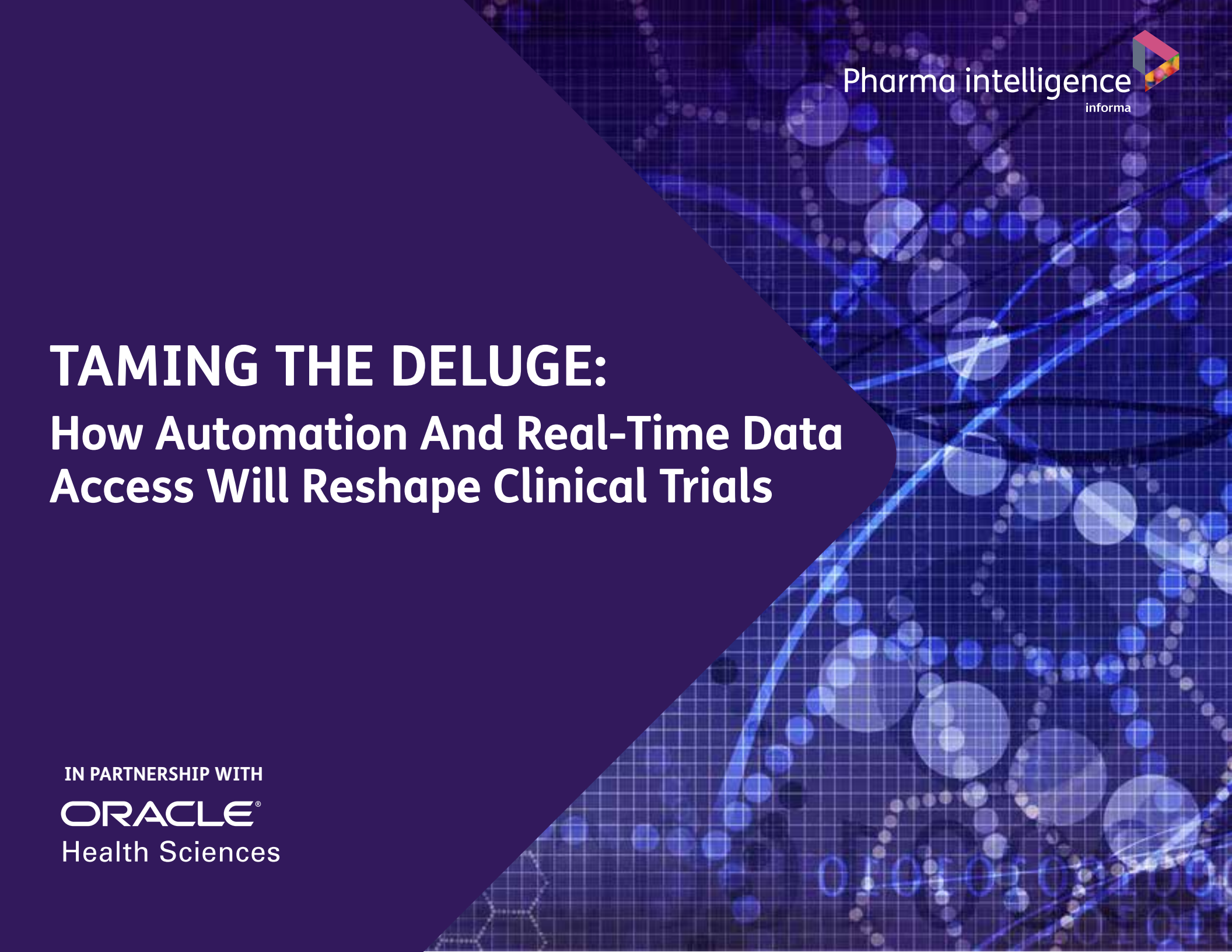


Pharma intelligence
informa

TAMING THE DELUGE:

