



How Decentralization Is Bringing Down Barriers To Patient Participation In Clinical Trials





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Decentralized clinical trials (DCTs) offer new opportunities to improve access to clinical research by reducing visit burden, building the trial around convenience for patients and their caregivers.

Research shows that around 70% of participants live two hours or more from their nearest study center.¹ For many patients, the distance may prevent them from participating, demonstrated by the fact that two-thirds of oncologists are unlikely to refer patients who live two hours from a site.² Other patients may enroll but drop out as the burden of long trips to and from sites takes its toll. DCTs can lessen those burdens.

“It makes study visit planning much more flexible. You can work more to the patient’s schedule. You may be able to arrange a home visit on an evening or weekend, or meet the patient close to their home or place of work. So, having a DCT really reduces some of the practical and financial challenges associated with patients having to go to a site, enabling participation from people in some underrepresented communities,” Ada Middleton, Senior Director within Parexel’s Patient Innovation Center, said.

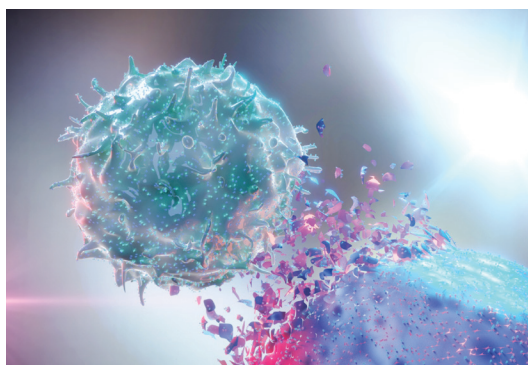
What The Validation of DCTs Revealed

Out of the necessity to ensure continuity of care, access to investigational medications and oversight of patient safety, the adoption of DCTs was accelerated as a way to mitigate the negative impacts of the COVID-19 pandemic. DCTs have quickly become a cornerstone of clinical trial delivery. The challenge now is to operationalize the lessons, keep listening and learning from sites and patients, and iterate to continually improve how trials are delivered remotely.

“We now know that decentralization works. We know it is much more patient centric. And so there is an expectation that you incorporate that into your everyday business. Every study that comes in is being looked at to say, ‘is there a way some of this can be done remotely or in a decentralized approach?’ It really has changed our thinking,” Middleton said.

The validation of DCTs has also expanded the frontiers of decentralization. For example, oncology was initially seen as unsuited to decentralization because assessments need in-person interactions, and the administration of the therapies requires the supervision of a health care professional.

“We’ve learned that you can incorporate DCT design into an oncology study. There are some medications that can safely be given in a home. There are some in between visit assessments that you could do remotely, some safety assessments or some patient questionnaires. So, there’s been a shift to say, ‘this is something that we can introduce as a DCT design to make it more patient centric, to make it easier for those patients. We absolutely could do a hybrid design’. Barriers remain, but forward-thinking drug developers



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have shown hybrid trials are viable,” Middleton said.

Why Technology Is Critical

Technology is enabling sponsors and CROs to use DCT designs for more trials. Telemedicine platforms, smartphone apps and wearable devices enable patients to connect and share data remotely, and the range of validated technologies now extends beyond those cornerstones of DCTs. As the lessons of recent years show, technology is steadily reducing

the data that needs to be gathered on site.

“In some asthma studies, you might do respiratory assessments or spirometry. Historically, you would do that at a site, but we now have technology and home nurse experts who are able to do some of those assessments in the home. The nurses are with the patient and do the spirometry. There’s definitely been a shift,” Middleton said.

Yet, deploying technology creates new challenges. Some patients lack smart devices capable of running study apps, meaning trials need to provide some or all participants with devices. The provision of study devices is subject to import laws, national regulatory requirements and other rules that add complexity and the potential for delays, particularly in global studies. An understanding of those differences, along with proactive planning, can mitigate the risk, enabling participation from patients in some underrepresented communities to access research in a way that has not previously been possible. There are other points of divergence too, such as the acceptability of e-signatures, which is vital to DCTs where eConsent is used instead.

“In one country, you may be able to use an eConsent

with an electronic signature, but in other countries there can be some restrictions. Patients may be able to have the consent presented to them on a phone or a tablet, but the e-signatures may not be allowed in that country or region. We may have one country where it's electronic signature, and we may have another country where patients need to download and print and sign an actual paper copy," Middleton said.

The technology needs to be simple and intuitive to use, too. As with consumer technologies, the goal is to enable patients to access everything they need in one place and with just a few clicks. When multiple pieces of software are needed, single sign-on can keep the experience simple and frustration-free for the patient.

Recentering Trials Around Patients

Technology is enabling DCTs but it is only part of the story. For Middleton, the adoption of DCTs is part of a broader recentering of protocols around the needs of patients. The process begins before the protocol has been developed, both by considering whether DCT elements would enhance the patient experience, and by thinking more broadly about when, where and how data is collected.

That entails questioning whether data for some endpoints needs collecting at all. If there are data deemed essential that cannot be gathered remotely, Middleton advises trying to take the readings or samples when the patient is already at the site for another purpose. Collecting data on the days patients attend sites, for more complex assessments such as MRI or x-ray scans, can reduce the number of times subjects need to visit centers.

COVID-19 demonstrated that patient-centric approaches work. The challenge now is to use lessons learned in the crucible of COVID-19 to operationalize DCTs for the post-pandemic era. That effort is well underway. Leading proponents of DCTs understand the challenges around matters such as patient privacy and regional regulations, and are using that knowledge to craft bespoke approaches to DCTs.

As sponsors continue to focus strongly on patients, different potential future state scenarios will start to come into focus. One possibility is that more activities will take place locally in the community. While there are limitations on what can be done at home, most people live close to a pharmacy or community clinic that could handle tasks such as phlebotomy, physical exams and medication administration that are currently done at sites, thereby eliminating some or all of the trips to distant study centers.

Parexel is already advancing its community care capabilities, through partnerships and other options, as it seeks to connect patients to trials through means other than home nurses and technology. Ultimately,

the expansion of the DCT toolkit will give teams more ways to operationalize patient centricity and tailor designs to the unique needs of each study.

"There's no one-size-fits-all approach with DCT. It really needs to be a bespoke solution applied to any individual protocol. So, even where you can have some consistency in approach, there still needs to be a very careful look at individual protocols and the requirements of it. We can build that bespoke approach using patient insights, technologies and the rest of our DCT toolbox," Middleton said.



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References

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About Parexel

Parexel supports the development of innovative new medicines to improve the health of patients. We provide services to help life sciences and biopharmaceutical clients everywhere transform scientific discoveries into new treatments. From decentralized clinical trials to regulatory consulting services to leveraging real world insights, our therapeutic, technical, and functional ability is underpinned by a deep conviction in what we do.