorithm converged.	-0.017	0.017	0.99	Algorithm converged	0.06	14.99	0.9951	1.0000	1.00	Algorithm converged	0.07	16.86
	< 60	328	66.3	0	0.0	331	66.5	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
Geographic Region	Western Europe/United States/Canada/Australia	298	60.2	1	0.3	301	60.4	0	0.0	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 44.804738292 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged	NE	NE	NE	NE	NE	Algorithm converged	NE	NE
	Asia	140	28.3	0	0.0	139	27.9	1	0.7	*	Quasi-complete separation of data points detected.			*	WARNING: The relative Hessian convergence criterion of 19.680043228 is greater than the limit of 0.0001. The convergence is questionable.			0.99	Algorithm converged	0.00	NE	0.9999		>999.99	Algorithm converged	0.00	NE
	Rest of World	57	11.5	0	0.0	58	11.6	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
IPI score at Screening	1-2	167	33.7	0	0.0	167	33.5	0	0.0	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
	3-5	328	66.3	1	0.3	331	66.5	1	0.3	0.99	Convergence criterion (GCONV=1E-6) satisfied	0.06	15.95	0.000	Algorithm converged.	-0.010	0.010	0.99	Algorithm converged	0.06	15.96	0.9724		1.00	Algorithm converged	0.07	16.73
	4-5	173	35.0	1	0.6	174	35.1	1	0.6	NE		NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to HALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_eg2_HEPTX_HE_POOLED_15JUN2022_39942.xls
08FEB2023 15:37

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Infections
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	237	47.9	498	100.0	218	43.8	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.92	1.51	0.041	Algorithm converged.	-0.021	0.103	1.09	Algorithm converged.	0.96	1.25	0.1949		0.91	Algorithm converged.	0.80	1.03
Sex	Male	265	53.5	114	43.0	269	54.0	109	40.5	1.11	Convergence criterion (GCONV=1E-8) satisfied.	0.79	1.56	0.025	Algorithm converged.	-0.059	0.109	1.06	Algorithm converged.	0.87	1.30	0.5584	0.6814	0.94	Algorithm converged.	0.77	1.15
	Female	230	46.5	123	53.5	229	46.0	109	47.6	1.27	Convergence criterion (GCONV=1E-8) satisfied.	0.88	1.83	0.059	Algorithm converged.	-0.033	0.150	1.12	Algorithm converged.	0.94	1.35	0.2088		0.89	Algorithm converged.	0.74	1.07
Age	<= 60	167	33.7	72	43.1	157	31.5	75	47.8	0.83	Convergence criterion (GCONV=1E-8) satisfied.	0.53	1.28	-0.047	Algorithm converged.	-0.155	0.062	0.90	Algorithm converged.	0.71	1.15	0.4002	0.0547	1.11	Algorithm converged.	0.87	1.41
	> 60	328	66.3	165	50.3	341	68.5	143	41.9	1.40	Convergence criterion (GCONV=1E-8) satisfied.	1.03	1.90	0.084	Algorithm converged.	0.008	0.159	1.20	Algorithm converged.	1.02	1.41	0.0303		0.83	Algorithm converged.	0.71	0.98
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	151	50.7	300	60.2	127	42.3	1.40	Convergence criterion (GCONV=1E-8) satisfied.	1.01	1.93	0.083	Algorithm converged.	0.004	0.163	1.20	Algorithm converged.	1.01	1.42	0.0419	0.1025	0.84	Algorithm converged.	0.70	0.99
	Asia	140	28.3	58	41.4	139	27.9	67	48.2	0.76	Convergence criterion (GCONV=1E-8) satisfied.	0.47	1.22	-0.068	Algorithm converged.	-0.184	0.049	0.86	Algorithm converged.	0.66	1.12	0.2568		1.14	Algorithm converged.	0.90	1.51
	Rest of World	57	11.5	28	49.1	59	11.8	24	40.7	1.41	Convergence criterion (GCONV=1E-8) satisfied.	0.68	2.93	0.084	Algorithm converged.	-0.096	0.265	1.21	Algorithm converged.	0.80	1.81	0.3624		0.83	Algorithm converged.	0.55	1.24
IPI score at Screening	1-2	187	37.8	88	47.1	187	37.6	79	42.2	1.22	Convergence criterion (GCONV=1E-8) satisfied.	0.81	1.83	0.048	Algorithm converged.	-0.053	0.149	1.11	Algorithm converged.	0.89	1.40	0.3500	0.0753	0.90	Algorithm converged.	0.72	1.13
	3	196	39.6	87	44.4	186	37.3	89	47.8	0.87	Convergence criterion (GCONV=1E-8) satisfied.	0.58	1.30	-0.035	Algorithm converged.	-0.135	0.065	0.93	Algorithm converged.	0.75	1.15	0.4975		1.08	Algorithm converged.	0.87	1.34
	4-5	112	22.6	62	55.4	125	25.1	50	40.0	1.86	Convergence criterion (GCONV=1E-8) satisfied.	1.11	3.12	0.154	Algorithm converged.	0.028	0.279	1.38	Algorithm converged.	1.05	1.82	0.0190		0.72	Algorithm converged.	0.55	0.95

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_INF_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:28