How Automation And Real-Time Data Access Will Reshape Clinical Trials

IN PARTNERSHIP WITH

ORACLE®
Health Sciences

TABLE OF CONTENTS

FOREWORD

JAMES STREETER
GLOBAL VICE PRESIDENT, LIFE SCIENCES PRODUCT STRATEGY, ORACLE

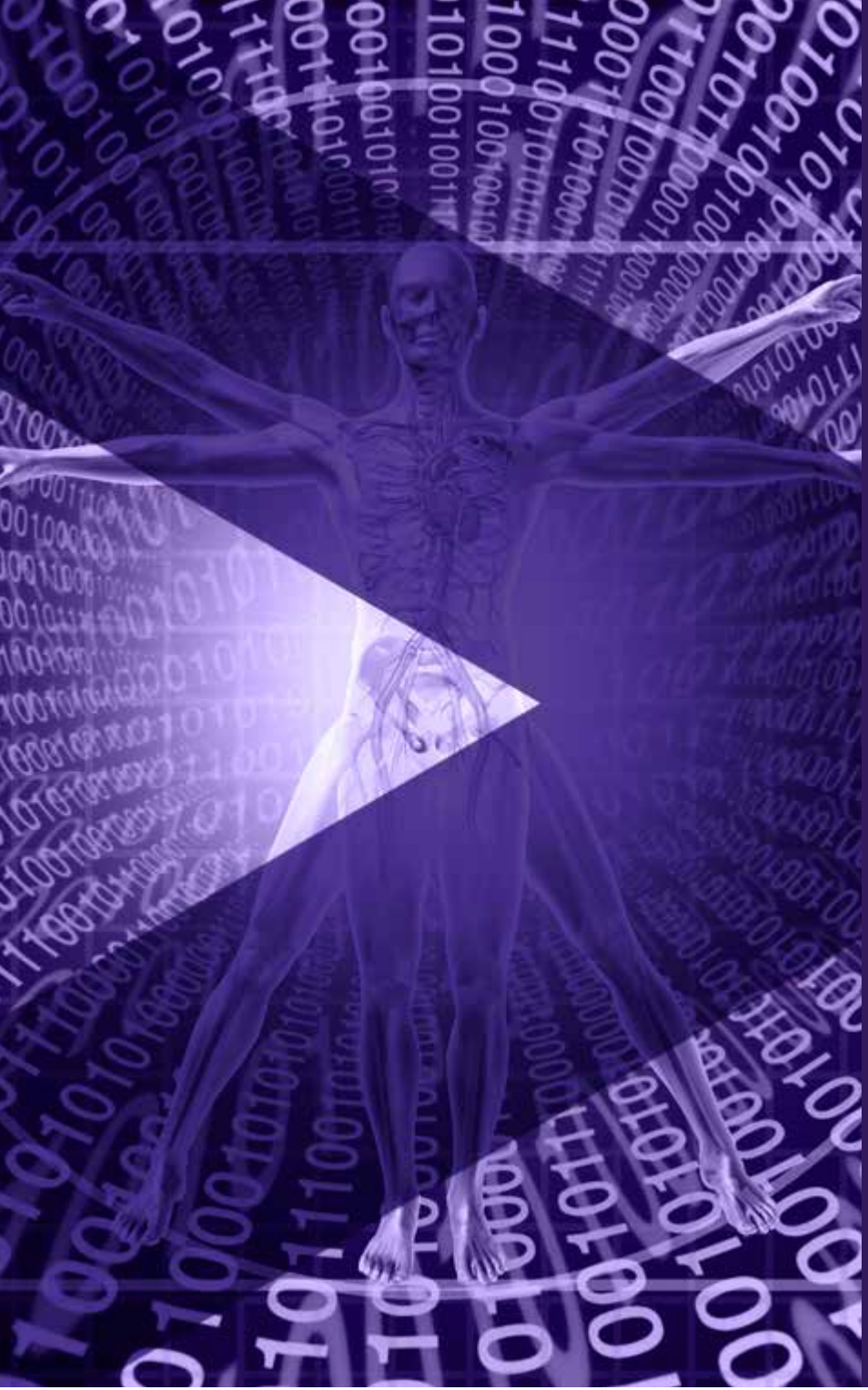
DATA IS THE LIFEBLOOD OF A CLINICAL TRIAL. Every data point collected becomes part of a large, complex process aimed at turning the hope of a promising new therapy or treatment into reality. However, managing that data has always been problematic, as voiced by clinical trial professionals in a recent Pharma Intelligence survey commissioned by Oracle Health Sciences. Respondents confirmed that manual data handling and management is nearly universal, while real-time access to data is rare, and data governance remains extremely challenging.

