Avoca Quality Consortium® Leading Change Collaborative Forum

Meeting Highlights

Topic: Rapid Innovation in Clinical Research

Meeting Date: April 20, 2021

Background Information

The emergence of the COVID-19 pandemic has caused the pharmaceutical industry to rapidly adapt its processes and technologies, including clinical trials. In Avoca's Leading Change Series, AQC Members have discussed the QMS Ecosystem Divide, FDA Voluntary Remote Inspections, Diversity in Clinical Research, Innovative and Flexible Protocol Design, Patient Engagement Trends and Solutions, and more.

During the April session, the focus was on the "big picture" of innovation in clinical research, reflecting on why it took a crisis to move the industry rapidly forward, what the industry has learned about the costs and benefits of doing so, and how companies will be collecting, quantifying, and leveraging lessons learned, including interactions with regulators.

Discussion Summary

The panel reflected on structural aspects of the clinical research industry that have impacted whether and how it has adopted innovations, characterizing studies as:

- Regulated and high stakes
- Highly regimented, with complex processes and many dependencies
- Heavily reliant on sponsor-provider relationships, sometimes with multiple interfaces, without complete trust, and with some history of non-performance
- Traditional and often behemoth corporate and departmental structures
- Cultural and workforce aspect challenges

Additionally, the group provided ideas, perspectives, and solutions around:

- What is it that allowed the industry to have so much potential that went chronically unrealized, but that was realizable upon the flip of a switch?
- How is the industry seizing upon this moment to understand this and "bottle" it for future use, informing the path forward with respect to, e.g., interactions with regulators, relationships with providers, levels of regimentation, role fixation, etc.?
- Can companies visualize an example of how they can put learnings to use in support of future innovations?

Some of the key takeaways from the panelists:

- Speaking with peers about innovations, taking a risk-based approach, and developing methods to obtain management support when the risk/benefit ratio was helpful.
- Regulators were receptive to companies approaching them proactively and early to describe what deviations to protocol would be required and how they would be documented and tracked.
- One element that enabled companies to move quickly to decentralized or hybrid trials was the availability of local resources, effectively bringing a trial to the patient rather than the patient to the trial.
- Larger companies may need to deploy teams focused on innovation to work with study teams to assess needs and coach them on effective approaches.
- Input from CROs and other service providers is useful in moving to different models.
- Using data to evaluate proposed innovations is vital.
- Though local labs may be impacting the data, companies can have samples drawn locally and work with data management to develop normal ranges.
- Decentralized clinical trials with vendors who maintain strong security safeguards can be more expensive.
- Some companies have only documented protocol deviations so as not to overwhelm health authorities and ethics committees.
- There is a risk of large numbers of protocol deviations moving forward.

The macro level on drug development strategy, practice, and trends affecting performance, cost, and efficiency.

- Studies are involving open collaboration and are patient centric.
- Changes may be more behavior based than solution based. Every company pivoted in different ways. Four broad areas may be sustainable:
    - More accommodation by regulators. Their proactive involvement was pivotal in the ability to continue studies during the pandemic.
    - Open collaboration between silos within sponsors and between sponsors, CROs, and third-party providers, and sites.
    - The agile way every organization has juggled the challenges to develop solutions. Most people agree the industry is in a hybrid environment.
    - Complexity in trials is through the roof right now, but the industry has been able to keep up the speed. The industry had capabilities before the pandemic and now it has leveraged them. It applied lots of resources and compressed the phases.

If you are interested in learning more about the Avoca Quality Consortium (AQC) or its Leading Change series, please contact Dawn.Auerbach@theavocagroup.com.