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Infections Grade 3-5
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	76	15.4	498	100.0	66	13.3	1.19	Convergence criterion (GCONV=1E-8) satisfied.	0.83	1.70	0.021	Algorithm converged.	-0.023	0.065	1.16	Algorithm converged.	0.83	1.57	0.3451		0.86	Algorithm converged.	0.64	1.17
Sex	Male	265	53.5	46	17.4	269	54.0	39	14.5	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.78	1.97	0.029	Algorithm converged.	-0.033	0.091	1.20	Algorithm converged.	0.81	1.77	0.3673	0.8041	0.84	Algorithm converged.	0.56	1.24
	Female	230	46.5	30	13.0	229	46.0	27	11.8	1.12	Convergence criterion (GCONV=1E-8) satisfied.	0.64	1.96	0.013	Algorithm converged.	-0.048	0.073	1.11	Algorithm converged.	0.68	1.80	0.6842		0.96	Algorithm converged.	0.56	1.47
Age	<= 60	167	33.7	23	13.8	157	31.5	20	12.7	1.09	Convergence criterion (GCONV=1E-8) satisfied.	0.58	2.08	0.016	Algorithm converged.	-0.063	0.084	1.08	Algorithm converged.	0.62	1.89	0.7842	0.7634	0.92	Algorithm converged.	0.53	1.62
	> 60	328	66.3	53	16.2	341	68.5	46	13.5	1.24	Convergence criterion (GCONV=1E-8) satisfied.	0.81	1.90	0.027	Algorithm converged.	-0.027	0.081	1.20	Algorithm converged.	0.83	1.73	0.3320		0.83	Algorithm converged.	0.58	1.20
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	51	17.1	309	60.2	34	11.3	1.62	Convergence criterion (GCONV=1E-8) satisfied.	1.01	2.58	0.058	Algorithm converged.	0.002	0.114	1.51	Algorithm converged.	1.01	2.26	0.0452	0.0907	0.66	Algorithm converged.	0.44	0.99
	Asia	140	28.3	15	10.7	139	27.9	22	15.8	0.64	Convergence criterion (GCONV=1E-8) satisfied.	0.32	1.28	-0.052	Algorithm converged.	-0.133	0.028	0.68	Algorithm converged.	0.37	1.25	0.2121		1.48	Algorithm converged.	0.80	2.73
	Rest of World	57	11.5	10	17.5	59	11.8	10	16.9	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.40	2.73	0.006	Algorithm converged.	-0.132	0.143	1.04	Algorithm converged.	0.47	2.30	0.9324		0.97	Algorithm converged.	0.44	2.14
IPI score at Screening	1-2	187	37.8	19	10.2	187	37.6	13	7.0	1.51	Convergence criterion (GCONV=1E-8) satisfied.	0.72	3.16	0.032	Algorithm converged.	-0.025	0.089	1.46	Algorithm converged.	0.74	2.87	0.2710	0.4747	0.68	Algorithm converged.	0.35	1.34
	3	196	39.6	32	16.3	186	37.3	32	17.2	0.94	Convergence criterion (GCONV=1E-8) satisfied.	0.55	1.61	-0.009	Algorithm converged.	-0.084	0.066	0.95	Algorithm converged.	0.61	1.48	0.8184		1.05	Algorithm converged.	0.67	1.65
	4-5	112	22.6	25	22.3	125	25.1	21	16.8	1.42	Convergence criterion (GCONV=1E-8) satisfied.	0.75	2.72	0.055	Algorithm converged.	-0.046	0.156	1.33	Algorithm converged.	0.79	2.24	0.2852		0.75	Algorithm converged.	0.45	1.27

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_INFGR35_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:30

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Serious Infections
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	70	14.1	498	100.0	53	10.6	1.38	Convergence criterion (GCONV=1E-8) satisfied.	0.94	2.02	0.035	Algorithm converged.	-0.006	0.076	1.33	Algorithm converged.	0.95	1.86	0.0958		0.75	Algorithm converged.	0.54	1.05
Sex	Male	265	53.5	43	16.2	269	54.0	32	11.9	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.88	2.35	0.043	Algorithm converged.	-0.016	0.102	1.36	Algorithm converged.	0.89	2.09	0.1522	0.8564	0.73	Algorithm converged.	0.48	1.12
	Female	230	46.5	27	11.7	229	46.0	21	9.2	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.72	2.41	0.026	Algorithm converged.	-0.030	0.082	1.28	Algorithm converged.	0.75	2.20	0.3702		0.78	Algorithm converged.	0.46	1.34
Age	<= 60	167	33.7	19	11.4	157	31.5	17	10.8	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.53	2.12	0.005	Algorithm converged.	-0.063	0.074	1.05	Algorithm converged.	0.57	1.95	0.8751	0.3687	0.95	Algorithm converged.	0.51	1.76
	> 60	328	66.3	51	15.5	341	68.5	36	10.6	1.56	Convergence criterion (GCONV=1E-8) satisfied.	0.99	2.46	0.050	Algorithm converged.	-0.001	0.101	1.47	Algorithm converged.	0.99	2.19	0.0571		0.68	Algorithm converged.	0.46	1.01
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	45	15.1	309	60.2	28	9.3	1.73	Convergence criterion (GCONV=1E-8) satisfied.	1.05	2.85	0.058	Algorithm converged.	0.008	0.110	1.62	Algorithm converged.	1.04	2.52	0.0336	0.2415	0.62	Algorithm converged.	0.40	0.96
	Asia	140	28.3	14	10.0	139	27.9	17	12.2	0.80	Convergence criterion (GCONV=1E-8) satisfied.	0.38	1.69	-0.022	Algorithm converged.	-0.096	0.051	0.82	Algorithm converged.	0.42	1.59	0.5543		1.22	Algorithm converged.	0.62	2.38
	Rest of World	57	11.5	11	19.3	59	11.8	8	13.6	1.52	Convergence criterion (GCONV=1E-8) satisfied.	0.56	4.12	0.057	Algorithm converged.	-0.077	0.192	1.42	Algorithm converged.	0.62	3.28	0.4073		0.70	Algorithm converged.	0.30	1.62
IPI score at Screening	1-2	187	37.8	19	10.2	187	37.6	11	5.9	1.81	Convergence criterion (GCONV=1E-8) satisfied.	0.84	3.92	0.043	Algorithm converged.	-0.013	0.098	1.73	Algorithm converged.	0.85	3.53	0.1337	0.5602	0.58	Algorithm converged.	0.28	1.18
	3	196	39.6	29	14.8	186	37.3	25	13.4	1.12	Convergence criterion (GCONV=1E-8) satisfied.	0.63	1.99	0.014	Algorithm converged.	-0.056	0.083	1.10	Algorithm converged.	0.67	1.81	0.7042		0.91	Algorithm converged.	0.55	1.49
	4-5	112	22.6	22	19.6	125	25.1	17	13.6	1.55	Convergence criterion (GCONV=1E-8) satisfied.	0.78	3.10	0.060	Algorithm converged.	-0.035	0.155	1.44	Algorithm converged.	0.81	2.58	0.2135		0.69	Algorithm converged.	0.35	1.24

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_INFS_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:32

