

SPOTLIGHT NEWS

Announcements

Welcome to the first edition of Spotlight News! As the name suggests, we'll use this as an opportunity to share the latest news about the resources produced by the eCOA Consortium and other notable industry events. Speaking of which, we are excited to announce the upcoming launch of the eCOA Consortium's LinkedIn Group, CONNECT!



C-Path's eCOA Consortium: eCOA CONNECT

in https://linkedin.com/groups/14297072

We invite **all** industry colleagues operating in the eCOA space to join us and drive the discussion. The group is open to all eCOA Consortium Member colleagues now and we will begin accepting requests to join the group from other industry colleagues in October.

eCOA Educational Series

In response to appeals from Consortium members and other industry colleagues, the eCOA Consortium is launching our eCOA Educational Series on September 27! The series will feature three different formats:

eCOA Exchange

Join our panel of eCOA Consortium colleagues with specific

expertise as they explore key eCOA/DHT topics.

live during the discussion.

30 minutes + Q&A time

Bring your eCOA questions! A panel of experts will be ready to discuss questions and suggestions on general eCOA-related matters; this is an open forum for all industry colleagues to

engage in. Questions may be submitted in advance or raised

Maximum 30 minutes

eCOA Masterclass

A more traditional, didactic webinar that will provide a deep exploration of an eCOA-related topic and share experience-based best practices.

55 minutes including Q&A

Please be sure to register for our first eCOA Exchange coming up on September 27!



The series will continue with events through the end of 2023 that will focus on:

- eCOA Exchange: What is (and what is not) an appropriate wearable device?
- eCOA Exchange: What is (and what is not) an appropriate wearable device.
 eCOA Masterclass: eCOA project planning with multiple stakeholders.
- eCOA Clinic: BYOD

Suggested topics are always welcome!

CONTACT US



Impact

The eCOA Consortium's work is improved quality, practicality and acceptability of electronic capture of clinical trial endpoint data. Since its inception in 2011, the eCOA Consortium members have produced, independently or in collaboration, the following educational resources for the medical product development community:

- 6 best practices white papers14 webinars
- 14 webinars16 peer-reviewed publications10 poster presentations
- 17 podium presentations
 More information about these resources can be found



Project Spotlight: Translations and Licensing Management



<u>here</u>.

In early 2022, the eCOA Consortium proposed a project in the field of eCOA translations and the associated process of licensing COA measures for electronic implementation. These two activities are persistent points of friction in the start-up phase of clinical trials with an eCOA component, so a collaborative project between the eCOA Consortium, the PRO Consortium and ISOQOL's Translations and Cultural Adaptation Special Interest Group was launched in late 2022 to develop tools, resources and best practices to support

those critical processes. Eleven sub-teams were formed covering a range of sub-topics from copyright requirements to libraries. A number of the sub-teams are close to completing their target outputs, and these resources will be presented to the industry in 2024.

Recent Publications



The output of our collaborative effort with the PRO Consortium and CDISC entitled Best Practice Recommendations for Electronic Patient-Reported Outcome Dataset Structure and Standardization to Support Drug Development was fully published in *Value in Health* in August. This paper provides best practice recommendations covering the application of CDISC standards to maintain the integrity of ePRO datasets, reduce stakeholder burden, and ensure regulatory compliance.



The eCOA Consortium has an ongoing series of articles in <u>Applied Clinical Trials</u> magazine, the latest of which to be published summarizes the first eCOA Forum, which was held in Silver Spring, MD in April 2023 and saw members of the eCOA Consortium, the PRO Consortium and FDA convene to discuss two key topics; BYOD and item skipping.

Upcoming Events

| | eCOA Exchange #2 | |
|---|--------------------------------------|--------------------------|
| Topic | Date/Location | Registration Information |
| What is (and what is not) an appropriate wearable device for use in clinical trials? | October 19, 2023 | Coming Soon! |
| | SCOPE EU | |
| Topic | Date/Location | Registration Information |
| eCOA- and ePRO-Centricity in a Digital Health World and BYOD: The Critical Enabler of Digital Health Hybrid Trials | October 18, 2023 Barcelona, Spain | Registration Link |
| 2023 E | EU eCOAC Face-to-Face | Meeting* |
| Date/Location | Registration Information | |
| November 16, 2023 AC Hotel Marriott Bella Sky Copenhagen | Registra | tion Link |
| | | |

Members







For questions or information on becoming a member of the eCOA Consortium, click here.

c-path.org/ecoac