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Will Decentralized Trials Continue Growing After COVID-19 Pandemic Ends?

Some Patients Still Prefer In-Person Clinic Visits

by Alaric DeArment

Some of the changes from the pandemic are here to stay, but so are some of the concerns that kept them from taking root.

As the COVID-19 pandemic forced drug makers to hit the pause button on clinical trials last year, many sponsors adapted quickly to adopt remote and decentralized practices like telemedicine. That accelerated the trend toward decentralized trials already under way and has led many to believe that the pandemic may lead to more widespread, lasting change. But as the end of the pandemic is in sight, the question that now arises is how many of the changes will take root and continue, and what effect they will have on trial recruitment.

Since early in the pandemic, the general consensus has been that a type of hybrid model would become more prevalent, but would not replace trials requiring hospital-based tests. (Also see "*COVID-19 Will Spur Decentralized and Hybrid Trials – Novartis Hails Digital Investment*" - Scrip, 9 Apr, 2020.)

Still, some level of decentralization could hold up even in some more complicated disease states such as cancers, given the challenges to recruitment and how cumbersome it can be for patients to have to go to the clinic every few weeks, although in-person visits would be a must for procedures like PET and CT scans.

“I think companies will look for ways to be flexible because as you know, clinical trial enrollment is one of the challenges of the industry right now,” former *VelosBio Inc.* chief financial officer and current board member of *Zentalis Pharmaceuticals* Enoch Kariuki told *Scrip*. “And so if you can create flexible ways for patients to be part of these clinical trials, I think that will be attractive.”

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How Many Changes Will Stick?

"One of the misleading perceptions of decentralized clinical trials is that everything must be remote or the trial is not decentralized," PRA Health Sciences chief scientific officer Kent Thoelke said in an interview.

The clinical trial landscape going forward is most likely to include a lot of hybrid approaches. The pandemic has offered many lessons about flexibility and logistics, and the necessary adoption of some practices may have de-risked them long term, as well as shown them to be efficient, effective and popular. (Also see "*COVID-19 Pandemic Accelerates Shift Toward Virtual Trials*" - In Vivo, 1 Apr, 2020.)

What The Pandemic Can Teach Us About Running Clinical Trials

By Ian Schofield

22 May 2020
Participants in a recent webinar looked at how the coronavirus is changing the way we look at clinical trials and whether new EU COVID-19 guidance might hold lessons for future approaches to study design.

Read the full article here

There are options beyond home-based care and a traditional research center setting; many elements of hybrid trials could happen at places like mini-clinics set up in retail pharmacies. While chains like CVS and Walmart have built these clinics to administer care, WCG Inc. CEO Don Deieso told *Scrip* it is not a stretch to adapt them for use in decentralized trials.

"It's perfectly logical to think that that creates a decentralized network that can augment if not replace what was done in a brick-and-mortar clinical site," Deieso said. "It was not built for clinical research – it was built for clinical care – but it can easily be adapted and is easily being adapted on the clinical trial side."

Other changes likely to remain include use of video interactions with investigators in clinical trials through services like Teledoc, Deieso added.

"Video exchanges with investigators and/or the clinical site staff is just such a natural and logical winner," he said.

Tufts University Center for the Study of Drug Development deputy director Kenneth Getz said in an interview that he agreed with the view that a hybrid model was likely to emerge, driven by patient preference. But at the same time, he said he was already hearing anecdotal reports from investigative sites that although most trial activities in late 2020 were virtual and remote approaches, some patients were already asking if they could come back in for visits.

"What it really suggests is that we should be focusing less on the technologies, and we should be

focusing more on the agility, the training, the skills of the clinical research community to adapt and adjust so that we can entertain even more solutions as part of a hybrid offering," Getz said.

Getz envisioned a scenario in which 40% of trial participants still want to come in for in-person visits, while another 25% would want an in-person visit but prefer that it take place closer to home.

