



Pulling back the curtain:
Multi-stakeholder insights on
electronic clinical outcome
assessment implementation

Clinical Outcome Assessment Program Annual Meeting
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Session objectives

- Explore a number of frequently occurring scenarios in clinical trial execution and their corresponding impact on eCOA implementation.
- Allow multiple stakeholders to share their own perspectives based on their individual experiences and roles, of how they are affected by these scenarios, sharing details that would not normally be visible to other stakeholders involved in the process.

Session format

- Audience will be presented with 5 theoretical scenarios that represent real-life experiences of the panel
- For each scenario, the Audience are invited to respond to a related question using Mentimeter
- The Panel will discuss each scenario from their individual perspectives
- Q&A session

Audience Participation with Mentimeter

There are two ways to join
by phone!

1. Join by webpage at menti.com

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2. Join by QR code



Please Note

- You will not be able to skip ahead with the questions
- If you have trouble with the QR code capture, please join by web browser at menti.com
- Your submission will be anonymous
- Overall results will be available on your screen at the end of polling

Our Panel

- eCOA Provider: **Paul O'Donohoe (Medidata)**
- Sponsor: **Lynne Germscheid (BMS)**
- Sponsor: **Alex Rokotas (Bayer)**
- Translations/Licensing: **Caroline Anfray (IQVIA)**
- Site Representative: **Jennifer Cook (Accellacare Site Network)**

Scenario 1: Unresponsive copyright holder

It is May 2026. A global clinical trial (10 countries) has several PROs to be captured electronically that support a key primary endpoint. The Sponsor requires first Site Initiation Visit by end of August, but the copyright holder of one specific PRO is not responding to questions on licensing of the measure.



Scenario 2: Protocol amendment, new country

The sponsor wishes to enforce a protocol amendment that will include a new country while the eCOA system build is in mid-development.



Scenario 3: BYOD concerns

A clinical trial team is considering the use of BYOD. There is support from Patient Advisory Groups but concerns remain around perceived operational risks, evidence of acceptance of BYOD by sites and participants, and regulatory acceptance.



Scenario 4: Screening diary for inclusion/exclusion criteria

The inclusion/exclusion criteria for a trial requires completion of a screening diary for 7 days with completion expectation of 6/7 days.



Scenario 5: Unapproved paper PROs in site use

A site elects to print off paper copies of PROs for a participant to complete as the participant doesn't like using the provisioned eCOA device. The paper versions are not approved.



Questions and Answers



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