COVID-19 Rapid Response Working Group

Meeting Highlights

Topic: Expediting Protocol Amendments in the Age of COVID-19

Meeting Date: April 2, 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 second session of the Rapid Response Working Group, a group of 78 Avoca Quality Consortium (AQC) members representing over 55 member companies gathered to discuss the specific challenges, lessons learned, and promising solutions to navigate the waters of **Expediting Protocol Amendments**. 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, it appears that companies are currently working to limit protocol amendments and manage the process through documented mitigation plans, contingency plans, and deviations where possible. Based upon 27 Mar 2020 updated guidance from the FDA (in the FAQ section), some within the industry have a concern that all implemented mitigations or contingencies may need to be included in a protocol amendment, even if the amendment is primarily driven for a different purpose (i.e., extending patient IP exposure). In addition to discussing the management of protocol deviations and amendments, questions were posed to AQC members on data interpretability, patient safety, and communication/contact with sites and IRBs.

Below please find a summary broken down into several key focus areas from the discussion:

1. **Regulatory Guidance is Dynamic, Important to Monitor through Internal Efforts or Leverage your CRO Partners**

   The Working Group discussion began with the recent update to the FDA Guidance, where FAQs had been added. It was noted that it is critically important to keep up with these changes and updates and ensure that current information is shared with team members.

2. **Making Decision on Protocol Amendment vs. a Written Contingency Plan and Documented Protocol Deviations**

   Based on the discussion, it appears that companies are currently working to limit protocol amendments and manage the process through documented contingency/mitigation plans and deviations where possible.

3. **Data Interpretability**

   Ensuring data integrity and interpretability is critical to the success of a clinical trial, and it is important to understand the impact and ways to minimize the impact where possible.

4. **Maintain Strong Communications with Sites and IRBs**

   Maintaining an open dialogue of communication with sites and IRBs is critical, especially as the situation changes daily in some instances. Knowing how busy and inundated some sites are, some sponsors are being creative on how they approach and review data to manage proactively if the site may need support. This has been particularly true in hard hit countries like Spain and Italy.

5. **Maintaining Patient Safety**

   Following the discussion on protocol amendments and deviation management, participants asked several questions around alternative methods for managing patients and maintaining their safety, including the ability to leverage home visits for assessments and IP management. There was discussion if site staff and coordinators could be used for this purpose.

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 (AQC) or the COVID-19 Rapid Response Working Group, please contact Dawn.Auerbach@theavocagroup.com.