COVID-19 Rapid Response Working Group

Headlines Summary

Topic: Current State of Site Monitoring in the Age of COVID-19

Meeting Date: March 26, 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 this inaugural meeting of the Rapid Response Working Group, 120 AQC Members representing over 70 Member companies gathered to discuss challenges, lessons learned, and promising solutions to navigate the waters of **Site Monitoring**. Senior leaders from large pharma, biotech, site networks, and CROs shared their experiences.

Based on polling questions presented to participants, companies are relatively equally split in making decisions to start new clinical trials, and some companies are making decisions to limit enrollment in specific ongoing trials.

Below is a brief synopsis of the results from the Site Monitoring Rapid Response Working Group session:

1. **Remote Monitoring: Get clear on what you mean and understand what is and isn't possible.**

   In the age of COVID-19, it's easy to say that we should move to remote monitoring, but there are many factors to consider before making that decision and implementing it. Per our polling question, 68% of participants/companies are modifying their Monitoring Plans to incorporate some aspects of Remote Monitoring.

2. **Develop Support Teams and Provide Reference/Guidance documents with Considerations for COVID-19.**

   It's important to drive consistency across your project teams. Several participants highlighted that they were creating various templates and guidance documents for their teams to follow.

3. **Document, Document, Document.**

   While clearly, this is a known element of critical importance in the highly regulated world of clinical development, the daily and sometimes hourly changes will have an impact on staff as they focus on patient safety and driving quality data. It was noted by all the speakers that robust change control is essential as these plans are dynamic and will evolve over time.

4. **Understand what the regulatory guidance documents will and won't let you do, especially in the EU.**
   While there's a great deal of interest and enthusiasm around remote monitoring and remote SDV/SDR, the updated EMA guidance is still limiting the practice due to patient privacy concerns.

5. **Maintain contact with sites.**
   During this critical and fluid time, it's essential to maintain contact with your sites as things are changing on almost a daily basis. Sponsors and CROs need to be able to support sites based on their changing requirements

6. **Keep patients safe and active in ongoing trials.**
   Patient safety is front and center for all ongoing and future trials. Several sponsors noted they are delaying some if not all new study start-ups, and several are suspending enrollment in some if not all current studies.

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.