

PRO Consortium
Proposal for a New Working Group

PRO Instrument Not Yet in Development

NOTE: The PRO Consortium will own the copyright on any PRO instrument for which a new working group is formed.

1. Target population

- a. Disease or condition with stage, severity, or category, if relevant
- b. Clinical trial population (e.g., age group, sex, other characteristics), if relevant

2. Proposed concept(s) and conceptual framework

3. Targeted labeling language

4. Proposed endpoint model

- a. If available, provide known or hypothesized relationship among PRO and non-PRO study endpoints
- b. Proposed position of the PRO measure in the endpoint hierarchy (e.g., primary, co-primary, secondary)

5. Unmet need and rationale for PRO instrument development

6. Questions for FDA advisors*

7. If applicable, vendor(s) involved and any contractual commitments and/or plans that must be considered (If there are existing contracts in place, please confirm that the proposal is made on behalf of all signatories.)
8. If applicable, consultants and/or advisory panel members involved and any commitments and/or plans that need to be considered
9. Appendices – any existing documentation that supports this proposal
10. Proposing member company (or companies) and project leader's name and contact information. Please confirm whether project leader would be willing to serve as working group chair.

***The *Feasibility Document* submitted to the FDA will consist of the highlighted sections above. These sections should not exceed a total of 3 pages.**