



Challenges And Opportunities In Clinical Data Management

RESEARCH REPORT
SEPTEMBER 2018

Conducted by:
Pharma Intelligence

Sponsored by:

ORACLE
Health Sciences

TABLE OF CONTENTS

Introduction.....	4
Research Methodology.....	5
Results.....	7
Operational Challenges Impacting Clinical Data Management.....	7
Lack Of Timely Access To Clinical Data.....	9
Data Governance Issues.....	10
Future Outlook.....	13
Conclusion.....	14



Challenges And Opportunities In Clinical Data Management

INTRODUCTION

Breakthrough medical interventions are nothing without accurate, comprehensive clinical trial data. Without such data, pharmaceutical and biotech companies are unable to provide the safety and efficacy validations needed to bring therapeutics to market and to the patients who need them.

Unfortunately, in today's high-pressured, fast-paced clinical development environment a huge challenge exists with the cleanliness, completeness and quality of clinical trial data. Clinical teams are spending valuable time cleaning data rather than analyzing it. The time wasted reconciling clinical trial data issues is detrimental and costly and can result in anything from small delays through to catastrophic setbacks that necessitate reruns of clinical trials. This challenge will only become more difficult to navigate as the volume and variety of data and data sources continue to increase.

To explore these issues and their impact, Pharma Intelligence and Oracle Health Sciences surveyed professionals involved in clinical data management at large pharma companies, biotechs, device developers and CROs based around the world.

The research provided valuable insight into operational issues around clinical trial data, quality issues related to clinical data and the implications of these issues, and a view into what this audience thinks the most urgent data issues will be five years from now.

Key findings from the research:

- **Managing clinical trial data is manual** – for 95% of respondents, manual effort is involved in aggregating, cleaning and transforming clinical trial data and two out of three respondents experience issues with this process.
- **Real-time access to clinical trial data is not the norm** – the majority of respondents do not have real-time access to their clinical data which can cause problems that can go undetected.
- **Data governance is the #1 issue for regulatory compliance** – 81% of respondents indicated data governance issues as the biggest challenge with clinical trial data in meeting regulatory compliance, and cited several serious and negative risks that can result from inconsistent or incomplete data.
- **eSource data is the future** – managing data from mHealth sources such as wearables, smartphones and other sources – and finding resources that know how to manage and clean new forms of data – will be the most urgent clinical trial data challenges five years from now.

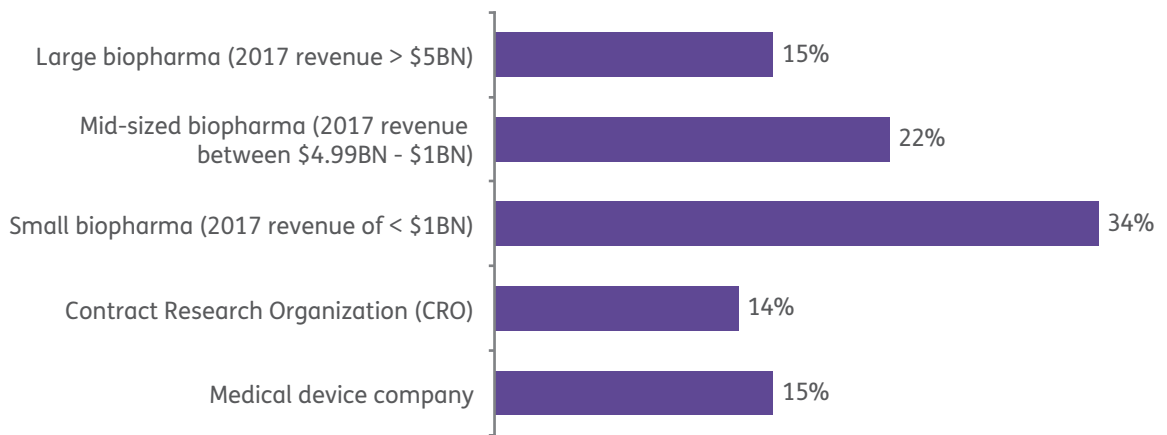
Continue reading for deeper insight into these key findings.