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Serious Infections Grade 3-5
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	64	12.9	498	100.0	51	10.2	1.30	Convergence criterion (GCONV=1E-8) satisfied.	0.88	1.92	0.027	Algorithm converged.	-0.013	0.067	1.26	Algorithm converged.	0.89	1.78	0.1870		0.79	Algorithm converged.	0.56	1.12
Sex	Male	265	53.5	40	15.1	269	54.0	31	11.5	1.36	Convergence criterion (GCONV=1E-8) satisfied.	0.83	2.26	0.036	Algorithm converged.	-0.022	0.093	1.31	Algorithm converged.	0.85	2.03	0.2264	0.8009	0.76	Algorithm converged.	0.49	1.18
	Female	230	46.5	24	10.4	229	46.0	20	8.7	1.22	Convergence criterion (GCONV=1E-8) satisfied.	0.65	2.27	0.017	Algorithm converged.	-0.037	0.071	1.19	Algorithm converged.	0.68	2.10	0.5366		0.84	Algorithm converged.	0.48	1.47
Age	<= 60	167	33.7	19	11.4	157	31.5	15	9.6	1.22	Convergence criterion (GCONV=1E-8) satisfied.	0.59	2.48	0.018	Algorithm converged.	-0.048	0.085	1.19	Algorithm converged.	0.63	2.26	0.5933	0.8222	0.84	Algorithm converged.	0.44	1.59
	> 60	328	66.3	45	13.7	341	68.5	36	10.6	1.35	Convergence criterion (GCONV=1E-8) satisfied.	0.84	2.15	0.032	Algorithm converged.	-0.018	0.081	1.30	Algorithm converged.	0.86	1.98	0.2117		0.77	Algorithm converged.	0.51	1.16
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	42	14.1	309	60.2	27	9.0	1.66	Convergence criterion (GCONV=1E-8) satisfied.	0.99	2.77	0.051	Algorithm converged.	0.008	0.102	1.57	Algorithm converged.	0.99	2.47	0.0539	0.2184	0.64	Algorithm converged.	0.40	1.01
	Asia	140	28.3	13	9.3	139	27.9	17	12.2	0.73	Convergence criterion (GCONV=1E-8) satisfied.	0.34	1.58	-0.029	Algorithm converged.	-0.102	0.043	0.76	Algorithm converged.	0.38	1.50	0.4292		1.32	Algorithm converged.	0.67	2.61
	Rest of World	57	11.5	9	15.8	59	11.8	7	11.9	1.39	Convergence criterion (GCONV=1E-8) satisfied.	0.48	4.03	0.039	Algorithm converged.	-0.086	0.165	1.33	Algorithm converged.	0.53	3.33	0.5418		0.75	Algorithm converged.	0.30	1.88
IPI score at Screening	1-2	187	37.8	16	8.6	187	37.6	10	5.3	1.66	Convergence criterion (GCONV=1E-8) satisfied.	0.73	3.75	0.032	Algorithm converged.	-0.019	0.084	1.60	Algorithm converged.	0.76	3.43	0.2277	0.7227	0.63	Algorithm converged.	0.29	1.34
	3	196	39.6	28	14.3	186	37.3	24	12.9	1.12	Convergence criterion (GCONV=1E-8) satisfied.	0.63	2.02	0.014	Algorithm converged.	-0.055	0.083	1.11	Algorithm converged.	0.67	1.84	0.6939		0.90	Algorithm converged.	0.54	1.50
	4-5	112	22.6	20	17.9	125	25.1	17	13.6	1.38	Convergence criterion (GCONV=1E-8) satisfied.	0.68	2.78	0.043	Algorithm converged.	-0.059	0.136	1.31	Algorithm converged.	0.72	2.38	0.3690		0.76	Algorithm converged.	0.42	1.38

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_INFSGR35_SK_POOLED_15JUN2022_39942.xls
08FEB2023 15:17

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Neutropenia incl. Febrile Neutropenia
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	240	48.5	498	100.0	228	45.8	1.11	Convergence criterion (GCONV=1E-8) satisfied.	0.87	1.43	0.027	Algorithm converged.	-0.025	0.089	1.06	Algorithm converged.	0.93	1.21	0.3940		0.94	Algorithm converged.	0.82	1.08
Sex	Male	265	53.5	122	46.0	269	54.0	118	43.9	1.09	Convergence criterion (GCONV=1E-8) satisfied.	0.78	1.54	0.022	Algorithm converged.	-0.063	0.106	1.05	Algorithm converged.	0.87	1.27	0.6141	0.8961	0.95	Algorithm converged.	0.79	1.15
	Female	230	46.5	118	51.3	229	46.0	110	48.0	1.14	Convergence criterion (GCONV=1E-8) satisfied.	0.79	1.64	0.033	Algorithm converged.	-0.059	0.124	1.07	Algorithm converged.	0.89	1.28	0.4840		0.94	Algorithm converged.	0.78	1.13
Age	<= 60	167	33.7	72	43.1	157	31.5	60	38.2	1.23	Convergence criterion (GCONV=1E-8) satisfied.	0.79	1.91	0.049	Algorithm converged.	-0.058	0.156	1.13	Algorithm converged.	0.87	1.47	0.3734	0.5983	0.89	Algorithm converged.	0.68	1.15
	> 60	328	66.3	168	51.2	341	68.5	168	49.3	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.80	1.46	0.020	Algorithm converged.	-0.036	0.095	1.04	Algorithm converged.	0.89	1.21	0.6135		0.96	Algorithm converged.	0.82	1.12
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	116	38.9	300	60.2	116	38.7	1.01	Convergence criterion (GCONV=1E-8) satisfied.	0.73	1.40	0.003	Algorithm converged.	-0.074	0.081	1.01	Algorithm converged.	0.82	1.23	0.9481	0.7285	0.99	Algorithm converged.	0.81	1.21
	Asia	140	28.3	96	68.6	139	27.9	85	61.2	1.39	Convergence criterion (GCONV=1E-8) satisfied.	0.85	2.27	0.074	Algorithm converged.	-0.028	0.186	1.12	Algorithm converged.	0.94	1.33	0.1960		0.80	Algorithm converged.	0.75	1.06
	Rest of World	57	11.5	28	49.1	59	11.8	27	45.8	1.14	Convergence criterion (GCONV=1E-8) satisfied.	0.55	2.37	0.034	Algorithm converged.	-0.148	0.215	1.07	Algorithm converged.	0.73	1.57	0.7172		0.93	Algorithm converged.	0.63	1.37
IPI score at Screening	1-2	187	37.8	84	44.9	187	37.6	82	43.9	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.69	1.57	0.011	Algorithm converged.	-0.090	0.111	1.02	Algorithm converged.	0.82	1.28	0.8351	0.5733	0.98	Algorithm converged.	0.78	1.22
	3	196	39.6	92	46.9	186	37.3	86	46.2	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.69	1.54	0.007	Algorithm converged.	-0.093	0.107	1.02	Algorithm converged.	0.82	1.26	0.8906		0.99	Algorithm converged.	0.79	1.22
	4-5	112	22.6	64	57.1	125	25.1	60	48.0	1.44	Convergence criterion (GCONV=1E-8) satisfied.	0.86	2.41	0.091	Algorithm converged.	-0.035	0.218	1.19	Algorithm converged.	0.93	1.52	0.1595		0.84	Algorithm converged.	0.66	1.07

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_NEUT_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:18

