

# Exploring Clinical Trial Design and Data Collection in a New Environment

Research insights into how the COVID-19 pandemic is changing clinical trials



WHITE PAPER


By **Jim Streeter**, global vice president life sciences product strategy, Oracle

*As COVID-19 spread across the globe, life sciences organizations were forced to quickly change their approach to clinical trials. With travel restrictions and lockdowns, physical access to patients became almost impossible. Organizations accelerated their plans to shift to decentralized clinical trial models that leverage remote data collection technologies and processes to engage with patients, rather than in-person visits.*

To better understand how organizations are adapting to this new clinical trial environment, 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's 252 qualified respondents were mostly from North America and Europe.

The vast majority of respondents indicated that the COVID-19 pandemic has accelerated their adoption of decentralized clinical trial methods. Three in four said that at least some of their trials were decentralized, with many indicating they use this approach for more than half of their trials. The survey also revealed that this quick pivot toward decentralized clinical trials has been fraught with challenges centered around remote data collection.

Although the technology and approaches to support new types of data collection and analysis are available, respondents indicated that data quality was a top challenge in adopting decentralized clinical trial methods and their primary concern when it comes to data collection from



remote patients. Understanding and complying with regulatory guidance surrounding decentralized trials and data collection emerged as another source of confusion in this new environment.

## Embracing Remote Data Collection

Many decentralized approaches require new methods of collecting patient data. While most of those surveyed have incorporated remote data collection into clinical trials to some degree—or are planning to soon—the extent of the use of several decentralized methods within a single trial was unclear. The top approaches being used included smartphone apps used by patients, electronic patient-reported outcomes (ePROs), and wearables and devices that collect data.

Wearable and remote monitoring technologies come with a variety of benefits, which were also reflected in the survey. Respondents reported the top advantages were patient convenience, more comprehensive real-time data and insight, and savings in terms of time and resources for site staff.


By collecting data without requiring patients to come to the site, remote technologies make it easier for patients to participate in clinical trials and greatly reduce the number of site visits required. Although this data collection approach may be a necessity due to the pandemic, it could also help solve the long-standing challenge of recruiting enough participants and achieving diversity in clinical trials.

Mobile phones, patient apps, and wearable devices – collectively known as mHealth – provide around-the-clock data that comes in various forms. The huge volumes of interrelated information coming from these devices can be used to form a real-world picture of how a patient is responding to a drug. The data provides faster and more complete information because the clinical team can see everything that occurred instead of relying on tests and patient data acquired during a few office visits. This reveals drug efficacy and safety issues sooner, allowing pharmaceutical companies to make informed and faster decisions about their drug.

## What are the Challenges?

Although the benefits of wearable and remote data collection are many, half of the survey's respondents indicated a significant disadvantage: the need for new processes to review, manage, and interpret the large variety and volume of data. Expense and complicated regulatory considerations were also selected as top disadvantages for this technology.

When asked about remote data collection specifically, the survey respondents' primary concerns were data quality followed by data



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protection/privacy, and lack of standardization in data. This is not surprising, since regulatory review and approval focuses on trial data and monitoring. In terms of operational challenges, around half of the survey respondents identified compliance, effectively tracking all the data, and the ability to integrate with other platforms as the primary challenges for adopting decentralized clinical trial methods in the current environment.

The transition to more heavy reliance on remote data collection has been challenging because the electronic data capture (EDC) systems used in clinical trials for years have not evolved to support it. EDC systems are not designed to collect this extreme volume and variety of data, including unstructured data, from non-traditional sources. Another challenge is that a single trial can require sites and study teams to work with up to 30 different systems, all with separate credentials, training, interfaces, support, validations, upgrades, and builds. In addition to being an administrative burden, this makes it extremely difficult for sites to get a complete picture of a patient's experience in the trial.

The rapid shift to decentralized clinical trial approaches has brought many changes in protocols and procedures. New methods and technologies for data collection need to be set up quickly, and study teams must be prepared to work with these new innovations and adapt seamlessly. Even once a trial is in place, mid-study protocol changes are often inevitable. These changes are not only tough to implement but can be costly and cause significant delays. Protocol changes traditionally take one to two weeks and sometimes bringing down EDC and other systems.

Just under a quarter of respondents reported that the pandemic has not accelerated their adoption of decentralized clinical trial methods. For these respondents, regulatory concerns were their number one reason. The survey also revealed that regulatory guidance surrounding decentralized trials and data collection needs improvement, with around half of the respondents indicating that current regulatory guidance is not clear.

