TRIAL INTERACTIVE

The Ultimate Clinical Trial Tracking Checklist

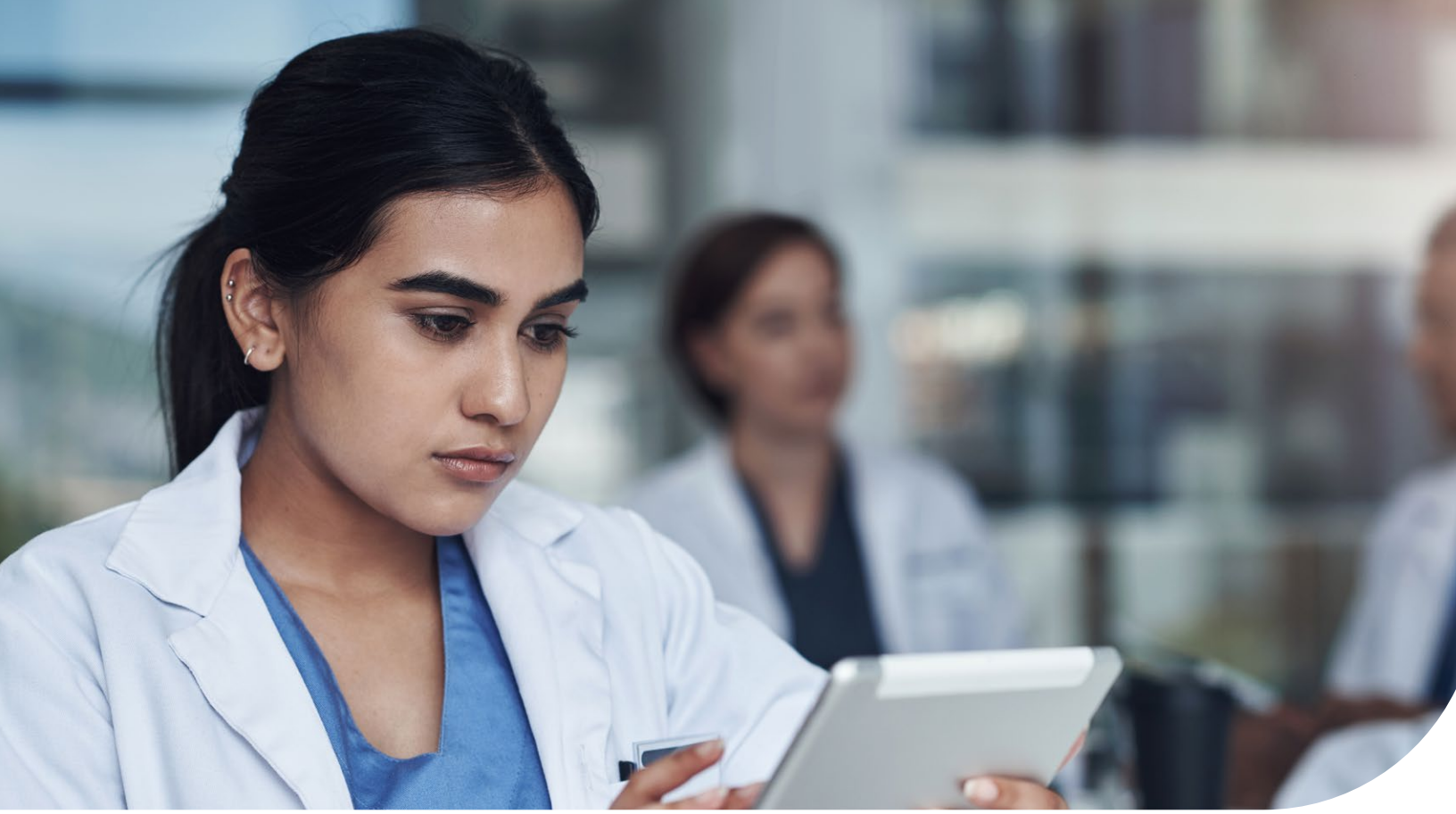
THE KEYS TO INCREASED VISIBILITY, BETTER DECISIONS, AND ENHANCED COMPLIANCE

YOUR KEY TAKEAWAYS

Clinical research is a complicated and resource-intensive process. Success depends on eliminating unnecessary expenditures, redundancies, and delays. Inefficient data collection, syncing, and reporting lengthens timelines and leads to less informed decision making. As a clinical leader, **it's essential that your organization has the right systems in place**, so that your team is armed with the best possible tools to streamline clinical trial management, and effectively reduce cycle times.

