TRIAL INTERACTIVE

The CTMS Buyer's Guide

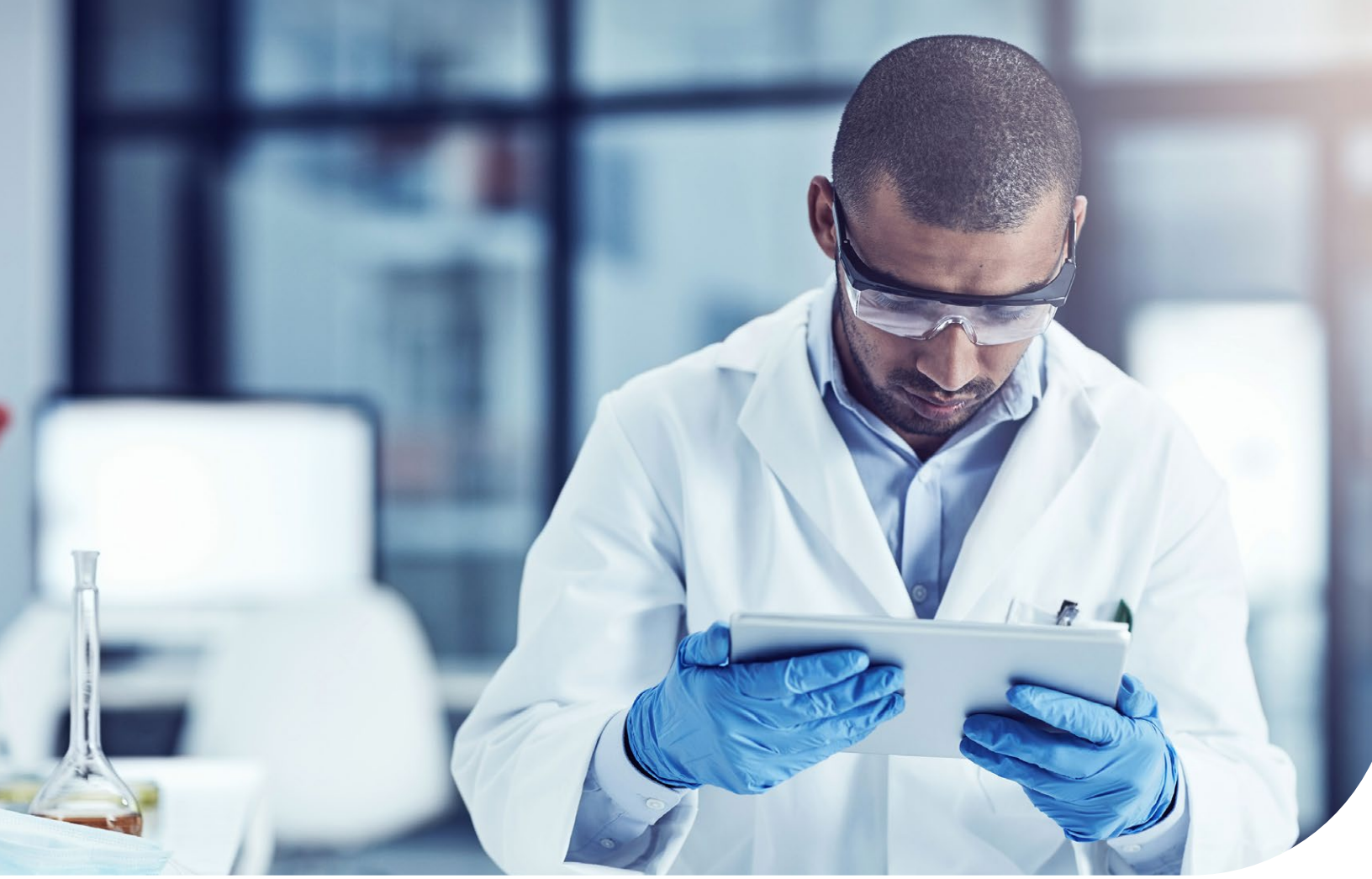
CONSIDERATIONS FOR SELECTING YOUR NEW CTMS

THE PURPOSE OF A BUYER'S GUIDE

If you are considering buying and implementing a CTMS for the first time or replacing a legacy system, there are many factors that go into your buying decision. As a clinical leader, it is essential that your organization starts preparations now, so you can ensure your teams' success through the buying, implementation, and daily use of your CTMS.

