

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

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Meeting Highlights

Topic: Challenges of Using Emerging Technology: eConsent and Telemedicine

Meeting Date: May 18, 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. In Avoca's Leading Change Series, AQC Members have discussed the QMS Ecosystem Divide, FDA Voluntary Remote Inspections, Diversity in Clinical Research, Protocol Design, Patient Engagement Trends and Solutions, and more.

During the May session, the focus was on the challenges that are faced when implementing new technologies such as eConsent and Telemedicine into clinical trial conduct, including:

- How is patient identity confirmed?
- How can subject privacy be appropriately maintained?
- How is responsibility for ensuring systems comply with requirements divided between the sponsor and the system vendor?
- What are the challenges faced by CRAs when monitoring studies using these systems?
- What challenges do sites face with the use of multiple systems?

Discussion Summary

How have introducing these types of systems impacted other processes within your organization? Do they impact protocol design and how do they impact other systems?

- eConsent has taken a long time to implement due to multiple considerations around integration of systems and data flows across programs in a study.
 - People and processes, including site personnel and patients, should be considered when any technology is to be incorporated. Even with the best platform, if people do not use the technology, it doesn't improve the process.
 - Health Authority perspectives should also be considered.
- Site networks can have multiple electronic platforms from different vendors. They have to learn each system since they don't necessarily communicate.
- Companies need to collaborate with vendors and create SOPs to ensure all platforms are integrated and communicate with each other. This takes time, testing, and customization.
- Piloting is helpful in determining ramifications downstream and that integration is seamless.
- Considerations around patients' perceptions of maintenance of confidentiality needed.
- Sites need to buy in and understand the requirements of them.

- One challenge that a panelist faced in implementing eConsent/Televisits solutions was working with ethics committees in getting it approved. Some countries are very strict and require detailed information of how participant's information is protected. There are some countries that would allow eConsent but not Televisits and vice versa, and the company needed to ensure that each country was set up with specific restrictions if needed within the technology solution.
- There is no one-size-fits-all, even between US states. Need to consider design and preparation.
- The system needs to be flexible based on different sponsor requirements.
- Decentralized clinical trials are transforming how the industry delivers trials. There is a heavy learning process in adopting technology and learning. There is a great deal of integration of systems, both internally and with vendors and providers. There is a need to develop a flexible, open system. That is predicted to take several years.
- A dedicated project manager with a high level of clinical operations expertise with vendor management experience should be considered for leading the implementation.

How is responsibility for ensuring systems comply with requirements divided between the sponsor, the system vendor, and the sites?

- Vendors may have a validated platform but not have fully thought how to use it in a clinical trial since they may not be knowledgeable in that area. Ongoing meetings are usually required to ensure vendors meet all of the study requirements prior to deployment.
- Incorporating eConsent and telemedicine technologies require a new way of working with vendors. Quality representation should be considered.
 - Go through the vendor qualification checklist and do a risk assessment.
 - Each vendor should be Part 11 compliant.
 - See how data is stored, how it's encrypted, and how data and safety are protected.

What processes are used to confirm patient identity? What challenges have you seen with maintaining subject privacy and how has that been managed?

- Position papers have been offered. FDA did come out with an outline on what to consider. There are many factors to check to verify identity.
- The more security, the harder it becomes for participants to work within the system. There needs to be a balance. Two factor authorization raises the bar.
- Biometrics would add a level of security and serves to authenticate but adds complexity.
- One panelist encourages the sites to utilize the Televisit functionality to actually have a video call with the participant to ensure they are speaking to the real subject.
- Participants can make errors in completing forms and must be caught in real time. Example: pop-ups that alert the participant when an inappropriate answer has been provided.
- Something as simple as access to Wi-Fi can create issues. One panelist reported offering provisioned devices for subjects that don't have web-enabled devices readily available for their use. This has been especially helpful with the older population.

What are the challenges faced by CRAs when monitoring studies using these systems? How could risk-based monitoring be impacted by use of eConsent and Telemedicine?

- A case was cited where a monitor could log in and review consents remotely, but the downloaded copy of the consent was cached. Deleting the cache is critical.
- Though monitors can have the capabilities to see progress, errors created by sites are still possible. It's not just technology to be considered.

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