

Atidarsagen autotemcel/OTL-200 (Libmeldy)

Orchard Therapeutics

Anhang 4H zu Modul 4A

*Behandlung der metachromatischen Leukodystrophie
(MLD) bei Kindern*

Stand: 01.05.2021

Ergebnisse:
Studie 201222, Wirksamkeit und Sicherheit,
Sensitivitätsanalysen

Stand: 01.05.2021

[1] "Survival Rate"

\$ITT

\$ITT\$all

\$ITT\$all\$ntab

	CTRL	TRT
N	31	20
n_all	31	20
n_event	16	18
n_event_pct	52	90

\$ITT\$all\$stats

	estimate	se	lo95ci	hi95ci	pvalue
RR_TRTvsCTRL	1.743750	0.1892022	1.2034692	2.526582	0.0032942720
OR_TRTvsCTRL	8.437500	0.8274794	1.6667176	42.713540	0.0099567376
ARR_TRTvsCTRL	0.383871	0.1120541	0.1642489	0.603493	0.0006130724

\$MSAS

\$MSAS\$all

\$MSAS\$all\$ntab

	CTRL	TRT
N	10	11
n_all	10	11
n_event	6	11
n_event_pct	60	100

\$MSAS\$all\$stats

	estimate	se	lo95ci	hi95ci	pvalue
RR_TRTvsCTRL	1.621795	0.2579927	0.97811993	2.6890553	0.060900996
OR_TRTvsCTRL	15.923077	1.5694027	0.73476587	345.0682572	0.077802483
ARR_TRTvsCTRL	0.400000	0.1549193	0.09636369	0.7036363	0.009823275

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[1] "Age to Death"

\$ITT

\$ITT\$all

\$ITT\$all\$stats_num

	TRT01P=TIGET-NHx	TRT01P=OTL-200
n_all	31.0	20
n_event	15.0	2
n_event_pct	48.0	10
time-to-event-yr-10th	5.2	7
time-to-event-yr-25th	9.4	NA
time-to-event-yr-50th	13.3	NA
time-to-event-yr-75th	NA	NA
time-to-event-yr-90th	NA	NA
time-to-event-yr-50th-loci	10.5	NA
time-to-event-yr-50th-hici	NA	NA

\$ITT\$all\$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.32270	0.77000	0.07136	1.46000	0.14190

\$ITT\$all\$plot

```

$MSAS
$MSAS$all
$MSAS$all$stats_num
                                TRT01P=TIGET-NHx TRT01P=OTL-200
n_all                            10.0                11
n_event                          4.0                0
n_event_pct                      40.0               0
time-to-event-yr-10th           4.3                NA
time-to-event-yr-25th           5.7                NA
time-to-event-yr-50th           NA                 NA
time-to-event-yr-75th           NA                 NA
time-to-event-yr-90th           NA                 NA
time-to-event-yr-50th-loci      5.7                NA
time-to-event-yr-50th-hici      NA                 NA

```

```

$MSAS$all$stats_HR_TRTvsCTRL
      HR SE_logHR HR.lo95ci HR.hi95ci p.value
4.715e-10 2.037e+04 0.000e+00      Inf 9.992e-01

```

```
$MSAS$all$plot
```

```

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```

```
[1] "Severe motor-free Survival"
```

```
$ITT
```

```
$ITT$all
```

```
$ITT$all$ntab
```

	CTRL	TRT
N	31	20
n_all	31	20
n_event	3	16
n_event_pct	10	80

```
$ITT$all$stats
```

	estimate	se	lo95ci	hi95ci	pvalue
RR_TRTvsCTRL	8.2666667	0.5599779	2.7585214	24.7733361	1.619505e-04
OR_TRTvsCTRL	37.3333333	0.8255590	7.4025218	188.2841839	1.161082e-05
ARR_TRTvsCTRL	0.7032258	0.1040175	0.4993552	0.9070964	1.373768e-11

```
$MSAS
```

```
$MSAS$all
```

```
$MSAS$all$ntab
```

	CTRL	TRT
N	10	11
n_all	10	11
n_event	0	10
n_event_pct	0	91

```
$MSAS$all$stats
```

	estimate	se	lo95ci	hi95ci	pvalue
RR_TRTvsCTRL	19.2500000	1.38599988	1.2725226	291.203085	0.032855344
OR_TRTvsCTRL	147.0000000	1.69030851	5.3520988	4037.481510	0.003153349

ARR_TRTvsCTRL 0.9090909 0.08667842 0.7392043 1.078977 0.000000000

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[1] "Age to severe motor Impairment or Death"

\$ITT

\$ITT\$all

\$ITT\$all\$stats_num

	TRT01P=TIGET-NHx	TRT01P=OTL-200
n_all	31.0	20.0
n_event	28.0	4.0
n_event_pct	90.0	20.0
time-to-event-yr-10th	2.3	5.7
time-to-event-yr-25th	2.6	NA
time-to-event-yr-50th	3.4	NA
time-to-event-yr-75th	6.4	NA
time-to-event-yr-90th	8.2	NA
time-to-event-yr-50th-loci	2.7	NA
time-to-event-yr-50th-hici	6.3	NA

\$ITT\$all\$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
1.023e-01	5.422e-01	3.536e-02	2.962e-01	2.623e-05

\$ITT\$all\$plot

\$MSAS

\$MSAS\$all

\$MSAS\$all\$stats_num

	TRT01P=TIGET-NHx	TRT01P=OTL-200
n_all	10.0	11
n_event	10.0	1
n_event_pct	100.0	9
time-to-event-yr-10th	2.1	NA
time-to-event-yr-25th	2.7	NA
time-to-event-yr-50th	4.0	NA
time-to-event-yr-75th	6.3	NA
time-to-event-yr-90th	8.7	NA
time-to-event-yr-50th-loci	2.7	NA
time-to-event-yr-50th-hici	NA	NA

\$MSAS\$all\$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.058870	1.054000	0.007454	0.464900	0.007223

\$MSAS\$all\$plot

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[1] "Rate GMFC-Level < 5"

\$ITT

\$ITT\$all

\$ITT\$all\$ntab

	CTRL	TRT
N	31	20
n_all	31	20
n_event	3	18
n_event_pct	10	90

\$ITT\$all\$stats

	estimate	se	lo95ci	hi95ci	pvalue
RR_TRTvsCTRL	9.3000000	0.55374256	3.1414954	27.5314745	5.645266e-05
OR_TRTvsCTRL	84.0000000	0.96156288	12.7583784	553.0483417	4.066927e-06
ARR_TRTvsCTRL	0.8032258	0.08555492	0.6355413	0.9709104	0.000000e+00

\$MSAS

\$MSAS\$all

\$MSAS\$all\$ntab

	CTRL	TRT
N	10	11
n_all	10	11
n_event	0	10
n_event_pct	0	91

\$MSAS\$all\$stats

	estimate	se	lo95ci	hi95ci	pvalue
RR_TRTvsCTRL	19.2500000	1.38599988	1.2725226	291.203085	0.032855344
OR_TRTvsCTRL	147.0000000	1.69030851	5.3520988	4037.481510	0.003153349
ARR_TRTvsCTRL	0.9090909	0.08667842	0.7392043	1.078977	0.000000000

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[1] "Age to GMFC-Level >= 5"

\$ITT

\$ITT\$all

\$ITT\$all\$stats_num

	TRT01P=TIGET-NHx	TRT01P=OTL-200
n_all	31.0	20.0
n_event	28.0	2.0
n_event_pct	90.0	10.0
time-to-event-yr-10th	2.3	5.7
time-to-event-yr-25th	2.7	NA
time-to-event-yr-50th	3.4	NA
time-to-event-yr-75th	6.4	NA
time-to-event-yr-90th	8.2	NA
time-to-event-yr-50th-loci	2.7	NA
time-to-event-yr-50th-hici	6.3	NA

\$ITT\$all\$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.101800	0.733100	0.024190	0.428100	0.001826

\$ITT\$all\$plot

\$MSAS

```

$MSAS$all
$MSAS$all$stats_num
                                TRT01P=TIGET-NHx TRT01P=OTL-200
n_all                            10.0                11.0
n_event                          10.0                1.0
n_event_pct                      100.0             9.0
time-to-event-yr-10th           2.2                2.7
time-to-event-yr-25th           2.7                NA
time-to-event-yr-50th           4.0                NA
time-to-event-yr-75th           6.3                NA
time-to-event-yr-90th           8.7                NA
time-to-event-yr-50th-loci      2.7                NA
time-to-event-yr-50th-hici      NA                 NA

```

```

$MSAS$all$stats_HR_TRTvsCTRL
      HR SE_logHR HR.lo95ci HR.hi95ci p.value
0.15390 1.05200 0.01957 1.21000 0.07527

```

```
$MSAS$all$plot
```

```

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```

```
[1] "GMFM"
```

```
$MAS
```

```
$MAS$distype_all
```

```

$MAS$distype_all$`Total GMFM % Score`
$MAS$distype_all$`Total GMFM % Score`$`Year 2`
$MAS$distype_all$`Total GMFM % Score`$`Year 2`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      29.000000      20.000000
n      20.000000      17.000000
mean   24.472000      73.417647
sd     28.778250      27.744580
se     6.435012       6.729049
median 9.655000      85.840000
min    1.180000      8.330000
max    96.400000     100.000000
sum    489.440000    1248.100000

```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 2`$ls_mw
```

```

      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200 74.09      6.481      60.922      87.264
2      TIGET-NHx 23.90      5.974      11.757      36.039

```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 2`$diffgrp_TRTvsCTRL
```

```

      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
5.019465e+01 8.822781e+00 3.226460e+01 6.812470e+01
2.182600e-06

```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 2`$Hedgesg_TRTvsCTRL
```

```

      est lo95ci hi95ci pv
1.690 0.927 2.456 0.000

```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`$numbers_eachgrp
```

	TIGET-NHx	OTL-200
N	29.000000	20.000000
n	23.000000	18.000000
mean	18.619565	71.376111
sd	28.050125	29.723462
se	5.848855	7.005887
median	3.410000	78.815000
min	1.180000	4.200000
max	96.400000	100.000000
sum	428.250000	1284.770000

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`$ls_mw
  TRTVsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  71.77    6.507      58.601      84.944
2  TIGET-NHx 18.31    5.756      6.658      29.961
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`$diffgrp_TRTVsCTRL
  LSM_Diff    LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  5.346288e+01  8.690015e+00  3.587087e+01  7.105490e+01
3.520236e-07
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`$Hedgesg_TRTVsCTRL
  est lo95ci hi95ci    pv
1.800 1.057 2.537 0.000
```

```
$MAS$distype_all$`Total Dimension A`%`
$MAS$distype_all$`Total Dimension A`%`$`Year 2`
$MAS$distype_all$`Total Dimension A`%`$`Year 2`$numbers_eachgrp
  TIGET-NHx    OTL-200
N      29.000000  20.000000
n      19.000000  17.000000
mean   42.416316  91.464706
sd     33.181649  18.972737
se     7.612392   4.601565
median 25.490000  100.000000
min    5.880000   33.330000
max   100.000000  100.000000
sum   805.910000  1554.900000
```

```
$MAS$distype_all$`Total Dimension A`%`$`Year 2`$ls_mw
  TRTVsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  91.80    6.419      78.744     104.863
2  TIGET-NHx 42.11    6.071      29.761     54.466
```

```
$MAS$distype_all$`Total Dimension A`%`$`Year 2`$diffgrp_TRTVsCTRL
  LSM_Diff    LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  4.969026e+01  8.838703e+00  3.170779e+01  6.767274e+01
2.941059e-06
```

```
$MAS$distype_all$`Total Dimension A`%`$`Year 2`$Hedgesg_TRTVsCTRL
  est lo95ci hi95ci    pv
1.750 0.967 2.530 0.000
```

```
$MAS$distype_all$`Total Dimension A`%`$`Year 3`
$MAS$distype_all$`Total Dimension A`%`$`Year 3`$numbers_eachgrp
```


	TIGET-NHx	OTL-200
N	29.000000	20.000000
n	22.000000	18.000000
mean	29.768636	89.106667
sd	30.650940	21.649128
se	6.534802	5.102748
median	13.730000	100.000000
min	5.880000	17.650000
max	100.000000	100.000000
sum	654.910000	1603.920000

```
$MAS$distype_all$`Total Dimension A %`$`Year 3`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  89.31    5.819      77.524      101.104
2  TIGET-NHx 29.60    5.263      18.935      40.264
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 3`$diffgrp_TRTvsCTRL
  LSM_Diff    LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  5.971452e+01    7.846662e+00    4.381567e+01    7.561337e+01
4.429645e-09
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 3`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci    pv
  2.150  1.357  2.951  0.000
```

```
$MAS$distype_all$`Total Dimension B %`
$MAS$distype_all$`Total Dimension B %`$`Year 2`
$MAS$distype_all$`Total Dimension B %`$`Year 2`$numbers_eachgrp
  TIGET-NHx    OTL-200
N      29.000000    20.000000
n      19.000000    17.000000
mean   24.999474    86.568235
sd     30.802076    28.446223
se     7.066481     6.899223
median 10.000000    100.000000
min    0.000000     8.330000
max    86.670000    100.000000
sum    474.990000   1471.660000
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 2`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  86.97    6.885      72.960      100.976
2  TIGET-NHx 24.64    6.512      11.392      37.892
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 2`$diffgrp_TRTvsCTRL
  LSM_Diff    LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  6.232571e+01    9.480782e+00    4.303691e+01    8.161450e+01
1.799970e-07
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 2`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci    pv
  2.030  1.205  2.847  0.000
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 3`
$MAS$distype_all$`Total Dimension B %`$`Year 3`$numbers_eachgrp
```

	TIGET-NHx	OTL-200
N	29.000000	20.000000
n	22.000000	18.000000
mean	17.727273	84.536667
sd	30.191038	28.906308
se	6.436751	6.813282
median	1.670000	99.165000
min	0.000000	3.330000
max	86.670000	100.000000
sum	390.000000	1521.660000

```
$MAS$distype_all$`Total Dimension B %`$`Year 3`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  84.73    6.557      71.448      98.021
2  TIGET-NHx 17.57    5.931      5.547      29.583
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 3`$diffgrp_TRTvsCTRL
  LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  6.716957e+01    8.842495e+00    4.925297e+01    8.508617e+01
4.619991e-09
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 3`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
  2.210  1.405  3.016  0.000
```

```
$MAS$distype_all$`Total Dimension C %`
$MAS$distype_all$`Total Dimension C %`$`Year 2`
$MAS$distype_all$`Total Dimension C %`$`Year 2`$numbers_eachgrp
  TIGET-NHx      OTL-200
N      29.000000    20.000000
n      19.000000    17.000000
mean   11.277895    76.472353
sd     22.696621    32.438225
se     5.206962     7.867425
median 0.000000     90.480000
min    0.000000     0.000000
max    69.050000    100.000000
sum    214.280000   1300.030000
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 2`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  76.75    6.601      63.321      90.181
2  TIGET-NHx 11.03    6.244      -1.675      23.732
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 2`$diffgrp_TRTvsCTRL
  LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  6.572286e+01    9.089667e+00    4.722980e+01    8.421593e+01
2.720256e-08
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 2`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
  2.300  1.437  3.164  0.000
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 3`
$MAS$distype_all$`Total Dimension C %`$`Year 3`$numbers_eachgrp
```

	TIGET-NHx	OTL-200
N	29.000000	20.000000
n	22.000000	18.000000
mean	10.714091	72.883889
sd	21.855521	36.194100
se	4.659613	8.531031
median	0.000000	92.860000
min	0.000000	0.000000
max	69.050000	100.000000
sum	235.710000	1311.910000

```
$MAS$distype_all$`Total Dimension C %`$`Year 3`$ls_mw
  TRTvSCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  72.97    6.861      59.071      86.875
2  TIGET-NHx 10.64    6.206      -1.934      23.216
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 3`$diffgrp_TRTvSCTRL
  LSM_Diff    LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  6.233171e+01  9.252316e+00  4.358474e+01  8.107868e+01
6.370814e-08
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 3`$Hedgesg_TRTvSCTRL
  est lo95ci hi95ci    pv
  2.090 1.302 2.878 0.000
```

```
$MAS$distype_all$`Total Dimension D %`
$MAS$distype_all$`Total Dimension D %`$`Year 2`
$MAS$distype_all$`Total Dimension D %`$`Year 2`$numbers_eachgrp
  TIGET-NHx    OTL-200
N      29.000000  20.000000
n      19.000000  17.000000
mean   15.384737  63.650000
sd     25.297186  33.162418
se     5.803573   8.043068
median 0.000000   76.920000
min    0.000000   0.000000
max    69.230000  100.000000
sum    292.310000 1082.050000
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 2`$ls_mw
  TRTvSCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  64.05    6.774      50.265      77.827
2  TIGET-NHx 15.03    6.407      1.995      28.065
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 2`$diffgrp_TRTvSCTRL
  LSM_Diff    LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  4.901612e+01  9.327094e+00  3.004001e+01  6.799224e+01
8.687915e-06
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 2`$Hedgesg_TRTvSCTRL
  est lo95ci hi95ci    pv
  1.610 0.849 2.377 0.000
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`
$MAS$distype_all$`Total Dimension D %`$`Year 3`$numbers_eachgrp
```

	TIGET-NHx	OTL-200
N	29.000000	20.000000
n	22.000000	18.000000
mean	10.955909	60.112778
sd	21.397108	35.005406
se	4.561879	8.250853
median	0.000000	73.075000
min	0.000000	0.000000
max	69.230000	100.000000
sum	241.030000	1082.030000

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`$ls_mw
  TRTvSCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  60.22      6.596      46.858      73.589
2  TIGET-NHx 10.87      5.966      -1.224      22.954
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`$diffgrp_TRTvSCTRL
  LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  4.935822e+01      8.894824e+00      3.133560e+01      6.738085e+01
2.562288e-06
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`$Hedgesg_TRTvSCTRL
  est lo95ci hi95ci      pv
1.700 0.966 2.439 0.000
```

```
$MAS$distype_all$`Total Dimension E %`
$MAS$distype_all$`Total Dimension E %`$`Year 2`
$MAS$distype_all$`Total Dimension E %`$`Year 2`$numbers_eachgrp
  TIGET-NHx      OTL-200
N      29.000000      20.000000
n      19.000000      17.000000
mean    9.356842      48.937059
sd     17.066019      36.722590
se      3.915213      8.906536
median  0.000000      58.330000
min     0.000000      0.000000
max     62.500000      100.000000
sum    177.780000      831.930000
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 2`$ls_mw
  TRTvSCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  49.28      6.581      35.891      62.669
2  TIGET-NHx 9.05      6.225      -3.614      21.714
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 2`$diffgrp_TRTvSCTRL
  LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  4.022985e+01      9.061872e+00      2.179333e+01      5.866637e+01
9.518615e-05
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 2`$Hedgesg_TRTvSCTRL
  est lo95ci hi95ci      pv
1.3800 0.6420 2.1140 0.0002
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 3`
$MAS$distype_all$`Total Dimension E %`$`Year 3`$numbers_eachgrp
```

	TIGET-NHx	OTL-200
N	29.000000	20.000000
n	22.000000	18.000000
mean	6.250000	50.233333
sd	14.514505	38.854101
se	3.094503	9.157999
median	0.000000	47.225000
min	0.000000	0.000000
max	62.500000	100.000000
sum	137.500000	904.200000

```
$MAS$distype_all$`Total Dimension E %`$`Year 3`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200   50.3    6.665      36.794      63.803
2  TIGET-NHx   6.2    6.029      -6.018      18.412
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 3`$diffgrp_TRTvsCTRL
  LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  4.410143e+01    8.987716e+00    2.589058e+01    6.231227e+01
1.880421e-05
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 3`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
1.530 0.816 2.248 0.000
```

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```
$MSAS$distype_all
$MSAS$distype_all$`Total GMFM % Score`
$MSAS$distype_all$`Total GMFM % Score`$`Year 2`
$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$numbers_eachgrp
  TIGET-NHx      OTL-200
N      10.000000    11.000000
n      8.000000    10.000000
mean   29.302500    80.303000
sd     34.286390    26.998533
se     12.122070    8.537686
median 14.330000    89.465000
min     1.180000    8.330000
max     96.400000    99.440000
sum    234.420000   803.030000
```

```
$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200   80.50    7.576      64.349      96.646
2  TIGET-NHx  29.06    8.471      11.004      47.114
```

```
$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$diffgrp_TRTvsCTRL
  LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  5.143804e+01    1.136510e+01    2.721392e+01    7.566217e+01
4.019615e-04
```

```
$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
1.6000 0.4960 2.6990 0.0045
```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`
$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.00000    11.000000
n      9.00000    11.000000
mean   23.02444    80.766364
sd     35.08467    27.483123
se     11.69489     8.286473
median 1.90000    90.170000
min    1.18000     4.200000
max    96.40000   100.000000
sum    207.22000  888.430000

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  82.23      8.327          64.665          99.803
2      TIGET-NHx 21.23      9.212          1.796           40.666

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      6.100338e+01    1.245349e+01    3.472882e+01    8.727794e+01
1.355785e-04

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
1.7800 0.7040 2.8530 0.0012

```

```

$MSAS$distype_all$`Total Dimension A`%`
$MSAS$distype_all$`Total Dimension A`%`$`Year 2`
$MSAS$distype_all$`Total Dimension A`%`$`Year 2`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.00000    11.00000
n      7.00000    10.00000
mean   39.49571    93.33300
sd     28.80719    21.08291
se     10.88809     6.66700
median 33.33000   100.00000
min    5.88000    33.33000
max    70.59000   100.00000
sum    276.47000  933.33000

```

```

$MSAS$distype_all$`Total Dimension A`%`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  92.58      6.950          77.675          107.485
2      TIGET-NHx 40.57      8.311          22.747           58.397

```

```

$MSAS$distype_all$`Total Dimension A`%`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      5.200811e+01    1.084963e+01    2.873796e+01    7.527826e+01
2.860191e-04

```

```

$MSAS$distype_all$`Total Dimension A`%`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
2.0900 0.8340 3.3430 0.0011

```

```

$MSAS$distype_all$`Total Dimension A %`$`Year 3`
$MSAS$distype_all$`Total Dimension A %`$`Year 3`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.00000      11.000000
n      8.00000      11.000000
mean   23.28375      91.444545
sd     28.71318      24.727851
se     10.15164       7.455728
median 7.84000      100.000000
min    5.88000      17.650000
max    70.59000     100.000000
sum    186.27000    1005.890000

```

```

$MSAS$distype_all$`Total Dimension A %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  91.83      7.012      76.962      106.694
2      TIGET-NHx 22.76      8.224      5.324      40.190

```

```

$MSAS$distype_all$`Total Dimension A %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      6.907097e+01      1.081063e+01      4.615346e+01      9.198847e+01
8.968663e-06

```

```

$MSAS$distype_all$`Total Dimension A %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
2.4600 1.1960 3.7280 0.0001

```

```

$MSAS$distype_all$`Total Dimension B %`
$MSAS$distype_all$`Total Dimension B %`$`Year 2`
$MSAS$distype_all$`Total Dimension B %`$`Year 2`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.00000      11.00000
n      7.00000      10.00000
mean   27.61857      90.66600
sd     33.81560      28.93468
se     12.78109       9.14995
median 13.33000     100.00000
min    0.00000       8.33000
max    86.67000     100.00000
sum    193.33000     906.66000

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  89.53      8.148      72.049      107.002
2      TIGET-NHx 29.25      9.744      8.348      50.147

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      6.027781e+01      1.272098e+01      3.299402e+01      8.756159e+01
3.172836e-04

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
1.9300 0.7140 3.1490 0.0019

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 3`
$MSAS$distype_all$`Total Dimension B %`$`Year 3`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.00000    11.000000
n      8.00000    11.000000
mean   18.75125    89.544545
sd     34.44331    29.022896
se     12.17755     8.750732
median 0.83500    100.000000
min    0.00000     3.330000
max    86.67000    100.000000
sum    150.01000   984.990000

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  89.99      8.412      72.152      107.818
2 TIGET-NHx  18.15      9.865      -2.768      39.058

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      7.184008e+01    1.296836e+01    4.434838e+01    9.933178e+01
4.484409e-05

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
2.1600 0.9630 3.3480 0.0004

```

```

$MSAS$distype_all$`Total Dimension C %`
$MSAS$distype_all$`Total Dimension C %`$`Year 2`
$MSAS$distype_all$`Total Dimension C %`$`Year 2`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.000000    11.000000
n      7.000000    10.000000
mean   13.265714    85.002000
sd     26.150094    30.139361
se     9.883806     9.530903
median 0.000000    94.050000
min    0.000000     0.000000
max    69.050000    100.000000
sum    92.860000    850.020000

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  83.97      7.624      67.623      100.325
2 TIGET-NHx  14.73      9.117      -4.820      34.288

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      6.924021e+01    1.190208e+01    4.371279e+01    9.476762e+01
4.464801e-05

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
2.3800 1.0510 3.7090 0.0004

```



```

$MSAS$distype_all$`Total Dimension C %`$`Year 3`
$MSAS$distype_all$`Total Dimension C %`$`Year 3`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.000000    11.000000
n      8.000000    11.000000
mean   11.607500    84.849091
sd     24.660397    30.755818
se     8.718767     9.273228
median 0.000000    95.240000
min    0.000000    0.000000
max    69.050000   100.000000
sum    92.860000   933.340000

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  85.13      8.234      67.679      102.590
2      TIGET-NHx 11.22      9.656      -9.255      31.686

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      7.391844e+01    1.269397e+01    4.700842e+01    1.008285e+02
2.592968e-05

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
2.4600 1.1970 3.7290 0.0001

```

```

$MSAS$distype_all$`Total Dimension D %`
$MSAS$distype_all$`Total Dimension D %`$`Year 2`
$MSAS$distype_all$`Total Dimension D %`$`Year 2`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.000000    11.000000
n      7.000000    10.000000
mean   12.45429     73.077000
sd     21.97984     30.845200
se     8.30760     9.754109
median 0.000000    82.050000
min    0.000000    0.000000
max    56.41000    100.000000
sum    87.18000    730.770000

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  72.13      7.519      55.999      88.252
2      TIGET-NHx 13.81      8.992      -5.472      33.099

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      5.831202e+01    1.173849e+01    3.313547e+01    8.348858e+01
2.065775e-04

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
2.0800 0.8290 3.3350 0.0011

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 3`
$MSAS$distype_all$`Total Dimension D %`$`Year 3`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.000000    11.000000
n      8.000000    11.000000
mean   10.577500    72.959091
sd     20.985792    29.085147
se     7.419598     8.769502
median 0.000000    79.490000
min    0.000000     0.000000
max    56.410000   100.000000
sum    84.620000   802.550000

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  73.24      7.489      57.360      89.110
2      TIGET-NHx 10.20      8.782      -8.419      28.815

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      6.303689e+01  1.154477e+01  3.856308e+01  8.751071e+01
5.238195e-05

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
2.2900 1.0640 3.5100 0.0002

```

```

$MSAS$distype_all$`Total Dimension E %`
$MSAS$distype_all$`Total Dimension E %`$`Year 2`
$MSAS$distype_all$`Total Dimension E %`$`Year 2`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.000000    11.000000
n      7.000000    10.000000
mean   5.754286    59.444000
sd     10.220044    35.049610
se     3.862813    11.083660
median 0.000000    70.140000
min    0.000000     0.000000
max    25.000000    97.220000
sum    40.280000   594.440000

```

```

$MSAS$distype_all$`Total Dimension E %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  58.62      8.036      41.385      75.858
2      TIGET-NHx 6.93      9.611      -13.684     27.542

```

```

$MSAS$distype_all$`Total Dimension E %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      51.692746647  12.546501782  24.783176644  78.602316649
0.001040511

```

```

$MSAS$distype_all$`Total Dimension E %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
1.8300 0.6330 3.0190 0.0027

```

```

$MSAS$distype_all$`Total Dimension E %`$`Year 3`
$MSAS$distype_all$`Total Dimension E %`$`Year 3`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.000000    11.000000
n      8.000000    11.000000
mean   5.035000    65.02727
sd     9.678168    34.61470
se     3.421749    10.43672
median 0.000000    77.78000
min    0.000000    0.000000
max    25.000000   100.00000
sum    40.280000   715.30000

```

```

$MSAS$distype_all$`Total Dimension E %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  65.23      8.176      47.895      82.559
2      TIGET-NHx  4.76      9.588     -15.565     25.086

```

```

$MSAS$distype_all$`Total Dimension E %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      6.046666e+01    1.260402e+01    3.374733e+01    8.718600e+01
1.973665e-04

```

```

$MSAS$distype_all$`Total Dimension E %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
2.1000 0.9220 3.2820 0.0005

```

```

\#####
#####

```

```

[1] "GMFM presymptomatic vs. symptomatic comparison"
$MAS

```

```

$MAS$distype_all
$MAS$distype_all$`Total GMFM % Score`
$MAS$distype_all$`Total GMFM % Score`$`Year 2`
$MAS$distype_all$`Total GMFM % Score`$`Year 2`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      29.000000    20.000000
n      16.000000    11.000000
mean   26.190625    87.173636
sd     29.401489    12.899709
se     7.350372     3.889409
median 13.270000    91.010000
min    1.180000    57.450000
max    96.400000   100.000000
sum    419.050000   958.910000

```

```

$MAS$distype_all$`Total GMFM % Score`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      OTL-200  89.83      6.125      77.191     102.472
2      TIGET-NHx  24.36      5.066     13.908     34.819

```

```

$MAS$distype_all$`Total GMFM % Score`$`Year 2`$diffgrp_TRTvsCTRL

```

	LSM_Diff	LSM_Diff_se	LSM_Diff_lo95ci	LSM_Diff_hi95ci
LSM_Diff_pv	6.546766e+01	7.998685e+00	4.895919e+01	8.197614e+01
	2.101602e-08			

\$MAS\$distype_all\$`Total GMFM % Score`\$`Year 2`\$Hedgesg_TRTVsCTRL

	est	lo95ci	hi95ci	pv
	2.440	1.402	3.487	0.000

\$MAS\$distype_all\$`Total GMFM % Score`\$`Year 3`

\$MAS\$distype_all\$`Total GMFM % Score`\$`Year 3`\$numbers_eachgrp

	TIGET-NHx	OTL-200
N	29.000000	20.000000
n	18.000000	12.000000
mean	11.051111	85.740833
sd	15.613391	17.337712
se	3.680112	5.004966
median	4.000000	92.670000
min	1.180000	40.580000
max	56.410000	100.000000
sum	198.920000	1028.890000

\$MAS\$distype_all\$`Total GMFM % Score`\$`Year 3`\$ls_mw

	TRTVsCTRL	LSMean	LSMean_se	LSMean_lo95ci	LSMean_hi95ci
1	OTL-200	87.51	4.513	78.232	96.784
2	TIGET-NHx	10.07	3.775	2.312	17.832

\$MAS\$distype_all\$`Total GMFM % Score`\$`Year 3`\$diffgrp_TRTVsCTRL

	LSM_Diff	LSM_Diff_se	LSM_Diff_lo95ci	LSM_Diff_hi95ci
LSM_Diff_pv	7.743577e+01	5.953930e+00	6.519729e+01	8.967425e+01
	6.899103e-13			

\$MAS\$distype_all\$`Total GMFM % Score`\$`Year 3`\$Hedgesg_TRTVsCTRL

	est	lo95ci	hi95ci	pv
	4.450	3.042	5.868	0.000

\$MAS\$distype_all\$`Total Dimension A %`

\$MAS\$distype_all\$`Total Dimension A %`\$`Year 2`

\$MAS\$distype_all\$`Total Dimension A %`\$`Year 2`\$numbers_eachgrp

	TIGET-NHx	OTL-200
N	29	20
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

\$MAS\$distype_all\$`Total Dimension A %`\$`Year 2`\$ls_mw

	TRTVsCTRL	LSMean	LSMean_se	LSMean_lo95ci	LSMean_hi95ci
[1,]	NA	NA	NA	NA	NA
[2,]	NA	NA	NA	NA	NA

\$MAS\$distype_all\$`Total Dimension A %`\$`Year 2`\$diffgrp_TRTVsCTRL

	LSM_Diff	LSM_Diff_se	LSM_Diff_lo95ci	LSM_Diff_hi95ci
LSM_Diff_pv	NA	NA	NA	NA
NA				

```
$MAS$distype_all$`Total Dimension A %`$`Year 2`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
  NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 3`
$MAS$distype_all$`Total Dimension A %`$`Year 3`$numbers_eachgrp
  TIGET-NHx OTL-200
N           29      20
n           0       0
mean        NA      NA
sd          NA      NA
se          NA      NA
median      NA      NA
min         NA      NA
max         NA      NA
sum         NA      NA
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 3`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 3`$diffgrp_TRTvsCTRL
  LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  NA           NA           NA           NA
NA
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 3`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
  NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension B %`
$MAS$distype_all$`Total Dimension B %`$`Year 2`
$MAS$distype_all$`Total Dimension B %`$`Year 2`$numbers_eachgrp
  TIGET-NHx OTL-200
N           29      20
n           0       0
mean        NA      NA
sd          NA      NA
se          NA      NA
median      NA      NA
min         NA      NA
max         NA      NA
sum         NA      NA
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 2`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 2`$diffgrp_TRTvsCTRL
```

	LSM_Diff	LSM_Diff_se	LSM_Diff_lo95ci	LSM_Diff_hi95ci
LSM_Diff_pv	NA	NA	NA	NA
NA				

	est	lo95ci	hi95ci	pv
\$MAS\$distype_all\$`Total Dimension B %`\$`Year 2`\$Hedgesg_TRTVsCTRL	NA	NA	NA	NA

	TIGET-NHx	OTL-200
\$MAS\$distype_all\$`Total Dimension B %`\$`Year 3`	29	20
\$MAS\$distype_all\$`Total Dimension B %`\$`Year 3`\$numbers_eachgrp	0	0
N	29	20
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

	TRTVsCTRL	LSMean	LSMean_se	LSMean_lo95ci	LSMean_hi95ci
\$MAS\$distype_all\$`Total Dimension B %`\$`Year 3`\$ls_mw	NA	NA	NA	NA	NA
[1,]	NA	NA	NA	NA	NA
[2,]	NA	NA	NA	NA	NA

	LSM_Diff	LSM_Diff_se	LSM_Diff_lo95ci	LSM_Diff_hi95ci
\$MAS\$distype_all\$`Total Dimension B %`\$`Year 3`\$diffgrp_TRTVsCTRL	NA	NA	NA	NA
LSM_Diff_pv	NA	NA	NA	NA
NA				

	est	lo95ci	hi95ci	pv
\$MAS\$distype_all\$`Total Dimension B %`\$`Year 3`\$Hedgesg_TRTVsCTRL	NA	NA	NA	NA

	TIGET-NHx	OTL-200
\$MAS\$distype_all\$`Total Dimension C %`	29	20
\$MAS\$distype_all\$`Total Dimension C %`\$`Year 2`	0	0
\$MAS\$distype_all\$`Total Dimension C %`\$`Year 2`\$numbers_eachgrp	0	0
N	29	20
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

	TRTVsCTRL	LSMean	LSMean_se	LSMean_lo95ci	LSMean_hi95ci
\$MAS\$distype_all\$`Total Dimension C %`\$`Year 2`\$ls_mw	NA	NA	NA	NA	NA
[1,]	NA	NA	NA	NA	NA
[2,]	NA	NA	NA	NA	NA

\$MAS\$distype_all\$`Total Dimension C %`\$`Year 2`\$diffgrp_TRTVsCTRL
--

	LSM_Diff	LSM_Diff_se	LSM_Diff_lo95ci	LSM_Diff_hi95ci
LSM_Diff_pv	NA	NA	NA	NA
NA				

```
$MAS$distype_all$`Total Dimension C %`$`Year 2`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
  NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 3`
$MAS$distype_all$`Total Dimension C %`$`Year 3`$numbers_eachgrp
  TIGET-NHx OTL-200
N           29      20
n           0       0
mean        NA      NA
sd          NA      NA
se          NA      NA
median      NA      NA
min         NA      NA
max         NA      NA
sum         NA      NA
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 3`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA      NA      NA              NA          NA
[2,]        NA      NA      NA              NA          NA
```

	LSM_Diff	LSM_Diff_se	LSM_Diff_lo95ci	LSM_Diff_hi95ci
LSM_Diff_pv	NA	NA	NA	NA
NA				

```
$MAS$distype_all$`Total Dimension C %`$`Year 3`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
  NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension D %`
$MAS$distype_all$`Total Dimension D %`$`Year 2`
$MAS$distype_all$`Total Dimension D %`$`Year 2`$numbers_eachgrp
  TIGET-NHx OTL-200
N           29      20
n           0       0
mean        NA      NA
sd          NA      NA
se          NA      NA
median      NA      NA
min         NA      NA
max         NA      NA
sum         NA      NA
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 2`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA      NA      NA              NA          NA
[2,]        NA      NA      NA              NA          NA
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 2`$diffgrp_TRTvsCTRL
```

	LSM_Diff	LSM_Diff_se	LSM_Diff_lo95ci	LSM_Diff_hi95ci
LSM_Diff_pv	NA	NA	NA	NA
NA				

```
$MAS$distype_all$`Total Dimension D %`$`Year 2`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
  NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`
$MAS$distype_all$`Total Dimension D %`$`Year 3`$numbers_eachgrp
  TIGET-NHx OTL-200
N           29      20
n           0       0
mean        NA      NA
sd          NA      NA
se          NA      NA
median      NA      NA
min         NA      NA
max         NA      NA
sum         NA      NA
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA      NA      NA              NA          NA
[2,]        NA      NA      NA              NA          NA
```

	LSM_Diff	LSM_Diff_se	LSM_Diff_lo95ci	LSM_Diff_hi95ci
LSM_Diff_pv	NA	NA	NA	NA
NA				

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
  NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension E %`
$MAS$distype_all$`Total Dimension E %`$`Year 2`
$MAS$distype_all$`Total Dimension E %`$`Year 2`$numbers_eachgrp
  TIGET-NHx OTL-200
N           29      20
n           0       0
mean        NA      NA
sd          NA      NA
se          NA      NA
median      NA      NA
min         NA      NA
max         NA      NA
sum         NA      NA
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 2`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA      NA      NA              NA          NA
[2,]        NA      NA      NA              NA          NA
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 2`$diffgrp_TRTvsCTRL
```


	LSM_Diff	LSM_Diff_se	LSM_Diff_lo95ci	LSM_Diff_hi95ci
LSM_Diff_pv	NA	NA	NA	NA
NA				

```

$MAS$distype_all$`Total Dimension E %`$`Year 2`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
  NA      NA      NA      NA

```

```

$MAS$distype_all$`Total Dimension E %`$`Year 3`
$MAS$distype_all$`Total Dimension E %`$`Year 3`$numbers_eachgrp
  TIGET-NHx  OTL-200
N           29      20
n           0       0
mean        NA      NA
sd          NA      NA
se          NA      NA
median      NA      NA
min         NA      NA
max         NA      NA
sum         NA      NA

```

```

$MAS$distype_all$`Total Dimension E %`$`Year 3`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA      NA      NA           NA           NA
[2,]        NA      NA      NA           NA           NA

```

```

$MAS$distype_all$`Total Dimension E %`$`Year 3`$diffgrp_TRTvsCTRL
  LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  NA           NA           NA           NA
NA

```

```

$MAS$distype_all$`Total Dimension E %`$`Year 3`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
  NA      NA      NA      NA

```

\$MSAS

\$MSAS\$distype_all

```

$MSAS$distype_all$`Total GMFM % Score`
$MSAS$distype_all$`Total GMFM % Score`$`Year 2`
$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$numbers_eachgrp
  TIGET-NHx  OTL-200
N           10.00000  11.000000
n           7.00000  8.000000
mean        24.75286  90.712500
sd          34.32623  7.421543
se          12.97409  2.623912
median      9.33000  91.860000
min         1.18000  76.230000
max         96.40000  99.440000
sum         173.27000  725.700000

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci

```

1	OTL-200	89.43	6.878	74.444	104.418
2	TIGET-NHx	26.22	7.356	10.190	42.244

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  6.321392e+01    1.009470e+01    4.121945e+01    8.520839e+01
4.178013e-05

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
2.5900 1.1100 4.0740 0.0006

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`
$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$numbers_eachgrp
      TIGET-NHx      OTL-200
N      10.000000    11.000000
n       7.000000     9.000000
mean    8.580000    90.483333
sd     13.759284     9.503448
se      5.200521     3.167816
median  3.080000    95.170000
min     1.180000    71.210000
max     39.140000   100.000000
sum     60.060000   814.350000

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200    90.39    3.829      82.123      98.666
2  TIGET-NHx  8.69     4.342     -0.685      18.074

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  8.169977e+01    5.790186e+00    6.919084e+01    9.420871e+01
2.928822e-09

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
6.720 3.863 9.579 0.000

```

```

$MSAS$distype_all$`Total Dimension A %`
$MSAS$distype_all$`Total Dimension A %`$`Year 2`
$MSAS$distype_all$`Total Dimension A %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N       10      11
n        0       0
mean    NA     NA
sd     NA     NA
se     NA     NA
median  NA     NA
min     NA     NA
max     NA     NA
sum     NA     NA

```

```

$MSAS$distype_all$`Total Dimension A %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci

```

[1,]	NA	NA	NA	NA	NA
[2,]	NA	NA	NA	NA	NA

```

$MSAS$distype_all$`Total Dimension A %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA              NA              NA              NA
NA

```

```

$MSAS$distype_all$`Total Dimension A %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA

```

```

$MSAS$distype_all$`Total Dimension A %`$`Year 3`
$MSAS$distype_all$`Total Dimension A %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N          10      11
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MSAS$distype_all$`Total Dimension A %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA              NA              NA
[2,]      NA      NA      NA              NA              NA

```

```

$MSAS$distype_all$`Total Dimension A %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA              NA              NA              NA
NA

```

```

$MSAS$distype_all$`Total Dimension A %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA

```

```

$MSAS$distype_all$`Total Dimension B %`
$MSAS$distype_all$`Total Dimension B %`$`Year 2`
$MSAS$distype_all$`Total Dimension B %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N          10      11
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci

```

[1,]	NA	NA	NA	NA	NA
[2,]	NA	NA	NA	NA	NA

```

$MSAS$distype_all$`Total Dimension B %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA              NA              NA              NA
NA

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 3`
$MSAS$distype_all$`Total Dimension B %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N          10      11
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA              NA              NA              NA
NA

```

```

$MSAS$distype_all$`Total Dimension B %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA

```

```

$MSAS$distype_all$`Total Dimension C %`
$MSAS$distype_all$`Total Dimension C %`$`Year 2`
$MSAS$distype_all$`Total Dimension C %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N          10      11
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci

```

[1,]	NA	NA	NA	NA	NA
[2,]	NA	NA	NA	NA	NA

```

$MSAS$distype_all$`Total Dimension C %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA              NA              NA              NA
NA

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 3`
$MSAS$distype_all$`Total Dimension C %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N          10      11
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA              NA              NA
[2,]      NA      NA      NA              NA              NA

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA              NA              NA              NA
NA

```

```

$MSAS$distype_all$`Total Dimension C %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA

```

```

$MSAS$distype_all$`Total Dimension D %`
$MSAS$distype_all$`Total Dimension D %`$`Year 2`
$MSAS$distype_all$`Total Dimension D %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N          10      11
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci

```

[1,]	NA	NA	NA	NA	NA
[2,]	NA	NA	NA	NA	NA

```

$MSAS$distype_all$`Total Dimension D %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA              NA              NA              NA
NA

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 3`
$MSAS$distype_all$`Total Dimension D %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N          10      11
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA              NA              NA              NA
NA

```

```

$MSAS$distype_all$`Total Dimension D %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA

```

```

$MSAS$distype_all$`Total Dimension E %`
$MSAS$distype_all$`Total Dimension E %`$`Year 2`
$MSAS$distype_all$`Total Dimension E %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N          10      11
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MSAS$distype_all$`Total Dimension E %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci

```

```
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA              NA              NA              NA
NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 3`
$MSAS$distype_all$`Total Dimension E %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N          10      11
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA              NA              NA              NA
NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
\#####
#####
```

```
[1] "GMFM sensitivity"
```

```
$MAS
```

```
$MAS$distype_all
```

```
$MAS$distype_all$`Total GMFM % Score`
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 2`
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 2`$numbers_eachgrp
```

```
      TIGET-NHx      OTL-200
N          29.000000    20.000000
n          20.000000    17.000000
mean       6.960500    73.417647
sd         18.432365    27.744580
```

se	4.121602	6.729049
median	0.000000	85.840000
min	0.000000	8.330000
max	74.440000	100.000000
sum	139.210000	1248.100000

```
$MAS$distype_all$`Total GMFM % Score`$`Year 2`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  73.77    5.547      62.493      85.040
2  TIGET-NHx  6.66    5.114      -3.728      17.056
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 2`$diffgrp_TRTvsCTRL
  LSM_Diff    LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  6.710272e+01  7.551576e+00  5.175607e+01  8.244937e+01
2.193601e-10
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 2`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci    pv
  2.810  1.872  3.744  0.000
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`
$MAS$distype_all$`Total GMFM % Score`$`Year 3`$numbers_eachgrp
  TIGET-NHx    OTL-200
N      29.000000    20.000000
n      23.000000    18.000000
mean   7.948696    71.376111
sd     18.482045    29.723462
se     3.853773    7.005887
median 0.000000    78.815000
min    0.000000    4.200000
max    74.440000    100.000000
sum    182.820000    1284.770000
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  71.45    5.641      60.027      82.868
2  TIGET-NHx  7.89    4.991      -2.210      17.996
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`$diffgrp_TRTvsCTRL
  LSM_Diff    LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  6.355409e+01  7.532481e+00  4.830538e+01  7.880280e+01
3.068780e-10
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci    pv
  2.590  1.735  3.441  0.000
```

```
$MAS$distype_all$`Total Dimension A %`
$MAS$distype_all$`Total Dimension A %`$`Year 2`
$MAS$distype_all$`Total Dimension A %`$`Year 2`$numbers_eachgrp
  TIGET-NHx    OTL-200
N      29      20
n      0      0
mean   NA     NA
sd     NA     NA
```


se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MAS$distype_all$`Total Dimension A %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 3`
$MAS$distype_all$`Total Dimension A %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N      29      20
n      0      0
mean   NA      NA
sd     NA      NA
se     NA      NA
median NA      NA
min    NA      NA
max    NA      NA
sum    NA      NA
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension B %`
$MAS$distype_all$`Total Dimension B %`$`Year 2`
$MAS$distype_all$`Total Dimension B %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N      29      20
n      0      0
mean   NA      NA
sd     NA      NA
```

se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MAS$distype_all$`Total Dimension B %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA          NA          NA          NA
[2,]      NA      NA          NA          NA          NA
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA          NA          NA          NA
NA
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 3`
$MAS$distype_all$`Total Dimension B %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N          29      20
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA          NA          NA          NA
[2,]      NA      NA          NA          NA          NA
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA          NA          NA          NA
NA
```

```
$MAS$distype_all$`Total Dimension B %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension C %`
$MAS$distype_all$`Total Dimension C %`$`Year 2`
$MAS$distype_all$`Total Dimension C %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N          29      20
n           0       0
mean       NA      NA
sd         NA      NA
```

se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MAS$distype_all$`Total Dimension C %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 3`
$MAS$distype_all$`Total Dimension C %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N      29      20
n      0      0
mean   NA      NA
sd     NA      NA
se     NA      NA
median NA      NA
min    NA      NA
max    NA      NA
sum    NA      NA
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MAS$distype_all$`Total Dimension C %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension D %`
$MAS$distype_all$`Total Dimension D %`$`Year 2`
$MAS$distype_all$`Total Dimension D %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N      29      20
n      0      0
mean   NA      NA
sd     NA      NA
```

se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MAS$distype_all$`Total Dimension D %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`
$MAS$distype_all$`Total Dimension D %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N      29      20
n      0      0
mean   NA      NA
sd     NA      NA
se     NA      NA
median NA      NA
min    NA      NA
max    NA      NA
sum    NA      NA
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension E %`
$MAS$distype_all$`Total Dimension E %`$`Year 2`
$MAS$distype_all$`Total Dimension E %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N      29      20
n      0      0
mean   NA      NA
sd     NA      NA
```

se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MAS$distype_all$`Total Dimension E %`$`Year 2`$ls_mw
      TRTVsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 2`$diffgrp_TRTVsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 2`$Hedgesg_TRTVsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 3`
$MAS$distype_all$`Total Dimension E %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N      29      20
n      0      0
mean   NA      NA
sd     NA      NA
se     NA      NA
median NA      NA
min    NA      NA
max    NA      NA
sum    NA      NA
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 3`$ls_mw
      TRTVsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 3`$diffgrp_TRTVsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 3`$Hedgesg_TRTVsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MSAS
$MSAS$distype_all
$MSAS$distype_all$`Total GMFM % Score`
$MSAS$distype_all$`Total GMFM % Score`$`Year 2`
$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$numbers_eachgrp
      TIGET-NHx      OTL-200
```

N	11.000000	11.000000
n	9.000000	10.000000
mean	5.051111	80.303000
sd	13.093545	26.998533
se	4.364515	8.537686
median	0.000000	89.465000
min	0.000000	8.330000
max	39.580000	99.440000
sum	45.460000	803.030000

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  80.16      6.245      66.923      93.402
2  TIGET-NHx  5.21      6.583      -8.749      19.163

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$diffgrp_TRTvsCTRL
  LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  7.495521e+01    9.074861e+00    5.571736e+01    9.419306e+01
3.655154e-07

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
3.330 1.837 4.819 0.000

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`
$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$numbers_eachgrp
  TIGET-NHx      OTL-200
N      11.000000    11.000000
n      9.000000    11.000000
mean   4.740000    80.766364
sd     13.083245    27.483123
se     4.361082     8.286473
median 0.000000    90.170000
min    0.000000     4.200000
max    39.580000   100.000000
sum    42.660000   888.430000

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  81.29      6.609      67.343      95.231
2  TIGET-NHx  4.10      7.310      -11.319     19.525

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$diffgrp_TRTvsCTRL
  LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
  7.718420e+01    9.875043e+00    5.634968e+01    9.801872e+01
5.002367e-07

```

```

$MSAS$distype_all$`Total GMFM % Score`$`Year 3`$Hedgesg_TRTvsCTRL
  est lo95ci hi95ci      pv
3.270 1.837 4.704 0.000

```

```

$MSAS$distype_all$`Total Dimension A %`
$MSAS$distype_all$`Total Dimension A %`$`Year 2`
$MSAS$distype_all$`Total Dimension A %`$`Year 2`$numbers_eachgrp
  TIGET-NHx OTL-200

```

N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MSAS$distype_all$`Total Dimension A %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension A %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MSAS$distype_all$`Total Dimension A %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension A %`$`Year 3`
$MSAS$distype_all$`Total Dimension A %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N      11      11
n      0      0
mean   NA      NA
sd     NA      NA
se     NA      NA
median NA      NA
min    NA      NA
max    NA      NA
sum    NA      NA
```

```
$MSAS$distype_all$`Total Dimension A %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension A %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MSAS$distype_all$`Total Dimension A %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension B %`
$MSAS$distype_all$`Total Dimension B %`$`Year 2`
$MSAS$distype_all$`Total Dimension B %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
```

N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MSAS$distype_all$`Total Dimension B %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension B %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MSAS$distype_all$`Total Dimension B %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension B %`$`Year 3`
$MSAS$distype_all$`Total Dimension B %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N      11      11
n      0      0
mean   NA      NA
sd     NA      NA
se     NA      NA
median NA      NA
min    NA      NA
max    NA      NA
sum    NA      NA
```

```
$MSAS$distype_all$`Total Dimension B %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension B %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MSAS$distype_all$`Total Dimension B %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension C %`
$MSAS$distype_all$`Total Dimension C %`$`Year 2`
$MSAS$distype_all$`Total Dimension C %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
```


N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MSAS$distype_all$`Total Dimension C %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension C %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MSAS$distype_all$`Total Dimension C %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension C %`$`Year 3`
$MSAS$distype_all$`Total Dimension C %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N      11      11
n      0      0
mean   NA      NA
sd     NA      NA
se     NA      NA
median NA      NA
min    NA      NA
max    NA      NA
sum    NA      NA
```

```
$MSAS$distype_all$`Total Dimension C %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension C %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MSAS$distype_all$`Total Dimension C %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension D %`
$MSAS$distype_all$`Total Dimension D %`$`Year 2`
$MSAS$distype_all$`Total Dimension D %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
```

N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MSAS$distype_all$`Total Dimension D %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension D %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MSAS$distype_all$`Total Dimension D %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension D %`$`Year 3`
$MSAS$distype_all$`Total Dimension D %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N      11      11
n      0      0
mean   NA      NA
sd     NA      NA
se     NA      NA
median NA      NA
min    NA      NA
max    NA      NA
sum    NA      NA
```

```
$MSAS$distype_all$`Total Dimension D %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension D %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MSAS$distype_all$`Total Dimension D %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension E %`
$MSAS$distype_all$`Total Dimension E %`$`Year 2`
$MSAS$distype_all$`Total Dimension E %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
```

N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MSAS$distype_all$`Total Dimension E %`$`Year 2`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 3`
$MSAS$distype_all$`Total Dimension E %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N      11      11
n      0      0
mean   NA      NA
sd     NA      NA
se     NA      NA
median NA      NA
min    NA      NA
max    NA      NA
sum    NA      NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]      NA      NA      NA      NA      NA
[2,]      NA      NA      NA      NA      NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      NA      NA      NA      NA
NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
      NA      NA      NA      NA
```

```
\#####  
#####
```

```
[1] "GMFM sensitivity Kruskal Wallis"
```

```
$MAS
```

```
$MAS$distype_all
```

```
$MAS$distype_all$`Total GMFM % Score`
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 2`
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 2`$numbers_eachgrp
```

	TIGET-NHx	OTL-200
N	29.000000	20.000000
n	20.000000	17.000000
mean	6.960500	73.417647
sd	18.432365	27.744580
se	4.121602	6.729049
median	0.000000	85.840000
min	0.000000	8.330000
max	74.440000	100.000000
sum	139.210000	1248.100000

```
$MAS$distype_all$`Total GMFM % Score`$`Year 2`$effect_TRTvsCTRL
```

```
est pv  
25.47 0.00
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`
```

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`$numbers_eachgrp
```

	TIGET-NHx	OTL-200
N	29.000000	20.000000
n	23.000000	18.000000
mean	7.948696	71.376111
sd	18.482045	29.723462
se	3.853773	7.005887
median	0.000000	78.815000
min	0.000000	4.200000
max	74.440000	100.000000
sum	182.820000	1284.770000

```
$MAS$distype_all$`Total GMFM % Score`$`Year 3`$effect_TRTvsCTRL
```

```
est pv  
26.2 0.0
```

```
$MAS$distype_all$`Total Dimension A %`
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 2`
```

```
$MAS$distype_all$`Total Dimension A %`$`Year 2`$numbers_eachgrp
```

	TIGET-NHx	OTL-200
N	29	20
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MAS$distype_all$`Total Dimension A %`$`Year 2`$effect_TRTvsCTRL
```

```
est pv  
NA NA
```

```

$MAS$distype_all$`Total Dimension A %`$`Year 3`
$MAS$distype_all$`Total Dimension A %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N          29      20
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MAS$distype_all$`Total Dimension A %`$`Year 3`$effect_TRTvsCTRL
est  pv
NA  NA

```

```

$MAS$distype_all$`Total Dimension B %`
$MAS$distype_all$`Total Dimension B %`$`Year 2`
$MAS$distype_all$`Total Dimension B %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N          29      20
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MAS$distype_all$`Total Dimension B %`$`Year 2`$effect_TRTvsCTRL
est  pv
NA  NA

```

```

$MAS$distype_all$`Total Dimension B %`$`Year 3`
$MAS$distype_all$`Total Dimension B %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N          29      20
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MAS$distype_all$`Total Dimension B %`$`Year 3`$effect_TRTvsCTRL
est  pv
NA  NA

```

```

$MAS$distype_all$`Total Dimension C %`

```

```

$MAS$distype_all$`Total Dimension C %`$`Year 2`
$MAS$distype_all$`Total Dimension C %`$`Year 2`$numbers_eachgrp
      TIGET-NHx  OTL-200
N          29      20
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MAS$distype_all$`Total Dimension C %`$`Year 2`$effect_TRTvsCTRL
est  pv
NA  NA

```

```

$MAS$distype_all$`Total Dimension C %`$`Year 3`
$MAS$distype_all$`Total Dimension C %`$`Year 3`$numbers_eachgrp
      TIGET-NHx  OTL-200
N          29      20
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MAS$distype_all$`Total Dimension C %`$`Year 3`$effect_TRTvsCTRL
est  pv
NA  NA

```

```

$MAS$distype_all$`Total Dimension D %`
$MAS$distype_all$`Total Dimension D %`$`Year 2`
$MAS$distype_all$`Total Dimension D %`$`Year 2`$numbers_eachgrp
      TIGET-NHx  OTL-200
N          29      20
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA

```

```

$MAS$distype_all$`Total Dimension D %`$`Year 2`$effect_TRTvsCTRL
est  pv
NA  NA

```

```

$MAS$distype_all$`Total Dimension D %`$`Year 3`
$MAS$distype_all$`Total Dimension D %`$`Year 3`$numbers_eachgrp
      TIGET-NHx  OTL-200
N          29      20

```

n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MAS$distype_all$`Total Dimension D %`$`Year 3`$effect_TRTvsCTRL
est pv
NA NA
```

```
$MAS$distype_all$`Total Dimension E %`
$MAS$distype_all$`Total Dimension E %`$`Year 2`
$MAS$distype_all$`Total Dimension E %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N      29      20
n      0      0
mean   NA     NA
sd     NA     NA
se     NA     NA
median NA     NA
min    NA     NA
max    NA     NA
sum    NA     NA
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 2`$effect_TRTvsCTRL
est pv
NA NA
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 3`
$MAS$distype_all$`Total Dimension E %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N      29      20
n      0      0
mean   NA     NA
sd     NA     NA
se     NA     NA
median NA     NA
min    NA     NA
max    NA     NA
sum    NA     NA
```

```
$MAS$distype_all$`Total Dimension E %`$`Year 3`$effect_TRTvsCTRL
est pv
NA NA
```

```
$MSAS
$MSAS$distype_all
$MSAS$distype_all$`Total GMFM % Score`
$MSAS$distype_all$`Total GMFM % Score`$`Year 2`
$MSAS$distype_all$`Total GMFM % Score`$`Year 2`$numbers_eachgrp
```

	TIGET-NHx	OTL-200
N	11.000000	11.000000
n	9.000000	10.000000
mean	5.051111	80.303000
sd	13.093545	26.998533
se	4.364515	8.537686
median	0.000000	89.465000
min	0.000000	8.330000
max	39.580000	99.440000
sum	45.460000	803.030000

\$MSAS\$distype_all\$`Total GMFM % Score`\$`Year 2`\$effect_TRTvsCTRL
 est pv
 13.5700 0.0002

\$MSAS\$distype_all\$`Total GMFM % Score`\$`Year 3`
 \$MSAS\$distype_all\$`Total GMFM % Score`\$`Year 3`\$numbers_eachgrp

	TIGET-NHx	OTL-200
N	11.000000	11.000000
n	9.000000	11.000000
mean	4.740000	80.766364
sd	13.083245	27.483123
se	4.361082	8.286473
median	0.000000	90.170000
min	0.000000	4.200000
max	39.580000	100.000000
sum	42.660000	888.430000

\$MSAS\$distype_all\$`Total GMFM % Score`\$`Year 3`\$effect_TRTvsCTRL
 est pv
 13.9500 0.0002

\$MSAS\$distype_all\$`Total Dimension A %`
 \$MSAS\$distype_all\$`Total Dimension A %`\$`Year 2`
 \$MSAS\$distype_all\$`Total Dimension A %`\$`Year 2`\$numbers_eachgrp

	TIGET-NHx	OTL-200
N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

\$MSAS\$distype_all\$`Total Dimension A %`\$`Year 2`\$effect_TRTvsCTRL
 est pv
 NA NA

\$MSAS\$distype_all\$`Total Dimension A %`\$`Year 3`
 \$MSAS\$distype_all\$`Total Dimension A %`\$`Year 3`\$numbers_eachgrp

	TIGET-NHx	OTL-200
N	11	11
n	0	0
mean	NA	NA

sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

\$MSAS\$distype_all\$`Total Dimension A %`\$`Year 3`\$effect_TRTvsCTRL
est pv
NA NA

\$MSAS\$distype_all\$`Total Dimension B %`
\$MSAS\$distype_all\$`Total Dimension B %`\$`Year 2`
\$MSAS\$distype_all\$`Total Dimension B %`\$`Year 2`\$numbers_eachgrp
TIGET-NHx OTL-200

N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

\$MSAS\$distype_all\$`Total Dimension B %`\$`Year 2`\$effect_TRTvsCTRL
est pv
NA NA

\$MSAS\$distype_all\$`Total Dimension B %`\$`Year 3`
\$MSAS\$distype_all\$`Total Dimension B %`\$`Year 3`\$numbers_eachgrp
TIGET-NHx OTL-200

N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

\$MSAS\$distype_all\$`Total Dimension B %`\$`Year 3`\$effect_TRTvsCTRL
est pv
NA NA

\$MSAS\$distype_all\$`Total Dimension C %`
\$MSAS\$distype_all\$`Total Dimension C %`\$`Year 2`
\$MSAS\$distype_all\$`Total Dimension C %`\$`Year 2`\$numbers_eachgrp
TIGET-NHx OTL-200

N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA

median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

\$MSAS\$distype_all\$`Total Dimension C %`\$`Year 2`\$effect_TRTvsCTRL
 est pv
 NA NA

\$MSAS\$distype_all\$`Total Dimension C %`\$`Year 3`
 \$MSAS\$distype_all\$`Total Dimension C %`\$`Year 3`\$numbers_eachgrp
 TIGET-NHx OTL-200

N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

\$MSAS\$distype_all\$`Total Dimension C %`\$`Year 3`\$effect_TRTvsCTRL
 est pv
 NA NA

\$MSAS\$distype_all\$`Total Dimension D %`
 \$MSAS\$distype_all\$`Total Dimension D %`\$`Year 2`
 \$MSAS\$distype_all\$`Total Dimension D %`\$`Year 2`\$numbers_eachgrp
 TIGET-NHx OTL-200

N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

\$MSAS\$distype_all\$`Total Dimension D %`\$`Year 2`\$effect_TRTvsCTRL
 est pv
 NA NA

\$MSAS\$distype_all\$`Total Dimension D %`\$`Year 3`
 \$MSAS\$distype_all\$`Total Dimension D %`\$`Year 3`\$numbers_eachgrp
 TIGET-NHx OTL-200

N	11	11
n	0	0
mean	NA	NA
sd	NA	NA
se	NA	NA
median	NA	NA
min	NA	NA
max	NA	NA
sum	NA	NA

```
$MSAS$distype_all$`Total Dimension D %`$`Year 3`$effect_TRTvsCTRL
est pv
NA NA
```

```
$MSAS$distype_all$`Total Dimension E %`
$MSAS$distype_all$`Total Dimension E %`$`Year 2`
$MSAS$distype_all$`Total Dimension E %`$`Year 2`$numbers_eachgrp
      TIGET-NHx OTL-200
N          11      11
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 2`$effect_TRTvsCTRL
est pv
NA NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 3`
$MSAS$distype_all$`Total Dimension E %`$`Year 3`$numbers_eachgrp
      TIGET-NHx OTL-200
N          11      11
n           0       0
mean       NA      NA
sd         NA      NA
se         NA      NA
median     NA      NA
min        NA      NA
max        NA      NA
sum        NA      NA
```

```
$MSAS$distype_all$`Total Dimension E %`$`Year 3`$effect_TRTvsCTRL
est pv
NA NA
```

```
\#####
#####
[1] "IQ responder"
$ITT
$ITT$distype_all
$ITT$distype_all$`Total Intelligence quotient (IQ) - Composite`
$ITT$distype_all$`Total Intelligence quotient (IQ) - Composite`$Baseline
$ITT$distype_all$`Total Intelligence quotient (IQ) -
Composite`$Baseline$ntab
      CTRL TRT
N          20  20
n_all       8   8
```

n_event	8	8
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year 2`
 \$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 2`\$ntab

	CTRL	TRT
N	20	20
n_all	8	8
n_event	8	8
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 2.5`
 \$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 2.5`\$ntab

	CTRL	TRT
N	20	20
n_all	11	11
n_event	11	11
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year 3`
 \$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 3`\$ntab

	CTRL	TRT
N	20	20
n_all	12	12
n_event	12	12
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$ITT\$distype_all\$`Processing speed Index - Composite`
 \$ITT\$distype_all\$`Processing speed Index - Composite`\$Baseline
 \$ITT\$distype_all\$`Processing speed Index - Composite`\$Baseline\$ntab

	CTRL	TRT
N	20.00000	20.00000
n_all	7.00000	7.00000
n_event	6.00000	6.00000
n_event_pct	85.71429	85.71429
n_nonevent	1.00000	1.00000
n_nonevent_pct	14.28571	14.28571

\$ITT\$distype_all\$`Processing speed Index - Composite`\$`Year 2`
 \$ITT\$distype_all\$`Processing speed Index - Composite`\$`Year 2`\$ntab

	CTRL	TRT
N	20.00000	20.00000

n_all	7.00000	7.00000
n_event	5.00000	5.00000
n_event_pct	71.42857	71.42857
n_nonevent	2.00000	2.00000
n_nonevent_pct	28.57143	28.57143

\$ITTT\$distype_all\$`Processing speed Index - Composite`\$`Year 2.5`
 \$ITTT\$distype_all\$`Processing speed Index - Composite`\$`Year 2.5`\$ntab

	CTRL	TRT
N	20	20
n_all	8	8
n_event	6	6
n_event_pct	75	75
n_nonevent	2	2
n_nonevent_pct	25	25

\$ITTT\$distype_all\$`Processing speed Index - Composite`\$`Year 3`
 \$ITTT\$distype_all\$`Processing speed Index - Composite`\$`Year 3`\$ntab

	CTRL	TRT
N	20.00000	20.00000
n_all	11.00000	11.00000
n_event	8.00000	8.00000
n_event_pct	72.72727	72.72727
n_nonevent	3.00000	3.00000
n_nonevent_pct	27.27273	27.27273

\$ITTT\$distype_all\$`Working memory Index - Composite`
 \$ITTT\$distype_all\$`Working memory Index - Composite`\$Baseline
 \$ITTT\$distype_all\$`Working memory Index - Composite`\$Baseline\$ntab

	CTRL	TRT
N	20	20
n_all	3	3
n_event	3	3
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$ITTT\$distype_all\$`Working memory Index - Composite`\$`Year 2`
 \$ITTT\$distype_all\$`Working memory Index - Composite`\$`Year 2`\$ntab

	CTRL	TRT
N	20	20
n_all	6	6
n_event	6	6
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$ITTT\$distype_all\$`Working memory Index - Composite`\$`Year 2.5`
 \$ITTT\$distype_all\$`Working memory Index - Composite`\$`Year 2.5`\$ntab

	CTRL	TRT
N	20	20
n_all	5	5
n_event	5	5
n_event_pct	100	100

n_nonevent	0	0
n_nonevent_pct	0	0

\$ITT\$distype_all\$`Working memory Index - Composite`\$`Year 3`
\$ITT\$distype_all\$`Working memory Index - Composite`\$`Year 3`\$ntab

	CTRL	TRT
N	20	20
n_all	5	5
n_event	5	5
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$ITT\$distype_all\$`Language score - Composite`
\$ITT\$distype_all\$`Language score - Composite`\$Baseline
\$ITT\$distype_all\$`Language score - Composite`\$Baseline\$ntab

	CTRL	TRT
N	20	20
n_all	18	18
n_event	18	18
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$ITT\$distype_all\$`Language score - Composite`\$`Year 2`
\$ITT\$distype_all\$`Language score - Composite`\$`Year 2`\$ntab

	CTRL	TRT
N	20.00	20.00
n_all	16.00	16.00
n_event	15.00	15.00
n_event_pct	93.75	93.75
n_nonevent	1.00	1.00
n_nonevent_pct	6.25	6.25

\$ITT\$distype_all\$`Language score - Composite`\$`Year 2.5`
\$ITT\$distype_all\$`Language score - Composite`\$`Year 2.5`\$ntab

	CTRL	TRT
N	20.000000	20.000000
n_all	15.000000	15.000000
n_event	14.000000	14.000000
n_event_pct	93.333333	93.333333
n_nonevent	1.000000	1.000000
n_nonevent_pct	6.666667	6.666667

\$ITT\$distype_all\$`Language score - Composite`\$`Year 3`
\$ITT\$distype_all\$`Language score - Composite`\$`Year 3`\$ntab

	CTRL	TRT
N	20.00000	20.00000
n_all	13.00000	13.00000
n_event	11.00000	11.00000
n_event_pct	84.61538	84.61538
n_nonevent	2.00000	2.00000
n_nonevent_pct	15.38462	15.38462

\$ITT\$distype_all\$`Performance score - Composite`
 \$ITT\$distype_all\$`Performance score - Composite`\$Baseline
 \$ITT\$distype_all\$`Performance score - Composite`\$Baseline\$ntab
 CTRL TRT
 N 20.000000 20.000000
 n_all 19.000000 19.000000
 n_event 18.000000 18.000000
 n_event_pct 94.736842 94.736842
 n_nonevent 1.000000 1.000000
 n_nonevent_pct 5.263158 5.263158

\$ITT\$distype_all\$`Performance score - Composite`\$`Year 2`
 \$ITT\$distype_all\$`Performance score - Composite`\$`Year 2`\$ntab
 CTRL TRT
 N 20.000000 20.000000
 n_all 17.000000 17.000000
 n_event 15.000000 15.000000
 n_event_pct 88.23529 88.23529
 n_nonevent 2.000000 2.000000
 n_nonevent_pct 11.76471 11.76471

\$ITT\$distype_all\$`Performance score - Composite`\$`Year 2.5`
 \$ITT\$distype_all\$`Performance score - Composite`\$`Year 2.5`\$ntab
 CTRL TRT
 N 20.000000 20.000000
 n_all 15.000000 15.000000
 n_event 14.000000 14.000000
 n_event_pct 93.333333 93.333333
 n_nonevent 1.000000 1.000000
 n_nonevent_pct 6.666667 6.666667

\$ITT\$distype_all\$`Performance score - Composite`\$`Year 3`
 \$ITT\$distype_all\$`Performance score - Composite`\$`Year 3`\$ntab
 CTRL TRT
 N 20.000000 20.000000
 n_all 14.000000 14.000000
 n_event 12.000000 12.000000
 n_event_pct 85.71429 85.71429
 n_nonevent 2.000000 2.000000
 n_nonevent_pct 14.28571 14.28571

\$MSAS
 \$MSAS\$distype_all
 \$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`
 \$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$Baseline
 \$MSAS\$distype_all\$`Total Intelligence quotient (IQ) -
 Composite`\$Baseline\$ntab
 CTRL TRT
 N 11 11
 n_all 3 3
 n_event 3 3

n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year 2`
 \$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 2`\$ntab

	CTRL	TRT
N	11	11
n_all	4	4
n_event	4	4
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 2.5`

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 2.5`\$ntab

	CTRL	TRT
N	11	11
n_all	6	6
n_event	6	6
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year 3`
 \$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 3`\$ntab

	CTRL	TRT
N	11	11
n_all	7	7
n_event	7	7
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Processing speed Index - Composite`

\$MSAS\$distype_all\$`Processing speed Index - Composite`\$Baseline

\$MSAS\$distype_all\$`Processing speed Index - Composite`\$Baseline\$ntab

	CTRL	TRT
N	11	11
n_all	3	3
n_event	3	3
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Processing speed Index - Composite`\$`Year 2`

\$MSAS\$distype_all\$`Processing speed Index - Composite`\$`Year 2`\$ntab

	CTRL	TRT
N	11.00000	11.00000
n_all	3.00000	3.00000

n_event	2.00000	2.00000
n_event_pct	66.66667	66.66667
n_nonevent	1.00000	1.00000
n_nonevent_pct	33.33333	33.33333

\$MSAS\$distype_all\$`Processing speed Index - Composite`\$`Year 2.5`
 \$MSAS\$distype_all\$`Processing speed Index - Composite`\$`Year 2.5`\$ntab

	CTRL	TRT
N	11	11
n_all	4	4
n_event	4	4
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Processing speed Index - Composite`\$`Year 3`
 \$MSAS\$distype_all\$`Processing speed Index - Composite`\$`Year 3`\$ntab

	CTRL	TRT
N	11	11
n_all	6	6
n_event	6	6
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Working memory Index - Composite`
 \$MSAS\$distype_all\$`Working memory Index - Composite`\$Baseline
 \$MSAS\$distype_all\$`Working memory Index - Composite`\$Baseline\$ntab

	CTRL	TRT
N	11	11
n_all	1	1
n_event	1	1
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Working memory Index - Composite`\$`Year 2`
 \$MSAS\$distype_all\$`Working memory Index - Composite`\$`Year 2`\$ntab

	CTRL	TRT
N	11	11
n_all	3	3
n_event	3	3
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Working memory Index - Composite`\$`Year 2.5`
 \$MSAS\$distype_all\$`Working memory Index - Composite`\$`Year 2.5`\$ntab

	CTRL	TRT
N	11	11
n_all	2	2
n_event	2	2
n_event_pct	100	100
n_nonevent	0	0

n_nonevent_pct 0 0

\$MSAS\$distype_all\$`Working memory Index - Composite`\$`Year 3`
\$MSAS\$distype_all\$`Working memory Index - Composite`\$`Year 3`\$ntab

	CTRL	TRT
N	11	11
n_all	2	2
n_event	2	2
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Language score - Composite`
\$MSAS\$distype_all\$`Language score - Composite`\$Baseline
\$MSAS\$distype_all\$`Language score - Composite`\$Baseline\$ntab

	CTRL	TRT
N	11	11
n_all	10	10
n_event	10	10
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Language score - Composite`\$`Year 2`
\$MSAS\$distype_all\$`Language score - Composite`\$`Year 2`\$ntab

	CTRL	TRT
N	11	11
n_all	9	9
n_event	9	9
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Language score - Composite`\$`Year 2.5`
\$MSAS\$distype_all\$`Language score - Composite`\$`Year 2.5`\$ntab

	CTRL	TRT
N	11	11
n_all	8	8
n_event	8	8
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

\$MSAS\$distype_all\$`Language score - Composite`\$`Year 3`
\$MSAS\$distype_all\$`Language score - Composite`\$`Year 3`\$ntab

	CTRL	TRT
N	11	11
n_all	7	7
n_event	7	7
n_event_pct	100	100
n_nonevent	0	0
n_nonevent_pct	0	0

```
$MSAS$distype_all$`Performance score - Composite`
$MSAS$distype_all$`Performance score - Composite`$Baseline
$MSAS$distype_all$`Performance score - Composite`$Baseline$ntab
```

```
CTRL TRT
N          11  11
n_all     11  11
n_event   11  11
n_event_pct 100 100
n_nonevent 0   0
n_nonevent_pct 0   0
```

```
$MSAS$distype_all$`Performance score - Composite`$`Year 2`
$MSAS$distype_all$`Performance score - Composite`$`Year 2`$ntab
```

```
CTRL TRT
N          11  11
n_all     10  10
n_event    9   9
n_event_pct 90  90
n_nonevent 1   1
n_nonevent_pct 10 10
```

```
$MSAS$distype_all$`Performance score - Composite`$`Year 2.5`
$MSAS$distype_all$`Performance score - Composite`$`Year 2.5`$ntab
```

```
CTRL TRT
N          11  11
n_all      8   8
n_event    8   8
n_event_pct 100 100
n_nonevent 0   0
n_nonevent_pct 0   0
```

```
$MSAS$distype_all$`Performance score - Composite`$`Year 3`
$MSAS$distype_all$`Performance score - Composite`$`Year 3`$ntab
```

```
CTRL TRT
N         11.0 11.0
n_all     8.0  8.0
n_event   7.0  7.0
n_event_pct 87.5 87.5
n_nonevent 1.0  1.0
n_nonevent_pct 12.5 12.5
```

```
\#####
#####
[1] "IQ Means"
$ITT
$ITT$distype_all
$ITT$distype_all$`Total Intelligence quotient (IQ) - Composite`
$ITT$distype_all$`Total Intelligence quotient (IQ) - Composite`$Baseline
$ITT$distype_all$`Total Intelligence quotient (IQ) -
Composite`$Baseline$numbers_eachgrp
```

	N	n	mean	sd	se	median
min	max	sum				
20.000000	8.000000	96.000000	22.462667	7.941752	95.000000	
58.000000	131.000000	768.000000				

\$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year 2`
 \$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 2`\$numbers_eachgrp

	N	n	mean	sd	se	median
min	max	sum				
20.000000	8.000000	101.000000	18.913336	6.686874	93.500000	
83.000000	132.000000	808.000000				

\$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 2.5`

\$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 2.5`\$numbers_eachgrp

	N	n	mean	sd	se	median
min	max	sum				
20.000000	11.000000	98.909091	20.300022	6.120687	98.000000	
76.000000	136.000000	1088.000000				

\$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year 3`
 \$ITT\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year
 3`\$numbers_eachgrp

	N	n	mean	sd	se	median
min	max	sum				
20.000000	12.000000	93.666667	18.227518	5.261831	99.500000	
64.000000	119.000000	1124.000000				

\$ITT\$distype_all\$`Processing speed Index - Composite`
 \$ITT\$distype_all\$`Processing speed Index - Composite`\$Baseline
 \$ITT\$distype_all\$`Processing speed Index -
 Composite`\$Baseline\$numbers_eachgrp

	N	n	mean	sd	se	median
min	max	sum				
20.000000	7.000000	73.428571	23.351354	8.825982	65.000000	
47.000000	106.000000	514.000000				

\$ITT\$distype_all\$`Processing speed Index - Composite`\$`Year 2`
 \$ITT\$distype_all\$`Processing speed Index - Composite`\$`Year
 2`\$numbers_eachgrp

	N	n	mean	sd	se	median
min	max	sum				
20.000000	7.000000	67.571429	18.146231	6.858631	59.000000	
47.000000	94.000000	473.000000				

\$ITT\$distype_all\$`Processing speed Index - Composite`\$`Year 2.5`
 \$ITT\$distype_all\$`Processing speed Index - Composite`\$`Year
 2.5`\$numbers_eachgrp

	N	n	mean	sd	se	median
min	max	sum				

20.000000 8.000000 73.000000 19.220525 6.795482 73.000000
 50.000000 94.000000 584.000000

\$ITTT\$distype_all\$`Processing speed Index - Composite`\$`Year 3`
 \$ITTT\$distype_all\$`Processing speed Index - Composite`\$`Year
 3`\$numbers_eachgrp
 N n mean sd se median
 min max sum
 20.000000 11.000000 74.090909 18.954971 5.715139 79.000000
 50.000000 97.000000 815.000000

\$ITTT\$distype_all\$`Working memory Index - Composite`
 \$ITTT\$distype_all\$`Working memory Index - Composite`\$Baseline
 \$ITTT\$distype_all\$`Working memory Index -
 Composite`\$Baseline\$numbers_eachgrp
 N n mean sd se median
 min max sum
 20.000000 3.000000 101.000000 9.165151 5.291503 103.000000
 91.000000 109.000000 303.000000

\$ITTT\$distype_all\$`Working memory Index - Composite`\$`Year 2`
 \$ITTT\$distype_all\$`Working memory Index - Composite`\$`Year
 2`\$numbers_eachgrp
 N n mean sd se median
 min max sum
 20.000000 6.000000 99.000000 14.532722 5.932959 95.500000
 82.000000 118.000000 594.000000

\$ITTT\$distype_all\$`Working memory Index - Composite`\$`Year 2.5`
 \$ITTT\$distype_all\$`Working memory Index - Composite`\$`Year
 2.5`\$numbers_eachgrp
 N n mean sd se median
 min max sum
 20.000000 5.000000 103.600000 21.881499 9.785704 115.000000
 73.000000 121.000000 518.000000

\$ITTT\$distype_all\$`Working memory Index - Composite`\$`Year 3`
 \$ITTT\$distype_all\$`Working memory Index - Composite`\$`Year
 3`\$numbers_eachgrp
 N n mean sd se median min
 max sum
 20.000000 5.000000 95.20000 11.34460 5.07346 97.00000 82.00000
 106.00000 476.00000

\$ITTT\$distype_all\$`Language score - Composite`
 \$ITTT\$distype_all\$`Language score - Composite`\$Baseline
 \$ITTT\$distype_all\$`Language score - Composite`\$Baseline\$numbers_eachgrp
 N n mean sd se median
 min max sum
 20.000000 18.000000 103.055556 15.198577 3.582339 105.000000
 76.000000 130.000000 1855.000000

```

$ITT$distype_all$`Language score - Composite`$`Year 2`
$ITT$distype_all$`Language score - Composite`$`Year 2`$numbers_eachgrp
      N          n      mean      sd      se      median
min      max      sum
  20.000000  16.000000  102.812500  23.648027  5.912007  97.000000
47.000000  146.000000  1645.000000

```

```

$ITT$distype_all$`Language score - Composite`$`Year 2.5`
$ITT$distype_all$`Language score - Composite`$`Year 2.5`$numbers_eachgrp
      N          n      mean      sd      se      median
min      max      sum
  20.000000  15.000000  98.133333  24.227690  6.255563  100.000000
50.000000  146.000000  1472.000000

```

```

$ITT$distype_all$`Language score - Composite`$`Year 3`
$ITT$distype_all$`Language score - Composite`$`Year 3`$numbers_eachgrp
      N          n      mean      sd      se      median
min      max      sum
  20.000000  13.000000  90.769231  22.004370  6.102914  95.000000
50.000000  124.000000  1180.000000

```

```

$ITT$distype_all$`Performance score - Composite`
$ITT$distype_all$`Performance score - Composite`$Baseline
$ITT$distype_all$`Performance score - Composite`$Baseline$numbers_eachgrp
      N          n      mean      sd      se      median
min      max      sum
  20.000000  19.000000  97.631579  17.289080  3.966387  95.000000
50.000000  124.000000  1855.000000

```

```

$ITT$distype_all$`Performance score - Composite`$`Year 2`
$ITT$distype_all$`Performance score - Composite`$`Year 2`$numbers_eachgrp
      N          n      mean      sd      se      median
min      max      sum
  20.000000  17.000000  101.823529  24.341927  5.903784  98.000000
55.000000  143.000000  1731.000000

```

```

$ITT$distype_all$`Performance score - Composite`$`Year 2.5`
$ITT$distype_all$`Performance score - Composite`$`Year
2.5`$numbers_eachgrp
      N          n      mean      sd      se      median
min      max      sum
  20.000000  15.000000  104.466667  20.680794  5.339758  105.000000
55.000000  139.000000  1567.000000

```

```

$ITT$distype_all$`Performance score - Composite`$`Year 3`
$ITT$distype_all$`Performance score - Composite`$`Year 3`$numbers_eachgrp
      N          n      mean      sd      se      median
min      max      sum
  20.000000  14.000000  98.857143  24.942571  6.666183  102.500000
55.000000  135.000000  1384.000000

```

\$MSAS

\$MSAS\$distype_all

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$Baseline

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) -

Composite`\$Baseline\$numbers_eachgrp

	N	n	mean	sd	se	median	min
max	sum						
	11.00000	3.00000	116.33333	17.47379	10.08850	121.00000	97.00000
	131.00000	349.00000					

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year 2`

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year

2`\$numbers_eachgrp

	N	n	mean	sd	se	median	min
max	sum						
	11.00000	4.00000	107.00000	25.07323	12.53661	106.50000	83.00000
	132.00000	428.00000					

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year 2.5`

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year

2.5`\$numbers_eachgrp

	N	n	mean	sd	se	median	min
min	max	sum					
	11.000000	6.000000	110.000000	18.286607	7.465476	108.000000	
	86.000000	136.000000	660.000000				

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year 3`

\$MSAS\$distype_all\$`Total Intelligence quotient (IQ) - Composite`\$`Year

3`\$numbers_eachgrp

	N	n	mean	sd	se	median	min
min	max	sum					
	11.000000	7.000000	103.000000	13.089436	4.947342	104.000000	
	78.000000	119.000000	721.000000				

\$MSAS\$distype_all\$`Processing speed Index - Composite`

\$MSAS\$distype_all\$`Processing speed Index - Composite`\$Baseline

\$MSAS\$distype_all\$`Processing speed Index -

Composite`\$Baseline\$numbers_eachgrp

	N	n	mean	sd	se	median	min
max	sum						
	11.00000	3.00000	92.33333	23.67136	13.66667	106.00000	65.00000
	106.00000	277.00000					

\$MSAS\$distype_all\$`Processing speed Index - Composite`\$`Year 2`

\$MSAS\$distype_all\$`Processing speed Index - Composite`\$`Year

2`\$numbers_eachgrp

	N	n	mean	sd	se	median	min
max	sum						

11.00000 3.00000 67.66667 22.85461 13.19512 56.00000 53.00000
 94.00000 203.00000

\$MMSAS\$distype_all\$`Processing speed Index - Composite`\$`Year 2.5`
 \$MMSAS\$distype_all\$`Processing speed Index - Composite`\$`Year
 2.5`\$numbers_eachgrp

N		n	mean	sd	se	median
min	max	sum				
11.000000	4.000000	81.500000	17.916473	8.958236	88.000000	
56.000000	94.000000	326.000000				

\$MMSAS\$distype_all\$`Processing speed Index - Composite`\$`Year 3`
 \$MMSAS\$distype_all\$`Processing speed Index - Composite`\$`Year
 3`\$numbers_eachgrp

N		n	mean	sd	se	median
min	max	sum				
11.000000	6.000000	83.666667	15.370968	6.275172	88.000000	
56.000000	97.000000	502.000000				

\$MMSAS\$distype_all\$`Working memory Index - Composite`
 \$MMSAS\$distype_all\$`Working memory Index - Composite`\$Baseline
 \$MMSAS\$distype_all\$`Working memory Index -
 Composite`\$Baseline\$numbers_eachgrp

N	n	mean	sd	se	median	min	max	sum
11	1	109	NA	NA	109	109	109	109

\$MMSAS\$distype_all\$`Working memory Index - Composite`\$`Year 2`
 \$MMSAS\$distype_all\$`Working memory Index - Composite`\$`Year
 2`\$numbers_eachgrp

N		n	mean	sd	se	median
min	max	sum				
11.000000	3.000000	109.000000	13.076697	7.549834	115.000000	
94.000000	118.000000	327.000000				

\$MMSAS\$distype_all\$`Working memory Index - Composite`\$`Year 2.5`
 \$MMSAS\$distype_all\$`Working memory Index - Composite`\$`Year
 2.5`\$numbers_eachgrp

N	n	mean	sd	se	median	min	max	sum
11	2	121	0	0	121	121	121	242

\$MMSAS\$distype_all\$`Working memory Index - Composite`\$`Year 3`
 \$MMSAS\$distype_all\$`Working memory Index - Composite`\$`Year
 3`\$numbers_eachgrp

N	n	mean	sd	se	median	min	max	sum
11	2	106	0	0	106	106	106	212

\$MMSAS\$distype_all\$`Language score - Composite`
 \$MMSAS\$distype_all\$`Language score - Composite`\$Baseline
 \$MMSAS\$distype_all\$`Language score - Composite`\$Baseline\$numbers_eachgrp

N		n	mean	sd	se	median
min	max	sum				

11.000000 10.000000 104.800000 18.084985 5.718974 109.000000
 79.000000 130.000000 1048.000000

\$MSAS\$distype_all\$`Language score - Composite`\$`Year 2`
 \$MSAS\$distype_all\$`Language score - Composite`\$`Year 2`\$numbers_eachgrp
 N n mean sd se median
 min max sum
 11.000000 9.000000 109.777778 22.637236 7.545745 97.000000
 86.000000 146.000000 988.000000

\$MSAS\$distype_all\$`Language score - Composite`\$`Year 2.5`
 \$MSAS\$distype_all\$`Language score - Composite`\$`Year 2.5`\$numbers_eachgrp
 N n mean sd se median
 min max sum
 11.000000 8.000000 111.375000 20.106413 7.108691 101.500000
 90.000000 146.000000 891.000000

\$MSAS\$distype_all\$`Language score - Composite`\$`Year 3`
 \$MSAS\$distype_all\$`Language score - Composite`\$`Year 3`\$numbers_eachgrp
 N n mean sd se median
 min max sum
 11.000000 7.000000 100.428571 14.374249 5.432956 98.000000
 78.000000 124.000000 703.000000

\$MSAS\$distype_all\$`Performance score - Composite`
 \$MSAS\$distype_all\$`Performance score - Composite`\$Baseline
 \$MSAS\$distype_all\$`Performance score -
 Composite`\$Baseline\$numbers_eachgrp
 N n mean sd se median
 min max sum
 11.000000 11.000000 103.000000 13.740451 4.142902 100.000000
 80.000000 124.000000 1133.000000

\$MSAS\$distype_all\$`Performance score - Composite`\$`Year 2`
 \$MSAS\$distype_all\$`Performance score - Composite`\$`Year
 2`\$numbers_eachgrp
 N n mean sd se median
 min max sum
 11.000000 10.000000 103.100000 27.032696 8.548489 95.000000
 55.000000 143.000000 1031.000000

\$MSAS\$distype_all\$`Performance score - Composite`\$`Year 2.5`
 \$MSAS\$distype_all\$`Performance score - Composite`\$`Year
 2.5`\$numbers_eachgrp
 N n mean sd se median
 min max sum
 11.000000 8.000000 111.125000 18.871274 6.672003 112.000000
 90.000000 139.000000 889.000000

\$MSAS\$distype_all\$`Performance score - Composite`\$`Year 3`
 \$MSAS\$distype_all\$`Performance score - Composite`\$`Year
 3`\$numbers_eachgrp

	N	n	mean	sd	se	median
min	max	sum				
11.000000	8.000000	105.625000	25.634449	9.063147	108.000000	
55.000000	135.000000	845.000000				

```
\#####
#####
```

```
[1] "DQ Performance Year 2/3"
```

```
$MAS
```

```
$MAS$distype_all
```

```
$MAS$distype_all$`Development Quotient (Performance)`
```

```
$MAS$distype_all$`Development Quotient (Performance)`$`Year 2`
```

```
$MAS$distype_all$`Development Quotient (Performance)`$`Year
```

```
2`$numbers_eachgrp
```

	TIGET-NHx	OTL-200
N	29.000000	20.000000
n	16.000000	17.000000
mean	22.740000	92.124118
sd	27.492574	36.895517
se	6.873143	8.948477
median	7.810000	98.000000
min	0.890000	6.320000
max	82.000000	143.000000
sum	363.840000	1566.110000

```
$MAS$distype_all$`Development Quotient (Performance)`$`Year 2`$ls_mw
```

	TRTvsCTRL	LSMean	LSMean_se	LSMean_lo95ci	LSMean_hi95ci
1	OTL-200	93.40	7.898	77.270	109.531
2	TIGET-NHx	21.38	8.145	4.749	38.019

```
$MAS$distype_all$`Development Quotient (Performance)`$`Year
```

```
2`$diffgrp_TRTvsCTRL
```

	LSM_Diff	LSM_Diff_se	LSM_Diff_lo95ci	LSM_Diff_hi95ci
LSM_Diff_pv	7.201613e+01	1.143450e+01	4.866376e+01	9.536851e+01
	6.077990e-07			

```
$MAS$distype_all$`Development Quotient (Performance)`$`Year
```

```
2`$Hedgesg_TRTvsCTRL
```

	est	lo95ci	hi95ci	pvalue
	2.070	1.205	2.937	0.000

```
$MAS$distype_all$`Development Quotient (Performance)`$`Year 3`
```

```
$MAS$distype_all$`Development Quotient (Performance)`$`Year
```

```
3`$numbers_eachgrp
```

	TIGET-NHx	OTL-200
N	29.000000	20.000000
n	16.000000	14.000000
mean	12.048750	91.71857
sd	21.689502	40.32099
se	5.422376	10.77624
median	2.105000	102.50000
min	0.570000	4.43000
max	71.000000	135.00000

sum 192.780000 1284.06000

```

$MSAS$distype_all$`Development Quotient (Performance)`$`Year 3`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  93.39      8.411      76.132      110.649
2  TIGET-NHx 10.59      7.858      -5.539      26.710

```

```

$MSAS$distype_all$`Development Quotient (Performance)`$`Year
3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      8.280489e+01      1.161546e+01      5.897193e+01      1.066379e+02
1.150170e-07

```

```

$MSAS$distype_all$`Development Quotient (Performance)`$`Year
3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
2.440 1.466 3.420 0.000

```

\$MSAS

```

$MSAS$distype_all
$MSAS$distype_all$`Development Quotient (Performance)`
$MSAS$distype_all$`Development Quotient (Performance)`$`Year 2`
$MSAS$distype_all$`Development Quotient (Performance)`$`Year
2`$numbers_eachgrp
      TIGET-NHx  OTL-200
N      11.00000  11.00000
n      6.00000  10.00000
mean   46.83667  91.64000
sd     29.73390  36.46448
se     12.13881  11.53108
median 52.28000  92.46500
min    2.41000  6.32000
max    82.00000  143.00000
sum    281.02000  916.40000

```

```

$MSAS$distype_all$`Development Quotient (Performance)`$`Year 2`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1  OTL-200  93.65      8.193      75.953      111.353
2  TIGET-NHx 43.48     10.596     20.592      66.372

```

```

$MSAS$distype_all$`Development Quotient (Performance)`$`Year
2`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      50.170896968      13.437334062      21.141301635      79.200492301
0.002504012

```

```

$MSAS$distype_all$`Development Quotient (Performance)`$`Year
2`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
1.2400 0.1120 2.3640 0.0312

```

\$MSAS\$distype_all\$`Development Quotient (Performance)`\$`Year 3`

```

$MSAS$distype_all$`Development Quotient (Performance)`$`Year
3`$numbers_eachgrp
      TIGET-NHx   OTL-200
N      11.00000   11.00000
n      6.00000   8.00000
mean   21.87500   99.30375
sd     31.28872   41.33098
se     12.77357   14.61271
median 2.87500  108.00000
min    0.57000   4.43000
max    71.00000  135.00000
sum    131.25000 794.43000

```

```

$MSAS$distype_all$`Development Quotient (Performance)`$`Year 3`$ls_mw
      TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1   OTL-200 105.01    11.071      80.647      129.380
2  TIGET-NHx  14.26     12.866     -14.055     42.579

```

```

$MSAS$distype_all$`Development Quotient (Performance)`$`Year
3`$diffgrp_TRTvsCTRL
      LSM_Diff      LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci
LSM_Diff_pv
      9.075148e+01  1.734138e+01  5.258336e+01  1.289196e+02
2.797292e-04

```

```

$MSAS$distype_all$`Development Quotient (Performance)`$`Year
3`$Hedgesg_TRTvsCTRL
      est lo95ci hi95ci      pv
1.9300 0.5800 3.2890 0.0051

```

```

\#####
#####

```

```

[1] "DQ Performance responder Year2/3"
$MAS

```

```

$MAS$distype_all
$MAS$distype_all$`Development Quotient (Performance)`
$MAS$distype_all$`Development Quotient (Performance)`$`Year 2`
$MAS$distype_all$`Development Quotient (Performance)`$`Year 2`$ntab
      CTRL TRT
N      29  20
n_all   16  17
n_event  0  13
n_event_pct  0  76

```

```

$MAS$distype_all$`Development Quotient (Performance)`$`Year 2`$stats
      estimate      se lo95ci      hi95ci      pvalue
RR_TRTvsCTRL 25.5000000 1.3998911 1.640404 396.3963199 2.069397e-02
OR_TRTvsCTRL 99.0000000 1.5352206 4.884870 2006.3992502 2.761292e-03
ARR_TRTvsCTRL 0.7647059 0.1028794 0.563066 0.9663457 1.061373e-13

```

```

$MAS$distype_all$`Development Quotient (Performance)`$`Year 3`
$MAS$distype_all$`Development Quotient (Performance)`$`Year 3`$ntab
      CTRL TRT
N      29  20

```

```
n_all      16  14
n_event    0  11
n_event_pct 0  79
```

```
$MSAS$distype_all$`Development Quotient (Performance)`$`Year 3`$stats
      estimate      se      lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  26.0666667 1.4005236 1.6747796  405.707783 1.990307e-02
OR_TRTvsCTRL  108.4285714 1.5598964 5.0975030 2306.375326 2.663640e-03
ARR_TRTvsCTRL  0.7857143 0.1096642 0.5707764  1.000652 7.793766e-13
```

```
$MSAS
$MSAS$distype_all
$MSAS$distype_all$`Development Quotient (Performance)`
$MSAS$distype_all$`Development Quotient (Performance)`$`Year 2`
$MSAS$distype_all$`Development Quotient (Performance)`$`Year 2`$ntab
      CTRL TRT
N      11  11
n_all   6  10
n_event 0   7
n_event_pct 0  70
```

```
$MSAS$distype_all$`Development Quotient (Performance)`$`Year 2`$stats
      estimate      se      lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  9.545455 1.3782478 0.6406634 142.2208597 1.016497e-01
OR_TRTvsCTRL  27.857143 1.6040242 1.2011263 646.0773003 3.805945e-02
ARR_TRTvsCTRL  0.700000 0.1449138 0.4159742  0.9840258 1.362187e-06
```

```
$MSAS$distype_all$`Development Quotient (Performance)`$`Year 3`
$MSAS$distype_all$`Development Quotient (Performance)`$`Year 3`$ntab
      CTRL TRT
N      11  11
n_all   6   8
n_event 0   7
n_event_pct 0  88
```

```
$MSAS$distype_all$`Development Quotient (Performance)`$`Year 3`$stats
      estimate      se      lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  11.66667 1.3708994 0.7943925  171.339876 7.312314e-02
OR_TRTvsCTRL  65.00000 1.7186757 2.2385869 1887.351379 1.514724e-02
ARR_TRTvsCTRL  0.87500 0.1169268 0.6458277  1.104172 7.238654e-14
```

```
\#####
#####
```

```
> sink()
```

1. ITT: ARSA

ITT	Behandlungsgruppe
	OTL-200
N	20
ITT: ARSA	
Baseline	
n (%)	19 (95)
MW (SD)	25,91 (0,502)
geometrisches Mittel	25,90
Median [Min; Max]	25,79 [25,79; 27,98]
LS MW (SE)	26,78 (0,51)
95%-KI	[9,030; 79,400]
Ratio (LS MD)	
Month 3	
n (%)	20 (100)
MW (SD)	275,06 (278,332)
geometrisches Mittel	185,01
Median [Min; Max]	143,41 [50,22; 1126,34]
LS MW (SE)	319,30 (0,51)
95%-KI	[107,695; 946,685]
Ratio (LS MD)	11,92 [4,499; 31,610] p=0,0001
Month 6	
n (%)	16 (80)
MW (SD)	153,06 (102,035)
geometrisches Mittel	121,05
Median [Min; Max]	137,04 [25,79; 379,17]
LS MW (SE)	232,00 (0,52)
95%-KI	[77,338; 695,938]
Ratio (LS MD)	8,66 [2,940; 25,532] p=0,0035

ITT	Behandlungsgruppe
	OTL-200
N	20
Year 1	
n (%)	17 (85)
MW (SD)	304,31 (498,024)
geometrisches Mittel	156,15
Median [Min; Max]	180,06 [46,30; 2126,50]
LS MW (SE)	235,39 (0,51)
95%-KI	[79,402; 697,843]
Ratio (LS MD)	8,79 [2,960; 26,107] p=0,0035
Year 1.5	
n (%)	17 (85)
MW (SD)	406,67 (486,304)
geometrisches Mittel	197,35
Median [Min; Max]	213,50 [25,79; 1472,84]
LS MW (SE)	240,71 (0,51)
95%-KI	[80,793; 717,180]
Ratio (LS MD)	8,99 [3,001; 26,927] p=0,0034
Year 2	
n (%)	16 (80)
MW (SD)	287,31 (312,160)
geometrisches Mittel	185,74
Median [Min; Max]	183,53 [25,79; 1242,30]
LS MW (SE)	186,46 (0,52)
95%-KI	[62,564; 555,731]
Ratio (LS MD)	6,96 [2,322; 20,882] p=0,0154
Year 2.5	
n (%)	15 (75)
MW (SD)	453,75 (762,901)
geometrisches Mittel	236,91

ITT	Behandlungsgruppe
	OTL-200
N	20
Median [Min; Max]	228,57 [41,96; 3122,56]
LS MW (SE)	499,60 (0,52)
95%-KI	[166,488; 1499,178]
Ratio (LS MD)	18,66 [6,184; 56,294] p=<0,0001
Year 3	
n (%)	17 (85)
MW (SD)	720,09 (1065,182)
geometrisches Mittel	306,53
Median [Min; Max]	281,85 [25,79; 3876,98]
LS MW (SE)	705,02 (0,51)
95%-KI	[237,805; 2090,173]
Ratio (LS MD)	26,33 [8,819; 78,611] p=<0,0001

2. MSAS: ARSA

MSAS	Behandlungsgruppe
	OTL-200
N	11
MSAS: ARSA	
Baseline	
n (%)	11 (100)
MW (SD)	25,79 (0,000)
geometrisches Mittel	25,79
Median [Min; Max]	25,79 [25,79; 25,79]
LS MW (SE)	25,79 (0,32)
95%-KI	[12,522; 53,118]
Ratio (LS MD)	
Month 3	
n (%)	11 (100)
MW (SD)	337,68 (352,313)
geometrisches Mittel	207,00
Median [Min; Max]	162,10 [60,98; 1126,34]
LS MW (SE)	192,89 (0,32)
95%-KI	[93,651; 397,272]
Ratio (LS MD)	7,48 [3,974; 14,075] p=<0,0001
Month 6	
n (%)	10 (91)
MW (SD)	158,44 (105,388)
geometrisches Mittel	130,87
Median [Min; Max]	138,66 [36,81; 379,17]
LS MW (SE)	138,81 (0,32)
95%-KI	[66,564; 289,453]
Ratio (LS MD)	5,38 [2,828; 10,245] p=0,0001
Year 1	
n (%)	11 (100)

MSAS	Behandlungsgruppe
	OTL-200
N	11
MW (SD)	327,64 (603,926)
geometrisches Mittel	150,76
Median [Min; Max]	180,06 [46,30; 2126,50]
LS MW (SE)	132,99 (0,32)
95%-KI	[64,570; 273,908]
Ratio (LS MD)	5,16 [2,739; 9,707] p=0,0001
Year 1.5	
n (%)	10 (91)
MW (SD)	461,56 (484,715)
geometrisches Mittel	253,75
Median [Min; Max]	262,85 [28,08; 1410,98]
LS MW (SE)	187,77 (0,32)
95%-KI	[90,085; 391,401]
Ratio (LS MD)	7,28 [3,827; 13,854] p=<0,0001
Year 2	
n (%)	10 (91)
MW (SD)	348,77 (381,656)
geometrisches Mittel	202,77
Median [Min; Max]	192,36 [25,79; 1242,30]
LS MW (SE)	228,66 (0,32)
95%-KI	[109,655; 476,838]
Ratio (LS MD)	8,87 [4,658; 16,877] p=<0,0001
Year 2.5	
n (%)	8 (73)
MW (SD)	281,48 (210,802)
geometrisches Mittel	217,18
Median [Min; Max]	259,70 [78,08; 706,15]
LS MW (SE)	223,01 (0,35)

MSAS	Behandlungsgruppe
	OTL-200
N	11
95%-KI	[101,119; 491,816]
Ratio (LS MD)	8,65 [4,321; 17,305] p=<0,0001
Year 3	
n (%)	10 (91)
MW (SD)	698,05 (1148,335)
geometrisches Mittel	302,01
Median [Min; Max]	311,46 [25,79; 3876,98]
LS MW (SE)	344,19 (0,34)
95%-KI	[160,389; 738,609]
Ratio (LS MD)	13,35 [6,834; 26,063] p=<0,0001

1. ITT: ARSA_Sensitivitätsanalyse

ITT	Behandlungsgruppe
	OTL-200
N	20
ITT: ARSA	
Baseline	
n (%)	19 (95)
MW (SD)	9,18 (7,149)
geometrisches Mittel	6,67
Median [Min; Max]	5,41 [0,69; 27,98]
LS MW (SE)	9,31 (0,25)
95%-KI	[5,499; 15,762]
Ratio (LS MD)	
Month 3	
n (%)	20 (100)
MW (SD)	275,06 (278,332)
geometrisches Mittel	185,01
Median [Min; Max]	143,41 [50,22; 1126,34]
LS MW (SE)	192,43 (0,25)
95%-KI	[113,682; 325,733]
Ratio (LS MD)	20,67 [12,943; 33,009] p=<0,0001
Month 6	
n (%)	16 (80)
MW (SD)	153,06 (102,035)
geometrisches Mittel	121,05
Median [Min; Max]	137,04 [25,79; 379,17]
LS MW (SE)	141,06 (0,26)
95%-KI	[80,524; 247,109]
Ratio (LS MD)	15,15 [8,824; 26,016] p=<0,0001

ITT	Behandlungsgruppe
	OTL-200
N	20
Year 1	
n (%)	17 (85)
MW (SD)	304,31 (498,024)
geometrisches Mittel	156,15
Median [Min; Max]	180,06 [46,30; 2126,50]
LS MW (SE)	163,03 (0,26)
95%-KI	[93,744; 283,519]
Ratio (LS MD)	17,51 [10,199; 30,065] p=<0,0001
Year 1.5	
n (%)	17 (85)
MW (SD)	406,67 (486,304)
geometrisches Mittel	197,35
Median [Min; Max]	213,50 [25,79; 1472,84]
LS MW (SE)	195,42 (0,26)
95%-KI	[112,027; 340,901]
Ratio (LS MD)	20,99 [12,172; 36,201] p=<0,0001
Year 2	
n (%)	16 (80)
MW (SD)	287,31 (312,160)
geometrisches Mittel	185,74
Median [Min; Max]	183,53 [25,79; 1242,30]
LS MW (SE)	202,85 (0,27)
95%-KI	[114,309; 359,966]
Ratio (LS MD)	21,79 [12,438; 38,169] p=<0,0001
Year 2.5	
n (%)	15 (75)
MW (SD)	453,75 (762,901)
geometrisches Mittel	236,91

ITT	Behandlungsgruppe
	OTL-200
N	20
Median [Min; Max]	228,57 [41,96; 3122,56]
LS MW (SE)	282,99 (0,27)
95%-KI	[159,137; 503,222]
Ratio (LS MD)	30,40 [17,318; 53,352] p=<0,0001
Year 3	
n (%)	17 (85)
MW (SD)	720,09 (1065,182)
geometrisches Mittel	306,53
Median [Min; Max]	281,85 [25,79; 3876,98]
LS MW (SE)	321,60 (0,26)
95%-KI	[185,128; 558,668]
Ratio (LS MD)	34,54 [20,097; 59,376] p=<0,0001

2. MSAS: ARSA_Sensitivitätsanalyse

MSAS	Behandlungsgruppe
	OTL-200
N	11
MSAS: ARSA	
Baseline	
n (%)	11 (100)
MW (SD)	8,21 (6,021)
geometrisches Mittel	5,88
Median [Min; Max]	5,13 [0,69; 17,86]
LS MW (SE)	8,52 (0,36)
95%-KI	[3,711; 19,549]
Ratio (LS MD)	
Month 3	
n (%)	11 (100)
MW (SD)	337,68 (352,313)
geometrisches Mittel	207,00
Median [Min; Max]	162,10 [60,98; 1126,34]
LS MW (SE)	185,77 (0,36)
95%-KI	[80,936; 426,379]
Ratio (LS MD)	21,81 [10,810; 44,009] p=<0,0001
Month 6	
n (%)	10 (91)
MW (SD)	158,44 (105,388)
geometrisches Mittel	130,87
Median [Min; Max]	138,66 [36,81; 379,17]
LS MW (SE)	135,10 (0,36)
95%-KI	[58,471; 312,155]
Ratio (LS MD)	15,86 [8,001; 31,447] p=<0,0001
Year 1	
n (%)	11 (100)

MSAS	Behandlungsgruppe
	OTL-200
N	11
MW (SD)	327,64 (603,926)
geometrisches Mittel	150,76
Median [Min; Max]	180,06 [46,30; 2126,50]
LS MW (SE)	122,10 (0,36)
95%-KI	[53,200; 280,249]
Ratio (LS MD)	14,34 [7,265; 28,291] p=<0,0001
Year 1.5	
n (%)	10 (91)
MW (SD)	461,56 (484,715)
geometrisches Mittel	253,75
Median [Min; Max]	262,85 [28,08; 1410,98]
LS MW (SE)	170,29 (0,36)
95%-KI	[73,581; 394,124]
Ratio (LS MD)	19,99 [10,055; 39,760] p=<0,0001
Year 2	
n (%)	10 (91)
MW (SD)	348,77 (381,656)
geometrisches Mittel	202,77
Median [Min; Max]	192,36 [25,79; 1242,30]
LS MW (SE)	243,84 (0,36)
95%-KI	[105,547; 563,310]
Ratio (LS MD)	28,63 [14,422; 56,835] p=<0,0001
Year 2.5	
n (%)	8 (73)
MW (SD)	281,48 (210,802)
geometrisches Mittel	217,18
Median [Min; Max]	259,70 [78,08; 706,15]
LS MW (SE)	229,42 (0,38)

MSAS	Behandlungsgruppe
	OTL-200
N	11
95%-KI	[96,558; 545,083]
Ratio (LS MD)	26,94 [13,221; 54,881] p=<0,0001
Year 3	
n (%)	10 (91)
MW (SD)	698,05 (1148,335)
geometrisches Mittel	302,01
Median [Min; Max]	311,46 [25,79; 3876,98]
LS MW (SE)	347,14 (0,37)
95%-KI	[146,608; 821,975]
Ratio (LS MD)	40,76 [20,069; 82,782] p=<0,0001

1. ITT: ARSA_Langzeitanalyse

ITT	Behandlungsgruppe
	OTL-200
N	20
ITT: ARSA	
Baseline	
n (%)	19 (95)
MW (SD)	25,91 (0,502)
geometrisches Mittel	25,90
Median [Min; Max]	25,79 [25,79; 27,98]
LS MW (SE)	26,86 (0,52)
95%-KI	[9,553; 75,540]
Ratio (LS MD)	
Month 3	
n (%)	20 (100)
MW (SD)	275,06 (278,332)
geometrisches Mittel	185,01
Median [Min; Max]	143,41 [50,22; 1126,34]
LS MW (SE)	324,35 (0,52)
95%-KI	[115,341; 912,087]
Ratio (LS MD)	12,07 [2,798; 52,105] p=0,0778
Month 6	
n (%)	16 (80)
MW (SD)	153,06 (102,035)
geometrisches Mittel	121,05
Median [Min; Max]	137,04 [25,79; 379,17]
LS MW (SE)	200,49 (0,53)
95%-KI	[69,956; 574,593]
Ratio (LS MD)	7,46 [1,706; 32,645] p=0,3713

ITT	Behandlungsgruppe
	OTL-200
N	20
Month 9	
n (%)	18 (90)
MW (SD)	241,93 (220,788)
geometrisches Mittel	148,68
Median [Min; Max]	173,49 [25,79; 721,13]
LS MW (SE)	380,96 (0,52)
95%-KI	[135,472; 1071,282]
Ratio (LS MD)	14,18 [3,286; 61,199] p=0,0410
Year 1	
n (%)	17 (85)
MW (SD)	304,31 (498,024)
geometrisches Mittel	156,15
Median [Min; Max]	180,06 [46,30; 2126,50]
LS MW (SE)	231,94 (0,52)
95%-KI	[82,480; 652,235]
Ratio (LS MD)	8,63 [2,001; 37,260] p=0,2399
Year 1.5	
n (%)	17 (85)
MW (SD)	406,67 (486,304)
geometrisches Mittel	197,35
Median [Min; Max]	213,50 [25,79; 1472,84]
LS MW (SE)	271,15 (0,53)
95%-KI	[95,638; 768,750]
Ratio (LS MD)	10,09 [2,326; 43,812] p=0,1518
Year 2	
n (%)	16 (80)
MW (SD)	287,31 (312,160)
geometrisches Mittel	185,74

ITT	Behandlungsgruppe
	OTL-200
N	20
Median [Min; Max]	183,53 [25,79; 1242,30]
LS MW (SE)	174,37 (0,53)
95%-KI	[61,504; 494,375]
Ratio (LS MD)	6,49 [1,496; 28,175] p=0,4936
Year 2.5	
n (%)	15 (75)
MW (SD)	453,75 (762,901)
geometrisches Mittel	236,91
Median [Min; Max]	228,57 [41,96; 3122,56]
LS MW (SE)	463,40 (0,53)
95%-KI	[161,691; 1328,063]
Ratio (LS MD)	17,25 [3,944; 75,453] p=0,0197
Year 3	
n (%)	17 (85)
MW (SD)	720,09 (1065,182)
geometrisches Mittel	306,53
Median [Min; Max]	281,85 [25,79; 3876,98]
LS MW (SE)	699,17 (0,52)
95%-KI	[248,631; 1966,115]
Ratio (LS MD)	26,03 [6,031; 112,319] p=0,0023
Year 3.5	
n (%)	10 (50)
MW (SD)	344,82 (258,430)
geometrisches Mittel	241,20
Median [Min; Max]	357,23 [31,15; 886,31]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA

ITT	Behandlungsgruppe
	OTL-200
N	20
Year 4	
n (%)	11 (55)
MW (SD)	420,38 (306,981)
geometrisches Mittel	317,66
Median [Min; Max]	328,97 [36,41; 1099,11]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA
Year 4.5	
n (%)	7 (35)
MW (SD)	348,66 (273,000)
geometrisches Mittel	272,69
Median [Min; Max]	314,09 [82,61; 911,77]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA
Year 5	
n (%)	7 (35)
MW (SD)	502,50 (305,666)
geometrisches Mittel	354,51
Median [Min; Max]	510,91 [27,58; 979,43]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA
Year 5.5	
n (%)	4 (20)
MW (SD)	836,02 (502,715)
geometrisches Mittel	679,86

ITT	Behandlungsgruppe
	OTL-200
N	20
Median [Min; Max]	852,08 [205,36; 1434,55]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA
Year 6	
n (%)	4 (20)
MW (SD)	422,15 (381,295)
geometrisches Mittel	305,96
Median [Min; Max]	311,61 [95,36; 970,04]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA
Year 6.5	
n (%)	3 (15)
MW (SD)	999,60 (819,149)
geometrisches Mittel	708,51
Median [Min; Max]	958,36 [201,85; 1838,59]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA
Year 7	
n (%)	3 (15)
MW (SD)	1047,43 (243,759)
geometrisches Mittel	1026,51
Median [Min; Max]	1158,95 [767,86; 1215,48]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA

2. MSAS: ARSA_Langzeitanalyse

MSAS	Behandlungsgruppe
	OTL-200
N	11
MSAS: ARSA	
Baseline	
n (%)	11 (100)
MW (SD)	25,79 (0,000)
geometrisches Mittel	25,79
Median [Min; Max]	25,79 [25,79; 25,79]
LS MW (SE)	25,79 (0,32)
95%-KI	[13,756; 48,350]
Ratio (LS MD)	
Month 3	
n (%)	11 (100)
MW (SD)	337,68 (352,313)
geometrisches Mittel	207,00
Median [Min; Max]	162,10 [60,98; 1126,34]
LS MW (SE)	192,90 (0,32)
95%-KI	[102,894; 361,639]
Ratio (LS MD)	7,48 [3,075; 18,192] p=0,0022
Month 6	
n (%)	10 (91)
MW (SD)	158,44 (105,388)
geometrisches Mittel	130,87
Median [Min; Max]	138,66 [36,81; 379,17]
LS MW (SE)	125,70 (0,33)
95%-KI	[65,802; 240,118]
Ratio (LS MD)	4,87 [1,977; 12,014] p=0,0605
Month 9	
n (%)	11 (100)

MSAS	Behandlungsgruppe
	OTL-200
N	11
MW (SD)	244,14 (157,106)
geometrisches Mittel	187,37
Median [Min; Max]	212,20 [25,79; 540,54]
LS MW (SE)	187,97 (0,32)
95%-KI	[100,266; 352,403]
Ratio (LS MD)	7,29 [2,997; 17,727] p=0,0027
Year 1	
n (%)	11 (100)
MW (SD)	327,64 (603,926)
geometrisches Mittel	150,76
Median [Min; Max]	180,06 [46,30; 2126,50]
LS MW (SE)	132,98 (0,32)
95%-KI	[70,932; 249,306]
Ratio (LS MD)	5,16 [2,120; 12,541] p=0,0360
Year 1.5	
n (%)	10 (91)
MW (SD)	461,56 (484,715)
geometrisches Mittel	253,75
Median [Min; Max]	262,85 [28,08; 1410,98]
LS MW (SE)	208,96 (0,33)
95%-KI	[109,389; 399,173]
Ratio (LS MD)	8,10 [3,287; 19,972] p=0,0014
Year 2	
n (%)	10 (91)
MW (SD)	348,77 (381,656)
geometrisches Mittel	202,77
Median [Min; Max]	192,36 [25,79; 1242,30]
LS MW (SE)	207,09 (0,33)

MSAS	Behandlungsgruppe
	OTL-200
N	11
95%-KI	[108,410; 395,599]
Ratio (LS MD)	8,03 [3,258; 19,793] p=0,0016
Year 2.5	
n (%)	8 (73)
MW (SD)	281,48 (210,802)
geometrisches Mittel	217,18
Median [Min; Max]	259,70 [78,08; 706,15]
LS MW (SE)	211,87 (0,37)
95%-KI	[101,869; 440,639]
Ratio (LS MD)	8,22 [3,130; 21,563] p=0,0039
Year 3	
n (%)	10 (91)
MW (SD)	698,05 (1148,335)
geometrisches Mittel	302,01
Median [Min; Max]	311,46 [25,79; 3876,98]
LS MW (SE)	311,24 (0,35)
95%-KI	[155,810; 621,724]
Ratio (LS MD)	12,07 [4,739; 30,733] p=0,0001
Year 3.5	
n (%)	7 (64)
MW (SD)	397,37 (272,139)
geometrisches Mittel	307,56
Median [Min; Max]	429,07 [82,34; 886,31]
LS MW (SE)	319,70 (0,42)
95%-KI	[138,168; 739,748]
Ratio (LS MD)	12,40 [4,346; 35,362] p=0,0008
Year 4	
n (%)	7 (64)

MSAS	Behandlungsgruppe
	OTL-200
N	11
MW (SD)	512,93 (357,000)
geometrisches Mittel	361,90
Median [Min; Max]	446,92 [36,41; 1099,11]
LS MW (SE)	347,80 (0,55)
95%-KI	[117,752; 1027,269]
Ratio (LS MD)	13,49 [3,855; 47,173] p=0,0081
Year 4.5	
n (%)	5 (45)
MW (SD)	388,22 (314,775)
geometrisches Mittel	294,45
Median [Min; Max]	314,09 [82,61; 911,77]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA
Year 5	
n (%)	4 (36)
MW (SD)	573,23 (407,427)
geometrisches Mittel	322,53
Median [Min; Max]	642,96 [27,58; 979,43]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA
Year 5.5	
n (%)	4 (36)
MW (SD)	836,02 (502,715)
geometrisches Mittel	679,86
Median [Min; Max]	852,08 [205,36; 1434,55]
LS MW (SE)	NA (NA)

MSAS	Behandlungsgruppe
	OTL-200
N	11
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA
Year 6	
n (%)	3 (27)
MW (SD)	442,77 (464,252)
geometrisches Mittel	289,72
Median [Min; Max]	262,90 [95,36; 970,04]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA
Year 6.5	
n (%)	2 (18)
MW (SD)	1020,22 (1157,350)
geometrisches Mittel	609,20
Median [Min; Max]	1020,22 [201,85; 1838,59]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA
Year 7	
n (%)	3 (27)
MW (SD)	1047,43 (243,759)
geometrisches Mittel	1026,51
Median [Min; Max]	1158,95 [767,86; 1215,48]
LS MW (SE)	NA (NA)
95%-KI	[NA; NA]
Ratio (LS MD)	NA [NA; NA] p= NA

1. tödliche UE nach SOC und PT

1.1. Patienten mit einem tödlichen UE nach SOC und PT

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
Patienten mit einem tödlichen UE nach SOC und PT	
SOC Erkrankungen des Gastrointestinaltrakts	2 (10)
PT Dysphagie	2 (10)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

1.2. Zeit bis zum Erleiden eines tödlichen UEs nach SOC und PT

201222	OTL-200-f
N = 20 ^a	Min; Median [95%KI]; Max
Zeit bis zum Erleiden eines tödlichen UEs nach SOC und PT	
SOC Erkrankungen des Gastrointestinaltrakts	26,00; NA [NA; NA]; 391,71
PT Dysphagie	26,00; NA [NA; NA]; 391,71
<p>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</p> <p>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</p>	

1. UE mit SMQ nach SOC und PT

1.1. Patienten mit mindestens einem UE mit SMQ nach SOC und PT

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
Patienten mit mindestens einem UE mit SMQ nach SOC und PT	
SOC Erkrankungen des Blutes und des Lymphsystems	15 (75)
PT Febrile Neutropenie	15 (75)
PT Neutropenie	2 (10)
SOC Erkrankungen des Gastrointestinaltrakts	11 (55)
PT Stomatitis	8 (40)
PT Dysphagie	4 (20)
SOC Untersuchungen	8 (40)
PT Erhöhtes Immunoglobulin E im Blut	8 (40)
SOC Erkrankungen der Haut und des Unterhautzellgewebes	8 (40)
PT Erythematöser Hautausschlag	3 (15)
PT Ausschlag	1 (5)
PT Dermatitis	1 (5)
PT DERMATITIS BULLOUS	1 (5)
PT Medikamentenausschlag	1 (5)
PT RASH PRURITIC	1 (5)
PT SKIN EXFOLIATION	1 (5)
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	6 (30)
PT Schleimhautentzündung	6 (30)
SOC Infektionen und parasitäre Erkrankungen	5 (25)
PT Konjunktivitis	5 (25)
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums	4 (20)

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
PT Bronchospasmus	2 (10)
PT Allergische Rhinitis	1 (5)
PT Asthma	1 (5)
SOC Augenerkrankungen	2 (10)
PT Konjunktivitis allergisch	1 (5)
PT Okulaere Hyperaemie	1 (5)
SOC Gefäßerkrankungen	1 (5)
PT KAWASAKI'S DISEASE	1 (5)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

1.2. Zeit bis zum Erleiden eines UEs mit SMQ nach SOC und PT

201222	OTL-200-f
N = 20 ^a	Min; Median [95%KI]; Max
Zeit bis zum Erleiden eines UEs mit SMQ nach SOC und PT	
SOC Erkrankungen des Blutes und des Lymphsystems	2,29; 2,79 [2,714; 3,571]; 391,71
PT Febrile Neutropenie	2,29; 2,79 [2,714; 3,571]; 391,71
PT Neutropenie	7,29; NA [NA; NA]; 391,71
SOC Erkrankungen des Gastrointestinaltrakts	2,14; 168,00 [2,429; NA]; 391,71
PT Stomatitis	2,14; NA [2,429; NA]; 391,71
PT Dysphagie	26,00; NA [282,714; NA]; 391,71
SOC Untersuchungen	2,14; NA [26,286; NA]; 365,43
PT Erhöhtes Immunglobulin E im Blut	2,14; NA [26,286; NA]; 365,43
SOC Erkrankungen der Haut und des Unterhautzellgewebes	1,86; NA [4,143; NA]; 365,43
PT Erythematöses Hautausschlag	1,86; NA [NA; NA]; 391,71
PT Ausschlag	33,43; NA [301,714; NA]; 391,71
PT Dermatitis	4,86; NA [NA; NA]; 365,43
PT DERMATITIS BULLOUS	33,43; NA [NA; NA]; 391,71
PT Medikamentenausschlag	33,43; NA [NA; NA]; 391,71
PT RASH PRURITIC	3,00; NA [NA; NA]; 391,71
PT SKIN EXFOLIATION	4,14; NA [NA; NA]; 391,71
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	2,14; NA [2,286; NA]; 365,43
PT Schleimhautentzündung	2,14; NA [2,286; NA]; 365,43
SOC Infektionen und parasitäre Erkrankungen	4,71; NA [136,429; NA]; 391,71
PT Konjunktivitis	4,71; NA [136,429; NA]; 391,71
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums	33,43; NA [179,857; NA]; 365,43
PT Bronchospasmus	33,43; NA [NA; NA]; 391,71
PT Allergische Rhinitis	33,43; NA [NA; NA]; 391,71
PT Asthma	33,43; NA [NA; NA]; 365,43
SOC Augenerkrankungen	3,29; NA [334,857; NA]; 391,71

201222	OTL-200-f
N = 20^a	Min; Median [95%KI]; Max
PT Konjunktivitis allergisch	33,43; NA [334,857; NA]; 391,71
PT Okulaere Hyperaemie	3,29; NA [NA; NA]; 391,71
SOC Gefäßerkrankungen	33,43; NA [NA; NA]; 391,71
PT KAWASAKI'S DISEASE	33,43; NA [NA; NA]; 391,71
<p>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</p> <p>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</p>	

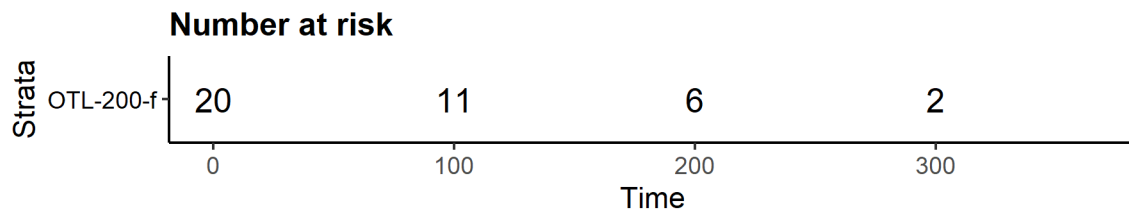
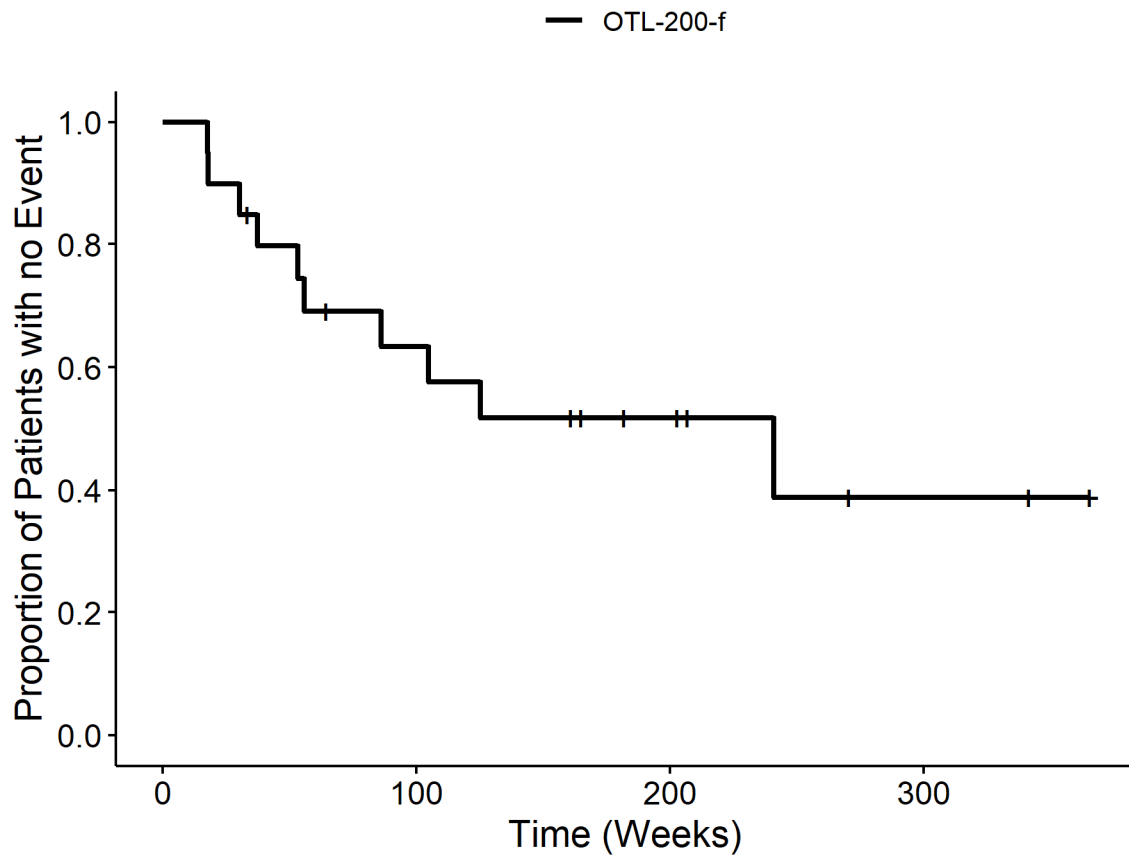
1. Patienten mit mindestens einem zur Hospitalisierung führenden UE

201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem zur Hospitalisierung führenden UE	
n (%)	20 (100)
Ja (%)	10 (50)
Nein (%)	10 (50)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

2. Zeit bis zum Erleiden eines zur Hospitalisierung führenden UEs

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines zur Hospitalisierung führenden UEs	
n (%)	10 (50)
[Min; Max] (Wochen)	[17,86; 365,43]
10. Perzentil (Wochen)	24,14
25. Perzentil (Wochen)	53,29
50. Perzentil (Median) (Wochen) [95 %-KI]	241,00 [53,286; NA]
75. Perzentil (Wochen)	NA
90. Perzentil (Wochen)	NA
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to hosp AE



3. Patienten mit mindestens einem UE

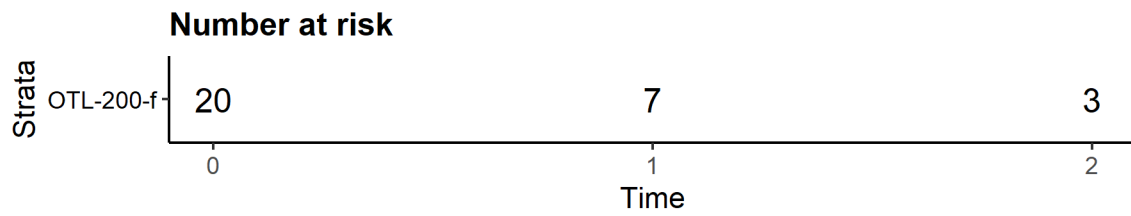
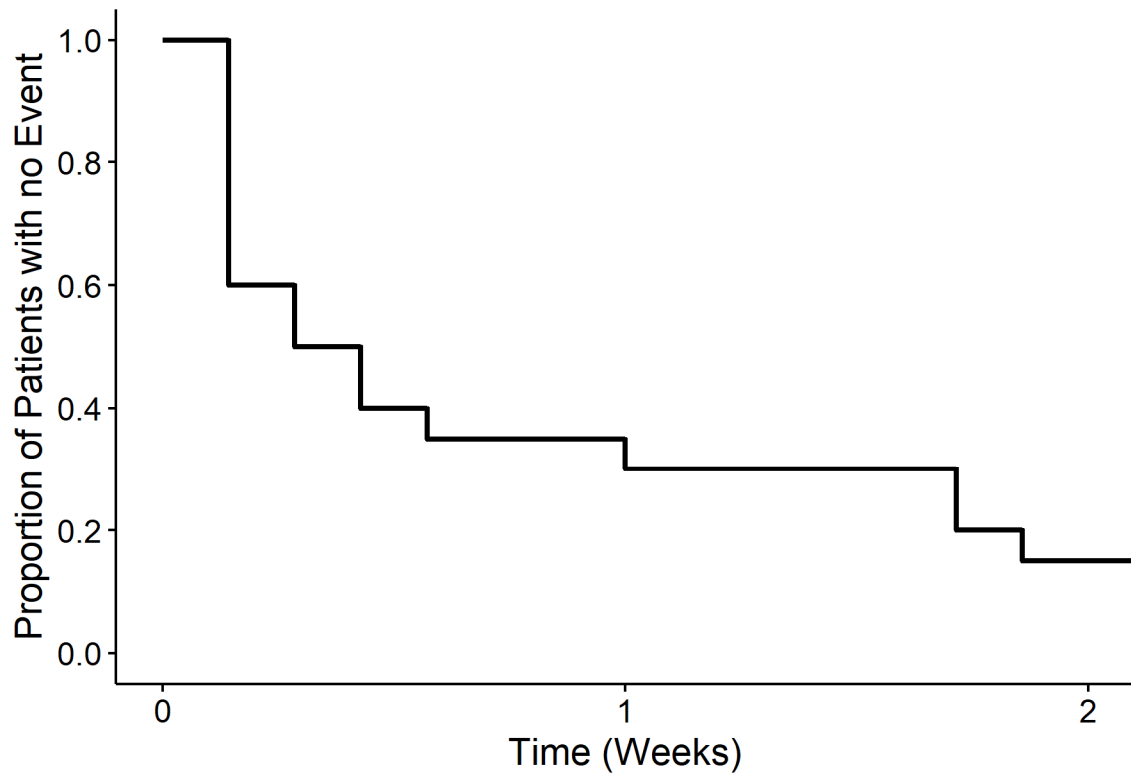
201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem UE	
n (%)	20 (100)
Ja (%)	20 (100)
Nein (%)	0 (0)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

4. Zeit bis zum Erleiden eines UEs

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines UEs	
n (%)	20 (100)
[Min; Max] (Wochen)	[0,14; 2,29]
10. Perzentil (Wochen)	0,14
25. Perzentil (Wochen)	0,14
50. Perzentil (Median) (Wochen) [95 %-KI]	0,36 [0,143; 1,714]
75. Perzentil (Wochen)	1,71
90. Perzentil (Wochen)	2,21
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to all AE

— OTL-200-f



5. Patienten mit mindestens einem milden UE

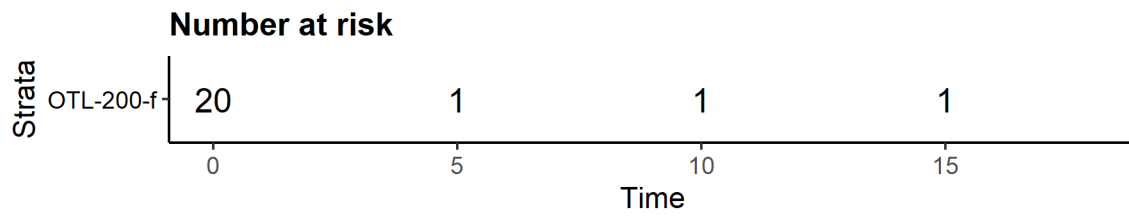
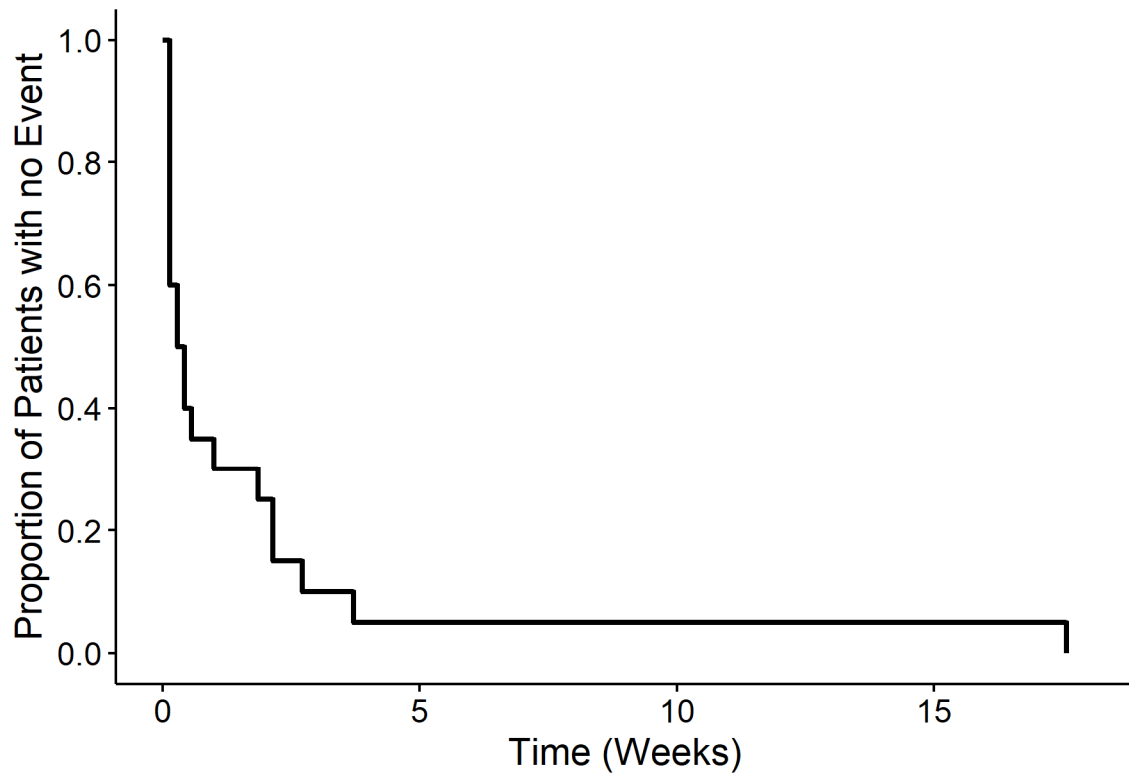
201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem milden UE	
n (%)	20 (100)
Ja (%)	20 (100)
Nein (%)	0 (0)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

6. Zeit bis zum Erleiden eines milden UEs

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines milden UEs	
n (%)	20 (100)
[Min; Max] (Wochen)	[0,14; 17,57]
10. Perzentil (Wochen)	0,14
25. Perzentil (Wochen)	0,14
50. Perzentil (Median) (Wochen) [95 %-KI]	0,36 [0,143; 1,857]
75. Perzentil (Wochen)	2,00
90. Perzentil (Wochen)	3,21
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to mild AE

— OTL-200-f



7. Patienten mit mindestens einem schweren UE

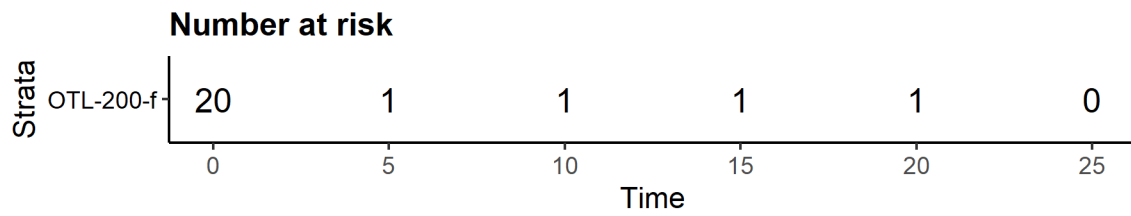
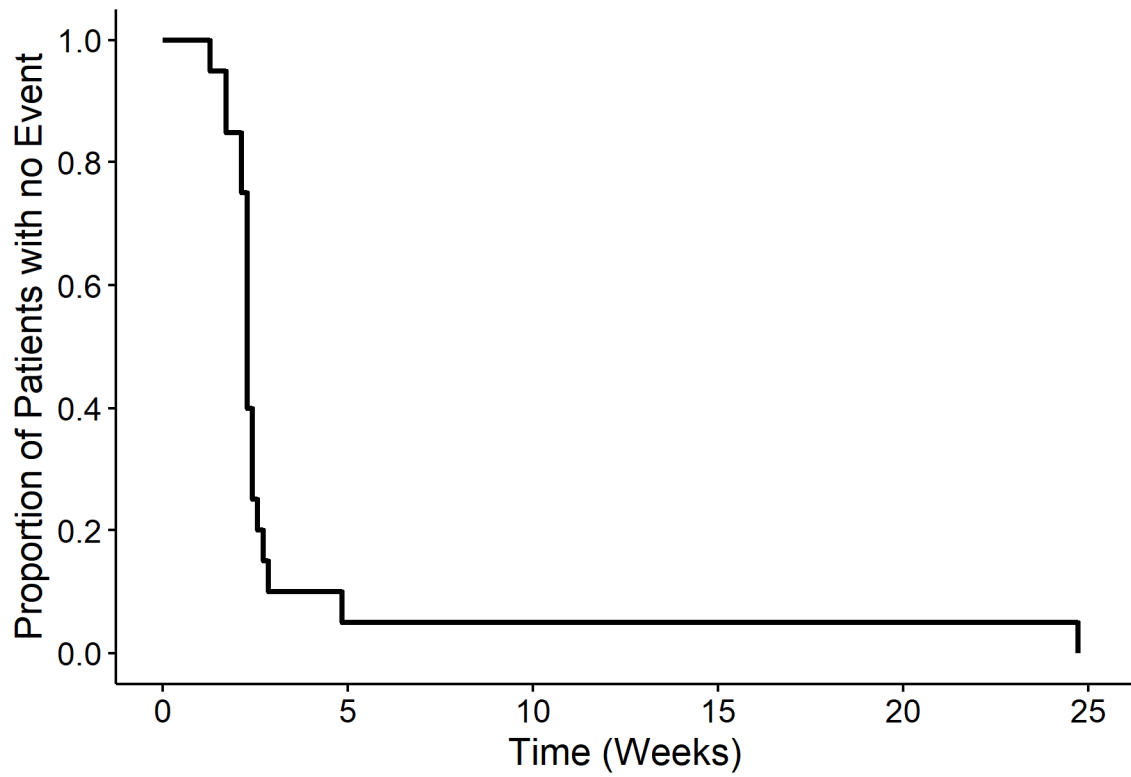
201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem schweren UE	
n (%)	20 (100)
Ja (%)	20 (100)
Nein (%)	0 (0)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

8. Zeit bis zum Erleiden eines schweren UEs

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines schweren UEs	
n (%)	20 (100)
[Min; Max] (Wochen)	[1,29; 24,71]
10. Perzentil (Wochen)	1,71
25. Perzentil (Wochen)	2,21
50. Perzentil (Median) (Wochen) [95 %-KI]	2,29 [2,143; 2,429]
75. Perzentil (Wochen)	2,50
90. Perzentil (Wochen)	3,86
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to severe AE

— OTL-200-f



9. Patienten mit mindestens einem schwerwiegenden UE

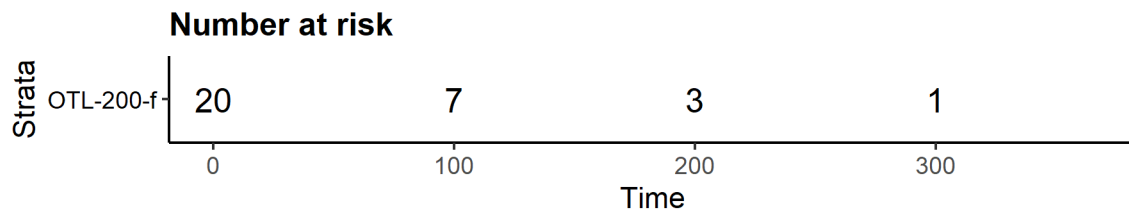
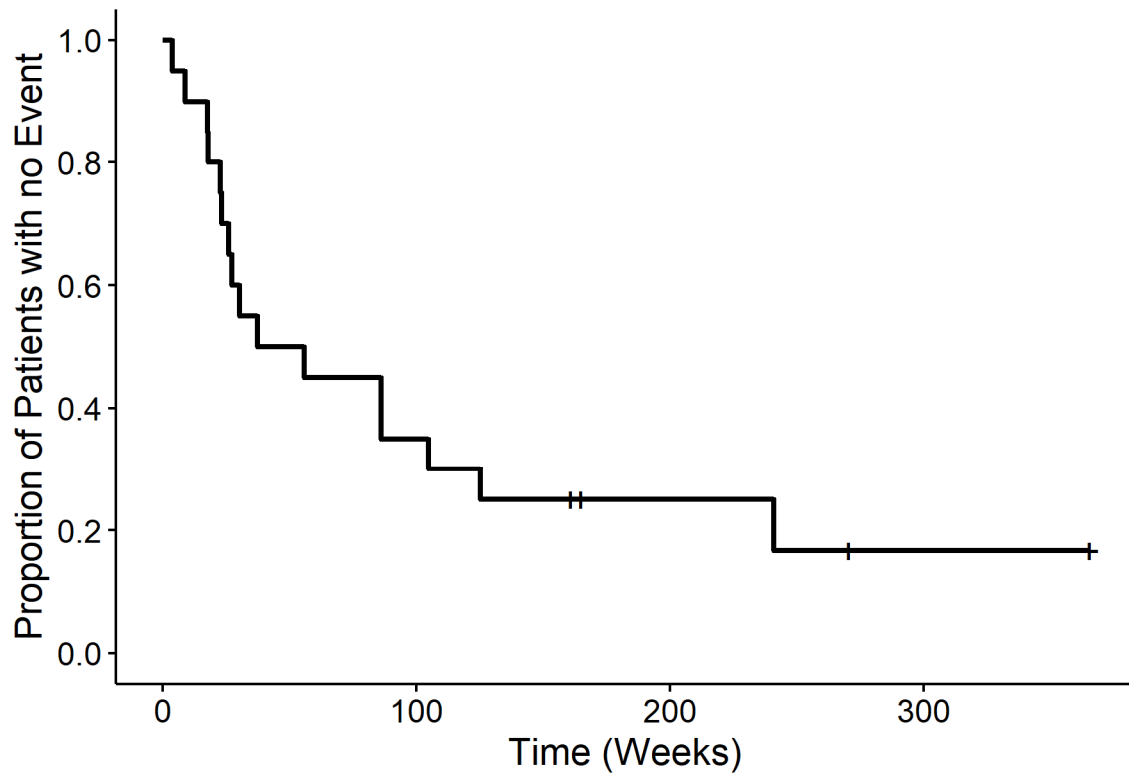
201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem schwerwiegenden UE	
n (%)	20 (100)
Ja (%)	16 (80)
Nein (%)	4 (20)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

10. Zeit bis zum Erleiden eines schwerwiegenden UEs

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines schwerwiegenden UEs	
n (%)	16 (80)
[Min; Max] (Wochen)	[4,00; 365,43]
10. Perzentil (Wochen)	13,36
25. Perzentil (Wochen)	23,14
50. Perzentil (Median) (Wochen) [95 %-KI]	46,79 [22,857; 125,286]
75. Perzentil (Wochen)	183,14
90. Perzentil (Wochen)	NA
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to serious AE

— OTL-200-f



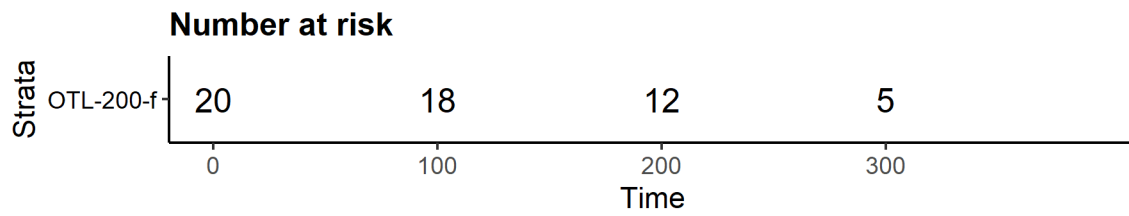
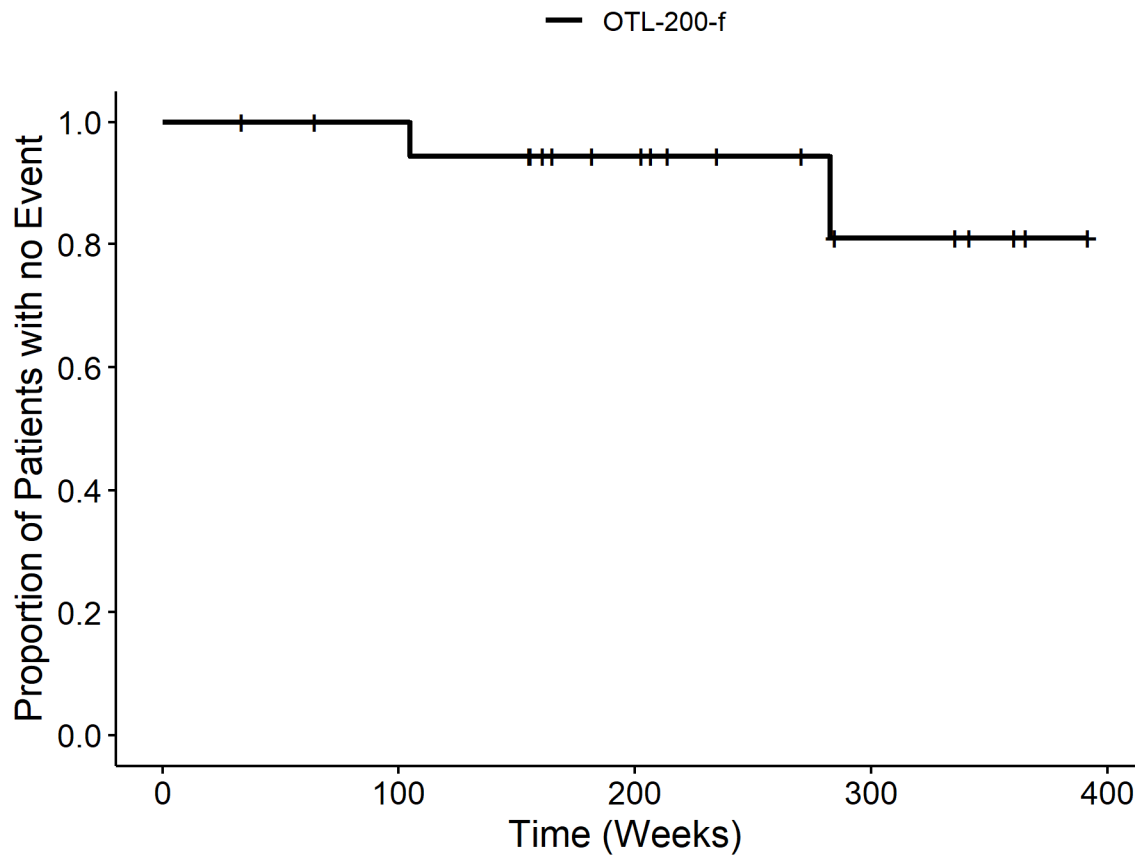
11. Patienten mit mindestens einem zur Hospitalisierung führenden UE SMQ

201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem zur Hospitalisierung führenden UE SMQ	
n (%)	20 (100)
Ja (%)	2 (10)
Nein (%)	18 (90)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

12. Zeit bis zum Erleiden eines zur Hospitalisierung führenden UEs SMQ

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines zur Hospitalisierung führenden UEs SMQ	
n (%)	2 (10)
[Min; Max] (Wochen)	[33,43; 391,71]
10. Perzentil (Wochen)	282,71
25. Perzentil (Wochen)	NA
50. Perzentil (Median) (Wochen) [95 %-KI]	NA [282,714; NA]
75. Perzentil (Wochen)	NA
90. Perzentil (Wochen)	NA
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to hosp AE SMQ



13. Patienten mit mindestens einem UE SMQ

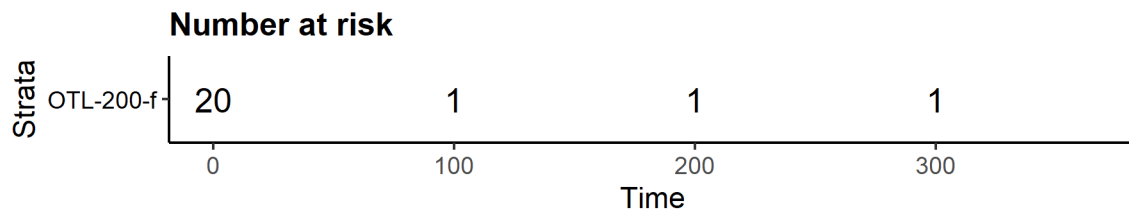
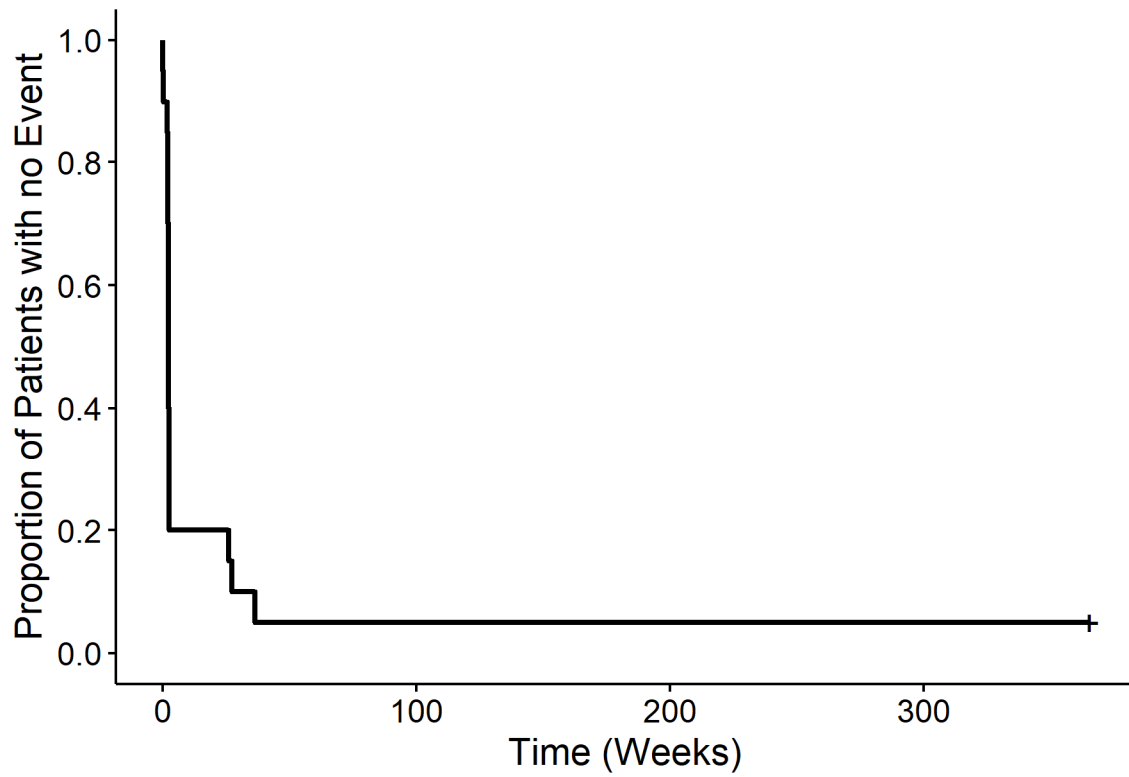
201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem UE SMQ	
n (%)	20 (100)
Ja (%)	19 (95)
Nein (%)	1 (5)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

14. Zeit bis zum Erleiden eines UEs SMQ

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines UEs SMQ	
n (%)	19 (95)
[Min; Max] (Wochen)	[0,14; 365,43]
10. Perzentil (Wochen)	1,07
25. Perzentil (Wochen)	2,14
50. Perzentil (Median) (Wochen) [95 %-KI]	2,43 [2,143; 2,714]
75. Perzentil (Wochen)	2,71
90. Perzentil (Wochen)	31,86
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to all AE SMQ

— OTL-200-f



15. Patienten mit mindestens einem milden UE SMQ

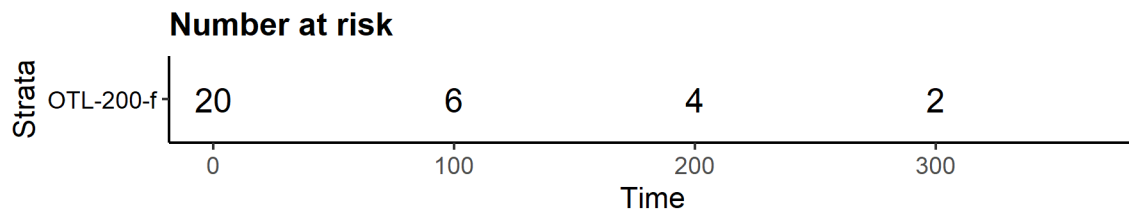
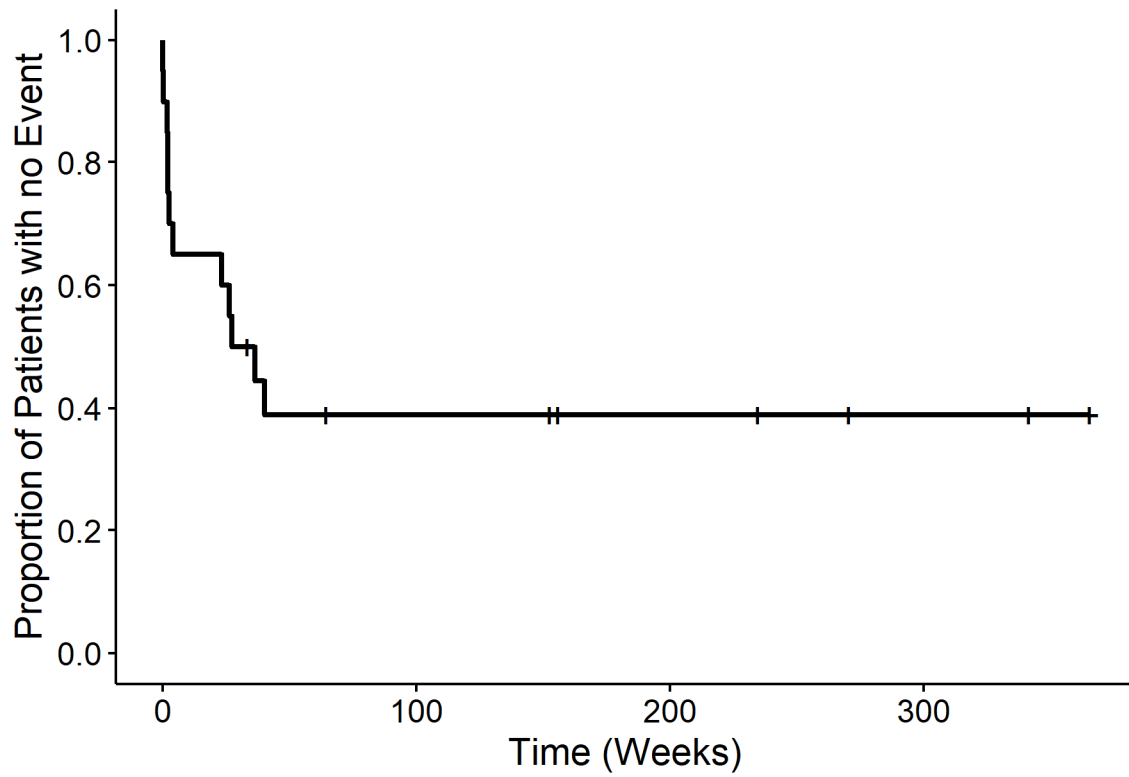
201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem milden UE SMQ	
n (%)	20 (100)
Ja (%)	12 (60)
Nein (%)	8 (40)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

16. Zeit bis zum Erleiden eines milden UEs SMQ

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines milden UEs SMQ	
n (%)	12 (60)
[Min; Max] (Wochen)	[0,14; 365,43]
10. Perzentil (Wochen)	1,07
25. Perzentil (Wochen)	2,43
50. Perzentil (Median) (Wochen) [95 %-KI]	31,86 [2,143; NA]
75. Perzentil (Wochen)	NA
90. Perzentil (Wochen)	NA
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to mild AE SMQ

— OTL-200-f



17. Patienten mit mindestens einem schweren UE SMQ

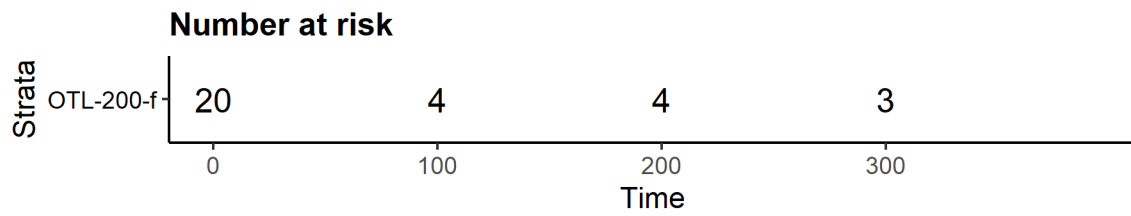
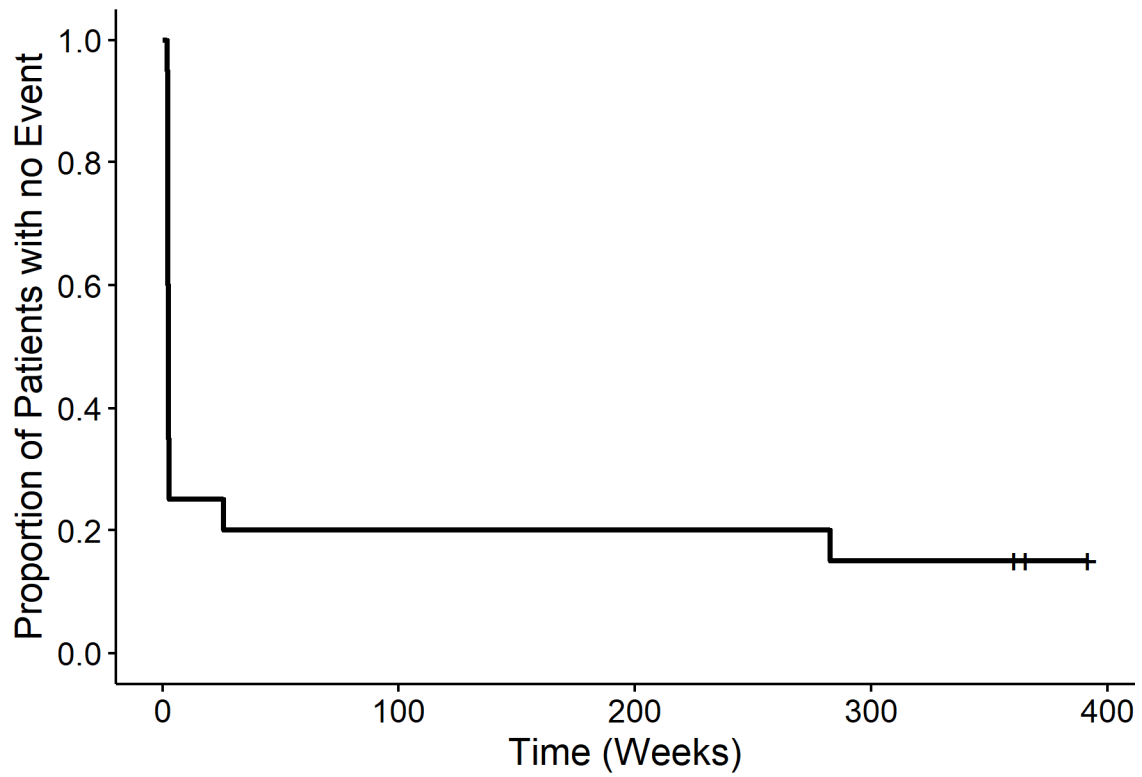
201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem schweren UE SMQ	
n (%)	20 (100)
Ja (%)	17 (85)
Nein (%)	3 (15)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

18. Zeit bis zum Erleiden eines schweren UEs SMQ

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines schweren UEs SMQ	
n (%)	17 (85)
[Min; Max] (Wochen)	[2,14; 391,71]
10. Perzentil (Wochen)	2,29
25. Perzentil (Wochen)	2,29
50. Perzentil (Median) (Wochen) [95 %-KI]	2,43 [2,286; 2,714]
75. Perzentil (Wochen)	14,36
90. Perzentil (Wochen)	NA
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to severe AE SMQ

— OTL-200-f



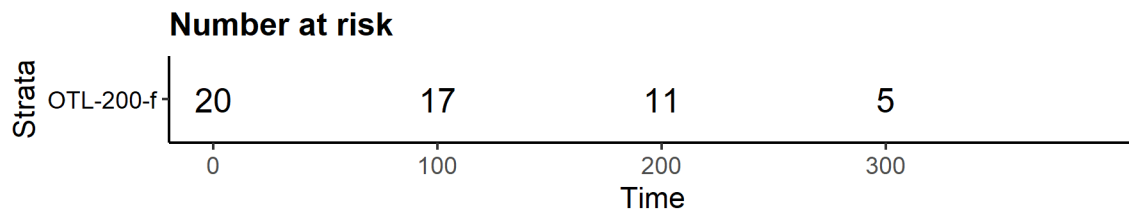
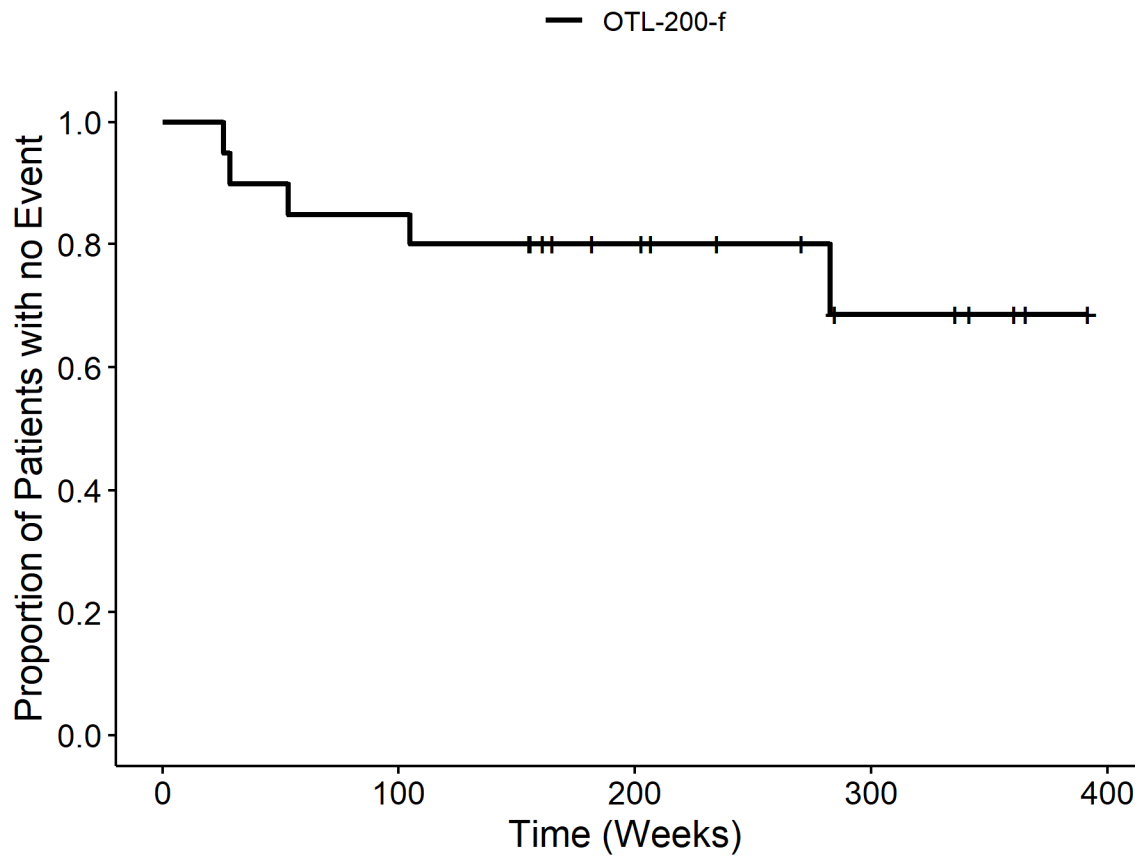
19. Patienten mit mindestens einem schwerwiegenden UE SMQ

201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem schwerwiegenden UE SMQ	
n (%)	20 (100)
Ja (%)	5 (25)
Nein (%)	15 (75)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

20. Zeit bis zum Erleiden eines schwerwiegenden UEs SMQ

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines schwerwiegenden UEs SMQ	
n (%)	5 (25)
[Min; Max] (Wochen)	[26,00; 391,71]
10. Perzentil (Wochen)	41,00
25. Perzentil (Wochen)	282,71
50. Perzentil (Median) (Wochen) [95 %-KI]	NA [282,714; NA]
75. Perzentil (Wochen)	NA
90. Perzentil (Wochen)	NA
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to serious AE SMQ



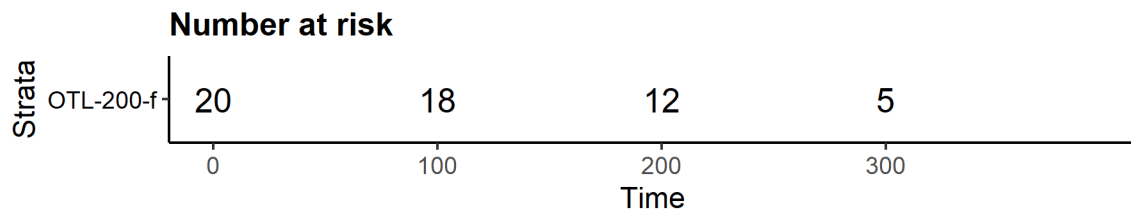
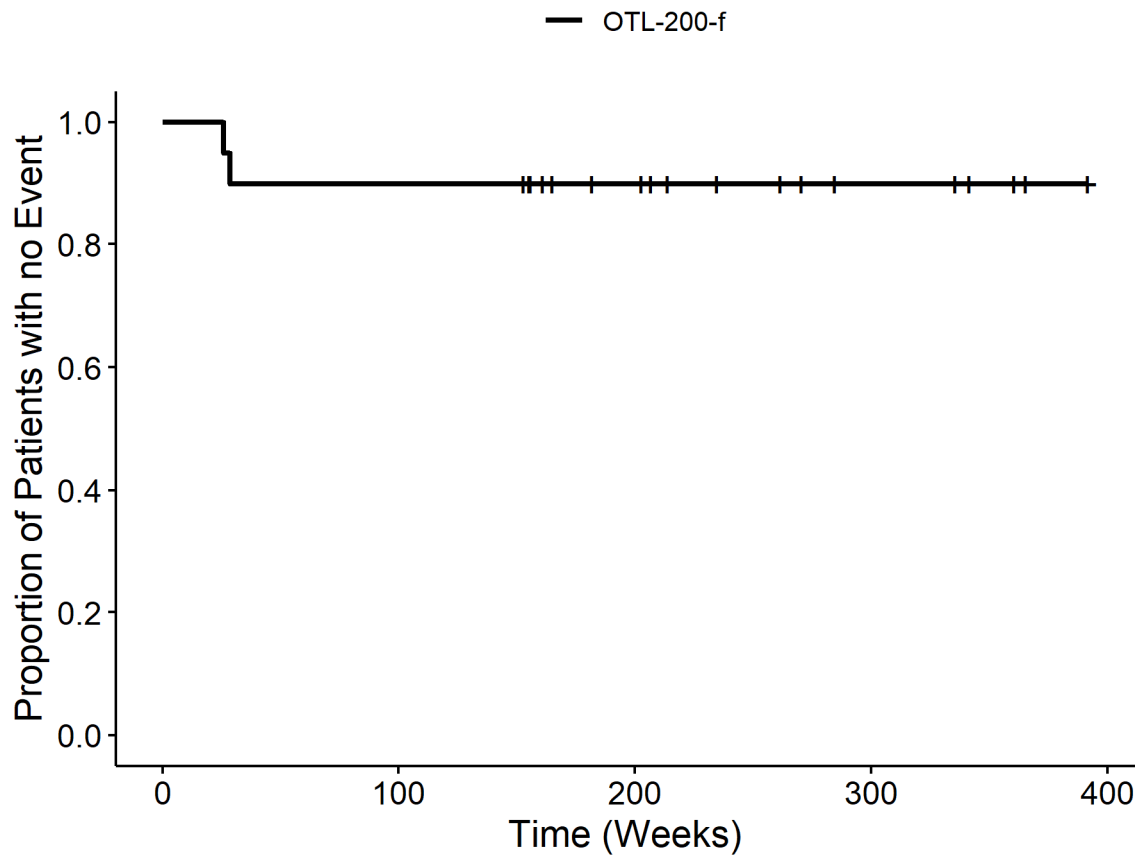
21. Patienten mit mindestens einem UE, der tödlich verlaufen ist

201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem UE, der tödlich verlaufen ist	
n (%)	20 (100)
Ja (%)	2 (10)
Nein (%)	18 (90)
^a N: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.	

