

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. This template should be considered a draft that will change as more experience with such summaries is gained.

Scoping Stage Summary Document

This document is compiled by the Working Group (WG) during the scoping stage and submitted to the PRO Consortium Coordinating Committee (CC). The CC reviews the document, asks for any necessary clarification and/or content from the WG, and forwards the completed summary document to the FDA (SEALD) representative on the CC. FDA personnel from both the SEALD team and the specific review division will review the document. This *Scoping Stage Summary Document* needs to contain sufficient detail for the FDA personnel to provide feedback to the Consortium regarding whether the plan for development of the proposed PRO measure is reasonable. This feedback from the FDA does not imply that the dossier presented for qualification will result in a “fit for purpose” determination at the end of the development process. The discussions with the FDA will be similar to the scope of a pre-IND or pre-IDE meeting, and not an official determination or agreement under 21 CFR §10.85.

The *Scoping Stage Summary Document* should include the following:

- Rationale for PRO instrument development
- Concept Identification
 - Target population
 - Disease or condition with stage, severity, or category, if relevant
 - Clinical trial population (e.g., age group, sex, other characteristics), if relevant
 - Proposed concept(s) and preliminary conceptual framework
 - Rationale for selection of the concept(s) being proposed for measurement (e.g., supporting literature, current PRO-related labeling [Table 1])
 - Proposed labeling language
 - If known, proposed PRO instrument content, response options, recall period, and mode of administration
- Endpoint Model
 - If available, provide known or hypothesized relationship among PRO and non-PRO study endpoints
 - Proposed position of the PRO measure in the endpoint hierarchy (e.g., primary, co-primary, secondary)
- Planned approach to achieving PRO measurement (e.g., use or modification of existing measure, development of new measure) and rationale.
- Specific questions from the Working Group to the FDA

Table 1: PRO-Related Concepts in Current Labeling for [disease/condition]

Concept	How was it measured?	Label Language	Product	What section of label? (e.g., Clinical Trials, Indications)