



# eCOA Consortium Update

Clinical Outcome Assessment Program Annual Meeting  
April 16-17, 2026  
Washington, D.C.

# Disclaimer

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# eCOA Consortium Members





*15 Year Anniversary*  
**Electronic Clinical Outcome  
Assessment Consortium**



# Selected Highlights



# eCOA & the EU's Clinical Trial Regulation

Contemporary Clinical Trials Communications 50 (2026)

## 1.24 Question: How are patient facing documents expected to be submitted ?

77. **Answer:** Patient facing documents are documents, other than recruitment material or subject information sheets, presented to clinical trial participants during the conduct of the clinical trial. These can be questionnaires, patient diary, patient card or patient reported outcomes (PRO/ePRO). Below, the text explains the difference between recruitment material and patient facing documents.

78. Annex I of the CTR describes the content of the clinical trial application part I and part II. Section K60 of annex I refers exclusively to recruitment material (copies of the advertising material, including any printed materials, and audio or visual recordings), and section L61 refers exclusively to all information given to the subjects together with the informed consent form (or, where applicable, to their legally designated representatives) before their decision to participate or abstain from participation in the clinical trial. Recruitment material or subject information sheets are to be submitted in part II, and no other documentation shall be submitted under these sections. If along the clinical trial duration specific concerns arise requiring informing the clinical trial participants or requiring a re-consent these materials should also be provided within a substantial modification as part II documents.

79. Patient facing documents that are linked to the endpoints of the clinical trial shall be provided together with the protocol in part I of the clinical trial application, in line with Annex I of the CTR (section D14 and D17I). These documents will be assessed during the part I assessment. See also Q1.5.

80. Patient facing documents will need to be submitted in line with Annex II of this document (i.e., for several Member States patient facing documents should be provided to the CT participants in a language understandable for the CT participants). Sponsors are responsible for ensuring the quality of the texts to be provided to the participants.

81. There is currently no legal basis in the CTR to request the submission of all patient facing documents in the part II documentation package and/or to require their translation.

EU's EUDRALEX Volume 10  
Q&A – Version 7.1

available at ScienceDirect

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www.elsevier.com/locate/

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EU-CTR's success depends on collective awareness  
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## 1.24. Question: How are patient facing documents expected to be submitted ?

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76. Patient facing documents that are related to primary and secondary endpoints of the clinical trial shall be provided together with the protocol in part I of the clinical trial application, in line with Annex I of the CTR (section D14 and D17I). Patient facing documents that are linked to other endpoints of the clinical trial shall not be submitted.

77. In case a clinical trial will only be conducted in one MS (mononational), patient facing document should only be submitted in Part I in the MS language (or English if acceptable according to Annex II of this document).

78. In case a clinical trial will be conducted in more than one Member State (multinational), patient facing documents should be submitted in English in Part I.

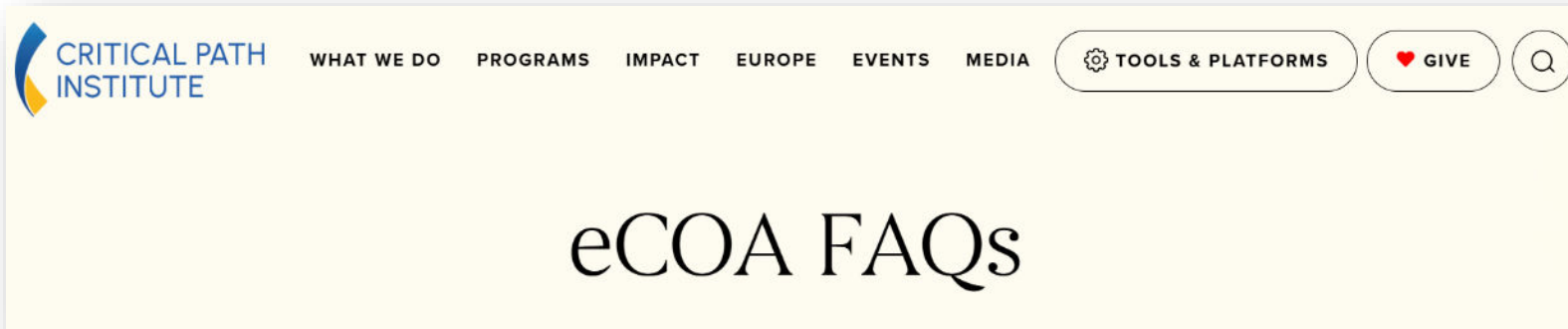
79. Any translation of the patient facing documents will need to be submitted in Part II in line with Annex II of this document (i.e., for several Member States).

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patient facing documents in the part II documentation package and/or to

EU's EUDRALEX Volume 10  
Q&A – Version 7.2



# eCOA & DHT FAQs



<https://c-path.org/ecoa-faqs/>

**eCOA Basics**

**Bring Your Own Device (BYOD)**

**COA-specific Considerations**

**Data Management**

**DHTs/Sensor-based Wearables (sDHTs)**

**Migration, Implementation, and Design**

**Regulatory**

# DHT Accelerator

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- A **pre-competitive arena** for expression of and alignment on the specific needs of DHT provider community, both independent of and supplementary to sponsor/CRO/intermediary perspectives
- Identify **opportunities** for standardization, best practice development and industry education
- Serve as the conduit for DHT provider access to broader **C-Path DHT Coalition**
- Support the development of what **evidence** – both quantitative and qualitative - looks like for DHTs
- Strategise on **disease-specific** opportunities

