

RESEARCH REPORT

The Accelerated Evolution of Clinical Trials in a Pandemic Environment

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Conducted by

PharmaIntelligence
Informa 

ORACLE



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Introduction

The COVID-19 pandemic has—without warning—turned clinical operations on its head, forcing the clinical research community to re-evaluate how to manage clinical trials. In an instant, physical access to patients across the globe ceased to be an option, having a significant impact on data collection and patient monitoring.

In this new environment that is forcing change, many organizations have accelerated their plans to shift to a decentralized clinical trial model. With this transition comes many benefits and challenges, and begs the question: are clinical development organizations prepared for this paradigm shift?

To explore the impact of the current environment on clinical trial management, Informa Pharma Intelligence and Oracle Health Sciences surveyed

professionals involved in clinical trials at biopharmaceutical companies, medical device companies, and contract research organizations (CROs) based around the world.

The research results provide valuable insight into how the COVID-19 pandemic is changing the way clinical trials are being conducted, and identifies the key challenges and opportunities surrounding these changes.

Key Findings from the Research

The pandemic has accelerated adoption of decentralized clinical trial methods

Seventy-six percent of respondents indicated that the COVID-19 pandemic has accelerated their adoption of decentralized clinical trial methods.

Data quality is the number one concern with remote data collection

Respondents indicated that data quality is a top challenge in adopting decentralized clinical trial methods and their primary concern when it comes to remote data collection.

The industry is divided regarding the clarity of regulatory guidance

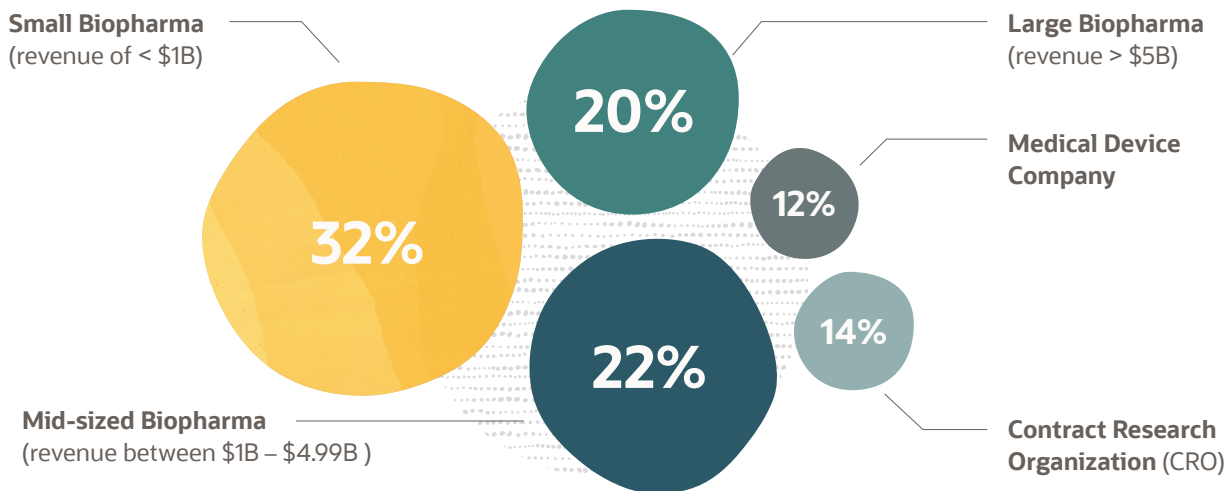
When asked if the current regulatory guidance surrounding decentralized trials and data collection was clear, 52% of respondents said “yes” and 48% said “no.” Additionally, the vast majority of respondents (88%) reported that they were experiencing some difficulty complying with new guidance.

Continue reading for deeper insight into these key findings.

Research Methodology

This research was conducted by Informa Engage on behalf of Oracle. Data was collected from September 21 through November 11, 2020. The research methodology used conformed to accepted marketing research methods, practices, and procedures. The research was conducted through an online survey sent to Informa Pharma Intelligence subscribers around the world who work in organizations involved in clinical research. Only respondents who worked for biopharmaceuticals, CROs, and medical device companies qualified to participate.

The breakout of company types represented by the respondents is as follows:

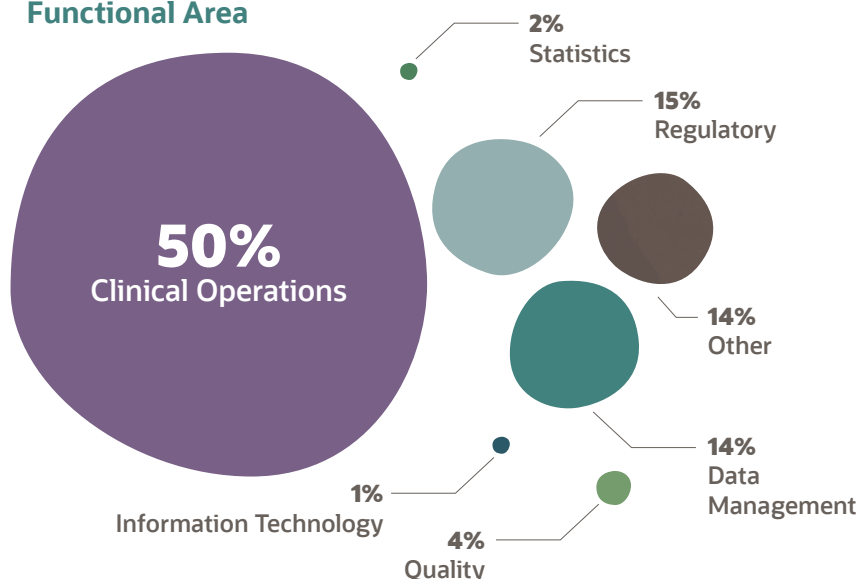


Respondents were primarily located in North America and Europe, with some representation from Asia Pacific and the rest of the world.