22. Zeit bis zum Erleiden eines UEs, der tödlich verlaufen ist

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines UEs, der tödlich verlaufen ist	
n (%)	2 (10)
[Min; Max] (Wochen)	[26,00; 391,71]
10. Perzentil (Wochen)	210,21
25. Perzentil (Wochen)	NA
50. Perzentil (Median) (Wochen) [95 %-KI]	NA [NA; NA]
75. Perzentil (Wochen)	NA
90. Perzentil (Wochen)	NA
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to all AE death



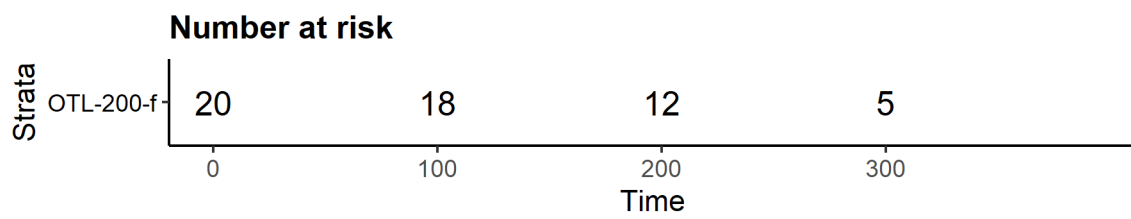
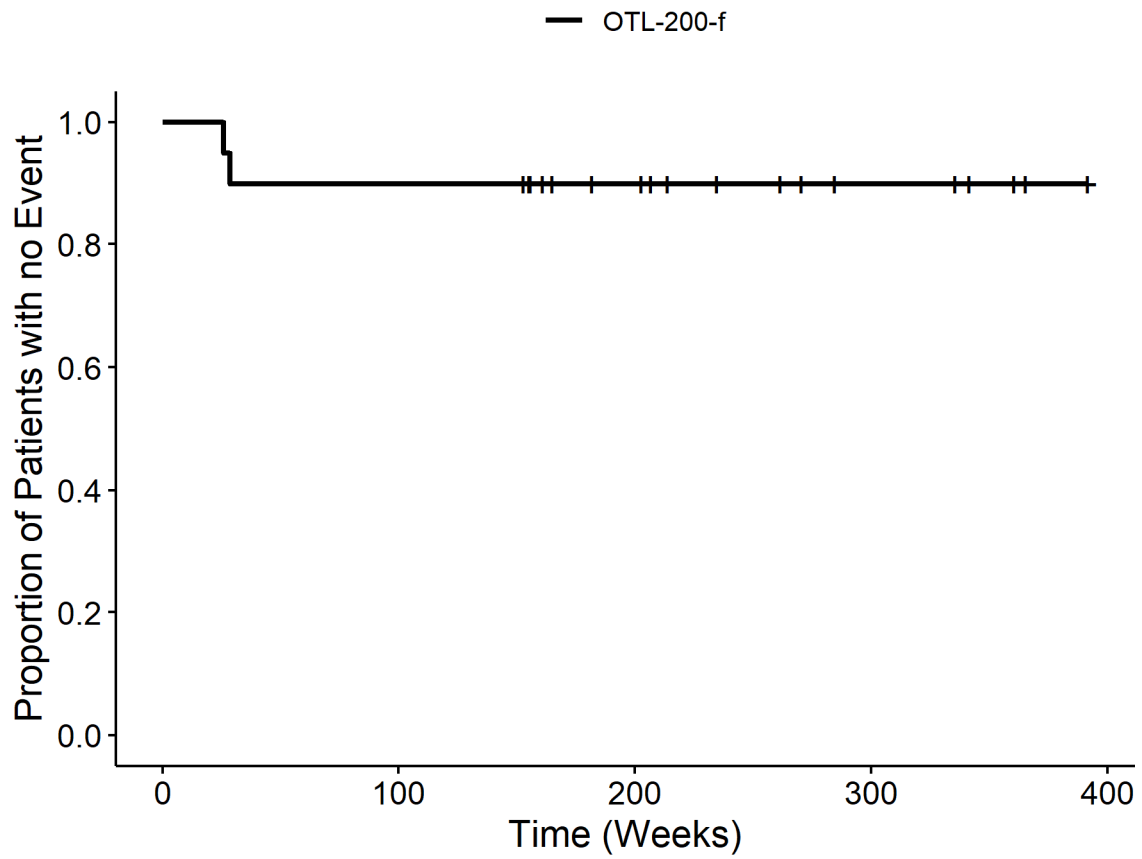
23. Patienten mit mindestens einem schweren UE, der tödlich verlaufen ist

201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem schweren UE, der tödlich verlaufen ist	
n (%)	20 (100)
Ja (%)	2 (10)
Nein (%)	18 (90)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

24. Zeit bis zum Erleiden eines schweren UEs, der tödlich verlaufen ist

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines schweren UEs, der tödlich verlaufen ist	
n (%)	2 (10)
[Min; Max] (Wochen)	[26,00; 391,71]
10. Perzentil (Wochen)	210,21
25. Perzentil (Wochen)	NA
50. Perzentil (Median) (Wochen) [95 %-KI]	NA [NA; NA]
75. Perzentil (Wochen)	NA
90. Perzentil (Wochen)	NA
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to severe AE death



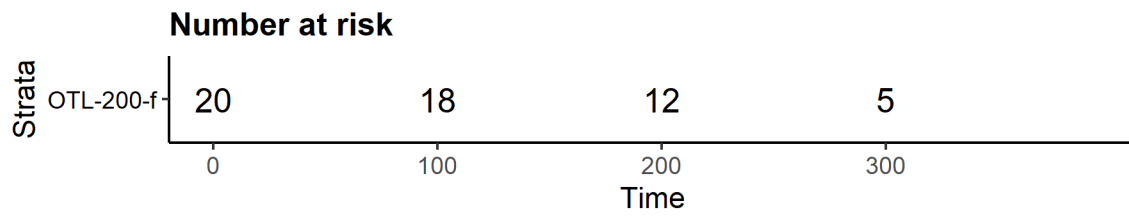
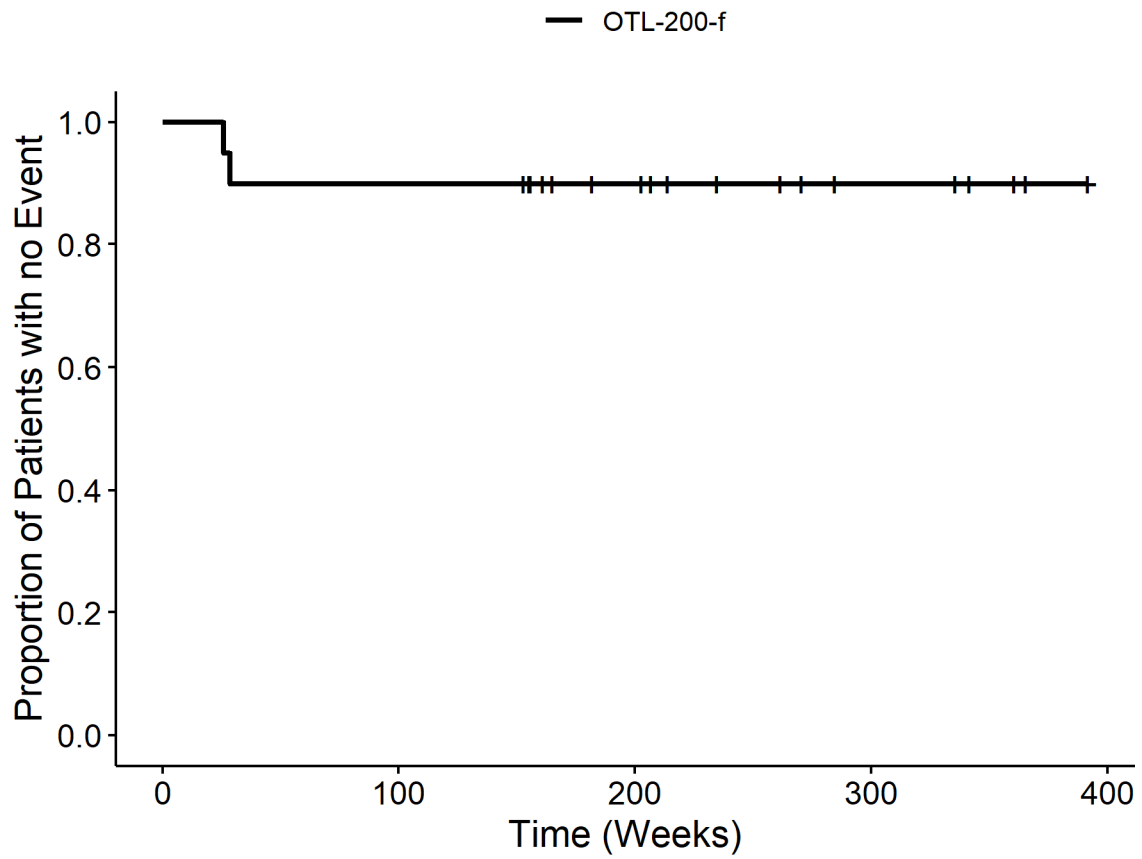
25. Patienten mit mindestens einem schwerwiegenden UE, der tödlich verlaufen ist

201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten mit mindestens einem schwerwiegenden UE, der tödlich verlaufen ist	
n (%)	20 (100)
Ja (%)	2 (10)
Nein (%)	18 (90)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

26. Zeit bis zum Erleiden eines schwerwiegenden UEs, der tödlich verlaufen ist

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines schwerwiegenden UEs, der tödlich verlaufen ist	
n (%)	2 (10)
[Min; Max] (Wochen)	[26,00; 391,71]
10. Perzentil (Wochen)	210,21
25. Perzentil (Wochen)	NA
50. Perzentil (Median) (Wochen) [95 %-KI]	NA [NA; NA]
75. Perzentil (Wochen)	NA
90. Perzentil (Wochen)	NA
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

Kaplan Meier Plot for Time to serious AE death



1. UEs nach SOC und PT

1.1. Patienten mit mindestens einem UE nach SOC und PT, das bei mindestens 10% der Patienten in einem Studienarm auftrat

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
Patienten mit mindestens einem UE nach SOC und PT, das bei mindestens 10% der Patienten in einem Studienarm auftrat	
SOC Infektionen und parasitäre Erkrankungen	18 (90)
PT Infektion der oberen Atemwege	10 (50)
PT Konjunktivitis	5 (25)
PT Ohreninfektion	5 (25)
PT Gastroenteritis	3 (15)
PT Infektion im Zusammenhang mit einem Medizinprodukt	5 (25)
PT Pneumonie	3 (15)
PT Scharlach	3 (15)
PT Atemwegsinfektion	3 (15)
PT Clostridium difficile-Kolitis	3 (15)
PT Harnwegsinfektion	2 (10)
PT Pharyngitis	2 (10)
PT Windpocken	2 (10)
SOC Erkrankungen des Gastrointestinaltrakts	16 (80)
PT Enteritis	6 (30)
PT Stomatitis	8 (40)
PT Erbrechen	4 (20)
PT Dysphagie	4 (20)
PT Karies	2 (10)
SOC Untersuchungen	15 (75)
PT Erhöhtes Immunoglobulin E im Blut	8 (40)
PT Erhöhtes Serum-Ferritin	5 (25)

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
PT Erniedrigter BMI	4 (20)
PT Vitamin D erniedrigt	6 (30)
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	15 (75)
PT Fieber	6 (30)
PT Gangstoerung	10 (50)
PT Schleimhautentzündung	6 (30)
SOC Erkrankungen des Blutes und des Lymphsystems	15 (75)
PT Febrile Neutropenie	15 (75)
PT Neutropenie	2 (10)
SOC Erkrankungen des Nervensystems	12 (60)
PT Spastik	9 (45)
PT Ataxie	5 (25)
PT Motorische Funktionsstoerung	7 (35)
PT Aphasie	6 (30)
PT Dysarthrie	5 (25)
PT Kognitive Stoerung	4 (20)
PT Epilepsie	2 (10)
PT Krampfanfall	2 (10)
SOC Leber- und Gallenerkrankungen	11 (55)
PT Hepatomegalie	4 (20)
PT Gallenblasenpolyp	3 (15)
PT Vergrößerung der Gallenblase	3 (15)
PT DRUG-INDUCED LIVER INJURY	2 (10)
SOC Erkrankungen der Haut und des Unterhautzellgewebes	10 (50)
PT Erythematöser Hautausschlag	3 (15)
PT Hautlaesion	2 (10)

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums	7 (35)
PT Epistaxis	3 (15)
PT Bronchospasmus	2 (10)
SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	7 (35)
PT Kopfverletzung	3 (15)
PT Fraktur des Fusses	2 (10)
PT Schmerzen waehrend eines Eingriffes	2 (10)
SOC Stoffwechsel- und Ernährungsstörungen	5 (25)
PT Metabolische Azidose	4 (20)
PT Eisenmangel	2 (10)
SOC Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen	5 (25)
PT Osteoporose	3 (15)
SOC Kongenitale, familiäre und genetische Erkrankungen	5 (25)
PT Phimose	3 (15)
PT Kryptorchismus	2 (10)
SOC Augenerkrankungen	4 (20)
SOC Erkrankungen der Nieren und Harnwege	3 (15)
PT RENAL TUBULAR ACIDOSIS	2 (10)
SOC Gefäßerkrankungen	2 (10)
^a N: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.	

1.2. Zeit bis zum Erleiden eines UEs nach SOC und PT, das bei mindestens 10% der Patienten in einem Studienarm auftrat

201222	OTL-200-f
N = 20 ^a	Min; Median [95%KI]; Max
Zeit bis zum Erleiden eines UEs nach SOC und PT, das bei mindestens 10% der Patienten in einem Studienarm auftrat	
SOC Infektionen und parasitäre Erkrankungen	1,29; 9,14 [2,857; 40,000]; 341,43
PT Infektion der oberen Atemwege	6,29; 232,71 [46,857; NA]; 365,43
PT Konjunktivitis	4,71; NA [136,429; NA]; 391,71
PT Ohreninfektion	12,43; NA [133,429; NA]; 365,43
PT Gastroenteritis	17,57; NA [300,857; NA]; 391,71
PT Infektion im Zusammenhang mit einem Medizinprodukt	3,43; NA [106,429; NA]; 365,43
PT Pneumonie	33,43; NA [NA; NA]; 365,43
PT Scharlach	33,43; NA [319,143; NA]; 391,71
PT Atemwegsinfektion	33,43; NA [285,429; NA]; 365,43
PT Clostridium difficile-Kolitis	2,29; NA [NA; NA]; 391,71
PT Harnwegsinfektion	7,86; NA [NA; NA]; 391,71
PT Pharyngitis	33,43; 398,43 [253,857; NA]; 398,43
PT Windpocken	33,43; NA [282,286; NA]; 391,71
SOC Erkrankungen des Gastrointestinaltrakts	2,14; 22,00 [2,429; 93,000]; 365,43
PT Enteritis	18,00; NA [93,000; NA]; 365,43
PT Stomatitis	2,14; NA [2,429; NA]; 391,71
PT Erbrechen	2,86; NA [241,000; NA]; 391,71
PT Dysphagie	26,00; NA [282,714; NA]; 391,71
PT Karies	33,43; NA [360,857; NA]; 391,71
SOC Untersuchungen	2,14; 9,57 [4,857; 79,286]; 365,43
PT Erhöhtes Immunoglobulin E im Blut	2,14; NA [26,286; NA]; 365,43
PT Erhöhtes Serum-Ferritin	4,86; NA [9,286; NA]; 391,71
PT Erniedrigter BMI	23,29; NA [235,286; NA]; 391,71
PT Vitamin D erniedrigt	33,43; 339,57 [207,714; NA]; 365,43
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	2,14; 18,14 [2,286; 79,286]; 365,43

201222	OTL-200-f
N = 20^a	Min; Median [95%KI]; Max
PT Fieber	6,14; NA [52,429; NA]; 391,71
PT Gangstoerung	4,86; 163,29 [11,571; NA]; 365,43
PT Schleimhautentzündung	2,14; NA [2,286; NA]; 365,43
SOC Erkrankungen des Blutes und des Lymphsystems	2,29; 2,79 [2,714; 3,571]; 391,71
PT Febrile Neutropenie	2,29; 2,79 [2,714; 3,571]; 391,71
PT Neutropenie	7,29; NA [NA; NA]; 391,71
SOC Erkrankungen des Nervensystems	5,14; 124,93 [27,571; NA]; 365,43
PT Spastik	8,86; 265,71 [76,429; NA]; 365,43
PT Ataxie	9,43; NA [79,286; NA]; 391,71
PT Motorische Funktionsstoerung	5,29; NA [86,143; NA]; 391,71
PT Aphasie	5,29; NA [128,286; NA]; 391,71
PT Dysarthrie	5,29; NA [157,429; NA]; 391,71
PT Kognitive Stoerung	22,43; NA [261,714; NA]; 391,71
PT Epilepsie	33,43; NA [NA; NA]; 391,71
PT Krampfanfall	33,43; NA [NA; NA]; 391,71
SOC Leber- und Gallenerkrankungen	1,00; 102,71 [4,857; NA]; 360,57
PT Hepatomegalie	1,00; NA [NA; NA]; 360,57
PT Gallenblasenpolyp	22,86; NA [NA; NA]; 391,71
PT Vergrößerung der Gallenblase	8,57; NA [210,714; NA]; 391,71
PT DRUG-INDUCED LIVER INJURY	1,14; NA [NA; NA]; 391,71
SOC Erkrankungen der Haut und des Unterhautzellgewebes	1,71; 166,57 [3,143; NA]; 365,43
PT Erythematöses Hautausschlag	1,86; NA [NA; NA]; 391,71
PT Hautlaesion	4,00; NA [NA; NA]; 391,71
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums	1,86; NA [80,429; NA]; 365,43
PT Epistaxis	2,29; NA [NA; NA]; 391,71
PT Bronchospasmus	33,43; NA [NA; NA]; 391,71
SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	11,29; NA [178,429; NA]; 365,43

201222	OTL-200-f
N = 20^a	Min; Median [95%KI]; Max
PT Kopfverletzung	11,29; NA [205,000; NA]; 365,43
PT Fraktur des Fusses	33,43; NA [214,000; NA]; 391,71
PT Schmerzen waehrend eines Eingriffes	33,43; NA [257,857; NA]; 391,71
SOC Stoffwechsel- und Ernährungsstörungen	2,43; NA [210,571; NA]; 391,71
PT Metabolische Azidose	2,43; NA [162,857; NA]; 391,71
PT Eisenmangel	33,43; NA [NA; NA]; 391,71
SOC Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen	5,86; NA [210,429; NA]; 365,43
PT Osteoporose	33,43; NA [214,429; NA]; 391,71
SOC Kongenitale, familiäre und genetische Erkrankungen	26,29; NA [209,286; NA]; 365,43
PT Phimose	26,29; NA [209,286; NA]; 391,71
PT Kryptorchismus	33,43; NA [264,286; NA]; 365,43
SOC Augenerkrankungen	3,29; NA [334,857; NA]; 391,71
SOC Erkrankungen der Nieren und Harnwege	1,71; NA [NA; NA]; 391,71
PT RENAL TUBULAR ACIDOSIS	1,71; NA [NA; NA]; 391,71
SOC Gefäßerkrankungen	5,86; NA [NA; NA]; 391,71
<i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i>	
<i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i>	

1.3. Patienten mit mindestens einem UE nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
Patienten mit mindestens einem UE nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat	
SOC Infektionen und parasitäre Erkrankungen	18 (90)
PT Infektion der oberen Atemwege	10 (50)
SOC Erkrankungen des Gastrointestinaltrakts	16 (80)
SOC Untersuchungen	15 (75)
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	15 (75)
PT Gangstoerung	10 (50)
SOC Erkrankungen des Blutes und des Lymphsystems	15 (75)
PT Febrile Neutropenie	15 (75)
SOC Erkrankungen des Nervensystems	12 (60)
SOC Leber- und Gallenerkrankungen	11 (55)
SOC Erkrankungen der Haut und des Unterhautzellgewebes	10 (50)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

1.4. Zeit bis zum Erleiden eines UEs nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat

201222	OTL-200-f
N = 20 ^a	Min; Median [95%KI]; Max
Zeit bis zum Erleiden eines UEs nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat	
SOC Infektionen und parasitäre Erkrankungen	1,29; 9,14 [2,857; 40,000]; 341,43
PT Infektion der oberen Atemwege	6,29; 232,71 [46,857; NA]; 365,43
SOC Erkrankungen des Gastrointestinaltrakts	2,14; 22,00 [2,429; 93,000]; 365,43
SOC Untersuchungen	2,14; 9,57 [4,857; 79,286]; 365,43
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	2,14; 18,14 [2,286; 79,286]; 365,43
PT Gangstoerung	4,86; 163,29 [11,571; NA]; 365,43
SOC Erkrankungen des Blutes und des Lymphsystems	2,29; 2,79 [2,714; 3,571]; 391,71
PT Febrile Neutropenie	2,29; 2,79 [2,714; 3,571]; 391,71
SOC Erkrankungen des Nervensystems	5,14; 124,93 [27,571; NA]; 365,43
SOC Leber- und Gallenerkrankungen	1,00; 102,71 [4,857; NA]; 360,57
SOC Erkrankungen der Haut und des Unterhautzellgewebes	1,71; 166,57 [3,143; NA]; 365,43
^a Die Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.	
KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).	

2. milde UEs nach SOC und PT

2.1. Patienten mit mindestens einem milden UE nach SOC und PT, das bei mindestens 10% der Patienten in einem Studienarm auftrat

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
Patienten mit mindestens einem milden UE nach SOC und PT, das bei mindestens 10% der Patienten in einem Studienarm auftrat	
SOC Infektionen und parasitäre Erkrankungen	17 (85)
PT Infektion der oberen Atemwege	10 (50)
PT Konjunktivitis	5 (25)
PT Ohreninfektion	5 (25)
PT Gastroenteritis	3 (15)
PT Scharlach	3 (15)
PT Atemwegsinfektion	2 (10)
PT Harnwegsinfektion	2 (10)
PT Pharyngitis	2 (10)
PT Windpocken	2 (10)
SOC Untersuchungen	15 (75)
PT Erhöhtes Immunoglobulin E im Blut	8 (40)
PT Erhöhtes Serum-Ferritin	5 (25)
PT Vitamin D erniedrigt	6 (30)
PT Erniedrigter BMI	3 (15)
SOC Leber- und Gallenerkrankungen	11 (55)
PT Hepatomegalie	4 (20)
PT Gallenblasenpolyp	3 (15)
PT Vergrößerung der Gallenblase	3 (15)
PT DRUG-INDUCED LIVER INJURY	2 (10)
SOC Erkrankungen der Haut und des Unterhautzellgewebes	9 (45)
PT Erythematöses Hautausschlag	2 (10)
PT Hautläsion	2 (10)

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	8 (40)
PT Fieber	6 (30)
SOC Erkrankungen des Gastrointestinaltrakts	7 (35)
PT Enteritis	3 (15)
PT Erbrechen	3 (15)
PT Karies	2 (10)
SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	7 (35)
PT Kopfverletzung	3 (15)
PT Fraktur des Fusses	2 (10)
PT Schmerzen wachrend eines Eingriffes	2 (10)
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums	6 (30)
PT Bronchospasmus	2 (10)
PT Epistaxis	2 (10)
SOC Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen	5 (25)
PT Osteoporose	3 (15)
SOC Kongenitale, familiäre und genetische Erkrankungen	5 (25)
PT Phimose	3 (15)
PT Kryptorchismus	2 (10)
SOC Augenerkrankungen	4 (20)
SOC Erkrankungen des Nervensystems	4 (20)
PT Epilepsie	2 (10)
SOC Stoffwechsel- und Ernährungsstörungen	3 (15)
PT Eisenmangel	2 (10)
PT Metabolische Azidose	2 (10)
SOC Erkrankungen der Nieren und Harnwege	2 (10)

201222	Behandlungsgruppe
	OTL-200-f
N^a	N = 20
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

2.2. Zeit bis zum Erleiden eines milden UEs nach SOC und PT, das bei mindestens 10% der Patienten in einem Studienarm auftrat

201222	OTL-200-f
N = 20 ^a	Min; Median [95%KI]; Max
Zeit bis zum Erleiden eines milden UEs nach SOC und PT, das bei mindestens 10% der Patienten in einem Studienarm auftrat	
SOC Infektionen und parasitäre Erkrankungen	3,57; 27,50 [7,857; 46,857]; 341,43
PT Infektion der oberen Atemwege	6,29; 169,86 [46,857; NA]; 365,43
PT Konjunktivitis	4,71; NA [136,429; NA]; 391,71
PT Ohreninfektion	12,43; NA [133,429; NA]; 365,43
PT Gastroenteritis	17,57; NA [300,857; NA]; 391,71
PT Scharlach	33,43; NA [319,143; NA]; 391,71
PT Atemwegsinfektion	33,43; NA [NA; NA]; 365,43
PT Harnwegsinfektion	7,86; NA [NA; NA]; 391,71
PT Pharyngitis	33,43; 398,43 [253,857; NA]; 398,43
PT Windpocken	33,43; NA [282,286; NA]; 391,71
SOC Untersuchungen	2,14; 9,64 [4,857; 79,286]; 365,43
PT Erhöhtes Immunoglobulin E im Blut	2,14; NA [26,286; NA]; 365,43
PT Erhöhtes Serum-Ferritin	4,86; NA [9,286; NA]; 391,71
PT Vitamin D erniedrigt	33,43; 339,57 [207,714; NA]; 365,43
PT Erniedrigter BMI	33,43; NA [235,286; NA]; 391,71
SOC Leber- und Gallenerkrankungen	1,00; 102,71 [4,857; NA]; 360,57
PT Hepatomegalie	1,00; NA [NA; NA]; 360,57
PT Gallenblasenpolyp	22,86; NA [NA; NA]; 391,71
PT Vergrößerung der Gallenblase	8,57; NA [210,714; NA]; 391,71
PT DRUG-INDUCED LIVER INJURY	1,14; NA [NA; NA]; 391,71
SOC Erkrankungen der Haut und des Unterhautzellgewebes	1,71; NA [4,143; NA]; 365,43
PT Erythematöser Hautausschlag	1,86; NA [NA; NA]; 391,71
PT Hautläsion	4,00; NA [NA; NA]; 391,71
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	2,14; NA [45,143; NA]; 365,43
PT Fieber	8,29; NA [52,429; NA]; 391,71

201222	OTL-200-f
N = 20^a	Min; Median [95%KI]; Max
SOC Erkrankungen des Gastrointestinaltrakts	2,86; NA [73,857; NA]; 365,43
PT Enteritis	33,43; NA [NA; NA]; 391,71
PT Erbrechen	2,86; NA [NA; NA]; 391,71
PT Karies	33,43; NA [360,857; NA]; 391,71
SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	11,29; NA [178,429; NA]; 365,43
PT Kopfverletzung	11,29; NA [205,000; NA]; 365,43
PT Fraktur des Fusses	33,43; NA [214,000; NA]; 391,71
PT Schmerzen waehrend eines Eingriffes	33,43; NA [257,857; NA]; 391,71
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums	1,86; NA [94,000; NA]; 365,43
PT Bronchospasmus	33,43; NA [NA; NA]; 391,71
PT Epistaxis	3,71; NA [NA; NA]; 391,71
SOC Skelettmuskulatur-, Bindegewebs- und Knochenkrankungen	5,86; NA [210,429; NA]; 365,43
PT Osteoporose	33,43; NA [214,429; NA]; 391,71
SOC Kongenitale, familiäre und genetische Erkrankungen	26,29; NA [209,286; NA]; 365,43
PT Phimose	26,29; NA [209,286; NA]; 391,71
PT Kryptorchismus	33,43; NA [264,286; NA]; 365,43
SOC Augenerkrankungen	3,29; NA [334,857; NA]; 391,71
SOC Erkrankungen des Nervensystems	5,14; NA [NA; NA]; 391,71
PT Epilepsie	33,43; NA [NA; NA]; 391,71
SOC Stoffwechsel- und Ernährungsstörungen	33,43; NA [210,571; NA]; 391,71
PT Eisenmangel	33,43; NA [NA; NA]; 391,71
PT Metabolische Azidose	33,43; NA [NA; NA]; 391,71
SOC Erkrankungen der Nieren und Harnwege	2,86; NA [NA; NA]; 391,71
<i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i>	
<i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i>	

2.3. Patienten mit mindestens einem milden UE nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
Patienten mit mindestens einem milden UE nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat	
SOC Infektionen und parasitäre Erkrankungen	17 (85)
PT Infektion der oberen Atemwege	10 (50)
SOC Untersuchungen	15 (75)
SOC Leber- und Gallenerkrankungen	11 (55)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

2.4. Zeit bis zum Erleiden eines milden UEs nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat

201222	OTL-200-f
N = 20 ^a	Min; Median [95%KI]; Max
Zeit bis zum Erleiden eines milden UEs nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat	
SOC Infektionen und parasitäre Erkrankungen	3,57; 27,50 [7,857; 46,857]; 341,43
PT Infektion der oberen Atemwege	6,29; 169,86 [46,857; NA]; 365,43
SOC Untersuchungen	2,14; 9,64 [4,857; 79,286]; 365,43
SOC Leber- und Gallenerkrankungen	1,00; 102,71 [4,857; NA]; 360,57
<p>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</p> <p>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</p>	

3. schwere UEs nach SOC und PT

3.1. Patienten mit mindestens einem schweren UE nach SOC und PT, das bei mindestens 5% der Patienten in einem Studienarm auftrat

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
Patienten mit mindestens einem schweren UE nach SOC und PT, das bei mindestens 5% der Patienten in einem Studienarm auftrat	
SOC Erkrankungen des Blutes und des Lymphsystems	15 (75)
PT Febrile Neutropenie	15 (75)
PT Neutropenie	2 (10)
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	14 (70)
PT Gangstoerung	10 (50)
PT Schleimhautentzündung	5 (25)
PT Fieber	1 (5)
SOC Erkrankungen des Gastrointestinaltrakts	14 (70)
PT Stomatitis	8 (40)
PT Dysphagie	4 (20)
PT Enteritis	3 (15)
PT Erbrechen	2 (10)
SOC Erkrankungen des Nervensystems	11 (55)
PT Spastik	9 (45)
PT Ataxie	5 (25)
PT Motorische Funktionsstoerung	7 (35)
PT Aphasie	6 (30)
PT Dysarthrie	5 (25)
PT Kognitive Stoerung	4 (20)
PT Krampfanfall	2 (10)
PT Status epilepticus	1 (5)
SOC Infektionen und parasitäre Erkrankungen	10 (50)

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
PT Infektion im Zusammenhang mit einem Medizinprodukt	4 (20)
PT Pneumonie	2 (10)
PT Clostridium difficile-Kolitis	2 (10)
PT Escherichia-Infektion	1 (5)
PT Atemwegsinfektion	1 (5)
PT BACTERIAL SEPSIS	1 (5)
PT CYTOMEGALOVIRUS INFECTION	1 (5)
PT CYTOMEGALOVIRUS VIRAEMIA	1 (5)
PT Gastroenteritis	1 (5)
PT GASTROENTERITIS AEROMONAS	1 (5)
PT Haemophilus-Infektion	1 (5)
PT Infektion der oberen Atemwege	1 (5)
PT Staphylokokkeninfektion	1 (5)
PT UPPER RESPIRATORY FUNGAL INFECTION	1 (5)
SOC Untersuchungen	3 (15)
PT Erniedrigter BMI	1 (5)
PT Sauerstoffsättigung erniedrigt	1 (5)
PT Stenotrophomonas-Test positiv	1 (5)
SOC Stoffwechsel- und Ernährungsstörungen	3 (15)
PT Metabolische Azidose	3 (15)
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums	2 (10)
PT Epistaxis	2 (10)
PT Aspirationspneumonie	1 (5)
SOC Erkrankungen der Haut und des Unterhautzellgewebes	2 (10)
PT Erythematöser Hautausschlag	1 (5)
PT RASH PRURITIC	1 (5)

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
SOC Erkrankungen der Nieren und Harnwege	1 (5)
PT RENAL TUBULAR ACIDOSIS	1 (5)
SOC Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen	1 (5)
PT Deformitaet des Fusses	1 (5)
SOC Gefäßerkrankungen	1 (5)
PT KAWASAKI'S DISEASE	1 (5)
SOC Herzerkrankungen	1 (5)
PT Bradykardie	1 (5)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

3.2. Zeit bis zum Erleiden eines schweren UEs nach SOC und PT, das bei mindestens 5% der Patienten in einem Studienarm auftrat

201222	OTL-200-f
N = 20 ^a	Min; Median [95%KI]; Max
Zeit bis zum Erleiden eines schweren UEs nach SOC und PT, das bei mindestens 5% der Patienten in einem Studienarm auftrat	
SOC Erkrankungen des Blutes und des Lymphsystems	2,29; 2,79 [2,714; 3,571]; 391,71
PT Febrile Neutropenie	2,29; 2,79 [2,714; 3,571]; 391,71
PT Neutropenie	7,29; NA [NA; NA]; 391,71
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	2,29; 18,14 [2,429; NA]; 365,43
PT Gangstoerung	4,86; 163,29 [11,571; NA]; 365,43
PT Schleimhautentzündung	2,29; NA [2,429; NA]; 391,71
PT Fieber	6,14; NA [NA; NA]; 391,71
SOC Erkrankungen des Gastrointestinaltrakts	2,14; 39,64 [2,429; 282,714]; 365,43
PT Stomatitis	2,14; NA [2,429; NA]; 391,71
PT Dysphagie	26,00; NA [282,714; NA]; 391,71
PT Enteritis	18,00; NA [NA; NA]; 365,43
PT Erbrechen	6,29; NA [241,000; NA]; 391,71
SOC Erkrankungen des Nervensystems	5,29; 205,50 [27,571; NA]; 365,43
PT Spastik	8,86; 265,71 [76,429; NA]; 365,43
PT Ataxie	9,43; NA [79,286; NA]; 391,71
PT Motorische Funktionsstoerung	5,29; NA [86,143; NA]; 391,71
PT Aphasie	5,29; NA [128,286; NA]; 391,71
PT Dysarthrie	5,29; NA [157,429; NA]; 391,71
PT Kognitive Stoerung	22,43; NA [261,714; NA]; 391,71
PT Krampfanfall	33,43; NA [NA; NA]; 391,71
PT Status epilepticus	33,43; NA [NA; NA]; 391,71
SOC Infektionen und parasitäre Erkrankungen	1,29; 102,57 [2,857; NA]; 341,43
PT Infektion im Zusammenhang mit einem Medizinprodukt	3,43; NA [NA; NA]; 365,43
PT Pneumonie	33,43; NA [NA; NA]; 365,43

201222	OTL-200-f
N = 20^a	Min; Median [95%KI]; Max
PT Clostridium difficile-Kolitis	2,29; NA [NA; NA]; 391,71
PT Escherichia-Infektion	1,71; NA [NA; NA]; 365,43
PT Atemwegsinfektion	33,43; NA [285,429; NA]; 391,71
PT BACTERIAL SEPSIS	30,29; NA [NA; NA]; 391,71
PT CYTOMEGALOVIRUS INFECTION	33,43; NA [NA; NA]; 365,43
PT CYTOMEGALOVIRUS VIRAEMIA	2,86; NA [NA; NA]; 391,71
PT Gastroenteritis	33,43; NA [NA; NA]; 391,71
PT GASTROENTERITIS AEROMONAS	1,29; NA [NA; NA]; 391,71
PT Haemophilus-Infektion	1,71; NA [NA; NA]; 365,43
PT Infektion der oberen Atemwege	33,43; NA [NA; NA]; 391,71
PT Staphylokokkeninfektion	7,86; NA [NA; NA]; 365,43
PT UPPER RESPIRATORY FUNGAL INFECTION	3,71; NA [NA; NA]; 391,71
SOC Untersuchungen	2,14; NA [NA; NA]; 365,43
PT Erniedrigter BMI	23,29; NA [NA; NA]; 391,71
PT Sauerstoffsättigung erniedrigt	28,43; NA [NA; NA]; 365,43
PT Stenotrophomonas-Test positiv	2,14; NA [NA; NA]; 391,71
SOC Stoffwechsel- und Ernährungsstörungen	2,43; NA [NA; NA]; 391,71
PT Metabolische Azidose	2,43; NA [NA; NA]; 391,71
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums	2,29; NA [NA; NA]; 391,71
PT Epistaxis	2,29; NA [NA; NA]; 391,71
PT Aspirationspneumonie	33,43; NA [NA; NA]; 391,71
SOC Erkrankungen der Haut und des Unterhautzellgewebes	3,00; NA [NA; NA]; 391,71
PT Erythematöser Hautausschlag	3,14; NA [NA; NA]; 391,71
PT RASH PRURITIC	3,00; NA [NA; NA]; 391,71
SOC Erkrankungen der Nieren und Harnwege	1,71; NA [NA; NA]; 391,71
PT RENAL TUBULAR ACIDOSIS	1,71; NA [NA; NA]; 391,71
SOC Skelettmuskulatur-, Bindegewebs- und Knochenkrankungen	33,43; NA [NA; NA]; 391,71

201222	OTL-200-f
N = 20 ^a	Min; Median [95%KI]; Max
PT Deformitaet des Fusses	33,43; NA [NA; NA]; 391,71
SOC Gefäßerkrankungen	33,43; NA [NA; NA]; 391,71
PT KAWASAKI'S DISEASE	33,43; NA [NA; NA]; 391,71
SOC Herzerkrankungen	33,43; NA [NA; NA]; 391,71
PT Bradykardie	33,43; NA [NA; NA]; 391,71
<p>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</p> <p>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</p>	

3.3. Patienten mit mindestens einem schweren UE nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
Patienten mit mindestens einem schweren UE nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat	
SOC Erkrankungen des Blutes und des Lymphsystems	15 (75)
PT Febrile Neutropenie	15 (75)
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	14 (70)
PT Gangstoerung	10 (50)
SOC Erkrankungen des Gastrointestinaltrakts	14 (70)
SOC Erkrankungen des Nervensystems	11 (55)
SOC Infektionen und parasitäre Erkrankungen	10 (50)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

3.4. Zeit bis zum Erleiden eines schweren UEs nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat

201222	OTL-200-f
N = 20 ^a	Min; Median [95%KI]; Max
Zeit bis zum Erleiden eines schweren UEs nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat	
SOC Erkrankungen des Blutes und des Lymphsystems	2,29; 2,79 [2,714; 3,571]; 391,71
PT Febrile Neutropenie	2,29; 2,79 [2,714; 3,571]; 391,71
SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	2,29; 18,14 [2,429; NA]; 365,43
PT Gangstoerung	4,86; 163,29 [11,571; NA]; 365,43
SOC Erkrankungen des Gastrointestinaltrakts	2,14; 39,64 [2,429; 282,714]; 365,43
SOC Erkrankungen des Nervensystems	5,29; 205,50 [27,571; NA]; 365,43
SOC Infektionen und parasitäre Erkrankungen	1,29; 102,57 [2,857; NA]; 341,43
^a Die Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.	
KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).	

4. SUEs nach SOC und PT

4.1. Patienten mit mindestens einem SUE nach SOC und PT, das bei mindestens 5% der Patienten in einem Studienarm auftrat

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
Patienten mit mindestens einem SUE nach SOC und PT, das bei mindestens 5% der Patienten in einem Studienarm auftrat	
SOC Infektionen und parasitäre Erkrankungen	7 (35)
PT Pneumonie	2 (10)
PT Atemwegsinfektion	2 (10)
PT Infektion im Zusammenhang mit einem Medizinprodukt	2 (10)
PT BACTERIAL SEPSIS	1 (5)
PT Escherichia-Infektion	1 (5)
PT Gastroenteritis	1 (5)
SOC Erkrankungen des Gastrointestinaltrakts	7 (35)
PT Dysphagie	4 (20)
PT Enteritis	2 (10)
PT Erbrechen	1 (5)
SOC Erkrankungen des Nervensystems	5 (25)
PT Motorische Funktionsstoerung	4 (20)
PT Spastik	2 (10)
PT Krampfanfall	2 (10)
PT Status epilepticus	1 (5)
SOC Leber- und Gallenerkrankungen	2 (10)
PT Gallenblasenpolyp	2 (10)
SOC Stoffwechsel- und Ernährungsstörungen	2 (10)
PT Metabolische Azidose	2 (10)
SOC Skelettmuskulatur-, Bindegewebs- und Knochenkrankungen	1 (5)
PT Deformitaet des Fusses	1 (5)

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums	1 (5)
PT Aspirationspneumonie	1 (5)
SOC Gefäßerkrankungen	1 (5)
PT KAWASAKI'S DISEASE	1 (5)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

4.2. Zeit bis zum Erleiden eines SUEs nach SOC und PT, das bei mindestens 5% der Patienten in einem Studienarm auftrat

201222	OTL-200-f
N = 20 ^a	Min; Median [95%KI]; Max
Zeit bis zum Erleiden eines SUEs nach SOC und PT, das bei mindestens 5% der Patienten in einem Studienarm auftrat	
SOC Infektionen und parasitäre Erkrankungen	17,86; NA [102,571; NA]; 365,43
PT Pneumonie	33,43; NA [NA; NA]; 365,43
PT Atemwegsinfektion	33,43; NA [285,429; NA]; 391,71
PT Infektion im Zusammenhang mit einem Medizinprodukt	17,86; NA [NA; NA]; 391,71
PT BACTERIAL SEPSIS	30,29; NA [NA; NA]; 391,71
PT Escherichia-Infektion	33,43; NA [NA; NA]; 365,43
PT Gastroenteritis	33,43; NA [NA; NA]; 391,71
SOC Erkrankungen des Gastrointestinaltrakts	18,00; NA [114,286; NA]; 365,43
PT Dysphagie	26,00; NA [282,714; NA]; 391,71
PT Enteritis	18,00; NA [NA; NA]; 365,43
PT Erbrechen	33,43; NA [241,000; NA]; 391,71
SOC Erkrankungen des Nervensystems	5,29; NA [145,286; NA]; 391,71
PT Motorische Funktionsstoerung	5,29; NA [NA; NA]; 391,71
PT Spastik	8,86; NA [NA; NA]; 391,71
PT Krampfanfall	33,43; NA [NA; NA]; 391,71
PT Status epilepticus	33,43; NA [NA; NA]; 391,71
SOC Leber- und Gallenerkrankungen	22,86; NA [NA; NA]; 391,71
PT Gallenblasenpolyp	22,86; NA [NA; NA]; 391,71
SOC Stoffwechsel- und Ernährungsstörungen	4,00; NA [NA; NA]; 391,71
PT Metabolische Azidose	4,00; NA [NA; NA]; 391,71
SOC Skelettmuskulatur-, Bindegewebs- und Knochenkrankungen	33,43; NA [NA; NA]; 391,71
PT Deformitaet des Fusses	33,43; NA [NA; NA]; 391,71
SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums	33,43; NA [NA; NA]; 391,71
PT Aspirationspneumonie	33,43; NA [NA; NA]; 391,71

201222	OTL-200-f
N = 20^a	Min; Median [95%KI]; Max
SOC GefäÙerkrankungen	33,43; NA [NA; NA]; 391,71
PT KAWASAKI'S DISEASE	33,43; NA [NA; NA]; 391,71
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

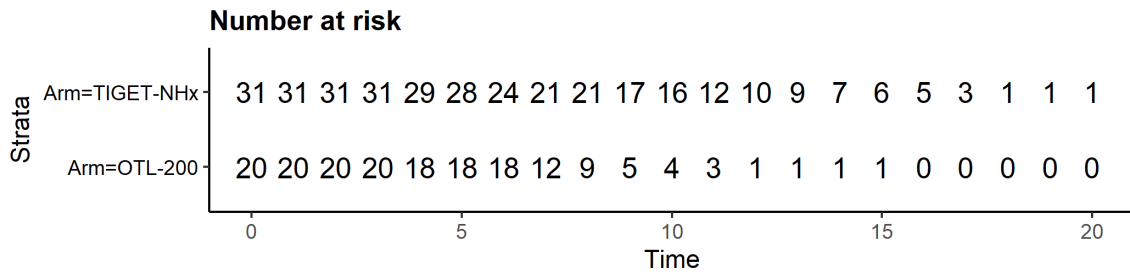
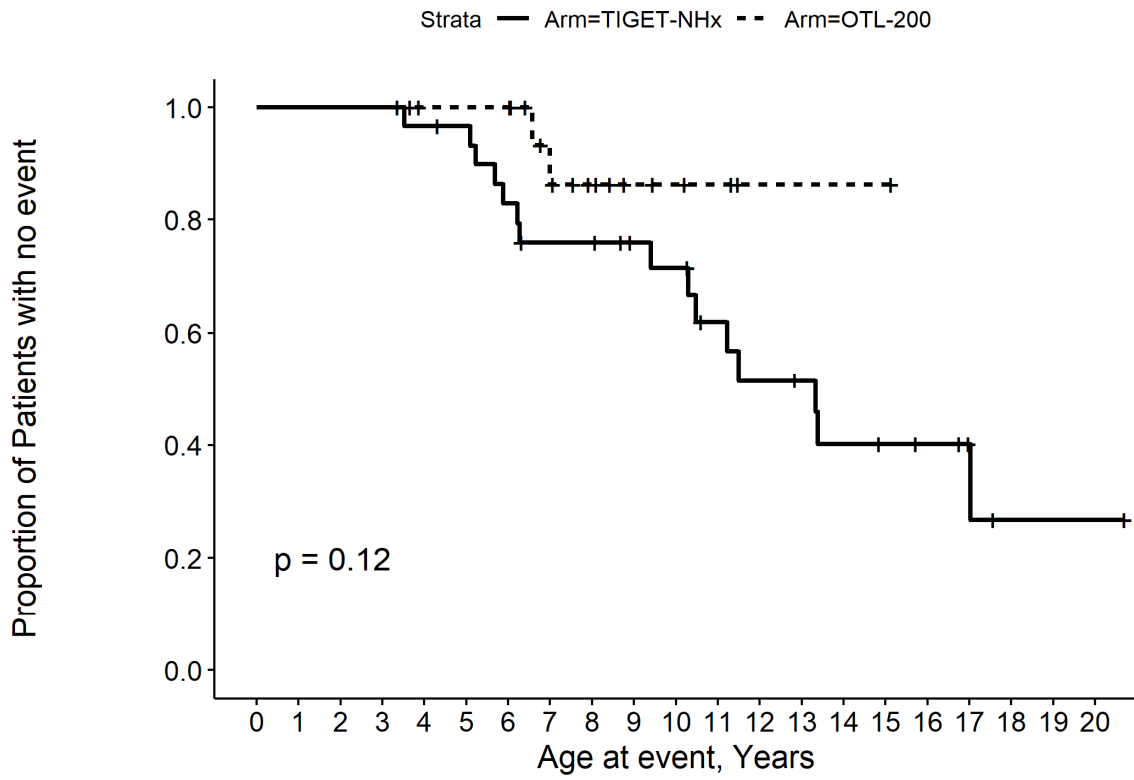
4.3. Patienten mit mindestens einem SUE nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat

4.4. Zeit bis zum Erleiden eines SUEs nach SOC und PT, das bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat

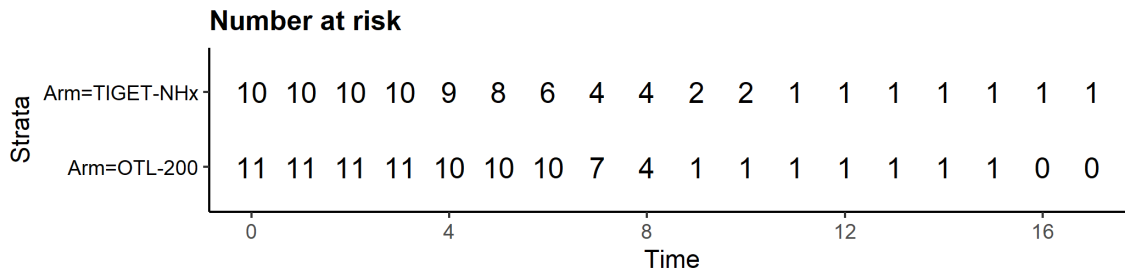
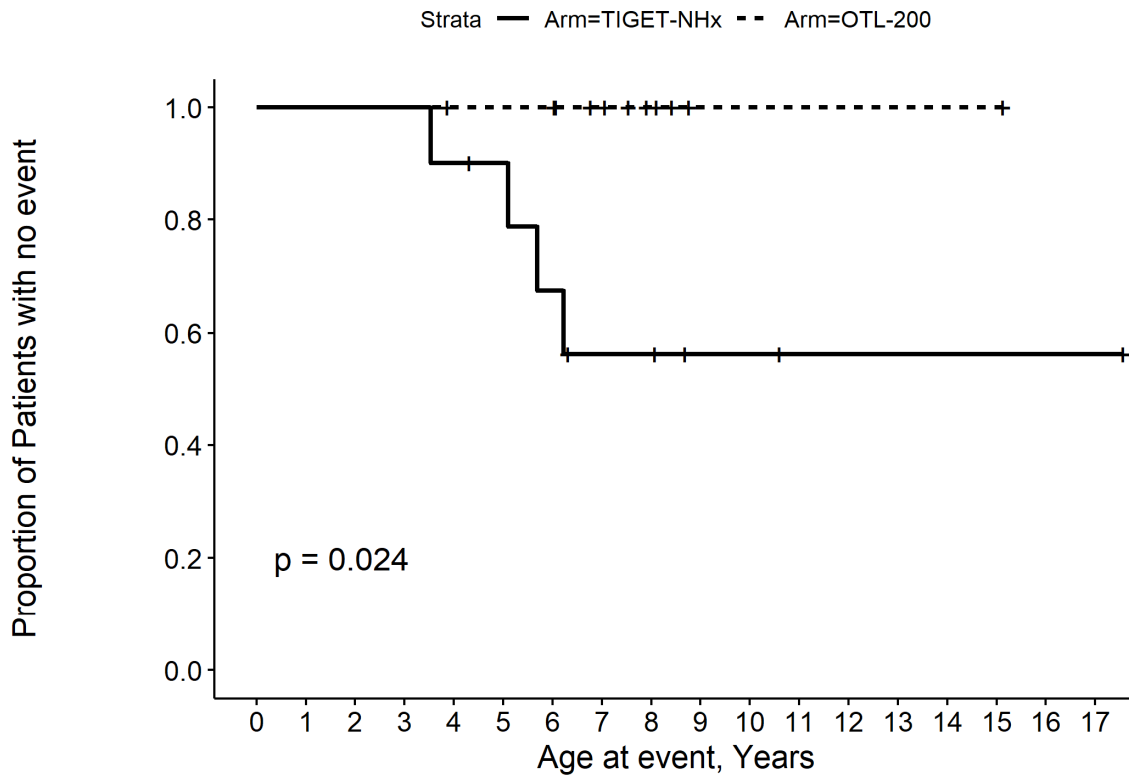
Abbildungen:
**Studie 201222, Wirksamkeit und Sicherheit,
Sensitivitätsanalysen**

Stand: 01.05.2021

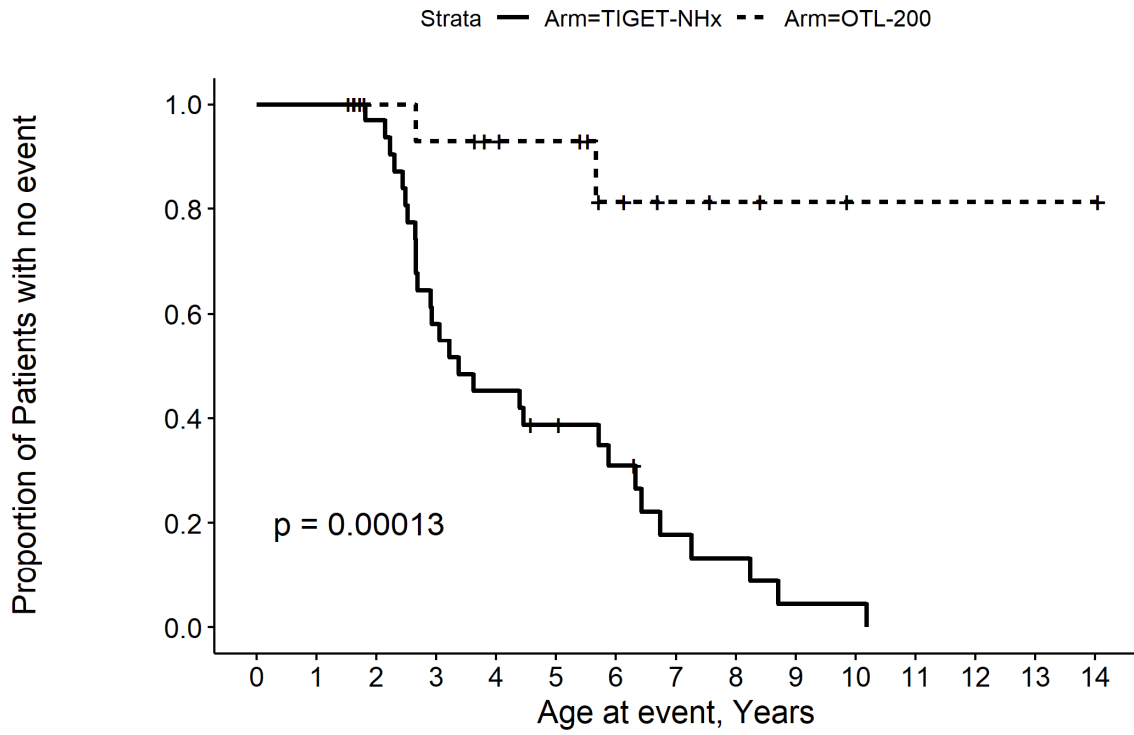
201222: Kaplan Meier Plot for Age at Death ITT



201222: Kaplan Meier Plot for Age at Death MSAS



201222: Kaplan Meier Plot for Age at GMFC Level 5 ITT

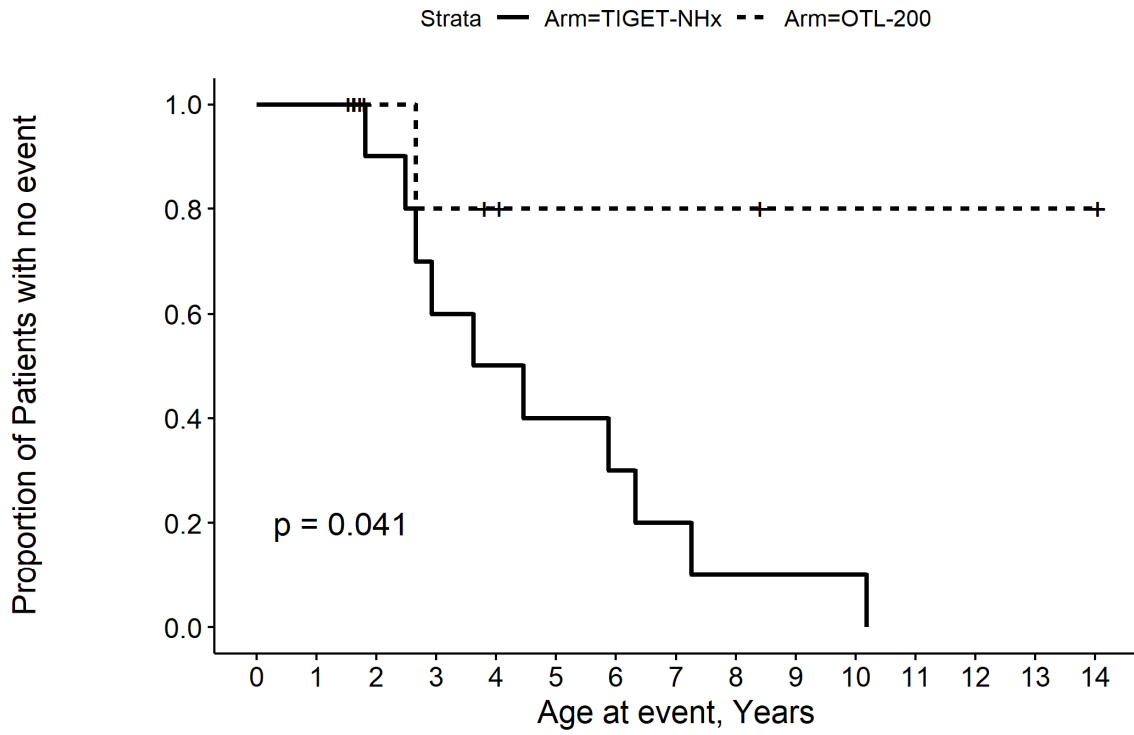


Number at risk

Strata	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Arm=TIGET-NHx	31	31	30	18	14	11	8	4	3	1	1	0	0	0	0
Arm=OTL-200	20	20	14	13	11	10	6	4	3	2	1	1	1	1	1

Time

201222: Kaplan Meier Plot for Age at GMFC Level 5 MSAS

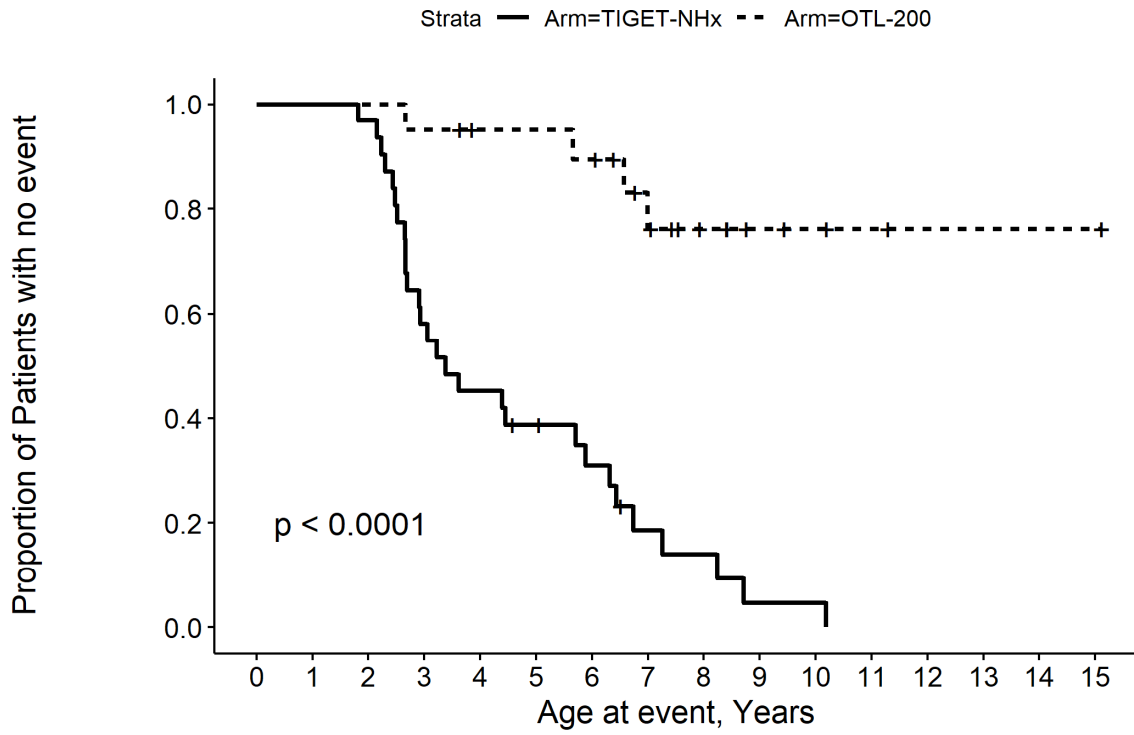


Number at risk

Strata	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Arm=TIGET-NHx	10	10	9	6	5	4	3	2	1	1	1	0	0	0	0
Arm=OTL-200	11	11	5	4	3	2	2	2	2	1	1	1	1	1	1

Time

201222: Kaplan Meier Plot for Age at Severe Motor Impairment or Death ITT

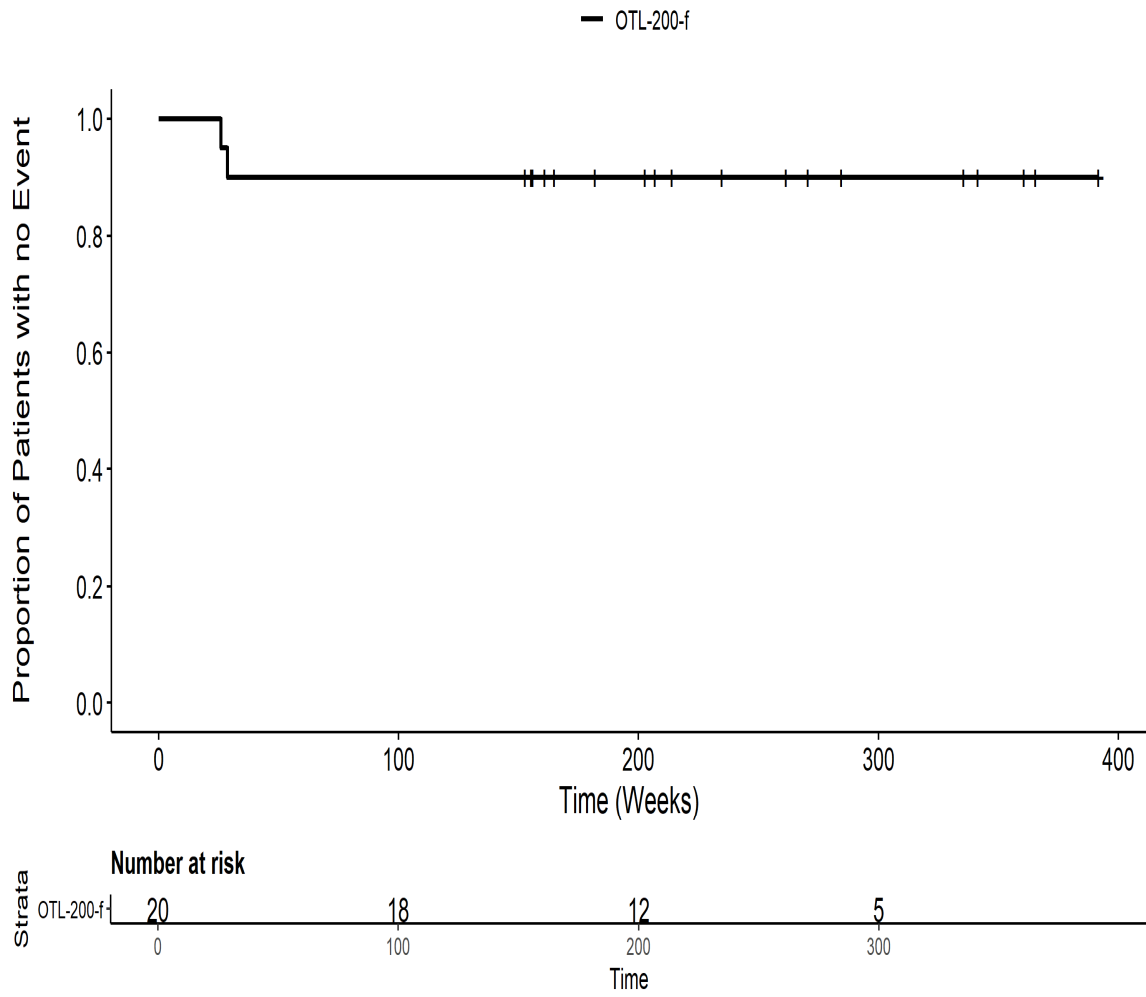


Number at risk

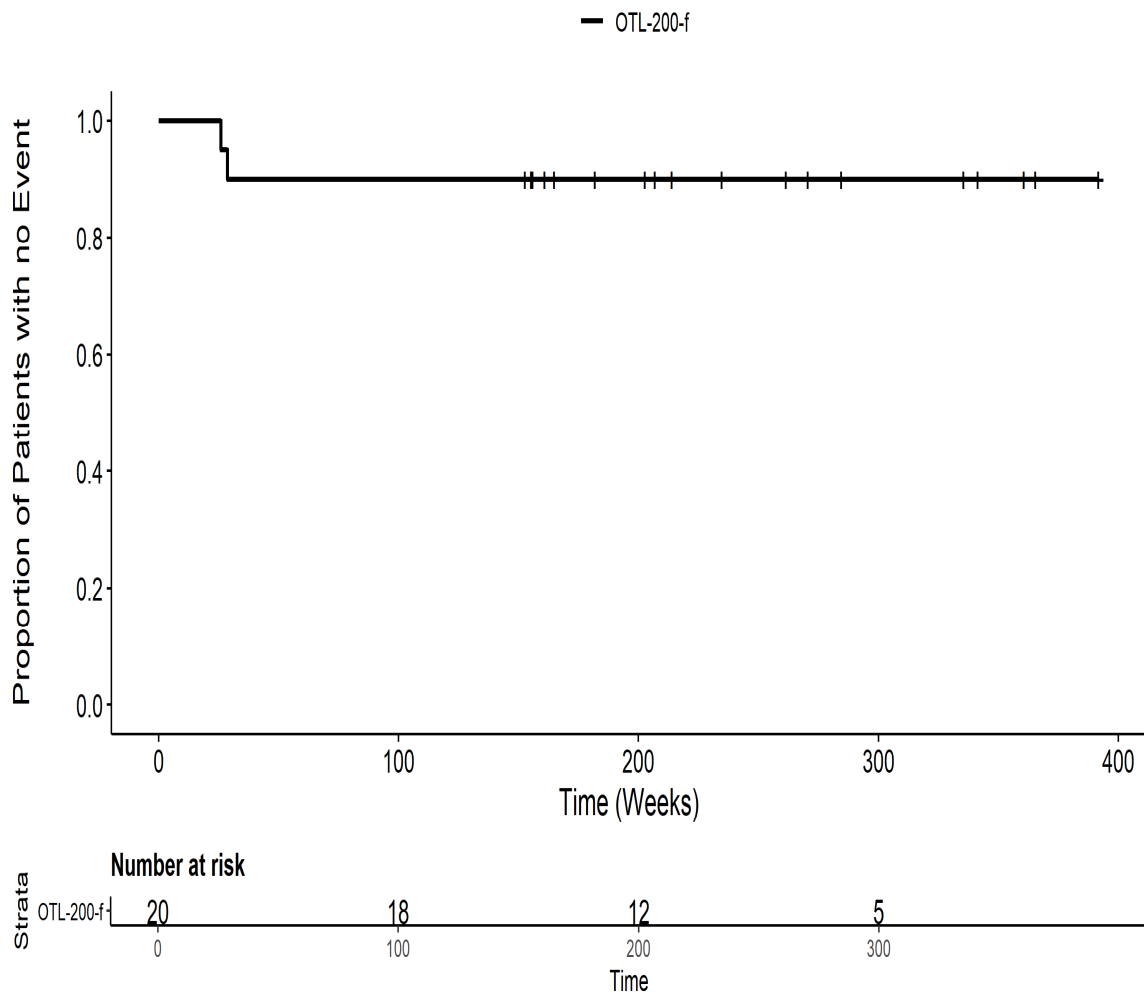
Strata	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Arm=TIGET-NHx	31	31	30	18	14	11	8	4	3	1	1	0	0	0	0	0
Arm=OTL-200	20	20	20	19	17	17	16	11	7	4	3	2	1	1	1	1

Time

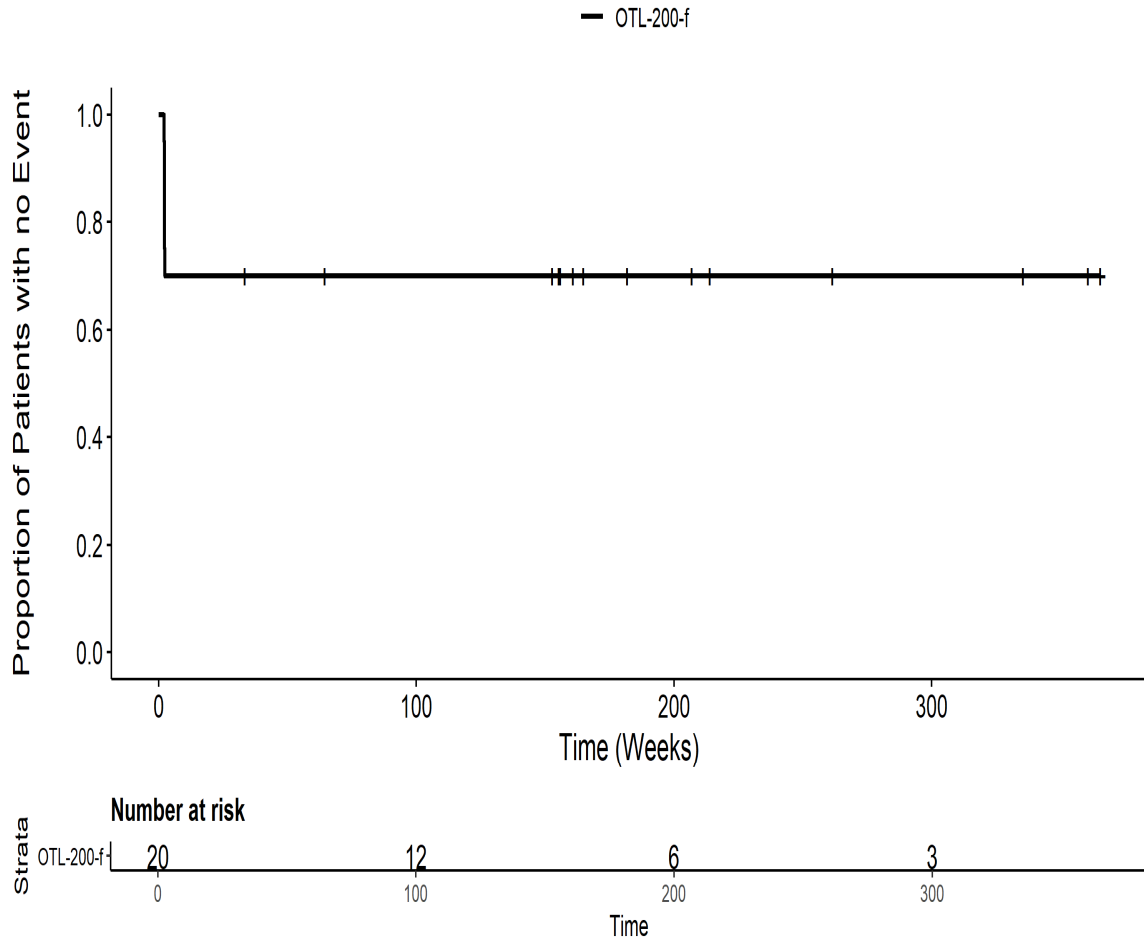
201222: Kaplan Meier Plot for Time to AE all AE death by SOC
Erkrankungen des Gastrointestinaltrakts PT pts Dysphagie ITT



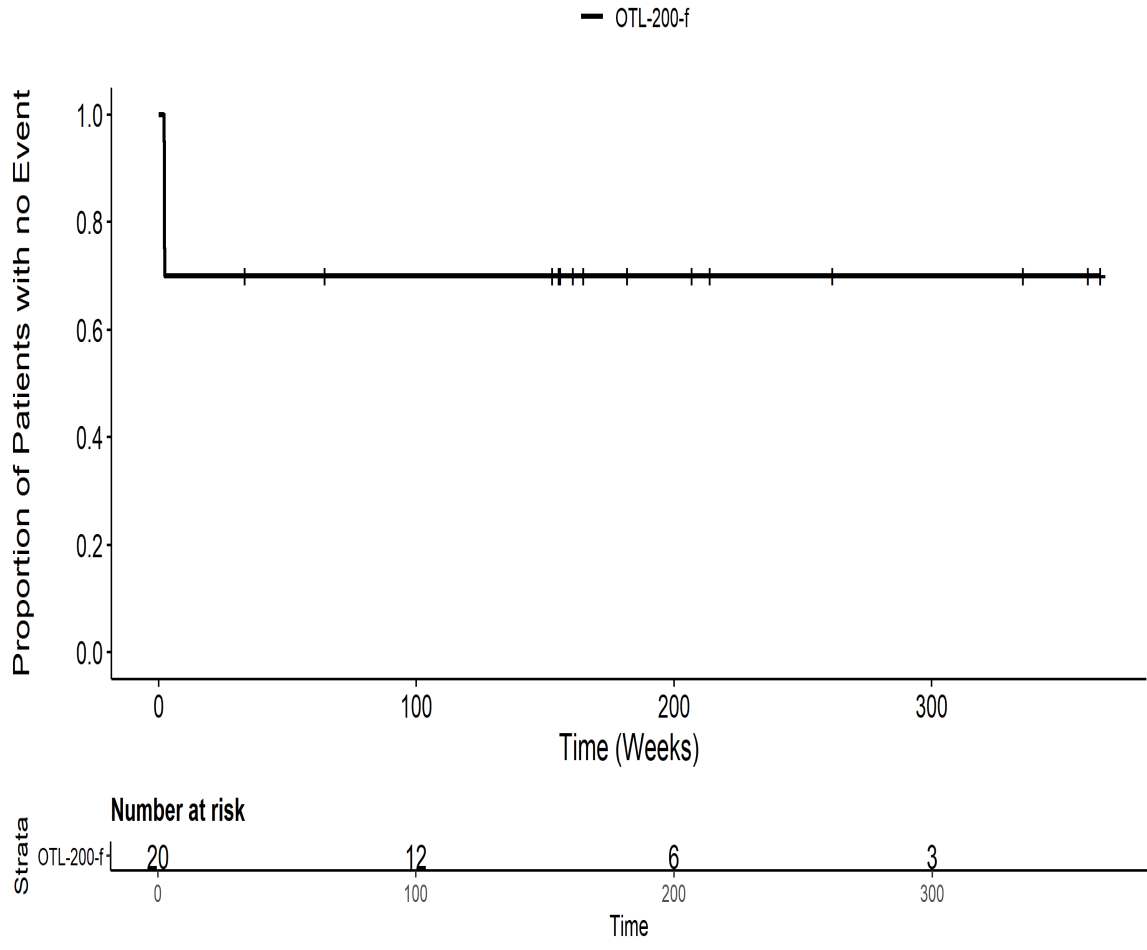
201222: Kaplan Meier Plot for Time to AE all AE death by SOC
Erkrankungen des Gastrointestinaltrakts PT pts Gesamt SOC ITT



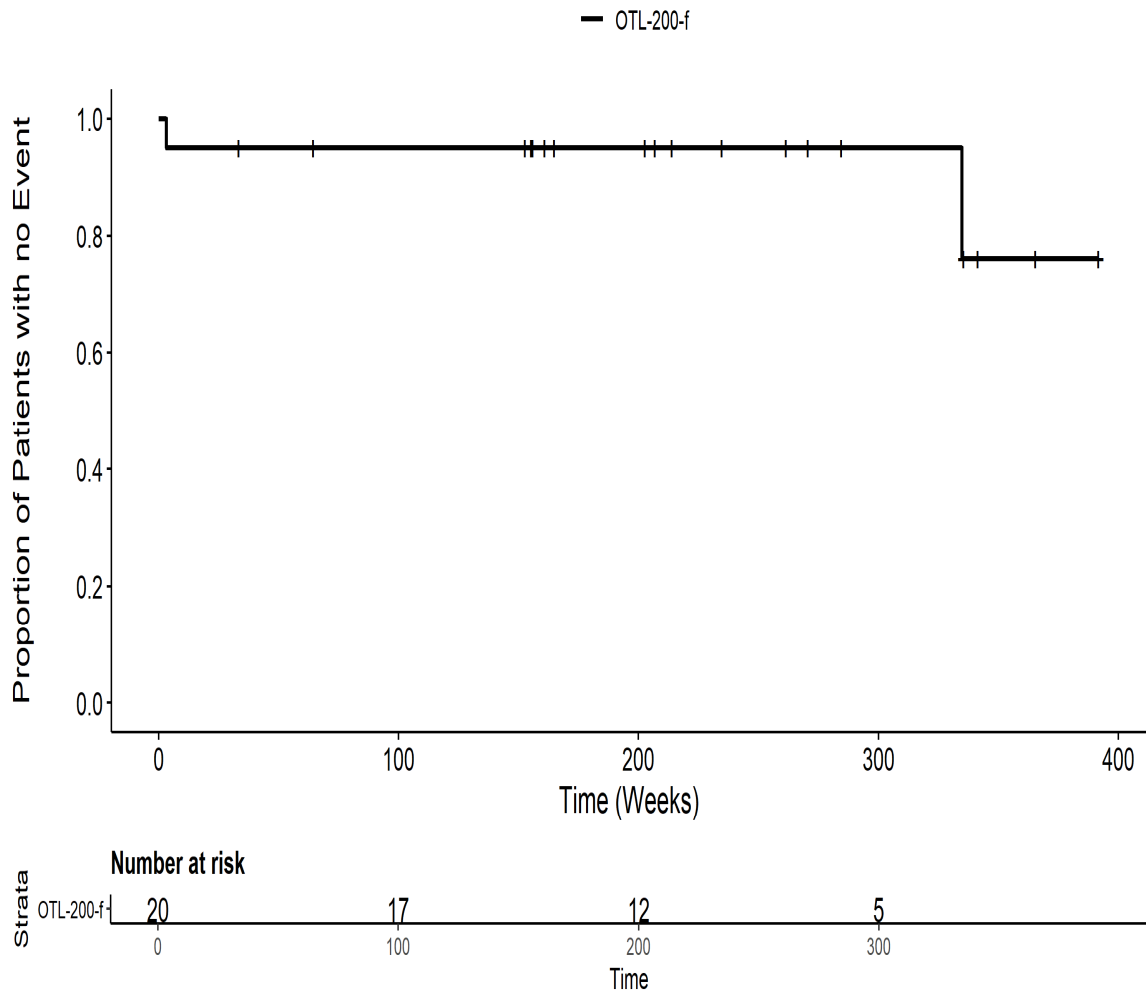
201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort PT pts Gesamt SOC
ITT



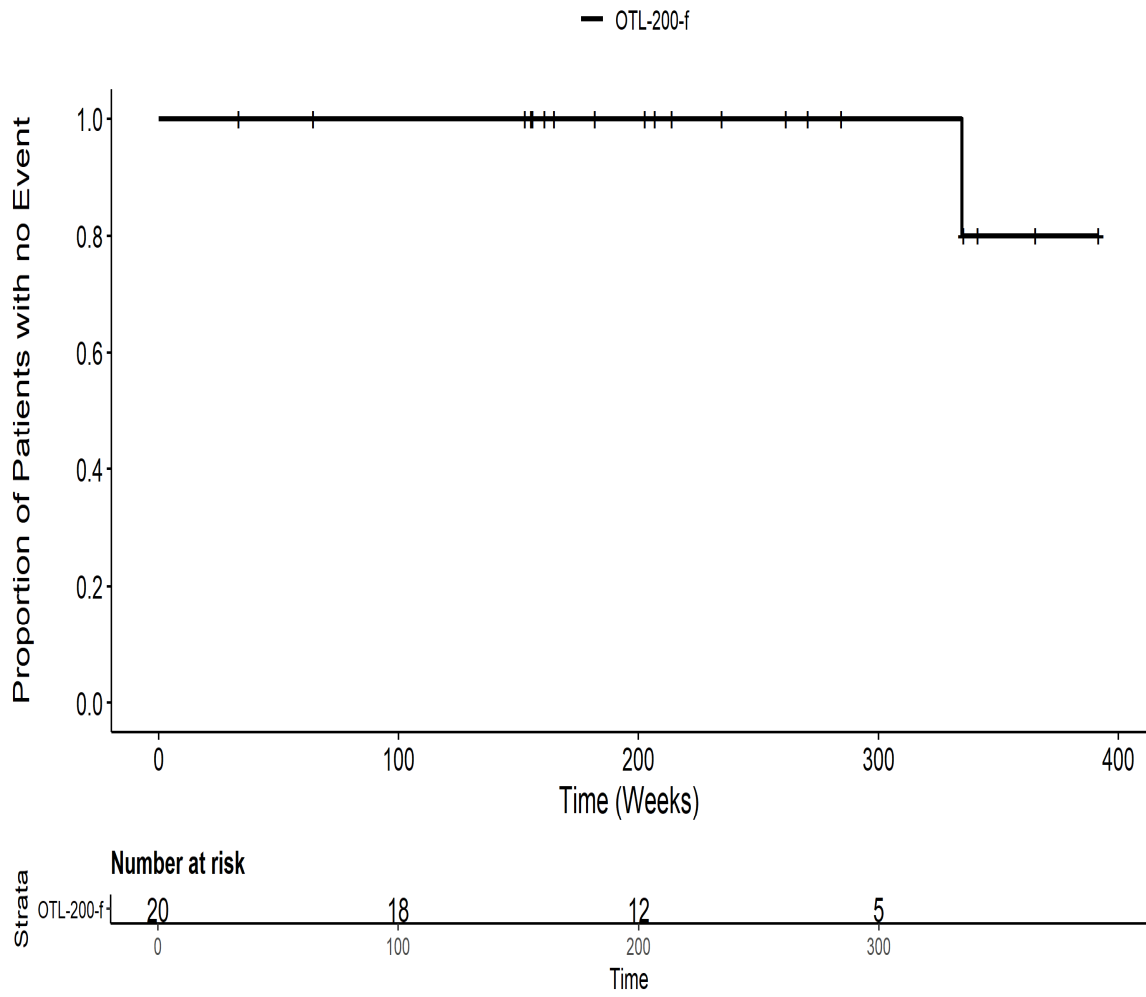
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Allgemeine Erkrankungen und Beschwerden am Verabreichungsort PT pts
Schleimhautentzündung ITT



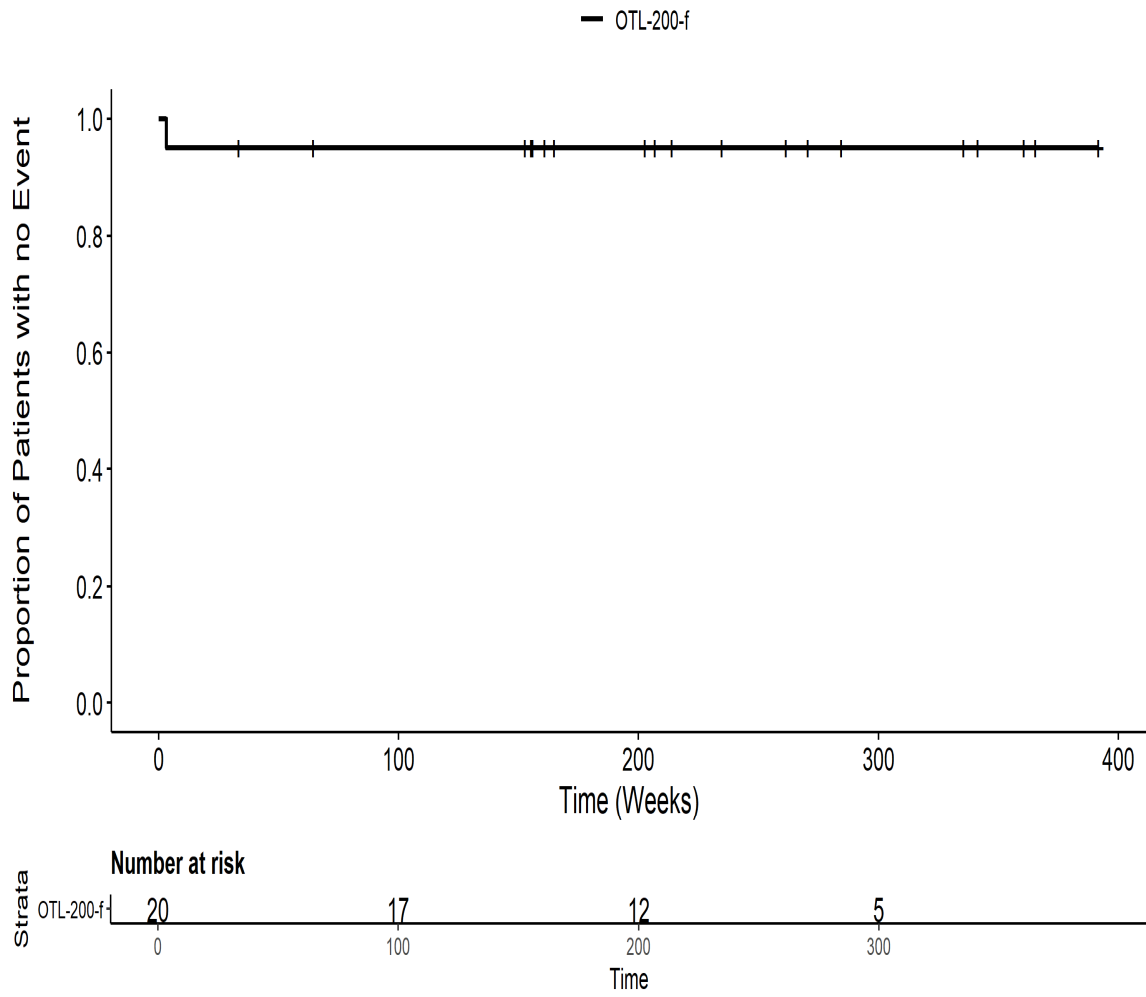
201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Augenerkrankungen PT pts Gesamt SOC ITT



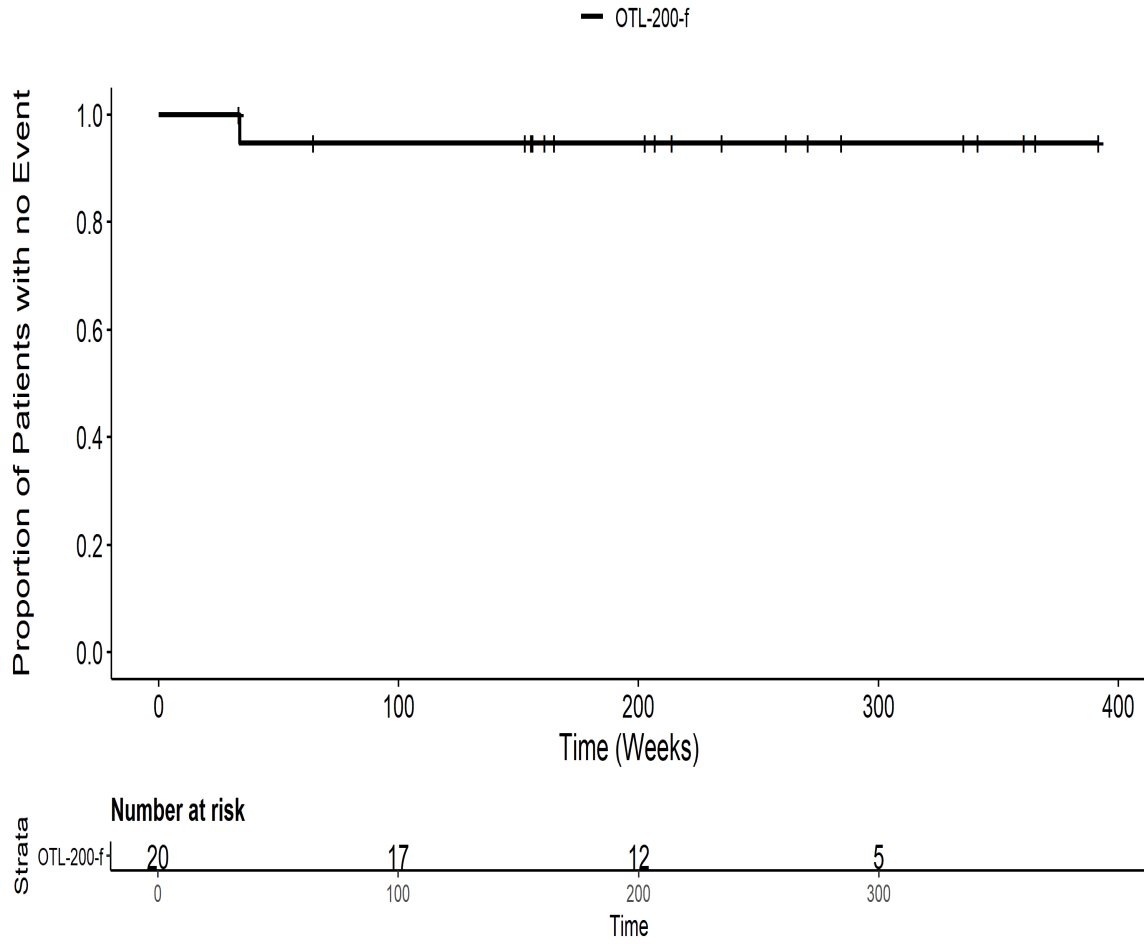
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Augenerkrankungen PT pts Konjunktivitis allergisch ITT



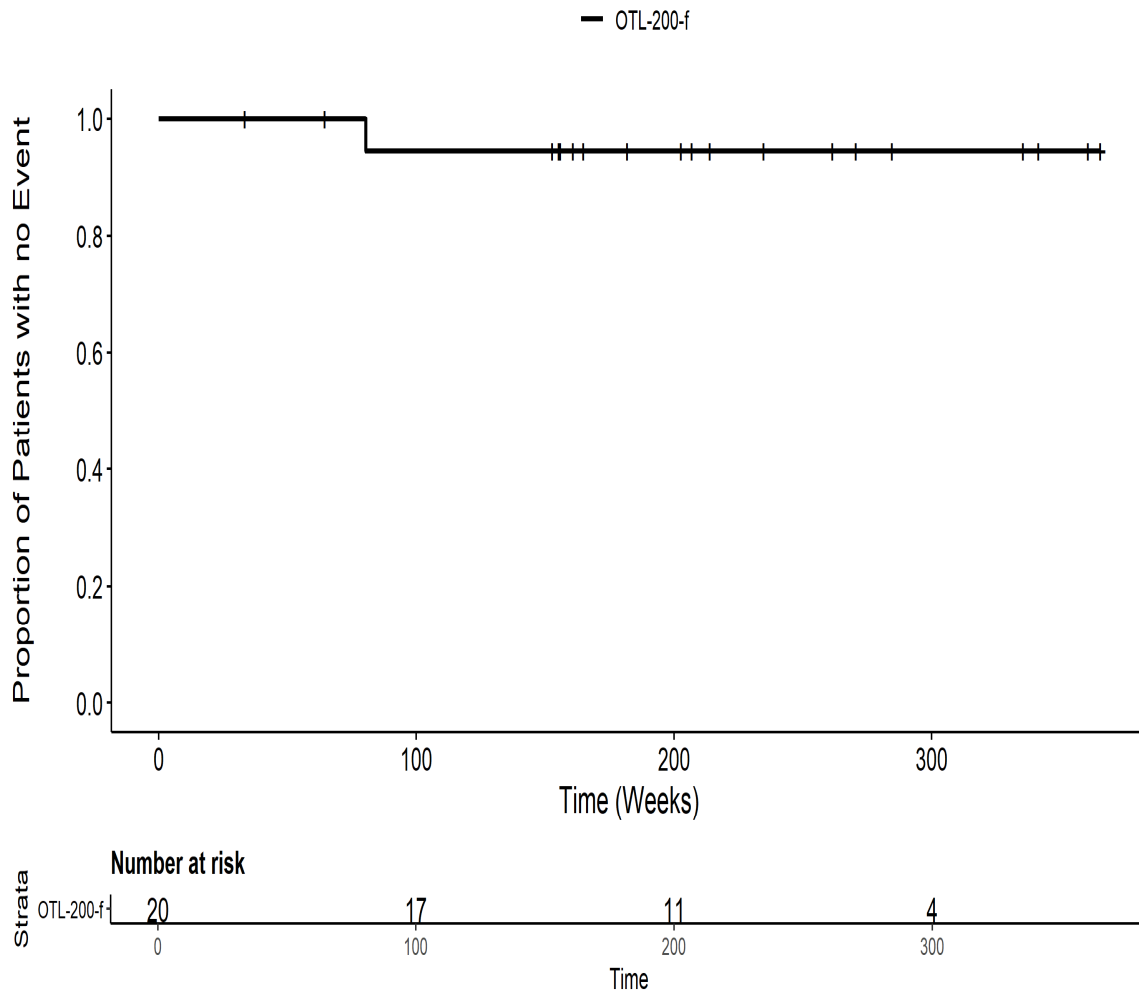
201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Augenerkrankungen PT pts Okulaere Hyperaemie ITT



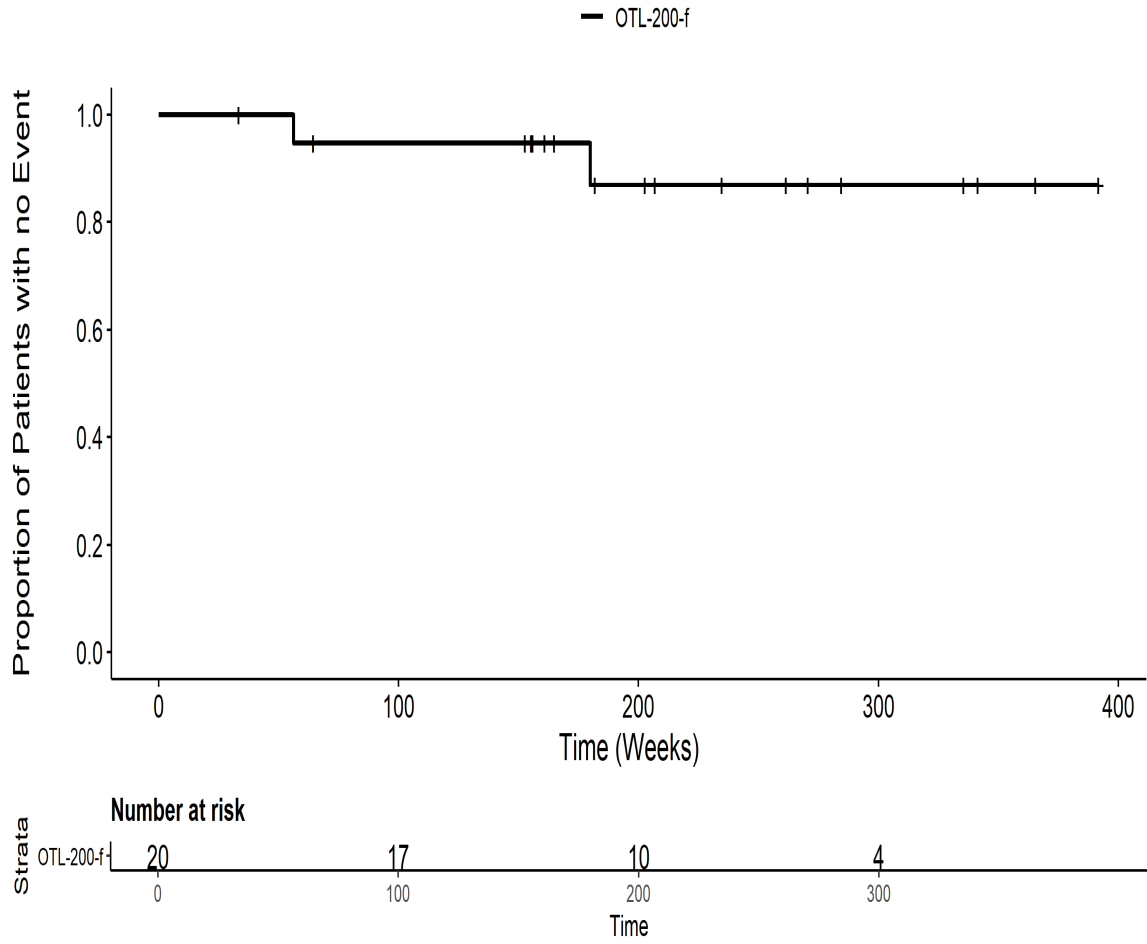
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Erkrankungen der Atemwege, des Brustraums und Mediastinums PT pts Allergische
Rhinitis ITT



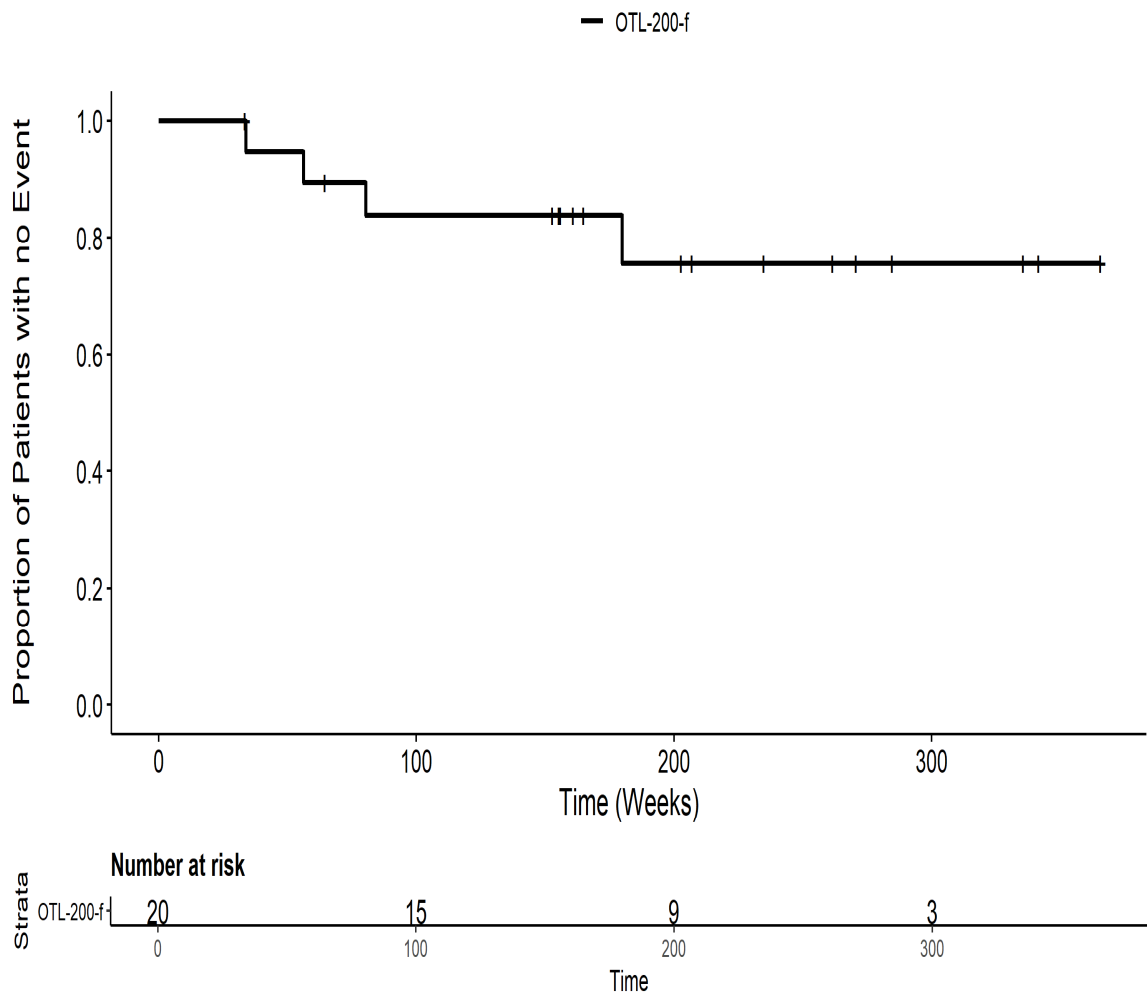
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Erkrankungen der Atemwege, des Brustraums und Mediastinums PT pts Asthma ITT



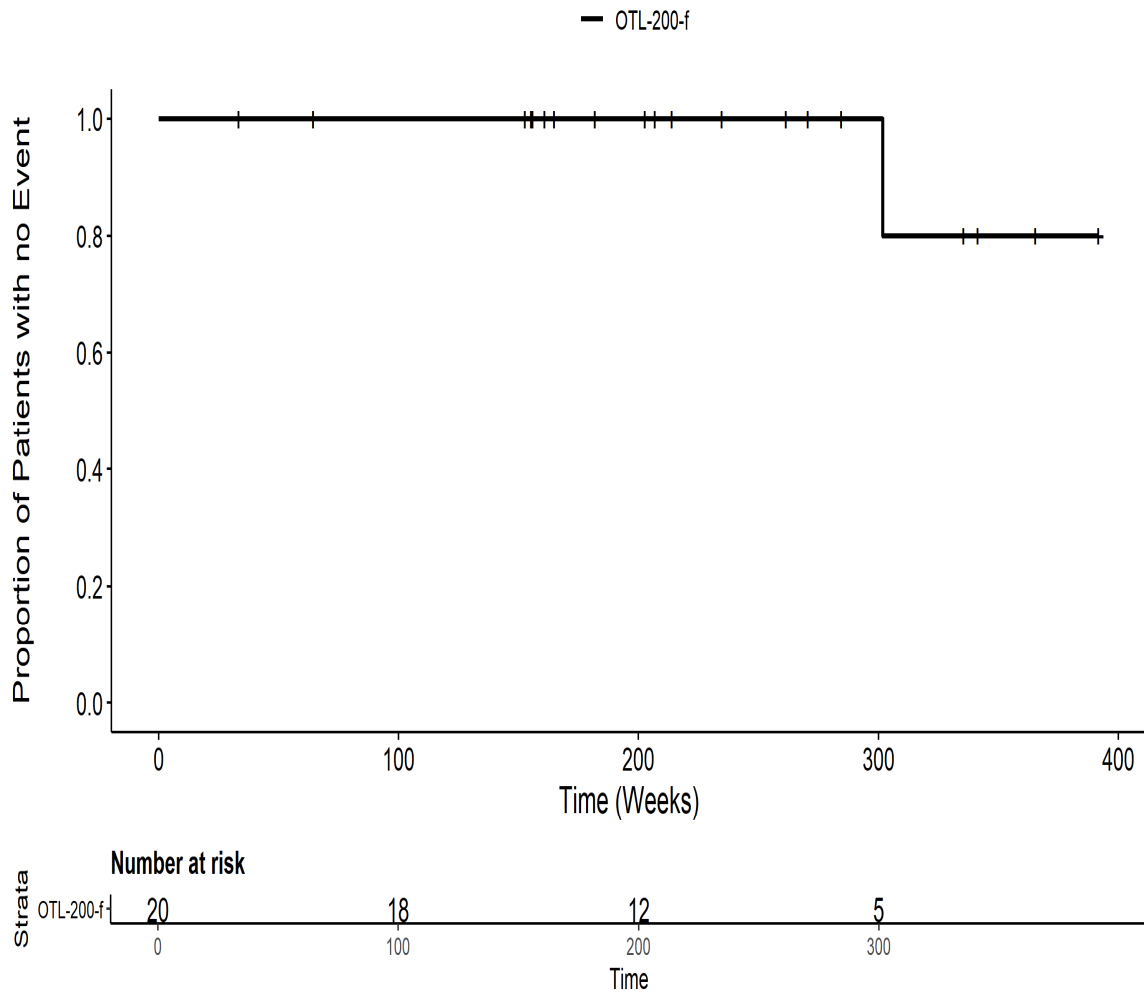
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 Erkrankungen der Atemwege, des Brustraums und Mediastinums PT pts Bronchospasmus
 ITT



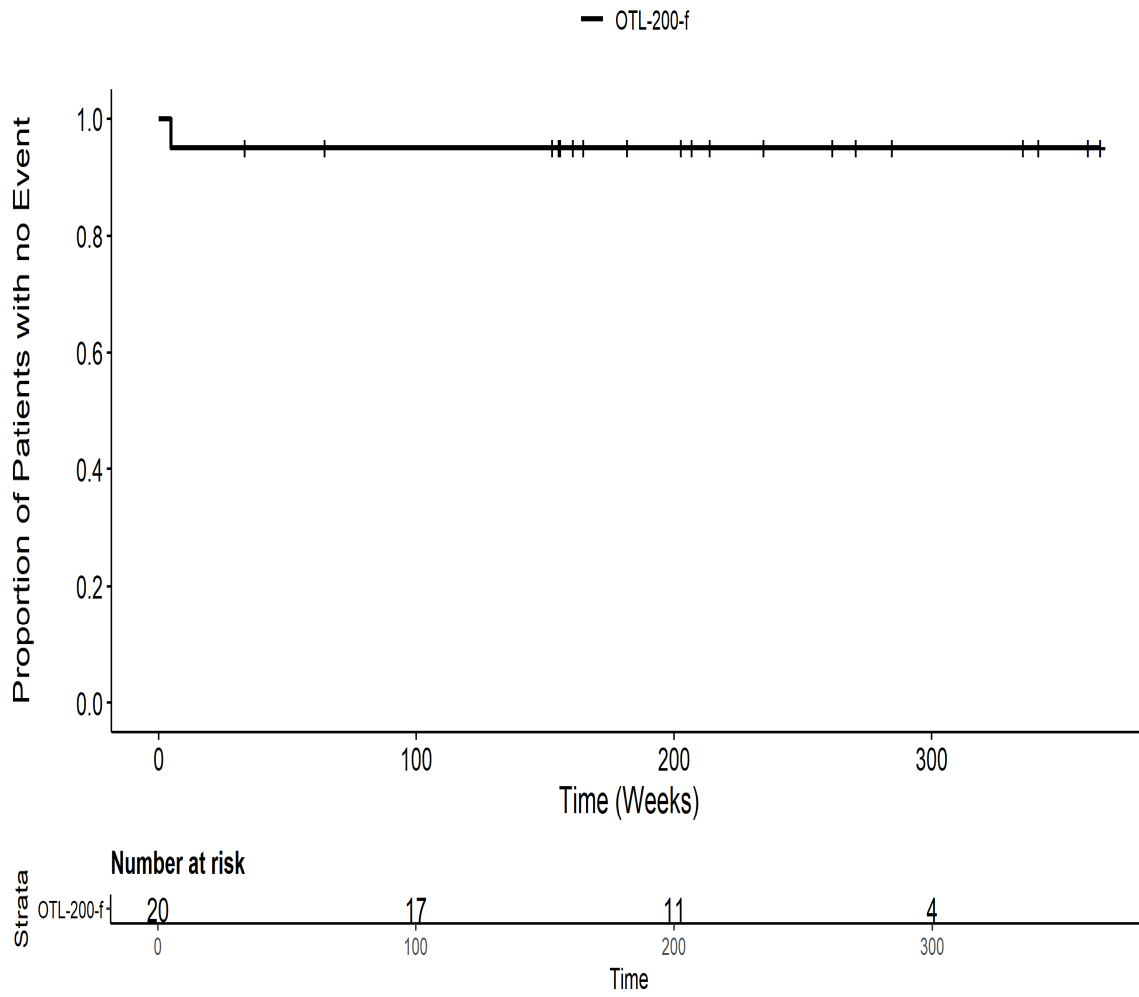
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 Erkrankungen der Atemwege, des Brustraums und Mediastinums PT pts Gesamt SOC ITT



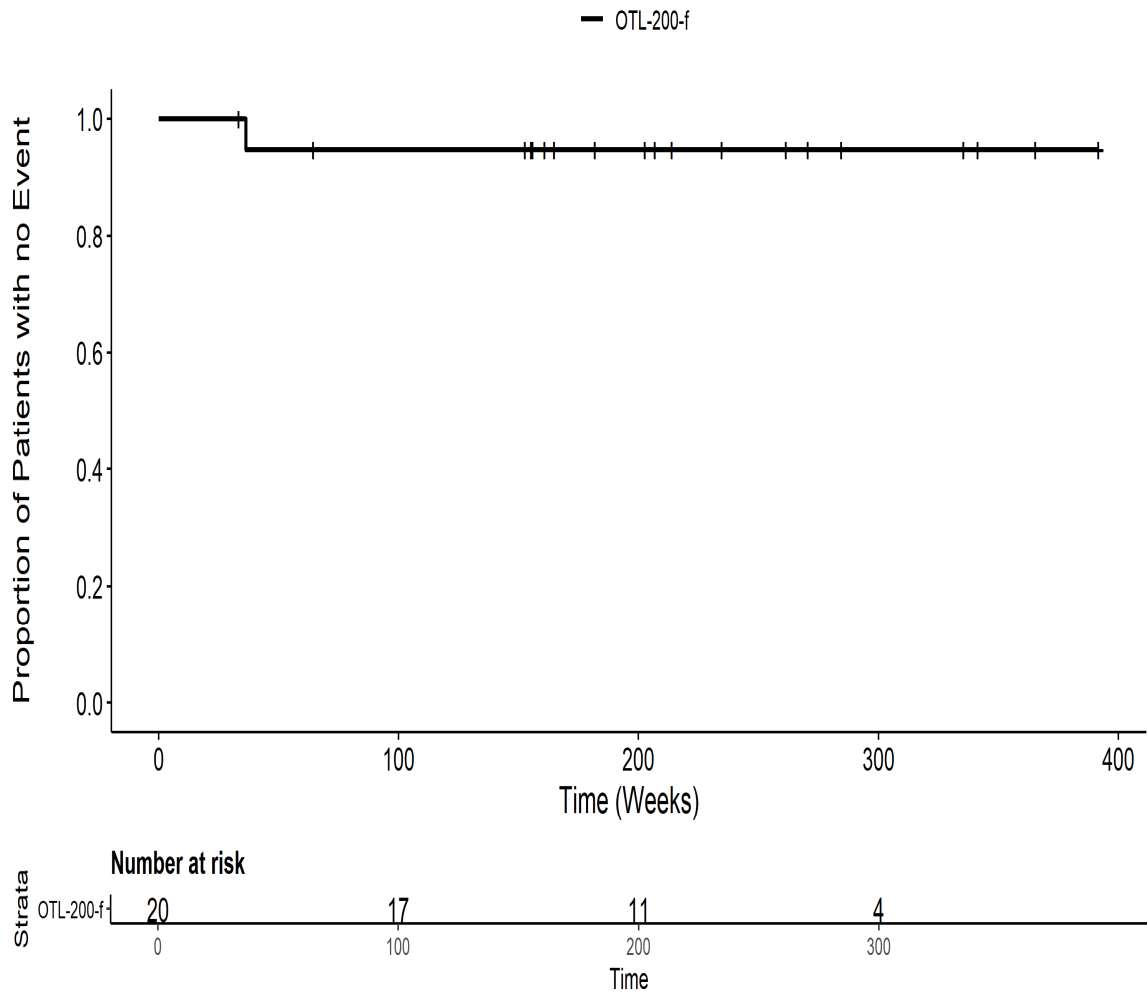
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Erkrankungen der Haut und des Unterhautzellgewebes PT pts Ausschlag ITT



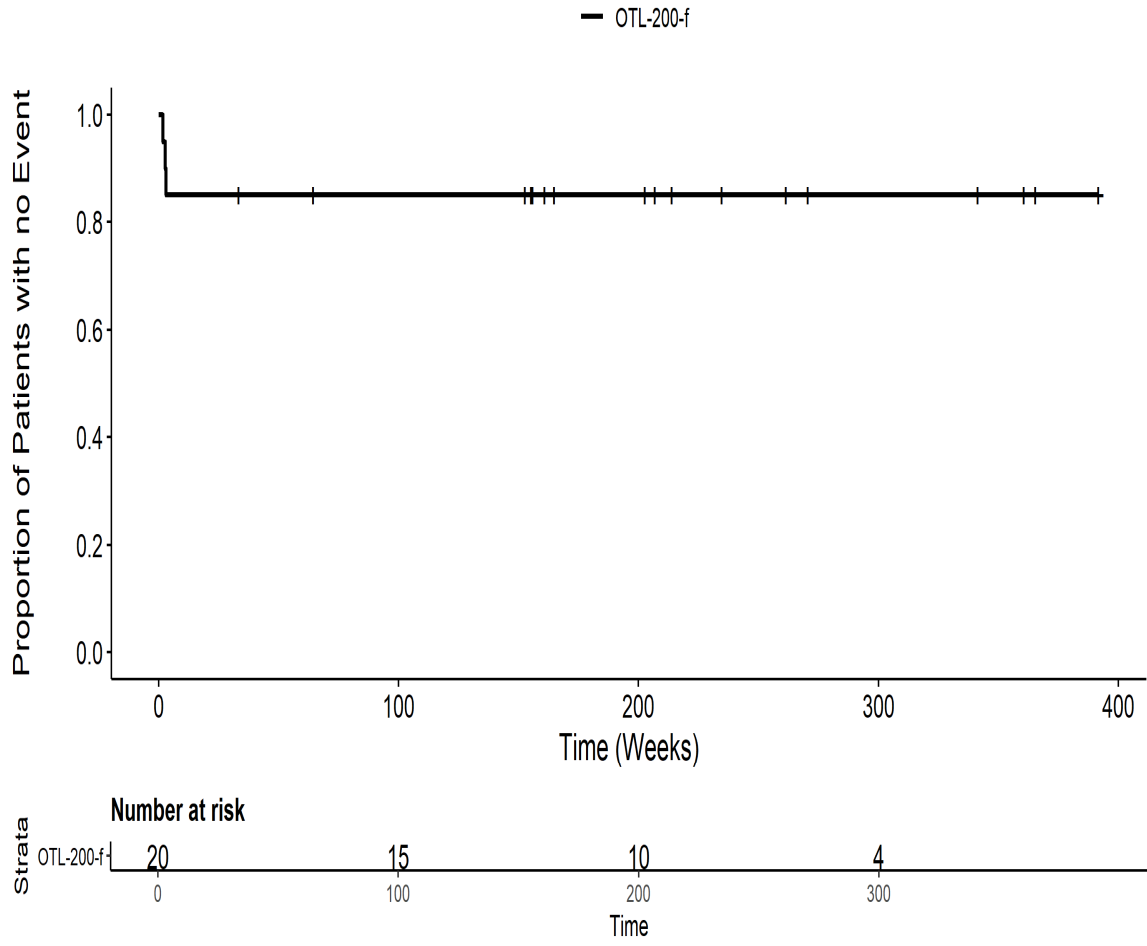
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Erkrankungen der Haut und des Unterhautzellgewebes PT pts Dermatitis ITT



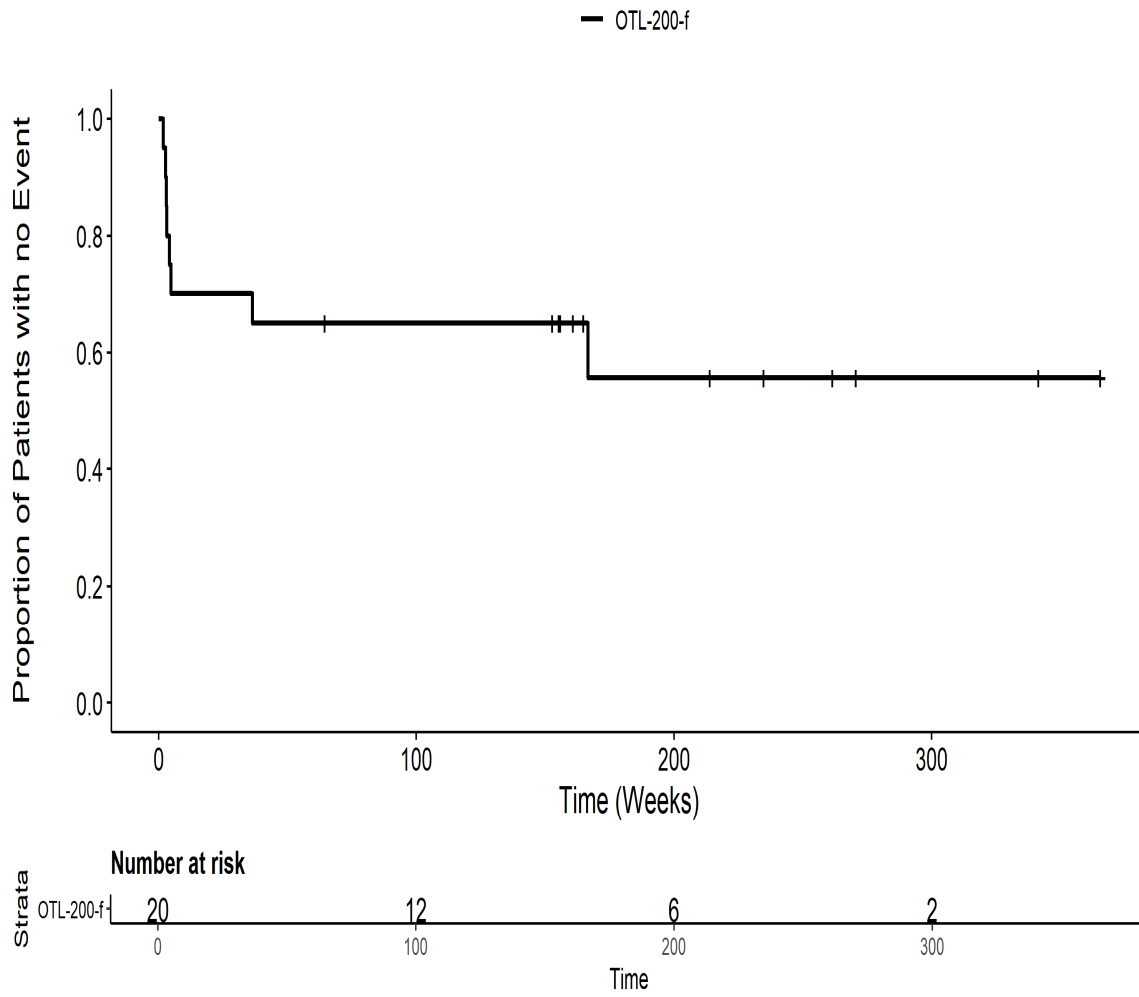
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Erkrankungen der Haut und des Unterhautzellgewebes PT pts DERMATITIS BULLOUS ITT



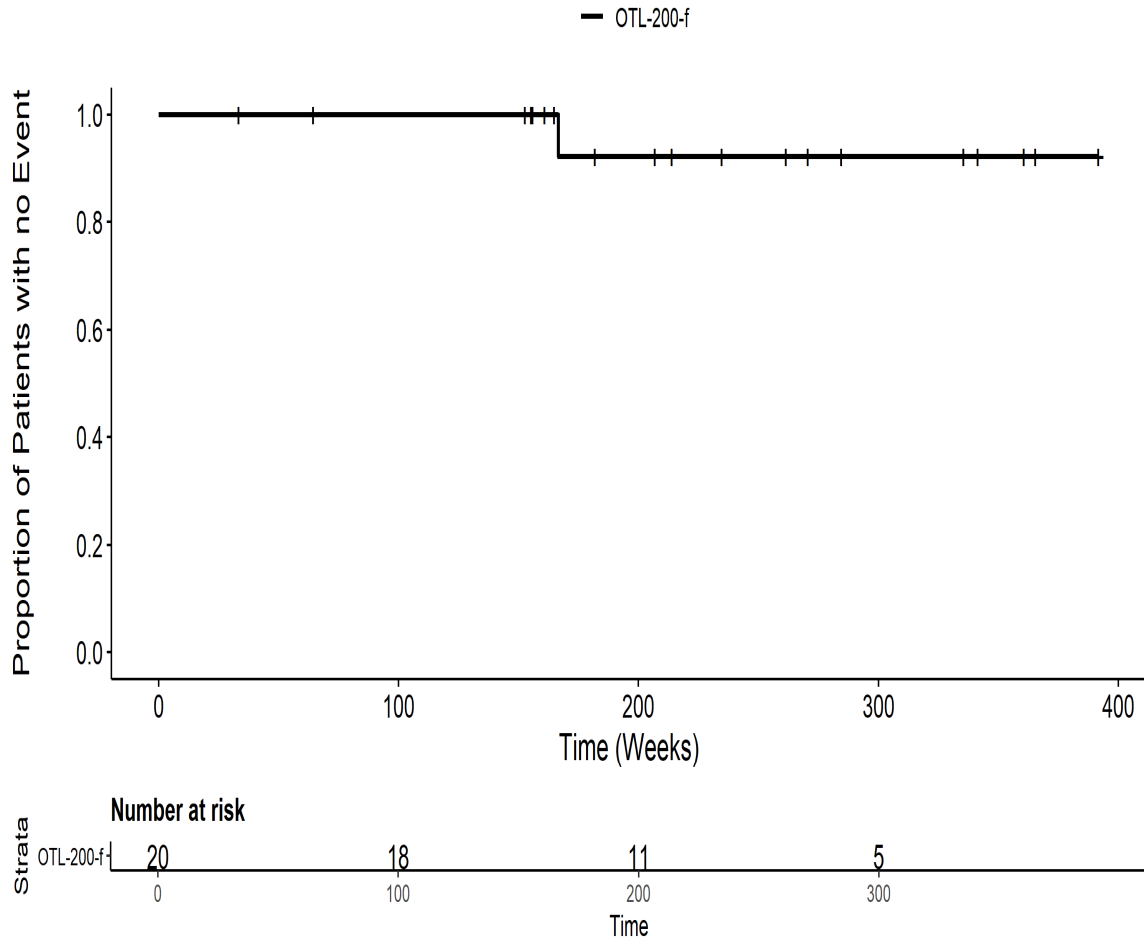
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Erkrankungen der Haut und des Unterhautzellgewebes PT pts Erythematoseser
Hautausschlag ITT



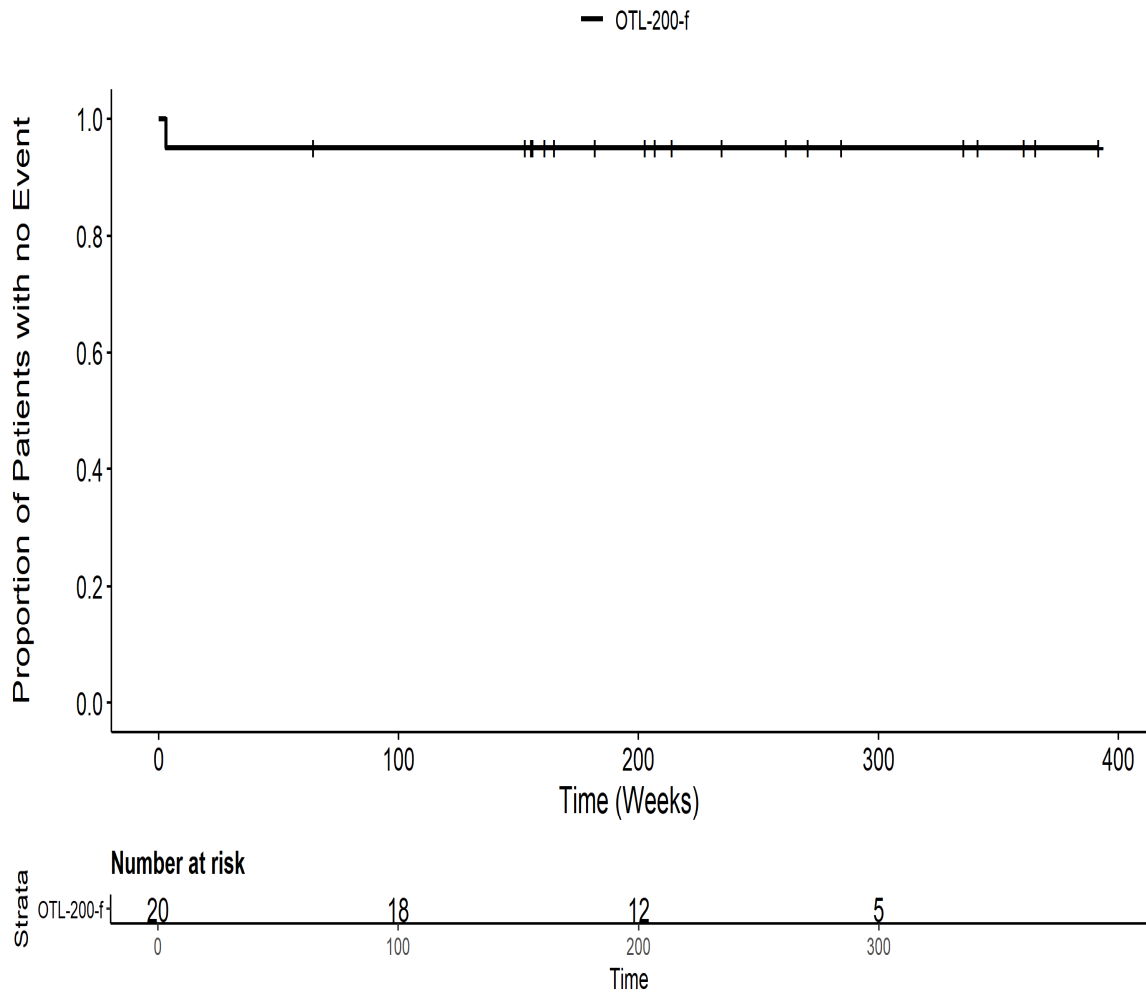
201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Erkrankungen der Haut und des Unterhautzellgewebes PT pts Gesamt SOC ITT



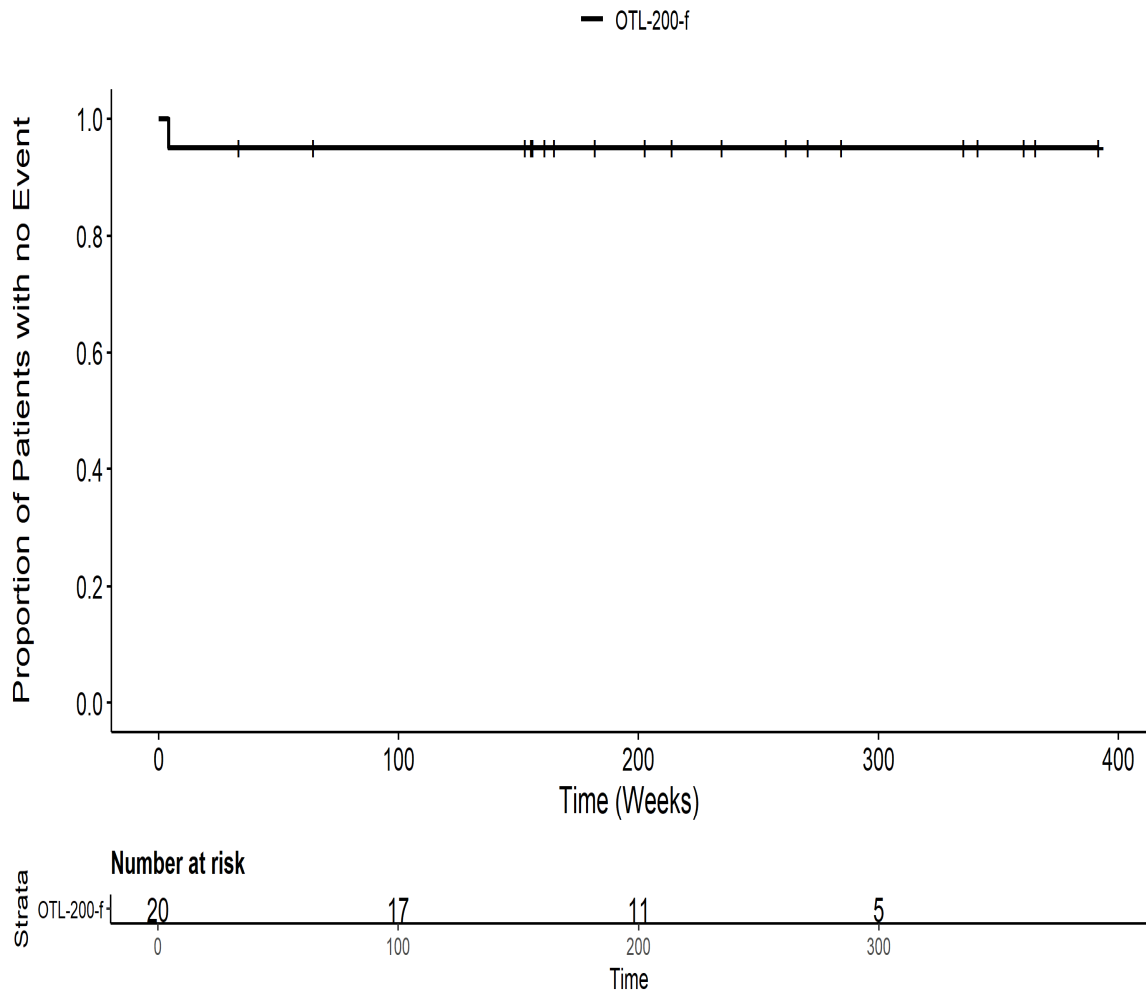
201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Erkrankungen der Haut und des Unterhautzellgewebes PT pts Medikamentenausschlag
ITT



201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Erkrankungen der Haut und des Unterhautzellgewebes PT pts RASH PRURITIC ITT

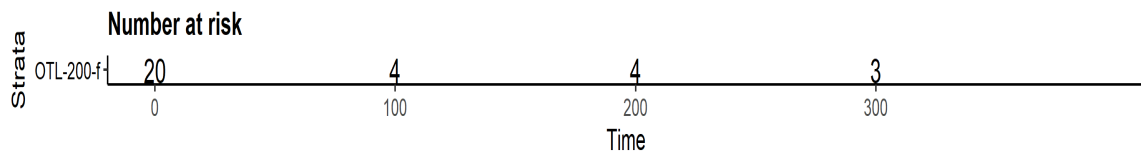
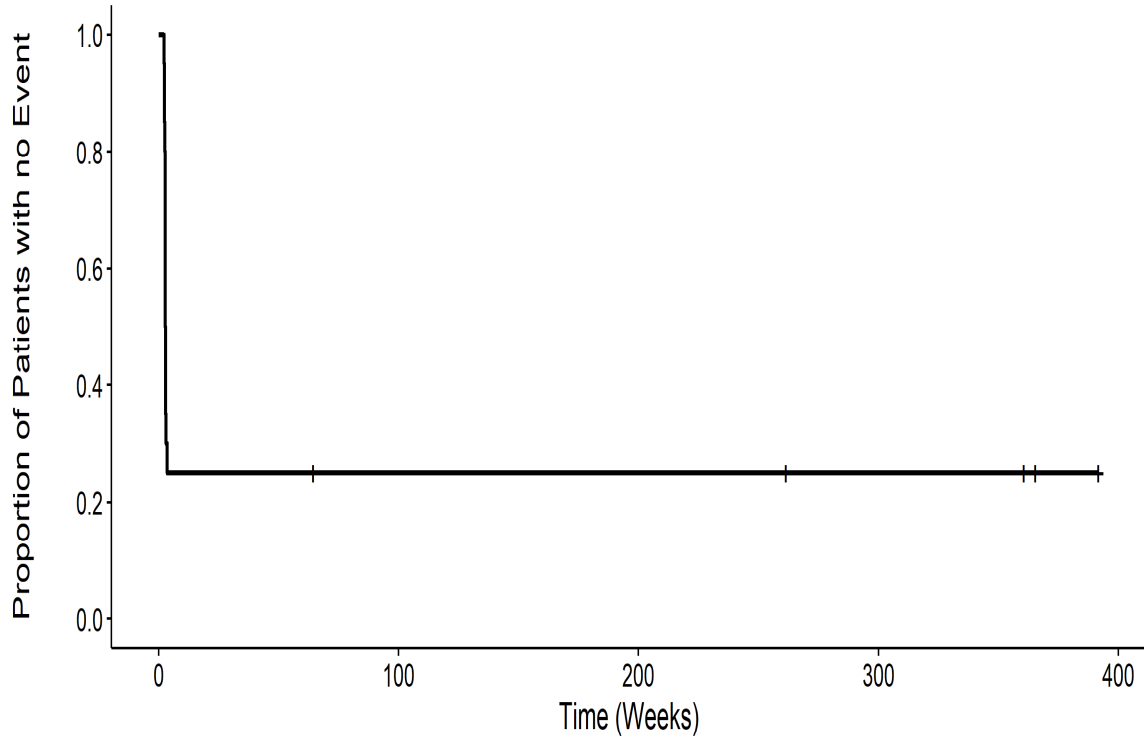


201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Erkrankungen der Haut und des Unterhautzellgewebes PT pts SKIN EXFOLIATION ITT

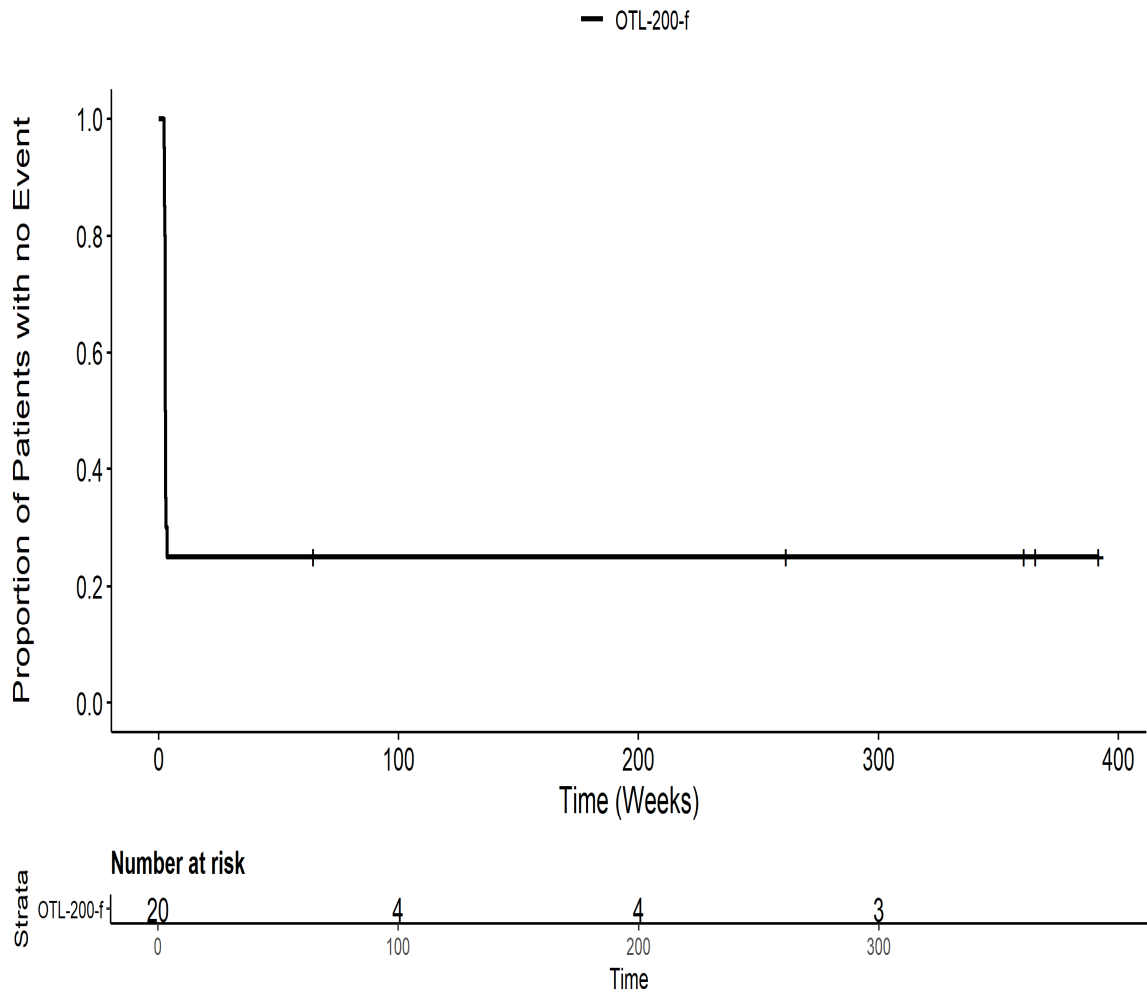


201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Erkrankungen des Blutes und des Lymphsystems PT pts Febrile Neutropenie ITT