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Neutropenia incl. Febrile Neutropenia Grade 3-5
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	216	43.6	498	100.0	204	41.0	1.12	Convergence criterion (GCONV=1E-8) satisfied.	0.87	1.44	0.027	Algorithm converged.	-0.035	0.088	1.07	Algorithm converged.	0.92	1.23	0.3943		0.94	Algorithm converged.	0.81	1.09
Sex	Male	265	53.5	111	41.9	269	54.0	103	38.3	1.16	Convergence criterion (GCONV=1E-8) satisfied.	0.82	1.64	0.036	Algorithm converged.	-0.047	0.119	1.09	Algorithm converged.	0.89	1.35	0.3969	0.7089	0.91	Algorithm converged.	0.74	1.13
	Female	230	46.5	105	45.7	229	46.0	101	44.1	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.74	1.54	0.015	Algorithm converged.	-0.076	0.106	1.04	Algorithm converged.	0.85	1.27	0.7390		0.97	Algorithm converged.	0.79	1.18
Age	<= 60	167	33.7	60	35.9	157	31.5	54	34.4	1.07	Convergence criterion (GCONV=1E-8) satisfied.	0.68	1.69	0.015	Algorithm converged.	-0.089	0.119	1.04	Algorithm converged.	0.78	1.40	0.7728	0.8425	0.96	Algorithm converged.	0.71	1.29
	> 60	328	66.3	156	47.6	341	68.5	150	44.0	1.15	Convergence criterion (GCONV=1E-8) satisfied.	0.85	1.57	0.038	Algorithm converged.	-0.040	0.111	1.08	Algorithm converged.	0.92	1.28	0.3539		0.92	Algorithm converged.	0.78	1.09
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	106	35.6	300	60.2	108	36.0	0.98	Convergence criterion (GCONV=1E-8) satisfied.	0.70	1.37	-0.004	Algorithm converged.	-0.081	0.073	0.99	Algorithm converged.	0.80	1.22	0.9128	0.3951	1.01	Algorithm converged.	0.82	1.25
	Asia	140	28.3	85	60.7	139	27.9	70	50.4	1.52	Convergence criterion (GCONV=1E-8) satisfied.	0.95	2.45	0.104	Algorithm converged.	-0.012	0.220	1.21	Algorithm converged.	0.98	1.49	0.0840		0.83	Algorithm converged.	0.67	1.03
	Rest of World	57	11.5	25	43.9	59	11.8	26	44.1	0.99	Convergence criterion (GCONV=1E-8) satisfied.	0.48	2.06	-0.002	Algorithm converged.	-0.183	0.179	1.00	Algorithm converged.	0.66	1.50	0.9820		1.00	Algorithm converged.	0.67	1.52
IPI score at Screening	1-2	187	37.8	71	38.0	187	37.6	73	39.0	0.96	Convergence criterion (GCONV=1E-8) satisfied.	0.63	1.45	-0.011	Algorithm converged.	-0.108	0.088	0.97	Algorithm converged.	0.75	1.26	0.8317	0.6259	1.03	Algorithm converged.	0.80	1.33
	3	196	39.6	85	43.4	186	37.3	73	39.2	1.19	Convergence criterion (GCONV=1E-8) satisfied.	0.79	1.78	0.041	Algorithm converged.	-0.057	0.140	1.10	Algorithm converged.	0.87	1.40	0.4148		0.90	Algorithm converged.	0.71	1.15
	4-5	112	22.6	60	53.6	125	25.1	58	46.4	1.33	Convergence criterion (GCONV=1E-8) satisfied.	0.80	2.22	0.072	Algorithm converged.	-0.055	0.199	1.15	Algorithm converged.	0.89	1.49	0.2701		0.87	Algorithm converged.	0.67	1.12

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_NEUTGR35_SK_POOLED_15JUN2022_39942.xls
08FEB2023 15:20

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Serious Neutropenia incl. Febrile Neutropenia
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	58	11.7	498	100.0	40	8.0	1.52	Convergence criterion (GCONV=1E-8) satisfied.	0.99	2.32	0.037	Algorithm converged.	0.000	0.074	1.46	Algorithm converged.	0.99	2.14	0.0534		0.69	Algorithm converged.	0.47	1.01
Sex	Male	265	53.5	33	12.5	269	54.0	22	8.2	1.60	Convergence criterion (GCONV=1E-8) satisfied.	0.90	2.82	0.043	Algorithm converged.	-0.009	0.094	1.52	Algorithm converged.	0.91	2.54	0.1076	0.8069	0.66	Algorithm converged.	0.39	1.10
	Female	230	46.5	25	10.9	229	46.0	18	7.9	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.76	2.70	0.030	Algorithm converged.	-0.023	0.083	1.38	Algorithm converged.	0.78	2.46	0.2713		0.72	Algorithm converged.	0.41	1.29
Age	<= 60	167	33.7	15	9.0	157	31.5	10	6.4	1.45	Convergence criterion (GCONV=1E-8) satisfied.	0.63	3.33	0.026	Algorithm converged.	-0.032	0.084	1.41	Algorithm converged.	0.65	3.05	0.3816	0.9031	0.71	Algorithm converged.	0.33	1.53
	> 60	328	66.3	43	13.1	341	68.5	30	8.8	1.56	Convergence criterion (GCONV=1E-8) satisfied.	0.96	2.56	0.043	Algorithm converged.	-0.004	0.090	1.49	Algorithm converged.	0.96	2.32	0.0762		0.67	Algorithm converged.	0.43	1.04
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	36	12.1	309	60.2	23	7.3	1.74	Convergence criterion (GCONV=1E-8) satisfied.	1.00	3.03	0.047	Algorithm converged.	0.000	0.095	1.65	Algorithm converged.	0.99	2.73	0.0530	0.6947	0.61	Algorithm converged.	0.37	1.01
	Asia	140	28.3	15	10.7	139	27.9	11	7.9	1.40	Convergence criterion (GCONV=1E-8) satisfied.	0.62	3.16	0.028	Algorithm converged.	-0.040	0.096	1.35	Algorithm converged.	0.64	2.84	0.4234		0.74	Algorithm converged.	0.35	1.53
	Rest of World	57	11.5	7	12.3	59	11.8	7	11.9	1.04	Convergence criterion (GCONV=1E-8) satisfied.	0.34	3.18	0.004	Algorithm converged.	-0.114	0.123	1.04	Algorithm converged.	0.39	2.78	0.9451		0.97	Algorithm converged.	0.36	2.58
IPI score at Screening	1-2	187	37.8	21	11.2	187	37.6	9	4.8	2.50	Convergence criterion (GCONV=1E-8) satisfied.	1.11	5.62	0.064	Algorithm converged.	0.009	0.119	2.33	Algorithm converged.	1.10	4.96	0.0277	0.2269	0.43	Algorithm converged.	0.20	0.91
	3	196	39.6	23	11.7	186	37.3	15	8.1	1.52	Convergence criterion (GCONV=1E-8) satisfied.	0.76	3.00	0.037	Algorithm converged.	-0.023	0.096	1.46	Algorithm converged.	0.78	2.70	0.2348		0.69	Algorithm converged.	0.37	1.28
	4-5	112	22.6	14	12.5	125	25.1	16	12.8	0.97	Convergence criterion (GCONV=1E-8) satisfied.	0.45	2.10	-0.003	Algorithm converged.	-0.088	0.082	0.98	Algorithm converged.	0.50	1.91	0.9447		1.02	Algorithm converged.	0.52	2.00

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_NEUTS_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:22

