COVID-19 Rapid Response Working Group

Meeting Highlights

Topic: Determining Strategies and Criteria for Safely Restarting Current Trials and Starting New Trials in the "New" Normal

Meeting Date: May 7, 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 seventh session of the Rapid Response Working Group, a group of over 50 AQC Members representing approximately 40 Member companies gathered to **"Determine Strategies and Criteria for Safely Restarting Current Trials and Starting New Trials in the 'New' Normal."** The speakers shared their strategies for developing and executing on re-entry plans as sites begin coming back online. The re-entry plan for the post-COVID environment should be based on epidemiological data, site availability, and patient/trial priority aligned to patient safety, data integrity, and regulatory compliance. The speakers were focused on the theme to "not go back to business as before" and the need for a collaboration with Regulators to move forward with innovative ways of trial conduct and the use of technology with a confidence that Regulators are in alignment. The speakers suggested that we should all take the opportunity to move the industry forward by looking at targeted site visits, remote monitoring, and conducting remote SDV. Another consistent message was the standardization of deviations and planned deviations that were pivotal to protect patient safety and data integrity. And, as always, decisions should be taken with a risk-based approach.

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

1. **Re-entry Plans/Process**
   There are several factors to consider for a re-entry plan while continuously ensuring patient safety, data integrity, and regulatory compliance. Importance should also be placed on maintaining communications with sites, being diligent on what needs to be performed on-site, and taking a risk-based approach to a reduced-SDV strategy. Sponsors, sites, and CROs will want to review the strategies and technologies that were put in place in response to the COVID-19 pandemic and determine what can and should remain in place. The speakers challenged the audience to not revert back to original plans and strategies where the newly implemented procedures and innovations have created efficiencies.

Key elements of re-entry/re-start plans include:

- Considering site input, maintaining support of the sites, as well as continuous communications with sites.
- Prioritizing studies/study deliverables with importance placed on factors related to patient safety, data integrity, and regulatory compliance.
- Accounting for locational variation based on geographic hotspots for COVID-19.
- Combining input from internal strategic teams with current site information and epidemiological output from dashboards tracking the pandemic.
- Implementing a phased-in approach on where and when to move forward with trial activity.
- Instituting a SOP allowing for utilization of planned non-compliance.
- Implementing a Risk Mitigation Plan.
- Ensuring thorough documentation around the impact of COVID-19 on trial activities.

2. Database Locks during the COVID-19 Pandemic

A sponsor shared that during the pandemic they had successfully completed two final database locks. A risk-based approach was taken in making the decision to proceed with the lock. The decision was based on the stage of the trial and that the majority of data had been SDV'ed (99%). The sponsor noted that a statement will be included in the CSR based on EMA and FDA guidance.

3. Maintaining Compliance and Documentation of Oversight – Considerations

Speakers addressed some considerations for maintaining compliance as well as appropriate documentation. Utilization of storyboards help to improve documentation, track decisions, and will eventually assist in proving compliance to regulators. In creating storyboards, operational components need to be accurately captured and depict the full story and rationale behind the actions taken and decisions made in the COVID-19 environment.

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.