



Overview of the PRO Consortium

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FIRST ANNUAL

PATIENT-REPORTED OUTCOMES (PRO) CONSORTIUM WORKSHOP

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Co-sponsored by



PRO Consortium



- Formed in late 2008 by C-Path, in cooperation with the FDA and the pharmaceutical industry
- **Mission Statement**

To establish and maintain a collaborative framework with appropriate stakeholders for the development of qualified, publicly available PRO instruments for use in clinical trials where PRO endpoints are used to support product labeling claims.

PRO Consortium



- Governed by the *PATIENT-REPORTED OUTCOMES CONSORTIUM AGREEMENT* signed by the individual member firms and Critical Path Institute
- **Membership**
Only available to medical product companies (pharmaceutical, diagnostic, and medical device)
- **Non-Voting Participants**
 - Representatives of governmental agencies
 - Consultants, scientists from non-profit organizations, or commercial vendors developing PRO measures

PRO Consortium



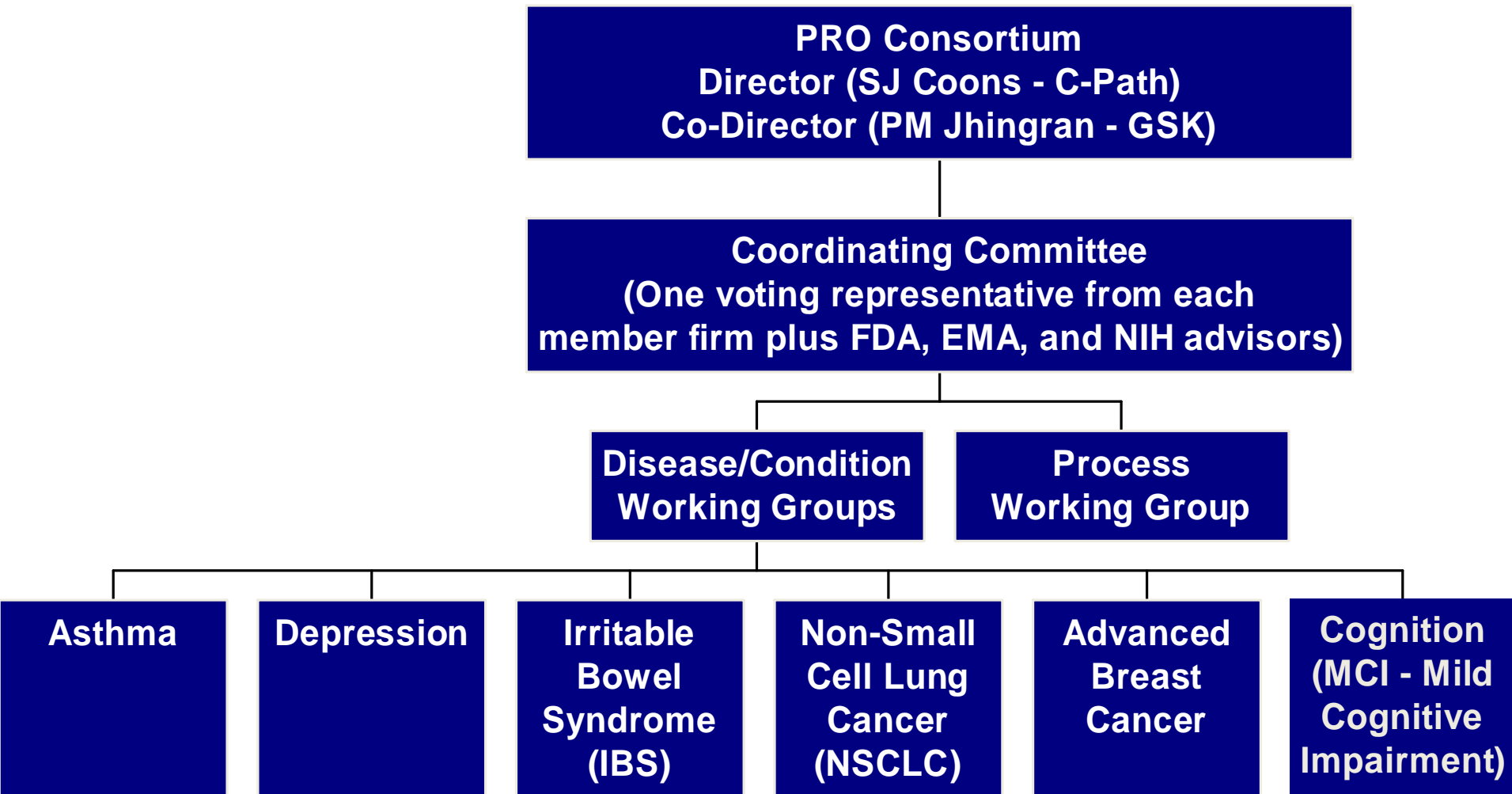
- **Membership Fee**
 - **Annual membership fee, used for**
 - **Meeting and teleconference costs**
 - **Legal/IP expenses**
 - **Data storage and maintenance**
 - **Not used to fund the PRO instrument development costs**
 - **No salaries or travel expenses for any scientific or administrative staff at C-Path are paid from PRO Consortium membership fees**