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Peripheral Neuropathy (sensory and/or motor)
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polatuzumab Vedotin + R-CHP vs. R-CHOP															R-CHOP vs. Polatuzumab Vedotin + R-CHP				
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	249	50.3	498	100.0	259	52.0	0.93	Convergence criterion (GCONV=1E-8) satisfied.	0.73	1.20	-0.017	Algorithm converged.	-0.079	0.045	0.97	Algorithm converged.	0.86	1.09	0.5911		1.03	Algorithm converged.	0.92	1.17
Sex	Male	265	53.5	144	54.3	269	54.0	137	50.9	1.15	Convergence criterion (GCONV=1E-8) satisfied.	0.82	1.61	0.034	Algorithm converged.	-0.051	0.119	1.07	Algorithm converged.	0.91	1.25	0.4303	0.0800	0.94	Algorithm converged.	0.80	1.10
	Female	230	46.5	105	45.7	229	46.0	122	53.3	0.74	Convergence criterion (GCONV=1E-8) satisfied.	0.51	1.06	-0.076	Algorithm converged.	-0.167	0.015	0.86	Algorithm converged.	0.71	1.03	0.1037		1.17	Algorithm converged.	0.97	1.41
Age	<= 60	167	33.7	75	44.9	157	31.5	92	58.6	0.58	Convergence criterion (GCONV=1E-8) satisfied.	0.37	0.89	-0.137	Algorithm converged.	-0.245	-0.029	0.77	Algorithm converged.	0.62	0.95	0.0145	0.0087	1.30	Algorithm converged.	1.05	1.62
	> 60	328	66.3	174	53.0	341	68.5	167	49.0	1.18	Convergence criterion (GCONV=1E-8) satisfied.	0.87	1.59	0.041	Algorithm converged.	-0.035	0.116	1.08	Algorithm converged.	0.93	1.26	0.2920		0.92	Algorithm converged.	0.80	1.07
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	171	57.4	300	60.2	168	56.0	1.06	Convergence criterion (GCONV=1E-8) satisfied.	0.77	1.46	0.014	Algorithm converged.	-0.068	0.093	1.02	Algorithm converged.	0.89	1.18	0.7330	0.4094	0.98	Algorithm converged.	0.85	1.12
	Asia	140	28.3	62	45.0	139	27.9	71	51.1	0.78	Convergence criterion (GCONV=1E-8) satisfied.	0.49	1.25	-0.061	Algorithm converged.	-0.178	0.056	0.88	Algorithm converged.	0.69	1.13	0.3107		1.14	Algorithm converged.	0.89	1.45
	Rest of World	57	11.5	15	26.3	59	11.8	20	33.9	0.70	Convergence criterion (GCONV=1E-8) satisfied.	0.31	1.55	-0.078	Algorithm converged.	-0.242	0.090	0.78	Algorithm converged.	0.44	1.36	0.3771		1.29	Algorithm converged.	0.73	2.26
IPI score at Screening	1-2	187	37.8	96	51.3	187	37.6	99	52.9	0.94	Convergence criterion (GCONV=1E-8) satisfied.	0.62	1.41	-0.016	Algorithm converged.	-0.117	0.085	0.97	Algorithm converged.	0.80	1.18	0.7562	0.9932	1.03	Algorithm converged.	0.85	1.25
	3	196	39.6	97	49.5	186	37.3	96	51.6	0.92	Convergence criterion (GCONV=1E-8) satisfied.	0.61	1.37	-0.021	Algorithm converged.	-0.122	0.079	0.96	Algorithm converged.	0.79	1.17	0.6782		1.04	Algorithm converged.	0.86	1.27
	4-5	112	22.6	56	50.0	125	25.1	64	51.2	0.95	Convergence criterion (GCONV=1E-8) satisfied.	0.57	1.58	-0.012	Algorithm converged.	-0.139	0.115	0.98	Algorithm converged.	0.76	1.26	0.8538		1.02	Algorithm converged.	0.80	1.32

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_PERN_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:23

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Peripheral Neuropathy (sensory and/or motor) Grade 2-5
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polaturumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polaturumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polaturumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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	495	100.0	63	12.7	498	100.0	77	15.5	0.80	Convergence criterion (GCONV=1E-8) satisfied.	0.56	1.14	-0.027	Algorithm converged.	-0.071	0.016	0.82	Algorithm converged.	0.60	1.12	0.2168		1.21	Algorithm converged.	0.89	1.63
Sex	Male	265	53.5	35	13.2	269	54.0	34	12.6	1.05	Convergence criterion (GCONV=1E-8) satisfied.	0.63	1.74	0.006	Algorithm converged.	-0.051	0.063	1.04	Algorithm converged.	0.67	1.62	0.8449	0.1310	0.96	Algorithm converged.	0.62	1.49
	Female	230	46.5	28	12.2	229	46.0	43	18.8	0.60	Convergence criterion (GCONV=1E-8) satisfied.	0.36	1.00	-0.066	Algorithm converged.	-0.132	0.000	0.65	Algorithm converged.	0.42	1.01	0.0532		1.54	Algorithm converged.	0.99	2.39
Age	<= 60	167	33.7	13	7.8	157	31.5	22	14.0	0.52	Convergence criterion (GCONV=1E-8) satisfied.	0.25	1.07	-0.062	Algorithm converged.	-0.130	0.006	0.56	Algorithm converged.	0.29	1.06	0.0764	0.1535	1.80	Algorithm converged.	0.94	3.45
	> 60	328	66.3	50	15.2	341	68.5	55	16.1	0.94	Convergence criterion (GCONV=1E-8) satisfied.	0.62	1.42	-0.009	Algorithm converged.	-0.064	0.046	0.95	Algorithm converged.	0.66	1.34	0.7531		1.06	Algorithm converged.	0.74	1.50
Geographic region	Western Europe/United States/Canada/Australia	298	60.2	52	17.4	309	60.2	59	19.7	0.86	Convergence criterion (GCONV=1E-8) satisfied.	0.57	1.30	-0.022	Algorithm converged.	-0.084	0.040	0.89	Algorithm converged.	0.63	1.24	0.4861	0.4307	1.13	Algorithm converged.	0.80	1.58
	Asia	140	28.3	8	5.7	139	27.9	10	7.2	0.78	Convergence criterion (GCONV=1E-8) satisfied.	0.30	2.04	-0.015	Algorithm converged.	-0.072	0.043	0.79	Algorithm converged.	0.32	1.95	0.6158		1.26	Algorithm converged.	0.51	3.10
	Rest of World	57	11.5	3	5.3	59	11.8	8	13.6	0.35	Convergence criterion (GCONV=1E-8) satisfied.	0.09	1.41	-0.083	Algorithm converged.	-0.188	0.022	0.39	Algorithm converged.	0.11	1.39	0.1461		2.58	Algorithm converged.	0.72	9.23
IPI score at Screening	1-2	187	37.8	28	15.0	187	37.6	26	13.9	1.09	Convergence criterion (GCONV=1E-8) satisfied.	0.61	1.94	0.011	Algorithm converged.	-0.061	0.082	1.08	Algorithm converged.	0.66	1.76	0.7687	0.3978	0.93	Algorithm converged.	0.57	1.52
	3	196	39.6	22	11.2	186	37.3	30	16.1	0.66	Convergence criterion (GCONV=1E-8) satisfied.	0.36	1.19	-0.049	Algorithm converged.	-0.118	0.020	0.70	Algorithm converged.	0.42	1.16	0.1654		1.44	Algorithm converged.	0.86	2.40
	4-5	112	22.6	13	11.6	125	25.1	21	16.8	0.65	Convergence criterion (GCONV=1E-8) satisfied.	0.31	1.37	-0.052	Algorithm converged.	-0.140	0.036	0.69	Algorithm converged.	0.36	1.31	0.2597		1.45	Algorithm converged.	0.76	2.75

