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

Objectives: To collectively….

- develop methodological and operational best practices to support the electronic capture of clinical outcome assessment (COA) data in clinical trials
- gather evidence supporting the measurement equivalence of the various PRO (and other COA) data collection modes
- interact with developers/copyright holders to gain permission and collaborate on testing new data collection modes for targeted instruments

Recent Manuscripts (Published, submitted, or under development)

Published

- "Selection of and Evidentiary Considerations for Wearable Devices and Their Measurements for use in Regulatory Decision Making: Recommendations from the ePRO Consortium"

Submitted for Publication

- "Best Practices for Avoiding Paper Backup When Implementing Electronic Approaches to Patient-Reported Outcome Data Collection in Clinical Trials"
- "Training on the Use of Technology to Collect Patient-Reported Outcome Data Electronically in Clinical Trials: Best Practice Recommendations from the ePRO Consortium"
- "Perceived Burden of Completion of Patient-Reported Outcome Measures in Clinical Trials: Results of a Preliminary Study"

Under Development

- "Best Practices for User Acceptance Training prior to Deployment of Electronic Data Collection Systems"
- "Best Practices Document for Electronic Implementation of Clinician-Reported Outcome (ClinRO) Assessments"
- "Demystifying Submissions of eCOA Documentation for Ethics Review: Are We Making Submissions More Difficult than Necessary?"

A full list of our publications is available on the ePRO Consortium's website.

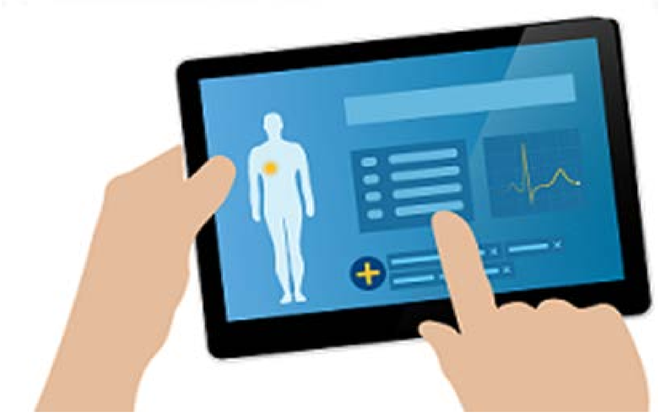
Good Clinical Practice Inspectors Working Group (GCP IWG)

Contributed to EMA's Good Clinical Practice Inspectors Working Group (GCP IWG) by offering the ePRO Consortium's stakeholder perspective during past meetings of the GCP IWG on topics such as: responsibilities of ePRO providers regarding source data, use of electronic informed consent, and responsibilities of ePRO providers when collecting electronic signatures

FDA Critical Path Innovation Meeting (CPIM)

- On September 14, 2017, C-Path's PRO Consortium and ePRO Consortium participated in a CPIM with FDA titled "The Use of Wearable Devices to Collect Endpoint Data in Clinical Trials," to achieve the following objectives:
  - Discuss activity monitor-based examples of proposed uses of wearable technology to measure patients' real-life physical functioning to inform or support endpoints in clinical trials
  - Discuss ePRO Consortium recommendations on evidentiary requirements when using wearable devices to collect data for labeling claims
  - Work toward a shared understanding of some of the open regulatory and scientific issues related to the use of wearable devices to collect endpoint (i.e., treatment benefit) data in clinical trials

Those participating in the CPIM included representatives from the PRO Consortium, ePRO Consortium, C-Path, and FDA



Equivalence Studies Completed in 2017

EQ-5D-5L

- In conjunction with the EuroQol Research Foundation, a project was completed that assessed the measurement equivalence of the EQ-5D-5L across five data collection platforms (i.e., paper, handheld, tablet, web, and IVR).

Bring-Your-Own-Device (BYOD)

- In conjunction with the PRO Consortium, a project was completed that assessed the measurement comparability of a provisioned handheld device versus a bring your own device (BYOD) approach to PRO data collection in subjects with Chronic Obstructive Pulmonary Disease.

Summary reports for both of the above projects will be presented at the *Ninth Annual PRO Consortium Workshop* on April 25, 2018.

Webinars

Upcoming Webinars

- "Training on the Use of Technology to Collect Patient-Reported Outcome Data Electronically in Clinical Trials: Best Practice Recommendations from the ePRO Consortium" to be presented by Jenny Ly (ERT) and Serge Bodart (Bracket) on **May 10, 2018, from 11AM-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); date to be announced

Poster Presentations in 2017

ISPOR 20th Annual European Congress, Glasgow, Scotland, 4-8 November 2017

- "Allowing Respondents to Skip Items During Electronic Collection of Patient-Reported Outcome (PRO) Data: Does it Matter?"
- "Electronic Capture of Clinical Outcome Assessment Data: Why is It Not Used More in Clinical Studies?"
- "Evaluating the Conceptual Equivalence Between Paper and Three Electronic Data Collection Modes of the EQ-5D-5L Health Status Instrument"

ePRO Consortium Leadership

Leadership Role	Name (Organization)
Director	Mabel Crescioni, DrPH, JD, LLM (C-Path)
Industry Vice Director	Bill Byrom, PhD (CRF Health)
Co-Chairs - Instrument Migration and Operations Subcommittee	Valdo Arnera, MD (ERT) Cindy Howry, MS (.assisTek)
Co-Chairs - Publications and Presentations Subcommittee	Jennifer Crager (ICON) Chris Watson, PhD (ERT)
Co-Chairs - Research Subcommittee	Paul O'Donohoe, MSc (Medidata) Sue Vallow, RPh, MBA (MedAvante)