PRO Consortium Members



- **Abbott**
- **Actelion Pharmaceuticals**
- **Allergan**
- **Amgen**
- **Astellas Pharma**
- **AstraZeneca**
- **Boehringer-Ingelheim**
- **Bristol-Myers Squibb**
- **Dainippon Sumitomo Pharma America**
- **Eisai**
- **Eli Lilly & Company**
- **Forest Laboratories**
- **Genentech/Roche**
- **GlaxoSmithKline**
- **Ironwood Pharmaceuticals**
- **Johnson & Johnson**
- **Merck Sharp & Dohme Corp.**
- **Novartis**
- **Novo Nordisk**
- **Pfizer**
- **sanofi-aventis**
- **Takeda Pharmaceuticals**
- **UCB**

Organizational Chart



Participation by Member Firms



- Over 150 scientists and/or clinicians from member firms participate in the six disease/condition-targeted working groups
- At least seven member firms have been represented on each working group during its initial (Scoping) stage

Participation by Member Firms



- Three member firms have committed to funding the qualitative research stage in the IBS Working Group
- 10 member firms have committed to funding the qualitative research stage in the Cognition Working Group

Process Working Group



- Reports to the Coordinating Committee
- Co-chaired by Brigitta Monz (Boehringer-Ingelheim) and Smita Kothari (Astellas)
- Develops policies and procedures necessary to achieve the Consortium's objectives (e.g., criteria for establishing new working groups)
- Develops templates that help operationalize the Consortium's activities (e.g., summary documents submitted for review by the FDA)

Formal FDA Feedback on Working Group Deliverables



1. *Scoping Stage Summary Document:*

- PRO concept identification
- Proposed...
 - target population
 - conceptual framework
 - labeling language
 - endpoint model (showing endpoint hierarchy)

Upon submission of the *Scoping Document*, an FDA Qualification Review Team (QRT) is convened

Formal FDA Feedback on Working Group Deliverables



2. Qualitative Research Summary Document:

- Evidence that supports the development and content validity of draft PRO measure, including confirmation or revision of the proposed conceptual framework

Formal FDA Feedback on Working Group Deliverables



3. Quantitative Research Summary Document:

- Evidence supporting other measurement properties (e.g., reliability, construct validity, responsiveness) of final PRO instrument, draft user manual, and other documentation

Formal FDA Feedback on Working Group Deliverables



4. Upon successful completion and review by the FDA of the above three documents, the combined documents form the basis of the ***Qualification Dossier*** submitted to FDA's QRT

PRO Consortium



- A structured process for collaborative, pre-competitive PRO instrument development has been established
- The process will be refined and improved as we learn what works and what doesn't
- Much has been accomplished in the past year, but most of our work lies ahead
- Further details will emerge over the course of the day (however, if questions remain, I will try to answer them during this afternoon's open panel discussion)