Welcome to the 13th Annual Patient-Reported Outcome Consortium Workshop

Event will begin at 11:01 am US ET

April 13-14, 2022

Acknowledgments

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- Support for the Electronic Clinical Outcome Assessment (eCOA) Consortium comes from membership fees paid by members of the eCOA Consortium (https://c-path.org/programs/ecoac).

- Additional support for the Patient-Reported Outcome (PRO) Consortium comes from membership fees paid by members of the PRO Consortium (https://c-path.org/programs/proc/).

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eCOA: Getting Better Together Initiative Update

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Executive Director, eCOA Consortium
Critical Path Institute

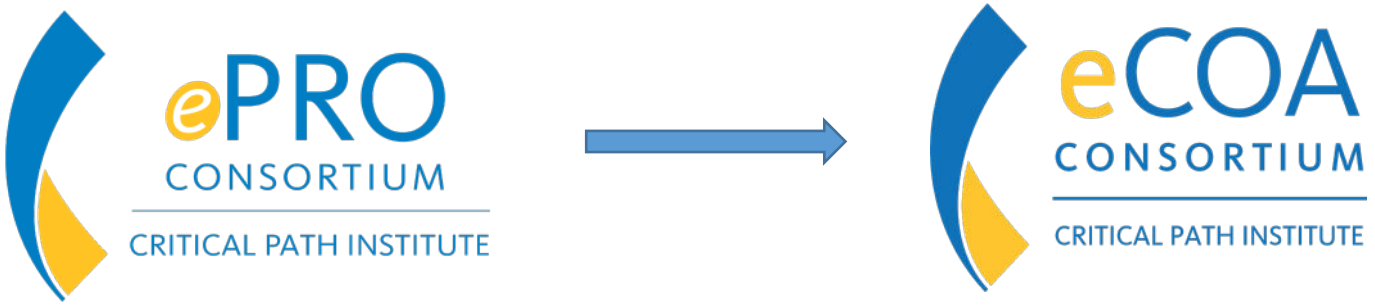
Agenda

- eCOA Consortium Overview
- Collaboration between Consortia
  - eCOA: Getting Better Together Initiative
    - Wave 1 Topics
      - Update
    - Wave 2 Topics
      - Update
    - Proposed Projects

eCOA Consortium

Background

The eCOA Consortium was established as the *ePRO Consortium* in 2011. With C-Path as the managing member, the 17 other 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. The name was changed to the *eCOA Consortium* in January 2022 to better reflect the capabilities of the membership and the scope of the Consortium's interests and direction.



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

eCOA Consortium: Members

eCOA Consortium: Active, Planned and Potential Projects

PRO CONSORTIUM
CRITICAL PATH INSTITUTE

Active

- Update to Best Practices Recommendations for Paper to Electronic Migration of PRO Measures
  - Updating established best practices with new recommendations addressing newer technology capabilities as well as the creation of a single point of reference for all migration best practices.
  - Target output: Peer-reviewed manuscript
- eCOA systems and Conformitè Européenne (CE) Mark
  - Examining how and when eCOA systems would be in-scope for CE certification
  - Target output: Self-published white paper

Planning

- Practical considerations for the implementation of wearables in clinical trials
- Opportunities for enhancing uptake of *bring your own device* (BYOD) methods for COA data collection

Potential

- Methods standardization for remote assessment of dermatological conditions
  - Candidate for FDA's Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program
  - In collaboration with PRO Consortium
- Methods standardization for assessing wearable device data collection compliance in clinical trials
  - In collaboration with PRO Consortium

eCOA Consortium: Recent publications

- Measurement Comparability of Electronic and Paper Administration of Visual Analogue Scales: A Review of Published Studies
  - The article was published in *Therapeutic Innovation & Regulatory Science* on February 10, 2022
  - Link: https://link.springer.com/article/10.1007/s43441-022-00376-2

- Best Practice Recommendations: User Acceptance Testing for Systems Designed to Collect Clinical Outcome Assessment Data Electronically
  - In collaboration with PRO Consortium
  - The article was published in with open access in *Therapeutic Innovation & Regulatory Science* on March 1, 2022.
  - Link: https://doi.org/10.1007/s43441-021-00363-z