Included in this Checklist:

- Expert perspective on the scope of study and site oversight
- Five ways risks play a part in clinical trial management
- Checklist to help you understand the clinical trial data you could be tracking throughout your clinical trial
- How you can more easily manage, report on, and understand your clinical trial data
- The value of a CTMS for growing biotech and pharma companies



Efficiently managing and reusing your clinical trial data is critical to bringing your studies through each phase in a timely manner. Maintaining your records and global regulatory compliance requires accurate and complete tracking of protocol adherence and deviations, participant communications, staff schedules, payments, site visit reports, status tracking, and more.

There are a variety of methods for aggregating and reviewing study and site data, but some methods are riskier than others. For example, spreadsheet trackers, Sharepoint-based systems, and legacy CTMS systems introduce a wide variety of risks. They also reduce your ability to make fast risk-based decisions based on your real-time global study data.

There are five factors that you need to consider when identifying the right method for tracking and monitoring your studies.

1. **The Human Factor**
2. **The Compliance Factor**
3. **The Visibility Factor**
4. **The Productivity Factor**
5. **The Speed Factor**

THE HUMAN FACTOR

When managing clinical trial data, you need to consider the Human Factor. Do your systems support your business process and mitigate the risk of human error?

When study teams track clinical data in spreadsheet trackers or Sharepoint-based systems, they have to manually input data into every field. Even traditional CTMS lack the capabilities for data reuse, syncing, and deduplication. Studies typically have dozens of data tables and hundreds of fields of tracked data, each with hundreds to hundreds of thousands of rows. It's easy for data to get out of date if humans need to update it in multiple places.

Here are some important questions to ask when considering systems for tracking and managing your clinical data. Does the system you have, or are considering:

- Maintain real-time insight, or require manual reporting?
- Provide the ability to automatically import data from, and sync with, your other systems?
- Allow for updates to additional databases when any data point is updated?
- Offer configurable field types so that all of your study and site information is unique to your business needs?
- Provide role-based assigned access permissions on a study by study basis?
- Show historical reference when needed?
- Display an audit trail of all actions performed on the data with timestamps, user name, and side-by-side comparisons?

If not, the result can be inconsistent, invalid, inaccurate or accidentally (or maliciously) erased data.

A modern CTMS increases efficiency and saves time because you're capturing data within fields in order to reuse the data. The result is minimized duplication of data entry, higher productivity, easier user onboarding, and improved data integrity. A CTMS provides a centralized location for consistently accessing and maintaining data in real-time, allowing authorized users to access data insights in real time and make better decisions.

THE COMPLIANCE FACTOR

When managing clinical trial data, you need to consider the Compliance Factor. How do your systems simplify regulatory compliance?

The reason that biotech and pharma companies typically move beyond spreadsheet trackers and legacy systems is that they run into compliance and access issues. When data is stored in multiple locations on laptops, desktops, and email, it is vulnerable to data loss that can result in severe consequences, including regulatory action, financial penalties, and damage to the organization's reputation.

Another important factor in maintaining compliance is ensuring that only authorized personnel have access to sensitive data. Spreadsheets, home-grown solutions, and legacy CTMS lack the sophisticated access control settings that modern CTMS provides.

Does your solution:

- Provide role-based access levels so that authorized individuals have access to only the appropriate data for their job responsibilities?
- Meet global regulatory standards such as 21 CFR Part 11, GDPR, ISO 27001, Annex 11, GxP, HITRUST, and HIPAA?
- Store data in a centralized cloud-based location?

