COVID-19 Rapid Response Working Group

Meeting Summary

Topic: The Use of Technologies/Tools to Support Patient Access and Safety Concerns Arising from COVID-19

Meeting Date: April 16, 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 fourth session of the Rapid Response Working Group, a group of AQC members representing over 40 member companies gathered to discuss **The Use of Technologies/Tools to Support Patient Access and Safety Concerns Arising from COVID-19.** The session focused on the following capabilities: Telemedicine, eConsent, eSource, IP Home Delivery, and Home Health Nursing and included topics on general implementation considerations, privacy requirements, and technology considerations. Based on the discussion, several organizations had been utilizing several of these capabilities in a limited fashion prior to COVID-19. Based on the polling results, there was some modest increase in usage, but given the uncertainty on the length of the COVID-19 impact and delays, large investments were not made. Proper risk assessments were conducted to determine the best approach for a given trial and patient population requirements. Looking ahead, an overwhelming majority of polling respondents felt that these new technologies and tools would play a much more significant role in trials in the post-COVID environment, so it is important for organizations to begin planning and developing playbooks to capture needs and requirements as well as lessons learned from these early pilots.

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

1. **Overarching Perspectives & Technology Considerations**

   The speakers—representing pharma, sites, and CRO—shared some general perspectives on the aspects of moving to these new technologies, including implementation, site impact, and technology considerations. The decisions to move to these new technologies vs. pausing studies were inherently based on a risk assessment, taking into account the best interest of patients and data requirements of the particular study. Other considerations include privacy concerns for patients and what additional consent may be required. It is also important to

consider the impact on sites and how they will interact with the technology or tool. Many of the sites have several of these technologies in play, and it is up to the sponsor to determine whether to leverage them.

2. **Telemedicine**

   Telemedicine has not been extensively used in the clinical trial space among the participants, and sponsors discussed limited experiences to date. For implementation purposes, it will be critical to understanding the patient population and their acceptance of this technology. Also, telemedicine will not be able to cover all required in-person assessments. Companies need to consider technology requirements and limitations and need to ensure an audit trail and backup plans are in place in case there is a failure of the technology or network.

3. **eConsent and Remote Consent**

   There are several considerations when implementing eConsent. Sponsors need to ensure that the requirements are carefully documented when considering various technologies so that all requirements can be supported. Also, given the challenges of COVID-19, sponsors not only need to consider eConsent, but also how patients can provide remote consent due to stay-at-home orders. Finally, sponsors need to ensure a mechanism that separate consents are available to those that may be doing remote assessments.

4. **eSource**

   Based on polling results, eSource was the most predominantly used technology/tool prior to the outbreak of COVID-19. There are several general considerations and questions that should be considered, including, data storage, audit trails, data accessibility, AE collection capability, and backup solutions.

5. **Home Health Nursing**

   Several participants shared their general considerations for leveraging home health nursing. Sponsor needs to be comfortable with the site's delegation of authority and ensure that appropriate documentation is collected for training and CVs, especially for research naïve staff. Home health nursing can be an expensive option to implement, so consider carefully, but will become more common post-COVID-19.

6. **Direct to Patient IP**

   Of all the various solutions and technologies discussed, IP home delivery was the solution that was most significantly leveraged following the outbreak. While easier to support in the US with the use of central pharmacies, MHRA is allowing IP shipment to patient home without the requirement of a substantial amendment, but all privacy requirements are still in place. There were several elements to consider – shipping across borders, maintaining temperature control, maintaining chain of custody, managing unused IP or other supplies requiring special handling or disposal, storage, and administration. Leveraging a knowledgeable vendor is essential for successful implementation.

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.