These challenges are not new or surprising – they cost valuable time and prevent effective decision making - but the real concern is the growing severity of the situation. A typical clinical trial now costs in excess of $30,000 a day to operate, making trials the single largest cost component of clinical R&D. And with the sheer volume of data mushrooming along with the costs, handling that data efficiently and effectively has never been more vital to both the success of a clinical trial, and to containing costs.

At the same time, the pressure to properly manage and leverage incoming data from new sources like mobile devices and wearable sensors, as well as from genomic tests, environmental sources, and even unstructured voice recognition applications, is exacerbating this data problem. These new, real-world evidence data streams are becoming more important to modern trials because they offer a high-definition view of the subject. That granularity can make it possible to gain more insight with fewer subjects. While this type of data is critical to the advancement of clinical trials, it creates a more complex environment, compounding the problems surrounding data management.

What we heard clearly from the survey was the overwhelming need to streamline trials and remove bottlenecks caused by old data handling processes, while simultaneously having the ability to make more efficient and informed decisions. Study teams need to access all data and insights in real-time in order to quickly enroll more subjects, change protocols or handle any task required to move a trial forward.

Our goal in conducting this research was to explore and quantify the issues faced by clinical data management professionals in the current clinical trial environment and understand what technological support would help them do their jobs better.



MORE CLINICAL DATA, MORE PROBLEMS

Trend For More Data Rich Trials

MORE DATA FROM MORE SOURCES THAN EVER BEFORE is being collected over the course of a clinical trial. This data provides companies greater insight into patient populations and the effects of their drugs and devices. However, this influx of data has also put a strain on data management systems.

The proliferation of clinical trial data is illustrated by research from the Tufts Center for the Study of Drug Development, which tracked an 86% increase in the number of endpoints over a decade. Results from a recent survey of more than 250 clinical trial professionals revealed that respondents frequently work with 15 or more data sources, and more than half typically manage six or more sources.

$9 million
in lost sales for a blockbuster product, due to the increase in data management cycle times.

But with the expansion of data sources comes new costs. This is evident in data Tufts gathered from 260 sponsors and CROs. Tufts found cycle time from last patient, last visit to database lock increased by 9% over the past decade, a fact it said was "due in large part to the rapid growth in eClinical data volume and diversity of data captured." That translates to approximately $9 million in lost sales for a blockbuster product, due to the increase in data management cycle times.

