

Better Trials, Better Outcomes

Why Every Biopharma Needs a CTMS



Groundbreaking research conducted through clinical trials propels medical advancements. Managing these trials, however, is a costly and complex endeavor.

As sponsors, you drive these initiatives while considering insourcing or outsourcing trials to contract research organizations (CROs). Regardless of the approach, a robust clinical trial management system (CTMS) is essential to drive the efficiency and timeliness of your trials, accelerate study completion, and facilitate earlier drug submission to regulatory authorities.

This comprehensive guide will explore how a CTMS can help you take control of your trials regardless of your operating model.

We'll dive into the challenges of managing clinical trials without a centralized system and share how a CTMS:

- Improves efficiency and reduces errors with automated workflows and centralized data management
- Fosters seamless communication and data sharing between internal teams and CROs
- Ensures regulatory compliance
- Enables data-driven decision-making with comprehensive reporting and analytics

What is your clinical trial operating model?



My team outsources most clinical trial activities to a CRO

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My team performs most clinical trial activities in-house

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Outsourcing clinical trial activities without sacrificing study oversight

The journey of a new drug from scientific concept to NDA submission is fraught with complexities. The stakes are high: successful development offers the potential to save lives and revolutionize treatment, while failures can be financially devastating.

In this age of relentless innovation, the pressure to bring new drugs to market faster and more efficiently has fueled a rise in clinical trial outsourcing. Sponsors are increasingly leveraging the expertise of CROs to navigate the intricacies of global trials. Biotechs are leading the charge investing twice as much in R&D spending than large pharmaceutical companies.¹

Outsourcing offers several benefits for fast-growing biotechs, including access to strategic expertise, improved efficiency, and a global development engine. But, it also introduces a new set of challenges that sponsors must overcome because they are responsible for the trial's integrity, safety, and success.

Hidden challenges in outsourced clinical trials

Despite CROs' resources, reach, and infrastructure, sponsors often encounter obstacles when outsourcing trials that can impact timely study execution.



Fragmented data

Data resides in various CRO systems, spreadsheets, and legacy databases, making it difficult to gain a holistic view of trial progress. Essential insights and trends can remain hidden, hindering informed decision-making.



Communication silos

Silos can form between sponsor and CRO teams, leading to misunderstandings, delays, and quality issues. Critical updates can get lost, and timelines can slip due to a lack of clear and consistent communication channels.



Oversight burden

Ensuring adherence to regulations across multiple CROs, each with its own processes and systems, becomes a major hurdle. The risk of inconsistencies and errors increases dramatically, diverting resources and focus from core trial activities.



Inadequate technology

Many sponsors rely on tools like Excel, SharePoint, and data lakes to monitor the progress of their outsourced trials. These solutions aren't built to handle the complex requirements of clinical trials, leading to data integrity issues and delays.

Beyond the challenges, however, are effective solutions. A CTMS can act as a bridge, connecting disparate teams and data, fostering collaboration, and ensuring smoother processes.

Are you at risk for a critical inspection finding?

Sponsors who are unable to show adequate documentation of their oversight can be penalized with severe fines from regulatory bodies.

Bridging the gap: the CTMS advantage

By providing a central platform for study oversight, communication, and information sharing, a CTMS eliminates silos, fosters real-time transparency, and ensures alignment across all trial partners. This improved communication and visibility allows for faster issue identification and resolution, accelerating the path to more efficient trials.

The CTMS is the central hub where all pertinent information resides, creating a single source of truth. It eliminates the need to compile data scattered across disparate systems, improving accessibility for all stakeholders and providing a holistic view of progress across the portfolio.

Documenting a comprehensive oversight plan, a critical step for regulatory compliance, is straightforward with a CTMS. You can clearly define roles and responsibilities for both sponsor and CRO teams, monitor performance metrics to ensure CROs adhere to agreed-upon timelines, conduct co-monitoring visits, and capture all activities and communications to make compliance audits easy.

Why do I need a CTMS if a CRO runs my trials?

A CTMS centralizes planning, performance tracking, subject information, deadlines, oversight, and trial milestones in a simple and direct way. Having an auditable and reportable record of oversight activities is critical to satisfy regulatory requirements.

Taking control: leveraging a CTMS for successful outsourced trials

Sponsors can unlock several benefits
by embracing a CTMS.



Efficiency

Automate data transfers, optimize workflows, and collaborate on study execution. Manual data entry and extracts become a thing of the past, freeing sponsors to identify trends faster and focus on strategic initiatives.



