ePRO CONSORTIUM
CRITICAL PATH INSTITUTE

WHO WE ARE

The Electronic Patient-Reported Outcome (ePRO) Consortium was established by Critical Path Institute (C-Path) in 2011. Along with C-Path, the members of the ePRO Consortium are firms that provide electronic data collection technologies and services for capturing patient-reported outcome (PRO) and other clinical outcome assessment (COA) data in clinical trials.

OUR MISSION

The ePRO Consortium's mission is 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.

HOW WE DO IT

The ePRO Consortium provides a pre-competitive environment in which leading industry experts can collaborate to develop specification documents and data standards, provide guidelines on methodological considerations related to eCOA applications, and generate measurement equivalence data.

MEMBER FIRMS

ActiGraph, assisTek, Clinical Ink (Confident Decisions, Faster), ERT (Getting It Done. Right.), IMS Health & Quintiles are now IQVIA, 捷信医药 Jsure Health (无捷径 有信念), Kayentis (Dedicated to eCOA & Patient Engagement), koneksa, MedAvante, medidata, medrio, SIGNANT HEALTH, yprime

eCOA: Getting Better Together Initiative - Launched June 2019

- What: A collaborative, pre-competitive initiative among C-Path, clinical trials sponsors from the PRO Consortium, eCOA providers and CROs from the ePRO Consortium, and FDA
- Aims:
  - Identify and address the root cause of issues with eCOA implementation in clinical trials
  - Elevate eCOA improvement efforts above the individual company level
  - Drive positive and lasting change across the clinical trial eCOA ecosystem

Recent Presentations

Byrom B, Eremenco S, Muehlhausen W, Howry C, Watson C, Bodart S, Platko JV, Elash CA. "Measurement Comparability of Electronic and Paper Administered Visual Analogue Scales: A Review of Published Studies" presented at ISPOR 2019 on May 22, 2019 (New Orleans, LA)

Romero H, Eremenco S, Wyrwich KW, O'Donohoe P, DeBonis D, Arnera V, Steele S, Willgoss T, Harris K, Howry C, Crescioni C, Platko J. "Best Practices for the Electronic Migration and Implementation of Clinician-Reported Outcome Assessments in Clinical Trials" presented at DIA 2019 on June 26, 2019 (San Diego, CA)

ePRO Consortium Membership

Membership is open to companies providing services and/or technology associated with the electronic collection of COAs. New members welcome!

COVID-19: Risk Assessment and Mitigation Strategies

In collaboration with C-Path's PRO Consortium, the ePRO Consortium developed the presentation titled "Coronavirus Disease 2019 (COVID-19): Risk Assessment and Mitigation Strategies for the Collection of PRO Data through Clinical Sites." This presentation provides:

- ✓ An overview of the current challenges of capturing PRO data originally intended to be collected electronically from study participants during in-person visits to study sites
- ✓ Recommended risk assessment and mitigation strategies for consideration by trials sponsors and eCOA providers to facilitate the continued collection of PRO data in clinical trials

September 18, 2019
Demystifying Submissions of eCOA Documentation for Ethics Review: Are We Making Submissions More Difficult Than Necessary?

May 16, 2019
Best Practices for Avoiding Paper Backup When Implementing Electronic Approaches to Patient-Reported Outcome Data Collection in Clinical Trials

VISIT www.c-path.org/epro FOR MORE ON OUR LATEST WEBINARS!

Wearable Devices in Clinical Trials

C-Path received an FDA grant titled "Preliminary Research to Support Qualification of an Activity Monitor-based Endpoint Measure to Evaluate Physical Activity in Persons with Chronic Heart Failure (CHF)" on September 2, 2019.

- The purpose of this project is to increase the understanding of the nature of physical activity carried out by persons with CHF and characterize the level and types of physical activity identified as being important and meaningful in their daily lives, which will address an unmet need in CHF drug development.
- The evidence generated by this project will support the qualification of an activity monitor-based endpoint measure by FDA's COA Qualification Program.

Key Event – Virtual Conference

DIA Digital Technology in Clinical Trials Conference
Dates: August 18-19, 2020
The ePRO Consortium is co-sponsor of the 2020 DIA Digital Technology in Clinical Trials Conference

ePRO Consortium Leadership

Acting Director	Sonya Eremenco, MA – Critical Path Institute
Industry Vice Director	Paul O'Donohoe, MSc – Medidata Solutions