[1]https://bit.ly/2Vf4UKP

HOW CLINICAL DATA MANAGEMENT SYSTEMS ARE FAILING USERS

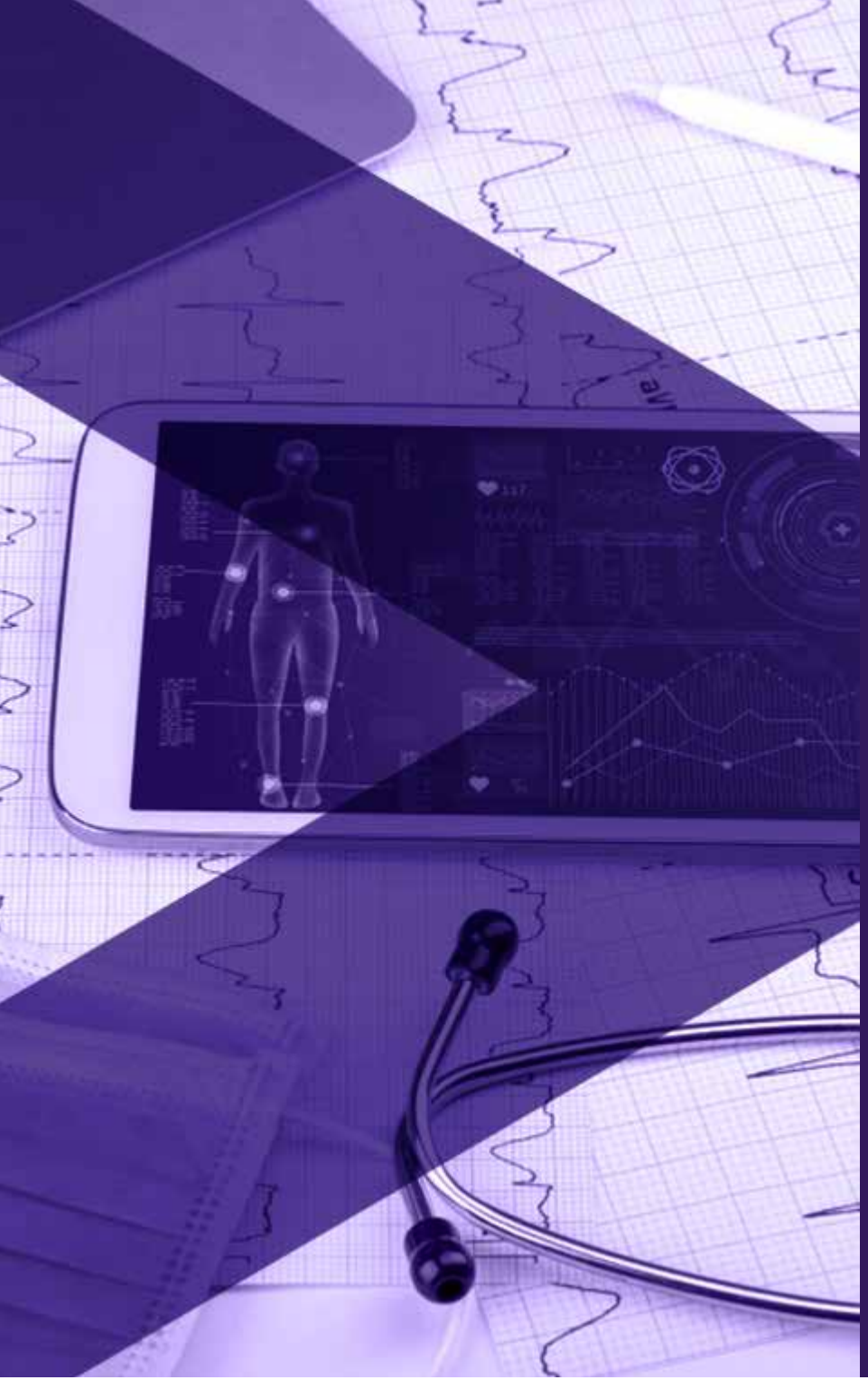
THE PHARMA INTELLIGENCE-ORACLE HEALTH Sciences survey identified two main ways clinical data management systems are failing users. Firstly, almost all study teams remain reliant on manual processes Secondly, most people cannot access their data in real time.

The problems stem from the emergence of disconnects between the needs of users and the capabilities of data management systems. Datasets have become larger and more diverse, yet 95% of respondents confirm manual effort is involved in aggregating; cleaning and transforming clinical trial data and two out of three respondents experience issues with this process.

BARRIERS:

1. Manual processes
2. Lack of real-time data

Over the same period, the daily cost of running a clinical trial has ballooned without teams gaining access to the real-time insights they need to make timely, informed decisions that accelerate studies.



