How Unified Trial Management Future-Proofs Clinical Trials

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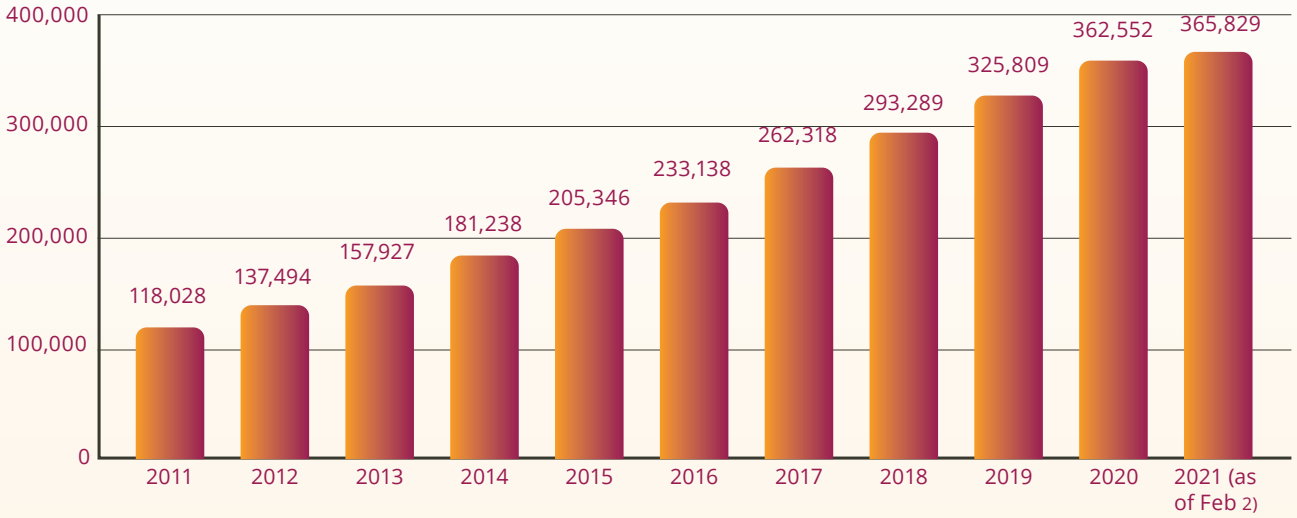
The nature of managing clinical research has evolved greatly since the initial clinical trial management systems (CTMS) and other early eClinical technologies were introduced. As the traditional trial paradigm has shifted, new technologies have been introduced and existing ones have evolved to keep up with the industry. As trial operators look to the future of clinical research, it's imperative that they unify their trial management solutions to create a flexible and agile response. This paper will explore the ways that unifying your eClinical stack can help future-proof your clinical trials.

Clinical research is in a period of hyper-growth. Despite trial interruptions caused by the global pandemic, 2020 saw a record number of registered studies.[1] By February of 2021, registered clinical trials were already outpacing the previous year's performance.

But despite all of the promise and positive outcomes that clinical trials offer, the rapid acceleration of research, paired with increasingly complex workflows, has put tremendous strain on the industry.

As trial operators look to the future of clinical research, it's imperative that they unify their trial management solutions to create a flexible and agile response.

Total Registered Clinical Trials Globally



As the demand for new trials grows, the traditional infrastructure and workflows in place are not equipped to support them. For study staff, especially clinical research associates (CRAs), the demands of the growing industry are hitting hardest because:

- There aren't enough specialized staff to support this research boom.[2] Current staff are overloaded or burdened by manual processes, resulting in massive turnover and leaving trial sponsors and CROs scrambling for suitable solutions.
- These growing pains ripple over to sites, who report feeling overwhelmed by increasing cost and trial complexity.[3]
- Study timelines and budgets are inflating as trials become more complex, mid-study changes become more frequent, and dispersed teams grapple with data delays.

On top of this, sponsors and CROs face added pressure to keep pace with a changing landscape of remote monitoring, electronic consent, and other decentralized trial technologies. But when studies are run on the wrong eClinical solutions, trials can be made more complicated by the very technology designed to improve them.

Fred Martin, COO of Medrio, is all too familiar with the changing landscape of the clinical trial industry. As he sees it, "The industry needs scalable solutions that reduce redundancies in trial operations, remove silos between teams, and alleviate inefficient processes that overburden sites and study staff. Selecting the right technology stack can be the difference between scaling with industry and getting left behind."

