eCOA: Getting Better Together Initiative

Q4 2023

PRO CONSORTIUM
CRITICAL PATH INSTITUTE

eCOA CONSORTIUM
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Electronic Clinical Outcome Assessment (eCOA) Consortium Overview

eCOA Consortium

Background

The eCOA Consortium was established by C-Path in 2011. Along with C-Path, the 23 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 electronically 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

- Generate evidence and provide methodological and operational guidelines on the collection of COAs electronically (i.e., eCOAs) in clinical trials
- Provide best practice recommendations regarding migration of COAs from paper to electronic data collection modes and between/among electronic modes
- Work closely with C-Path's PRO Consortium to make newly developed and qualified PRO measures and other COAs available in multiple data collection formats

Current Membership

Patient-Reported Outcome (PRO) Consortium Overview

PRO Consortium

- Formed in late 2008 by C-Path in cooperation with FDA's Center for Drug Evaluation and Research (CDER) and the pharmaceutical industry

- Membership
  - 26 members (pharmaceutical firms)

- 9 therapeutic area working groups with 15 COAs in FDA COA Qualification Program

- Additional Participants
  - Representatives of governmental agencies (FDA, NIH)
  - Clinical consultants, patients, academic researchers, and contract research organizations partnering in the development of PRO measures and other COAs

PRO Consortium: Members

PRO Consortium Mission and Goals

Mission:

To establish and maintain a collaborative framework with appropriate stakeholders for the qualification of patient-reported outcome (PRO) measures and other clinical outcome assessments (COAs) that will be publicly available for use in clinical trials **where COA-based endpoints are used to support product labeling claims**

Goals:

- Enable pre-competitive collaboration that includes FDA input and expertise
- Obtain FDA qualification of PRO measures and other COAs that will be publicly available for use in assessing primary or secondary clinical trial endpoints
- Avoid development of multiple endpoint measures for the same purpose
- Share costs of developing new endpoint measures
- Facilitate FDA's review of medical products by standardizing COAs used as endpoint measures for specific concepts of interest and contexts of use

Collaboration between Consortia

eCOA: Getting Better Together Initiative

Background

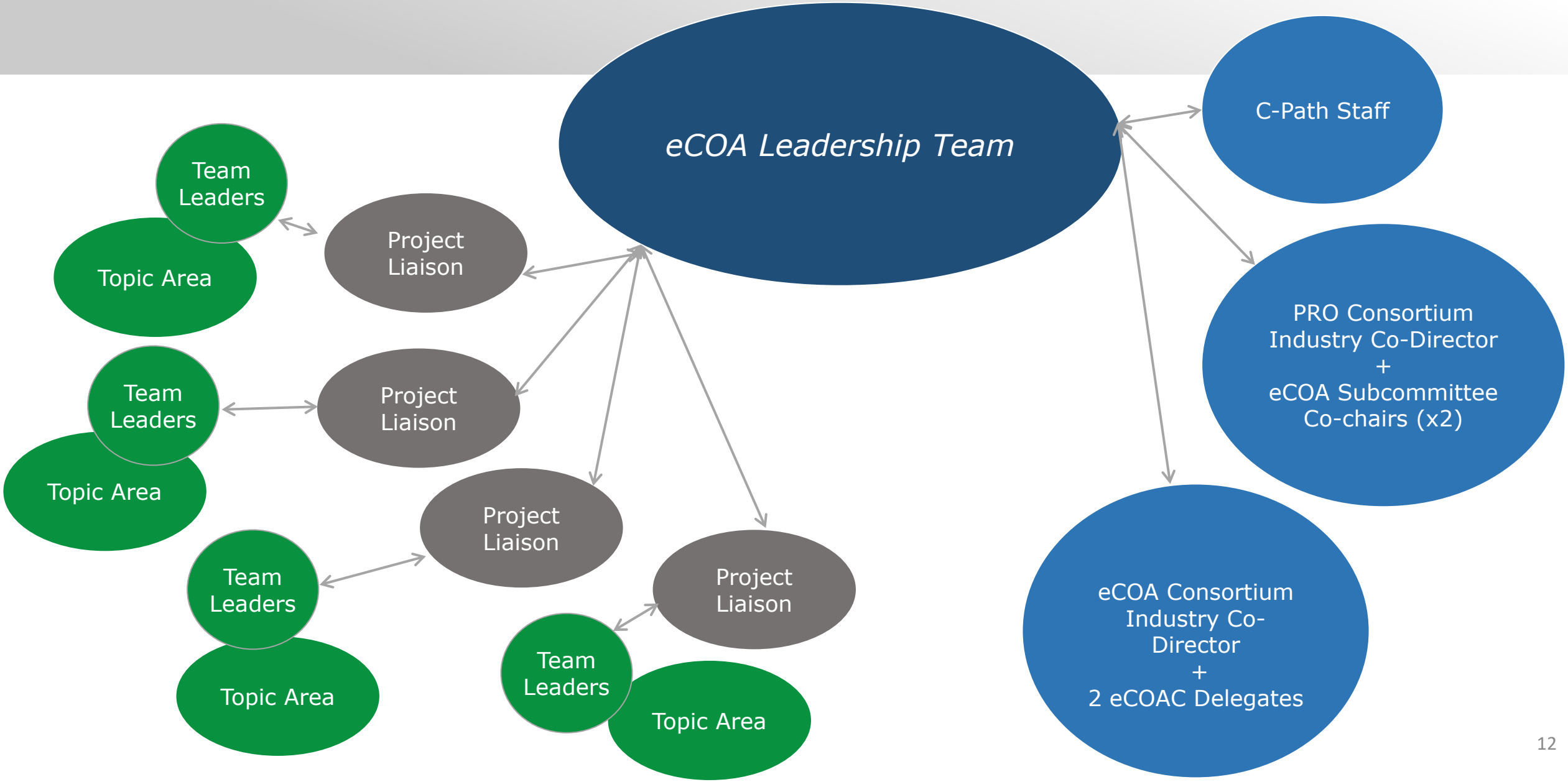
What it is:

A collaborative, pre-competitive initiative among C-Path, clinical trial sponsors from the PRO Consortium, eCOA providers from the eCOA Consortium, contract research organizations, and regulators (FDA)

Aims:

- Identify and address the root cause of issues with eCOA implementation in clinical trials
- Drive positive and lasting change in the eCOA ecosystem for the benefit of all stakeholders

Organizational Structure



Wave 1 Launch Date: June 2019
Topic 1: eCOA Lexicon

Project Liaison: Paul O'Donohoe (Medidata)

Project Team Leaders: Megan Turner (GSK) and Lisa Nguyen (MedAvante)

Objective:

- Without a common lexicon among eCOA providers, sponsors, study site staff, and regulators, the chance for miscommunication, errors, and inefficiencies increases. The objective of this team is to review terminology and create an aligned eCOA Lexicon for use by stakeholders across the eCOA ecosystem.

Status:

- This project will likely run through the duration of Waves 1, 2, and 3.
- February 2021: Version 1 was completed and posted to the C-Path website.
- March 2022: Version 2 was completed and posted to the C-Path website.
- June 2023: Version 3 was completed and posted to the C-Path website.

Final Deliverable:

- A searchable PDF document is available via the webpage for the PRO Consortium (www.c-path.org/proc) and the "Resources" tab for the eCOA Consortium webpage (www.c-path.org/ecoac).

Topic 2: eCOA Process/Workflow and Roles/Responsibilities

Project Liaison: Kate Zarzar (Genentech)
Project Team Leader: Jennifer Lord-Bessen (BMS)

Objective:

- Define an eCOA workflow or process aligning expectations for successful eCOA strategy development and deployment and clarifying roles and responsibilities.

Status:

- February 2021: Final documents were completed and posted to the C-Path website.
- Q3 2022: A small team was assembled to review the deliverables to ensure they still reflect current industry standards. The target date for completion is Q2 2024.

Final Deliverables:

- A searchable PDF document is available via the webpage for the PRO Consortium (www.c-path.org/proc) and the "Resources" tab for the eCOA Consortium webpage (www.c-path.org/ecoac).
  - Abbreviations, Roles, Process Step Table, Workflow

Topic 3: Best Practice Recommendations for User Acceptance Testing

Manuscript Title: *Best Practice Recommendations: User Acceptance Testing for Systems Designed to Collect Clinical Outcome Assessment Data Electronically*

Writing Team: The writing team includes members from the PRO Consortium's eCOA Subcommittee and the eCOA Consortium.

Status - Complete:

- The article was published with open access in *Therapeutic Innovation & Regulatory Science* on March 1, 2022.
- Link: https://link.springer.com/article/10.1007/s43441-021-00363-z

Topic 4: Best Practice Recommendations for ePRO Dataset Structure and Standardization

Manuscript Title: *Best Practice Recommendations for ePRO Dataset Structure and Standardization to Support Drug Development*

Writing Team: The writing team included stakeholders representing FDA, analytic vendors, CDISC, sponsors from the PRO Consortium's eCOA Subcommittee, and eCOA providers from the eCOA Consortium.