Included in this Guide:

- The value and importance of a CTMS
- Checklist for getting your team ready for a new CTMS
- Vendor evaluation resources
- Guidelines for CTMS implementation



THE CTMS BUYER'S GUIDE: THE VALUE OF A CTMS

The first step is to align on the value of a CTMS for your organization, which lies in its ability to enhance efficiency, accuracy, and compliance throughout the clinical trial life cycle. By determining your goals for the CTMS, you will better position your organization for success.

It is also essential to understand the fundamental business problems that organizations often encounter. Recognizing these challenges enables you to lay a solid foundation for a successful purchasing journey.

By understanding any inefficiencies that may exist within your current clinical trial processes, you can better evaluate potential CTMS solutions and align them with your specific requirements. This will empower you to make informed decisions and move forward with a solution that helps your study team be more efficient.

THE CTMS BUYER'S GUIDE: GETTING YOUR TEAM READY FOR A NEW CTMS

Before purchasing a CTMS, it is important to establish effective processes—like building a CTMS team, defining roles, organizing your legacy data and more—that will enable clinical trial efficiency from the outset. To succeed with this, here are eight questions to consider and align with as a team:

1. Do you have a CTMS team?
2. Do you have a CTMS strategy?
3. Have you determined the potential impact of redefining and redocumenting business processes?
4. Have you determined each user's role and access level?
5. Do you want to migrate data from your legacy system?
6. Have you set your expectations for system validation?
7. Have you determined training requirements and materials?
8. Have you looked into the benefits of a mobile-first CTMS?

This checklist will help you focus on some primary considerations to reduce risks, maintain compliance, and establish effective processes before purchasing a CTMS.

ESTABLISH A CTMS TEAM

Companies often face the challenge of ensuring they have enough time and expertise to form a strong CTMS team. It is crucial to vet potential team members carefully to ensure they possess the necessary time, skills, and knowledge to evaluate and choose the right CTMS for your organization.

Key decision makers are typically a mix of business leadership and IT, as these individuals have a clear understanding of the system to ensure it meets business and technology needs.

When evaluating stakeholders to build your CTMS team, ask yourself the following questions:

- How can we allocate **sufficient time** to assemble a strong CTMS team made up of key decision-makers?
- What **criteria** should we consider when selecting team members?
- How can we ensure a **clear understanding** of the CTMS expectations among key decision makers?
- Do we need to engage with any **external stakeholders** to determine impact and requirements?
- How can we foster **alignment and effective communication** between our internal and external stakeholders?
- How can we secure **executive support** to make CTMS implementation and adoption a priority?

DEFINE YOUR CTMS STRATEGY

Companies often face challenges when determining CTMS expectations within their organization. Ensure your organization has a clearly defined strategy for implementing a CTMS. Having a CTMS strategy provides clear expectations, direction and clarity.

Ask yourself the following questions when creating a CTMS strategy:

- ☐ Do you have a clearly defined set of **high-level CTMS requirements** (e.g. Site Visit Reports expectations, desired system outputs/reports, etc.)?
- ☐ Does your organization have a clearly defined **implementation strategy**?
- ☐ Have you considered **timelines and milestones** for each phase of the implementation process?
- ☐ Have you allocated **resources** effectively?
- ☐ Have you accounted for **integration** with potential systems?
- ☐ Have you defined a **validation approach**?
- ☐ What are our **training and documentation** expectations?

DETERMINE THE POTENTIAL IMPACT OF REDEFINING BUSINESS PROCESSES FOR COMPANY PERSONNEL

After establishing a CTMS team to spearhead the selection process and building your CTMS strategy, conduct a review of current business processes to determine if new business processes may be needed or current business processes may be impacted. Examples of business processes include standard operating procedures and work instructions based on your company's specifications.

Without clearly defined business processes, company personnel may not understand the value or goals of the new CTMS. Clearly defined business processes will increase the adoption of a new system, helping to ensure alignment within the organization.