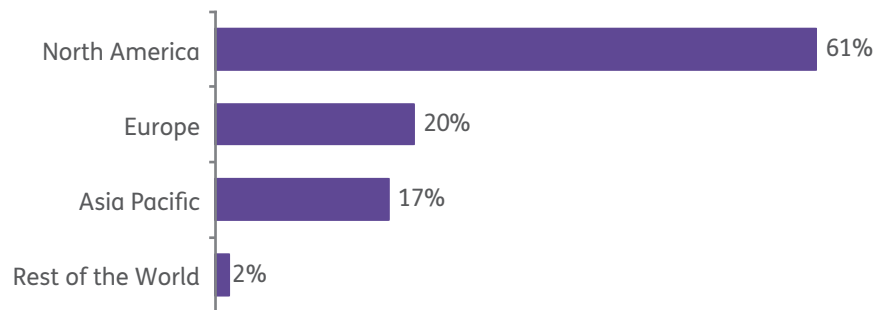
RESEARCH METHODOLOGY

This research was conducted in August and September of 2018 by Pharma Intelligence. The research methodology used conformed to accepted marketing research methods, practices and procedures. The research was conducted through an online survey sent to Pharma Intelligence subscribers around the world who work in organizations involved in clinical research. Only respondents who work for biopharma, Contract Research Organizations (CRO) and medical device companies qualified to participate.

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

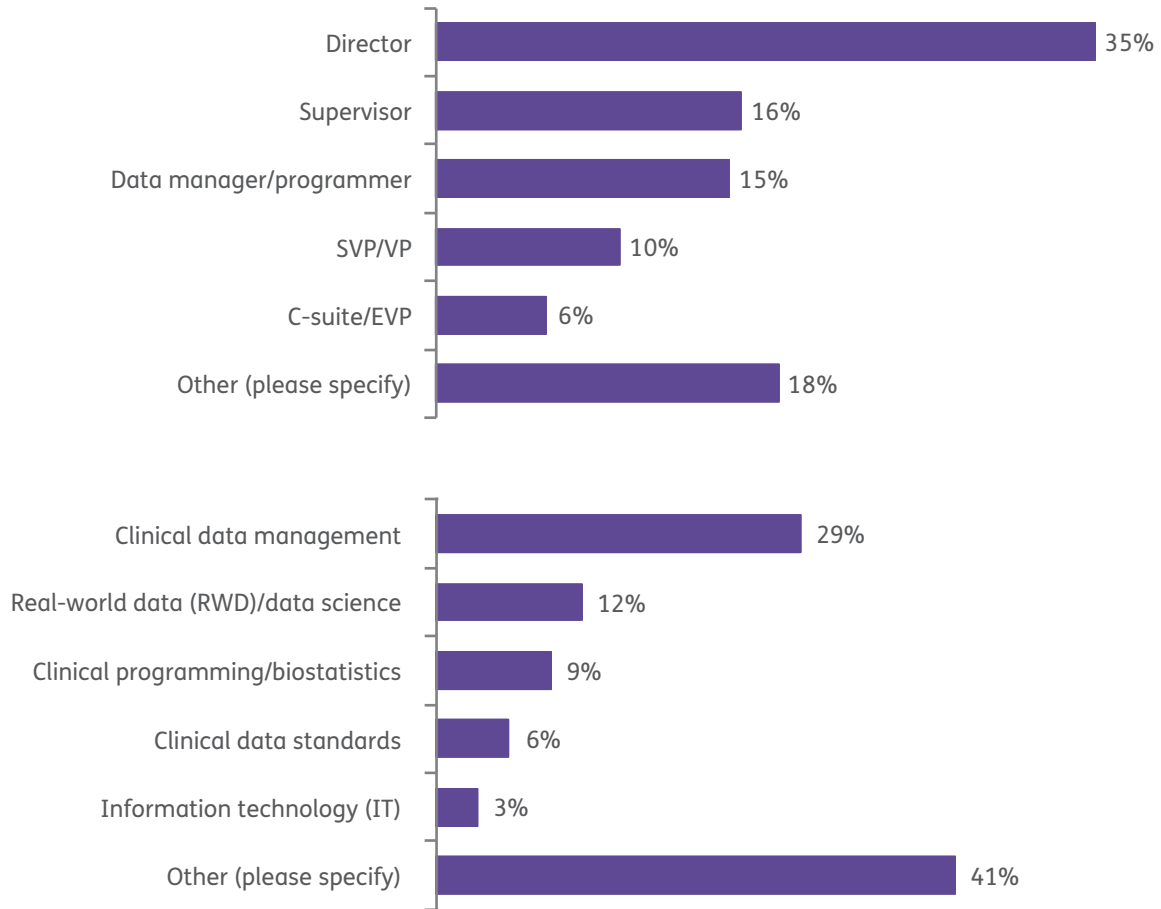


Respondents were primarily located in North America, followed by Europe and Asia Pacific.





In order to qualify to participate, respondents had to be involved in clinical data management. In terms of job function and seniority, respondents were senior professionals representing a variety of areas engaged in clinical data management.



