Educational Series Webinars

- Monthly, usually last Wednesday
- Attendees are asked to join DIA
- If you'd like to present or have suggestions for topics, please contact emuella.flood@astrazeneca.com
- To ask a question, use the Q & A button

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DIA

eCOA: Getting Better Together Initiative – An Update from C-Path's PRO Consortium and ePRO Consortium

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Housekeeping

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SUBMIT QUESTIONS USING THE Q & A FEATURE

RECORDING

This webinar is being recorded. Following the webinar, the recording will be available on the C-Path website (https://c-path.org/programs/eproc/) and on DIA Study Endpoints Community website (https://diaglobal/en/get-involved/communities)

Electronic Patient-Reported Outcome (ePRO) Consortium Webinars

eCOA: Getting Better Together Initiative – An Update from C-Path's PRO Consortium and ePRO Consortium

February 17, 2021

ePRO CONSORTIUM
CRITICAL PATH INSTITUTE

PRO CONSORTIUM
CRITICAL PATH INSTITUTE

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- Support for the ePRO Consortium comes from membership fees paid by members of the ePRO Consortium (https://c-path.org/programs/epro/).
- 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/).

Disclaimer

- The views and opinions expressed in the following slides are those of the individual presenters and should not be attributed to their respective organizations/companies or the Critical Path Institute.

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Agenda

- C-Path Overview
- ePRO Consortium Overview
- PRO Consortium Overview
- Collaborations between consortia
  - eCOA: Getting Better Together Initiative
  - COVID-19 Risk Assessment and Mitigation Strategies
- Collaboration with DIA
- Q & A

About Critical Path Institute (C-Path)

- Established in 2005 by the University of Arizona and the U.S. Food and Drug Administration (FDA)
- An independent, non-profit organization
  - Dedicated to implementing FDA's Critical Path Initiative
  - Enables pre-competitive collaboration that includes regulatory input/expertise
- C-Path's aim is to accelerate the pace and reduce the costs of medical product development through the creation of new data standards, measurement standards, and methods standards that aid in the scientific evaluation of the efficacy and safety of new therapies.

ePRO Consortium Overview

Overview

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.

ePRO Consortium: Members

ePRO Consortium Activities

The ePRO Consortium:

- Collaborates with PRO Consortium member firm representatives
- Interacts with regulatory agencies
- Provides scientific leadership for eCOA studies
- Performs electronic implementation assessments
- Provides educational opportunities
- Participates in innovative research
- Contributes to eCOA scientific literature
- Develops best practice recommendations

Best Practice Recommendations

- Best Practices for Migrating Existing Patient-Reported Outcome Measures to a New Data Collection Mode
- Best Practices for Maximizing Electronic Data Capture Options during the Development of New Patient-Reported Outcome Measures
- Best Practices for Electronic Implementation of Response Scales for Patient-Reported Outcome Measures
- COVID-19: Risk Assessment and Mitigation Strategies for the Collection of Patient-Reported Outcome Data through Clinical Sites

Available at www.c-path.org/eproc

Webinars

- **October 29, 2020:** COVID-19: Risk Assessment and Mitigation Strategies for the Collection of PRO Data through Clinical Sites – Lessons Learned

- **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

PRO Consortium Overview

PRO Consortium

- The PRO Consortium was formed in late 2008 by C-Path in cooperation with FDA's Center for Drug Evaluation and Research and the pharmaceutical industry, and formally launched in March 2009.
- The mission of the PRO Consortium is to establish and maintain a collaborative framework with appropriate stakeholders for the qualification of PRO measures and other COAs that will be publicly available for use in clinical trials where COA-based endpoints are used to support product labeling claims.

