Endpoint Title: Assessment of Test-Retest Reliability (TRTR) Reported as the Intraclass Co-relation Coefficient Estimate Among Participants Reporting no Change on Respiratory PGI-S Score Applied to QOL-B Respiratory Domain 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 assessed among participants reporting no change on PGI-S between screening and baseline. PGI-S anchors are PRO specific, with a respiratory PGI-S applied to the QOL-B respiratory domain. As pre-specified in the statistical analysis plan (SAP), to adequately power the planned modern psychometric methods (MPMs) The cross-sectional validation sample was composed of a total of 97 participants enrolled in the INS-415 study who provided item-level QOL-B Respiratory domain data and Screening/Baseline data from the first 132 participants enrolled in the INS-416 study (NCT04677569) to yield a total sample of n=229.

Table 30. QOL-B Respiratory Domain TRTR Estimates Between Screening and Baseline

	ICC(A,1)
QOL-B Respiratory Domain Score	0.69