Implementing a centralized CTMS, especially one that is regulatory Compliant, mitigates compliance risks. A CTMS ensures everything is stored in one place, enabling teams to stay ahead of inspections and identify potential issues before they become bigger problems. The CTMS also controls access to sensitive data, ensuring only authorized personnel can access it, and provides an easier way to retrieve information during an audit. By bridging the gap between disparate data sources and implementing a centralized system, organizations can reduce compliance risks, improve efficiency, and ultimately increase their chances of success.

THE VISIBILITY FACTOR

When managing clinical trial data, you need to consider the Visibility Factor. Do your systems provide visibility into what's happening at all times with every aspect of your studies?

Without a centralized system, it can be challenging to know what's happening with every aspect of your studies in real-time. Spreadsheet tracking and home-grown solutions are notorious for causing delays, they rely on manually entered data, resulting in critical decision making data.. This slow turnaround of necessary reporting and insights is frustrating on its own.

To compound the problem, the manual rush to gather information - typically by teams already pressed for time - often results in reports that are based on inconsistent or error-riddled data, and it leaves teams guessing instead of making data-driven decisions. This lack of visibility can lead to problems going unnoticed, ultimately resulting in delays, errors, and additional costs.

Does your data tracking and decision making:

- Provide 360 degree visibility into your data?
- Require manual effort and lengthy turnaround time to compile reports?
- Rely on error-prone systems, like spreadsheets or home-grown solutions?
- Use a centralized database or is data scattered across different locations?

Modern CTMS automatically centralizes data from your eTMF, QMS, LMS, and other mission-critical systems. The result? Efficient monitoring, tracking, and decision making. The system also provides real-time access to study data, enabling teams to quickly identify potential issues, respond to problems promptly, and make informed decisions. By bridging the gap between disparate data sources and implementing a centralized system, organizations can reduce visibility risks, improve operational efficiency and timeliness, and ultimately increase the ability to get to market faster.

THE PRODUCTIVITY FACTOR

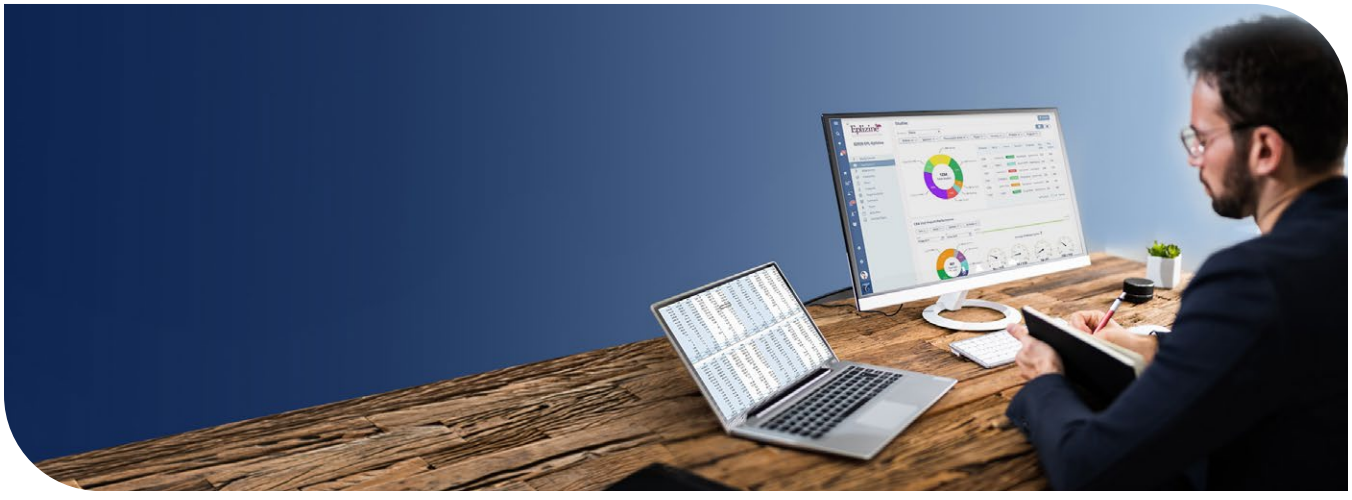
When managing clinical trial data, you need to consider the Productivity Factor. Do your systems increase productivity or contribute to timeline delays?

