CONNECTED TRIAL MANAGEMENT

Three ways to unlock hidden data for greater efficiency and clarity
New medicines offer hope, relief and the promise of a better tomorrow for millions of people, but the process of developing them is complex and lengthy. The time has come to rethink clinical trial management.

Over the next 10 years, 400 million more people will be 65 and older. Today alone, 39,000 people will be diagnosed with cancer and 1.4 million will be diagnosed with diabetes in the U.S.¹ The magnitude of sick populations places increased pressure on pharmaceutical companies to deliver new drugs faster and more cost-effectively.

The industry is aware of this need and opportunity for innovation. Yet while demand today is high, investments are often riddled with inefficiencies. Delays are common – and costly. In fact, the average duration from Investigational New Drug (IND) to approval has increased to 8.5 years. Not surprisingly, costs have followed suit. The cost to develop an approved drug has grown from $1 billion in 2003 to $2.6 billion in 2013.²

These increasing costs and complexities bring added risks and uncertainties. By innovating the trial management process, sponsors and CROs can move ahead more quickly and efficiently, whether that’s bringing drugs to market faster or killing an unviable compound sooner.
DISCONNECTED SYSTEMS. HIDDEN DATA.

Today’s complex studies generate more data from many disparate sources. Between 2002 and 2012, the average trial has seen the number of endpoints collected increase from seven to twelve. These intricate study designs require various systems and technologies to capture and manage data. In fact, most trials use five to seven different data capture systems.³

Data impact the people, processes and systems in every trial. Yet despite the complexity of incoming data, research suggests that 65% of clinical operations teams rely primarily on manually compiled spreadsheets for insight into issues across a portfolio of studies.⁴ Outdated processes and system disparities keep important data hidden, which slows decision making and makes it difficult to see potential problems before they arise. Issues like underperforming sites and patient drop-off can drive up costs when they’re spotted too late.

THE HIGH COST OF INEFFICIENCY

- 50% of sites fail to meet patient enrollment targets⁵
- Fewer than 10% of trials conclude on time⁶
- 80% are delayed by at least one month⁷
- Delays cause potential losses of $1 million+ a week ($155,000/day)⁸
DISCONNECTED PEOPLE.
INFORMATION SILOS.

The use of outdated manual processes worsens as more stakeholders enter the equation. With 65% of trials outsourced to one or more vendors, success depends on sponsors, CROs and other service providers working together. When equipped only with manually produced status reports from disconnected spreadsheets and systems, collaboration suffers. Error-prone processes mean important information is outdated and often missing, eroding confidence in the data and jeopardizing endpoints.

It’s clear that clinical trials have outgrown the manual processes that were designed around a paper-based process that no longer exists. Why are so many companies still reliant on plug-and-chug spreadsheets? In short, the alternative isn’t cutting it. Traditional clinical trial management systems (CTMS) require a huge up-front investment and can take years to implement. Even when up and running, a CTMS requires significant data entry and maintenance — and only offers a slightly more efficient means of managing some trial operations data. These systems inadvertently create information silos that are disconnected from the rest of the data lifecycle, leading to outdated and incorrect data that ultimately isn’t trusted by end users.

Typical CTMS require a huge up-front investment, take years to implement and offer a narrow view of data.
Emerging technology solutions are being developed based upon the premise that data should be accessible, error-free and shareable in near real-time. These systems use data integration frameworks to help automate data flows and remove people from the data aggregation process. It is only through these strategies and solutions that study teams can catch up to the speed of their data — and are able to proactively make decisions that can impact trial performance. What’s more, by providing access to both the CROs and sponsors, study team meetings are instantly more productive. Attendees show up with a clear understanding of current trends and challenges. Rather than spending time providing updates, they can work collaboratively to anticipate problems, mitigate risks, and ensure timelines and milestones are met as planned.

**THE CONNECTED TRIAL MANAGEMENT SYSTEM**

A cloud-based, connected trial management solution integrates all data to provide a clear view of every aspect of a trial in near real-time. Sponsors and CROs can mitigate risks faster without the burdens of a typical clinical trial management system (CTMS).
ALL TRIAL DATA IN ONE PLACE WITHOUT A BIG INVESTMENT

The industry needs to redefine the term “CTMS” to connote a connected trial management system. When key clinical and operational data can be aggregated within a single solution, workflows can leverage the instant insights provided and replace old reactive processes with evidence-based best practices. Having to manage large amounts of data can be overwhelming and create more confusion than clarity, so it’s critical that trial management solutions are not only connected, but also have the ability to convert data into information that can be used to drive processes and decisions.

This change represents the latest paradigm shift in clinical research since the introduction of Electronic Data Capture (EDC) systems. Attention is moving from the transactional data layer produced by EDC and other data capture systems toward an aggregated and harmonized view of trial data — a critical first step toward automating the inefficient, error-prone processes of the past.

