Why Do We Need a Clinical Trial Optimization System?

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Is the Era of **Clinical Trial Management Systems** Over?

Why technology must evolve from clinical trial management to optimization?

In a typical project management tool such as CTMS, actual progress data gets reported against the planned setup, but it lacks the ability to report on variance, non-compliance, or risk indicators on actual data. Evaluating risk and implementing mitigation measures are often considered an afterthought, which leads to detecting risks too late—a situation that could derail the trial.

Current risk-based quality management (RBQM) technology can identify errors and risks as they occur, allowing for mitigation by applying corrective measures. As business needs and technology evolve, clinical trial sponsors are expected to proactively identify possible risks by leveraging advance analytics, as well as predict possible scenarios to optimize the course of a trial. In other words, the industry is shifting from a corrective to a preventative mindset.

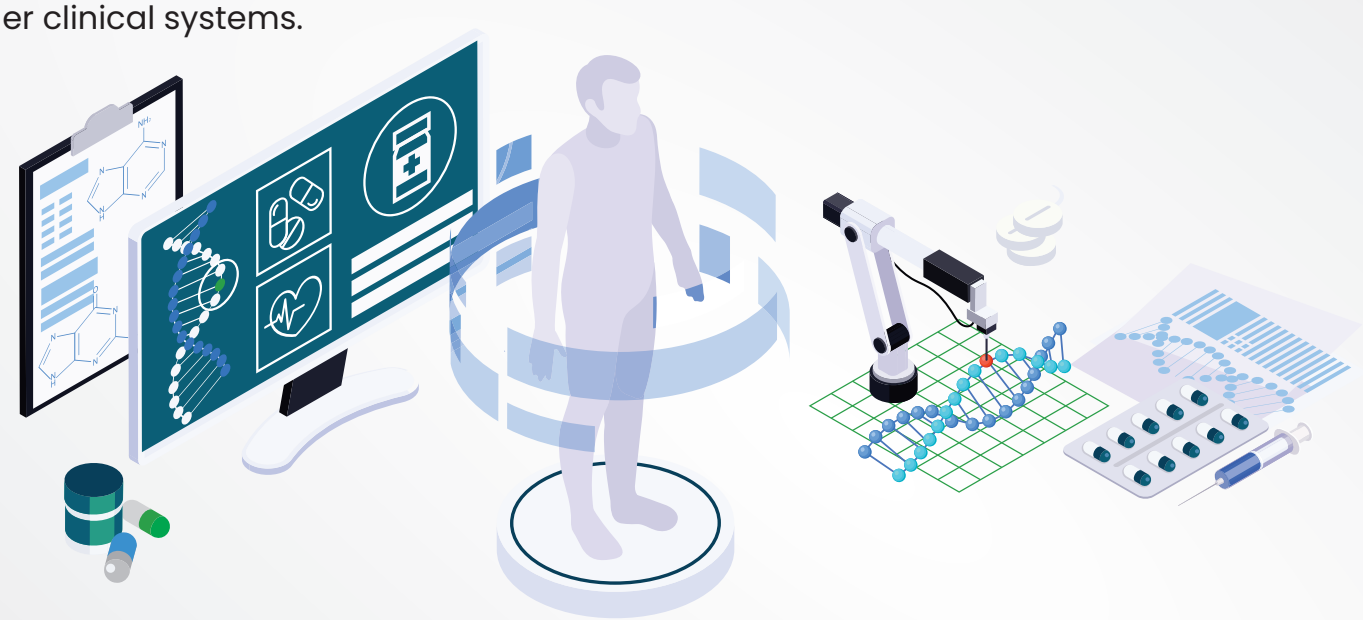
After too many years of stagnation, it's time for Clinical Trial Management Systems (CTMS) to evolve in alignment with that mindset. Operations management is not enough for today's complex trials and strict regulatory requirements.

Here, we explain how CTMS has evolved and will evolve from management to optimization.

What is a **Clinical Trial Management System?**

As the name implies, Clinical Trial Management Systems (CTMS) enable study teams to manage all aspects of clinical trials much more efficiently than a spreadsheet-based system. From protocol management and reporting to payment tracking and supply chain, these systems simplify routine tasks and provide robust insights.

A CTMS enables teams to manage data related to clinical trial conduct. It can also manage data from external systems such as Electronic Health Records (EHRs), Randomization and Trial Supply Management (RTSM) systems, Electronic Trial Master Files (eTMFs), Clinical Data Management Systems (CDMS), and Elec tronic Data Capture (EDC) systems, among others. In most cases, data must be manually entered. This is changing, however, as vendors implement APIs that enable integration with other clinical systems.