With spreadsheet trackers, Sharepoint-based systems, and legacy CTMS, creating workflows and tracking data can be time-consuming and challenging, resulting in reduced CRA productivity and time delays. Additionally, teams may need to go into other systems to find information, increasing navigation time and jumping between multiple systems. This can ultimately lead to lower productivity, missed deadlines, and increased costs.

When you track and manage your data, can you:

- Automate your data-related workflows?
- See information from all of your systems in one place?
- Utilize data from multiple systems to complete a single task?
- Pull in data from external systems like Excel and let your data drive the visualization?
- Utilize data previously captured to save time in data entry tasks?

The right CTMS simplifies workflows, enabling teams to track data more efficiently and reducing time spent on redundant tasks. Teams can also analyze where productivity issues exist to identify system issues, training issues, or other challenges and make informed decisions to improve processes.



THE SPEED FACTOR

When managing clinical trial data, you need to consider the Speed Factor. Do your systems support faster decision making?

Without a CTMS, it can be time-consuming for teams to aggregate data and compile reports. Additionally, waiting for data to be compiled can sideline decisions during strategy planning and leadership meetings, resulting in missed opportunities and decreased efficiency.

Within your current system, are you able to:

- Build reporting templates?
- Instantly view reporting insights with just a click of a button?
- See your data and reporting in real-time, without latency?
- Keep your team focused on the mission instead of manually aggregating data and reports from across your studies and systems?
- Export custom data directly from your system to share with non-study team members?

With the right CTMS, teams can access data in real-time, enabling them to make informed decisions quickly and efficiently. Actionable insights can be generated in minutes instead of days and shared with non-CTMS study team members for collaboration.

THE ULTIMATE CLINICAL TRIAL TRACKING CHECKLIST

There are over 200 study and site fields to track during your clinical trial. Can your system keep up with the demands of modern clinical trials? Support 360° clinical trial management with a CTMS that aggregates and reports on these fields faster and more efficiently than spreadsheet trackers and legacy clinical trial data systems.

Dashboards & Reports

Portfolio Level

- ☐ Top Countries
- ☐ Portfolio Geography
- ☐ Site Visit Report Review Status
- ☐ Studies Dashboard
- ☐ CRA Visit Report Performance
- ☐ Active User Report
- ☐ Inactive User Report

Country Level

- ☐ Country Timeline
- ☐ Activities

Study Level

- ☐ Protocol Deviations Report
- ☐ Study Milestones
- ☐ Study Enrollment
- ☐ Study Timeline
- ☐ Study Progress Report
- ☐ Activities
- ☐ Site Issue Activity Report
- ☐ Site Visit Report Review Status

Site Level

- ☐ Site Timeline
- ☐ Activities

Sites

- ☐ Study ID
- ☐ Sponsor ID
- ☐ Site ID
- ☐ Site Name
- ☐ Site Status
- ☐ Site Organization
- ☐ Site PI: ID
- ☐ Site PI: Name
- ☐ Site PI: Start
- ☐ Site PI: End
- ☐ Site PI: Status
- ☐ Site Primary Study Coordinator: Name
- ☐ Site Primary Study Coordinator: Start
- ☐ Site Primary Study Coordinator: End
- ☐ Site Primary Study Coordinator: Status
- ☐ Site Payment Summary
- ☐ Site Country
- ☐ Address 1: Main Mailing Address
- ☐ Address 2: Billing
- ☐ Address 3: Lab
- ☐ Address 4: Pharmacy
- ☐ Address 5: Primary Site
- ☐ Address 6: Shipping
- ☐ Site Team

