COVID-19 Rapid Response Working Group

Meeting Highlights

Topic: COVID-19 Implications for Documentation and Management of TMF/eTMF/eISF and Maintaining Inspection Readiness

Meeting Date: April 9, 2020

Objective of the COVID-19 Rapid Response Working Group: To enable the continuity of clinical trials with strategies and practical support, ensuring that there is a focus on patient safety, data integrity, and regulatory compliance as the COVID-19 situation evolves.

Executive Summary: In the third session of the Rapid Response Working Group, held April 9, 2020, a group of 71 AQC members representing over 50 member companies gathered to discuss the **Implications for Documentation and Management of Trial Master Files and Investigator Site Files and Maintaining Inspection Readiness**.

Avoca wants to be responsive to the questions that are impacting our consortium members and has gathered senior leaders from large pharma, biotech, site networks, and CROs to share their experiences as a means for opening the discussion. Based on the discussion, both site and sponsor inspections are continuing to be requested, while there have been delays and postponements. Many sites (especially those in Europe) are struggling to participate, given refocus and prioritization on COVID-19 patient care. While there are opportunities to move to more virtual settings for these inspections, these ideas are not being adopted uniformly by all regulatory agencies.

Below please find the meeting highlights broken down into several key focus areas from the discussion:

1. **Site Inspections**

   Sponsor organizations indicated that they have recently received email requests for virtual/remote site inspections. All were market authorization submission-review-based requests (i.e., not “for-cause”). The working group also discussed anticipated site resource capability and capacity during the recovery phase after COVID-19 begins to subside. Continuous review of how site recovery progresses beyond the COVID-19 pandemic will be required to understand how distribution of their resources will impact the ability to schedule site audits, monitoring visits, or

inspections. In terms of what the regulatory agencies will do as a whole or in general is hard to predict. However, to date, they did seem to be responsive to the rationale of COVID-19 resource reallocation needs when it comes to negotiating the timing of site inspections.

2. **Sponsor Documentation**

   Sponsors and CROs agreed that leveraging current processes as much as possible is the best route instead of creating new processes and tools to manage their response to COVID-19. Timely documentation of all actions and decisions is critical.

3. **Investigator Site Files**

   While ensuring completed documentation exists within the sponsor organization or at the CRO is relatively easy, it is more challenging at the site level, especially those sites that are being turned into COVID treatment sites or where resources are being diverted. Several tips for dealing with site documentation were shared by member organizations.

4. **Sponsor Inspections**

   Current situation is that some inspections are being paused without clear indication if these inspections will be delayed or cancelled. However, when these are being delayed or canceled there is also no indication on the impact it has with the PDUFA date. Other inspections are still occurring both virtually and in-person with some virtual components (hybrid). Two case studies were shared for hybrid PMDA inspection and an in-person routine BIMO inspection.

Links to COVID-19 Health Authority websites:

- World Health Organization (WHO) Coronavirus
- US Centers for Disease Control
- FDA Coronavirus
- European Medicines Agency
- European Centre for Disease Prevention and Control
- China National Medical Products Administration
- ProMED – International Society for Infectious Diseases
- ACRO COVID-19

If you are interested in learning more about the Avoca Quality Consortium or the COVID-19 Rapid Response Working Group, please contact Dawn.Auerbach@theavocagroup.com.