Top 5 Challenges Of Decentralized Clinical Trials And How To Overcome Them

WHITE PAPER

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As COVID-19 began to spread around the world, life sciences organizations conducting clinical trials had to quickly adopt remote data collection technologies and processes to keep patients safe and clinical trials running. As a result, 2020 saw many organizations adopting decentralized clinical trial models, even if they had never done so before. The big question now is to what extent these new approaches can remain in place once the pandemic is under control.

Virtual approaches come with a multitude of advantages. Patients tend to find virtual clinic visits and the ability to collect data at home more convenient, which can help increase the number and diversity of people willing to participate in a clinical study while also upping retention. Remote data collection also opens the potential to collecting a great deal more information than is available during the small moments in time when patients are in the clinic. This provides investigators with valuable patient insights and allows sponsors to answer their scientific questions even faster.

As we begin to look beyond the pandemic, it is important to take a closer look at some of the hurdles faced in implementing decentralized trials and how to address them. To gain insight into this area, Informa Pharma Intelligence and Oracle Health Sciences conducted a survey of biopharmaceutical companies, contract research organizations, and medical device companies involved in clinical trials around the world. The survey was conducted between September and November 2020 and included 252 qualified respondents, mostly from North America and Europe.

In addition to confirming that COVID-19 had indeed accelerated the adoption of decentralized trials, the survey revealed some important challenges faced during this transition. Survey respondents indicated their top concerns centered around ensuring compliance, tracking data, technology integration, patient engagement, and data reliability and quality.

Challenge 1: Compliance

Ensuring compliance remains one of the top operational issues when companies implement decentralized trial methods. Although remote data collection can improve patient compliance, it presents some challenges in other areas, such as data privacy and authentication.

Privacy laws and legal considerations are already quite complex. They not only vary from country to country but can also be handled differently at various clinical sites. Integrating more diverse ways of collecting data into a trial and moving that data collection from the clinic to a patient's home introduces even more privacy considerations. It also raises new questions, such as who controls and owns the data — the technology vendor, the sponsor, or the trial site? Moving forward, the industry will need to work together to figure out the best ways to address these issues on a global scale.

Authentication is another important issue. If data is being collected through a wearable sensor, it's critical to know that the patient is actually wearing the device and hasn't given it to someone else. Here, there is a need for advanced technologies such as facial recognition to be integrated into new data collection approaches.

Challenge 2: Tracking Data

When moving to decentralized models, tracking data can be burdensome. Virtual approaches are dramatically changing how data is collected. Mobile phones and wearable devices can provide around-the-clock data in a variety of forms. Although these approaches provide a better picture of how a patient is responding to a drug, it can be tough to manage and track data using traditional electronic data capture (EDC) systems.

EDC systems are based on paper forms and paper-based processes, which means they aren't designed to collect large volumes of data or to handle various data in one place. They also don't allow clinical research teams to collect new types of unstructured data from these new sources.

For the industry to continue embracing virtual approaches will require new tools that integrate data collection and data management and offer the ability to collect data from new sources and in non-conventional formats. It is also important to understand how data flows to and from

study participants, clinical sites, and everyone else involved in a trial. This requires careful consideration of timelines and data formats and the development of new data standards.

Challenge 3: Integrating new technologies

It's not surprising that life sciences companies are finding it challenging to integrate new technologies with all the various platforms used in clinical trials. Just one clinical study can involve up to 30 different systems, each with separate credentials, training, interfaces, support, validations, upgrades, and builds. Dealing with so many systems can create challenges on several levels. For patients, it creates a very fragmented and possibly frustrating experience. It also makes it extremely difficult for sites to get a complete picture of the patient experience in the trial.

Before COVID-19, many integration challenges centered around how to seamlessly transfer data from health records to EDC systems. More recently, hospitals and clinics have been adopting their own technologies to handle things like telemedicine or e-consents. Since sites often work with multiple sponsors that each use different systems and technology, there is need to design clinical trials in a way that leverages the tools that healthcare systems already have in place.

For decentralized trial models to be successful will require a concerted focus on integrating all the different systems and platforms into a seamless experience for everyone involved: the sponsor, the site, and the patients.

Challenge 4: Keeping patients engaged

Even though virtual methods can help with recruiting and retaining clinical trial participants, the survey showed that life sciences companies are still struggling with keeping those participants engaged. While this may seem surprising, it likely has to do with the fact that while some patients like the convenience of decentralized approaches, others prefer the face-to-face interaction with clinicians.

Decentralized trials offer an important opportunity to engage with patients who may not typically be able to or willing to visit a brick-and-mortar site because they live too far away or due to socioeconomic reasons. It's important not to squander this opportunity by applying a one-size-fits all solution for patient engagement. Instead, different approaches will need to be developed to best meet the needs of various patient populations.

Challenge 5: Data reliability and quality

Although the additional data available from new remote sensors and wearables is one of the most valuable aspects of decentralized methods, these data collection methods are still evolving. There are still many questions about which methods are the most reliable and how to compare data collected in different ways.

With decentralized models, the same information might be gathered virtually and in a face-to-face encounter within a study or even for a single patient. In some cases, regulators may want proof that data collected in different places is comparable and won't influence the overall outcome of the trial. Clinical trials can be designed to help with this challenge. For example, during a virtual visit, a healthcare professional can observe and guide patients in taking their vitals to enable more control and increase the reliability of data.

Many remote data collection approaches are still being developed on a case-by-case scenario. However, as an industry there is a need to look at each data collection method and figure out the best ways to increase reliability and achieve validation for that approach.

Embracing virtual trials as the way of the future

Well before COVID-19, Oracle was developing an eClinical platform that can overcome many of the challenges involved in adopting decentralized clinical trial methods. Clinical One is a unified platform that supports all types of trials in the simplest, most user-friendly way, providing a way to collect and manage all the clinical data in one place. Its intuitive user interface was built so that everybody can work together easily.

As clinical trials incorporate more virtual components, study teams and sites need more patient information, clinical insight, and control with less system complexity and burden. Clinical One not only collects and manages any data type from any source but also allows data to be easily tracked back to the source. This helps alleviate concerns about data integrity, accessibility, and visibility. Keeping all the data in one place means it is available any time and can be shared across people, processes, and systems throughout a trial.

Clinical One supports data collection as well as randomization and trial supplies management from the same platform, bringing two previously separate systems into a unified clinical trial workflow for sites and

study teams. The platform also integrates easily with other systems, electronic patient-reported outcomes systems, electronic health records, mHealth devices, and electronic trial master files.

By making it easier to incorporate new types of data collection and virtual components, Clinical One can help companies take full advantage of all the benefits of decentralized approaches and embrace changes that are still to come. As a result, life sciences companies can produce lifesaving therapies faster and more effectively.

Build a study once, enter data once, do everything in one place.

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