TRIAL INTERACTIVE

CTMS IMPLEMENTATION CHECKLIST

Whether you are implementing a clinical trial management system (CTMS) for the first time or replacing your legacy CTMS, the process necessitates intensive detail and planning. Like any initiative with myriad moving parts, it is helpful to start with a framework that keeps everyone focused on the most important considerations to ensure success. In the case of a CTMS, success means compliance, good data, process visibility, and risk reduction. The checklist below will help you prioritize and plan to establish effective processes and streamline global study management from the start.

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CHECKLIST

1	☐	Establish your CTMS team: sponsor, contract research organization (CRO), and vendor.
2	☐	Commit subject matter experts (SMEs) to implementation workshops.
3	☐	Have a CTMS plan (or plans to update your existing CTMS plan).
4	☐	If you have a legacy CTMS, outline your migration expectations.
5	☐	Determine each user's role and access (including any external users or vendor partners).
6	☐	Define clear data entry guidelines for company personnel.
7	☐	Determine the entry process for new protocols and studies.
8	☐	Make sure your CTMS is validated, and enable appropriate security and reliability.
9	☐	Make sure your visit-related document templates are available and provided to your CTMS vendor at the start of implementation.
10	☐	Using a CTMS that offers a mobile app? Make sure relevant staff download and access it.
11	☐	Verify all staff members are trained for their role in the CTMS.

☐ Establish your CTMS team: sponsor, contract research organization (CRO), and vendor.

Many CTMS implementations need both internal and external teams and resources to support successful execution. To build a strong internal team, you first need executive support to ensure CTMS implementation, rollout, and corporate adoption are organizational priorities. Then, specify your key decision-makers, and make it clear who is steering each aspect of the implementation. Next, identify whether your organization has all the in-house expertise available for effective implementation.

Your external CTMS team must include your CTMS and eClinical vendors as well as any CROs you work with on studies. If you have other vendor partners for study execution, determine which partners need to be on your external team and ones that do not. For example, if you are not planning to integrate your CTMS with your electronic data capture (EDC) system, you may not want to include your EDC vendor. Be sure to ask yourself these questions: Does your external team understand your needs, and can they meet all of them? Does your external team align with your internal team with key points of contact on both sides? Lastly, do all internal and external team members have proper access to the CTMS?

☐ Commit subject matter experts (SMEs) to implementation workshops.

Your study or organization-specific requirements may need special consideration for the configuration of your CTMS. It is important to be sure your CTMS allows for flexible configurations to accommodate your needs. Your organization's processes, standards, and expectations need to be agreed upon by all relevant stakeholders and reflected in your CTMS configuration. Your vendor-provided SMEs are equally critical, and you will want your vendor to provide experienced staff who have been through the process of implementing or using other CTMS solutions. Lessons learned from past experiences will lend themselves to informing you on best practices. Many small and mid-sized sponsors prefer the vendor to guide the implementation and related decision-making, so all considerations are captured in the implementation plan. Stakeholder and vendor SME collaboration is critical to the success of a smooth implementation, rollout, and user adoption. Workshops led by your vendor partner can help establish a healthy collaboration, as well as expedite the process of capturing requirements.

☐ Have a CTMS plan (or plans to update your existing CTMS plan).

It is critical that expectations be made explicit to all teams and team members. For example, does your study team know the data entry points for which they are responsible, and why? Is some information housed in other clinical systems or Excel trackers? Ensure your plan indicates who is responsible for each piece of data and where the data can be mapped if located elsewhere. Your plan should include:

- All company-specific processes
- Defined user groups for designated tasks
- Details on how you will enter studies
- What values you will need available within all the picklists
- Expectations on how you will use dashboards
- A clear understanding of what reports you will need your CTMS to produce
- All study-specific processes

☐ If you have a legacy CTMS, outline your migration expectations.

During the implementation phase, it is important to know the relevant information living in legacy systems or trackers that *should be* located in the new CTMS. Internal team members should determine what information to migrate based on business needs, such as:

- Only active studies
- Investigative sites (What sites are relevant? Only active ones?)
- Contacts
- Site visits including status
- Protocol deviations

This list is just a small sample of the information you may want to migrate. If you do not identify significant information at the start, the migration process may be compromised, leaving some information unavailable when needed. If informed on corporate objectives, some CTMS vendors can consult and strategize on the best path forward by reviewing source locations and seeing the format of other documentation.

☐ Determine each user's role and access (including any external users or vendor partners).

Older CTMS solutions may have outdated user roles and access, including an insufficient number of roles and inadequate security permissions. This deficiency could be the result of older systems lacking the ability to handle the different user access needs that modern clinical trials require. It is essential for your CTMS to have a complete security model that facilitates proper internal and external user access as required.

☐ Define clear data entry guidelines for company personnel.