NOTE: Other included Biomarkers validation, Business analytics, Chemical research, Clinical Affairs/Development/Endpoints/Marketing/Operation/Project Manager/Research/Trial Management, CMC data standards, Corporate strategy, Discovery Scientist, Drug Development, Knowledge Management, Librarian, Market Access, Patient Advocacy, Product Development and Commercialization, Product Management, R&D, Regulatory, Safety Data Consultant and Tech.

The survey garnered 155 qualified respondents, representing a significant voice of the market.

The survey consisted of 15 multiple choice questions exploring the state of clinical data management.



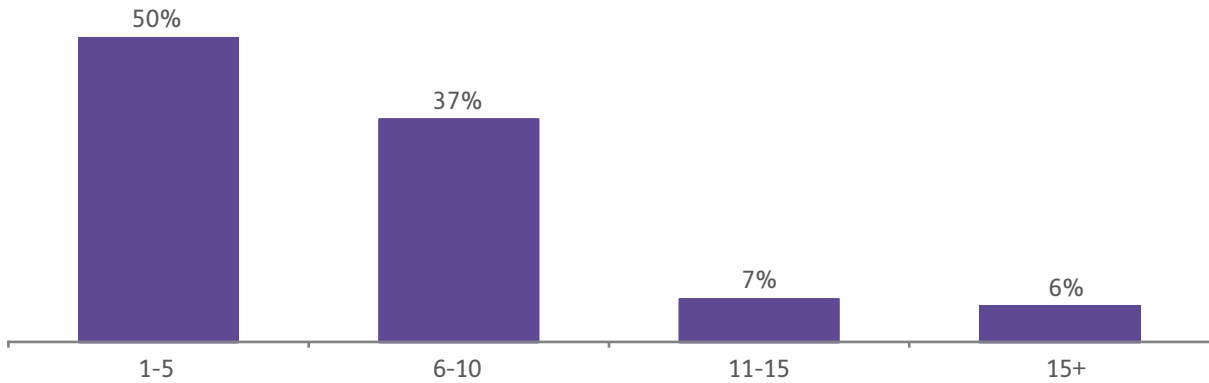
RESULTS

Operational Challenges In Clinical Data Management

When it comes to aggregating, cleaning and transforming clinical trial data, the effort is manual and laden with issues.

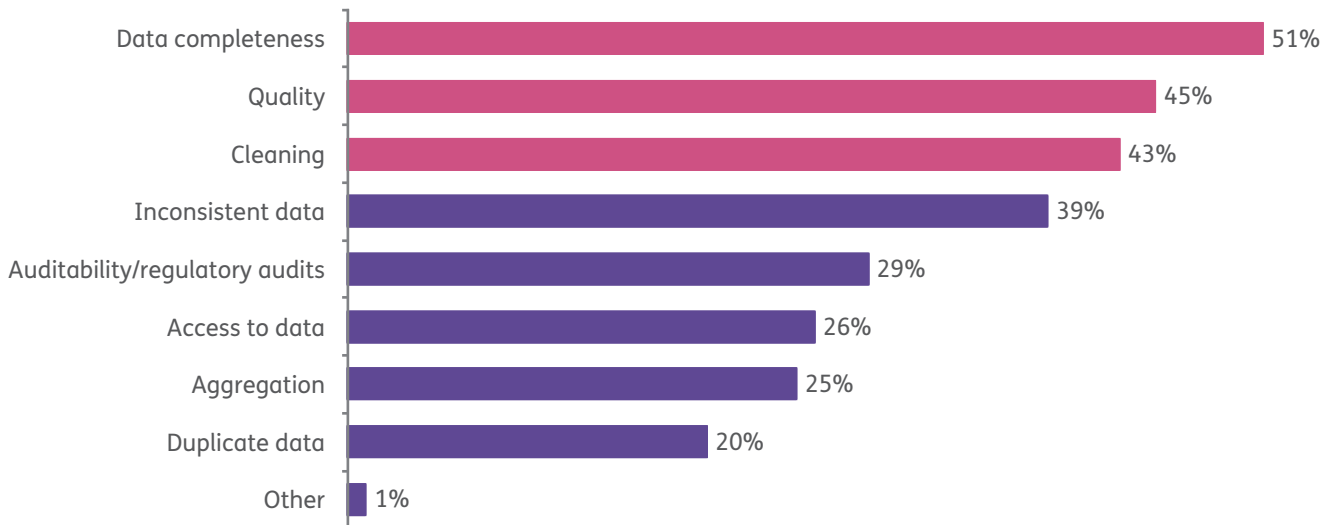
When asked how many different data sources they have for a typical clinical trial, 50% of respondents said between 1-5, 37% said between 6-10, and 13% said 11 or more.