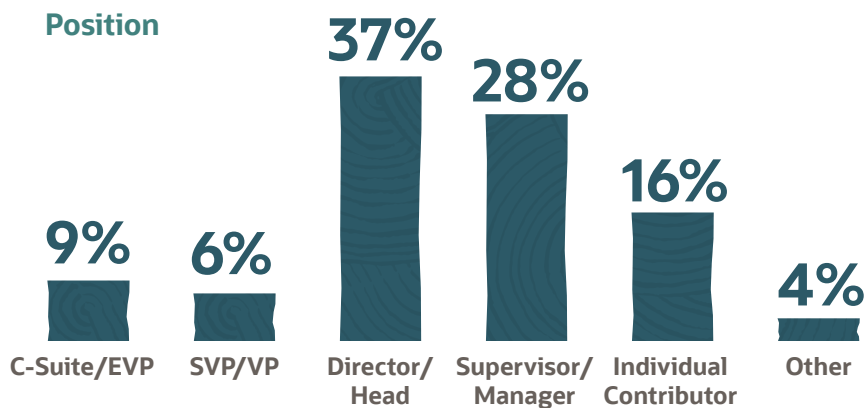


In order to qualify to participate, respondents had to be involved in the operation and management of clinical trials. In terms of job function and seniority, half of all respondents were in Clinical Operations (50%), holding Director-level or higher positions (52%).

Functional Area



Position



Qualified Respondents

252

The survey garnered 252 qualified respondents, representing a significant voice of the market.

Total Questions

26

The survey consisted of 26 multiple-choice questions exploring the impact of the current pandemic environment on clinical trial management.

Decentralized clinical trials are defined as those executed through telemedicine and mobile/local healthcare providers, using procedures that vary from the traditional clinical trial model (e.g., the investigational medical product is shipped directly to the trial participant).

Source: ctti-clinicaltrials.org



Results

The Impact of COVID-19 on Clinical Trial Operations

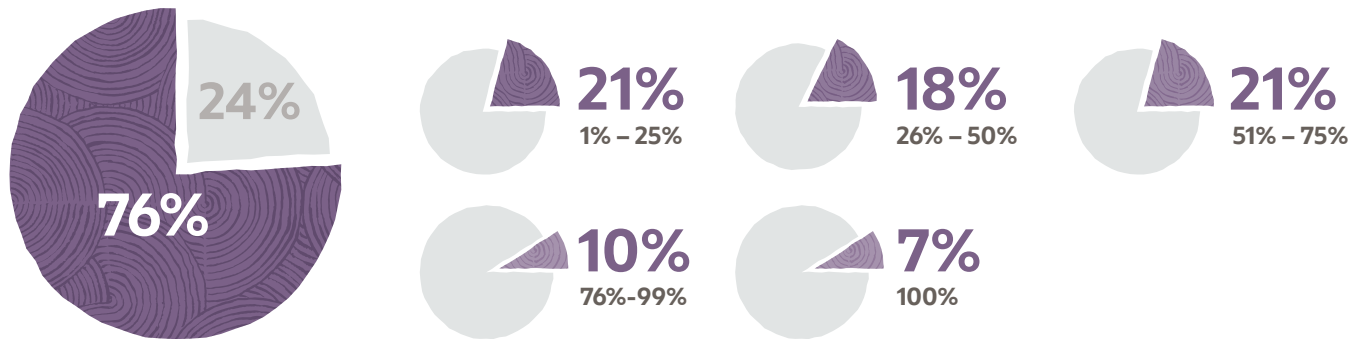
Decentralized clinical trials are no longer a vision of the future but a current reality. Additionally, the current pandemic environment has accelerated the move to this model of conducting clinical trials. But with it come many challenges, as well as opportunities.

What percentage of your trials are decentralized?

When it comes to decentralized clinical trials, three in four survey respondents (76%) report at least some of their trials are decentralized, including 38% who indicate more than half are.