PRO Consortium: Members

Goal of PRO Consortium Working Groups

To generate and/or compile the necessary evidence to enable new or existing COAs to be qualified by FDA for use in treatment trials where COA-based endpoints can be used to evaluate clinical benefit

The PRO Consortium has 9 active working groups with 15 COAs in CDER's COA Qualification Program

Working Groups that have Completed Initial Goal

- **Asthma WG** - Obtained FDA qualification of *Asthma Daytime Symptom Diary* (*ADSD*) and *Asthma Nighttime Symptom Diary* (*ANSD*) – March 2019
- **Non-Small Cell Lung Cancer WG** – Obtained FDA qualification of *Non-Small Cell Lung Cancer Symptom Assessment Questionnaire* (*NSCLC-SAQ*) – April 2018
- **Depression WG** – Obtained FDA qualification of *Symptoms of Major Depressive Disorder Scale* (*SMDDS*) – November 2017
- **Myelofibrosis WG** – Derived the consensus-defined *Myelofibrosis Symptom Assessment Form v4.0* (*MFSAF v4.0*)

The above measures are being actively licensed for use in clinical trials via the following website: https://www.c-pathcoas.org/

Most Recent Qualification

- **Irritable Bowel Syndrome (IBS) WG** –
  - *Diary for Irritable Bowel Syndrome Symptoms – Constipation (DIBSS-C)*
- Qualification Date: December 18, 2020
- Information available at FDA Qualified COAs website: https://www.fda.gov/drugs/clinical-outcome-assessment-coa-qualification-program/ddt-coa-000005-diary-irritable-bowel-syndrome-symptoms-constipation-dibss-c
- Licensing information will be available in the coming months at: https://www.c-pathcoas.org/

Collaboration between Consortia

eCOA: Getting Better Together Initiative

Background

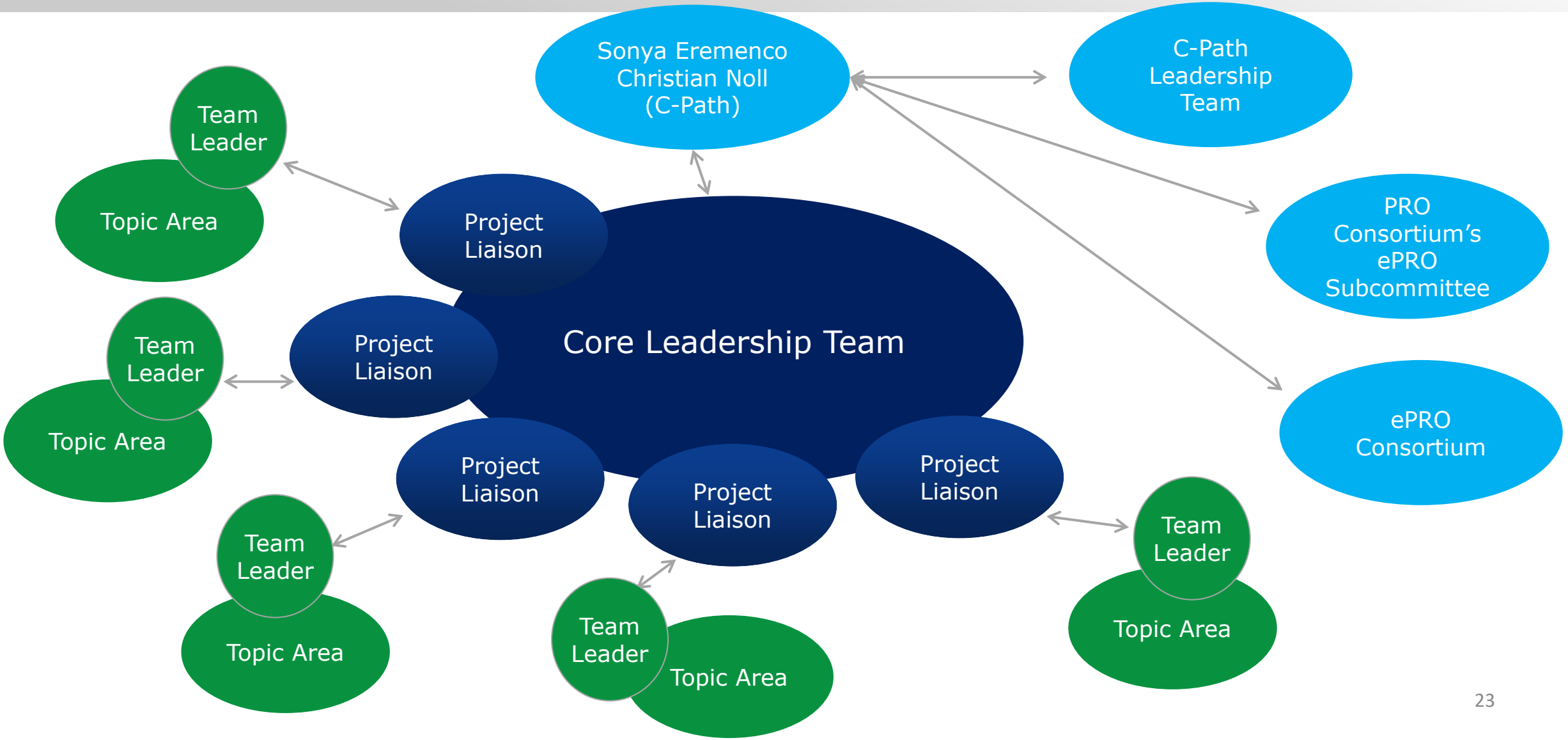
What it is:

A collaborative, pre-competitive initiative among C-Path, clinical trial sponsors from the PRO Consortium, eCOA providers from the ePRO 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 Topics
Launch Date: June 2019

Topic 1: eCOA Lexicon

Topic 2: eCOA Workflow/Process and Roles and Responsibilities

- Strategy/Protocol Design
- Study Start-up/Study Build
- Study Launch
- Study Conduct/Monitoring
- Study Close-out/Archive

Wave 1 Topics
Launch Date: June 2019 (continued)

Topic 3: Best Practice Recommendations: User Acceptance Testing for Systems Designed to Collect Clinical Outcome Assessment Data Electronically (manuscript in development)

Topic 4: Best Practice Recommendations for ePRO Dataset Structure and Standardization to Support Drug Development (manuscript in development)

Topic 5: Best Practice Recommendations for Changing eCOA Data (manuscript in development)

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 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.

Status:

- This project will likely run through the duration of Waves 1, 2, and 3.
- May 2020: Team finalized a review of the glossary contained in the manuscript titled "Best Practice Recommendations: User Acceptance Testing for Systems Designed to Collect Clinical Outcome Assessment Data Electronically"
- June 2020: Updated terms and phrases submitted by the other topic groups and refined original terms
- November 2020: Reviewed by members of eCOA: Getting Better Together Initiative team

Final Deliverable:

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

Topic 2: eCOA Process/Workflow and Roles/Responsibilities

Project Liaison: Kate Zarzar (Genentech)

Project Team Leaders: Gena Gough (Clinical Ink) and Jennifer Lord-Bessen (BMS)

Objective:

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

Status:

- January 2021: Final draft documents were circulated to the sub-teams and more broadly to members of the eCOA: Getting Better Together Initiative team for review and feedback.

Final Deliverables:

- Searchable PDF documents are available via the webpages for the PRO Consortium (www.c-path.org/proc) and the ePRO Consortium (www.c-path.org/eproc).
  - 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 ePRO Subcommittee and the ePRO Consortium.

Status:

- The manuscript was approved by the Coordinating Committees of the ePRO Consortium and PRO Consortium.
- The writing team is preparing to submit the manuscript to *Therapeutic Innovation & Regulatory Science* for publication consideration.

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 vendors, sponsors, CROs, analytic vendors, CDISC, the PRO Consortium's ePRO Subcommittee, and the ePRO Consortium.

Status:

- Progress on the manuscript is continuing
- First Draft Completed: Q2 2020
- Final Draft Target Date: Q2 2021
- Virtual Roundtable: Q3 2021

Topic 5: Best Practice Recommendations for Changing eCOA Data

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

Objective:

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

Status:

- Develop manuscript outlining problems and best practices for:
  - Handling requests from investigators to change PRO and other COA data
  - Core principles and processes to address these requests
  - eClinical Forum representatives joined the project team in October 2020.

Final Deliverable:

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

Wave 2 Topics – 2020/2021

Wave 2 topics will begin on a rolling basis as projects in Wave 1 are completed.