Visibility

Identify potential roadblocks early, adjust strategies on the fly, and make data-driven decisions that optimize trial success.



Accuracy

Centralizing data minimizes the risk of errors, providing confidence in the integrity of trial data.



Compliance

Alerts keep sponsors informed of upcoming deadlines and automatic document filing in eTMF ensures inspection readiness.

Oversight without overinvestment

Successful oversight is the result of harmonized people, processes, and technology. Technology supports both the data and processes, minimizing the effort required from people. For example:

- Automated data transfers maximize accuracy without manual intervention
- Workflows ensure that personnel comply with appropriate steps
- Reports provide an at-a-glance view of progress
- When a threshold is crossed, alerts notify teams to take action

Start with technology to ensure that data collection, process management, and reporting are handled well. With these foundational capabilities, oversight can become a positive opportunity for sponsors rather than an expensive burden.

Selecting the right CTMS

Clinical trials are dynamic, demanding flexibility and adaptability. Selecting the right CTMS is a crucial decision that can make or break the efficiency and success of your trials.



The power of scalability

Your organization's needs will evolve, so your CTMS should too. Look for a full-featured solution that addresses current requirements and accommodates future growth. Whether you handle trials in-house or outsource to CROs, a scalable CTMS ensures continued support regardless of operating model.



Connected clinical ecosystem

The right CTMS acts as a central hub, facilitating seamless data exchange and fostering collaboration. It also connects with other key applications to automate activities such as document filing in eTMF and study personnel training based on protocol updates and milestones.



Innovation is the engine of progress

Seek a CTMS from a forward-thinking provider with a commitment to continuous innovation. This commitment translates to a system that can adapt to changing regulations, industry best practices, and the ever-evolving needs of your clinical trials.

Key CTMS Capabilities

Maintain study roster

Track investigator, vendor, and site information

Manage study milestones

Track enrollment

Conduct monitoring oversight (MVR reviews)

Manage issues and protocol deviations

Document study oversight

Collaborate on study execution

Track trial trends and progress with real-time reports and dashboards

The Vault CTMS difference



Flexible

Easily support different operating models and study-specific needs in one system.



Unified and connected

Work seamlessly across data and documents and reduce integrations to drive cross-functional efficiencies.



Enhanced analysis and insights

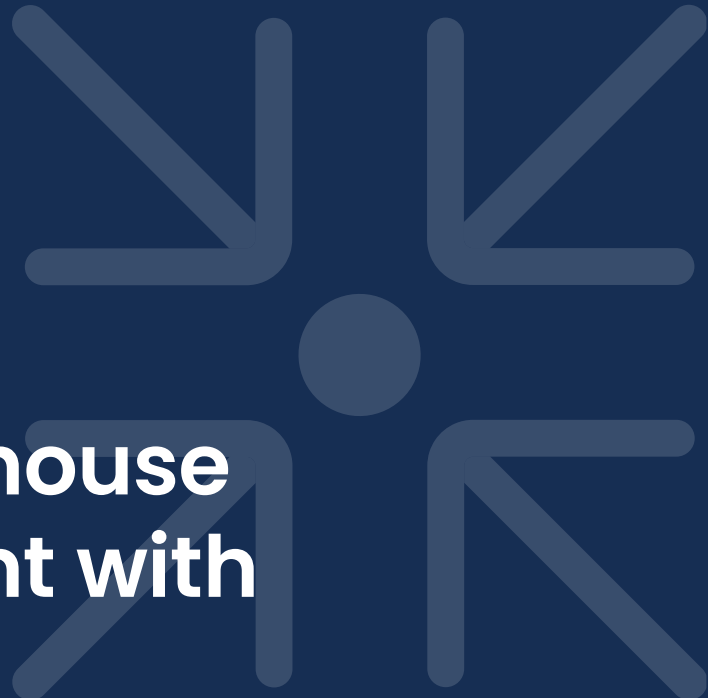
Interactive dashboards allow users to move directly from insight to action to optimize trial performance.

Clinical trials are the engine for growth and innovation. With the right tools and strategies in place when outsourcing, you can bring life-changing treatments to patients faster and more efficiently, fulfilling the true promise of clinical research.

Contact us to explore whether your outsourced trials are efficient and compliant.



Investment in a CTMS is the most impactful way to thrive in an outsourced environment. Take control, improve transparency, and minimize cost and risk to your organization, partners, and patients.



Streamlining in-house trial management with a modern CTMS

A CTMS is considered the hub of clinical operations. Yet some sponsors still rely on manual tools like redundant spreadsheets, local drives, SharePoint, and data lakes that aren't built to handle the complexity, data volume, and diverse regulations of modern clinical trials.