How many different data sources do you have for a typical clinical trial?



In identifying their top three operational challenges with clinical trial data, the key challenges cited were data completeness (51%), quality (45%), cleaning (43%) and inconsistent data (39%).

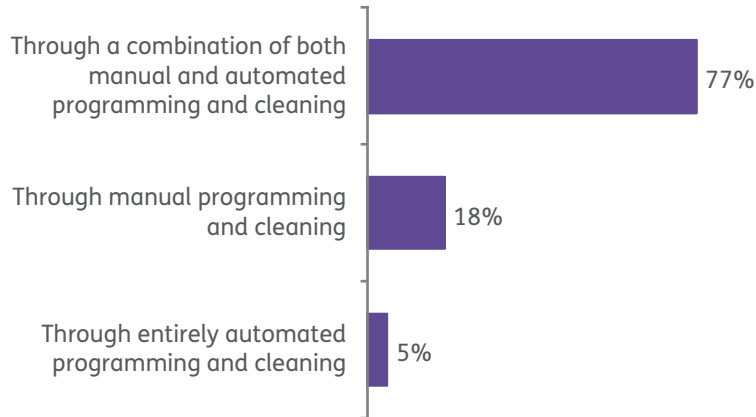
What are your top three operational challenges with clinical trial data?





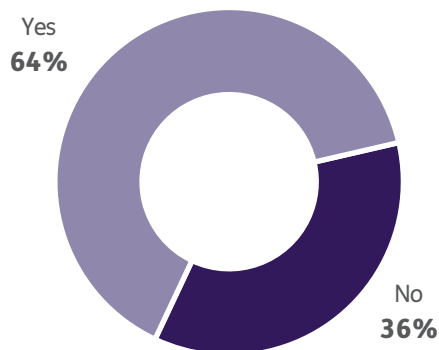
As it relates to how their data is prepared for use, 77% of respondents said their clinical trial data was aggregated, cleaned and transformed for use through a combination of both manual and automated processes, 18% said it was entirely manual, and only 5% said it was entirely automated.

How is your clinical trial data aggregated, cleaned and transformed for use?



When it comes to challenges, nearly two-thirds of respondents said they experienced issues when aggregating, cleaning and transforming clinical trial data.

Have you experienced any issues when aggregating, cleaning and transforming your clinical trial data?



Top issues experienced when trying to control clinical trial data
(sample of most common free-text answers)

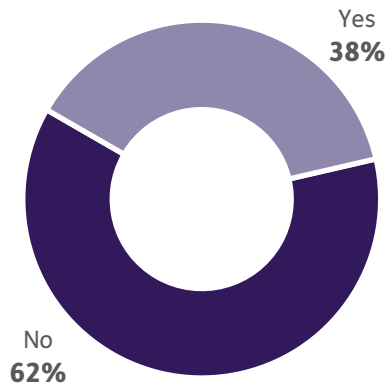
- No single place to perform review of clinical data in real-time
- Lag in getting the data
- Can be difficult to get errors corrected



Lack of Timely Access to Clinical Data

When it comes to accessing their clinical data, the majority of respondents do not have real-time access to their data, which can cause problems that can go undetected until it is too late.

Do you have real-time access to ALL of your clinical trial data?

