Table 14.2.2.4.1
Time to Confirmed Disability Progression for at Least 12 Weeks
(mITT Population)

Confirmed Disability Progression for at Least 12 Weeks	Ublituximab (N=543)	Teriflunomide (N=546)	P-Value	Hazard Ratio (95% CI)
Number of subjects with Confirmed Disability Progression for at Least 12 Weeks	28 (5.2%)	32 (5.9%)		
Number of subjects without Confirmed Disability Progression for at Least 12 Weeks	515 (94.8%)	514 (94.1%)		
Time to CDP (12w) Kaplan-Meier Estimates (weeks), 95% CI				
1st Quartile	- (-, -)	- (-, -)		
Median	- (-, -)	- (-, -)		
3rd Quartile	- (-, -)	- (-, -)		
Proportion free of CDP (12w) (%), 95% CI *				
at 24 weeks	98.5 (97.0, 99.2)	99.1 (97.7, 99.6)		
at 48 weeks	97.2 (95.3, 98.3)	96.9 (95.0, 98.1)		
at 96 weeks	94.6 (92.3, 96.3)	93.8 (91.3, 95.5)		
CDP (12w)- Unstratified Log-rank test *			0.5753	
CDP (12w)- Stratified Log-rank test *#			0.5099	
Hazard Ratio with 95% CI (Unstratified) &				0.865 (0.521, 1.437)
Hazard Ratio with 95% CI (Stratified) &#				0.843 (0.504, 1.407)

Data Cutoff: 2020-11-23 Date: 30JUN2021 15:34 FINAL
Note: Subjects are at risk until week 84; disability progression which occurred first at week 96 cannot be confirmed
Abbreviations: N = Number of subjects in population/treatment group, CI = Confidence Interval, CDP (12w) = Confirmed Disability Progression for at Least 12 Weeks
* Estimated by Kaplan-Meier method.
& Hazard ratio is estimated using Cox regression model with treatment group as covariate.
# The stratification factors include region, baseline EDSS and study
Program: Z:/Shared/STATS/prd/TG-1101 RMS (ULTIMATE Pooled)/csr/program/primary/tfl/t-cdp12-a-mitt.sas
Output: Z:/Shared/STATS/prd/TG-1101 RMS (ULTIMATE Pooled)/csr/output/t14-2-2-4-1-cdp12-a-mitt.rtf