Presented at the Seventh Annual PRO Consortium Workshop - Silver Spring, MD – April 27-28, 2016

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.

Goals
• Work with the PRO Consortium to migrate the PRO instruments developed within the PRO Consortium’s working groups to all relevant electronic data capture (EDC) platforms
• Provide a non-competitive, neutral environment to test measurement equivalence of PRO instruments migrated to or among alternative data collection modes
• 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 data collection modes
• Collectively interact with instrument developers to gain permission and collaborate on testing of new data collection modes
• Collective development of ePRO migration best practices
• Avoid duplicative measurement equivalence studies for 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)

Governance Structure
The ePRO Consortium is led by a Director, appointed by C-Path, and Vice Director, elected annually by members of the Consortium’s Coordinating Committee. The Vice-Director for 2015-2016 is Cindy Howry (YP Prime). The Coordinating Committee holds monthly teleconferences and two face-to-face meetings each year. The ePRO Consortium has three subcommittees: Instrument Migration, Research, and Publications and Presentations.

Webinars
• Intro to ePRO - Part I. Presented by Valdo Arnera, MD (ERT) and J. Jason Lundy, PhD (C-Path).
• Intro to ePRO - Part II. Presented by Cindy Howry, MS (YP Prime) and Jennifer Ross, MPH/PhD (Almac)
• Migrating a PRO Instrument. Presented by Sergey Bobat, MSc (Biomedical Systems) and Alixandra Johnson, BS (Bracket)
• Best Practices for ePRO Implementation in Clinical Trials. Presented by Sergey Bobat, MSc (Biomedical Systems) and Elsa Holtsbaum, BS, PMP (Almac)
• Bring Your Own Device (BYOD). Presented by Jennifer Crager (YP Prime) and Paul O’Donohoe (CRF Health)

Recordings of our Webinars are available at http://e-pro.org/programs/eopro/interaction-e6138.

Publications


Presentations
Lundy J, Symonds T, Howry C, Arnera V, Deplyoying ePRO Instruments in Clinical Trials: Challenges and Solutions. International Society for Pharmacoeconomics and Outcomes Research 18th Annual International Meeting; 2013 May 22; New Orleans, LA, USA.
Lundy JI, O’Donohoe P, Lundy JI, O’Gorman H, on behalf of the ePRO Consortium. Implementing New COA Instruments on Alternative Data Collection Modes: The Electronic Implementation Assessment. International Society for Pharmacoeconomics and Outcomes Research 17th Annual International Meeting; 2012 Jun 4; Washington, DC, USA.
Lundy J, on behalf of the ePRO Consortium. Implementing New COA Instruments on Alternative Data Collection Modes: The Electronic Implementation Assessment. International Society for Pharmacoeconomics and Outcomes Research 17th Annual International Meeting; 2012 Jun 4; Washington, DC, USA.

Publications and Presentations Subcommittee
• Co-Chairs: Serena Battor (Biomedical Systems) and Willie Muelhausen (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 the in-kind contributions from members to perform the designed studies

Instruments Migration Subcommittee
• Co-Chairs: Valdo Arnera (ERT) and Cindy Howry (YP Prime)
• Documents development principles for new 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 working group for consideration.

Research Subcommittee
• Co-Chairs: Serge Bodart (Biomedical Systems) and Willis Muelhausen (ICON)

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