

The Avoca Quality Consortium
**Leading Change
Collaborative Forum**

Avoca Quality Consortium® Leading Change Collaborative Forum

Meeting Highlights

Topic: The QMS Ecosystem Divide

Meeting Date: September 16, 2020

Meeting Objectives

To identify points of conflict between the QMSs of Sites, Sponsors, and CROs and thereby uncover opportunities to harmonize working practices through the creation of systems that reflect the needs of other stakeholders.

Discussion Summary

The growing focus on quality across all stakeholder groups is a positive force in clinical trials but is also creating emerging challenges. QMSs and policies adopted by Sponsors, CROs, Vendors, and Sites can differ in some regards, as can interpretations of regulations, leading to areas of conflict that impede the realization of the shared goal of running efficient, high-quality clinical trials. At the first session of Leading Change, AQC Members gathered to hear the perspectives and solutions of people working across the clinical trial ecosystem. The speakers identified how COVID-19 is shaping thinking on SDV, discussed how stakeholder-specific processes and perceptions of risk can create tension, and zeroed in on achievable fixes for the current causes of conflict.

Below, please find a summary covering the key points to emerge from the discussion:

1. Source Documents and SDV

Multiple speakers said how COVID-19 has both accelerated change and identified barriers to the execution of reforms. For example, the pandemic forced Sponsors to consider verifying less than 100% of source documents but, in doing so, revealed that determining how to do sampling is a barrier to change. Some databases lack features for indicating or documenting sampling; an issue that all speakers agreed is a problem. New EDCs support documentation of what is sampled, but they still struggle with the complexities of risk-based monitoring plans.

2. Viewing Risk Through Different Lenses

All stakeholders want to adopt risk-based approaches. The challenge, the speakers agreed, is Sponsors, CROs, and Sites all perceive risk differently. For a Sponsor, risks to the reliability of data and wellbeing of patients are top priorities. Sites are at least as focused on the safety of subjects, but they are typically less attuned to issues that could affect the regulatory validity of data.

3. Define the “Why”

The speakers identified differing perceptions of risk as part of a broader issue. Currently, one stakeholder can be unclear on why something is important to another stakeholder. The lack of that shared understanding manifests in stakeholders taking actions that cause problems for their collaborators. A Site, for example, may push back against the use of a central lab as a local lab delivers results faster. However, the Sponsor needs to use a central lab to ensure the data are consistent. That tension, and many like it, is best managed when stakeholders know why a requirement, which may be nonsensical from their perspective, is critical to the trial.

4. The Path Forward

The tensions identified by the speakers can be fixed. Sponsors and CROs have a track record of improving Sites by working with them over a period of time. The improvements stem from all parties gaining an understanding of the “why” of each other’s processes as they build the relationship. Sponsors and CROs can accelerate their education by reviewing Sites’ processes and, when possible, avoiding imposing ways of working that clash with existing workflows.

*If you are interested in learning more about the [Avoca Quality Consortium \(AQC\)](#) or its *Leading Change* series, please contact Dawn.Auerbach@theavocagroup.com.*