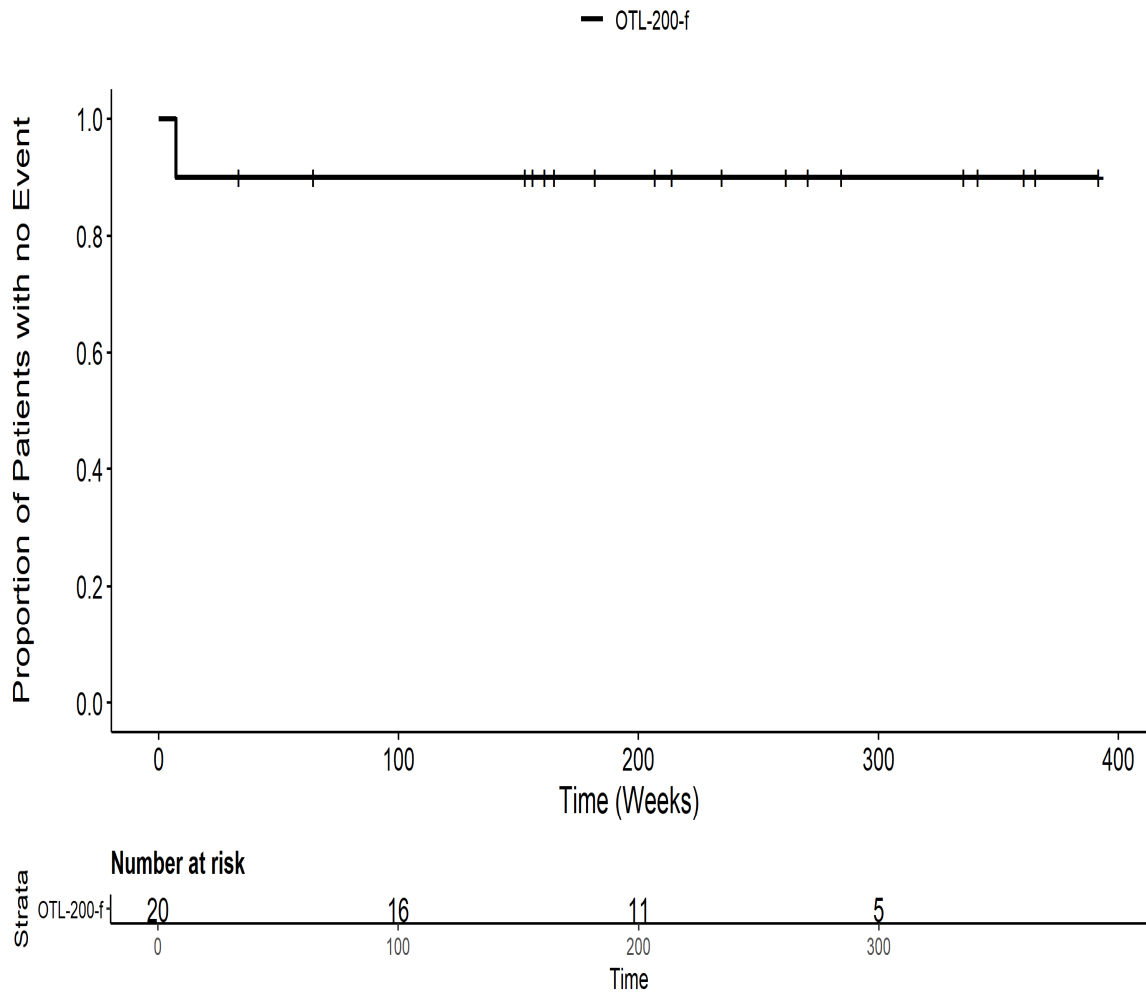
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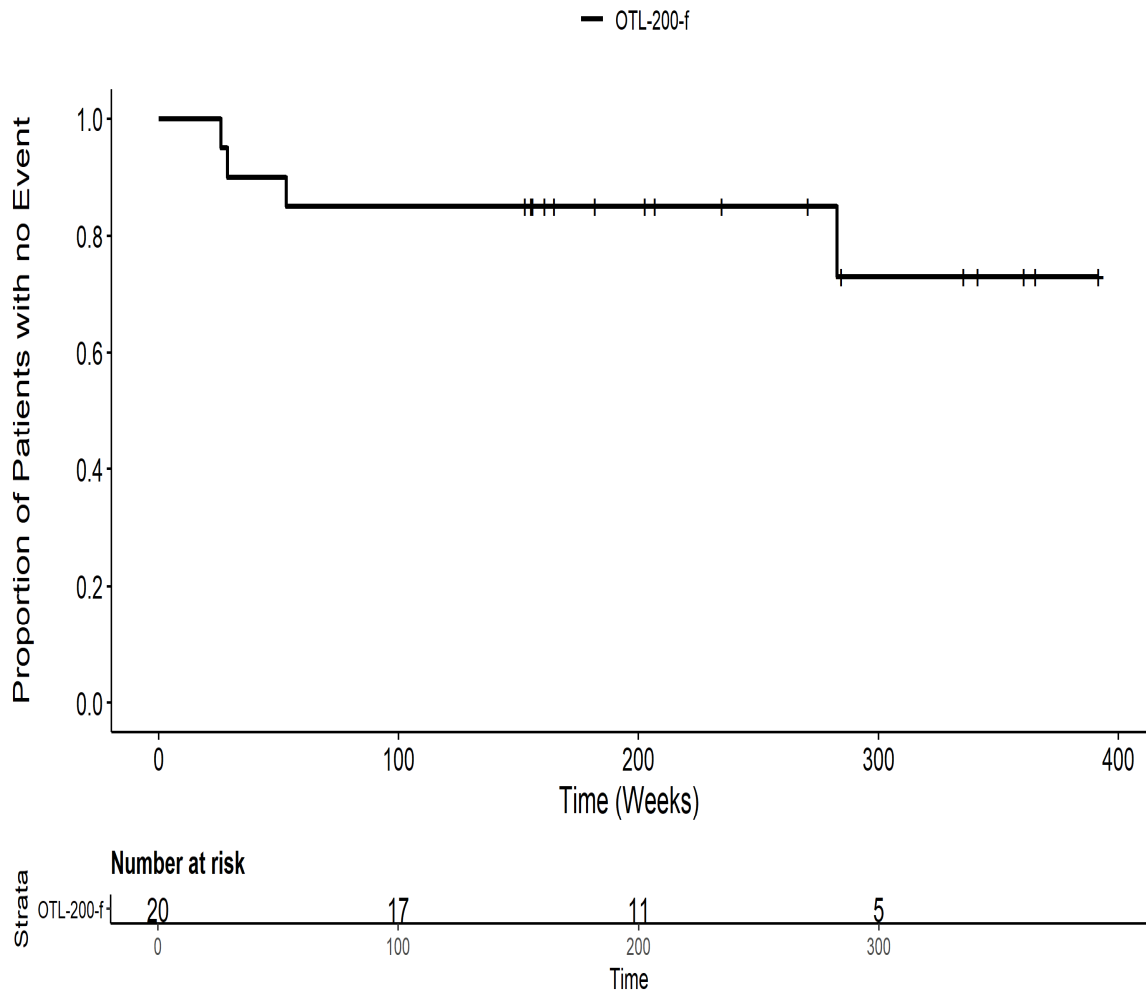
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Erkrankungen des Blutes und des Lymphsystems PT pts Gesamt SOC ITT



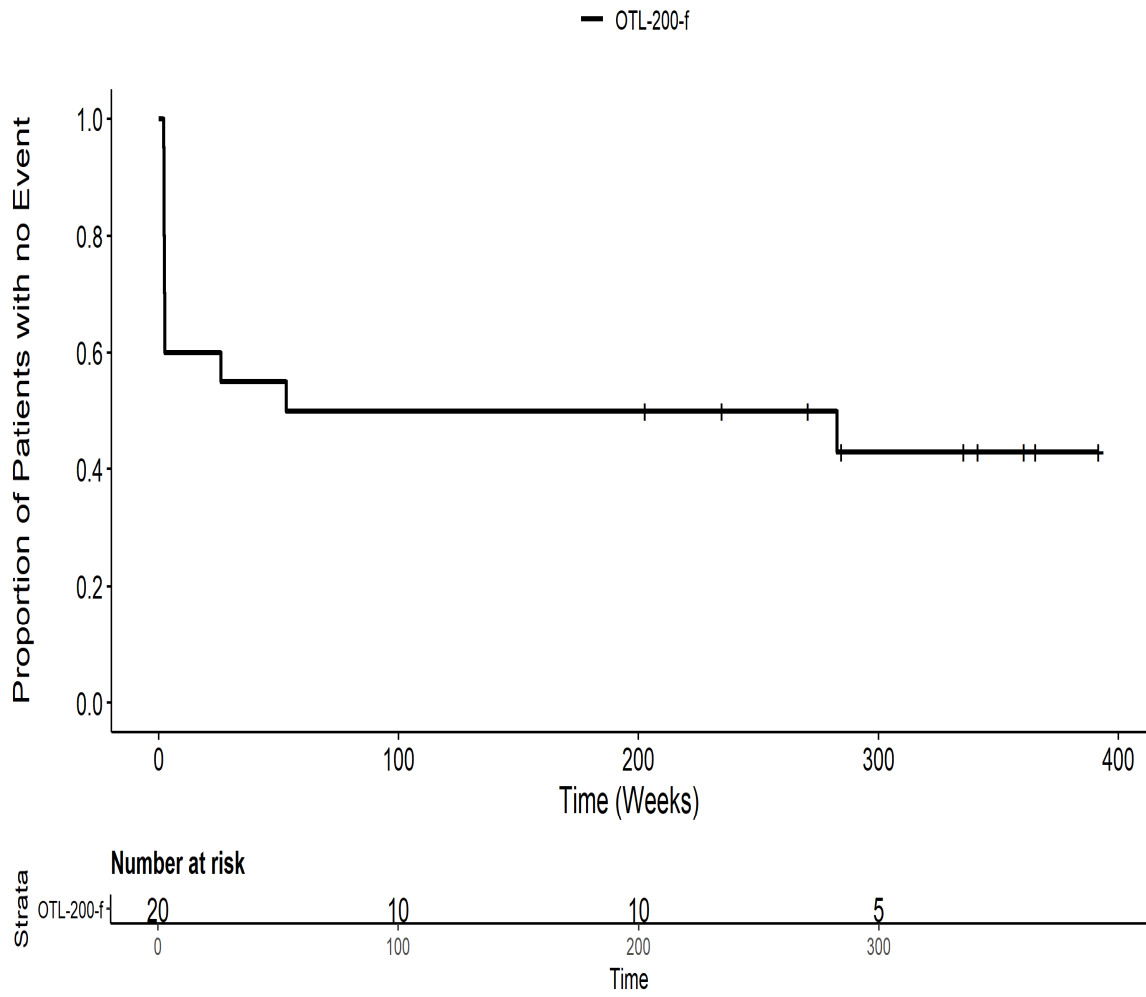
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Erkrankungen des Blutes und des Lymphsystems PT pts Neutropenie ITT



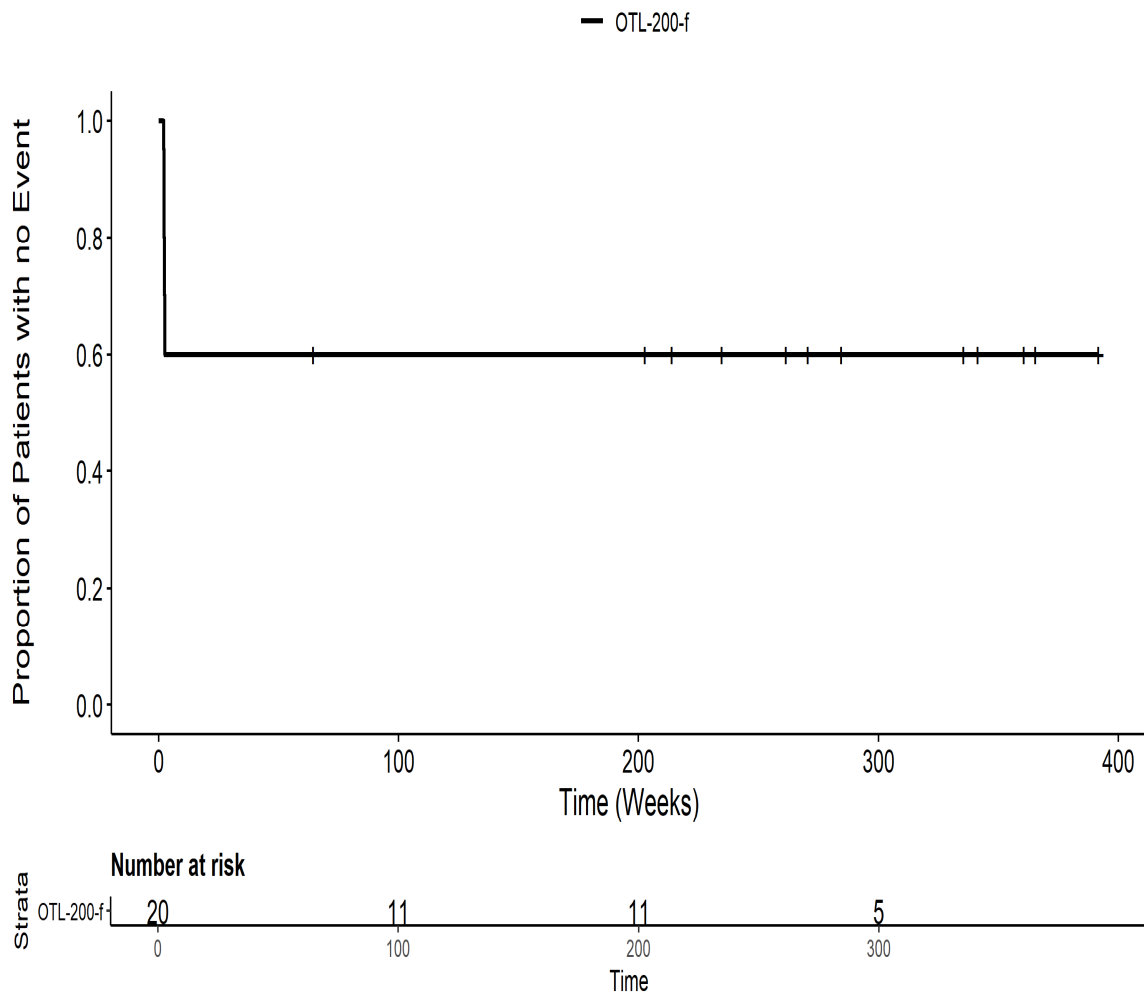
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Erkrankungen des Gastrointestinaltrakts PT pts Dysphagie ITT



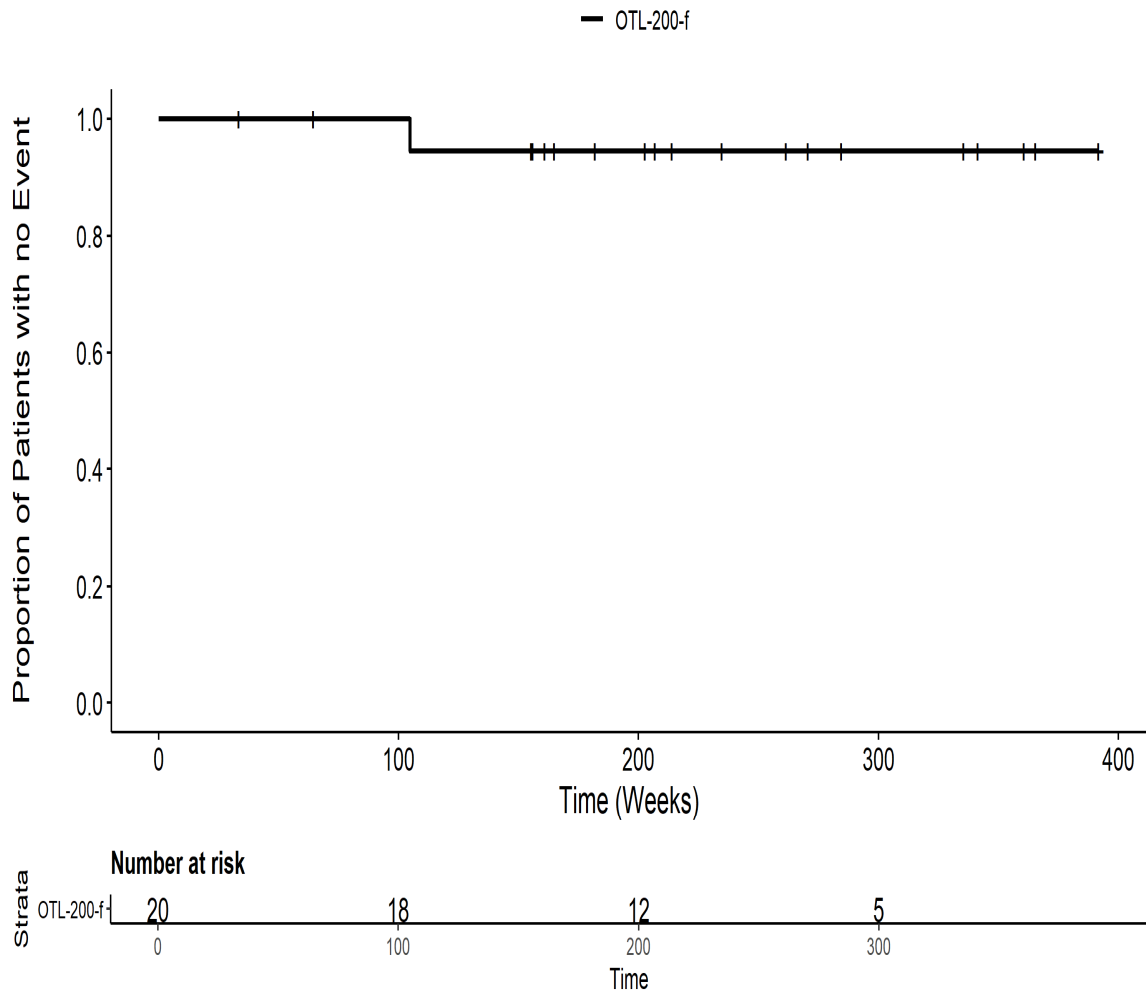
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Erkrankungen des Gastrointestinaltrakts PT pts Gesamt SOC ITT



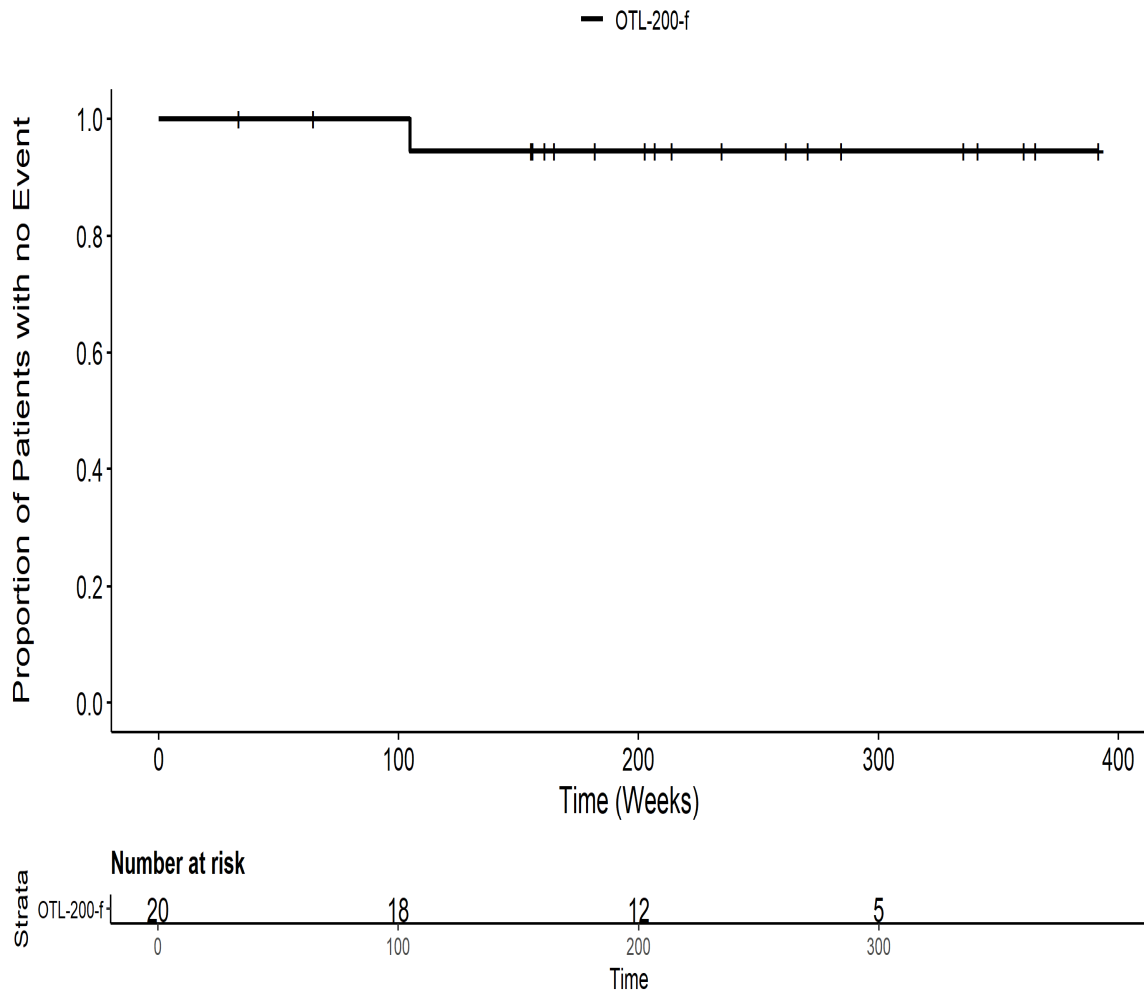
201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Erkrankungen des Gastrointestinaltrakts PT pts Stomatitis ITT



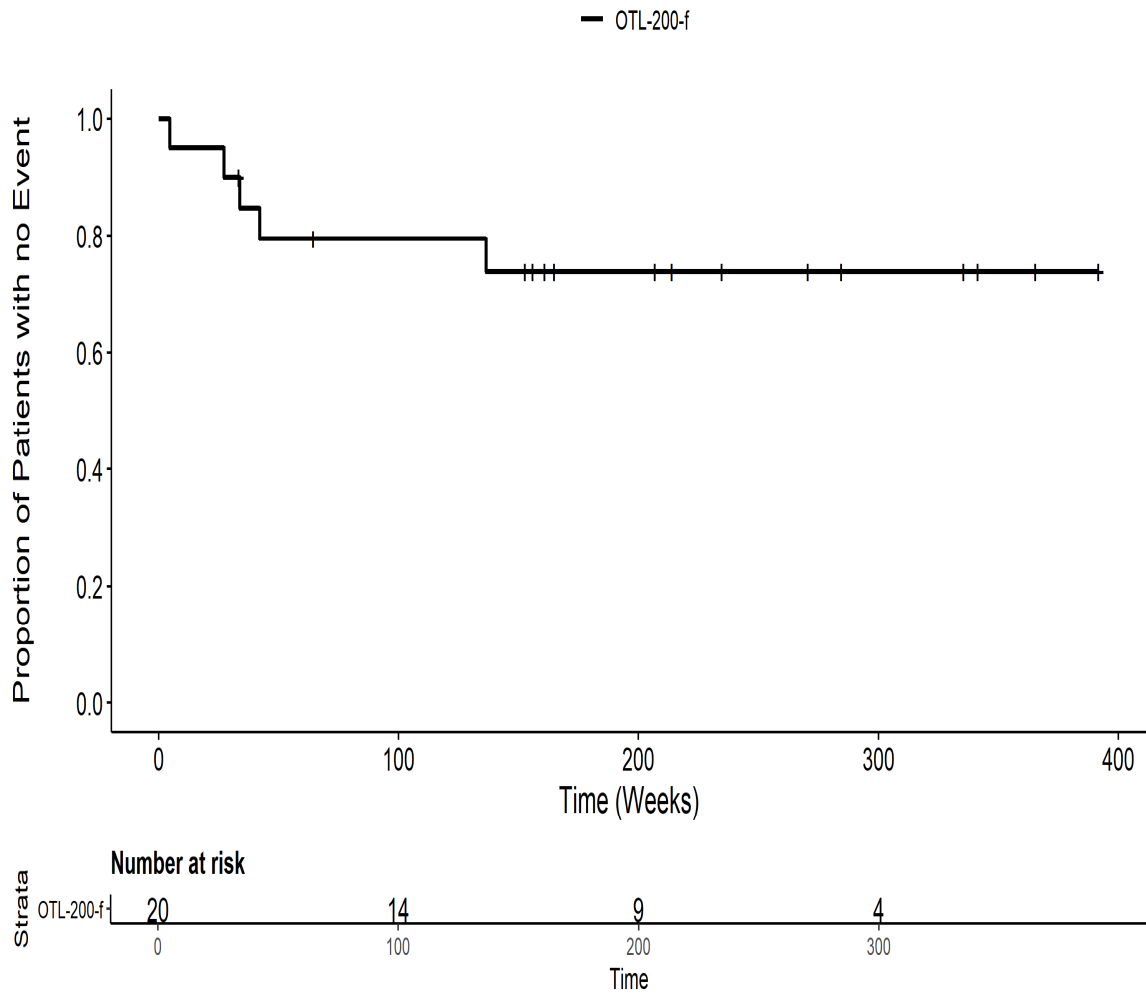
201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Gefäßserkrankungen PT pts Gesamt SOC ITT



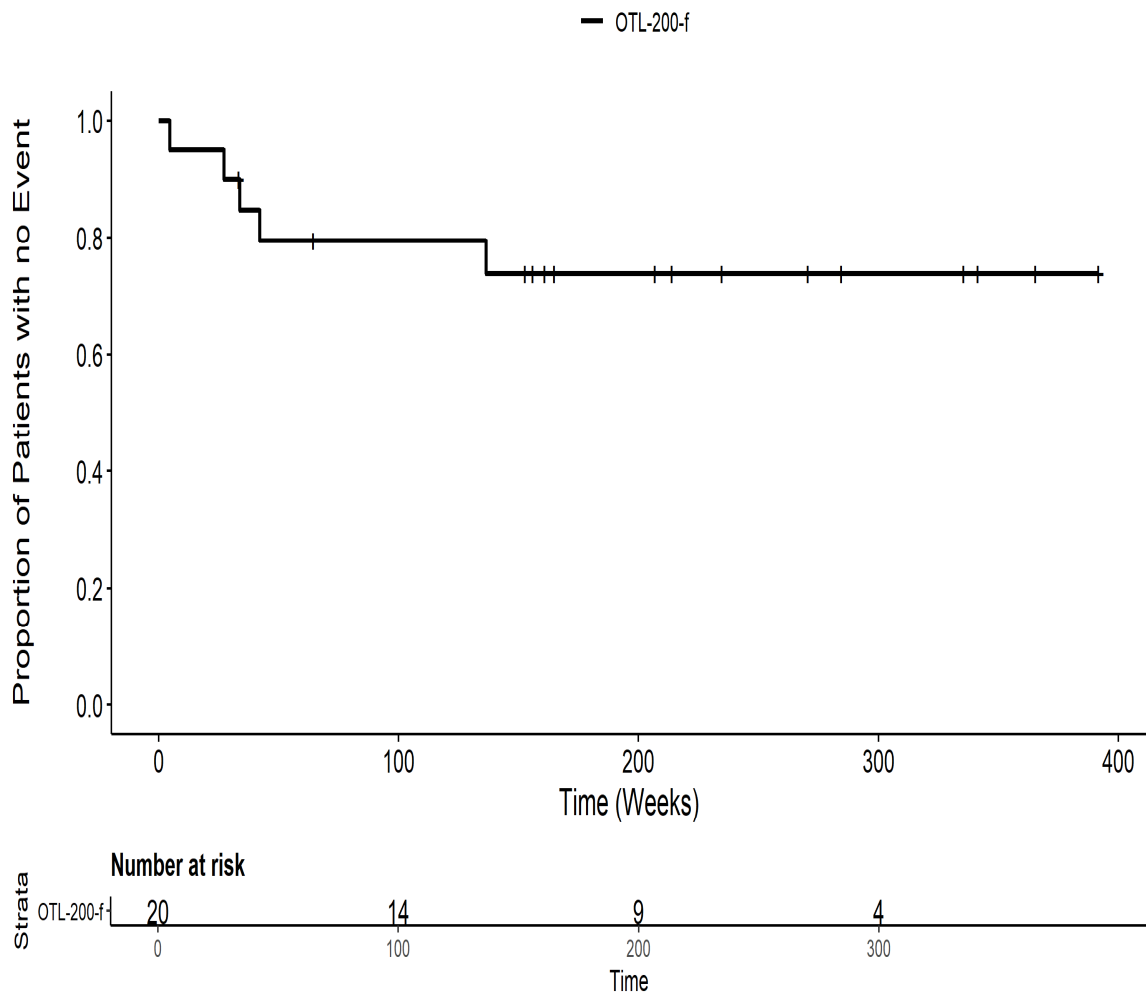
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Gefäßserkrankungen PT pts KAWASAKI'S DISEASE ITT



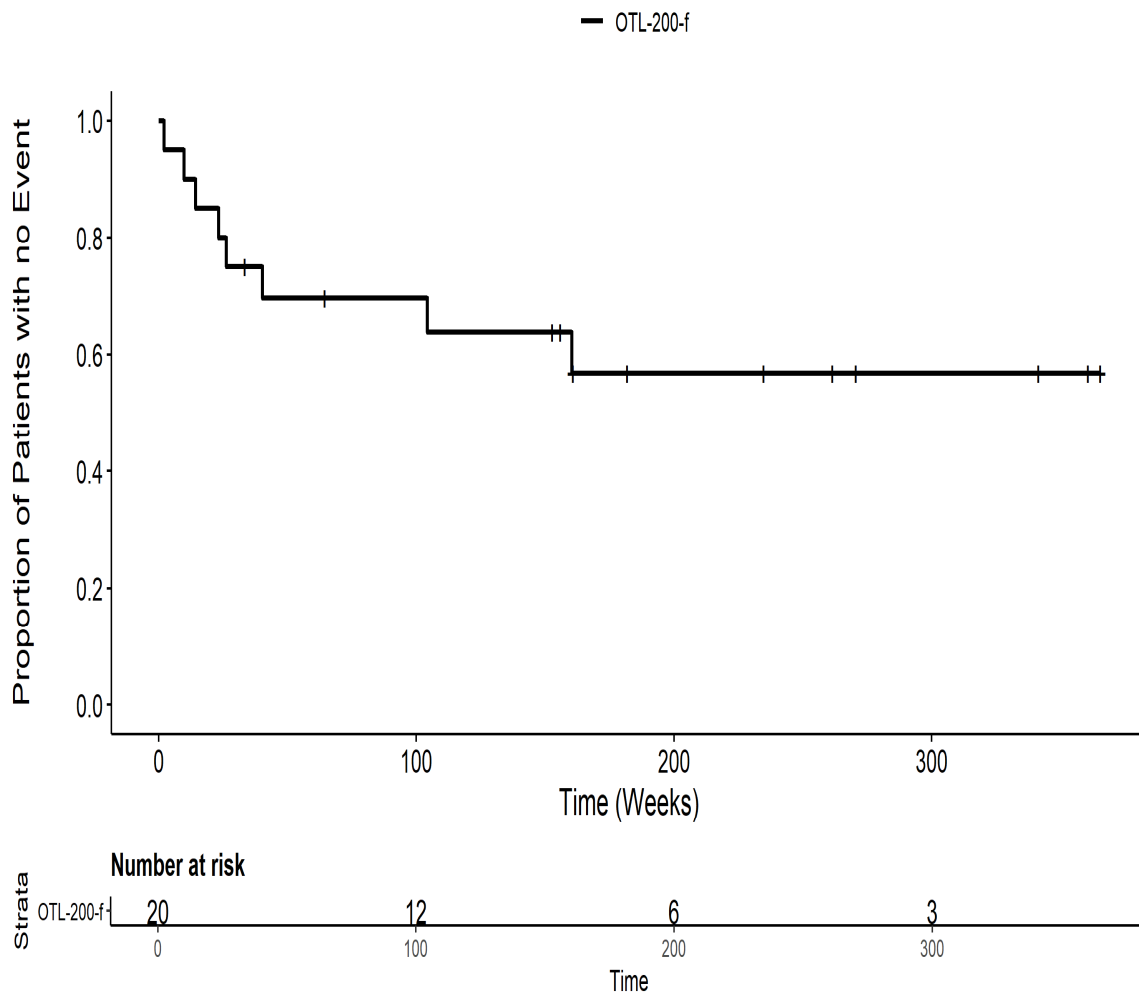
201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Infektionen und parasitäre Erkrankungen PT pts Gesamt SOC ITT



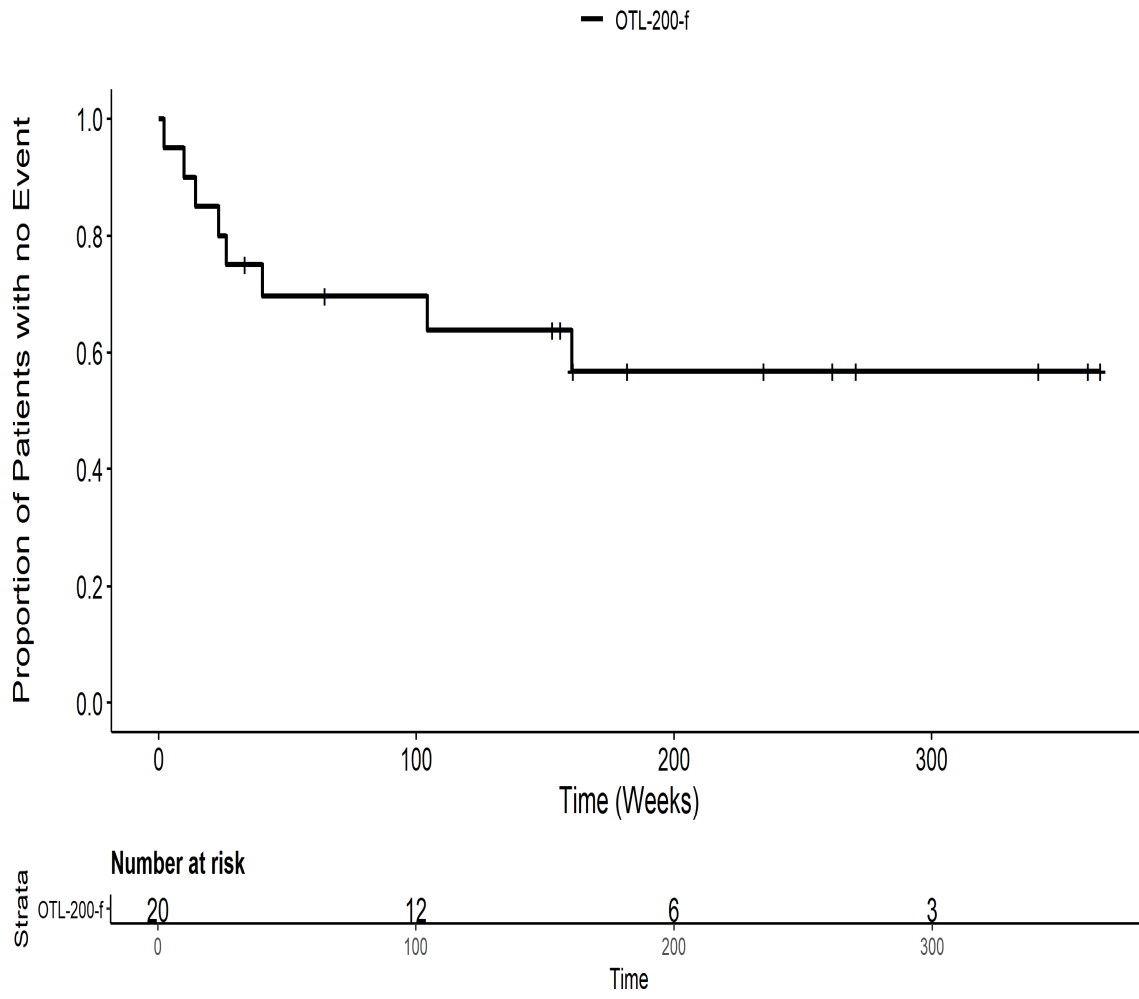
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Infektionen und parasitäre Erkrankungen PT pts Konjunktivitis ITT



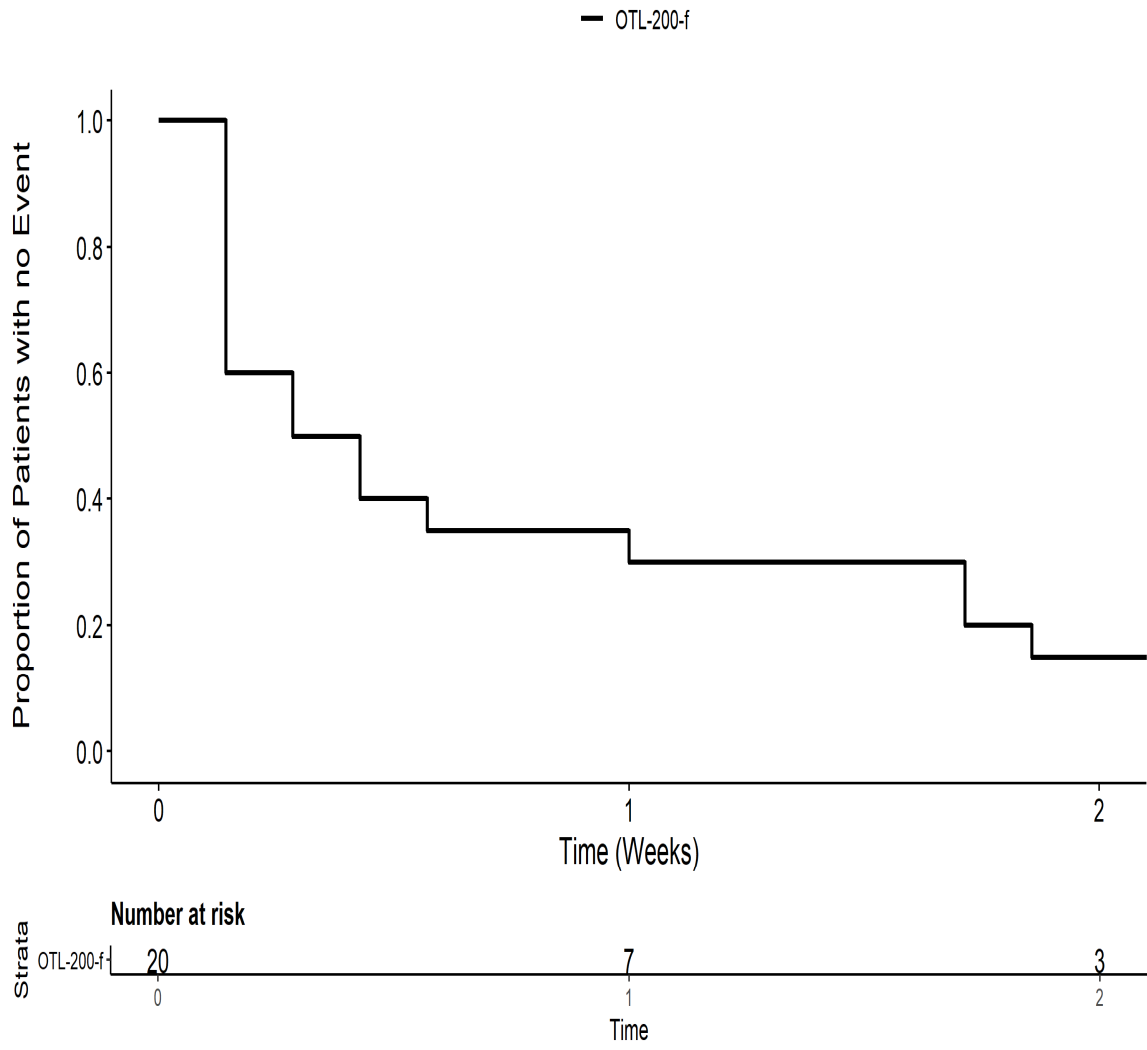
201222: Kaplan Meier Plot for Time to AE all AE SMQ by SOC
Untersuchungen PT pts Erhöhtes Immunglobulin E im Blut ITT



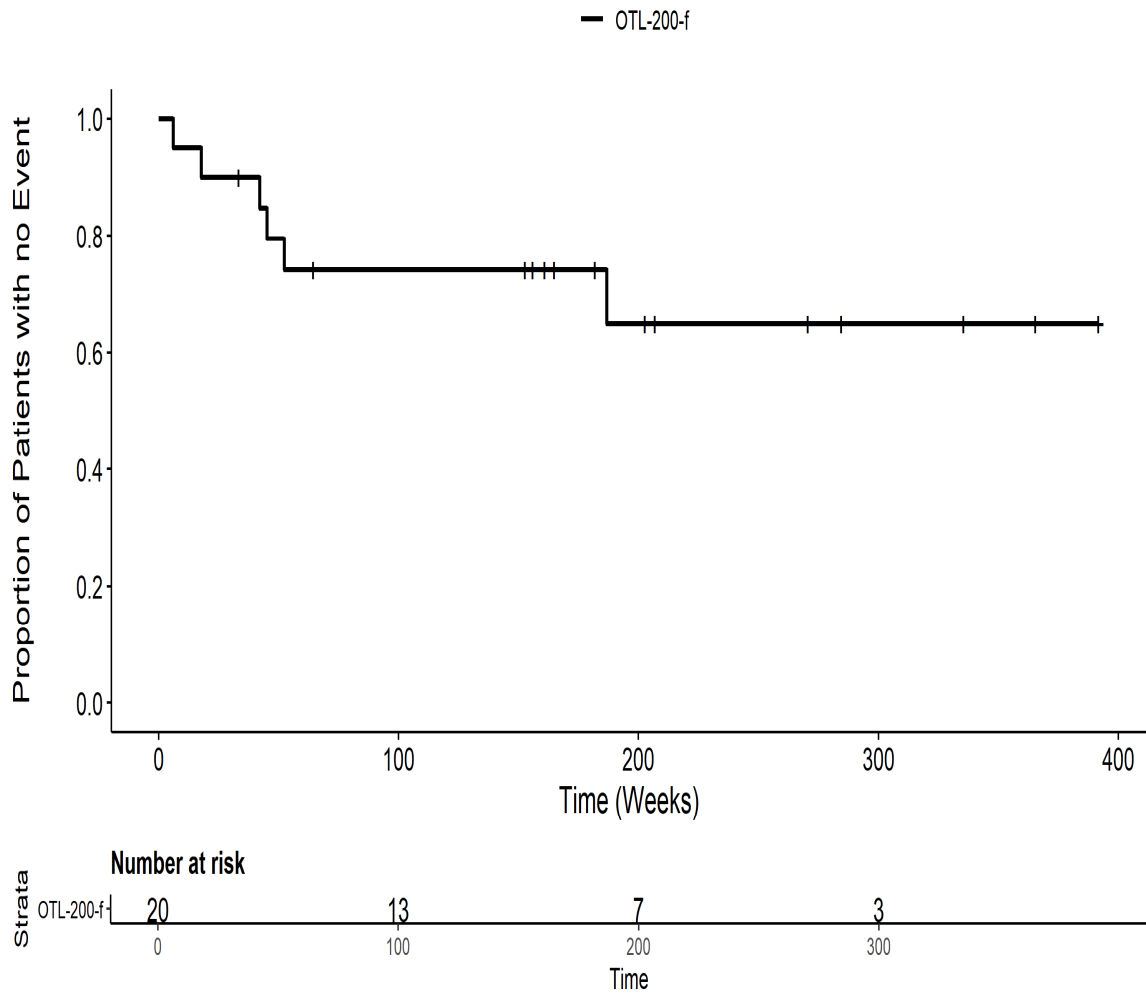
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Untersuchungen PT pts Gesamt SOC ITT



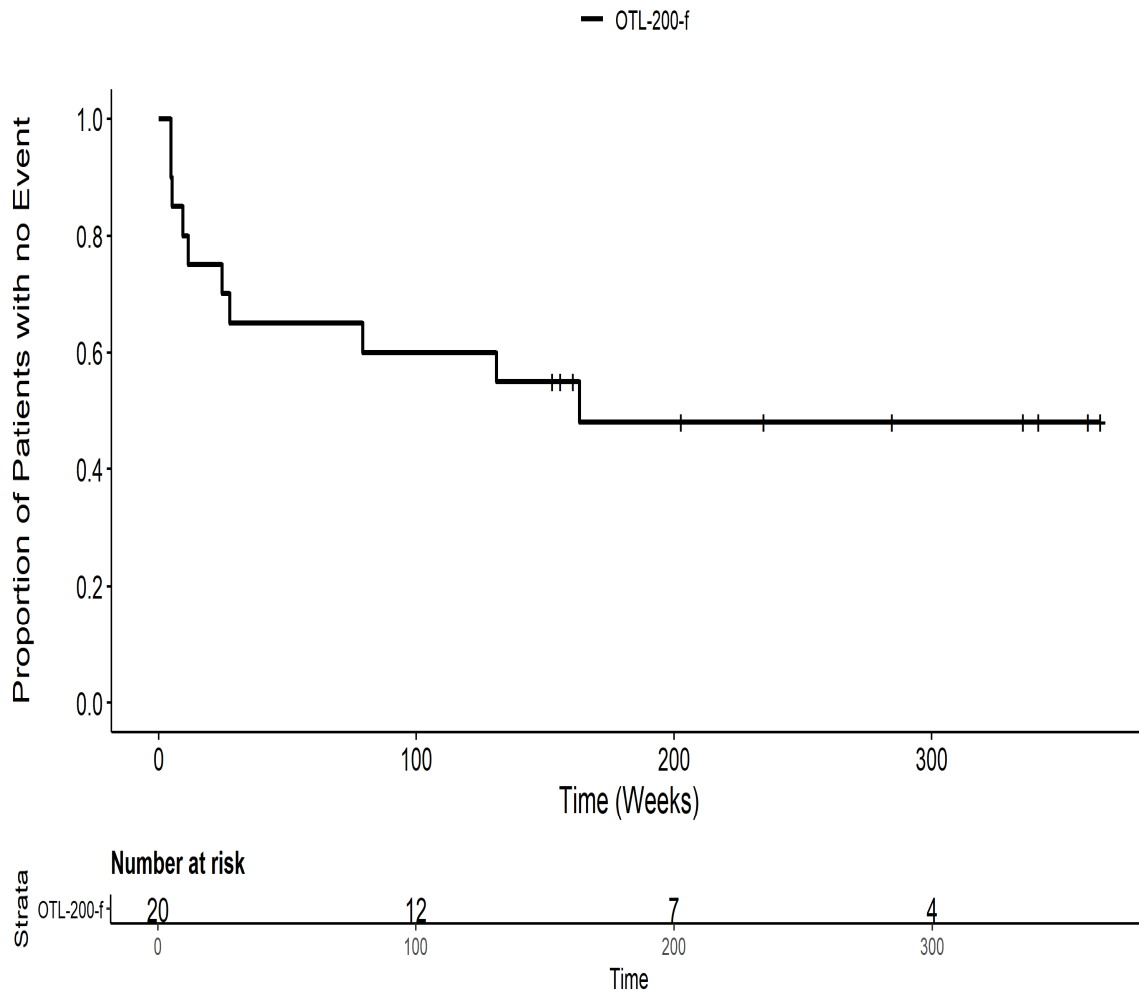
201222: Kaplan Meier Plot for Time to all AE ITT



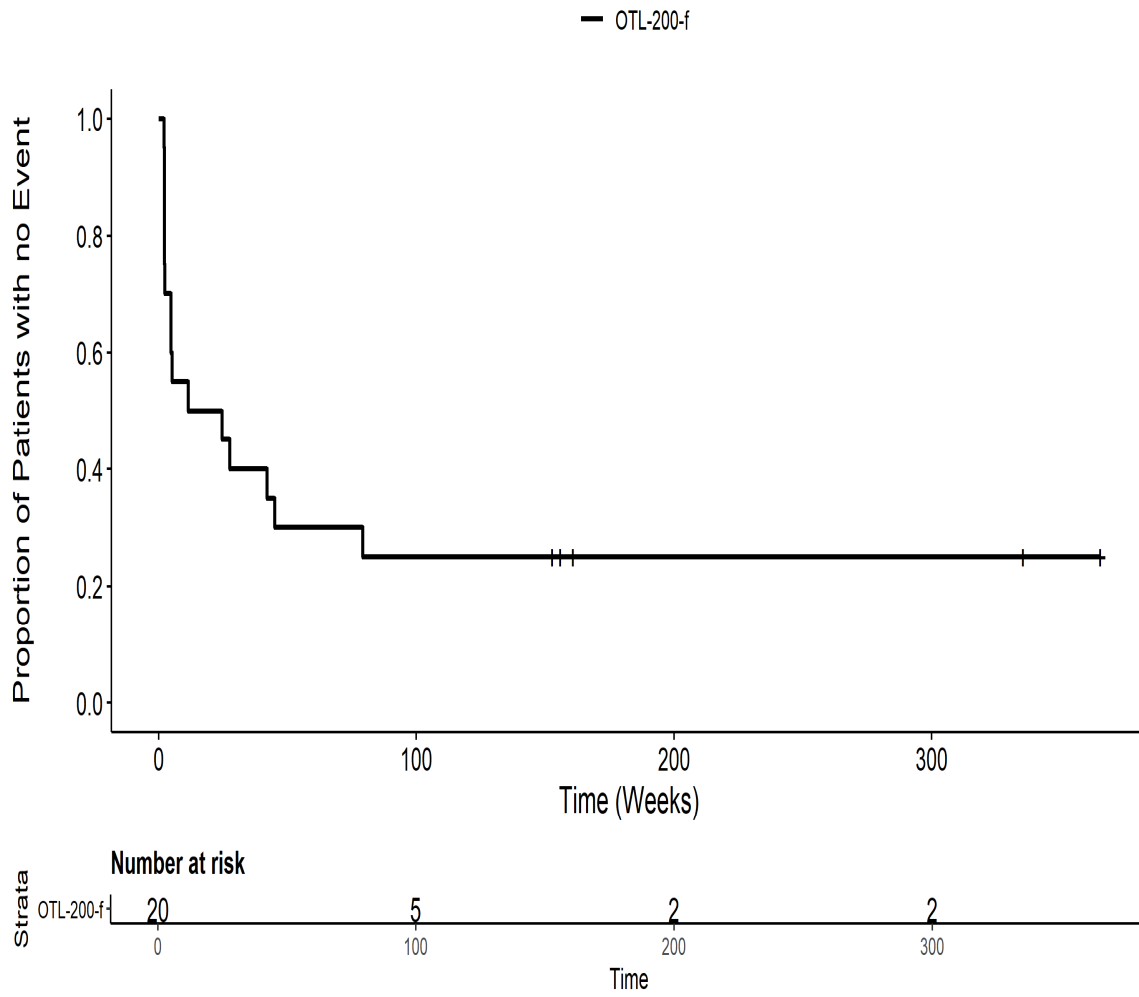
201222: Kaplan Meier Plot for Time to all AE by SOC Allgemeine
Erkrankungen und Beschwerden am Verabreichungsort PT pct Fieber/TT



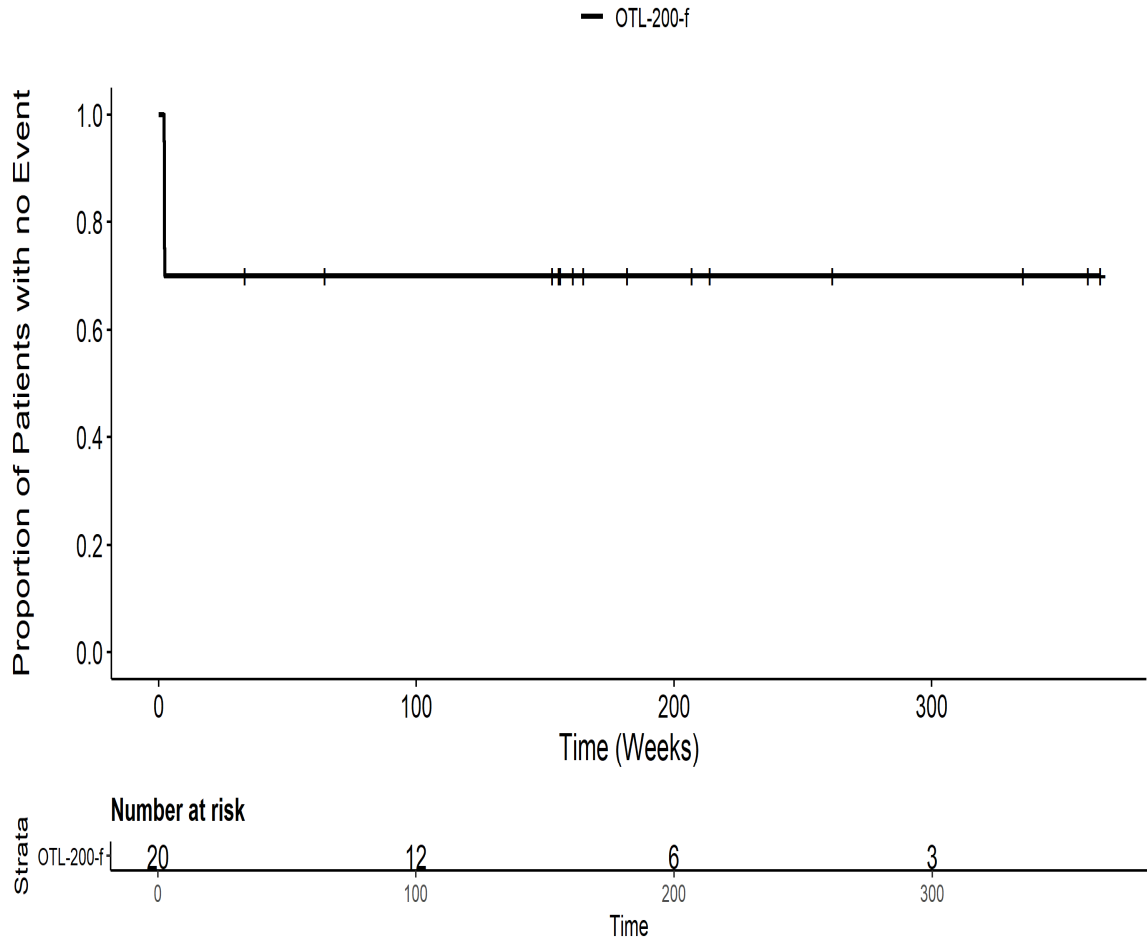
201222: Kaplan Meier Plot for Time to all AE by SOC Allgemeine
Erkrankungen und Beschwerden am Verabreichungsort PT pct GangstoerungITT



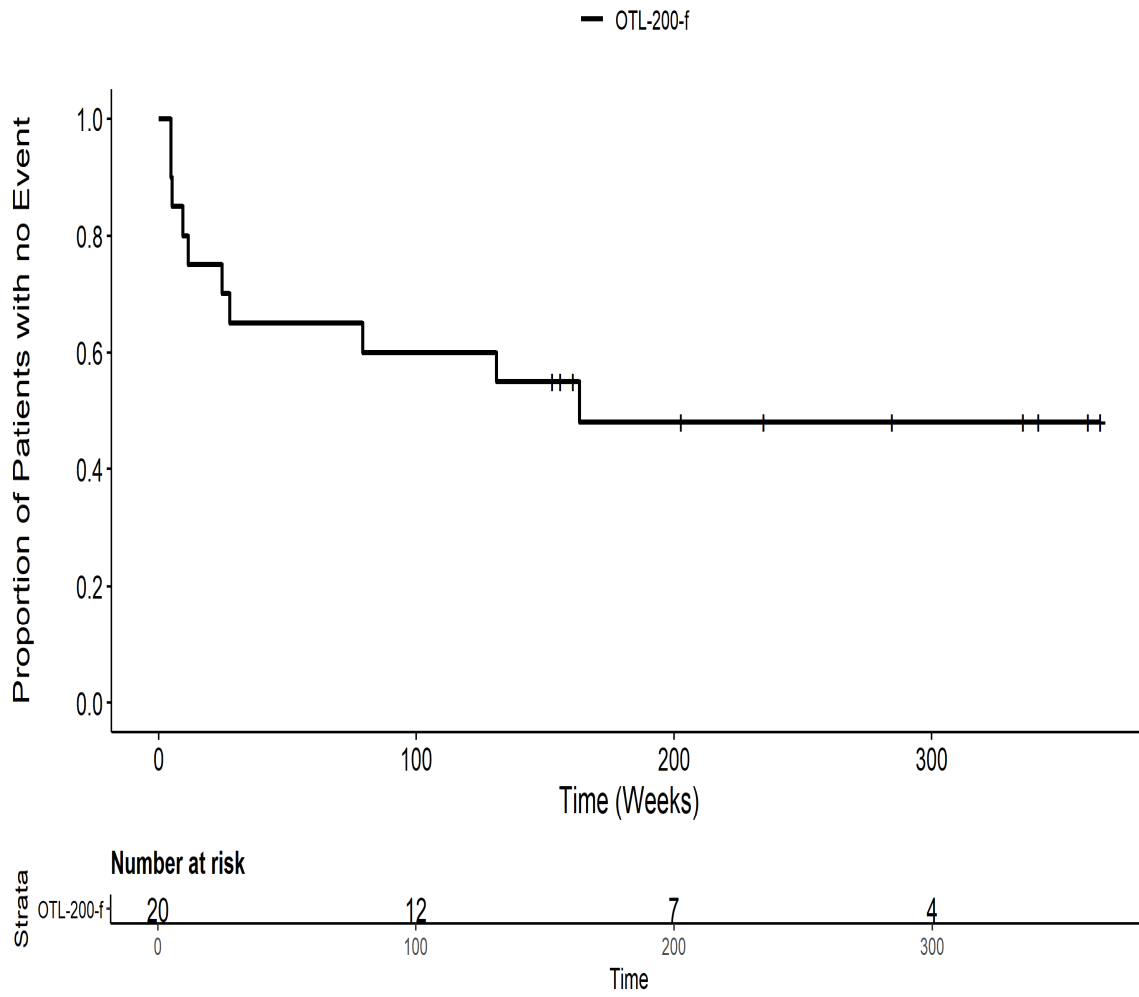
201222: Kaplan Meier Plot for Time to all AE by SOC Allgemeine
Erkrankungen und Beschwerden am Verabreichungsort PT pct Gesamt SOCITT



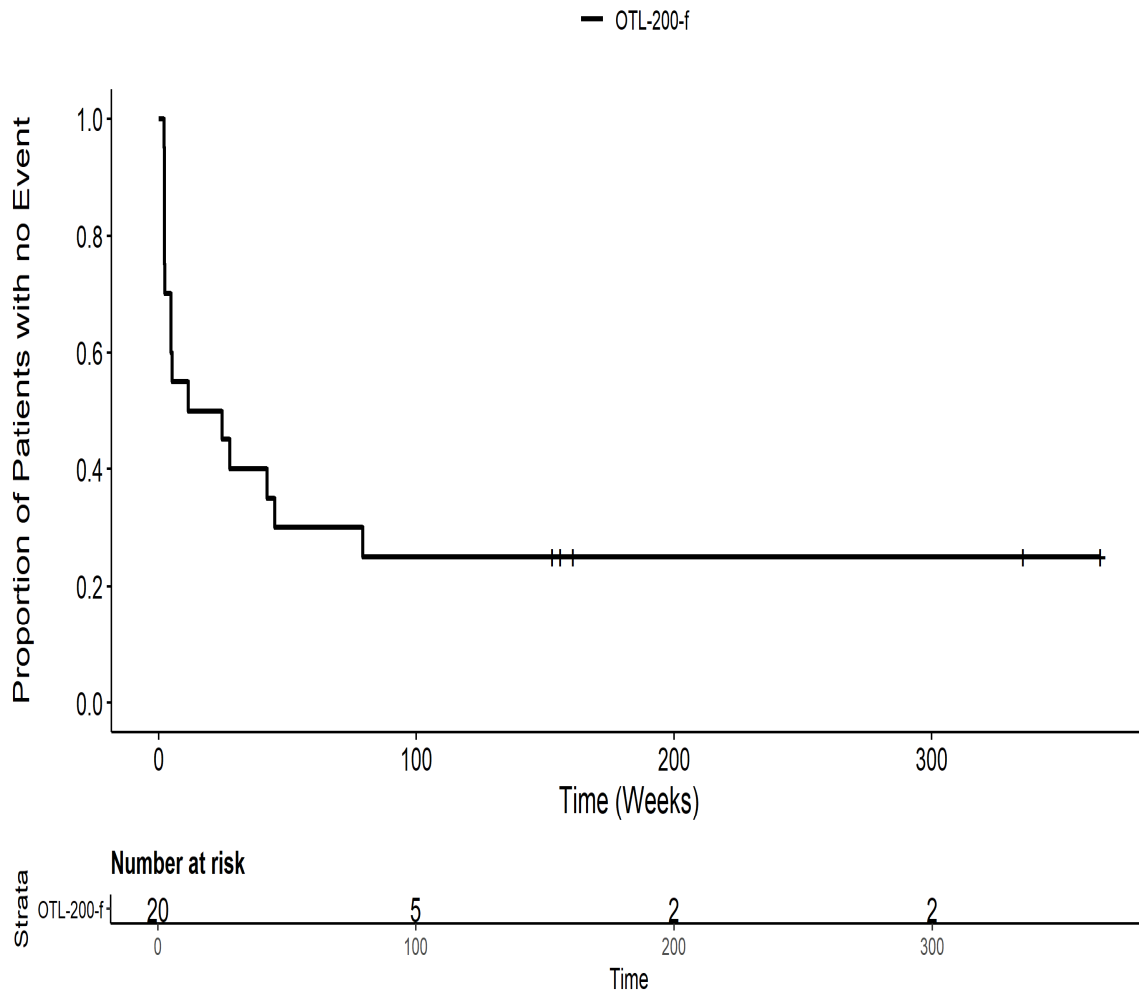
201222: Kaplan Meier Plot for Time to all AE by SOC Allgemeine Erkrankungen und Beschwerden am Verabreichungsort PT pct SchleimhautentzündungITT



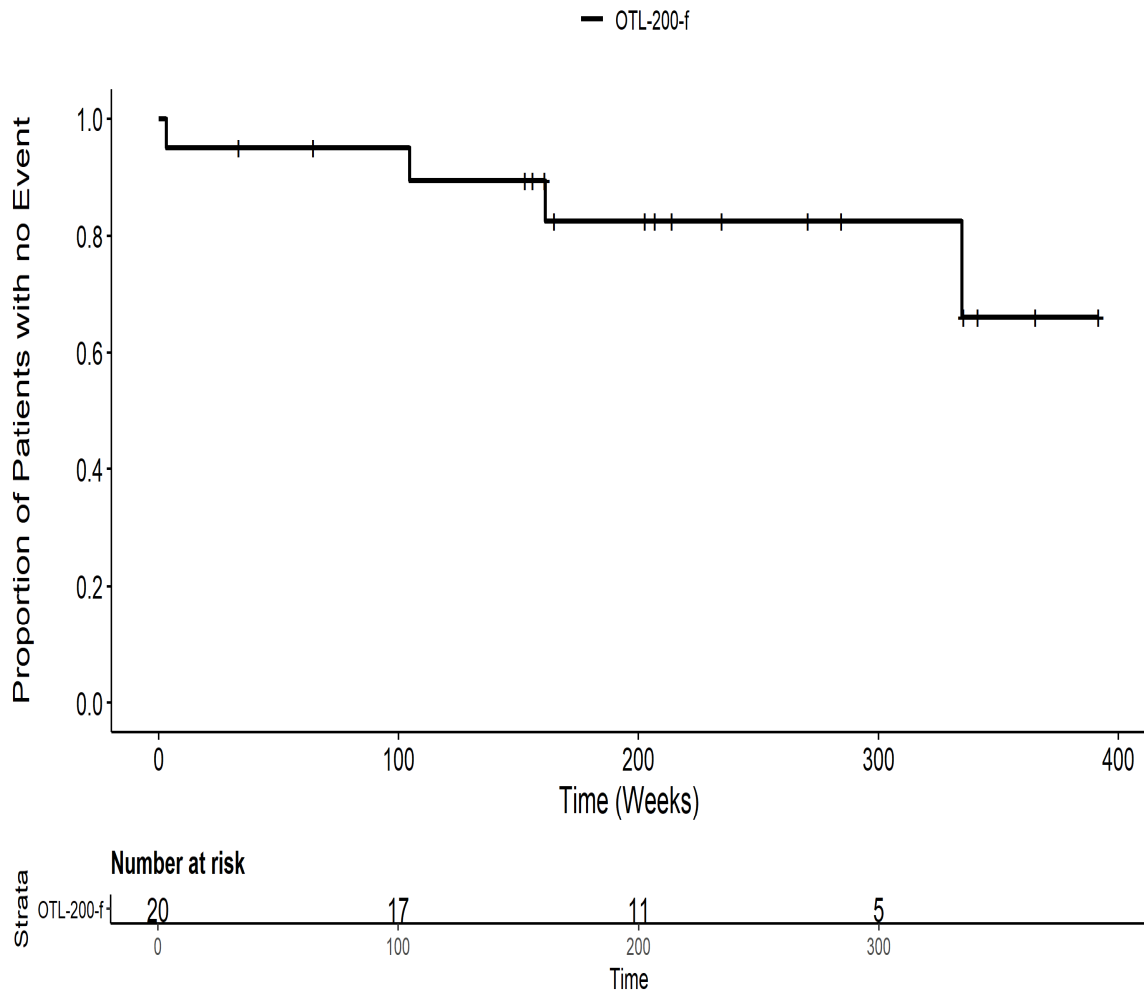
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Erkrankungen und Beschwerden am Verabreichungsort PT pts Gangstoerung ITT



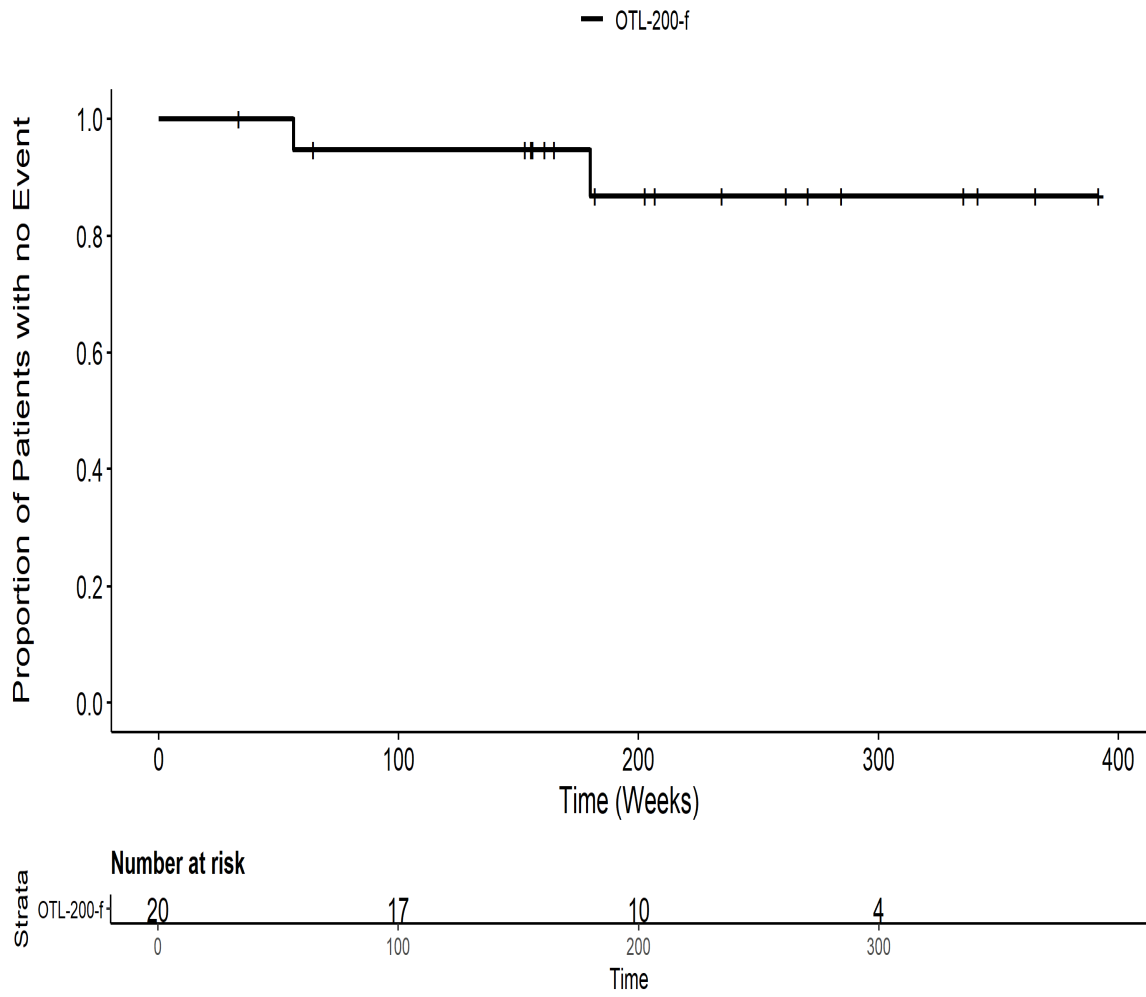
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Erkrankungen und Beschwerden am Verabreichungsort PT pts Gesamt SOC ITT



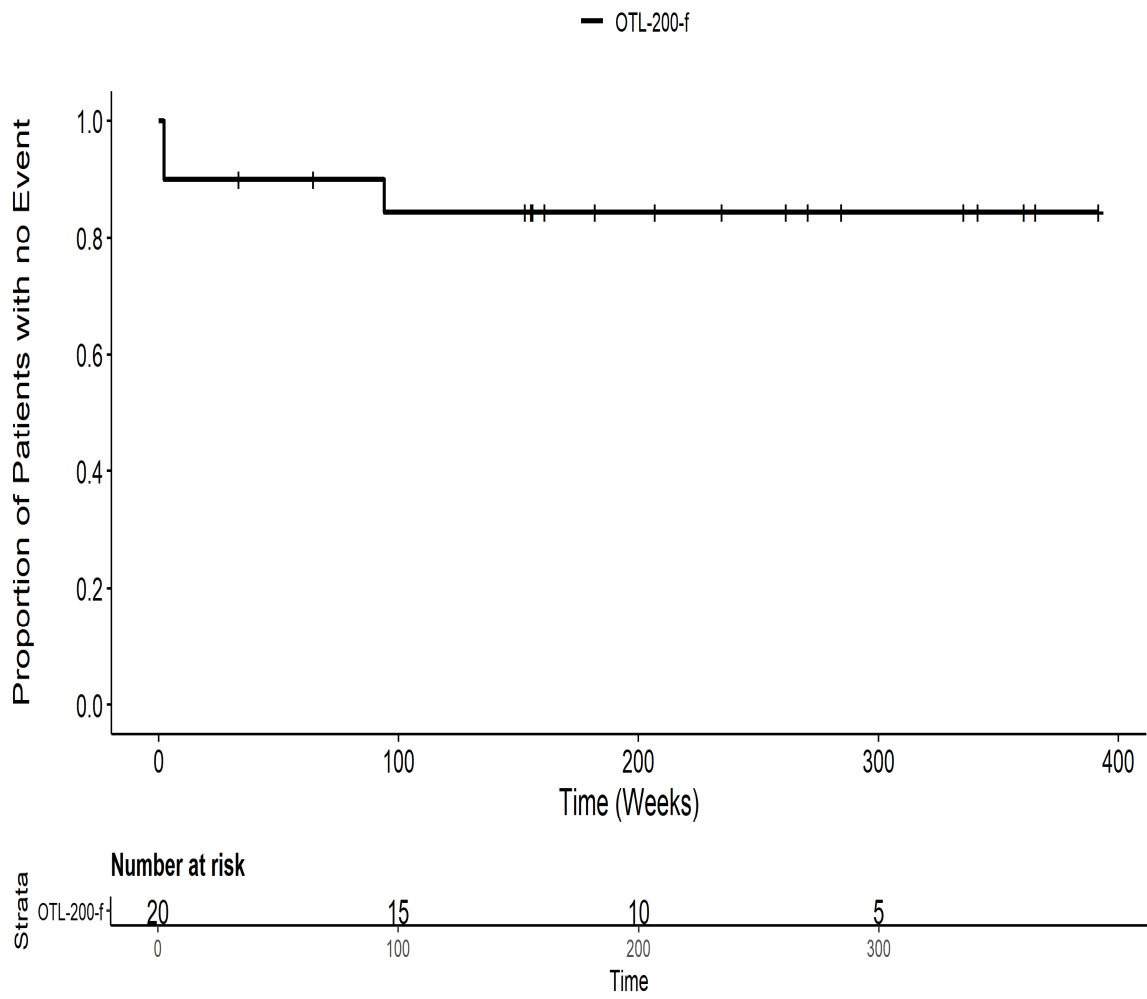
201222: Kaplan Meier Plot for Time to all AE by SOC
Augenerkrankungen PT pct Gesamt SOCITT



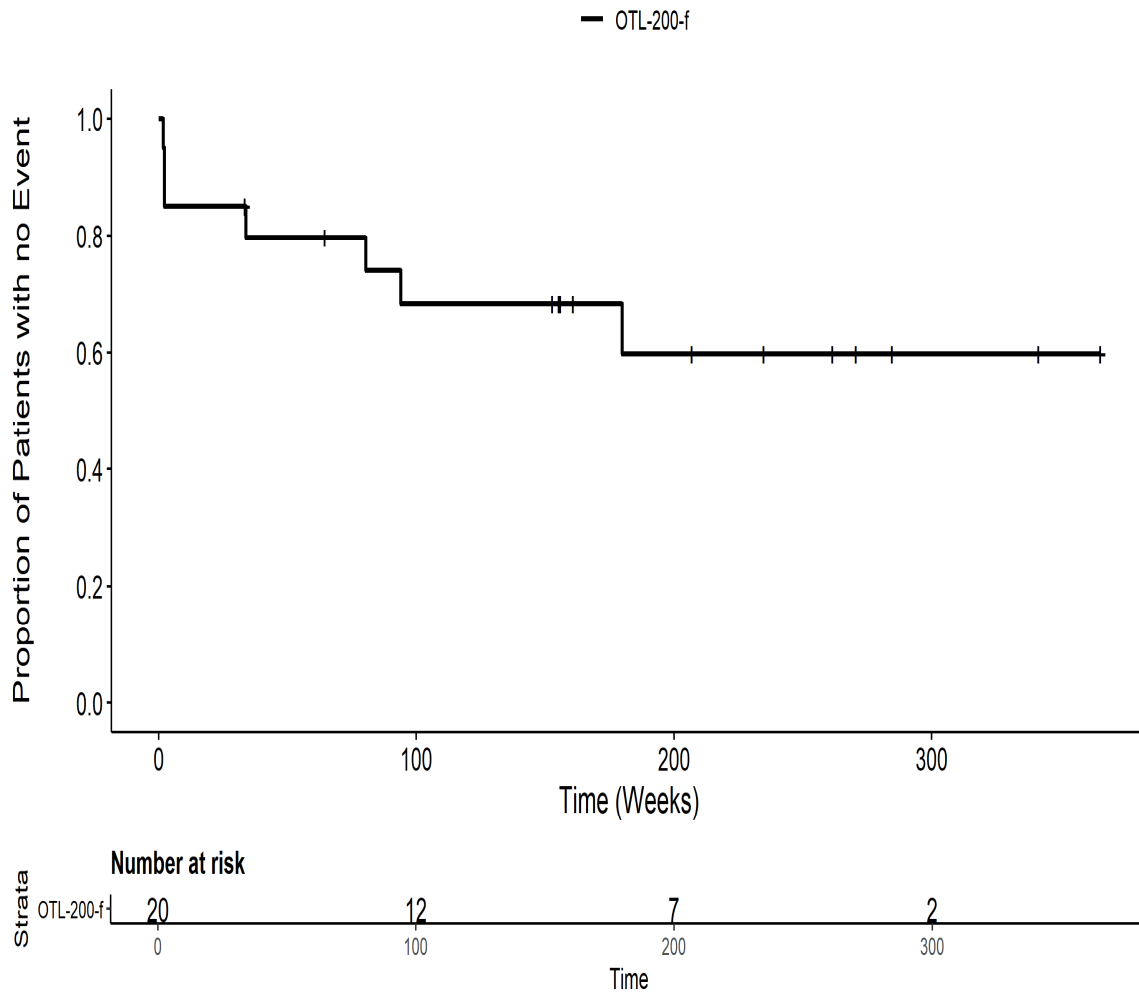
201222: Kaplan Meier Plot for Time to all AE by SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums PT pct BronchospasmusITT



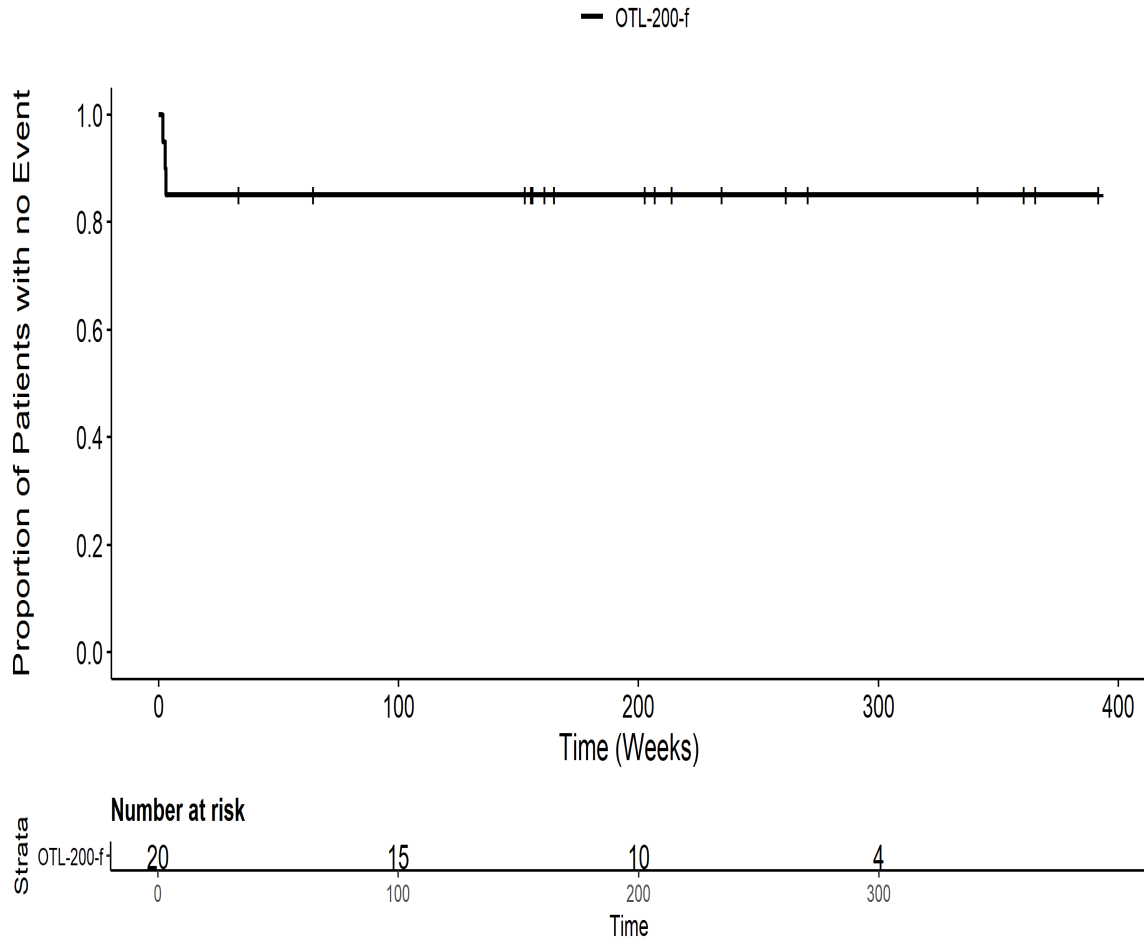
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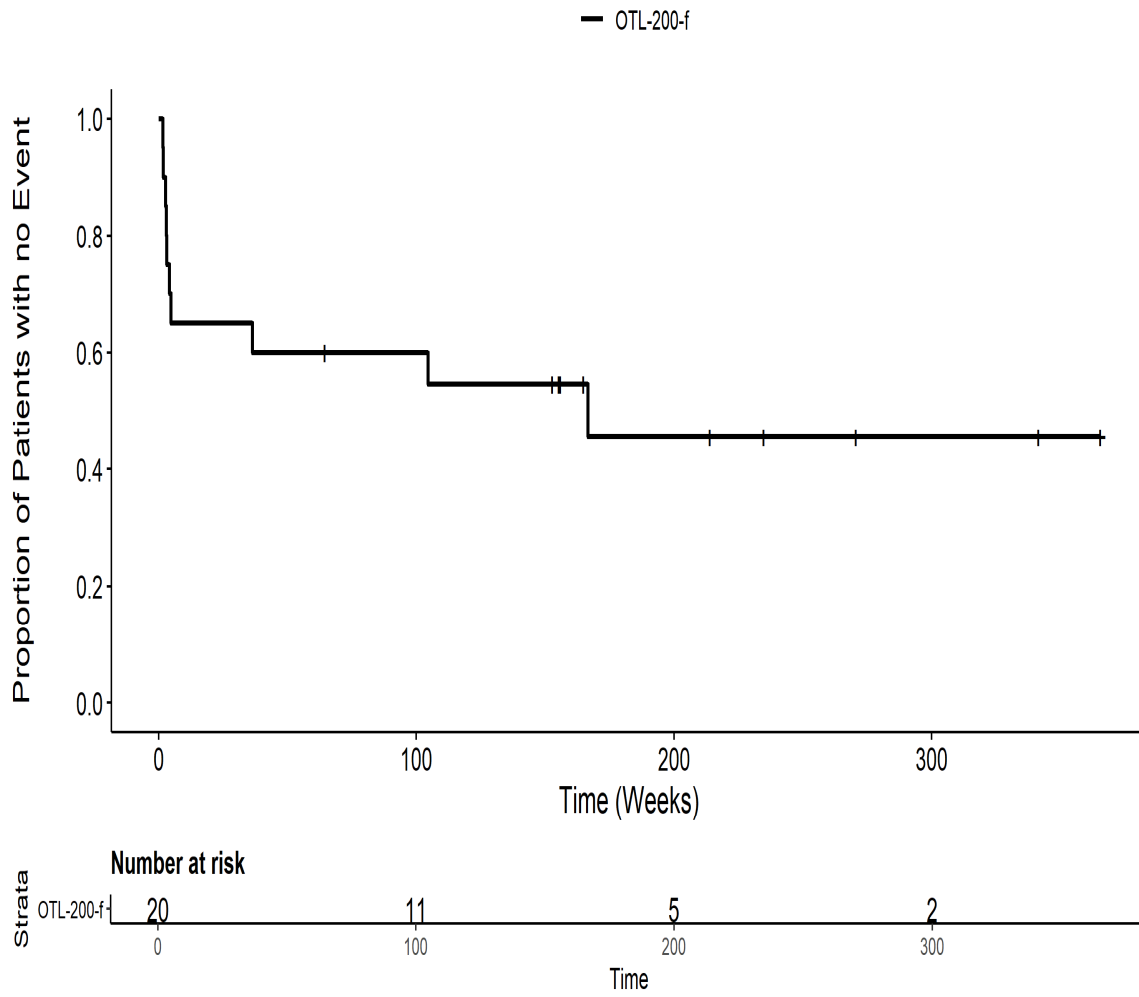
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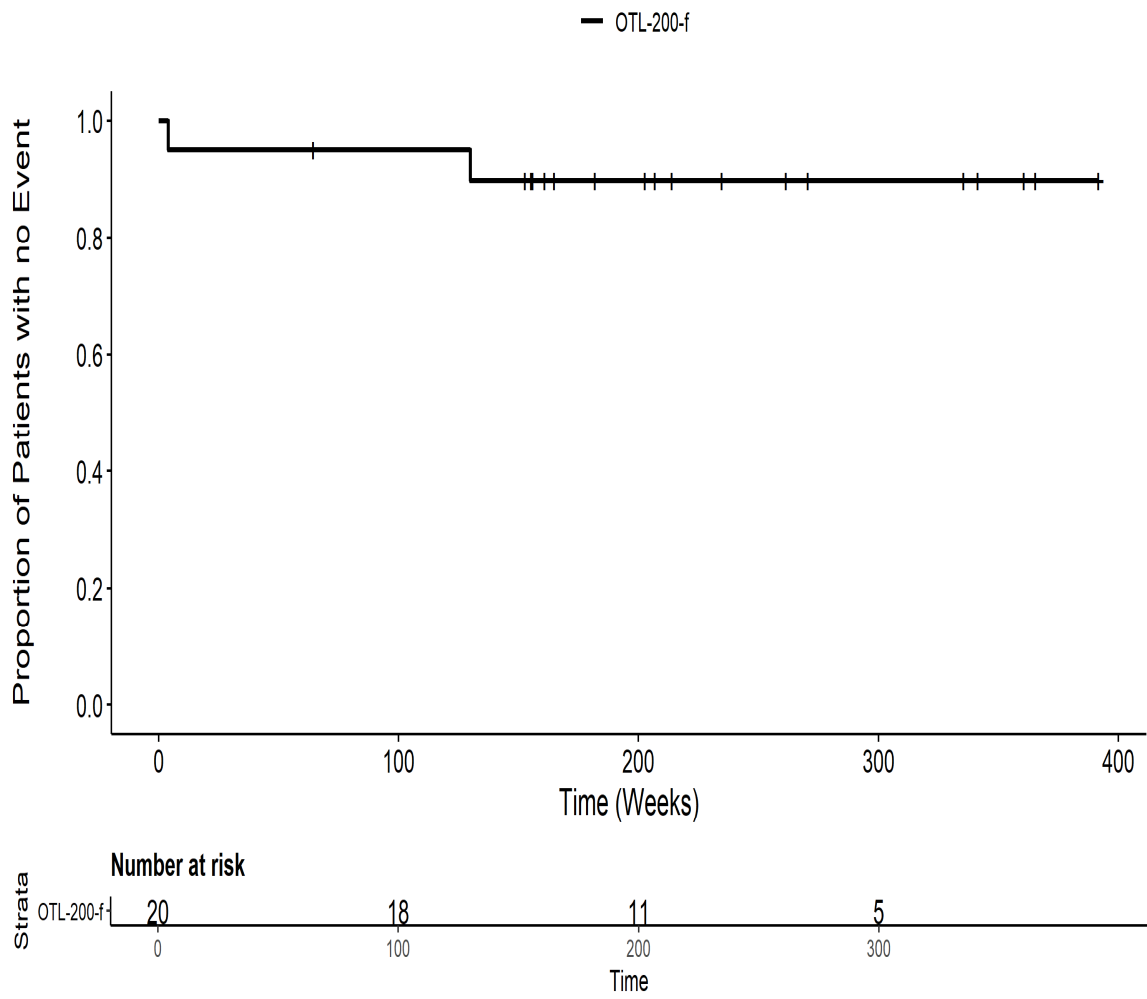
201222: Kaplan Meier Plot for Time to all AE by SOC Erkrankungen
der Haut und des Unterhautzellgewebes PT pct Erythematoseser
HautausschlagITT



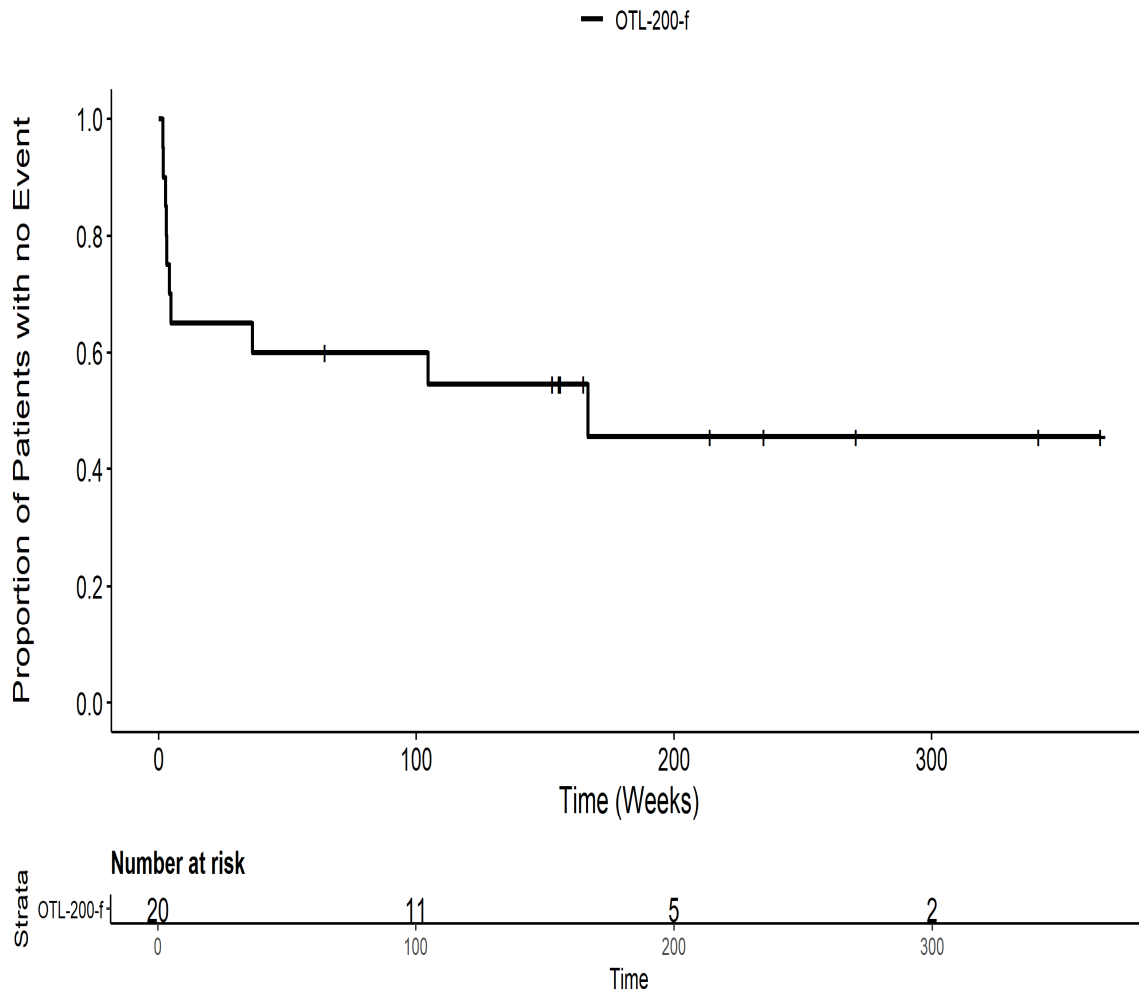
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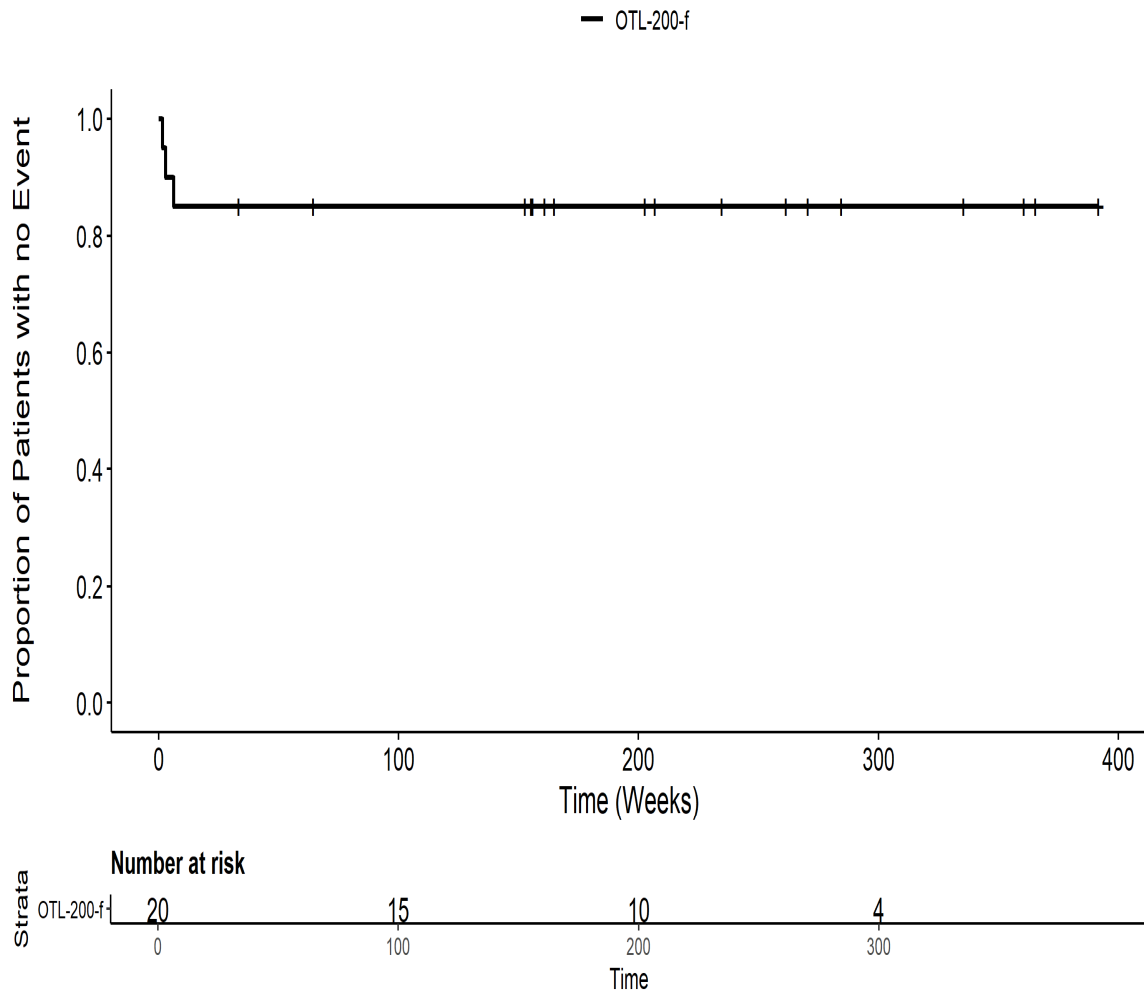
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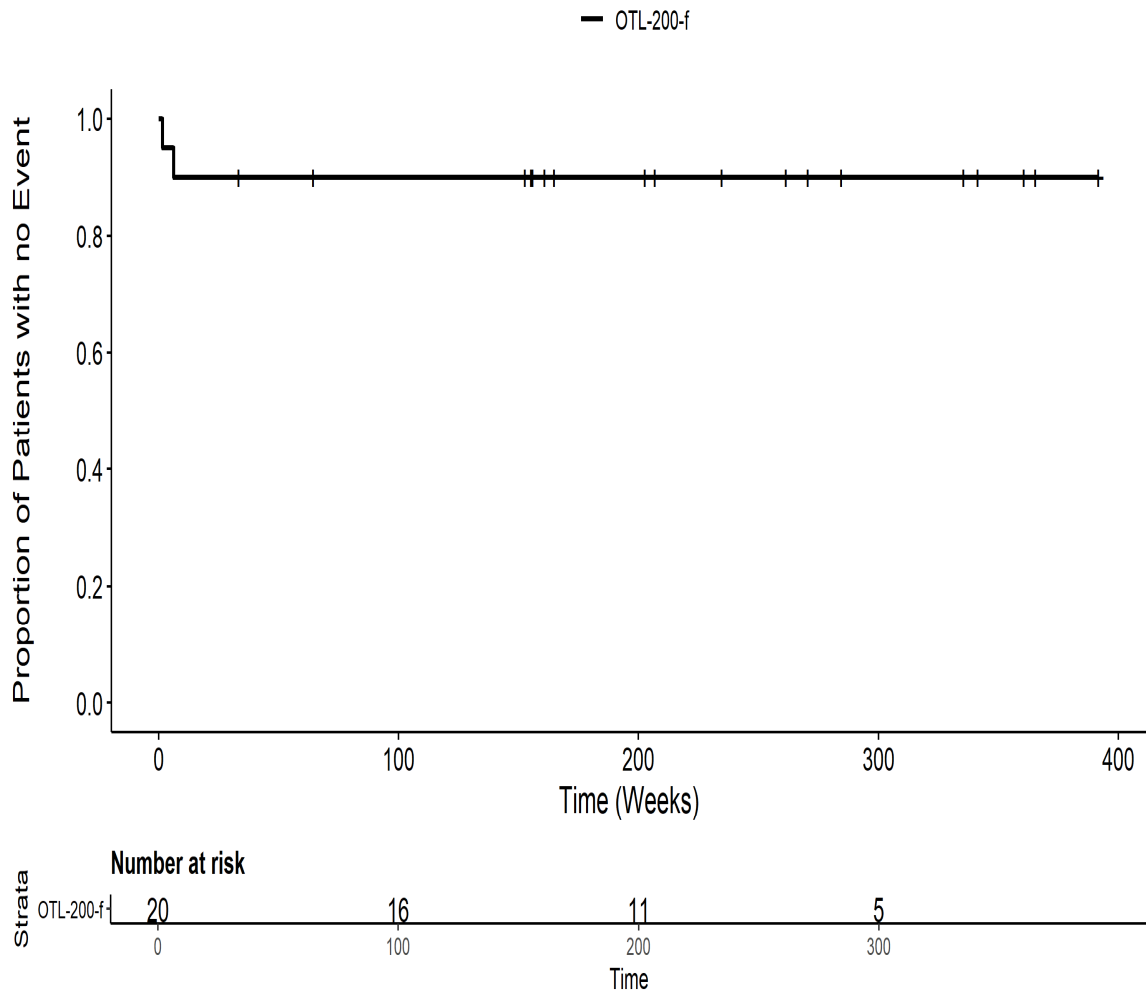
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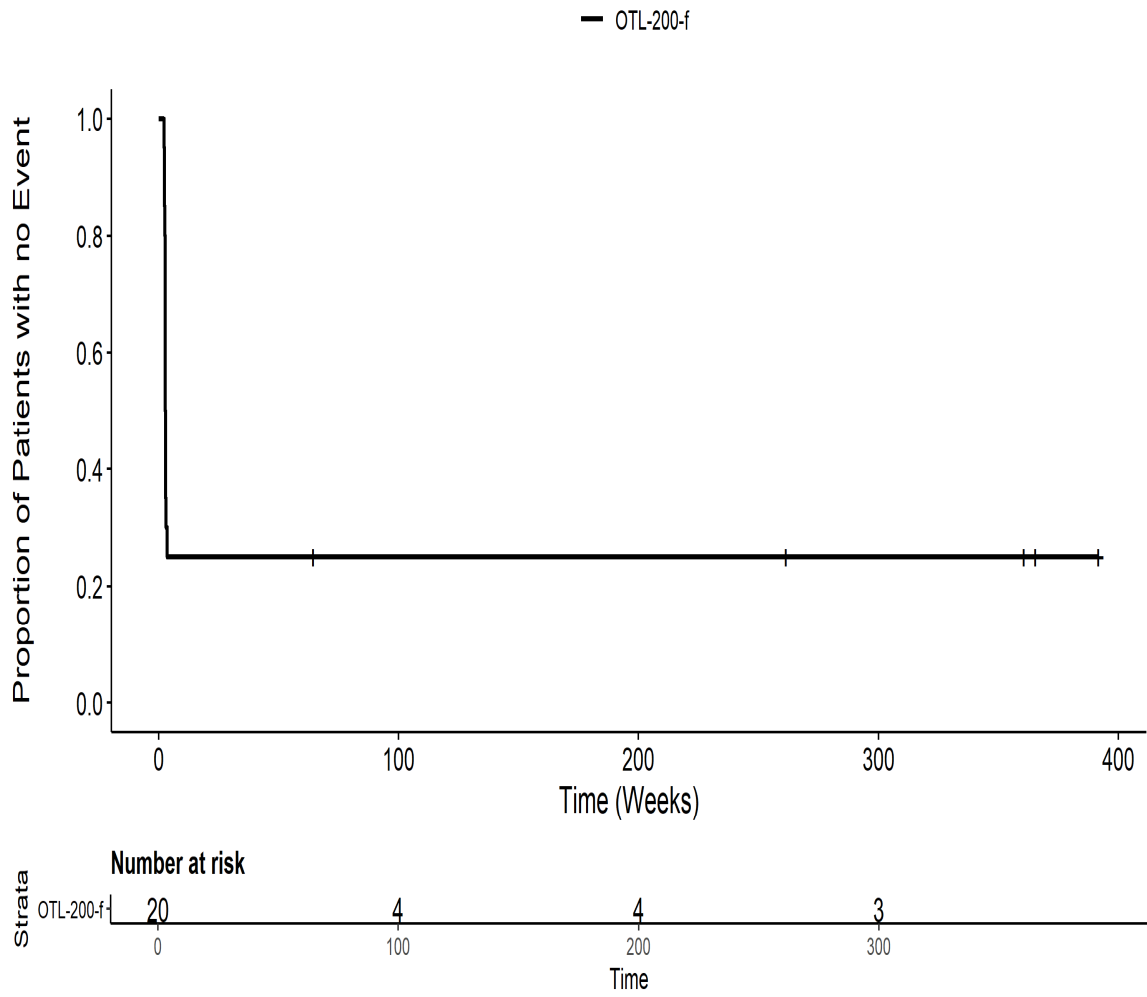
201222: Kaplan Meier Plot for Time to all AE by SOC Erkrankungen der Nieren und Harnwege PT pct Gesamt SOCITT



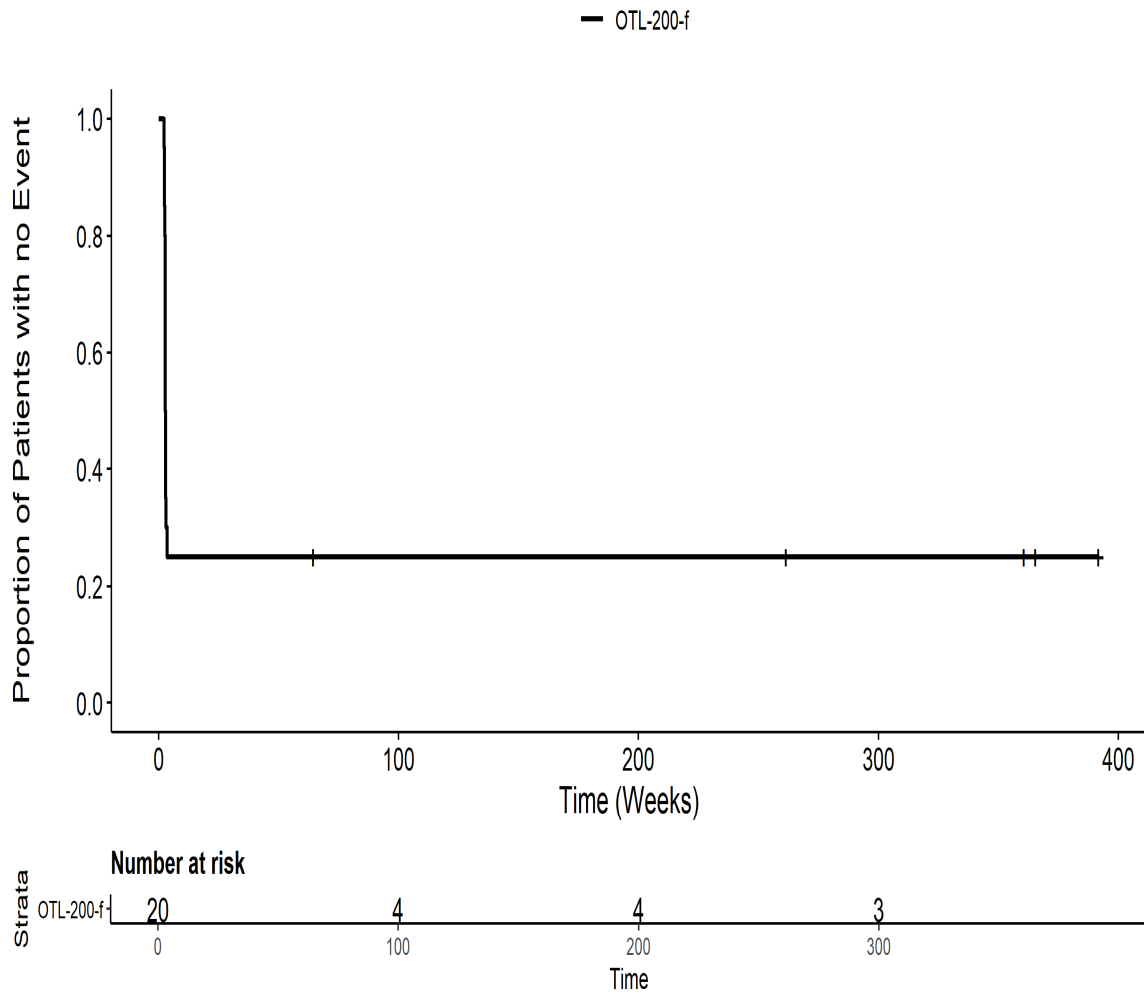
201222: Kaplan Meier Plot for Time to all AE by SOC Erkrankungen der Nieren und Harnwege PT pct RENAL TUBULAR ACIDOSISITT



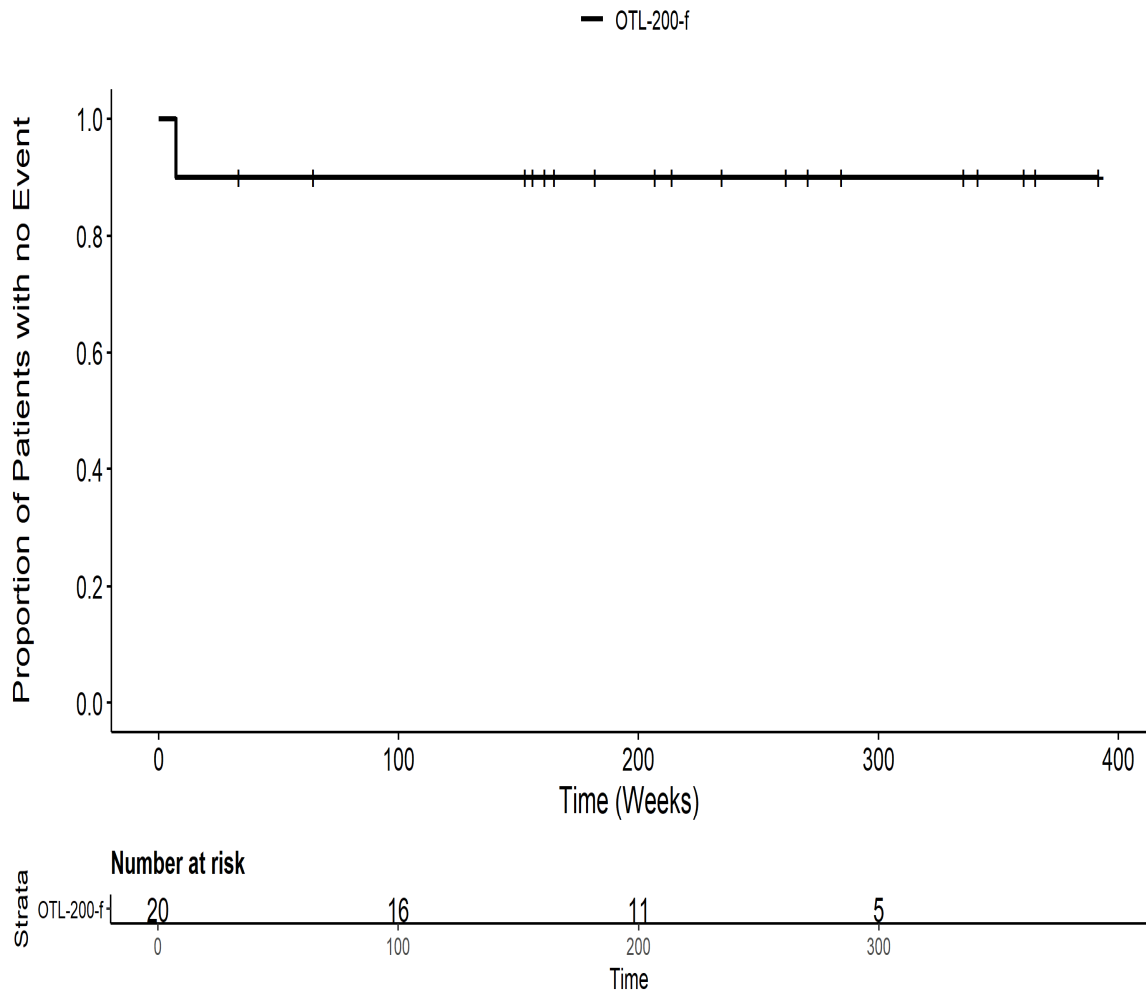
201222: Kaplan Meier Plot for Time to all AE by SOC Erkrankungen des Blutes und des Lymphsystems PT pct Febrile NeutropenieIT



201222: Kaplan Meier Plot for Time to all AE by SOC Erkrankungen des Blutes und des Lymphsystems PT pct Gesamt SOCITT

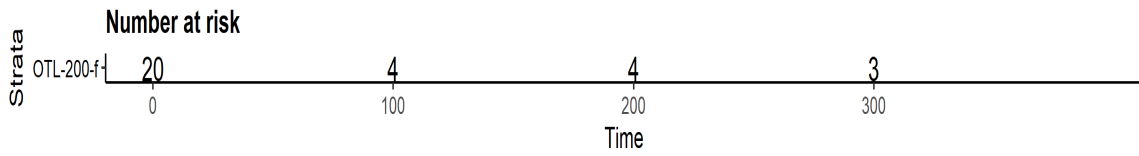
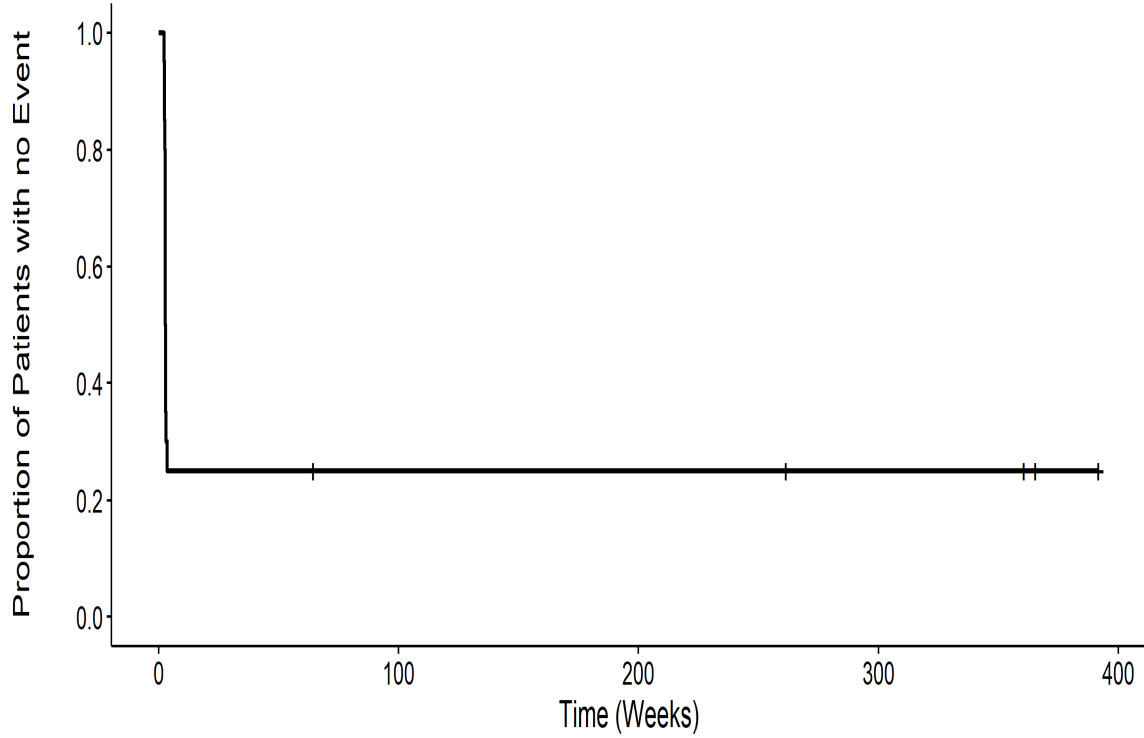


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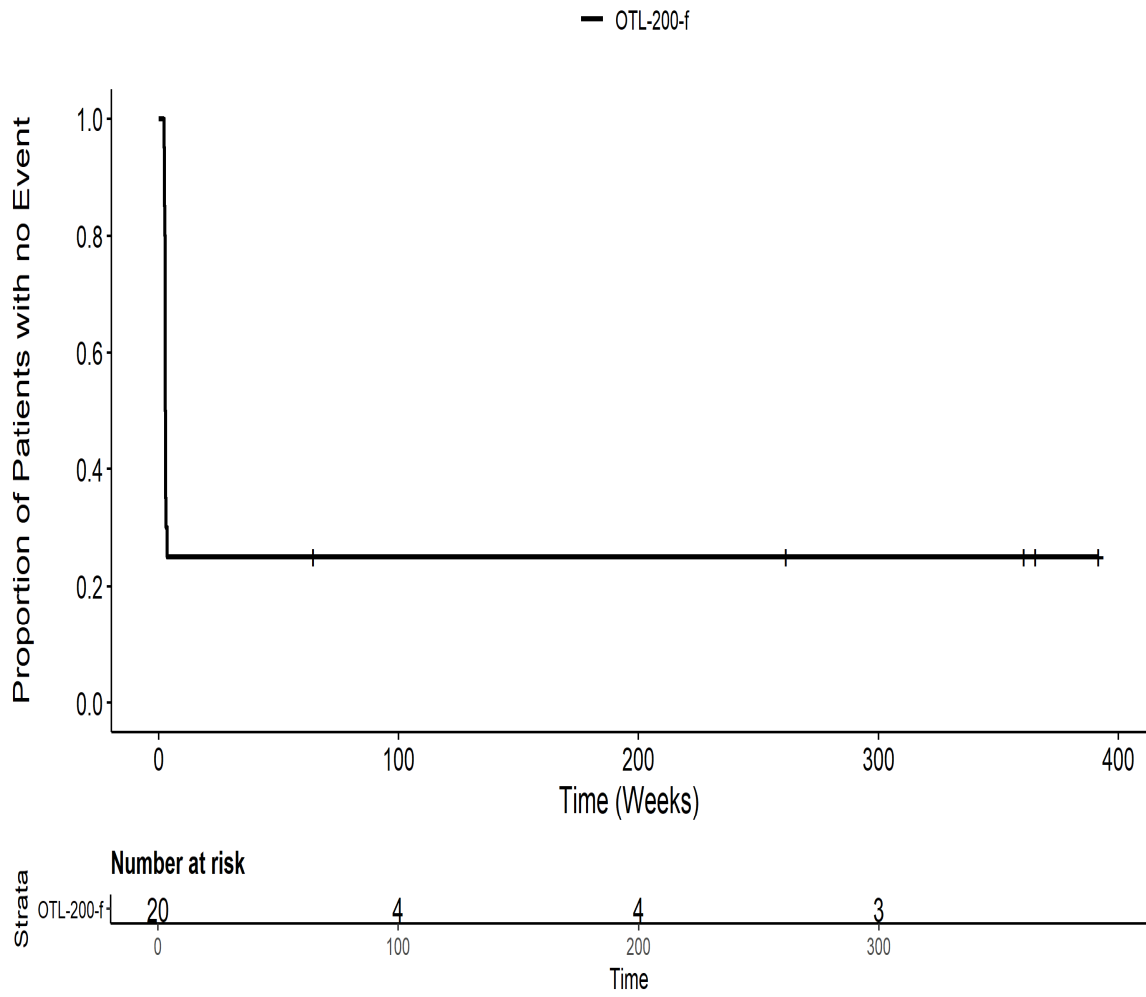


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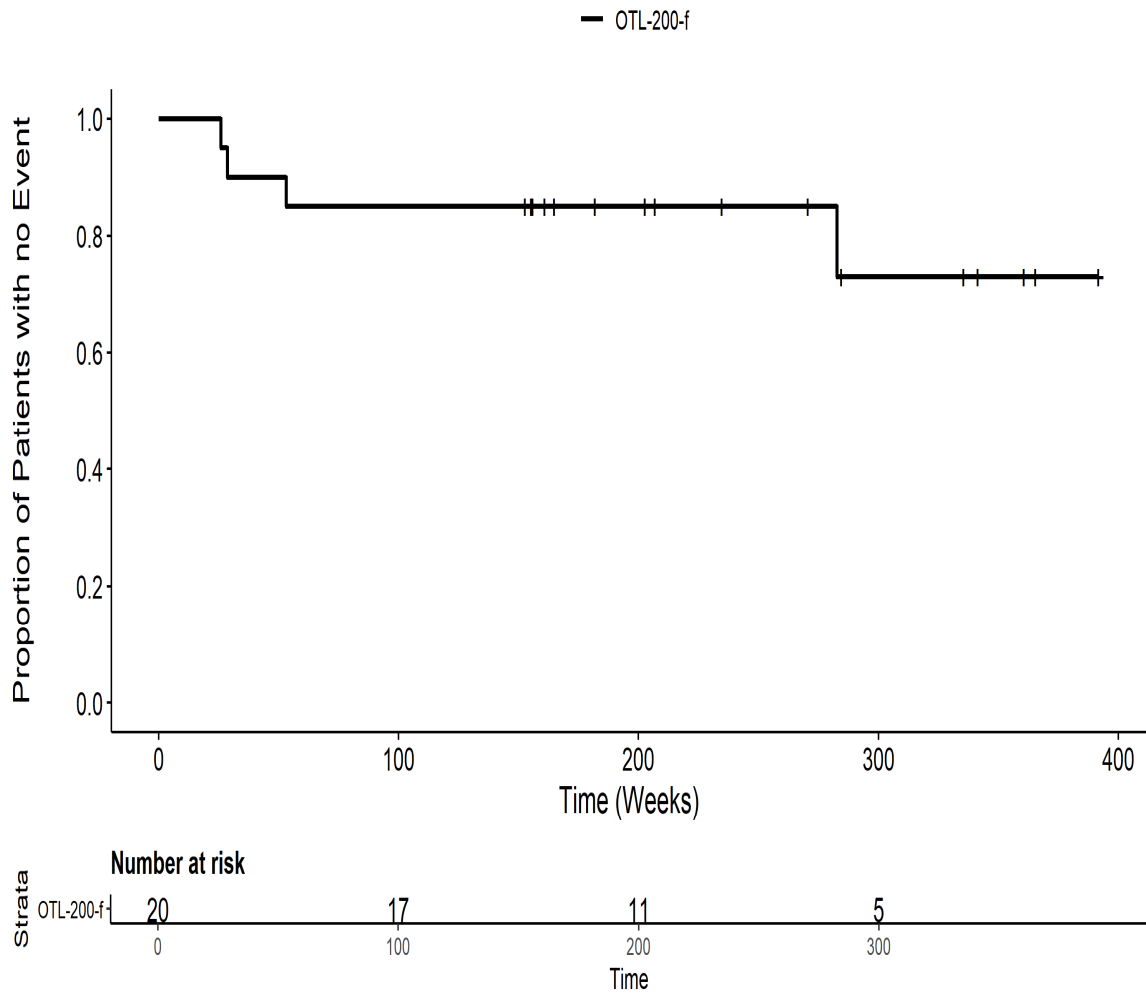
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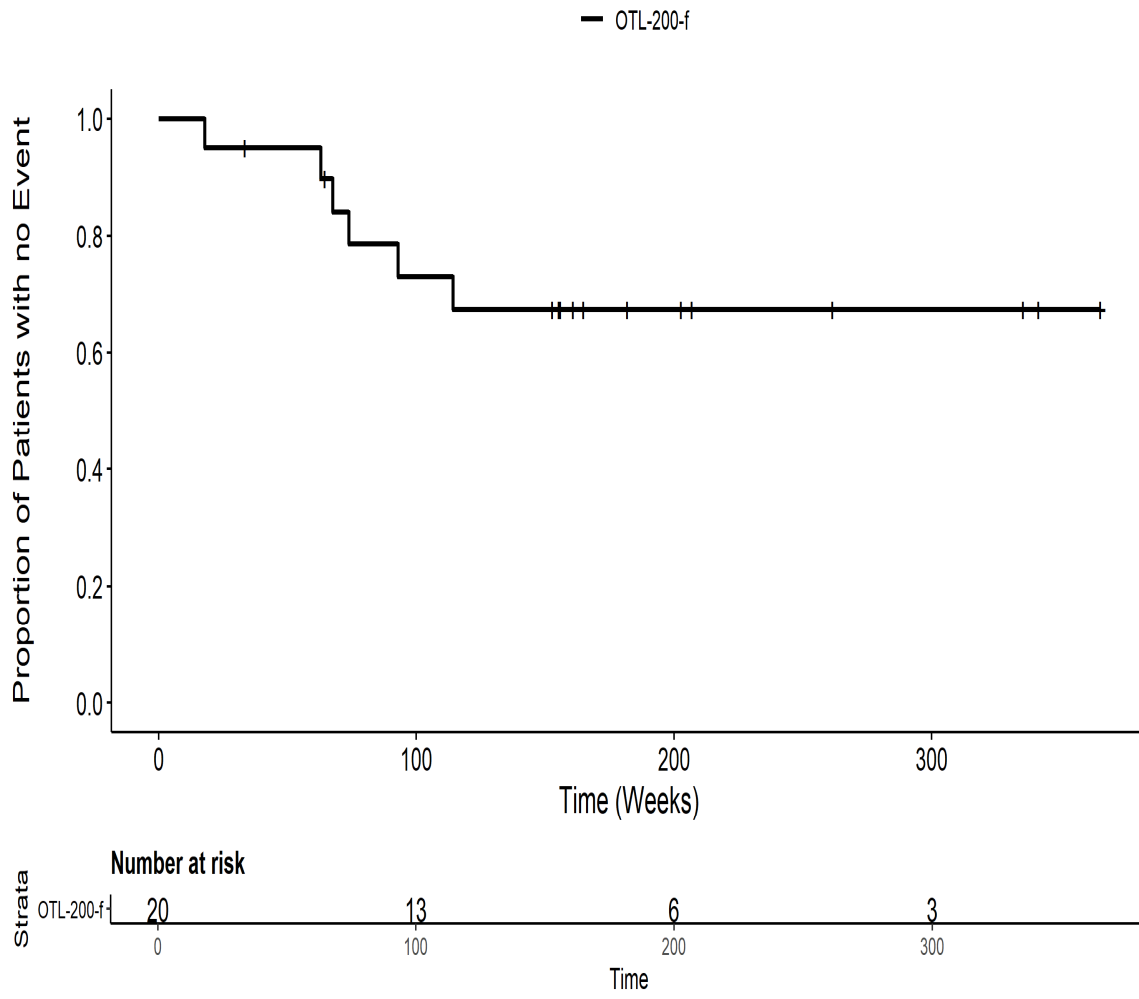
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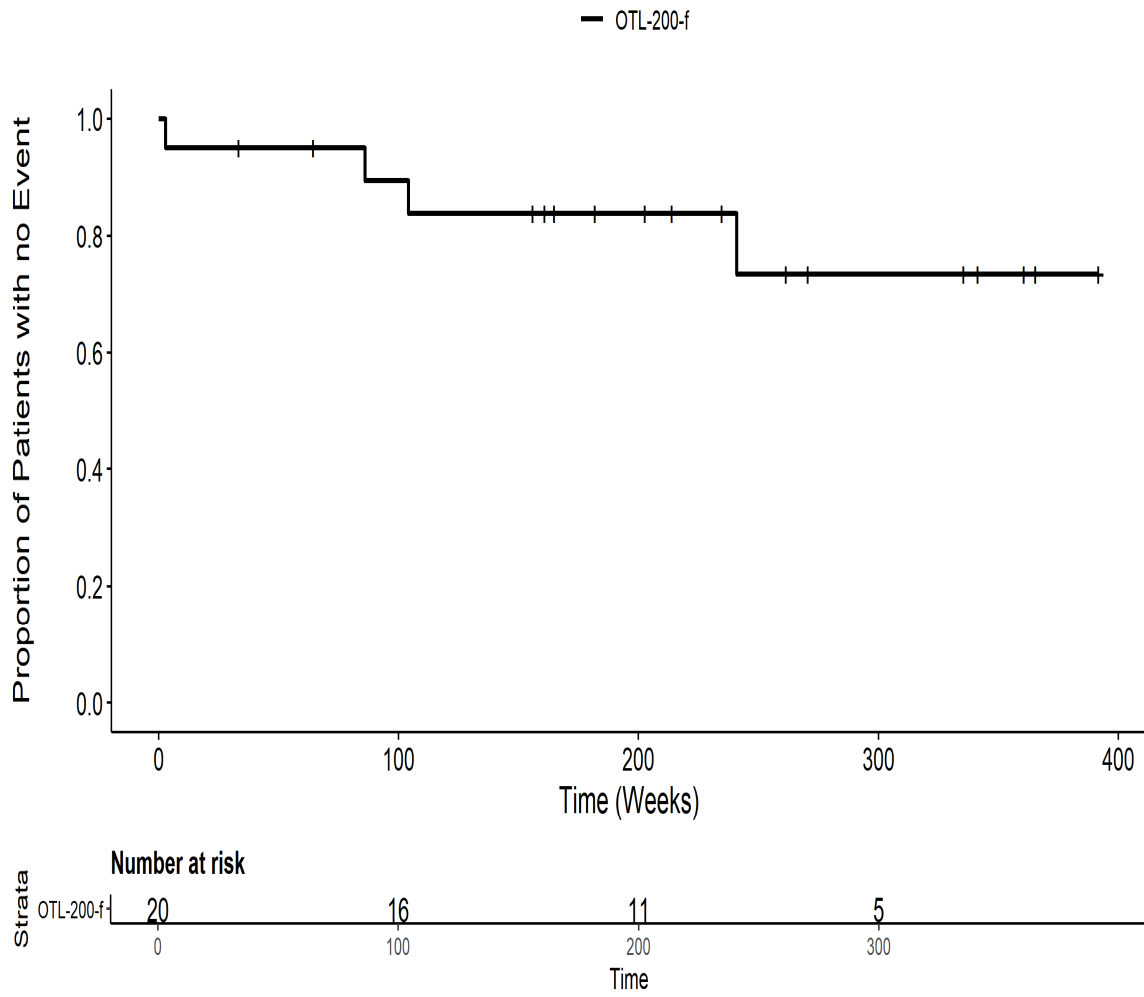
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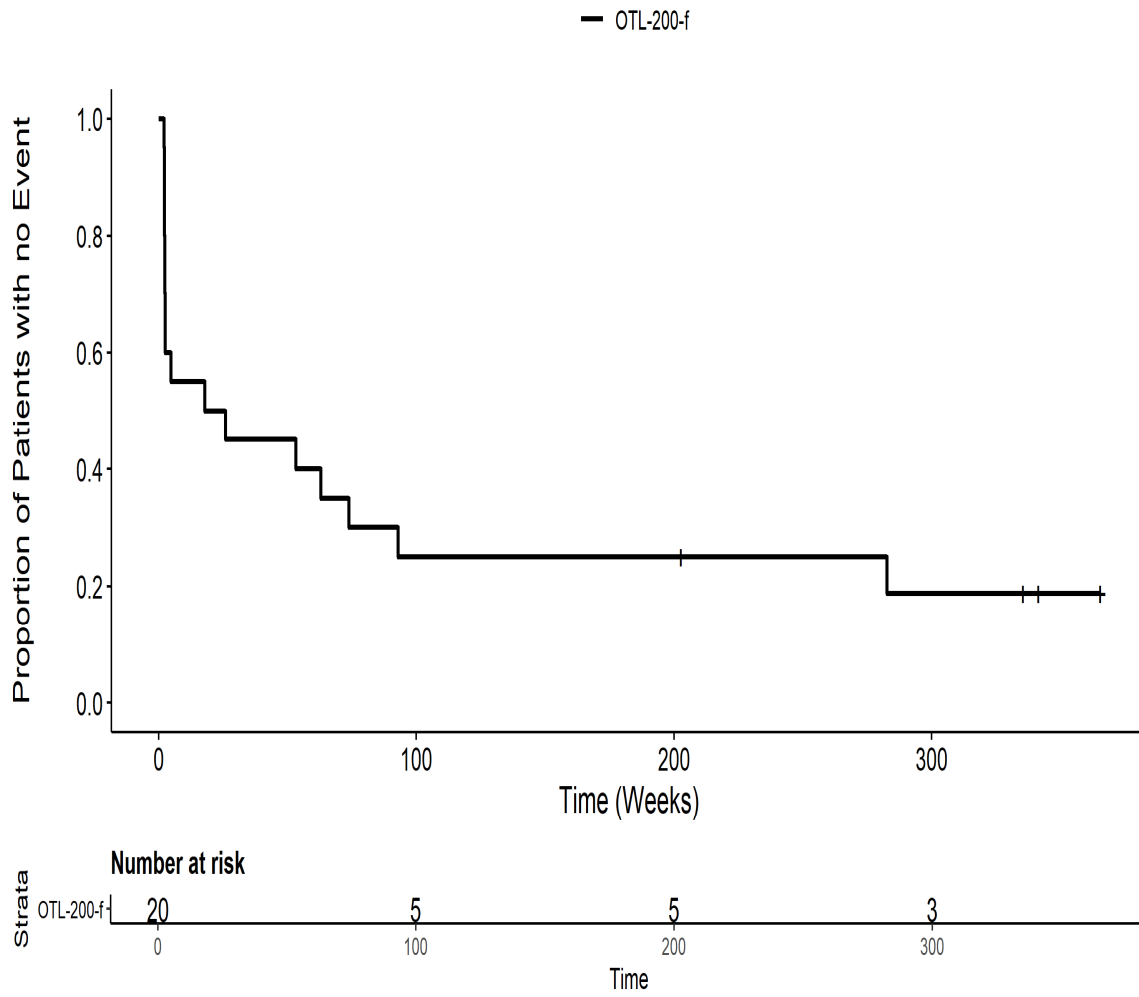
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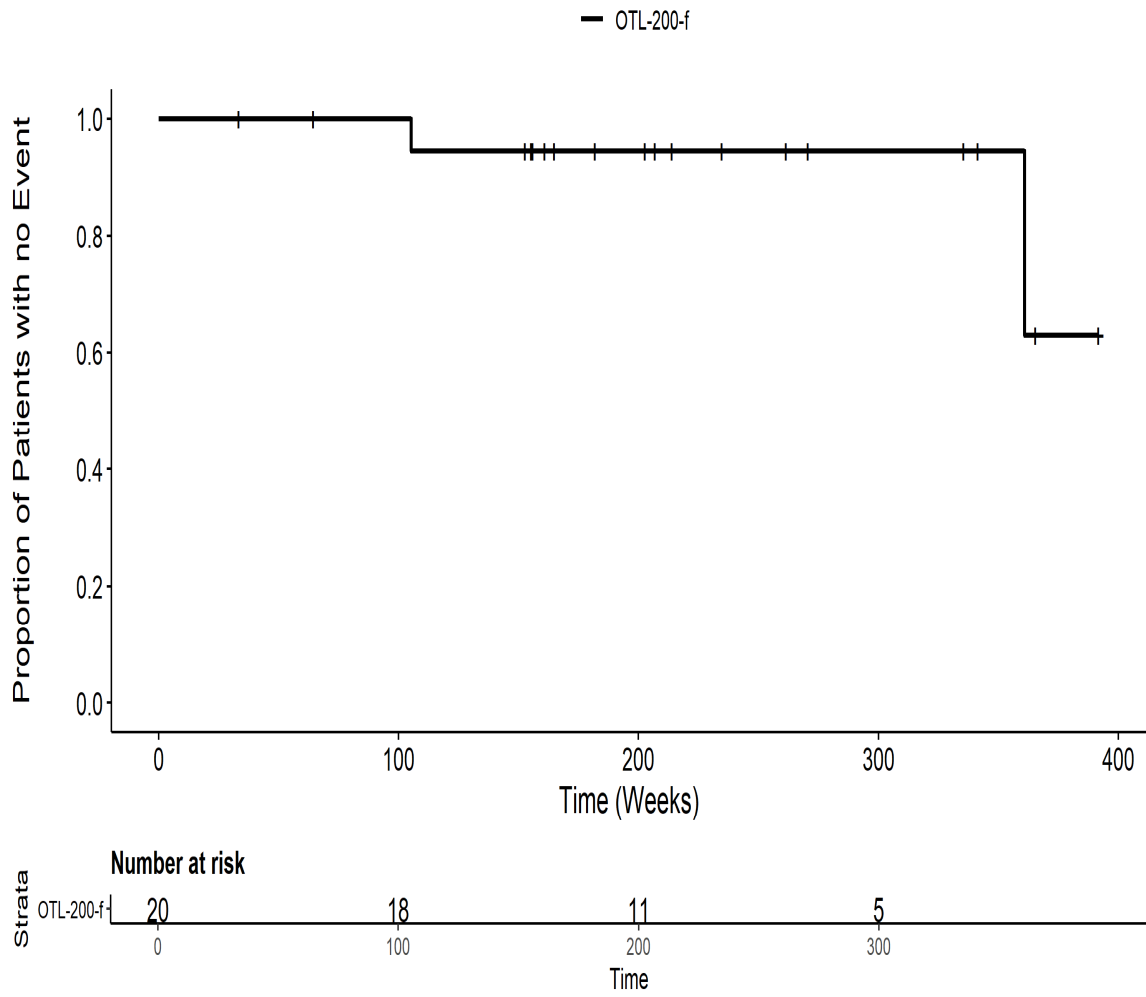
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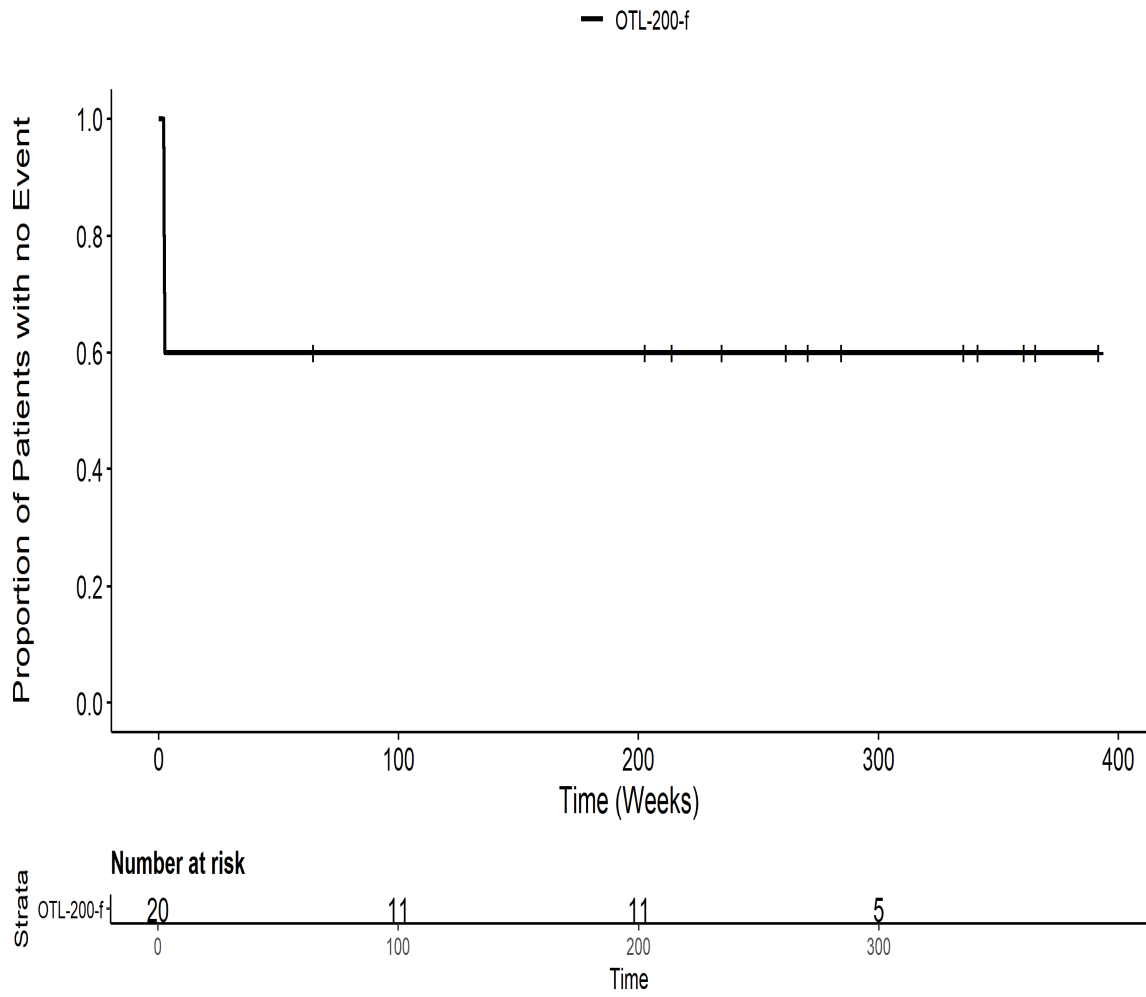
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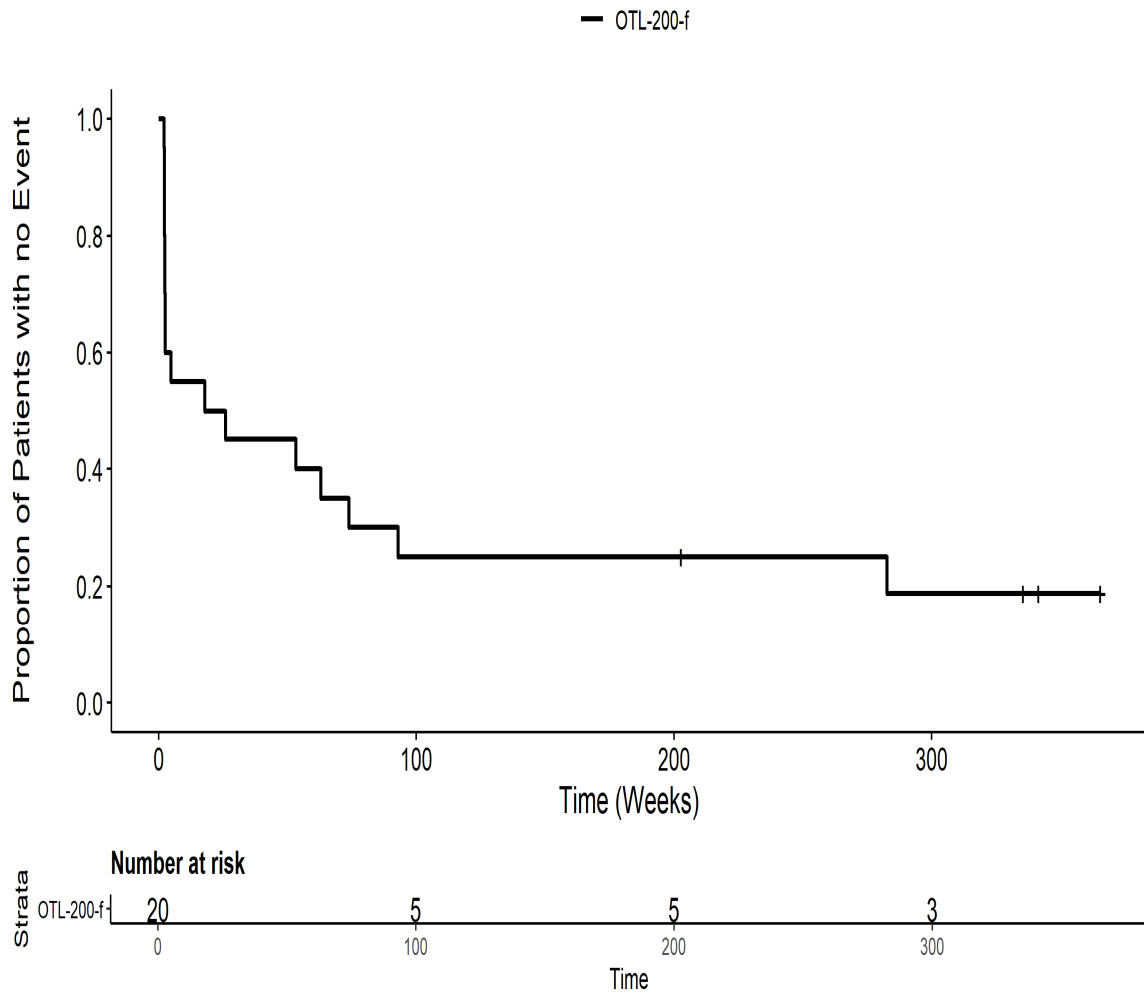
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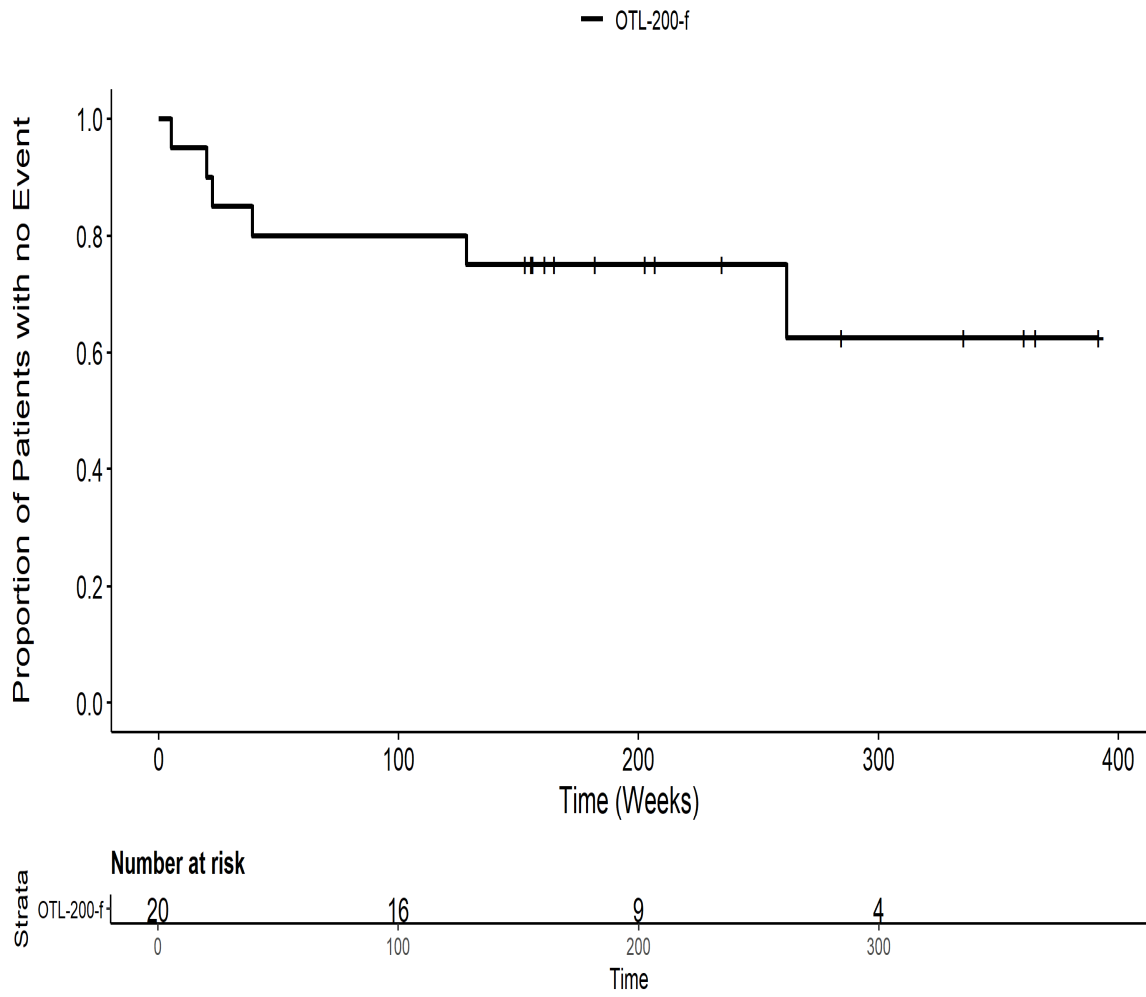
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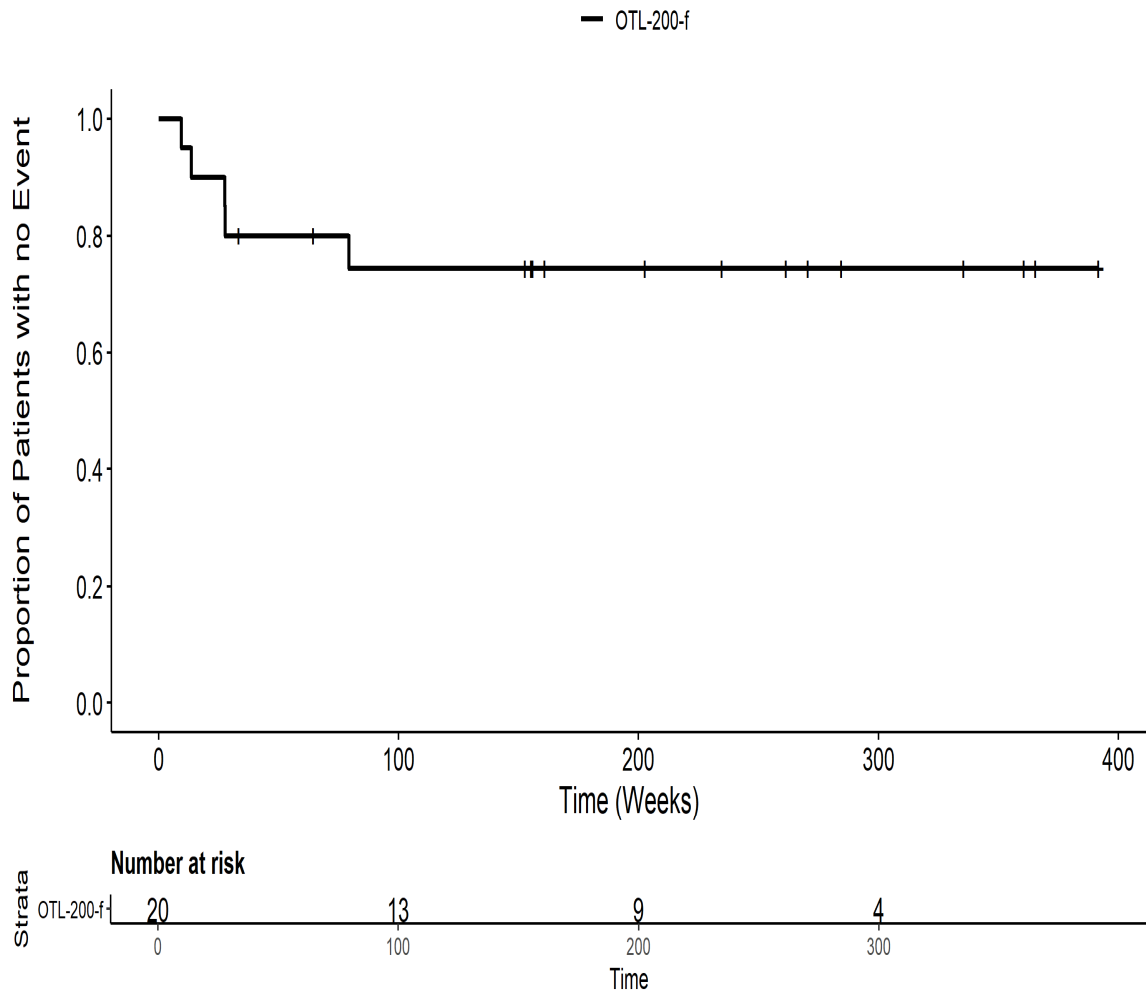
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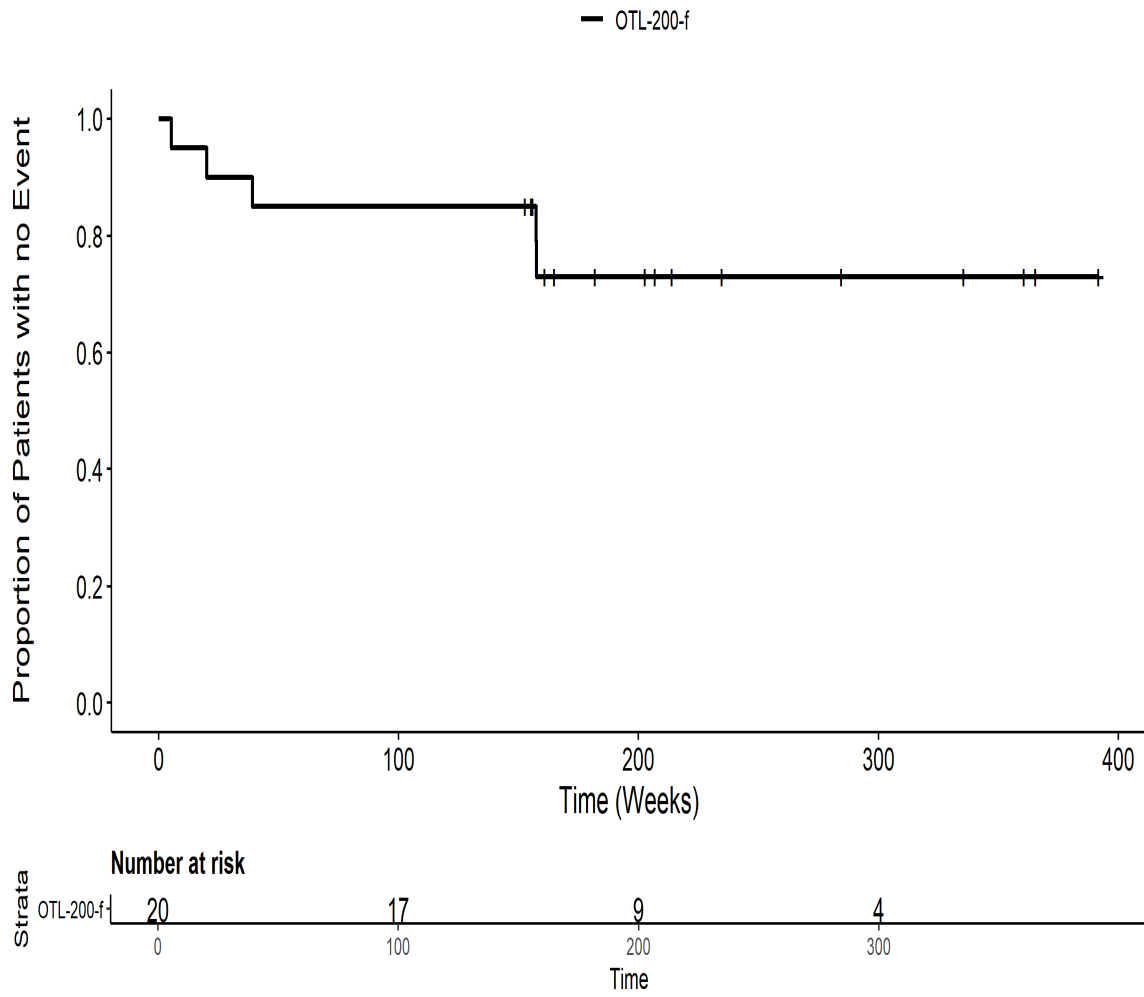
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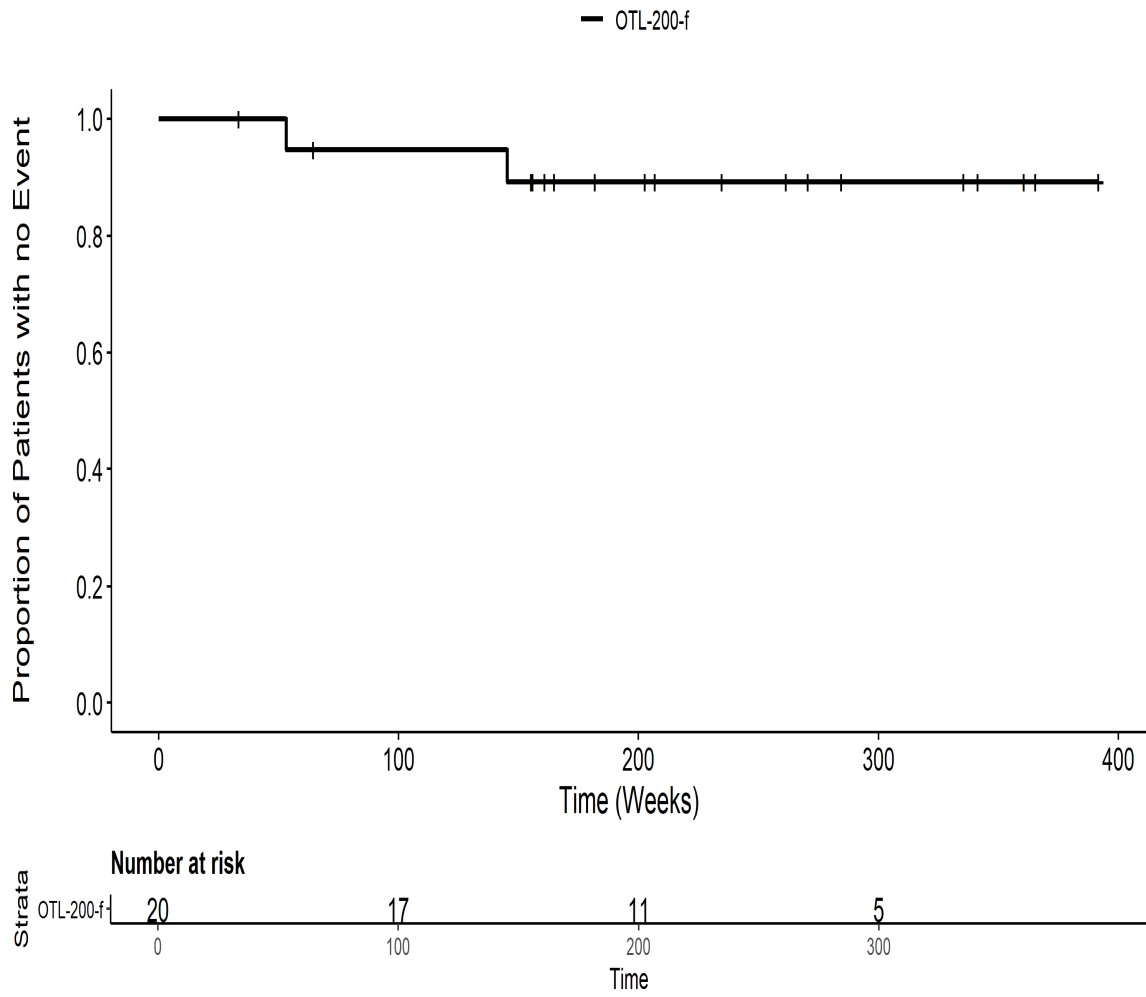
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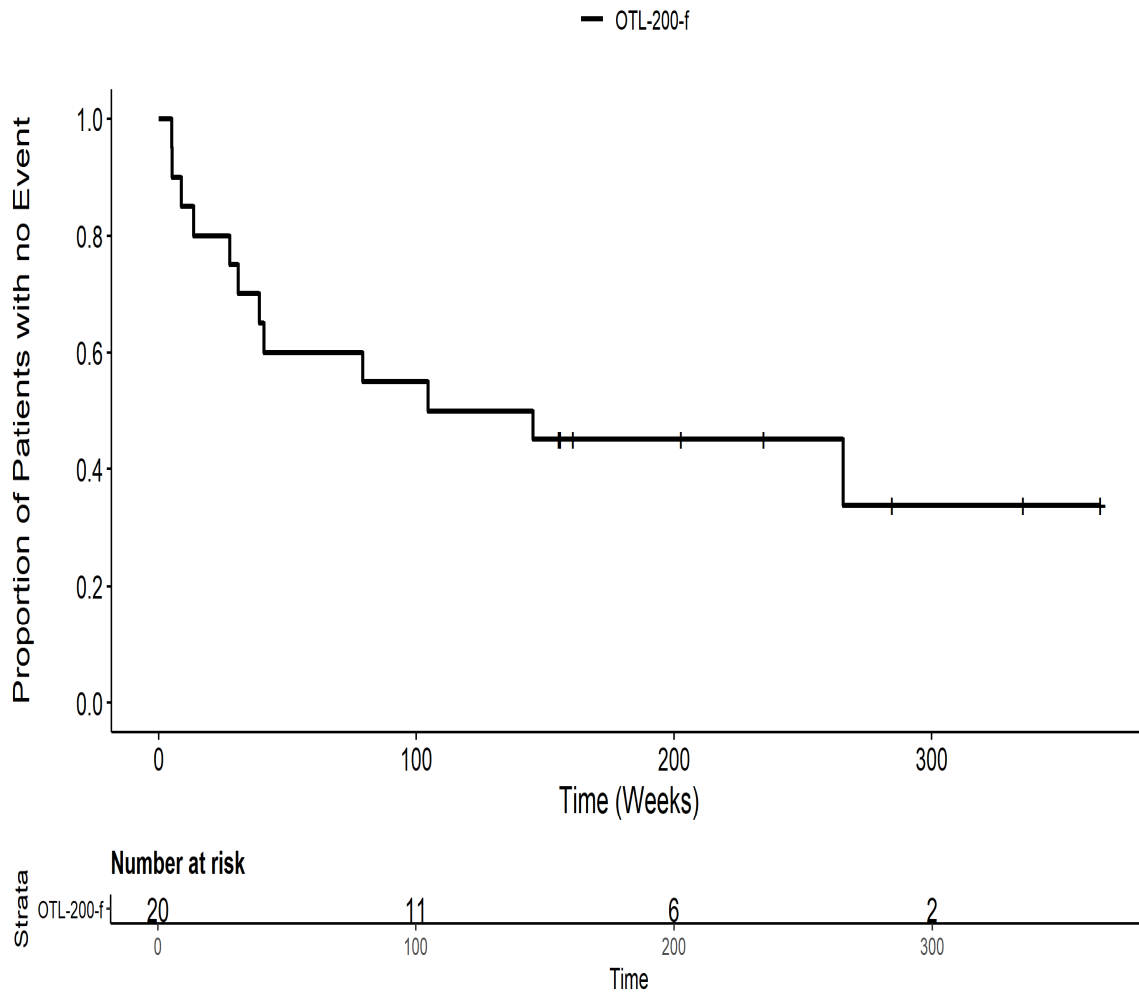
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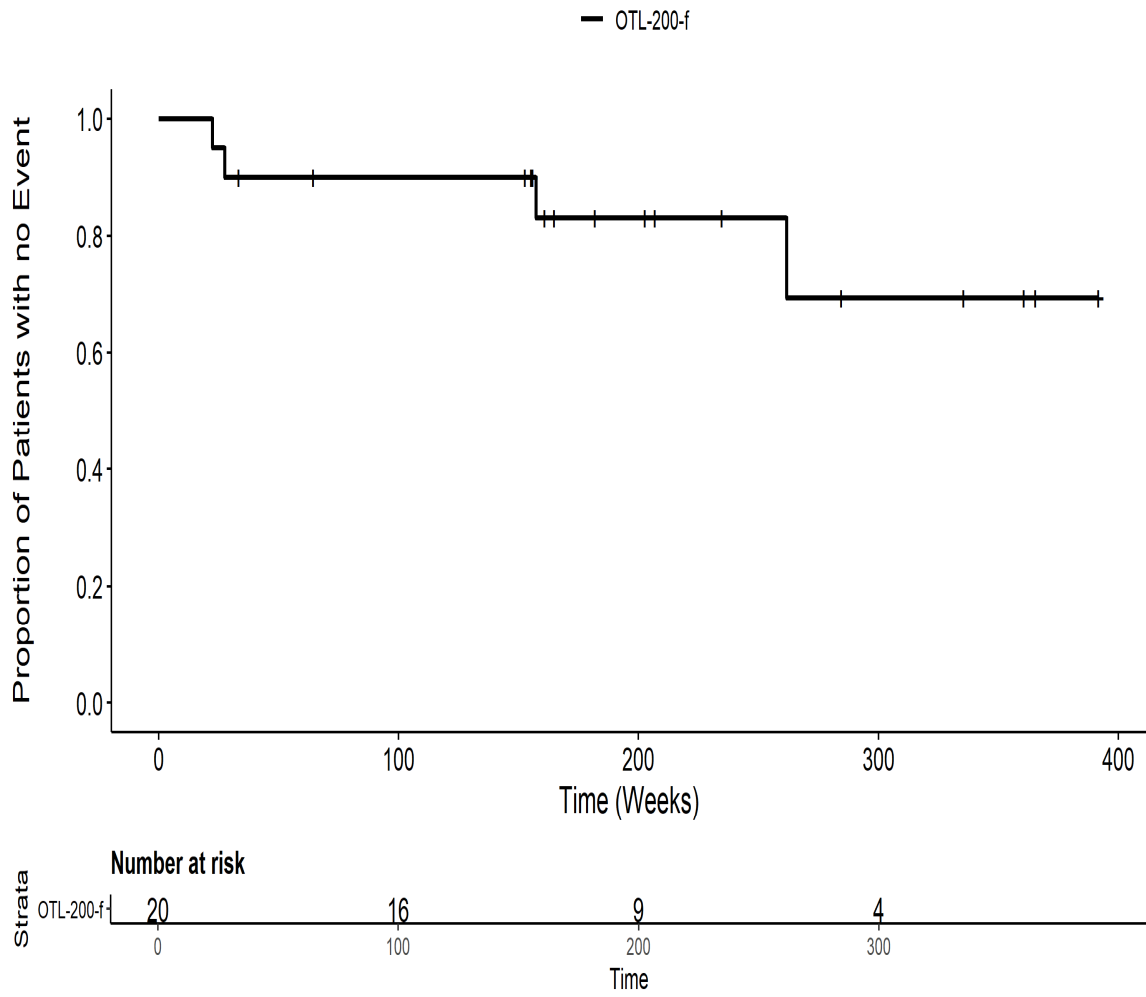
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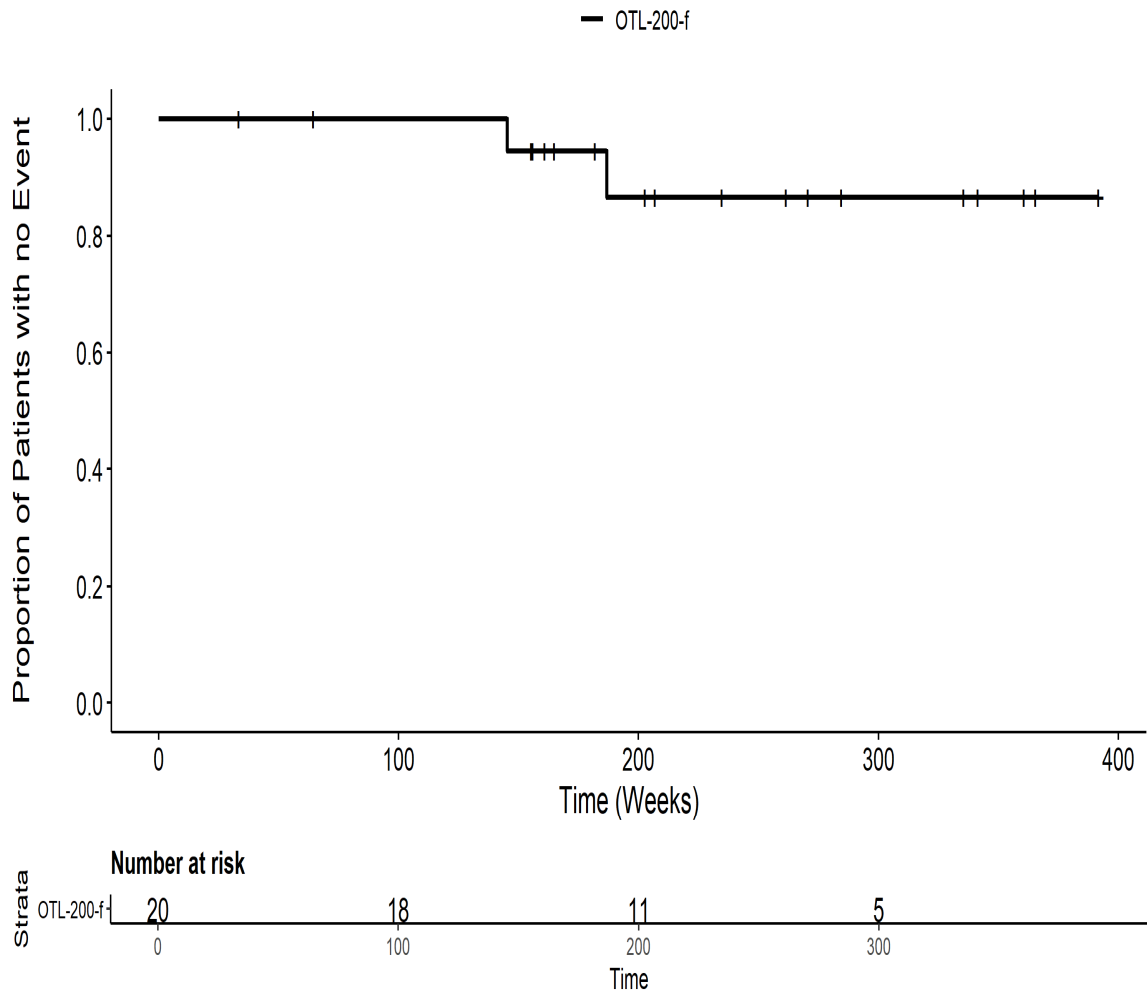
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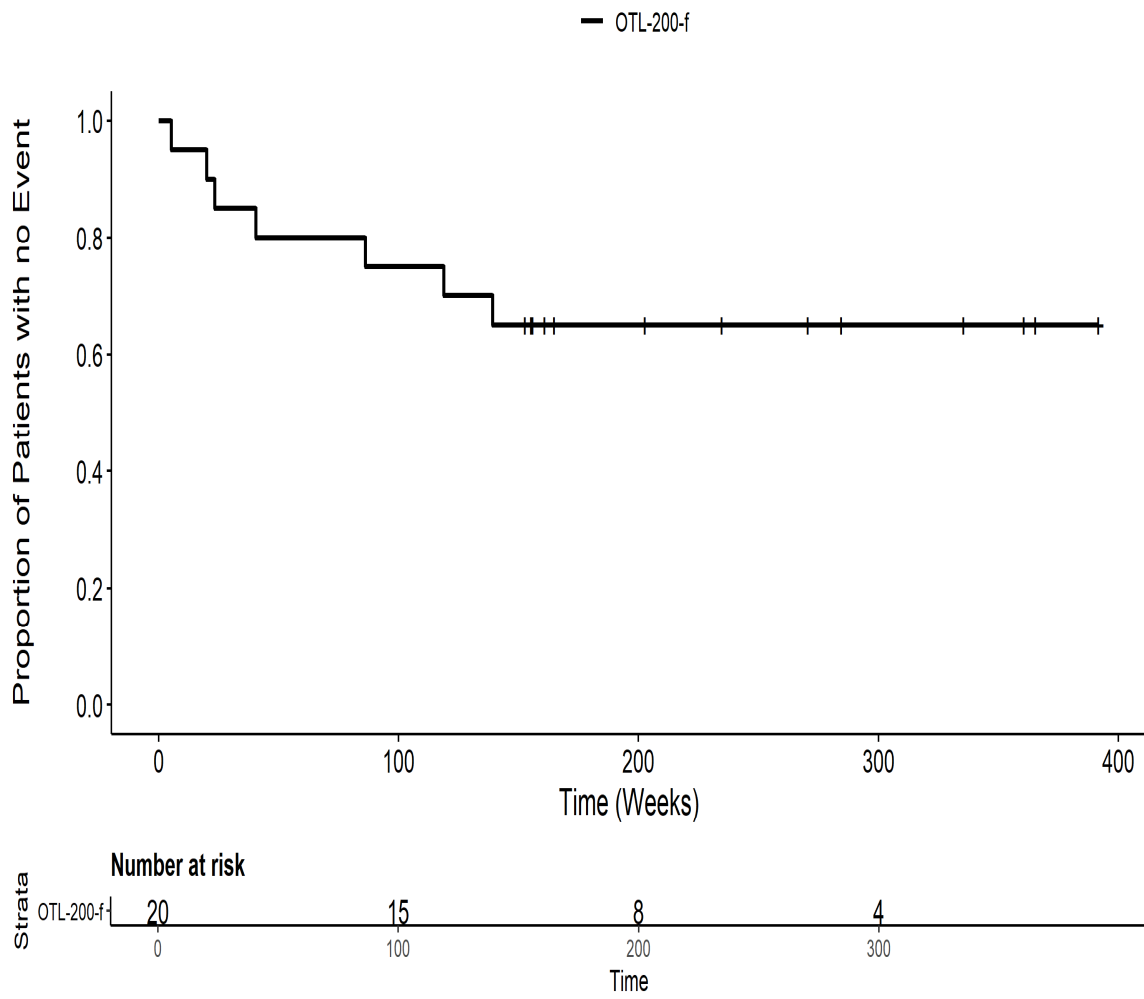
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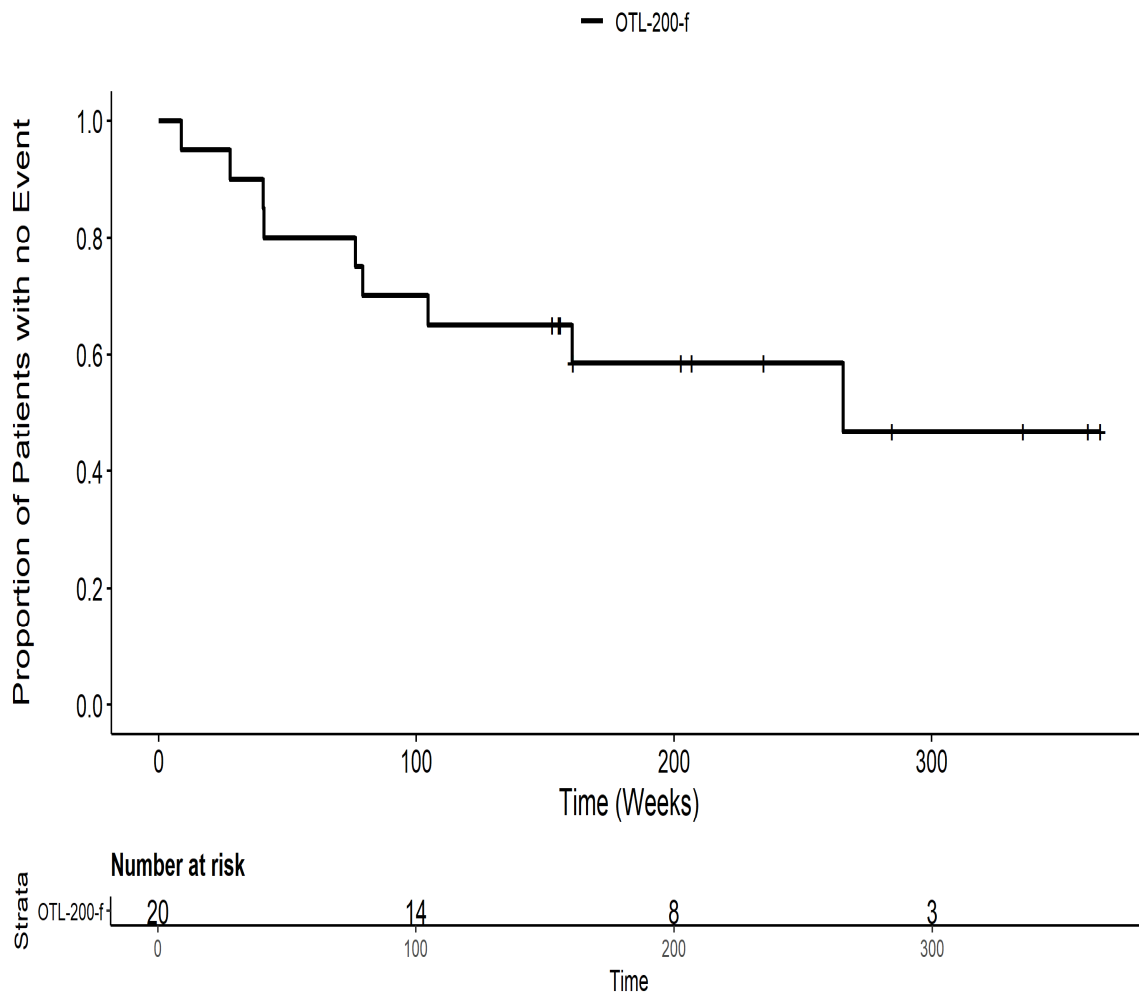
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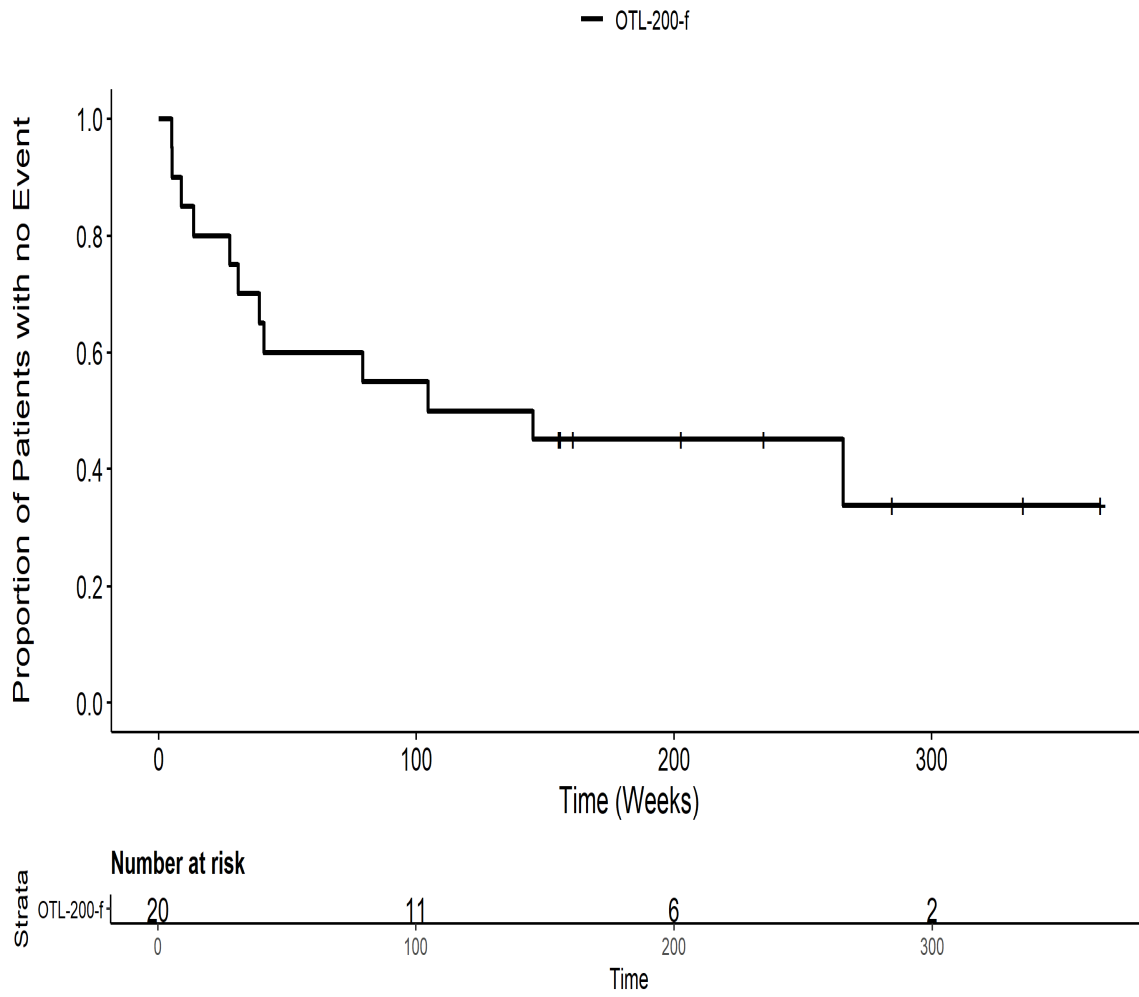
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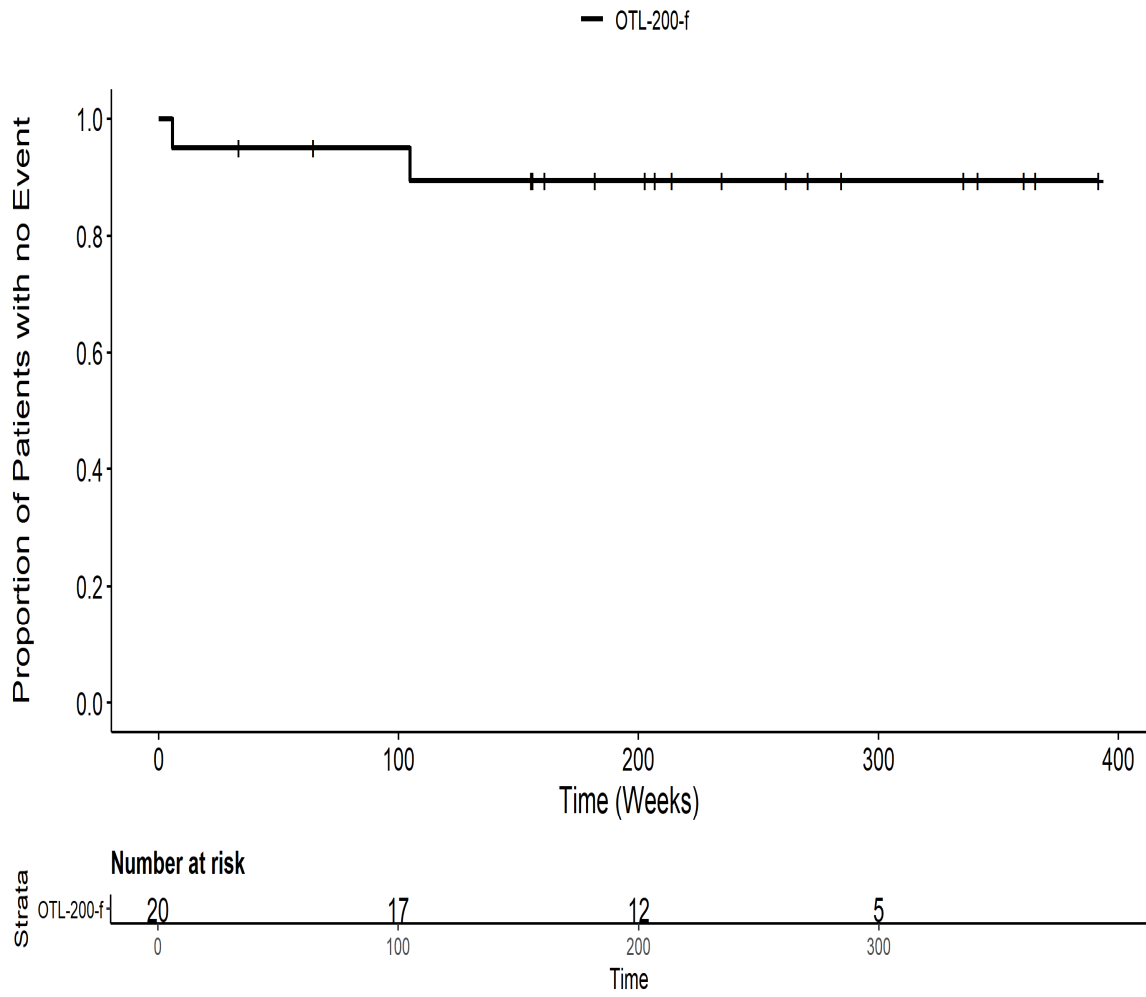
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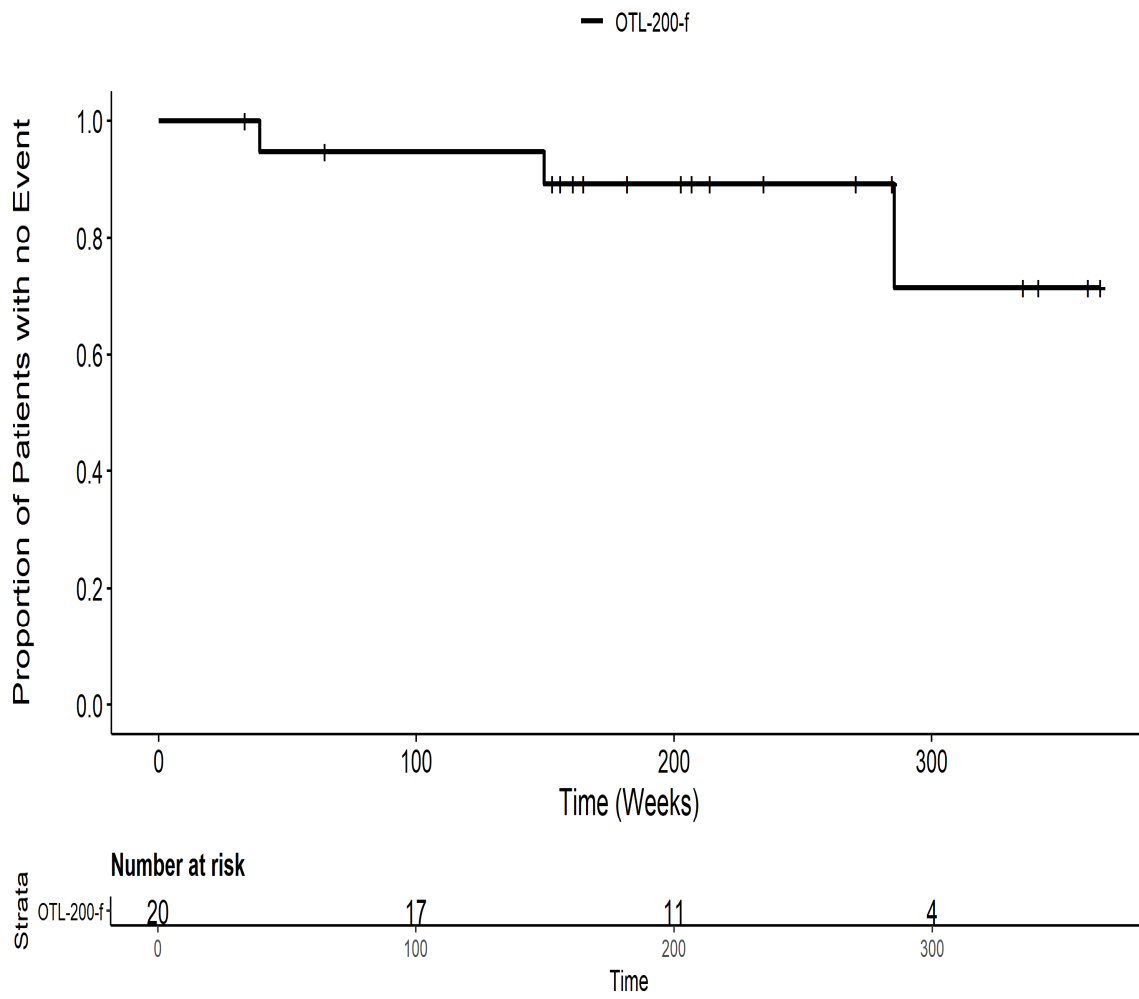
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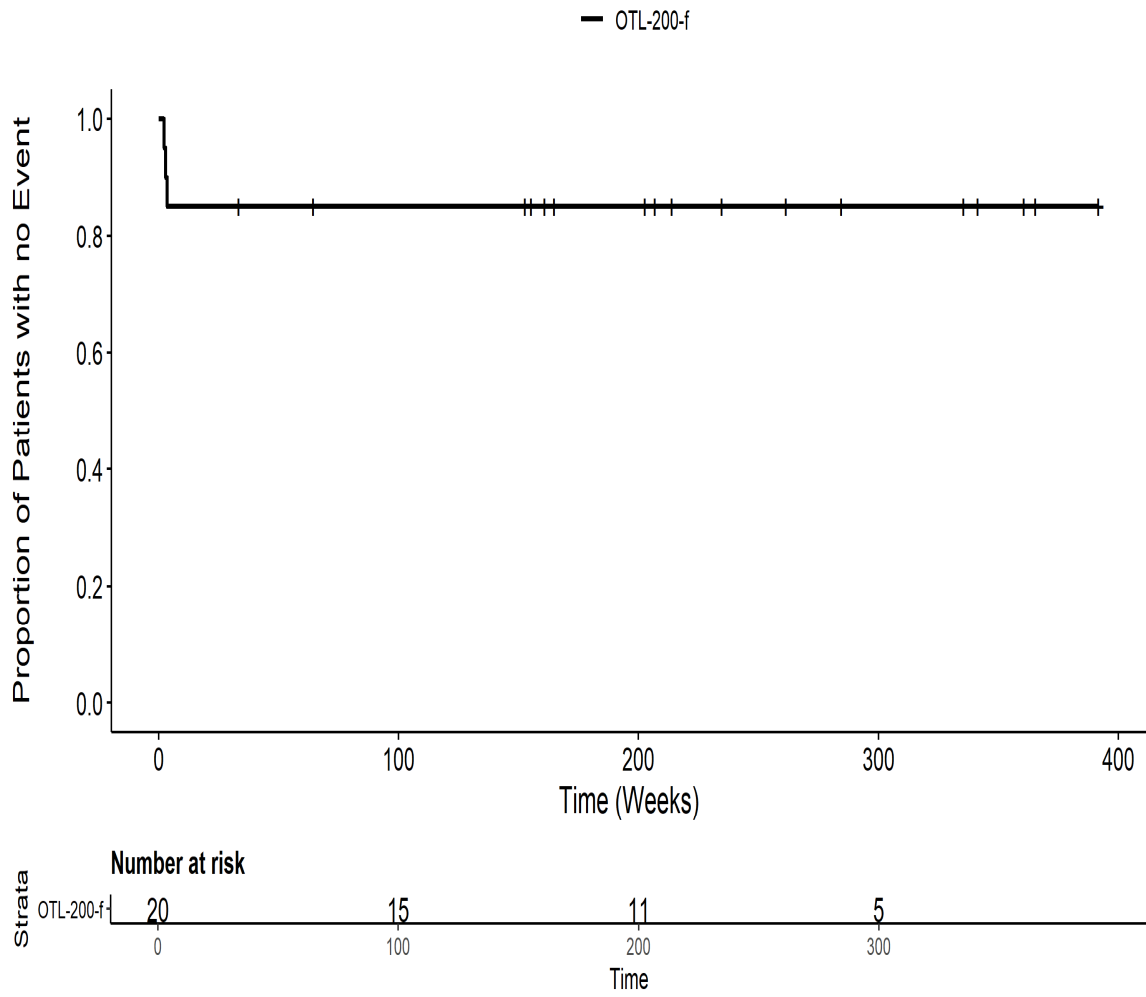
201222: Kaplan Meier Plot for Time to all AE by SOC
Gefäßserkrankungen PT pct Gesamt SOCITT



