

*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 qualitative research that ultimately will be fully described in the instrument development report (i.e., Qualification Dossier).*

## **Qualitative Research Summary Document**

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

- Reference to the current version of the *Scoping Stage Summary Document* (provide *Scoping Stage Summary Document* as Appendix A)
  - Specify the conceptual framework and endpoint model
- Content Validity Documentation
  - Literature review and documentation of expert input
  - Summary of qualitative protocols and results for:
    - Focus group testing (transcripts need to be available upon request)
    - Open-ended patient interviews (transcripts need to be available upon request)
    - Cognitive interviews (transcripts need to be available upon request)
  - Qualitative study summary that supports content validity for:
    - Item content
    - Response options
    - Recall period
    - Scoring
- Item Development Documentation
  - Origin and derivation of items with chronology of events for item generation, modification, and finalization
    - Item tracking matrix showing items retained and items deleted providing evidence of saturation
  - Summary of qualitative studies demonstrating how item pool was generated, reduced, and finalized.
    - Specify type of study (i.e., focus group, patient interview, or cognitive interview) and characteristics of study population
- Draft instrument resulting from qualitative research: Attach the instrument in its current layout (e.g. paper version, screen shots if electronic application) in Appendix B
- Outline plans for quantitative phase (attach protocol outline(s) in Appendix C, if applicable) and provide questions to the regulatory agency (if applicable)
- Key References List
  - Attach all relevant published and unpublished documents
  - Attach a listing of all reports used to populate the qualitative summary document and attach them in Appendix D

- Appendix A: Scoping Stage Summary Document
- Appendix B: Instrument (version to be used in quantitative phase)
- Appendix C: Protocol(s) (final or draft) for quantitative phase (if applicable)
- Appendix D: Qualitative study protocols, data collection forms, and qualitative reports