Site Contacts

- ☐ Site ID
- ☐ First Name
- ☐ Last Name
- ☐ Job Title
- ☐ Roles
- ☐ Start Date
- ☐ End Date
- ☐ Email
- ☐ Phone: Office
- ☐ Phone: Cell
- ☐ Shipping Address
- ☐ Experience Information

Team Contacts (Study, Country, & Site)

- ☐ First Name
- ☐ Last Name
- ☐ Roles
- ☐ Start Date
- ☐ End Date
- ☐ Email
- ☐ Phone: Office
- ☐ Phone: Cell
- ☐ Mailing Address

Sponsors

- ☐ Sponsor ID
- ☐ Sponsor Name
- ☐ Primary Contact
- ☐ Sponsor Type
- ☐ Sponsor Subtype
- ☐ Countries
- ☐ Phone: Primary
- ☐ Email: Primary
- ☐ Address 1: Main

PI

- ☐ Organization
- ☐ NPI
- ☐ First Name
- ☐ Last Name
- ☐ Job Title
- ☐ Status
- ☐ Email
- ☐ Phone: Office
- ☐ Phone: Cell
- ☐ Address 1: Main
- ☐ Time Zone
- ☐ Best Time to Contact
- ☐ Experience Information
- ☐ Preferred Language

Site Activities (Deviations, Actions, etc.)

- ☐ Site ID
- ☐ Identified Date
- ☐ Date It Occurred
- ☐ Resolution Date
- ☐ Due Date
- ☐ Severity
- ☐ Activity ID
- ☐ Activity Name
- ☐ Activity Type
- ☐ Activity Subtype
- ☐ Ownership
- ☐ Responsible Parties
- ☐ Activity Status
- ☐ Blinded / Unblinded
- ☐ Actions Taken
- ☐ Comments
- ☐ Created By
- ☐ Created Date
- ☐ Planned Date
- ☐ Completed Date

Site Visits

- ☐ Sponsor
- ☐ Visit Type
- ☐ Planned Date
- ☐ Start Date
- ☐ End Date
- ☐ Visit Start Time
- ☐ Duration
- ☐ Owner
- ☐ Co-Monitoring
- ☐ Visit Attendees (with name, role, type, presence, details)
- ☐ Visit Addresses and Location Types
- ☐ How Visit Was Conducted
- ☐ Overall Observation Comments
- ☐ Visit Checklist with Responses
- ☐ Activities
- ☐ Associated Subjects and Subject Visits with Documentation Verification
- ☐ Enrollment Summary
- ☐ Confirmation Letter Sent Date
- ☐ Follow-Up Letter Sent Date
- ☐ Site Visit Report with Status, Status Date, and Reviewer

Milestones

- ☐ Milestone Name
- ☐ Parent Milestone
- ☐ Status
- ☐ Risk
- ☐ Planned Date
- ☐ Due Date
- ☐ Completed Date
- ☐ Progress Percentage
- ☐ Owner
- ☐ Description
- ☐ Comments

Subjects

- ☐ Subject ID
- ☐ Screening Number
- ☐ Enrollment ID
- ☐ Randomization ID
- ☐ Subject Initials / Date of Birth
- ☐ Informed Consent and Signature Date
- ☐ Subject Status
- ☐ Screen Failure Reason
- ☐ Early Termination Reason
- ☐ General Notes
- ☐ Subject Outcome