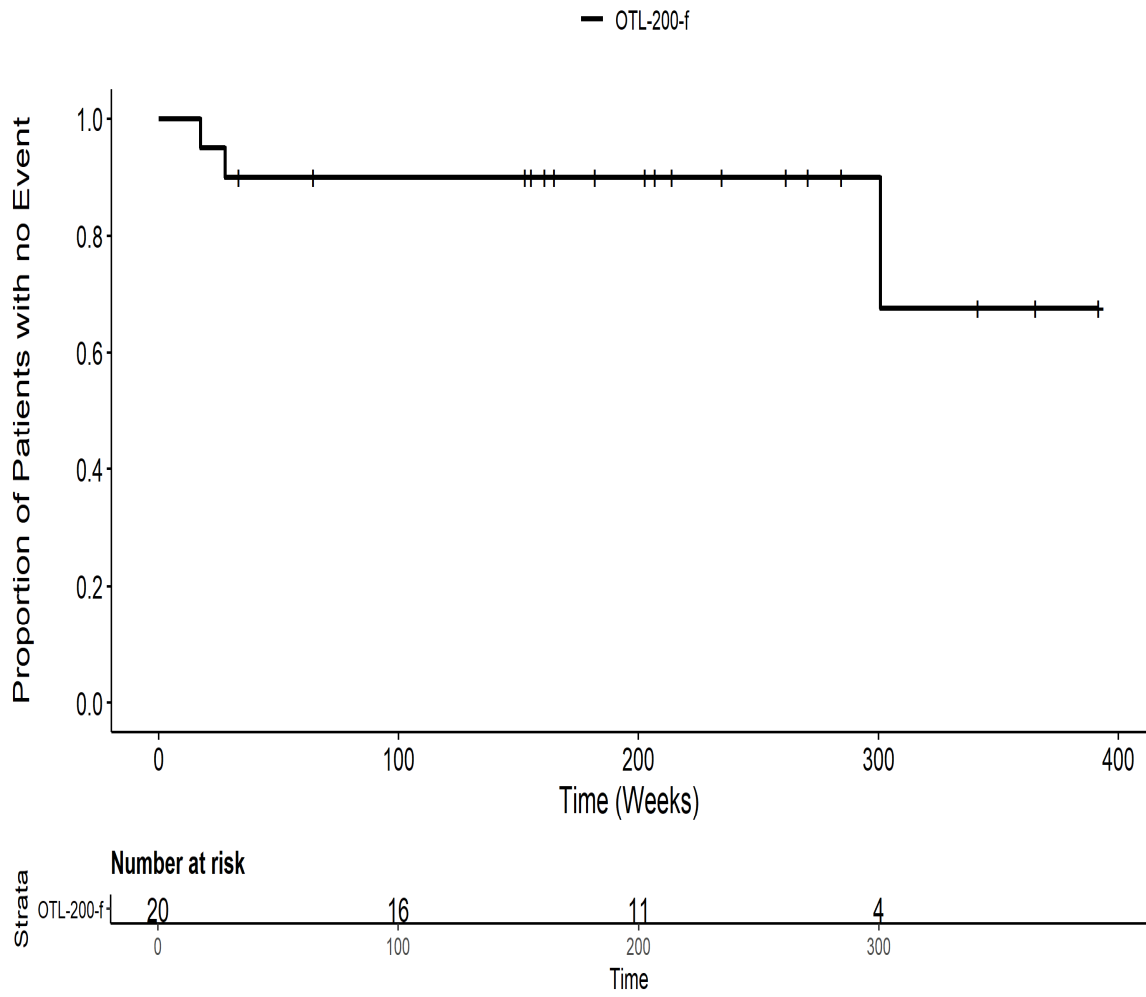
201222: Kaplan Meier Plot for Time to all AE by SOC Infektionen und parasitäre Erkrankungen PT pct AtemwegsinfektionITT



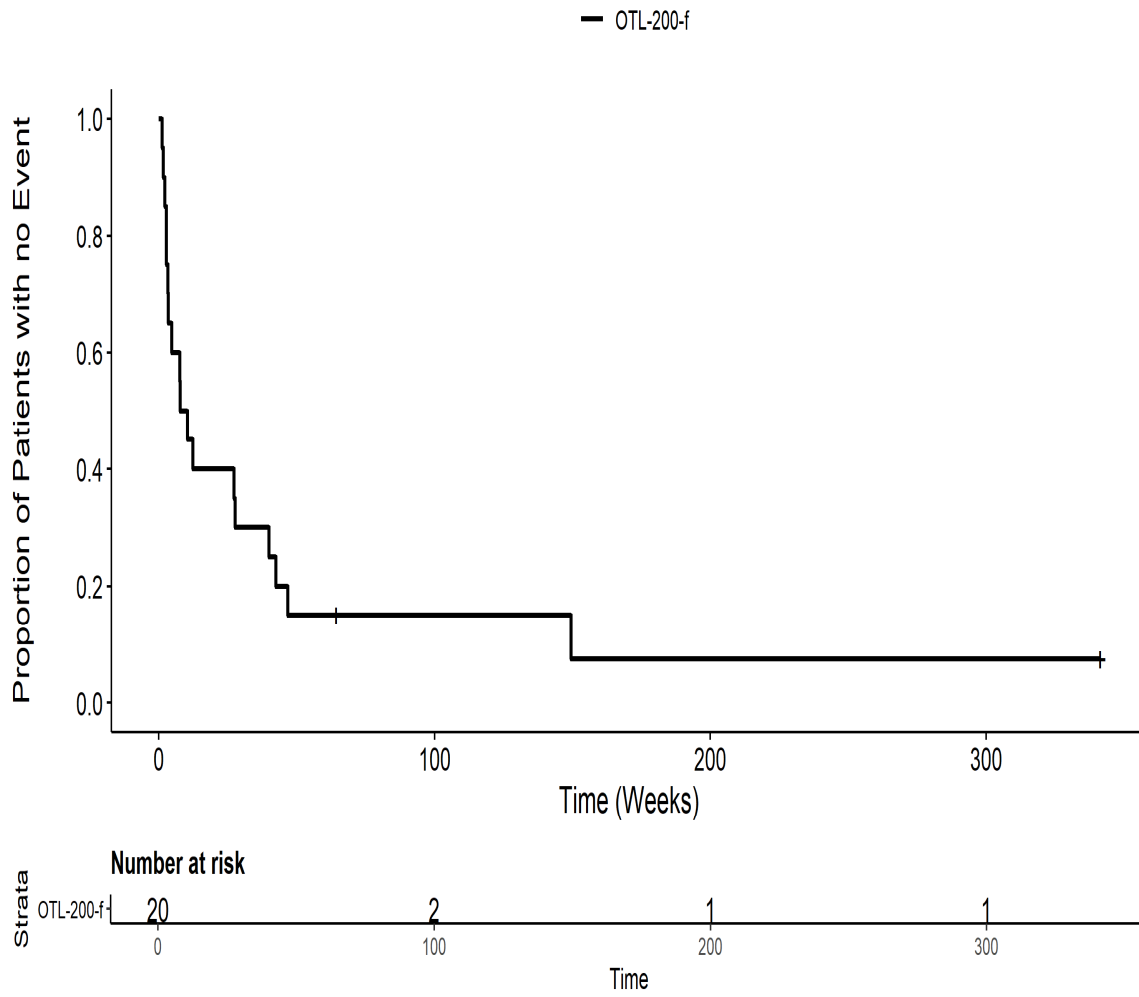
201222: Kaplan Meier Plot for Time to all AE by SOC Infektionen und parasitäre Erkrankungen PT pct Clostridium difficile : KolitisITT



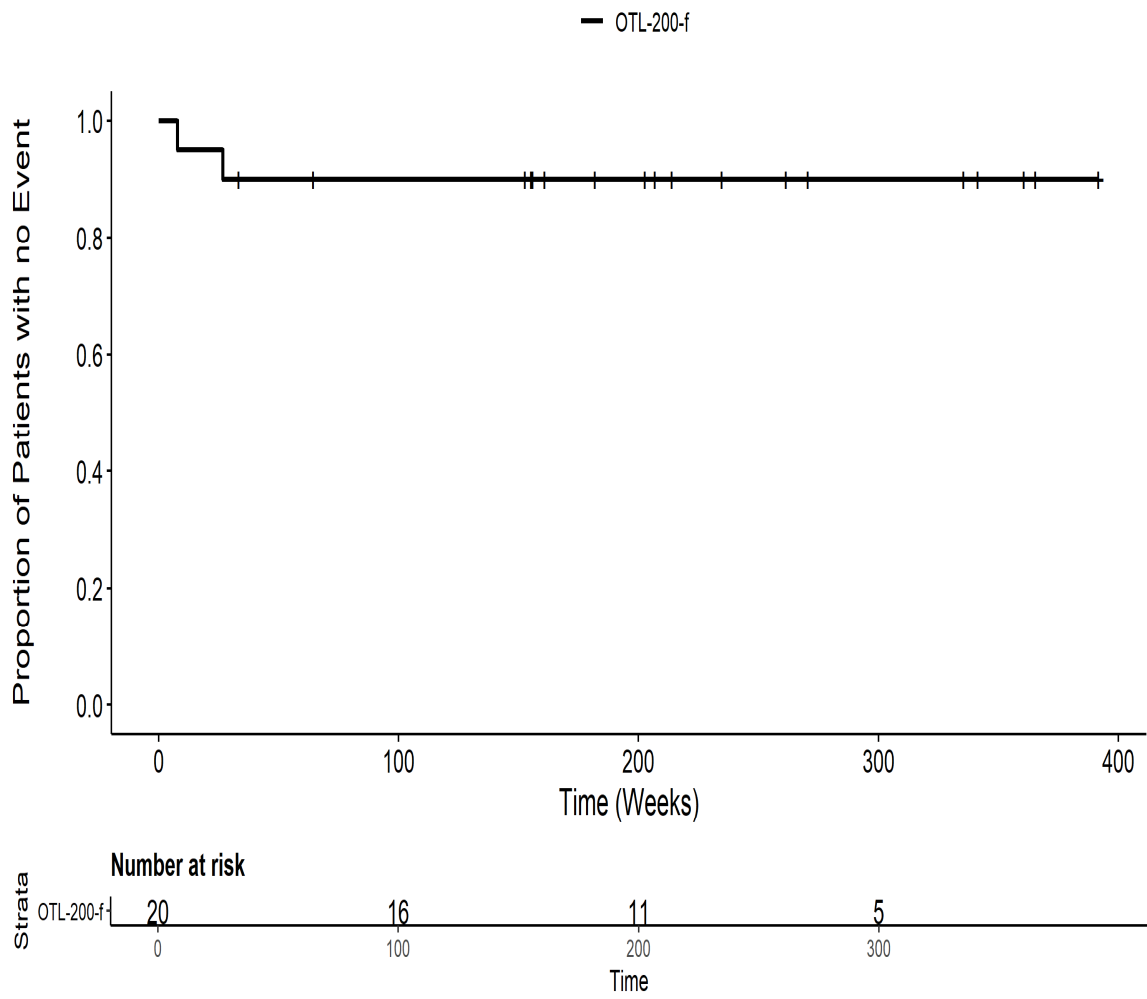
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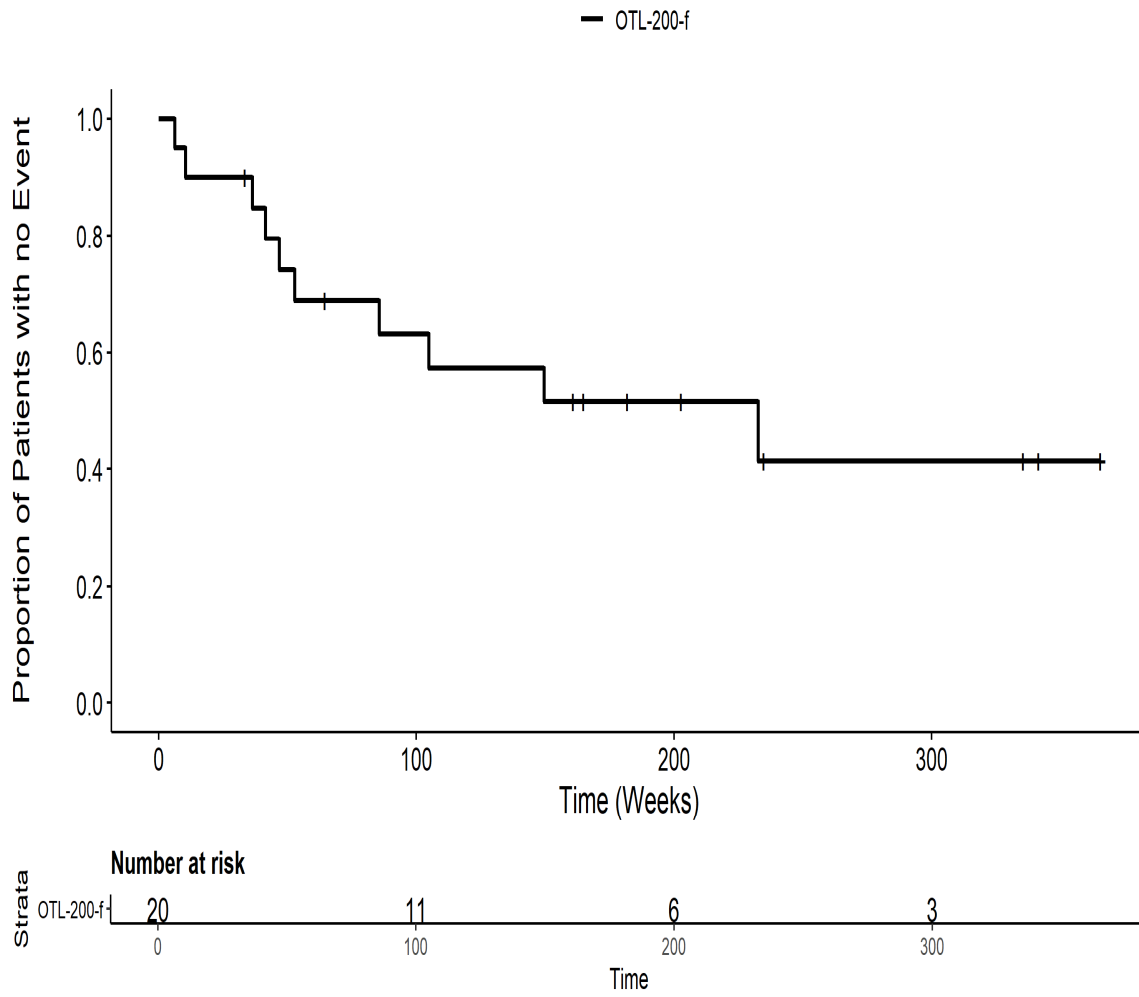
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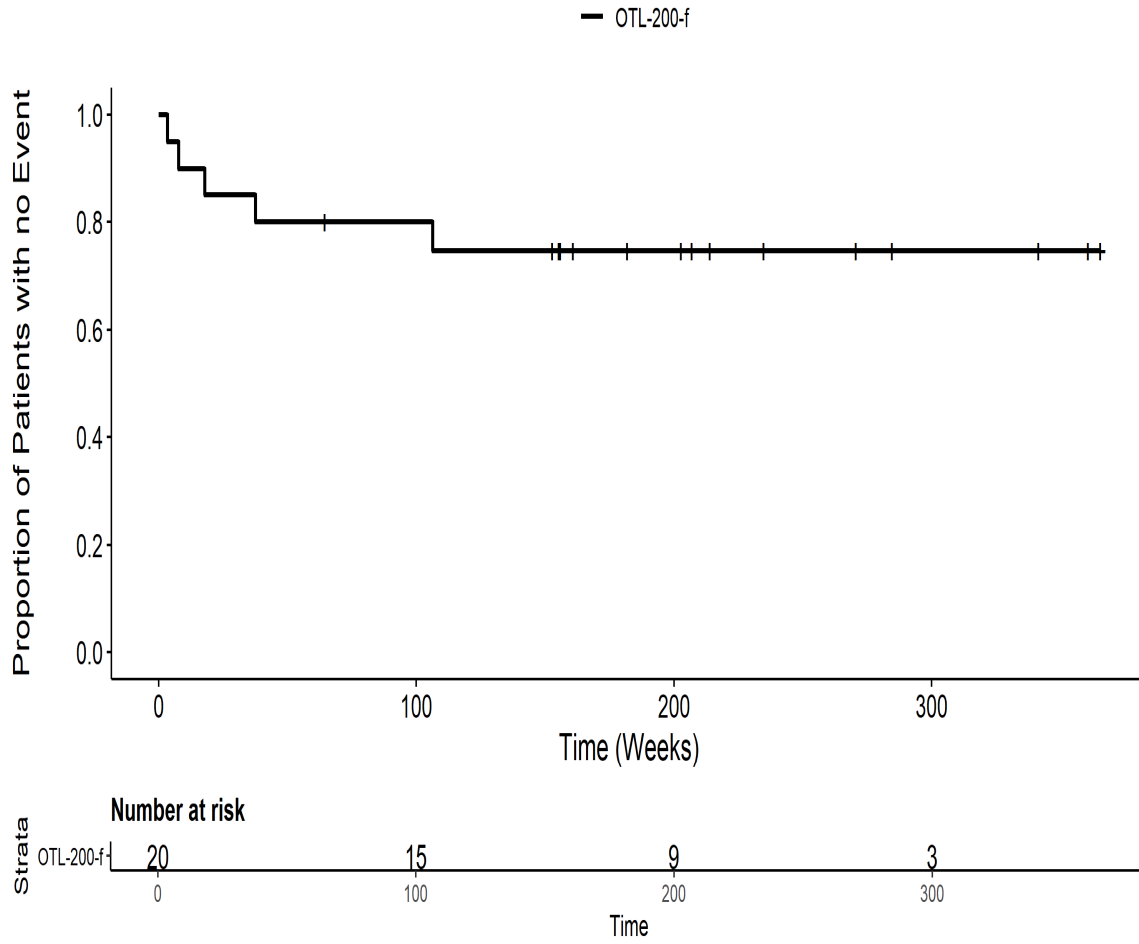
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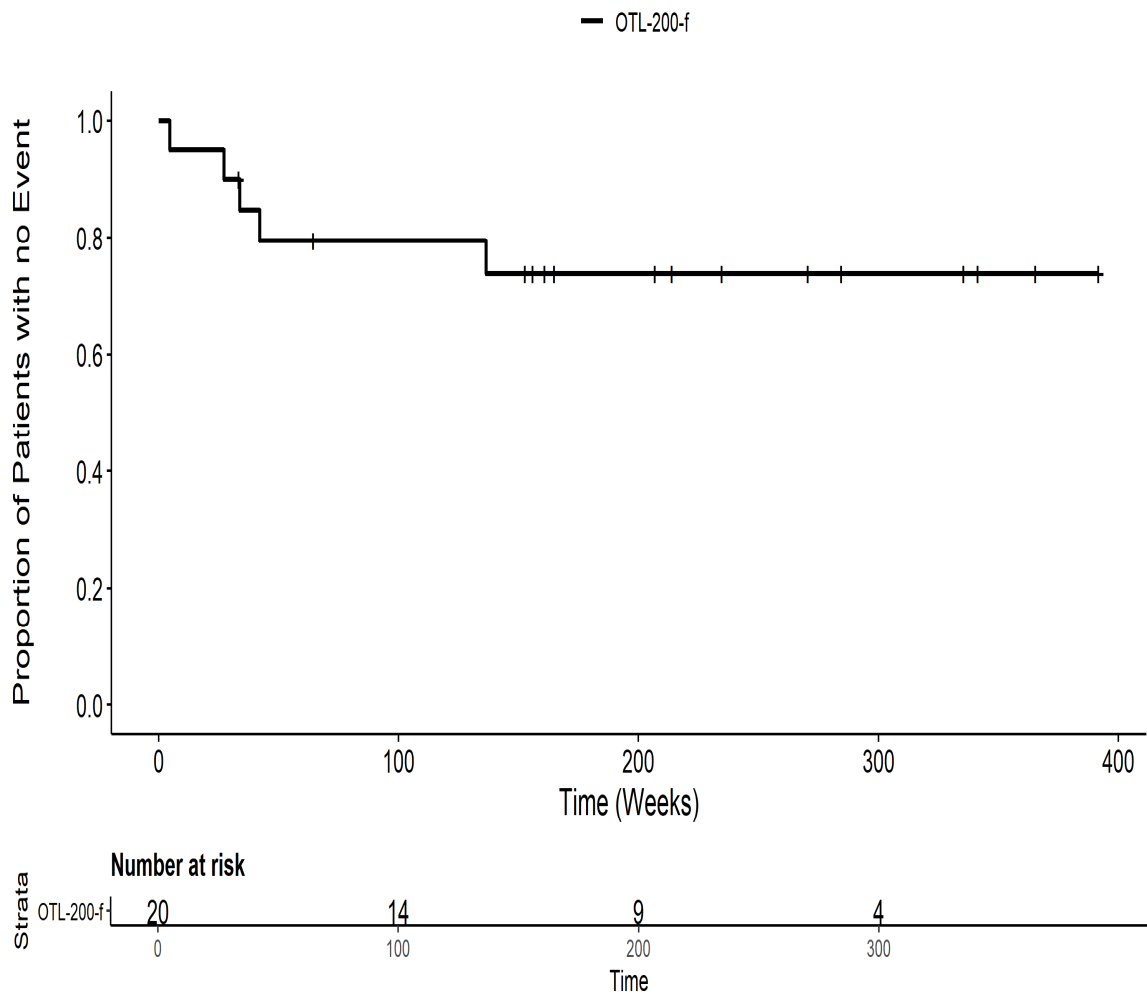
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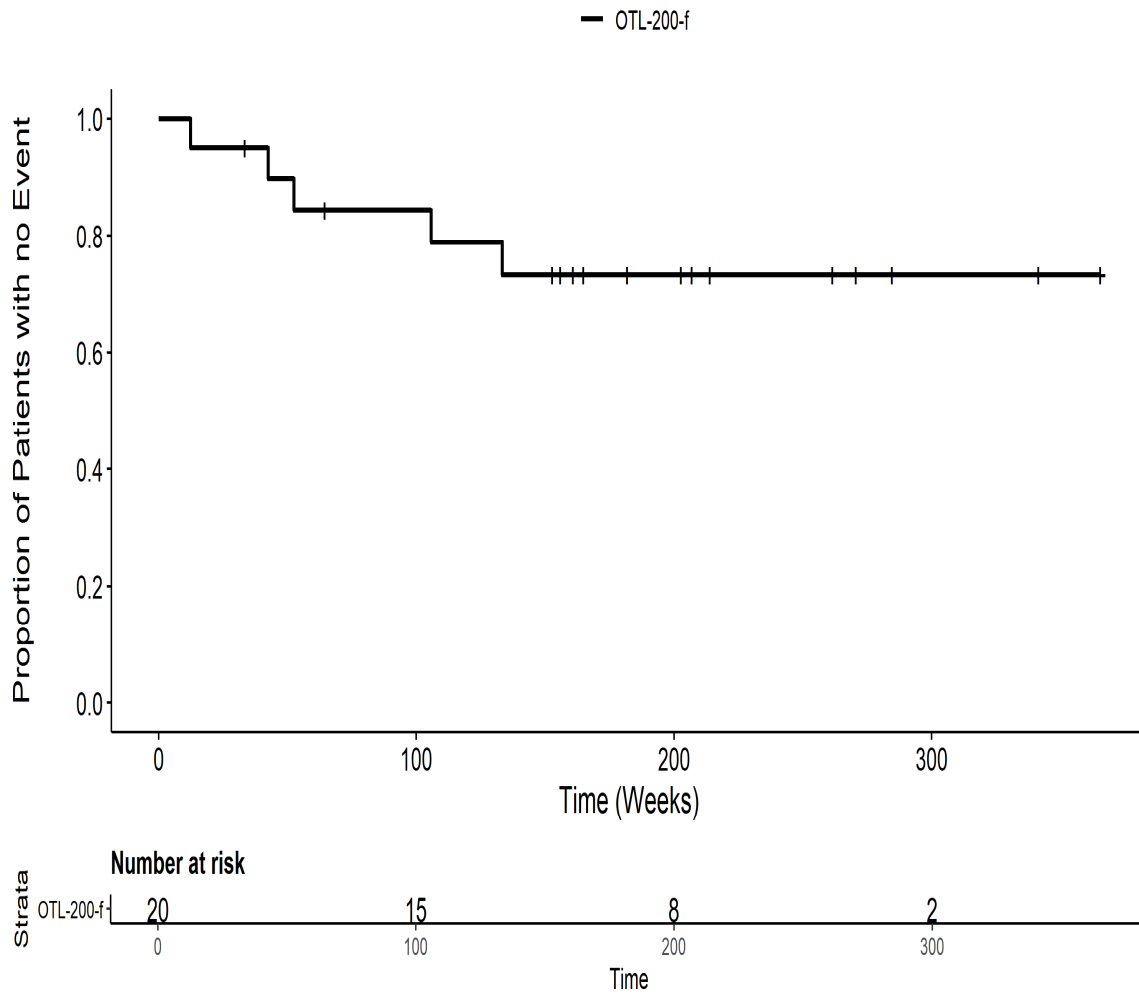
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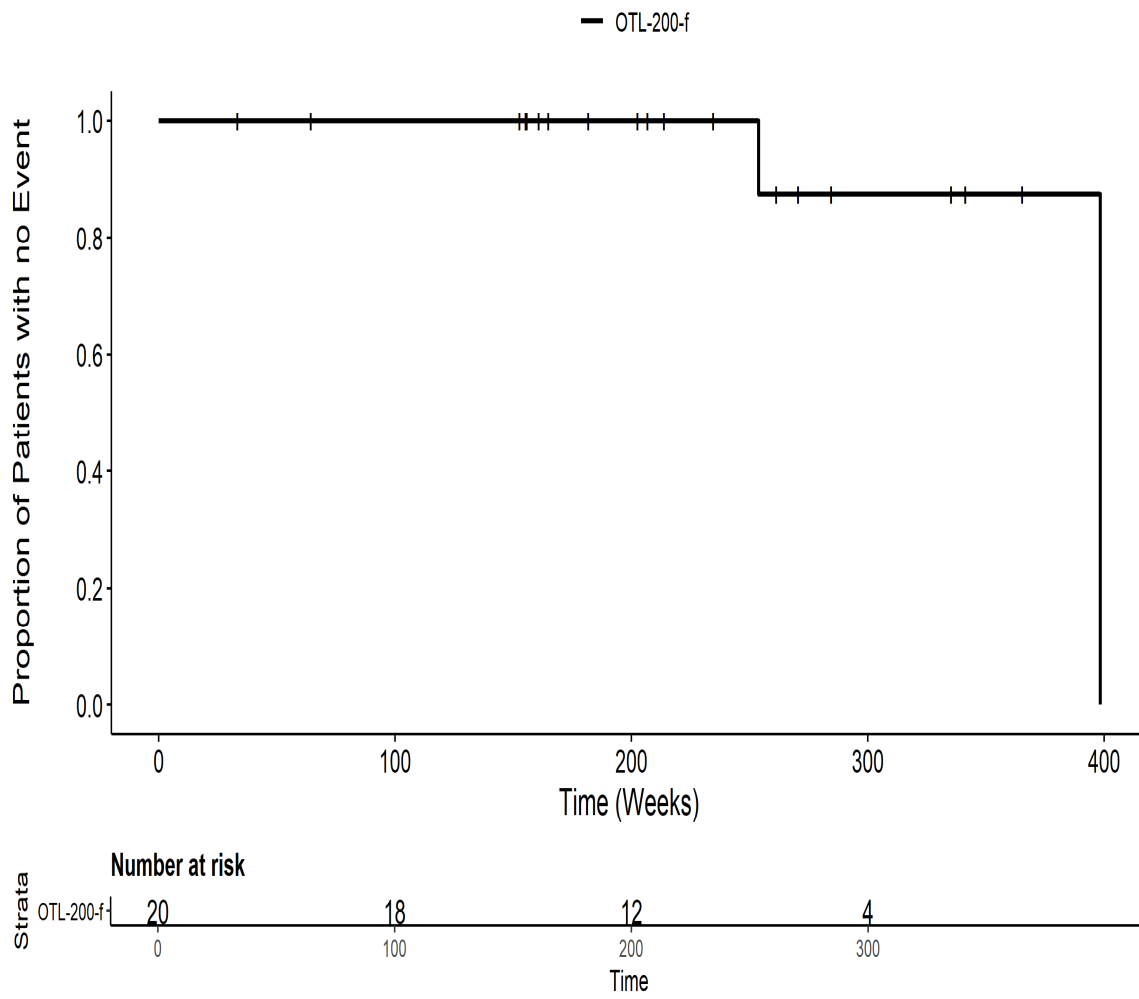
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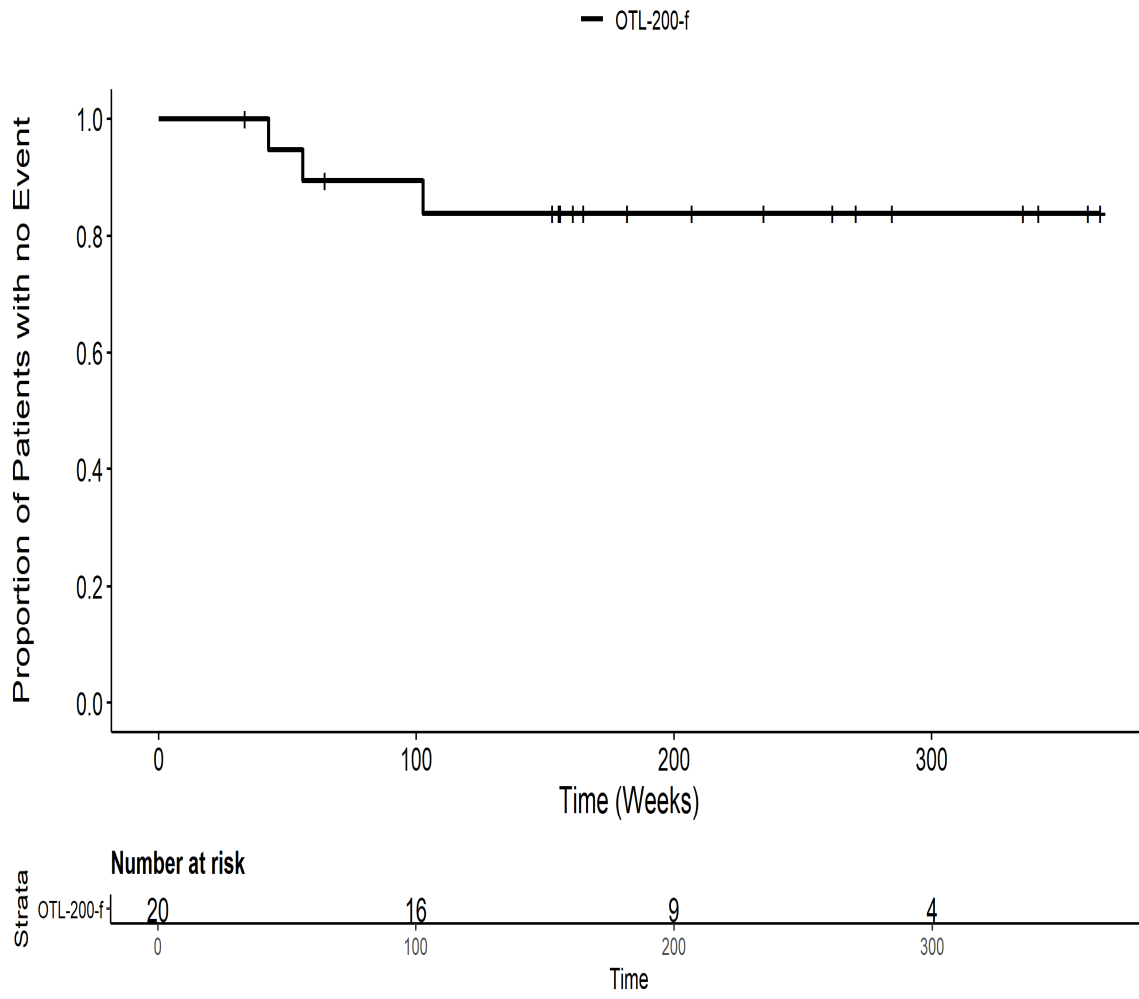
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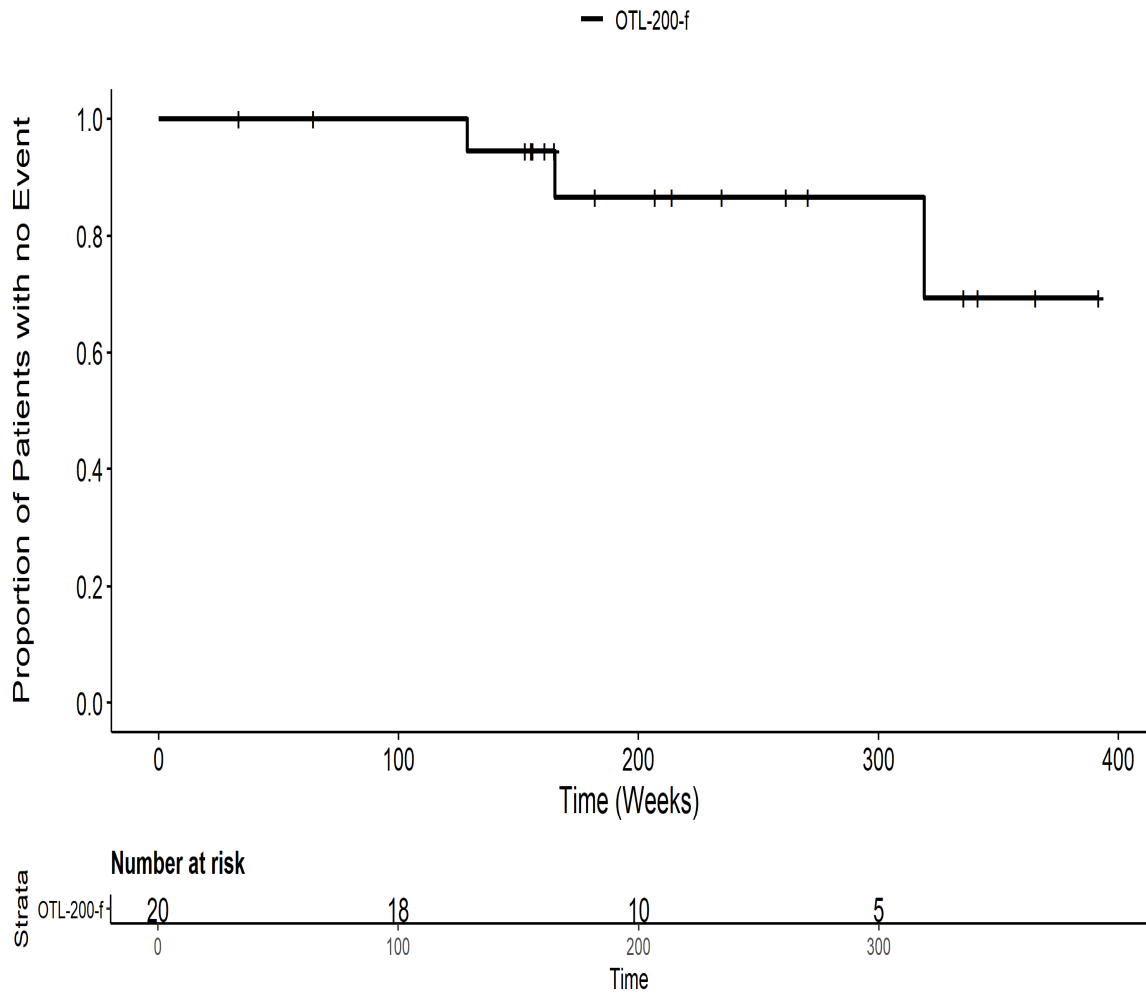
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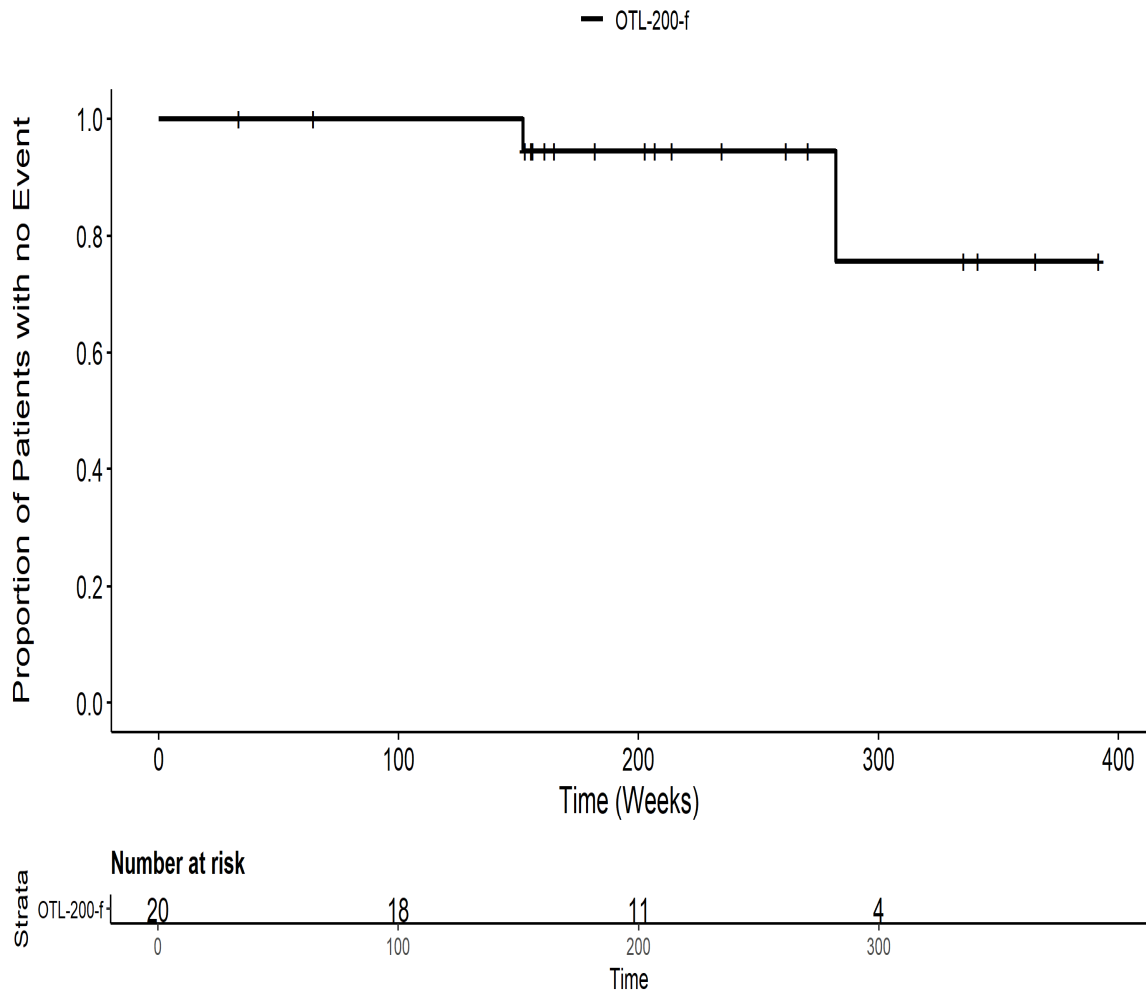
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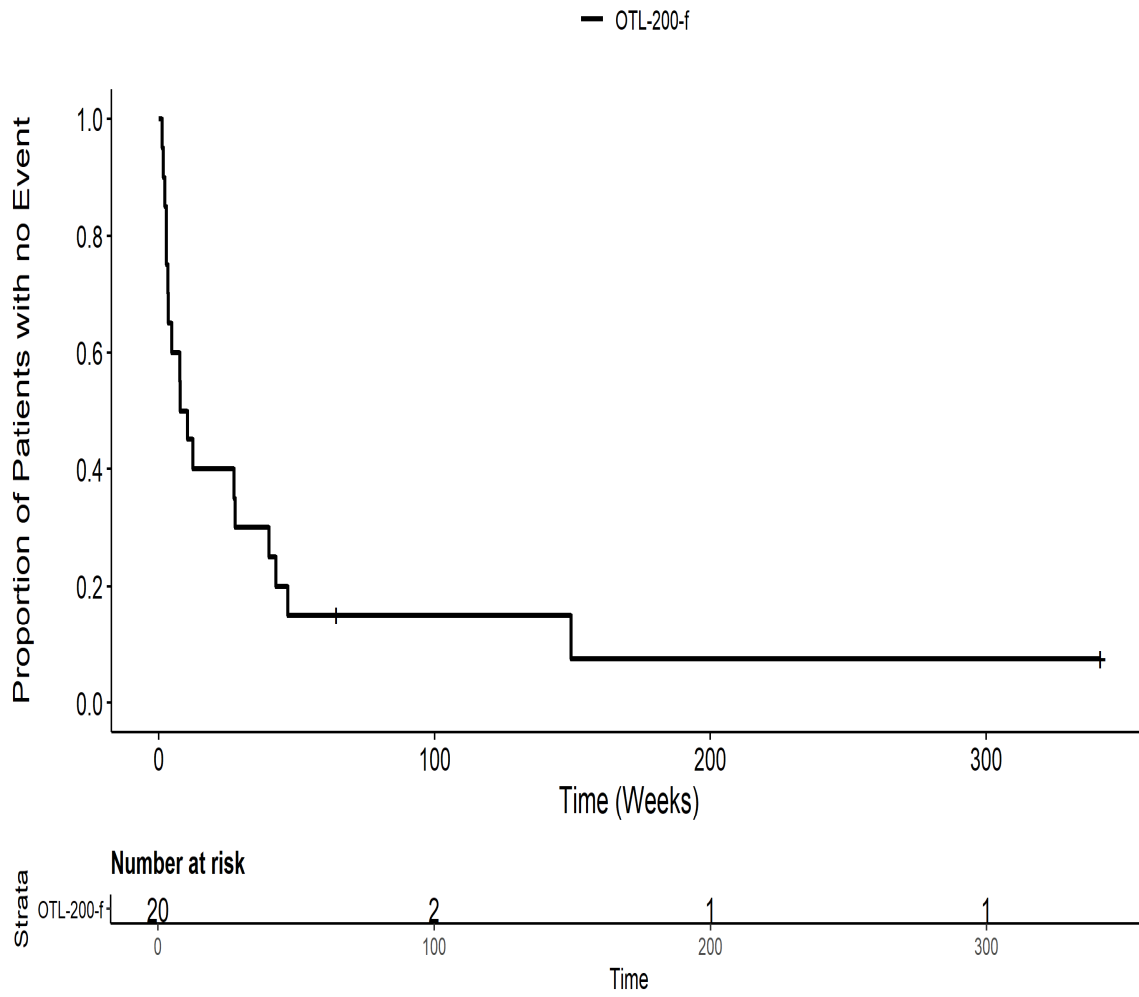
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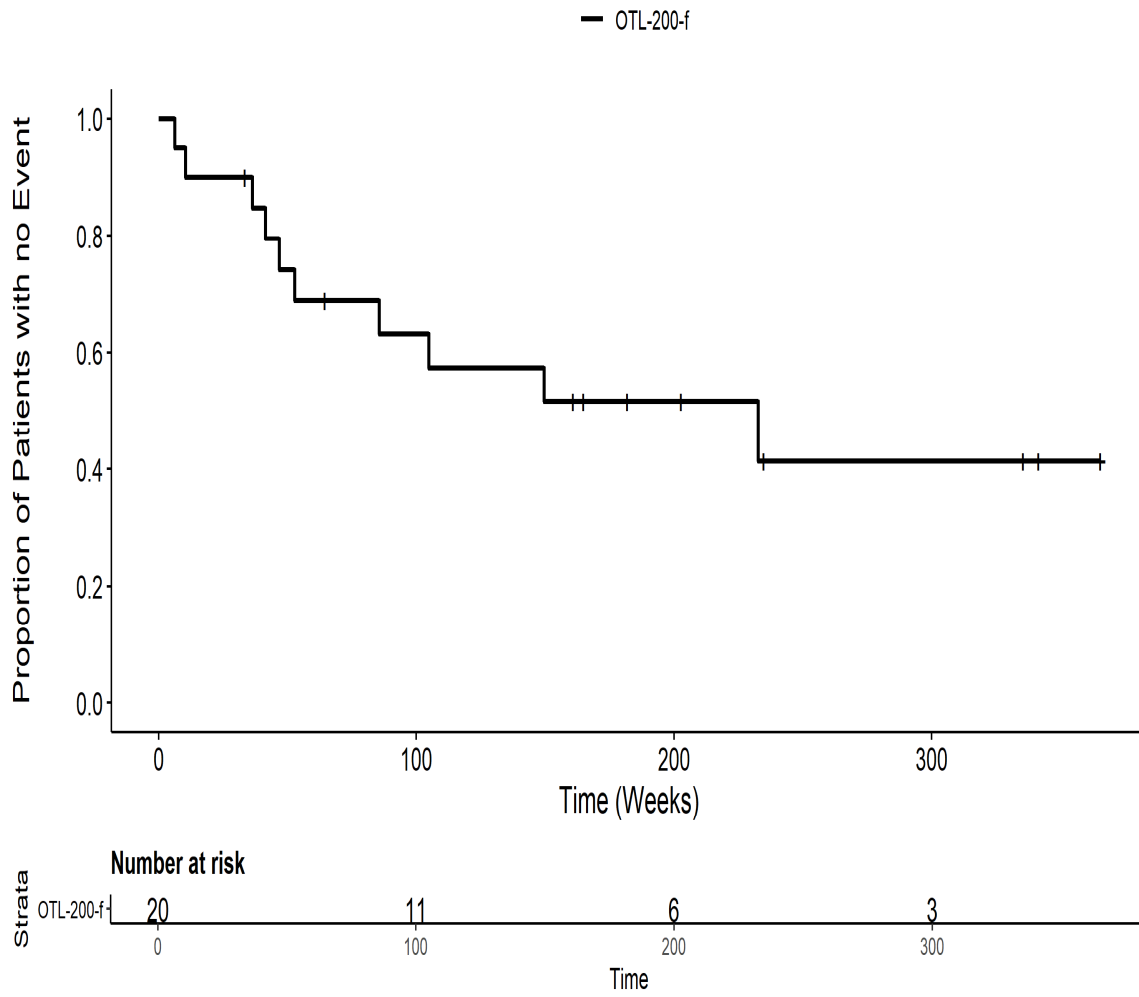
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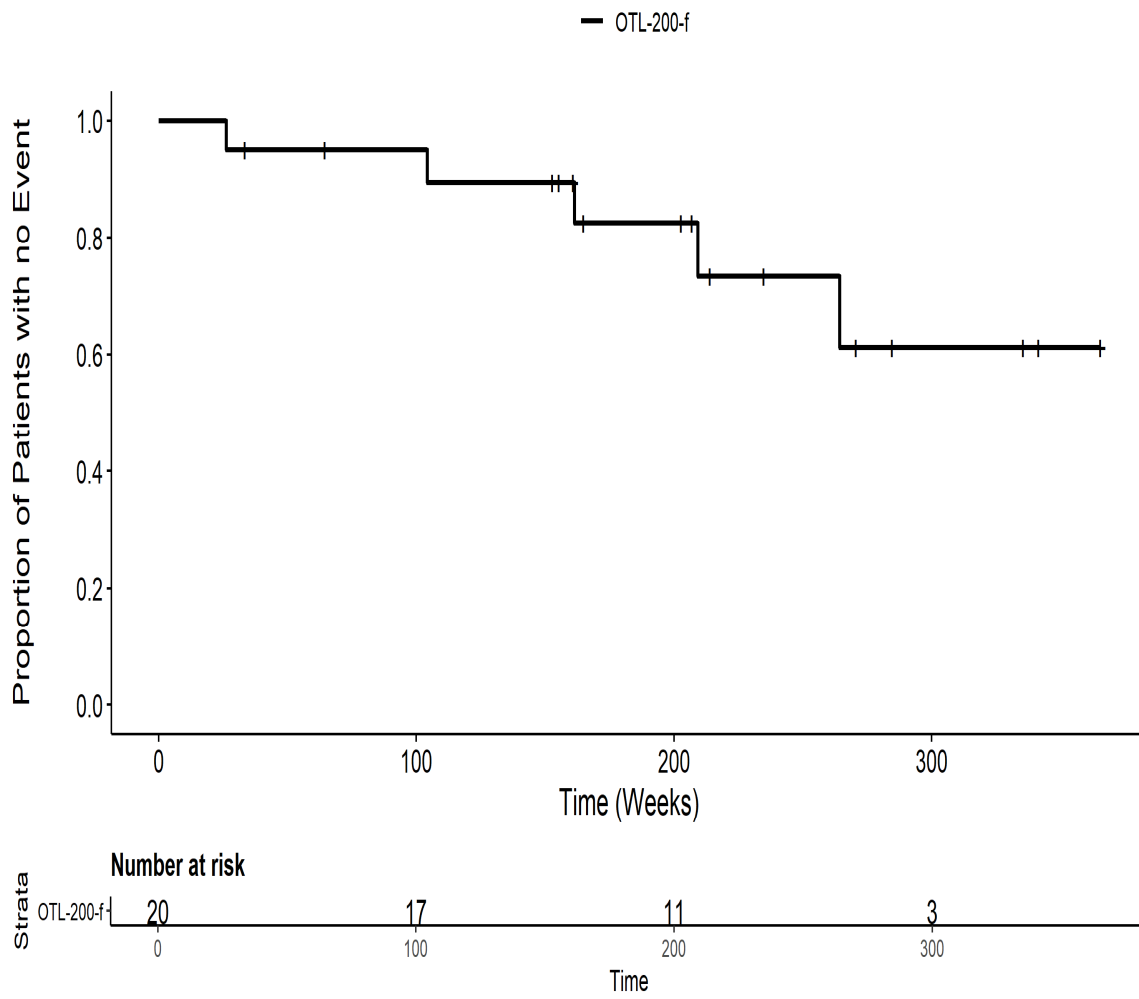
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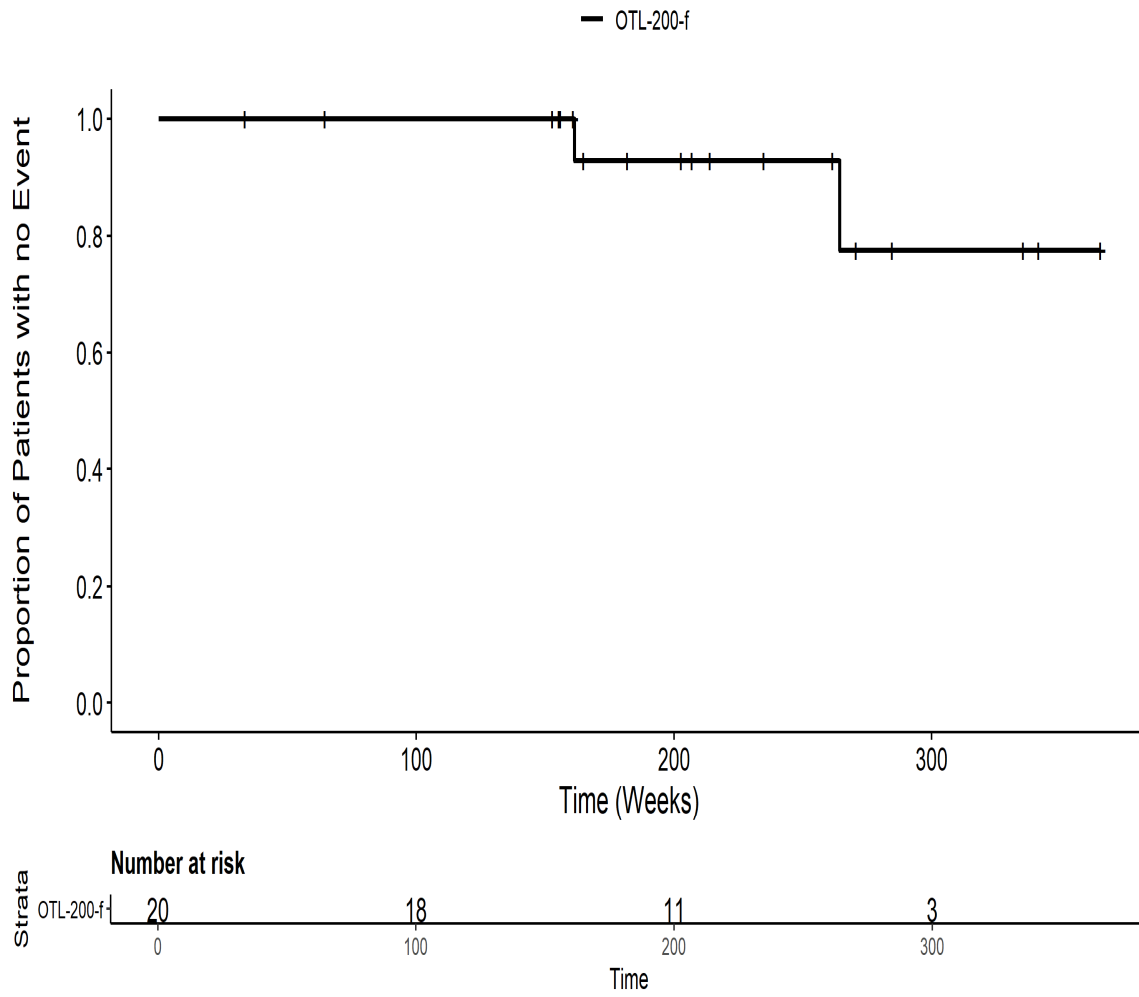
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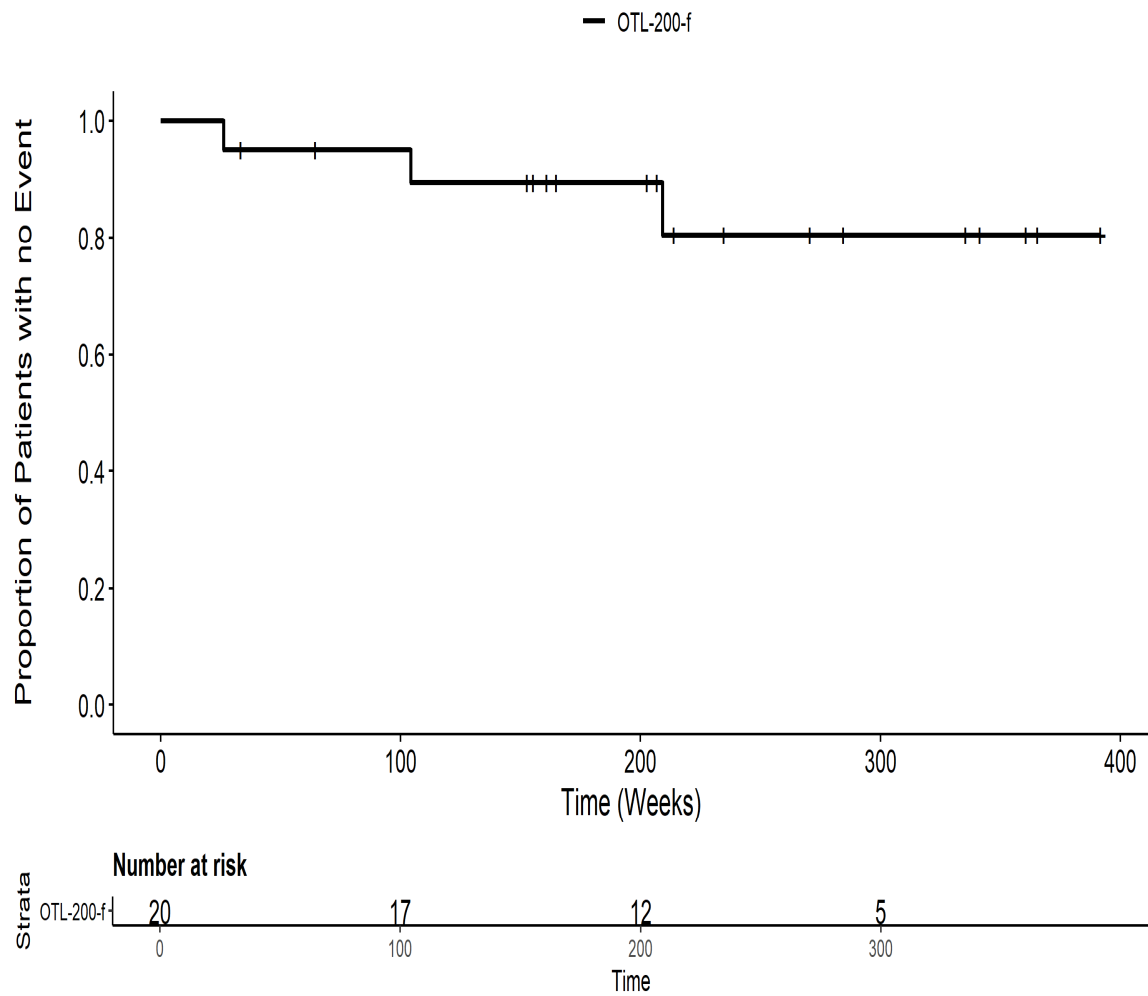
201222: Kaplan Meier Plot for Time to all AE by SOC Kongenitale, familiäre und genetische Erkrankungen PT pct Gesamt SOCITT



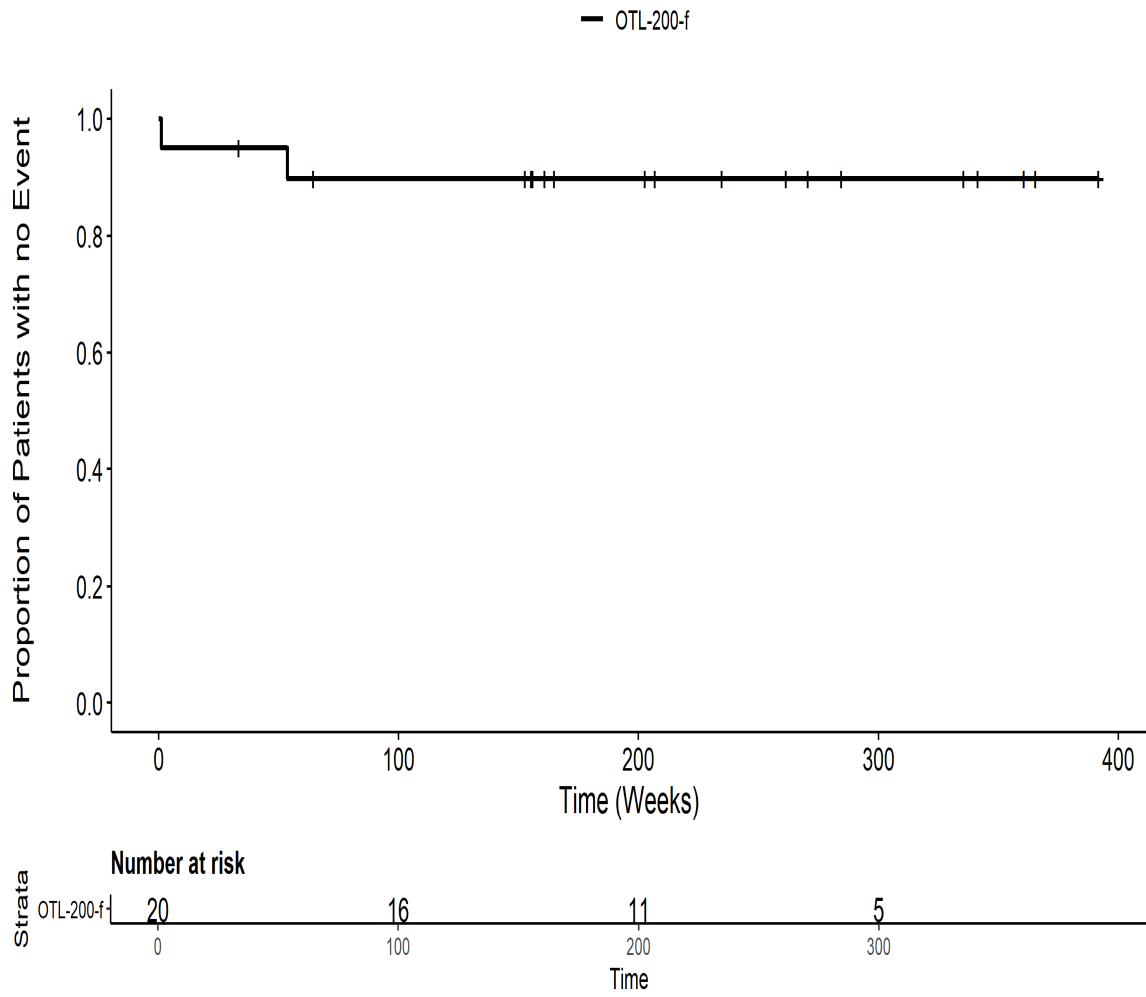
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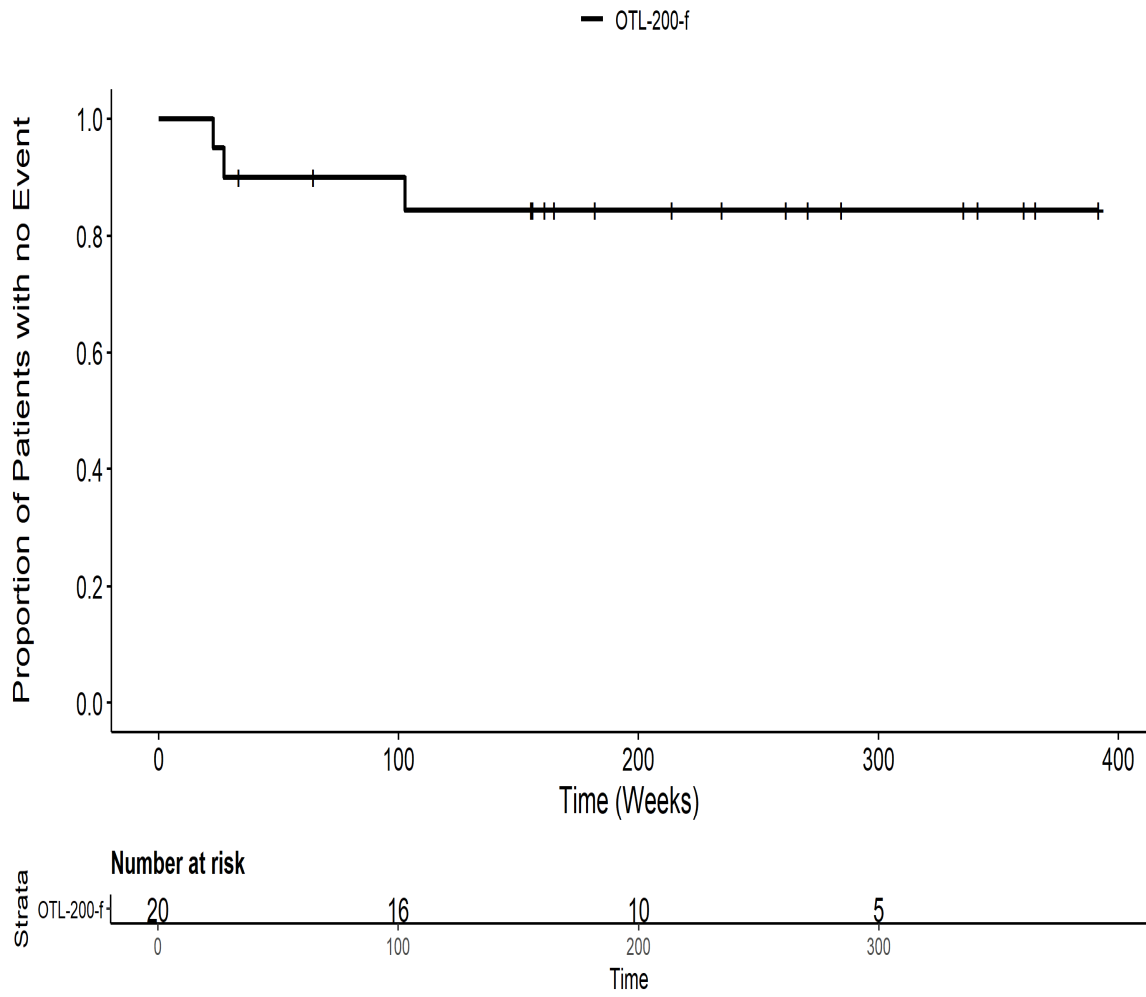
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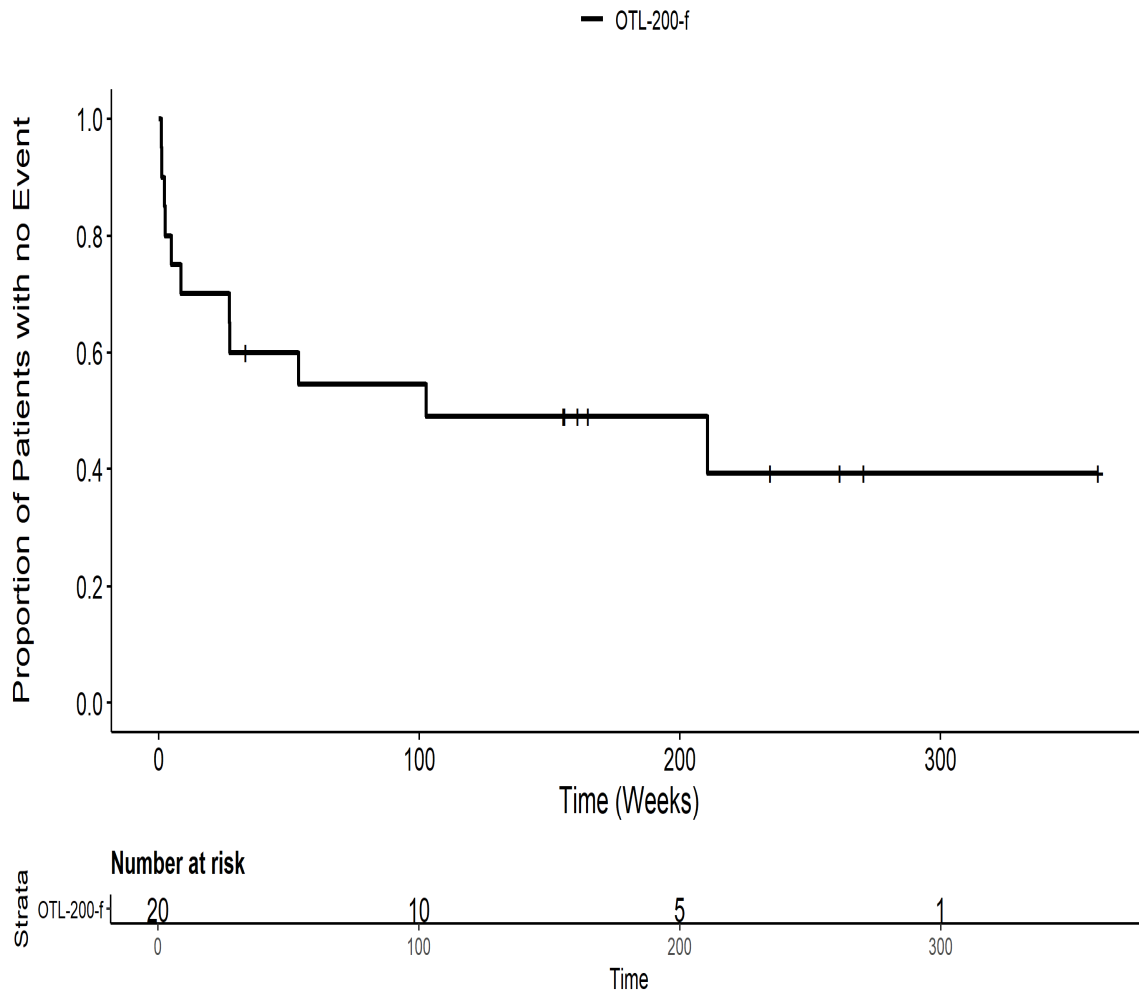
201222: Kaplan Meier Plot for Time to all AE by SOC Leber : und Gallenerkrankungen PT pct DRUG : INDUCED LIVER INJURYITT



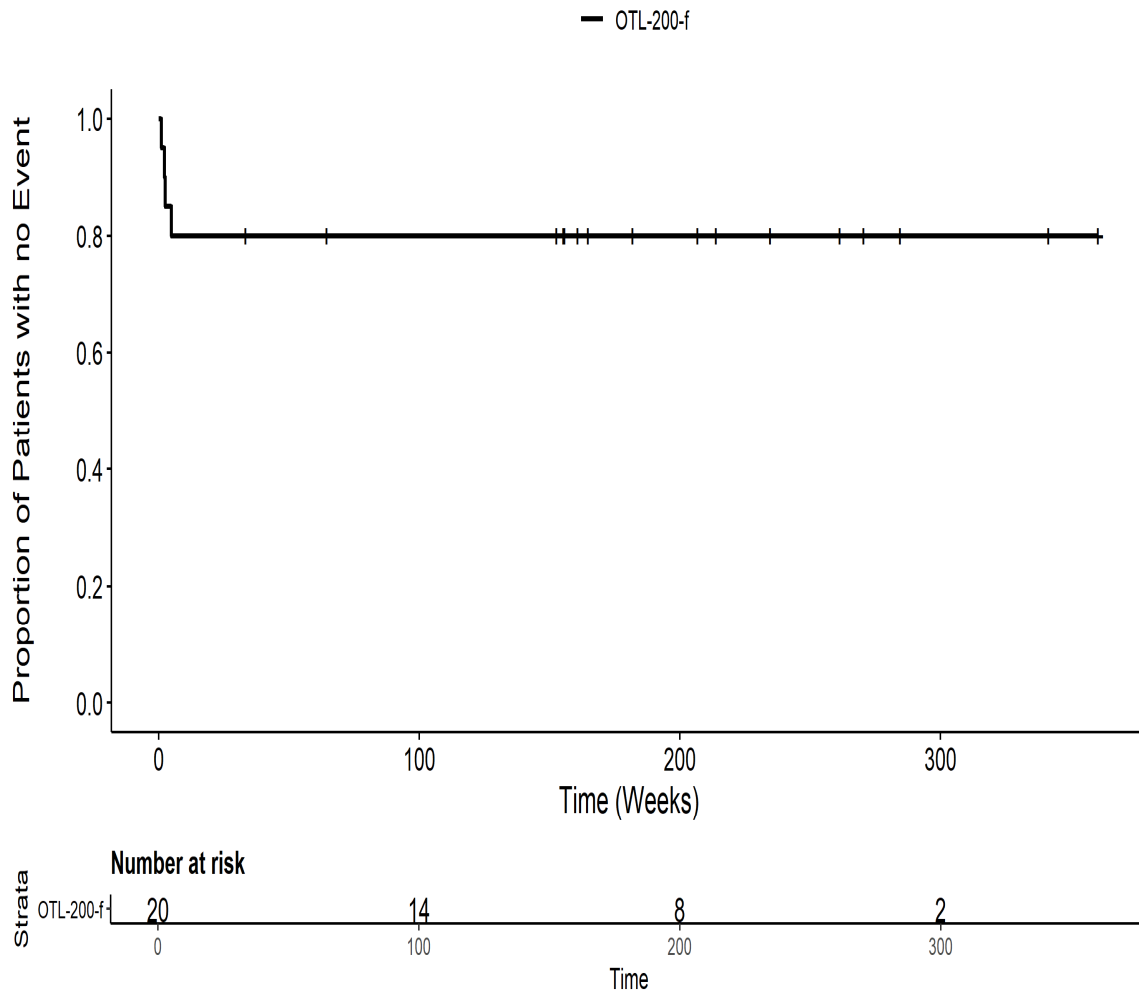
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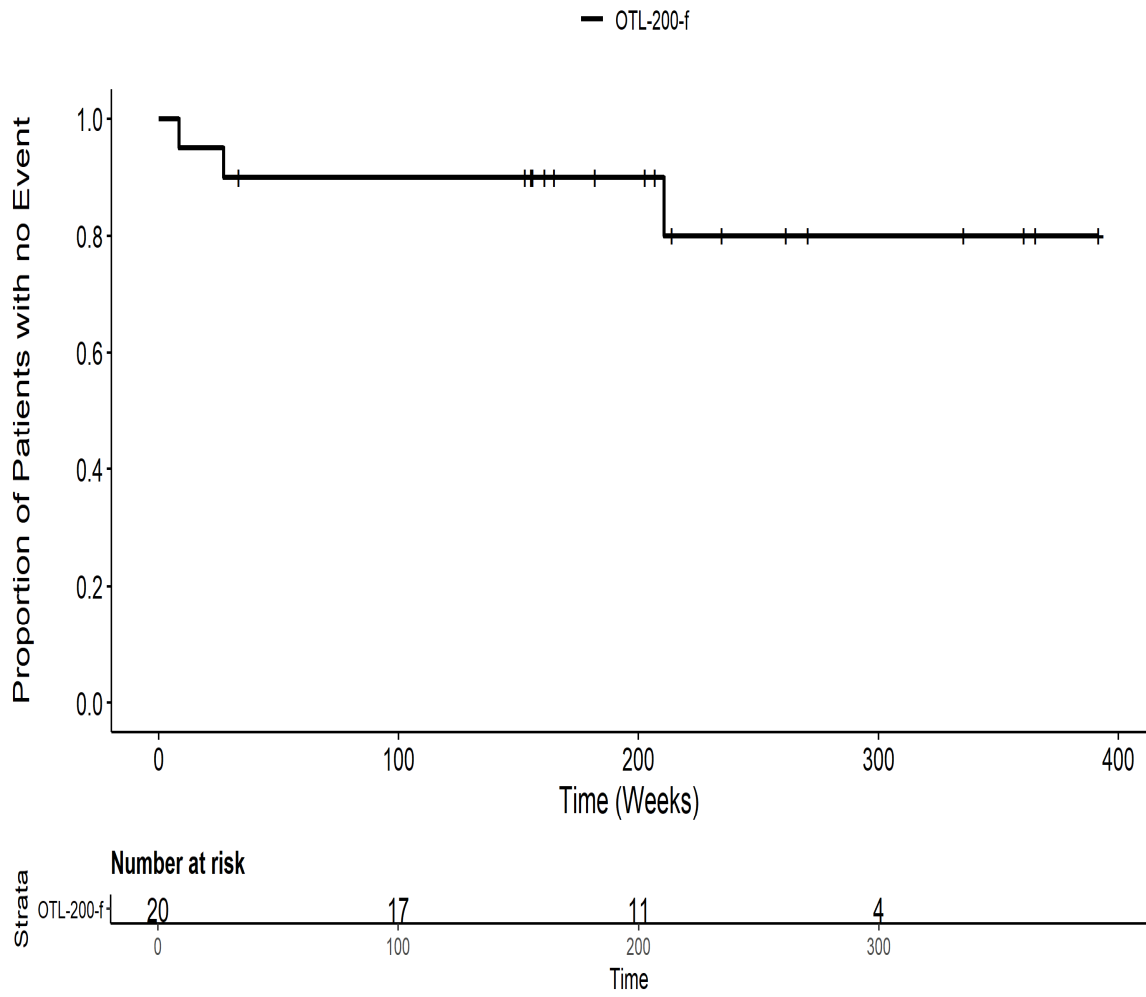
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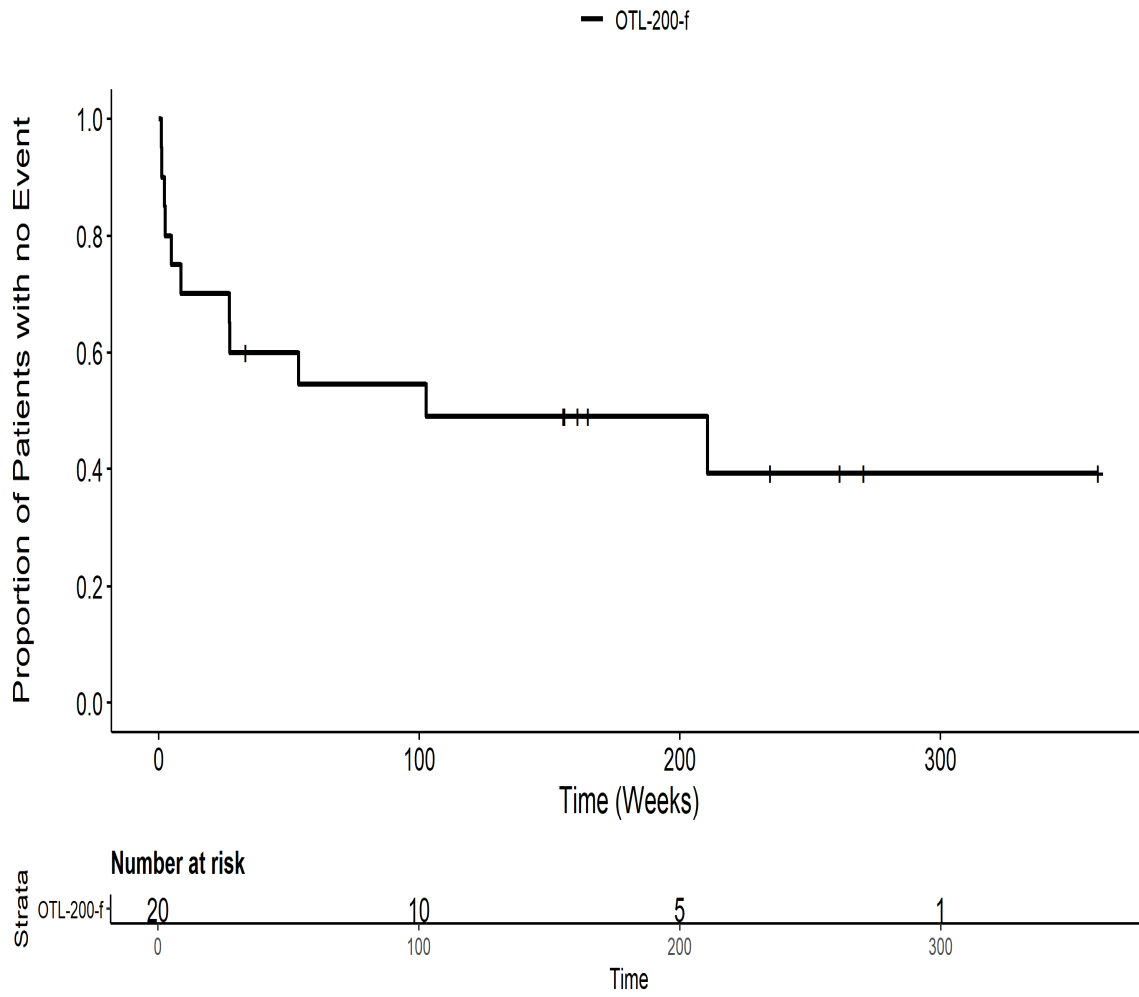
201222: Kaplan Meier Plot for Time to all AE by SOC Leber : und Gallenerkrankungen PT pct HepatomegalieIT



201222: Kaplan Meier Plot for Time to all AE by SOC Leber : und Gallenerkrankungen PT pct Vergrößerung der GallenblaseITT

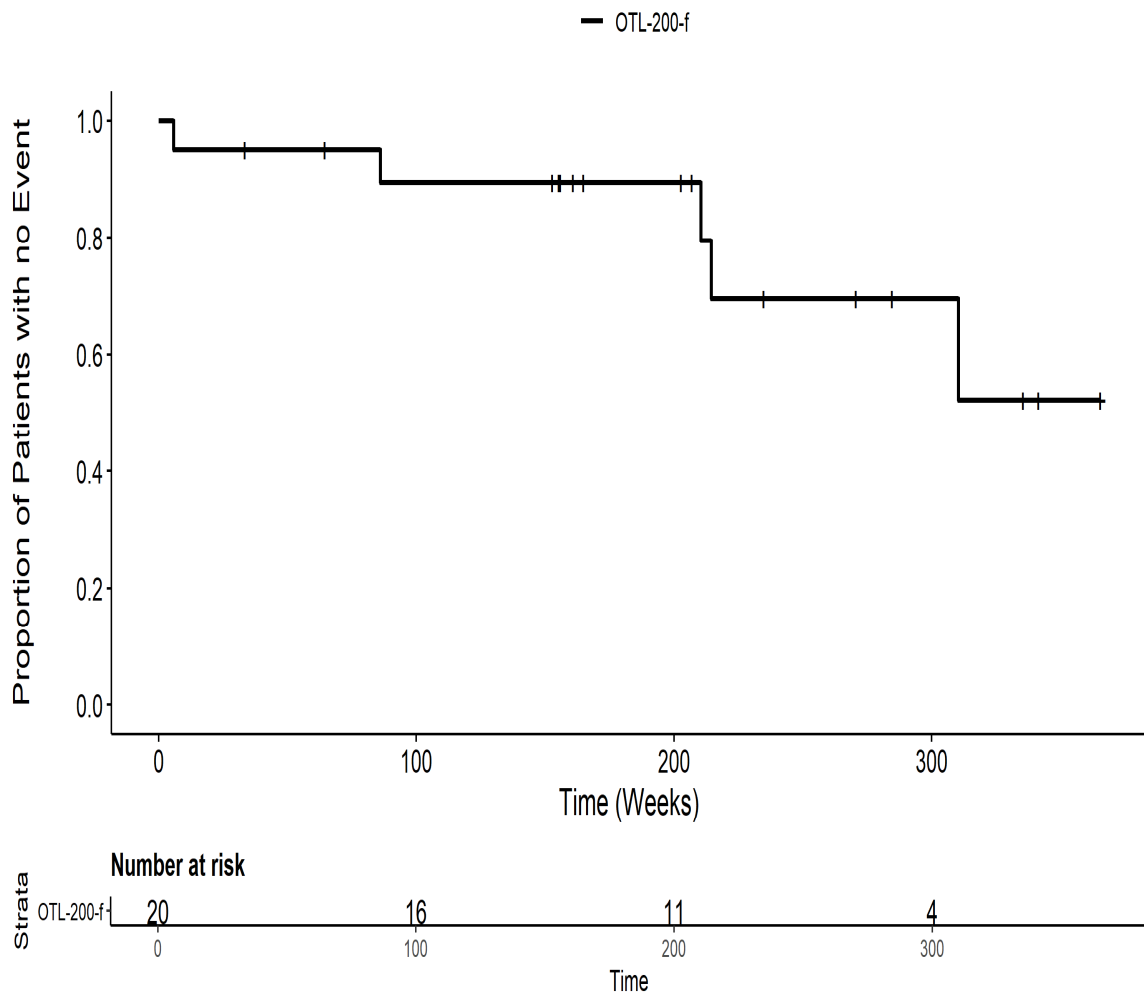


201222: Kaplan Meier Plot for Time to all AE by SOC Leber : und Gallenerkrankungen PT pts Gesamt SOC ITT



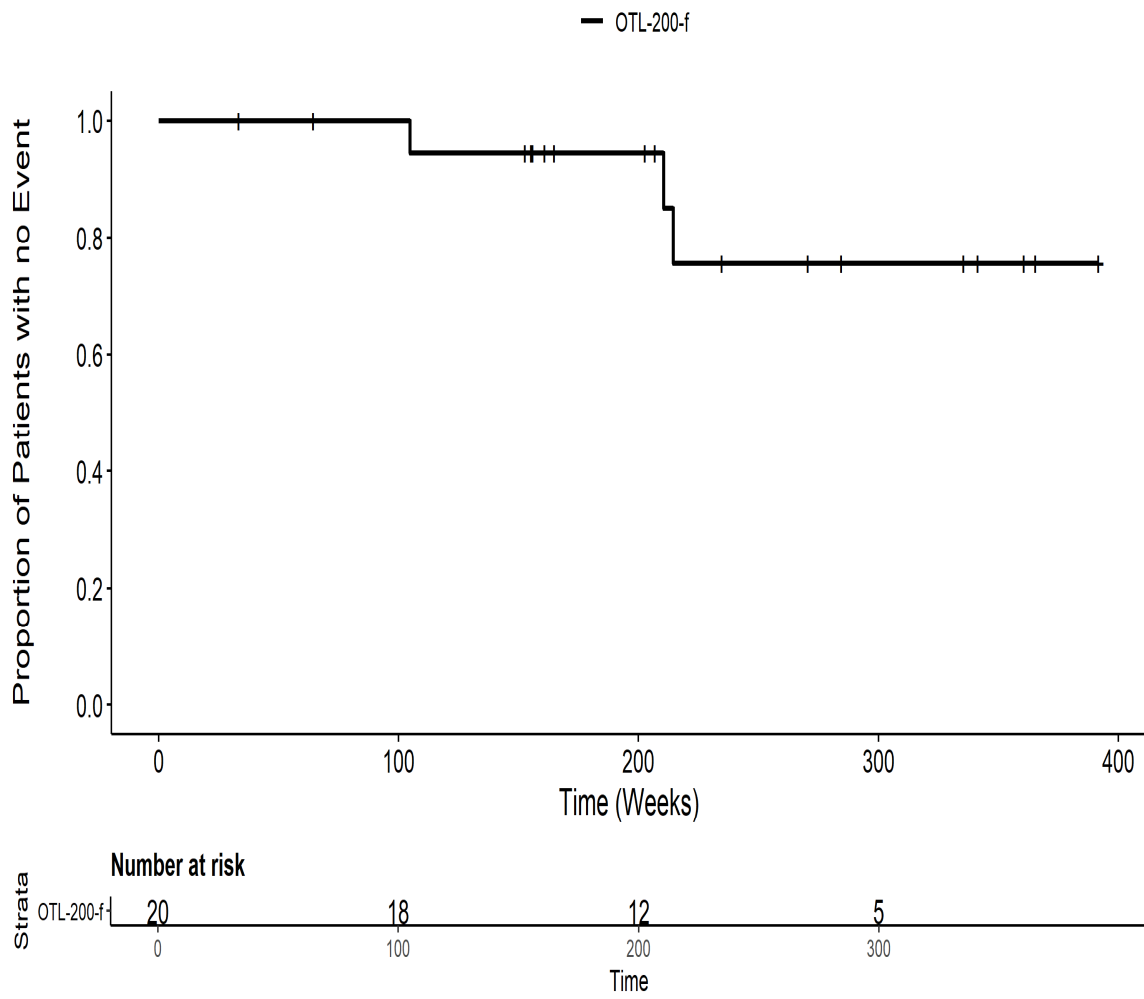
201222: Kaplan Meier Plot for Time to all AE by SOC

Skelettmuskulatur : , Bindegewebs : und Knochenkrankungen PT pct Gesamt SOCITT

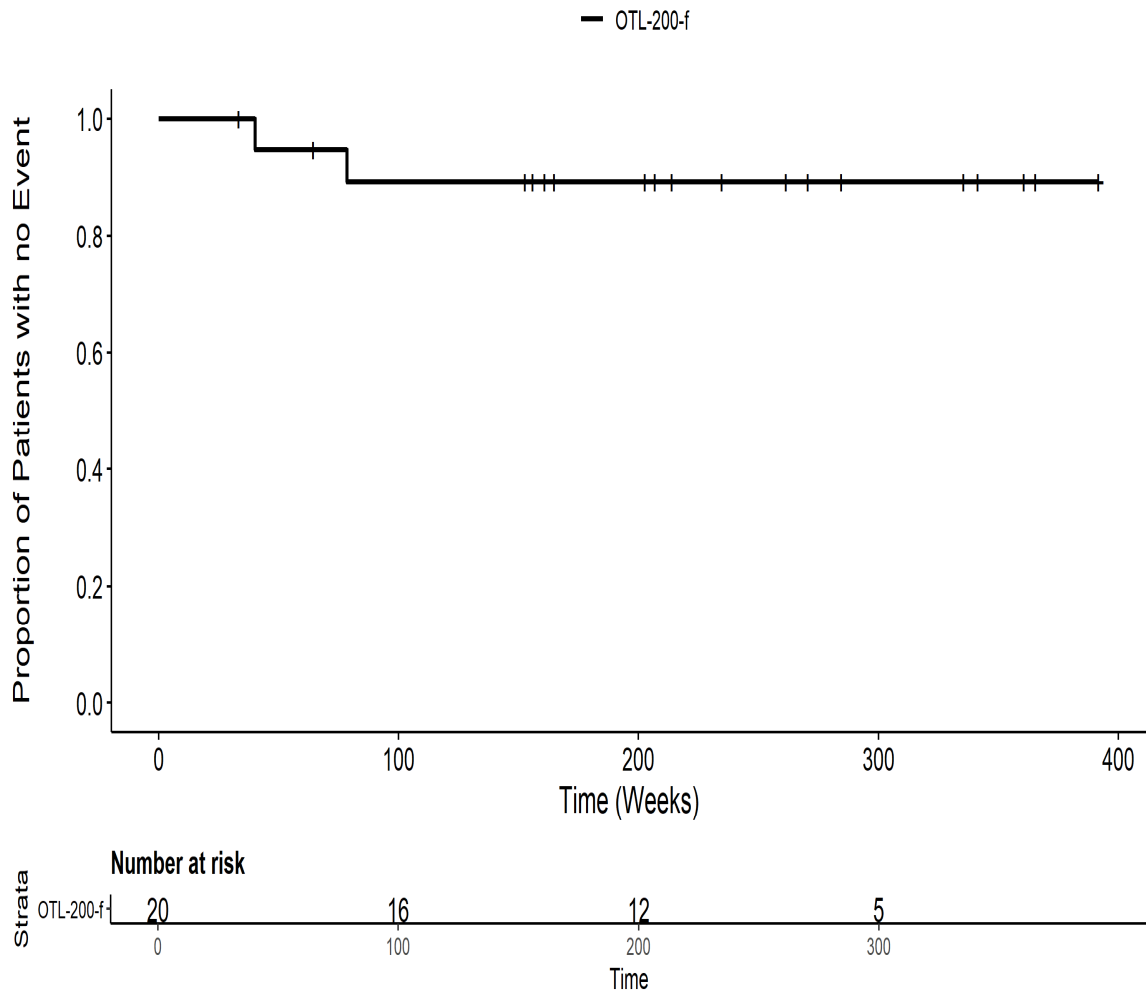


201222: Kaplan Meier Plot for Time to all AE by SOC

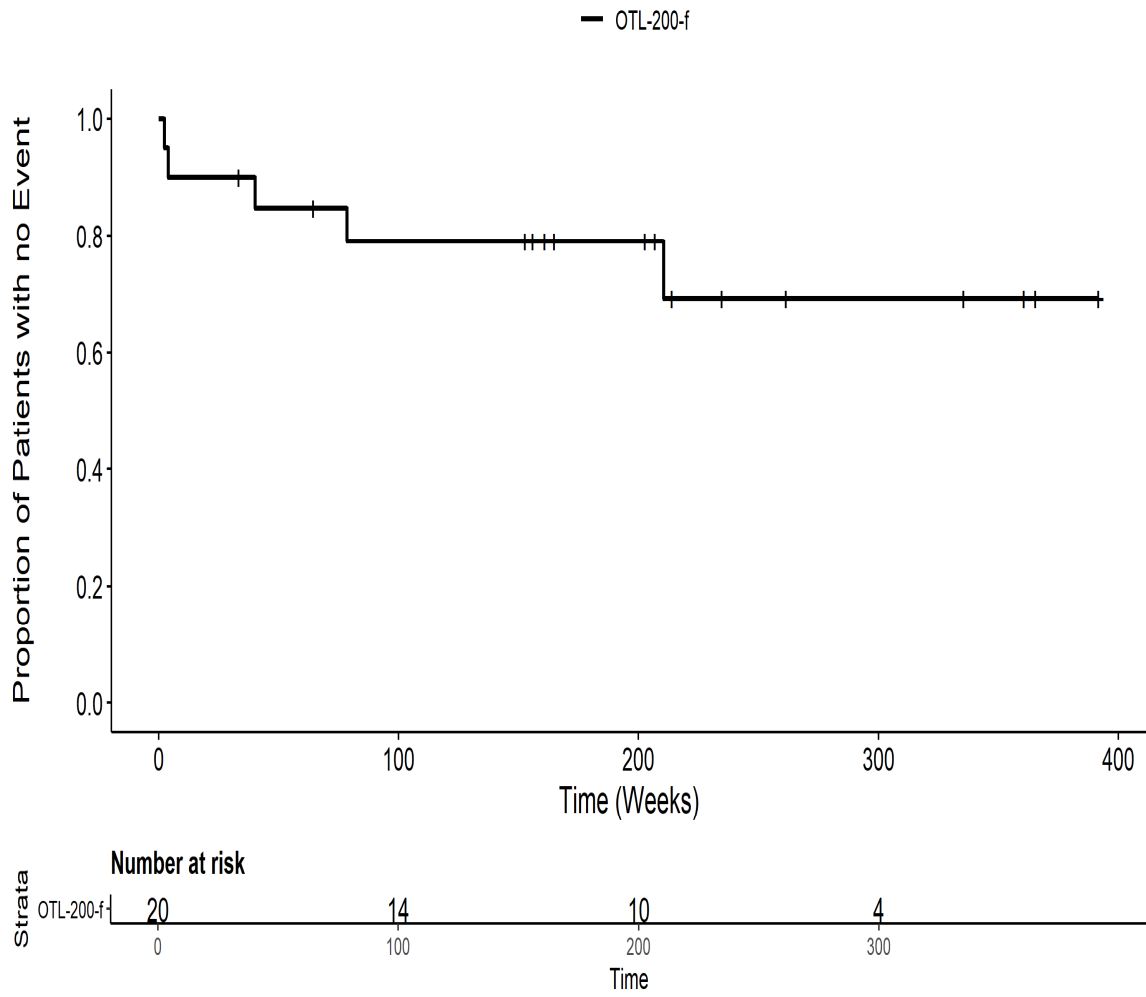
Skelettmuskulatur : , Bindegewebs : und Knochenkrankungen PT pct OsteoporoseITT



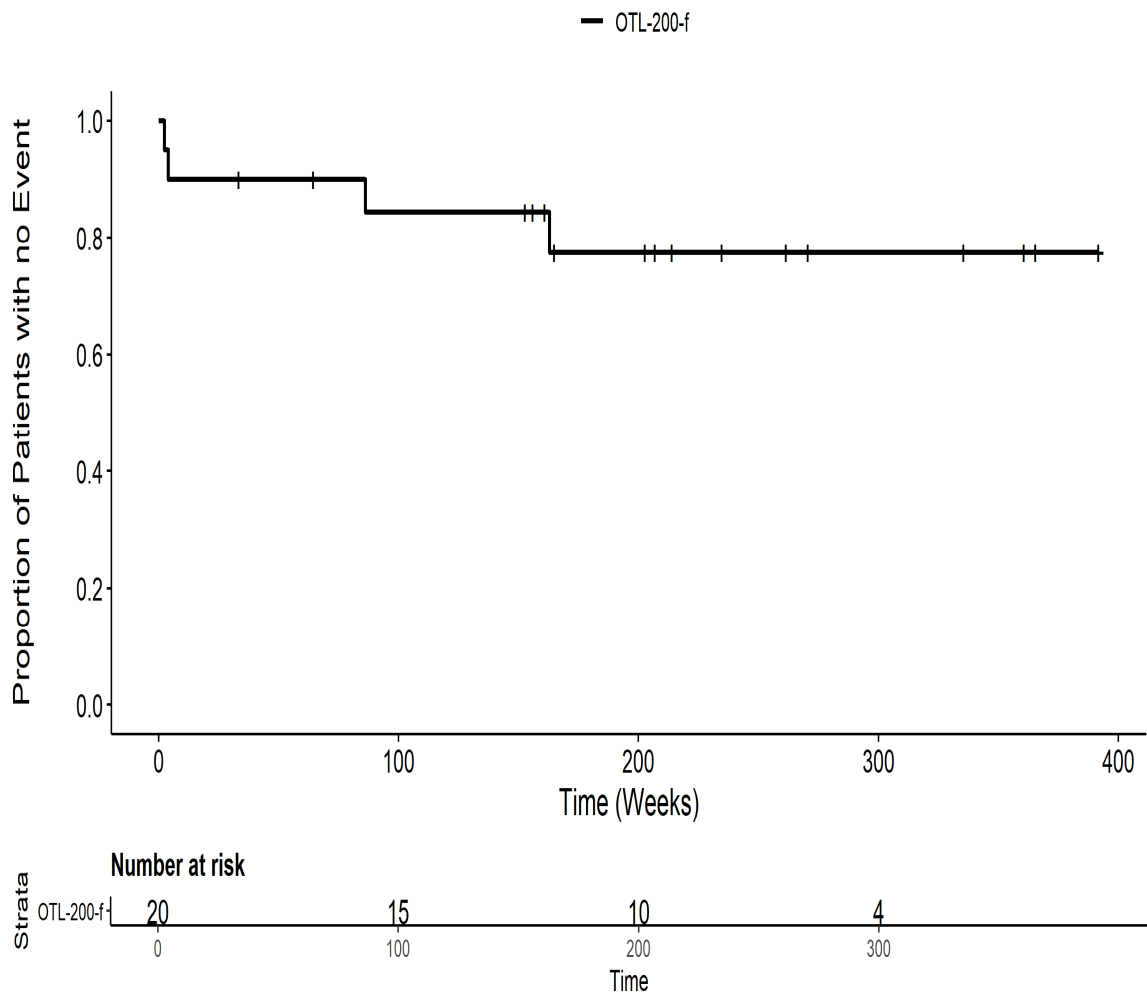
201222: Kaplan Meier Plot for Time to all AE by SOC Stoffwechsel :
und Ernährungsstörungen PT pct EisenmangelITT



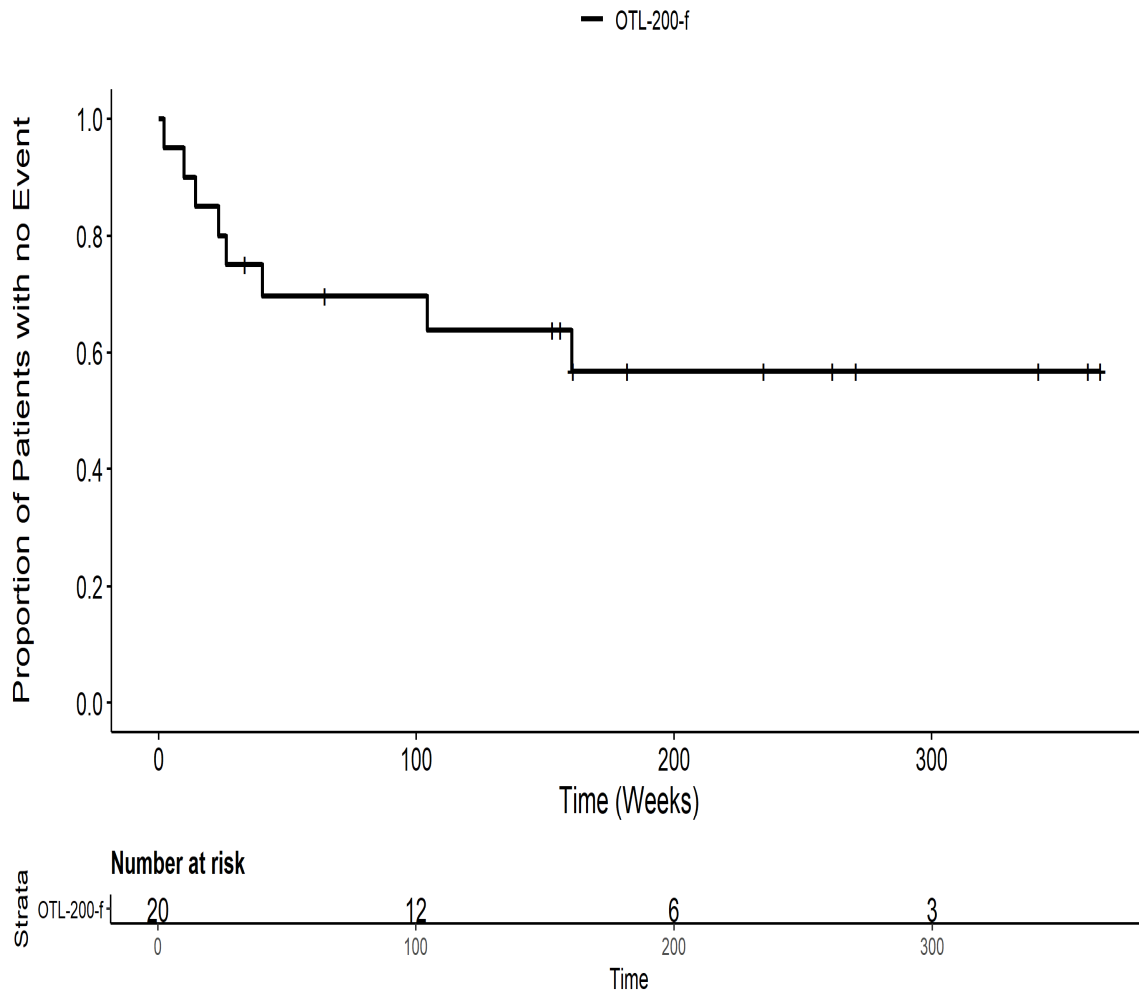
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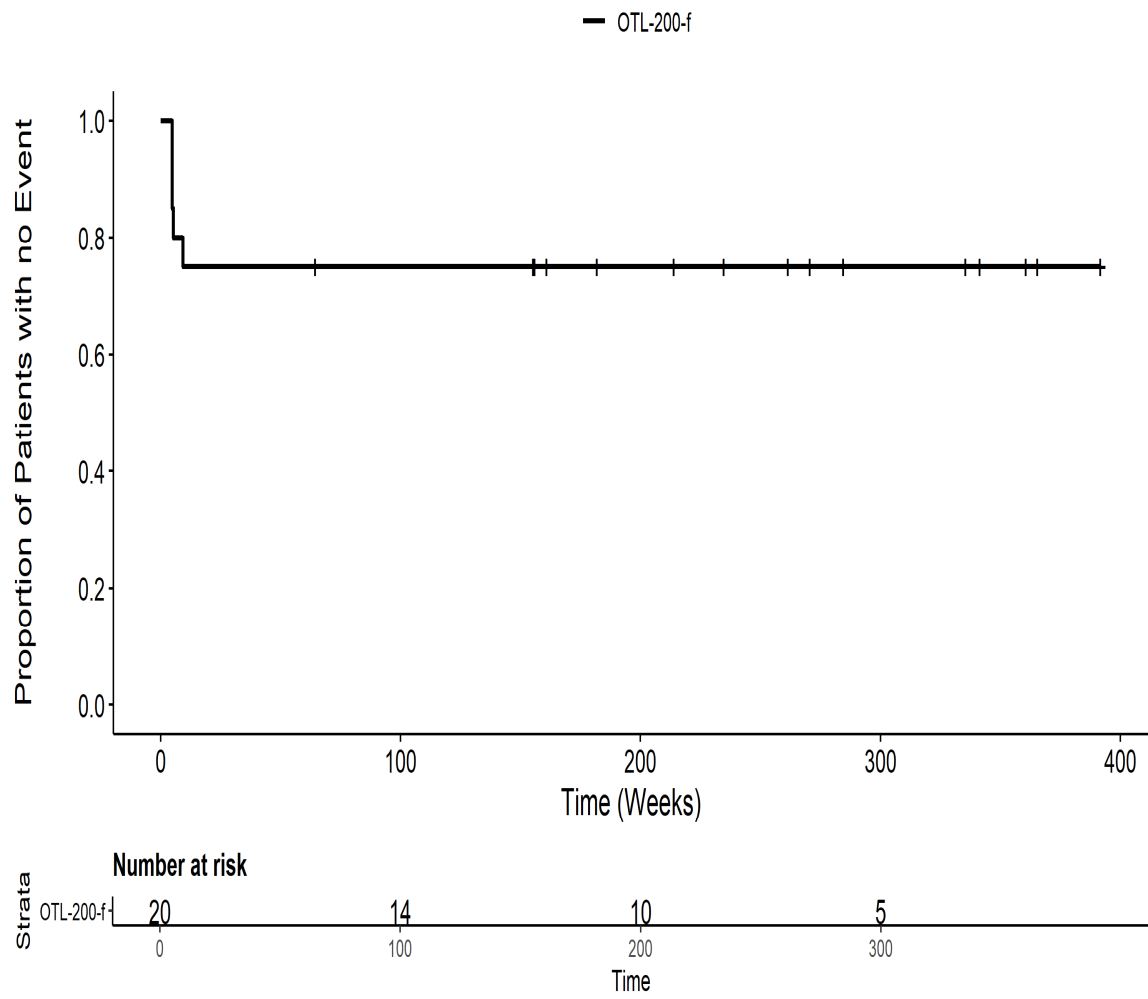
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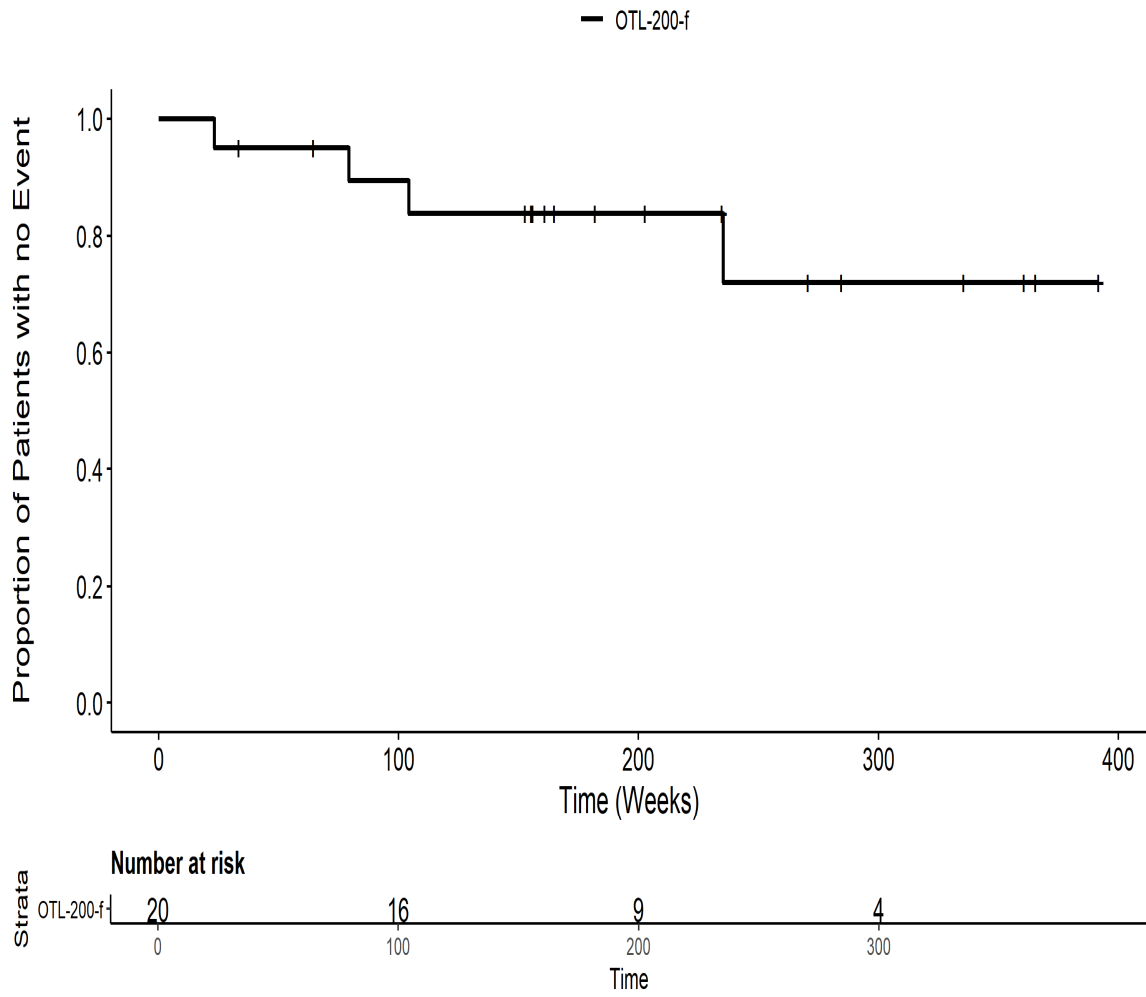
201222: Kaplan Meier Plot for Time to all AE by SOC Untersuchungen
PT pct Erhöhtes Immunglobulin E im BlutITT



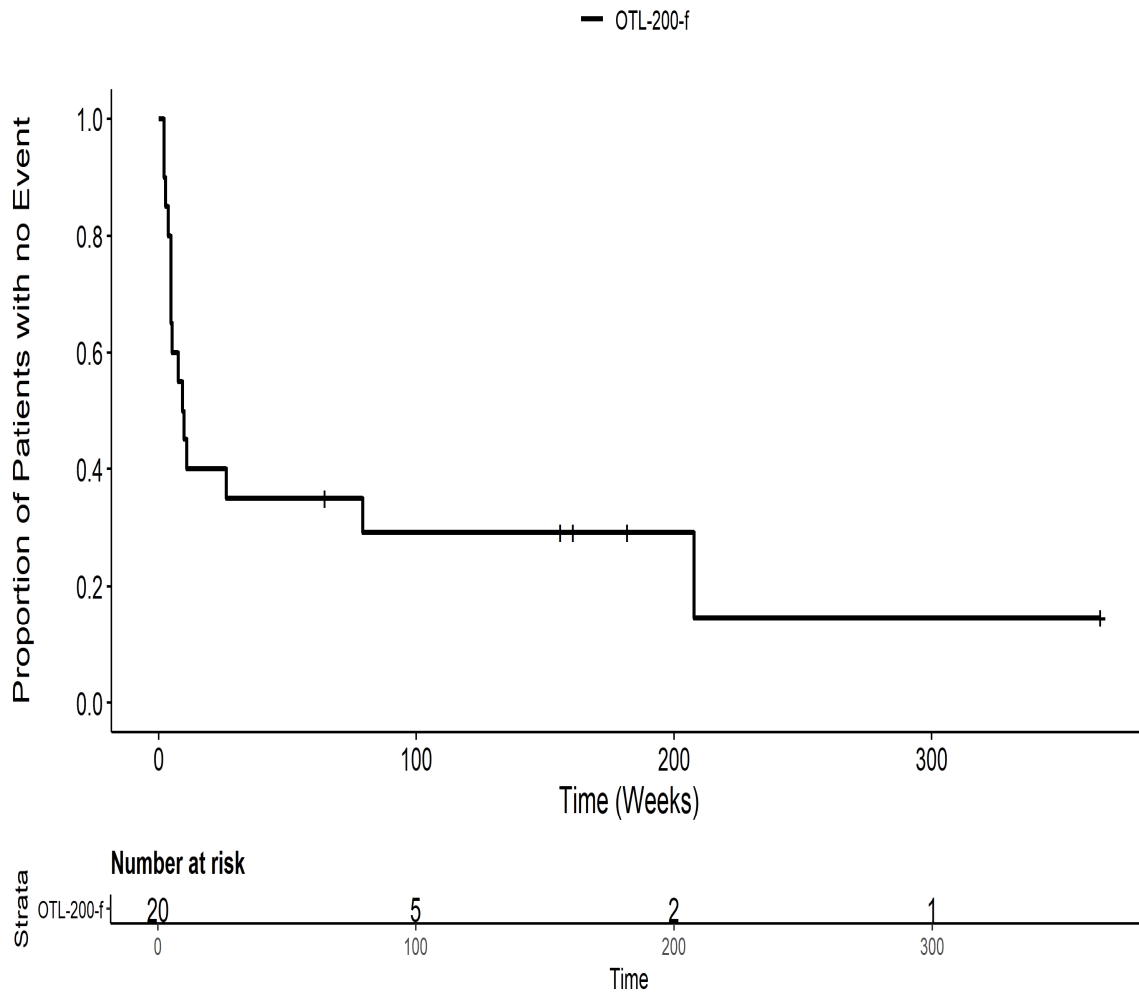
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PT pct Erhöhtes Serum : FerritinITT



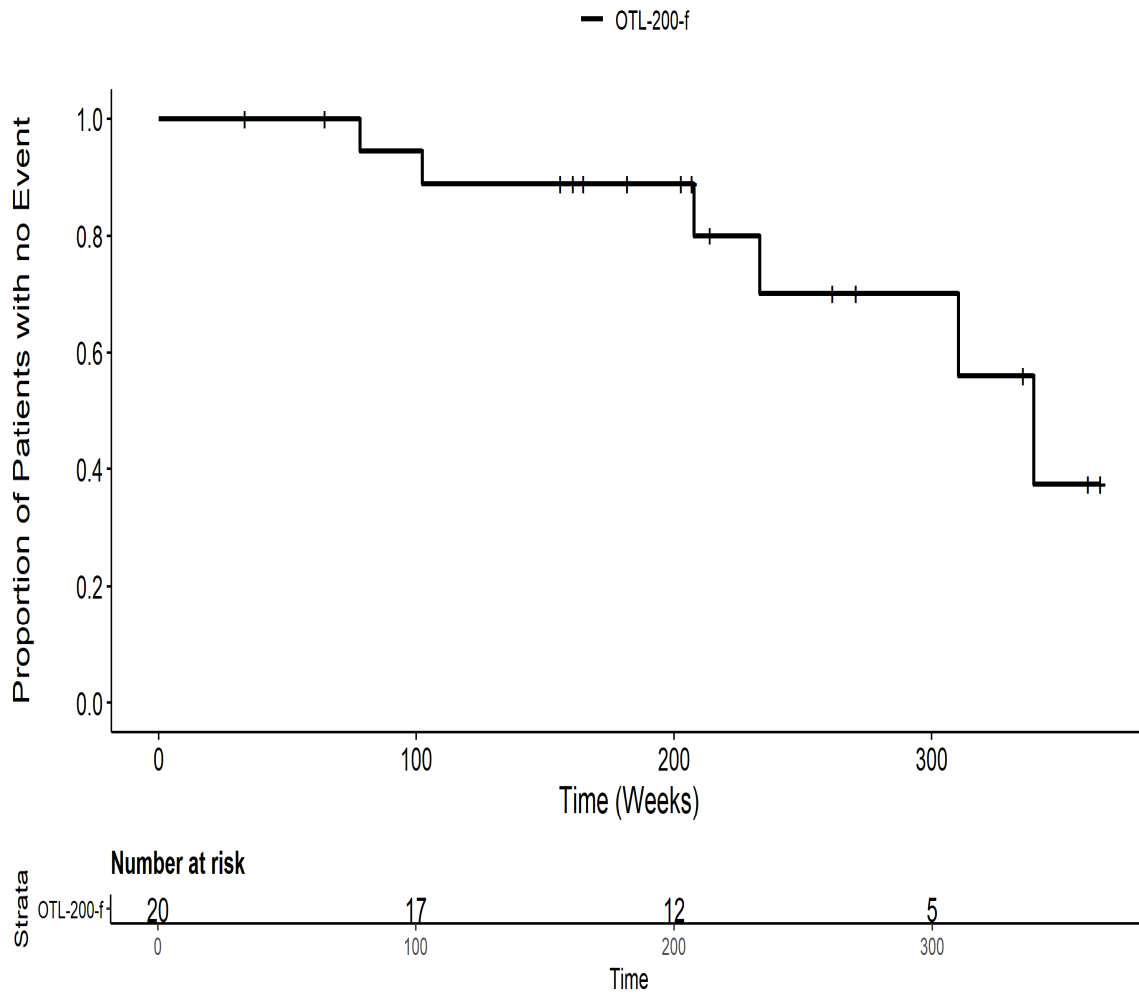
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PT pct Erniedrigter BMIITT



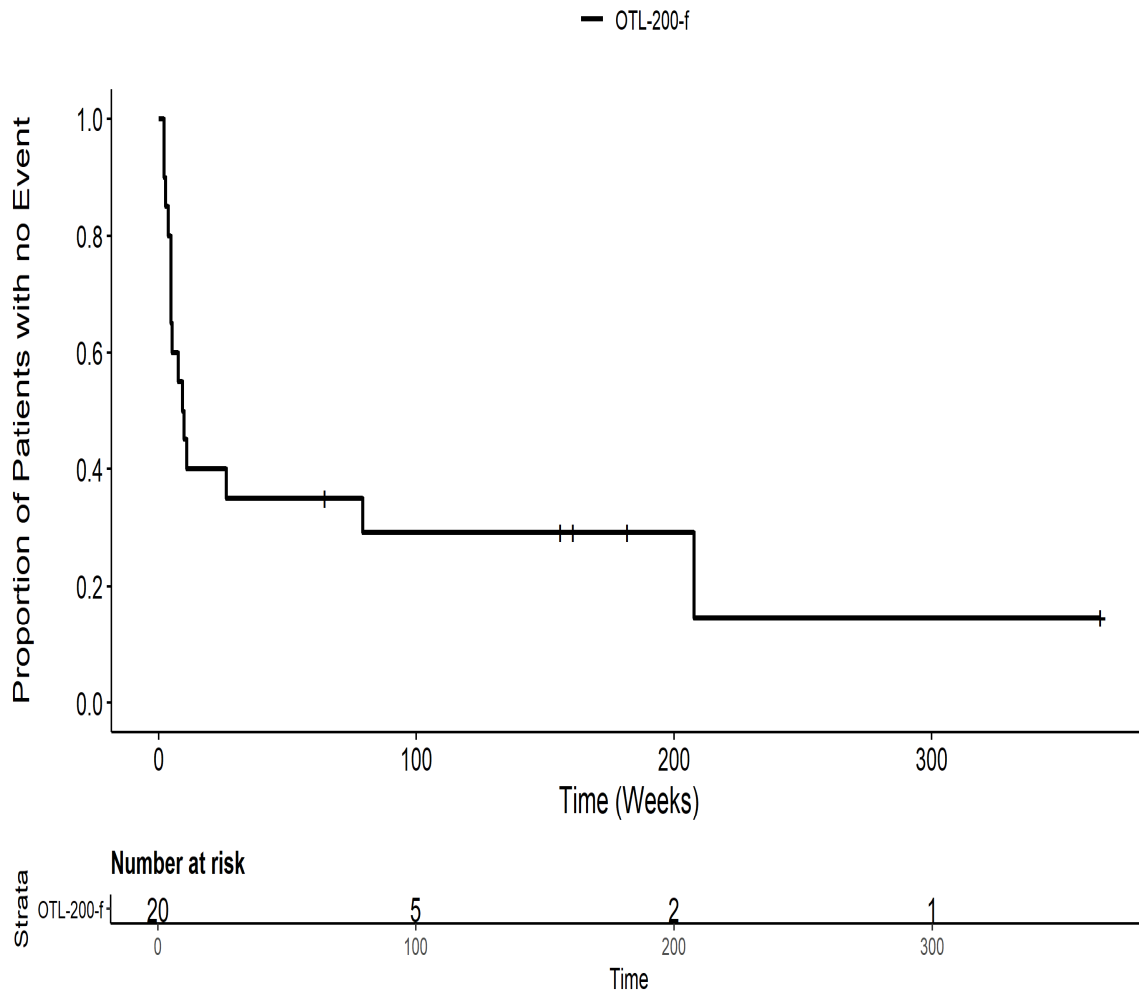
201222: Kaplan Meier Plot for Time to all AE by SOC Untersuchungen
PT pct Gesamt SOCITT



