Veeva

EBOOK

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

SHOW ME MORE

My team performs most clinical trial activities in-house

SHOW ME MORE

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.

Implementing a CTMS will mitigate these challenges. The system 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.

Bonne Adams is the vice president of operations at Inhibrx Biosciences, a clinical-stage biotech with a lean team of 17 clinical and four IT employees. Even though Inhibrx outsources 75% of its studies to CROs, Adams still views the company's CTMS as essential. "The CTMS is your base system for setting up all other systems. Study metrics, global contacts – they all flow from your CTMS to other systems," Adams explains.

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.

> "The CTMS is your base system for setting up all other systems. Study metrics, global contracts – they all flow from your CTMS to other systems."
>
> **Bonne Adams**
> Vice President of Operations
> Inhibrx Biosciences

Taking control: leveraging a CTMS for successful outsourced trials

Sponsors can unlock several benefits by embracing a CTMS, including:

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.

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

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

Oversight without overinvestment

Successful oversight is the result of harmonized people, processes, and technology. Having the right technology in place supports both the data and processes, minimizing the effort required from people.

For example:

- Automated data transfers maximize data accuracy and recency without manual intervention.
- Workflow capabilities ensure that accountable personnel comply with appropriate steps.
- Intuitive reports and dashboards give study teams an at-a-glance view of progress.
- When a threshold is crossed, alerts can notify study team members to take action.

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

The manager of clinical trial systems at a biotech that outsources 60% of its studies to CROs, started small when first implementing a CTMS. “Your process should be really simple to start, and that’s how you can scale up,” he advises. “We started by having everyone write their oversight monitoring reports in Veeva CTMS. Then, once they felt comfortable, we asked people to also put their KPIs in. Next, we moved on to risk management and more.”

The company’s clinical team also uses CTMS Transfer to easily receive data from one of their CROs. This feature automates the daily transfer of study data from its CRO, providing the team with secure, read-only access to their trial data. “With CTMS Transfer, we maintain oversight and visibility while allowing the CRO to leverage its own Veeva CTMS,” says the manager of clinical trial systems. “It saves us significant time, effort, and costs associated with manual data uploads and reconciliation.”

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Manager of clinical trial systems at a late-stage biotech

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.

For example, as the late-stage biotech grew to over 500 employees, the organization's needs changed. "We've had to upscale, but we have been able to do it without losing the integrity of the solution," says the company's manager of clinical trial systems. "Having a validated system like Veeva CTMS is much better for scalability and repeatability. It is so much easier to run reports and have top-level oversight."

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.

At Inhibrx, Adams has seen the financial and time savings of having a connected platform. "I've looked at our budgets, and we save a lot of time and money by having connected solutions like Veeva's. Plus, there's no redundancy anymore. The effort it takes to manage the systems goes down drastically," she explains.

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 Veeva 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.

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.

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.

[1] 2022. McKinsey & Company. CROs and biotech companies: Fine-tuning the partnership.

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.

John McAdory is vice president of operations at CG Oncology, a global biopharma with a small team of nine clinical and two IT employees. After bringing 70% of the company's trial management in-house, McAdory chose to implement Veeva CTMS rather than relying on a CRO's system.

"When I first started at CG Oncology, we were building our studies from scratch each time. We needed a repository to collect information like action items, deviations, and monitoring reports without relying on spreadsheets," he explains. "Ultimately, we decided to have our own CTMS rather than using a CRO's because we wanted real-time access to our data. If you're tied to a CRO and you're using their systems, you lose the system if you leave the CRO."

The potential value of a modern CTMS solution

Reduce trial execution costs by 70%[1]

Reduce time spent per monitoring event by 30 minutes[2]

Reduce filing time to just 10 minutes per document[3]

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 Veeva CTMS, we have a global site directory that houses all our information. We can see what sites and principal investigators we've worked with without relying on spreadsheets," says McAdory.

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

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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 CTMS."

Susan Stamford
Executive Director
of Clinical Operations
Heron Therapeutics

See case study

[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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