When reviewing business processes, consider:

- What are the **current business processes** that the CTMS should support?
- Are any **new processes** required as the result of a new CTMS implementation?
- Have you clearly **documented and communicated these processes** to relevant personnel?
- Have you identified any **gaps or areas for improvement** in your current processes?
- Are there any **specific expectations** for how the CTMS will streamline or improve existing processes?
- Have you considered the **time** it will take to redo your business processes, if applicable?

DETERMINE EACH USER'S ROLE AND ACCESS LEVEL

The issues companies face without establishing clear user roles and access levels for new technologies range from inefficient collaboration to data security risks. Before selecting and implementing your CTMS, it is mission critical to determine each user's role within a new CTMS, including any CRAs, study managers, administrators, CROs, sponsors, and vendors within and across studies.

Here are some questions to consider so you can ensure you and your team clearly think through the definition of access permissions:

- Have you identified the **specific user roles and responsibilities** to be used within the CTMS?
- What are the **access levels** required for each role?
- Are there any specific **security or confidentiality considerations** for certain user roles?
- Does the CTMS allow for **customization of user roles and access levels** to align with your organization's structure?
- Can your CTMS **adapt to potential changes** to processes and role definitions?

DETERMINE IF YOU WANT TO MIGRATE DATA FROM A LEGACY SYSTEM

Many organizations have legacy "trackers" and spreadsheets containing pertinent clinical trial data. Key stakeholders should determine whether or not they will migrate their data to the new CTMS and the expectations of how that data will be used if they choose to migrate it.

By having the business objectives readily available, you will provide the CTMS vendor with the opportunity to provide a well-informed review analysis and feedback on migration expectations. Failing to determine migration requirements can lead to implementation delays and incomplete data transfer.

When outlining migration expectations, ask yourself these questions:

- Do you want to **migrate your data** from the legacy system?
- What **data needs to be migrated** from a legacy system?
- Have you determined the **timelines for data migration and data availability**?
- Have you identified the potential **impact or complexity of the data** to be migrated?
- Are there any specific **requirements for data format or compatibility**, for example, data mapping between systems and potential data cleansing/ reconciliation?

SET EXPECTATIONS FOR SYSTEM VALIDATION

The CTMS vendor you choose to work with should know that the CTMS contains regulated data and should be validated prior to use by your company. Many of the more established CTMS vendors supply out-of-the-box validation packages as they release each version of their software. While the CTMS vendor may provide the base/final validation, you should consider performing user acceptance testing (UAT) after the configuration of the CTMS per your company's requirements.

Companies with a smaller staff should ensure the CTMS vendor or one of its partners offers validation support by way of validation scripts and validation consulting services. This can streamline the process, ensure compliance with regulatory requirements, and launch your CTMS in a more timely manner.

Ask yourself these questions when considering expectation for system validation:

- Are your company's **requirements for validation** clearly outlined?
- Does the CTMS vendor offer **validation support and compliance** with regulatory requirements?
- Is the vendor willing to meet your definition of **validation and documentation expectations**?

DETERMINE TRAINING EXPECTATIONS

Insufficient training and limited access to training materials can hinder user adoption and proficiency with the new CTMS. You will want to ensure your vendor has a dedicated training team for the CTMS that can review your company's specific training needs and customize the training to meet them. The vendor should also have intuitive job aids and mini-training videos.

Training is crucial for improving compliance. Here are some questions to ask yourself about implementing a comprehensive training program:

- What is your overall **approach to training**?
- What are the **benefits of providing comprehensive training** to the team?
- Do you want to provide **role-based training**?
- How can training materials be made **easily accessible** in a centralized location?

ASSESS THE BENEFITS OF MOBILE CTMS CAPABILITIES

The CTMS vendor you select should let you access the system from multiple access points and from your preferred mobile device (e.g. mobile phone or tablet). By selecting a CTMS vendor that provides mobile access, you increase clinical trial efficiencies.

Some of the new CTMS platforms take CRAs into consideration and developed mobile eClinical apps, including CTMS to assist them on the go, regardless of where they are in the world. The CTMS mobile app can be used on or offline to allow CRAs to schedule visits, prepare for site visits, complete visit reports, as well as scan and upload study site documents.

When evaluating systems based on their mobile functionality, ask yourself these questions:

- Would your company allow for the **use of an app** on your user's mobile devices?
- In what ways does a mobile app **improve efficiency and productivity** for CRAs and study team members?
- What advantages does a mobile app offer in terms of **simplified data capture and real-time updates**?