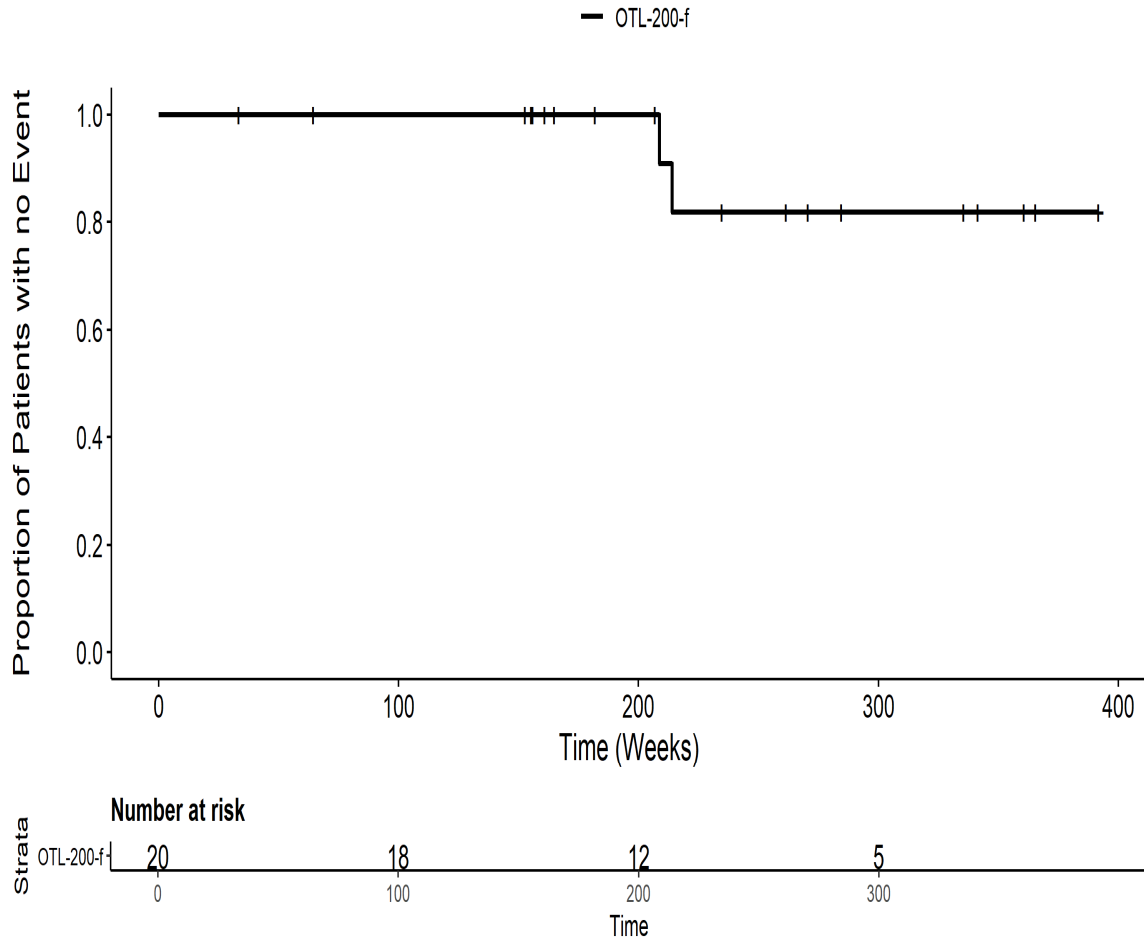
201222: Kaplan Meier Plot for Time to all AE by SOC Untersuchungen
PT pct Vitamin D erniedrigtITT



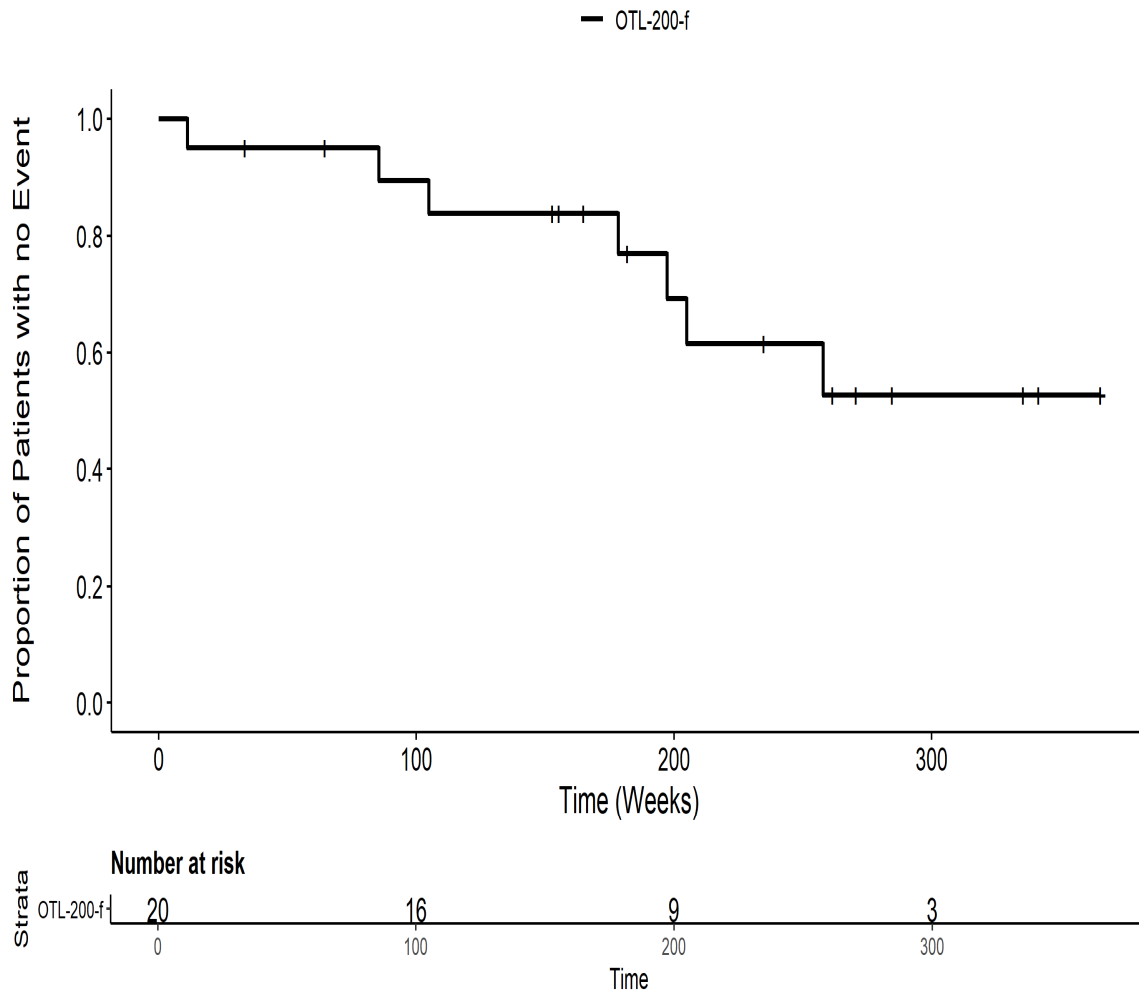
201222: Kaplan Meier Plot for Time to all AE by SOC Untersuchungen
PT pts Gesamt SOC ITT



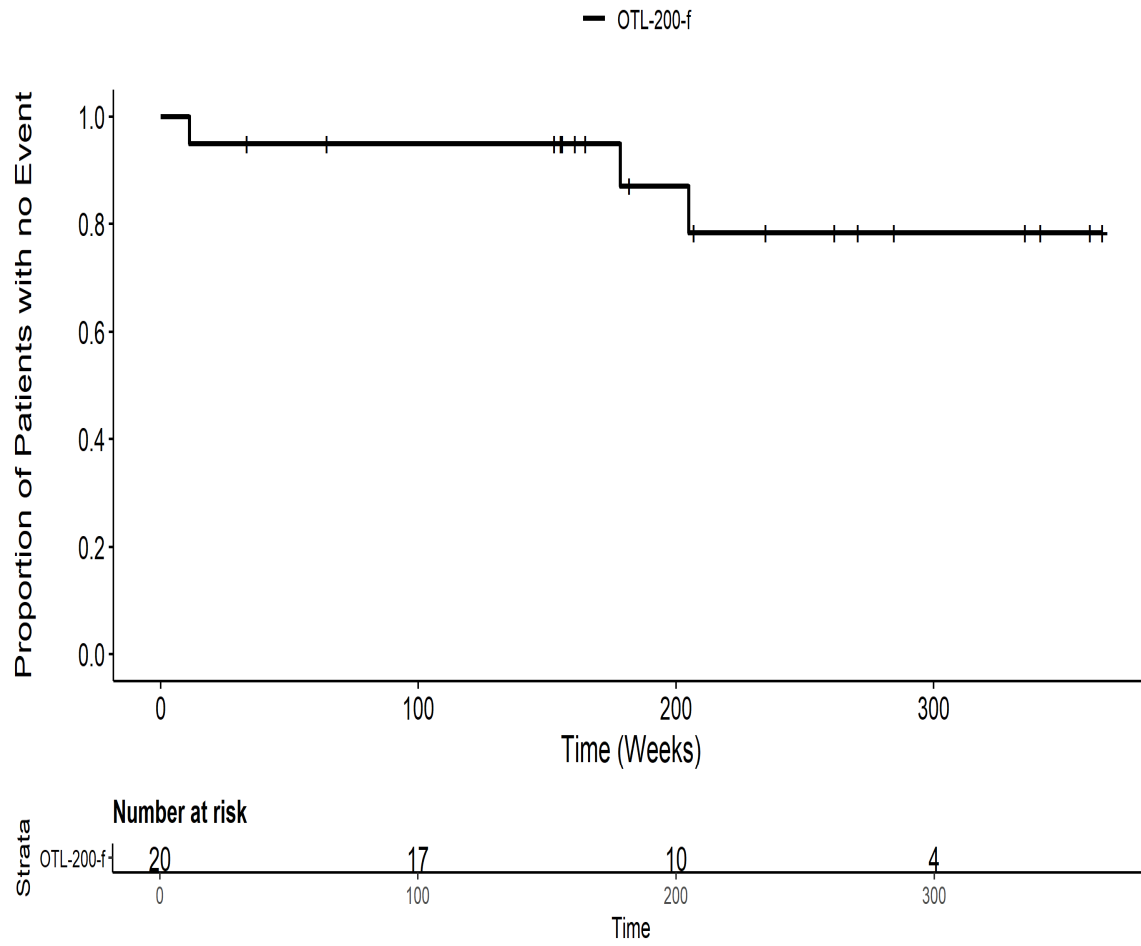
201222: Kaplan Meier Plot for Time to all AE by SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen PT pct Fraktur des FussesITT



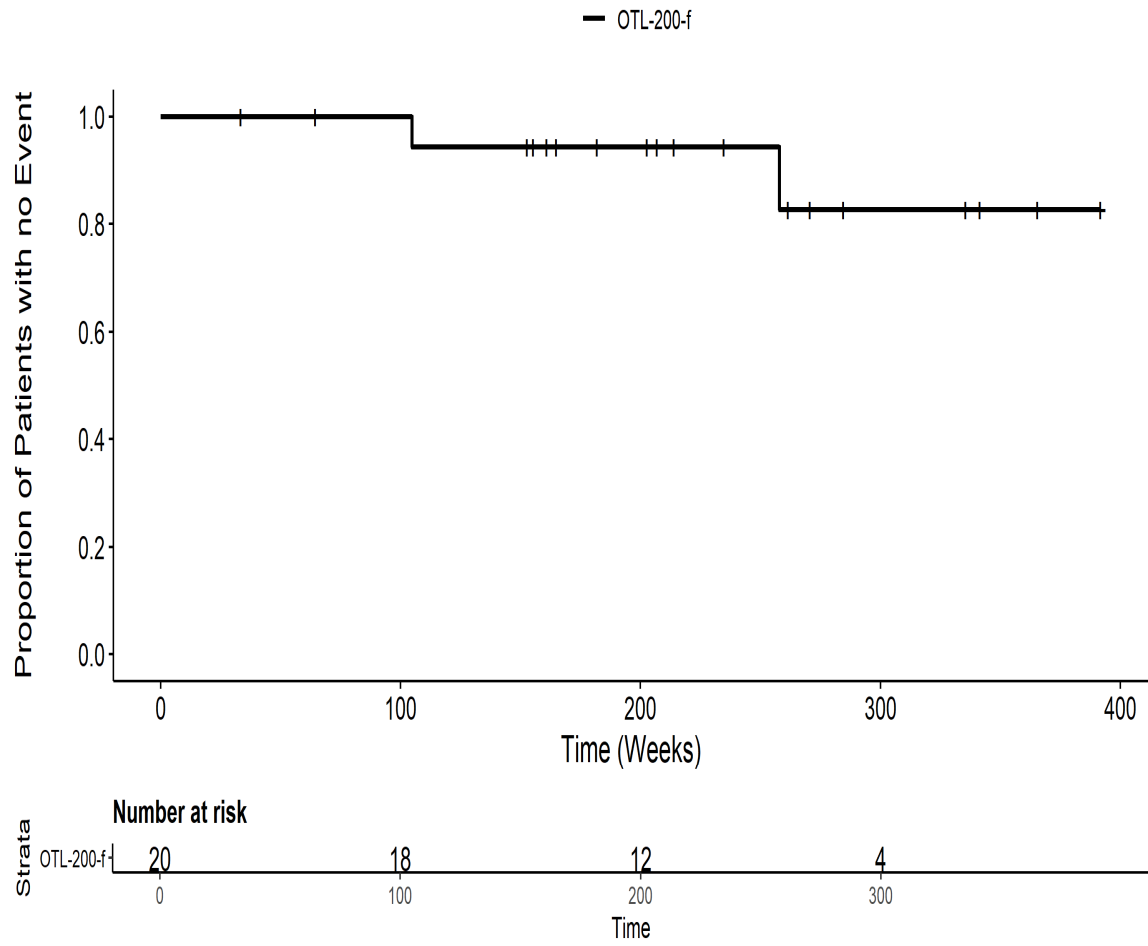
201222: Kaplan Meier Plot for Time to all AE by SOC Verletzung,
Vergiftung und durch Eingriffe bedingte Komplikationen PT pct Gesamt SOCITT



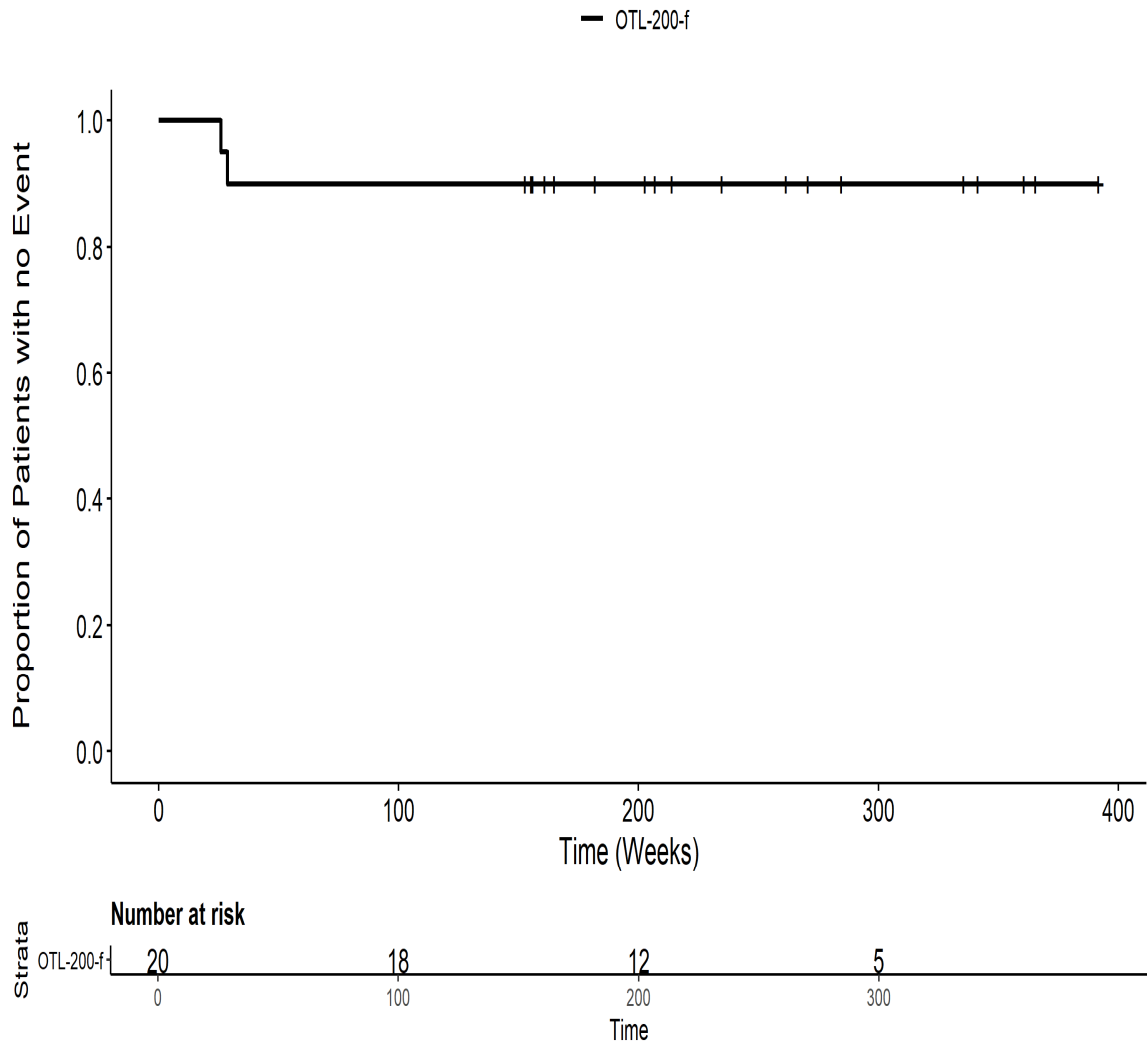
201222: Kaplan Meier Plot for Time to all AE by SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen PT pct KopfverletzungITT



201222: Kaplan Meier Plot for Time to all AE by SOC Verletzung,
 Vergiftung und durch Eingriffe bedingte Komplikationen PT pct Schmerzen
 waehrend eines EingriffesITT

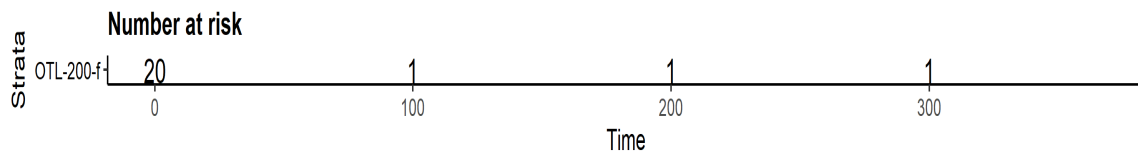
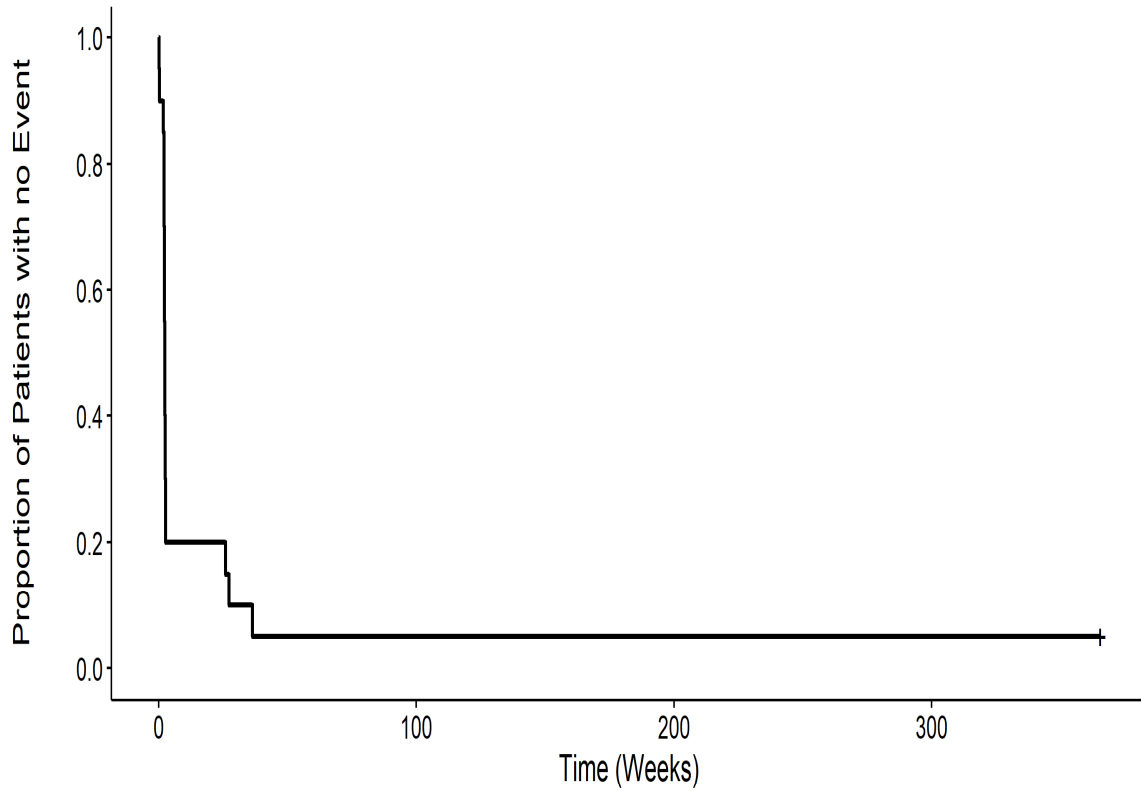


201222: Kaplan Meier Plot for Time to all AE death ITT

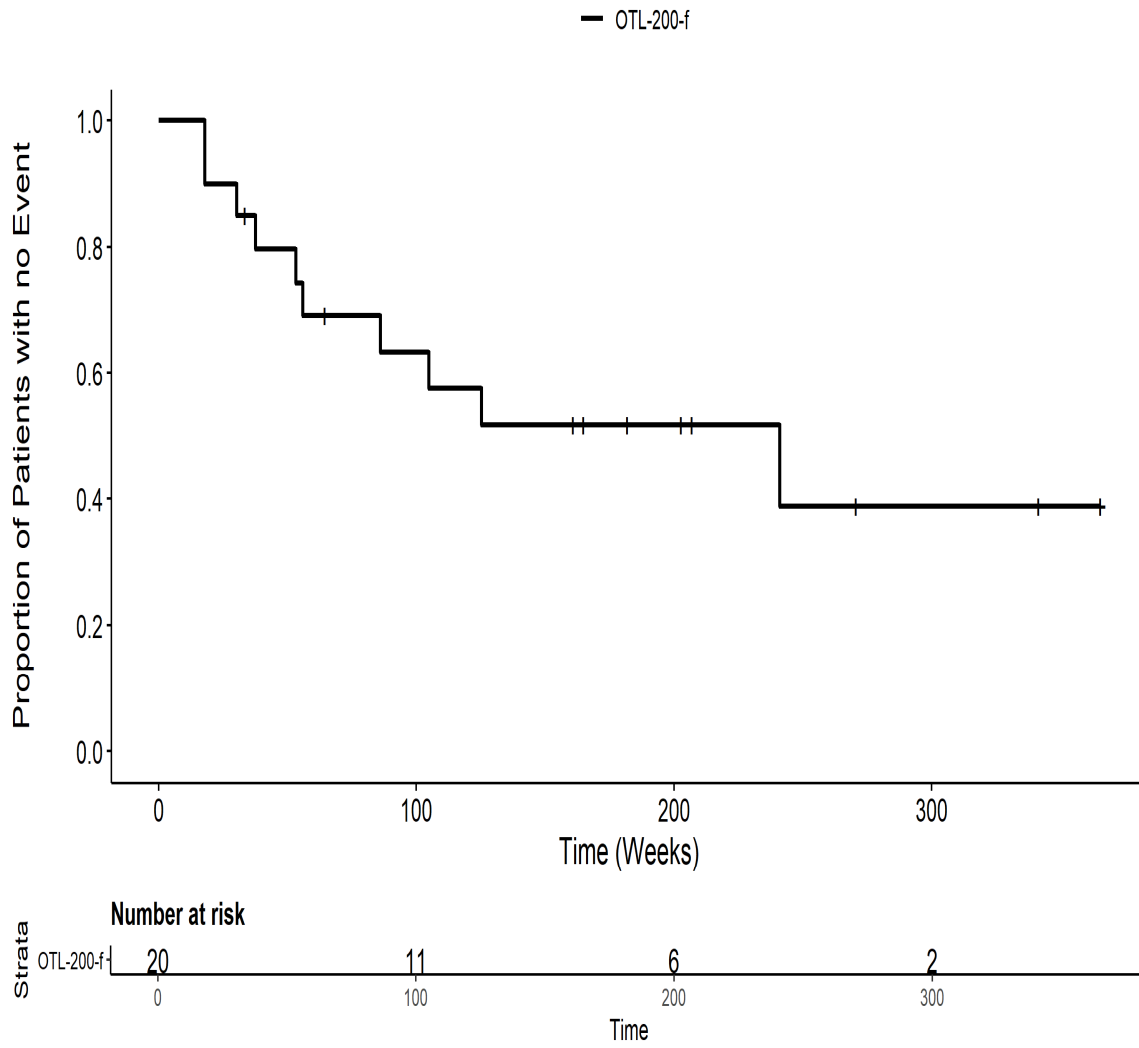


201222: Kaplan Meier Plot for Time to all AE SMQ ITT

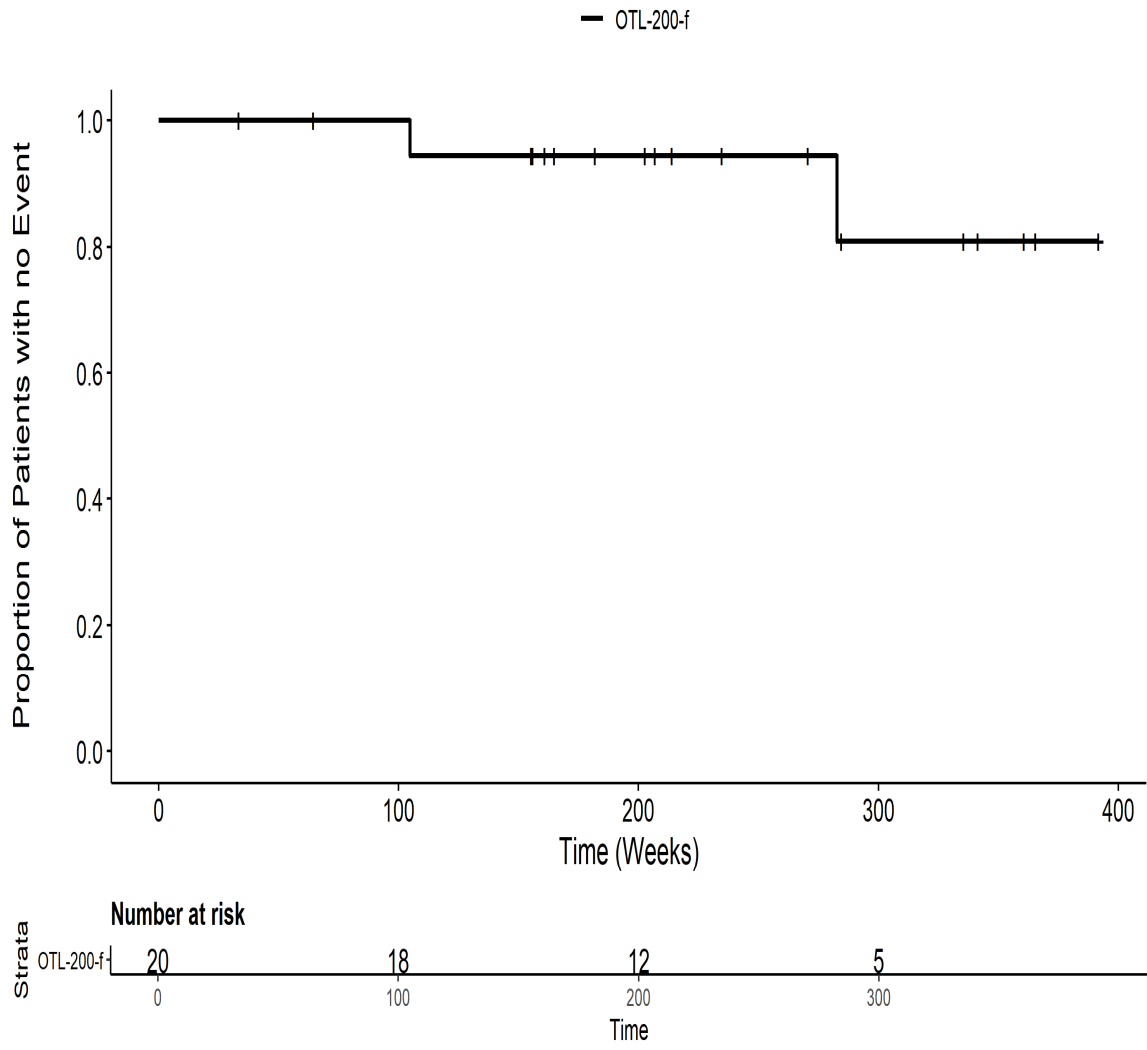
— OTL-200-f



201222: Kaplan Meier Plot for Time to hosp AE ITT

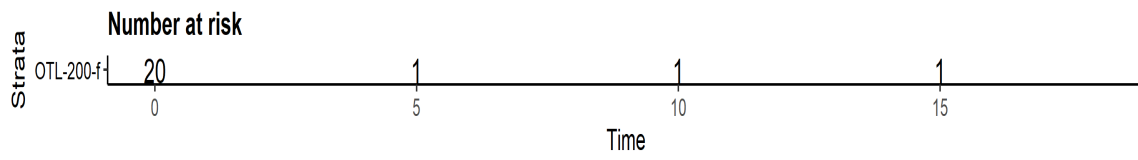
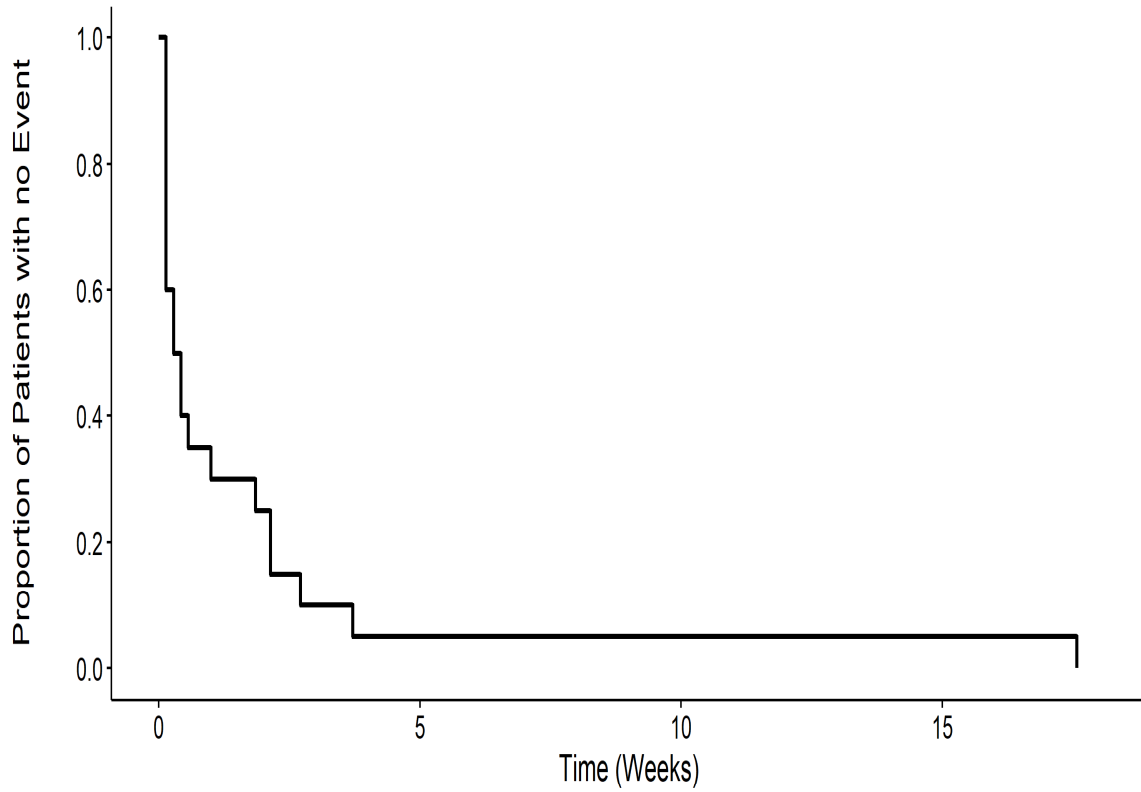


201222: Kaplan Meier Plot for Time to hosp AE SMQ ITT

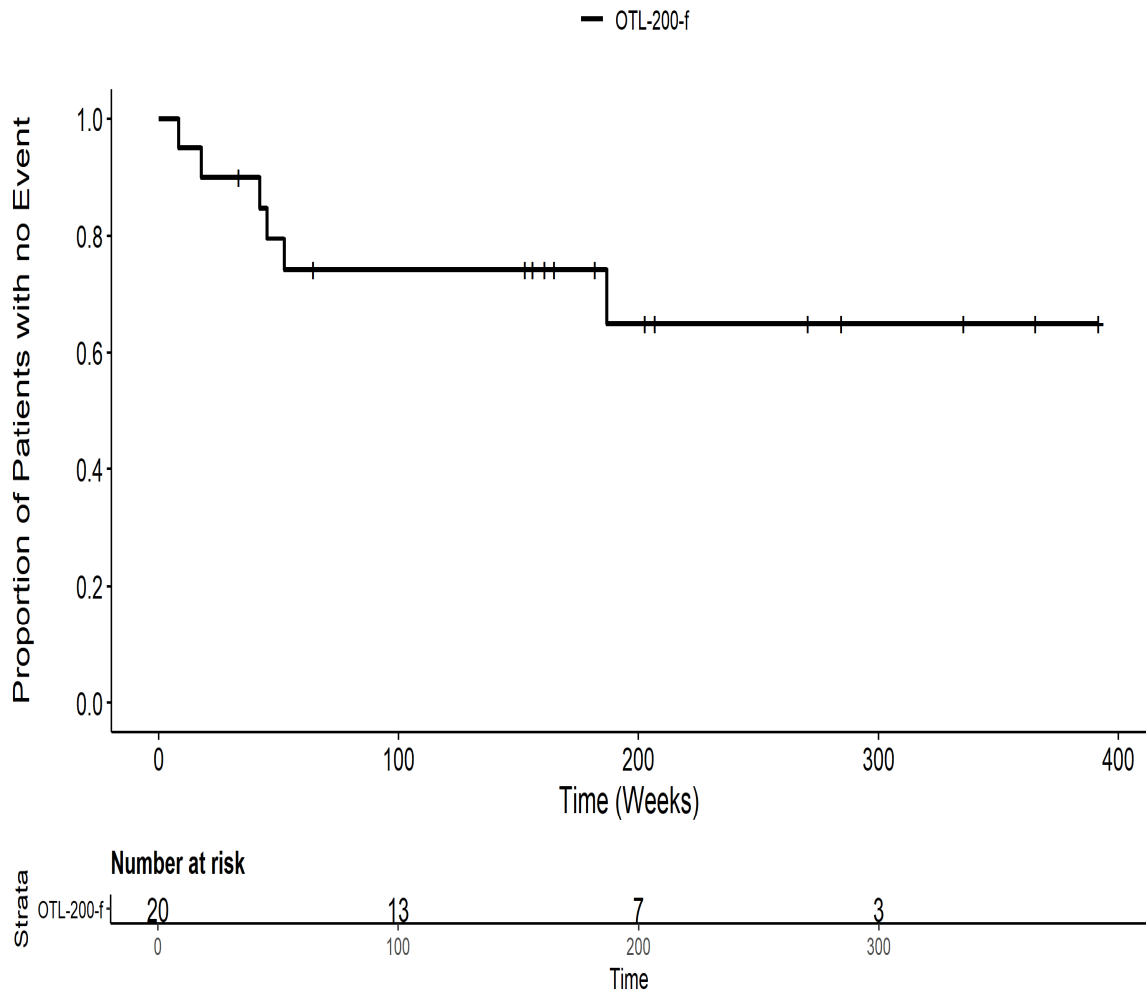


201222: Kaplan Meier Plot for Time to mild AE ITT

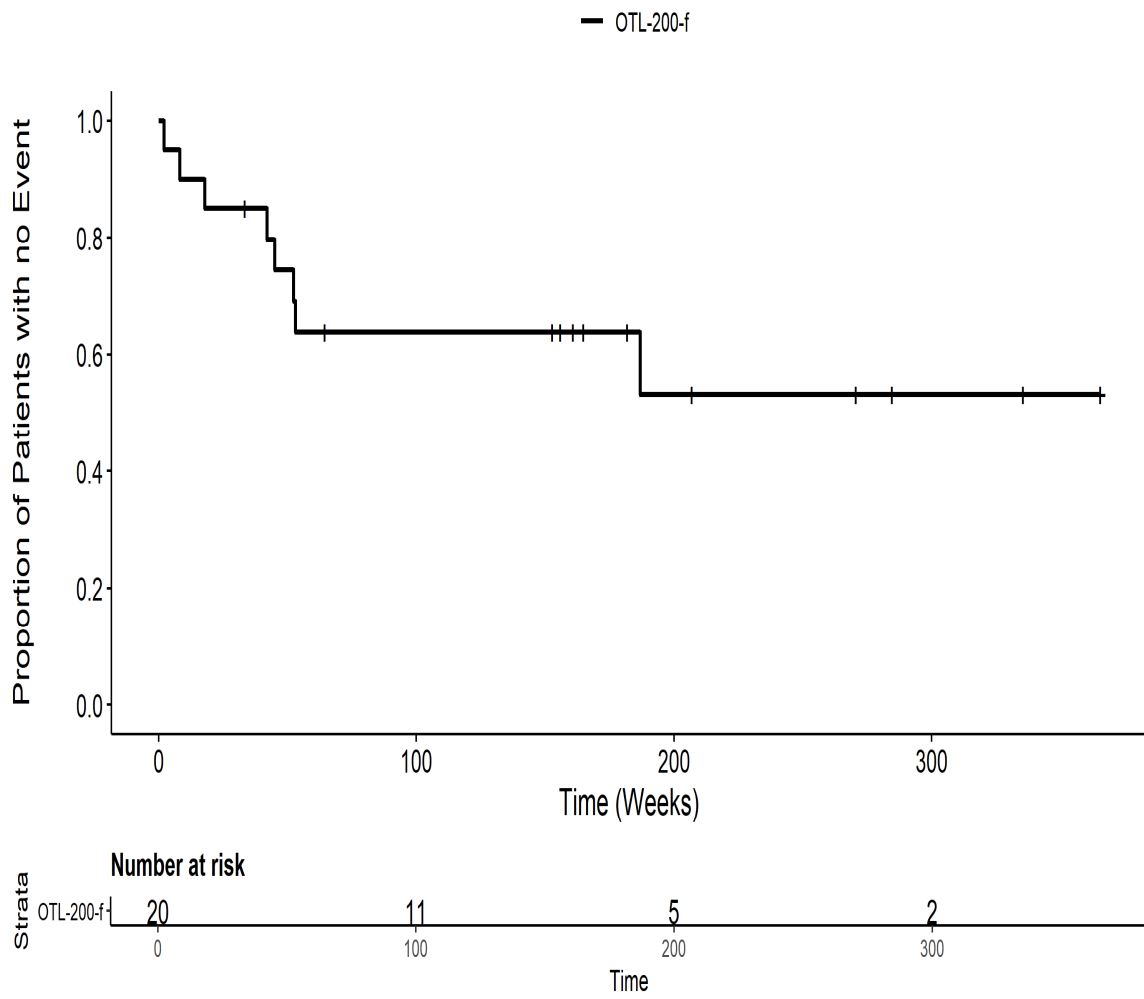
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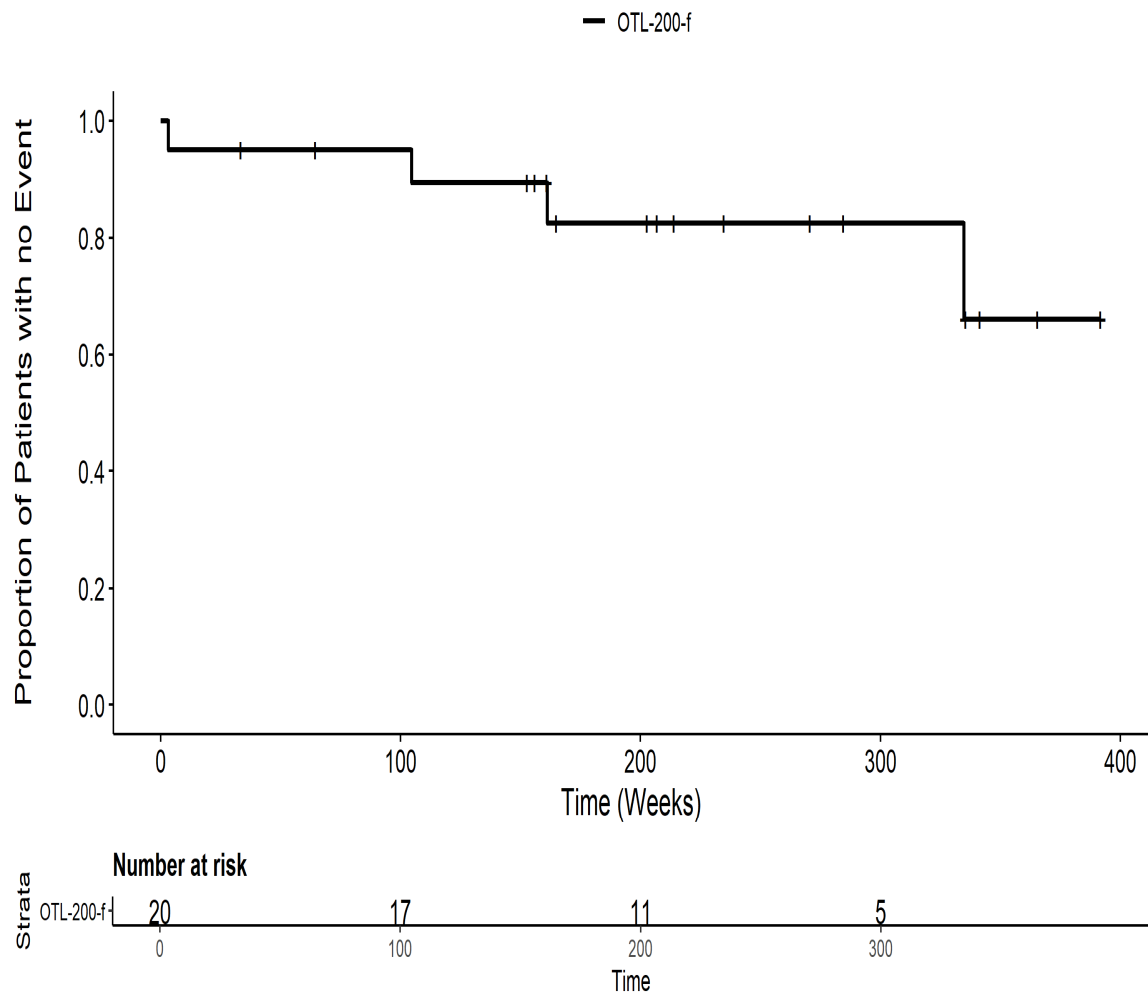
201222: Kaplan Meier Plot for Time to mild AE by SOC Allgemeine
Erkrankungen und Beschwerden am Verabreichungsort PT pct Fieber/TT



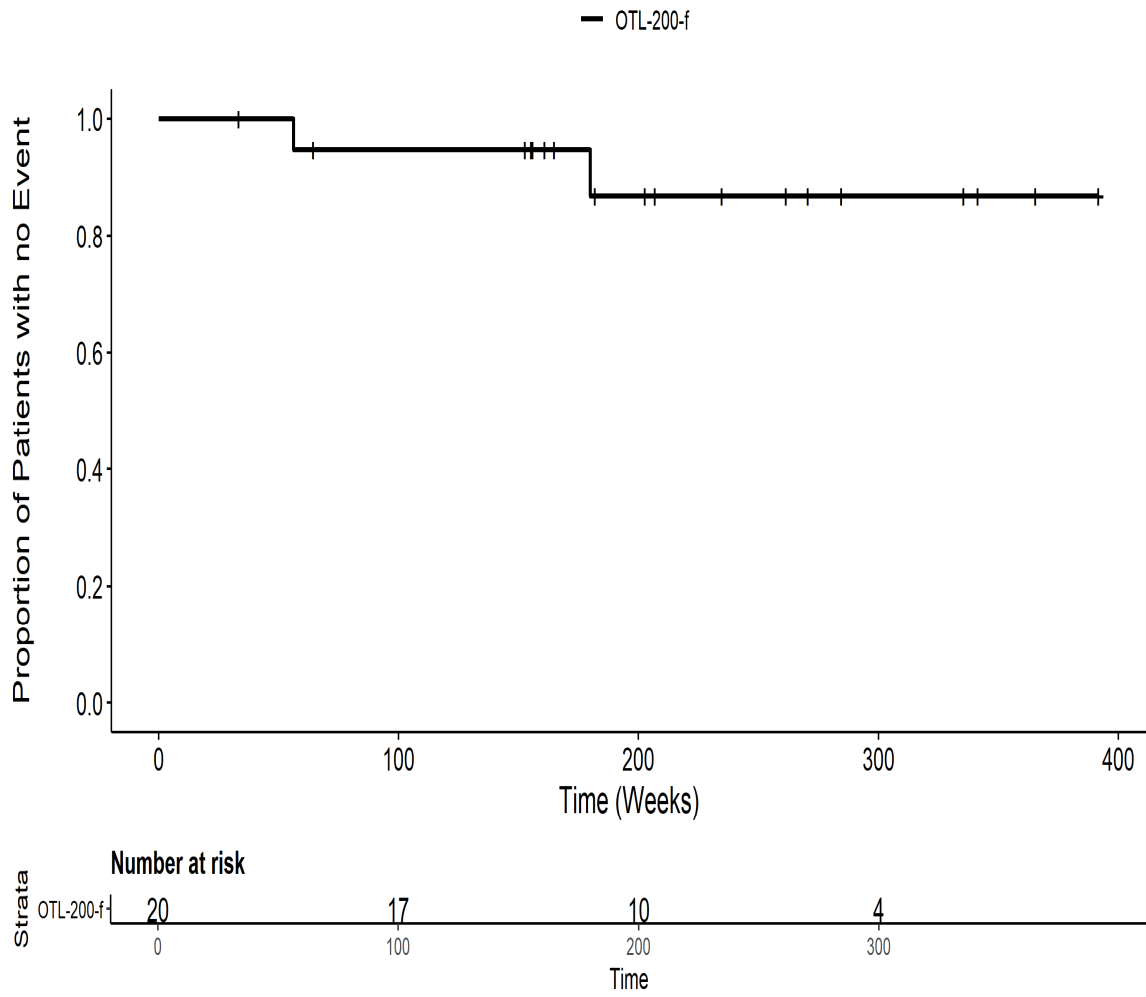
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Erkrankungen und Beschwerden am Verabreichungsort PT pct Gesamt SOCITT



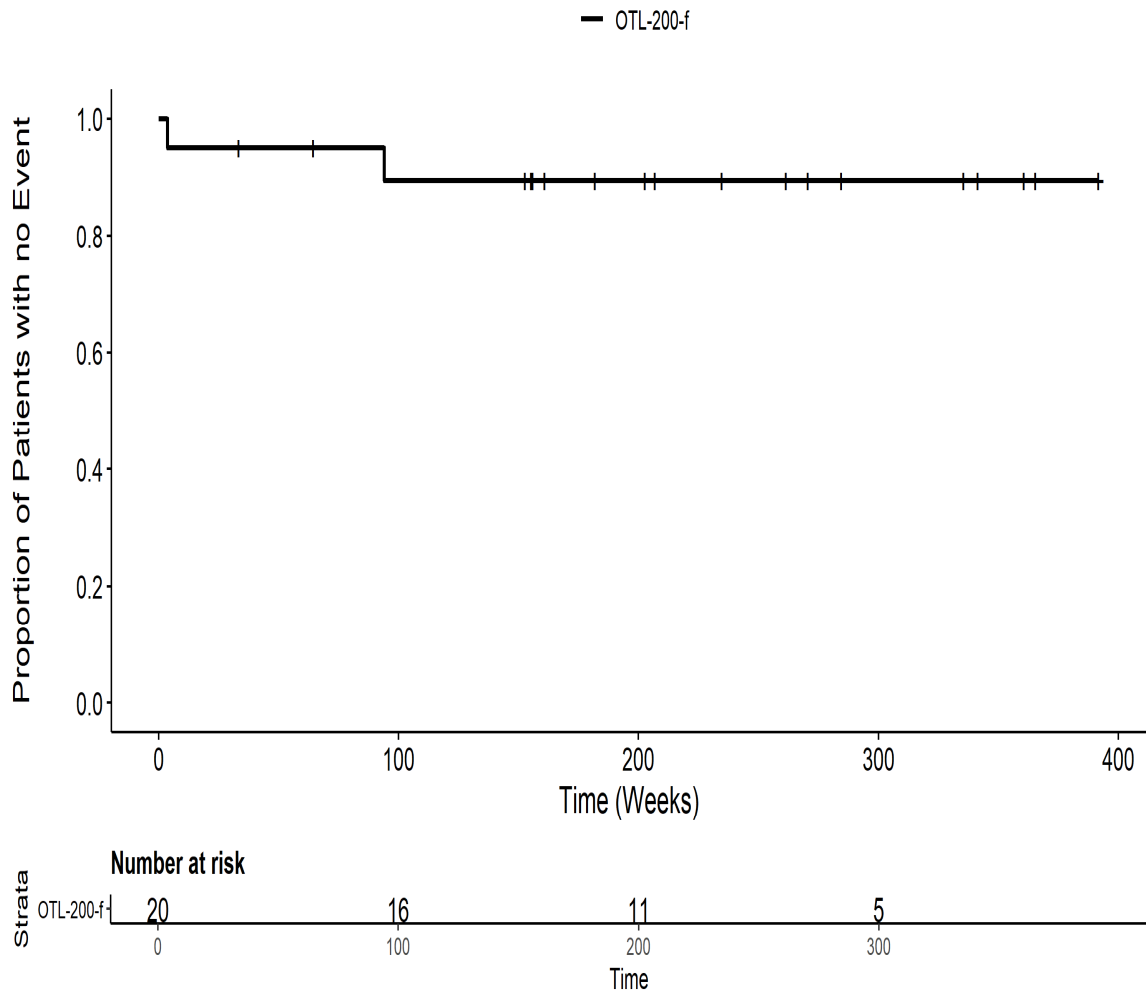
201222: Kaplan Meier Plot for Time to mild AE by SOC
Augenerkrankungen PT pct Gesamt SOCITT



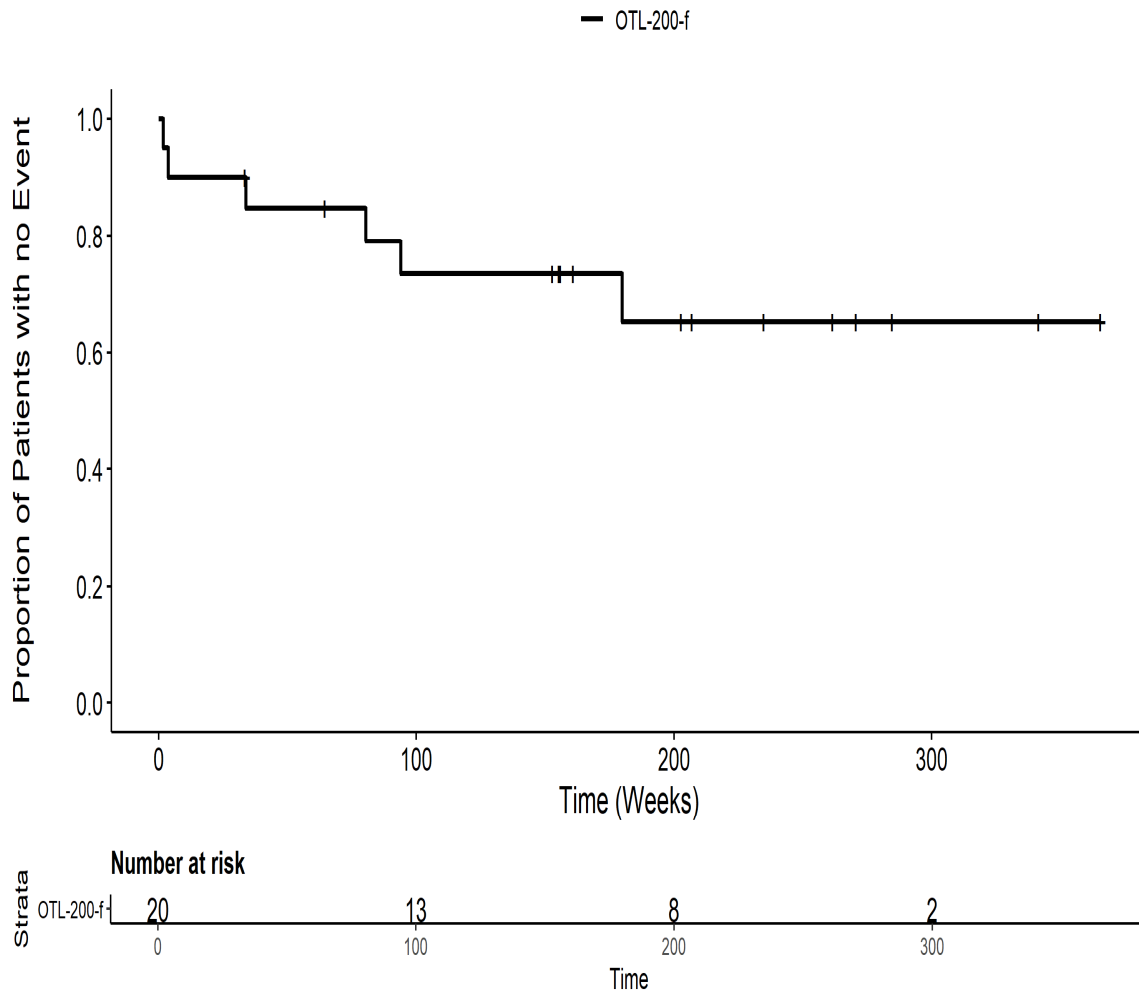
201222: Kaplan Meier Plot for Time to mild AE by SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums PT pct BronchospasmusITT



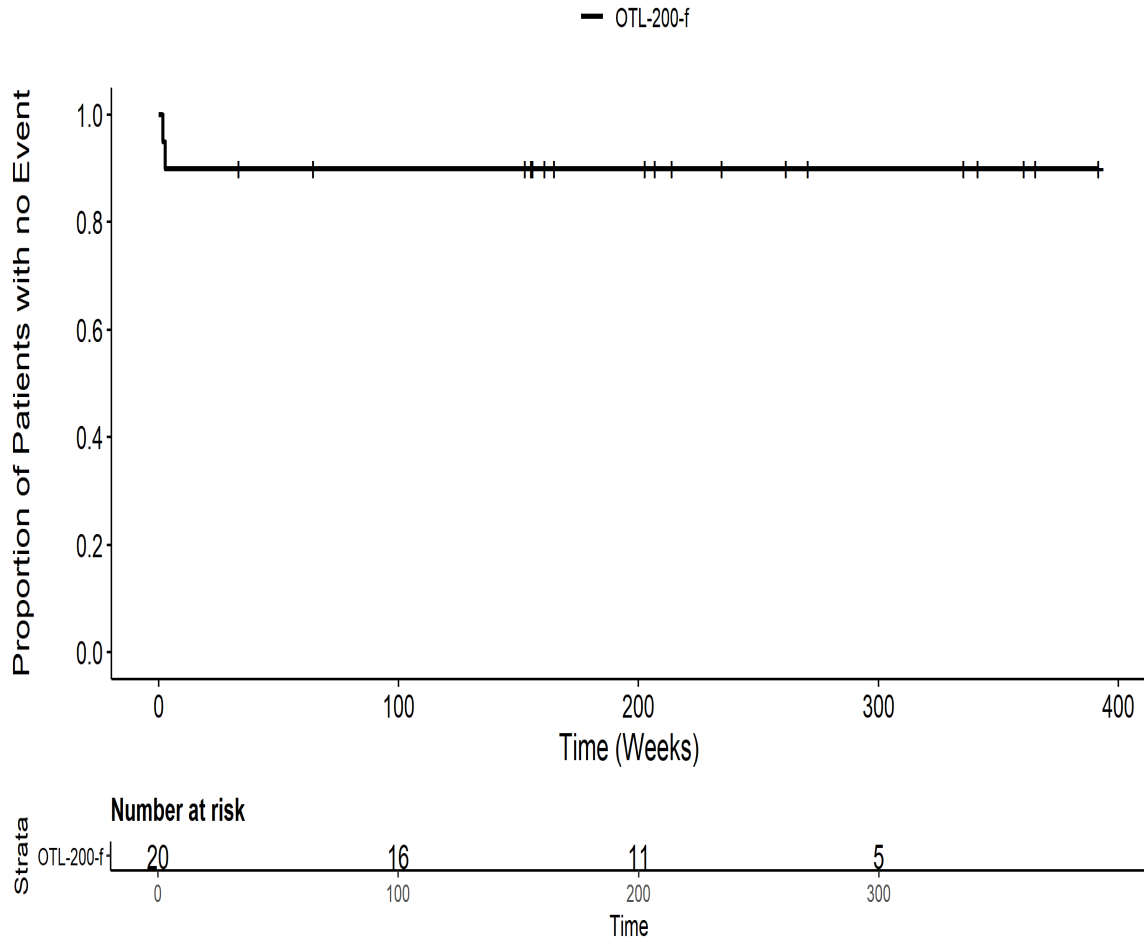
201222: Kaplan Meier Plot for Time to mild AE by SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums PT pct EpistaxisITT



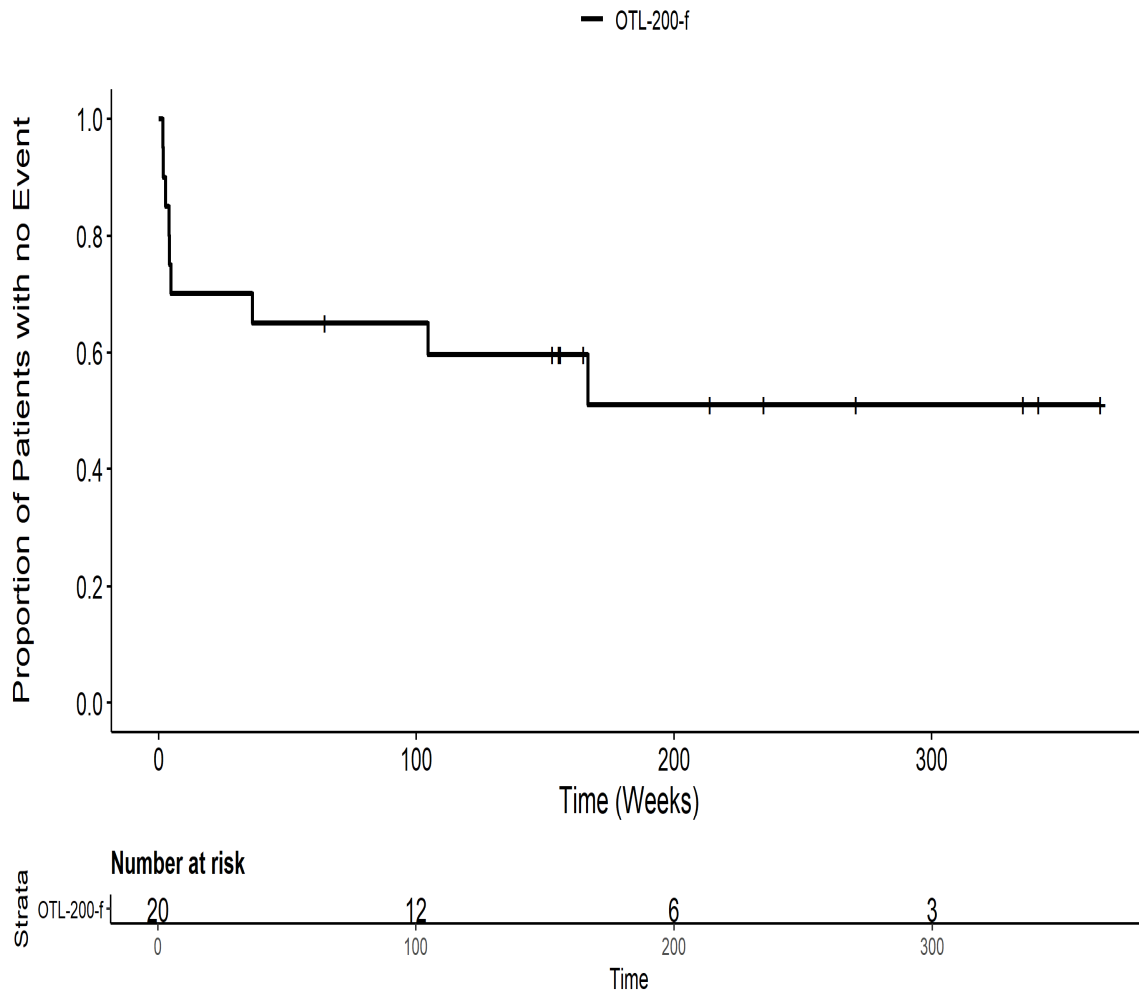
201222: Kaplan Meier Plot for Time to mild AE by SOC Erkrankungen der Atemwege, des Brustraums und Mediastinums PT pct Gesamt SOCITT



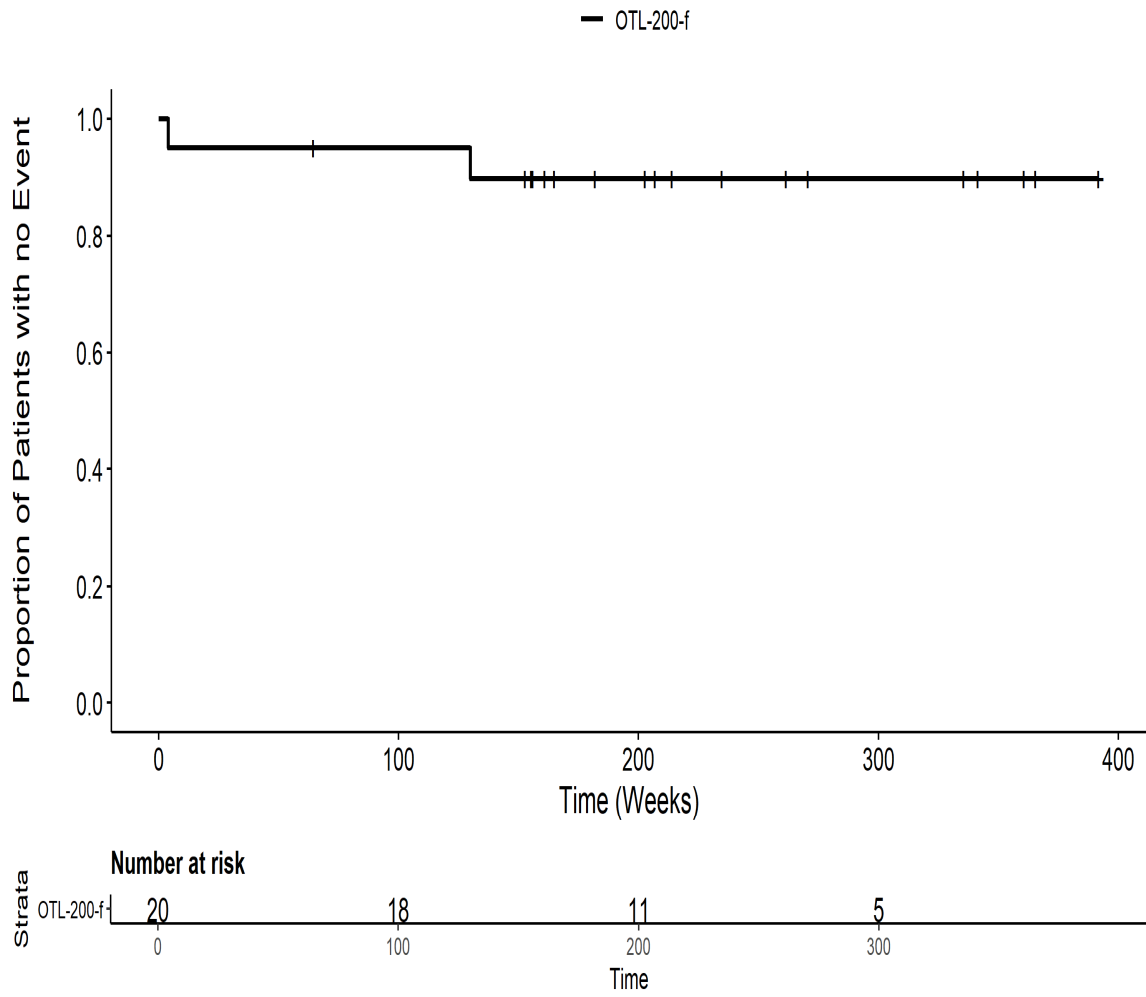
201222: Kaplan Meier Plot for Time to mild AE by SOC Erkrankungen
der Haut und des Unterhautzellgewebes PT pct Erythematoseser
HautausschlagITT



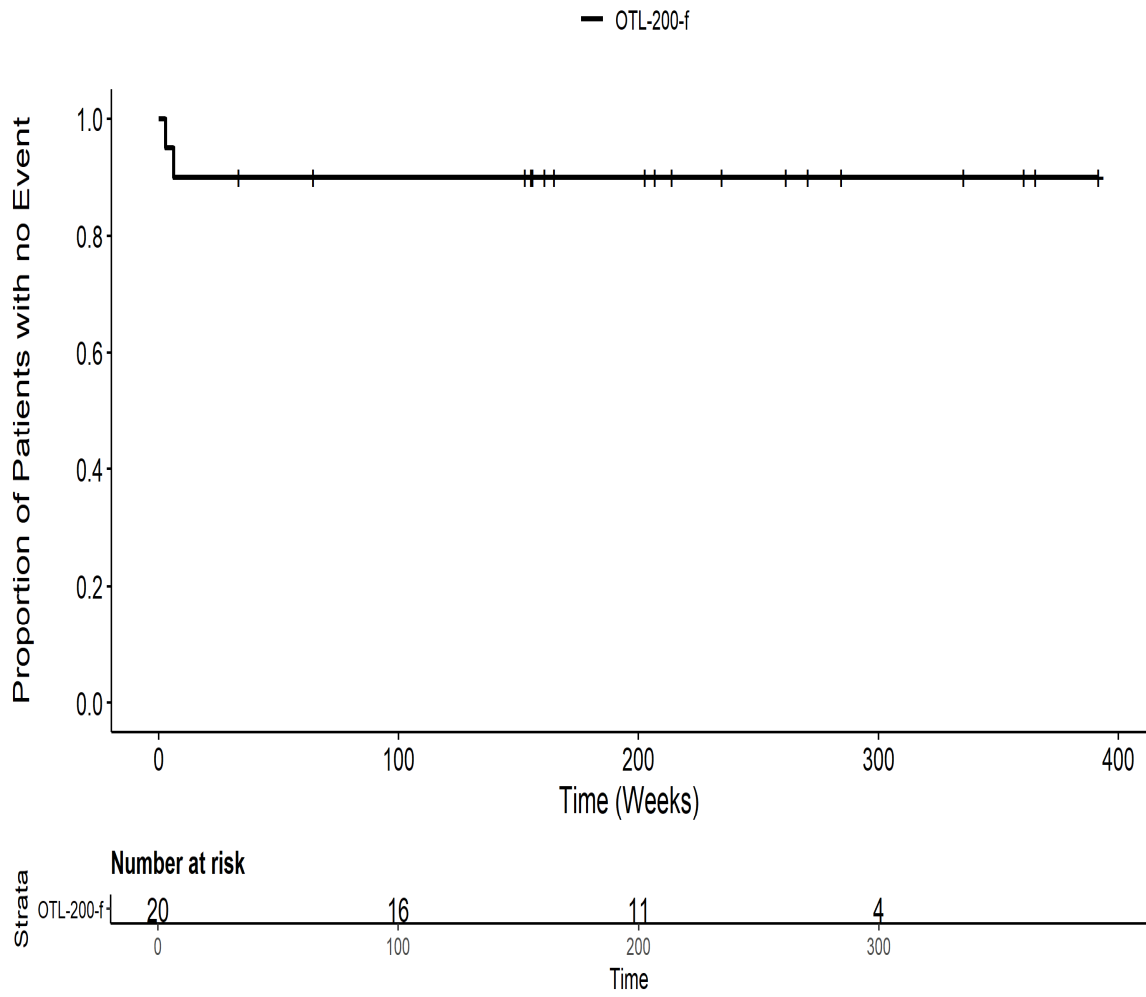
201222: Kaplan Meier Plot for Time to mild AE by SOC Erkrankungen der Haut und des Unterhautzellgewebes PT pct Gesamt SOCITT



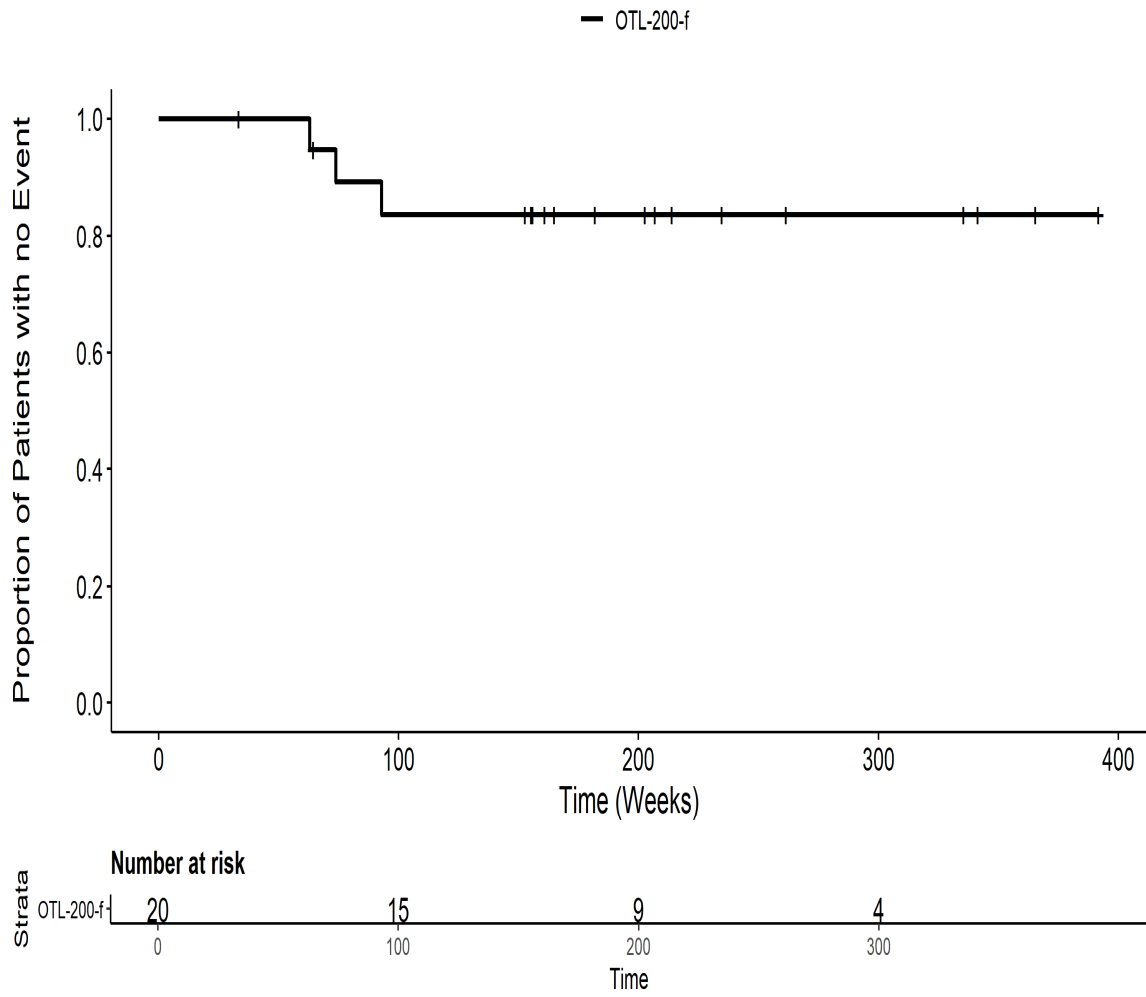
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der Haut und des Unterhautzellgewebes PT pct HautlaesionITT



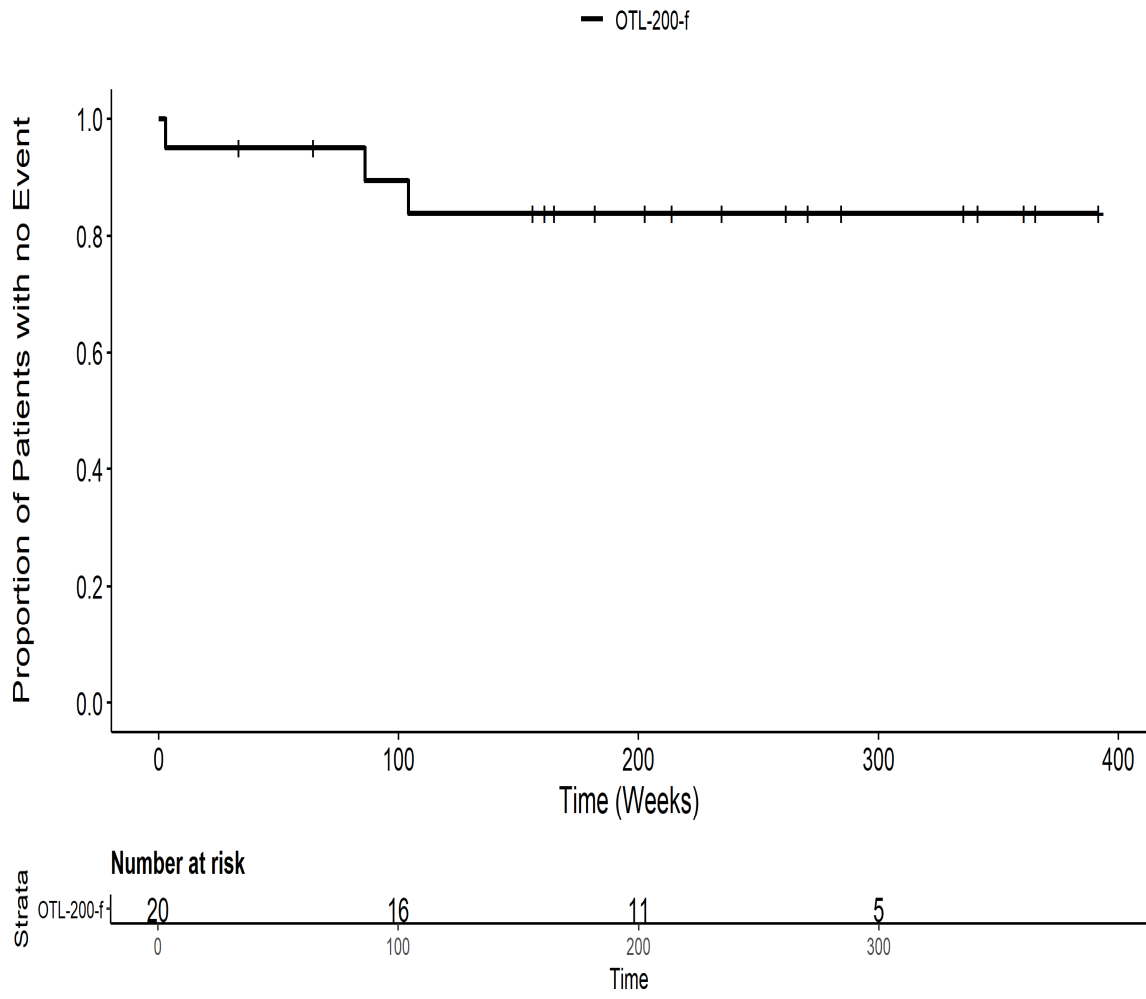
201222: Kaplan Meier Plot for Time to mild AE by SOC Erkrankungen der Nieren und Harnwege PT pct Gesamt SOCITT



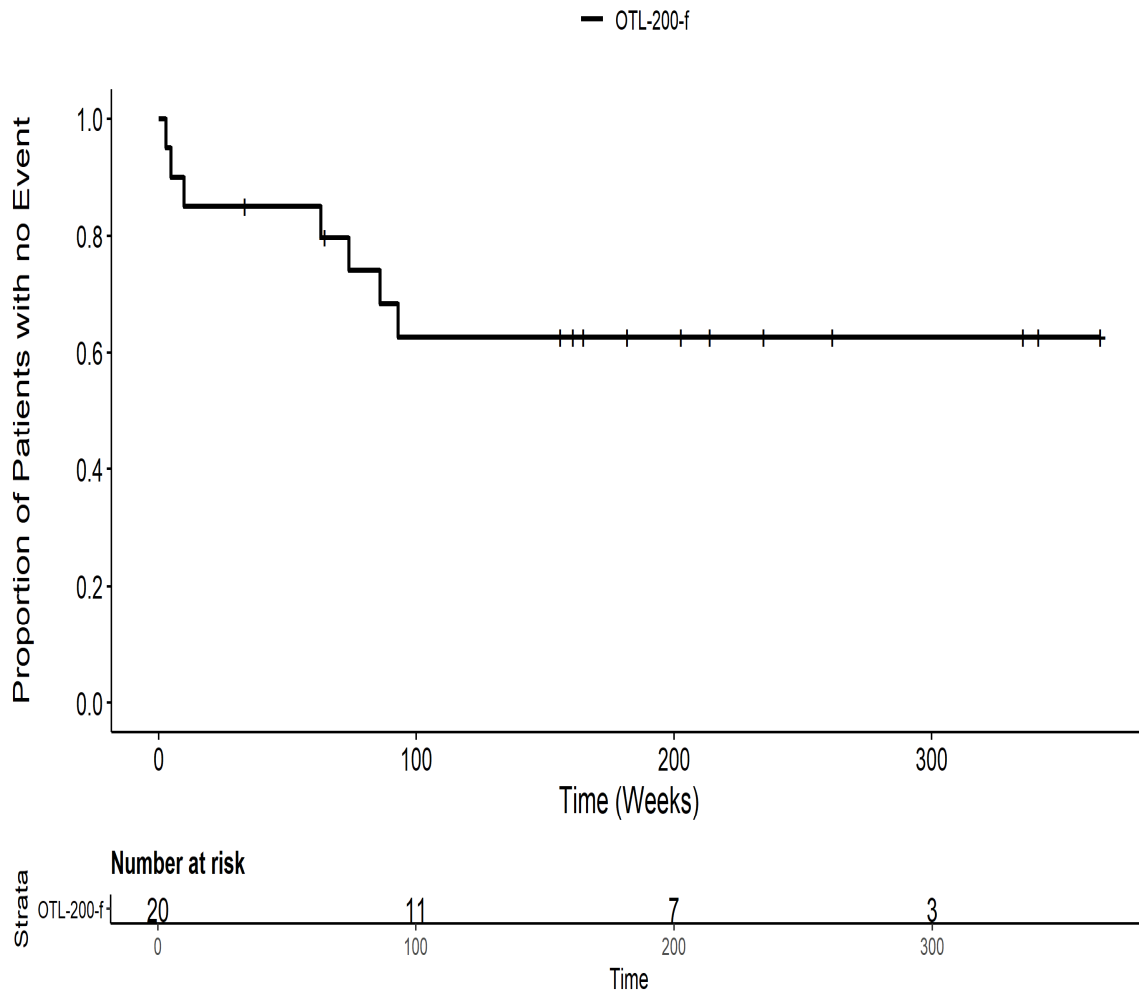
201222: Kaplan Meier Plot for Time to mild AE by SOC Erkrankungen des Gastrointestinaltrakts PT pct EnteritisITT



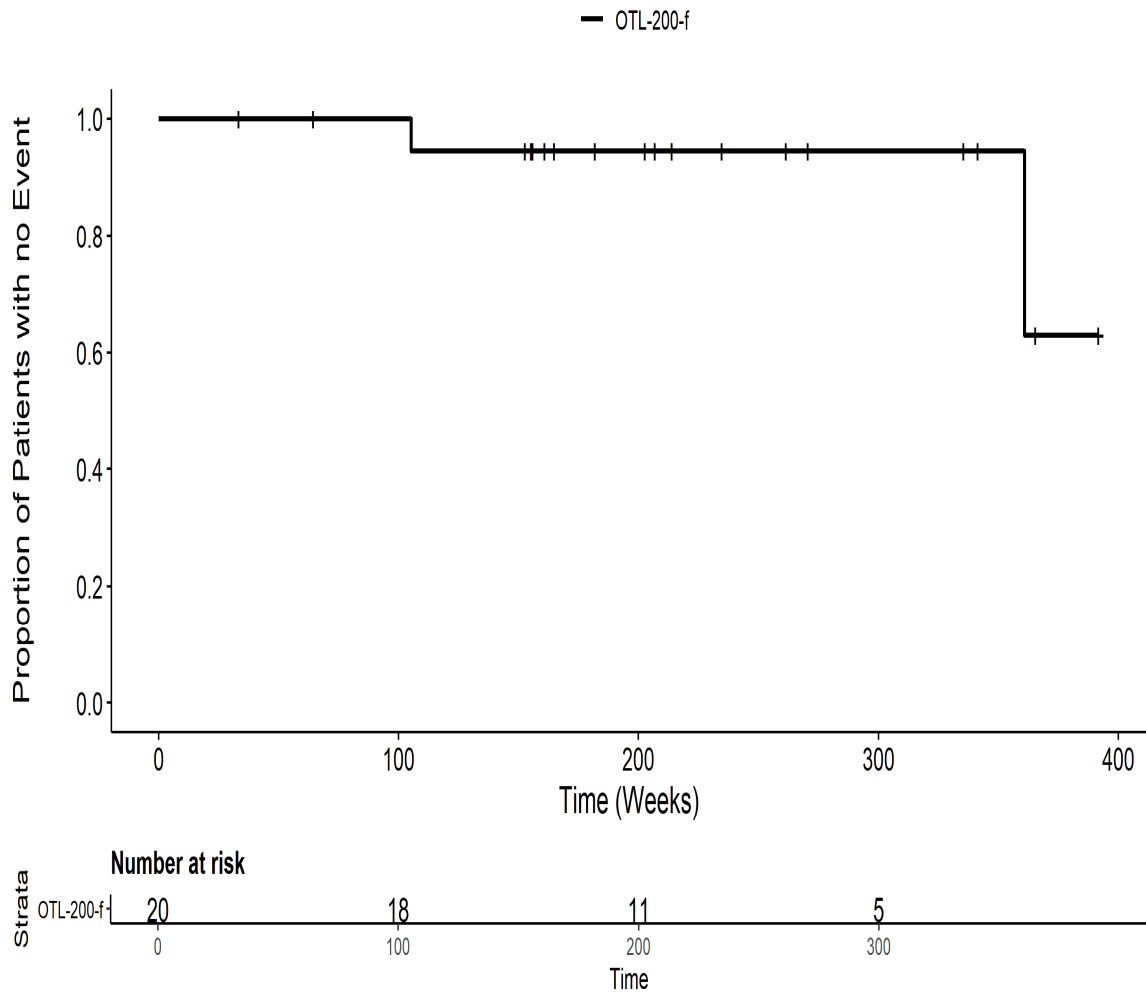
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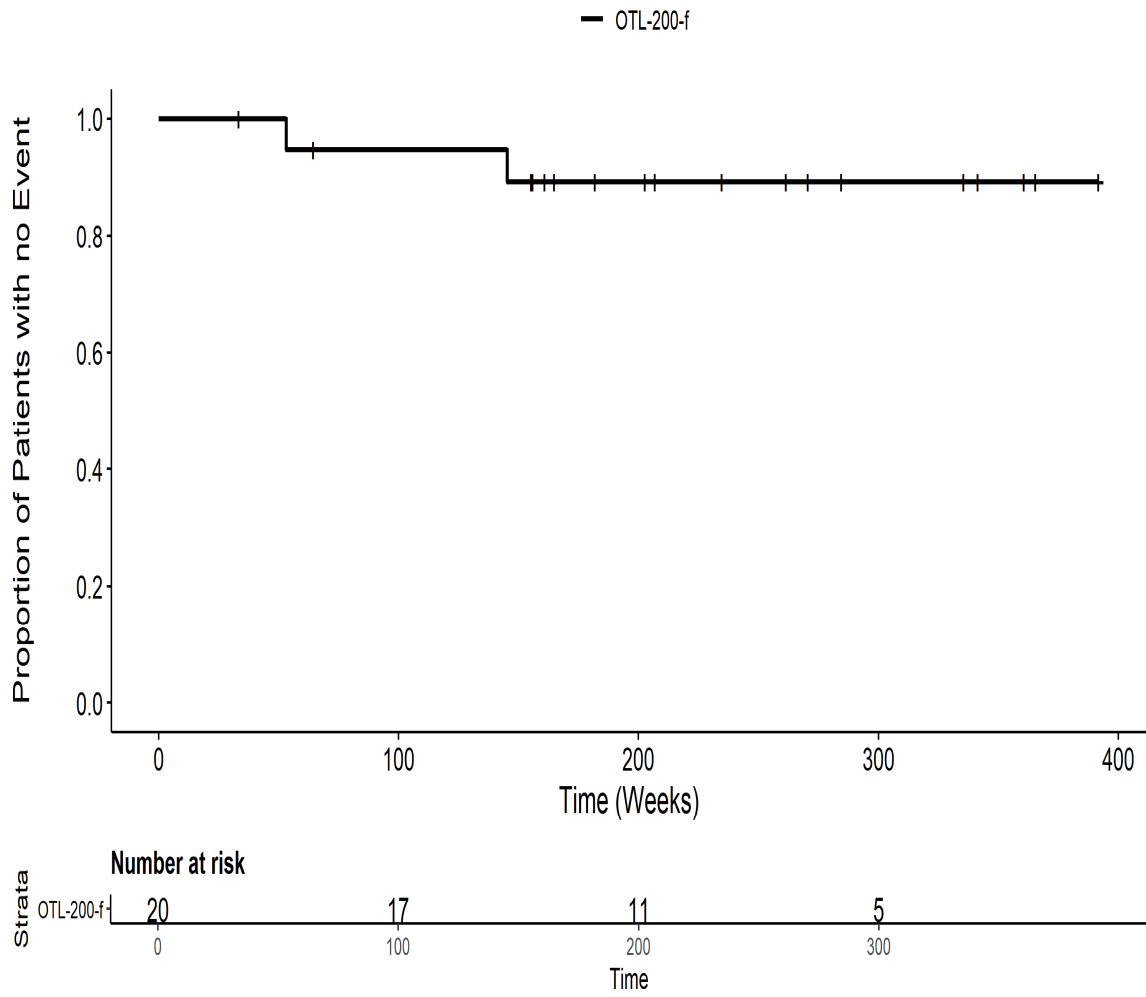
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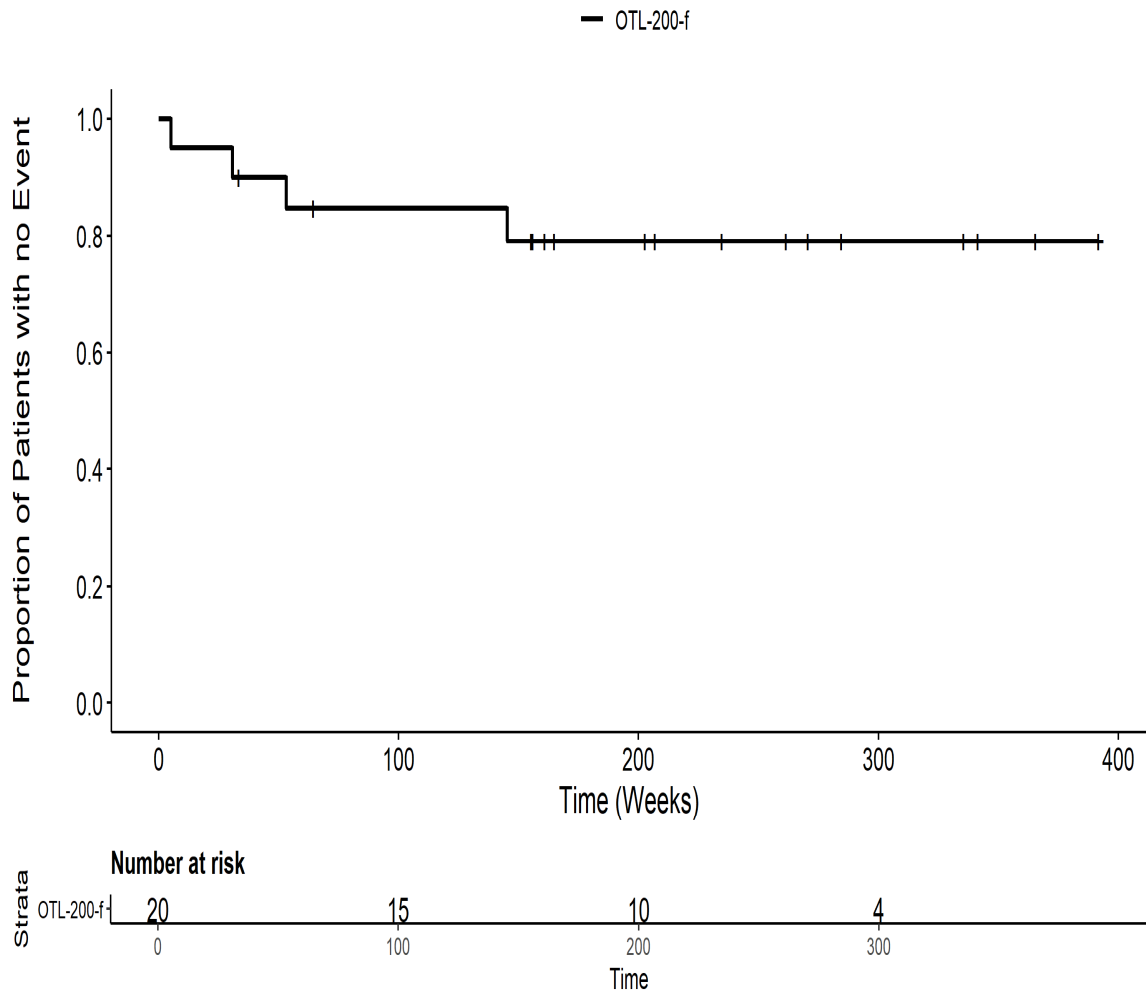
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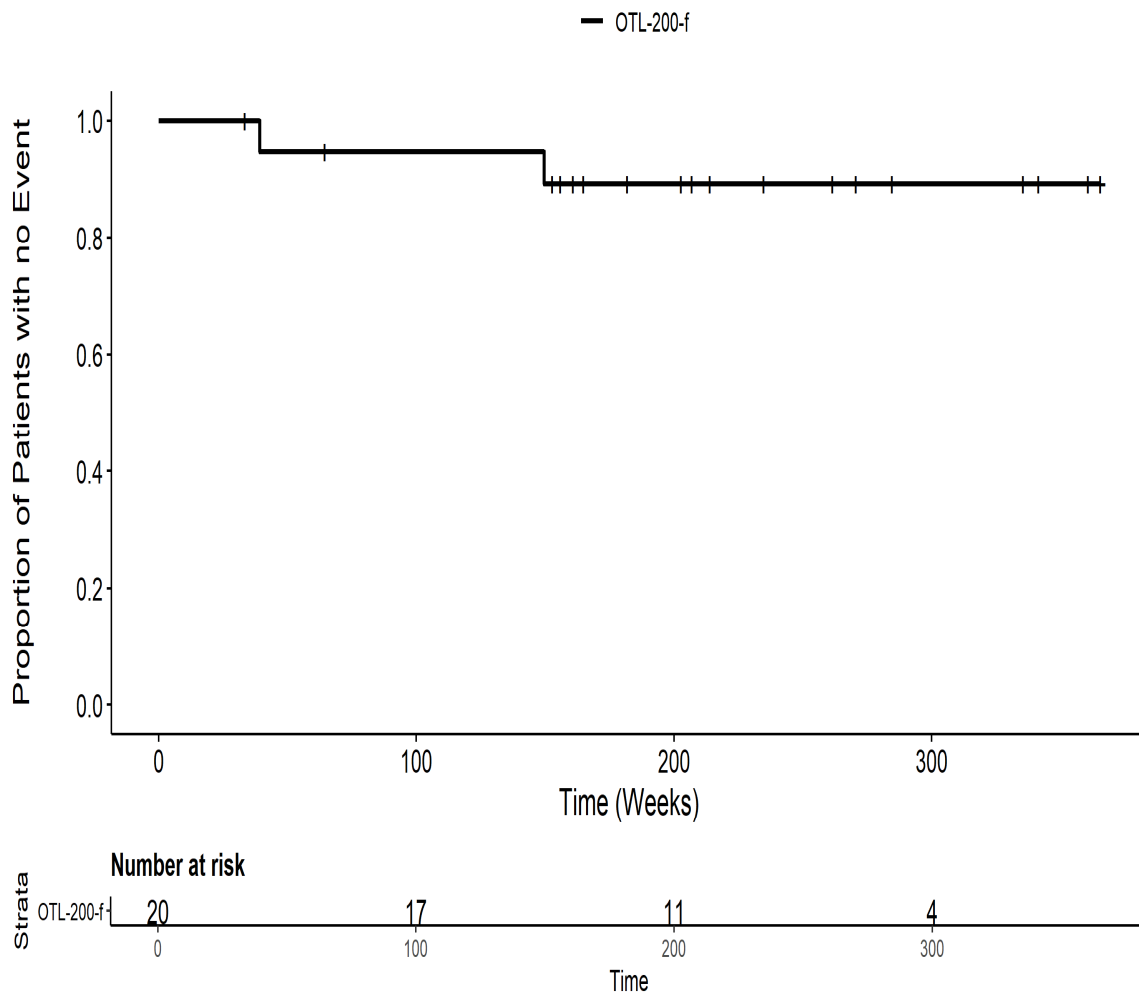
201222: Kaplan Meier Plot for Time to mild AE by SOC Erkrankungen des Nervensystems PT pct EpilepsieITT



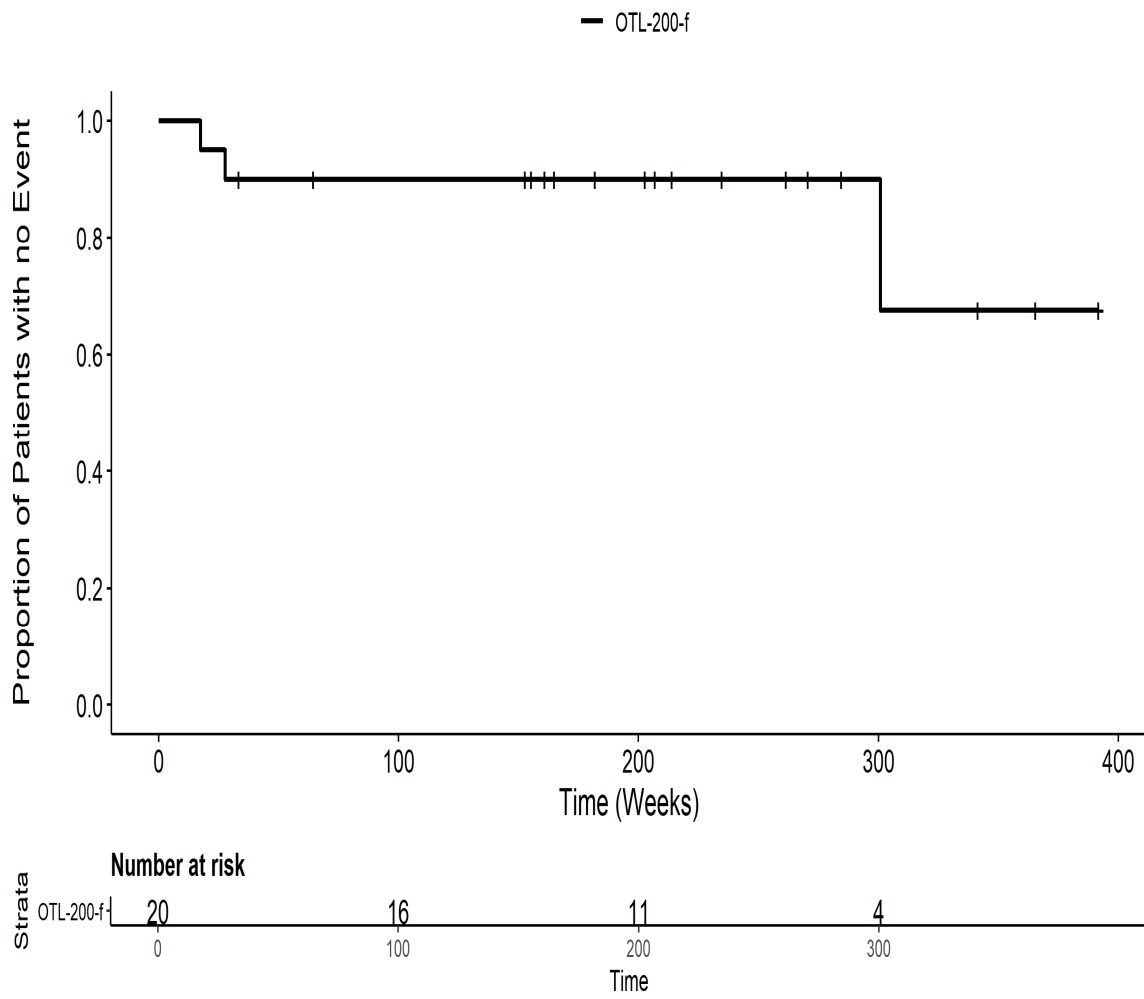
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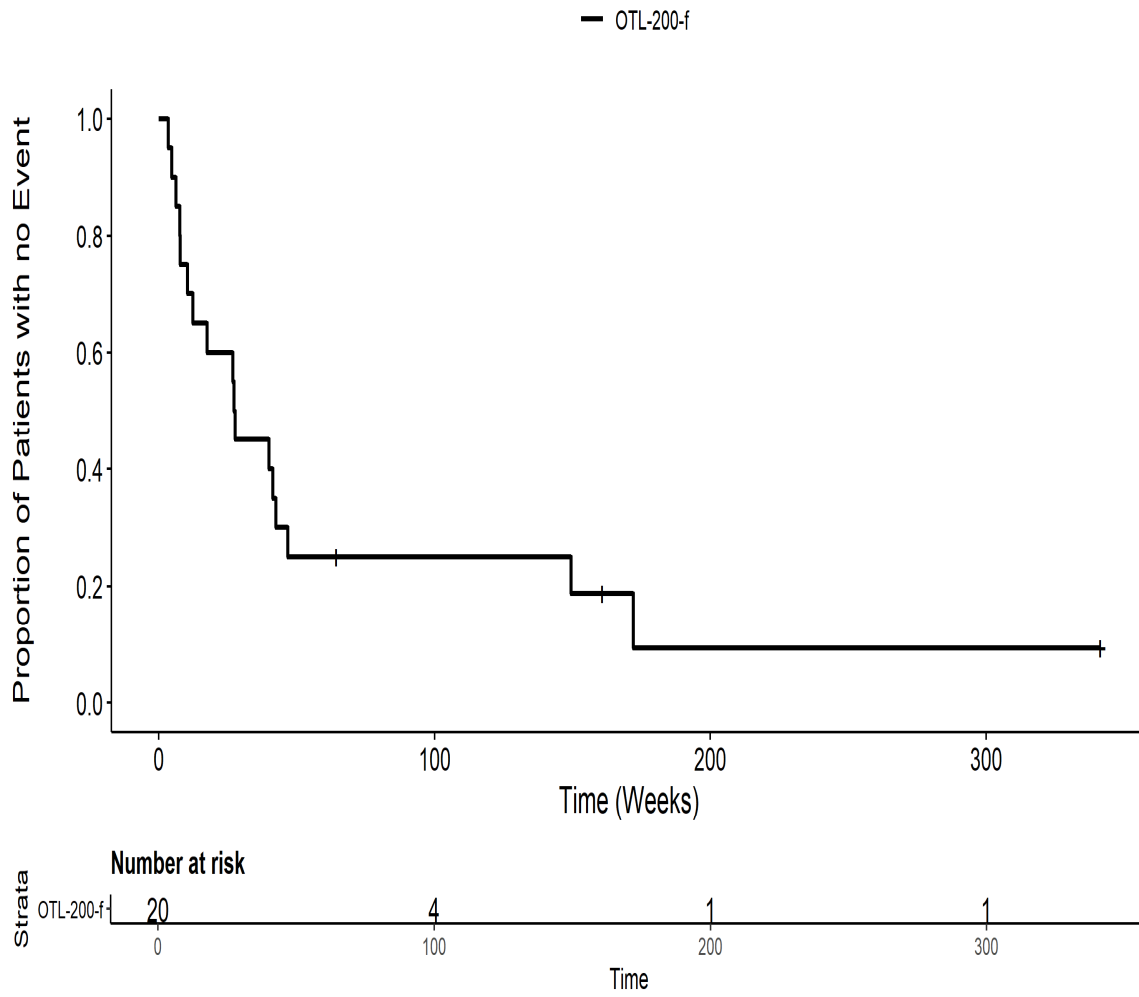
201222: Kaplan Meier Plot for Time to mild AE by SOC Infektionen und parasitäre Erkrankungen PT pct AtemwegsinfektionITT



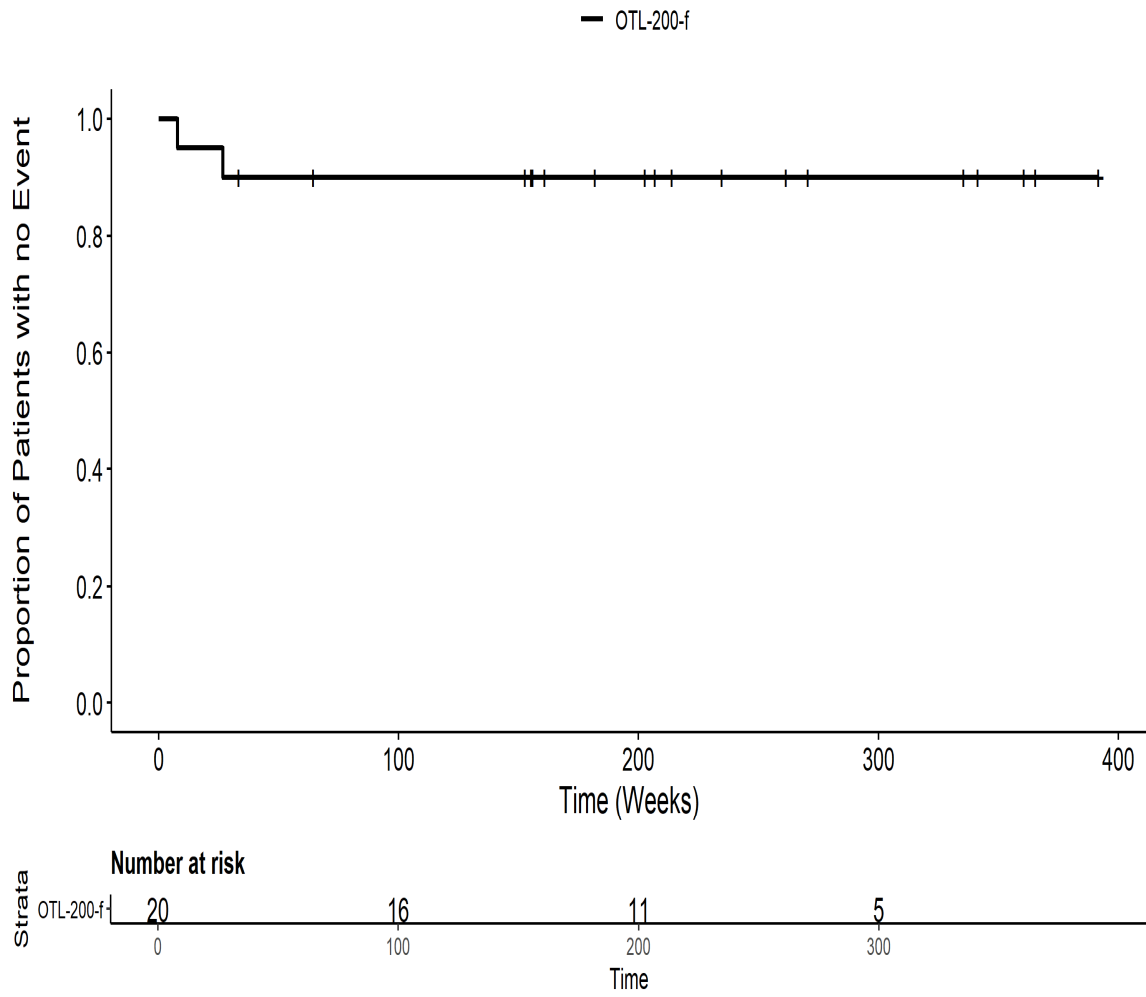
201222: Kaplan Meier Plot for Time to mild AE by SOC Infektionen und parasitäre Erkrankungen PT pct GastroenteritisITT



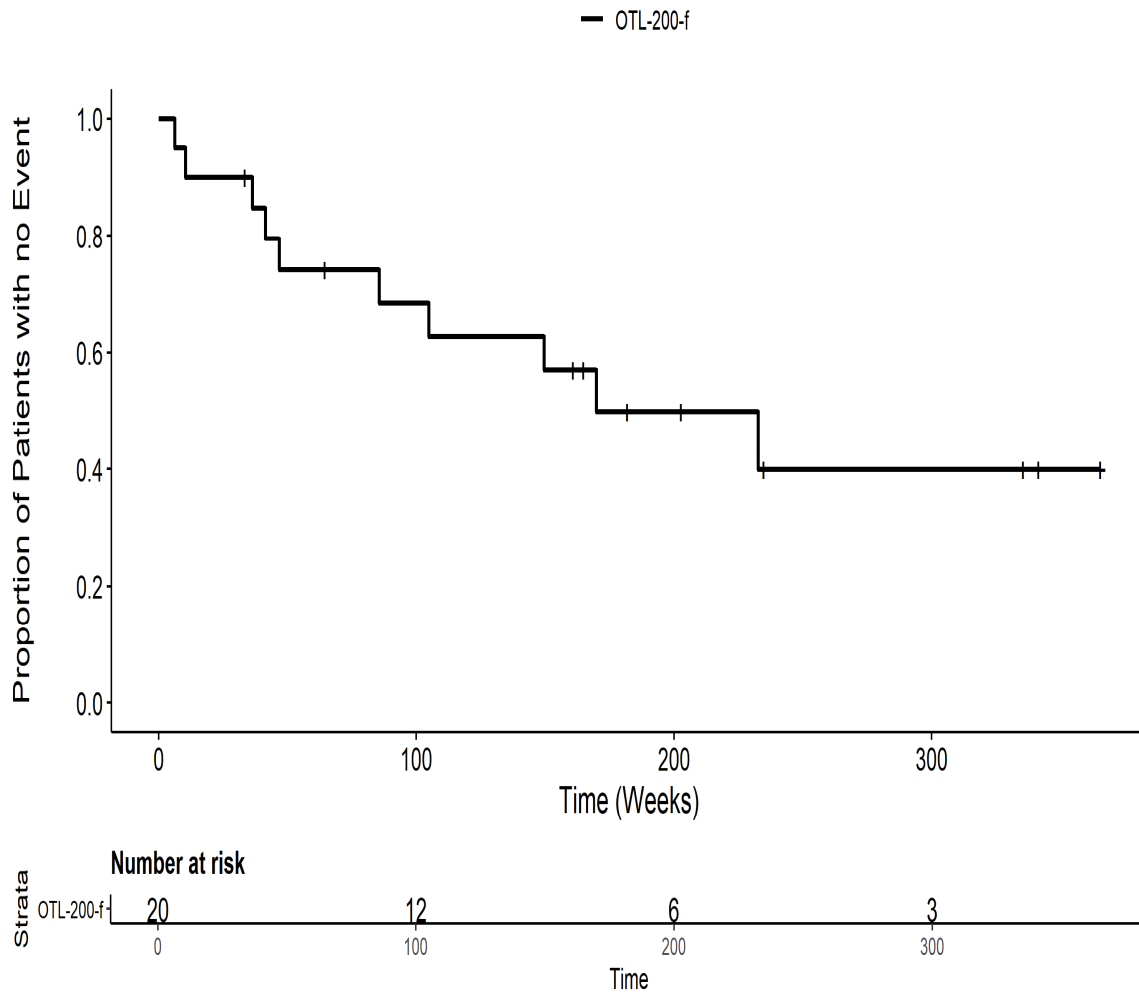
201222: Kaplan Meier Plot for Time to mild AE by SOC Infektionen und parasitäre Erkrankungen PT pct Gesamt SOCITT



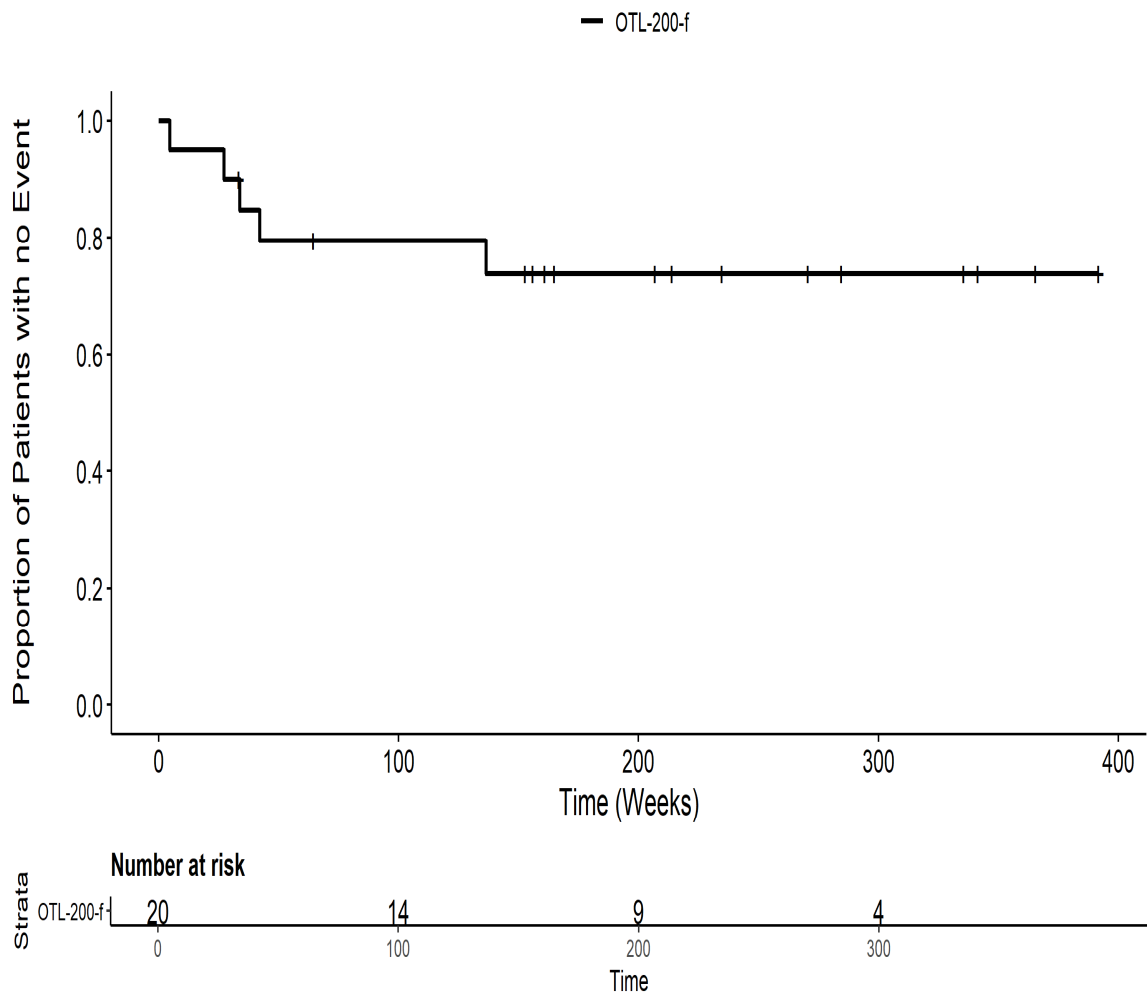
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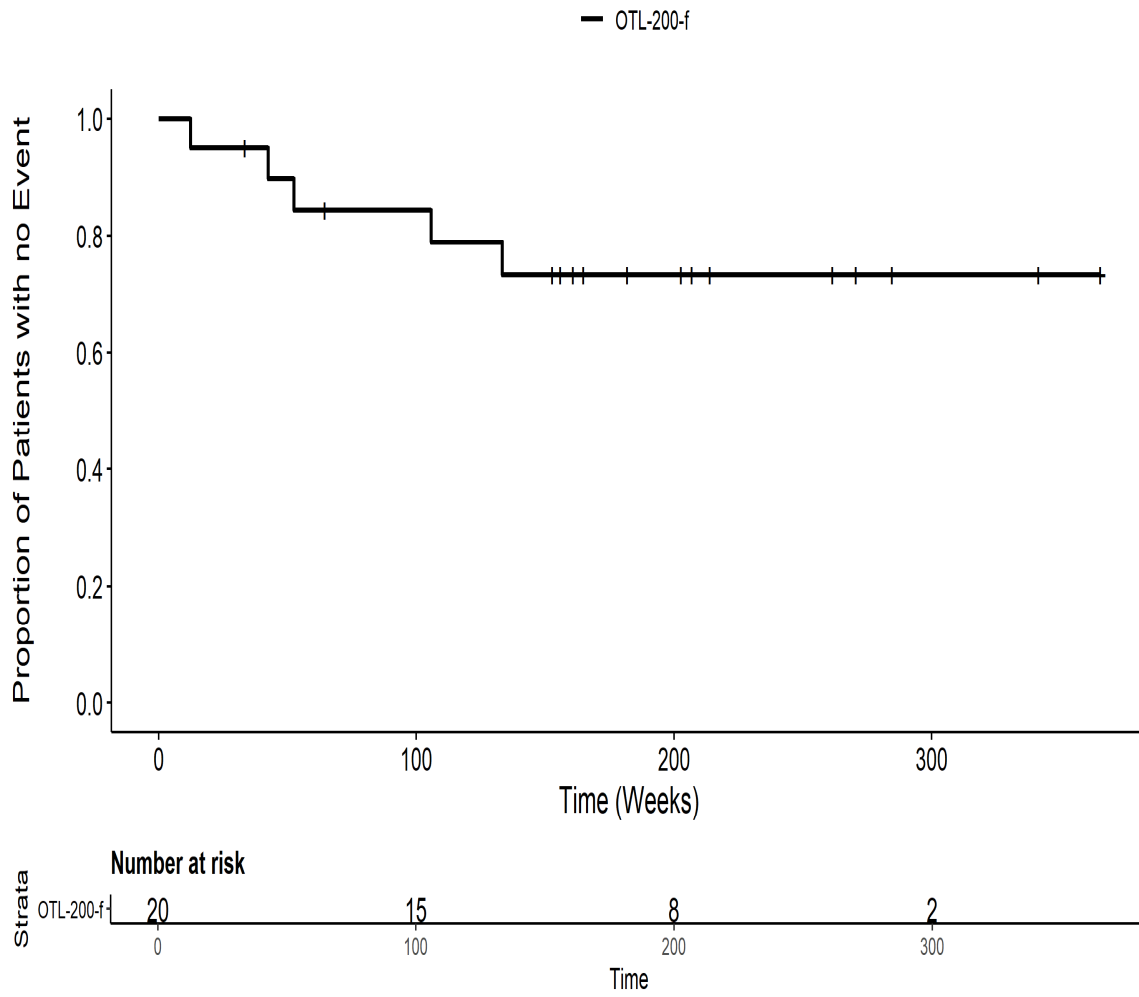
201222: Kaplan Meier Plot for Time to mild AE by SOC Infektionen und parasitäre Erkrankungen PT pct Infektion der oberen Atemwege|TT



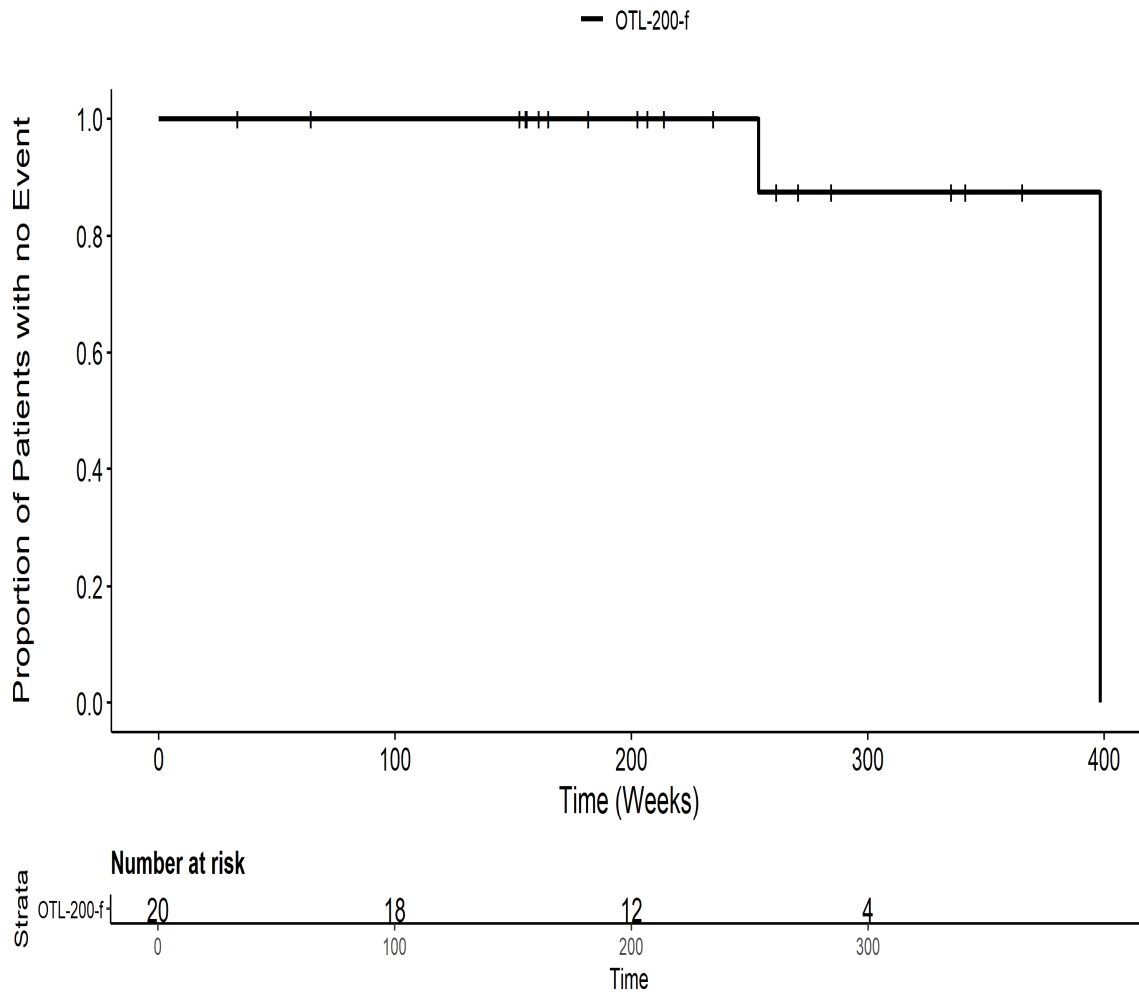
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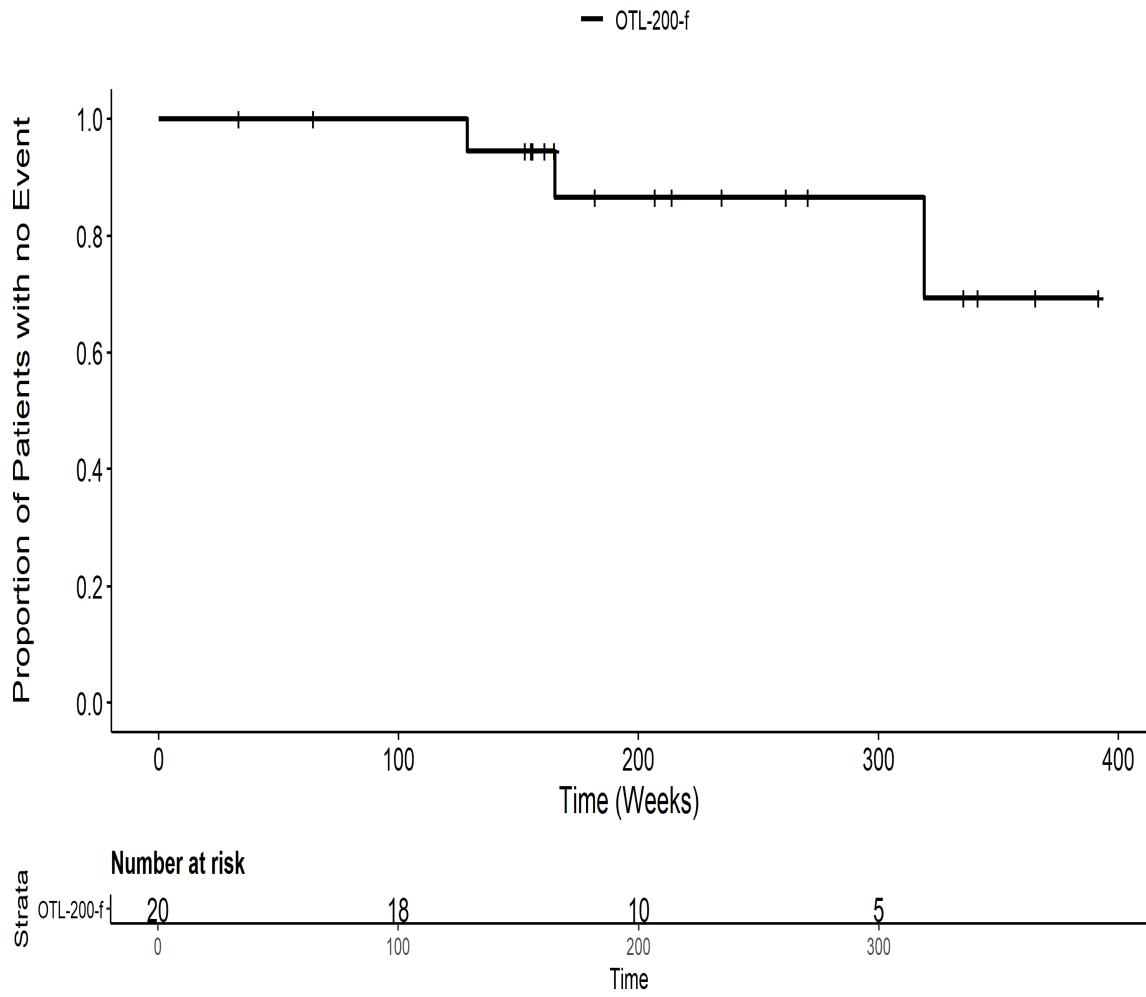
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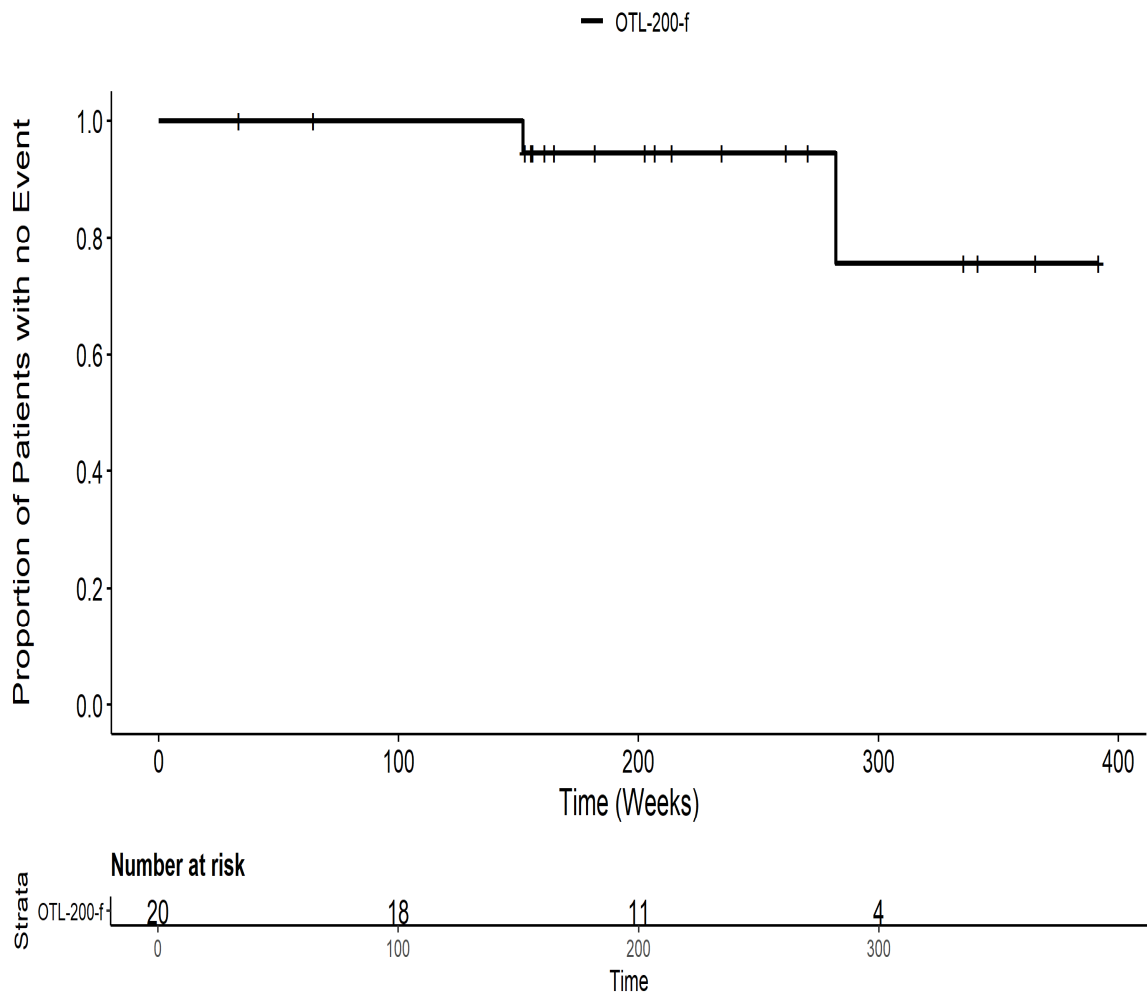
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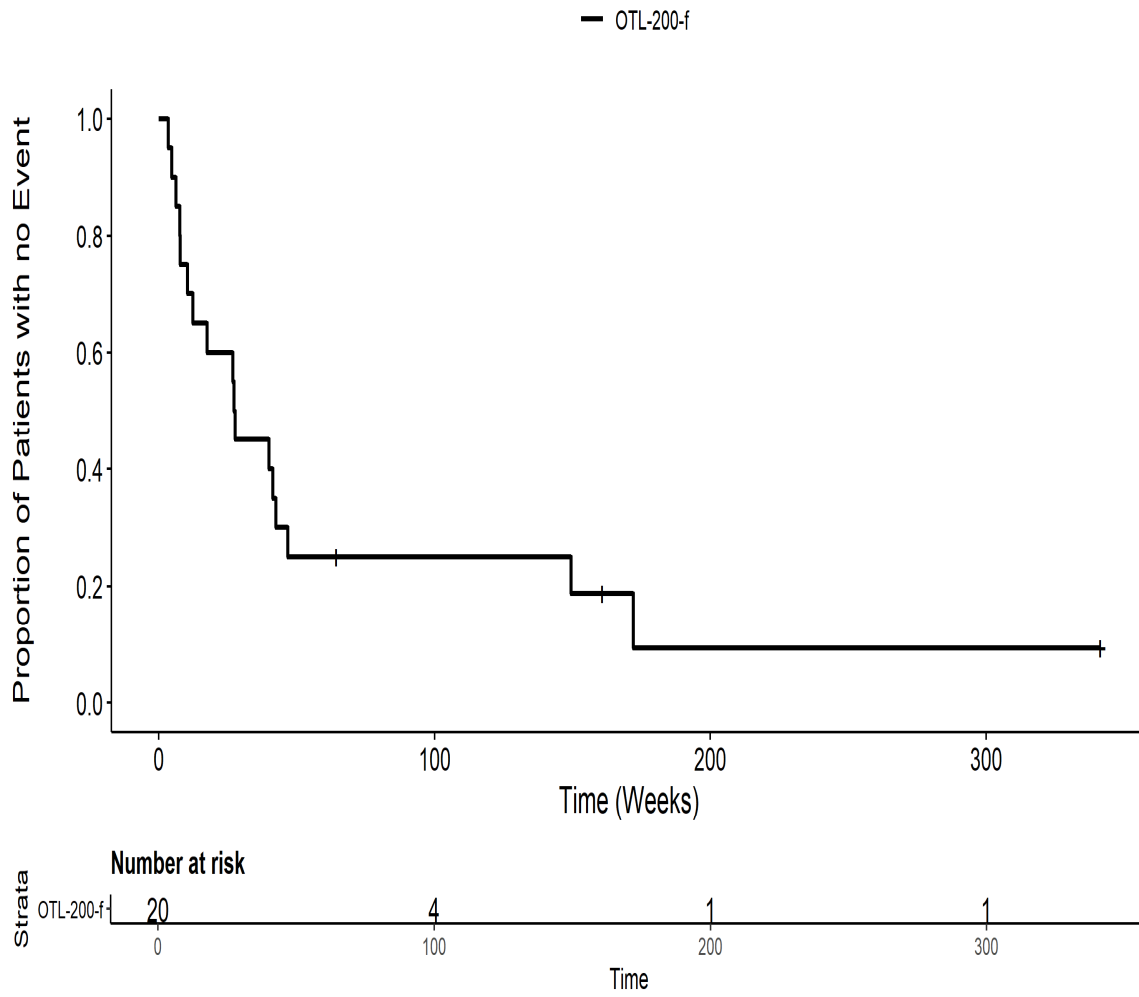
201222: Kaplan Meier Plot for Time to mild AE by SOC Infektionen und parasitäre Erkrankungen PT pct ScharlachITT



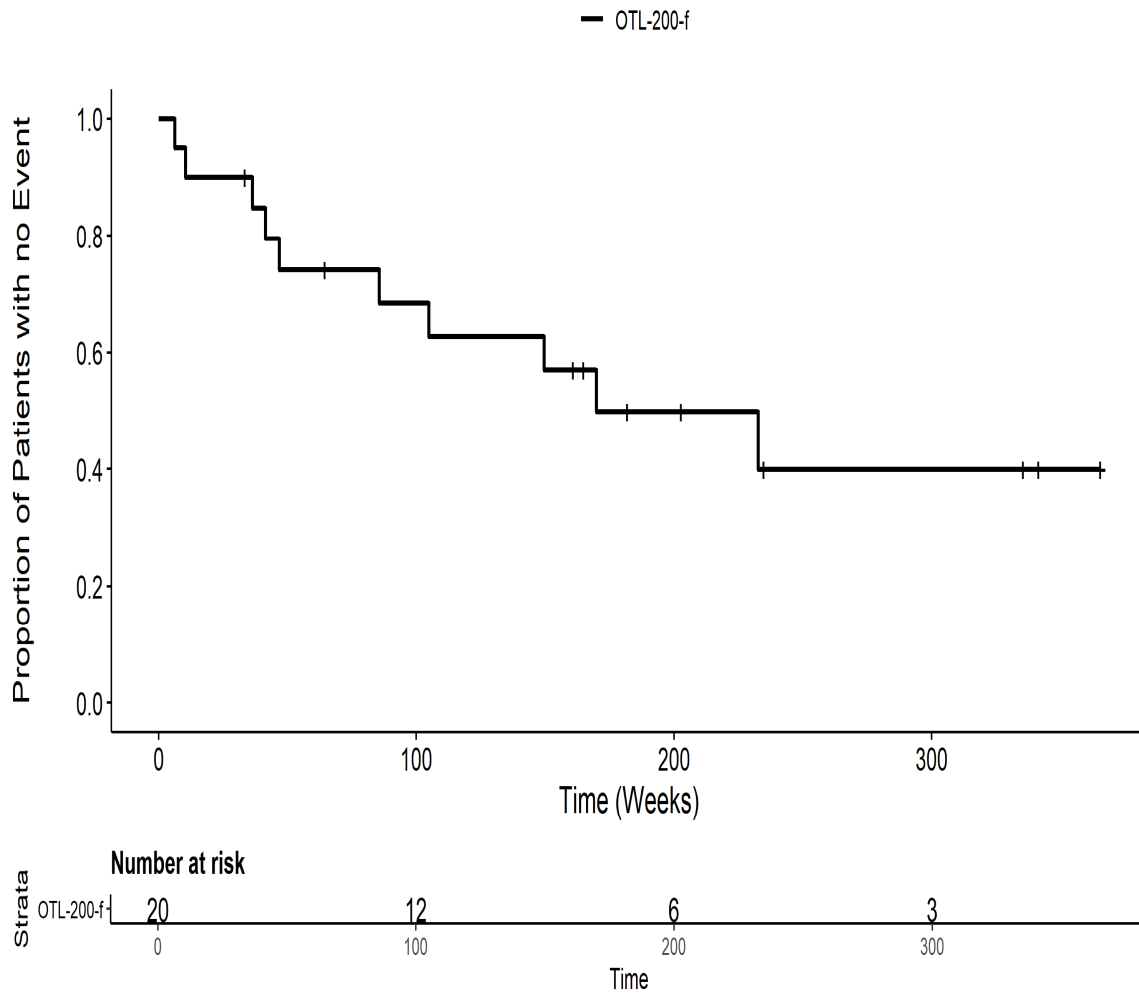
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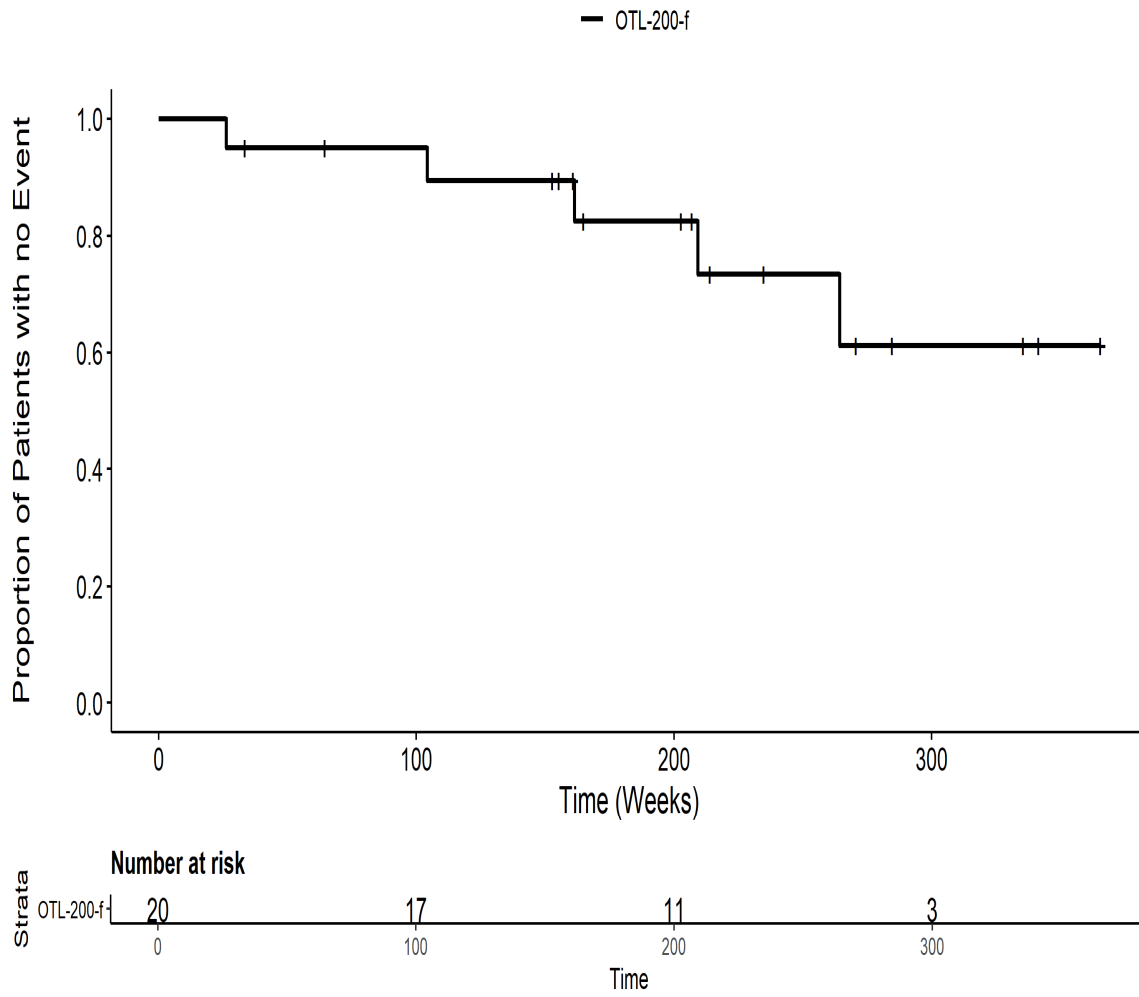
201222: Kaplan Meier Plot for Time to mild AE by SOC Infektionen und parasitäre Erkrankungen PT pts Gesamt SOC ITT



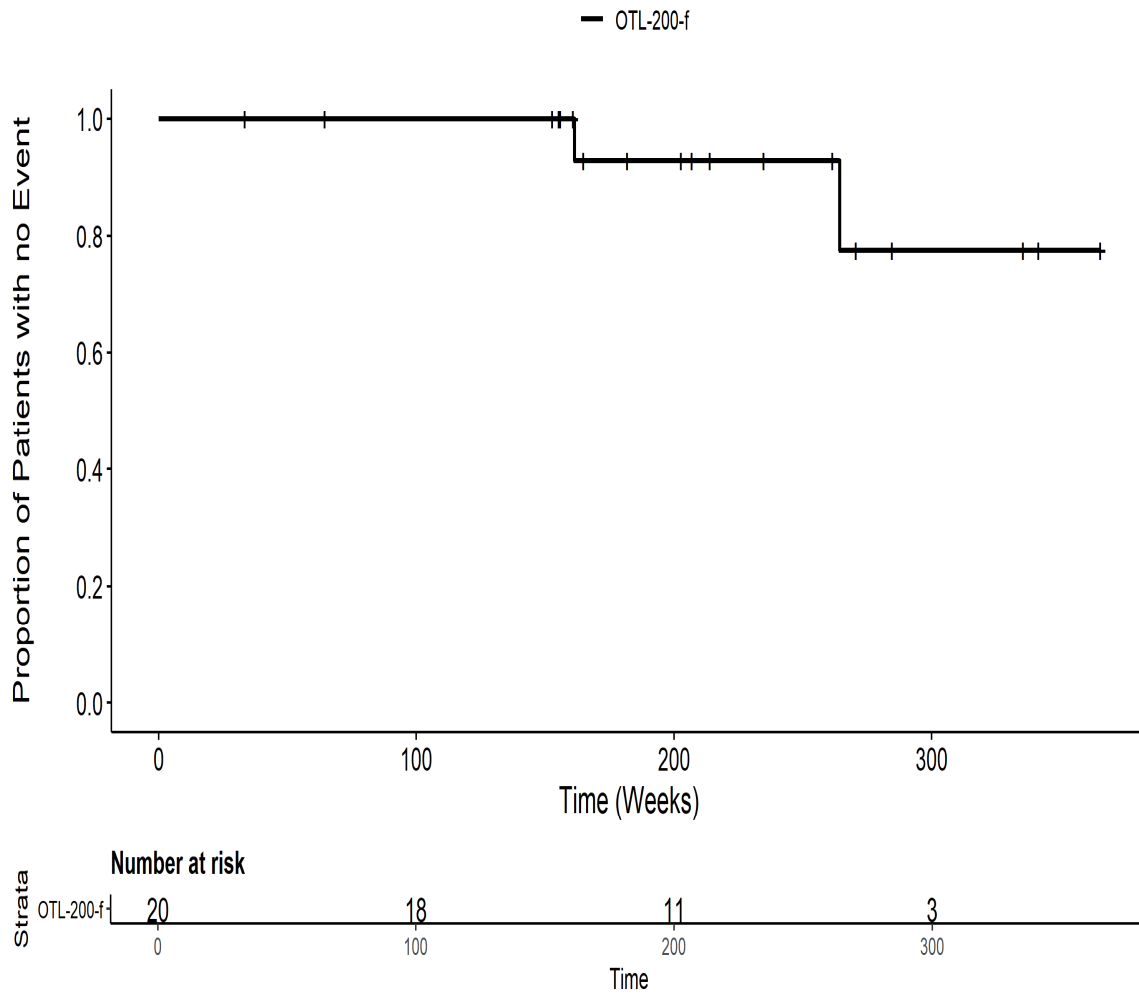
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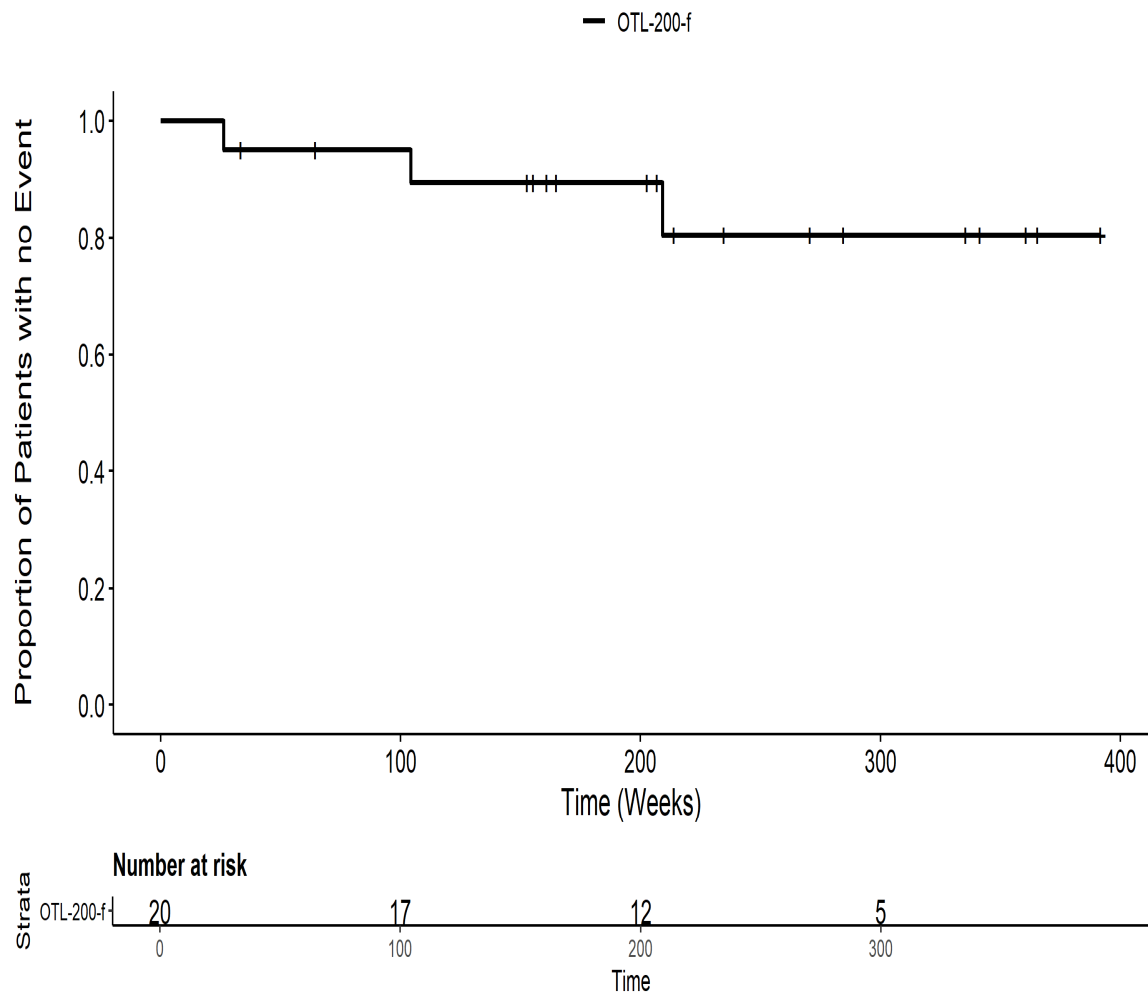
201222: Kaplan Meier Plot for Time to mild AE by SOC Kongenitale, familiäre und genetische Erkrankungen PT pct Gesamt SOCITT



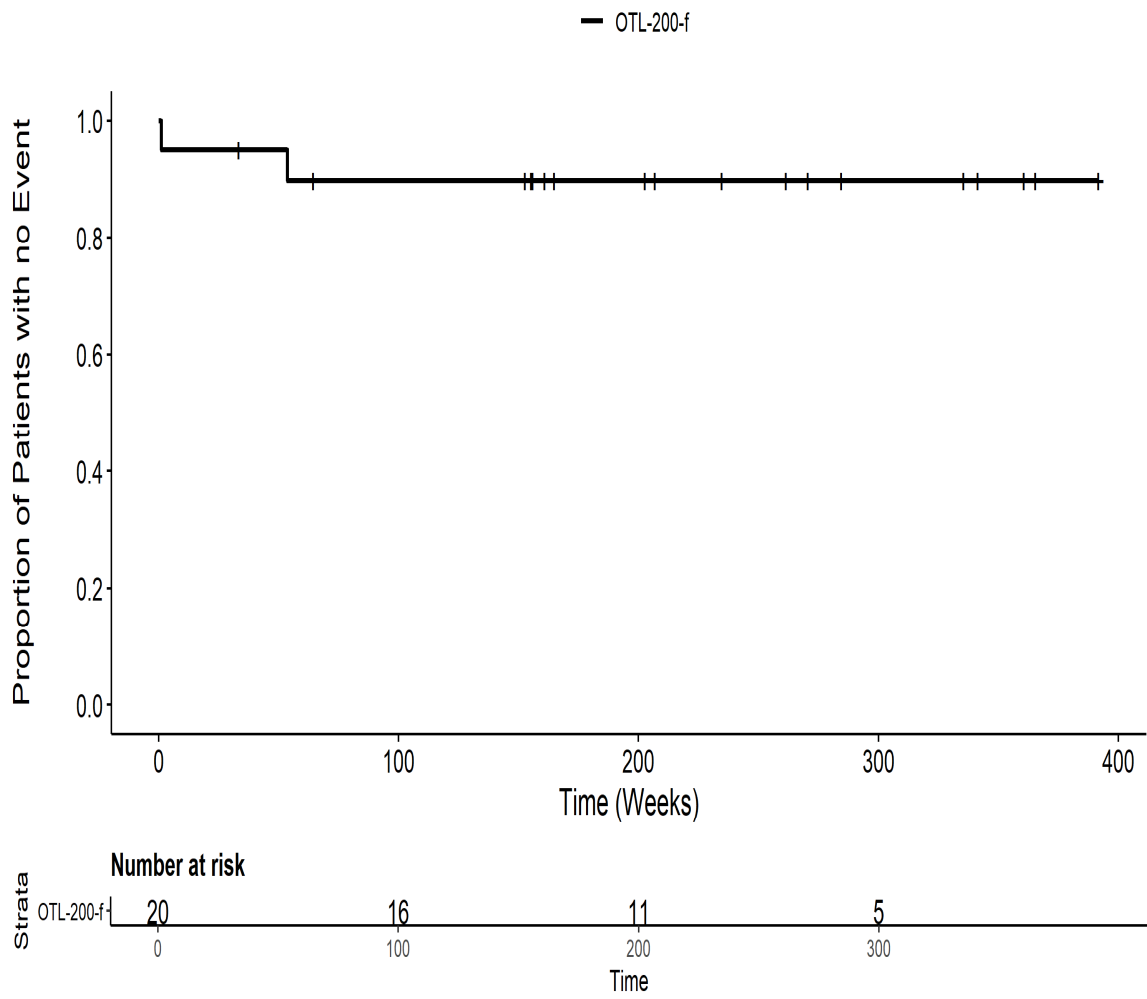
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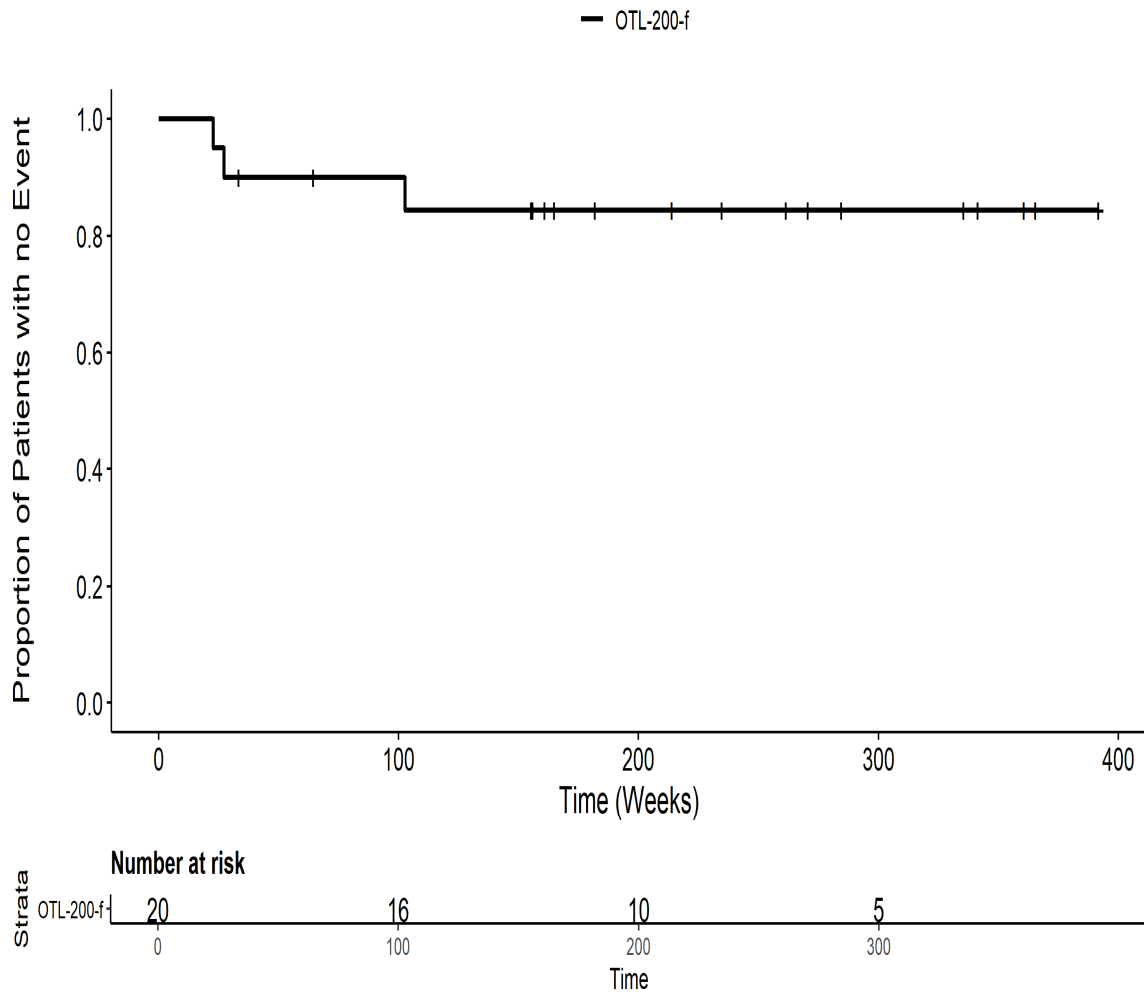
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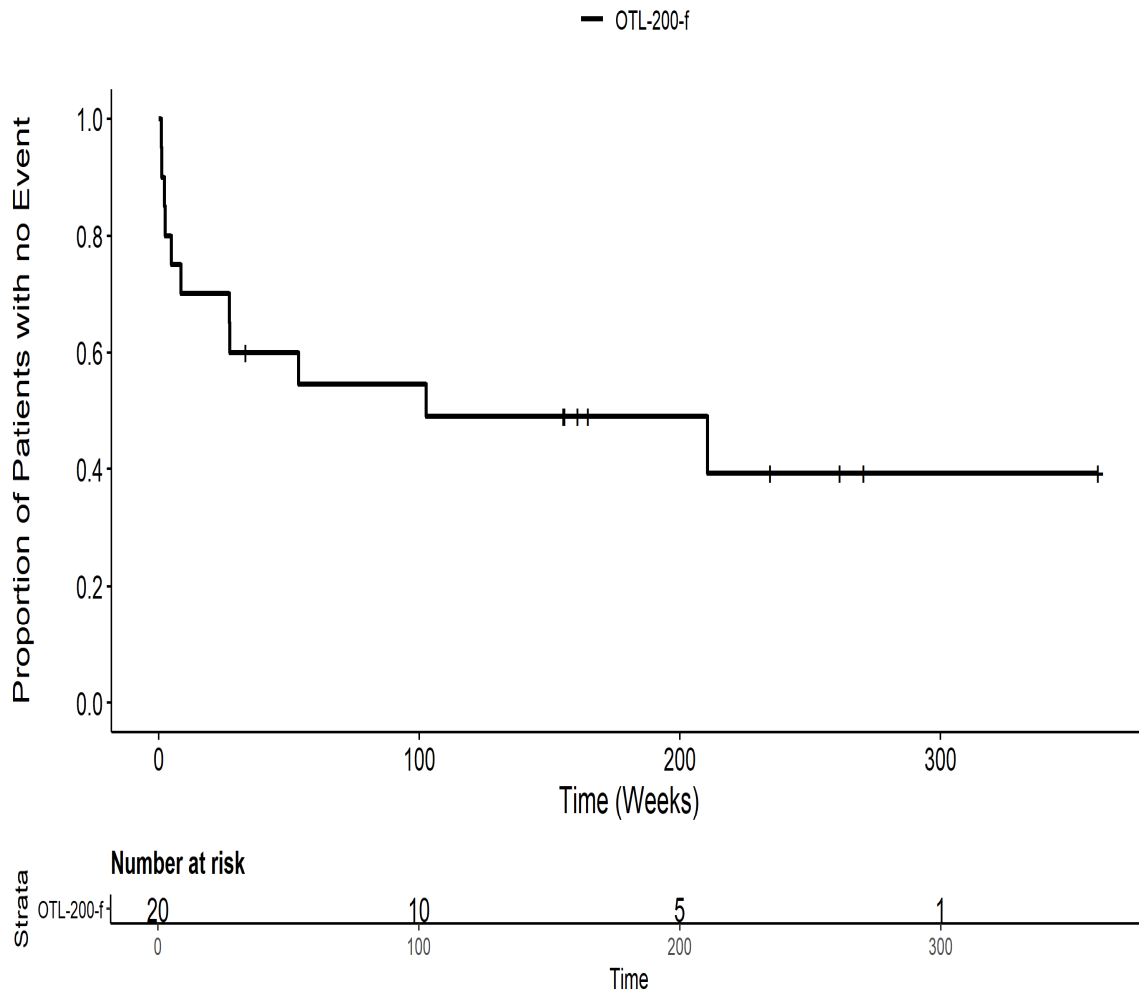
201222: Kaplan Meier Plot for Time to mild AE by SOC Leber : und Gallenerkrankungen PT pct DRUG : INDUCED LIVER INJURYITT