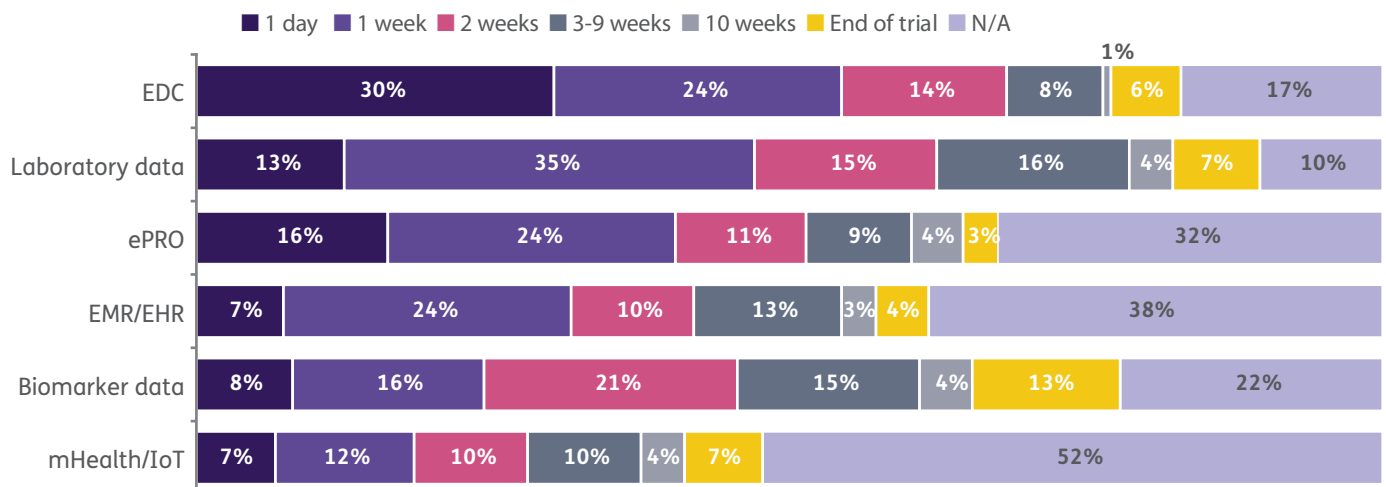


Top issues experienced in accessing real-time clinical trial data
(sample of most common free-text answers)

- Data entry delays, cleaning backlog, not being able to program complex edit checks
- Inconsistent data formats and meta data for different sources
- Latency issues with the system, missing data, inaccurate data

When asked how long it takes to receive clinical trial data from internal and external partners, once it has been requested, the survey revealed that Electronic Data Capture (EDC) and laboratory data have the fastest distribution times, while mHealth/IoT and Biomarker data was cited by respondents as having the longest delivery times.

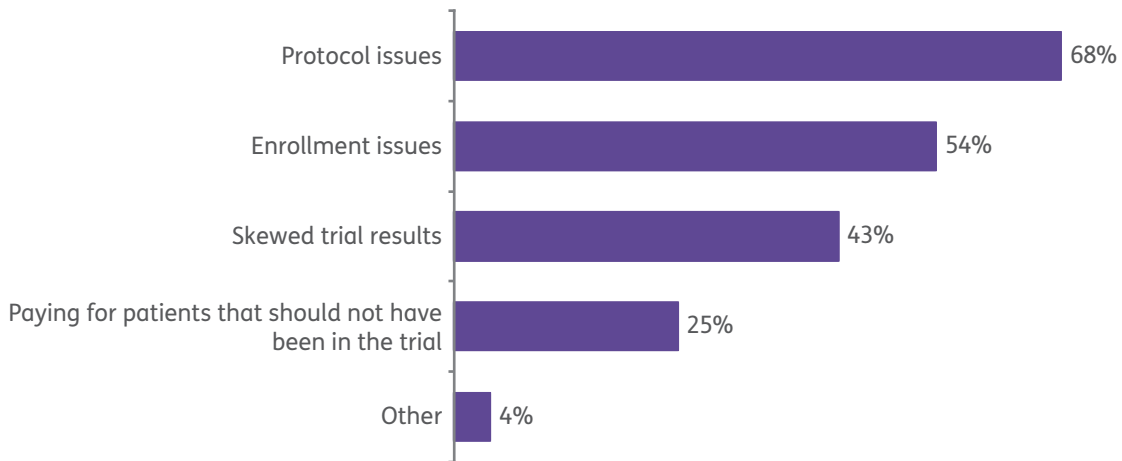
How long does it take to receive clinical trial data from internal and external partners, once it has been requested?





Survey respondents identified protocol issues, enrollment issues and skewed trial results as the most common problems that can go undetected without timely access to clinical trial data.

What are the most common problems that can go undetected without timely access to clinical trial data?

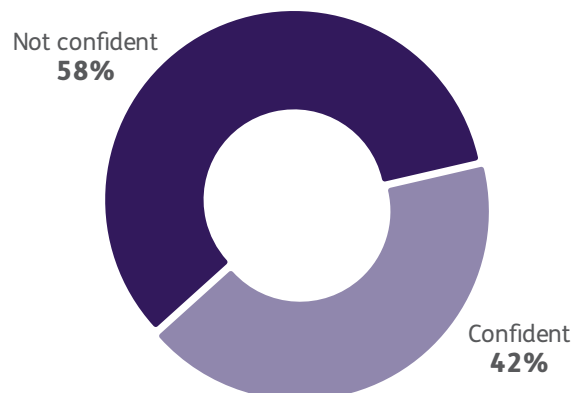


Data Governance Issues

Not surprisingly, data governance issues are the biggest challenge with clinical trial data in meeting regulatory compliance, and the negative implications of these challenges to a clinical trial are severe.

