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Real-time decisions.
Real-time difference.

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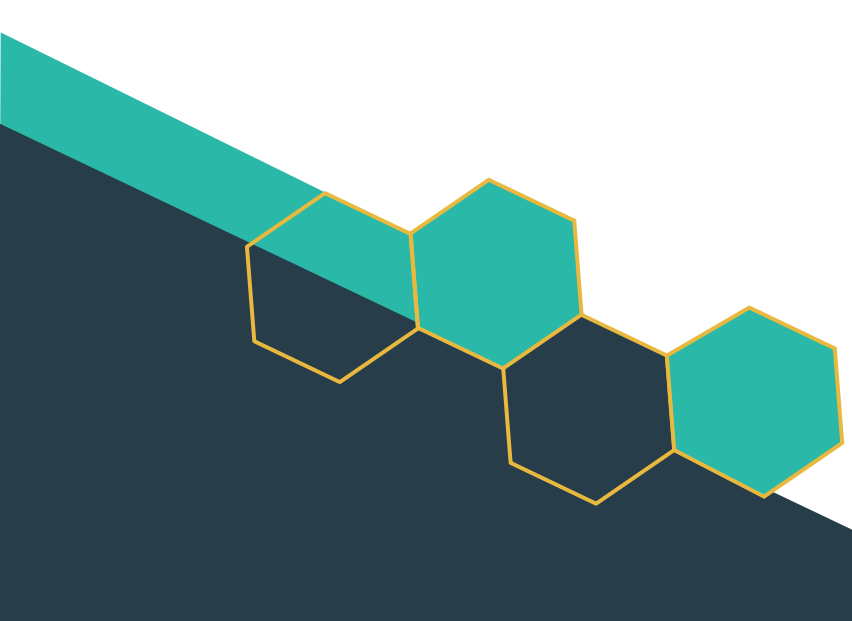
Pharma Intelligence decided to find out, surveying professionals involved in clinical data management. Their pool of respondents comes from large pharma companies, biotechcompanies, device developers, and contract research organizations worldwide.



It's 2020, and the digital revolution is well on its way. Yet, for clinical trials worldwide, real-time access to data is not the norm—and that lack can create a cascading set of issues affecting every aspect of a study. With critical decisions too often being made in a digital data vacuum, at best, processes are not as efficient as they could be; at worst, serious problems may go undetected for weeks or even months.

As the amount and types of data expand exponentially, this problem only intensifies. Yet, ironically, that very growth in data sources may be one reason solutions have been slow to take hold. In a recent analysis, the Tufts Center for the Study for Drug Development reported that more than two-thirds of all sponsors are using at least four different data sources. They find the tasks related to rendering that data usable—importing and ingesting data, transforming and mapping data, cleaning, and reviewing data—to be extremely time-consuming. That slows use. Worse, they also find initiating relationships with data vendors to be extremely time-consuming, so iterating to new technological solutions can feel daunting.

What does this mean for clinical trials? Pharma Intelligence decided to find out, surveying professionals involved in clinical data management. Their pool of respondents comes from large pharma companies, biotech companies, device developers, and contract research organizations worldwide. Their findings, published in Challenges and Opportunities in Clinical Data Management, Research Report September 2018, underscore the severity of the problem.

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Delayed data delivery is a growing problem

Study data is typically collected by internal andexternal partners. Researchers rely on these partners to distribute their findings in a useable format, which often only occurs once the data has been specifically requested. Frequently, this distribution can take up to 10 weeks—and sometimes it does not happen until after a trial is complete.

The Pharma Intelligence survey showed that 62% of respondents do not get their data in real-time. As much as 13% of biomarker data may not be available until post-trial, eliminating its value in developing and delivering personalized precision medicine. While electronic data capture (EDC) produces the swiftest overall data distribution, 6% of the time even EDC data is still not delivered until after trial completion 1 .