Collaboration between Consortia

eCOA: Getting Better Together Initiative

Background

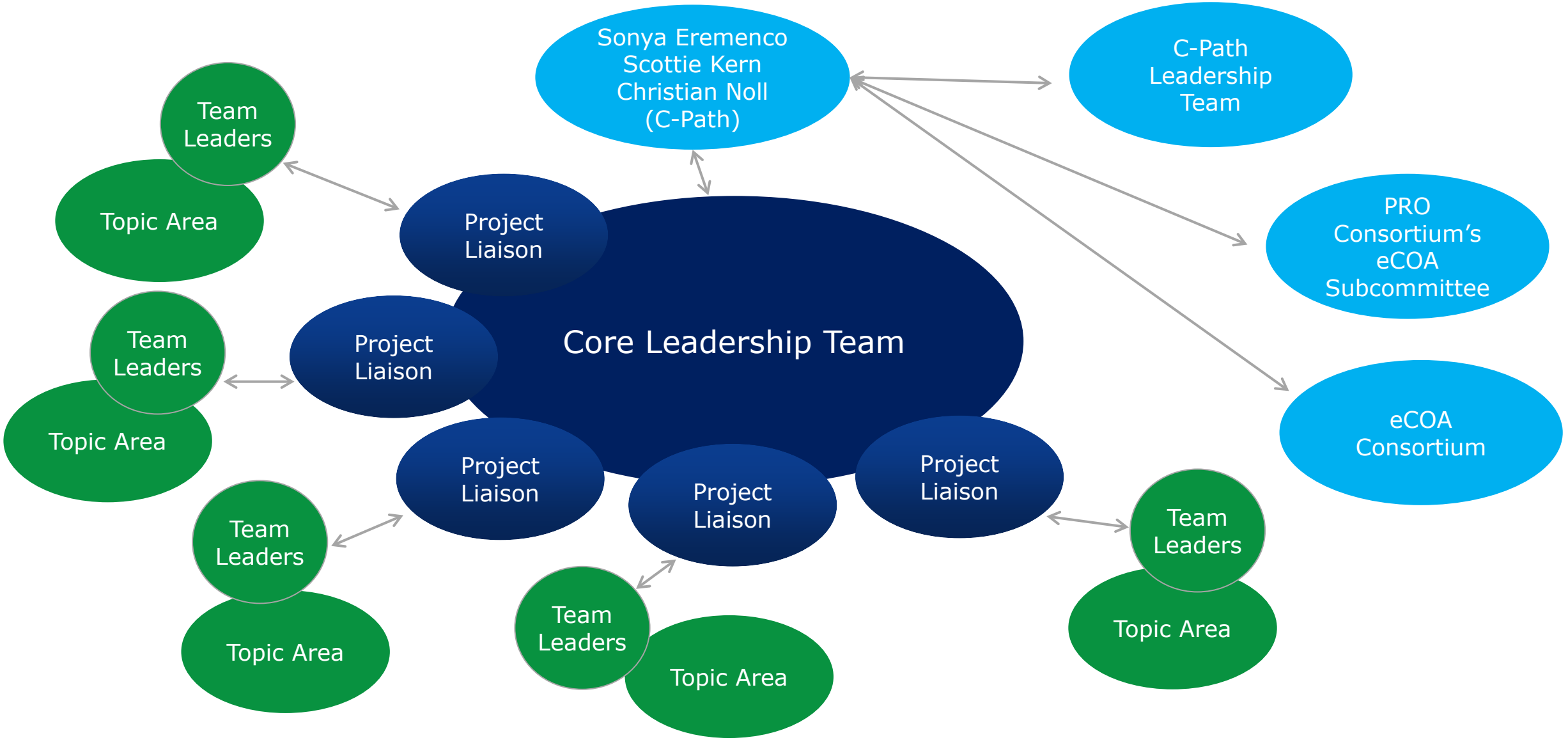
What it is:

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.

Final Deliverable:

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

Topic 2: eCOA Process/Workflow and Roles/Responsibilities

Project Liaison: Kate Zarzar (Genentech)
Project Team Leaders: Gena Gough (formerly of Clinical Ink) and 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 - Completed:

- February 2021: Final documents were completed and posted to the C-Path website.

Final Deliverables:

- Searchable PDF documents are available via the webpages for the PRO Consortium (www.c-path.org/proc) and the eCOA Consortium (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 - Completed:

- 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 includes stakeholders representing FDA, eCOA providers, sponsors, CROs, analytic vendors, CDISC, the PRO Consortium's eCOA Subcommittee, and the eCOA Consortium.

Status:

- Final Draft Completed: Q1 2022
- Target Submission Date: Q2 2022
  - The writing team will submit the manuscript to *Value in Health* in Q2 2022.

Final Deliverable:

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

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 practices 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 and 8, 2021, to discuss key highlights from the manuscript. A public webinar will be held following publication.
- Manuscript: The manuscript is nearing completion. The writing team will submit the manuscript to *Clinical Trials*.