% OF RESPONDENTS WITH AT LEAST SOME DECENTRALIZED TRIALS

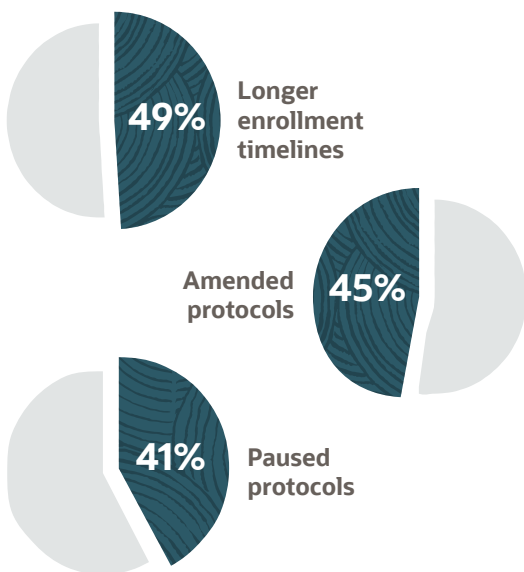
% OF TRIALS THAT ARE DECENTRALIZED



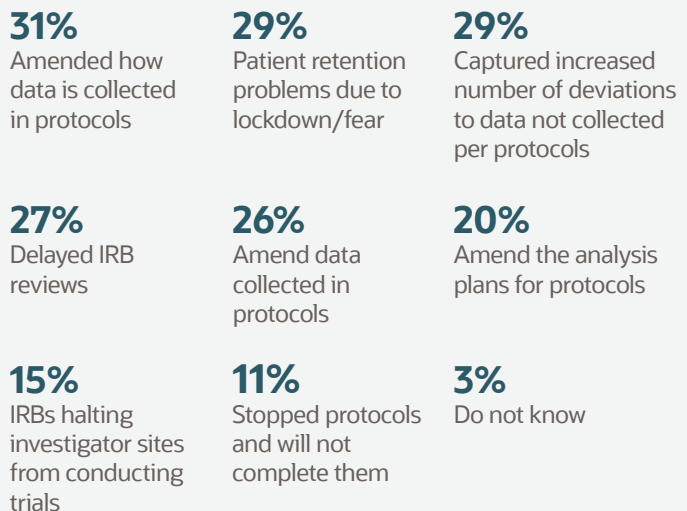
How has the COVID-19 pandemic impacted your ongoing clinical trials?

As it relates to current ongoing clinical trials, survey respondents identified the top impacts of the COVID-19 pandemic as being longer enrollment timelines (49%), amended protocols (45%), and paused protocols (41%).

BIGGEST IMPACTS



OTHER NOTED IMPACTS



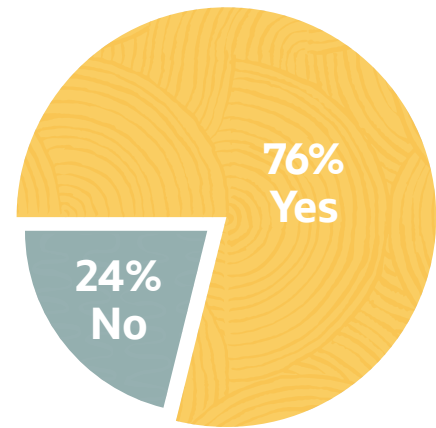
How has the COVID-19 pandemic impacted your strategy for running clinical trials?

When asked about how the COVID-19 pandemic has impacted their strategy for running clinical trials, 46% of respondents are planning or implementing decentralized trials, 44% are considering new vendors, and 36% are considering new geographies for trial locations.



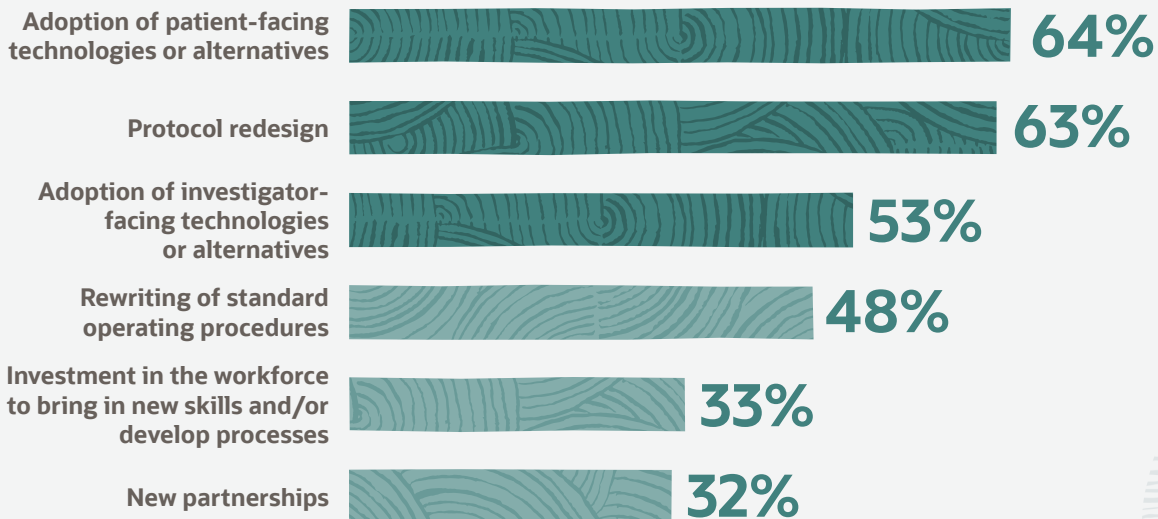
Has COVID-19 accelerated the adoption of decentralized clinical trial methods?

Digging into this a bit deeper, the survey revealed that the vast majority of respondents (76%) have accelerated their adoption of decentralized clinical trial methods as a result of the COVID-19 pandemic.



