

## Establishing a Standard Set of IBD Patient-Reported Outcomes for Universal Use

### Crohn's & Colitis Foundation Request for Proposals (RFP): Development of an Inventory of Patient-Reported Outcome Measures in IBD

#### OVERVIEW

Numerous patient-reported outcome (PRO) instruments are currently used in inflammatory bowel disease (IBD), creating challenges for standardizing outcome measurements across research and clinical care settings. While many instruments assess similar concepts, variation in measures, domains, item content, and methodologies limits the ability to compare findings across studies, aggregate data across cohorts, and evaluate outcomes consistently over time.

Establishing a standardized IBD PRO set would support greater consistency in clinical trials, broader adoption across research and healthcare initiatives, and alignment with regulatory expectations from agencies such as the FDA and EMA. To advance this goal, the Crohn's & Colitis Foundation (Foundation) seeks to develop a comprehensive inventory and characterization of existing IBD PRO instruments, including their frequency of use, domains assessed, source references, and item-level content.

Findings from this work will provide the evidence base for a future consensus-driven effort to define a standardized, actionable IBD PRO set for use across the IBD community.

#### BACKGROUND

Patient-reported outcomes are essential for measuring symptoms, health-related quality of life, functional status, and other outcomes that matter to people living with IBD. Over time, numerous PRO instruments have been developed and adopted across IBD research studies, clinical trials, and registries.

While these efforts have advanced patient-centered measurement, they have also resulted in a fragmented measurement landscape. Recent reviews identified more than 100 PRO instruments used across Foundation-supported cohorts and studies, many of which assess similar concepts using different questions, scales, scoring approaches, and methodologies. This variability limits the ability to compare outcomes across studies, combine datasets, and establish consistent patient-centered measures across the IBD community.

As regulatory agencies increasingly emphasize patient-focused outcome measurement, there is a need to harmonize PRO collection and align with current best practices. In response, the Foundation has launched an initiative to support a consensus-driven process to identify a core set of measures for broad use across IBD research and care.

#### NEED

**The Foundation seeks a qualified vendor to identify, compile, and characterize patient-reported outcome instruments currently used in IBD research and clinical care.** The primary deliverable will be a comprehensive inventory of IBD PRO measures and key instrument characteristics.

At a minimum, the inventory should include:

- Instrument name and acronym (if applicable)
- Source reference(s) and year of publication
- Frequency of use across clinical trials, research studies, cohorts, registries, and other initiatives
- Outcome domains measured (e.g., stool frequency, abdominal pain, fatigue, quality of life, mental health, social functioning)
- Instrument structure, including individual items, response options, scoring methodology, and recall period
- Validation status and available psychometric evidence
- Available translations and cultural adaptations
- Applicability across adult and pediatric populations
- Disease-specific versus generic instrument classification

The vendor should also characterize and organize instruments in a manner that supports:

- Classification and mapping of measured outcome domains
- Identification of overlapping and unique concepts across instruments
- Assessment of similarities and differences in item content
- Evaluation of opportunities for harmonization and standardization across measures

The resulting inventory will serve as the evidence-based resource for a future consensus process to establish a standardized set of IBD PRO measures for use across research and clinical care.

### SCOPE OF WORK and DELIVERABLES

Scope of Work Activities	Deliverable
<p><b>Activity #1: Project Planning and Methods</b></p> <ul style="list-style-type: none"> <li>• Document the proposed methodology for identifying and evaluating IBD PRO instruments</li> <li>• Identify sources to be reviewed (<i>published literature, clinical trial registries, cohort studies, registries, regulatory resources, etc.</i>)</li> <li>• Obtain Foundation approval of the methodology before initiating full review activities</li> </ul>	<p><b>Written Methodology Plan</b></p>
<p><b>Activity #2: Environmental Scan and Literature Review</b></p> <ul style="list-style-type: none"> <li>• Conduct a comprehensive review of IBD PRO instruments used in research and clinical care</li> <li>• Review peer-reviewed literature, systematic reviews, registries, clinical trials, other relevant sources</li> <li>• Identify both disease-specific and generic PRO instruments used within IBD populations</li> </ul>	<p><b>Comprehensive PRO Inventory Database*</b> A searchable excel workbook or other structured format containing all identified PRO instruments and associated metadata</p>
<p><b>Activity #3: Instrument Characterization</b></p> <ul style="list-style-type: none"> <li>• Extract and catalog predefined characteristics of each identified PRO instrument</li> <li>• Document instrument domains, structure, validation status, target population, translations, and other relevant attributes</li> <li>• Collect item-level content and response options where available and permissible</li> </ul>	<p><b>Domain Crosswalk Matrix*</b> Map instruments to outcome domains and concepts measured, identify areas of overlap and uniqueness across instruments, and facilitate comparison of item-level content</p>
<p><b>Activity #4: Domain Mapping and Comparative Analysis</b></p> <ul style="list-style-type: none"> <li>• Categorize instruments according to measured domains</li> <li>• Identify overlapping constructs across instruments</li> <li>• Characterize similarities and differences in item content and measurement approaches</li> <li>• Identify gaps, redundancies, and opportunities for harmonization</li> </ul>	<p><b>Summary Report and Presentation</b> Written summary of findings, key observations and recommendations for harmonization and standardization. Presentation to Foundation leadership and designated stakeholders<sup>†</sup></p>

\*Critical Deliverables

<sup>†</sup>The selected vendor will present the PRO Inventory Database, Domain Crosswalk Matrix, and Summary Report to a Foundation-convened Consensus Committee. Composed of leading IBD experts across pediatric, adult, and surgical disciplines—including subspecialties like perianal disease, pouches, and geriatrics—the committee also features external stakeholders from pharma and life sciences. Together,

this body will evaluate the findings to recommend the optimal IBD PRO instrument set to drive the next phase of the initiative.

Vendors should expect a check-in meeting with Foundation and physician leadership after 10% of the scope of work is completed to confirm alignment.

## **PROPOSAL REQUIREMENTS and EVALUATION CRITERIA**

Proposal should include:

- Proposed methodology
- Project team and roles
- Relevant experience
- Examples of similar work
- Expected Timeline\*\* (*see section below*)
- Budget

For relevant experience, vendors should describe experience with PRO development and evaluation, expertise in psychometrics and outcomes research, experience conducting systematic reviews or evidence mapping, and knowledge of FDA patient-focused drug development guidance.

### **Proposals will be evaluated based on:**

- Relevant experience (30%)
- Methodology (30%)
- Project team qualifications (20%)
- Budget/value (20%)

## **TIMELINE**

**Proposals are due by Friday, August 7** to Taylor Weyers at [tweyers@crohnscolitisfoundation.org](mailto:tweyers@crohnscolitisfoundation.org)

Notifications will be sent around the week of August 24.

\*\*The project start date and the timeline for associated activities will be determined in collaboration with the selected vendor. However, **all deliverables noted above must be completed and submitted to the Foundation within 90 calendar days of the agreed start date.**

## **BUDGET**

Allocated budget up to **\$50,000**

*Note: We encourage your submission even if your rate doesn't exactly match the amount listed above.*