Evolving Clinical Trial Design in a Post-Pandemic Landscape

By Caleigh Findley

The pandemic fundamentally shifted the way industry approaches clinical trials. Dealing with shutdowns and social distancing forced trial sponsors to consider the number of on-site visits necessary for each study. Now, conversations on decentralized trials, meaning those that are either partly or entirely completed offsite, predominate. The shift has proven beneficial for participants and budgets but also poses several challenges in its execution.

Read on to learn more about post-pandemic clinical trials (and how to use this information to empower your research).

The Emerging Popularity of Patient-Centric Trials

A significant problem has loomed over clinical trials: failure to meet primary goals due to inadequate recruitment and participant retention. Nearly 20% of clinical trials ended early because of this issue. Early termination causes large budget hits with no tangible return on investment, ultimately delaying scientific progress.

For decades, participation estimates have remained at less than 5% of eligible people. Some blame lies with a lack of tailored recruitment strategies for each patient population. Industry sponsors must be thoughtful and have a strategic plan for optimal recruitment. Blame also resides with the burden of trial participation—including travel to on-site visits, time investment, and more. Depending on the study, the required participation level could deter eligible people from joining.

Decentralized trials present solutions for both recruitment and retention challenges. With an informed approach, recruitment can happen digitally to enable faster completion and a higher yield than in traditional trials. Participating in a trial remotely is also less burdensome, with many decentralized trials reporting higher participant retention. Such a design benefits both parties, making the end-to-end clinical trial process more streamlined and cost-effective.

Decentralized Trials in 2024

The degree of offsite protocols and remote management incorporated into a decentralized trial can vary greatly. Many industry sponsors opt for a hybrid design, which still requires some in-office visits. However, it often reduces the total number of visits and remotely handles other trial processes. Some sponsors also leverage a network of local healthcare providers, preventing participants from having to travel long distances for the trial. A hybrid design is especially useful for studies using a treatment protocol that participants cannot complete at home, like an intravenous infusion. Studies that require biological sample collection, medical imaging, or other technical procedures may also consider this design.

Fully decentralized trials require no on-site visits and are handled 100% remotely. These trials often incorporate an entire toolbox of digital software for remote participant recruitment and consent, study monitoring, data collection, risk management, and regulatory compliance. Wearable devices are also commonly used for data collection. This design poses the least burden to participants and can save sponsors time and money when done properly. However, neither hybrid nor fully decentralized trials are without their shortcomings.

Challenges

COVID-19 set forth several regulatory guidances globally on how to incorporate digital tools and execute a decentralized trial. However, despite their sustained popularity, many countries are still without specific regulatory guidance for decentralized trials. As industry sponsors increasingly take on multinational clinical trials, the regulatory landscape can become daunting for those wishing to incorporate decentralized tools and protocols.

Further, sponsors taking on large hybrid trials (and fully decentralized trials) need a reliable system for data management and integration. This software will also be subject to best practices and regulatory guidelines for proper data handling and storage. Wearable devices especially generate a large amount of data that can easily get out of hand without an appropriate data management system.

Summary

In a post-pandemic era, decentralized trials remain incredibly popular and are becoming more adopted worldwide. This trial design offers a better, more accessible experience for participants, which can support timely study completion. Remote management may also help sponsors save time and money. However, implementing decentralized tools into a trial requires expertise in specific regulations (or lack thereof) and comprehensive clinical trial management systems. Most sponsors will benefit from in-house expertise or partnering with a Contract Research Organization specializing in decentralized trials.

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