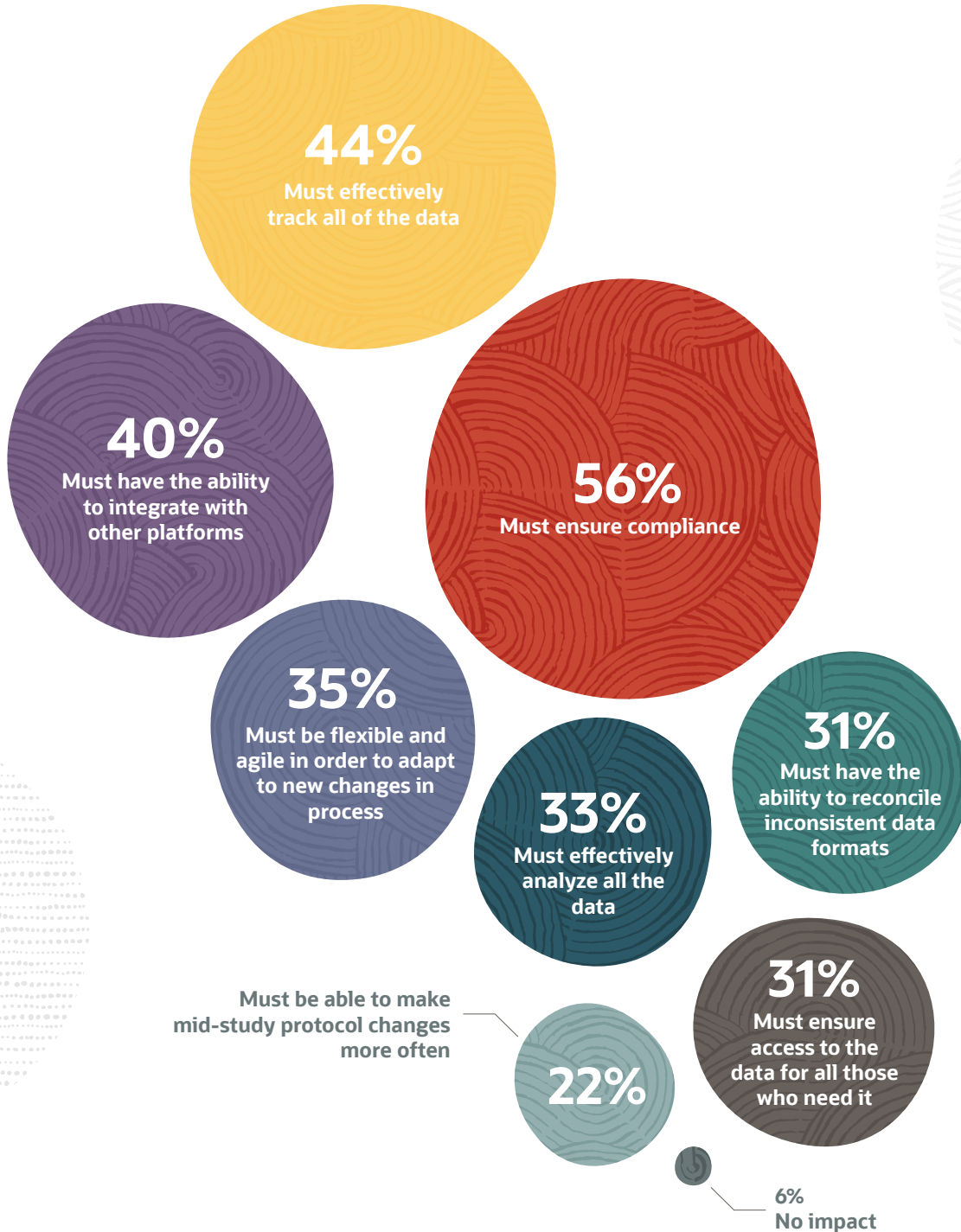
What steps have you taken to accelerate the adoption of decentralized trial methods?

In making this move to decentralized clinical trials, the most common steps taken by respondents are the adoption of patient-facing technologies or alternatives (64%) and protocol redesign (63%), followed by the adoption of investigator-facing technologies or alternatives (53%).



What impact will the adoption of decentralized trial methods have on your technology requirements/current environment?

However, with this shift to decentralized clinical trials comes operational challenges. When asked about the primary impact of adopting decentralized clinical trial methods on technology requirements and the current environment, survey respondents identified compliance (56%), effectively tracking all the data (44%), and the ability to integrate with other platforms (40%) as the top three challenges.