Poor data entry equals poor data availability (garbage in, garbage out!). CTMS is no different. While the modern CTMS provides built-in auto-naming and edit checks, no system can automate everything. Entering correct data for things like protocol and site information, subject and visit details, and monitoring information still matters. Picklists and tooltips can help study teams with proper data entry, however company conventions and processes must be laid out to ensure proper data entry. With a clear, effective data entry process, you will be able to fully leverage all the amazing search features, filtering options, and reporting aspects offered by next-generation CTMSs.

Determine the entry process for new protocols and studies.

Whether you are a sponsor or a CRO, it is crucial to define a process for entering new studies into your CTMS. Determine:

WHEN to add the study based on funding status (and in the case of the CRO, when awarded – verbal or signed?).

WHO will add it to the CTMS – Is it a senior-level clinical person or perhaps a clinical trial assistant (CTA) who can enter it? If you are a sponsor, would you prefer to have your CTMS vendor enter key protocol details, assuming your vendor provides these services? Alternatively, would you like your regulatory department to handle this?

WHAT to add to the CTMS – Some companies choose to enter limited information at the start and add new information later, for example when they choose a central lab or investigational product supply vendor.

Make sure your CTMS is validated, and enable appropriate security and reliability.

You must ensure that your potential CTMS vendor has a Software Development Life Cycle (SDLC) that adheres to global regulations, such as the Food and Drug Administration's (FDA) requirements in the Unites States (US), or the European Union's (EU) General Data Protection Regulation (GDPR). Your vendor's SDLC also must have documented, verifiable standard operating procedures (SOPs). This is key for ensuring your vendor is using an efficient, validated system to track requirements and meet all release criteria, so you can avoid risks and ensure the data in your CTMS is fully protected. Next, confirm that your vendor offers reliable hosting and security, so your clients have 24/7 access to the CTMS to enter information securely at any time. To ensure your clients also can easily enter information wherever they are, check that the vendor offers hosting facilities in multiple locations around the world, such as China, the EU, and the US.

Make sure your visit-related document templates are available and provided to your CTMS vendor at the start of implementation.

A successful implementation requires your CTMS vendor to have a complete understanding of your business process, so your vendor can ensure your internal stakeholders and SMEs interpret everything properly. Access to SOPs, business process documents, work instructions, and most importantly, site visit-related document templates is critical. This will allow your vendor to understand your monitoring process standards (internal or external by vendors), activity types and subtypes, site visit report, confirmation, and follow-up letter expectations from the start. These factors may be the company standards, or they may (and likely do) differ by study. Some older systems are unable to accommodate different visit report templates, so it is important to be sure your provider can handle the multiple variations.

Make sure your site contact lists are updated and in a file format that can be added to the CTMS easily. Real-time access to the most recent investigative site address list, including each site's current contacts and site address, is critical for CTMS users, especially clinical research associates (CRAs) and site-facing users. This ensures that investigational products and laboratory supplies ship to the correct site address. CRAs will use these lists when documenting and planning site visits, so having an accurate list will ensure monitoring visits are done and documented for the correct site locations with the correct investigators and sub-investigators.

An older CTMS may not have an easy, real-time process for importing documents. For a seamless implementation, know whether your new CTMS can easily import documents and what document formats it accepts.

Using a CTMS that offers a mobile app? Make sure relevant staff download and access it.

As the clinical trial industry moves toward decentralized clinical trials, in which many study activities are performed remotely, having real-time visibility and transparency into critical study information is key. This shift has caused mobile apps to quickly become a key component for study managers and CRAs, so they can get important data to make timely and informed decisions wherever they are, and whenever they need it. Since many older CTMS solutions were developed when mobile apps were not common, these systems do not offer the mobile capabilities that today's CRAs need in a hybrid or remote clinical trial landscape. For all modern CTMSs, it is expected that a mobile app will be provided that has an intuitive and accessible user interface. Make sure your provider offers these features to streamline implementation.

Verify all staff members are trained for their role in the CTMS.

The right training is essential for helping you and your staff learn how to fully leverage the key benefits a modern CTMS offers, such as the flexibility of user roles, group security, user actions, and configurable dashboards. Be sure each member of your current staff is trained before your CTMS goes live and new staff or vendors are trained as your organization onboards them. Verify that your vendor offers live, real-time eClinical training from qualified sources. By having these tools readily available to the user community, it makes training easy through enabling staff to select and complete the training they want, when they want. Users having access to job aids, videos for key use cases, and easily searchable online help will ensure their success as they begin to use your new CTMS. Many older providers offer outdated user manuals or just one of the components above.

Whether you're planning to implement a CTMS to replace an older system, or implementing your organization's very first CTMS, following the steps outlined above will ensure your CTMS is compliant and contains quality data. Beyond regulatory compliance and data quality, leveraging these steps can also help reduce clinical risks by enhancing process visibility, which ultimately improves collaboration and speeds timelines.

For more information about CTMS implementation, or to request a demo of the Trial Interactive CTMS, contact us at info@trialinteractive.com.