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_PERNGR25_SK_POOLED_15JUN2022_39942.xls
08FEB2023 15:14

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Peripheral Neuropathy (sensory and/or motor) Grade 3-5
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 Overall (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	495	100.0	7	1.4	498	100.0	7	1.4	1.41	Convergence criterion (GCONV=1E-8) satisfied.	0.47	4.48	0.004	Algorithm converged.	-0.005	0.014	1.84	Algorithm converged.	0.45	4.46	0.5423		0.71	Algorithm converged.	0.23	2.22
Sex	Male	245	49.5	4	1.6	253	50.8	1	0.4	4.11	Convergence criterion (GCONV=1E-8) satisfied.	0.45	36.99	0.011	Algorithm converged.	-0.005	0.026	4.08	Algorithm converged.	0.45	36.85	0.2087	0.1800	0.24	Algorithm converged.	0.03	2.14
	Female	250	50.5	3	1.2	245	49.2	6	2.4	0.24	Convergence criterion (GCONV=1E-8) satisfied.	0.06	0.96	-0.004	Algorithm converged.	-0.027	0.018	0.35	Algorithm converged.	0.07	1.70	0.2005		1.34	Algorithm converged.	0.30	5.95
Age	>= 60	167	33.7	0	0.0	167	33.5	0	0.0	NE		NE	NE	NE		NE	NE	NE		NE	NE	NE	1.0000	NE	NE	NE	NE
	< 60	328	66.3	7	2.1	331	66.5	7	1.5	1.43	Convergence criterion (GCONV=1E-8) satisfied.	0.44	4.64	0.007	Algorithm converged.	-0.014	0.027	1.46	Algorithm converged.	0.43	4.54	0.5178		0.43	Algorithm converged.	0.22	2.14
Geo-Yrahic region	Western Europe/United States/Canada/Australia	298	60.2	7	2.3	300	60.2	3	1.0	2.36	Convergence criterion (GCONV=1E-8) satisfied.	0.61	9.30	0.015	Algorithm converged.	-0.007	0.036	2.35	Algorithm converged.	0.61	9.05	0.2126	0.1292	0.43	Algorithm converged.	0.11	1.62
	Asia	140	28.3	0	0.0	138	27.8	1	0.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 19.480043294 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
	Rest of World	57	11.5	0	0.0	58	11.6	1	1.7		Quasi-complete separation of data points detected.				WARNING: The relative Hessian convergence criterion of 30.540248401 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
IPI score at Screening	1-2	167	33.7	0	0.0	167	33.5	3	1.8	1.36	Convergence criterion (GCONV=1E-8) satisfied.	0.36	6.82	0.005	Algorithm converged.	-0.022	0.033	1.35	Algorithm converged.	0.07	5.68	0.7028	0.4805	0.74	Algorithm converged.	0.17	3.31
	3	156	30.6	5	3.1	164	32.9	1	0.6	0.93	Convergence criterion (GCONV=1E-8) satisfied.	0.04	15.26	0.000	Algorithm converged.	-0.015	0.014	0.93	Algorithm converged.	0.04	15.56	0.9724		1.03	Algorithm converged.	0.03	16.73
	4-5	172	32.9	2	1.2	167	25.1	3	0.6	2.23	Convergence criterion (GCONV=1E-8) satisfied.	0.26	23.21	0.010	Algorithm converged.	-0.019	0.036	2.23	Algorithm converged.	0.23	22.08	0.5027		0.45	Algorithm converged.	0.04	4.87

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to HALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_PERMGR35_SE_POOLED_15JUN2022_39942.xls
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POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Herione Peripheral Neuropathy (sensory and/or motor)
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 Overall (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	495	100.0	3	0.6	498	100.0	1	0.2	3.01	Convergence criterion (GCONV=1E-6) satisfied.	0.241	37.547	0.005	Algorithm converged.	-0.004	0.014	3.01	Algorithm converged.	0.969	16.745	0.0563		0.33	Algorithm converged.	0.06	5.47
Sex	Male	265	53.5	3	0.6	269	54.0	0	0.0	.	Quasi-complete separation of data points detected.			.	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	0.9945	NE	Algorithm converged.	NE	NE
	Female	230	46.5	0	0.0	229	46.0	1	0.4	.	Quasi-complete separation of data points detected.			.	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	>999.99	Algorithm converged.	0.00	NE
Age	>= 60	167	33.7	0	0.0	167	33.5	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	1.0000	NE	NE	NE	NE
	< 60	328	66.3	3	0.9	331	66.5	1	0.3	3.04	Convergence criterion (GCONV=1E-6) satisfied.	0.241	38.351	0.006	Algorithm converged.	-0.004	0.016	3.04	Algorithm converged.	0.971	16.731	0.0742		0.34	Algorithm converged.	0.06	5.31
Geography region	Western Europe/United States/Canada/Australia	298	60.2	3	0.7	300	60.2	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
	Asia	140	28.3	0	0.0	139	27.9	0	0.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE
	Rest of World	57	11.5	0	0.0	59	11.8	1	1.7	.	Quasi-complete separation of data points detected.			.	WARNING: The relative Hessian convergence criterion of 10.540185601 is greater than the limit of 9.0201. The convergence is questionable.			0.00	Algorithm converged.	0.00	NE	0.9999	>999.99	Algorithm converged.	0.00	NE
IPI score at Screening	0-2	187	37.8	0	0.0	187	37.6	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
	3	190	38.4	0	0.0	189	37.9	1	0.5	.	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	1.0000	>999.99	Algorithm converged.	0.00	NE
	4-5	118	23.8	3	2.5	122	24.5	1	0.8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	NE	NE	NE

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: z:\clinical_studies\WO55410??\CDP??894\GO39942\data_analysis\ACR_FINAL_GS\prod\program\t_ae_raw.sas
Output: z:\clinical_studies\WO55410??\CDP??894\GO39942\data_analysis\ACR_FINAL_GS\prod\output\t_ae_raw_ag2_PERNS_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:27

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Herlove Peripheral Neuropathy (sensory and/or motor) Grade 2-5
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