In this paper we will explore solutions sponsors and CROs can introduce to their study teams to streamline trial management and embrace the growing industry.

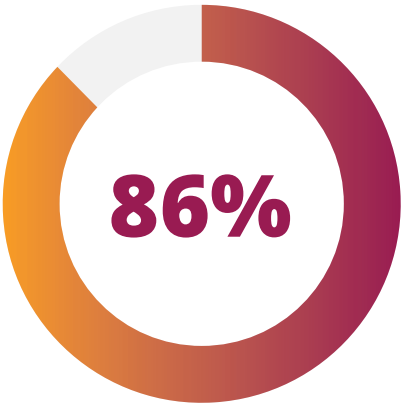
Simplify Data Collection and Management

Data management in clinical research is becoming increasingly time-consuming and labor-intensive. The average trial today pulls data from four unique sources and produces 86% more endpoints than the previous decade.[4,5] For CRAs who rely heavily on timely, accurate data to do a majority of their job function, this can pose a huge challenge.

If data sources are run on legacy systems or are collected by several disparate sources, it can result in multi-day population and visualization delays or produce incomplete, unreliable data. That translates to valuable time spent cleaning and reconciling data rather than analyzing and reporting it. And without complete, validated data, CRAs can't facilitate timely site payments, run sponsor monitoring reports, or proactively mitigate issues.

On top of that, many data management solutions require IT or third-party support in order to get set up, function, or implement changes. Not only does this add more complexity and costs to your studies, it also leaves sponsors in the precarious position of finding specialized staff to manage this software.

If sponsors and CROs want to future-proof their trials, they can no longer afford to rely on confusing eClinical solutions that degrade data quality for their study teams. The right trial management technology partnered with a native EDC integration shares data seamlessly between systems so sponsors, CRAs, and the entire study team can make timely, informed decisions.



The average trial produces 86% more endpoints than the previous decade.

Native integrations reduce the need for manual intervention that can be error prone by using pre-validated, automated workflows. When your data sources natively talk, it can benefit trial stakeholders in the following ways—

Study Teams	Sponsors and CROs
• Integrated data management unlocks visibility into live study progress so teams are equipped with the knowledge to resolve issues and protect study outcomes. • Trial timelines are accelerated without pesky data delays. • Monitoring documentation is generated with minimal intervention and confidence knowing the data is secure and accurate. • Manual duplicate entry and reconciliation is reduced across platforms. • Intuitive platforms reduce the need for costly CRA training and make study set-up and issue resolution autonomous. • Study teams can feel empowered to implement changes swiftly and focus on higher value activities.	• Unlock comprehensive study oversight with access to live study progress and configurable performance dashboards. • Have control over user access to sensitive data across shared systems. • Drill into the root cause of an issue with custom reporting. • Alleviate the need for highly specialized staff or budgeting for IT expenses.

Streamline Site Management

Managing site selection, initiation, and study oversight for a CRA can require many redundant processes, result in countless site visits, and create a stressful relationship between stakeholders. On top of that, sources find that 5% of sites conduct 70% of all clinical research.[6]

Together, these challenges reveal a need to better disperse site workloads and reduce manual or redundant workflows.

Sponsors and CROs can help CRAs streamline site management with purpose-built technology. The right site management software will natively sync with your EDC so teams can manage all aspects of global site and investigator monitoring, contracting, and payments from a single place.

This includes virtualizing trial elements, like replacing in-person monitoring visits with telehealth visits. Not only does it alleviate a major physical burden for CRAs, but sites are reporting that they prefer telehealth to in-person visits.[7]

Site management solutions can expedite initial study set-up with standardized and configurable organization assessments, site contracts, and reports. Teams can build a knowledge base about recurring sites and investigators by accessing site performance history and setting up automatic payments.

Once trials are in motion, unified site management solutions help simplify formerly complex or manual efforts for study teams. Juggling multiple payees or versions of site contract terms is made easy with pre-built workflows and triggered payment requests that can be tracked at the site and study level. Having increased visibility on site performance helps CRAs identify and mitigate issues quickly, which reduces the impact on your study and strengthens the CRA-site relationship.

The benefits seep over into all aspects of your trial. When teams have better oversight into site performance, they can make more proactive and data-driven decisions. This streamlined approach to study management is more sustainable and scalable for teams looking to grow with the industry.