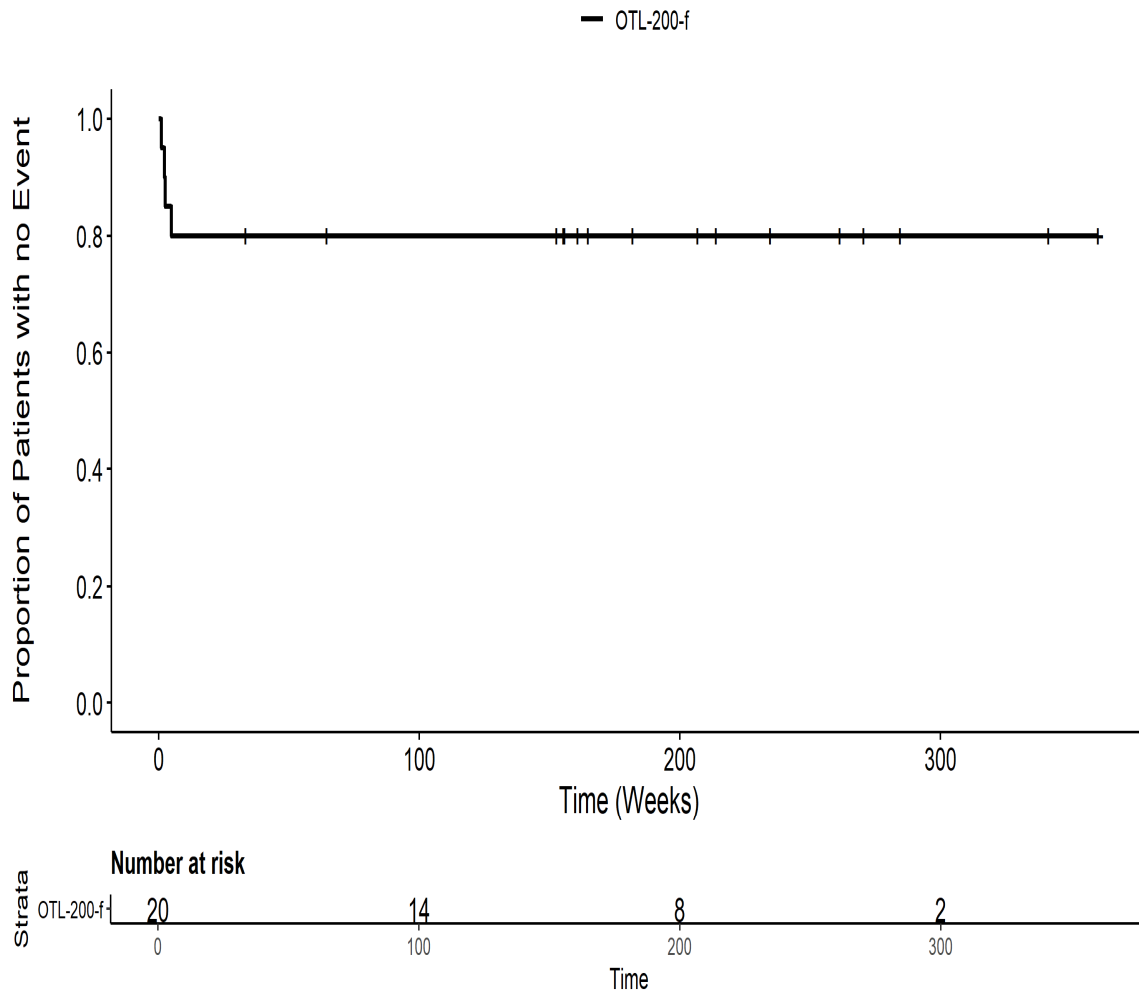
201222: Kaplan Meier Plot for Time to mild AE by SOC Leber : und Gallenerkrankungen PT pct GallenblasenpolypITT



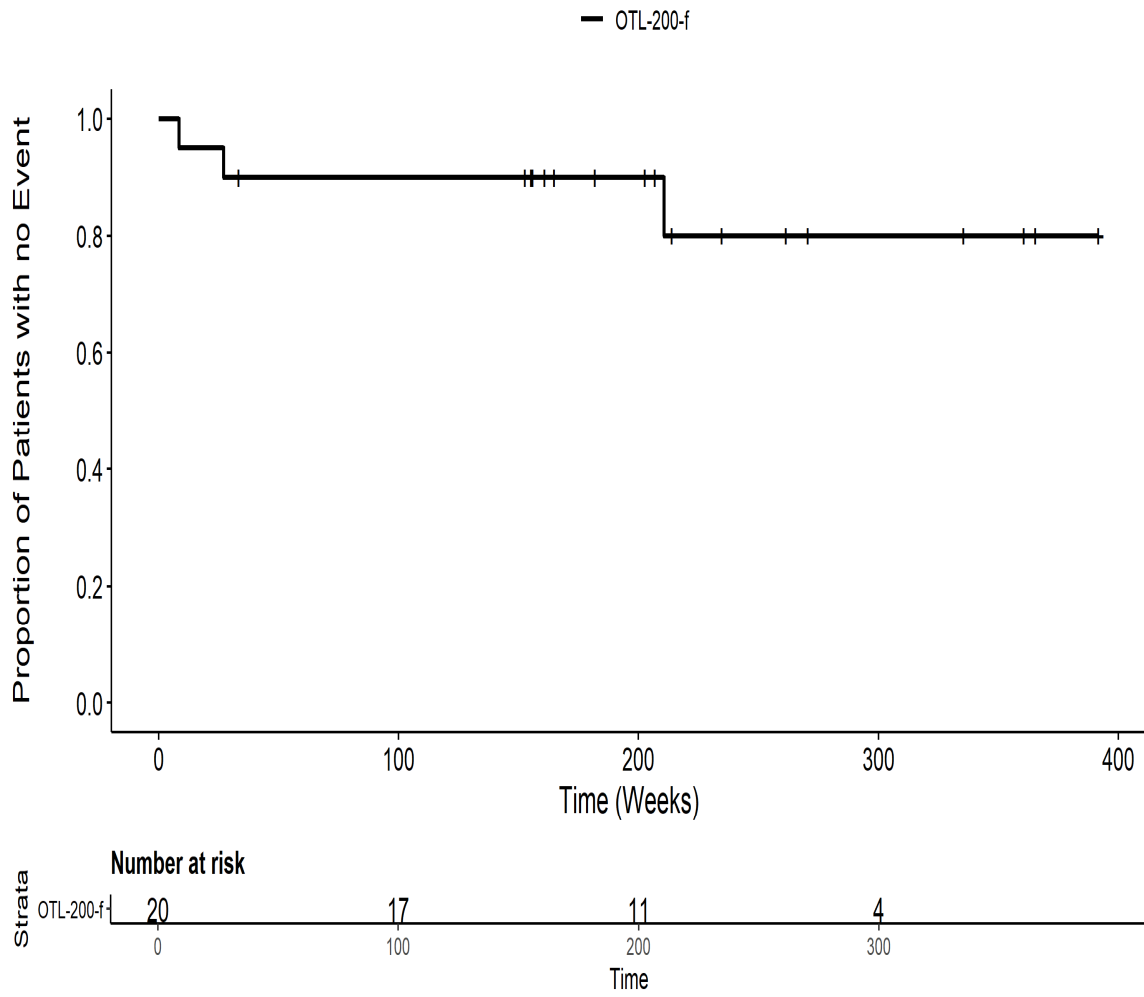
201222: Kaplan Meier Plot for Time to mild AE by SOC Leber : und Gallenerkrankungen PT pct Gesamt SOCITT



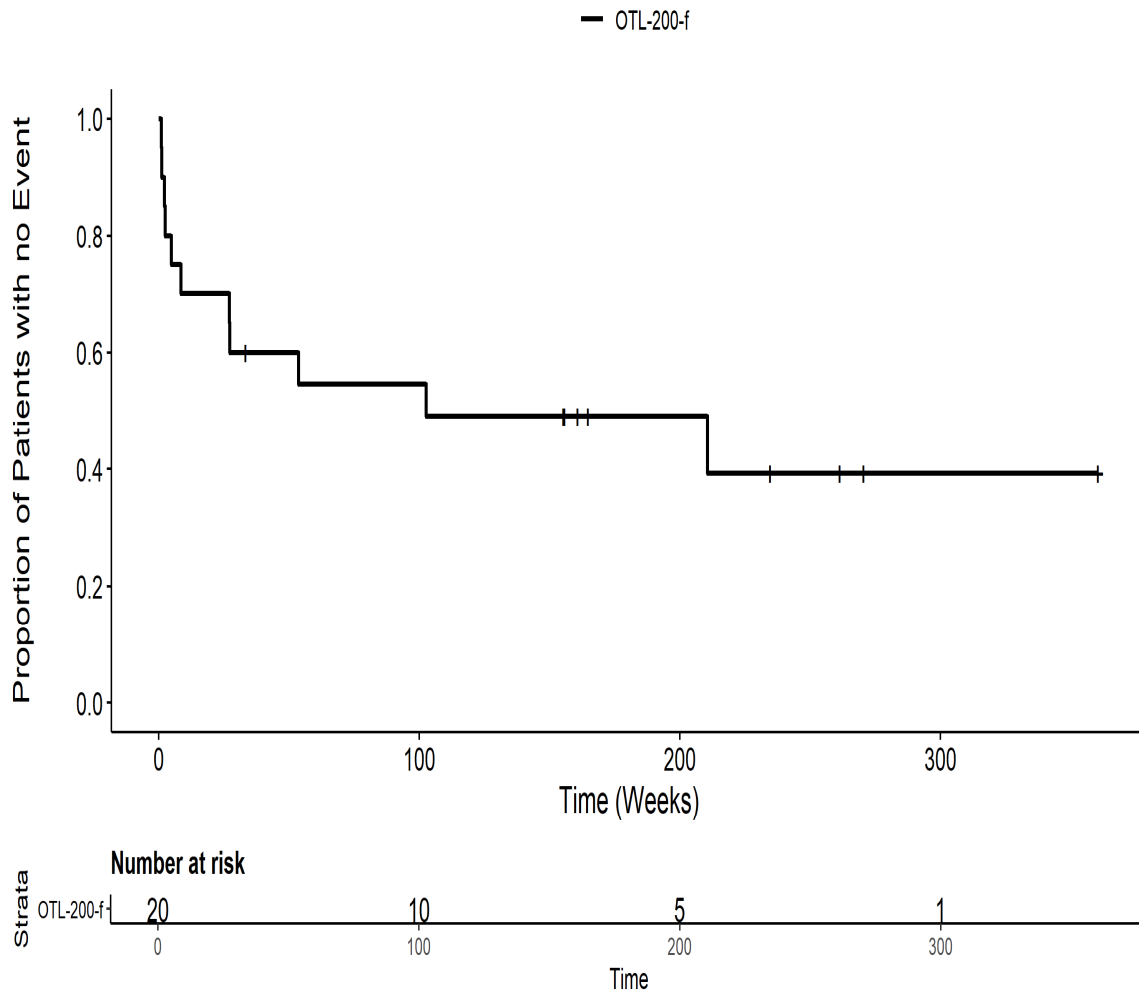
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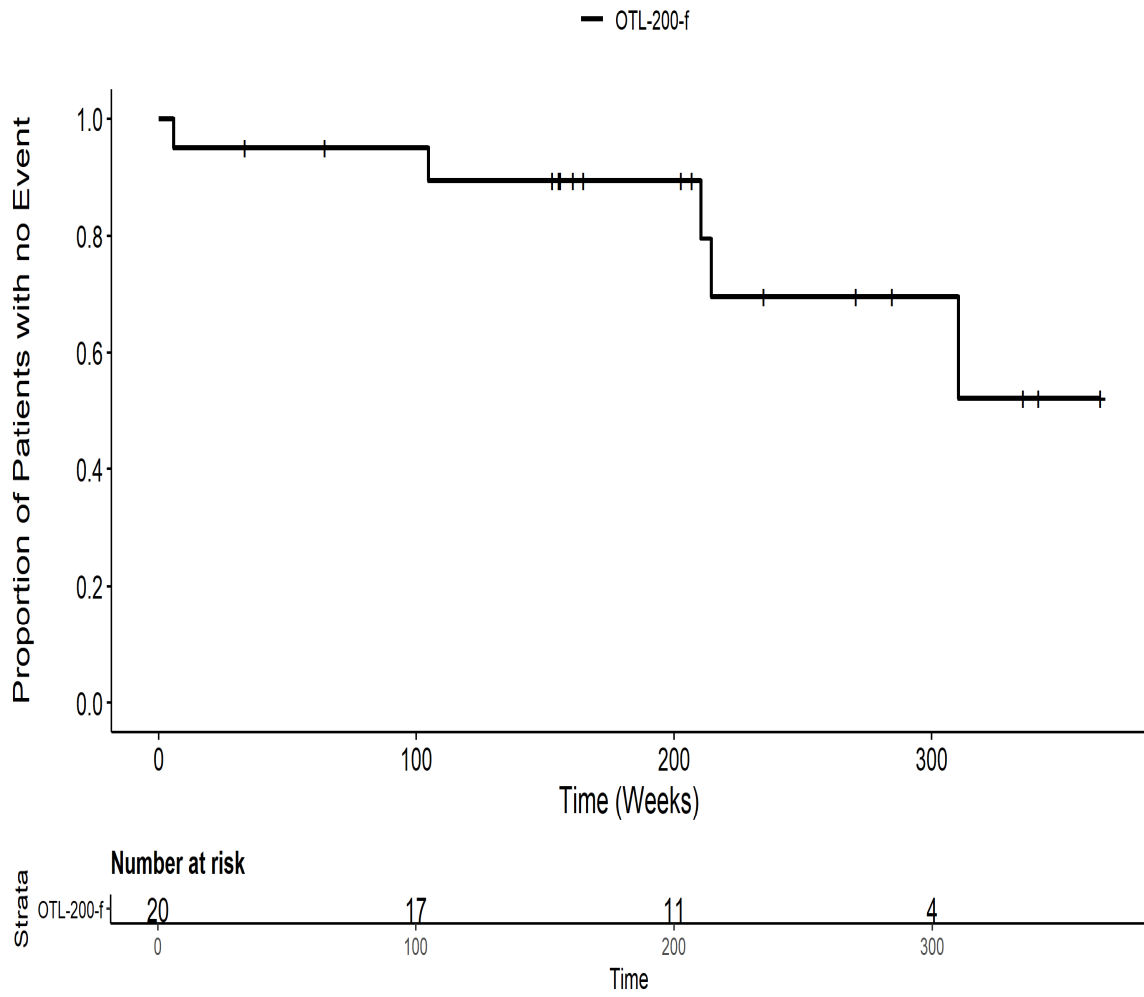
201222: Kaplan Meier Plot for Time to mild AE by SOC Leber : und Gallenerkrankungen PT pct Vergrößerung der GallenblaseITT



201222: Kaplan Meier Plot for Time to mild AE by SOC Leber : und Gallenerkrankungen PT pts Gesamt SOC ITT

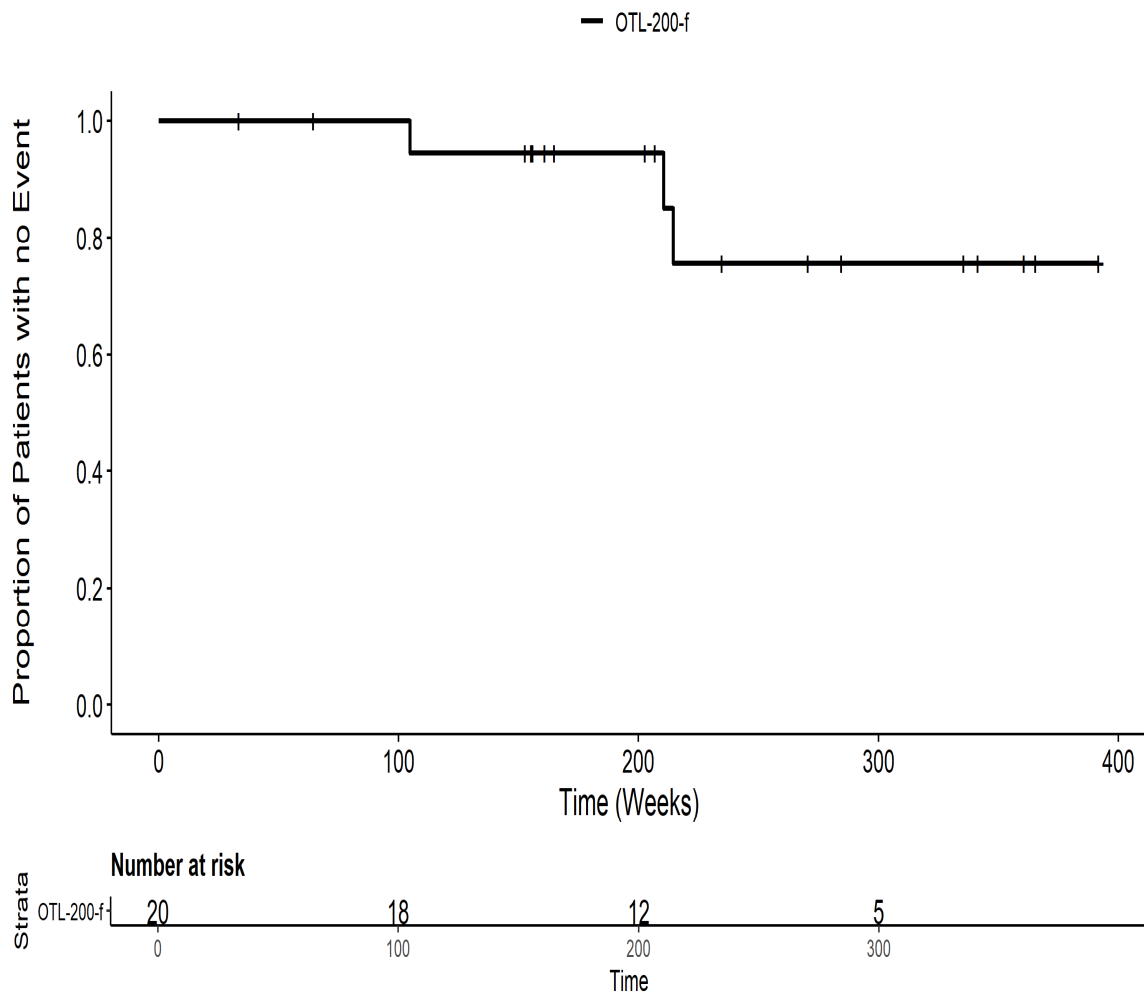


201222: Kaplan Meier Plot for Time to mild AE by SOC
Skelettmuskulatur : , Bindegewebs : und Knochenkrankungen PT pct Gesamt SOCITT

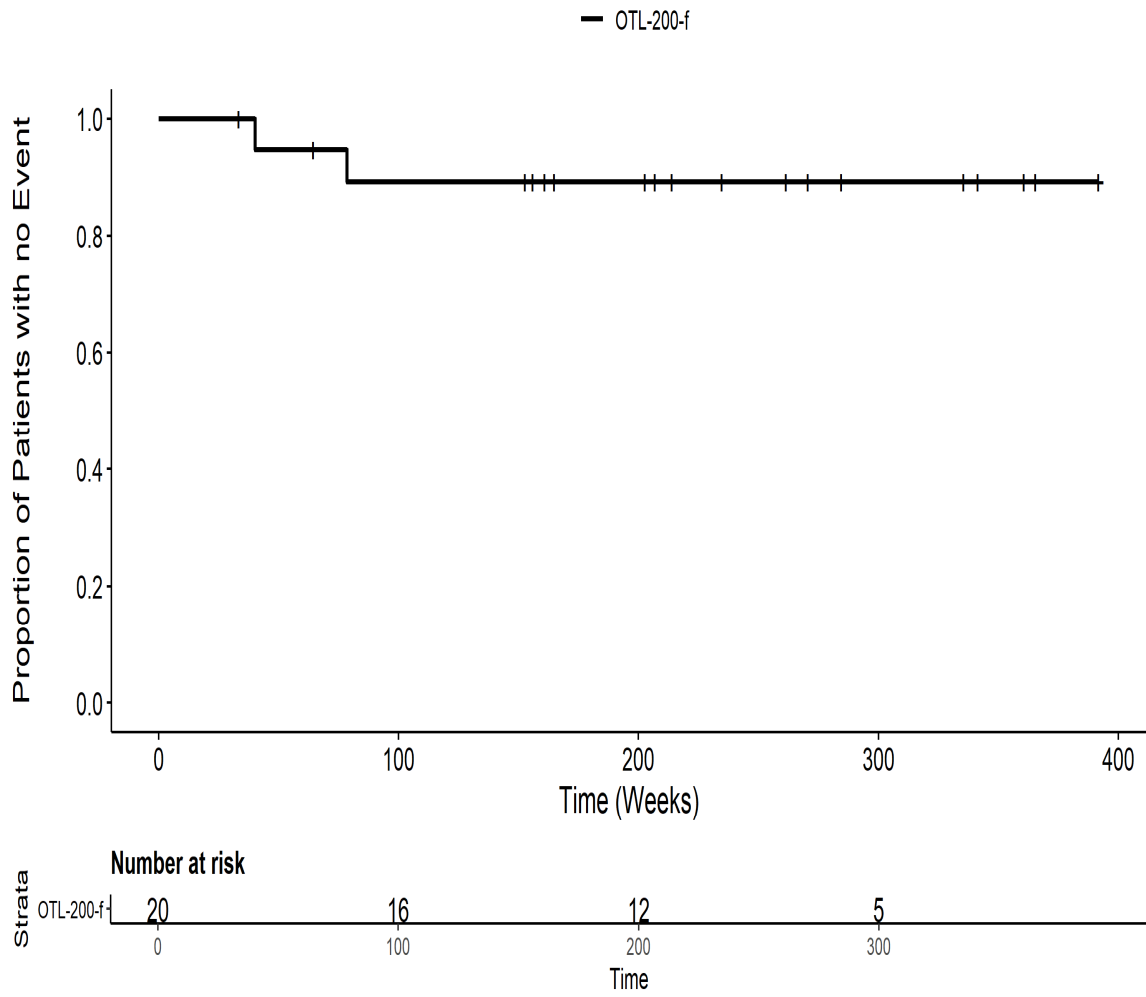


201222: Kaplan Meier Plot for Time to mild AE by SOC

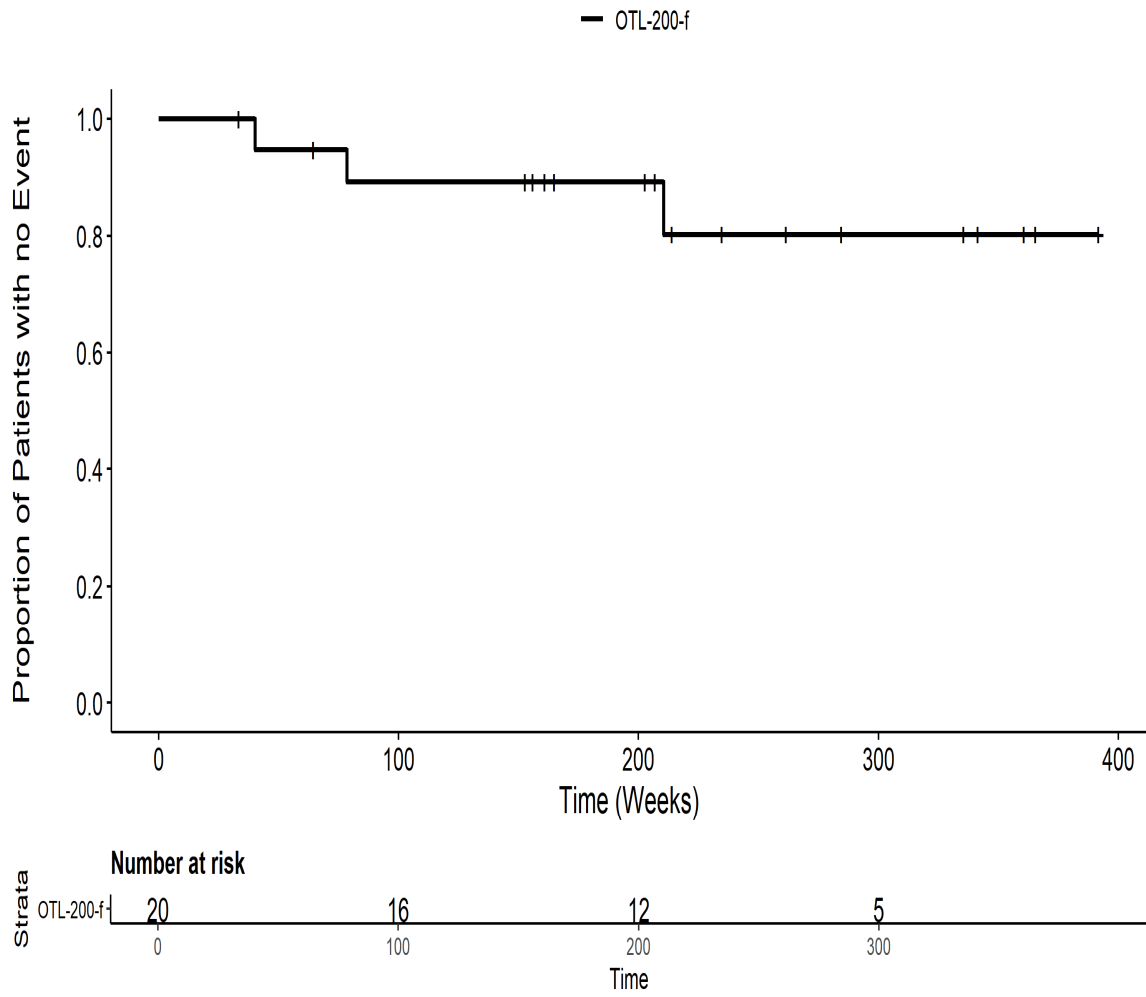
Skelettmuskulatur : , Bindegewebs : und Knochenkrankungen PT pct OsteoporoseITT



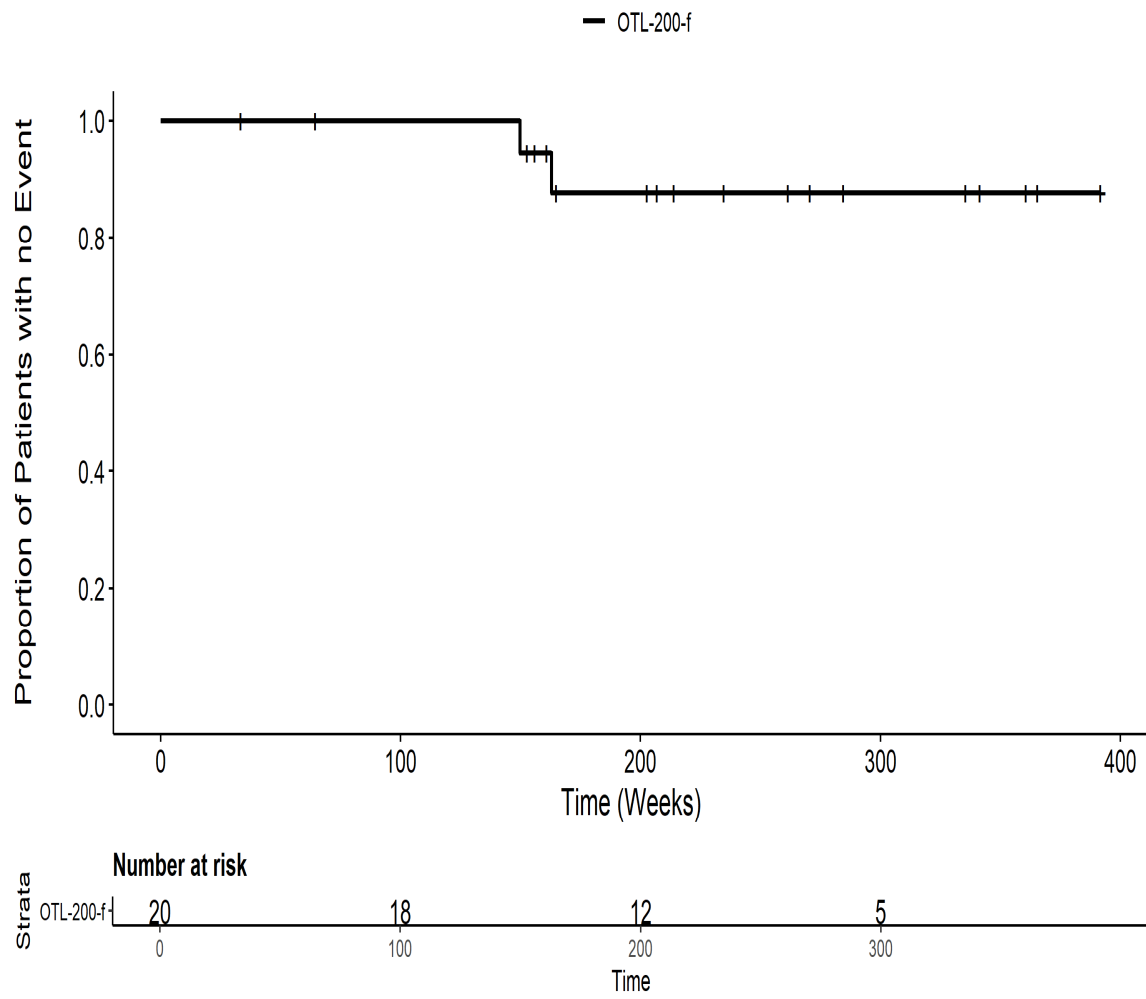
201222: Kaplan Meier Plot for Time to mild AE by SOC Stoffwechsel :
und Ernährungsstörungen PT pct EisenmangelITT



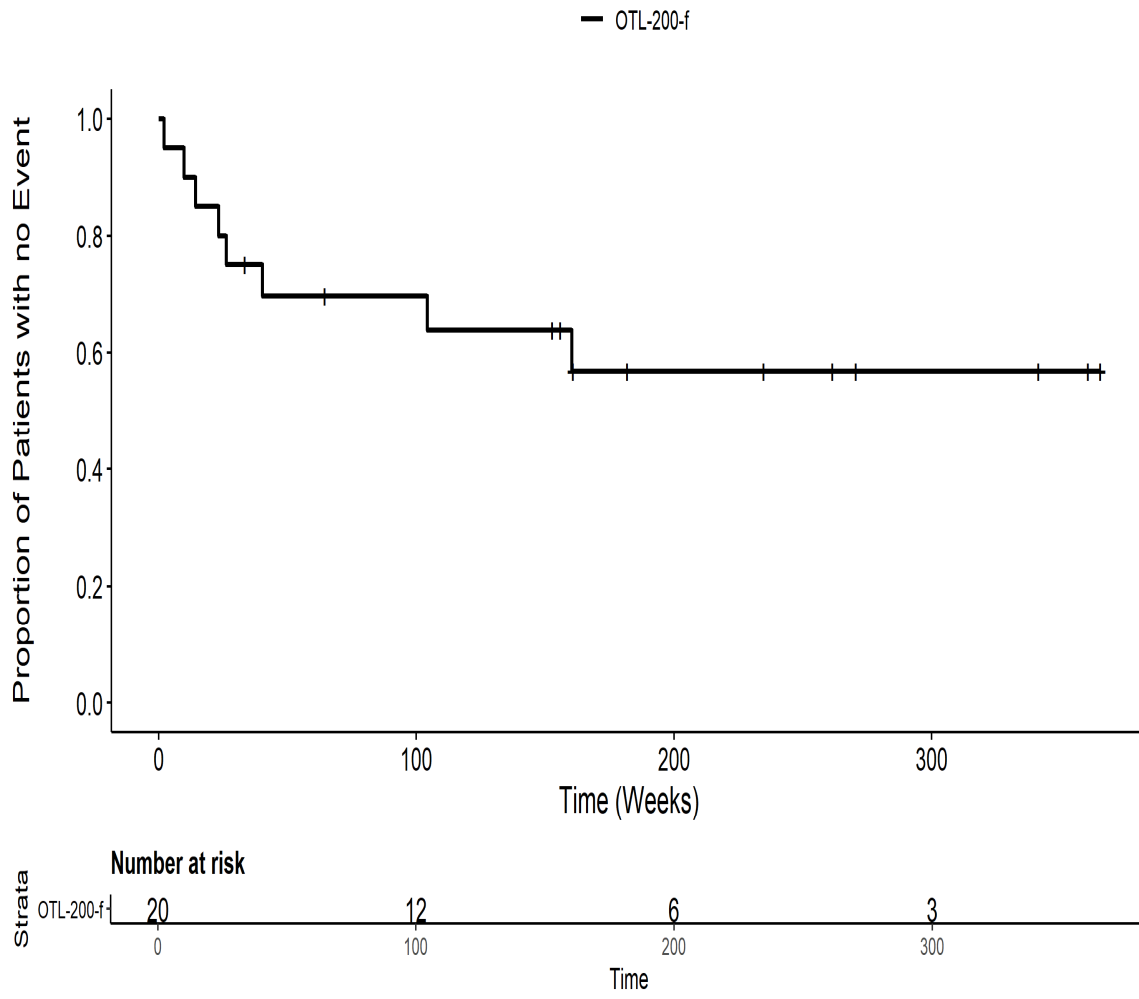
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und Ernährungsstörungen PT pct Gesamt SOCITT



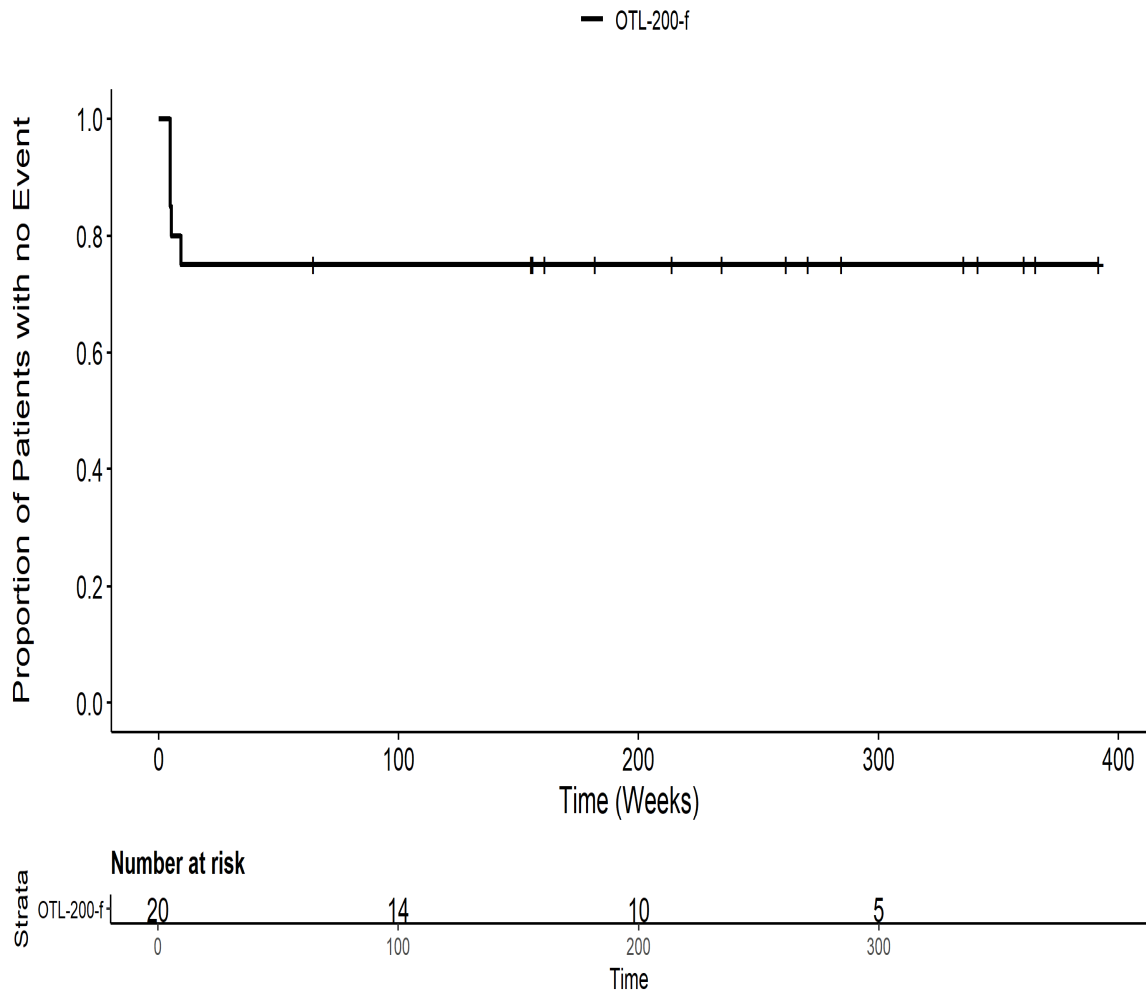
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und Ernährungsstörungen PT pct Metabolische AzidoseITT



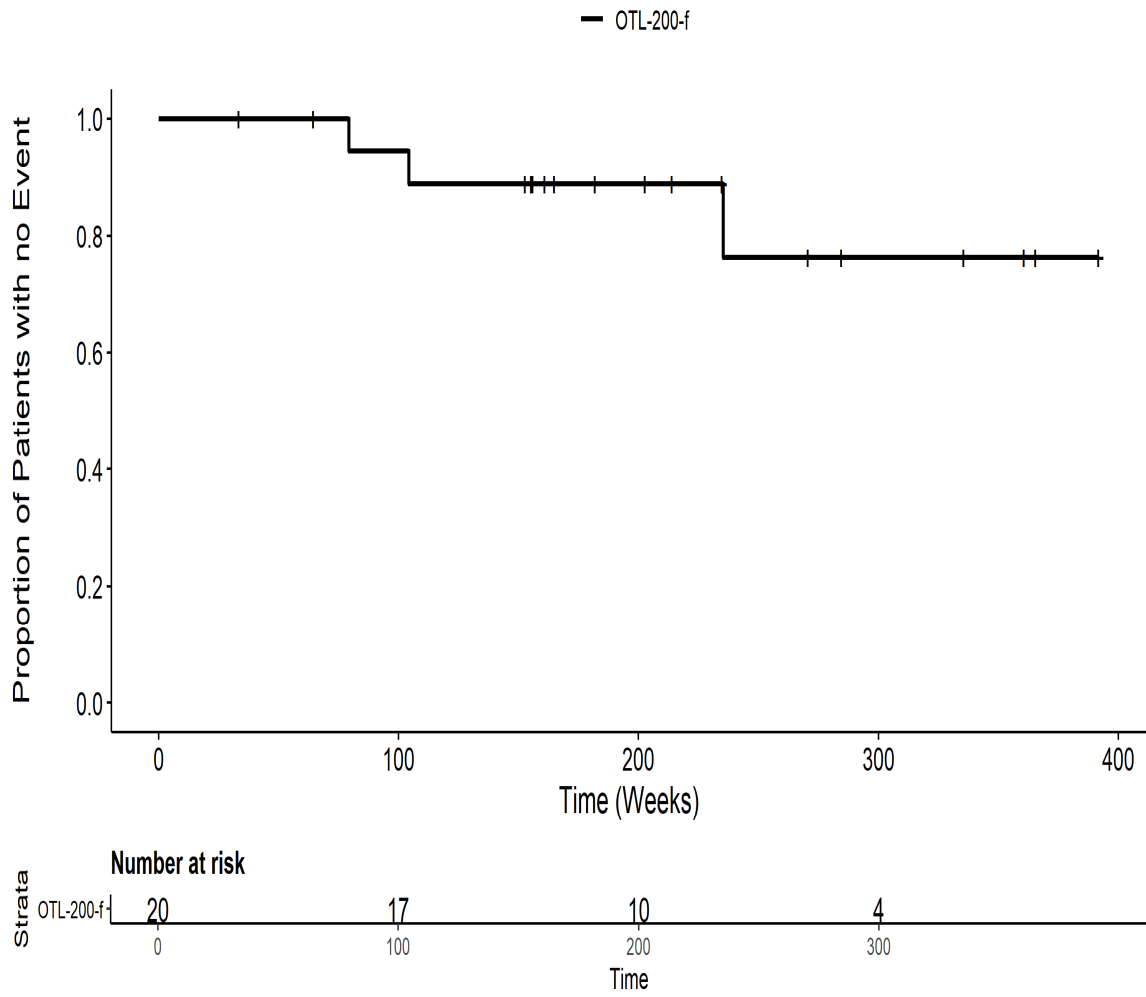
201222: Kaplan Meier Plot for Time to mild AE by SOC Untersuchungen
PT pct Erhöhtes Immunoglobulin E im BlutITT



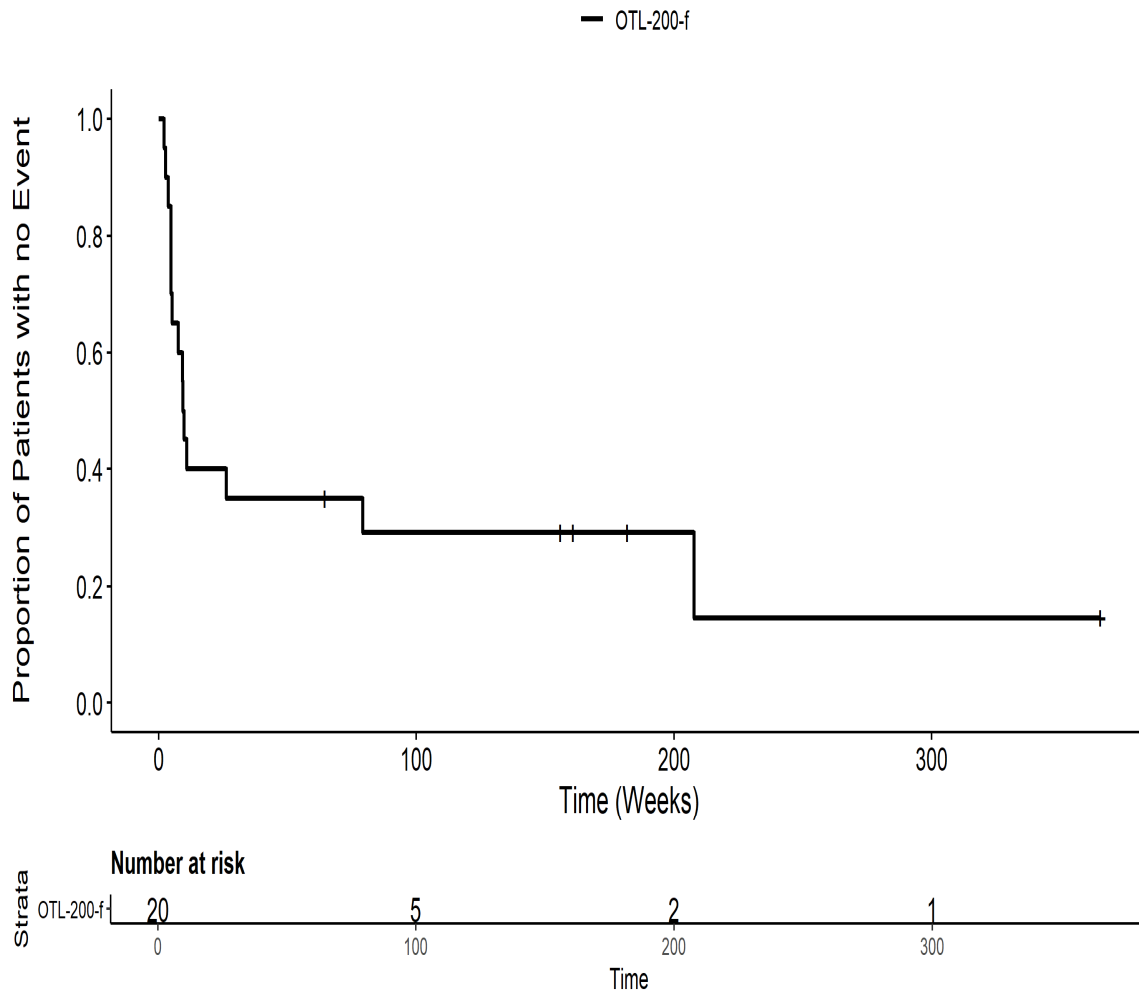
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PT pct Erhöhtes Serum : FerritinITT



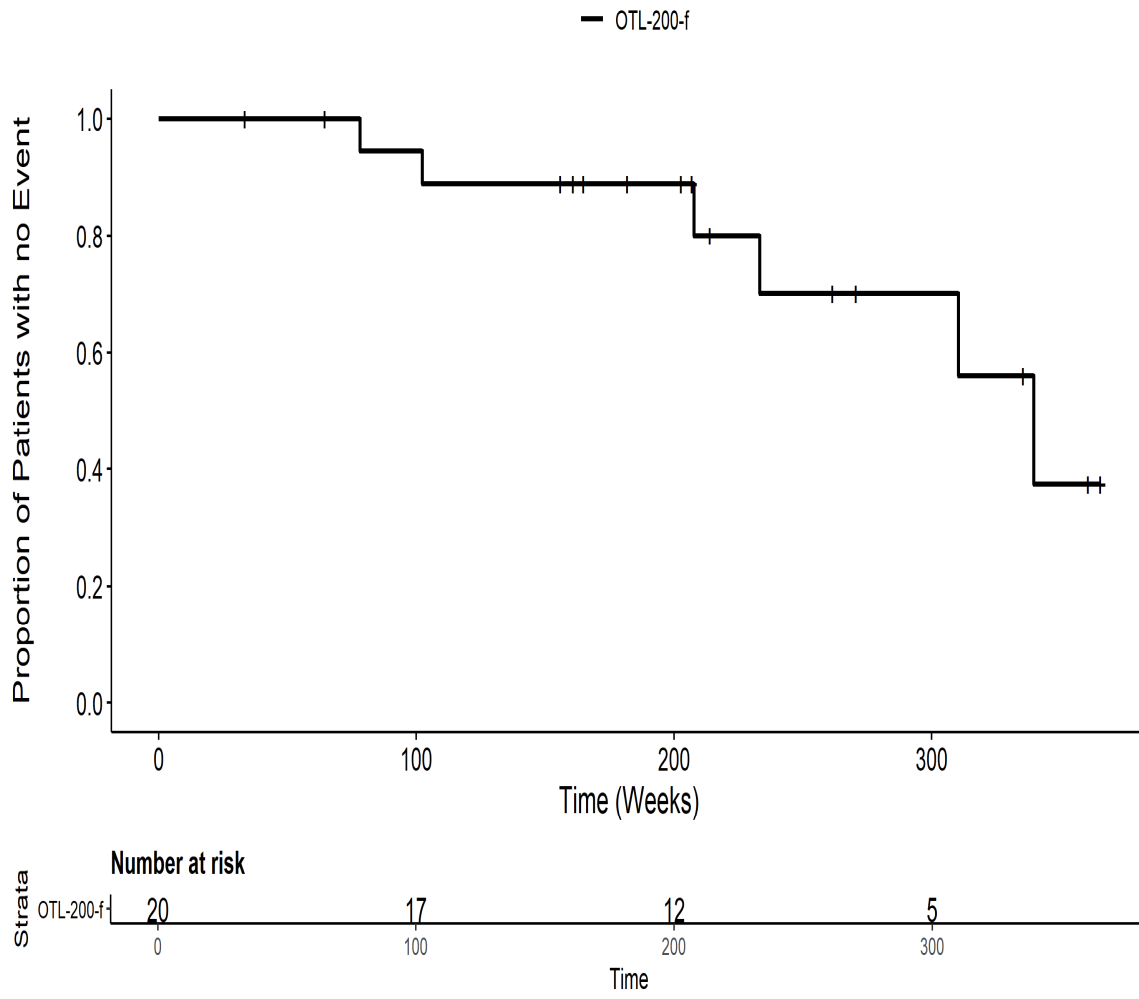
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PT pct Erniedrigter BMIITT



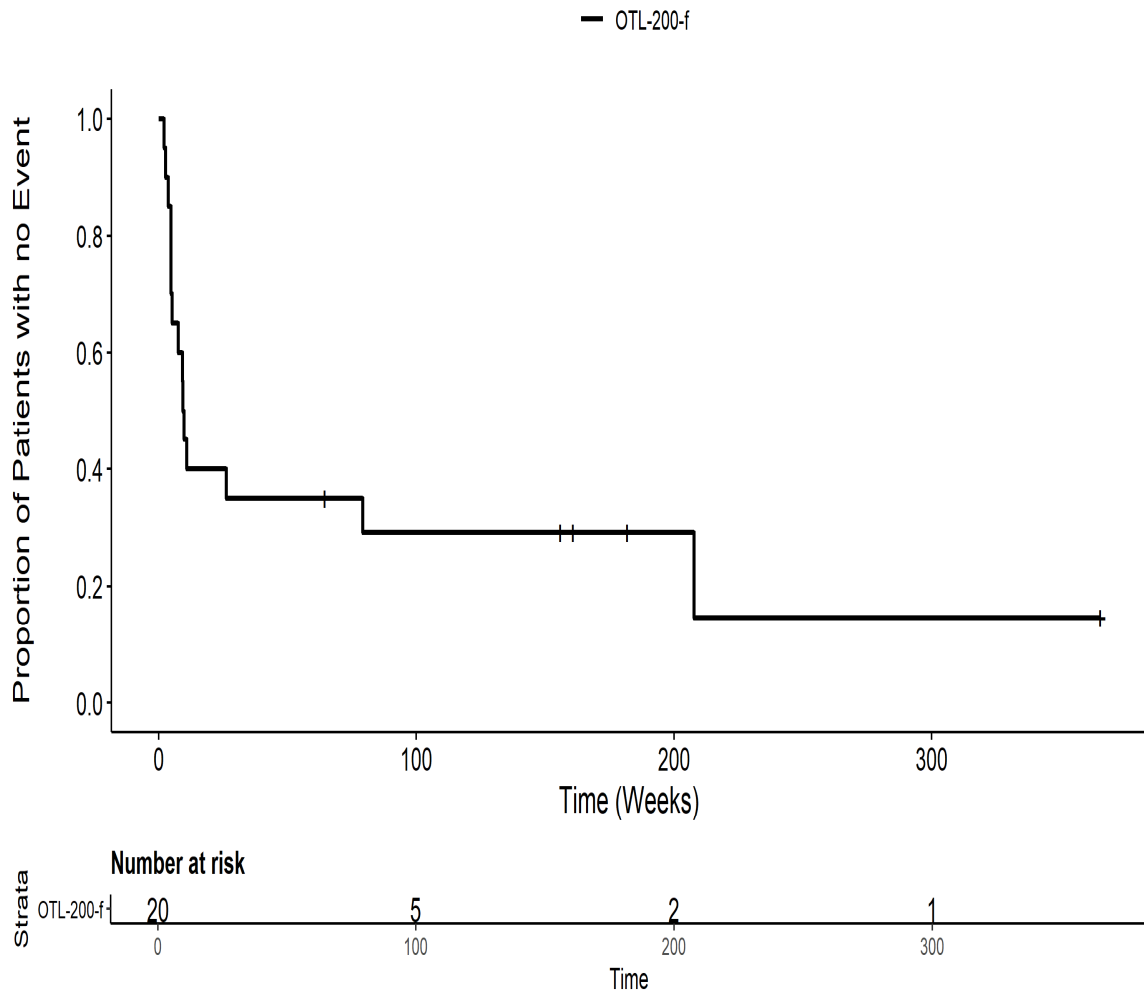
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PT pct Gesamt SOCITT



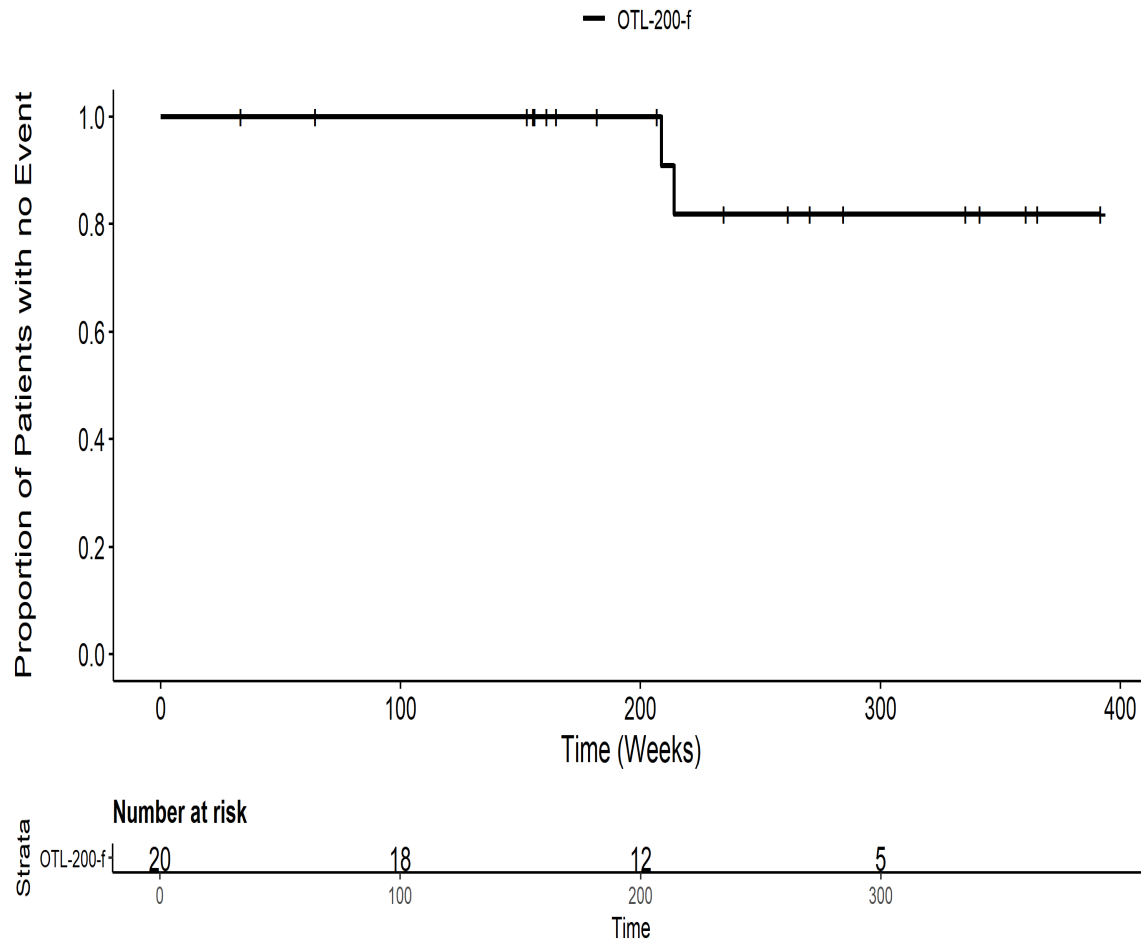
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PT pct Vitamin D erniedrigtITT



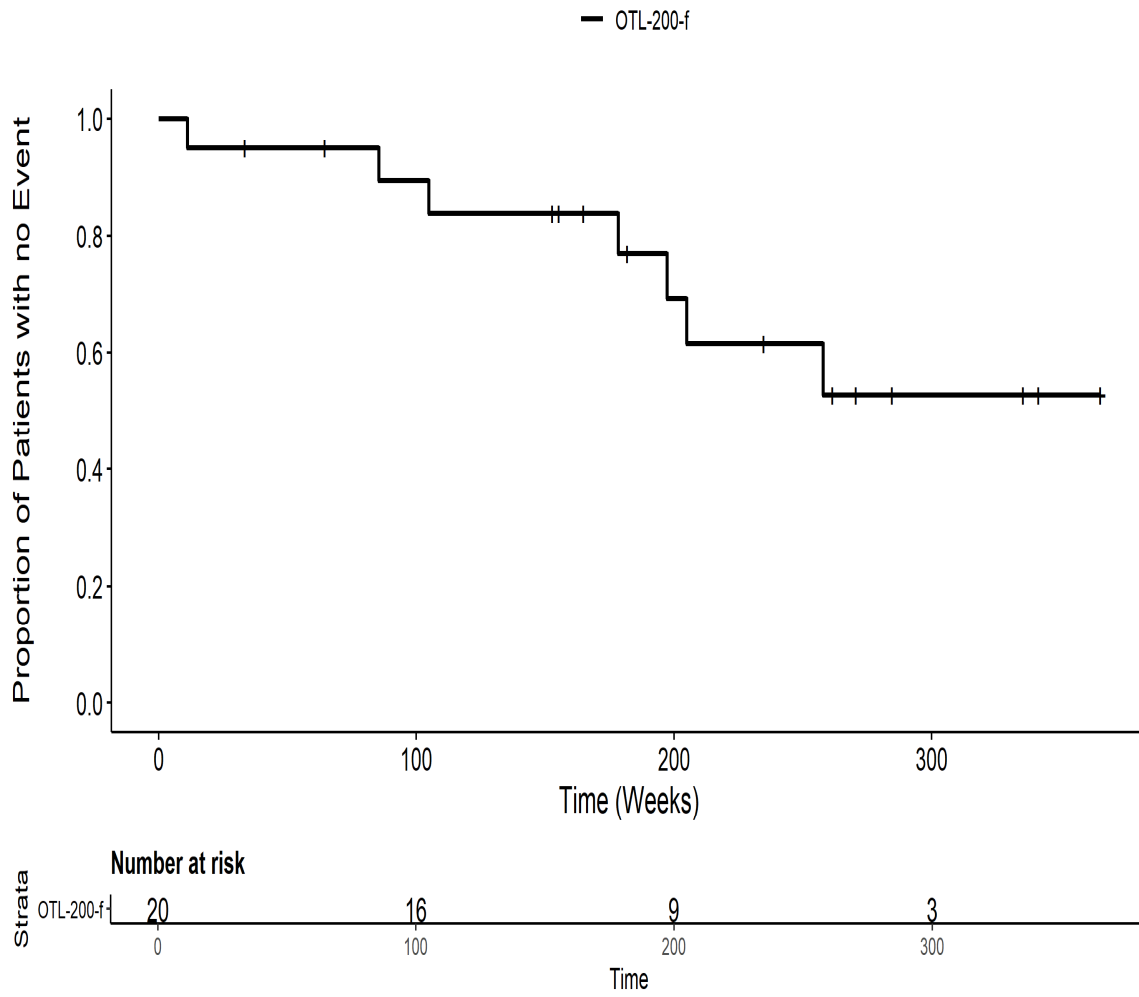
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PT pts Gesamt SOC ITT



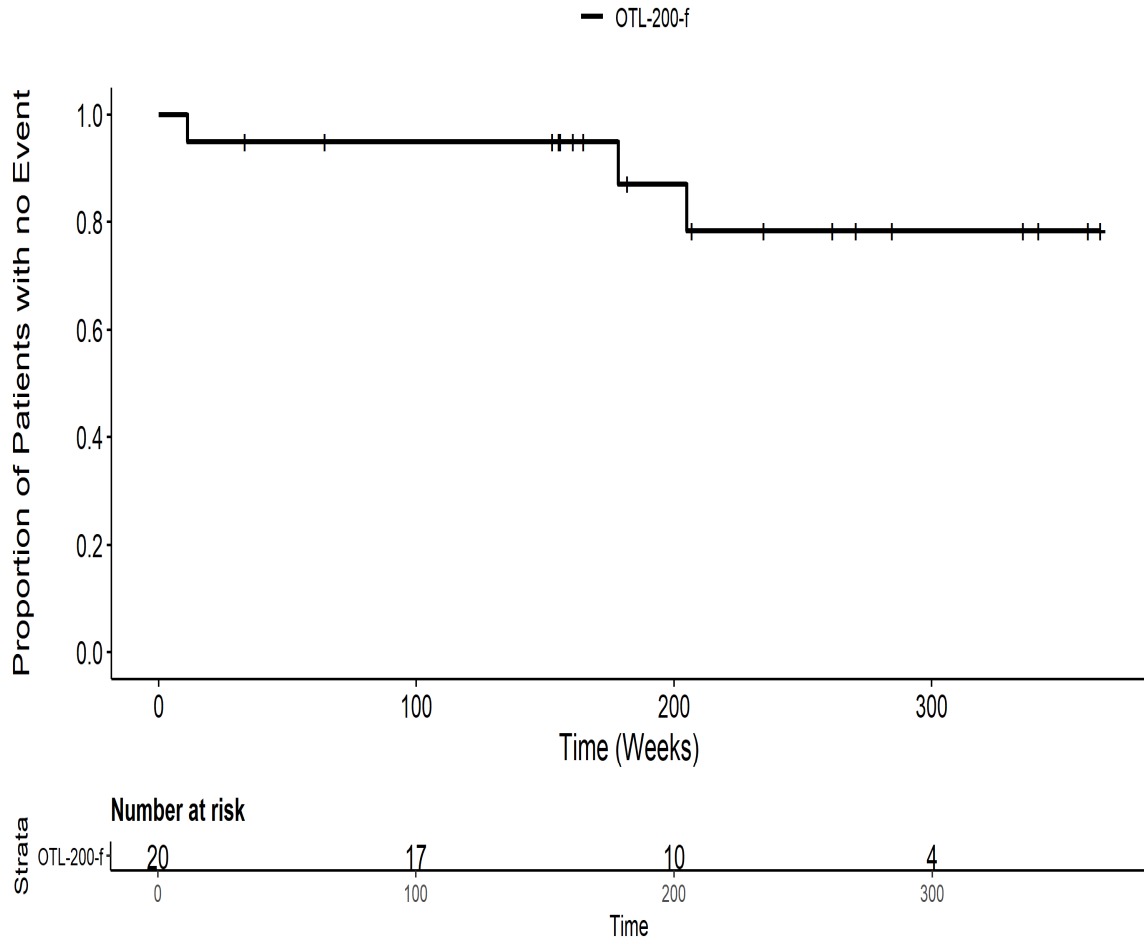
201222: Kaplan Meier Plot for Time to mild AE by SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen PT pct Fraktur des FussesITT



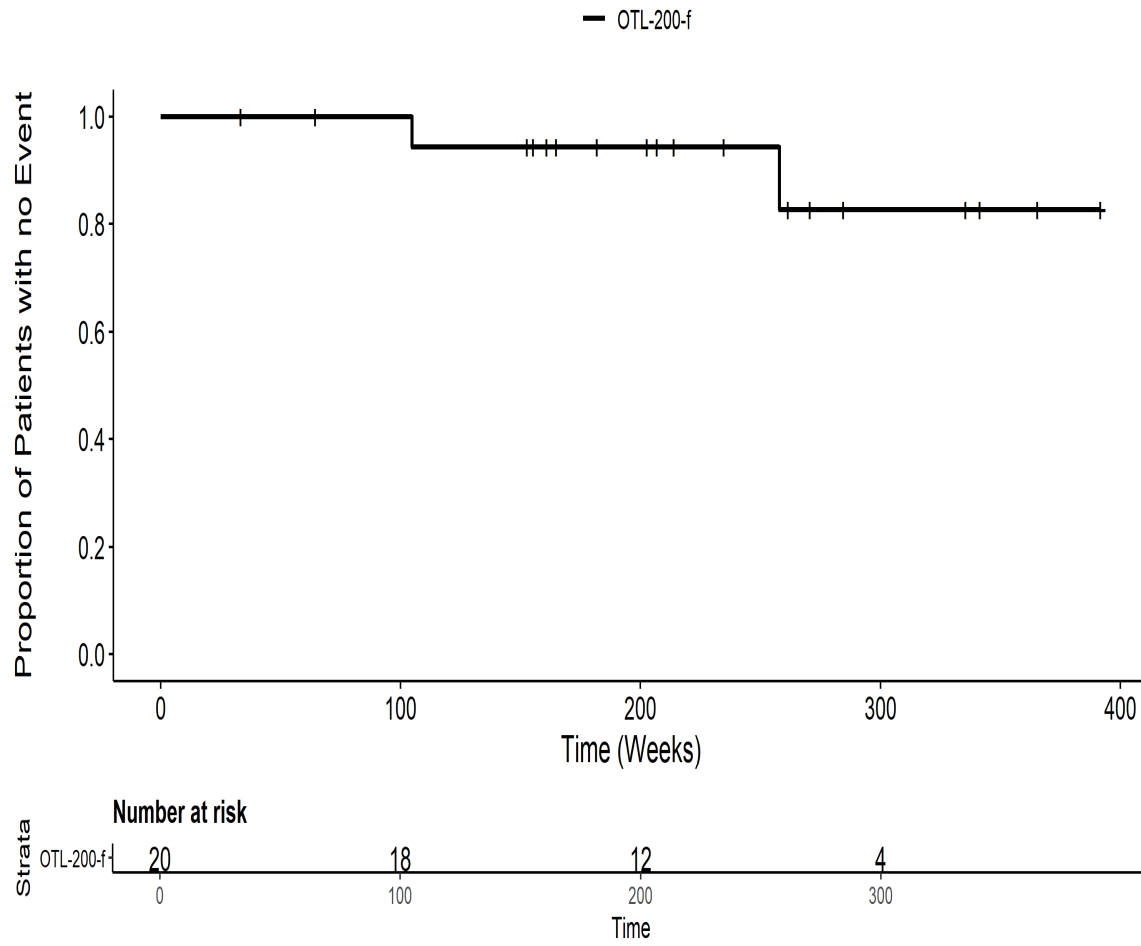
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Vergiftung und durch Eingriffe bedingte Komplikationen PT pct Gesamt SOCITT



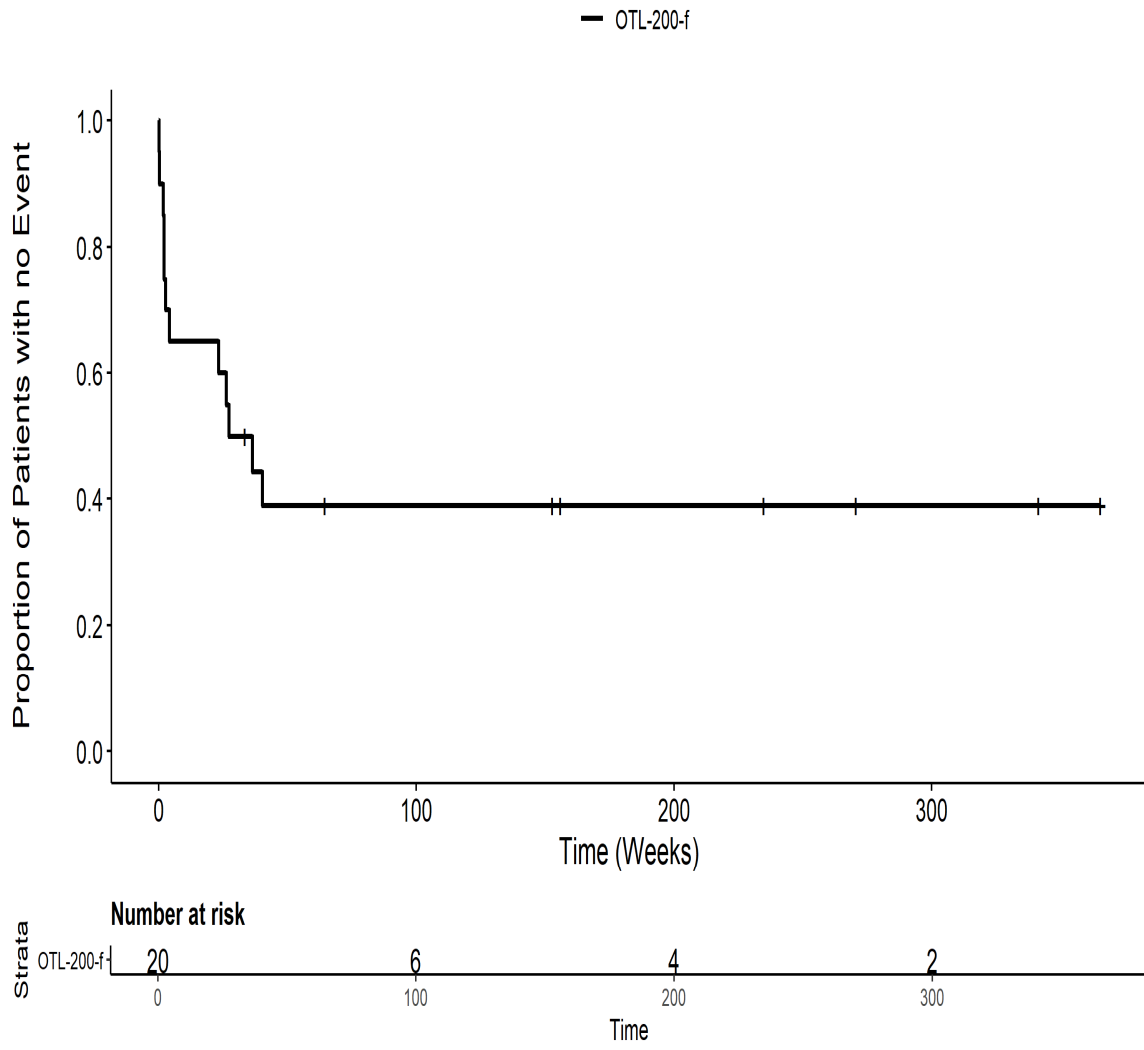
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 Vergiftung und durch Eingriffe bedingte Komplikationen PT pct
 KopfverletzungITT



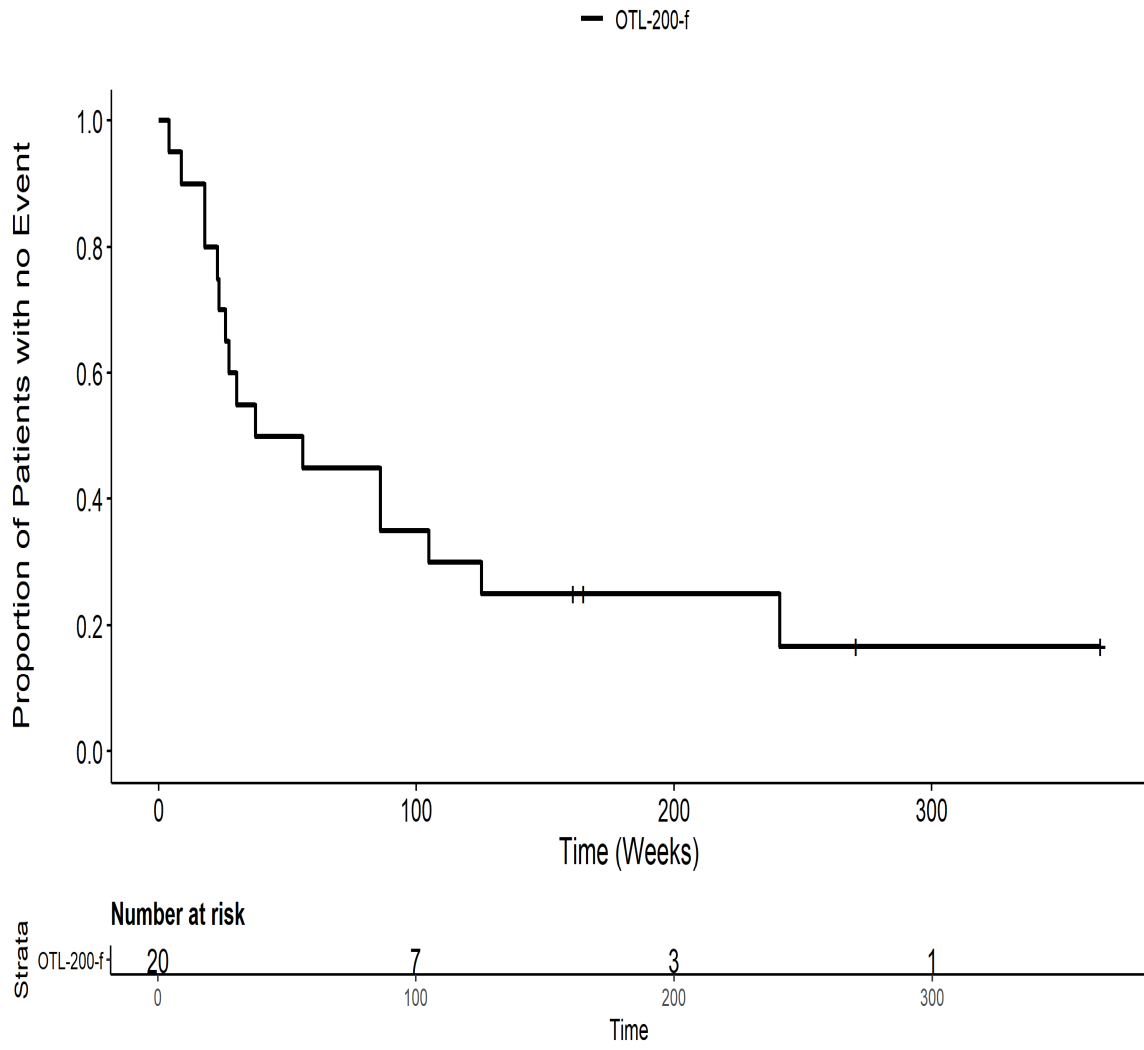
201222: Kaplan Meier Plot for Time to mild AE by SOC Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen PT pct Schmerzen waehrend eines EingriffesITT



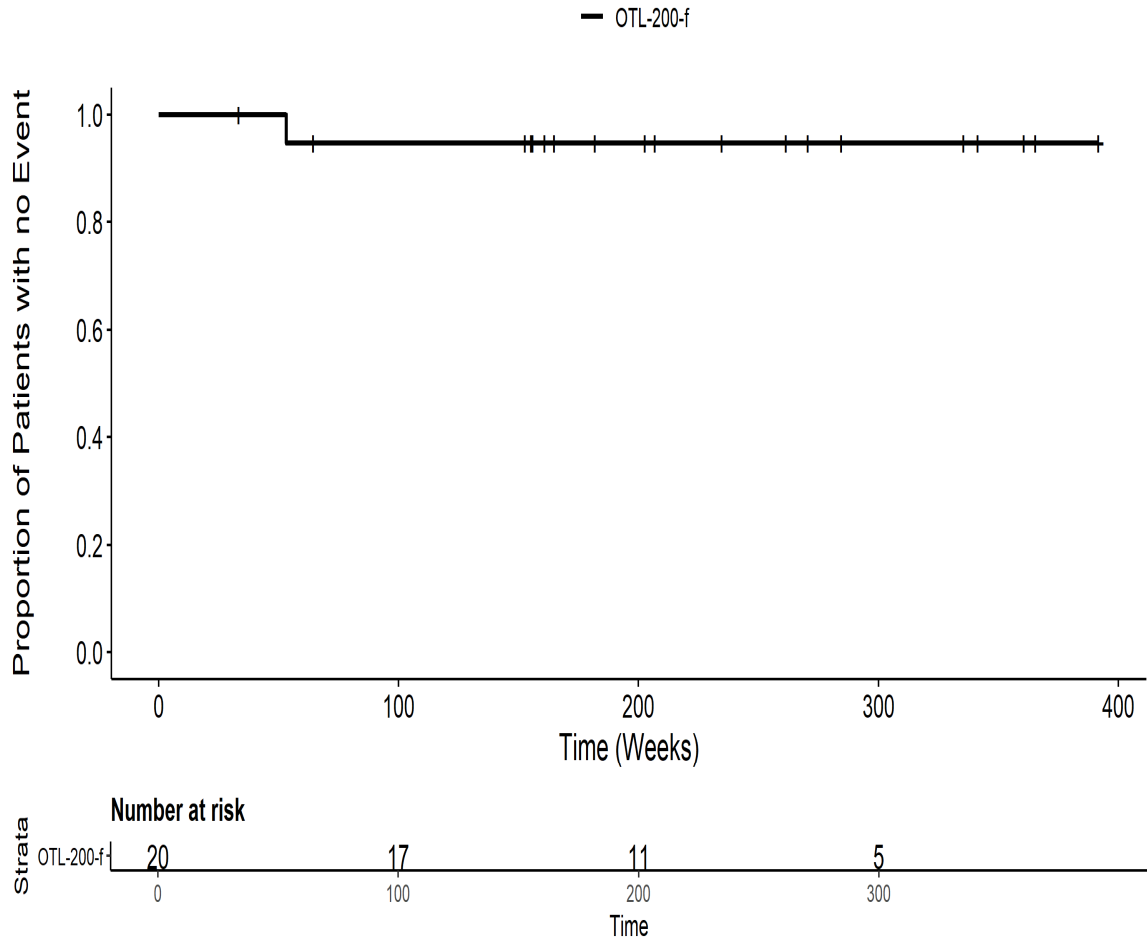
201222: Kaplan Meier Plot for Time to mild AE SMQ ITT



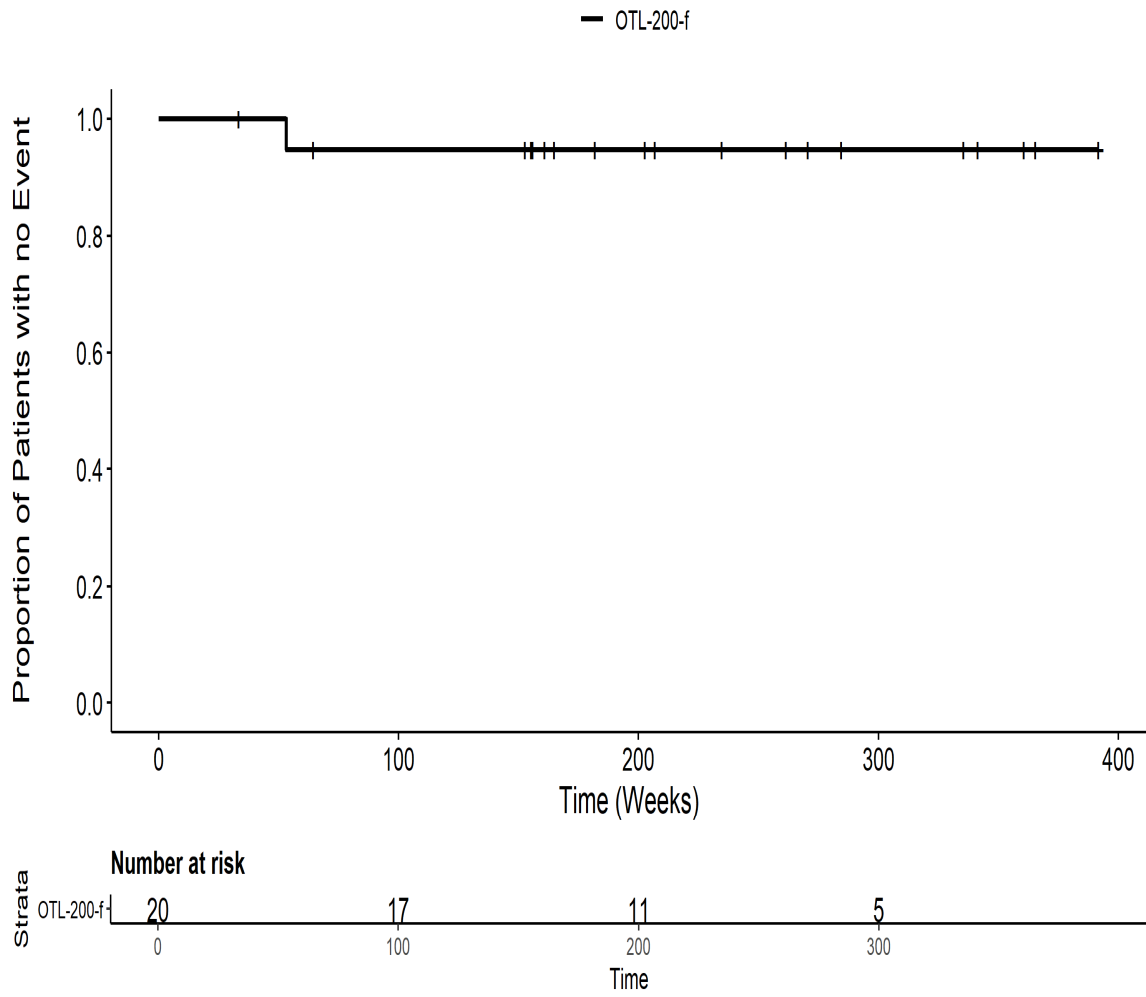
201222: Kaplan Meier Plot for Time to serious AE ITT



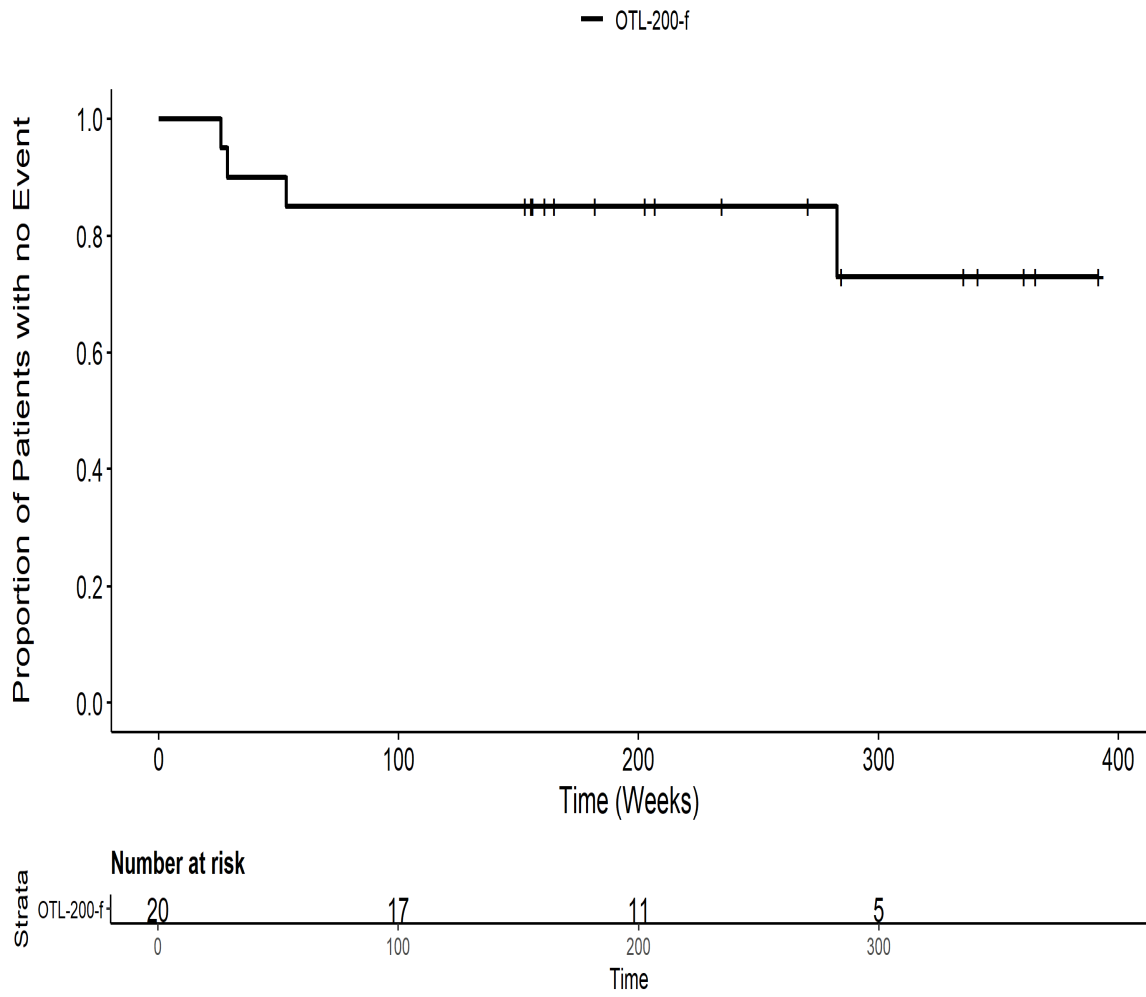
201222: Kaplan Meier Plot for Time to serious AE by SOC
 Erkrankungen der Atemwege, des Brustraums und Mediastinums PT pct
 AspirationspneumonieITT



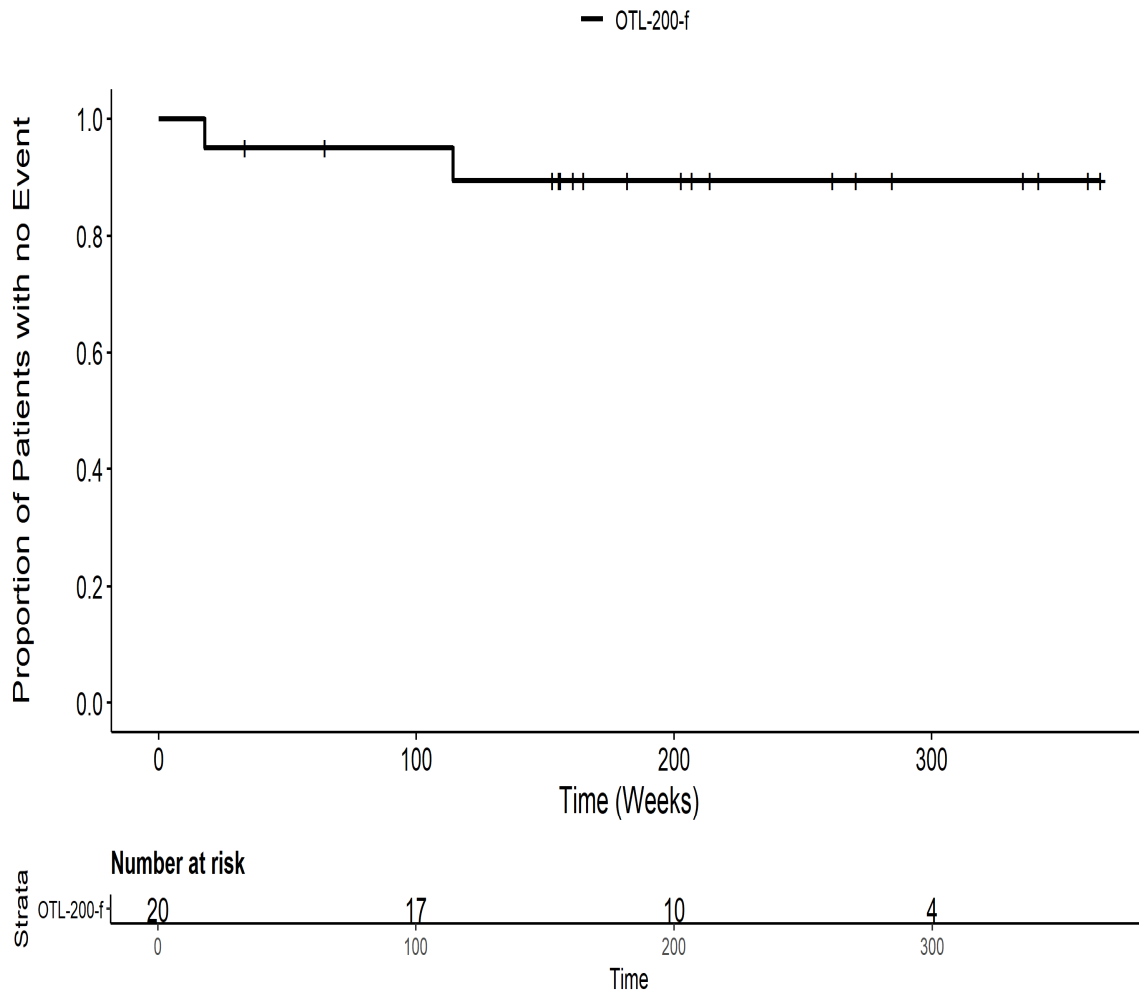
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Erkrankungen der Atemwege, des Brustraums und Mediastinums PT pct Gesamt SOCITT



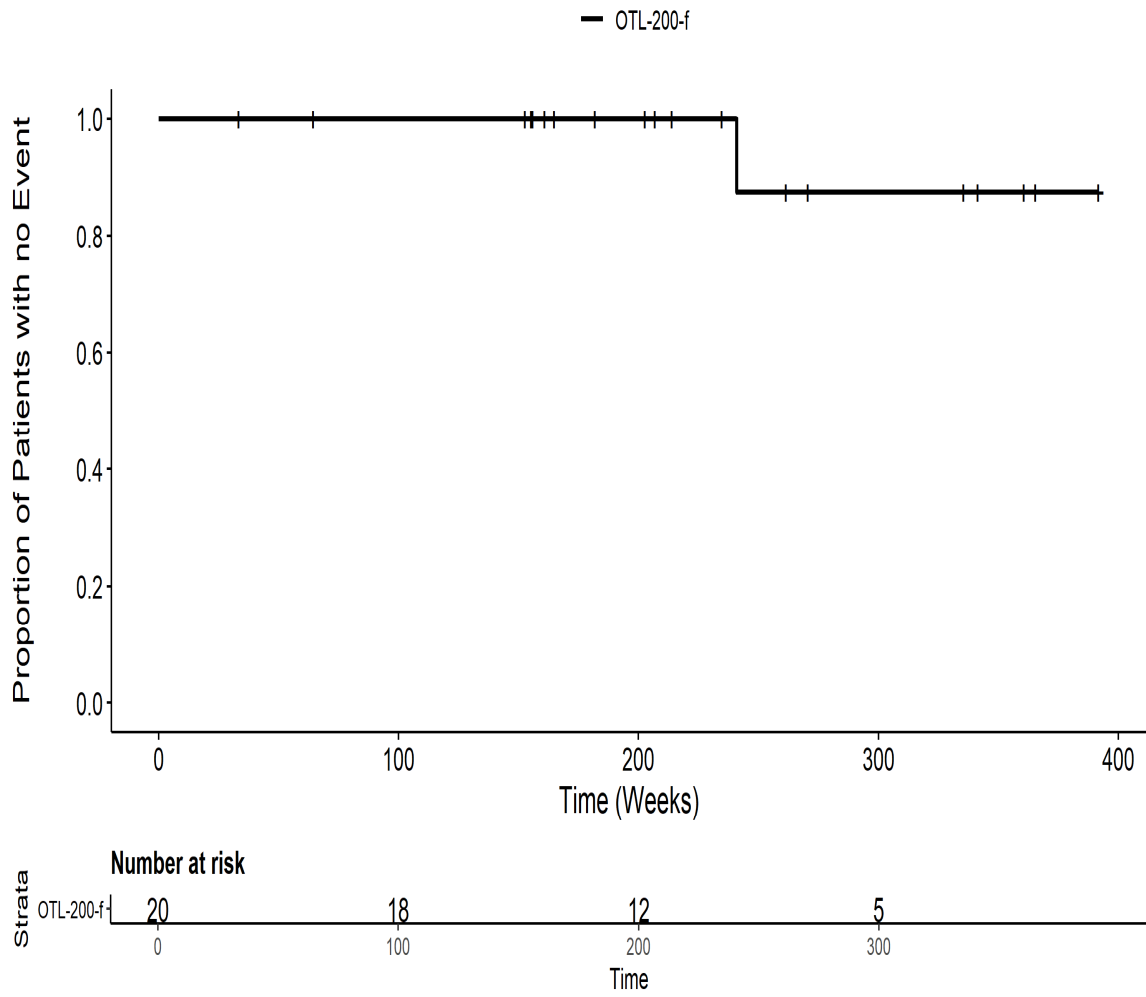
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Erkrankungen des Gastrointestinaltrakts PT pct DysphagieITT



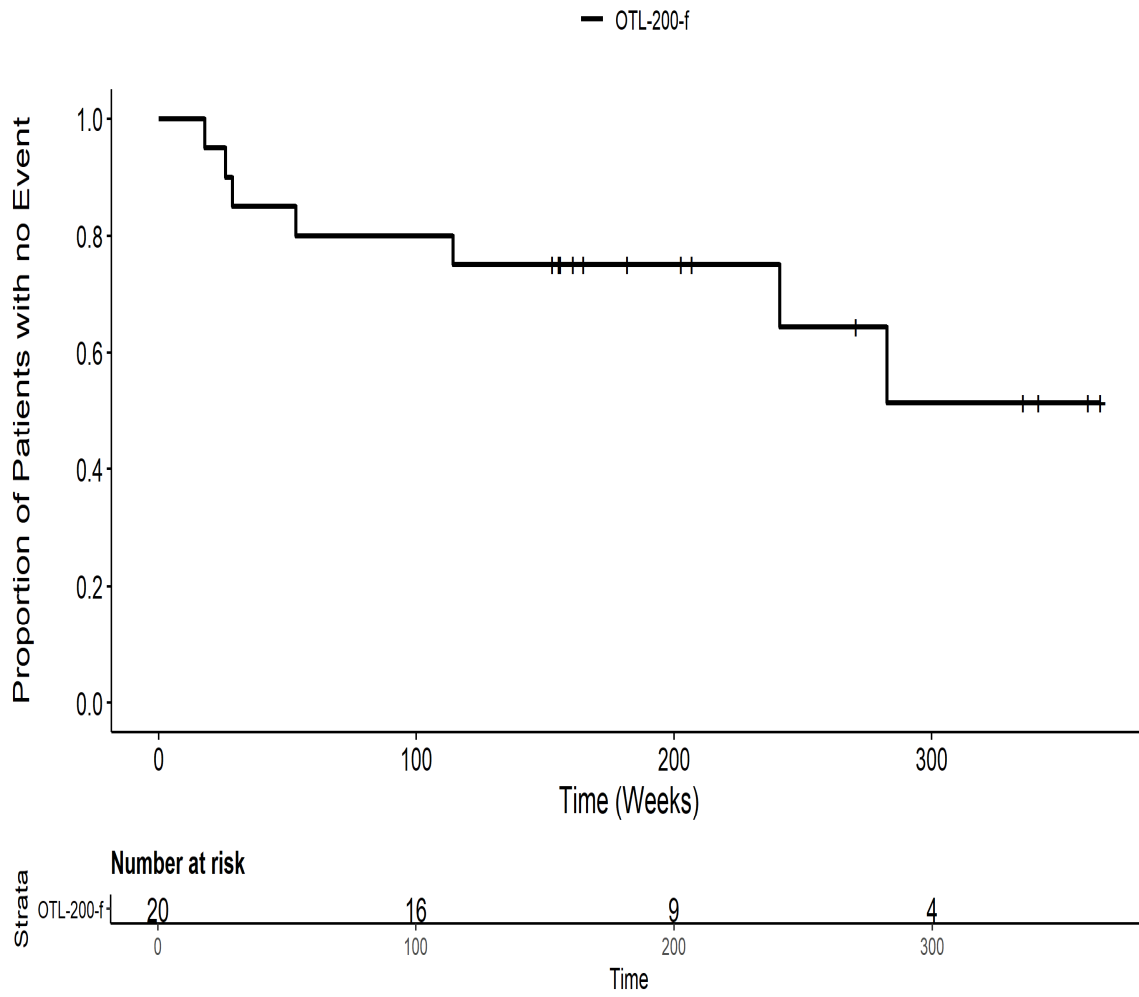
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Erkrankungen des Gastrointestinaltrakts PT pct EnteritisITT



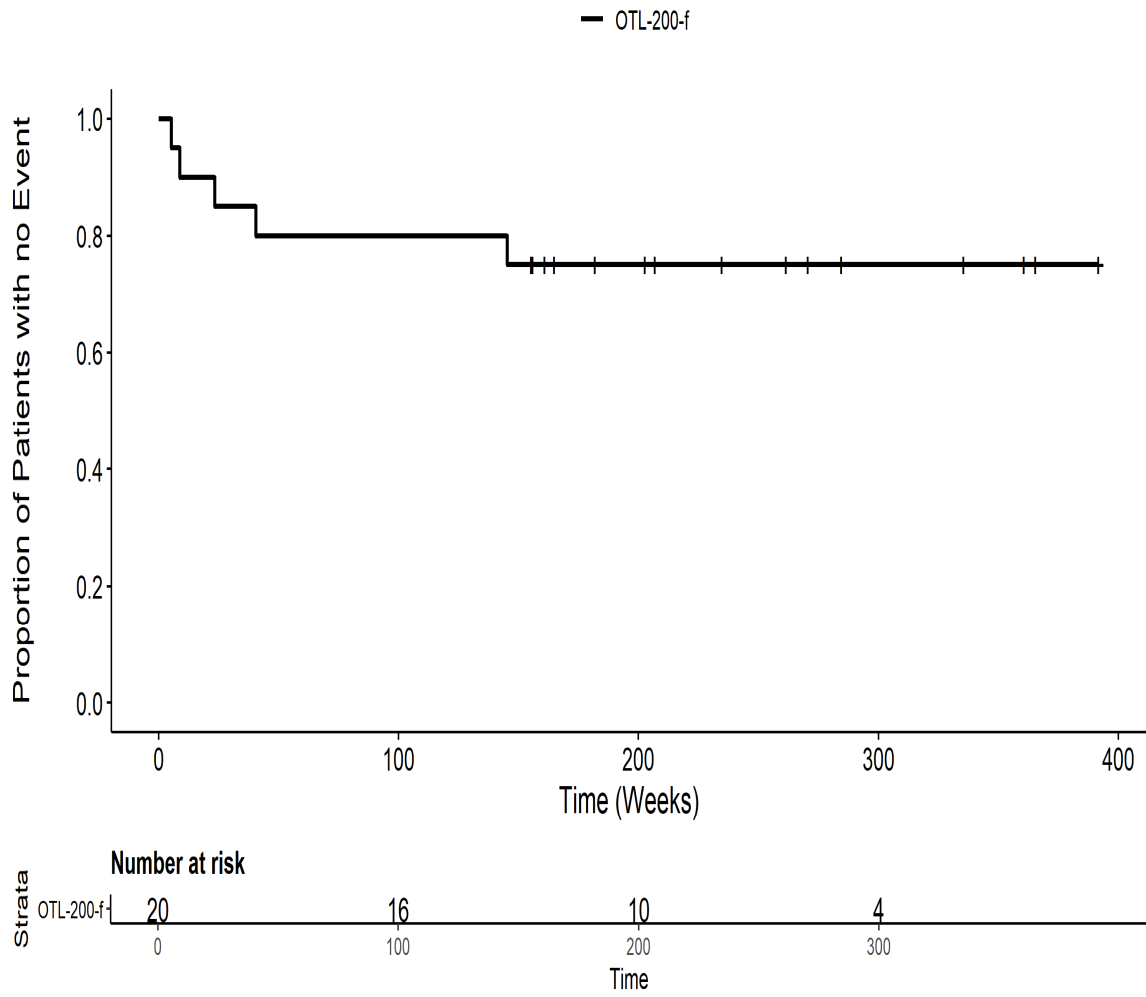
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Erkrankungen des Gastrointestinaltrakts PT pct ErbrechenITT



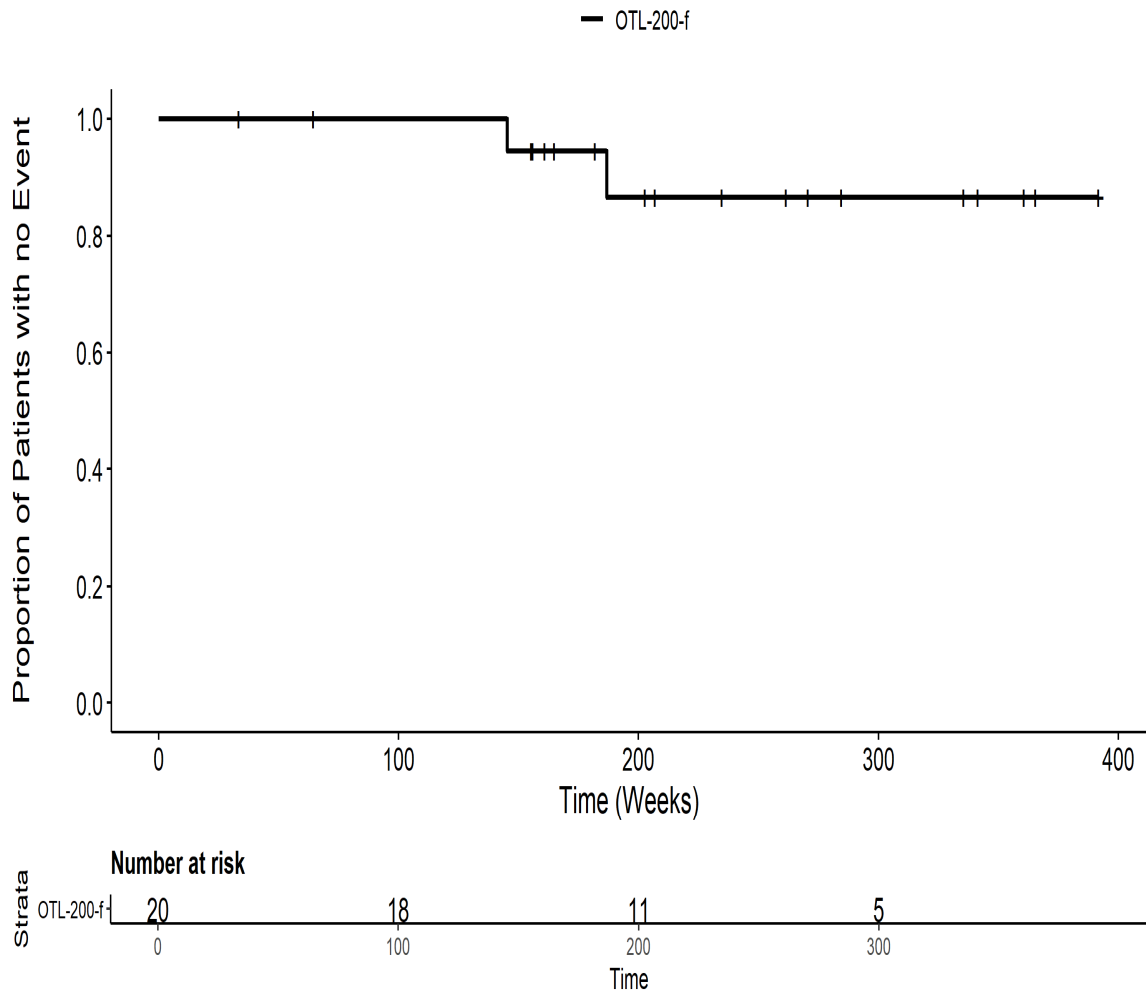
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Erkrankungen des Gastrointestinaltrakts PT pct Gesamt SOCITT



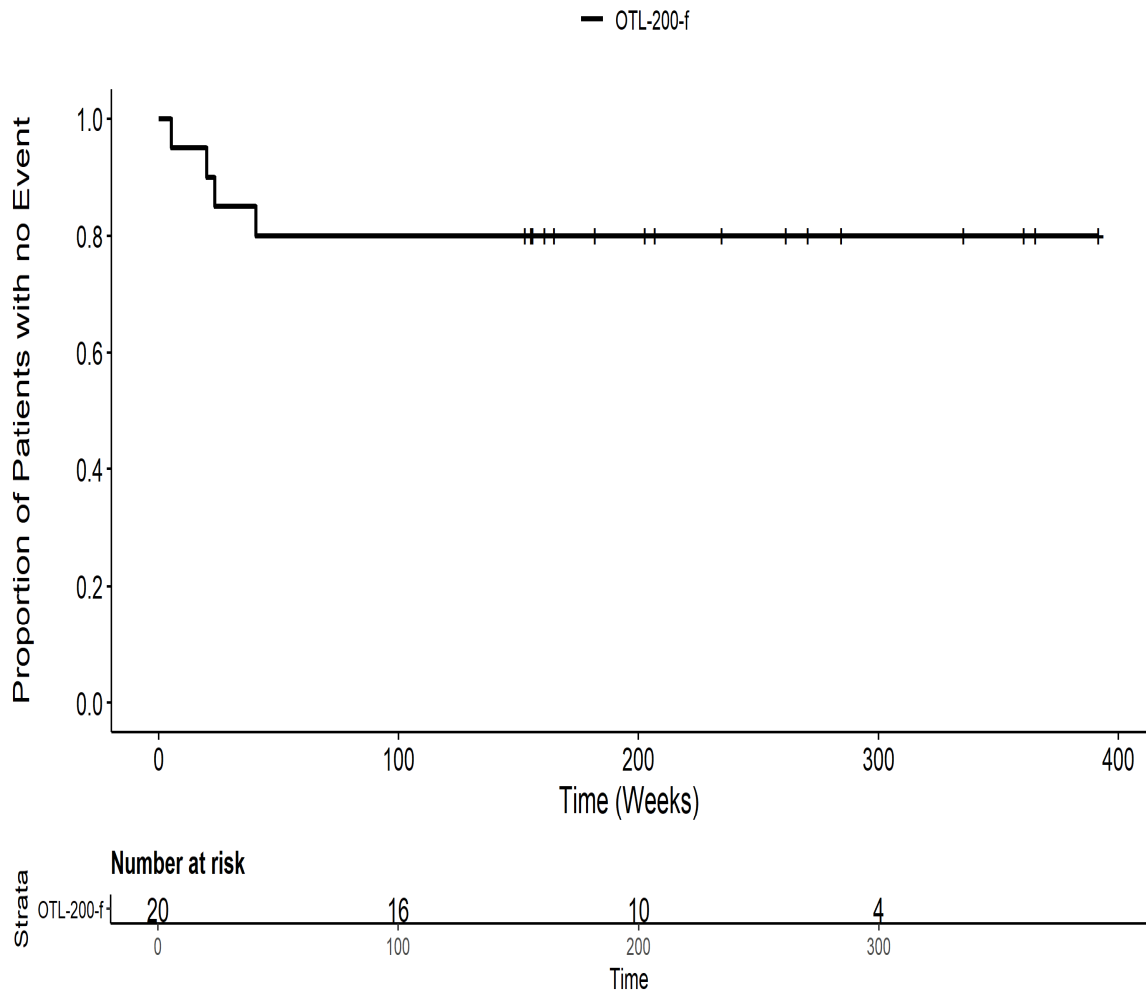
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Erkrankungen des Nervensystems PT pct Gesamt SOCITT



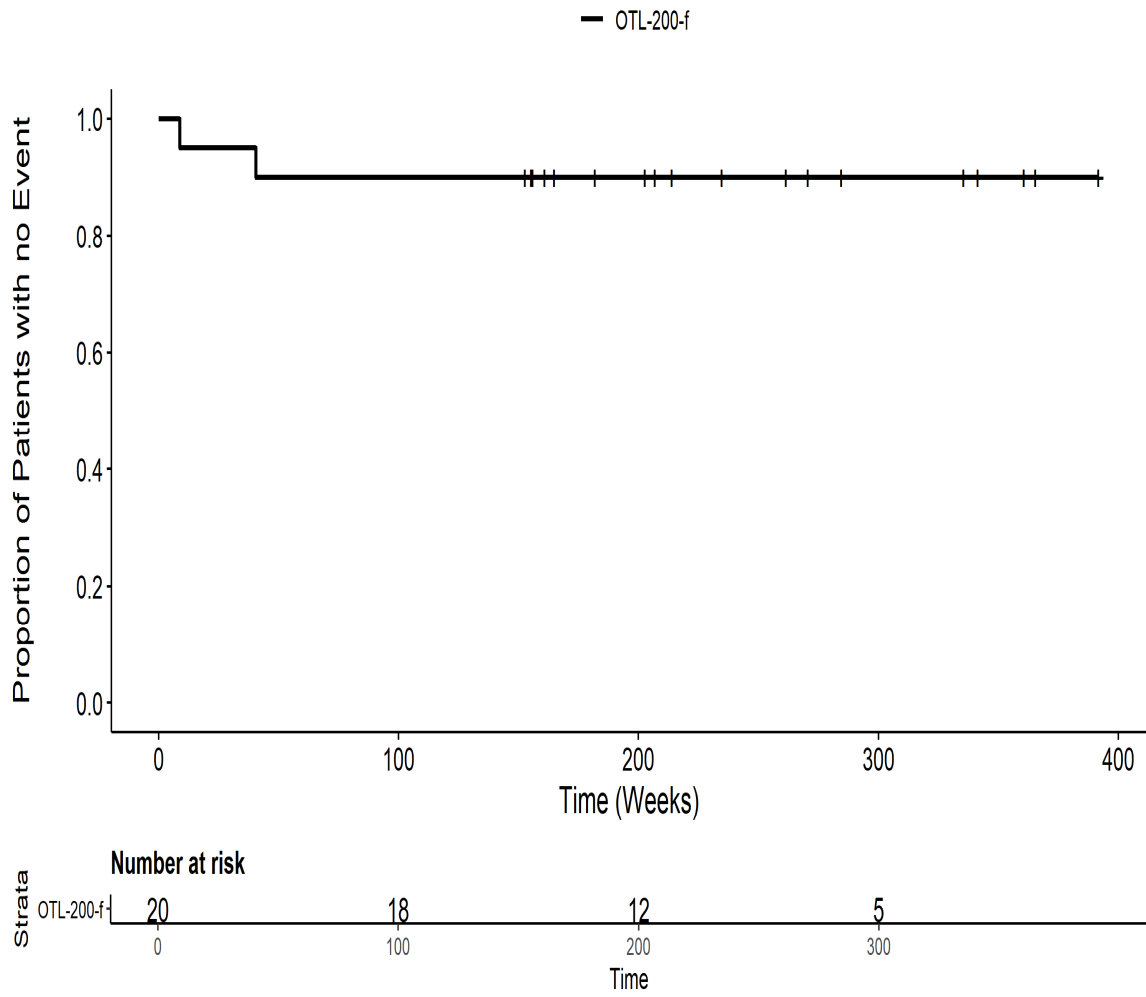
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Erkrankungen des Nervensystems PT pct KrampfanfallITT



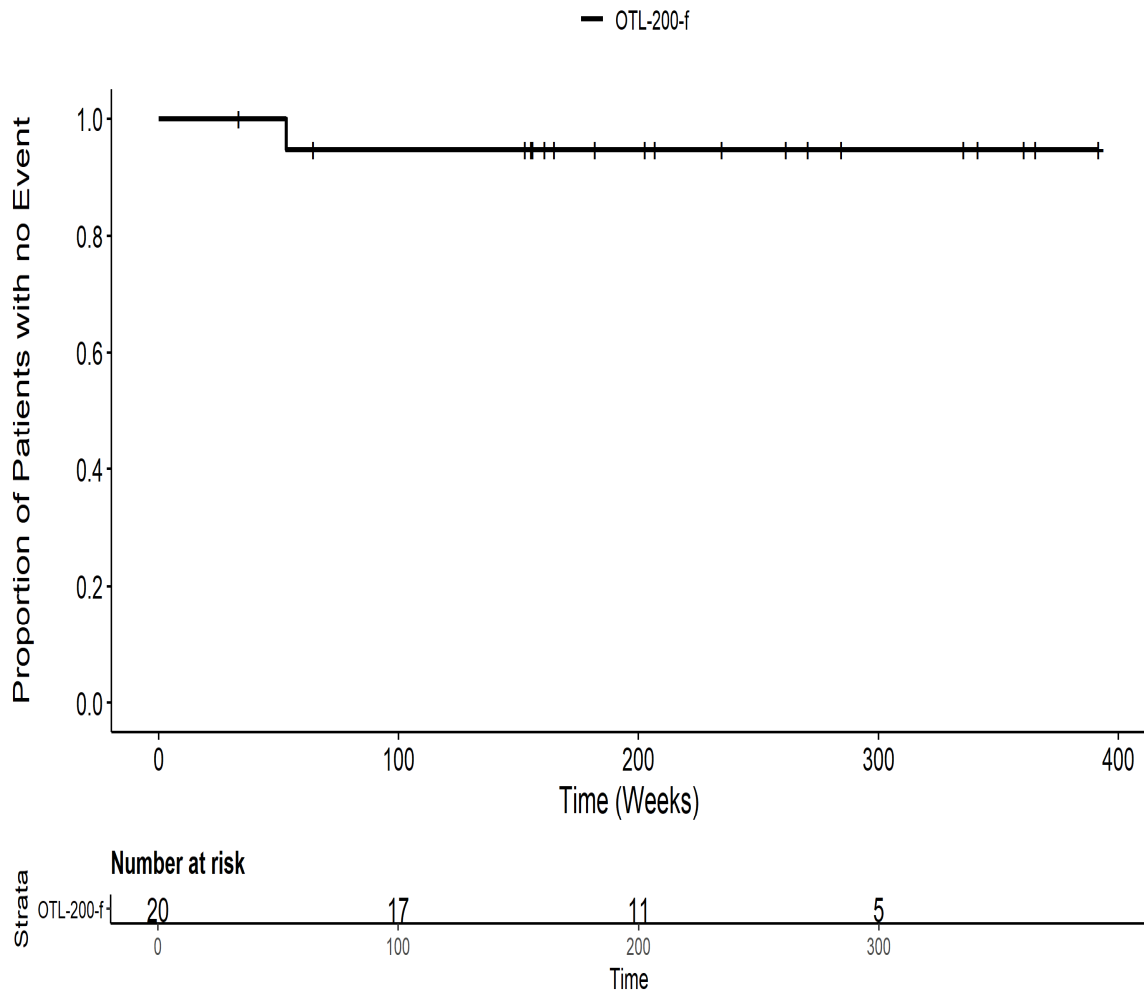
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Erkrankungen des Nervensystems PT pct Motorische FunktionsstoerungITT



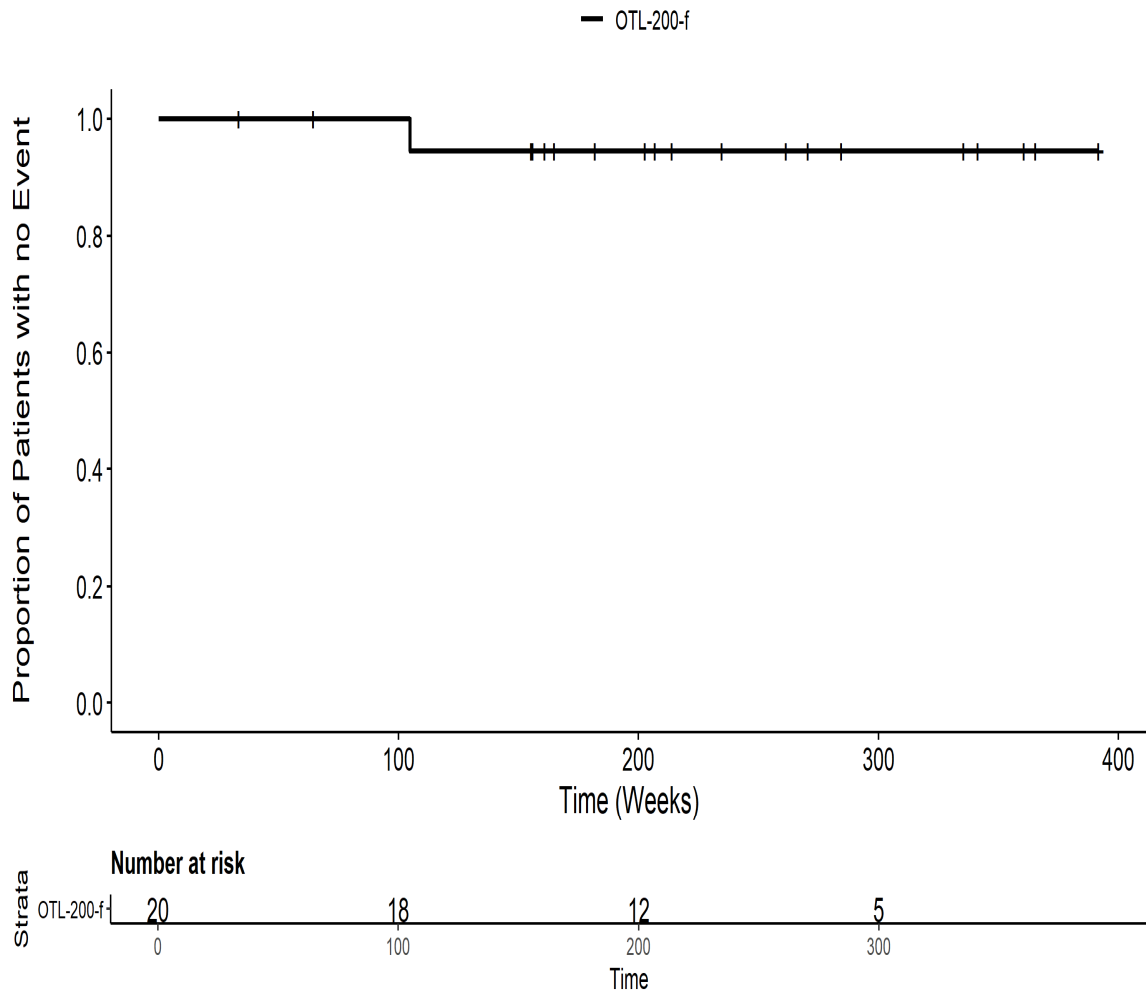
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Erkrankungen des Nervensystems PT pct SpastikITT



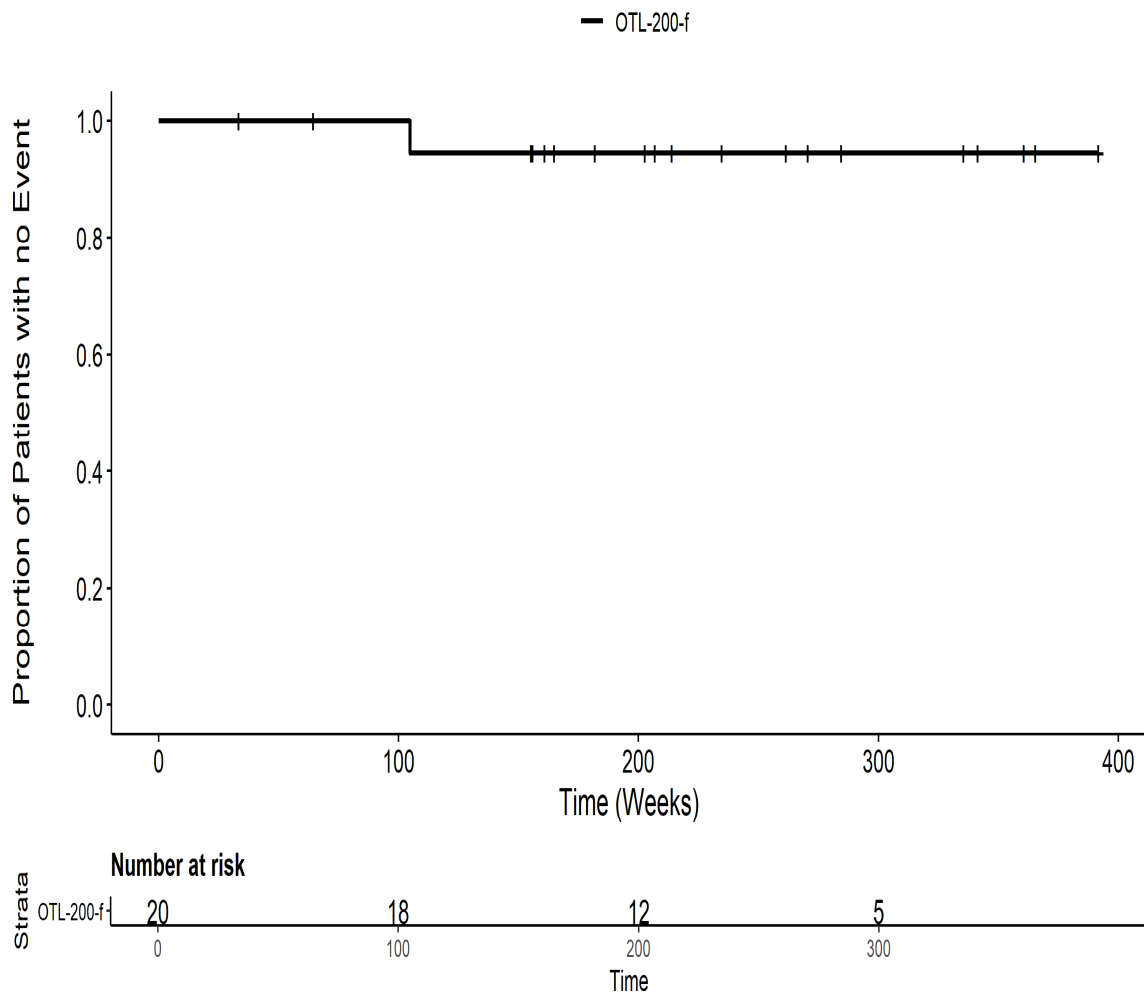
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Erkrankungen des Nervensystems PT pct Status epilepticusITT



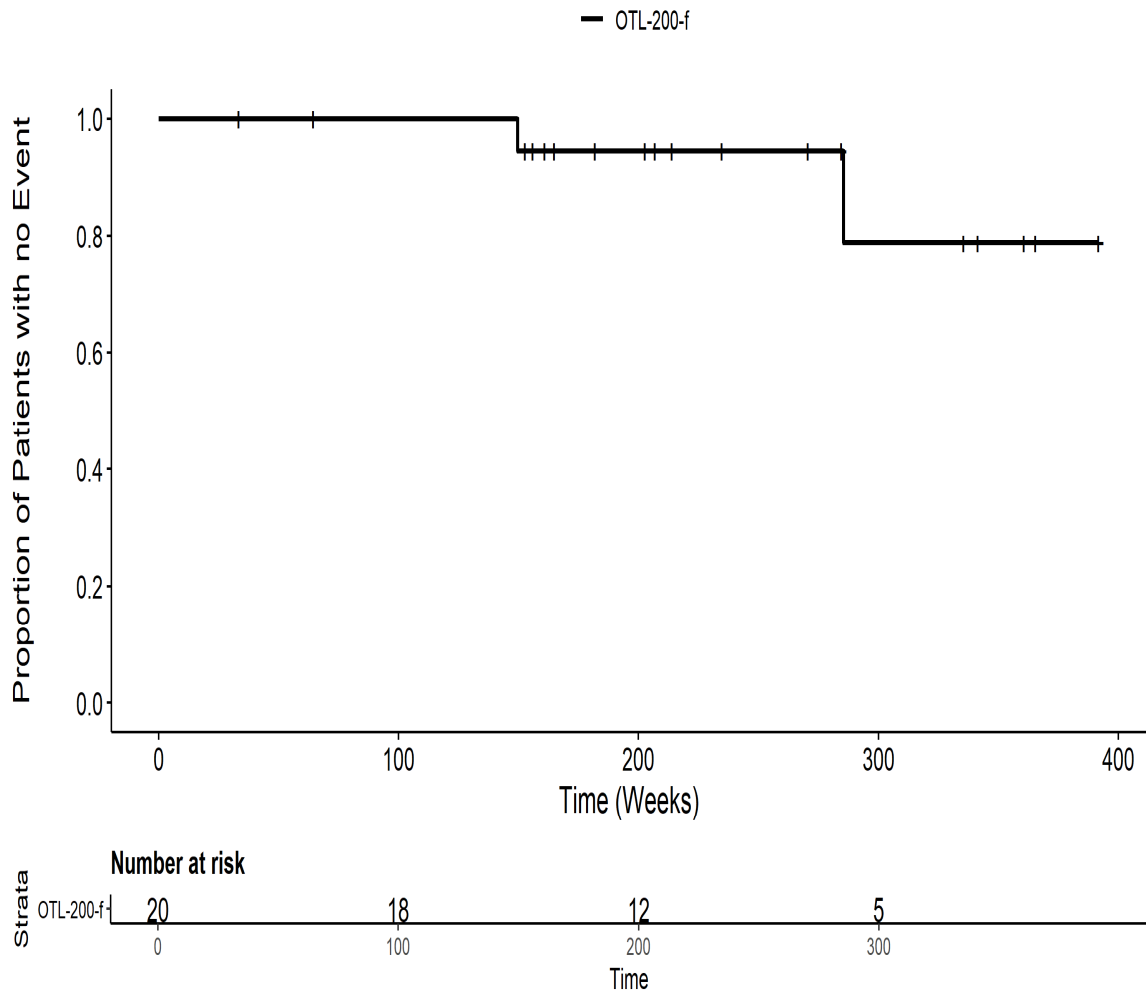
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Gefäßserkrankungen PT pct Gesamt SOCITT



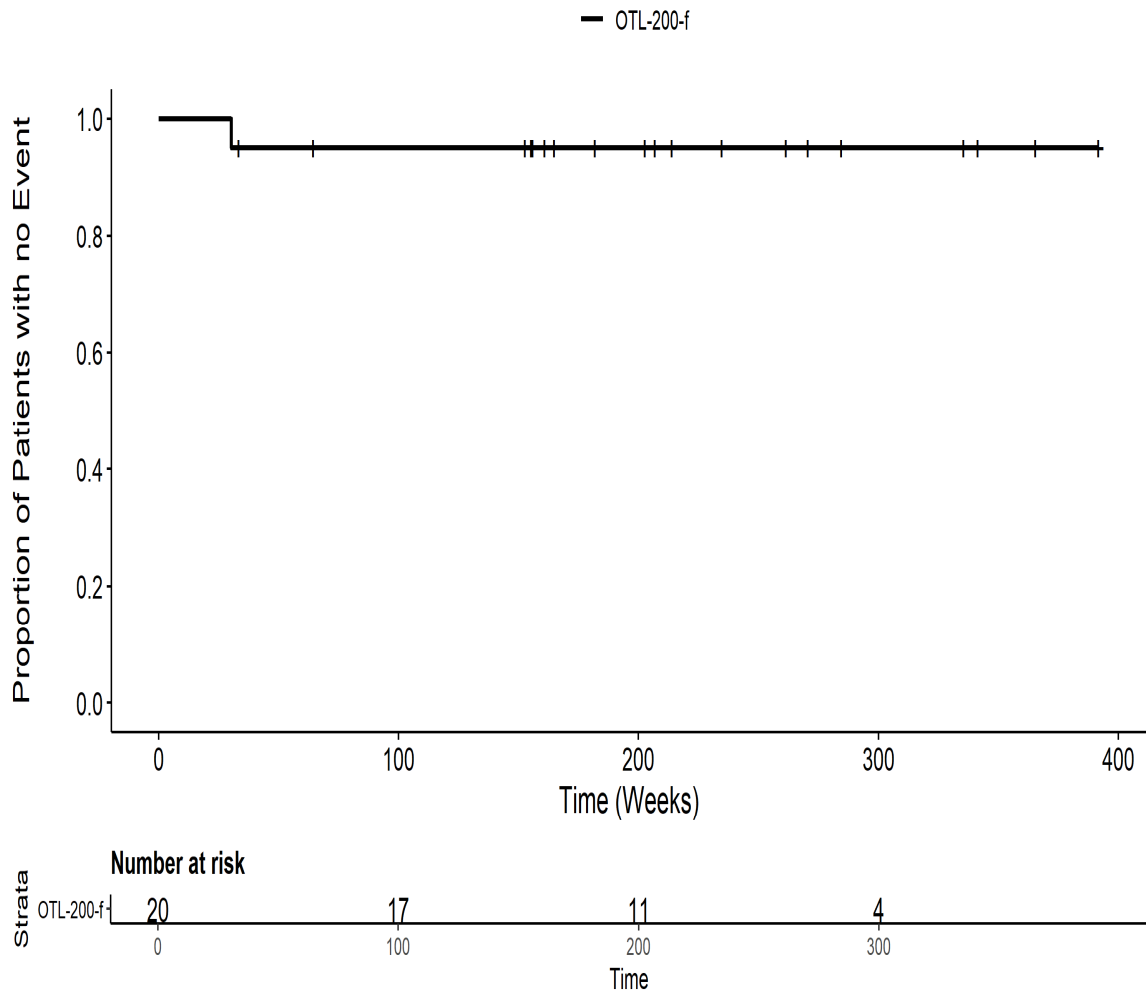
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Gefäßserkrankungen PT pct KAWASAKI'S DISEASEITT



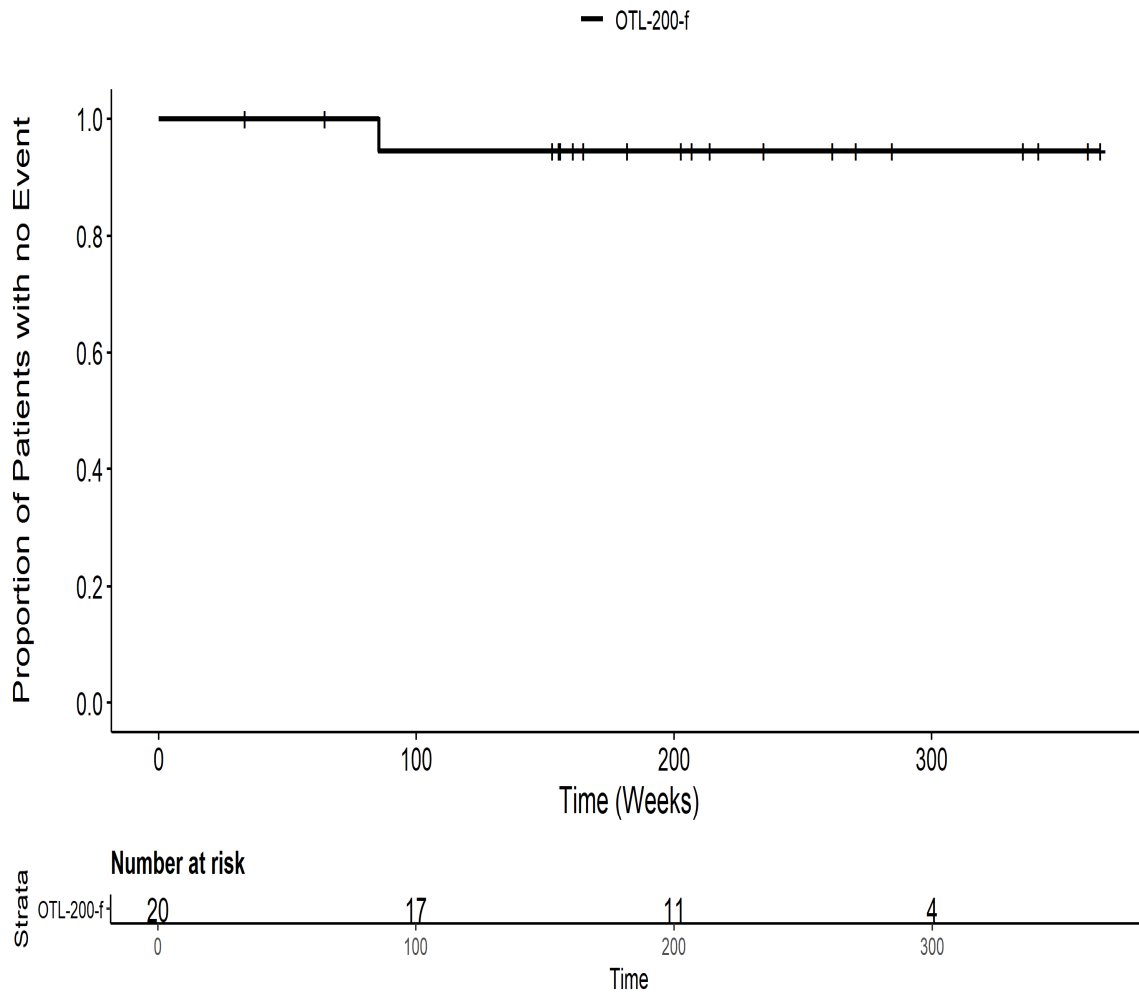
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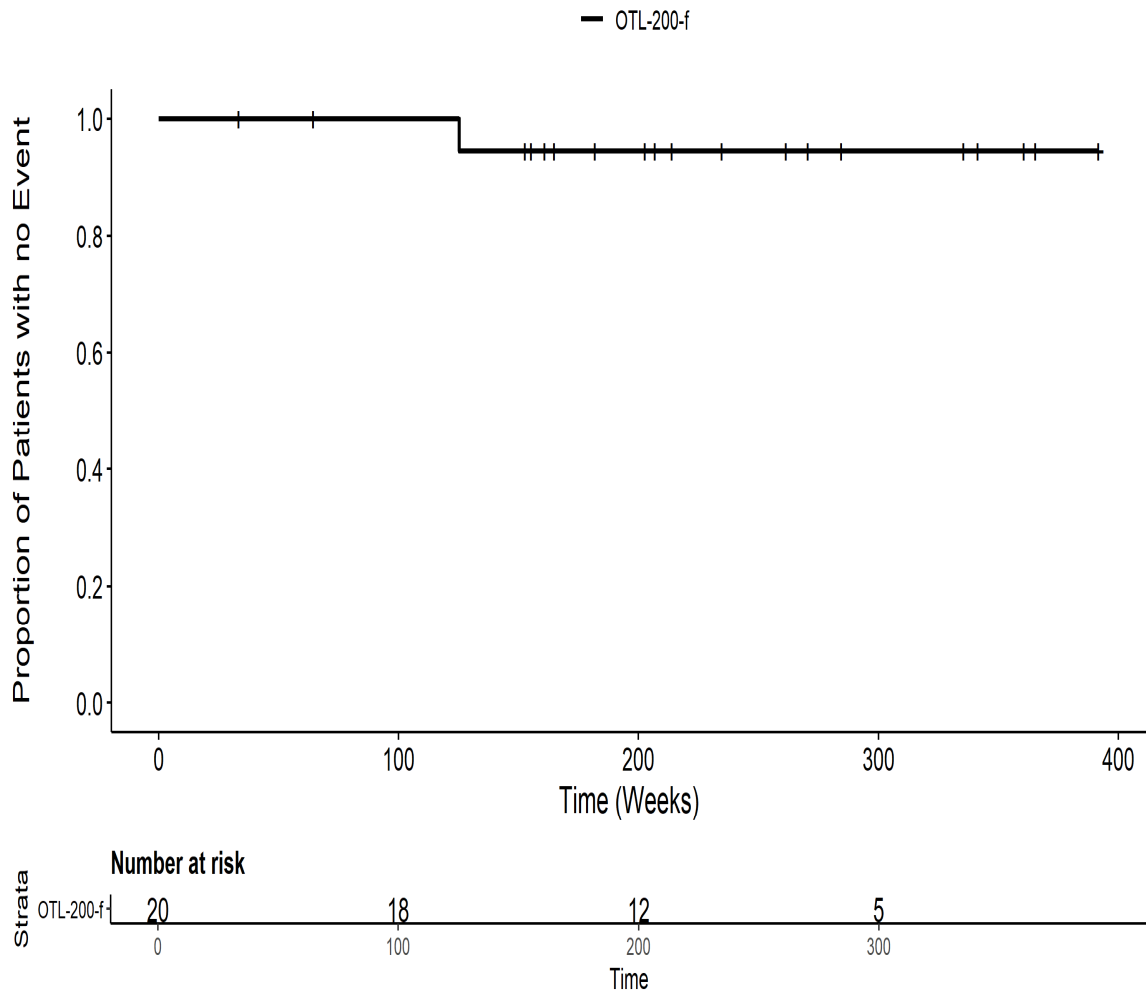
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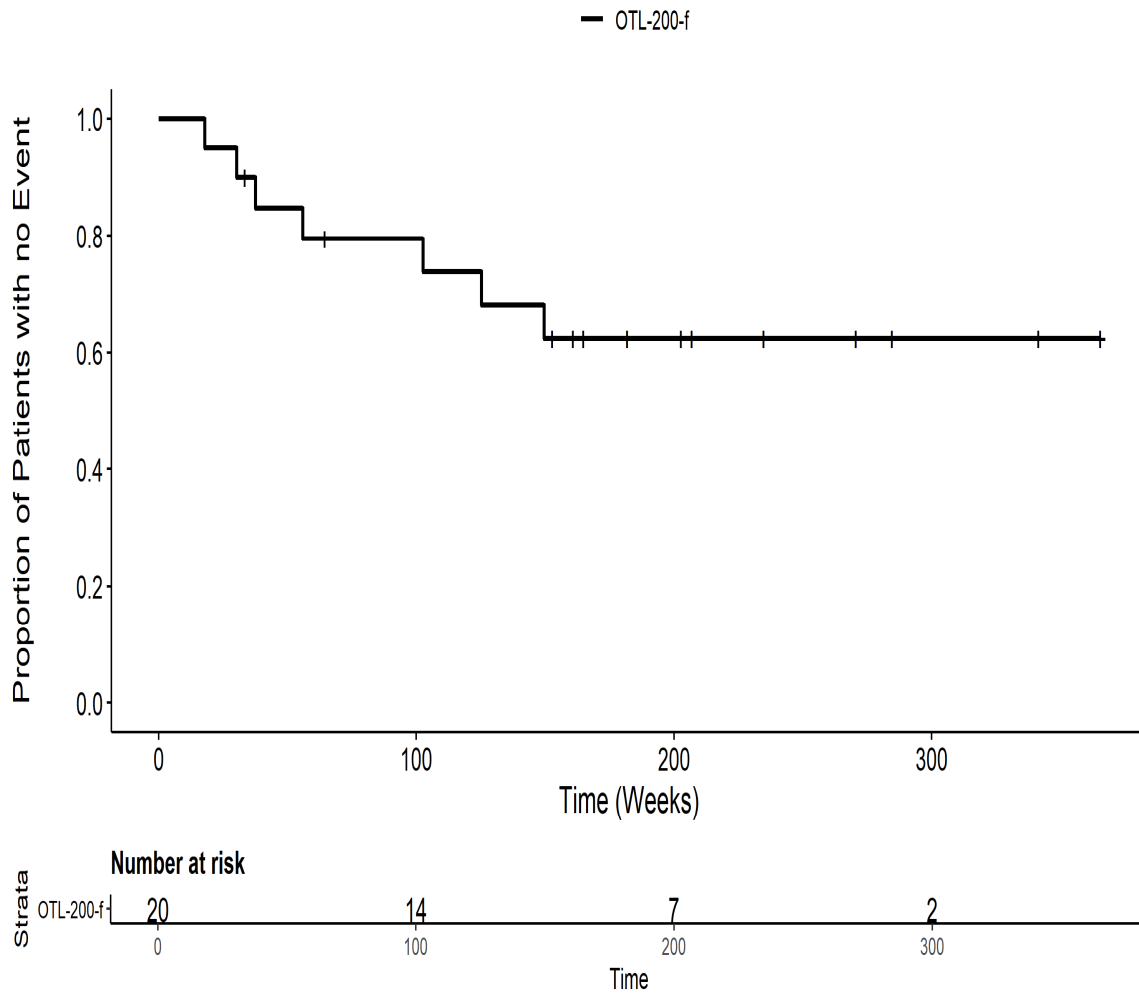
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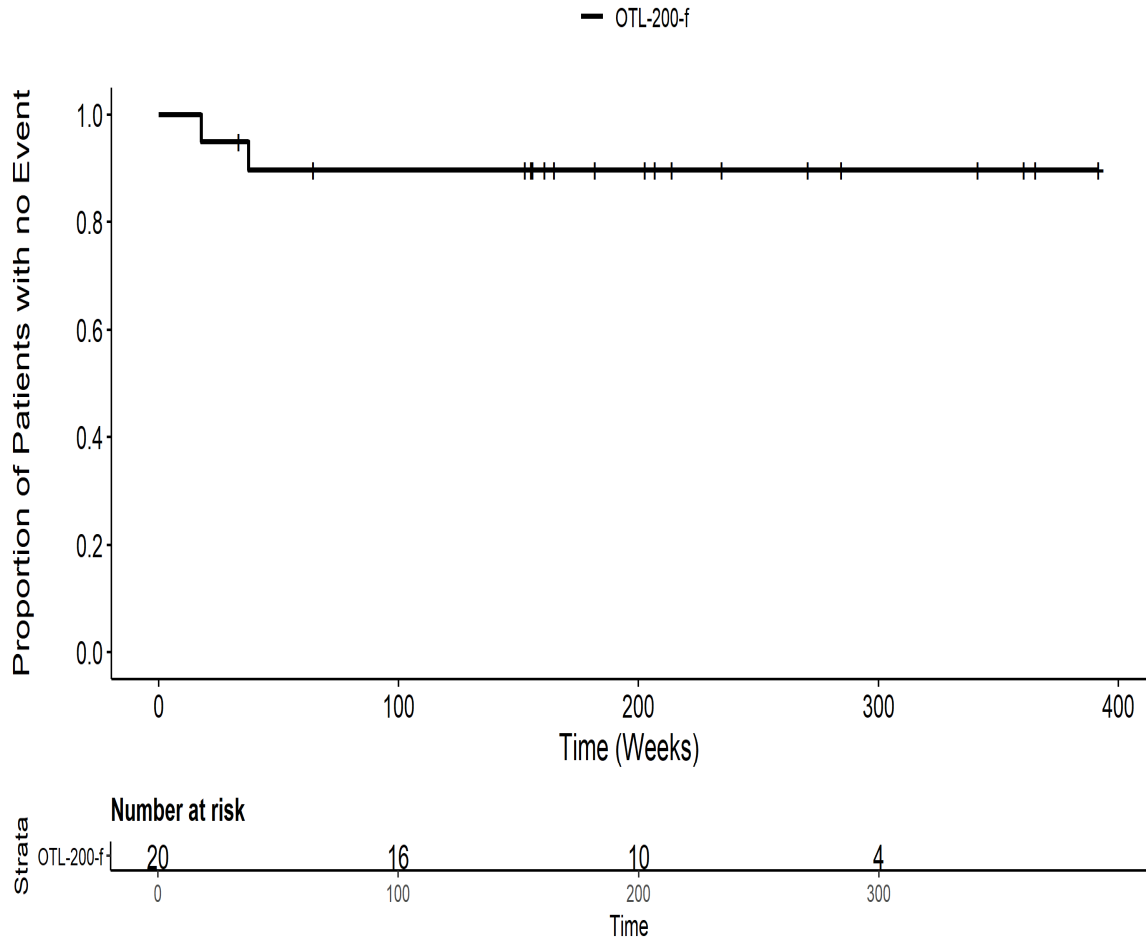
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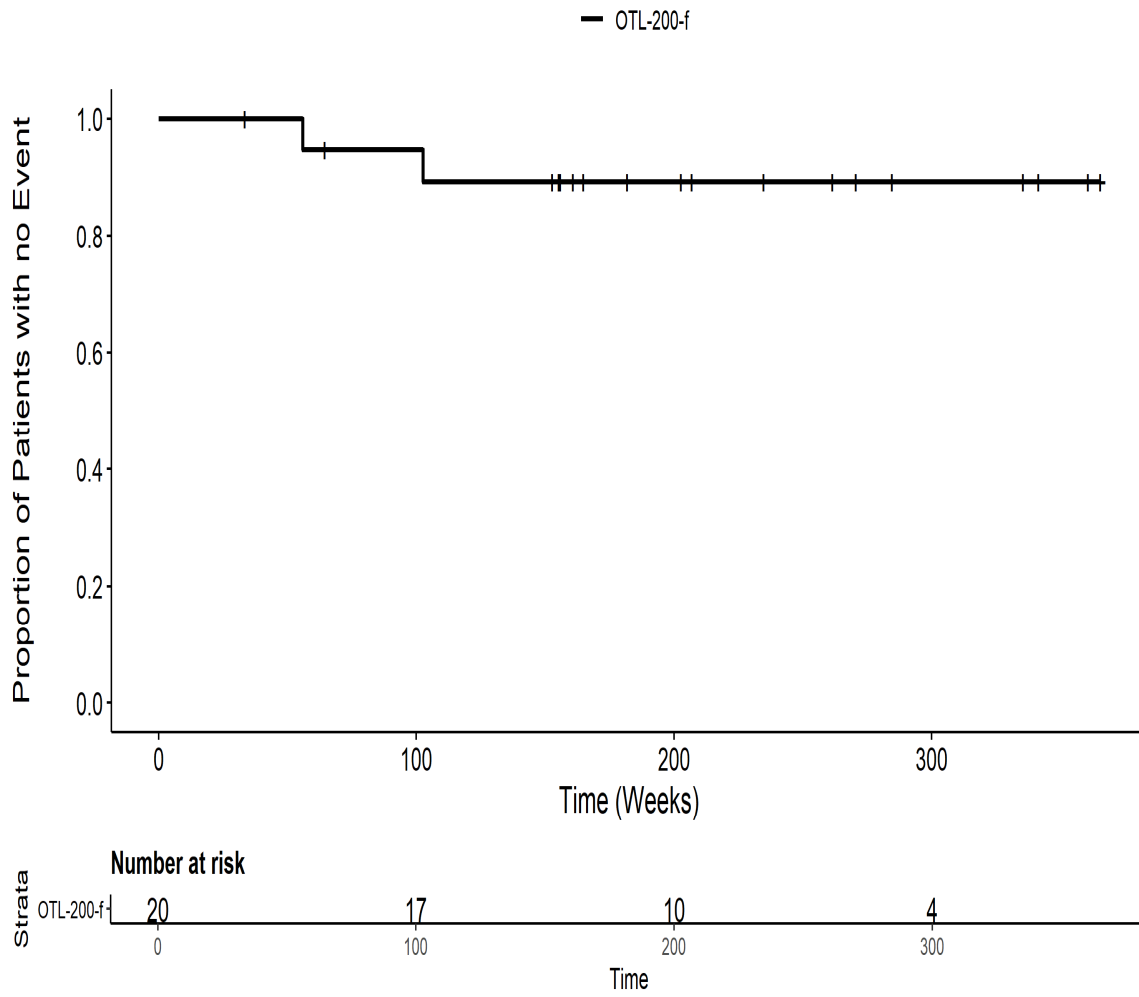
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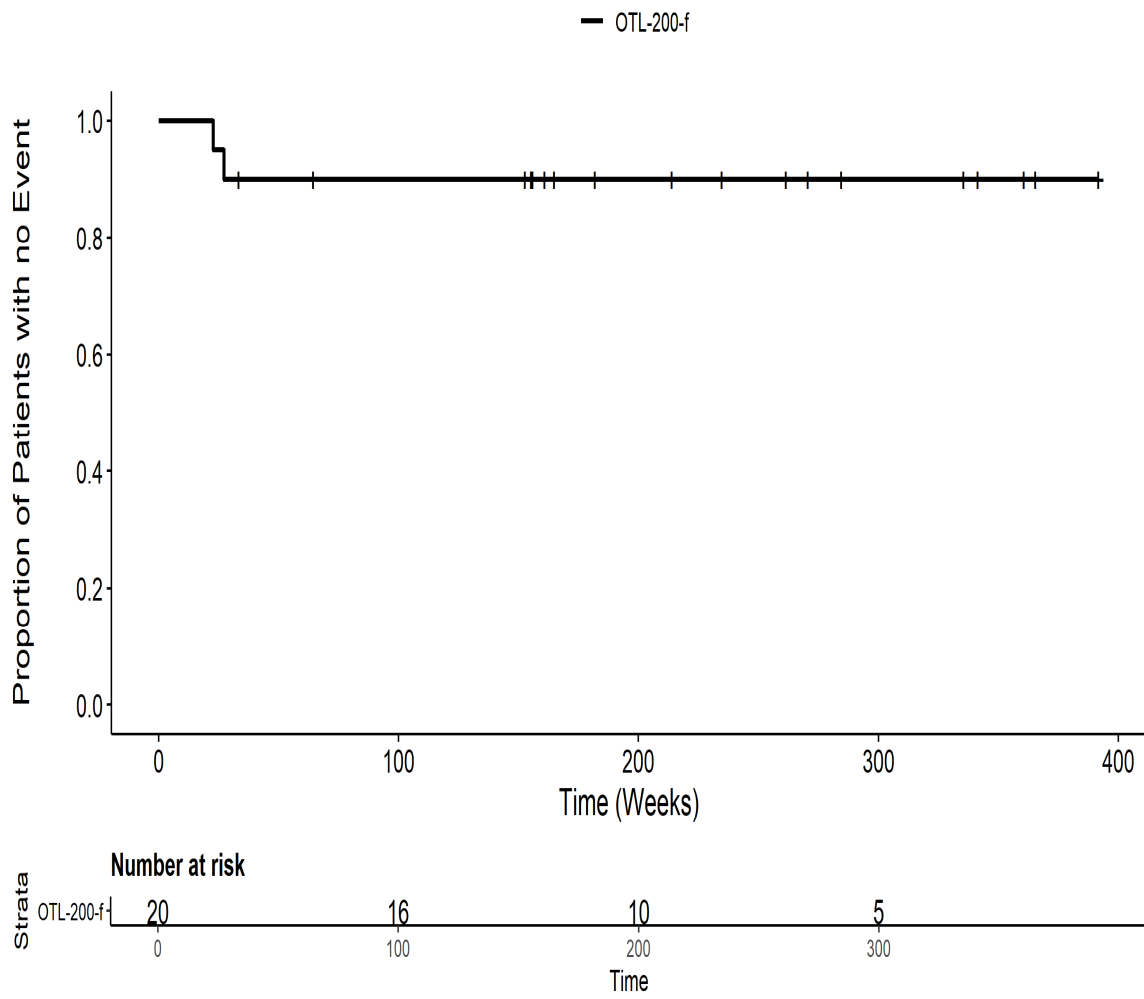
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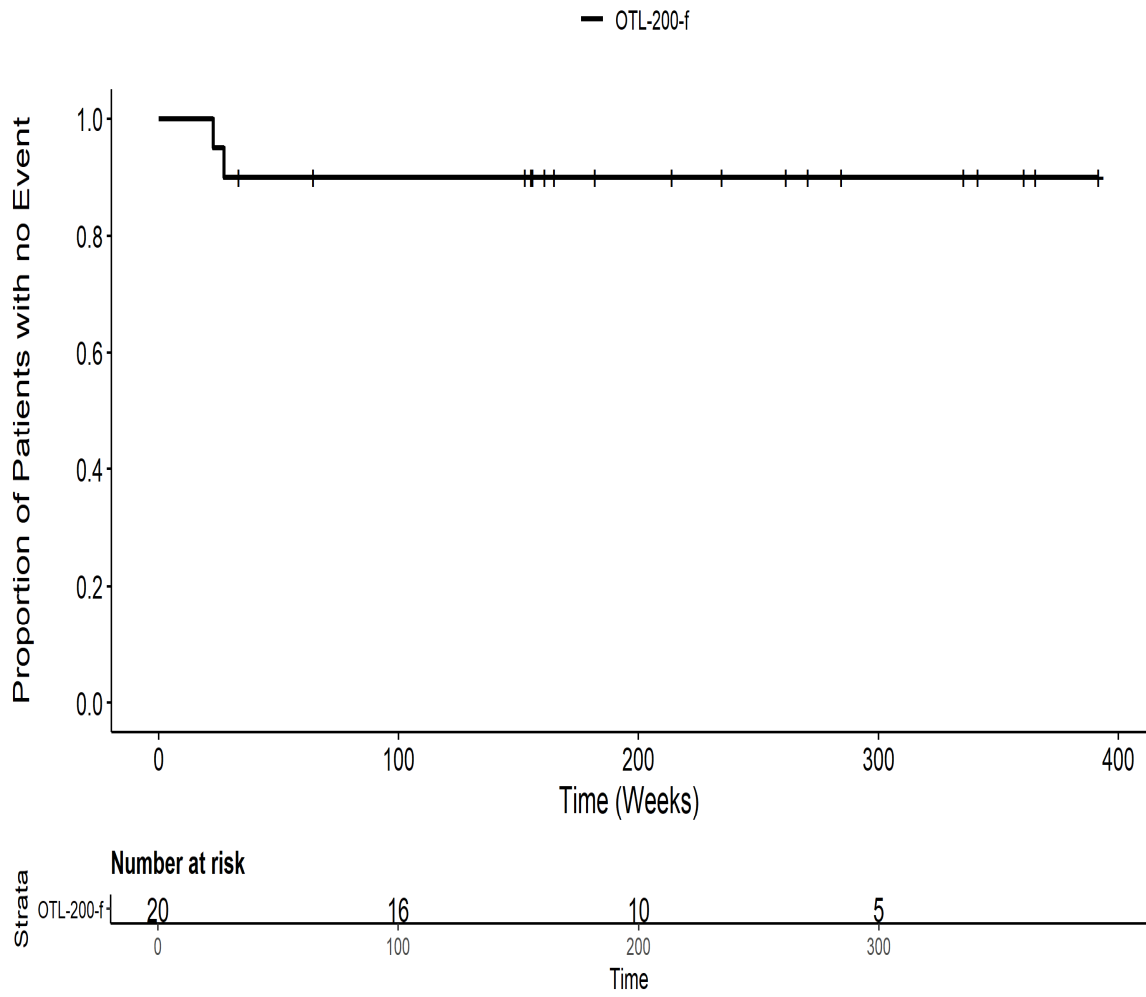
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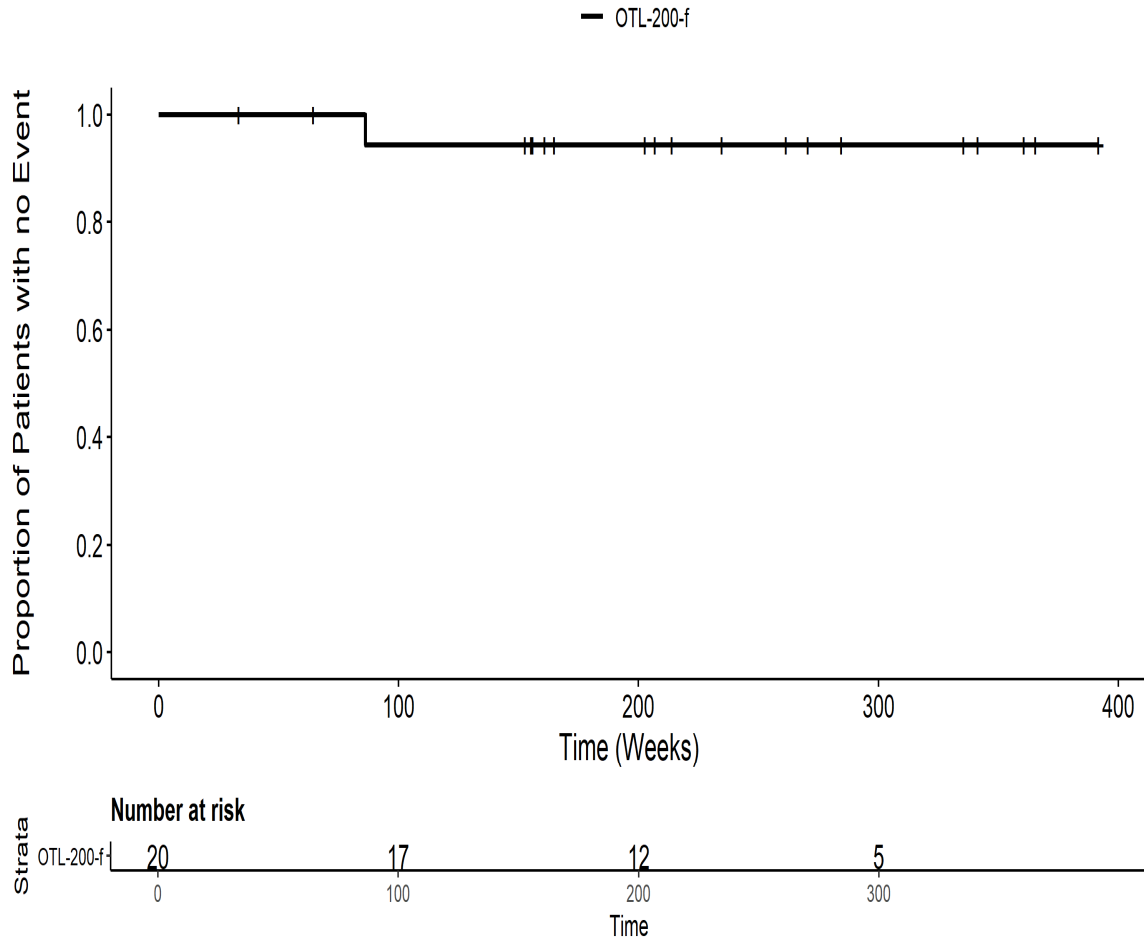
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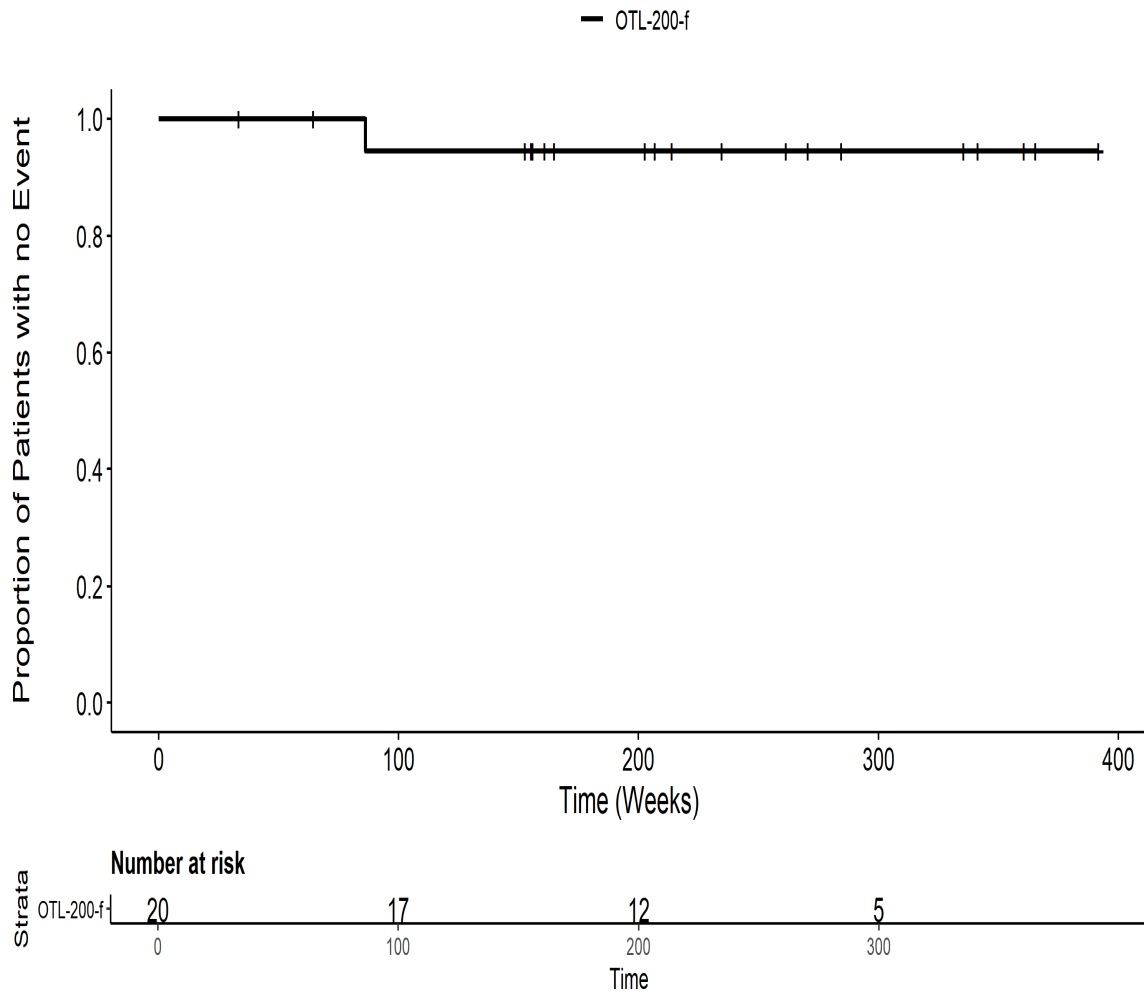
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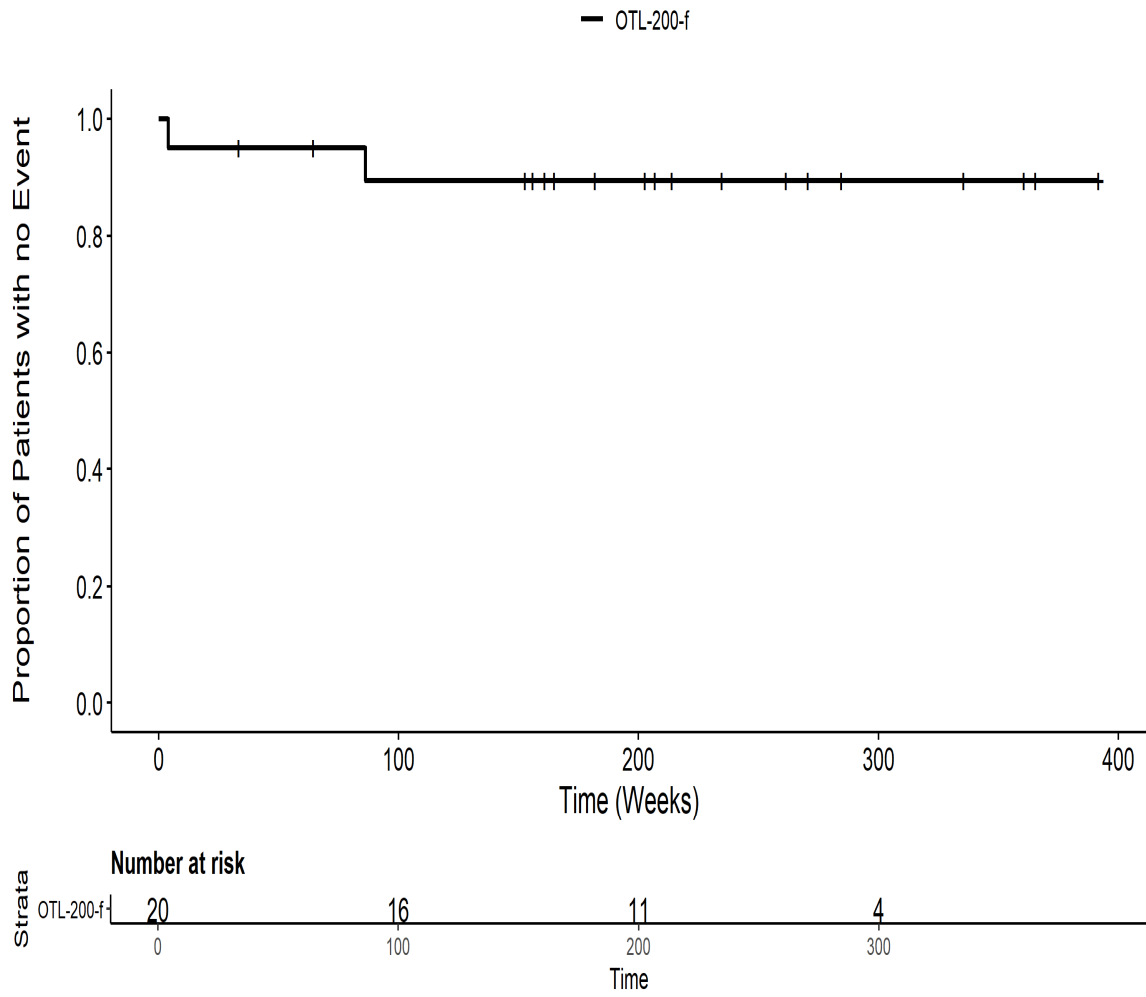
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Skelettmuskulatur : , Bindegewebs : und Knochenkrankungen PT pct Deformitaet des
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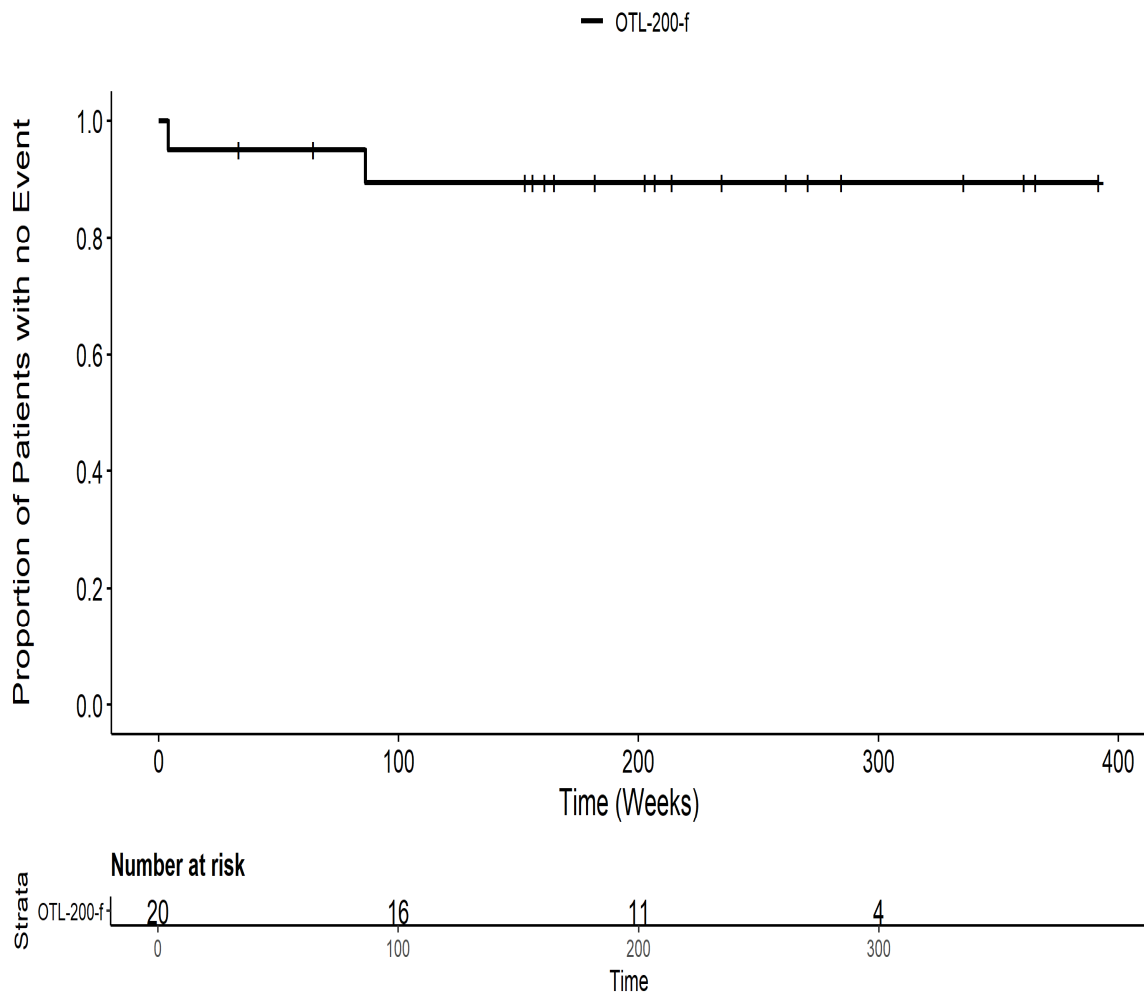
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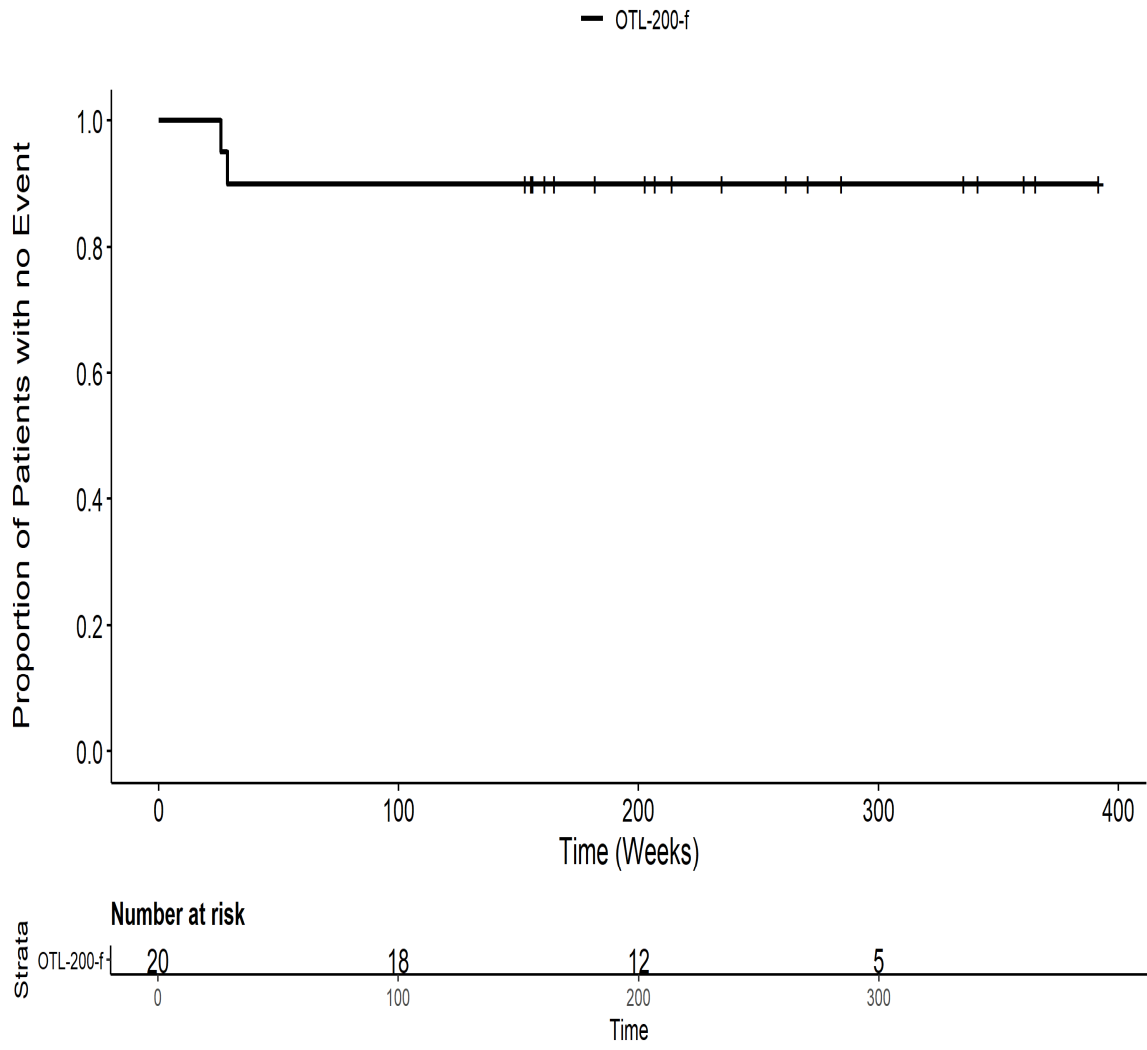
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Stoffwechsel : und Ernährungsstörungen PT pct Gesamt SOCITT