Now that you have reviewed the primary considerations before purchasing a CTMS, we will share high-level considerations for evaluating CTMS vendors. While organizations often have a robust vendor evaluation program, this checklist serves as a practical review of capabilities to look for in a CTMS.

THE CTMS BUYER'S GUIDE: EVALUATING CTMS VENDORS

A vendor's purpose is to reduce strain on your team, enable you to scale as needed, maintain and expedite timelines, and mitigate risk. When evaluating CTMS vendors, it is important to ask the right questions and select a partner who understands your organization, supports your goals and objectives, and provides a modern CTMS that meets the demands of your clinical trial.

If you are looking for a new CTMS, but do not know where to start, the 10 considerations below can help you identify a best-in-class system:

1. Scalability
2. Regulatory Compliance
3. User Interface
4. Security
5. Vendor Support and Training
6. Product Configuration
7. Data Management and Reporting
8. Interoperability
9. Vendor Reputation and Reliability
10. Functionality

SCALABILITY

Does the vendor listen to and adapt the CTMS based on your business needs?

Biotech and pharma of all sizes recognize the need for enterprise technology and require technology that scales with them. Not all CTMS vendors have the resources and expertise to grow with you. Depending on the size and scope of your trials, you need a system that can grow with your organization. Ensure that the CTMS can handle an increasing amount of data and more complex trials as your research expands.

Here are some considerations for evaluating your vendors. The CTMS should:

- Accommodate an increasing number of trial participants. A scalable CTMS will have **advanced access capabilities**, including both role-based and custom permissions.
- Handle more complex trials as your research expands. Your CTMS should be able to **manage a full portfolio** of global trials.
- Manage an increasing amount of data over time. All CTMS data – old and new – should be **easy to reference** without the system slowing or users experiencing performance issues.

REGULATORY COMPLIANCE

Does the vendor's CTMS support compliance with the most common regulatory standards?

Compliance with regulatory standards is crucial in clinical research. It helps to ensure patient safety, data integrity, ethical conduct, legal due diligence, reputation and trust, and product approval.

Not all vendors provide technologies that are compliant with ever-changing global regulations. The CTMS should meet:

- **FDA 21 CFR Part 11** by using compliant electronic records, electronic signatures, and handwritten signatures.
- **GDPR regulations** by sensitively and securely handling customers' personal information.
- **GxP regulations** by supporting quality processes that ensure biotech and pharmaceutical products are safe and meet their intended use.
- **HIPAA regulations** by sensitively and securely protecting individuals' PHI and other individually identifiable health information.
- **Annex 11 regulations** by providing compliant electronic record capabilities.

USER INTERFACE

Does the vendor's CTMS have a user-friendly interface and user experience based on user preference?

Not all CTMS are created equal, nor do they all provide user-friendly interfaces that have been designed by clinical professionals for clinical use. The design and functionality of the CTMS interface can significantly impact user satisfaction and system effectiveness. When we talk about a 'user-friendly' CTMS interface, we mean that the software is easy to navigate and supports more efficient data collection, tracking, and analysis. When a CTMS is user friendly, users find it intuitive and there is a smaller learning curve.

Here are some considerations for evaluating your vendors. The CTMS should:

- Facilitate **rapid adoption** by providing clear instructions and options at each step.
- **Support non-technical users** with clear menus, icons, and tool tips that can assist users in quickly understanding and utilizing the system.
- Offer **multiple languages** and allow users to choose their preferred languages from a list of available options.
- Prioritize the most important features and make them **easily accessible** by allowing users to display data based on their needs.
- Support **intuitive, 1-or-2 click navigation** through the system with a simplified menu structure and global navigation bar.
- Use a **responsive design approach** that adapts the CTMS interface to different screen sizes and resolutions for mobile and tablet access.

SECURITY

Does the vendor provide the security controls necessary to keep your clinical trial data safe?

Given the sensitive nature of clinical trial data and the serious consequences of data breaches, security is a top priority. Selecting a vendor who provides robust security controls, including encryption, user access controls, and secure audit trails, is essential.

It is crucial that vendors offer options that limit identification risk, such as using patient or subject IDs instead of more identifying data like initials and birth date. These controls should comply with HIPAA and GDPR regulations, protecting personally identifiable information (PII) and personal health information (PHI). In addition, good vendors often comply with regulations like 21 CFR Part 11, Annex 11, GxP, GDPR, and HIPAA.

