Four Insights on Decentralized Trials for Biotechs

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The COVID-19 pandemic accelerated the adoption of decentralized clinical trials (DCTs) by biopharma companies. The clinician-patient relationship will always be key to clinical trials, but decentralized aspects such as direct-to-patient shipments and telehealth are here to stay.

Here are four things we have learned about DCTs that biotech companies can consider when designing a decentralized or hybrid trial.

DCTs can be better for patients

Patient-centricity is a significant advantage of DCTs. "You can make a trial more patient-centric, reducing the burden on patients by not requiring them to travel to a site for every interaction," says Ada Wowk, Director of the Patient Innovation Center for Parexel.

Many aspects of clinical trials can now be performed while patients remain at home. E-Consent forms can be sent to patients and their parents or guardians in advance of talking through them on a video call that multiple family members can join. Patients and parents can sign and submit the forms electronically without leaving home. Direct-to-patient (DTP) logistics services can deliver study support materials such as devices and consumables and can also collect samples and return unused medicinal product and packaging materials. Consultations can take place over video calls, and even some clinical examinations, such as for skin conditions, can too.

During the COVID-19 pandemic, patients and sites engaged in clinical research have adapted to new devices and telehealth visits in what *The Lancet* recently called a "fast, effective readjustment." The risks to patient safety and trial integrity have been minimal. This success will accelerate adoption of DCTs.

DCTs can work for most therapeutic areas

There are no simple rules about which therapeutic areas (As) are most suitable for DCTs. Although it's probably true that a Phase I safety study is not a good candidate for a DCT. Evaluate each study on its merits.

Ada Wowk focuses on what the trial team is trying to accomplish. "What are your assessments? What are your primary and secondary endpoints? To do a DCT, you need to be able to take those assessments out of the clinic. So, we look at each study and determine whether it can work as a DCT. There is some dependency on the therapeutic area. For example, oncology studies often need site visits for radiographic assessments. But over the last six months, we've had several trials, including cancer studies, in which we used at least a hybrid DCT approach."

But just as cost shouldn't determine whether a trial is fully or partly decentralized, neither should the TA. Lisa Dilworth, Vice President and Head of Operations for Parexel Biotech Americas West, says, "Companies can best safeguard their investments by customizing trial designs to be fit-for-purpose and centered

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on patients." Depending on the target patient population, treatment, and indication, that design may recommend a DCT, a hybrid approach, or a traditional centralized trial.

It is challenging to decentralize an ongoing study

COVID-19 forced many clinical trials to pause or decentralize certain elements. Biotechs and their CRO partners had to determine if a DCT or hybrid model was possible and how any changes would impact their clinical studies.

Wowk notes that one of the first considerations was whether the patients could maintain access to their medication and how to minimize the loss of data. "It's difficult to pivot a study that didn't incorporate decentralized components from the start. As the industry adapts, it's increasingly clear that elements of decentralized and hybrid trials should be woven into study designs from the beginning."

"DCTs can engage more patients and improve retention. It is important to have clarity on the endpoints, assess and identify what can be decentralized, and focus on patients," says Natalia Grassis, Corporate Vice President, Head of Operations, Parexel Biotech Americas East.

Decentralized and hybrid approaches are here to stay. They are inherently patient-centric and can yield quality data, shortened timelines, cost efficiencies, and help patients more quickly get the therapies they need.

Only patients can define patient-centric

Patients know what works best for them. For example, patients in some cultures will not want home nursing visits because serious illness and disability are considered private. Others may feel embarrassed by constrained economic circumstances, such as many individuals living in one home, or by a psychological disorder such as hoarding.

To account for cultural and socioeconomic factors, talk with patients, caregivers, and sites, and solicit practical feedback about their needs. It's important to be flexible. If research shows that the target patient population doesn't want home nursing, local community centers, or even hotels can serve as alternatives. That still reduces travel time for trial participants, a prime benefit of DCTs.

DCTs enable patients to participate in clinical research when they otherwise would not have had access, which improves recruitment and retention. DCT technologies also offer the ability to collect data in real-time and allow data to be monitored earlier and more frequently than in traditional trials. Biotech companies that invest in gaining DCT expertise can deliver products to the patients who need them faster.

For more information on driving successful DCTs, read Top ten rules for success in decentralized trials.

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