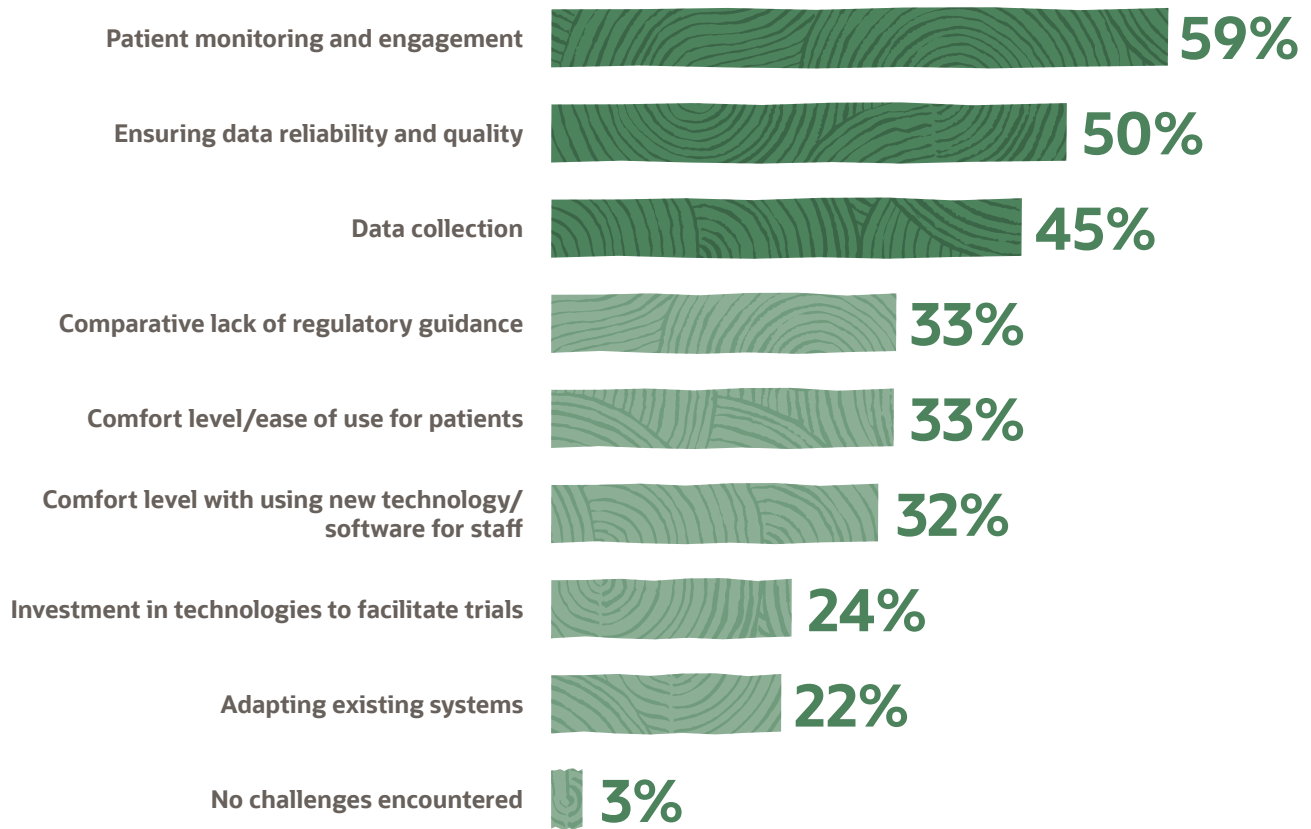


Tackling Decentralized Patient Monitoring and Data Collection

With the shift to decentralized clinical trials comes the introduction of wearables, remote patient monitoring, and the associated need for remote data collection.

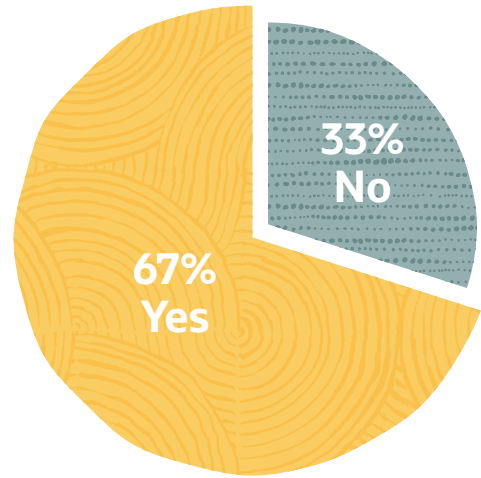
What are the main challenges you are facing in adopting decentralized trial methods?

When asked about the key challenges associated with moving to decentralized clinical trials, survey respondents cited patient monitoring and engagement (59%) as the top challenge, followed by ensuring data reliability and quality (50%), and data collection (45%).

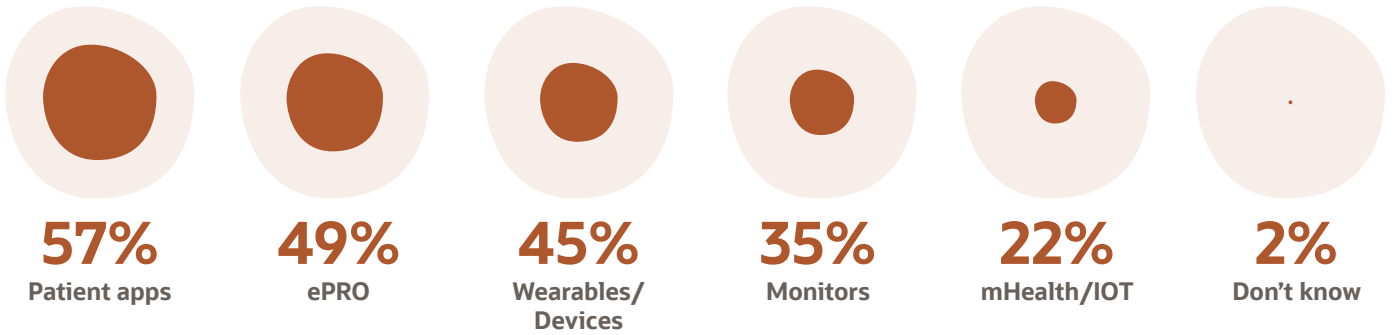


Have you implemented remote data collection into your clinical trials?