The risks associated with inadequate data security in clinical trials are not just ethical and legal, but also financial. For example, unblinding a study arm can invalidate the entire study, accrue significant HIPAA fines, and even jeopardize a company's market position, especially if a crucial Phase 3 trial is on the line.

Here are some considerations for evaluating your vendors. The CTMS should:

- Limit who can view and modify data through **user access controls**. Know this through the vendor's certifications and compliance with global regulations.
- Secure data with **encryption** in order to protect PII and PHI.
- Track data modifications with **audit trails** that use 21 CFR Part 11 and Annex 11 compliant eSignatures.
- Offer options that **limit identification risk**, such as using patient or subject IDs instead of more identifying data like initials and birth date.

VENDOR TRAINING AND SUPPORT

Does the vendor provide in-house training, customer service, and technology support?

Training is an increasingly crucial component of efficient clinical operations. The vendor you choose should offer comprehensive training to help your team get up to speed with system implementation, adoption, compliance, protocols, user roles, etc. In-house training helps to develop empowered, productive end users and administrators, ready to work at streamlining and automating their processes. In addition to training services, post-implementation support is also crucial for troubleshooting.

Here are some considerations for evaluating your vendors. The CTMS vendor should:

- Train users on **system implementation and adoption** through user guides, manuals, video tutorials, and hands-on training.
- Provide **compliance and business processes** training for your team through in-person or virtual training on data integrity, informed consent management, adverse event reporting, regulatory documentation, and audit trail requirements.
- Offer **24/7/365 dedicated customer support** following implementation with an expert service team.
- Make **communication and troubleshooting** easy with dedicated communication channels, a help desk system, and knowledgeable support staff.

PRODUCT CONFIGURATION

Can you configure the vendor's CTMS to suit your organization's unique processes?

Every clinical trial has unique needs. That is why the CTMS you choose needs to fit the way you and your team work. When evaluating vendors, consider the degree to which the product can be configured out-of-the-box to add additional fields, metadata, views, reports, and workflows for each of your work groups. Ensure the vendor's CTMS can track everything that is trial-related in the form of a configured set of activities and milestones against studies, countries, sites, organizations, contacts, and any other trial-related object.

Here are some considerations for evaluating your vendors. The CTMS vendor should:

- Help you configure the CTMS to meet your business processes by engaging in **detailed consultation sessions** to understand your specific requirements.
- **Configure the CTMS** to meet each unique clinical trial definition by gathering the study's design, objectives, business processes, data collection requirements, visit schedules, and any specific workflows involved.
- Listen to your **feedback** through an established and proven feedback mechanism and use it to enhance the CTMS based on business needs.

DATA MANAGEMENT AND REPORTING

Does the vendor's CTMS have robust data management and reporting capabilities?

When evaluating CTMS vendors, their system should provide robust data management capabilities, allowing for efficient collection, reuse, storage, and retrieval of data. It should also offer reporting capabilities to derive insights from the data collected.

Here are some considerations for evaluating your vendors. The CTMS should:

- Utilize **various data types and formats** such as PDF, Microsoft Office formats, image formats, XML, standard electronic formats, etc. Vendors should demonstrate how the system handles different file formats effectively.
- Allow access to your reporting data through a **mobile application** and real-time or near-real-time data synchronization.
- Provide **role-based access controls** so CTMS users only view the data and reports associated with their role.
- Offer **reporting tools** such as dashboards that provide KPIs and measurable metrics to gather insights.

INTEROPERABILITY

Does the vendor's CTMS seamlessly connect to your other eClinical systems?

CTMS interoperability refers to the ability of the CTMS to exchange data and collaborate seamlessly with other systems or applications involved in the clinical trial process. An interoperable CTMS allows different systems to work together, share information, and communicate. Interoperability in CTMS facilitates efficient and accurate data exchange, eliminates manual data entry and duplication, and improves overall data quality and integrity.

Interoperability can be achieved through various methods, including Application Programming Interfaces (APIs) that allow the systems to interact and exchange data in a standardized and structured manner.