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Connect Your Dispersed Teams

Clinical trials rely on an ecosystem of teams—who are often spread across dispersed geographies, facilities, and sites. The success of your studies relies on how seamlessly those teams can effectively communicate and share information.

The average Phase IV trial has 15 full-time employees ranging from clinical teams, project managers, CRAs, and more—each role has their own workflows, systems, and communication preferences.[8] But these disconnected processes can cause information sharing delays and prevent cross-team transparency, which hinders informed decision making.

Investing in unified eClinical solutions creates a single source of truth for dispersed teams to remove harmful silos and make informed, timely decisions. When your EDC data automatically reflects in your trial management software - and vice versa - you can ensure that all teams have access to the same information at the same time.

Teams can centralize protocols in a structured manner and create more standardization and collaboration around the study management process. Instead of toggling between platforms or waiting on manual reconciliation, interoperable solutions unlock faster access to trusted study data. Considering protocol complexity is rising in tandem with data complexity, having agile and configurable protocol management tools is essential to streamlining your study operations.[10]

Built-in audit trails and user restricted access add an extra layer of security and control around sharing data across dispersed teams. Regulatory submissions are also made easier by removing silos between teams expediting information sharing for inspection documents.

Not only do native integrations unlock data transparency between teams, they also remove a heavy manual burden so CRAs and study managers can focus on more high-value tasks. Investing in technology that connects your dispersed teams will be especially necessary as hybrid clinical trials continue to grow in popularity.[9]

Medrio + PHARMASEAL

are Your Single Source for Trial Management

As the industry continues to experience hyper-growth, sponsors and CROs need to find scalable solutions.

Just like selecting the right study staff with proper credentials and experience is crucial to ensuring the success of your study; so, too, is the technology stack you choose to equip them with. Medrio and PHARMASEAL were purpose-built to unlock unified trial management that starts with your teams and extends into all aspects of your study. By combining electronic data capture (EDC), randomization and trial supply management system (RTSM), clinical trial management system (CTMS), and electronic master file (eTMF) into a single solution you can revolutionize trial management and set your studies up for success.

Say goodbye to other third party tools that make clinical trials more complex. Discover why our native integration is helping teams revolutionize their data collection, streamline site management, and connect their dispersed teams in a pre-validated and unified environment.

Stop wasting time on manual processes and data delays. Future-proof your trials with Medrio and PHARMASEAL's single integration for clinical trial management.

About the Authors

As Vice President of Product at Medrio, Becky Capps plays a central role in the development of Medrio's electronic data capture, eConsent, ePRO, and trial management applications. In her current role, she works on the front line of the advent of eClinical technology in clinical research, helping organizations navigate eSuite implementation and regulatory considerations. She brings years of experience in healthcare-focused SaaS to Medrio, with a career that includes senior positions at MatrixCare, SigmaCare, and other companies in the SaaS space. Becky has a Master's Degree from Georgia State University and is based in Ocean Springs, MS.

Ricky is an ambitious product management professional with over a decade of global experience specialising in understanding customer requirements and developing products that are valuable, innovative and successful in supporting pharmacovigilance and clinical operations for life science organisations. Responsible for managing the entire product lifecycle from product strategy, planning and definition through to development and delivery. Ricky's career has included roles at Medidata, Roche, Amgen and IBM.

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About Medrio

At Medrio, we know that it takes a global village to achieve a healthier world. Our leading eClinical Data solutions have helped sponsors, CROs, and sites from all trial phases and therapeutic areas secure over 770 regulatory approvals. Whether conducting traditional, hybrid, or fully virtual trials—our adaptive platform of EDC, DDC, eConsent, RTSM, and ePRO/eCOA help streamline your studies, without compromising data quality. And our experts are on-call 24/7 to help you solve your most pressing needs. Discover the Medrio difference and learn more at **medrio.com**.

About PHARMASEAL

PHARMASEAL was founded in 2016 by a team of industry leaders who share a vision to create smarter technologies and innovative products for the improvement of human health. The company's SaaS platform Engility® simplifies the management and control of clinical trials for biopharmaceutical, CRO and medical device companies. Engility® utilises advanced engineering offering enterprise management with rapid deployment, an intuitive user interface and interoperability with other eClinical applications to optimise trial governance and oversight. Learn more at **pharmaseal.co.**

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