Yet mHealth and the Internet of Things cause the greatest trepidation among researchers. Today, only 7% of those results are reported the same day, and, over half of the reportable data takes between two and ten weeks to reach researchers. This in itself is troublesome—but as trials become increasingly decentralized and researchers rely more and more on digital health tools and patient-generated data, the problem will only be exacerbated. Indeed, handling such data and finding resources to clean and manage it was overwhelmingly cited by Pharma Intelligence respondents as the most urgent challenge facing researchers over the next five years.

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Lack of timely data can create catastrophic setbacks

When data delivery lags behind the pace of the trial, data entry is delayed—especially when data arrives in multiple formats and from different sources that need to be reconciled. Clearing redundant data becomes difficult, and programming complex edit checks becomes impossible. The lack of timely data wastes time and may require costly Corrective Action/ Preventive Action (CAPA) programs, causing even more expensive delays in trials.

Worse, however, data verification is hindered. Researchers are unable to ferret out missing and inconsistent data, sometimes with serious consequences. External and internal audits, when performed, typically reveal source document discrepancies, informed consent issues, and lack of drug accountability.

Such information is used to reveal protocol or enrollment issues; indeed, 25% of survey respondents said they have paid for patients who should not have been in their trials because they received the data too late[2].

Far more severe, skewed results—only uncovered when data is delivered post-trial—may necessitate rerunning the clinical trial at a colossal cost of time and money.

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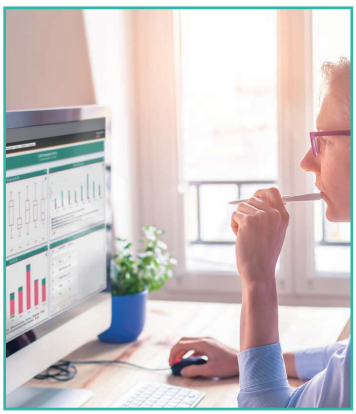

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New technology solutions will speed insights, enhance safety and produce cost-savings

Ironically, the need for greater data insight coincides with the rise of digital technologies that can track results in real-time. The hurdle lies in transferring those results to the sponsor swiftly and in a useable format. Fortunately, technology has a solution for that, too.

Remarque Systems is a single, vendor-agnostic platform that automatically aggregates all the data related to a trial, then applies machine learning algorithms to deliver accessible reports tailored to each trial role in real-time.

Such real-time data synthesis and analytics will transform clinical trials

Remarque Systems enables researchers to act quickly and decisively to protect patient safety when exploring next-generation therapies—biologics, cellular, and genetic modification treatments. Further, by eliminating both hard costs and errors, such technology could dramatically reduce trial expenses. Richer, more frequent data sets could support smaller patient sample sizes; workflow management tools increase process efficiency and reduce waste; while early, educated decision-making can inform mid-trial redesigns or termination.

So why have such systems not been universally adopted? Previous solutions have involved a host of barriers, from high up-front costs and complex technology integrations to a simple fear of change on the part of sponsors and CROs. Remarque Systems eliminates those concerns. Instead of reconfiguring existing systems, it simply adds a layer on top, easily adapting to the current IT environment and minimizing the need for costly change management.

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Real-time data synthesis and analysis can revolutionize clinical trials

Delays in data transfer from external and internal partners have long been an expected inconvenience in the course of a clinical trial—one that is becoming untenable as the amount and variety of trial-related data multiplies. Unable to view or verify data, researchers face errors, delays, inefficiencies, and costs that should be entirely avoidable.

By adopting new technology solutions, such as Remarque Systems, sponsors, and CROs can change this scenario. They can glean real-time insights—and revolutionize their clinical trials. Data quality will improve, decision-making will be more informed, trial timelines and costs will shrink, and patient safety will be more secure. That is good news for pharma companies; it could shift the productivity and economics of their business. Most importantly, however, it could mean providing life-changing new therapies to patients years sooner. That's transformative.

References: 1
Challenges And Opportunities In Clinical Data Management
RESEARCH REPORT 2018
by: Pharma Intelligence

References: 2
Challenges And Opportunities I n Clinical Data Management
RESEARCH REPORT 2018
by: Pharma Intelligenceent
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