Status - Complete:

- The article was published online with open access in *Value in Health* on February 25, 2023. The article was published in print in August 2023, Volume 26, Issue 8.
- Link: https://doi.org/10.1016/j.jval.2023.02.011

Topic 5: Best Practice Recommendations for Changing eCOA Data

Project Liaison: Trish Shepherd Delong (Janssen)

Project Team Leaders: Demian Humler (Clario) and Trish Shepherd Delong (Janssen)

Objective:

- Bring together experts across the eCOA ecosystem to develop best practice recommendations for handling COA data change requests.

Status:

- eClinical Forum representatives joined the project team in October 2020.
- Webinar: The team presented a joint webinar with eClinical Forum on December 7, 2022. A public webinar will be held on February 6, 2024.
- The article was published online by the *Journal of the Society for Clinical Data Management* (*JSCDM*) on December 14, 2023. Link: https://doi.org/10.47912/jscdm.249

Final Deliverable:

- A manuscript published in a peer-reviewed publication with open access with accompanying webinar

Wave 2 Launch Date: January 2021
Topic 1: Support Flexible Approaches to PRO Data Collection

Project Liaison: Andriani Athanasiou (Janssen)

Project Team Leaders: Valdo Arnera (Clario) and Andriani Athanasiou (Janssen)

Topic: Support flexible approaches to PRO data collection in terms of both timing and mode to reduce the burden on study participants and sites while meeting regulatory requirements

Objective: Develop best practice recommendations to support flexibility in PRO data collection in clinical trials

Timeframe: The goal is to finish this work by the end of Q1 2024.

Status: The kick-off meeting for this project was held on January 27, 2021. The project team is divided into 3 workstreams: 1) improving participant and site experience through simplification; 2) innovations in technology needed to support flexibility; and 3) instrument developer and regulatory perspectives. All workstreams will publish their papers as independent manuscripts.

- Workstream 1: The manuscript titled "Flexible Approaches to eCOA Administration in Clinical Trials: The Site Perspective" was published by *Contemporary Clinical Trials Communications* on December 7, 2023. Publication link: https://doi.org/10.1016/j.conctc.2023.101241
- Workstream 2: The manuscript tentatively titled "Best Practices for Flexible COA Data Capture" is a commentary focusing on technological innovations needed to support flexibility for COA data capture. The writing team is making final revisions; the target journal is *Contemporary Clinical Trials*.
- Workstream 3: The manuscript was circulated for review to the PRO Consortium's eCOA Subcommittee and the eCOA Consortium Coordinating Committee in July 2023. On August 8, 2023, the writing team began adjudicating the feedback received; revisions are in progress. The target journal is the *Journal of Patient-Reported Outcomes.*

Wave 2 - Topic 2:
Bring Your Own Device

Project Liaison: Shelly Steele (MedAvante)

Project Team Leaders: Karl McEvoy (YPrime) and Lisa Charlton (Science 37)

Topic: Bring Your Own Device (BYOD)

Objective: Develop best practice recommendations for clinical trial implementation of BYOD

Status: Kicked-off February 12, 2021.

- The project team divided into 2 workstreams:
  - Workstream 1: Definitions and an overview of how to decide if BYOD is right for your trial
  - Workstream 2: Equivalency and Regulatory perspective
- A podcast discussing the use of BYOD approaches for the collection of eCOA data was released on April 8, 2022.

Final Deliverables:

- A podcast, with a hosted slide deck and supporting webinar for delivery in Q1 2024.

Wave 2 - Topic 3:
eCOA Translations and Licensing Management

Project Liaison: Kate Zarzar (Roche/Genentech)

Project Team Leaders: Piero Bindi (IQVIA) and Teresa Williams (Lilly)

In collaboration with ISOQOL TCA-SIG

Topic: eCOA Translations and Licensing Management

Objective: Develop best practice recommendations for the licensing of COAs and management of translations in clinical trials

Timeframe: The goal is to finish this work in 12 months.

Status: Kick-off September 28, 2022

- Ten sub-teams were identified and launched in Q1 2023. Three sub-teams consolidated in Q2, leaving 8 total.
- The initial list of deliverables was provided to the eCOA Leadership Team on September 25, 2023, for review and feedback. The first wave of deliverables for review was provided in late Q4 2023.

Final Deliverables:

- Final deliverables to be determined and may include manuscripts in a peer-reviewed publication, guidance materials, educational resources and/or reference documents.

