SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

The Signal

7 eCOA Solution Design Recommendations: Applied Insights from Trial Sites and CRAs

Clinical trials continue to become more complex and whilst there is extensive evidence demonstrating the improvement of data quality through electronic collection of Clinical Outcomes Assessment (eCOA) data, trial complexity can place additional burden on clinical research sites. The Critical Path Institute launched the eCOA: Getting Better Together Initiative (GBTI) in 2019, which aims to address challenges and drive positive change in the implementation of electronic Patient-Reported Outcome (ePRO) in clinical trials.

Signant recently collaborated with a cross-industry group of C-Path members including other eCOA solution providers, sponsors, and regulators on a GBTI project called "Support Flexible Approaches to PRO Data Collection".

The project gathered responses from various site roles across global regions, with the largest contribution from the United States. Despite some limitations in the sample size and demographics, the research revealed several opportunities to improve eCOA usability and flexibility.

The group developed seven concrete ideas for sponsors to consider incorporating into protocol design for participant visits, technology use, devices, and methods of back-up data collection:

1. **Thoroughly assess sites' eCOA experience during site feasibility.**
2. **Provide on-time and flexible training, including hands-on sessions during Investigator Meetings (IMs).**
3. **Dedicate more time to training and provide refreshers before participant enrollment.**
4. **Develop effective manuals with detailed instructions on device setup and troubleshooting.**
5. **Design user-friendly eCOA systems with fitting assessment measures and simple reporting schedules.**
6. **Enhance technical support with features like live-chat assistance.**
7. **Consider hybrid approaches combining provisioned devices (PD) and Bring Your Own Device (BYOD) with electronic backup options.**

The findings are discussed in this recent article, "Flexible approaches to eCOA administration in clinical trials: The site perspective," published in Contemporary Clinical Trials Communications.

By implementing the recommendations identified through this project, stakeholders can work towards a seamless and participant-centric approach to ePRO implementation in clinical trials.

You might also be interested in my Site & Patient Research eBook, which explores how eCOA solutions can optimize participation experience for sites and patients, two of the most important stakeholders in clinical research.

Similar to this work with C-Path, Signant routinely engages with sponsors, sites, and potential or current trial participants in qualitative research. The outcomes from these endeavors provide tangible evidence that our eCOA solutions meet sites' and patients' needs and expectations. They also help shape the ongoing development of our technology and scientific approach.

When patients and sites find technology solutions easy-to-use, convenient, and intuitive, it can improve compliance and retention, and ultimately results in better-quality data for your trials.

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Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at www.signanthealth.com.