Before the pandemic, he said, there was a lot of reservation about moving to decentralized trial practices like remote monitoring because of issues like compatibility and infrastructure, as well as the additional burden that it placed on staff at investigative sites. As such, adoption of technologies like e-consents and use of wearable devices had been progressing at a very slow pace.

"The pandemic did not necessarily address all of the reservations, but out of necessity we had to embrace their use," Getz said. "But those reservations, while some of them may have more data [and] we have more input to inform … will reemerge and will have a louder voice when the pandemic is behind us."

But at least on the issue of consents, Litmus Health chief medical officer Sam Volchenboum said some change has already occurred. Historically, there had been a lot of pushback against doing consents remotely, and an insistence that they take place face-to-face.

"Now, we're seeing some real acceptance of the idea of doing remote consent, [as] long as the right structures are in place for people to answer questions and to get the information they need," Volchenboum said. He added that telehealth or remote interviews could also replace the sorts of procedures that require participants to travel 20-40 miles for 10-minute visits to "have a couple of boxes checked."

"So I think there's a great hope and I think an assumption that many of these advances are going to remain after COVID," he said. "There's always going to be the need sometimes for in-person visits and to be face-to-face with a clinician to go over particulars of a trial, to have a physical exam, obviously to have labs, but I have great hope that as we go forward, there'll be a much greater acceptance for being able to do many of the aspects of clinical trials remotely."

Patient acceptance presents another potential challenge.

"We may be getting into communities where there is less comfort level with some of these more impersonal approaches," Getz said. "There may be more skepticism in these communities, and it may vary certainly by age and by other demographic characteristics, so these are all things that we'll learn more about over time."

Meanwhile, sending staff to trial participants' homes can create a few challenges. For example, Deieso said sending nurses to visit people at home raises the question of whether nursing agencies are fully insured and whether drug companies have indemnified them in case of adverse events.

"There have been instances in which nurses have had to have physicians literally on the phone as they're infusing the drug, so should there be an event, they are in immediate contact," he said. "That's raised a whole series of other practical issues that are going to have to be addressed as we move more broadly to more decentralization."

Effect On Enrollment Still A Question

Another touted benefit of decentralized trials is their potential to help both with increasing enrollment and drawing from a more diverse pool of potential participants. It would stand to reason that the ability to reach more people in farther-flung geographies would equal more trial recruits.

That certainly made sense during COVID-19 when there was very real risk of exposure to SARS-CoV-2 if patients at high risk of severe disease came into the hospital. Volchenboum said there has been much more acceptance of "bringing the trial to the patient."

"If offered the chance to join a trial remotely versus having to come down to a hospital setting where they know they have a greater risk of exposure, I think people are going to be much more willing to enroll in a trial remotely," Volchenboum said. But he added that there is likely to be more and more use of technologies like Zoom, "and I hope that's here to stay."

In a 20 April Informa Pharma Intelligence webinar about clinical trial diversity, Harvard Medical School professor Barbara Bierer said that decentralization of trials could help extend them to remote communities far away from traditional academic medical centers. (Also see "*#ClinicalTrialsSoWhite: How Drug Makers Are Using COVID-19 To Improve Trial Diversity*" - Scrip, 16 Apr, 2021.)

But whether this is actually happening is another question.

"I think there are lots of conceptual advantages to offering more remote and virtual approaches," Getz said. "We have yet to see data that really demonstrates and proves that the conceptual promise is being recognized or realized."

But Thoelke said interview that in PRA's experience, decentralized approaches had sped up clinical trials.

"In our experience using decentralized approaches, PRA Health Sciences can recruit and dose

patients within weeks, or even days, compared to months or even years with traditional clinical trials," Thoelke said. "In addition to faster recruitment, we also found that patients are more compliant under decentralized methods.

Deieso echoed the view that decentralization could help drive trial diversity, especially through the aforementioned use of sites like mini-clinics and labs. For example, a drug store with a clinic that is close to someone's home can stay open later into the night than a traditional trial site can.

"If you can make some of that happen locally for [minorities], and you can create little centers where they can go, the success you're going to have in recruiting them and then keeping them in a clinical trial for the duration [goes up]," he said.