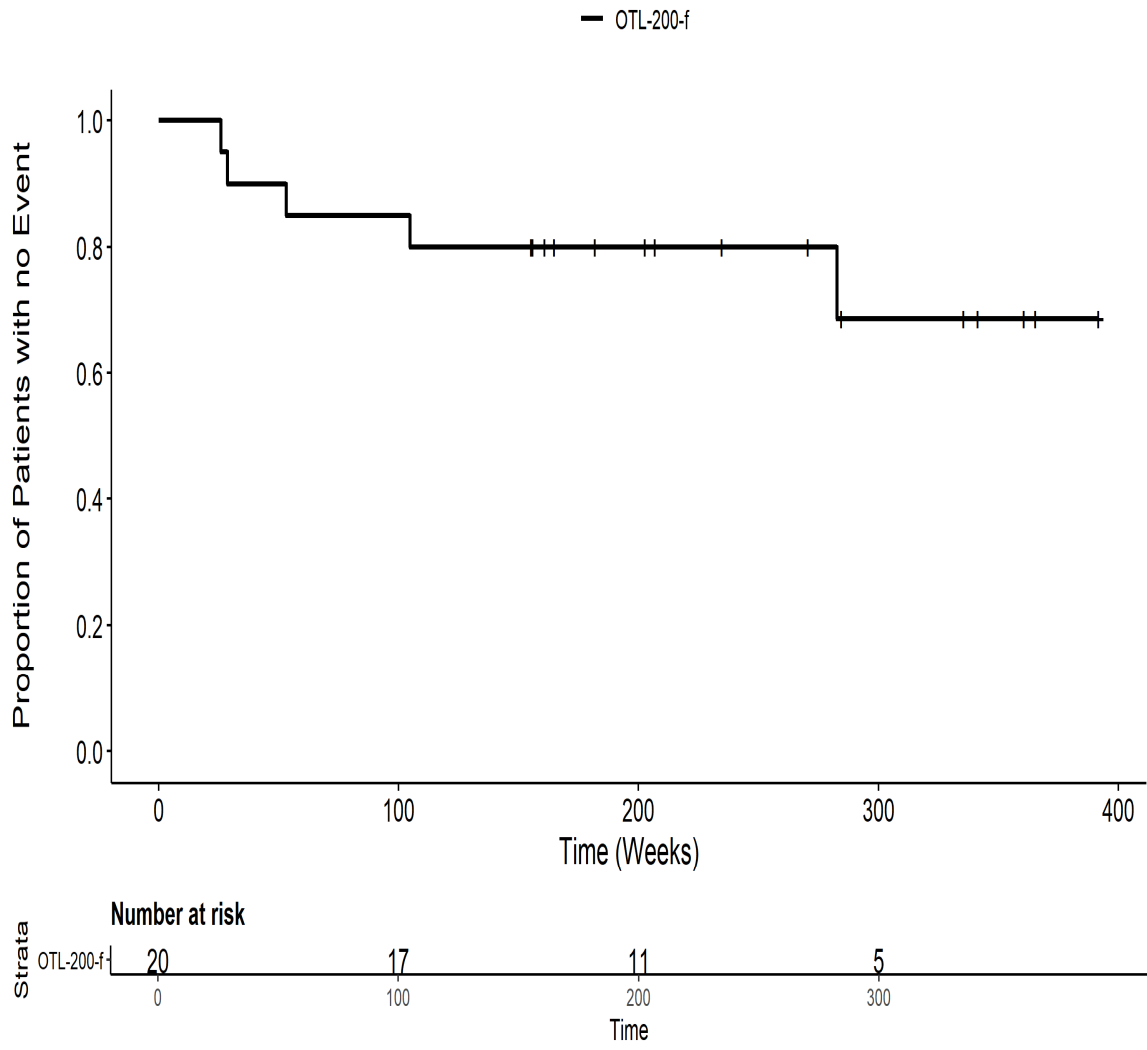
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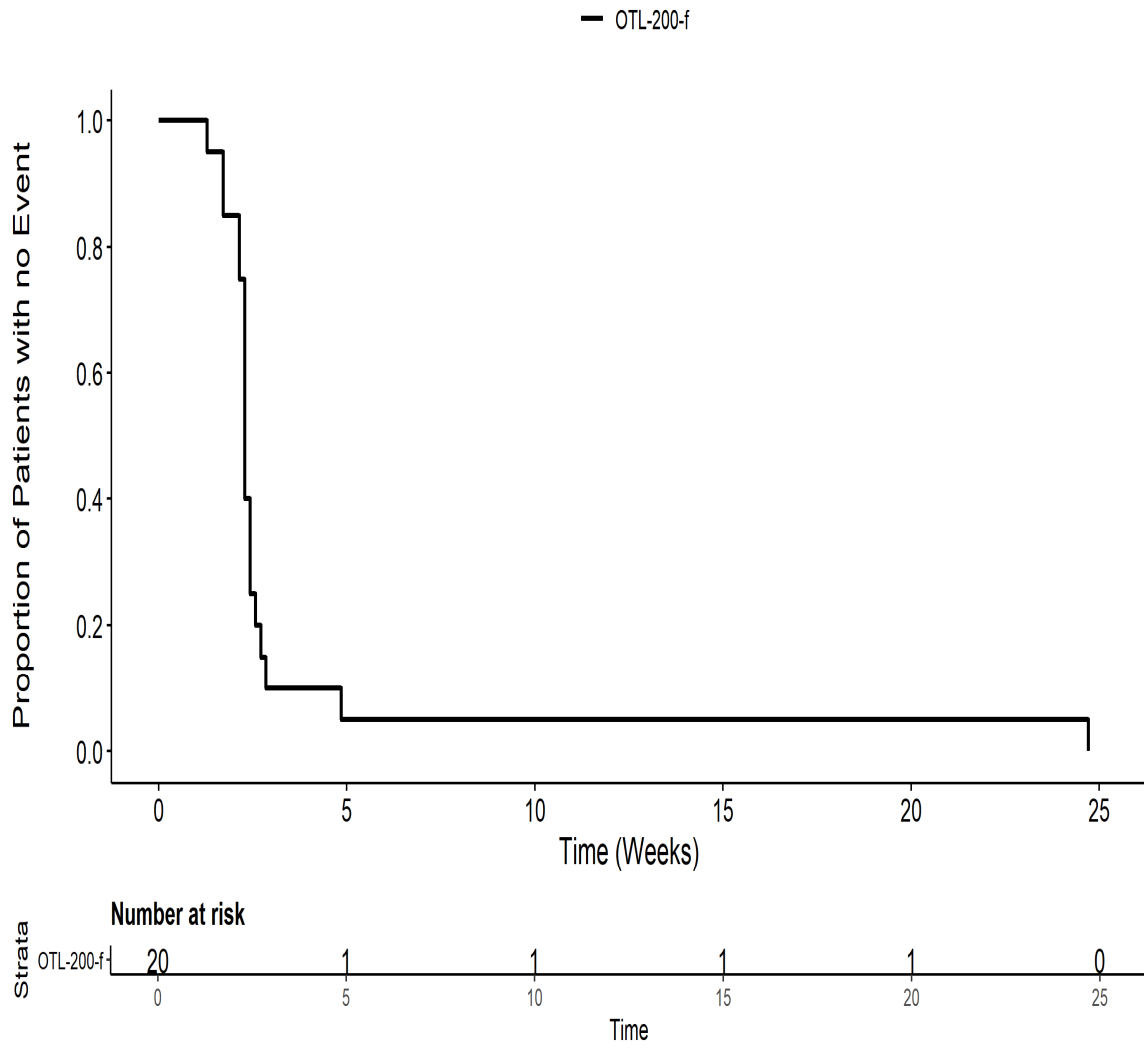
201222: Kaplan Meier Plot for Time to serious AE death ITT



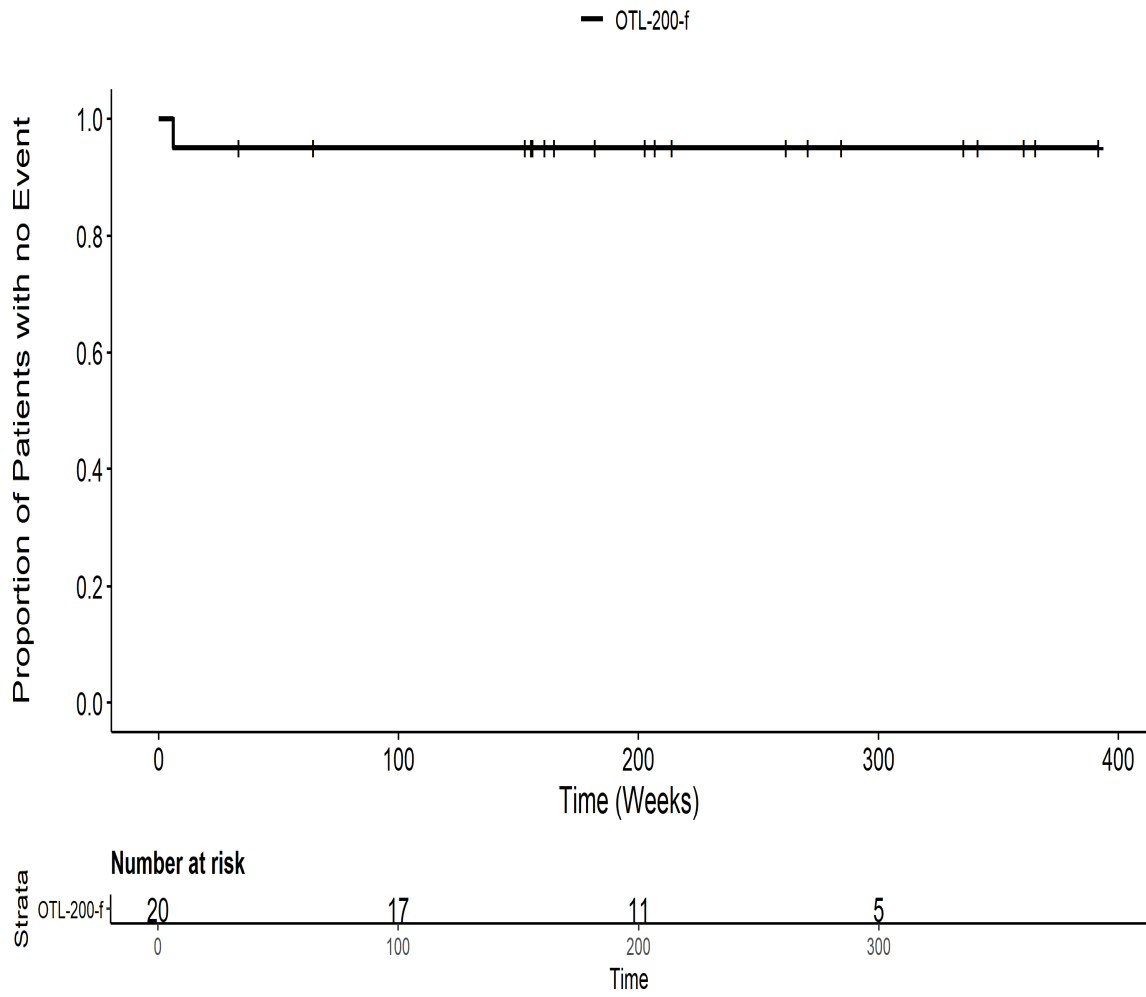
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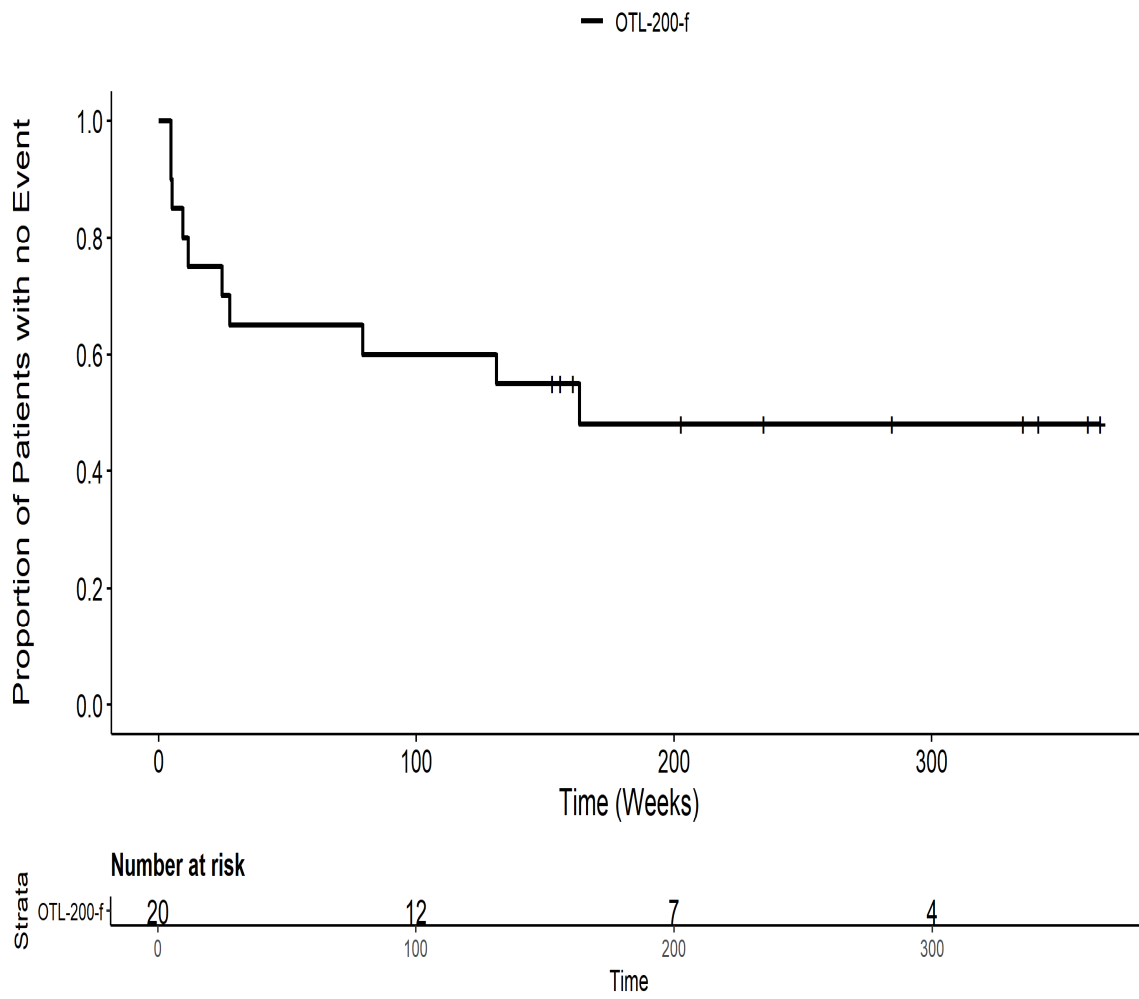
201222: Kaplan Meier Plot for Time to severe AE ITT



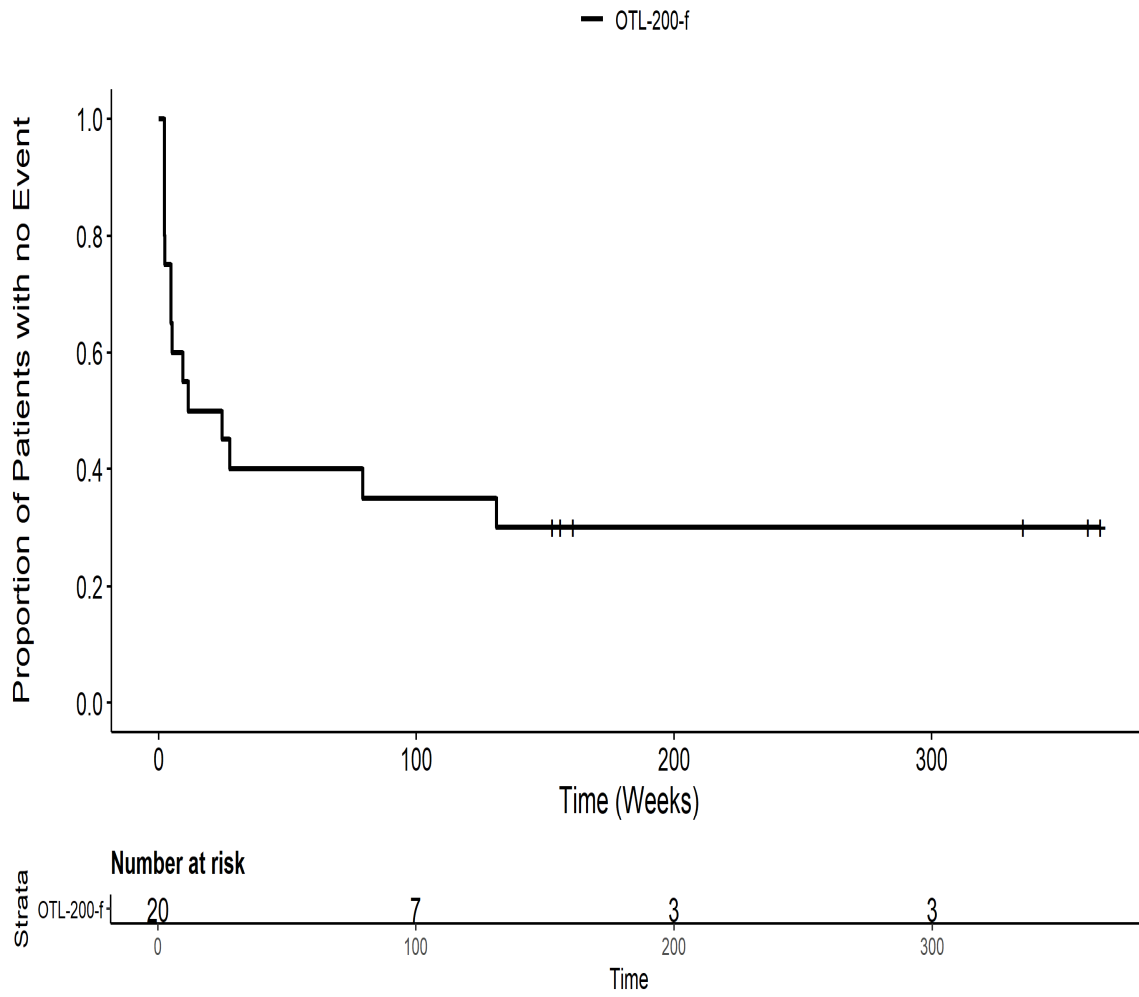
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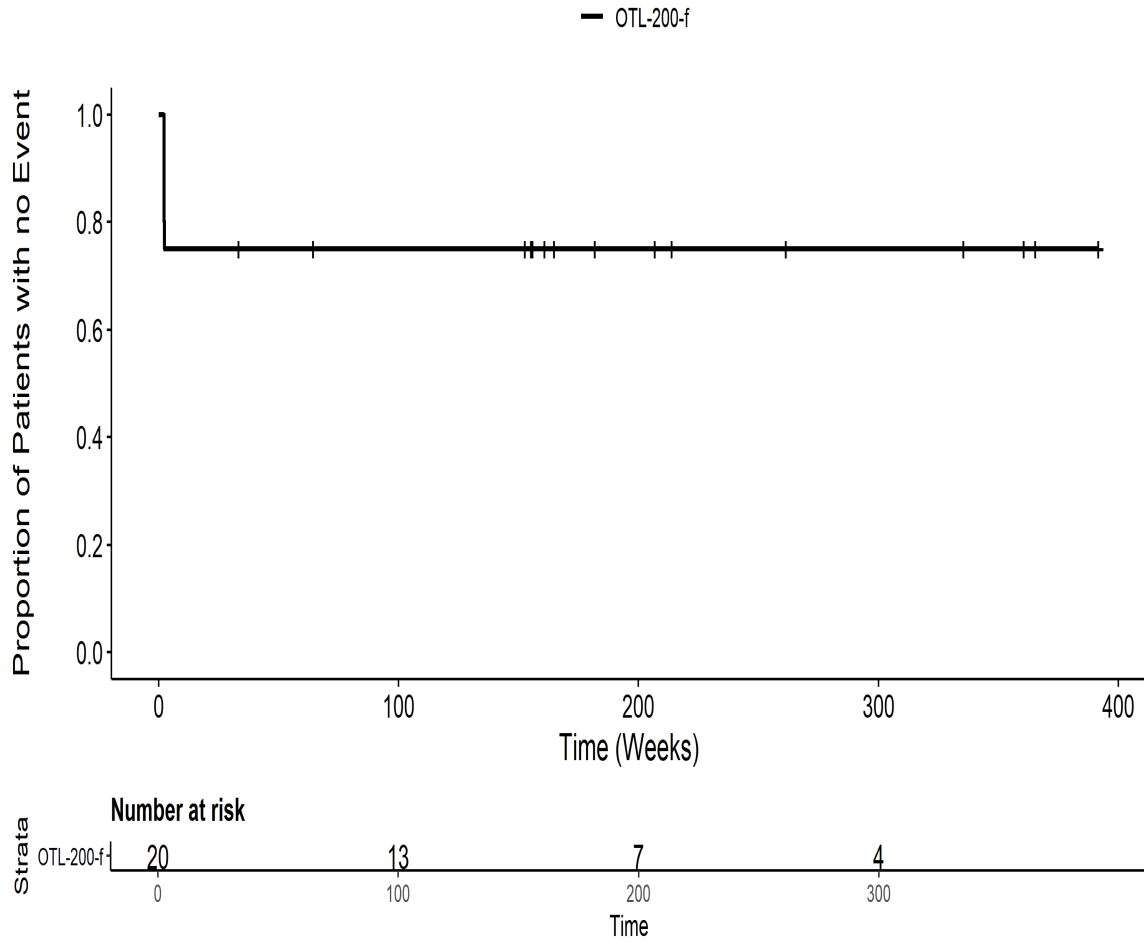
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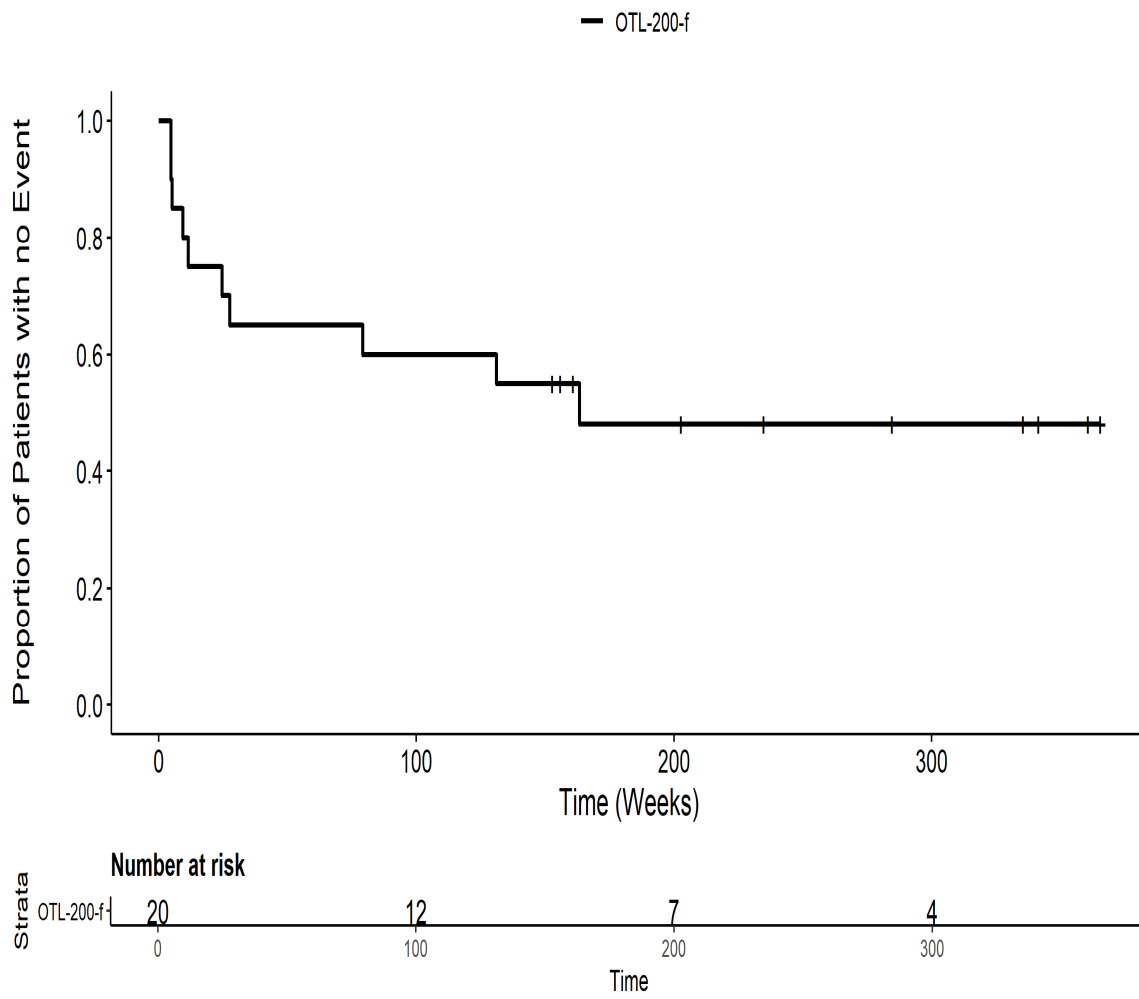
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Erkrankungen und Beschwerden am Verabreichungsort PT pct Gesamt SOCITT



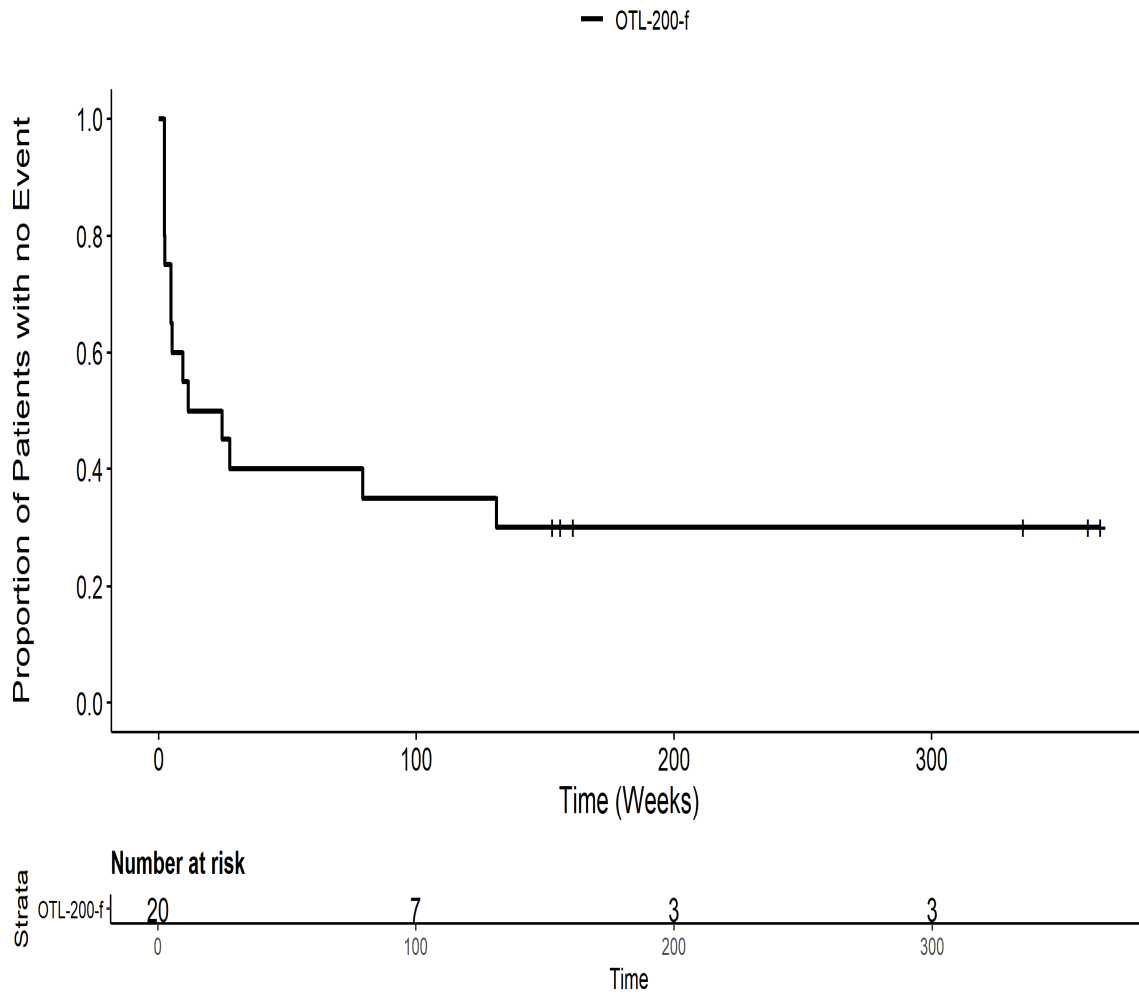
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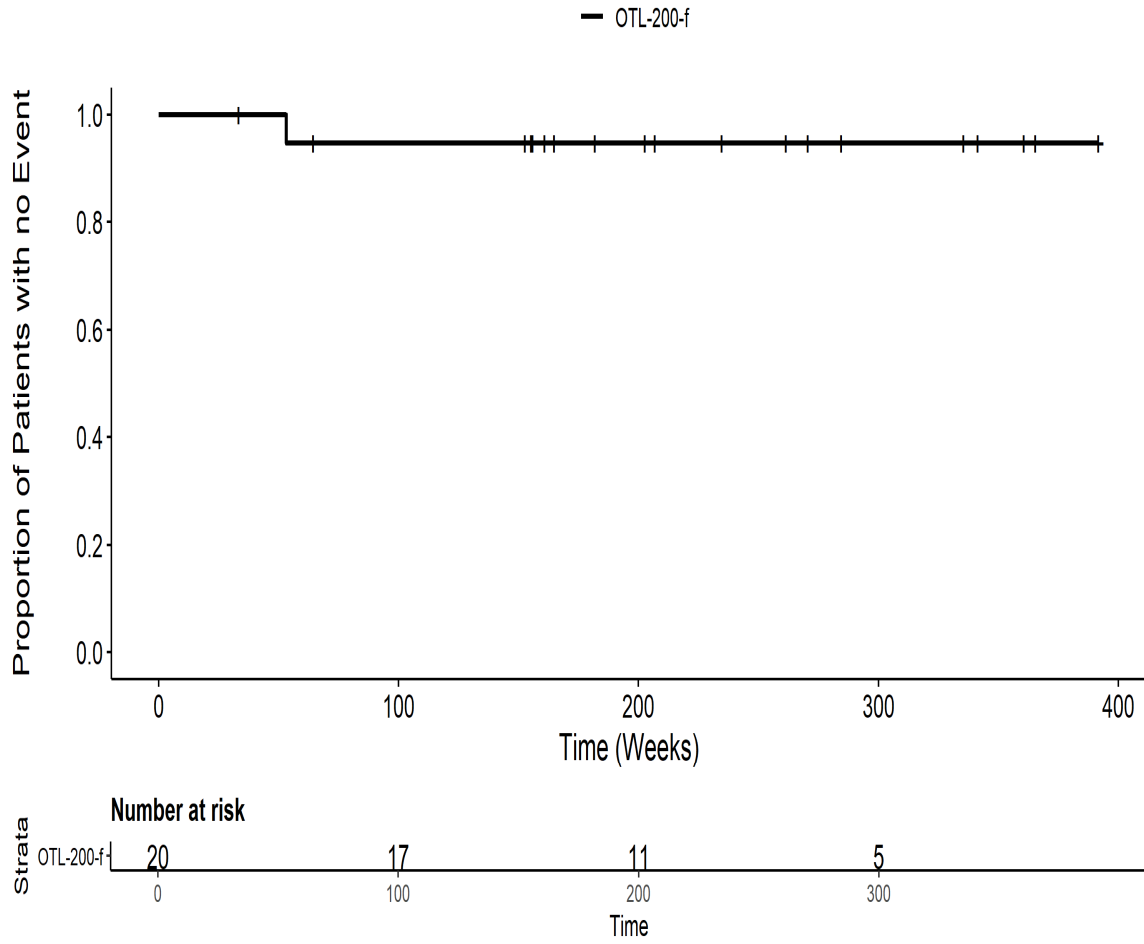
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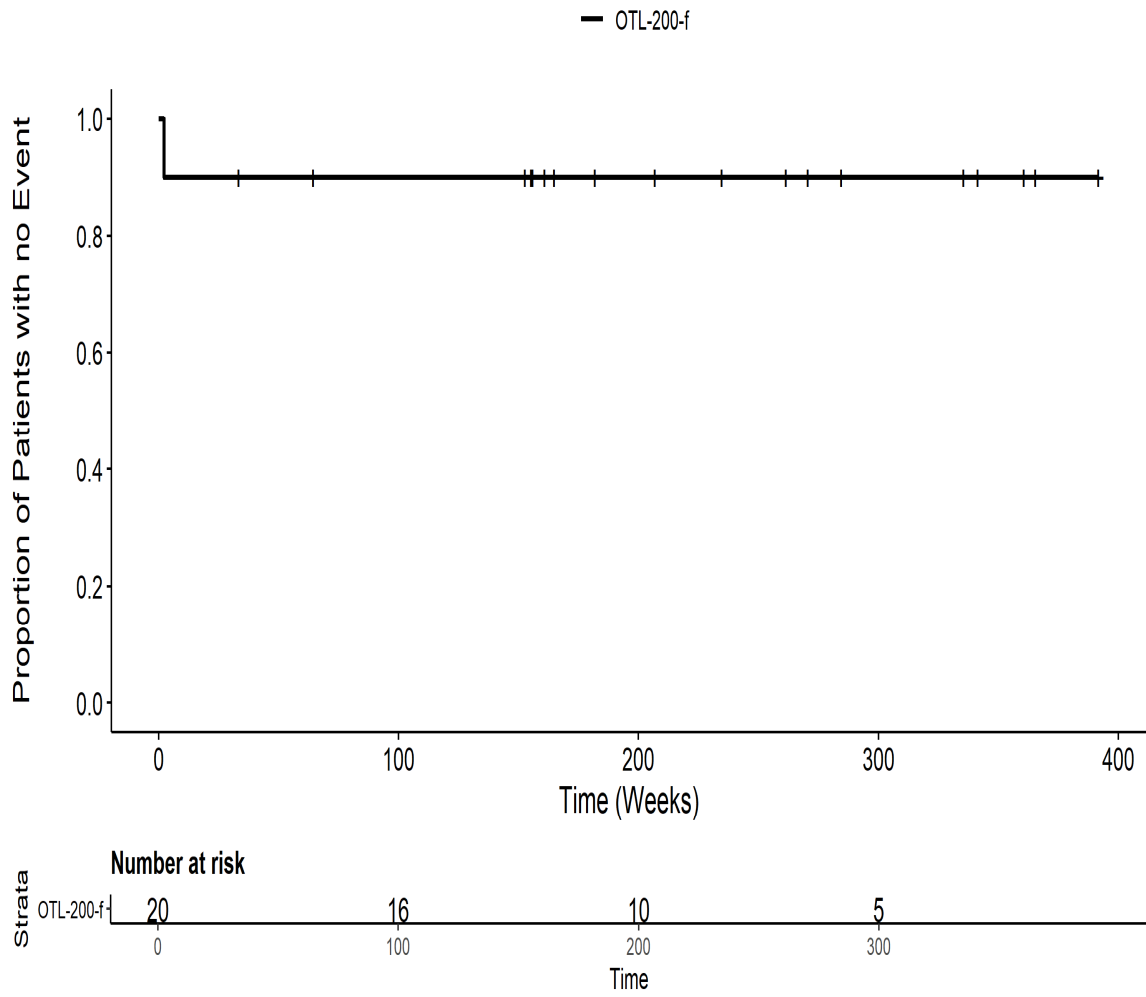
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Erkrankungen und Beschwerden am Verabreichungsort PT pts Gesamt SOC ITT



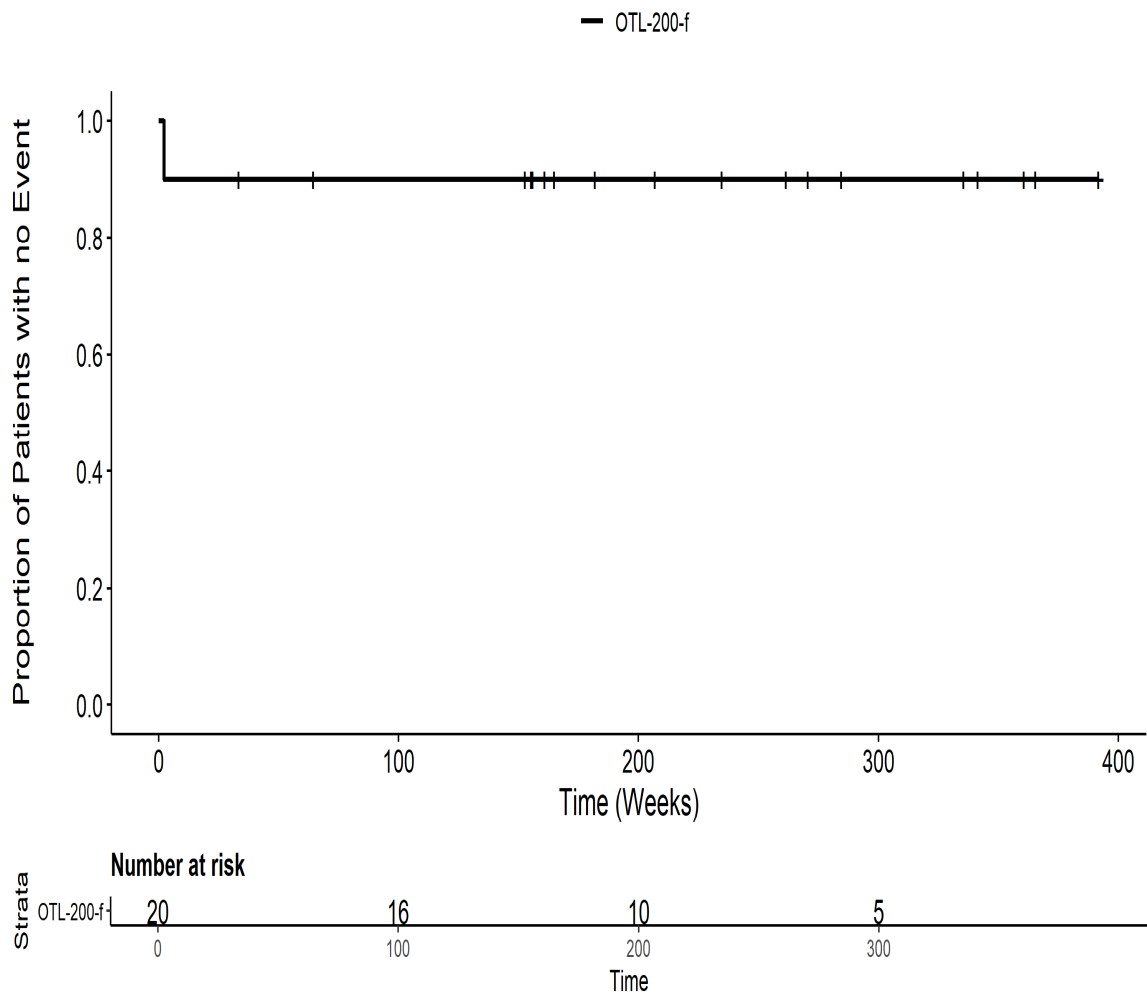
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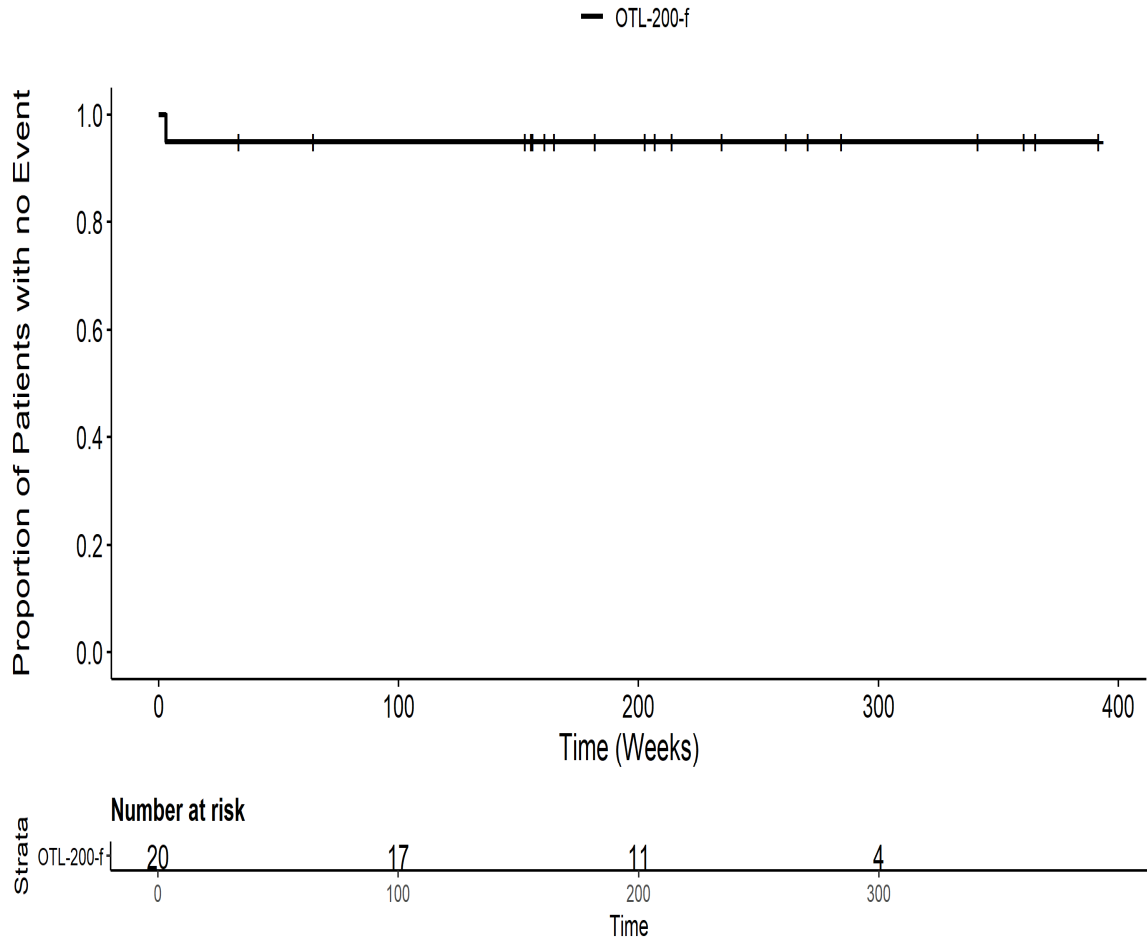
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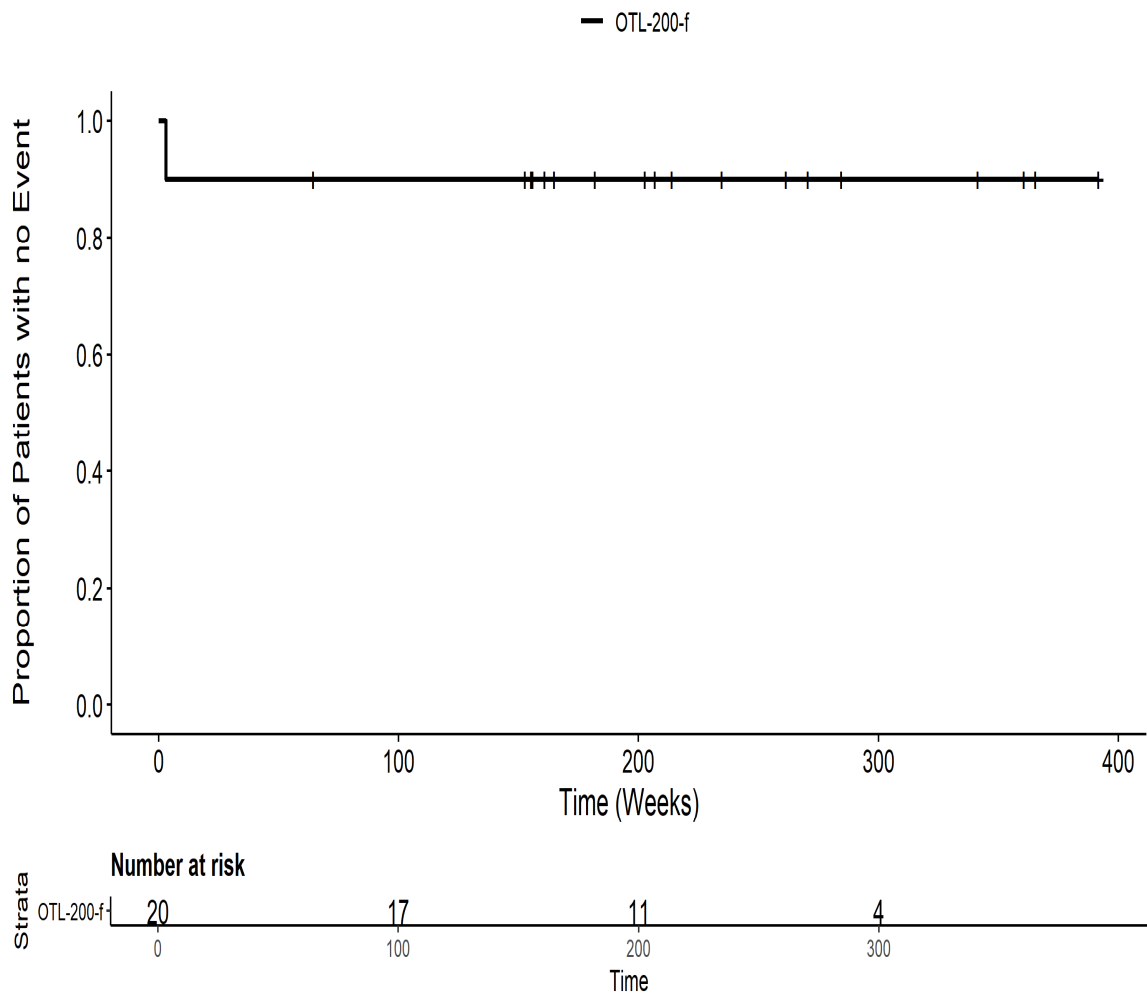
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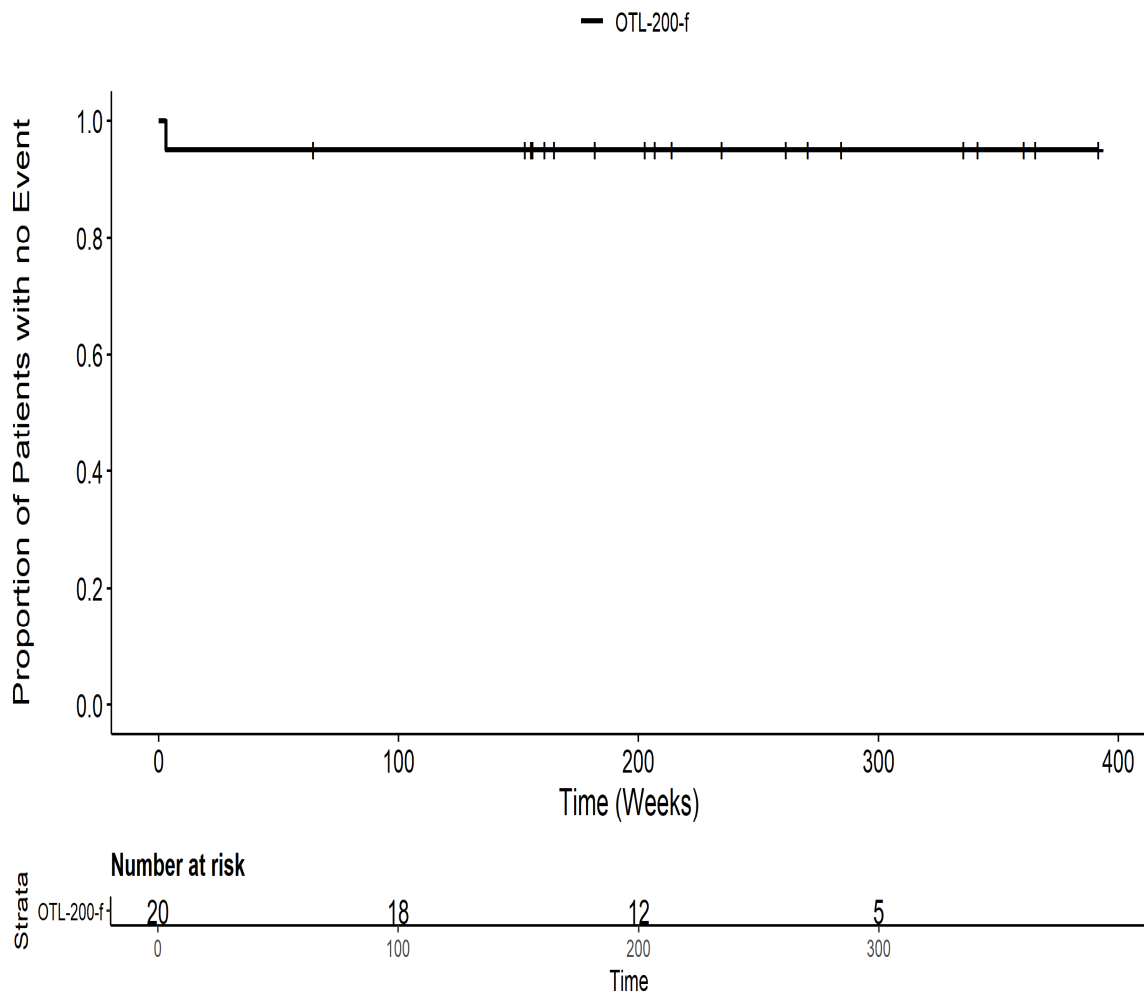
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der Haut und des Unterhautzellgewebes PT pct Erythematoseser
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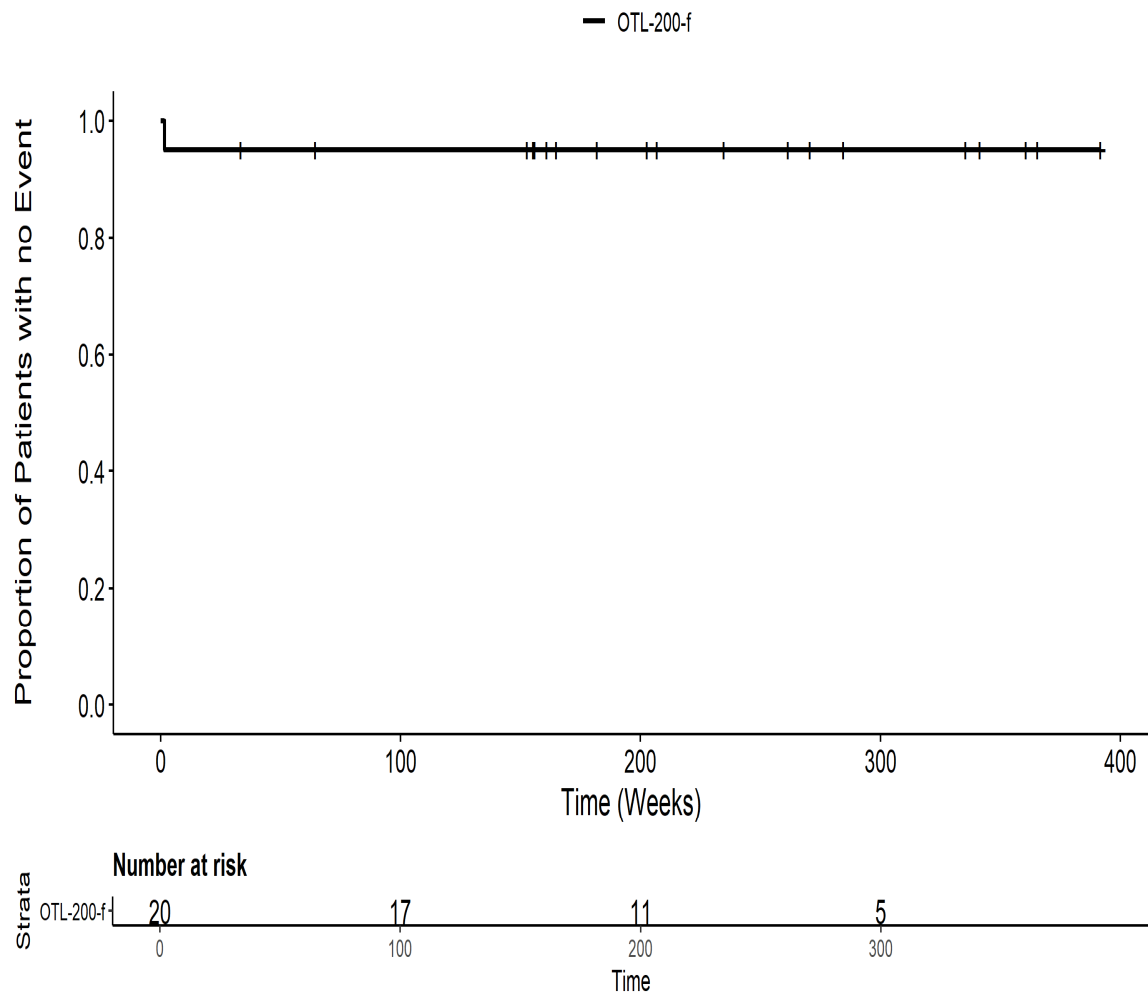
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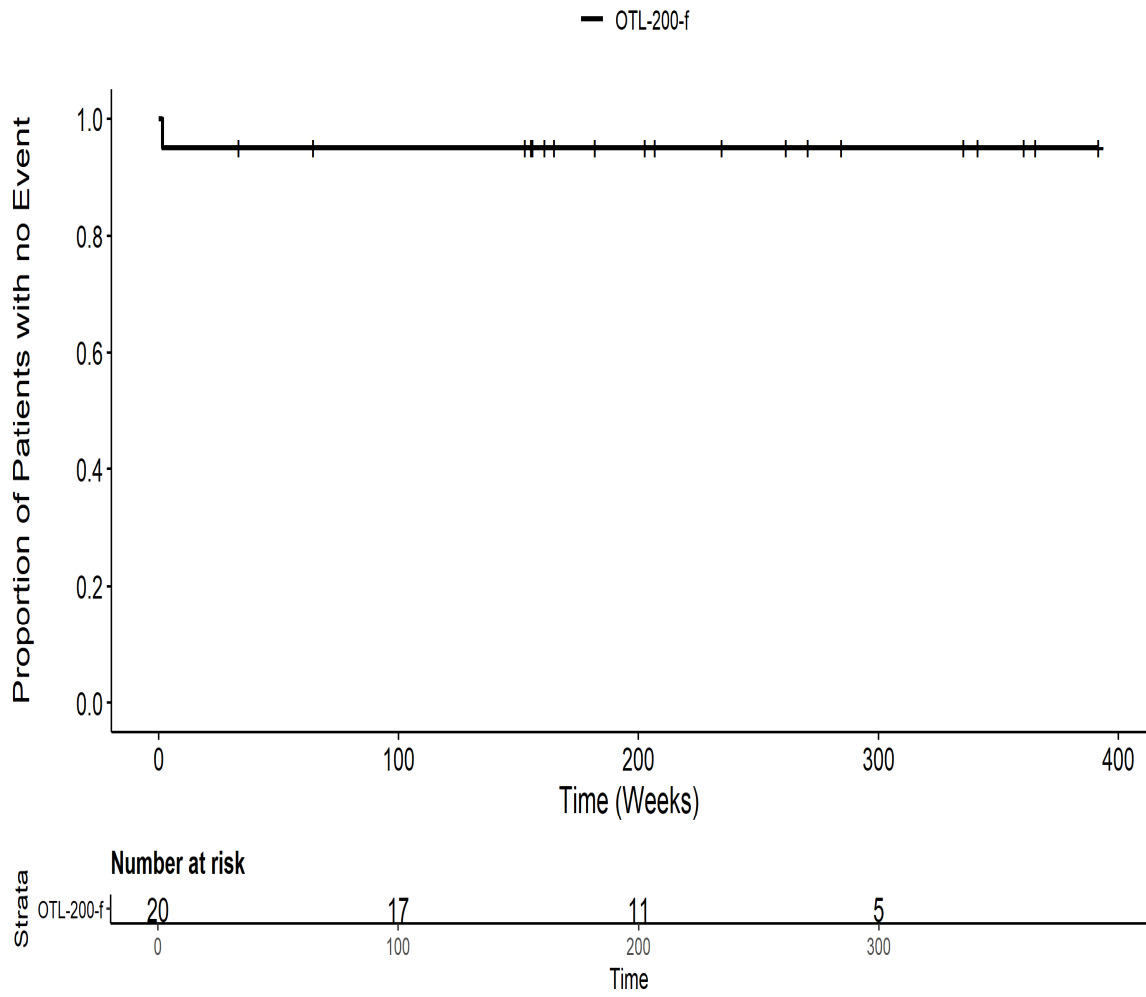
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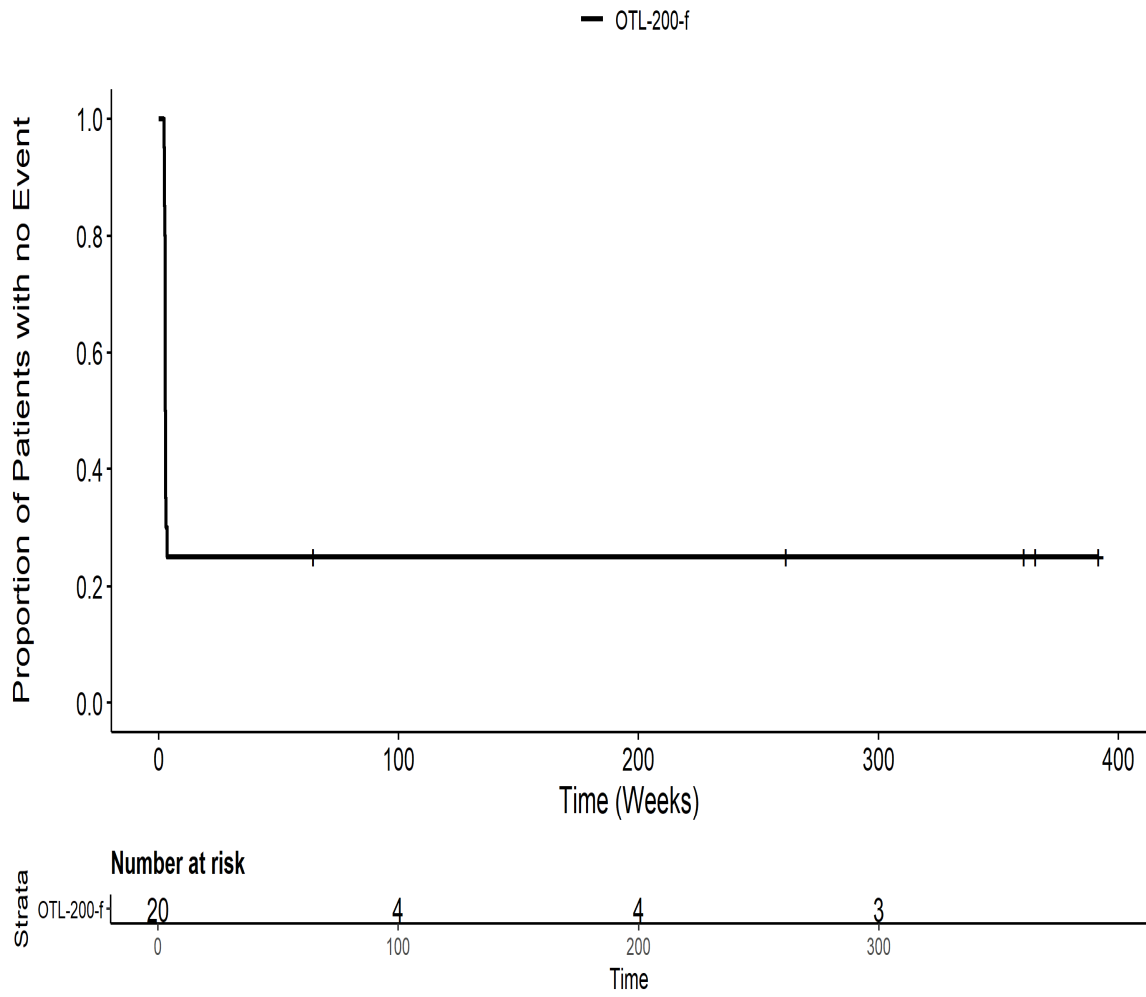
201222: Kaplan Meier Plot for Time to severe AE by SOC Erkrankungen der Nieren und Harnwege PT pct Gesamt SOCITT



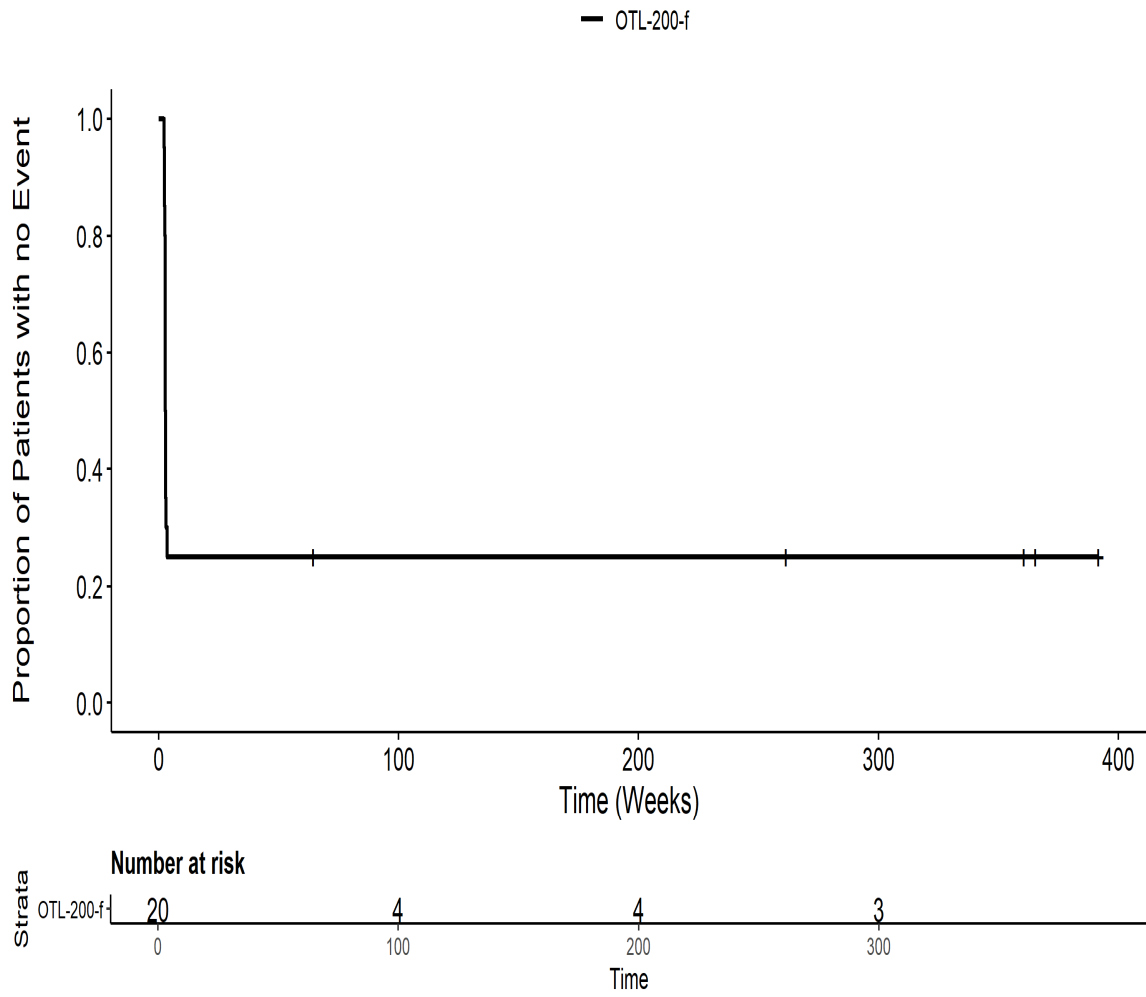
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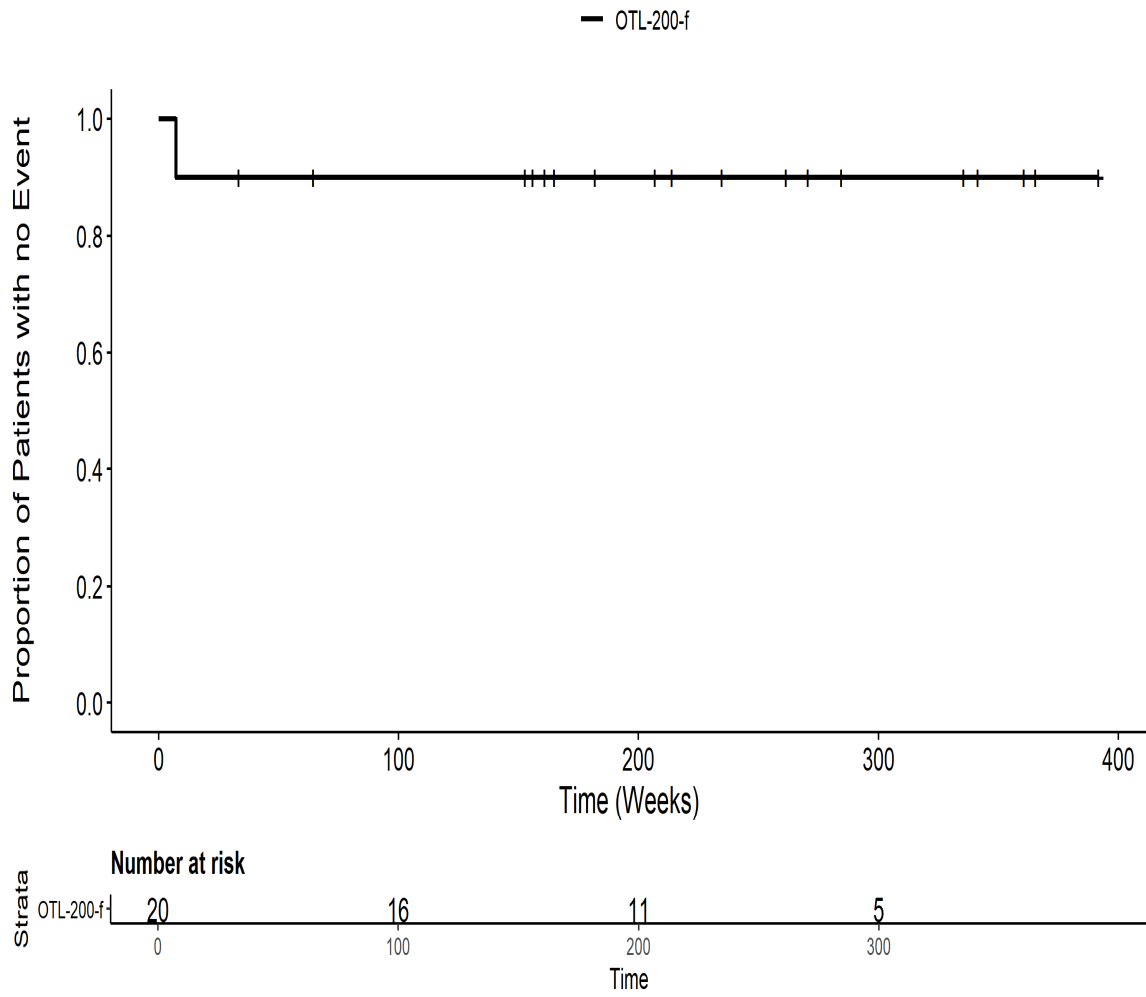
201222: Kaplan Meier Plot for Time to severe AE by SOC Erkrankungen des Blutes und des Lymphsystems PT pct Febrile NeutropenieIT



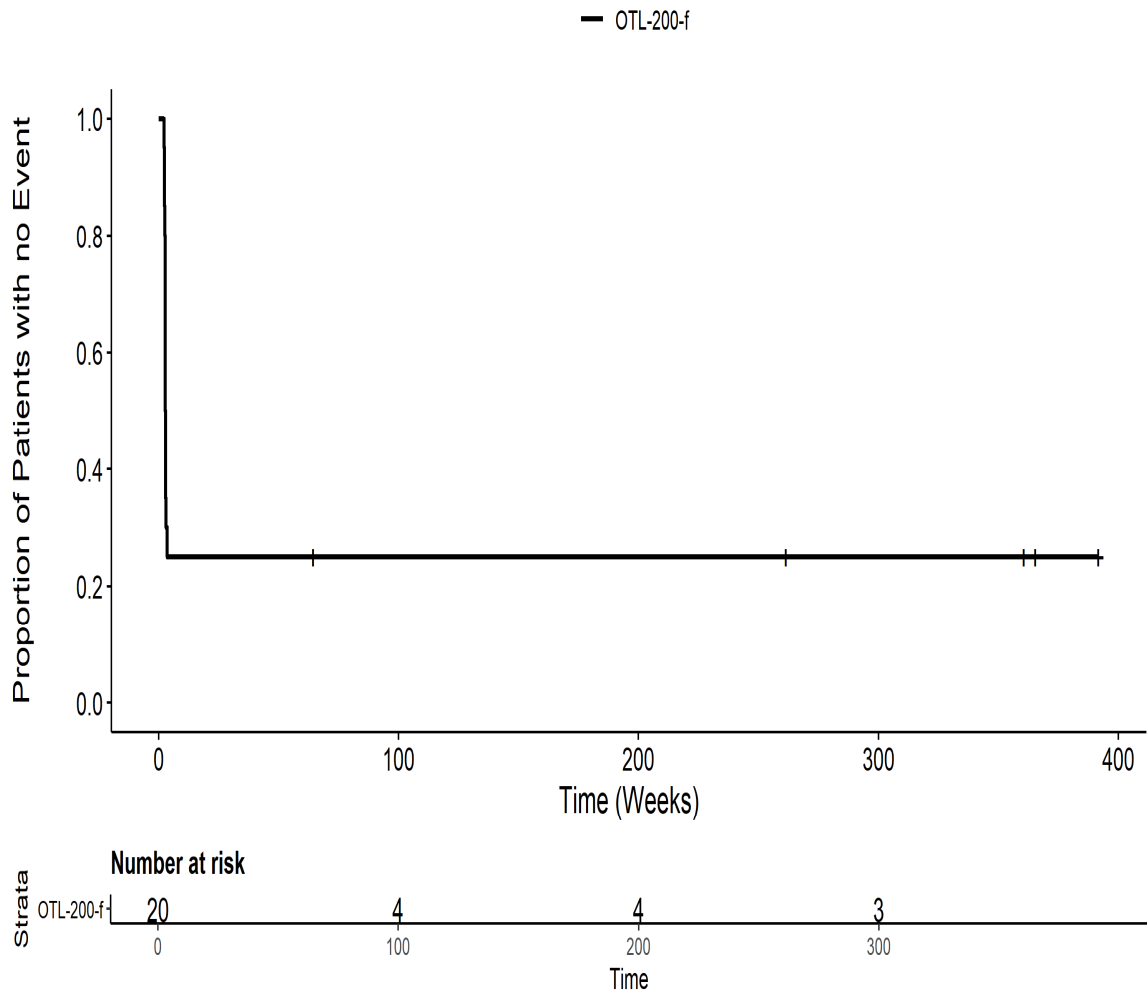
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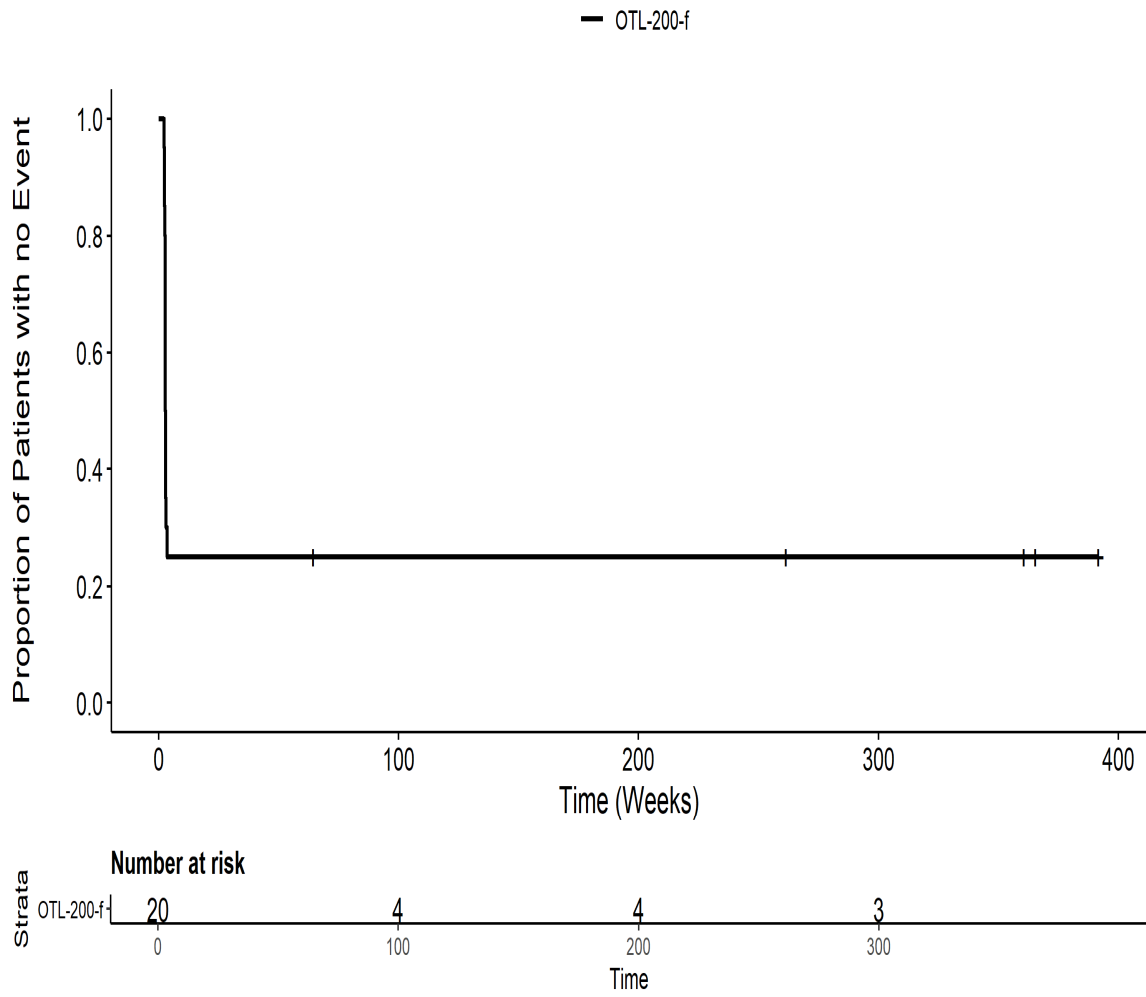
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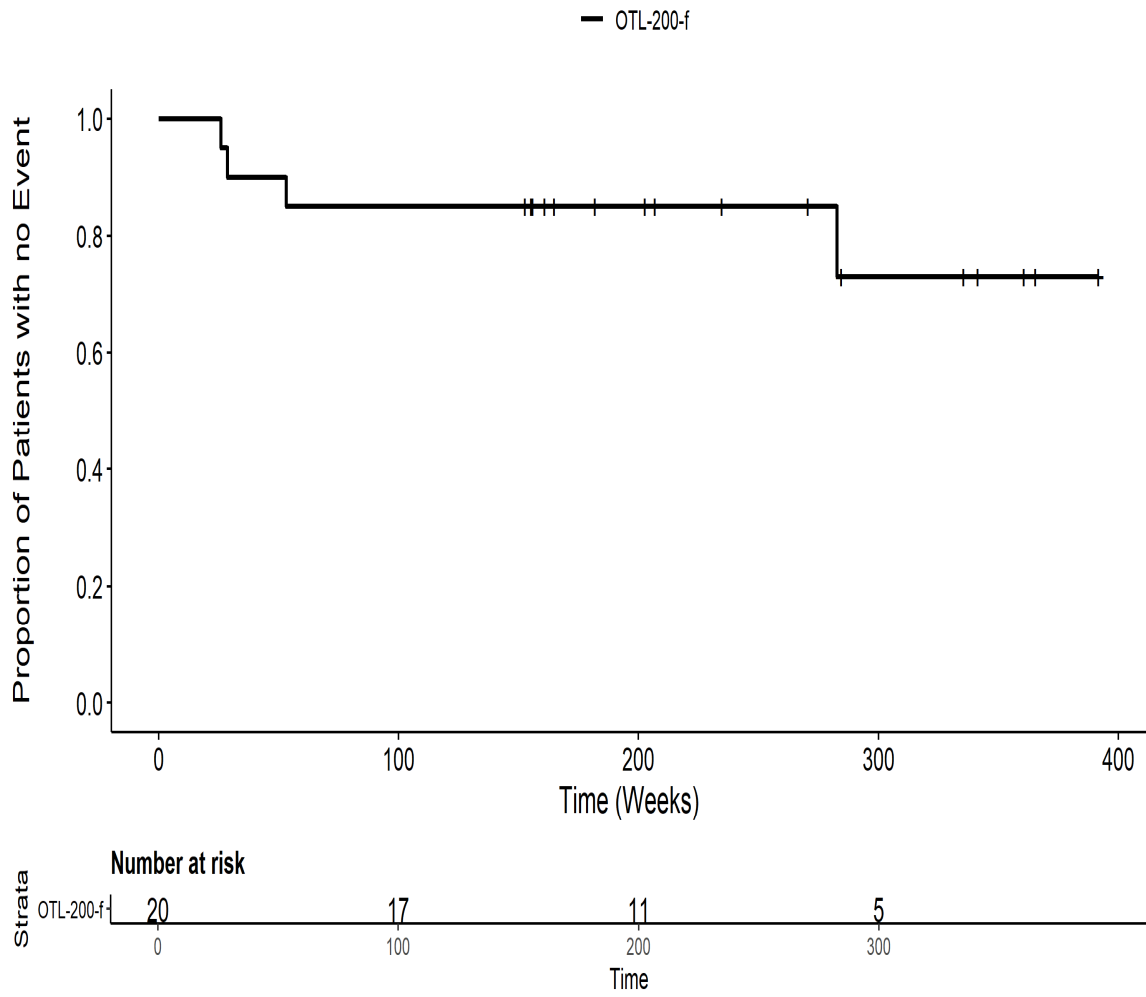
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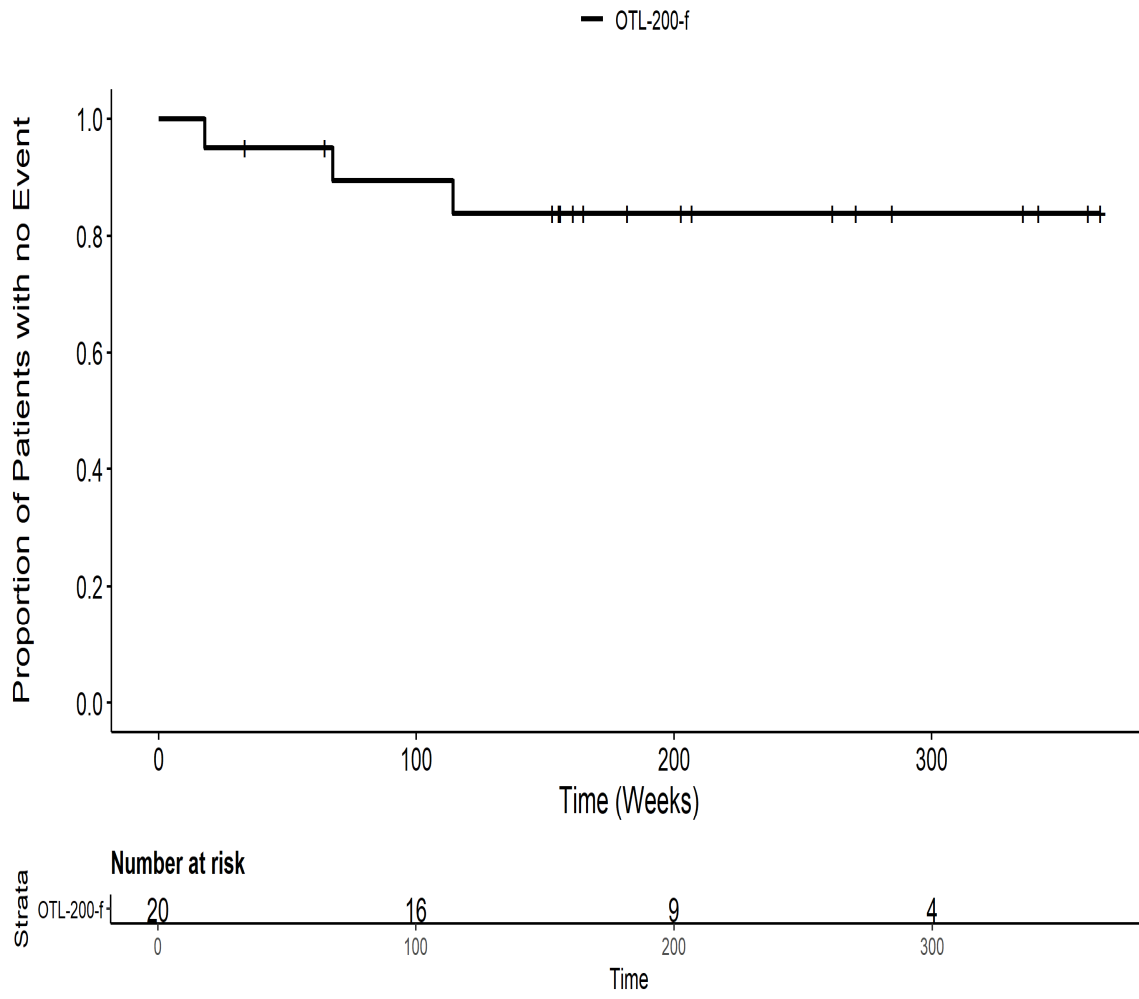
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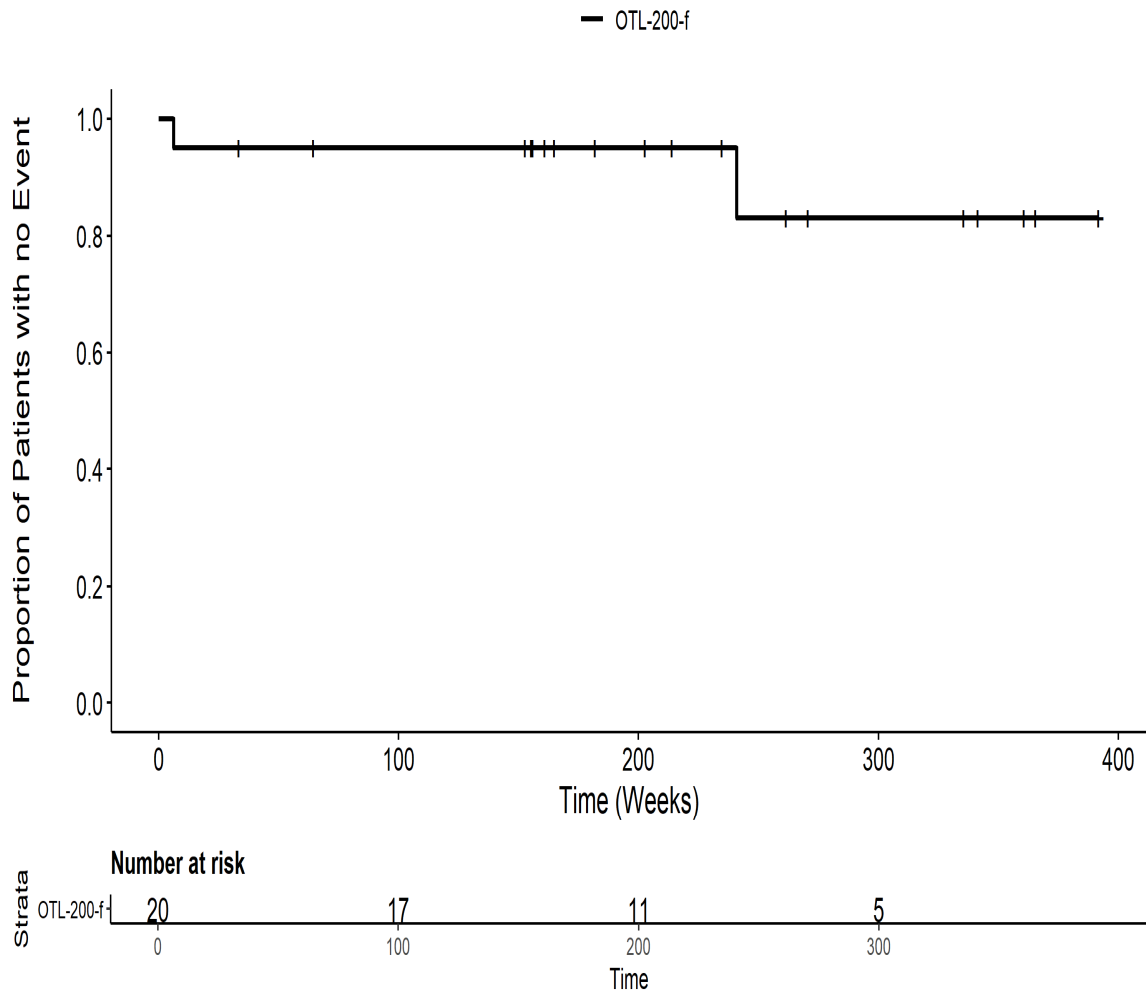
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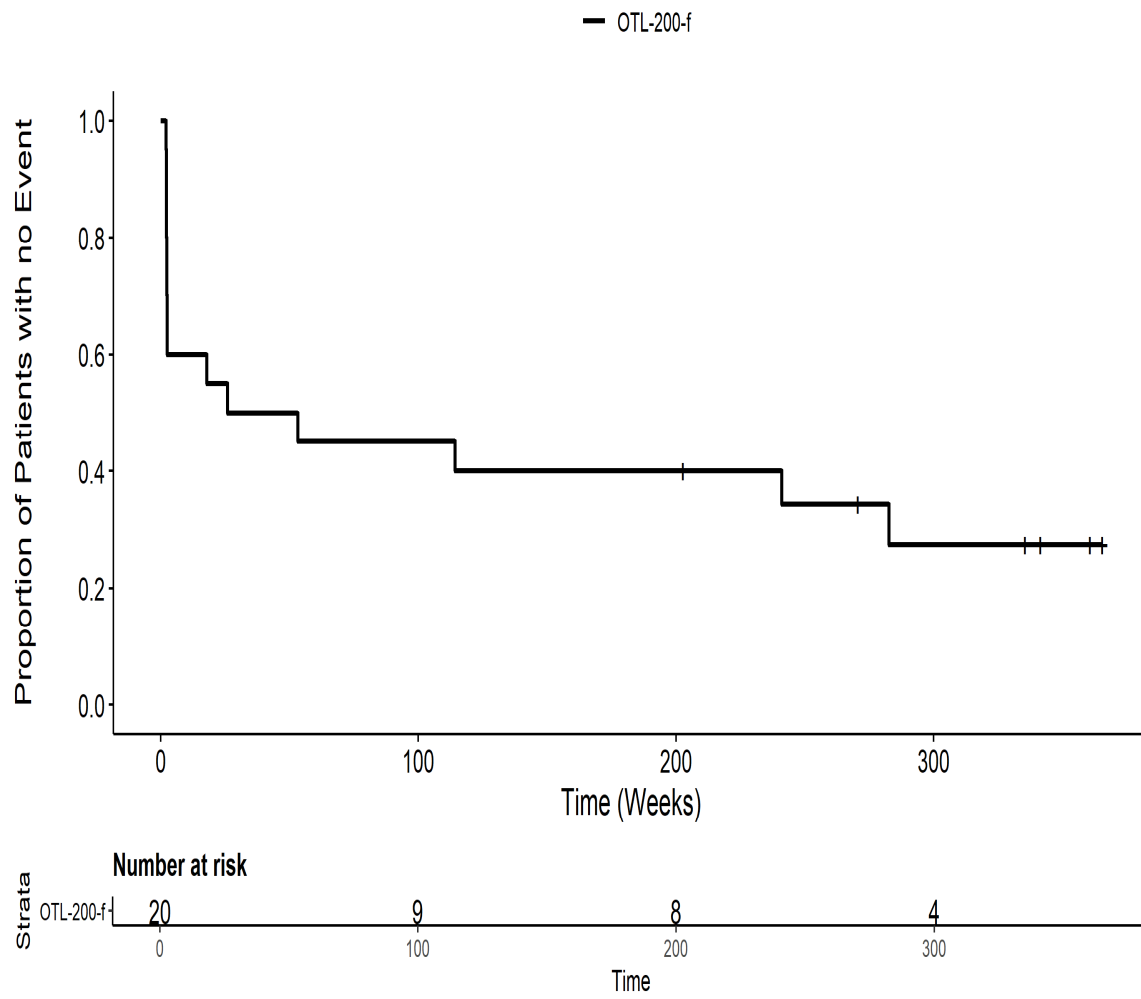
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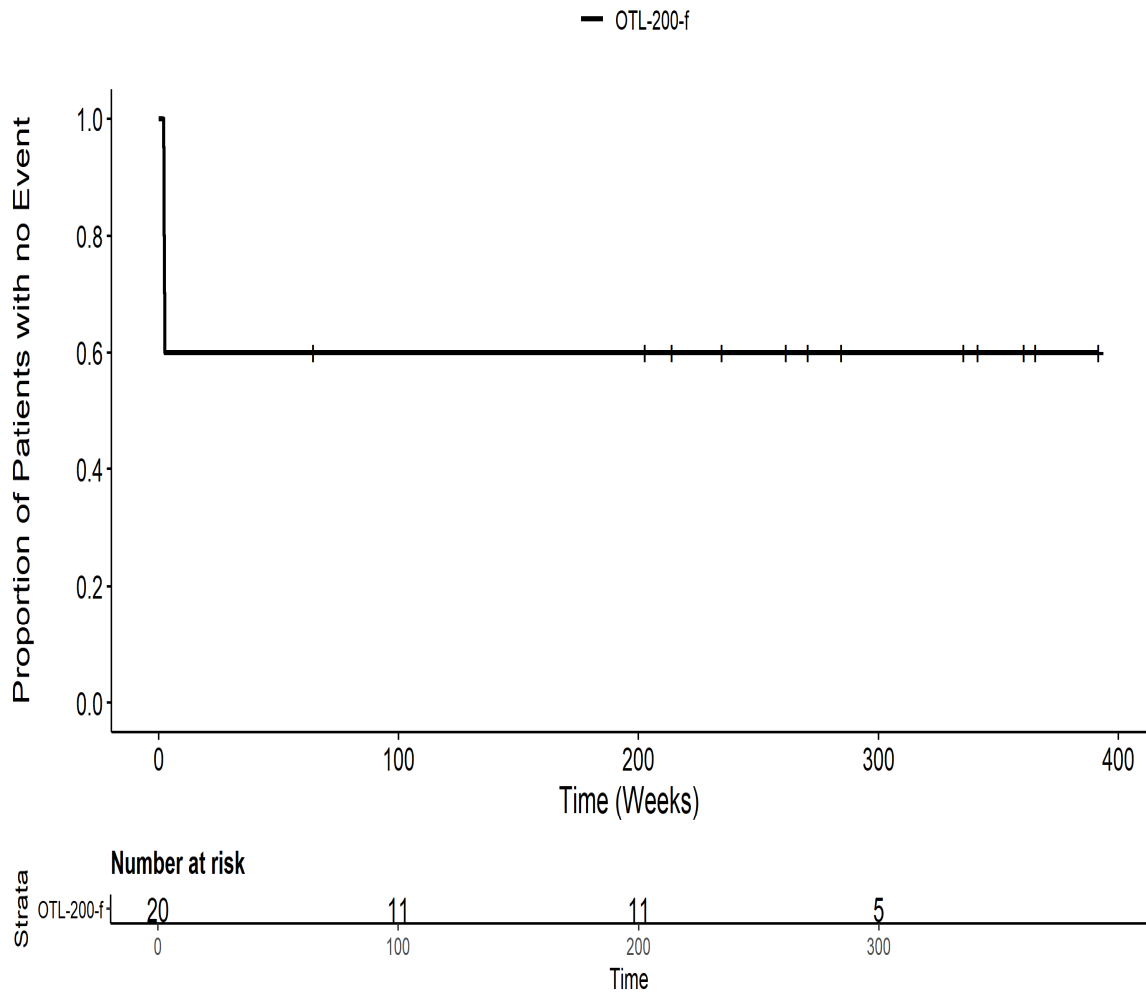
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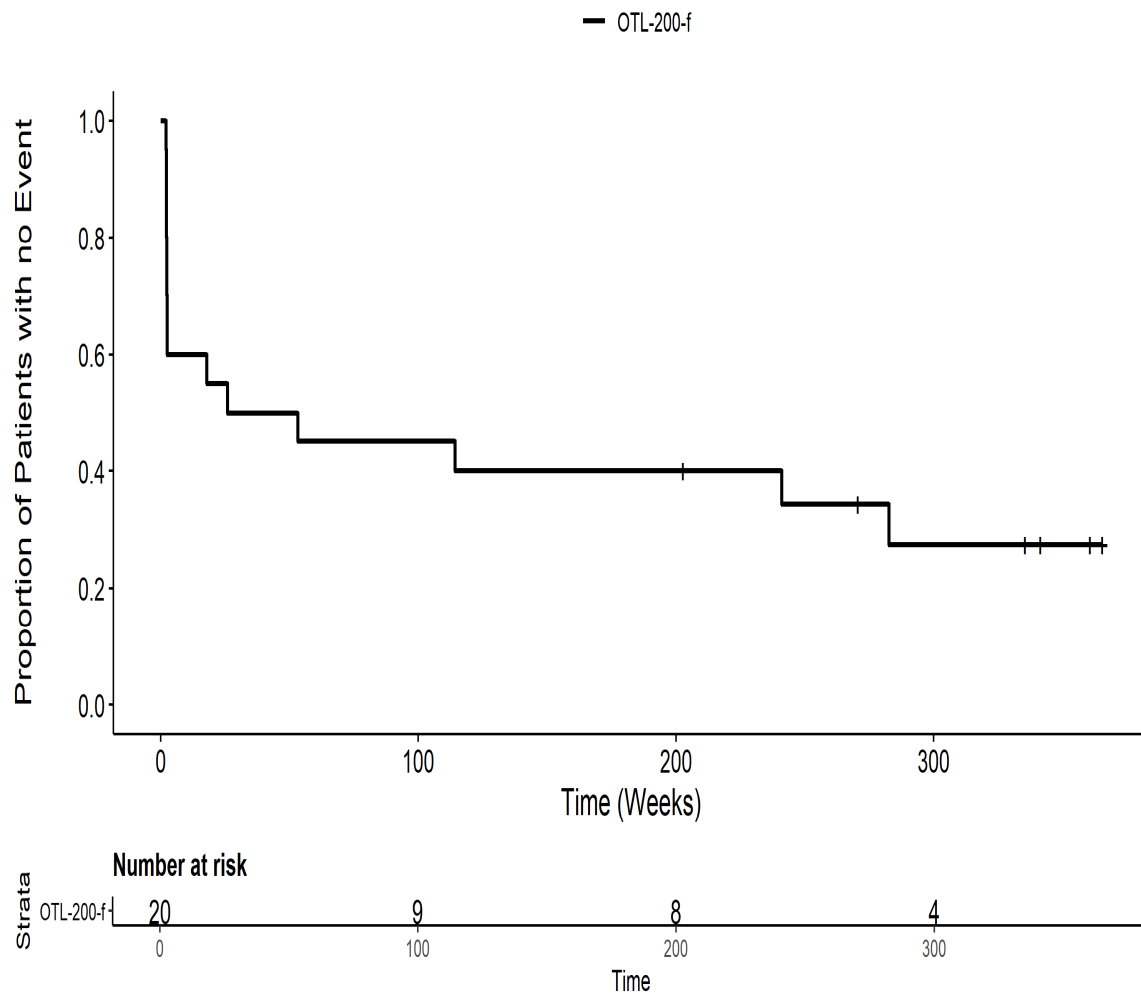
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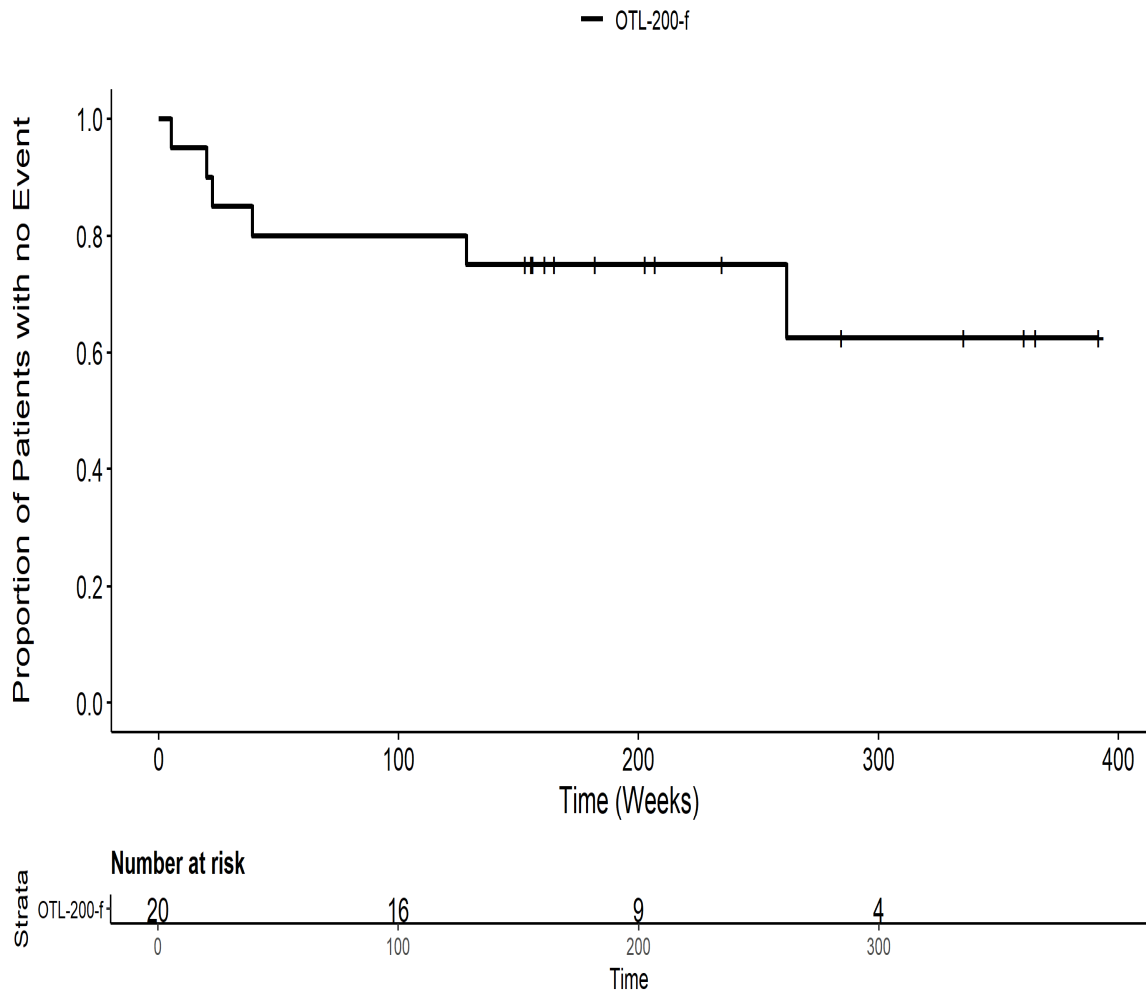
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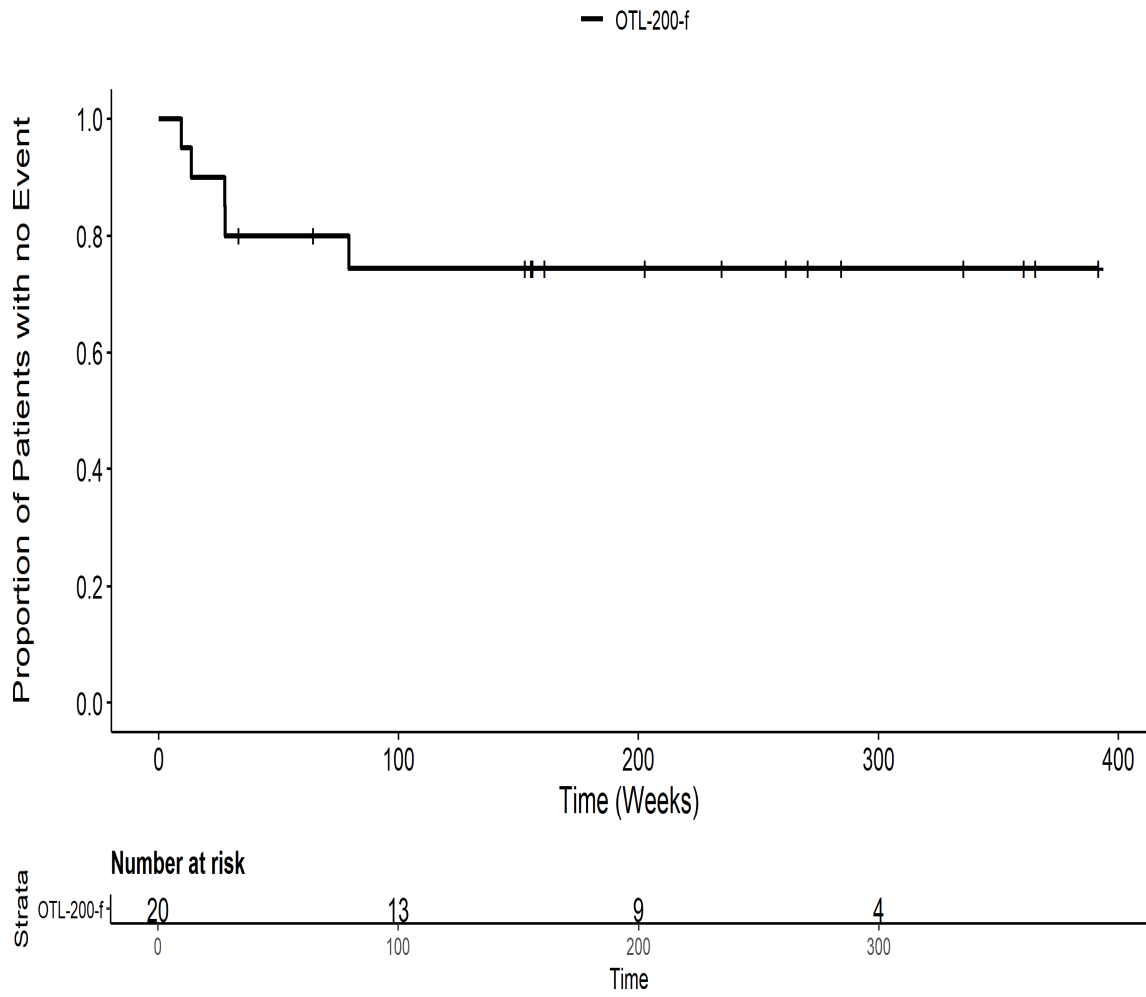
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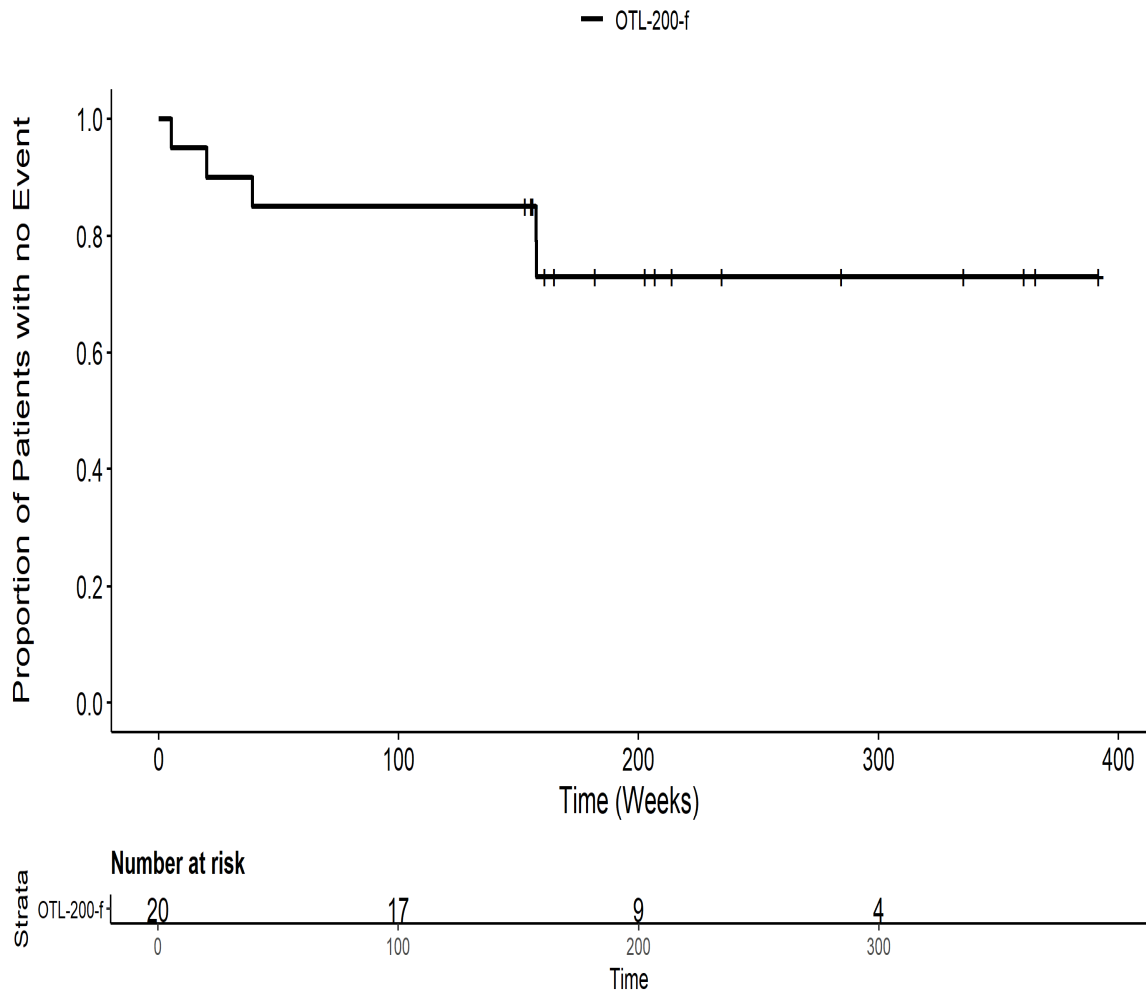
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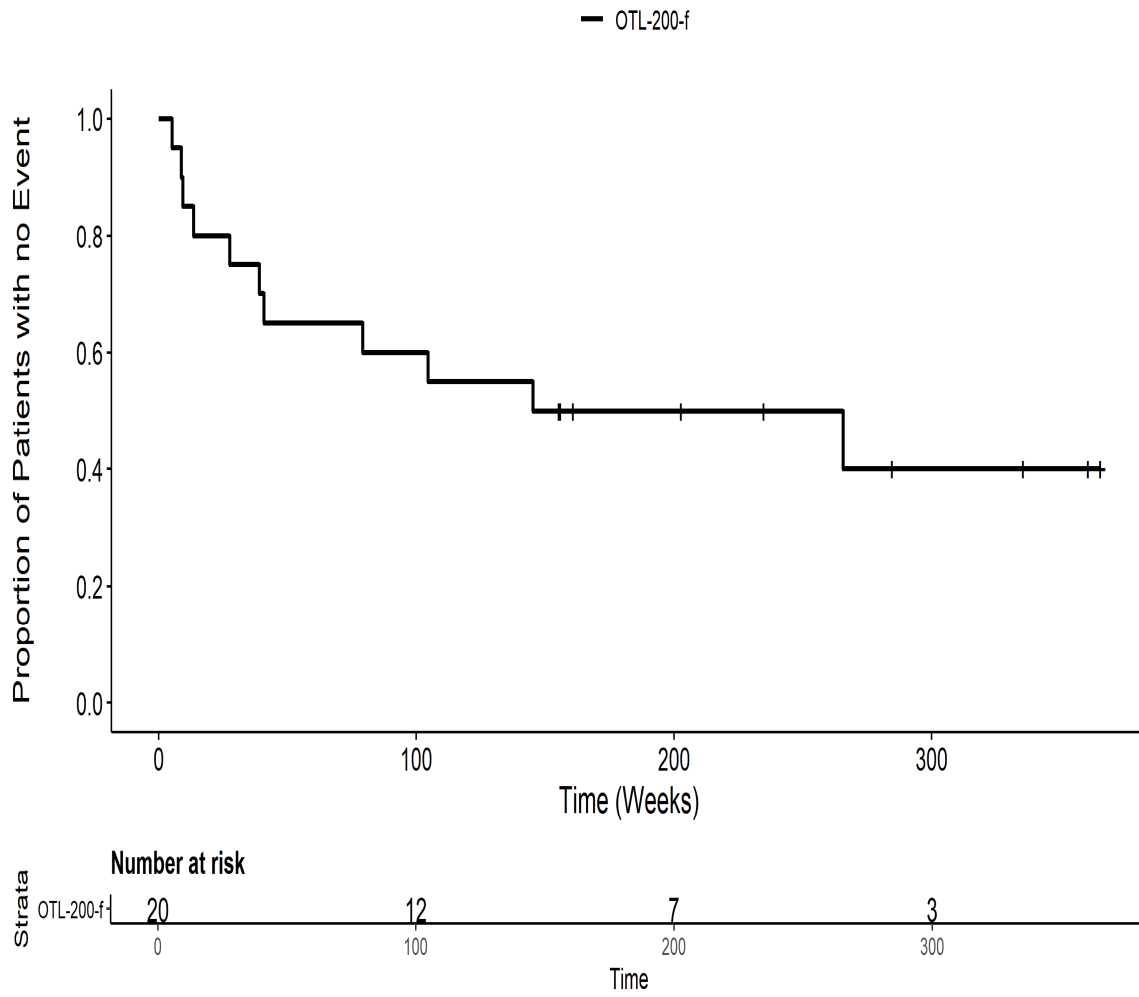
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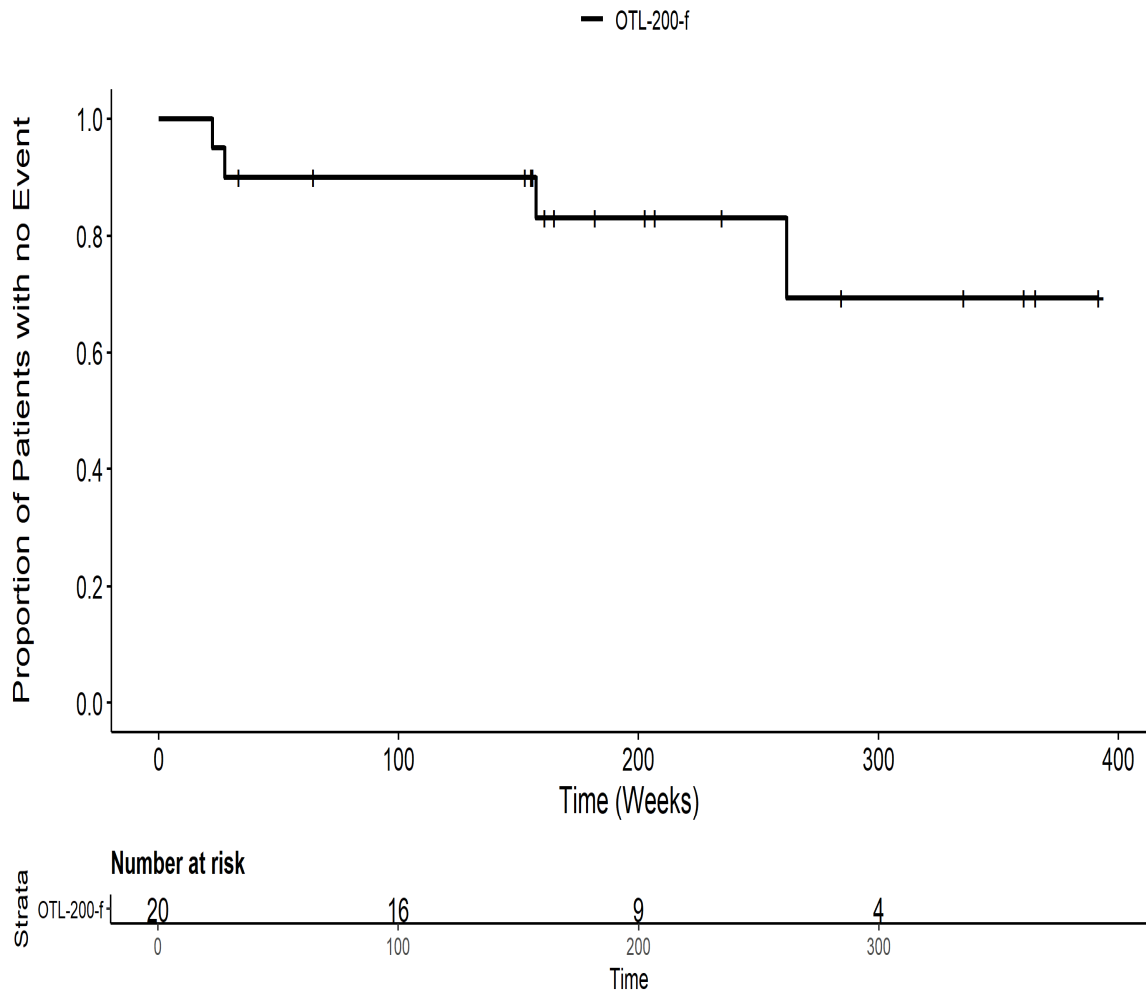
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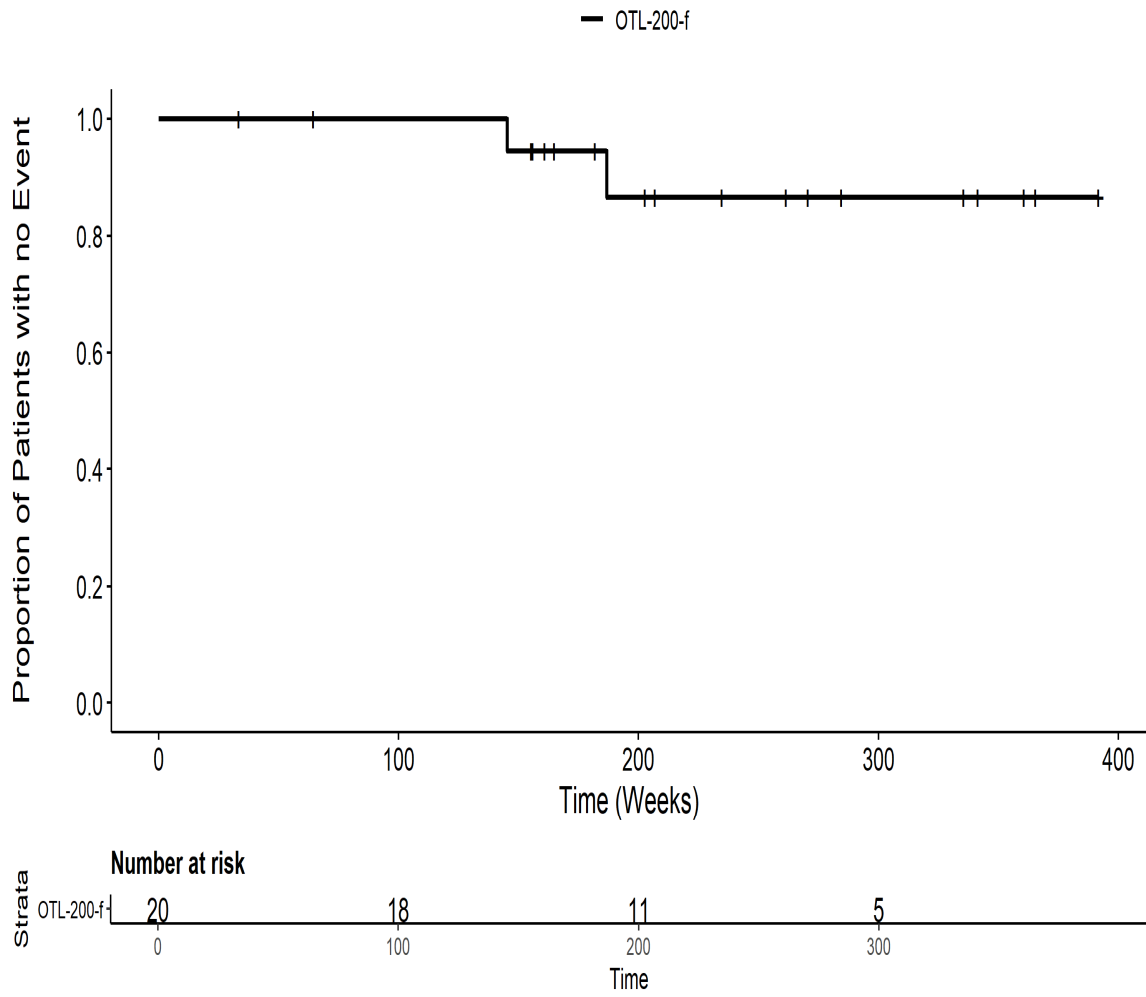
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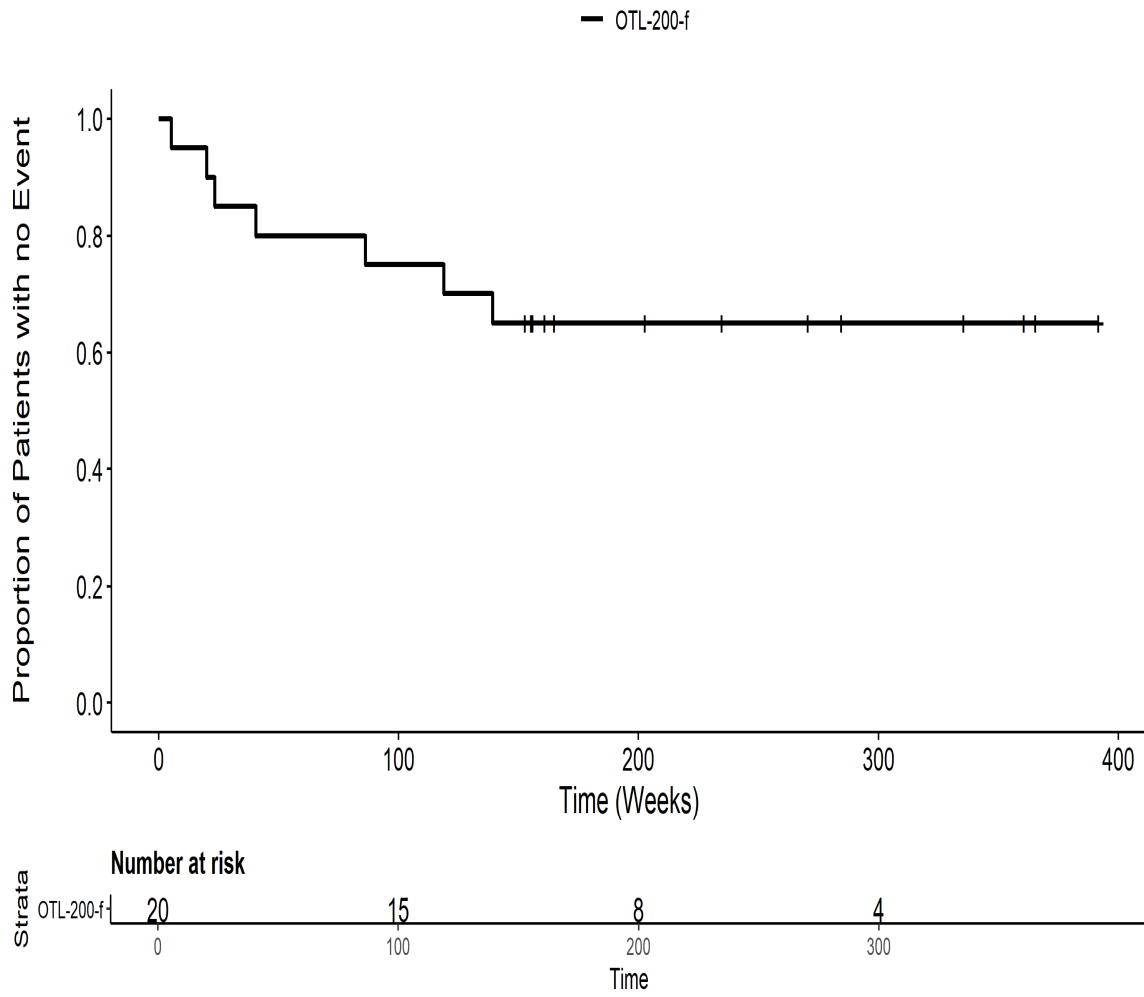
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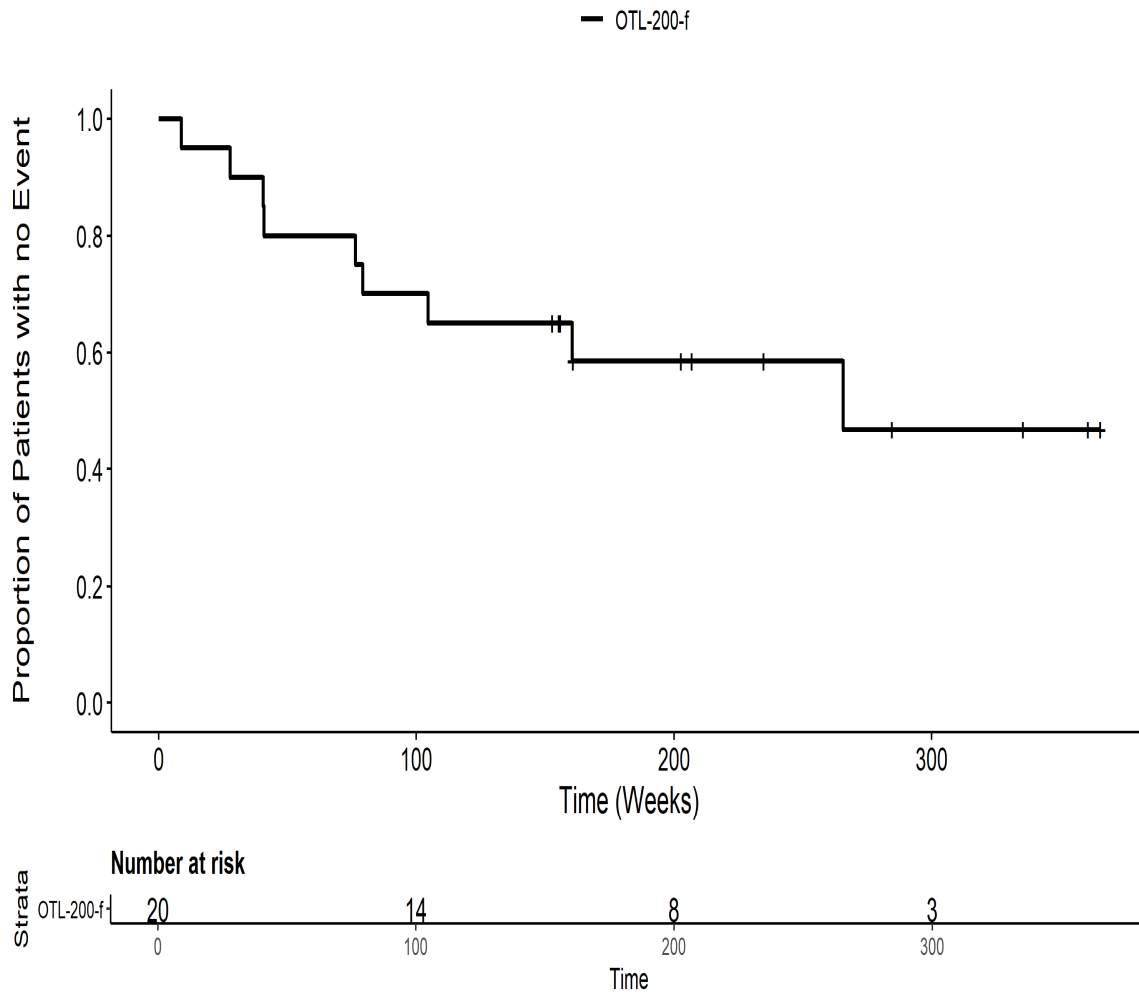
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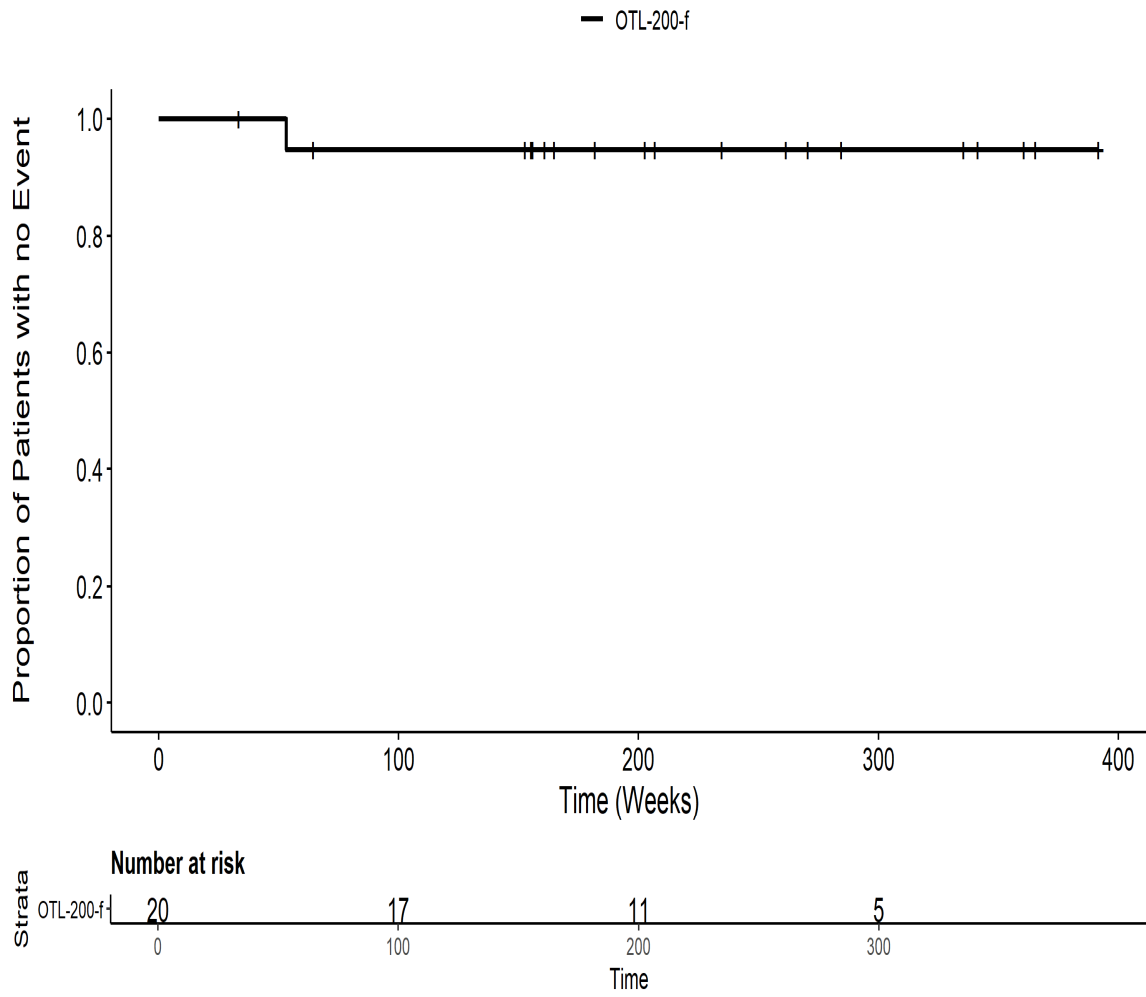
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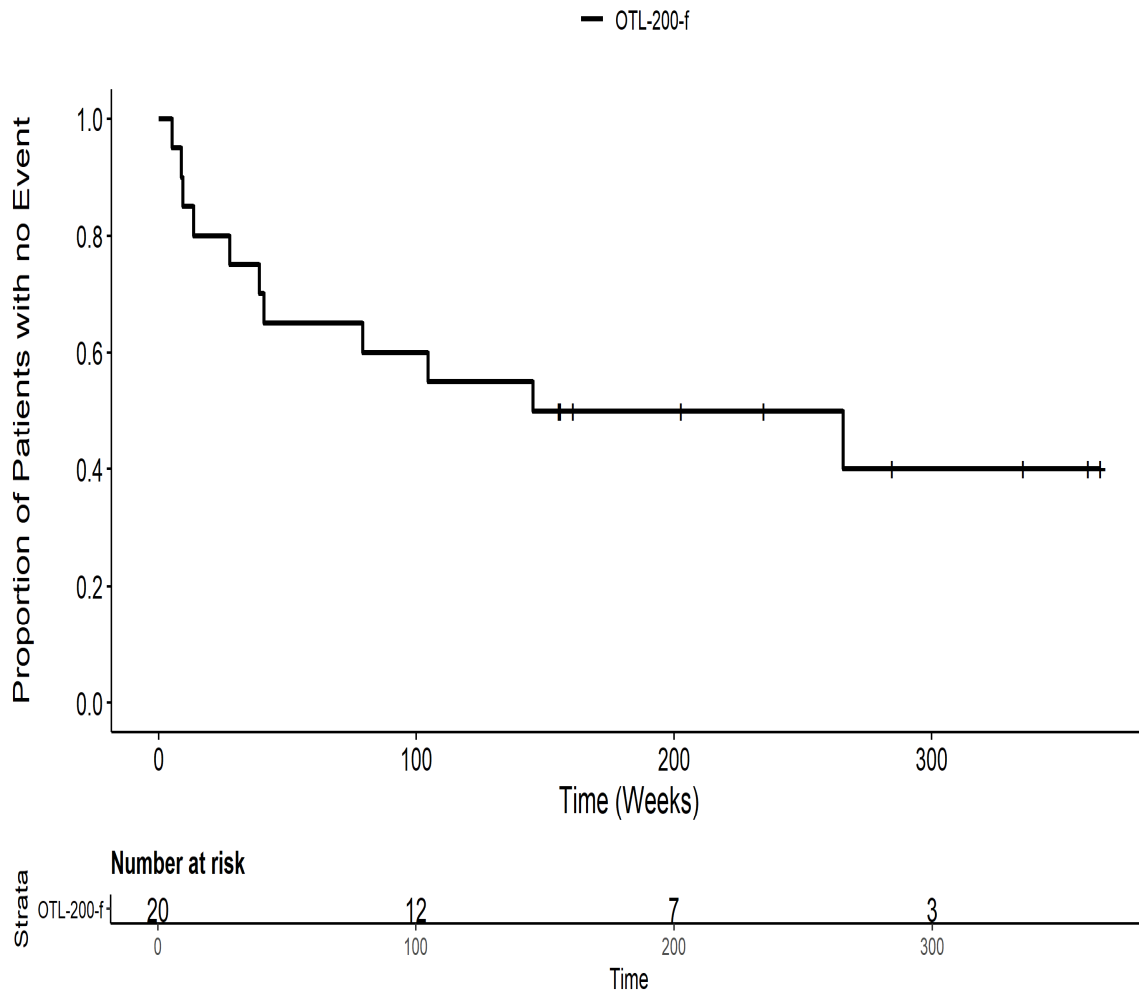
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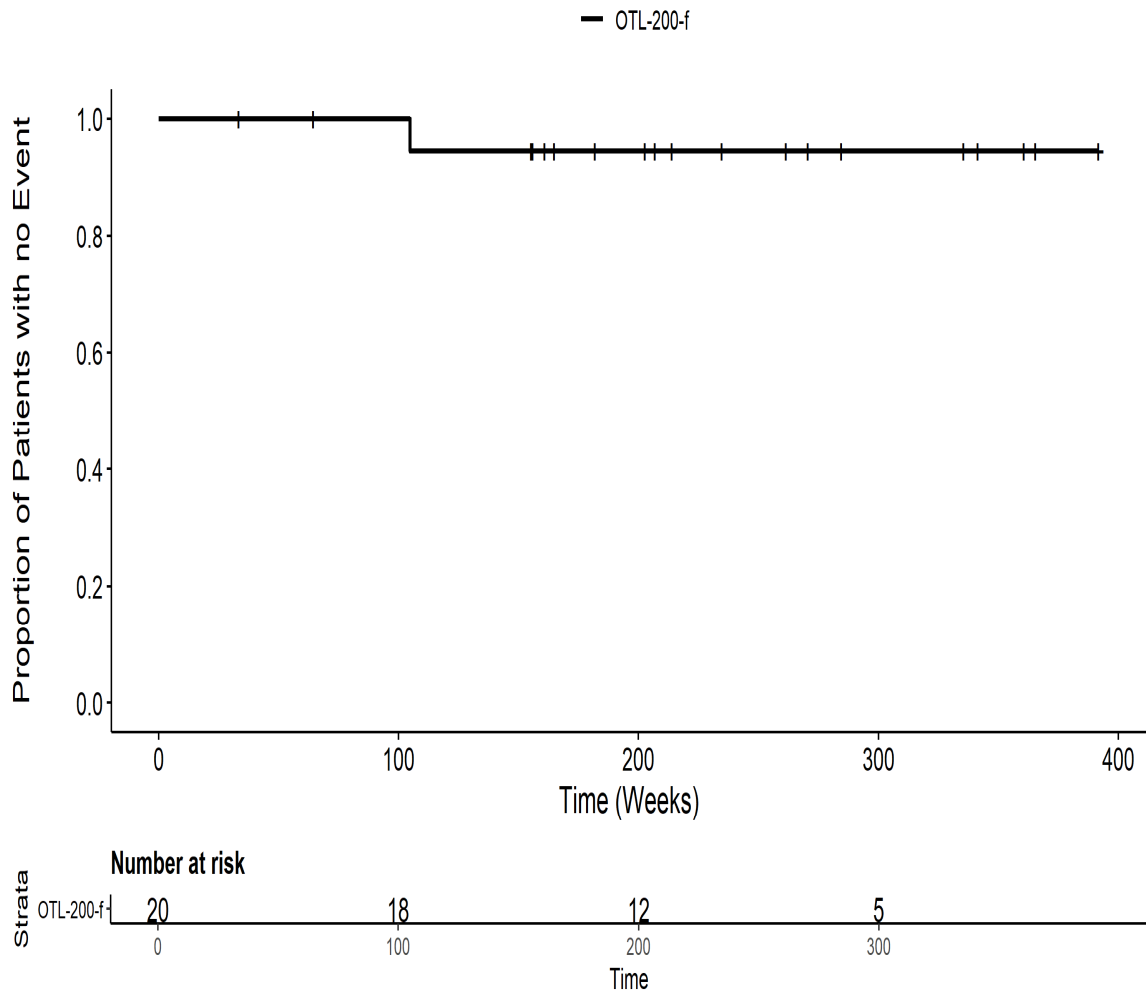
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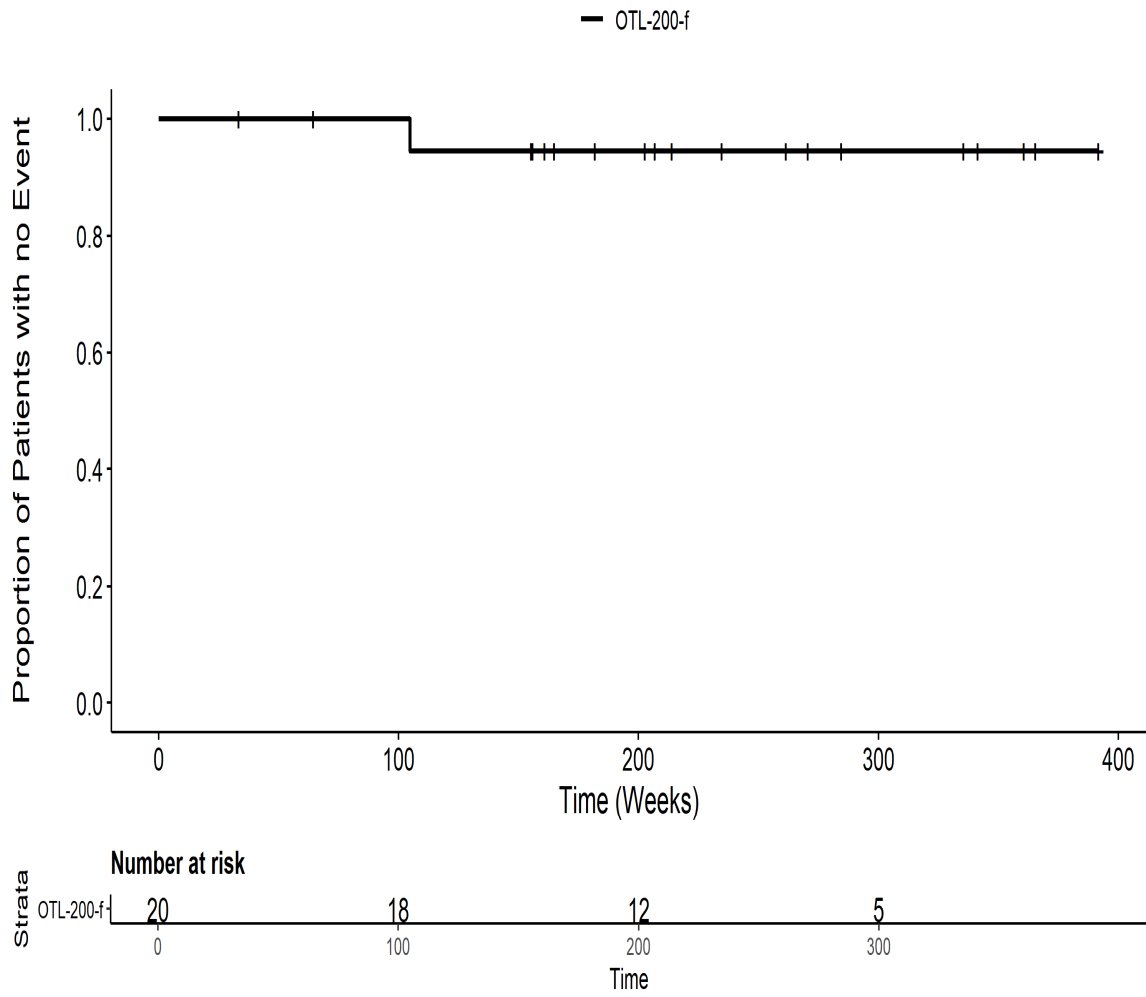
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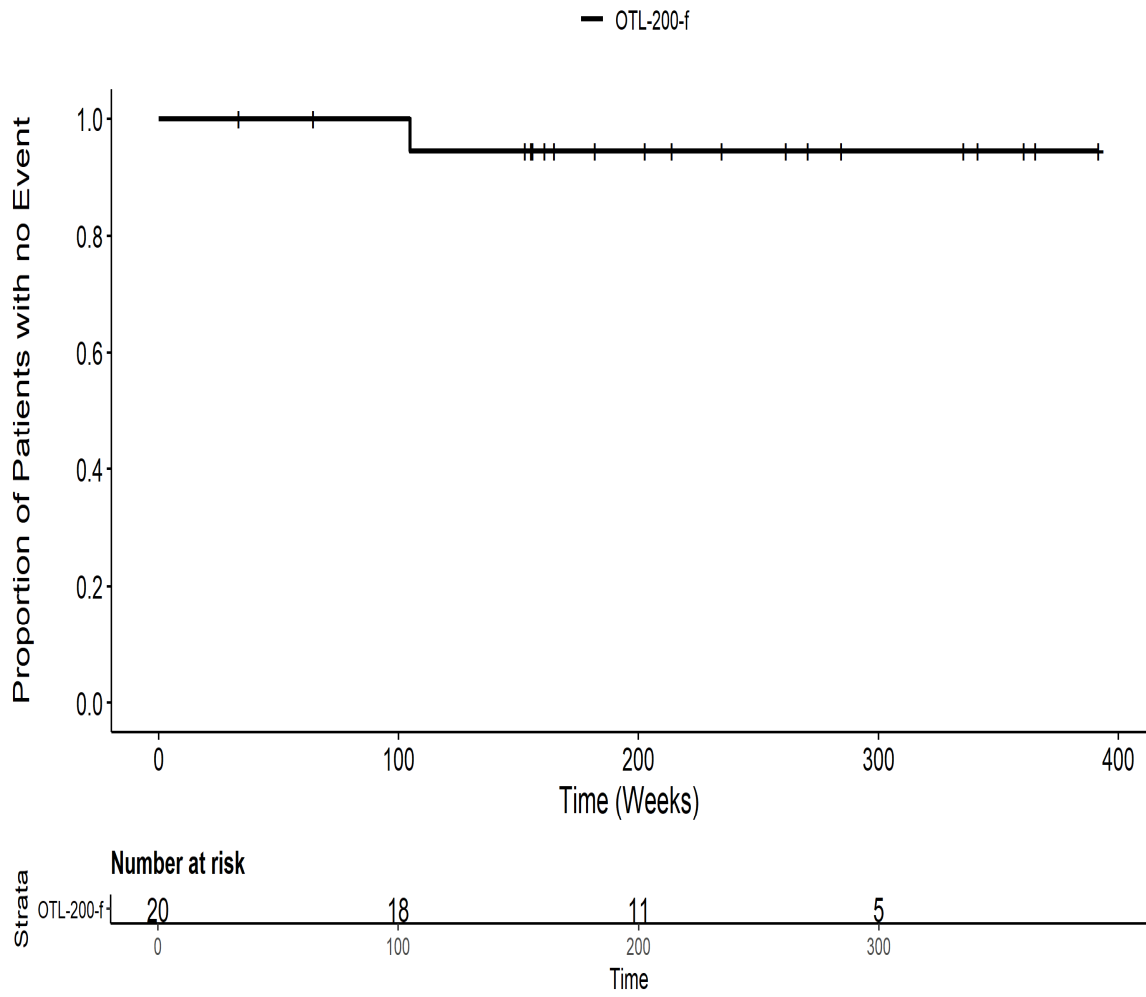
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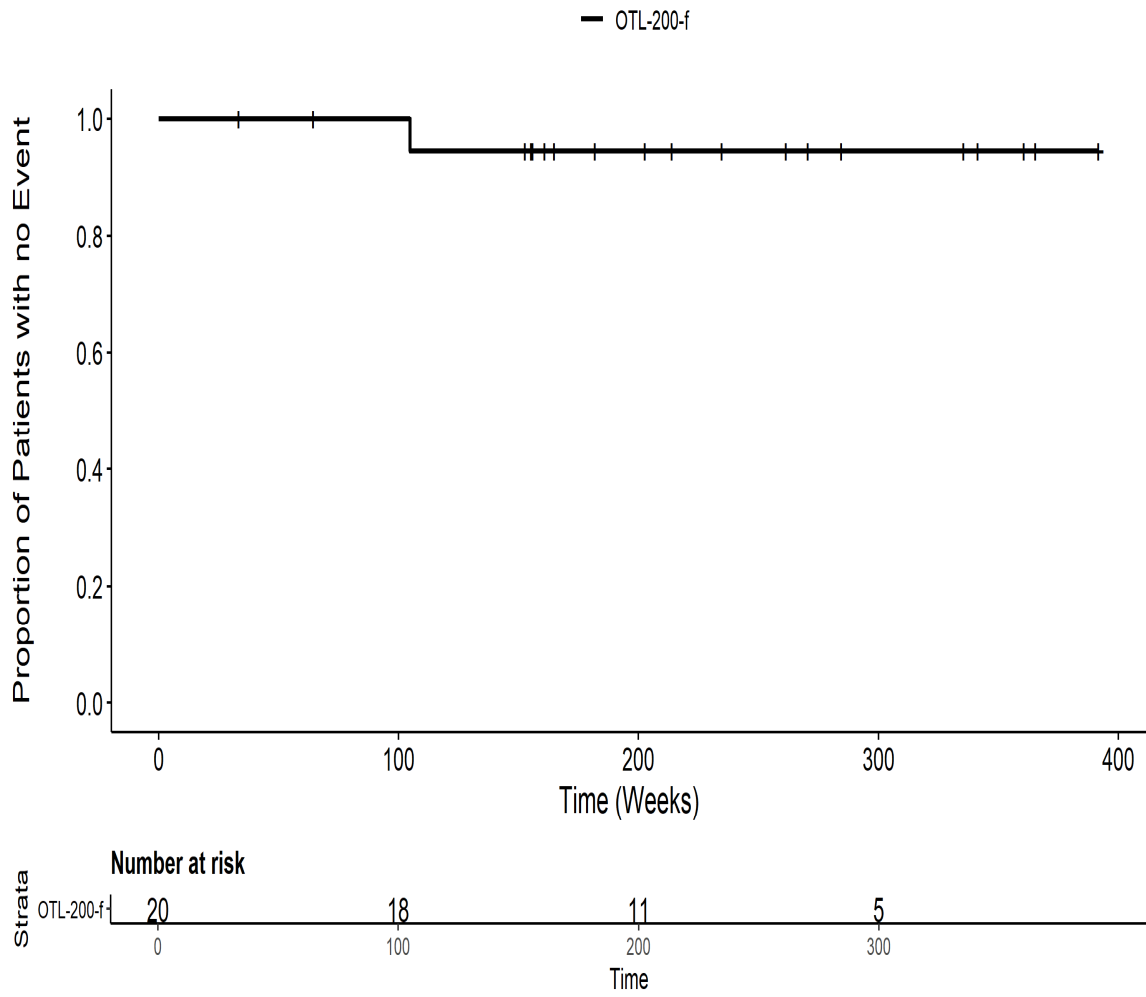
201222: Kaplan Meier Plot for Time to severe AE by SOC
Gefäßserkrankungen PT pct KAWASAKI'S DISEASEITT



