eCOA CONSORTIUM
CRITICAL PATH INSTITUTE

WHO WE ARE

The Electronic Clinical Outcome Assessment (eCOA) Consortium was established by Critical Path Institute (C-Path) in 2011 as the ePRO Consortium. Along with C-Path, the members of the eCOA 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 eCOA 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 eCOA 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, CLARIO., Clinical Ink (Confident Decisions, Faster), ICON, IMS Health & Quintiles are now IQVIA, Kayentis (Dedicated to eCOA & Patient Engagement), koneksa, Mapi Research Trust, Medable, medidata, medrio, SIGNANT HEALTH, Science 37, umotif, wcg MedAvante-ProPhase, yprime

Recent Publications

- Gordon S. et al. Best Practice Recommendations: User Acceptance Testing for Systems Designed to Collect Clinical Outcome Assessment Data Electronically. *Therapeutic Innovation & Regulatory Science* 2022
- Byrom B. et al. Measurement Comparability of Electronic and Paper Administration of Visual Analogue Scales: A Review of Published Studies. *Therapeutic Innovation & Regulatory Science* 2022
- Gertel A. et al. Demystifying Submissions of eCOA Documentation for Ethics Review: Are We Making Submissions More Difficult than Necessary? *Applied Clinical Trials* 2020
- Lundy JJ. et al. Agreement Among Paper and Electronic Modes of the EQ-5D-5L. *The Patient - Patient-Centered Outcomes Research* 2020

eCOA Consortium Leadership

Executive Director	Scottie Kern, BSc (Hons) Critical Path Institute
Industry Co-Director	Shelly Steele, MA WCG MedAvante-ProPhase

eCOA: Getting Better Together Initiative

- **What:** An ongoing collaborative, pre-competitive initiative among C-Path, clinical trial sponsors from the PRO Consortium, eCOA providers and CROs from the eCOA 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

- **Resources Online:** eCOA Consortium Website – eCOA Initiative Tab
  - **eCOA Lexicon**
    - An aligned eCOA Lexicon for use by stakeholders across the eCOA ecosystem
  - **eCOA: Process/Workflow and Roles/Responsibilities**
    - Defines an eCOA process and workflow that aligns expectations for successful eCOA strategy development and deployment and clarifies roles and responsibilities
  - **Podcast**
    - This podcast discusses the use of bring your own device (BYOD) approaches for the collection of eCOA data in clinical trials.

Active Projects

- Update to Best Practice Recommendations for Paper to Electronic Migration of PROMs
  - Updating established best practices with new recommendations for current technology capabilities
  - Development of a single point of reference for best practices on the migration of PROMs
- eCOA systems and the Conformité Européenne (CE) Mark
  - Examining how and when eCOA systems would be in-scope for CE certification

Upcoming Projects

- Practical considerations for the implementation of wearables in clinical trials
- Comparison of implementation of performance outcome (PerfO) measures in remote versus in-clinic settings
- Opportunities for enhancing uptake of bring your own device (BYOD) methods for COA data collection in clinical trials