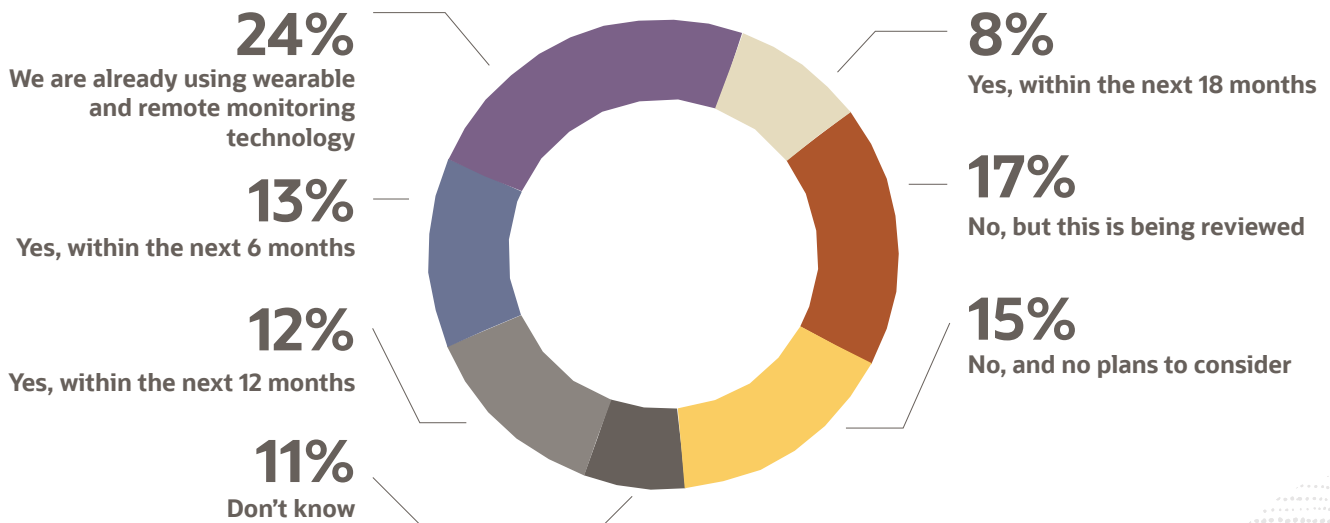
Although the pandemic has created urgency around making the jump to decentralized clinical trial models and remote patient monitoring and engagement, the majority of survey respondents have already implemented remote data collection into their clinical trials or are planning to.



Means of Implementing Remote Data Collection

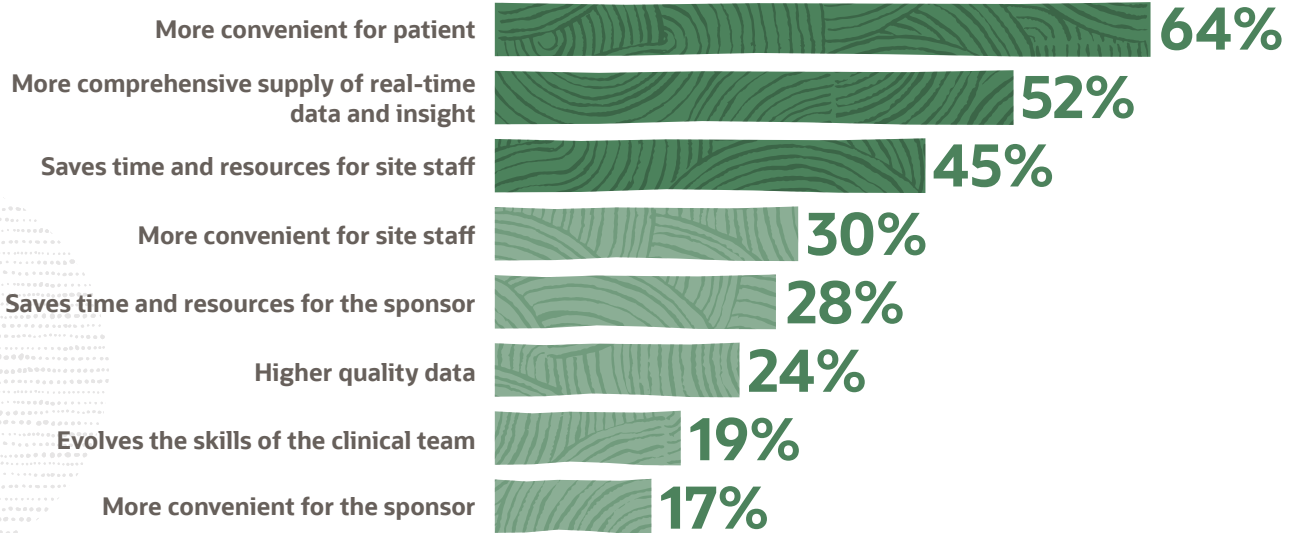


Do you have plans to introduce wearable and remote monitoring technology into your clinical trials?