When it comes to trust in their data, 58% of survey respondents indicated they are not confident in the quality or completeness of their clinical data from an audit and compliance perspective.

During your clinical trials, how confident are you in the quality and completeness of your data from an audit and compliance perspective?

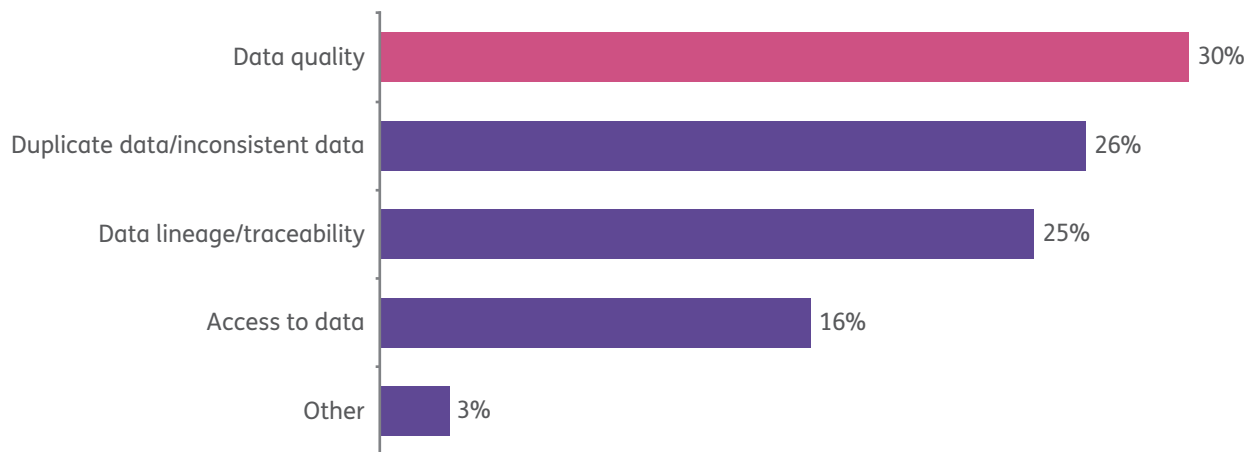


NOTE: 'Not confident' includes the options: Somewhat confident, Not very confident & Not at all confident.



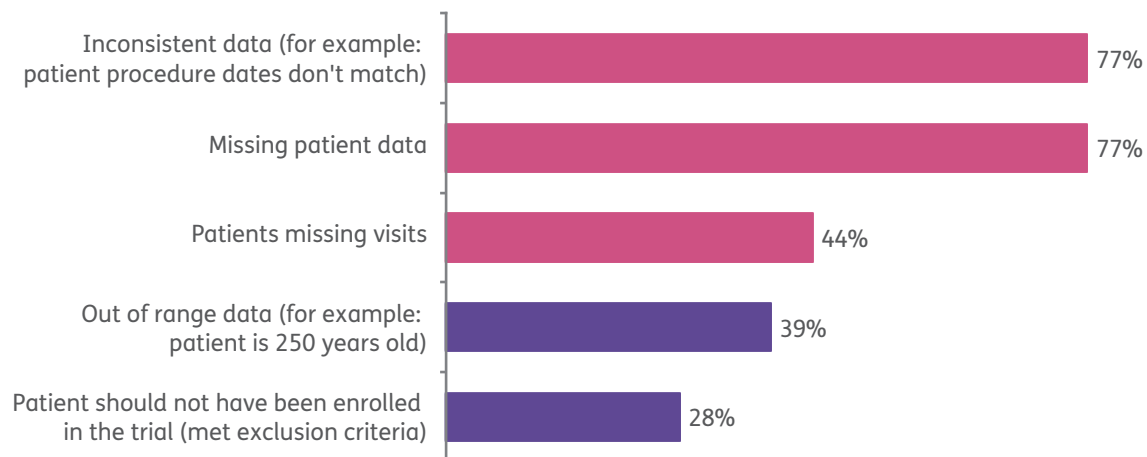
When asked about their biggest challenge with clinical trial data in meeting regulatory compliance, 81% of respondents indicated data governance issues. The top three data governance issues cited were data quality, duplicated data/inconsistent data, and data lineage/traceability.

What is your biggest challenge when it comes to meeting regulatory compliance with your clinical trial data?



When asked about the most critical problems to catch when looking at clinical trial data, the top three were inconsistent data, missing data, and patients missing visits.

