Research Results: Clinical Data Collection in a New Paradigm

Looking at the benefits and challenges of remote data collection

Kristin Letourneau, Ph.D.
Director of Market Research
Informa Engage

Jim Streeter
Global Vice President of Life Sciences Product Strategy
Oracle Health Sciences

The onset of the COVID-19 pandemic introduced significant clinical trial challenges, one of the foremost being remote data collection. Patients' reduced ability to travel to clinics for planned visits immediately presented obstacles to capturing data required to support study endpoints. It quickly became apparent that new strategies would be needed to operationalize the decentralization of data collection to meet patient needs while also ensuring compliant, regulatory-ready data for submission.

Almost a year into the pandemic, the environment continues to exert significant pressure on trial design and operations. Although the biggest impact is in extending trial enrollment timelines, protocol-related activities have also been disrupted. Many protocols have had to be amended, paused, or abandoned entirely, with the type and manner of data collection being primary topics for those carrying on.

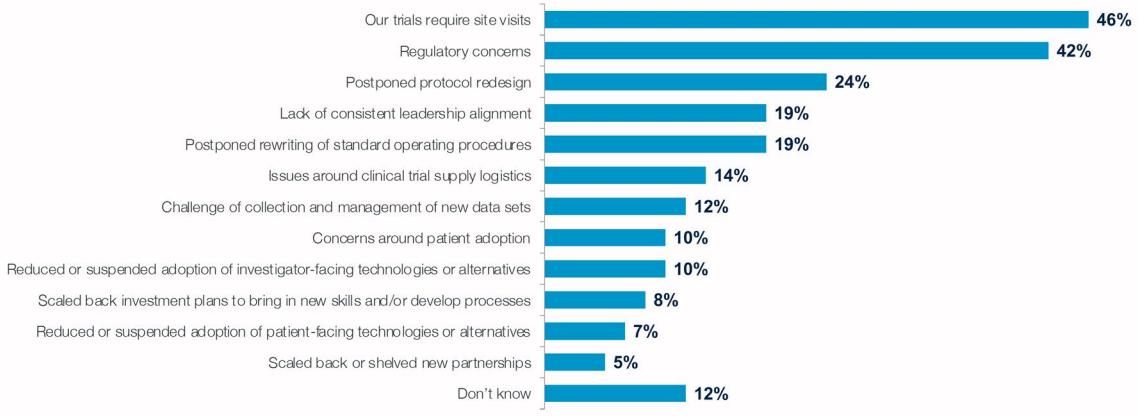
In partnership with Informa Connect, Oracle collected responses from 252 qualified respondents to gain insights into their experiences operationalizing trials in a pandemic. This article will explore these responses from a range of biopharma, contract research organization (CRO), and medical device companies on the approaches, benefits, and challenges of trial decentralization.

APPROACHES TO DECENTRALIZATION

To ensure respondents used the same concept when responding to the questions, decentralized clinical trials were defined as being "executed through telemedicine and mobile/local healthcare providers using procedures that vary from the traditional clinical trial model." An example of this would be an investigational medical product is shipped directly to a trial participant rather than being distributed by site personnel at a scheduled, in-clinic visit.

Figure 1: Reasons why decentralized trial methods have not been accelerated.

Those respondents reporting the pandemic has not accelerated decentralization of clinical trials report two key reasons: their trials require site visits (46%) and regulatory concerns (42%). One in four (24%) cite postponed protocol design.



Question: Why haven't decentralized trial methods accelerated in your organization? (Select all that apply.)

Base: Respondents reporting the pandemic has not accelerated decentralized trials; multiple responses permitted (n=59). Due to small sample size, this data should be used with caution, for directional purposes only.

Among respondents, 76% reported having some of their trials decentralized in this fashion, including 38% who say more than half of their trials fit this model.

Three-quarters of respondents stated that the pandemic accelerated the move to decentralized trial designs, but they varied in their approaches. No single strategy emerged as dominant among others that were employed. However, the incorporation of new technologies was one of the most important considerations. Patient-facing technologies or alternatives were used by 64% of those using decentralized models, while investigator-facing technologies were implemented by 53%. Technologies thus play a crucial role in transitioning from traditional clinical trial models to one that incorporates virtual visits and remote healthcare providers.

