

COVID-19 Rapid Response Working Group

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Meeting Highlights

Topic: COVID-19 Open Mic Session

Meeting Date: May 14, 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.

Audience: Targeting to include AQC Champion or another designee from each Member organization in order to allow for robust discussion. Meeting summaries will be provided to all AQC Members and posted on the Knowledge Center.

Executive Summary: In the eighth session of the Rapid Response Working Group, a group of over 33 AQC Members representing approximately 25 Member companies gathered to have an Open Mic discussion to address specific questions related to the COVID-19 pandemic and how companies addressed issues related to maintaining patient safety, data integrity, and regulatory compliance. Questions were posed by audience participants and taken from the [Aha! Online Community](#) to gather expert opinions. The speakers shared their strategies on a variety of different topics related to clinical trial continuity during the pandemic.

An introduction, prior to the Open Mic, noted the key areas where Members can expect to see changes within assets in the AQC Knowledge Center. Examples of this are updates to the AQC tools for de-risking protocols and protocol quality checklists to ensure that flexibility is retained within the protocol for off-site visits as necessary. Similarly, a Business Continuity Plan was in the strategies for the Site Centricity workstream in 2020. This deliverable was bumped up in priority to be the first document completed. Our Provider Qualification workstream is continuing to look at new technologies which will be imperative for operating within our new normal, and the standards now include additional details in terms of business continuity requirements from vendors. Our Change Control workstream will be assessing tools to ensure that there are probes for the users to think about these new circumstances to ensure that the lessons learned from these events are not lost on future study teams.

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.