

Is A Decentralized Clinical Trial Right For Your Trial? & 5 Tips For Success

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The COVID-19 pandemic has forced many drug developers to rethink the traditional clinical trial design. Catalyzed by the urgent need to protect patients from COVID infection risks while keeping drug development activities on track, many companies have had to explore innovative ways to expand their recruitment efforts by embracing remote or virtual “decentralized” trials that enable trial participants to avoid frequent travels to centralized trial locations. This shift, reinforced by rising interest overall in more patient-centric clinical trials, has been strongly supported

by the growth in innovative digital health technologies and leadership by regulatory authorities to address the issues posed by the pandemic and actively provide guidance for trial design.



By leveraging such strategies as telemedicine, mobile/local healthcare providers, virtual data collection methods, and home delivery of investigational therapies, companies have achieved considerable success in decentralizing clinical trials and shown that this model can offer significant benefits — not only during COVID but for drug development overall. The move toward decentralized trials has also encouraged smarter trial design while keeping costs down, speeding enrollment, and increasing patient retention, especially in cases where the nature of the disease or patient type poses challenges for traditional trials.

Which Trials Are Best Suited To Decentralization?

While some elements of decentralization -- such as video check-ins and e-consent procedures -- can be applied across all trial types, we have noted several specific trial characteristics that are particularly suited to remote studies. The more of these features that apply to a trial, the more likely it would benefit from a decentralized approach. These include:

- 1. The disease being addressed has low incidence/prevalence:** Opening participation to more and often geographically distant regions has a clear benefit for rare disease indications where it is often difficult to recruit in sufficient patient numbers. In this context, decentralized trials can result in faster recruitment and an increased ability to enroll enough patients even in indications with a very low prevalence. Increasing the number of trial participants can also improve the quality and robustness of data captured, and at lower cost than through a traditional trial design.
- 2. The trial involves patient-reported endpoints amenable to remote capture via digital tools:** Patient-reported outcome (PRO) measurements can be highly subjective. Connected technologies such as wearable devices and mobile health applications that can be easily adapted to the remote trial format have the potential to replace or complement PROs by enabling symptoms, medication side effects, and other patient-reported data to be tracked more frequently (even continuously) and accurately than can otherwise be accomplished.

3. **The trial involves a degenerative disease:** Degenerative diseases result in a high degree of physical impairment, making travel for even short distances burdensome for patients and caregivers. Home-based trial solutions – including home nurse visits, at-home lab tests, and virtual appointments – can be incorporated into decentralized clinical trials to increase convenience for the trial participants. Doing so can potentially lower the stress and cost of travel requirements, which in turn can translate to a higher willingness to participate and lower dropout rates. The number of companies that offer a variety of home-based trial services is growing quickly, thus increasing capabilities for providing more patients with easier access to clinical trials.
4. **The disease is amenable to visual assessment:** Conditions like dermatological indications that can be monitored visually through video, photography, or other imaging methods capable of being used remotely are particularly suited for decentralized trials.
5. **Trial participants tend to be tech-savvy “digital natives”:** Young adult or pediatric populations who are typically very comfortable and familiar with technology are natural candidates for participation in decentralized trials that use virtual formats and digital technology. Such digital natives are more likely to adapt quickly to complex user interfaces without the need for extensive training. However, recruitment efforts must be careful to avoid overrepresentation of such young, tech-savvy patients in studies that require participation over a range of ages.
6. **The trial is for a therapy that especially benefits from real-world evidence:** Real-world endpoints gathered by leveraging electronic medical records (EMRs) have been key to several recent new drug approvals and market expansions for existing products. Because decentralized trials are run outside the traditional structured clinical trial setting, they may introduce less bias in the data collected and lead to outcomes that are more likely to resemble those observed in the “real world” once a drug becomes commercially available. These considerations may lead physicians to have greater confidence in a drug’s benefit by strengthening their understanding of what might be expected from that drug in a real-world setting.

How Can Clinical Trial Executives Maximize Decentralized Trials’ Potential For Success?

To best capitalize on the potential benefits of decentralized trials and maximize the chances for success, we recommend that drug developers take five key actions:

1. Expand digital infrastructure both internally and at key clinical trial sites.

This includes investing in interconnected digital products and platforms that enable remote patient monitoring and data capture, facilitate data integration from multiple sources, and enable that data to be securely reviewed remotely in compliance with data privacy laws.

2. Increase data privacy to leverage EMRs.

EMRs are currently an underutilized trial monitoring resource due to concerns about data privacy, but the wealth of information they contain could be beneficial for further trial analyses. Minimizing the privacy concerns associated with decentralized clinical trials could increase participant engagement and expand the population willing to take part in a decentralized study, thus benefiting recruitment numbers and participant diversity.

3. Seek regulatory buy-in.

During COVID, regulators showed considerable flexibility and responsiveness in working with companies to address issues and provide the guidance needed to make decentralized clinical trials work. To retain this support, clinical trial executives need to continue to proactively engage with regulators and understand upcoming regulatory changes and requirements for the design of compliant trials. One way to do this is to foster inter-company collaboration and grow decentralization practices across the globe through consortia of biotech, pharma, and digital health companies working toward a common goal. One potential barrier to further decentralization perceived by many companies has been the need for greater clarity on whether validation trials will be needed to show the equivalence of data gathered remotely with traditional data collection methods. Consequently, investment in clinical trials that validate remote endpoints and biomarkers may be needed to achieve regulatory buy-in.

4. Design a comprehensive clinical trial strategy across the drug pipeline.

Understanding how decentralized trials fit into a company's overall pipeline is critical to designing a comprehensive future clinical trial strategy. For example, virtual control arms use predictive statistical data to replace placebo controls and enable the greater use of real-world data. Aggregated clinical data sets may improve comparisons between traditional and decentralized trials, decreasing the uncertainty when measuring the benefit of a new treatment. Furthermore, reducing the number of control patients or even eliminating such groups and instituting a synthetic control arm can increase trial efficiency, reduce delays and costs, aid recruitment (by eliminating fears of being assigned to a placebo group), and ultimately, help get a new drug to market more quickly.

5. Capitalize on digital innovation.

Digital healthcare and clinical trial support services have been growing quickly in recent years and are proving themselves to be valuable partners for drug developers who want to leverage decentralized trials without having to build the entire infrastructure needed to carry them out. Examples include companies offering end-to-end management of in-home trials, leveraging community doctors to help ensure a diverse investigator pool, and offering platform technologies that integrate a range of clinical research processes into a centralized research environment.

Conclusion

Decentralized trials have shown considerable benefit for reducing the time and cost of clinical trials as well as improving patient representation, and they are here to stay. A growing number of pharmaceutical/biotech companies are adopting remote clinical trial approaches outright or incorporating them in hybrid formats that combine traditional and decentralized strategies. However, choosing the right trial design, study population, or therapeutic indication for a decentralized study will be key to its success. Companies also need to make the right infrastructure and financial investments to best implement such strategies and seek regulatory buy-in along the way.

As the uptake of decentralized approaches to clinical trials continues to grow and becomes standard practice, it is becoming essential for pharmaceutical and biotechnology companies to take advantage of this evolving field to avoid missing out on significant clinical and commercial opportunities.

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