- **Priority 1 – Q4 2020**
  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
- **Priority 2 – Q4 2020**
  Topic: Bring Your Own Device (BYOD)
  Objective: Develop best practice recommendations for clinical trial implementation of BYOD
- **Priority 3 – Q3 2021**
  Topic: Data Management
  Objective: Develop best practice recommendations, with particular focus on the collaboration among sponsors, CROs, and eCOA partners
- **Priority 4 – Q4 2021**
  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

Wave 2 - Topic 1:
Support Flexible Approaches to PRO Data Collection

Project Liaison: Linda Nelsen (GSK)
Project Team Leaders: Linda Nelsen (GSK) and Valdo Arnera (ERT)

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

Status:

- The kick-off meeting for this project occurred on January 27, 2021.
- Meetings will be held every 2 weeks throughout Q1 2021.

Final Deliverable:

- TBD

Wave 2 - Topic 2:
Bring Your Own Device

Project Liaison: Shelly Steele (MedAvante)
Project Team Leaders: Karl McEvoy (Roche) and Lisa Charlton (Medrio)

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:

- The kick-off meeting for this project occurred on February 12, 2021.

Final Deliverable:

- TBD

Wave 3 Topics – 2022/2023

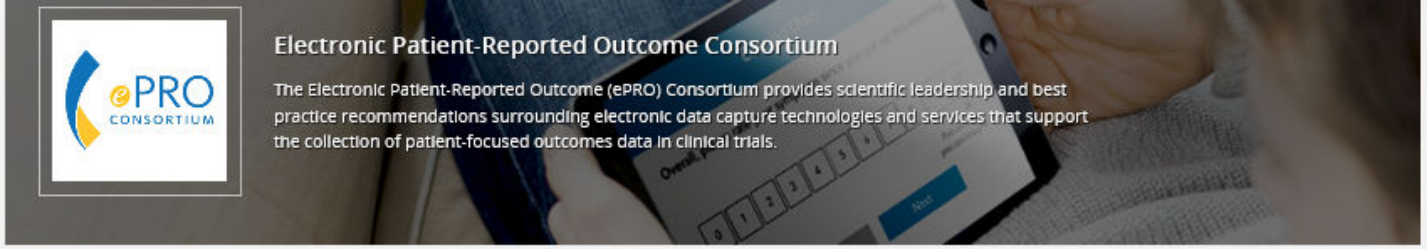
Wave 3 topics will begin on a rolling basis as projects in Wave 2 are completed.

- **Priority TBD**
  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
- **Priority TBD**
  Topic: Design Requirements
  Objective: Create best practice recommendations to define content when developing design requirements
- **Priority TBD**
  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
- **Priority TBD**
  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
- **Priority TBD**
  Topic: Approaches to Optimizing Timelines and Efficiencies for eCOA Deployment *New*

eCOA: Getting Better Together Initiative - Available Resources

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

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



Home > Programs > ePRO Consortium

OVERVIEW | Introduction | Best Practice Documents | Webinars | eCOA Initiative | Members | ePRO 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 Patient-Reported Outcome (ePRO) Consortium, contract research organizations (CROs), and regulators (FDA). The initiative was launched in 2019 to identify and address the root cause of challenges with the implementation of clinical outcome assessments collected electronically (eCOA) in clinical trials, elevate eCOA improvement efforts to the clinical trial industry level, and drive positive and lasting change in the eCOA ecosystem.

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	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 Process Step Table Process Workflow

UPCOMING EVENTS

Feb 17, 2021
CRITICAL PATH INSTITUTE
WEBINAR: eCOA: Getting Better Together Initiative – An Update from C-Path's PRO Consortium and ePRO Consortium

PAST EVENTS

Oct 29, 2020
ePRO CONSORTIUM
COVID-19: Risk Assessment and Mitigation Strategies for the Collection of PRO Data through Clinical Sites – Lessons Learned

More Events >>

PRESENTATIONS

Jun 25, 2019
Best Practices for the Electronic Migration and Implementation of Clinician-Reported Outcome Assessments in Clinical Trials

May 22, 2019
Measurement Comparability of Electronic and Paper Administered Visual Analogue Scales: A Review of Published Studies