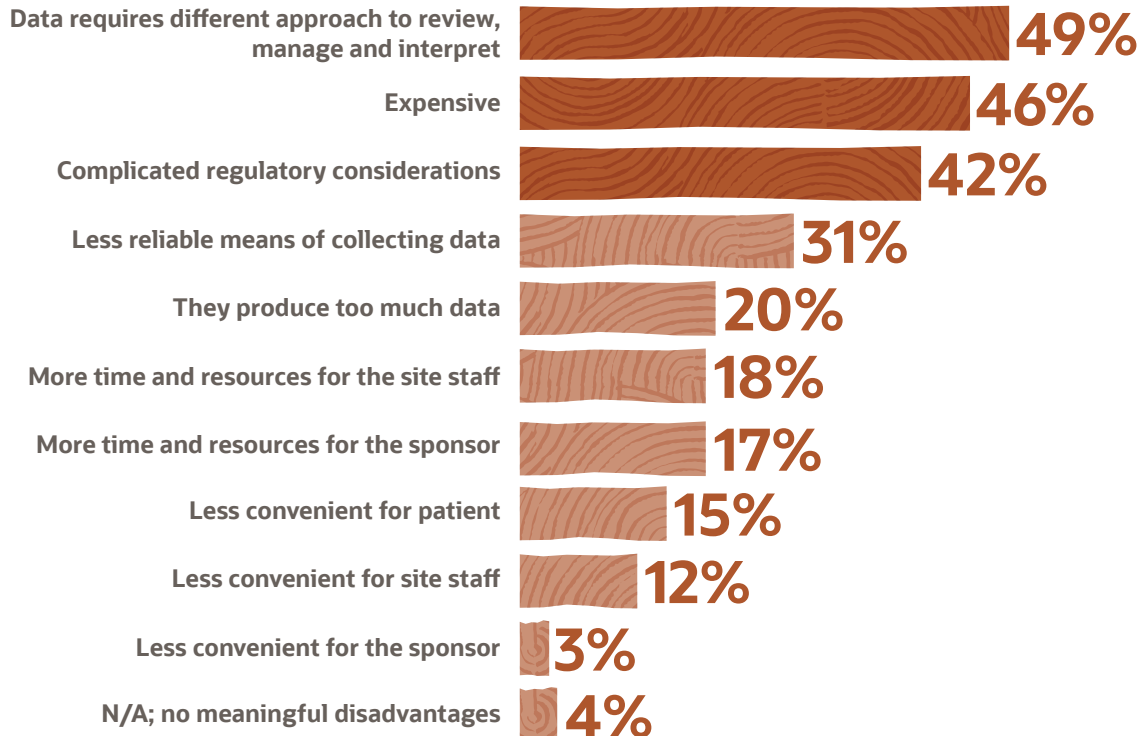
Benefits of utilizing wearable and remote monitoring technology

When asked about the key benefits of utilizing wearable and remote monitoring technology in clinical trials, survey respondents cited patient convenience (64%), followed by a more comprehensive supply of real-time data and insight (52%), and savings in terms of time and resources for site staff (45%).



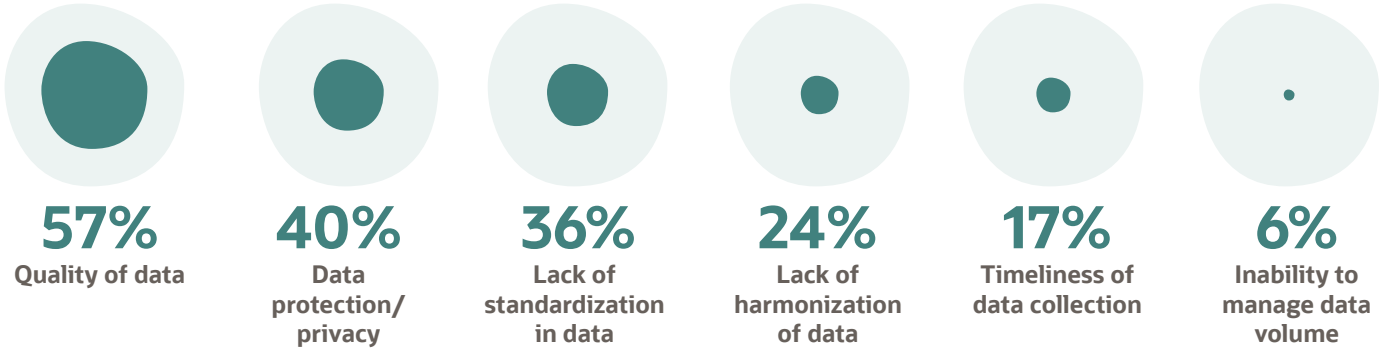
Disadvantages of utilizing wearable and remote monitoring technology

When asked about the disadvantages of utilizing wearable and remote monitoring technology in clinical trials, data requiring a different approach to review, manage, and interpret (49%) topped the list, followed by the expense (46%), and complicated regulatory considerations (42%).



What are your top two concerns regarding remote data collection?

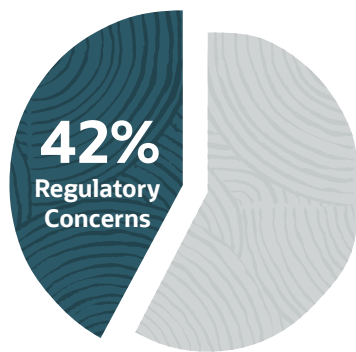
Naturally, with the introduction of remote data collection, there are concerns. Given that regulatory review and approval is focused on the data collected in clinical trials, it is not a surprise that survey respondents' primary concern regarding remote data collection is data quality (57%), followed by data protection/privacy (40%), and lack of standardization in data (36%).



The Murky Waters of Regulatory Guidance

While the move to decentralized clinical trials is underway and has been accelerated by the introduction of a global pandemic, the survey revealed that regulatory guidance around decentralized clinical trials is seen as unclear.

Why haven't decentralized trial methods accelerated in your organization?



The 24% of respondents who reported that the pandemic has not accelerated their adoption of decentralized clinical trial methods pointed to regulatory concerns (42%) as a top reason for this.