THE EFFECTS OF CLINICAL DATA MANAGEMENT SHORTCOMINGS

The Costly Impact Of Poor Data

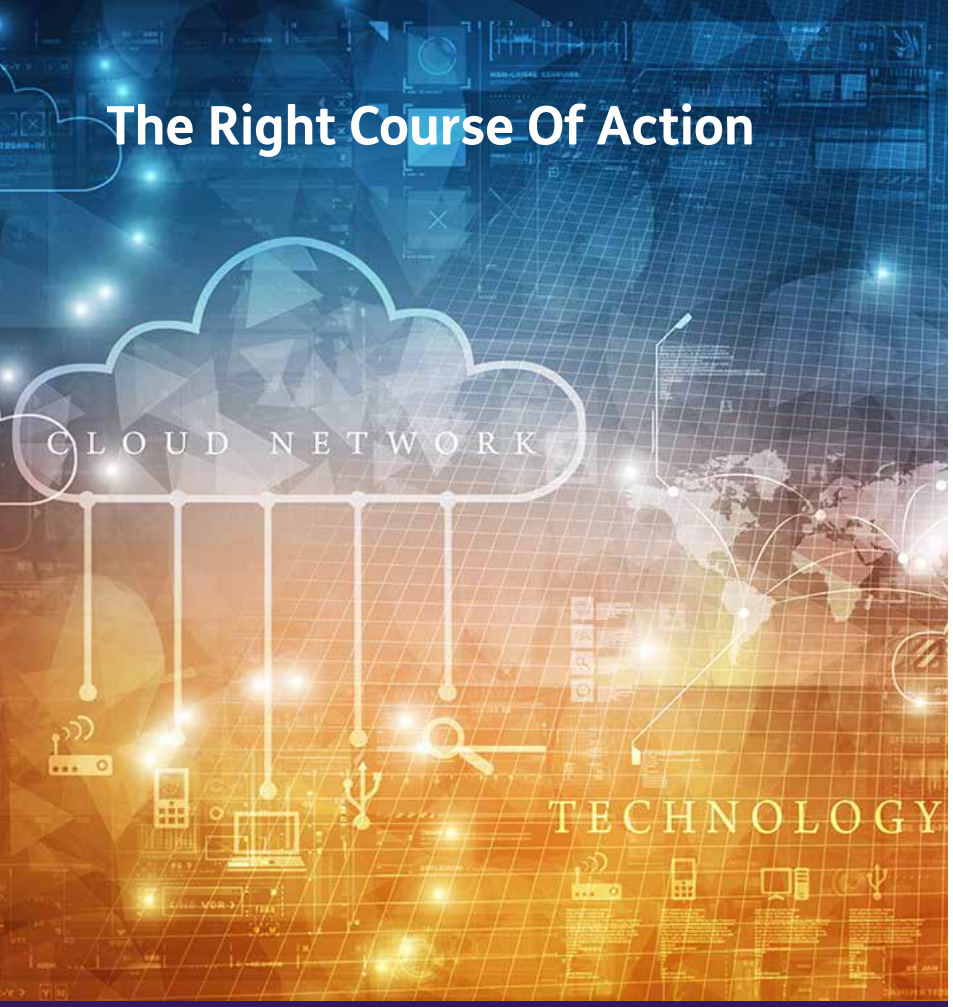
THE CORE PROBLEMS IDENTIFIED IN THE SURVEY have significant consequences. Nearly half of the survey respondents reported lack of confidence in quality and completeness of their clinical trial data. Around 70% of respondents said protocol issues go undetected because of the lack of real-time access to data.

Of the survey respondents, 57% indicate that clinical data issues could lead to trial delays and submission rejections. The inability to detect protocol issues and doubts about data quality contribute to clinical development taking longer and costing more.

Data management has become the chief source of delay and cost and has become an obstacle for study teams.

TECHNOLOGY INNOVATIONS IN CLINICAL DATA MANAGEMENT

The Right Course Of Action



AS THE PRESSURE ON CLINICAL TRIAL EFFICIENCY increases, data management has become the chief source of delay and cost and has become an obstacle for study teams trying to make vital and timely decisions. This research has uncovered the burgeoning severity of these challenges, and how they will continue to impact clinical R&D. It also underlines a lack of confidence in the completeness and cleanliness of clinical data. Study teams are not confident that their data provides an accurate, actionable picture of an ongoing trial.

With the ever-increasing investment in a promising new drug, it's critical that the industry take steps to address these challenges. Using the findings from this survey, we can better understand how to develop and implement effective data collection, handling, and analysis workflow and solutions.

The industry is struggling with these issues today, and what happens over the next five years depends on how the industry responds to the data challenge. By adopting technology innovations in data management to match the innovations that are driving data creation, clinical trials can be made more efficient, cost-effective, and bring more treatments to market faster for the benefit of patients and investors alike.