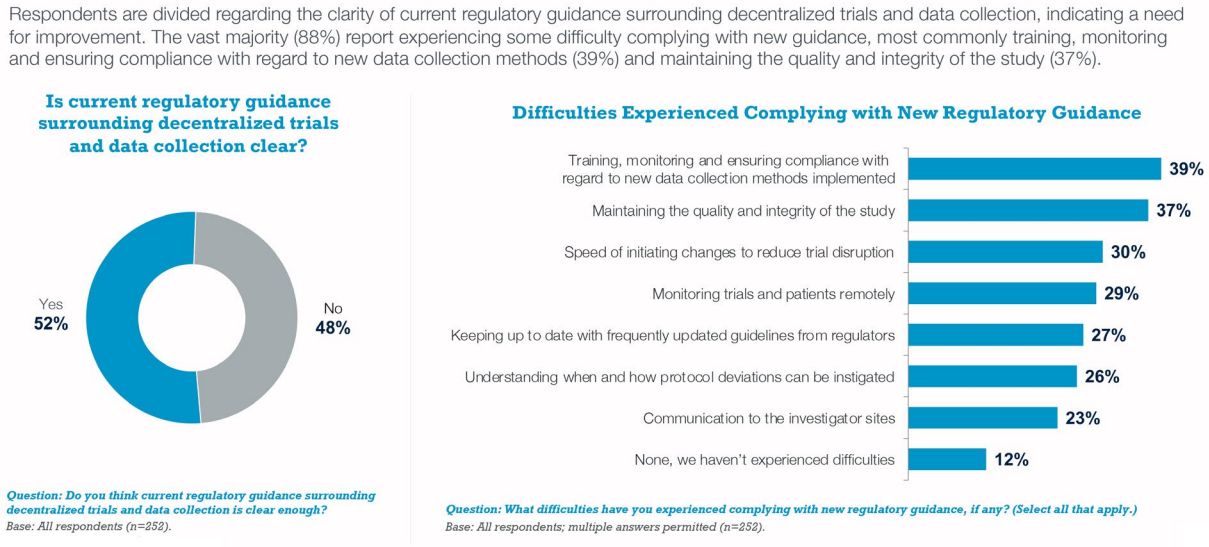
Operational changes made up the remainder of the approaches. Protocol redesign to accommodate the changes was the most favored method. Rewriting standard operating procedures (SOPs), developing new partnerships to manage the changes, and investing in the workforce to learn or develop the skills needed helped the sponsors, CROs, and device companies to meet demands. New partnerships and new technologies often go hand in hand, and many CROs have begun building services around managing these technologies to be adopted quickly in trials.

Despite the effects of the pandemic, not all trials moved toward a decentralized model. As shown in FIGURE 1, the most common reason was that the study required site visits to complete planned study procedures. Still, when moving to decentralization was a possibility, regulatory concerns were selected as the most frequent reason for not accelerating a new model. In a recent poll, responses were split on the clarity of regulatory guidance among the agencies on conducting decentralized trials, with nearly half stating the lack of confidence delaying the transition to a remote data collection model.

CHALLENGES FACED OPERATIONALIZING A DECENTRALIZED MODEL

When moving to a decentralized model, most sponsors and CROs indicated focusing on

Figure 2: Regulatory guidance and compliance challenges of decentralized trials.



guaranteeing proper patient monitoring and engagement as a concern in their responses. Complementary concerns were ensuring the quality and reliability of the data collected. Including new technologies into trials allowed for a level of continuity in trial operations, but adding new vendors or services also requires managing the new systems' build and maintenance. Study teams and CROs need to grow in size or adopt new skills to manage these operational difficulties to remain compliant and maintain trial oversight.

Regulatory compliance is always a concern during a trial, and decentralizing data collection and operations introduces a unique set of challenges. As mentioned above, sponsors believing the regulatory guidance is unclear has been a significant hindrance to accelerating decentralization. As seen in FIGURE 2, respondents worked to balance maintaining the speed of implementation and evolving regulatory guidance with study and data quality, specifically around remotely managing the training, monitoring, and compliance of sites and patients. This is especially challenging when the various agencies are not aligned on handling certain items, such as personal identifiable information.

One of the most practical intersections of the uncertainty around guidance is complying with agency regulations while employing innovative technologies. At the senior leadership level, regulatory agencies worldwide are pushing for the adoption of new tools. They are interested in speeding up clinical trials while still collecting clear data on drug efficacy and safety. Yet, in an audit, the auditor may not be fully aligned with the agency's upper levels about trial innovation. Many of the regulations developed over the past 20 years don't provide clear guidance on performing decentralized trials, further increasing confusion.

Sponsors are not the only stakeholder affected by the adoption of new data collection tools. As partners in the trial, sites have unique challenges. Research respondents also reported a need to cope with the comfort level of sites and patients while using unfamiliar technologies. In some trials, sites may become the technical point of support for the patient,

Figure 3: Impact of decentralized trial methods on technology requirements/current environment.

The primary impacts of adopting decentralized trial methods on technology requirements and the current environment include ensuring compliance (56%), effectively tracking all the data (44%), and the ability to integrate with other platforms (40%).

Question: What impact will the adoption of decentralized trial methods have on your technology requirements/current environment? (Select all that apply.)
Base: All respondents; multiple answers permitted (n=252).