Here are some considerations for evaluating your vendors. The CTMS should:

- Provide **APIs that enable integration** with external systems with available product specifications, developer resources, or API documentation.
- Use **single sign-on** mechanisms that allow users to access multiple systems with a single set of credentials. To know this, review their partnerships with SSO providers.
- **Interoperate with other systems** used in your organization, such as the electronic data capture (EDC) systems, eTMF, eISF, Remote Monitoring, Study Start-Up, QMS, and LMS as needed.
- Process a single data set from multiple sources by reviewing **integration documentation**.

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- **Exchange and use data from other systems** without compromising data integrity in accordance with industry standards.
- **Accept standard data exchange formats** or those aligned with industry best practices to support standard data exchange formats and protocols.
- **Interoperate out-of-the-box** with your existing eClinical suite without incurring additional costs to connect the CTMS to external systems.

VENDOR REPUTATION AND RELIABILITY

What is the vendor's reputation in the industry?

Clinical trial management is complex enough. Your vendor should provide stability and support throughout the process—not add to the complexity. When evaluating vendors, it is important to consider their standing and reputation in the industry, the size of the company, whether or not they have recently been acquired, or if they have experienced major leadership changes.

Check the vendor's track record in the industry and how clinical professionals react to their products. They should have a reputation for reliability, good customer support, and ongoing development to improve the system.

Here are some considerations for evaluating your vendors. The CTMS vendor should:

- Have a **good reputation** in the industry as evidenced by positive customer reviews and testimonials, industry awards and recognitions, client base and references, the vendor's longevity, thought leadership and industry involvement, etc.
- Be committed to **ongoing development and improvement** of their system as evidenced by their product roadmap, release history, customer involvement, track record of innovation, and industry recognition.

FUNCTIONALITY

What capabilities does the vendor's CTMS offer and do those functions meet your organization's specific needs?

The CTMS should enhance efficiency, accuracy, and compliance throughout the clinical trial life cycle. When evaluating vendors, ensure that their CTMS provides the features that you need to conduct your studies. This might include subject recruitment, subject scheduling, monitoring and tracking of subjects, data management, and report generation.

Here are some considerations for evaluating your vendors. The CTMS should:

- Provide a **mobile app** that grants access to key CTMS functionalities, and allows users to interact with study data and perform tasks on mobile devices such as phones and tablets.
- Generate **visual reporting through dashboards** to provide insights into study progress, enrollment, data quality, and other key performance indicators.
- Provide **comprehensive summary information across products, programs, and multiple studies**, for your clinical portfolio, program, and product management.
- Manage a **comprehensive contact database of organizations** including sponsors, investigators, sites, CROs and other vendors and control changes to contacts centrally.
- Provide **country and region management** to better split up site responsibility and categorization by geography and simplify regulatory activities during study start up and trial execution.

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- Allow **for activity plan templates** to be defined, created, and copied across the organization to allow for better process adherence.
- Manage **milestones** for a simple view of the overall study, showing both planned and actual milestones for consistent trial execution and operational checks.
- Manage enrollment activities and subject status for each site in a central location with **subject and subject visit management.**
- Provide **site visit preparation** through the review of available data to determine what data has relevance, and which should be reused for finalization of site visit report documentation.
- Produce **21 CFR Part 11 compliant** site visit documentation.
- Have **protocol deviation and issue tracking** through the use of activity and activity plan tracking to ensure compliance and traceability.
- Have powerful **clinical trial performance and reporting** functionality that provides KPIs, measurable metrics, simple Excel exports.
- Provide **custom configurable reports** including all available visible data points for each record.
- Provide **flexible support for various trial designs** by gathering the study's design, objectives, business processes, data collection requirements, and visit schedules.
- Have a **built-in content management and eTMF functionality** to easily monitor inspection readiness of all trial activities and required documentation.
- Improve **site activation and study start up** by the planning of activities for startup from site selection to subject enrollment.
- Support the full **document workflows with eSignature approvals** to meet regulatory requirements and improve decision making.
- Utilize **APIs to enable digital interoperability** with other clinical trial systems.

