# Avoca Quality Consortium Leading Change Collaborative Forum

**Meeting Highlights**

**Topic: "New" Technology in Clinical Trials – Focused on Oversight of eCOA Vendors, Data, and Other eSource Learning (ePRO, site reported, and wearables)**

**Meeting Date: October 19, 2021**

## Background Information

The emergence of the COVID-19 pandemic has caused the pharmaceutical industry to rapidly adapt its processes and technologies, including clinical trials. The AQC Leading Change Collaborative Forum features compelling topics designed to encourage provocative discussion. The priority is providing practical and actionable support and having immediate "peer-to-peer" benchmarking about how other organizations are managing the topic at hand, all while ensuring prioritization of patient safety, data integrity, and regulatory compliance.

Steve Whittaker, Senior Consultant, WCG Avoca, moderated a robust discussion that featured representatives from pharmaceutical companies and service providers. With such a rich topic and only 90 minutes, the panelists were able to touch on a few of the issues, but a second meeting is in the works.

If one theme emerged during this first session, it was the impact of COVID on advancing eCOA use and adoption in support of hybrid/remote trials. Large sponsors had been implementing eCOA for years but use dramatically increased during the pandemic: The flexibility of eCOA and other digital tools supported decentralized trials. This rapid uptake opened doors and allowed for more innovation, but, especially in terms of sites and regulators, it also created new challenges.

## Discussion Summary

### Heralding a Bigger Change

COVID made clear that you can collect data and perform the trials remotely. "You can have alternatives to that now, and that opens up a whole box of different opportunities," said one panelist.

Sponsors already using eCOA may have faced fewer disruptions, but it didn't necessarily guarantee a smooth transition to decentralized trials and remote data capture. "We are clearly looking at more advanced solutions vendors who can provide, or interconnect, all the services with –or without– telemedicine. Clearly that was a very quick acceleration we had to innovate."

One implication, noted another panelist, is this: "The simple eCOA–like it used to be until very recently–is soon going to be a thing of the past." There will be greater integration of eCOA into other platforms and tools (e.g., wearables), giving patients a suite of tools they can use at home, panelists noted. But we're not there yet, and sponsors and regulators have more work to do.

### Regulators May Not Be Keeping Up

"COVID caught authorities by surprise," said one panelist, noting that globally, regulators are taking different approaches.

But regulatory uncertainty around eCOA predates the pandemic. "Much of the perception of risk related to eCOA arose from the lack of detail and expectation from regulators–something they did provide during the pandemic," noted one of the panelists. In fact, for some, the guidance that came during the pandemic provided much-needed clarity.

Still, panelists agreed that guidance and regulations need to be modernized. For example, "GCP still has a paper-based mentality," said one panelist, adding that it may not be a problem in the future. "I understand that the upcoming revision of GCP will not be a "facelift" but will address the way innovative technologies in general should be looked into and should be scrutinized."

### Data Flow Matters

Among the areas of regulatory focus are vendor qualification and data flow.

Because dataflow requires a clear line back to the actual person, it can get complicated, agreed the panelists. For example, if you have an eCOA solution in place and it fails, you may have to resort to paper, pointed out a panelist. "But that means you also have to have this fully anticipated from the beginning, because if you cannot demonstrate that was an acceptable modality, then you may lose … your data. So, it means that internally you need to also have a very deep understanding of what you want to achieve."

At the same time, it's important to acknowledge that investigators are not going to be routinely checking on audit trails.

**Regulatory Requirements and Site Burden**

It gets to a larger problem, one of the panelists notes. "What drives me kind of crazy is that the new technologies should be implemented to make things easier to collect, train, and provide the data. And oftentimes I feel like the new technologies are being used, at least by some regulators, to catch people doing things that they shouldn't be doing or to catch mistakes. And to me, that's not the purpose of technology. The purpose of the technology is to make it easier for folks and to provide better data."

"Sites are being pushed and pulled in different directions when it comes to this new technology and it really should be implemented to make their lives easier, not to make it harder," observed a panelist. Another asked, "We, as an industry, are doing a lot for patient engagement. Do we need to be thinking about investigator engagement?"

There appeared to be consensus around providing support for the PIs, other investigators and study coordinators—especially given that investigator oversight has been a major source of regulatory citations. Anticipating the site burden and defining who's responsible for what are critical elements of oversight and management.

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