SECOND ANNUAL
PATIENT-REPORTED OUTCOME (PRO)
CONSORTIUM WORKSHOP

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Co-sponsored by

CRITICAL PATH INSTITUTE
FDA

collaborate . innovate . accelerate
Patient-Reported Outcome (PRO) Consortium: Update

Stephen Joel Coons, PhD
Executive Director, PRO Consortium
Critical Path Institute
Goals of PRO Consortium

- Enable pre-competitive collaboration that includes FDA input/expertise
- Avoid development of multiple PRO instruments for same purpose
- Share costs of developing new PRO instruments
- Develop qualified, publicly available PRO instruments
- Facilitate FDA’s review of medical products by standardizing PRO endpoints
Membership

- **Voting Members**
  Medical product (pharmaceutical, diagnostic, and medical device) companies

- **Non-Voting Participants**
  - Liaisons/advisors from governmental agencies
  - Clinician consultants, patient advocates, academic researchers, and commercial entities partnering in the development of the PRO instruments
Members

- Abbott
- Actelion Pharmaceuticals
- Allergan
- Amgen
- Astellas Pharma
- AstraZeneca
- Boehringer Ingelheim
- Bristol-Myers Squibb
- Daiichi Sankyo
- Eisai
- Eli Lilly & Company
- Forest Laboratories

- GlaxoSmithKline
- Ironwood Pharmaceuticals
- Johnson & Johnson
- Merck Sharp & Dohme Corp.
- Novartis
- Novo Nordisk
- Pfizer
- Roche
- sanofi-aventis
- Shire
- Sunovion
- Takeda Pharmaceuticals
- UCB
Over 150 scientists and/or clinicians participate
Working Groups as of Last Year’s Workshop

• Asthma
• Breast Cancer
• Cognition (Mild Cognitive Impairment)
• Depression
• Irritable Bowel Syndrome
• Lung Cancer (NSCLC)
New Working Groups

- In February 2010, proposals for the creation of seven new working groups were submitted by member firms for consideration.
- FDA reviewed six submitted *Feasibility Documents* based on the proposals.
- FDA was willing to consider PRO instruments for four of the six proposed new areas.
- Two new working groups were authorized at the end of 2010:
  - Functional Dyspepsia
  - Rheumatoid Arthritis
Path to Qualification of a New PRO Instrument

• **Feasibility Document**

• **Scoping Stage Summary Document**
  • Proposed target population, concepts, conceptual framework, labeling language, and endpoint model (showing endpoint hierarchy)

• **Qualitative Research Summary Document**:  
  • Evidence that supports the content validity of draft PRO measure, including confirmation or revision of the proposed conceptual framework

• **Quantitative Research Summary Document**:  
  • Evidence supporting other measurement properties (e.g., reliability, construct validity, responsiveness) of final PRO instrument, along with user manual, and other documentation

• **Qualification Dossier**
Overall Working Group Status

On Hold
- Breast Cancer WG

Scoping Stage
- Functional Dyspepsia WG
- Rheumatoid Arthritis WG
- Lung Cancer WG

Vendor Selection Stage (prior to qualitative research)
- Asthma WG
- Depression WG

Qualitative Research Stage
- Irritable Bowel Syndrome WG
- Cognition WG