

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

Avoca Quality Consortium® Leading Change Collaborative Forum

Meeting Highlights

Topic: Site Inspection Experiences With a Highlight of the AQC Site Centricity Workstream

Meeting Date: March 16, 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, Innovative and Flexible Protocol Design, and Patient Engagement Trends and Solutions. During the March session, pharmaceutical companies and site organizations weighed in on the impact of COVID-19 on regulators' approaches to site inspections.

Discussion Summary

During the pandemic, inspectors in the US are largely not taking advantage of virtual options available. In some cases, hybrid inspections are employed where on-site visits are minimized and documentation is reviewed off site. Therefore, site inspections tend to be more labor intensive and costly, and sites and sponsors must consider the technology perspective.

Panelists' Experiences with Site Inspections in Recent Months:

Panelists reported offering regulators the ability to conduct site inspections entirely virtually, but that to a large extent the agencies had not taken advantage of this option. Most US regulatory officials chose to come on site for at least part of the inspection.

- Though sites are prepared to send records electronically, some inspectors are requiring printed copies of large numbers of documents, costing significant time and resources for sites and sponsors.
 - Some inspectors asked for paper copies ahead of time, allowing sites to prepare.
- Sometimes there is a need for designated individuals to support these sorts of requests. The site should reach out to inspectors ahead of time for expectations.
- Some inspections are being conducted as a hybrid of virtual and on site.
- There were a few fully remote inspections reported by panelists, but with challenges.
 - One sponsor reported FDA piloting a remote inspection; it was not particularly successful. The time of the inspection and resources to produce scans and paper were significant. The site team also was required to be on Webex meetings for a great deal of time.

- Some inspections were done with a limited number of inspectors on site providing video to the team.
- Companies reported having some sites which could not physically host inspections. Need understanding of what the sites could do and what resources it would take.
- European inspections were cited as problematic for reasons including GDPR.
- There is a need to be prepared to submit information post investigation.

One sponsor noted their experience had been that when remote inspections of sites were conducted, FDA sent requirements to the sites.

- The expectation was as sponsor they would be involved and could assist the sites.
 - This sponsor spoke a great deal with inspectors. Because of the virtual nature, there was more interaction than there would have been normally.

Inspections in China:

A panelist who had not yet had a post-COVID-19 experience provided interesting information about site inspections in China.

- Inspections are combined site/sponsor inspections.
- Normally sponsors want lists of documentation submitted to be in place at sites to understand what has been submitted so they can build their story.
- Preparation time is greater, creating a higher cost.
 - Normally sites have only 2-to-3-day notice prior to the inspection, which is non-negotiable. Preparation of the sites, therefore, are done much earlier and started before database lock.
- In China, each site is based in hospital which has a GCP office. QC is required before database lock. The sponsor uses this time to do preparation.
- Inspectors prefer paper medical notes but are increasingly accessing the hospital information system.
- Most inspections include more than one team of inspectors.
 - The largest team experienced by this panelist was 9 inspectors divided into 2 teams.
- Investigators are mostly interested in data at the site but will request documents archived in TMF from the study level.

Regional Inspections in Germany and Australia:

One panelist had experienced a regional inspection in Germany. There was a great deal of surveillance on site where facility restrictions were not in place.

- There had not been much deviation from standard processes, except at facility level, in terms of accessing the pharmacy. Records were sent in hard copy.
 - If there is a policy that no records leave the pharmacy, planning is needed.

One panelist reported a three-day inspection pilot being planned in Australia. While generally Australian authorities rely on inspections conducted elsewhere, Australia has released draft guidance. It is anticipated that both FDA and EU regulators approach will be used. The sponsor offered a hybrid format, but the regulator plans to go on site only.

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