		Polatuzumab Vedotin + R-CHP (N=495)				R-CHOP (N=498)				Polatuzumab Vedotin + R-CHP vs. R-CHOP														R-CHOP vs. Polatuzumab Vedotin + R-CHP			
		Patients		Patients with Event		Patients		Patients with Event		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 Overall (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	495	100.0	3	0.6	498	100.0	1	0.2	3.01	Convergence criterion (GCONV=1E-6) satisfied.	0.24	13.11	0.005	Algorithm converged.	-0.004	0.014	3.01	Algorithm converged.	0.93	16.56	0.0643		0.33	Algorithm converged.	0.06	1.07
Sex	Male	265	53.5	3	0.6	269	54.0	0	0.0	.	Quasi-complete separation of data points detected.			.	WARNING: Negative of Hessian not positive definite.			NE	Algorithm converged.	NE	NE	NE	0.9945	NE	Algorithm converged.	NE	NE
	Female	230	46.5	0	0.0	229	46.0	1	0.4	.	Quasi-complete separation of data points detected.			.	WARNING: Negative of Hessian not positive definite.			0.00	Algorithm converged.	0.00	NE	0.9999	>999.99	Algorithm converged.	0.00	NE
Age	>= 60	167	33.7	0	0.0	167	33.5	0	0.0	NE		NE	NE	NE				NE		NE	NE	NE	1.0000	NE		NE	NE
	< 60	328	66.3	3	0.9	331	66.5	1	0.3	3.04	Convergence criterion (GCONV=1E-6) satisfied.	0.24	14.63	0.009	Algorithm converged.	-0.004	0.024	3.04	Algorithm converged.	0.93	16.53	0.9792		0.34	Algorithm converged.	0.06	15.31
Geography region	Western Europe/United States/Canada/Australia	298	60.2	3	0.7	300	60.2	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
	Asia	140	28.3	0	0.0	139	27.9	0	0.0	NE		NE	NE	NE				NE		NE	NE	NE		NE		NE	NE
	Rest of World	57	11.5	0	0.0	59	11.8	1	1.7	.	Quasi-complete separation of data points detected.			.	WARNING: The relative Hessian convergence criterion of 10.540185601 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
IPI score at Screening	0-2	187	37.8	0	0.0	187	37.6	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
	3	190	38.4	0	0.0	189	37.9	1	0.5	.	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	1.0000	>999.99	Algorithm converged.	0.00	NE
	4-5	118	23.8	3	2.5	122	24.5	1	0.8	NE		NE	NE	NE				NE		NE	NE	NE		NE		NE	NE

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/BO55410?7/CDP?7894/GO39942/data_analysis/ACR_FINAL_GS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/BO55410?7/CDP?7894/GO39942/data_analysis/ACR_FINAL_GS/prod/output/t_ae_raw_ag2_PERNSG25_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:15

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: STIAMP (suspected transmission of an infectious agent by the study drug)
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_STIA_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:11

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: STIAMP (suspected transmission of an infectious agent by the study drug) Grade 3-5
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_STIAGR35_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:12

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: Serious STIAMP (suspected transmission of an infectious agent by the study drug)
MODEL: Unstratified analysis
STUDY: GO39942
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_raw.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_raw_sg2_STIAS_SE_POOLED_15JUN2022_39942.xls
08FEB2023 15:13

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: All Patients
MODEL: descriptive
STUDY: GO39942
Outcome of Adverse Events

	Polatuzumab Vedotin + R-CHP (N=495)														R-CHOP (N=498)													
	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	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																														
All	6438	5542	86.1	25	0.4	694	10.8	14	0.2	153	2.4	10	0.2	0	0.0	6132	5179	84.5	33	0.5	769	12.5	10	0.2	132	2.2	9	0.1	0	0.0
Grade 1	3159	2649	83.9	7	0.2	407	12.9	0	0.0	95	3.0	1	<0.1	0	0.0	3048	2478	81.3	10	0.3	482	15.8	0	0.0	72	2.4	6	0.2	0	0.0
Grade 2	1968	1674	85.1	6	0.3	236	12.0	0	0.0	47	2.4	5	0.3	0	0.0	1925	1630	84.7	8	0.4	236	12.3	0	0.0	50	2.6	1	<0.1	0	0.0
Grade 3	852	784	92.0	8	0.9	46	5.4	0	0.0	10	1.2	4	0.5	0	0.0	727	666	91.6	12	1.7	41	5.6	0	0.0	6	0.8	2	0.3	0	0.0
Grade 4	445	435	97.8	4	0.9	5	1.1	0	0.0	1	0.2	0	0.0	0	0.0	419	403	96.2	3	0.7	9	2.1	0	0.0	4	1.0	0	0.0	0	0.0
Grade 5	14	0	0.0	0	0.0	0	0.0	14	100.0	0	0.0	0	0.0	0	0.0	10	0	0.0	0	0.0	0	0.0	10	100.0	0	0.0	0	0.0	0	0.0
Missing	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Any SAEs																														
All	351	312	88.9	9	2.6	13	3.7	14	4.0	3	0.9	0	0.0	0	0.0	285	249	87.4	7	2.5	13	4.6	10	3.5	6	2.1	0	0.0	0	0.0
Grade 1	9	9	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	9	7	77.8	0	0.0	1	11.1	0	0.0	1	11.1	0	0.0	0	0.0
Grade 2	45	41	91.1	2	4.4	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	37	35	94.6	1	2.7	1	2.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	220	201	91.4	7	3.2	9	4.1	0	0.0	3	1.4	0	0.0	0	0.0	172	155	90.1	5	2.9	9	5.2	0	0.0	3	1.7	0	0.0	0	0.0
Grade 4	63	61	96.8	0	0.0	2	3.2	0	0.0	0	0.0	0	0.0	0	0.0	57	52	91.2	1	1.8	2	3.5	0	0.0	2	3.5	0	0.0	0	0.0
Grade 5	14	0	0.0	0	0.0	0	0.0	14	100.0	0	0.0	0	0.0	0	0.0	10	0	0.0	0	0.0	0	0.0	10	100.0	0	0.0	0	0.0	0	0.0
Any AESI																														
All	1506	1349	89.6	11	0.7	121	8.0	6	0.4	18	1.2	1	<0.1	0	0.0	1387	1241	89.5	6	0.4	116	8.4	7	0.5	16	1.2	1	<0.1	0	0.0
Grade 1	499	412	82.6	4	0.8	67	13.4	0	0.0	16	3.2	0	0.0	0	0.0	438	354	80.8	1	0.2	73	16.7	0	0.0	9	2.1	1	0.2	0	0.0
Grade 2	383	337	88.0	2	0.5	42	11.0	0	0.0	1	0.3	1	0.3	0	0.0	400	359	89.8	2	0.5	33	8.3	0	0.0	6	1.5	0	0.0	0	0.0
Grade 3	322	307	95.3	3	0.9	11	3.4	0	0.0	1	0.3	0	0.0	0	0.0	258	247	95.7	2	0.8	8	3.1	0	0.0	1	0.4	0	0.0	0	0.0
Grade 4	296	293	99.0	2	0.7	1	0.3	0	0.0	0	0.0	0	0.0	0	0.0	283	280	98.9	1	0.4	2	0.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	6	0	0.0	0	0.0	0	0.0	6	100.0	0	0.0	0	0.0	0	0.0	7	0	0.0	0	0.0	0	0.0	7	100.0	0	0.0	0	0.0	0	0.0
Missing	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

