

This template has been prepared by the Critical Path Institute in conjunction with the PRO Consortium Coordinating Committee. The template represents the Consortium's current thinking on how to best organize and present critical information for review and discussion of a PRO instrument development project and for submission to regulatory agencies. This document is a summary of the quantitative research that ultimately will be fully described in the instrument development report (i.e., Qualification Dossier).

Quantitative Research Summary Document

The *Quantitative Research Summary Document* should include the following:

- Reference to the current version of the *Scoping Stage Summary Document* and the *Qualitative Research Summary Document* (provide documents as Appendix A)
- Instrument (review cannot begin without a copy of the proposed instrument):
 - Exact version of the instrument proposed or used in the clinical trial (protocol) under review and all instructions for use.
 - Include screen shots or interviewer scripts, if relevant.
 - Include prior versions, if relevant.
 - Instructions for use.
 - An instrument user manual can be provided as Appendix B and referenced here.
- Training method and materials used for questionnaire administration
 - Patient training - summarize here and include a copy of all materials in Appendix B1
 - Investigator training - summarize here and include a copy of all materials in Appendix B2
 - Other training - summarize here and include a copy of all materials in Appendix B3
- Instrument Administration
 - Timing, method (e.g., paper or pencil, electronic), and mode (e.g., self-, clinician-, or interviewer-administered)
- Instrument scoring algorithm
 - Methods for algorithm development
- Summary of protocols for quantitative instrument testing
 - Sample size
 - Sample recruitment
 - Inclusion and exclusion criteria
 - Research Design
 - Data entry
 - Description of Statistical analysis
- Summary of testing results for each domain or summary score proposed as support for claims:
 - Reliability (internal consistency; test-retest)
 - Construct validity (convergent, discriminant, known-groups)
 - Ability to detect change
 - Item performance and reduction

- Interpretation of Scores
 - Summary of the logic and methods used to interpret the clinical meaningfulness of clinical trial results
 - Responder definition (i.e., definition of meaningful within-person change specific to the clinical trial population)
- Identify further validation needs (if applicable) and provide questions to the regulatory agency (if applicable)
 - Provide rationale for conceptual framework revision and item revision or deletion, if applicable (provide updated item tracking matrix in Appendix C)
- Key References List
 - Attach all relevant published and unpublished documents
 - Attach a listing of all reports used to populate the quantitative research summary document and attach them in Appendix D
- Appendix A: *Scoping Stage Summary Document* and the *Qualitative Research Summary Document* (including Item Tracking Matrix)
- Appendix B: Instrument Users Manual
 - B1: Patient Training Manual
 - B2: Investigator Training Manual
 - B3: Other training materials
- Appendix C: Current item tracking matrix
- Appendix D: Study report(s) from quantitative phase, including statistical analysis plans, protocols, and data collection forms