These tedious processes slow clinical trials down, jeopardizing your company's growth. Implementing a modern CTMS that is optimized for your business operations is key to improving trial speed, timeliness, costs, and accuracy.

Challenges of managing clinical trials in-house

Having an in-house clinical operations team can help you maintain greater control over your trial design, execution, and data collection. But, it can also come with challenges if you don't have a CTMS – especially as your company grows and you manage more trials simultaneously.



Disconnected systems and spreadsheets

Data silos and redundant processes reduce productivity and prevent collaboration.



Difficulty configuring, customizing, and using manual tools

Rigid, inflexible legacy spreadsheets and systems struggle to support complex trials. They can also be challenging to integrate and costly to maintain.



High operational costs

Inefficient monitoring and cross-functional processes add costs and slow trials.



Limited visibility

Lack of real-time visibility to performance across the portfolio prevents proactive study and vendor management.

Benefits of having a CTMS for in-house clinical trials

Managing today's global trials requires an advanced, easy-to-use, and flexible CTMS that can deliver significant cost savings while improving execution.

The potential value of a modern CTMS solution



Reduce trial execution costs by 70%¹



Reduce time spent per monitoring event by 30 minutes²



Reduce filing time to just 10 minutes per document³

Modern clinical trial management systems on a unified platform eliminate silos and improve study visibility to effectively manage your trials. Role-based dashboards provide real-time insights, enabling users to take action at the point of decision without logging in and out of multiple systems. Configurable reports help identify and resolve issues immediately.

For example, role-based dashboards and a unified view across study activities make the monitoring process more efficient by better preparing CRAs to conduct study initiation visits and follow-up activities. This enables CRAs to prioritize critical tasks, track enrollment status for each site, and review open issues and missing

documents. They can resolve issues and request missing documents without leaving the system.

With a real-time view across end-to-end clinical trial processes, a modern CTMS can help you:

- Plan, track, and mitigate potential subject enrollment bottlenecks
- Seamlessly collaborate with study team members
- Identify and shut down low-enrolling and no-enrolling sites
- Proactively identify issues and take corrective action

Enhancing clinical data quality

Unifying trial documents and operational data in a single system centralizes clinical processes, improves accuracy, and enables strategic planning.

For example, if study team members can see all the information for an upcoming site initiation visit, they can prioritize their tasks in the optimal sequence. This might mean developing and reviewing a contract, then gathering documentation for an investigational medicinal product release, and finally briefing the monitor who will conduct the study initiation visit.

Selecting the right CTMS for your business

When searching for the right CTMS for your business needs, look for a full-featured, process-based solution. Some key features include:



Future-proofed trials

The right CTMS scales with you and supports both insourced and outsourced operating models.



Unified platform

The right CTMS is a central hub that easily connects with other clinical systems, eliminating costly integrations and facilitating seamless data exchange.



Continuous innovation

Modern cloud CTMS delivers continuous innovation and system upgrades, ensuring the system can support your evolving trial needs.

Key CTMS Capabilities

Study planning and management

Recruitment planning

Enrollment tracking

Site monitoring
(incl. risk-based approaches)

Issue management

Investigator relationship management

Interactive reports and dashboards

The Vault CTMS difference



Flexible

Easily support different operating models and study-specific needs in one system.



Unified and connected

Work seamlessly across data and documents and reduce integrations to drive cross-functional efficiencies.



Enhanced analysis and insights

Interactive dashboards allow users to move directly from insight to action to optimize trial performance.

Modern study management for faster clinical trials

The CTMS is central to a unified clinical operating environment, bringing together data, business processes, and system workflows to achieve operational improvements. CRAs can author and automatically file monitoring visit reports (MVR) in eTMF, shortening filing time and improving eTMF completeness. CTMS also simplifies regular protocol deviation reviews and action item management, enabling faster decision-making and keeping studies on track.

Contact us to start your journey to efficient in-house trial management.



One of the most important criteria was having a single source of truth so we could easily pull data together in one place to reduce errors. My sleepless nights stopped when we made the business decision to implement Veeva Vault CTMS.”

Susan Stamford,
Executive Director of
Clinical Operations,
Heron Therapeutics

¹ Tracon: Reducing Clinical Trial Cost by Connecting Systems.

² Heron Therapeutics Streamlines Clinical Trials with a Modern CTMS.

³ Heron Therapeutics Streamlines Clinical Trials with a Modern CTMS.



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