SECOND ANNUAL PATIENT-REPORTED OUTCOME (PRO) CONSORTIUM WORKSHOP

March 15, 2011 ■ Silver Spring, MD

Co-sponsored by

Proposed ePRO Consortium

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FDA

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 Consortum - 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.

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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

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- 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