Research Results: Clinical Data Collection in a New Paradigm

Looking at the benefits and challenges of remote data collection

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.

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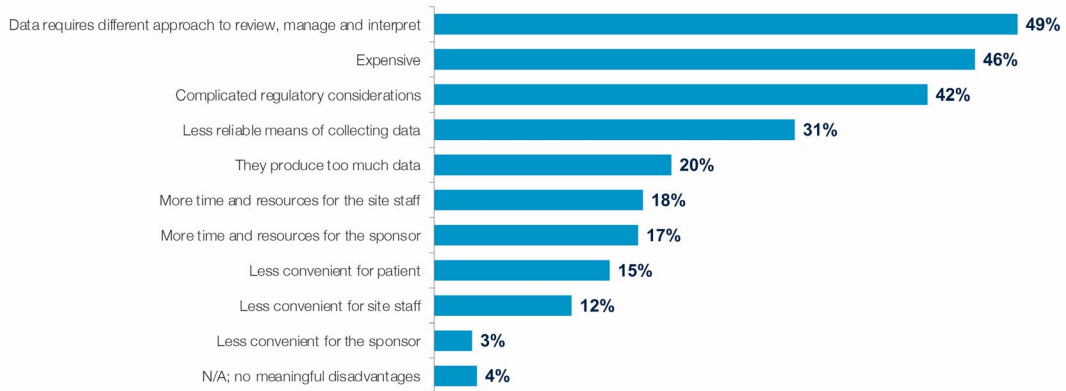*Director of Market Research*
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Figure 4: Disadvantages of utilizing wearable and remote monitoring technology in clinical trials.

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%).

Category	Percentage
Data requires different approach to review, manage and interpret	49%
Expensive	46%
Complicated regulatory considerations	42%
Less reliable means of collecting data	31%
They produce too much data	20%
More time and resources for the site staff	18%
More time and resources for the sponsor	17%
Less convenient for patient	15%
Less convenient for site staff	12%
Less convenient for the sponsor	3%
N/A; no meaningful disadvantages	4%

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.