Nov 10, 2018
Comparability of a Provisioned Device Versus Bring Your Own Device for Completion of Patient-Reported Outcome (PRO) Measures by Participants with Chronic Obstructive Pulmonary Disease (COPD): Quantitative Interview Findings

Coronavirus Disease 2019 (COVID-19): Risk Assessment and Mitigation Strategies for the Collection of Patient-Reported Outcome Data through Clinical Sites

Overview

- Members of the Electronic Patient-Reported Outcome (ePRO) Consortium and the Patient-Reported Outcome (PRO) Consortium were invited to collaborate on a risk assessment and mitigation plan for clinical trials in response to the impact of COVID-19.
- Over a 4-week period beginning in March 2020, member representatives participated in a series of teleconferences in which they engaged with others to provide suggestions for the assessment of risk and mitigation strategies for their firms.
- The resulting presentation focuses on the current challenges of capturing PRO data originally intended to be collected electronically (i.e., ePRO) from study participants during in-person visits to clinical trial sites. Recommended risk assessment and mitigation strategies are provided for consideration by trial sponsors and electronic clinical outcome assessment (eCOA) providers to facilitate the continued collection of PRO data in clinical trials.

Overview - Continued

- The presentation is available via C-Path's main website under News. The presentation is also posted in the Best Practice Documents section of the ePRO Consortium website.
- A webinar was presented on October 29, 2020, and a recording is available via the ePRO Consortium website under the Webinars section.

Collaboration with DIA

DIA's Meet the Experts: Digital Technology in Clinical Trials Knowledge Exchange

DIA's Meet the Experts: Digital Technology in Clinical Trials Knowledge Exchange – "Evaluation of Digital Technologies to Demonstrate Clinical and Analytical Validation and Meaningfulness of Technology-Driven Measures" with Live Question and Answer Following

- Date: April 30, 2021
- Time: 10:00 am – 1:00 pm Eastern (US)
- Registration is open: https://www.diaglobal.org/en/course-listing/webinar/2021/04/meet-the-experts-digital-technology-in-clinical-trials-knowledge-exchange

2021 DIA Global Annual Meeting

eCOA 102 – Beyond the Basics: Operational, Scientific, and Best Practices for eCOA and Wearable Devices in Clinical Trials

- Date: Wednesday, June 23, 2021
- Time: 2:00 pm – 5:00 pm Eastern (US)
- Learning Objectives:
  - Learn best practices for implementation, deployment, and operations of eCOA studies
  - Understand scientific and regulatory principles underlying eCOA data capture and the evolving thinking relating to the translation and comparability between modes of data collection
  - Discuss the emerging science of wearables/mobile sensors, and how to get the most out of these data to support trial endpoints
  - Registration is open: https://www.diaglobal.org/en/course-listing/tutorials/2021/06/033p-ecoa-102-beyond-the-basics-operational-scientific-and-best-practices-for-ecoa-and-wearable-devices-in-clinical-trials

2021 DIA Global Annual Meeting

The Rare Disease Clinical Outcome Assessment Consortium: Collaboration Aimed at Accelerating Rare Disease Drug Development

- Date: Wednesday, June 30, 2021
- Time: 4:00pm - 5:00pm EDT
- Learning Objectives:
  - Describe the unmet need that the Rare Disease Clinical Outcome Assessment Consortium seeks to address.
  - Describe the Rare Disease COA Resource, including the purpose, process for development, domains included, and progress to-date.
  - Describe findings of a literature review to identify measurement approaches to deal with heterogeneity in clinical trial settings and applications to rare diseases.

2021 DIA Digital Technology in Clinical Trials Conference

- The ePRO Consortium is a co-sponsor of the 2020 DIA Digital Technology in Clinical Trials Conference
- A virtual conference planned for October 28-29, 2021
- Members of the ePRO Consortium are represented on the Steering and Planning Committees
- Register: https://www.diaglobal.org/en/conference-listing/meetings/2021/10/digital-technology-in-clinical-trials#showcontent

To submit questions, use the Q & A feature

Electronic Patient-Reported Outcome (ePRO) Consortium Webinars

Thank you for attending this webinar!

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