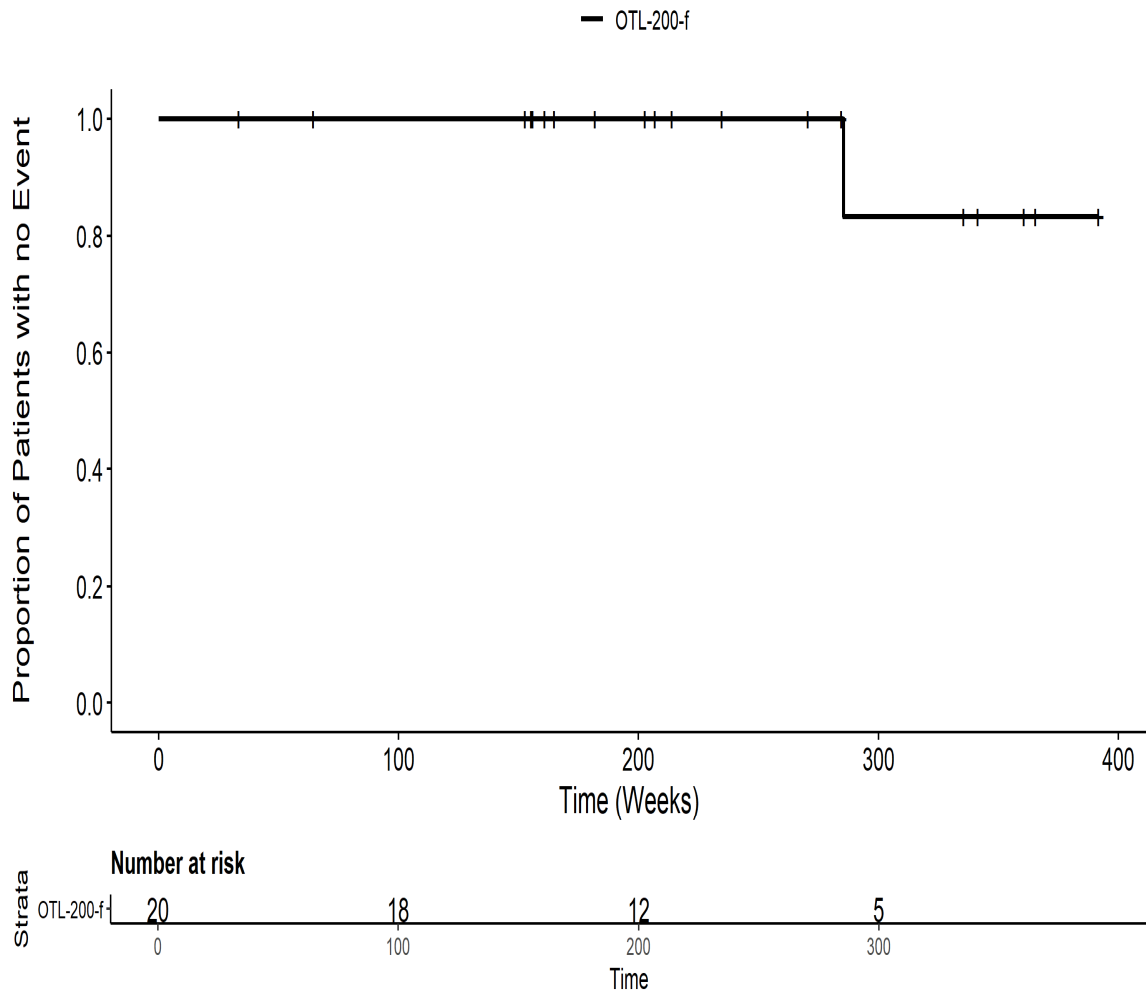
201222: Kaplan Meier Plot for Time to severe AE by SOC
Herzerkrankungen PT pct BradykardieIT



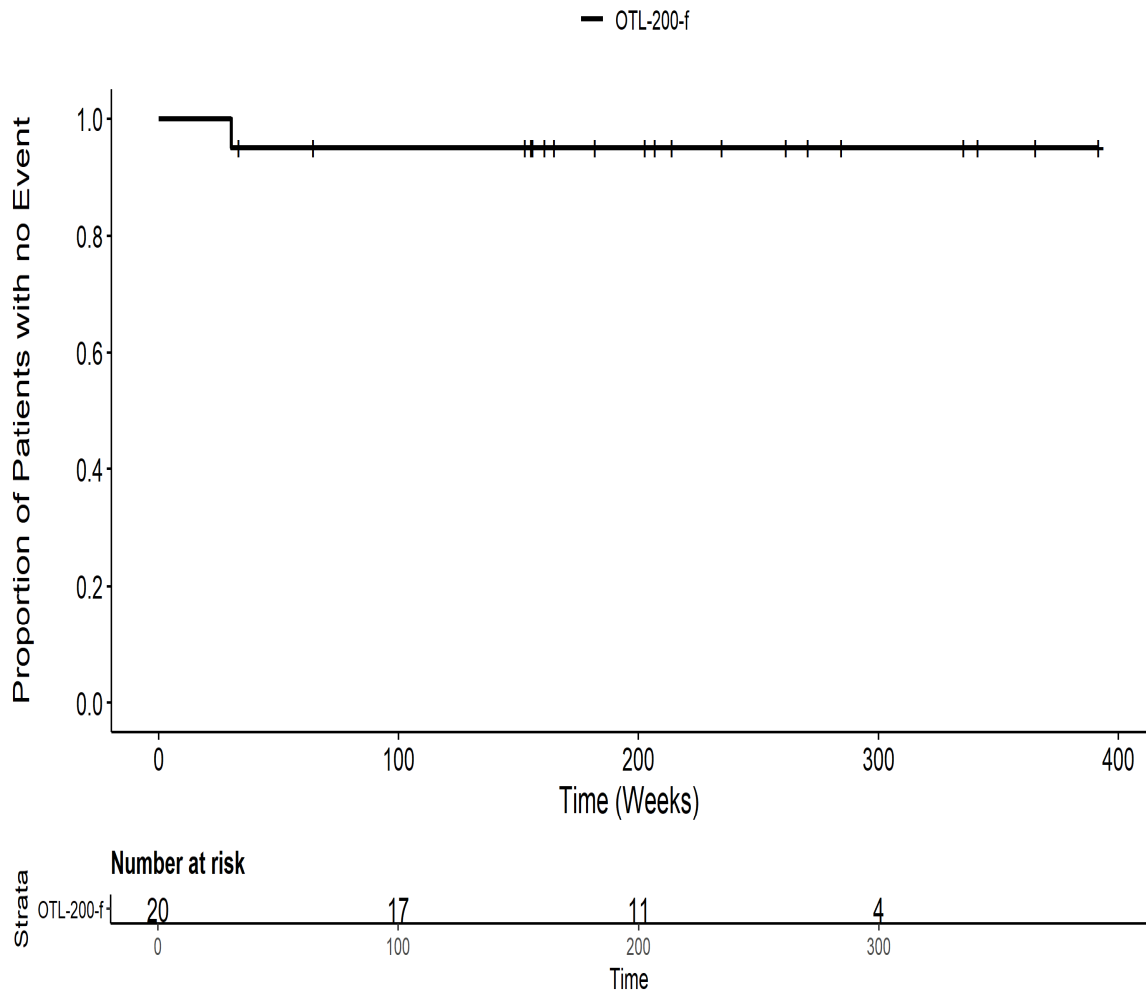
201222: Kaplan Meier Plot for Time to severe AE by SOC
Herzerkrankungen PT pct Gesamt SOCITT



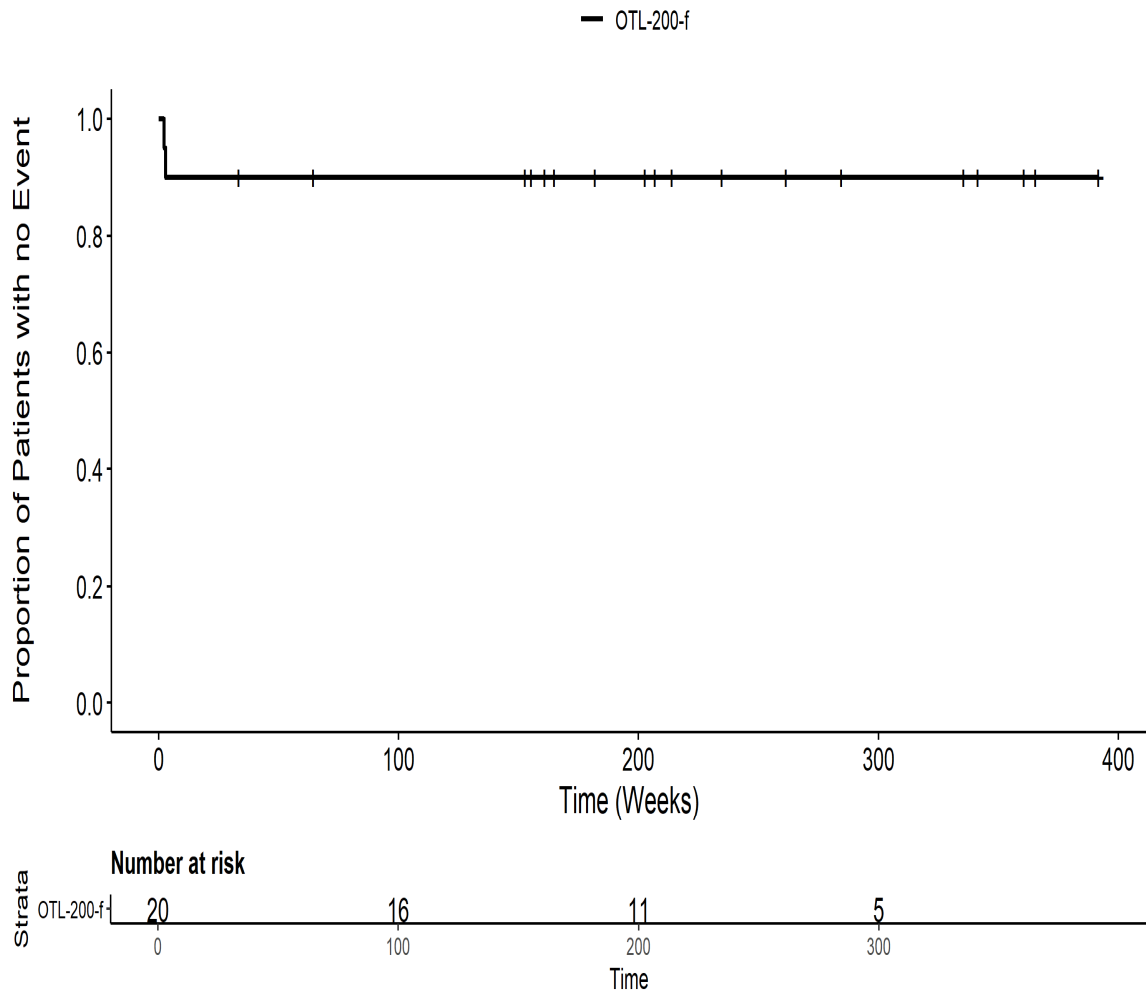
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct AtemwegsinfektionITT



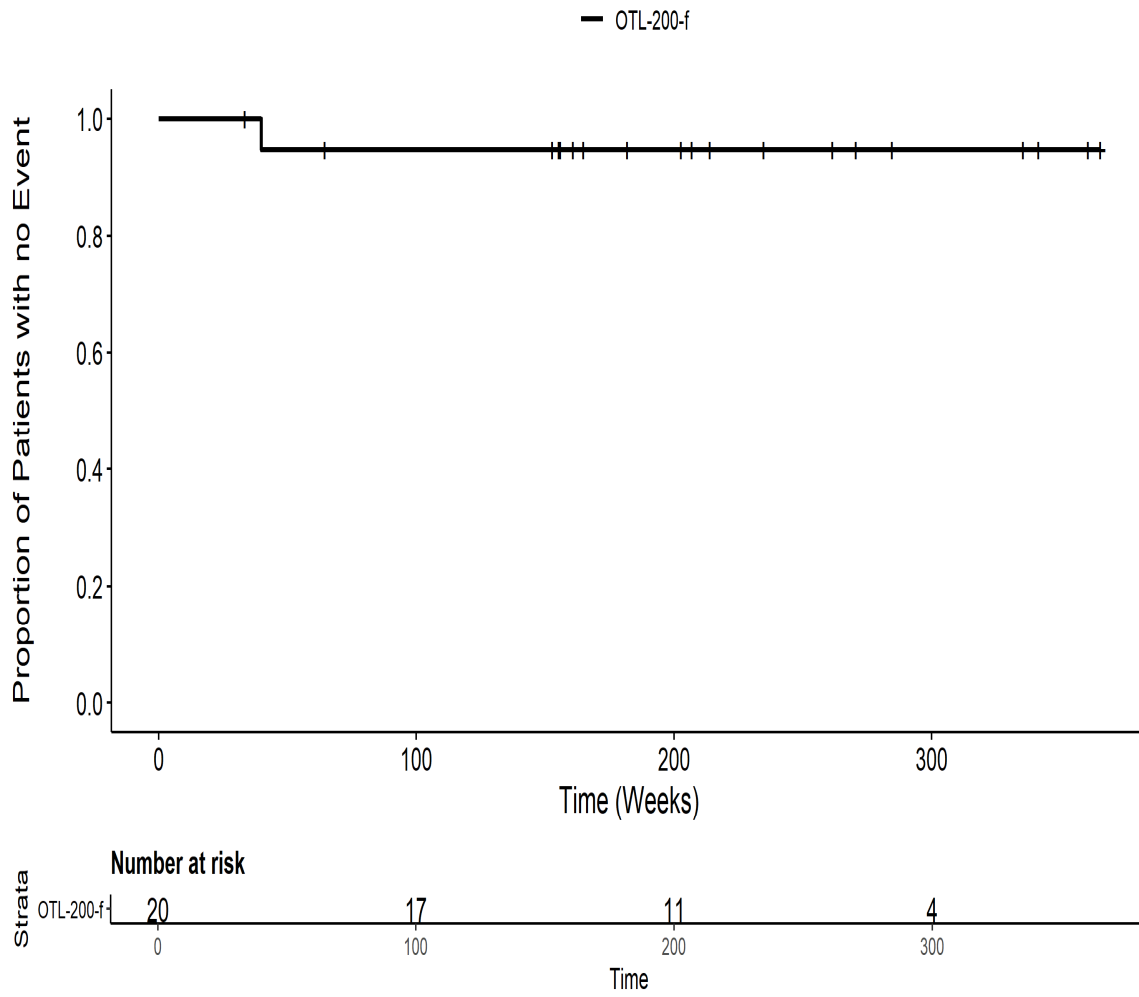
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct BACTERIAL SEPSISITT



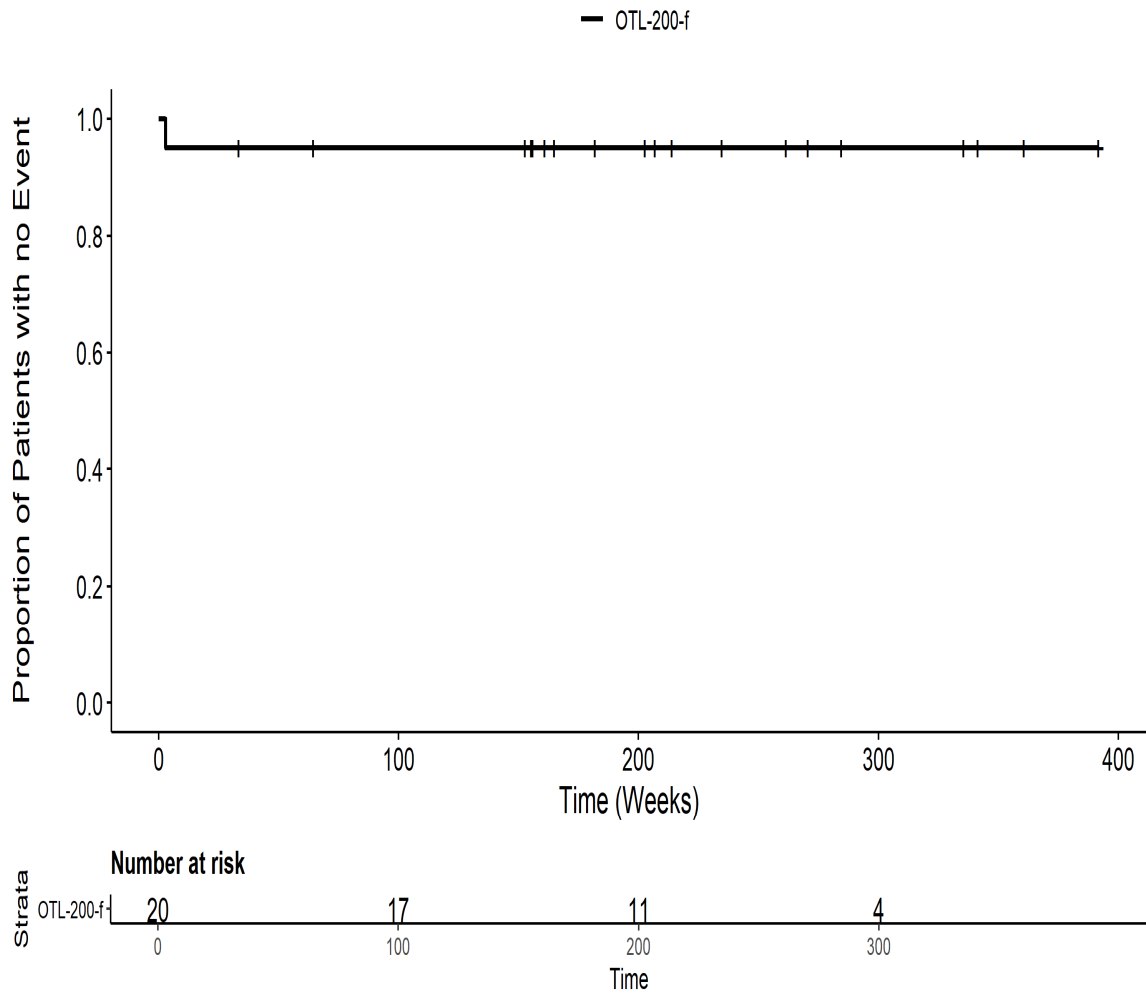
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct Clostridium difficile : KolitisITT



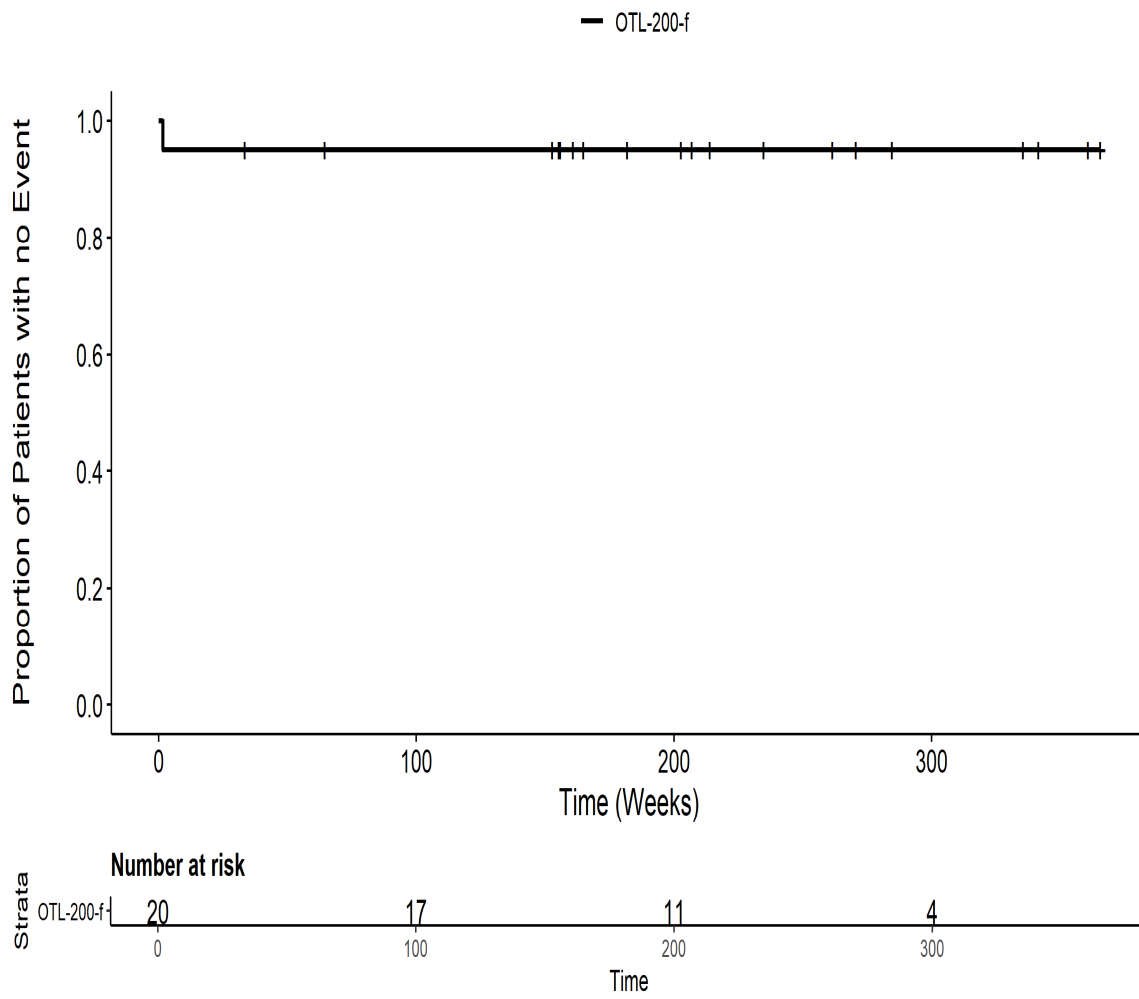
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct CYTOMEGALOVIRUS INFECTIONITT



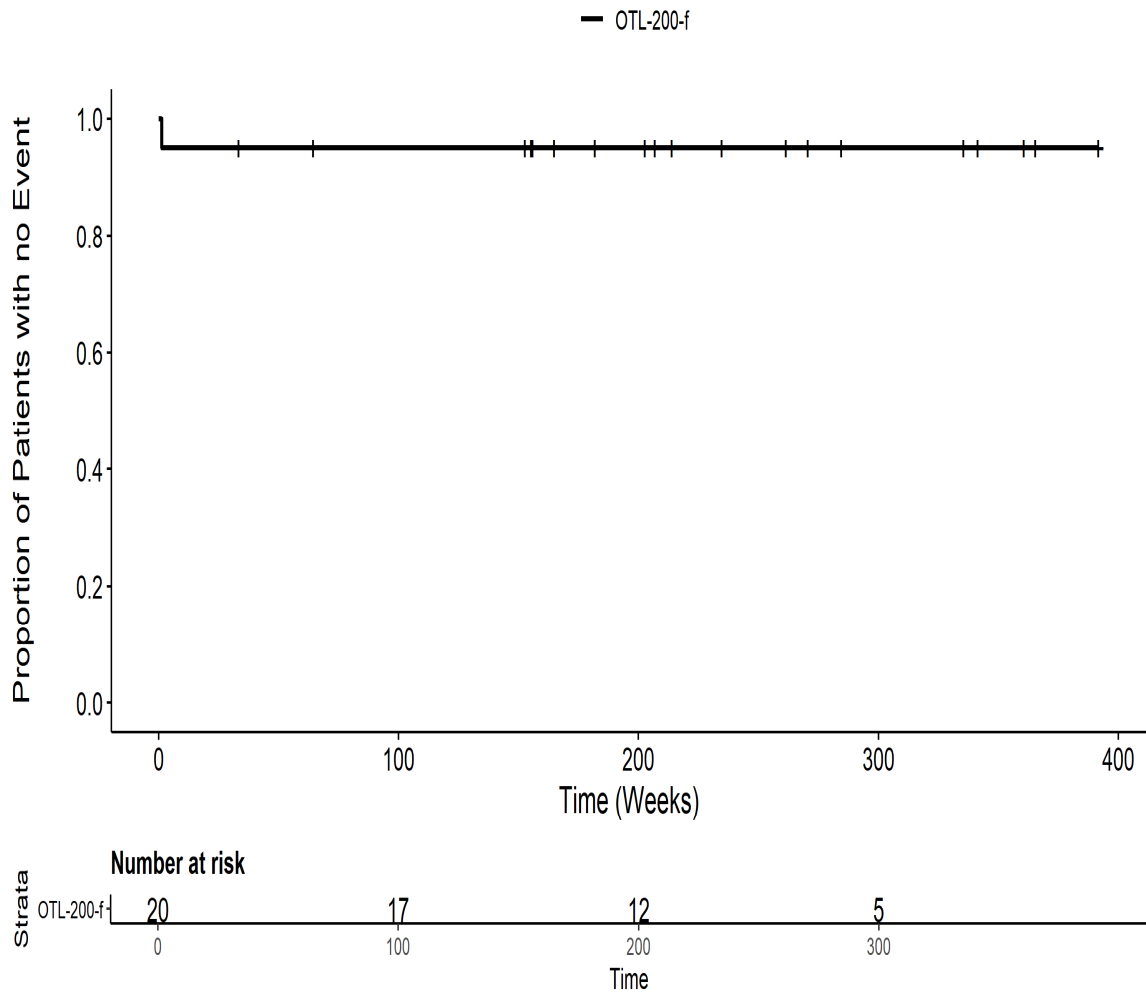
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct CYTOMEGALOVIRUS VIRAEMIAIT



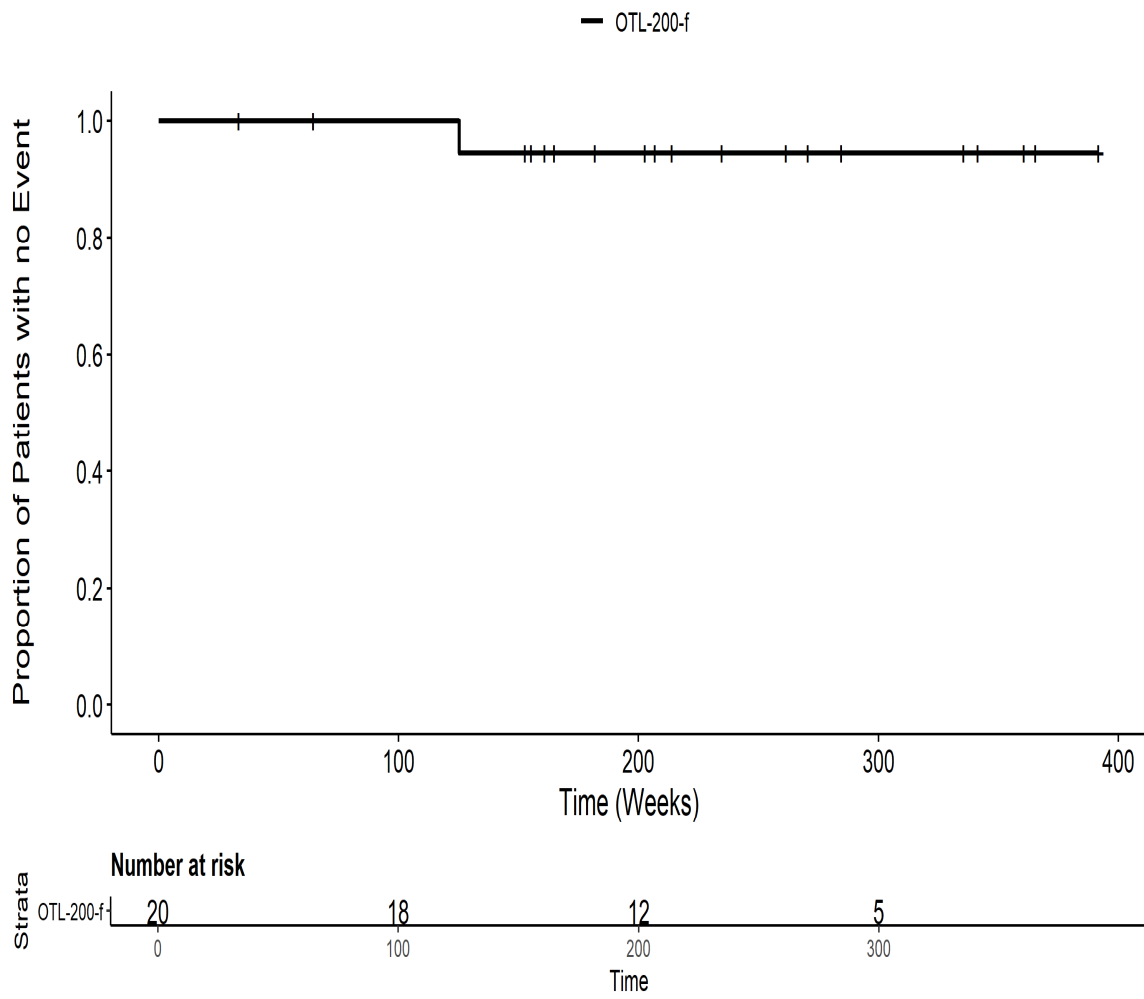
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct Escherichia : InfektionITT



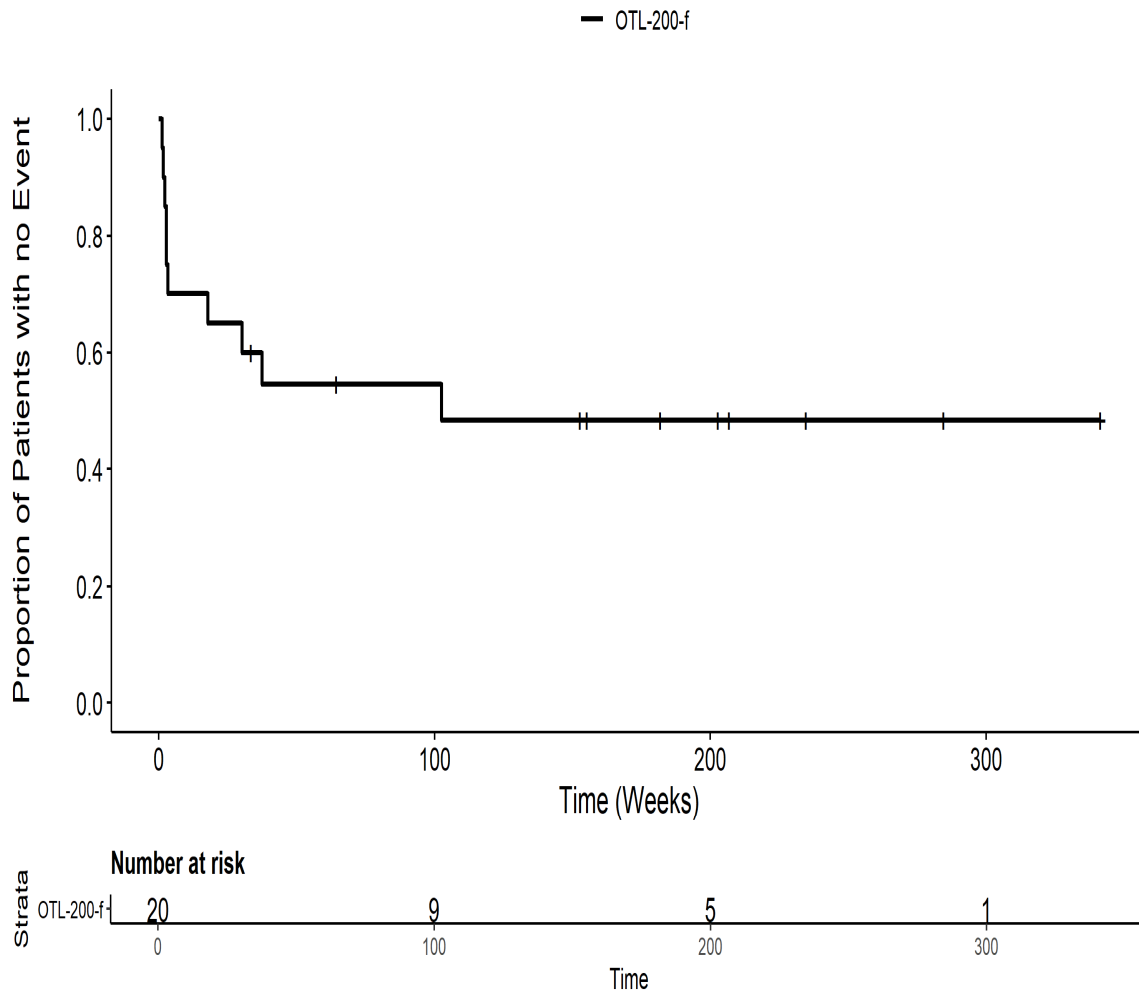
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct GASTROENTERITIS AEROMONASITT



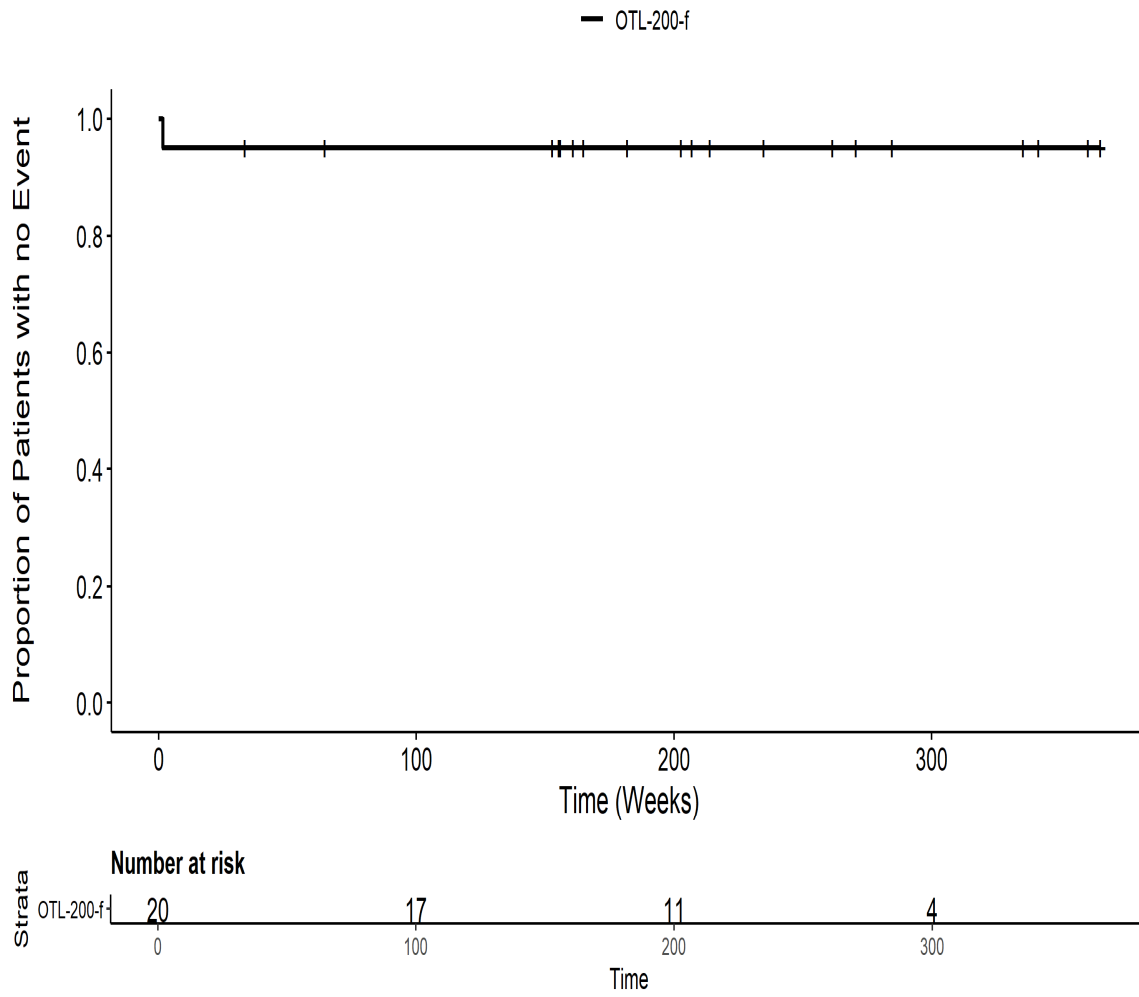
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct GastroenteritisITT



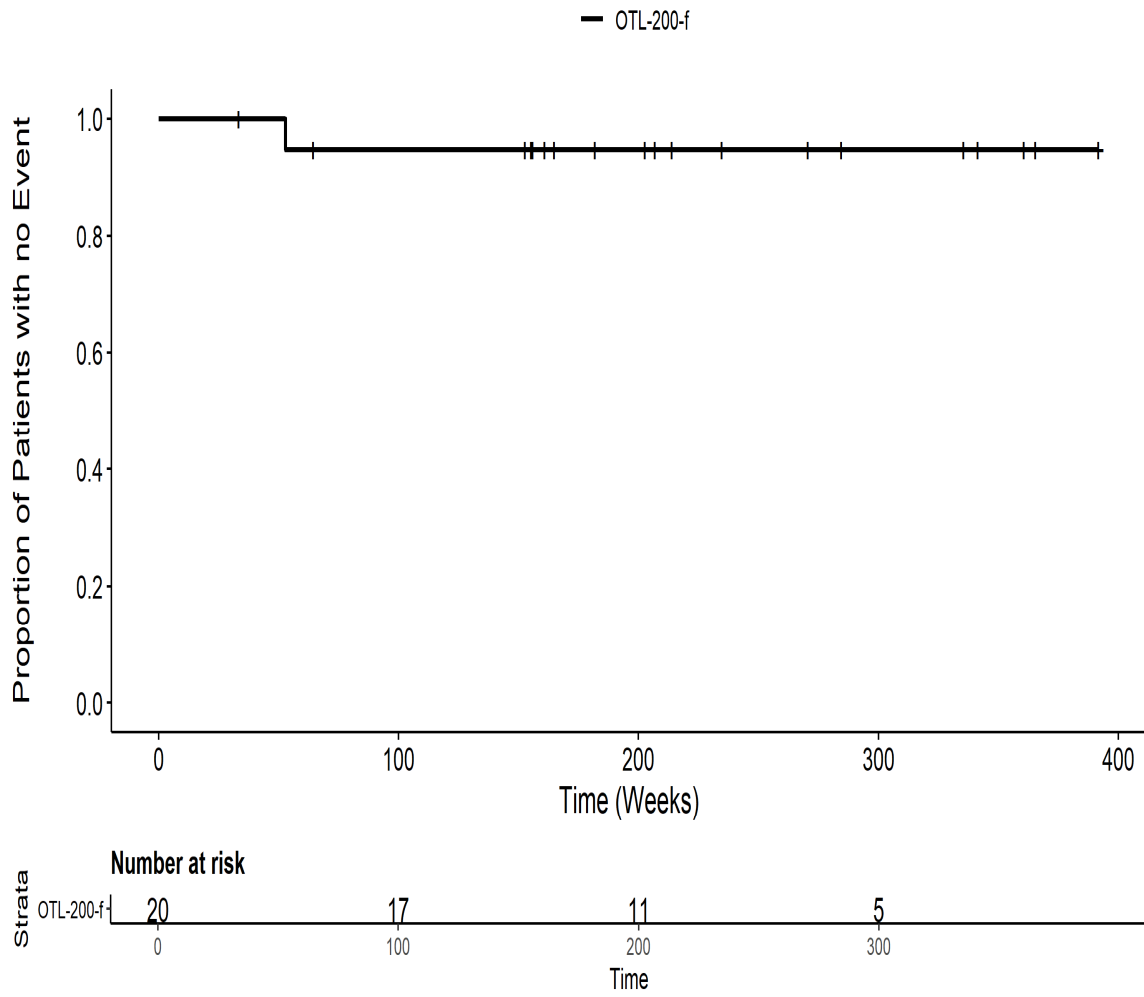
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct Gesamt SOCITT



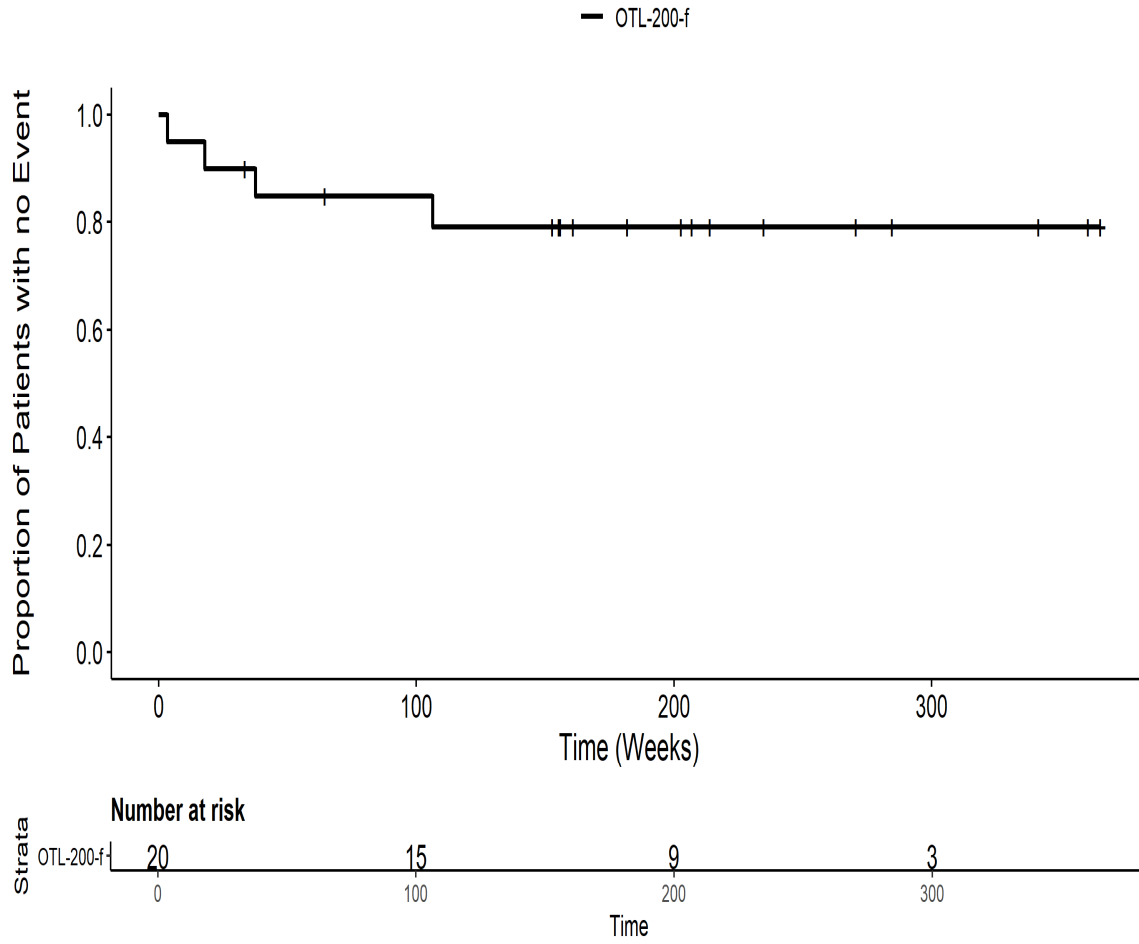
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct Haemophilus : InfektionITT



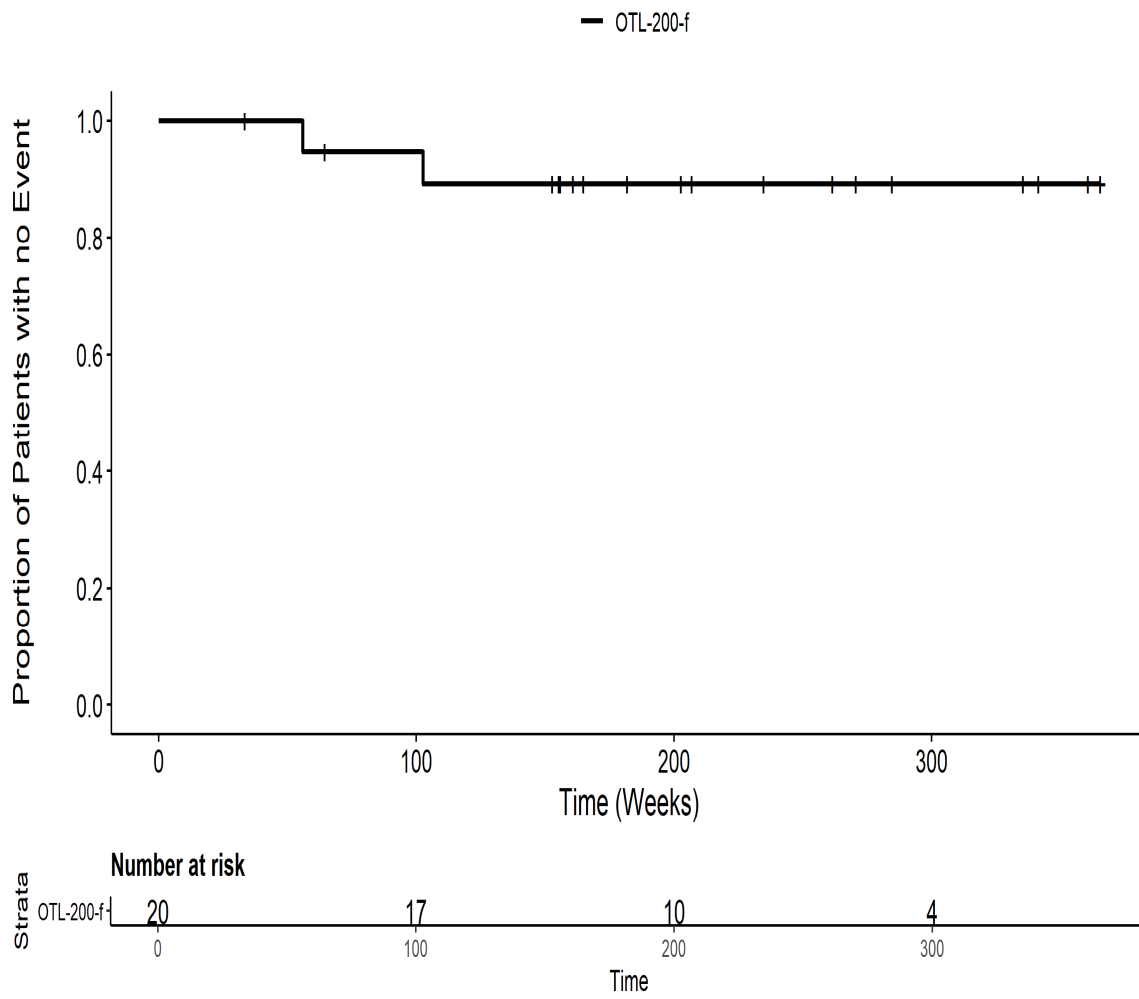
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct Infektion der oberen Atemwege|TT



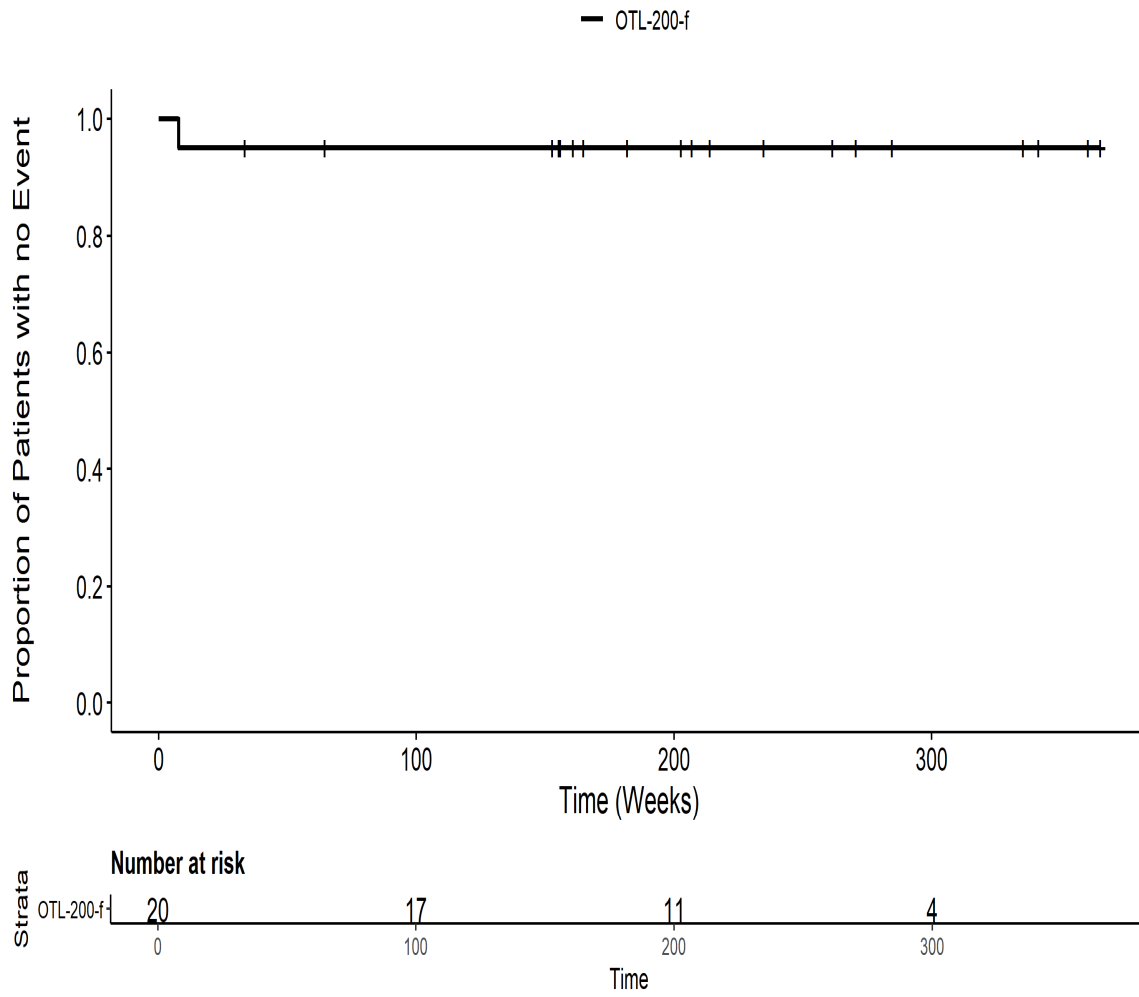
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct Infektion im Zusammenhang mit einem Medizinprodukt/TT



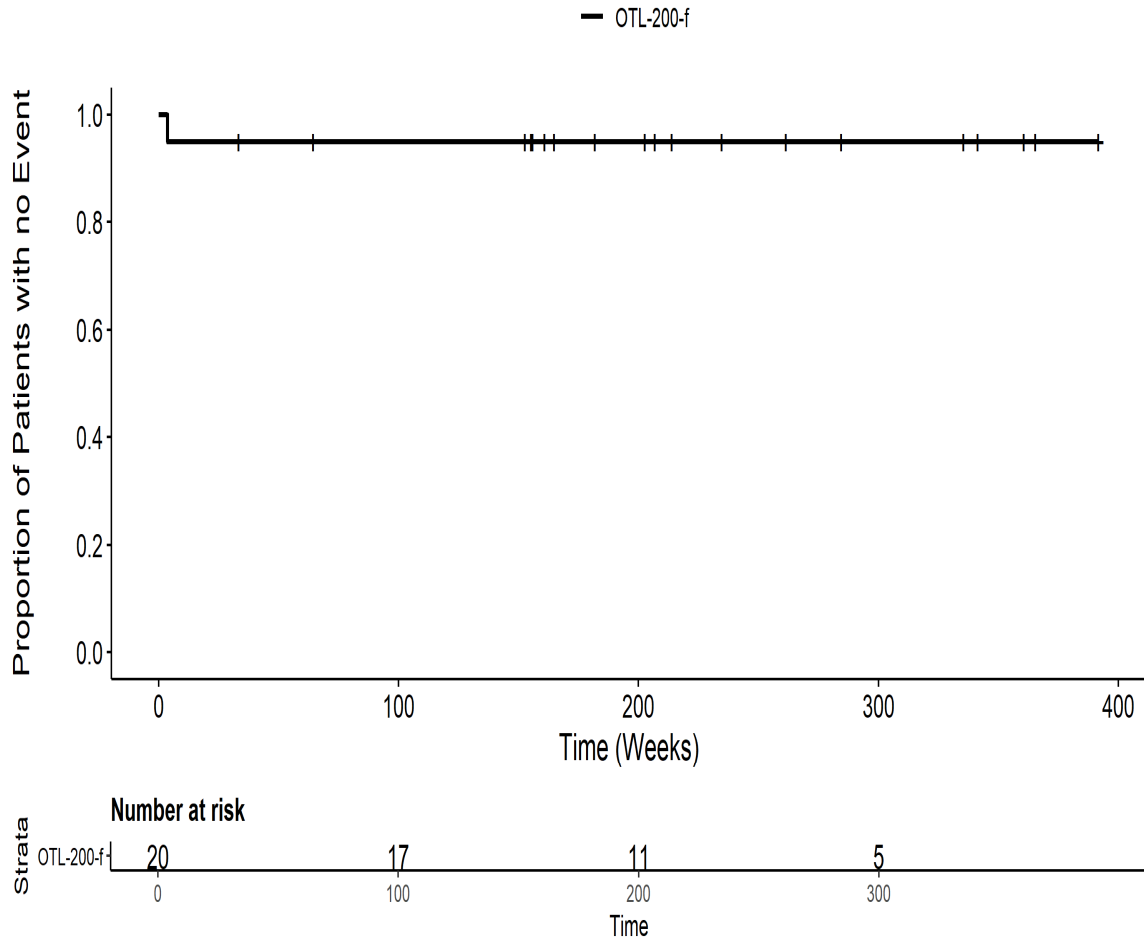
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct PneumonieITT



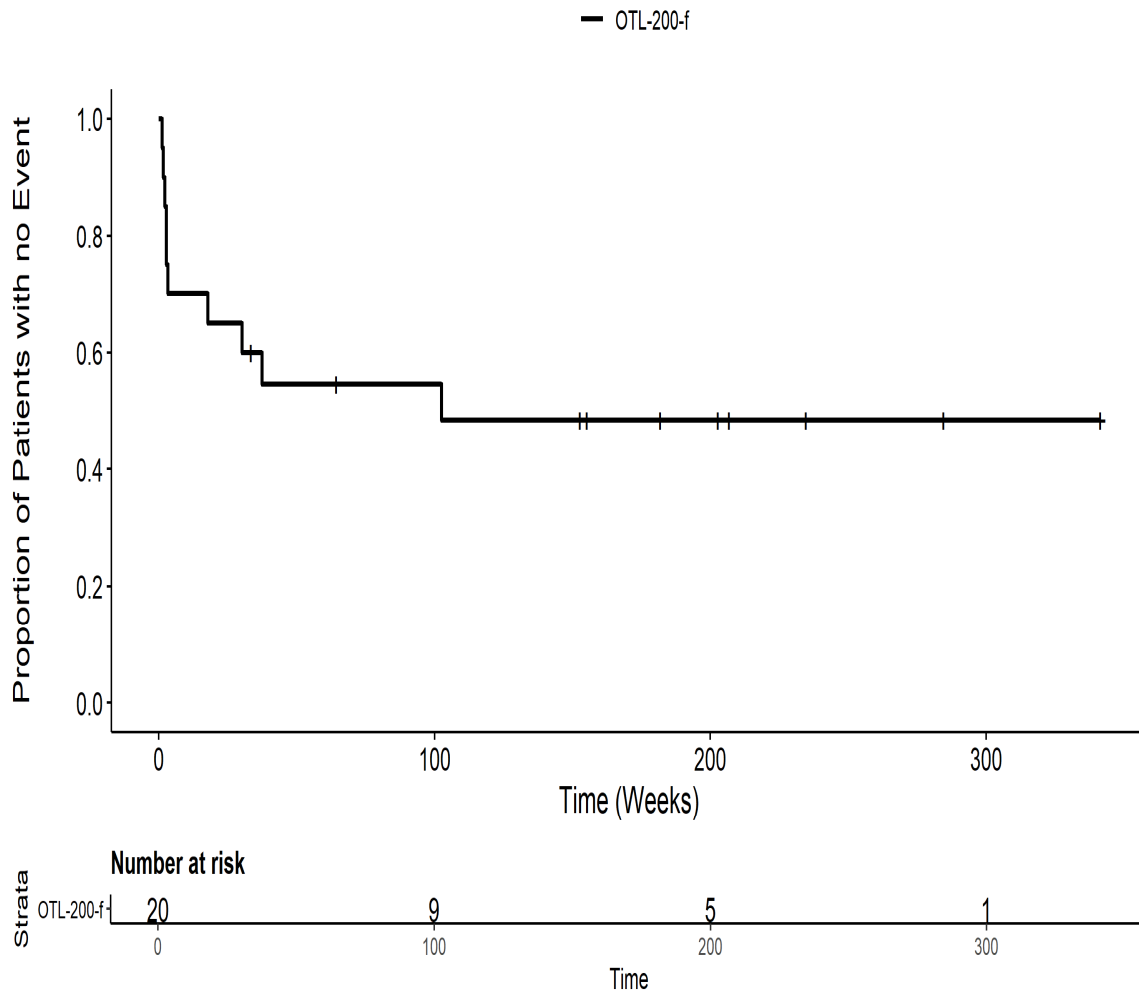
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct StaphylokokkeninfektionITT



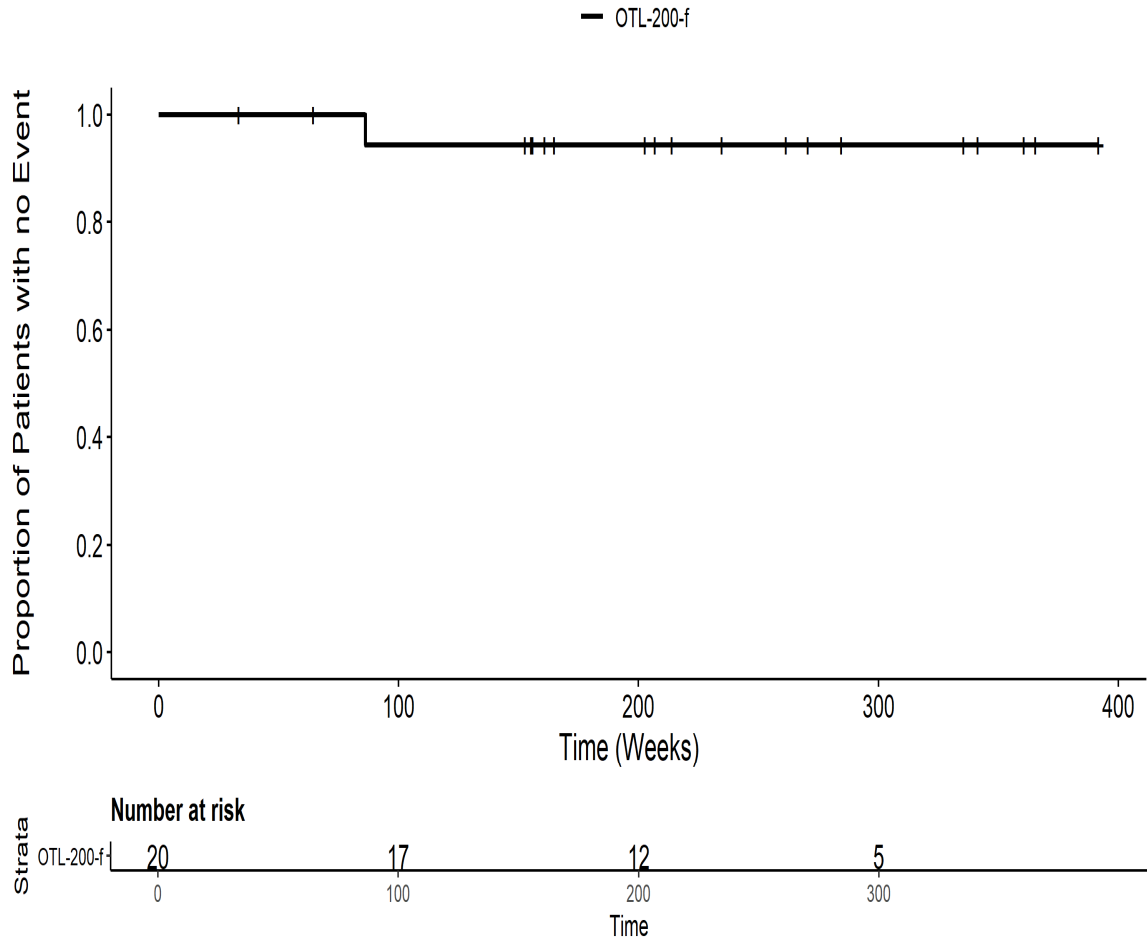
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pct UPPER RESPIRATORY FUNGAL INFECTIONITT



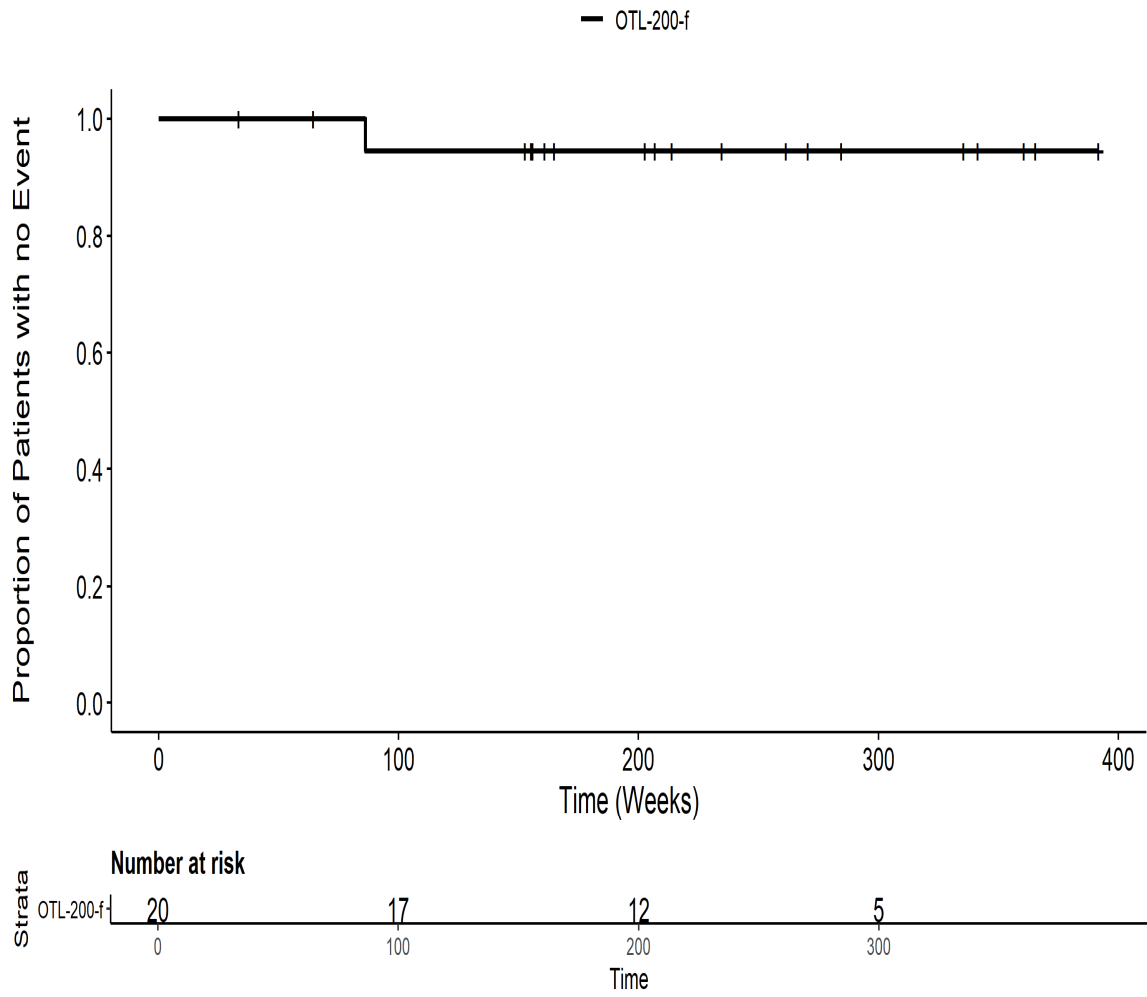
201222: Kaplan Meier Plot for Time to severe AE by SOC Infektionen und parasitäre Erkrankungen PT pts Gesamt SOC ITT



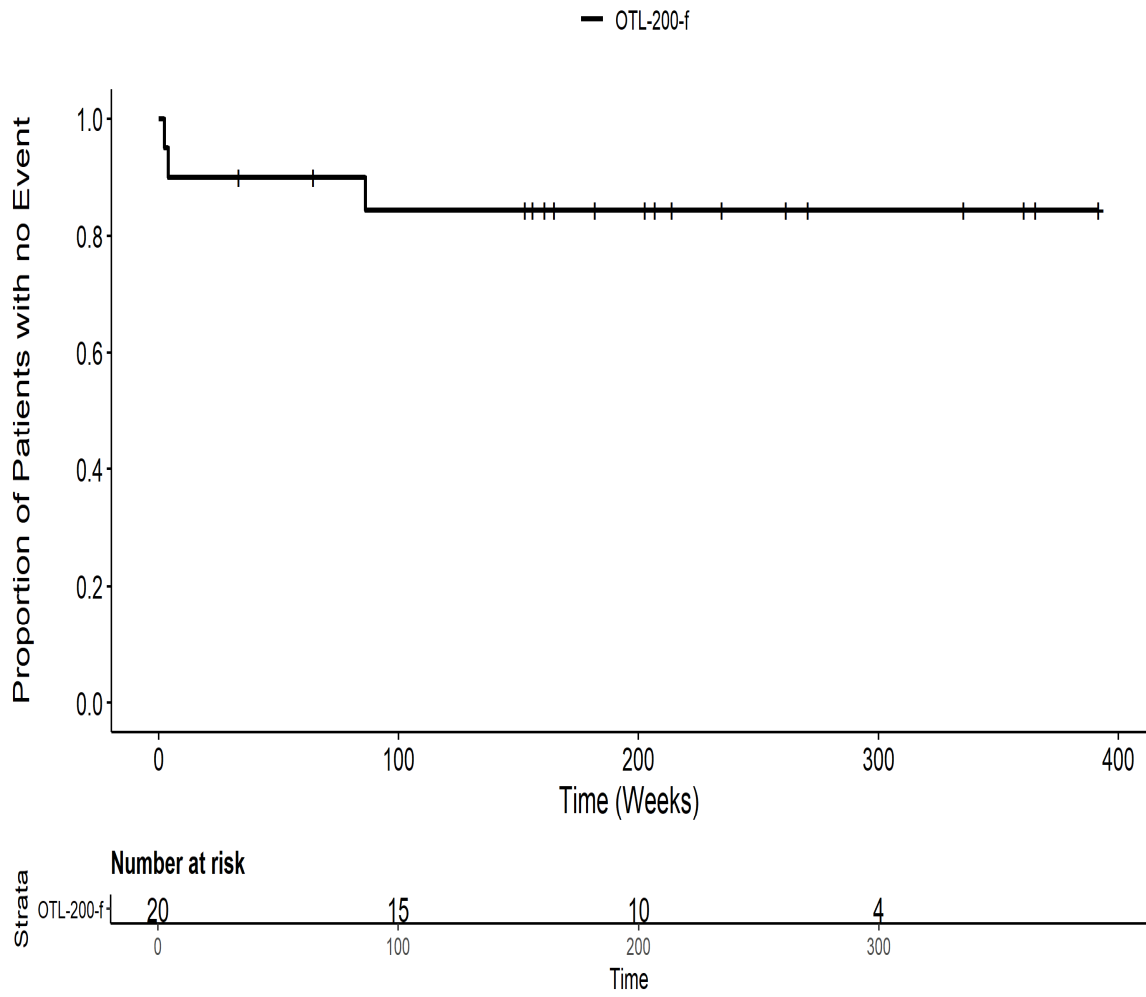
201222: Kaplan Meier Plot for Time to severe AE by SOC
 Skelettmuskulatur : , Bindegewebs : und Knochenkrankungen PT pct Deformitaet des
 FussesITT



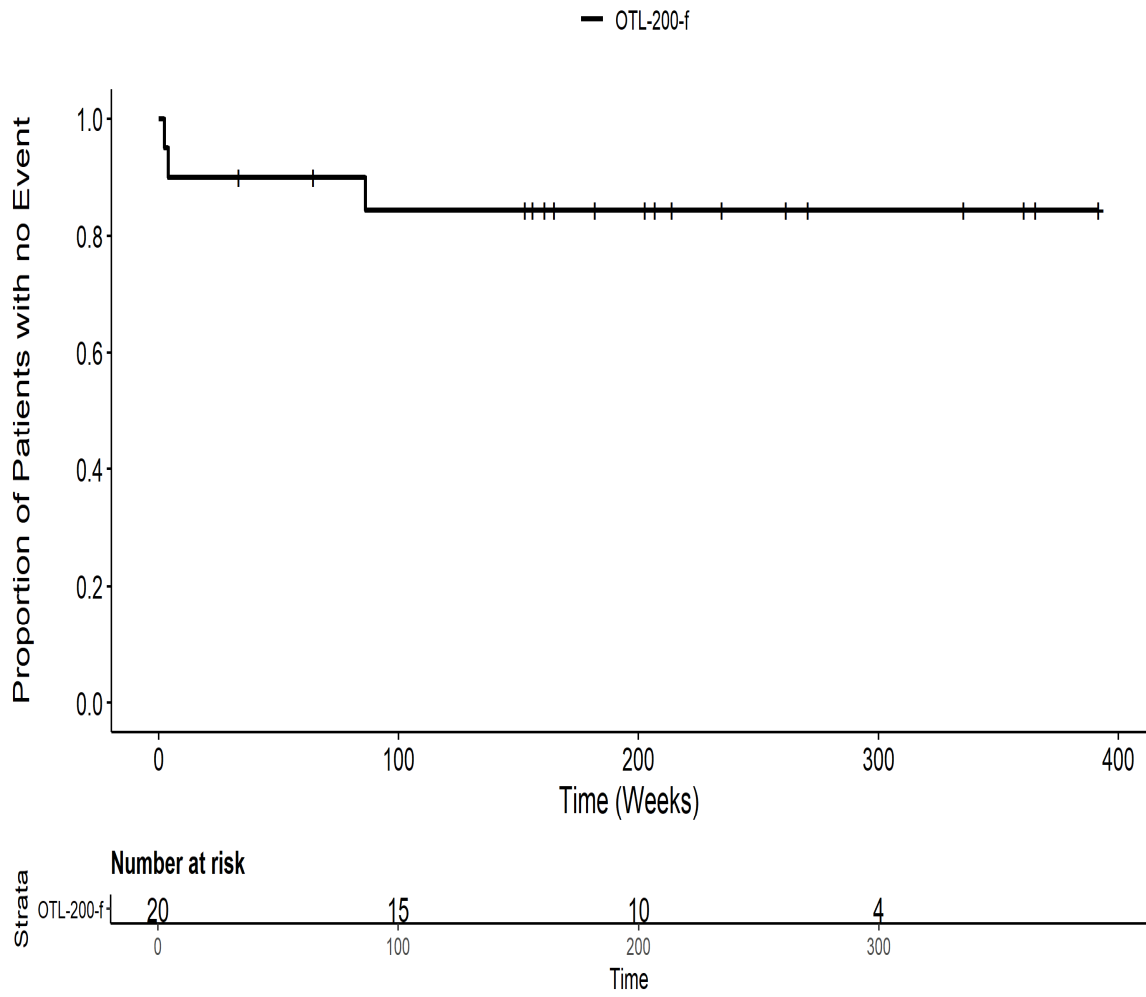
201222: Kaplan Meier Plot for Time to severe AE by SOC
Skelettmuskulatur : , Bindegewebs : und Knochenkrankungen PT pct Gesamt SOCITT



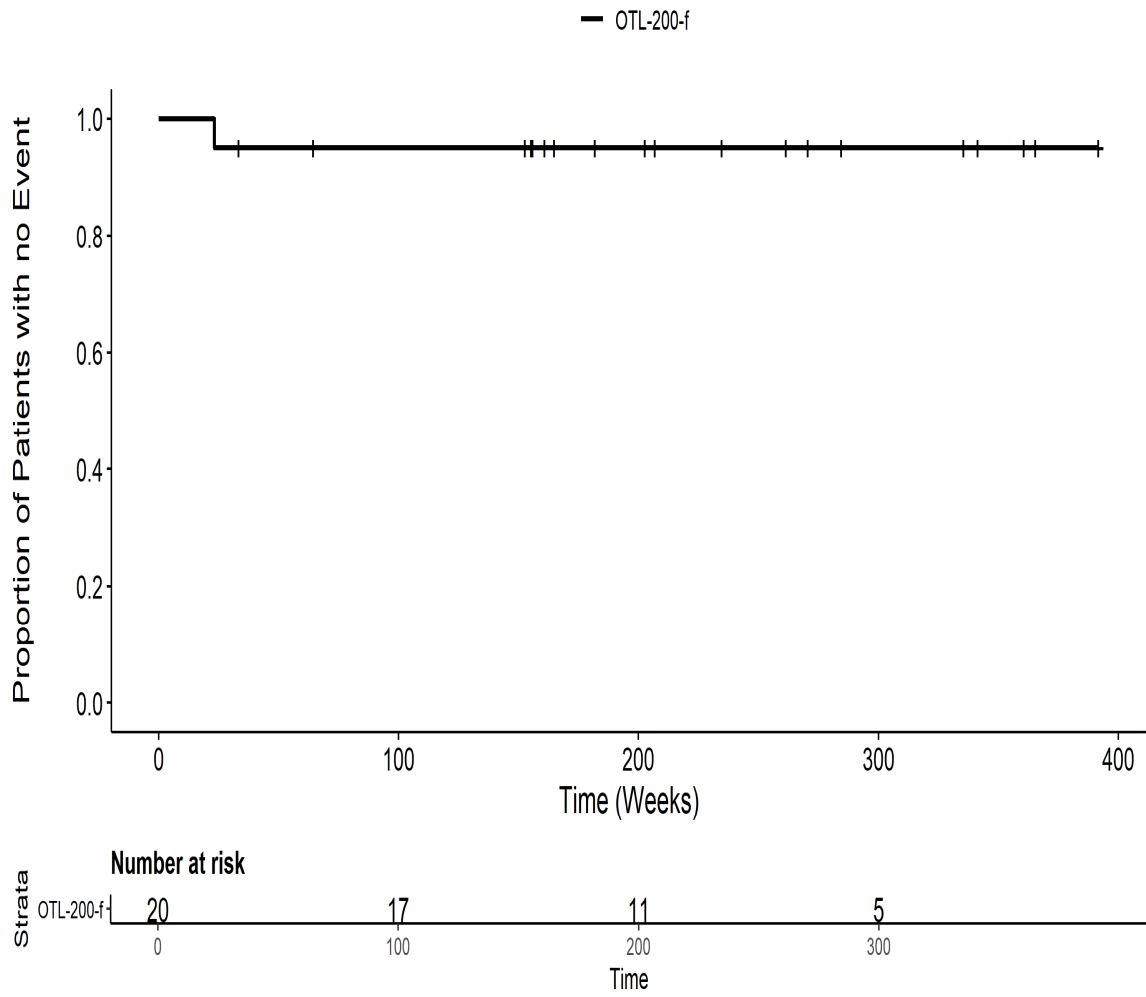
201222: Kaplan Meier Plot for Time to severe AE by SOC Stoffwechsel
: und Ernährungsstörungen PT pct Gesamt SOCITT



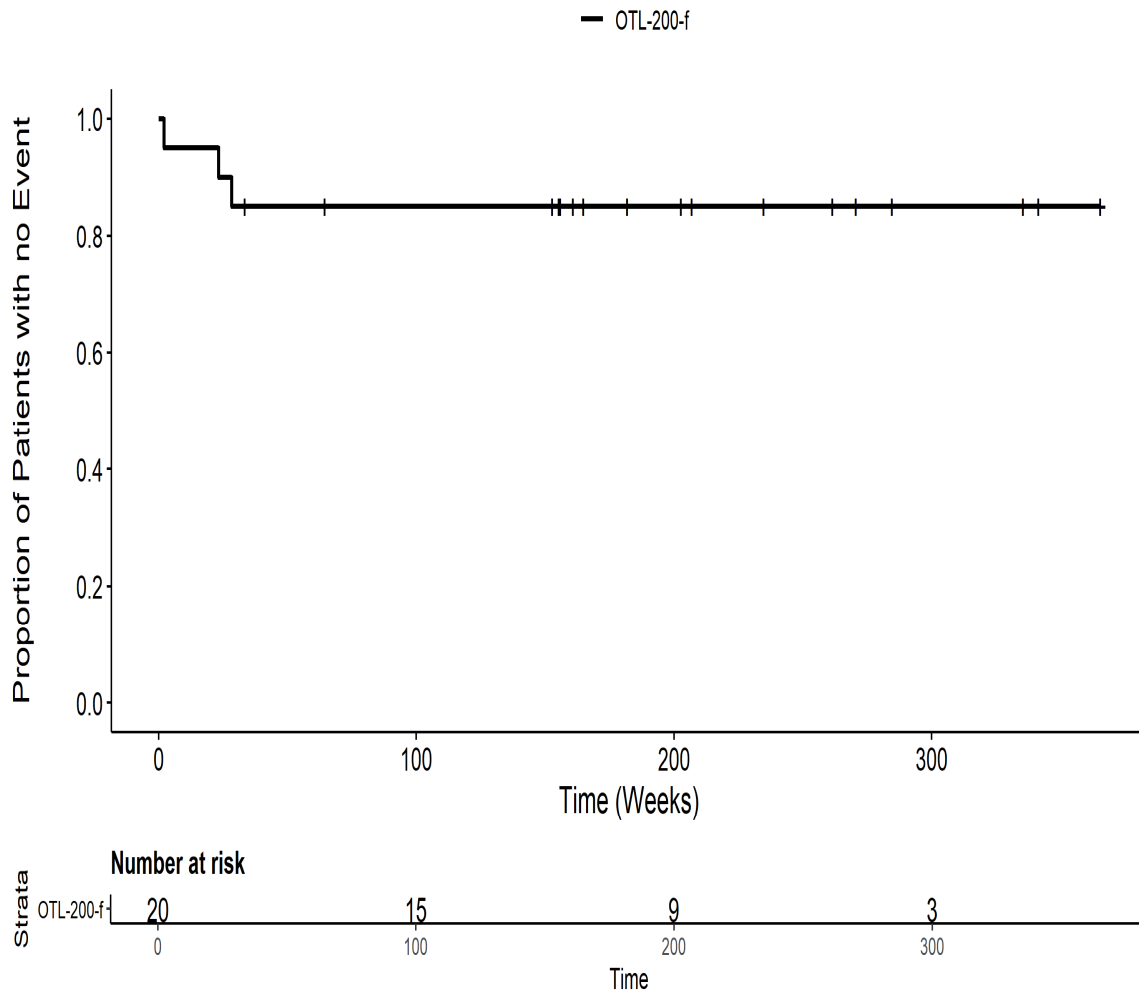
201222: Kaplan Meier Plot for Time to severe AE by SOC Stoffwechsel
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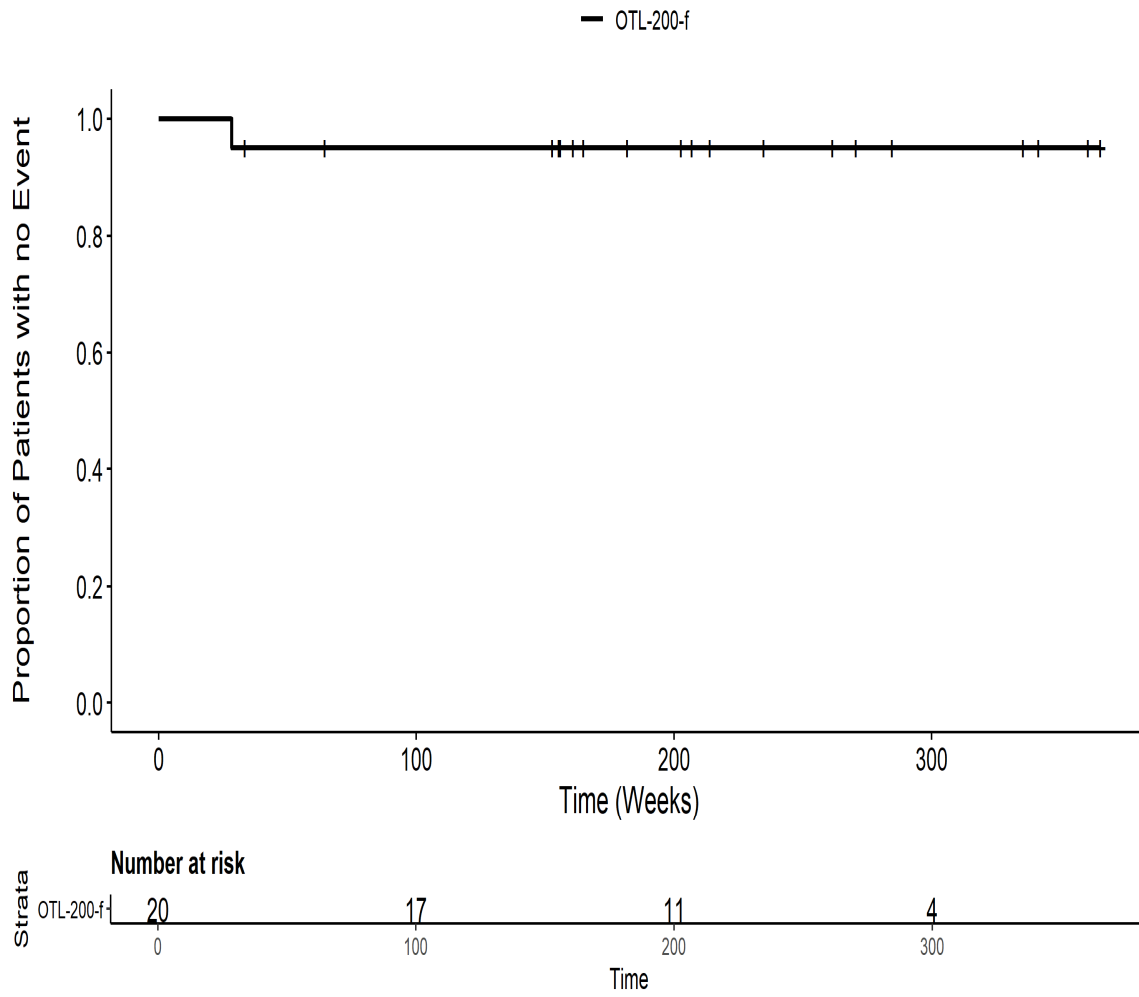
201222: Kaplan Meier Plot for Time to severe AE by SOC
Untersuchungen PT pct Erniedrigter BMIITT



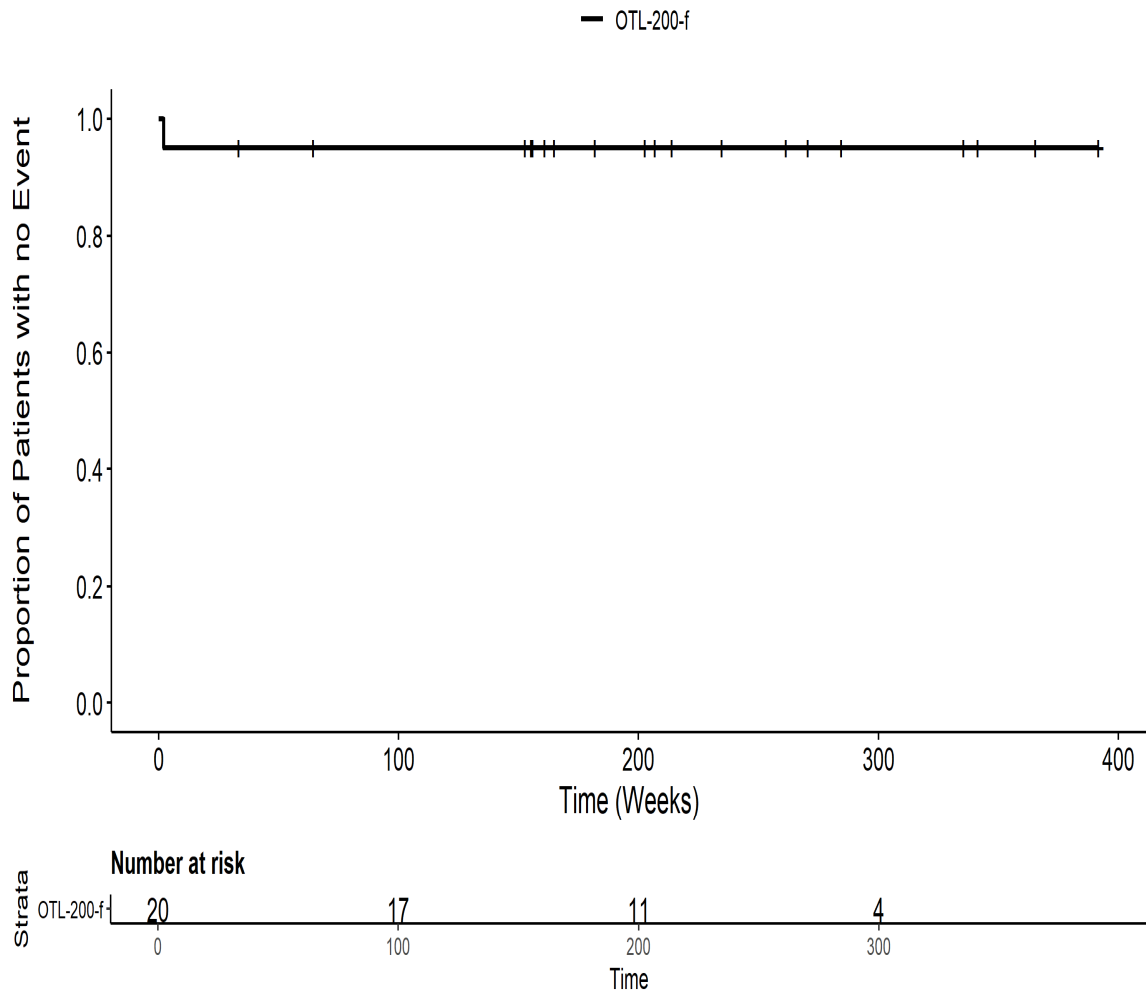
201222: Kaplan Meier Plot for Time to severe AE by SOC
Untersuchungen PT pct Gesamt SOCITT



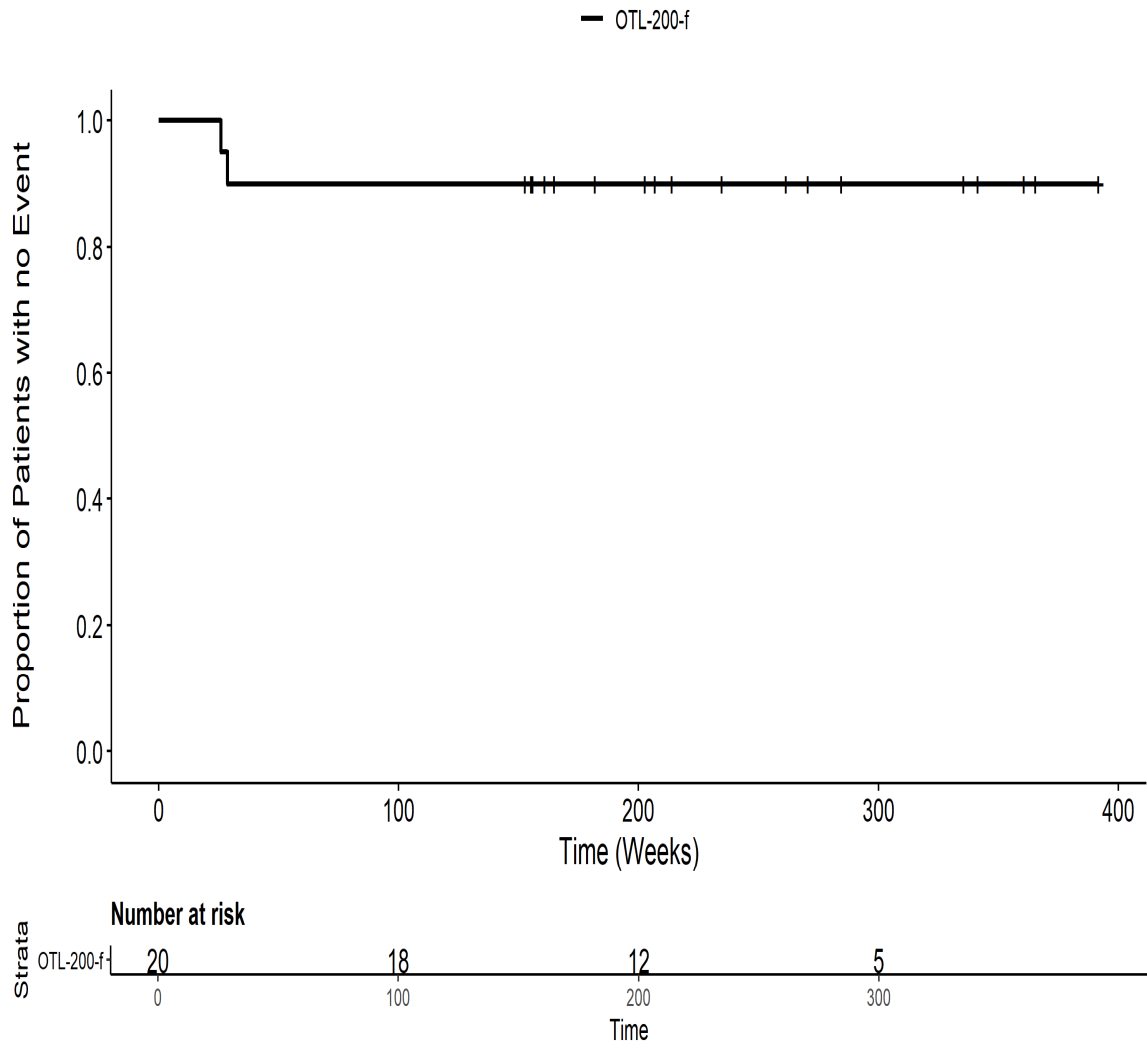
201222: Kaplan Meier Plot for Time to severe AE by SOC
Untersuchungen PT pct Sauerstoffsättigung erniedrigtITT



201222: Kaplan Meier Plot for Time to severe AE by SOC
Untersuchungen PT pct Stenotrophomonas : Test positivITT

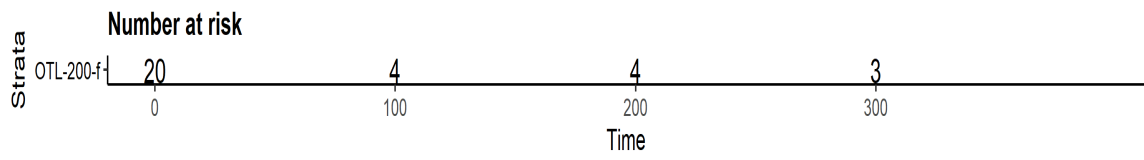
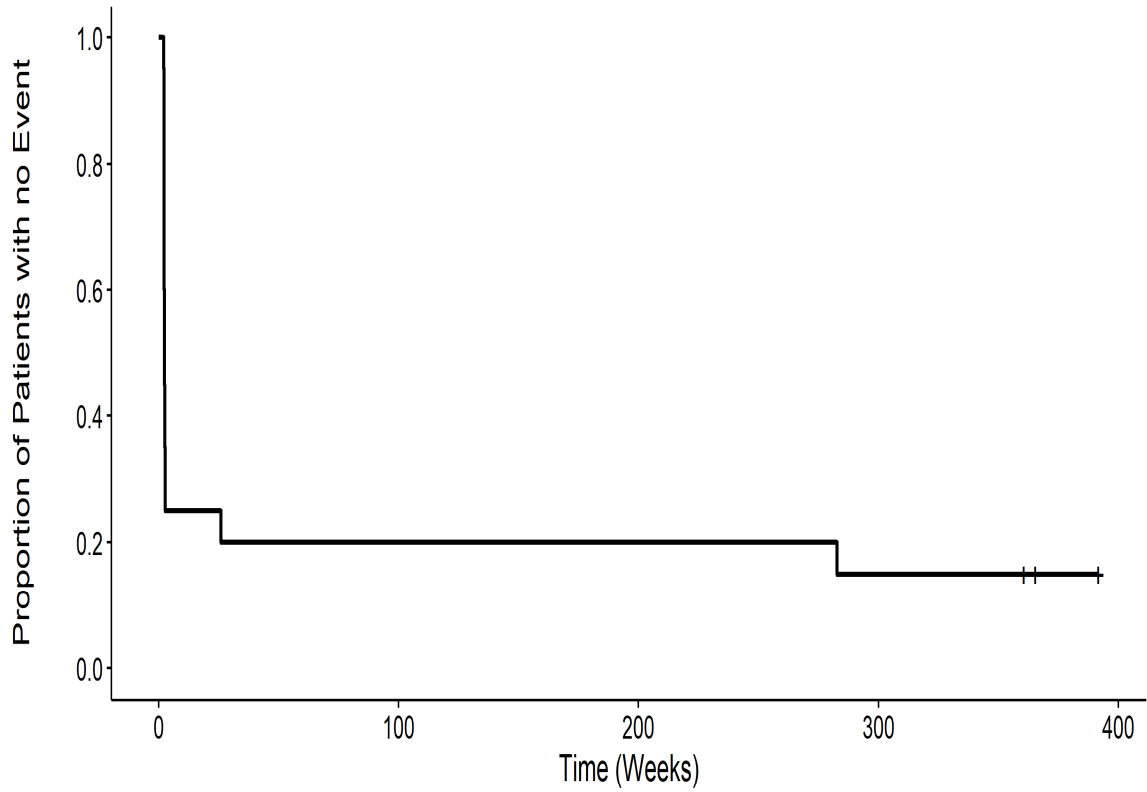


201222: Kaplan Meier Plot for Time to severe AE death ITT

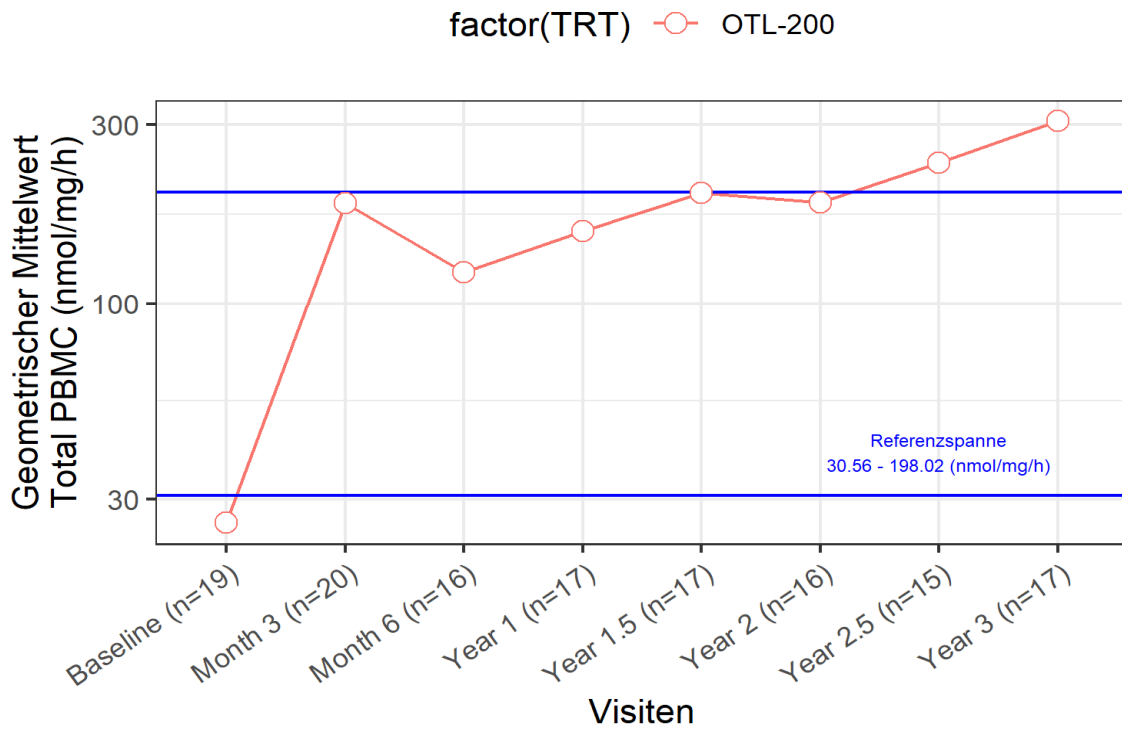


201222: Kaplan Meier Plot for Time to severe AE SMQ ITT

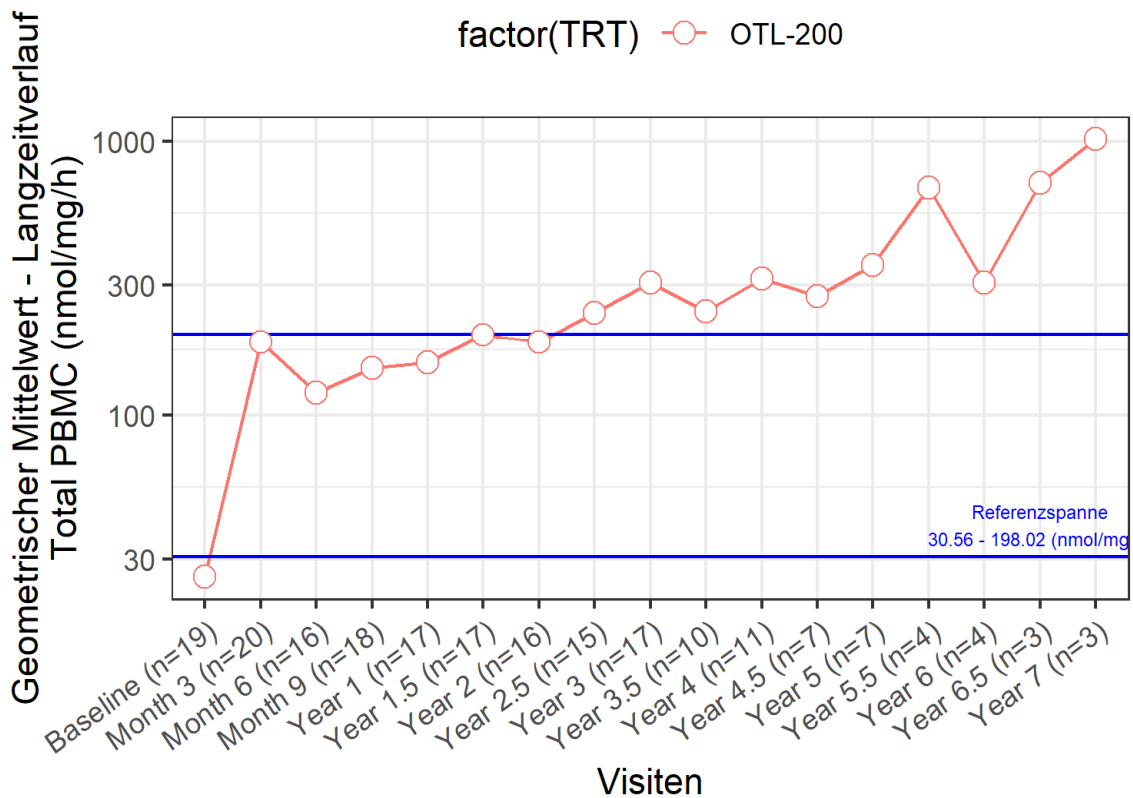
— OTL-200-f



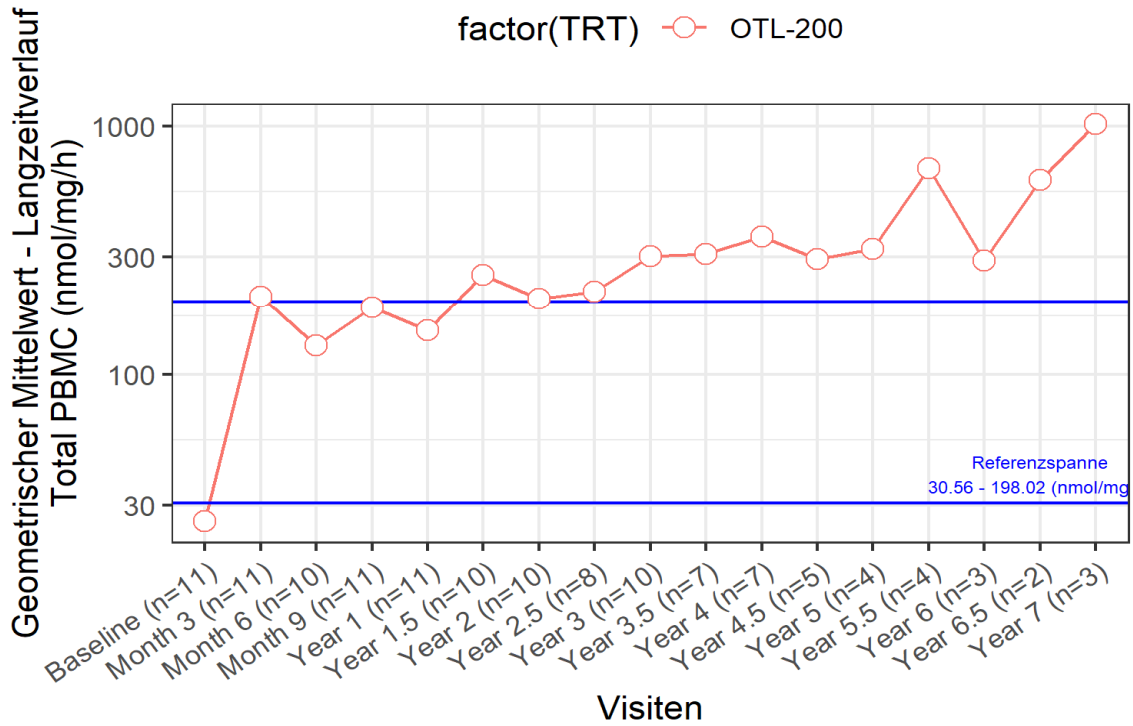
201222: Mittelwertveränderung der ARSA-Aktivität über die Visiten in ITT



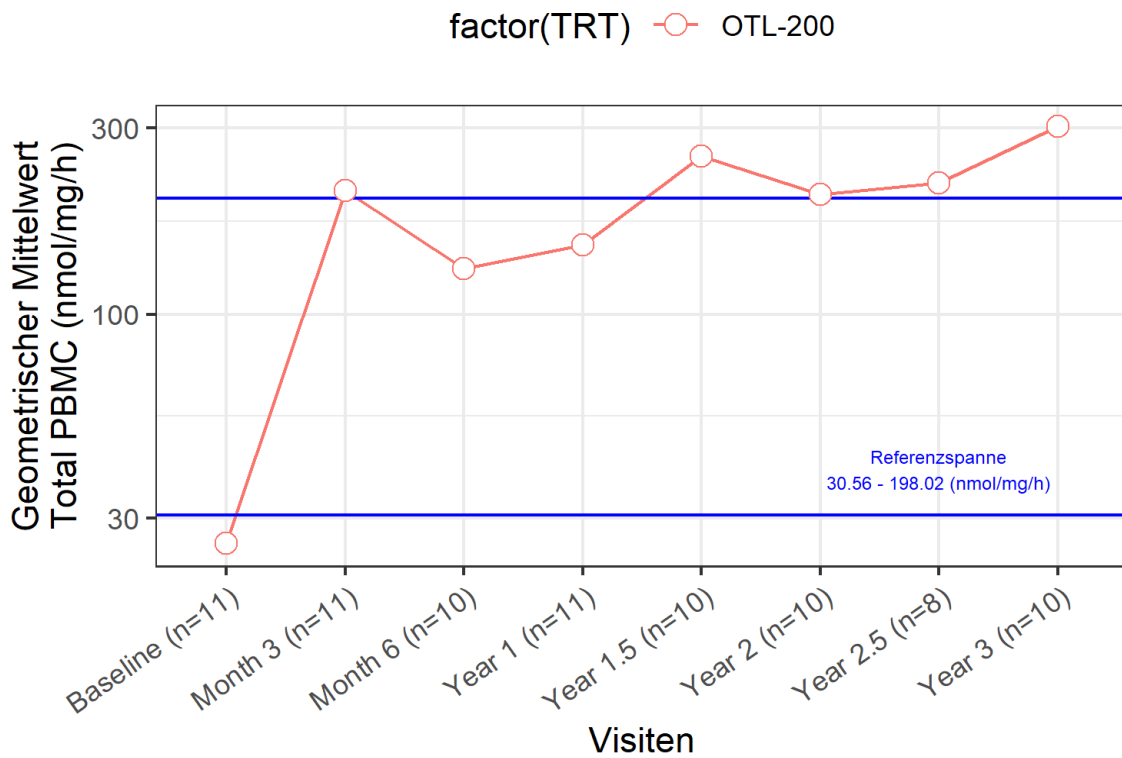
201222: Mittelwertveränderung der ARSA-Aktivität über die Visiten in ITT



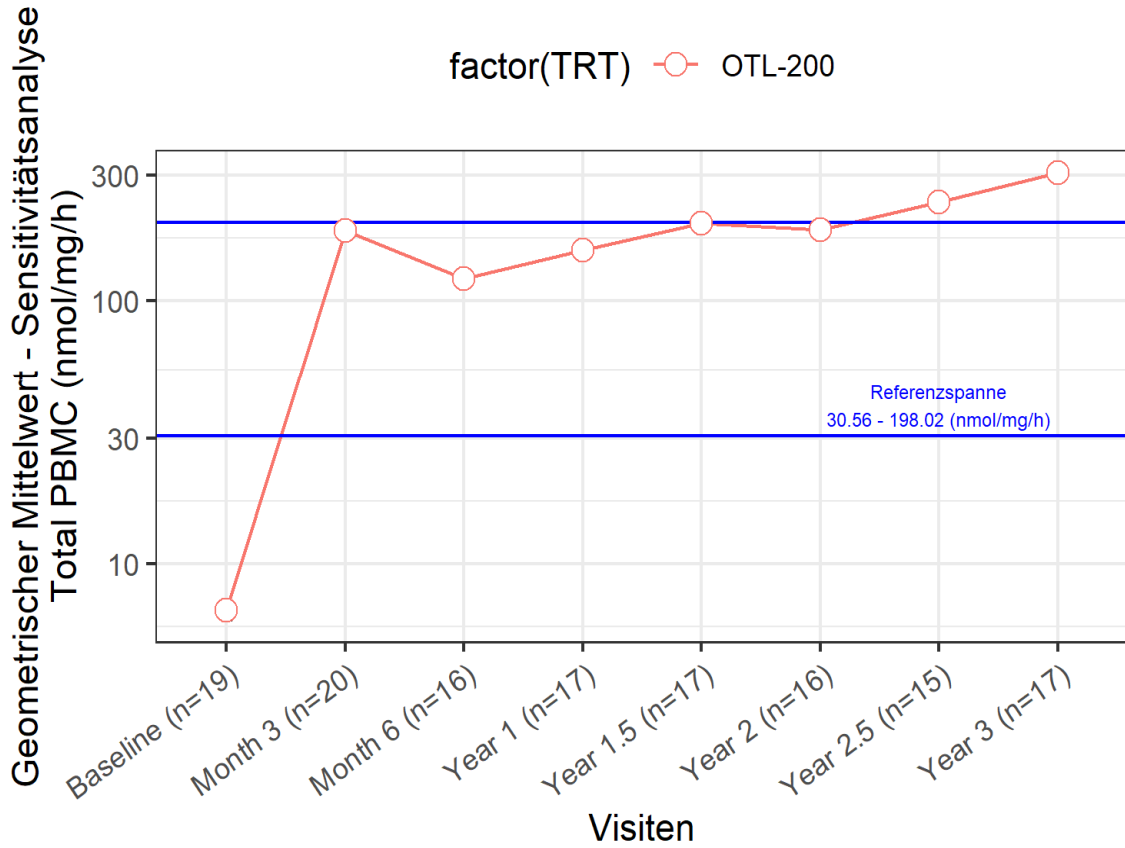
201222: Mittelwertveränderung der ARSA-Aktivität über die Visiten in MSAS



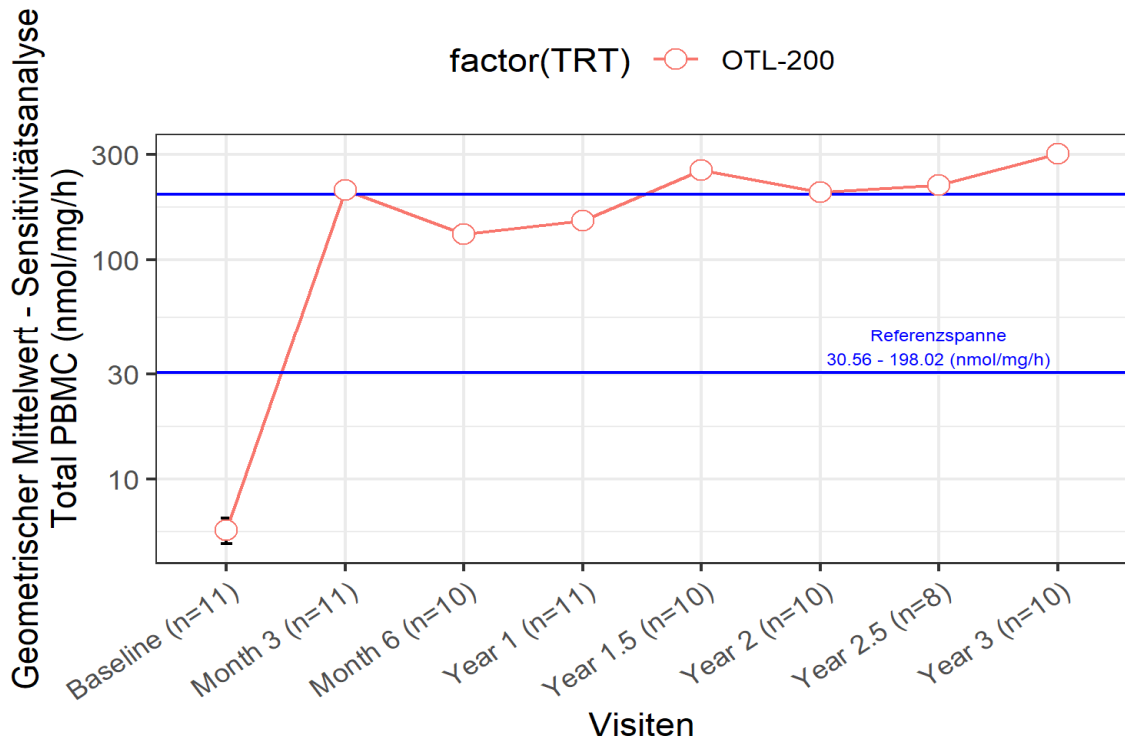
201222: Mittelwertveränderung der ARSA-Aktivität über die Visiten in MSAS



201222: Mittelwertveränderung der ARSA-Aktivität über die Visiten in ITT

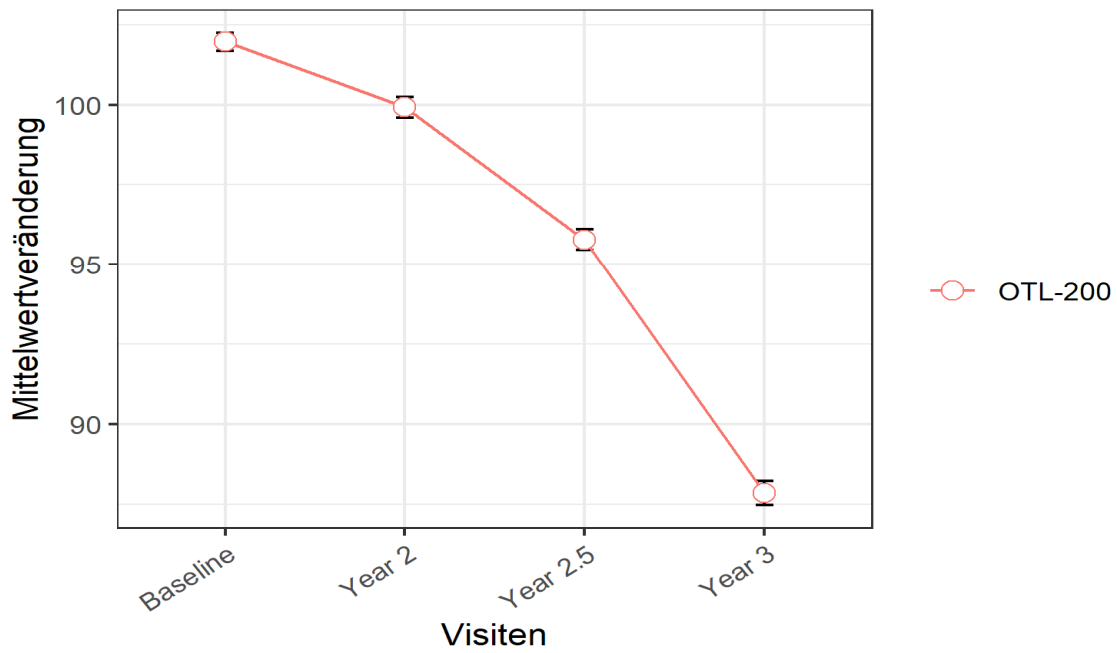


201222: Mittelwertveränderung der ARSA-Aktivität über die Visiten in MSAS



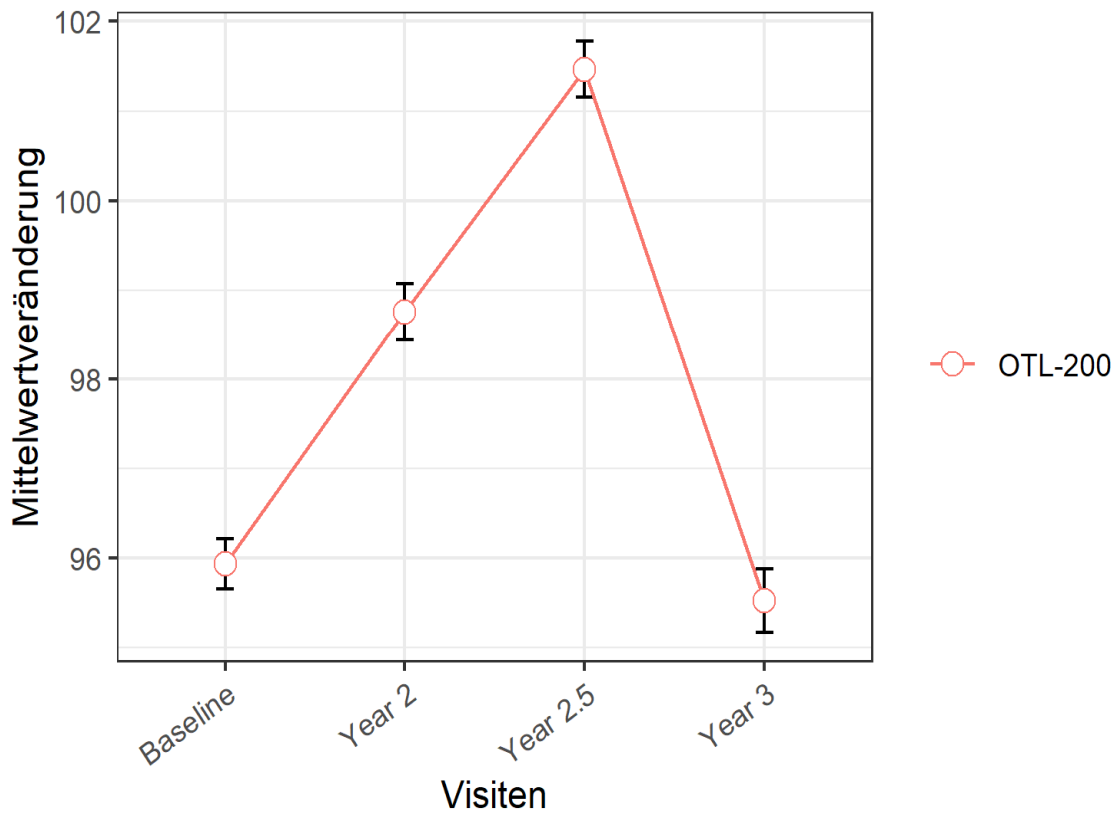
Mittelwertveränderung über die Visiten in

ITTdistype allLanguage score : Composite



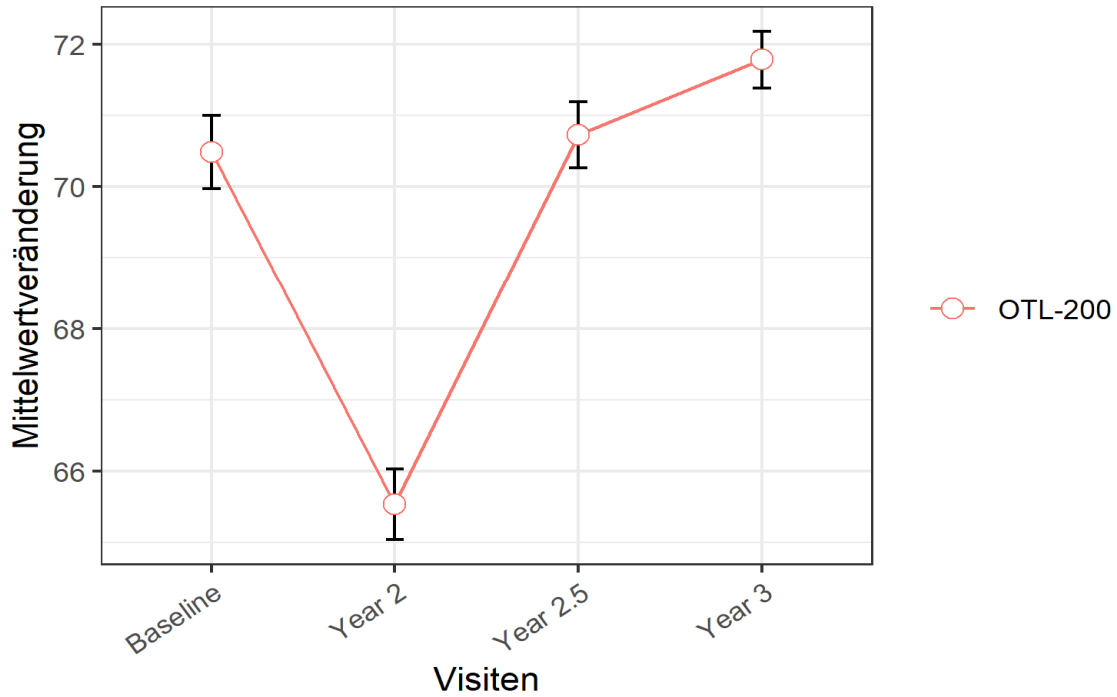
Mittelwertveränderung über die Visiten in

ITTdistype allPerformance score : Composite



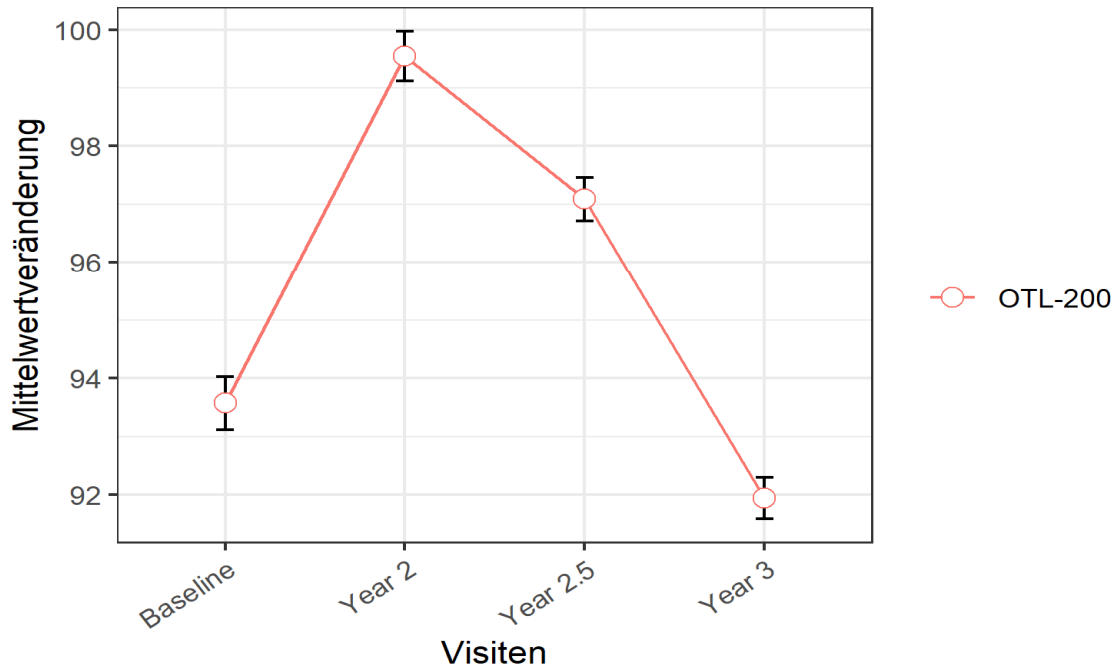
Mittelwertveränderung über die Visiten in

ITTdistype allProcessing speed Index : Composite



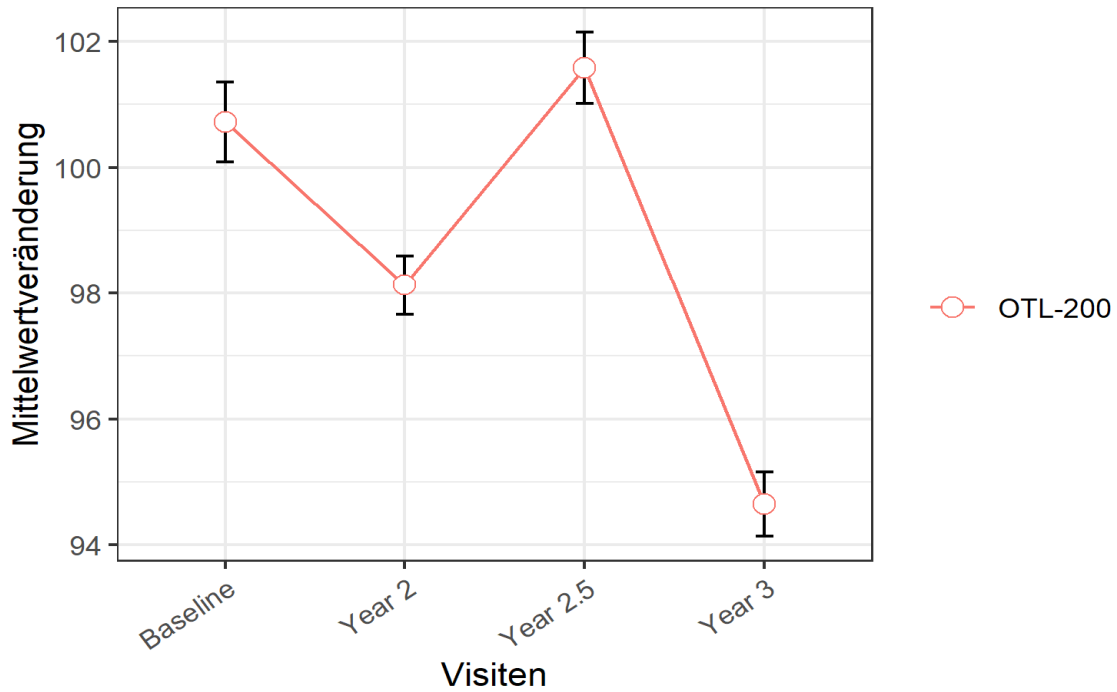
Mittelwertveränderung über die Visiten in

ITTdistype allTotal Intelligence quotient (IQ) : Compos



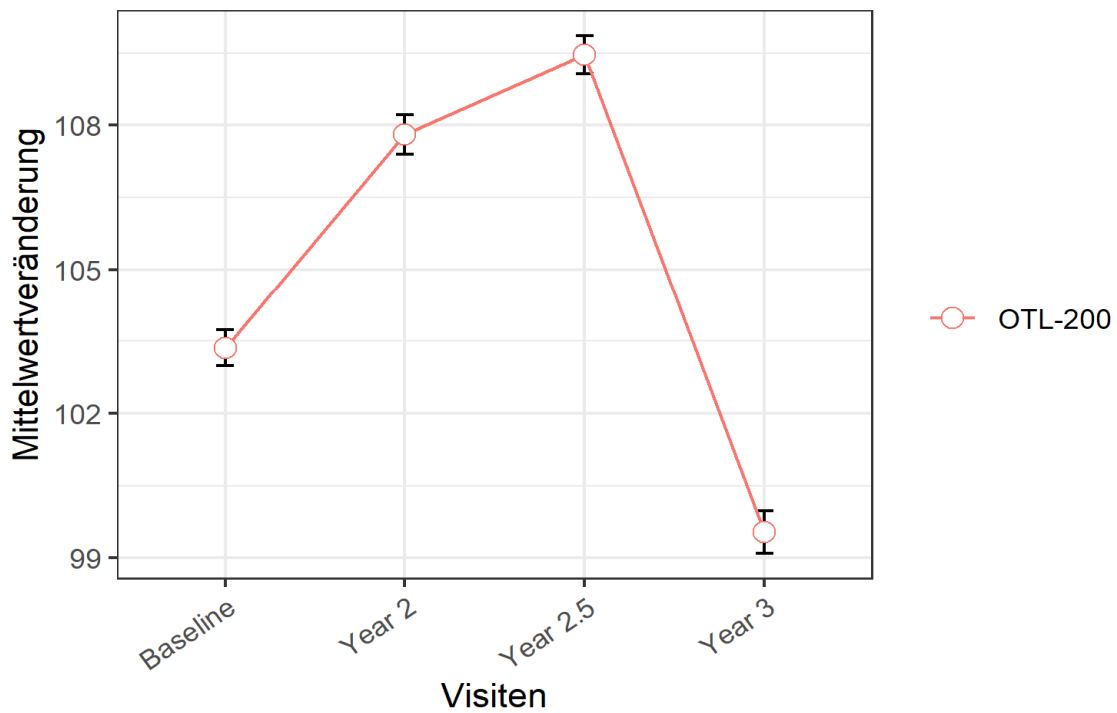
Mittelwertveränderung über die Visiten in

ITTdistype allWorking memory Index : Composite



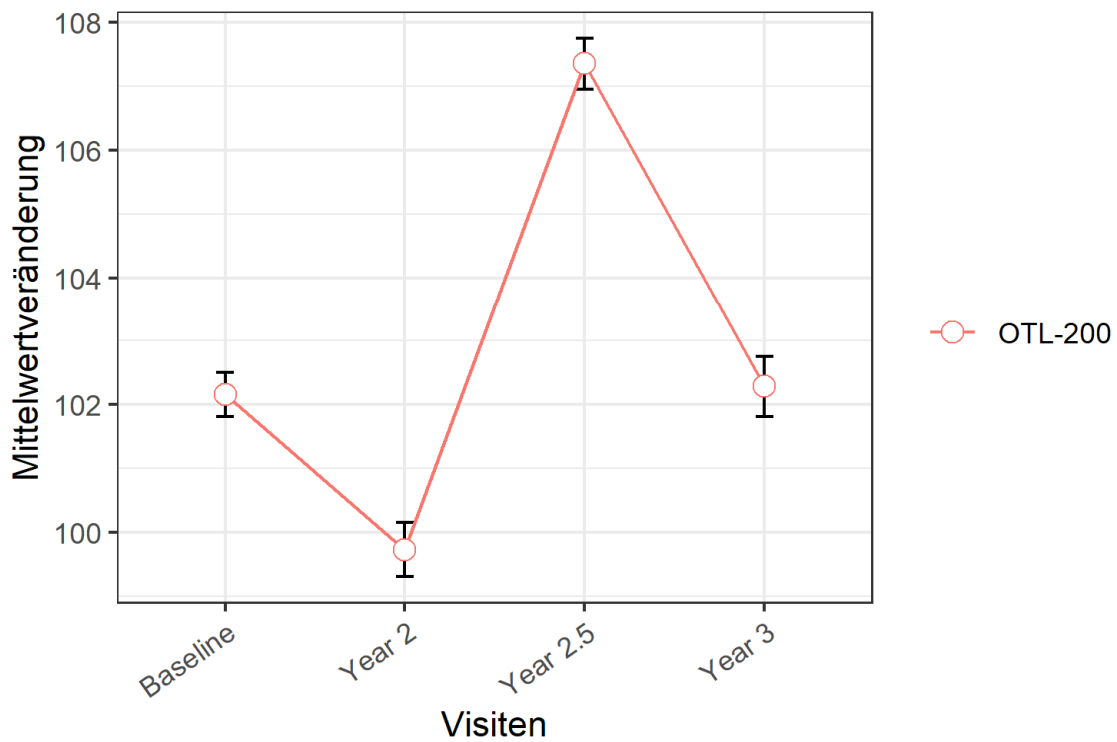
Mittelwertveränderung über die Visiten in

MSASdistype allLanguage score : Composite



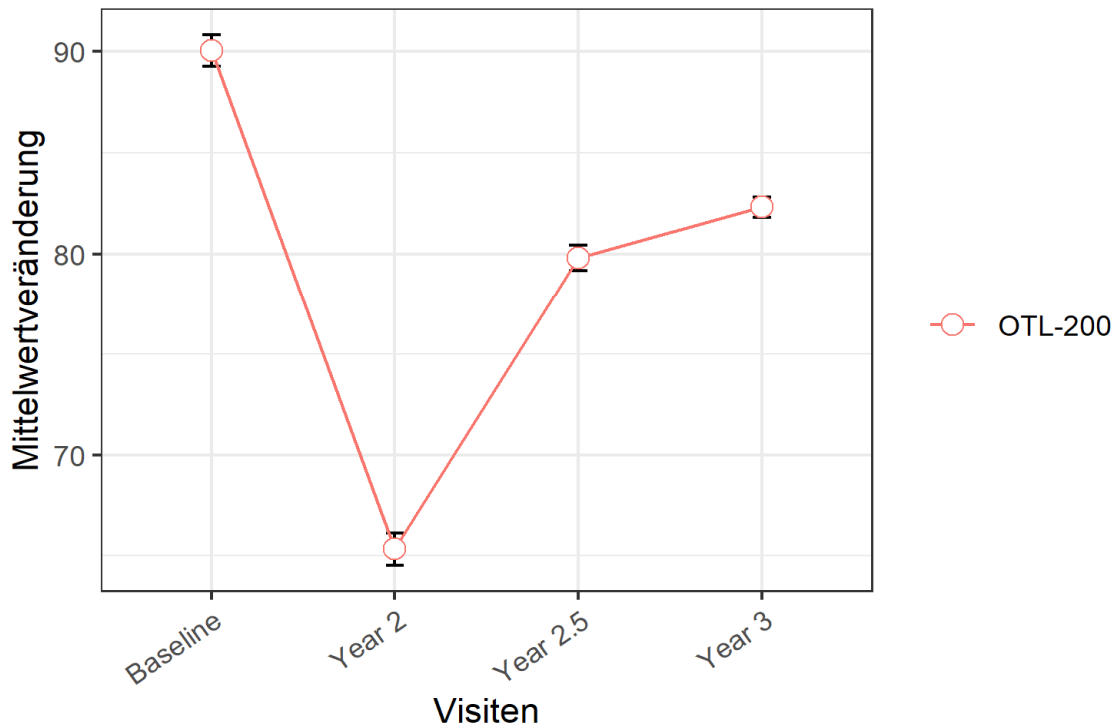
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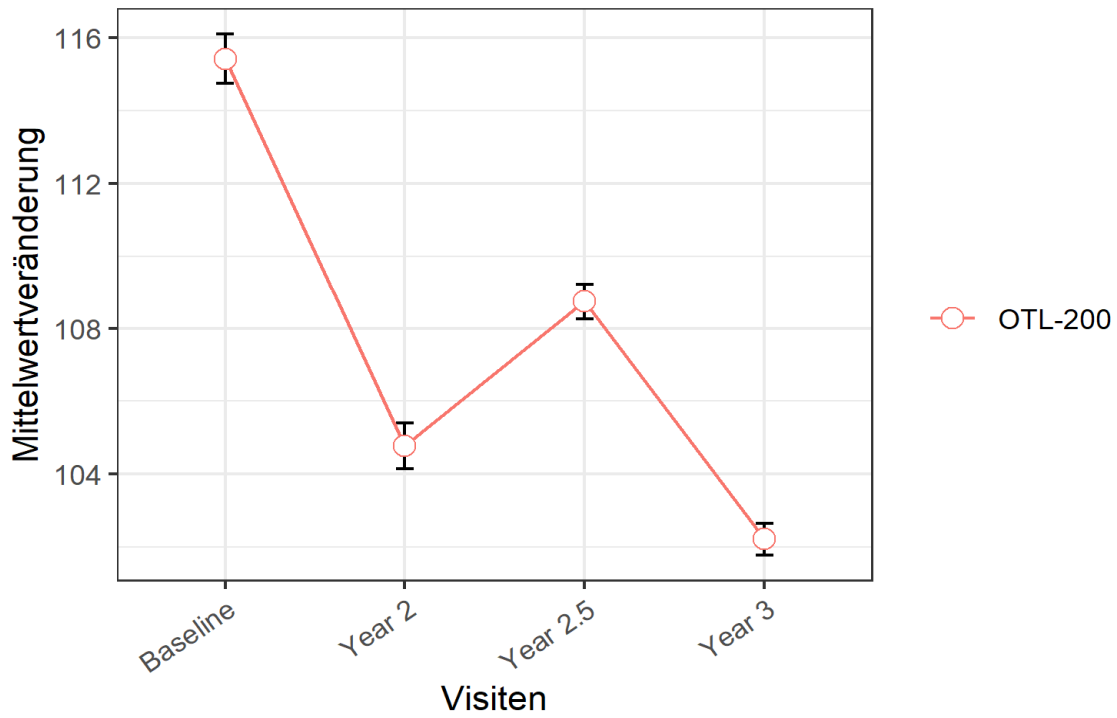
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MSASdistype allProcessing speed Index : Composite



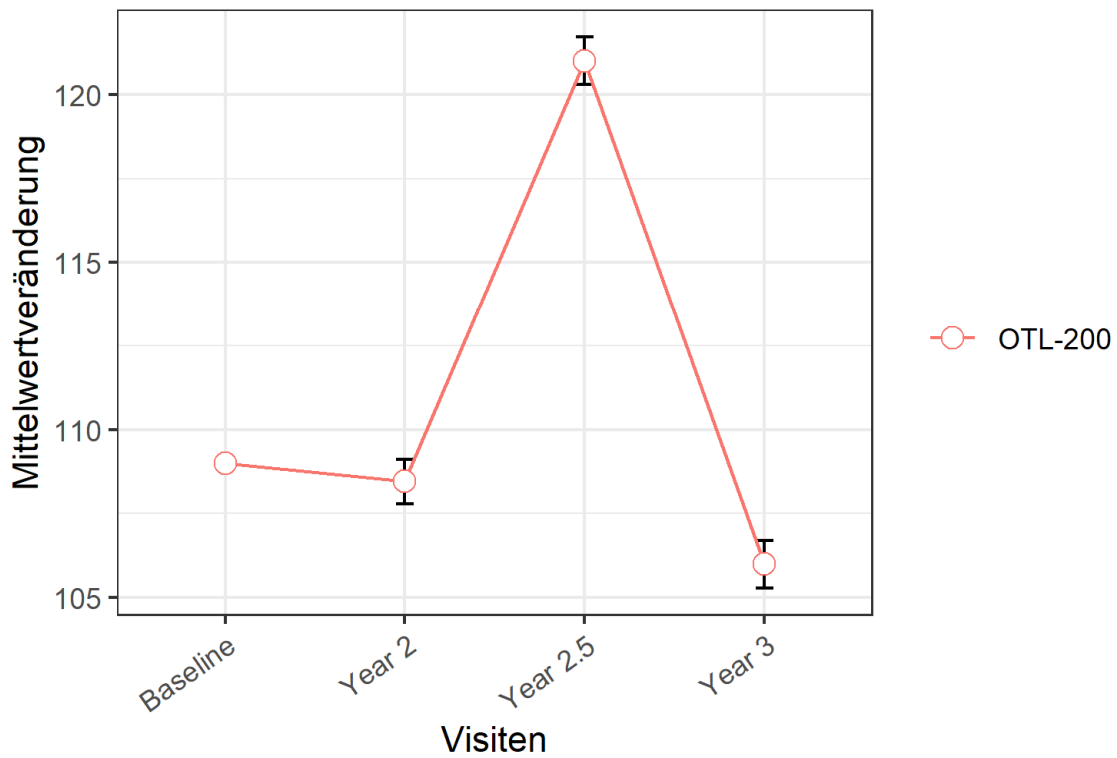
Mittelwertveränderung über die Visiten in

MSASdistype allTotal Intelligence quotient (IQ) : Comp



Mittelwertveränderung über die Visiten in

MSASdistype allWorking memory Index : Composite



1. Patienten, die die Therapie infolge eines UEs abgebrochen haben

201222	Behandlungsgruppe
	OTL-200-f
N ^a	20
Patienten, die die Therapie infolge eines UEs abgebrochen haben	
n (%)	20 (100)
Ja (%)	2 (10)
Nein (%)	18 (90)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

2. Zeit bis zum Erleiden eines UEs, das zum Therapieabbruch führte

201222	OTL-200-f
N ^a	20
Zeit bis zum Erleiden eines UEs, das zum Therapieabbruch führte	
n (%)	2 (10)
[Min; Max] (Wochen)	[26,00; 391,71]
10. Perzentil (Wochen)	210,21
25. Perzentil (Wochen)	NA
50. Perzentil (Median) (Wochen) [95 %-KI]	NA [NA; NA]
75. Perzentil (Wochen)	NA
90. Perzentil (Wochen)	NA
<p><i>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</i></p> <p><i>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</i></p>	

1. Patienten, die die Therapie infolge eines UEs nach SOC und PT abgebrochen haben

201222	Behandlungsgruppe
	OTL-200-f
N ^a	N = 20
Patienten, die die Therapie infolge eines UEs nach SOC und PT abgebrochen haben	
SOC Erkrankungen des Gastrointestinaltrakts	2 (10)
PT Dysphagie	2 (10)
<i>^aN: Anzahl der Patienten in der Population; n: Anzahl der Patienten in der Analyse.</i>	

2. Zeit bis zum Erleiden eines UEs nach SOC und PT, das zum Therapieabbruch führte

201222	OTL-200-f
N = 20 ^a	Min; Median [95%KI]; Max
Zeit bis zum Erleiden eines UEs nach SOC und PT, das zum Therapieabbruch führte	
SOC Erkrankungen des Gastrointestinaltrakts	26,00; NA [NA; NA]; 391,71
PT Dysphagie	26,00; NA [NA; NA]; 391,71
<p>^aDie Analysen der Dauer und Zeit bis zum Ereignis wurden mittels Kaplan-Meier-Methodik durchgeführt.</p> <p>KI: Konfidenzintervall; Max.: Maximum; Min.: Minimum; N: Anzahl der Patienten in der Population; n: Anzahl der Patienten mit Ereignis; SD: Standard Deviation (Standardabweichung).</p>	