Wave 2 - Topic 4:
eCOA Data Management

Project Liaison: Demian Humler (Clario)
Project Team Leaders: Alison Rowe (Roche) and Zinan Chen (Signant Health)

Topic: eCOA Data Management

Objective: Develop best practices and resources to support the range of different aspects of eCOA data management.

Timeframe: The goal is to finish this work in 12 months.

Status: The scoping phase completed in April 2023. The full project kick-off meeting occurred on September 15, 2023. Project team assignments are complete.

Final Deliverables: A number of outputs of different types and purposes are planned.

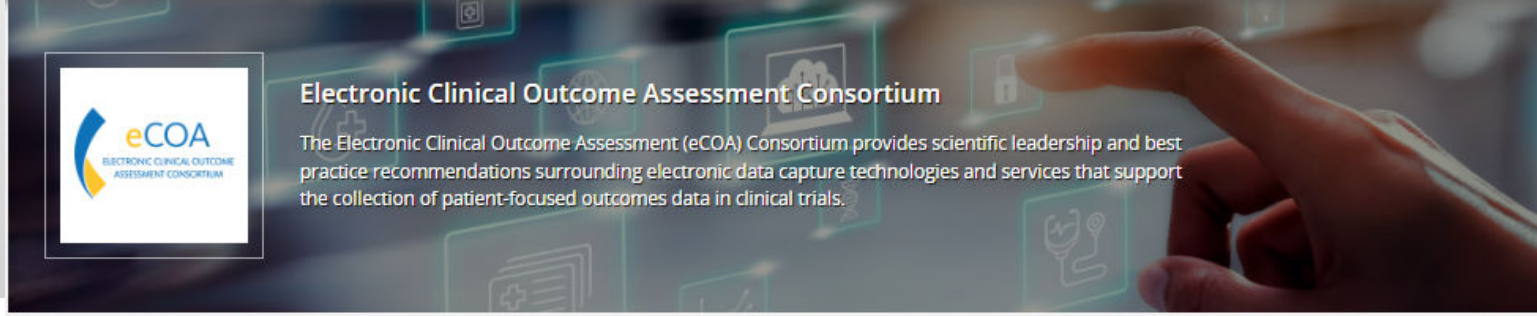
Proposed Projects

- **Topic: Site Readiness and Training**
  Objective: Work with collaborators from the 2019 DIA Forum on eCOA training to leverage outputs and enhance published best practice recommendations
- **Topic: Establishing Clinical Meaningfulness of Sensor-based Outcomes**
  Objective: To be developed

eCOA: Getting Better Together Initiative - Available Resources

https://c-path.org/programs/ecoac/

https://c-path.org/programs/proc/



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OVERVIEW

Introduction Resources Webinars Members eCOA Consortium Team

▸ eCOA Consortium Publications/White Papers Library

▾ eCOA: Getting Better Together Initiative

This initiative is a pre-competitive collaboration among Critical Path Institute, clinical trial sponsors from the Patient-Reported Outcome (PRO) Consortium, providers of electronic data collection technologies and services from the Electronic Clinical Outcome Assessment (eCOA) Consortium, contract research organizations, and regulators. The initiative was launched in 2019 to identify and address the root cause of challenges with the implementation of clinical outcome assessments collected electronically in clinical trials, elevate eCOA improvement efforts to the clinical trial industry level, and drive positive and lasting change in the eCOA ecosystem.

Quarterly Update

Please click here to view the most recent quarterly update, which includes the status of current and future areas of focus.

eCOA: Getting Better Together Initiative

Resources

Name	Description	Links
eCOA Lexicon	Without a common lexicon among eCOA vendors, sponsors, and regulators, the chance for miscommunication, errors, and inefficiencies increases. The objective of this team is to review the terminology and create an aligned eCOA Lexicon for use by stakeholders across the eCOA ecosystem.	eCOA Lexicon

PAST EVENTS

Oct 13, 2022 - Oct 14, 2022
DIA 2022 Digital Technology in Clinical Trials Conference

More Events >>

NEWS

Nov 3, 2022
eCOA Consortium Announces New Article for *Applied Clinical Trials*

Sep 29, 2022
eCOA Consortium Announces New Article for *Applied Clinical Trials*

Sep 27, 2022
Global Biopharmaceutical Leader to Usher C-Path in Next Phase of Growth and Innovation

Sep 8, 2022
C-Path's Kristen Swingle Named President

Thank you for supporting the eCOA: Getting Better Together Initiative

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