Avoca Quality Consortium Leading Change Collaborative Forum

Meeting Highlights

Topic: Opportunities and Challenges with the Adoption of Decentralized Clinical Trials (DCTs)

Meeting Date: July 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. The AQC Leading Change Collaborative Forum features compelling topics designed to encourage provocative discussion. The priority is providing practical and actionable support and having immediate "peer-to-peer" benchmarking about how other organizations are managing the topic at hand, all while ensuring prioritization of patient safety, data integrity, and regulatory compliance.

Discussion Summary

Establishing Definitions

Moderator Denise Calaprice, PhD, Senior Consultant at WCG Avoca, began the conversation by asking participants to define their use of the term Decentralized Clinical Trials. One participant offered, "A DCT enables study participation via remote visits, and remote visits are visits that occur anywhere other than a traditional investigator site."

Another expanded on that, characterizing DCTs as a spectrum: At one end are completely remote trials – "like a mega-site model, overseeing all the patients within a certain country." At the other end are studies in which most visits are conducted on site, but they may be supported by some digital elements.

However DCTs are defined, the patient/investigator relationship must remain central, warned one participant. "I think the one thing we can't lose track of in all this is that there is still an investigator that has management oversight of the patient care. […] Even though there may not be a site involved… you still need to have that investigator, and you need the trust that investigator can build with their patient."

The Trajectory of DCTs

Participants varied significantly in their predictions about how long it will take for fully decentralized trials to become the norm, ranging from 4 to 5 years to 20 years. Several mentioned the role of the pandemic. "What I'm concerned about is that we lose that sense of urgency. We've all come off this craziness, and we're all taking a sigh of relief, and I hope we don't snap backwards. We [need to] actually propel forward," said one participant.

"I think it'll be pretty much in a decentralized mode within the next five years… if not faster than that," said a pharmaceutical executive. "That's just my prediction based on the speed in which things were catapulted through the pandemic."

Another pharmaceutical executive was less bullish. "I think it will take longer until we get to a fully decentralized trial across the board [but there are] stepping-stones that we'll take." Consider patient and site preferences, and let that inform that trajectory, he added, pointing to the advent of electronic data collection. "If you remember back to when EDC started, there was lots of discussion that you're just pushing the workload from the sponsors doing double data entry to the sites to do it."

One question left largely unanswered was whether the industry even needed or wanted to move to fully decentralized trials. "Are we aiming for fully decentralized trials or not? So, to me, it's not obvious that's necessarily where we're going, especially with all trials," Calaprice observed.

Operationalizing DCTs: Not an Overlay

A key theme repeatedly emerged throughout the conversation: A DCT cannot be just an overlay. As one participant put it, "If you take a protocol designed, written, and done already and then try and throw a digital app on it, it doesn't work."

Just because you can do it doesn't mean you should, observed a service provider executive: "If we just overlay solutions, are we really making it easier on the patients and sites? Or are we creating a different burden? […] Just because you can use the technology doesn't mean you have to throw it out there and use it."

During the pandemic, companies had to take this approach, but as one pharmaceutical executive noted, "Slamming a decentralized capability into a trial after the protocol is finalized, or even after the trial is on the way is not the best way to implement moving forward." However, "if the pandemic heats back up, we'll probably do that again, because you do what you have to do to keep the continuity of care of patients going." To build for the future, build in DCT design up front, she added. "We have a playbook. So, we have an overview of what the capabilities are." Her company has an overarching strategy workstream and a delivery workstream. "That package helps us stay organized and helps our initiative move forward cohesively so that it's not like pieces and parts and all disparate."

Bringing the pieces together requires understanding the "digital ecosystem," explained one of the service provider executives. "Understanding the different kinds of LEGO bricks that you've got available to you and designing those into your protocol."

Barriers to Implementation

Failure to design protocols that can be implemented in a decentralized fashion is itself a barrier, as is failure to have a standardized approach to decentralization, several participants observed. However, based on participant responses, regulatory issues – especially the interpretation of regulations – pose the greatest barriers to DCT implementation, affecting other implementation issues, including logistics.

"Our biggest, most prominent challenge for global implementation is not the perception of the potential participants or patients in our trials or their perception of participation of investigators. It is regulatory acceptance, laws, and privacy laws," said one pharmaceutical executive.

Moreover, regulations aren't yet specific about various elements of DCTs, said another participant. "I'll give you an example. If you have a patient that is located in and they're seeing the site in New York, but maybe now with the decentralized approach, that patient is actually in California, can you ship to that patient? Is it a pharmacy law question or does it fall under the IND under federal guidance?"

Failing to appropriately onboard sites will also create problems. "If we just take a whole bunch of technology and dump it on a site, they are going to react negatively," said another participant. Overcoming that means helping sites with the change management process, he said, which segues into the final topic.

Industry Cooperation

Change management and collaboration were two key themes that emerged during this part of the discussion. "We have to make sure that the providers and the sponsors are working together on this. I think that's going to be critical for the industry to make sure that we are working together on this, because no single company is going to be able to go through and change everything that we're looking at," said a pharmaceutical executive.

"Pharma and CROs and the suppliers have to get together and make decisions about changing the way they're going to deliver research," one of the service provider executives said. They must also consider the patient experience, he added. "If we're not thinking about giving a patient the same experience they have in shopping with Amazon, or walking a block down the road to a strip mall and getting their blood tested – if we're not thinking that way, it's never going to change. I think the concern is that we can write all the regulations in the world, but we may never get there if we don't really force the change."

DCTs are definitely the way of the future, said one of the pharmaceutical executives. "We just have to figure out the best way to get them there. And I don't know if any single company can go and do it on their own. I really think it's got to be an industry approach. […] If we do it individually, we're going to end up with 10 different ways to do it in 10 different cost basis and structures and everything else that goes with it."

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