

Endpoint Title: Assessment of TRTR Reported as the Intraclass Co-relation Coefficient Estimate Among Participants Reporting no Change on Fatigue PGI-S Score Applied to PROMIS F-SF 7a Score Between Screening and Baseline

Description: TRTR consists of measuring the degree to which an instrument yield reproducible score at different points in time assessed across a fixed and common time interval for all subjects. TRTR co-relations were based on the two-way mixed effect intraclass co-relation coefficient estimated using the inter-rater reliability package, version 0.84.1. TRTR estimate of 0.7 and above indicated better retest reliability. TRTR was estimated using mean PROMIS F-SF 7a scores from participants who were stable as defined by a PGI-S-Fatigue change score of zero between screening and baseline. As pre-specified in the SAP, to adequately power the planned MPMs the cross-sectional validation sample was composed of a total of 98 participants enrolled in the INS-415 study who provided item-level PROMIS F-SF 7a data and Screening/Baseline data from the first 132 participants enrolled in the INS-416 study to yield a total sample of n=230.

Table 15. PROMIS F-SF 7a TRTR Estimate: Screening and Baseline

	ICC(A,1)
PROMIS F-SF 7a Score	0.76

Abbreviations: ICC = Intraclass Correlation Coefficient.