Sponsors and CROs can easily leverage the array of rich information being collected to increase efficiencies and reduce costs.
Here are three key ways to unlock hidden trial data:

1. **Seamlessly integrate data across systems to create a centralized view of trial operations**

   With a system-agnostic solution, sponsors and CROs can unlock hidden insights that reveal challenges, risks and process bottlenecks that may otherwise take weeks to identify. Visibility across multiple systems and studies allows for real-time decision-making, and more proactive trial management and oversight. Site-specific issues like low patient enrollment can be viewed geographically, or even across studies, so what may have looked like a site or study issue can be addressed holistically before snowballing into a more costly problem. With on-demand access and a sponsor-accessible platform, everyone with a seat at the table can collaborate for a better end result.

2. **Implement electronic workflow capabilities to offset or eliminate manual processes and tools**

   Access to powerful insights is obviously important, but how the information is used is really what matters. Is action needed in another system? Is additional follow-up that’s tracked in a different spreadsheet required? Having workflow tools that are driven by — and connected to — data analytics allows for a fully connected process that spans risk identification through mitigation and follow-up. This process lifecycle produces its own data that can be leveraged for subsequent planning activities in the next study, producing additional efficiencies.
Leverage built-in data analytics to create transparency among sponsors, CROs, study teams and other stakeholders

With better analytics, it’s easier to identify study-level trends, underperforming sites and data quality issues in near-real time. A holistic view of aggregate metrics and indicators provides a more accurate picture of the trial, including where issues may need mitigation. This enables CROs and sponsors to make quick decisions that can quell potential problems. Plus, the right reporting helps to monitor patient safety, compliance and outcomes data. Unlike cost-prohibitive CTMS options, a software license can typically be covered by the time and resources spent manually updating spreadsheets and trackers. In fact, one CRO reports saving nearly $170,000 per year just by eliminating spreadsheets.

Trials have evolved, yet management processes still lag behind. The magnitude and intricacy of today’s studies demand transparent information flows and insights on easily accessible platforms. When everyone has visibility into accurate data that connects disparate sites and systems, efficient trials are within reach.
CROs & SPONSORS SUCCEED TOGETHER

Sponsors have become increasingly reliant on CROs, and the relationship between the two has evolved from vendor to partner. Sponsors have a diverse set of needs that must be met, and CROs should anticipate these requirements and align their priorities.

A connected trial management system enables CROs and sponsors to work better together. This management solution not only delivers on key study requirements, but also does so in near real time.

On-demand access makes collaboration achievable for more efficient results.

FOR A TRIAL TO BE SUCCESSFUL, CROs AND SPONSORS NEED:

- Decision-ready study status information
- Useful clinical data to make mid-study decisions
- Well-executed risk-based monitoring paradigms
- Performance metrics that support appropriate – and proactive – oversight
- Risk management from protocol development through submission
- Historical data to create intelligent baseline assumptions
ON-DEMAND ACCESS ENABLES MORE PROACTIVE DECISION-MAKING, DRIVES EFFICIENCIES AND KEEPS TRIALS ON TRACK

CRO:
- Study planning & management
- Centralized & onsite monitoring
- Site & study documents
- Integrated PDV management
- Data surveillance
- Study management metrics

SPONSOR:
- Patient enrollment / retention data
- AEs/SAEs
- Site rankings
- Deviation metrics
- Trip reports / cycle times
- Essential documents
GETTING STARTED

Sponsors and CROs should take a step back and analyze current processes to determine if they’re running clinical trials efficiently. Several questions can aid in this assessment:

- What tools are used to manage data?
- How much time is invested in manual study tracking?
- How many data collection systems are used?
- Do users have the ability to see all data in one place?
- Are data visualizations actionable, timely and valuable to study teams?
- Does everyone involved in the clinical trial have access to up-to-date study information?
- How confident are you in your data?
IT’S TIME TO START THINKING DIFFERENTLY ABOUT TRIAL MANAGEMENT

Trial analytics already exist, but important data is often inaccessible. Though manual processes are largely inefficient, traditional CTMS are often too costly and time prohibitive. After all, technology should improve efficiencies and reduce costs, not the other way around.

By aggregating all trial data into a web-based tool that’s accessible to all stakeholders, trial leaders get a crystal clear picture of the next best action. Without this clarity, sponsors may be exposing trials to unnecessary risk, which could hurt their competitive edge.

As the industry continues to innovate new drugs and technologies, it’s important to keep trial management innovation at the forefront as well. A new CTMS – a connected trial management system – has the ability to connect people, processes and systems to improve efficiencies and reduce costs.

Premier Research automated trial management to improve efficiencies, productivity and data quality. Click here to watch the webinar: https://www.ERT.com/PremierResearch
# REFERENCES

ABOUT ERT

ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials so that customers can move ahead with confidence. With more than 40 years of clinical and therapeutic experience, ERT balances knowledge of what works with a vision for what’s next, so we can adapt without compromising standards.

Our solutions enhance trial oversight, enable site optimization, increase patient engagement and measure the efficacy of new clinical treatments while ensuring patient safety. Since 2014, more than half of all FDA-approved drugs were supported by ERT. Pharma companies, biotechs and CROs have relied on ERT solutions in 9500+ studies spanning three million patients to date. By identifying trial risks before they become problems, ERT enables customers to bring clinical treatments to patients quickly—and with confidence.