Background

The Electronic Patient-Reported Outcome (ePRO) Consortium was established on April 1st, 2011. The ePRO Consortium’s member firms provide electronic data collection technologies and services to the medical products industry for capturing PRO endpoints in clinical trials.

Mission

To advance the quality, practicality, and acceptability of electronic data collection modes used in clinical trials for PRO endpoint assessment.

Goals

- 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
- Provide guidance on methodological considerations for PRO instrument migration and adaptation

Benefits

- A coordinated approach to gathering evidence supporting the measurement equivalence of the various PRO instrument administration methods
- Collectively interact with instrument developers to gain permission and collaboration on testing of new administration methods
- Collective development of PRO migration best practices
- Avoid duplicative measurement equivalence studies for the same EDC device/system
- Development of publicly available specification documents for migrating specific PRO instruments to specific EDC systems/devices
- Provide methodological guidance on practical issues facing the pharmaceutical industry regarding the implementation of ePRO (e.g., mixing PRO instrument data collection modes within a trial)

Goverance Structure

The ePRO Consortium is led by a Director, appointed by C-Path, and a Vice Director, elected annually by members of the Consortium’s Coordinating Committee. The Coordinating Committee meets monthly via teleconference and holds two face-to-face meetings each year. There are three subcommittees of the ePRO Consortium: Instrument Migration Subcommittee, Research Subcommittee, and Publications and Presentations Subcommittee.

Instrument Migration Subcommittee

- Documents development principles for new clinical outcome assessments (COAs), electronic implementation principles for existing COAs, and best practices for electronic implementation of COA response scales
- Interfaces with the PRO Consortium’s working groups
- Provides instrument-level and item-level feedback on the draft PRO instruments emerging from the PRO Consortium’s working groups
- Developed methodology to evaluate the feasibility of implementing PRO instruments developed by the PRO Consortium on all electronic data collection platforms, called the Electronic Implementation Assessment
- The Electronic Implementation Assessment is conducted after the item generation process and after the instrument has undergone translatability assessment. The feedback is consolidated in a brief report and, along with a detailed feedback spreadsheet, is presented to the PRO Consortium WG for consideration.

Research Subcommittee

- Identifies research questions that should be addressed to advance the science of electronic data capture in clinical trials
- Designs studies and writes proposals to request funding
- Coordinates the in-kind contributions from members to perform the designed studies

Publications and Presentations Subcommittee

- Convenes and coordinates writing teams for preparation of abstracts, presentations (podium and poster), and manuscripts emerging from the ePRO Consortium
- Establishes a strategy for the dissemination of scientific data and operational expertise. The results of this subcommittee’s efforts are presented in the next column.

Publications


Presentations


Lundy J, Symonds T, Howry C, Amerra V. Deploying ePRO Instruments in Clinical Trials: Challenges and Solutions. International Society of Pharmacoeconomics and Outcomes Research 18th Annual International Meeting; 2013 May 22; New Orleans, LA, USA.


Lundy J, on behalf of the ePRO Consortium. Implementing New COA Instruments on Alternative Data Collection Modes: The Electronic Implementation Assessment. International Society of Pharmacoeconomics and Outcomes Research 17th Annual International Meeting; 2012 Jun 4; Washington, DC, USA.

Coons SJ, Eremenko S, Paty J, Lloyd A. Mixing Modes of Patient-Reported Outcomes Data Collection in Clinical Trials: Recommendations. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 14th Annual European Congress; 2011 Nov 3; Madrid, Spain.

Manuscripts Under Review

O’Donohoe et al. “Considerations for requiring subjects to provide a response to electronic patient-reported outcome instruments”

Gwaltney et al. “Bring Your Own Device (BYOD): The Future of Field-Based Patient-Reported Outcome Data Collection in Clinical Trials?”

Fleming et al. “Optimizing Electronic Capture of Clinical Outcome Assessment Data in Clinical Trials: The Case of Patient-Reported Endpoints”