Presented at the Eighth Annual PRO Consortium Workshop – Bethesda, MD - April 26-27, 2017

Background

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 and other clinical outcome assessment (COA) based endpoints in clinical trials.

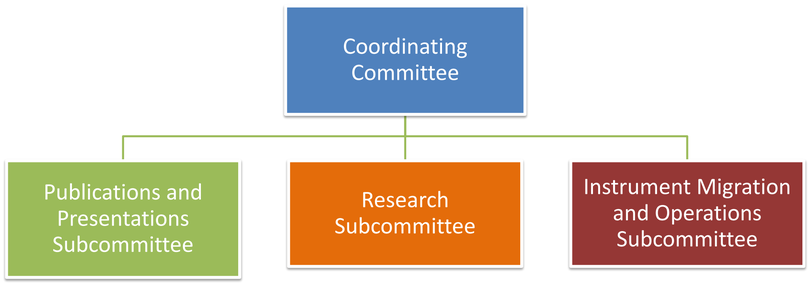
Mission

To advance the science of clinical trial endpoint assessment by collaboratively supporting and conducting research, designing and delivering educational opportunities, and developing and disseminating best practice recommendations for electronic collection of clinical outcome data.

Benefits

- A coordinated approach to gathering evidence supporting the measurement equivalence of the various PRO instrument data collection modes
- Collectively interact with instrument developers to gain permission and collaborate on testing of new data collection modes
- Develop methodological and operational best practices on issues faced during the implementation of ePRO in clinical trials

Governance Structure



The ePRO Consortium is led by a C-Path appointed Director and an Industry Vice Director, currently Bill Byrom, PhD (ICON), elected annually by consortia members.

Publications and Presentations Subcommittee

Co-Chairs: Jennifer Crager (ICON) and Chris Watson, PhD (ERT)

- 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.

Research Subcommittee

Co-Chairs: Serge Bodart, MS (Biomedical Systems) and Willie Muehlhausen, DVM (ICON)

- 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 in-kind contributions from members to perform designed studies

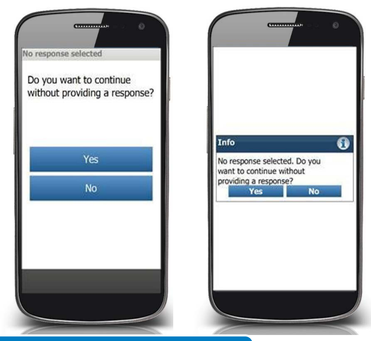
Instrument Migration and Operations Subcommittee

Co-Chairs: Valdo Arnera, MD (ERT) and Cindy Howry, MS (.assisTek)

- Develop electronic implementation principles and best practices for new and existing clinical outcome assessment (COA) measures
- Interface with the PRO Consortium's working groups and provide feedback on draft COA measures emerging from the PRO Consortium's working groups
- Evaluate the feasibility of implementing the PRO Consortium's COA measures on all appropriate electronic data collection platforms (i.e., "Electronic Implementation Assessment")
- Develop best practices on practical, operational, and technical aspects of the implementation of eCOA solutions in clinical trials, including aspects related to global deployments of eCOA solutions (e.g., IRB submissions, patient and site training, user acceptance testing (UAT), and other relevant issues)
- Evaluate the impact of new or pending laws and regulations on data security and protection

Best Practice: Item Skip Wording

- In cases where there is a pop-up heading, th heading would read, "No response selected, followed by the message text, "Do you want to continue without providing a response?" Yes/No
- In cases where no pop-up heading is used, the message text would read, "No response selected. Do you want to continue without providing a response?" Yes/No



Other ePRO Consortium Best Practice Documents are available at https://c-path.org/programs/epro/#section-5648

Examples of Ongoing Research Activities

- In conjunction with the EuroQol Foundation, a project to assess measurement equivalence of the EQ-5D-5L across various data collection platforms.
- In conjunction with the PRO Consortium, a project to assess bring-your-own-device (BYOD) versus provisioned device-based data collection.

Manuscripts in Preparation

- "Best Practices for Avoiding Paper Backup When Implementing Electronic Approaches to Patient-Reported Outcome Data Collection in Clinical Trials"
- "Selection and Evidentiary Considerations of Wearable Devices and their Measurements for use in Regulatory Decision Making: Recommendations from the ePRO Consortium"
- "Best Practices for Patient and Site Training Prior to Electronic Data Collection"
- "Best Practices for User Acceptance Training prior to Deployment of Electronic Data Collection Systems"

Upcoming Webinars

- "Selection and Evidentiary Considerations of Wearable Devices and their Measurements for use in Regulatory Decision Making: Recommendations of the ePRO Consortium" Presented by Bill Byrom (ICON); Moderator: Chris Watson (ERT); May 18, 2017 from 11-12PM (ET)
- "Best Practices for Avoiding Paper Backup When Implementing Electronic Approaches to Patient-Reported Outcome Data Collection in Clinical Trials" Presented by Cindy Howry (.assisTek); June 27, 2017 from 12-1PM (ET)

2016-2017 Webinars

- "Considerations for Requiring Subjects to Respond to PRO Instruments Collected Electronically" (February 28, 2017) Presenter: Paul O'Donohoe, MS (CRF Health)
- "Ensuring Equivalence of Electronic and Paper Administration of Patient-Reported Outcome Measures" (September 29, 2016) Presenters: Paul O'Donohoe, MS (CRF Health) and Willie Muehlhausen, DVM (ICON)
- "Bring Your Own Device (BYOD)" (March 10, 2016) Presenters: Jennifer Crager (YPrime) and Paul O'Donohoe, MS (CRF Health)

Recordings of past webinars are available at http://c-path.org/programs/epro/#section-6118

Presentations 2016

- Forum: "Equivalence of Paper and Electronic Modes of Patient-Reported Outcome Data Collection: An Answered Question?" presented at ISPOR's 21st Annual International Meeting held on May 23, 2016, (Washington, DC).
- Forum: "Electronic Implementation of New PRO Measures to Assess Treatment Benefit in Irritable Bowel Syndrome Trials: Lessons Learned" presented at DIA 52nd Annual Meeting on June 27, 2016 (Philadelphia, PA).
- Poster: Elash C, Ross J, Byrom W, O'Donohoe P, Crescioni M. "Best Practices for Development or Migration of PRO Measures for Use on Multiple Data Collection Modes" presented at DIA 52nd Annual Meeting on June 28, 2016 (Philadelphia, PA).