Limitations of CTMS

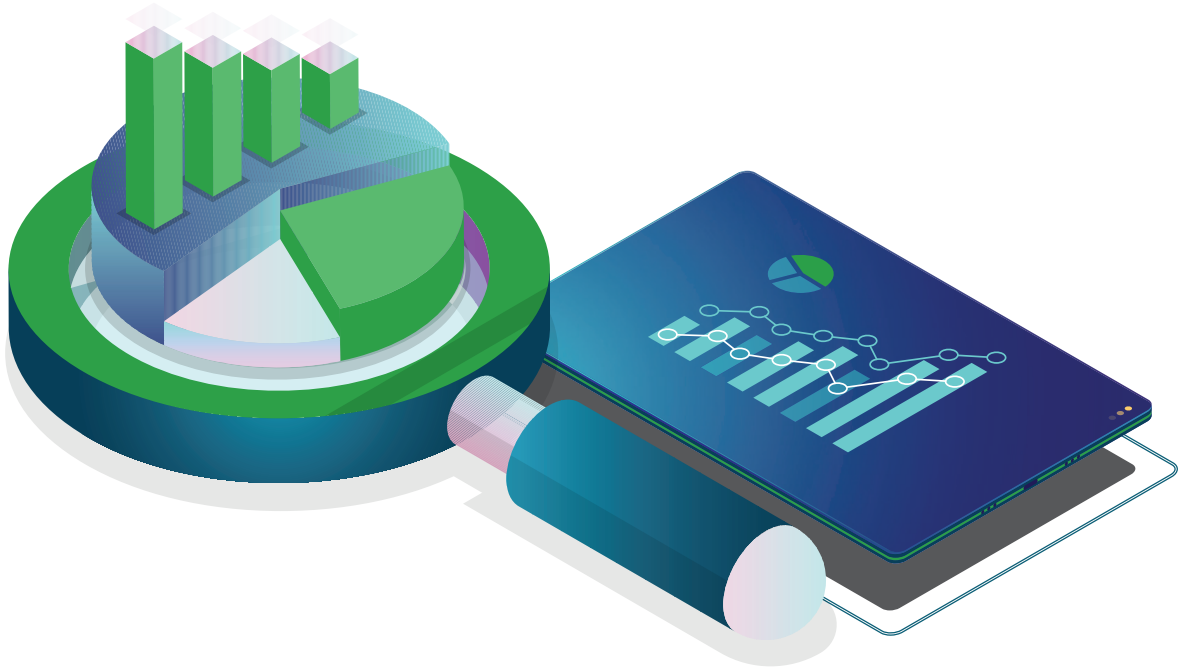
In addition to integration issues, CTMS systems may also lack central monitoring and risk-based management capabilities. Non-risk-based methods do the job, but they are slower and more expensive because they rely on on-site monitoring and 100% source-data verification. Monitoring data takes place after the fact, which leads to additional delays in responding to issues.

When the CTMS is run by a CRO, things get more complicated. Sponsors often lack real-time visibility into their data, which slows down data management, analytics, and regulatory activities. In short, with the wrong CTMS, sponsors lose control of their data.

Why the Industry Moved from **Management to Oversight?**

To improve data visibility between sites, CROs, and sponsors, MaxisIT launched the Clinical Trial Oversight System (CTOS) in 2017. We have successfully helped the industry move from reactive management to real-time oversight. The system-agnostic CTOS serves as a truly seamless, truly comprehensive data hub that integrates data across clinical operations, as well as from patient data sources, onto one secure platform.

Unlike the CTMS, data is shared concurrently, which fosters collaboration.
All stakeholders gain a complete real-time view of the trial. As a cloud-based system with powerful analytics, CTOS accommodates centralized and risk-based monitoring. Study teams can identify and mitigate issues as they occur, saving precious time downstream.



Characteristics of the **Clinical Trial Oversight System**

CTOS provides oversight across a single clinical trial and across an entire portfolio. The centralized command center offers an interactive solution with continuous monitoring of trial progress, performance, and quality, while also tracking patient safety, patient engagement, and protocol adherence.

Here's how it **stands apart** from traditional CTMS:

Seamless integration

An API-driven architecture enables seamless integration with virtually any EDC, RTMS, eTMF, and other eClinical systems. With data fully integrated, study teams have a more holistic view of their study and its participants for better informed decisions.

Real-time data access

By viewing data in the moment rather than after the fact, study teams can identify, assess, and mitigate risks sooner. This helps keep the study on track, with key milestones and KPIs met.

Improved visibility

Sponsors regain control of their data. Their research results are no longer held hostage within a rigid system. With real-time visibility and oversight, they can monitor their studies as they progress and call for adjustments as needed.

Enhanced usability

Role-based dashboards and an intuitive user interface make it easy for study teams to review key metrics. Because they can get their questions answered and act sooner, productivity goes up a notch.

Data-driven study planning

Sites give sponsors reasonable estimates of what they can achieve. Machine learning-based tools go one step further, helping study teams more accurately predict enrollment rates and adherence. This type of data helps sponsors design more patient-centric trials. Sponsors and sites can also analyze demographic information to ensure studies meet appropriate diversity criteria.