Digging into this issue further, the vast majority of survey respondents reported experiencing some difficulty complying with new guidance, most commonly maintaining the quality and integrity of the study, and training, monitoring, and ensuring compliance with regard to new data collection methods.

These results show that without clear guidance from regulatory bodies, organizations are worried about trying new technology. The fact that no standards exist for defining how new data collection technology can and should be applied in clinical trials is creating many unknowns. The best ways to work with regulatory agencies to apply these technologies in trials is still an open question.



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## A Better Way to Manage Data

When Oracle set out to work with Informa Pharma Intelligence on this research project, the goal was to understand where the industry stood regarding the adoption of decentralized trials, if the pandemic had, in fact, accelerated the rate of adoption, and what, if any, were the challenges and benefits of moving clinical trials in this direction. It was clear from the respondents that the time for change and adoption of decentralized trial methods is now but there are real concerns about data quality, data integrity, and regulatory guidance. None of this came as a huge surprise for Oracle, which has been leading the charge on eClinical software development for more than 30 years.

Before COVID-19 was a household name, Oracle was hard at work developing an eClinical platform that was future-proofed and ready for situations like the one our global community is facing today. And while no one could have predicted this pandemic and the immense impact it has had on clinical trials, not to mention the world, Oracle has been preparing for this moment for a long time.

Oracle's Clinical One next generation eClinical platform was designed to collect data from any source and allow faster adoption of new remote technologies. It lets a study team operationalize decentralized patient data capture and get a complete picture of a patient's experience in a single place. Study teams can also collect and consider data from electronic health record systems and genomics data.

The eClinical platform enables trials to be set up in just days using a point-and-click design. Setup is as easy as selecting which data to collect, and built-in features can be used to manage devices and how they get to patients, a task that can be complex for a large clinical trial. Protocol design changes or mid-study modifications can easily be made without any downtime. The platform is also designed to make it easy to share data across people, processes, and systems throughout a trial.

Until now, data collection and randomization and trial supplies management have always been two completely separate systems. However, Clinical One brings these two capabilities together into one unified clinical trial workflow that eliminates the time and costs of integrating these systems. This unified platform means a study is built once, data is entered once, and everything can be done from one place. Importantly, the platform remains functioning and accessible around the clock even when new features or upgrades are introduced.

## A New Way Forward

With Clinical One, the concerns around decentralized trials can be quieted. The platform was built to manage complex decentralized trials that leverage existing technologies as well as new and future technologies. And since Clinical One can be used to collect and manage any data type from any source, the result is a singular view and management of the patient. Worries about data integrity, data accessibility, and data visibility dissipate because data can be easily tracked back to the source through the platform. Any inconsistencies or missing data can be found without sifting through multiple systems to find the error. Additionally, monitoring and tracking data from any system or entry point is simplified. This makes it easy to report to regulators because all the patient data is in one place and available any time you need it.

In this challenging environment, it is more important than ever to have the ability to get clinical trials up and running quickly while maintaining full control of the data. Clinical One has proven it can provide the necessary platform and carry out a decentralized clinical trial while meeting the requirements set by any regulatory body. Although it typically takes eight to 12 weeks to set up a study, Clinical One is reducing that on an average of 50% or greater. In some cases, companies can even get clinical trials running in a matter of days. The faster a study can get up and running, the faster safety and efficacy results can be obtained, and the faster treatments can get to the patients who need them.

The COVID-19 pandemic has presented an opportunity to shift clinical trials to a more patient-centric model with improved data collection. Oracle's Clinical One can make it easier for organizations to transition to this new approach by helping them operationalize decentralized clinical trials and reap the full benefit of remote data collection, with the ultimate goal of bringing new therapies to patients, faster.

**To read more about what the industry had to say about decentralized clinical trials during the COVID-19 pandemic, download the full research report.**

### About Oracle Health Sciences

As a leader in life sciences cloud technology, Oracle Health Sciences' Clinical One and Safety One are trusted globally by professionals in both large and emerging companies engaged in clinical research and pharmacovigilance. With over 20 years' experience, Oracle Health Sciences is committed to supporting clinical development, delivering innovation to accelerate advancements, and empowering the life sciences industry to improve patient outcomes.

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

#### CONTACT

+1 800 633 0643

healthsciences\_ww\_grp@oracle.com

www.oracle.com/healthsciences

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