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

Coordinating Committee established (1Q09)


F2F Coordinating Committee: October 29th, 2009 - New Orleans

First Annual PRO Consortium Meeting: March 23th, 2010 – Washington DC
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...

- Coordinating Committee established (1Q09)
- F2F Coordinating Committee: October 29th, 2009 - New Orleans.
- Key Achievements
  - 7 WGs Established
  - 3 Scoping Stage Summary Document Submitted to FDA
  - 1 RFP and Vendor Selection
  - 7 New Proposal for WGs Evaluated
  - Active PWG
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