Subject Visits

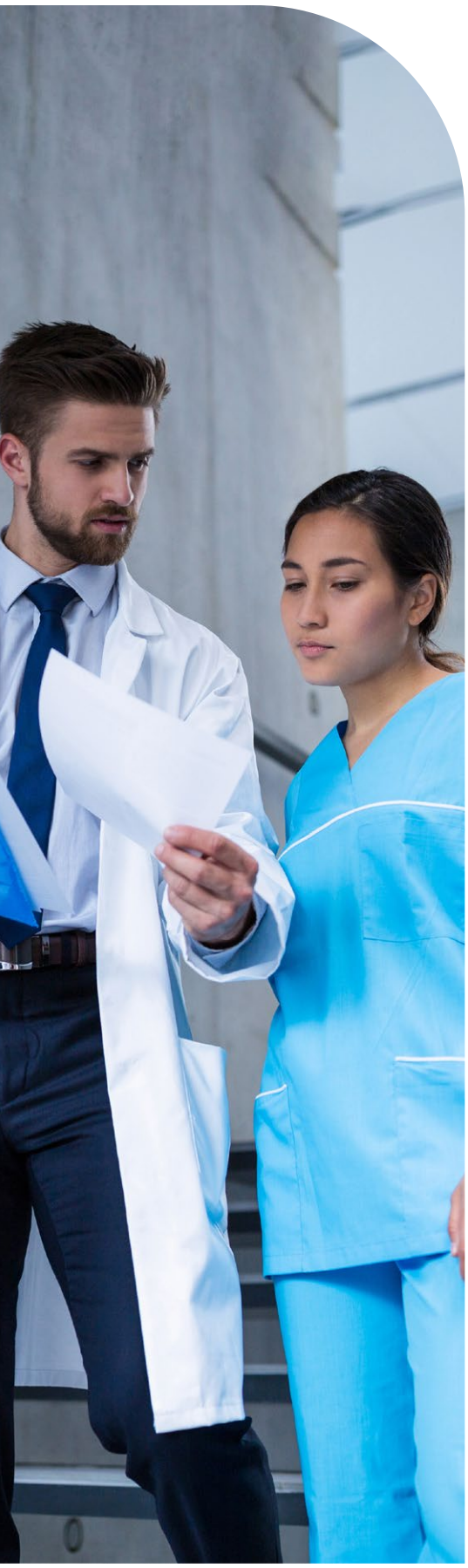
- ☐ Visit Type
- ☐ Visit Status
- ☐ Visit Date
- ☐ Notes
- ☐ SDV Date

Site Visit Details

- ☐ Visit Type
- ☐ Visit Status
- ☐ Visit Planned Date
- ☐ Visit Start Date
- ☐ Visit End Date
- ☐ Start Visit Time
- ☐ Duration
- ☐ Visit Name
- ☐ Owner
- ☐ Co-Monitor
- ☐ How Was Visit Conducted
- ☐ Comments
- ☐ Attendees
- ☐ Location(s)
- ☐ Associated Activities
- ☐ Associated Subjects
- ☐ Enrollment Summary
- ☐ Report Status, including Date Draft Submitted
- ☐ Status Date
- ☐ Reviewer
- ☐ Confirmation Letter Sent Date
- ☐ Follow Up Letter Sent Date
- ☐ Visit Checklist with Responses and Comments

Study List & Metrics

- ☐ Sponsor
- ☐ Protocol Number
- ☐ Study Name
- ☐ Study Number
- ☐ Protocol Title
- ☐ Study Type
- ☐ Study Status
- ☐ Associated Status Dates
- ☐ Primary Product
- ☐ Additional Products
- ☐ Primary Program
- ☐ Additional Programs
- ☐ Protocol Summary
- ☐ Therapeutic Area
- ☐ Indications
- ☐ Phase
- ☐ Mechanism
- ☐ Objectives
- ☐ Designs
- ☐ Projected Start Date
- ☐ Actual Start Date
- ☐ Projected End Date
- ☐ Actual End Date
- ☐ Database Lock Date
- ☐ Recruitment Months
- ☐ Site Recruitment Deadline
- ☐ Subject Recruitment Deadline
- ☐ Number of Planned Trial Sites
- ☐ First Site Enrolled
- ☐ Last Site Closed
- ☐ Number of Planned Subjects Entered Trial
- ☐ Number of Planned Subjects Entered Treatment
- ☐ Number of Planned Subjects Completed Treatment
- ☐ Informed Consent Template
- ☐ Monitoring Partner
- ☐ Data Management Partner
- ☐ Lab Handling Partner
- ☐ Milestones
- ☐ Countries
- ☐ Sites
- ☐ Contacts
- ☐ Team
- ☐ Activities
- ☐ Monitoring
- ☐ SVR Submission Days
- ☐ SVR Approval Days
- ☐ Site Visit Frequency by Visit Type
- ☐ Next Site Visit Forecast
- ☐ Reviewers
- ☐ Regions



There's a better way to track and oversee clinical trial data and gain real-time oversight of your studies.

