



PRO Consortium: Industry Perspective

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Presentation Outline



- Background
- Journey so Far
- Working Groups
- PRO Instrument Qualification
- Achievements
- Learning's so Far
- Summary Remarks

Rationale



- Facilitate inclusion of the patient's perspective in drug development to better inform physicians and patients
- Expedite development timelines for PRO instruments



of qualified, publicly available PRO instruments for use to support labeling claims

Benefits



- Establish /maintain a collaborative framework with appropriate stakeholders
- Facilitates FDA involvement early and throughout the process
 - Reviewing Division/SEALD
- Faster review
- Increased likelihood of success
- Qualified publicly available PRO instruments
- Cost sharing opportunities

Sequence of Events



Industry Member Involvement



- Many committees
 - Coordinating Committee (CC)
 - Working Groups (WG)
 - Process Working Group (PWG)
 - Subcommittees
- Role
 - Nominate representatives
 - Actively participate
 - Volunteer time, data, resources

Working Group Stages



Scoping Stage

FDA to review Scoping Stage Summary Document

Vendor Selection Stage (prepare/release RFP, proposal review, & vendor selection)

Development Stage I (contract implementation & qualitative research)

FDA to review Qualitative Research Summary Document

Development Stage II (quantitative research & preparation of “qualification dossier”)

FDA to review Quantitative Research Summary Document and draft “Qualification Dossier”

Pre-qualification Stage

FDA to review “Qualification Dossier” and make “fit-for-purpose” determination

Qualification and Maintenance Stage (post-qualification)

How Can Industry Contribute in Various Stages of WG ?



- Actively participate if area of interest, i.e., likelihood of funding high
- Provide leadership/technical expertise
 - Involve subject area experts within different functional areas
- Share learnings/data sources(lit searches, focus group, CT data)
- Ensure constant loop back mechanisms to ensure alignment
- Secure funding
- Ensure communication channels are open

How Can Industry Propose New Working Groups ?



- Periodically, PRO Consortium will be seeking proposals for new WGs from the member companies
 - Two categories
 - PRO instrument development has already begun
 - PRO instrument development has not begun
- Proposal templates will be provided by the PRO Consortium
- Sub-Committee of PRO CC established to evaluate submitted proposals

Adding WGs to PRO Consortium



- Criteria for adding WGs:
 - C-Path has capacity
 - Sufficient interest by Consortium members
 - Of interest to regulatory agencies
 - Willing leadership
 - Needs Evaluation
 - Prioritization
 - Available Resources
 - CC Approval

Challenge: What options should industry consider when proposals are not accepted?

Criteria for Terminating WGs

- Criteria:
 - Consensus of the WG
 - Terminated due to lack of progress
 - The work is no longer needed
 - All work has been completed

PRO Instruments Qualification: What will help Industry?



- More clarity of the Path for new PRO instruments qualified as “fit for purpose”
 - PRO instruments developed within the PRO Consortium
 - PRO instruments developed outside the Consortium
 - Other independent consortia
 - Individual sponsors
- A better understanding of path for qualification of existing PROs

What other Types for Qualification May be Considered ?

- Comparative effectiveness research
- Validation of biomarkers
- For use in dose ranging studies

Accomplishments so Far...



Learnings so far...



- Processes have to be in place to provide governance structure
- Learning from WGs
 - Clear and transparent process for establishment of WGs
 - Clearly structured working groups
 - Broad range for membership (clinical, regulatory, health outcomes)
 - Availability of adequate resources
 - Adequate input from the FDA
- Role of FDA in the PRO Consortium needs to be well understood

Closing Remarks



- Progress so far is commendable
 - Committed member company representatives
 - Governance structure provided by C-Path Institute
 - Communication maintained with the FDA