# The Critical Path Institute Podcast: eCOA Conversations with Florence Mowlem, Karl McEvoy, and Brian Lillis



Welcome to the latest Critical Path Institute Podcast episode—the first in the Electronic Clinical Outcome Assessment (eCOA) Conversations series. This engaging panel features industry veterans reacting to the question, "What makes a good eCOA partner?" In addition to host Scottie Kern, Executive Director of C-Path's eCOA Consortium, the panel includes Dr. Florence Mowlem, Chief Science Officer at uMotif, YPrime's Vice President of eCOA and Patient Technologies, Dr. Karl McEvoy, and Brian Lillis, Director of Clinical Outcome Technologies at ICON. Each guest shares their unique journey in the eCOA space, their perspectives on the evolving role of technology in clinical trials, and the importance of collaboration between sponsors and providers. The episode explores how meaningful partnerships can drive successful outcomes, enhance the quality of data collection, and ultimately, improve patient experiences in clinical studies. With insights on what constitutes a solid eCOA partnership, the participants discuss trust, transparency, and effective governance structures. The conversation emphasizes that while the challenges of eCOA may seem daunting, a robust public-private partnership grounded in mutual understanding can lead to the successful capture of trial participant voices in clinical research.

**Additional Highlights:**

- **Value of Partnerships**: Successful eCOA implementation relies on strong partnerships between sponsors and providers, enabling efficient communication and problem-solving outside of trial pressures.

- **Diverse Expertise:** The panelists highlight the importance of diverse backgrounds among team members to navigate the complexities of eCOA effectively.

- **Quality of Data:** Emphasis is placed on the necessity of robust data collection mechanisms to accurately reflect the drug's impact, particularly in therapeutic areas like neurology and dermatology.

- **Early Engagement:** Engaging with eCOA providers early in the study design process can streamline implementation, reducing last-minute challenges and enhancing efficiency.

- **Honest Communication:** Transparency in discussing challenges, including acknowledging when things go wrong, fosters trust and strengthens partnerships.

- **Operational Efficiency:** The need to prevent delays in study timelines emphasizes the importance of an eCOA provider's operational capabilities in ensuring smooth study conduct.

- **Shared Knowledge:** Leveraging the collective expertise of both sponsors and eCOA providers can address regulatory uncertainties and enhance trial efficacy.

**Key Insights:**

- **Critical Role of Trust in Partnerships:** Trust between sponsors and vendors is essential for an effective collaboration. Vendors who can openly discuss challenges create a more resilient partnership. When difficulties arise, taking the issue away from the study team to be resolved at a governance level protects ongoing study relationships.
- **Holistic Understanding of eCOA:** Successful eCOA partnerships require both parties to engage with a full understanding of the electronic implementation processes, from licensing to linguistic validation. A shared comprehension can alleviate undue confusion and facilitate better decision-making during the trial stages.
- **Operational Structure Matters:** For eCOA partnerships to thrive, a well-defined governance structure is essential. This includes clarifying roles and responsibilities, agreeing on metrics for success, and creating contingency plans for potential setbacks.
- **Learning from Past Experiences:** Vendors with a history of both positive and negative experiences can offer invaluable insights. A vendor's ability to articulate lessons learned and apply them to new challenges signifies their expertise and bolsters their responsiveness in partnership scenarios.
- **Adaptability to Diverse Needs:** Different sponsors may require varying degrees of support based on their familiarity with eCOA. Partnerships that can adapt to the unique needs of each sponsor enhance overall study success, reflecting an understanding of the learning curves that smaller organizations often face.
- **Value of Responsiveness:** The ability of eCOA vendors to deliver timely feedback regarding potential issues is crucial. Early identification of challenges allows both parties to focus more on quality data collection rather than getting mired in problem-solving under pressure.
- **Evolution of the Role:** As discussions evolve within the industry, sponsors increasingly recognize eCOA as a strategic asset rather than merely a data collection tool. This paradigm shift highlights the importance of embracing innovation and focusing on patient-centered methodologies in clinical trials

The podcast illustrates the critical need for collaboration across different facets of the clinical trial industry to address the complexities of eCOA effectively. By fostering partnerships rooted in trust, transparency, and mutual understanding, stakeholders can navigate the intricacies of drug development while ultimately prioritizing patient health outcomes.