Trial Interactive CTMS is the only system built by clinical professionals for clinical professionals. With our CTMS, every stakeholder—from CRAs and study managers, to IT teams and business leadership—is more efficient. Our CTMS delivers significant advantages, including:

- Advanced mobile capabilities that allow CRAs to perform critical tasks and oversight on the go.
- Flexible user navigation that allows individual users to choose their own path to execute common tasks.
- Simple out-of-the-box configurations to go live faster.
- Highly customizable features that can adapt to your business processes.
- Real-time visibility that supports faster decision making.
- Real-time audit trail that captures task, data, and correspondence.
- A single-source of truth for planning, tracking, and reporting on your study data.
- Powerful interoperability with eTMF, study start-up, content management, and collaboration.

These capabilities help clinical leaders deal with the risks associated with clinical trial management. You now know the five risk factors that you should consider when assessing your clinical trial data systems. You also know the 200+ data fields you should be tracking. Overseeing all your data doesn't have to be so burdensome with Trial Interactive's CTMS.

Trial Interactive CTMS is interoperable with our 21 CFR Part 11 compliant eClinical platform.

As we celebrate 15 years of serving biotechnology and pharmaceutical companies, Trial Interactive is the only platform that provides a comprehensive solution that enables clinical trial efficiency from site identification to study closeout. We ensure customer success through enterprise technology paired with comprehensive support services. Our platform grows with you, whether you're seeking a complete platform experience, or looking to phase in seamlessly connected solutions like CTMS, eTMF, eISF, Remote Monitoring, Study Start-Up, QMS, and LMS as needed.

Choose the platform that over 250 sponsors use to reduce 75% of their TMF inspection findings, speed up site activation by 50%, and save an average of $3.2M for a 50 site study.

To learn more about what Trial Interactive's suite of eClinical solutions and services has to offer, visit *trialinteractive.com*.

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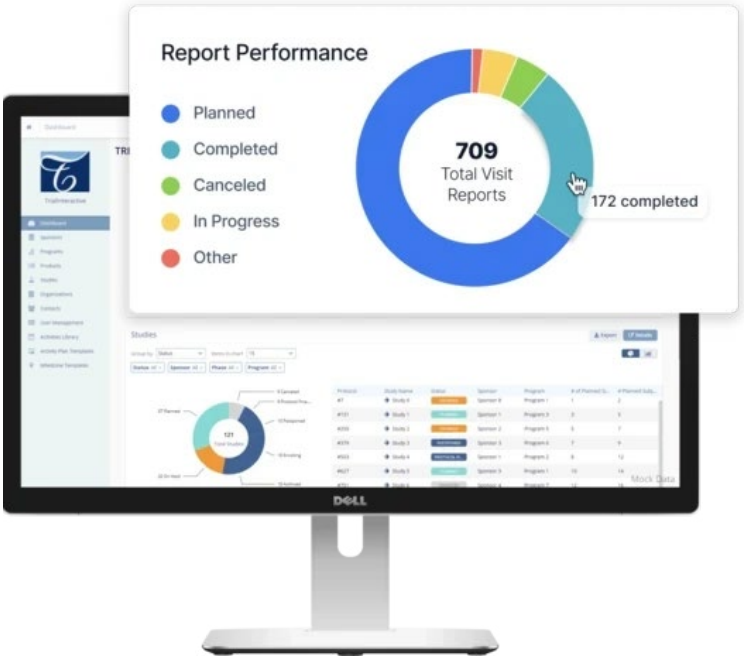

Take the Next Step

Get a demo of the CTMS for growing biotech, pharma, and medical device companies.

Schedule a Demo