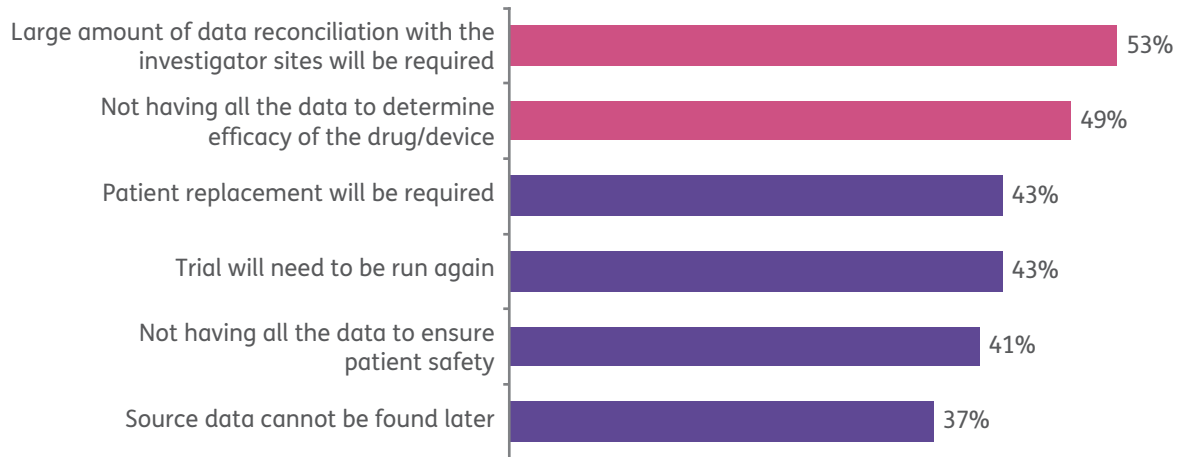
What are your top three most critical problems to catch when looking at clinical trial data?





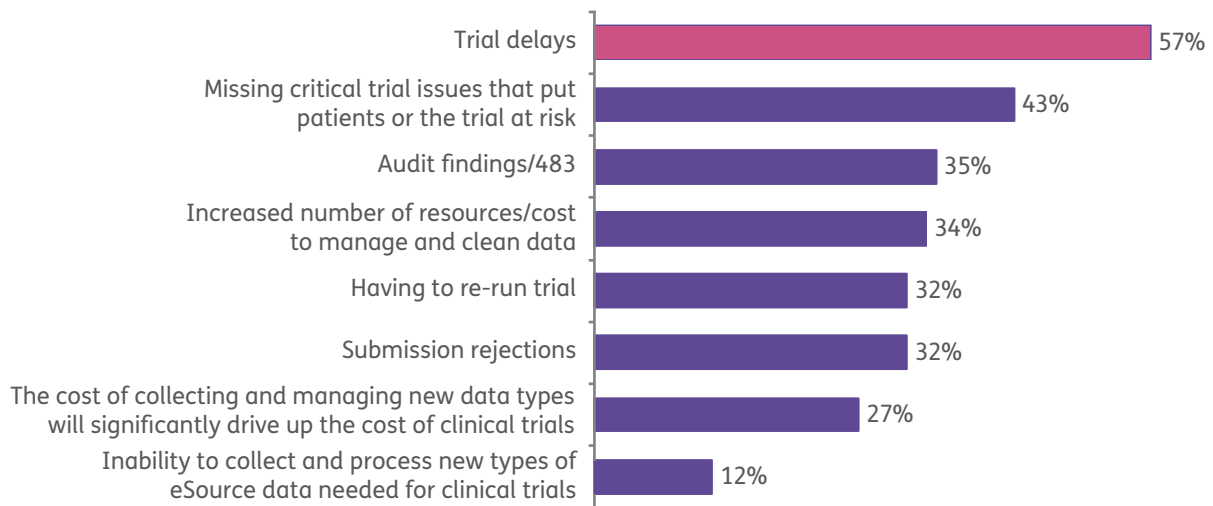
When asked about the biggest risks to a clinical trial caused by inconsistent or incomplete clinical trial data, several risks were cited by respondents.

What are the three biggest risks to a clinical trial caused by inconsistent or incomplete clinical trial data?



Delays to clinical trials, failing to recognize trial issues, and audit findings/483 were cited by respondents as the top three most critical problems that can result from clinical trial data issues.

What are the three most critical problems that can result from clinical data issues?