Final Deliverable:

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

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

Project Liaison: To be determined

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 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 in 12-15 months.

Status:

- The kick-off meeting for this project occurred on January 27, 2021. The project team 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.
- Workstream 1 issued an eCOA experience survey to sites and clinical research associates in March 2022. A similar survey for participants will be issued in April 2022.
- Workstream 3 completed a survey of instrument developers in November 2021 to identify concerns and barriers to flexibility that this workstream can address.

Final Deliverable: A manuscript published in a peer-reviewed publication with open access

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

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

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 was released on April 8, 2022.
- Manuscript development was initiated in March 2022; target completion September 2022

Final Deliverables:

- A podcast and a manuscript published in a peer-reviewed publication with open access

Wave 2 Topics – Planned

- **Priority 3 – Q2 2022 – NEW**
  Topic: eCOA Translations and Licensing Management Process (TLM)
  Objective: Develop best practices for the management of translations in clinical trials
  Tentative Launch Date: Q2 2022
- **Priority 4 – Q3 2022**
  Topic: Data Management
  Objective: Develop best practice recommendations, with particular focus on the collaboration among sponsors, CROs, and eCOA providers
- **Priority 5 – Q4 2022**
  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

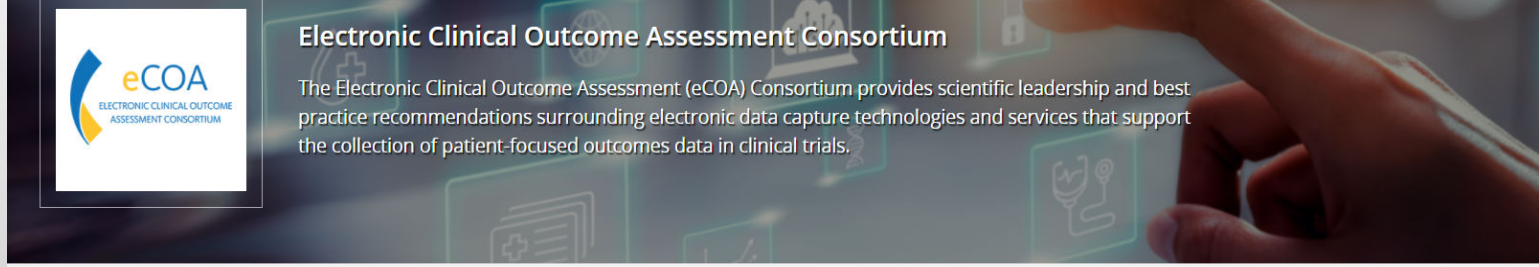
Proposed Projects

- **Topic: Request for Proposal (RFP) – Order Form/Annotated Checklist and Best Practice Recommendations**
  Objective: Align expectations on and define the RFP process; outline best practices for sponsors, CROs, and eCOA providers
- **Topic: Design Requirements**
  Objective: Create best practice recommendations to define content when developing design requirements
- **Topic: Data Transfers**
  Objective: Develop an annotated data transfer agreement (DTA) template and best practice recommendations for operational aspects (e.g., timing and stakeholder responsibilities) of data transfers
- **Topic: eCOA Compliance Thresholds**
  Objective: Create best practice recommendations for the development, implementation, and evaluation of eCOA compliance thresholds to determine the impact of data collection thresholds on the clinical statistical analysis plan
- **Topic: Approaches to Optimizing Timelines and Efficiencies for eCOA Deployment**
  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 | Best Practice Documents | Webinars | eCOA Initiative | Members | eCOA Consortium Team

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
eCOA: Process/Workflow and Roles/Responsibilities Contributors	Define an eCOA process and workflow that aligns expectations for successful eCOA strategy development and deployment and clarifies roles and responsibilities.	Abbreviations Table Roles Table

NEWS

Mar 2, 2022
C-Path Welcomes ActiGraph

Mar 2, 2022
eCOA Consortium Announces Publication of Open Access Article

Jan 11, 2022
C-Path's ePRO Consortium Announces Rebranding, Changes Name to eCOA Consortium

Dec 22, 2021
Welcome uMotif

More News >>

PUBLICATIONS

Mar 2, 2022
Measurement Comparability of Electronic and Paper Administration of Visual Analogue Scales: A Review of Published Studies

Contact Details

For further information about the eCOA Consortium and the eCOA: Getting Better Together Initiative, please contact us:

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- Christian Noll cnoll@c-path.org