46%
Our trials require site visits

24%
Postponed protocol redesign

19%
Postponed rewriting of standard operating procedures

19%
Lack of consistent leadership alignment

14%
Issues around clinical trial supply logistics

12%
Challenge of collection and management of new data sets

10%
Concerns around patient adoption

10%
Reduced or suspended adoption of investigator-facing technologies or alternatives

8%
Scaled back investment plans to bring in new skills and/or develop processes

7%
Reduced or suspended adoption of patient-facing technologies or alternatives

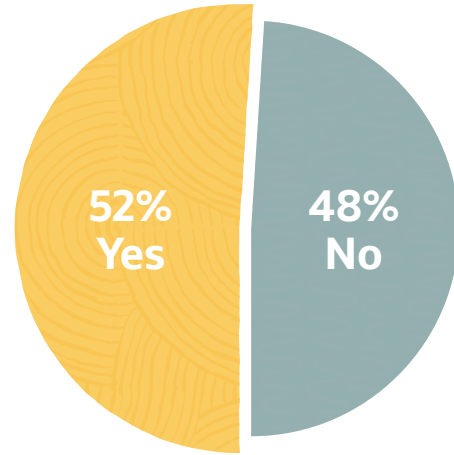
5%
Scaled back or shelved new partnerships

12%
Don't know



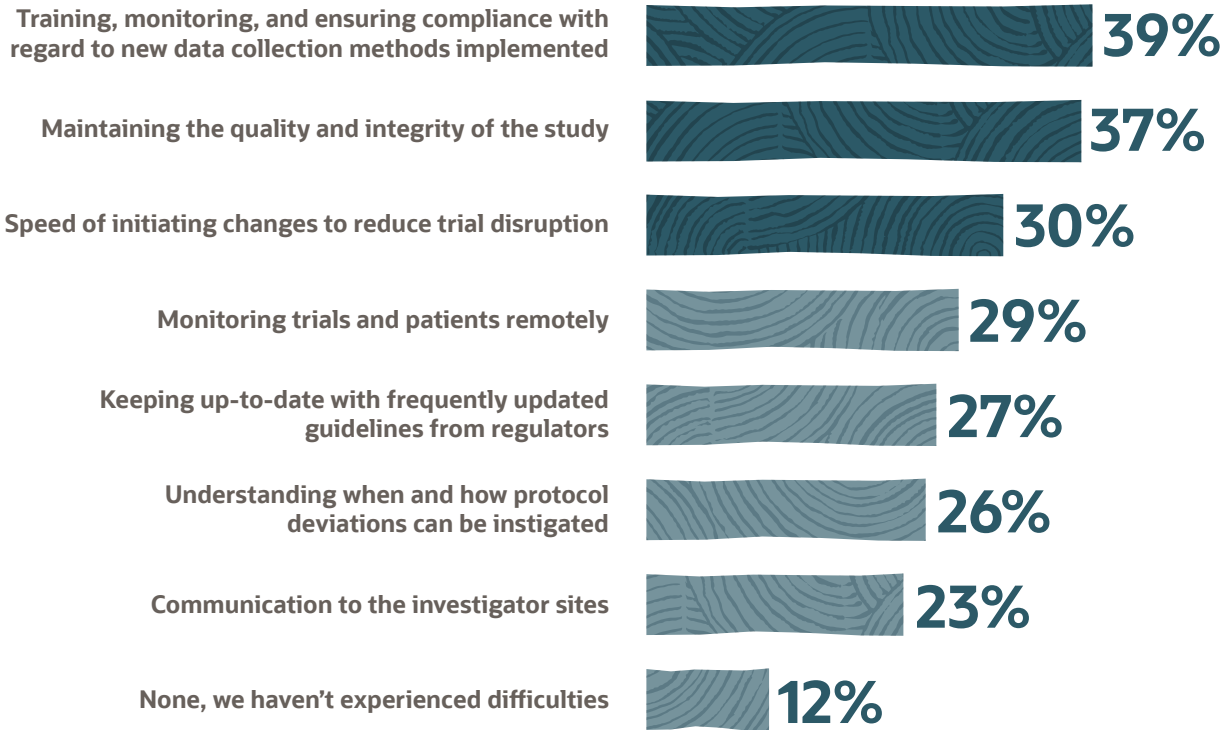
Is current regulatory guidance surrounding decentralized trials and data collection clear?

Respondents are divided regarding the clarity of current regulatory guidance surrounding decentralized trials and data collection, indicating a need for improvement.



What difficulties have you experienced complying with new regulatory guidance, if any?

Additionally, the vast majority of survey respondents (88%) report experiencing some difficulty complying with new guidance, most commonly training, monitoring, and ensuring compliance with regard to new data collection methods (39%), and maintaining the quality and integrity of the study (37%).



Conclusion

The COVID-19 pandemic has required Life Sciences organizations to extensively re-evaluate their approach to clinical trials. Travel restrictions and associated lockdowns have prevented physical access to patients across the globe, which has had significant consequences for data collection and patient monitoring.

While the industry was already shifting to adopt decentralized clinical trial methods, the pandemic has accelerated those efforts. Study teams are implementing wearables and remote patient monitoring technology, which allows patients to participate in clinical trials from the comfort of their home and eliminates or reduces the burden of in-person site visits. This change in how clinical trials are conducted is seen as being more convenient for the patient, providing more comprehensive data to study teams in real time, and saving time and resources for site staff.

But, as with any change, there are concerns and challenges. In the case of wearables and remote patient monitoring, worry is centered on data quality and management; in the case of decentralized clinical trials overall, concerns are primarily around regulatory guidance.

Fortunately, the technology and software to support decentralized clinical trials — the devices, the data, and the regulatory requirements — exist today and are designed to carry the industry into the future of clinical trials. As approaches to clinical trials continue to evolve, study teams can rest assured that technology will not slow them down.

For More Information

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