Using technology to collect data remotely provides several benefits to operating trials during a pandemic, chiefly convenience.

or the patient may need to work with several different vendor help desks to solve technical problems. Introducing new technologies that are not yet integrated with other systems means sites may not be able to review data collected in a single system, leading to increased work. Solving for these situations will lead to improved partnerships with sites and becoming a sponsor of choice.

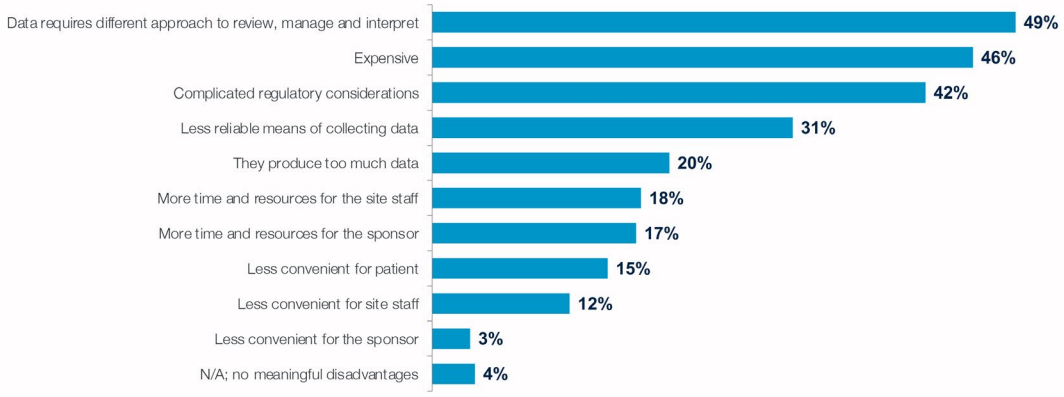
USING WEARABLES OR REMOTE TECHNOLOGIES TO DECENTRALIZE TRIALS

Sponsors have relied on several methods to decentralize trials, some new and others firmly established in trial operations. The most relied-upon method of remote data collection has been patient apps. Almost half of respondents used electronic patient-reported outcomes (ePRO) and wearables or devices to perform this role, a third amplifying monitoring activities, and a fifth incorporated mobile health or Internet of Things devices. ePRO and eCOA have seen increased use in local labs and imaging. One-quarter of respondents are already using wearables or remote technologies in a trial, and another 33% plan to do so within the next 18 months. FIGURE 3 illustrates the impact of decentralized trial methods on technology requirements in current environments.

Using technology to collect data remotely provides several benefits to operating trials during a pandemic, chiefly convenience. For patients, wearable technologies improve their experience in the study, simplifying data collection and reducing the burden of site visits. These tools also free site staff to focus on other trial activities and spend time with patients in the clinic. Sponsors also report more convenience and comprehensive, high-quality, real-time data with fewer resources committed.

Figure 4: Disadvantages of utilizing wearable and remote monitoring technology in clinical trials.

The primary disadvantages of utilizing wearable and remote monitoring technology in clinical trials include data requiring a different approach to review, manage and interpret (49%), the expense (46%) and complicated regulatory considerations (42%).



Question: What are the disadvantages of utilizing wearable and remote monitoring technology in clinical trials? (Select all that apply.)
Base: All respondents; multiple answers permitted (n=249).

Despite the many benefits wearable and remote monitoring technologies provide, they also have disadvantages to consider. FIGURE 4 shows the drawbacks as reported by respondents. The most-cited disadvantage, data requiring a different approach to review, manage, and interpret, can relate to the increased amount of data collected, as well as its availability. Depending on the data point being measured, wearable devices can generate enormous quantities of data.

Sponsors must be clear on the level of data they want to collect and determine efficient methods for cleaning and analyzing data. The ability to effectively analyze disparate data sets and reconcile inconsistencies across platforms presents a noteworthy challenge to overcome. To overcome this obstacle, many sponsors have fed raw data into a data lake for easier manipulation and analysis or used data cleaning to generate an optimized data set that yields clinically meaningful insights.

CONCLUSION

The initial phase of the pandemic response involved reacting to the unforseen challenges it introduced, but the next step will require refinement techniques to improve trial efficiencies. Sponsors will need to think through improving trial operations and experience for sites and patients. Automation will also play a large role, with tools like artificial intelligence and machine learning being harnessed to clean data more easily.

A recent webcast poll by Oracle indicated that 82% of respondents in the clinical trial industry expected the accelerated decentralization of trials to continue after the pandemic is over, indicating that the shift is not merely a response to a temporary set of challenges. As approvals of programs using decentralized trial methods increase, confidence and clarity around best practices, technology, and regulatory acceptance will help sponsors and their partners make informed decisions around trial designs.