# Collaborations with PCE Consortium

## Closing/Closed in 2026

- *Event-driven eDiaries*
- *Flexible approaches*
  - Peer-reviewed publication
  - 2 White papers
- ***Translations and Licensing Management (TLM)***
  - ***Microsite launch Q3***
- *Accessibility of ePROs*
  - Peer-reviewed publication
  - White paper

## Launching/early stage

- *COA Measure Owners Forum*
- *eCOA Scientific Strategy*
  - *eCOA and sDHTs (eCOAsT)*
    - Cross-consortia proposals
    - Scoping Committee
    - Top 3 candidates
- *Accessibility of ePROs*
  - eCOA, PCEC & RD-COAC

## Goals

- **Reduce the friction** inherent in the process of acquiring licenses for the use of COA measures in clinical trials and the subsequent electronic implementation of those measures
  - **Foster alignment** between all stakeholders involved in eCOA measure development, licensing and implementation
- **Issue prioritization by Measure Owners (MOs) via survey**
  - **2 meetings held**
    - December 2025: Processing timelines
    - March 2026: Sample copies
  - **Example outputs**
    - MO FAQs
    - Licensing information requirements
    - “What is public domain?”
  - **Upcoming topics**
    - Negotiations
    - Translations
    - Version control
    - Pricing...etc
  - **MO recruitment is ongoing**

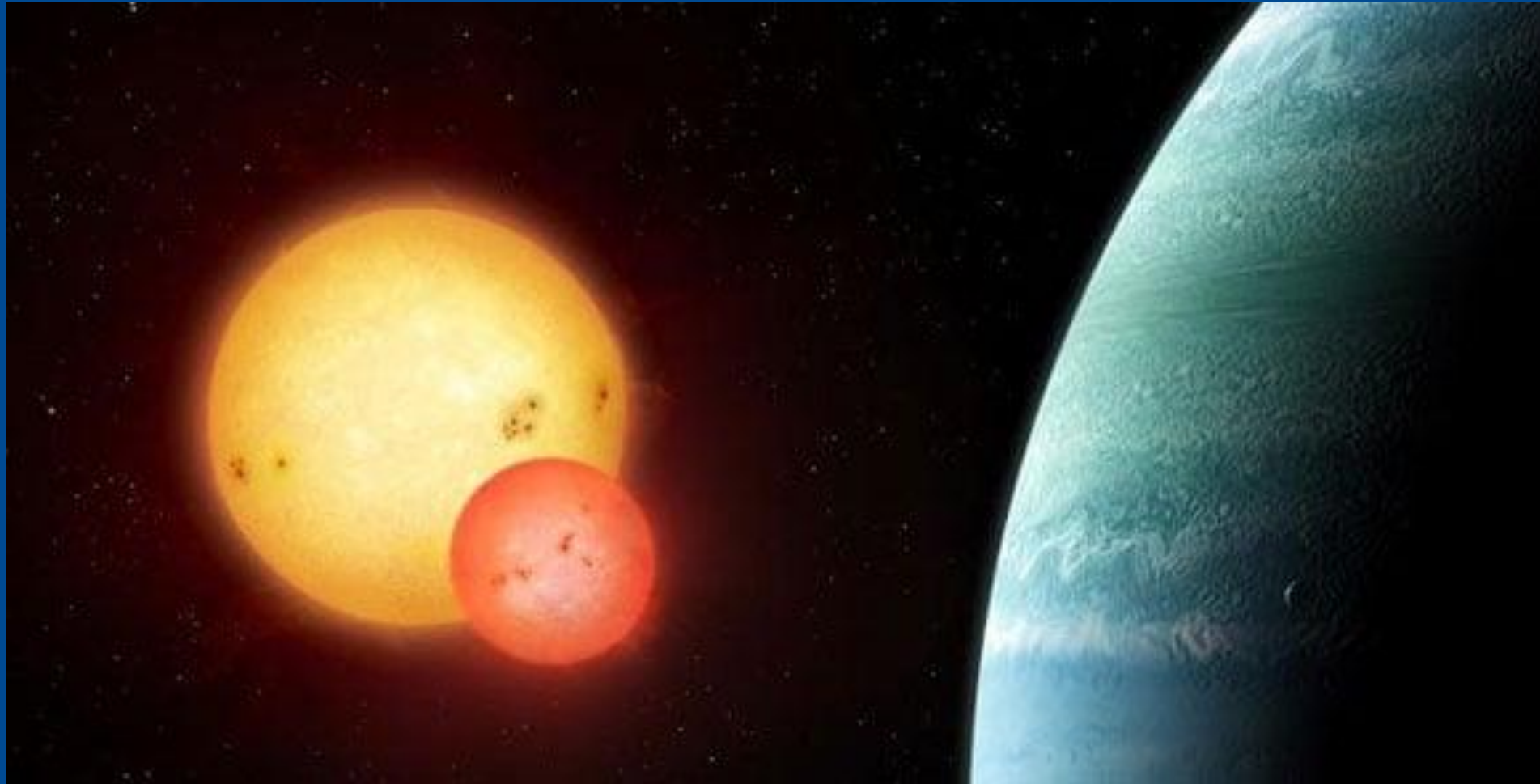
# 2025 EU F2F @ ICON HQ, Dublin



# 2026 US F2F



# Keplar-453





**Thank You!**

Advancing Drug Development. Improving Lives. Together