Advanced portfolio planning

CTOS enables biopharma leadership to develop strategic plans with optimal impact. Analytics identify gaps in the existing portfolio based on unmet needs. And because the platform helps facilitate shorter cycle times, companies accelerate time-to-market for additional revenue gains.

Why is **Clinical Trial Optimization** the Future?

To effectively manage all aspects of clinical trials, a CTMS was long overdue. Clinical trial enrollment rates are suboptimal. Overall timelines are too long, and the cost is too high. Meanwhile, patients with life-threatening diseases continue to wait for better treatments.

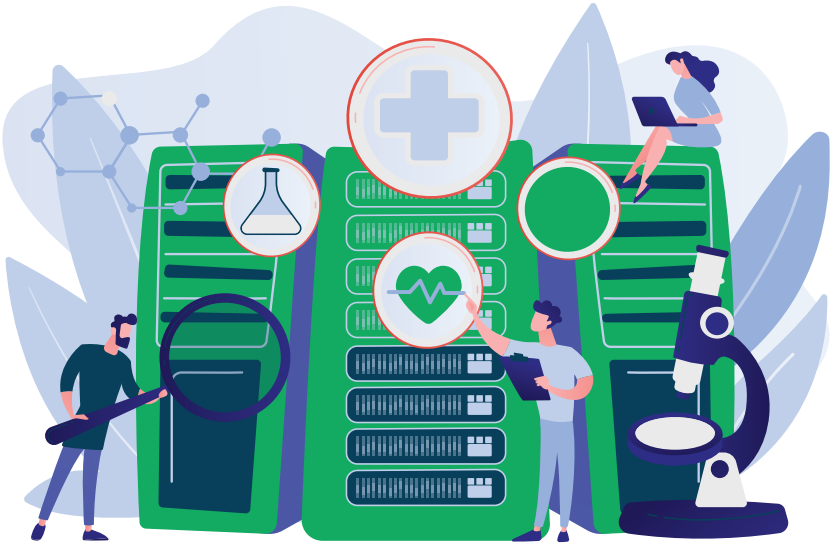
CTOS addresses these challenges by removing friction from clinical trial operations, data management, and reporting. Moving forward, CTOS will reinvent itself to meet the rapid advances of digital technology and clinical research.

The transformation from oversight to optimization will enable CTOS to lead the industry into a new era of clinical data management. An optimization-focused system leverages advanced AI and machine learning capabilities, both of which will become embedded within clinical trial conduct.

By optimization, we refer to the use of AI, an advanced integrated data architecture, automation, and analytics to anticipate risk. The process of analyzing trial data to foresee possible scenarios can be applied across various aspects of clinical trial conduct, compliance, outcomes, and the patient experience (e.g. techniques that improve enrollment and accrual[1].)

A Clinical Trials Optimization System will allow stakeholders to move beyond monitoring to foresee and mitigate risks and course-correct sooner. This level of optimization enables sponsors to improve the outcome of their trials.

Leveraging the cloud, a Clinical Trials Optimization System will continue to accommodate flexible study designs and collaborative workflows with the goal of more successful clinical trials—and potentially improved patient outcomes.



1. https://ascopubs.org/doi/full/10.1200/CCI.19.00033

Conclusion

It's time to reinvent the CTMS into a solution that not only facilitates end-to-end data management but optimizes that data for enhanced usability and productivity. With real-time data access, seamless integrations, and advanced data analytics, CTOS is ready to manage the adaptive, data-intensive studies of today, with the ability to scale for the clinical trials of tomorrow.

About MaxisIT

MaxisIT's purpose-fit and intelligent clinical data analytics platform helps improve clinical trial performance, mitigate risk, and optimize clinical outcomes. We provide a centralized and reliable source of truth for diverse data types from various sources, giving life sciences companies real-time insight to shorten cycle time and increase return on investment.

Incorporating an end-to-end clinical data pipeline from intake to visualization, MaxisIT's solutions are powered by AI/ML and metadata-centric approaches. Our impressive portfolio of over 3,300 clinical trials and an unparalleled 100% customer retention rate affirm the quality and reliability of our services.

Moulik Shah
Founder & CEO, MaxisIT

Moulik Shah is a passionate healthcare technology entrepreneur and the visionary CEO of MaxisIT, where he has been at the forefront of leveraging technology to transform pharmaceutical and life sciences clinical trials.

His dedication to improving patient outcomes and his leadership in directing patient-centricity, patient diversity, interoperability, and real-world-data-led collaborations have been at the core of his vision of an integrated healthcare ecosystem based on effective use of data and analytics platforms.

He has been instrumental in driving innovation and progress in the industry. Under Moulik's leadership, MaxisIT has become a leading provider of clinical data and analytics which is driving real-world impact in the pharmaceutical and life sciences clinical trials.

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