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_resolved.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_resolved_SE_POOLED_15JUN2022_39942.xls
08FEB2023 14:02

POPULATION: Global and China Extension Population, Safety-Evaluable Population
ENDPOINT: All Patients
MODEL: descriptive
STUDY: GO39942
Outcome of Adverse Events of Special Interest

	Polatuzumab Vedotin + R-CHP (N=495)															R-CHOP (N=498)													
	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	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
DILI (potential drug-induced liver injury)																													
All	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2	66.7	0	0.0	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0
Grade 2	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
Grade 3	2	2	100.0	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
Grade 5	0	0	0.0	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	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
Serious DILI (potential drug-induced liver injury)																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0
Grade 2	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
Grade 5	0	0	0.0	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	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
STIAMP (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
Serious STIAMP (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
Peripheral Neuropathy (sensory and/or motor)																													
All	324	220	67.9	4	1.2	87	26.9	0	0.0	12	3.7	1	0.3	0	0.0	321	238	74.1	3	0.9	71	22.1	0	0.0	8	2.5	1	0.3	0	0.0
Grade 1	254	185	72.8	4	1.6	53	20.9	0	0.0	12	4.7	0	0.0	0	0.0	239	178	74.5	1	0.4	54	22.6	0	0.0	5	2.1	1	0.4	0	0.0
Grade 2	62	32	51.6	0	0.0	29	46.8	0	0.0	0	0.0	1	1.6	0	0.0	77	59	76.6	2	2.6	13	16.9	0	0.0	3	3.9	0	0.0	0	0.0
Grade 3	8	3	37.5	0	0.0	5	62.5	0	0.0	0	0.0	0	0.0	0	0.0	5	1	20.0	0	0.0	4	80.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Peripheral Neuropathy (sensory and/or motor)																													
All	1	0	0.0	0	0.0	1	100.0	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
Grade 3	1	0	0.0	0	0.0	1	100.0	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
Infections																													
All	449	412	91.8	4	0.9	23	5.1	6	1.3	4	0.9	0	0.0	0	0.0	382	340	89.0	2	0.5	29	7.6	6	1.6	5	1.3	0	0.0	0	0.0
Grade 1	110	97	88.2	0	0.0	10	9.1	0	0.0	3	2.7	0	0.0	0	0.0	80	68	85.0	0	0.0	11	13.8	0	0.0	1	1.3	0	0.0	0	0.0
Grade 2	231	219	94.8	2	0.9	9	3.9	0	0.0	1	0.4	0	0.0	0	0.0	211	194	91.9	0	0.0	14	6.6	0	0.0	3	1.4	0	0.0	0	0.0
Grade 3	94	88	93.6	2	2.1	4	4.3	0	0.0	0	0.0	0	0.0	0	0.0	72	66	91.7	2	2.8	3	4.2	0	0.0	1	1.4	0	0.0	0	0.0
Grade 4	8	8	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	12	11	91.7	0	0.0	1	8.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	6	0	0.0	0	0.0	0	0.0	6	100.0	0	0.0	0	0.0	0	0.0	6	0	0.0	0	0.0	0	0.0	6	100.0	0	0.0	0	0.0	0	0.0
Missing	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
Serious Infections																													
All	98	87	88.8	4	4.1	1	1.0	6	6.1	0	0.0	0	0.0	0	0.0	73	61	83.6	1	1.4	4	5.5	6	8.2	1	1.4	0	0.0	0	0.0
Grade 1	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
Grade 2	10	8	80.0	2	20.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	74	71	95.9	2	2.7	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	53	49	92.5	1	1.9	2	3.8	0	0.0	1	1.9	0	0.0	0	0.0
Grade 4	7	7	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	11	10	90.9	0	0.0	1	9.1	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	6	0	0.0	0	0.0	0	0.0	6	100.0	0	0.0	0	0.0	0	0.0	6	0	0.0	0	0.0	0	0.0	6	100.0	0	0.0	0	0.0	0	0.0
Neutropenia incl. Febrile Neutropenia																													
All	595	586	98.5	3	0.5	5	0.8	0	0.0	1	0.2	0	0.0	0	0.0	569	562	98.8	1	0.2	6	1.1	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	27	25	92.6	0	0.0	2	7.4	0	0.0	0	0.0	0	0.0	0	0.0	32	29	90.6	0	0.0	3	9.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	68	67	98.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	90	88	97.8	0	0.0	2	2.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	211	208	98.6	1	0.5	1	0.5	0	0.0	1	0.5	0	0.0	0	0.0	176	176	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	289	286	99.0	2	0.7	1	0.3	0	0.0	0	0.0	0	0.0	0	0.0	271	269	99.3	1	0.4	1	0.4	0	0.0	0	0.0	0	0.0	0	0.0
Serious Neutropenia incl. Febrile Neutropenia																													
All	83	82	98.8	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	51	51	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	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
Grade 2	2	2	100.0	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
Grade 3	46	45	97.8	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	26	26	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	34	34	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	24	24	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hepatic Toxicity																													
All	140	133	95.0	0	0.0	6	4.3	0	0.0	1	0.7	0	0.0	0	0.0	115	102	88.7	0	0.0	10	8.7	0	0.0	3	2.6	0	0.0	0	0.0
Grade 1	108	105	97.2	0	0.0	2	1.9	0	0.0	1	0.9	0	0.0	0	0.0	87	79	90.8	0	0.0	5	5.7	0	0.0	3	3.4	0	0.0	0	0.0
Grade 2	22	19	86.4	0	0.0	3	13.6	0	0.0	0	0.0	0	0.0	0	0.0	22	18	81.8	0	0.0	4	18.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	10	9	90.0	0	0.0	1	10.0	0	0.0	0	0.0	0	0.0	0	0.0	6	5	83.3	0	0.0	1	16.7	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hepatic Toxicity																													
All	1	1	100.0	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
Grade 2	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
Grade 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

Includes treatment-emergent AEs during AE reporting period only, which is defined as new or worsening AE from the first dose of any study drug through 90 days after the last dose of any study drug or prior to NALT, whichever is earlier.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/program/t_ae_resolved.sas
Output: root/clinical_studies/RO5541077/CDPT7884/GO39942/data_analysis/ACE_FINAL_OS/prod/output/t_ae_resolved_aesi_SE_POOLED_15JUN2022_39942.xls
08FEB2023 14:00