SECOND ANNUAL PATIENT-REPORTED OUTCOME (PRO) CONSORTIUM WORKSHOP

March 15, 2011 ■ Silver Spring, MD

Co-sponsored by

CRITICAL PATH INSTITUTE

FDA
Proposed ePRO Consortium

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ePRO Consortium

- ePRO providers approached C-Path regarding the creation of an ePRO Consortium
- Purpose was to provide a coordinated approach to gathering evidence supporting the measurement equivalence of the various PRO instrument administration methods

Potential Efficiencies:

- Avoid duplicative measurement equivalence studies for the same EDC device/system
- Provide methodological guidance on practical issues facing the pharmaceutical industry regarding the implementation of ePRO
Mission and Objectives

Mission
• To advance the quality, practicality, and acceptability of electronic data capture (EDC) methods used in clinical trials for PRO endpoint assessment

Objectives
• Work with the PRO Consortium to migrate the PRO instruments developed within the PRO Consortium to all relevant EDC platforms
• Provide a non-competitive, neutral environment to test the measurement equivalence of PRO measures migrated to or among alternative administration methods
• Develop specification documents for the adaptation/migration of existing PRO instruments to the relevant EDC platforms
Membership

• The ePRO Consortium’s members would be firms that provide electronic data collection technologies/services to the medical products industry for capturing patient-reported outcome (PRO) endpoints in clinical trials.
Governance

• Coordinating Committee composed of primary and secondary representatives from member firms
• Industry Vice Director – elected by members
• Working groups - based on the PRO instrument being developed and/or migrated to EDC platforms

PRO Consortium - ePRO Subcommittee
• PRO Consortium’s ePRO Subcommittee (FDA inclusive) may serve as an advisory panel
• The ePRO Subcommittee provides guidance on the development and migration of the instruments being developed by the WG of the PRO Consortium
Governance Cont.

C-Path’s Responsibilities

• Appointment of management team and other administrative staff
• Recruit and enroll applicants for membership
• Administrative and financial oversight
• Identify and prioritize projects; establish working groups
• Project management
• Scientific oversight/consultation
Funding

Project Funding/Support

- Member firms provide (in-kind) electronic platform for testing
- Funding will be sought for measurement equivalence studies

Contracting

- C-Path with members (i.e., ePRO vendors/providers)
- C-Path with sponsors (e.g., pharmaceutical firms)
Scientific Purview

• Generate ePRO platform equivalence data
• Create ePRO device specification documents for each instrument
• Develop methodological guidance on measurement issues related to ePRO applications
• Develop standards for ease of use, system performance, and quality standards for ePRO platforms
• Other scientific endeavors aimed at advancing the science of PRO data capture
  • Publications, presentations
  • Other collaborations (e.g., PROMIS)
Next Steps

• Potential members reviewing the consortium agreement