COVID-19 Rapid Response Working Group

Meeting Highlights

Topic: Taking a Deeper Dive into Successful Approaches to SDR/SDV During Times When There is Inability to be On-Site

Meeting Date: April 30, 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 sixth session of the Rapid Response Working Group, a group of over 80 AQC Members representing over 50 Member companies gathered to **"Take a Deeper Dive into Successful Approaches to SDR/SDV During Times When There is Inability to be On Site".** Speakers discussed the strategy and plans for remote monitoring and how this has evolved as regulatory guidance has evolved. FDA guidance allowed for more flexibility and recent update to EMA guidance provided more clarity on what is allowed in terms of an established risk assessment framework focused on critical data but still maintains strict controls for patient privacy. Now that there is more guidance on remote SDV in Europe, plans can be adjusted accordingly. Even with the additional clarity, the challenge remains on how to manage a global trial running in different regions. After performing the risk assessment and determining the type of monitoring that can be done remotely, there is the additional factor of looking at where sites are located and what will be allowed. Therefore, instead of making a broad policy decision, teams need to review different options based on locations of their trials.

Sponsors, a CRO, and a site shared their perspectives and learnings when implementing remote monitoring that included SDR/SDV elements and how they managed with statistical modeling of the data when remote SDV was not feasible. A key component in developing these processes was performing a risk assessment and developing mitigation plans to support that assessment.

An integrated site network with sites primarily in the US and the UK described their successful implementation of remote monitoring including SDR and SDV reviews. The speaker shared their recommended components for a remote monitoring plan and described how they were supporting sites without an EMR. There was also a discussion on the various types of tools that were proving more successful in conducting remote data verification and how they protect patient privacy. Speakers seemed to agree in the potential that some interventions used during this challenging time might become business as usual in the future.

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

1. **Regulatory Guidance & Country Perspectives**

   Regulatory guidance on the topic of remote SDR/SDV has varied between regions and countries. Different regulators are taking different approaches and different countries within the European Union are not taking the same approach. Determining how to manage a global trial running in different regions is challenging given the varying regulatory landscape as well as additional factors for consideration including consent, privacy, and remote monitoring. It is important to have strategies in place at both a technical and procedural level to address these factors. After performing a risk assessment and determining the type of monitoring to be done remotely, there is the additional factor of looking at where sites are located and what will be allowed. Rather than making a broad policy decision, it is necessary to review different options based on trial locations and in some cases necessary to make decisions on a site-by-site basis.

2. **SDR/SDV from a Sponsor/CRO Perspective**

   Perspectives and learnings were shared by two sponsors and a CRO around implementing remote monitoring that included SDR/SDV elements and how they managed with statistical modeling of the data when remote SDV was not feasible. A key component in developing these processes was performing a risk assessment and developing mitigation plans to support that assessment. Additionally, we heard about database locks that took place in the COVID-19 environment. As with all clinical research decisions and activities, again, we were reminded of the importance of ensuring subject safety and thorough documentation.

   We heard about **a site risk assessment report** put in place by a CRO which is generated weekly to illustrate the impact of the COVID-19 situation on patient access/enrollment/IP interruption as well as impact on courier service. Data and observations generated by this assessment were discussed.

   A CRO working across multiple sponsors shared their perspective with a focus on North American SDR/SDV. We were provided an overview of the preparation activities, and we learned how, after careful planning, the CRO moved into the execution phase of remote monitoring of sites. The CRO worked with the sites to complete a highly effective off-site visit and review the source data. Information was shared around the utilization of risk assessments and site surveys, leveraging technology to perform a wide range of activities, including remote monitoring, web-based meetings, real-time video chat to reconcile IP products, and review completed/signed informed consents. CROs are working with EDC and CTMS vendors/teams with respect to the FDA guidance, to ensure they are properly capturing datapoints in the EDC to flag COVID-19 missing datapoints and documenting protocol deviations and protocol non-compliance.

3. SDR/SDV from a Site Perspective

An integrated site network with sites primarily in the US and UK described their successful implementation of remote monitoring including SDR and SDV reviews. The recommended components for a remote monitoring plan were shared, including outlining the expectations for scheduling remote visits (if it is different than what would normally be done for on-site visits) and being transparent with regard to the extent of accommodations that can and cannot be provided. Key success factors were discussed as well as some of the challenges encountered, such as a site's remote processes not aligning with those of the sponsor/CRO.

4. Tools for Conducting Remote Data Verification

There was a discussion on the various tools that were proving more successful in conducting remote data verification and how they protect patient privacy.

In thinking about the future, one speaker encourages meeting with technology partners to understand capabilities that will support study execution in the "new normal". An example given was an EDC system with ability for sites to upload documents which are then automatically redacted, which would greatly reduce site burden. Sponsors will likely want to consider how this can be leveraged in a more virtual, remote setting for CRAs to perform remote SDV.

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.