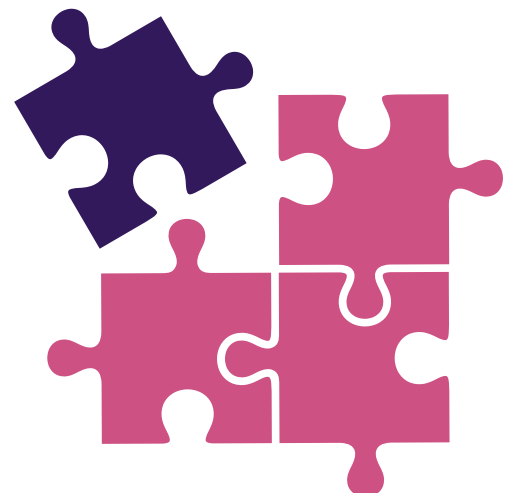
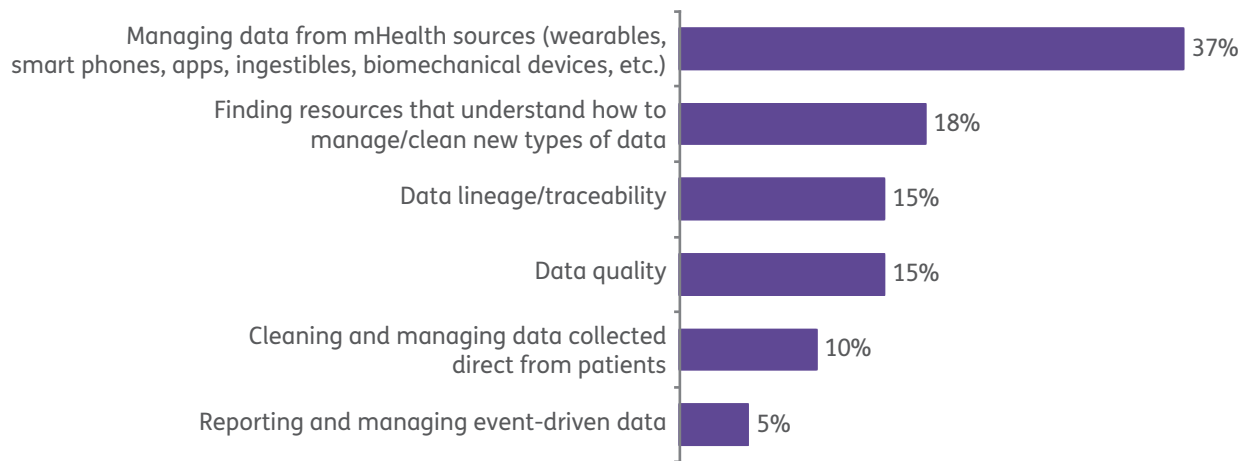


Future Outlook

While no one can predict the future, the majority of respondents agreed on where the challenges in the future lie.

Respondents feel that the management of mHealth clinical trial data sources is the most important issue to be addressed in the next five years. Finding a resource that has the capabilities to manage new clinical trial data (such as mHealth) was highlighted as the second biggest challenge to address.

Five years from now, what do you think will be the most urgent challenge, when it comes to clinical trial data?





CONCLUSION

The survey results shine a light on an industry that is struggling with processes and environments that fail to deliver the desired data governance and quality. Many people are concerned about the quality, consistency and traceability of their data. The impact of this is that most of the polled professionals lack confidence in the quality and completeness of their clinical trial data, from an audit and compliance perspective.

Given the potential for small data issues to undermine hundreds of millions of dollars of investment, the prevalence of doubts about quality and completeness is a major problem for the industry. It is a problem the industry cannot afford to ignore. While improving data management may take time and resources, the survey shows the cost of inaction is higher.

For More Information

Oracle Health Sciences Data Management Workbench (DMW) gives study teams a complete picture of trial data in real-time, so they can get visibility into the trial and make better decisions more quickly, effectively and easily.

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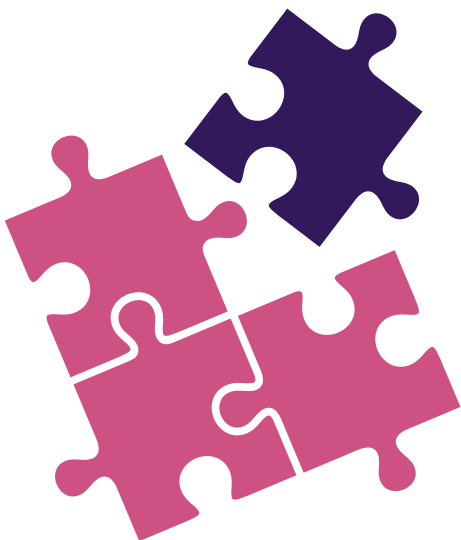
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