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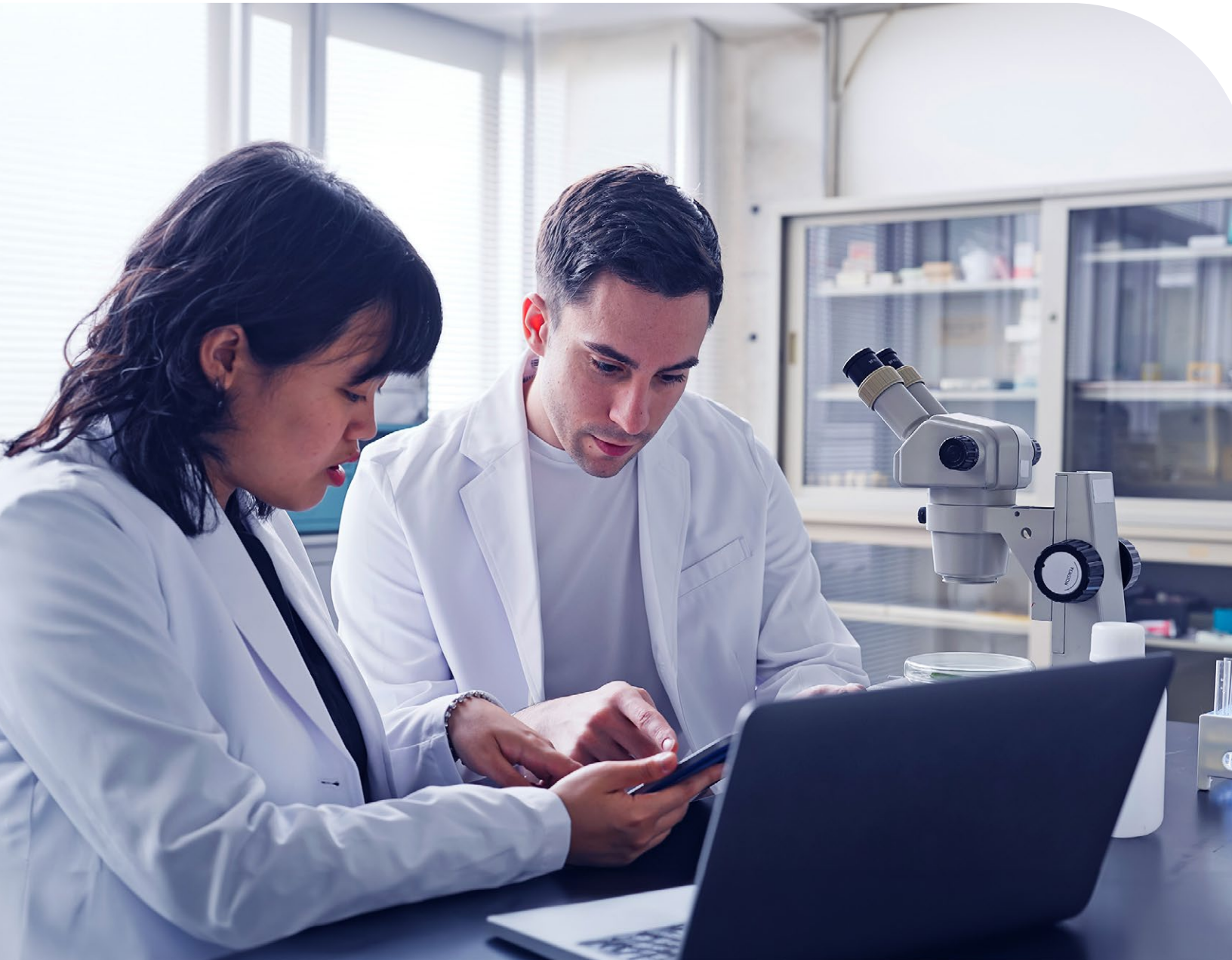
- **Capture and manage clinical trial data**, including EDC, IXRS, and payment Integrations to keep close track of all back-and-forth activity.
- Support all controls needed for **21 CFR Part 11 and EU Annex 11 compliance** to keep your studies always in a validated state.
- **Provide a flexible user defined experience** that allows individual users to choose their own path and data display to execute common tasks.
- View site visit tracking by relevance in a user friendly **site visit calendar view** to aid in study resource allocation.



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GET THE ULTIMATE CLINICAL TRIAL TRACKING CHECKLIST

Once you have evaluated vendors, you should also make sure that all the key metadata points are being tracked within their CTMS. Download the Ultimate Clinical Trial Tracking Checklist.

