Avoca Quality Consortium® Leading Change Collaborative Forum

Meeting Highlights

Topic: FDA Voluntary Virtual Remote Inspections

Meeting Date: October 20, 2020

Meeting Objectives

To share first-hand experiences of the FDA's voluntary remote assessments, thereby preparing AQC Members for an emerging method for overseeing Sponsors and investigative sites.

Discussion Summary

The FDA began conducting voluntary virtual remote assessments of Sponsors and investigative sites before the pandemic began. Yet, the remote assessment model played a very limited role in regulatory oversight before COVID-19. That is starting to change. Faced with the need to monitor Sponsors and investigative sites at a time of reduced travel and in-person interactions, the FDA is ramping up its use of voluntary virtual remote assessments. During the October session of Leading Change, AQC Members discussed their experiences of the remote assessment process, from how the FDA sets up and runs the inspections through to the outcomes of the virtual visits. The information is particularly valuable given the current lack of published FDA advice or guidance on the inspections. A full report of the session discussion is available to AQC Members.

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

1. **How the FDA is Setting up Virtual Visits**

   One Sponsor described the process that led to a remote assessment by the FDA. The local inspector who does the Sponsor's routine Pharmacovigilance assessments called to offer the opportunity to voluntarily undergo a remote assessment. The inspection was announced. No Form 482 — the Notice of Inspection — was distributed.

2. What to Expect

The FDA mandated use of its chosen file-sharing and communication technologies during its Pharmacovigilance inspection of the Sponsor. A communication channel between the FDA and Sponsor was open throughout the inspection. That sets the FDA's approach apart from that of its peers, which, due to direct system access, communicates with the Sponsor on an ad-hoc basis, and necessitates the presence of a "front room host" for the duration of the assessment.

3. Burdens Imposed by Remote Assessments

Two case studies shared during the session identified the requirement to scan documents to facilitate the FDA assessment as a burden imposed by the remote model on sites. In one case study, the uploading and scanning of documents was identified as an undue hardship on the sites — as a result, compromises were made to look at full files for a select few patients instead of all patients, which lasted one month. In the other example, the Sponsor sent delegates to the site to scan documents after getting institutional and ethics committee permissions. That inspection lasted a few weeks.

4. Outcomes of Virtual Visits

The Sponsor that underwent a remote Pharmacovigilance inspection said the FDA would not issue a Form 483 in response to its remote assessment, even if it found problems that under normal circumstances would cause the sharing of inspectional observations. Rather, the local inspector said information gathered during the remote assessment would be shared with the FDA's Washington office and used to inform the next routine, in-person inspection. If documentation of the observations were desired, they could be obtained by written request via the Freedom of Information Act.

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