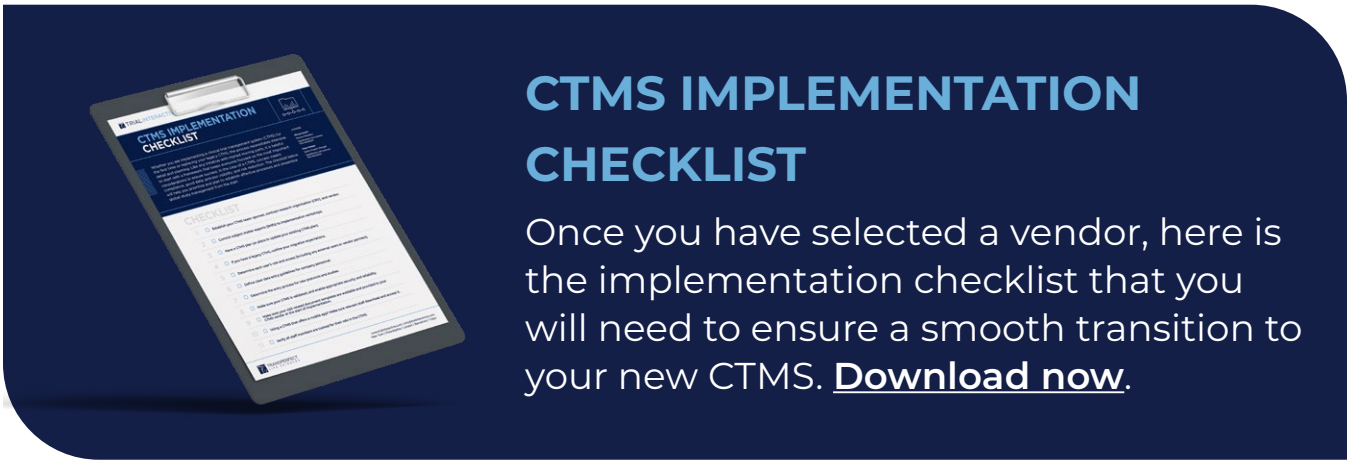
Download Now

THE CTMS BUYER'S GUIDE: THE VALUE OF TRIAL INTERACTIVE CTMS

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. High level advantages of our CTMS include:

- 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 and run more efficient studies.



CTMS IMPLEMENTATION CHECKLIST

Once you have selected a vendor, here is the implementation checklist that you will need to ensure a smooth transition to your new CTMS. **Download now**.

Trial Interactive's CTMS seamlessly connects to 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. Learn more at trialinteractive.com.

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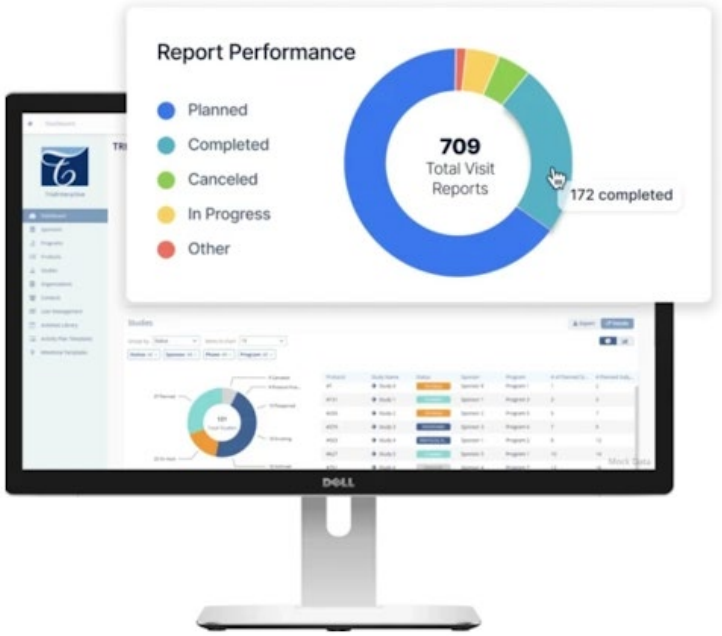

Take the Next Step

Get a demo of the TI CTMS for growing biotechnology, medical device, and pharmaceutical companies.

Schedule a Demo