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# Free Checklist: Kickstart Your CTMS Strategy

Use this checklist to establish a high-level plan with CTMS requirements, implementation timelines, user expectations, and training and documentation needs. This will help your organization align on how the CTMS fits into your existing processes and enhances efficiency.

## Establish a clearly defined set of high-level CTMS requirements.

- ☐ All site visit documentation templates
- ☐ Reporting requirements
- ☐ Process documentation for standardized processes
- ☐ Clear understanding of user community and user expectations
  - ☐ Use or necessity of a mobile device
  - ☐ Access permissions
- ☐ Regulatory compliance requirements

## Define a clear implementation strategy for your organization.

- ☐ Timelines and milestones
- ☐ Migration plan
- ☐ Rollout plan
- ☐ Integration with potential systems
- ☐ Validation approach
- ☐ Required system documentation

## Enlist subject matter experts.

- ☐ Configuration SMEs
- ☐ QA / Validation SMEs

## Establish training and documentation expectations.

- ☐ Job aids
- ☐ User guides
- ☐ Training videos
- ☐ Role-based training

# CHECKLIST DETAIL

## Establish a clearly defined set of high-level CTMS requirements.

**Determine requirements for site visit documentation templates.** Consider the information you will want your team to collect during site visits. Clear expectations for site visit documentation will help ensure that your study team captures all necessary information in the CTMS. With standardized templates, your team can prepare and complete documentation more efficiently, reducing administrative burden and keeping study timelines on track.

**Develop reporting requirements.** Start thinking about the metrics and KPIs you will want your reports to generate as outputs in the CTMS. Consider how data should be presented in a consistent, digestible format, enabling key stakeholders to make informed decisions faster.

**Build out process documentation.** When transitioning to a new system, you may need to develop new processes or amend your SOPs. Understand how big of a lift this will be for your organization. Well-documented processes enhance the quality of work by providing clear instructions for each activity, reducing the likelihood of missteps and improving the integrity of your clinical trials.

**Understand your user community.** Determine what your study team needs and prefers in a CTMS. Consider role-based access and how you will want the CTMS to allow users to complete tasks and activities. Technology that meets the specific needs and preferences of your user community, including mobile device accessibility, will see higher user satisfaction and adoption rates. This drives up the return on your technology investment and enhances productivity.

**Align on regulatory requirements.** Determine the relevant regulations that will ensure the success of your clinical trial throughout the various phases. Documenting your regulatory requirements helps ensure adherence to regulations, minimizing the risk of non-compliance penalties and safeguarding your organization's reputation.

## Define a clear implementation strategy for your organization.

**Consider timelines and milestones** for each phase of the implementation process. Start thinking about your ideal implementation timeline and how to determine milestones to ensure that you are on the right path. Clear timelines and milestones improve project management and resource allocation, resulting in smoother implementation and minimal disruptions to your ongoing operations.

**Determine your plan for data migration, if applicable.** Your plan for the legacy data will impact the implementation timeline. Consider whether or not the data in your current "tracker" or legacy CTMS should be migrated to the new system. If you decide to migrate legacy data, proper planning ensures that valuable historical data can be properly organized and accessible in the new system. If you decide to start fresh in your new CTMS, consider the timing and phase of your study for the best time to switch systems.

**Create your rollout plan.** When implementing new technology, consider the phases that will guide the implementation. A phased approach, especially in global organizations, can enable you to train a subset of users, conduct pilot tests, and make necessary adjustments before full-scale implementation. This reduces risks, ensures better user adoption, and allows for the customization of the rollout to suit unique regional needs.

**Account for integration with potential systems.** Interoperability allows different systems to work together, share information, and communicate. Consider the potential integrations with systems such as EDC, IXRS, eCOA, internal financial and/or HR systems, and eTMF. Determining the systems you would like to interoperate with your CTMS will ensure a more seamless data flow, improving efficiency and data reliability across your organization.

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**Define a validation approach.** Include who on your team or on your vendor's team will execute and document validation exercises to ensure the new CTMS system meets all operational and regulatory requirements. Before purchasing a CTMS, consider whether the vendor offers a variety of validation packages that allows you to select an option that best fits your needs, ensuring proper execution and documentation of validation exercises.

**Define required system documentation.** Minimize potential hiccups in CTMS implementation with a strategy that includes required system documentation. Ensure all essential information will be properly captured and available in the CTMS before you purchase one, enhancing system usability and compliance for all stakeholders.

## Enlist subject matter experts.

**Identify configuration SMEs.** Leveraging subject matter experts (SMEs) during CTMS configuration can significantly enhance its value and performance, maximizing the return on your CTMS investment. While you build your CTMS strategy, be sure to identify the right resources and allocate their time effectively so that they can assist with configuration. The SMEs' input helps you, or the vendor, configure the CTMS to meet each unique clinical trial definition by providing the study's design, objectives, business processes, data collection requirements, visit schedules, and any specific workflows involved.

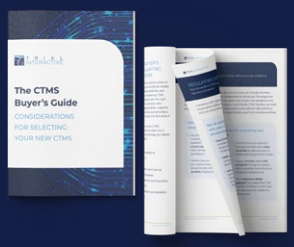
**Identify QA and Validation SMEs.** Leveraging the expertise of SMEs during CTMS validation and quality assurance can streamline compliance with regulatory requirements, help avoid non-compliance penalties, mitigate risks, ensure data integrity, and launch your CTMS in a more timely manner. Allocate SMEs to consult with the CTMS vendor to help them meet your definition of validation and documentation expectations. Consider the size of your team and how you can rely on the CTMS vendor for validation support by way of validation scripts and validation consulting services.

## Establish training and documentation expectations.

**Set training and documentation expectations.** Effective training and comprehensive documentation are critical for maximizing the value of your CTMS. You will need to provide job aids, user guides, training videos, and role-based training to support faster user adoption and proficiency with the new CTMS.

Each resource delivers value for your team. For example, job aids are practical tools that help users to quickly understand and apply complex processes. User guides serve as a comprehensive resource for CTMS functionality, enabling users to troubleshoot issues and understand features better. Training videos can significantly enhance learning and retention, leading to quicker system mastery and increased productivity. Role-based training ensures that each team member understands their interaction with the CTMS, optimizing its use across different roles.

Determine whether your internal team will create the training and documentation materials or if you will work with the CTMS vendor's training and education services to customize the training.

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Get free access to *"The CTMS Buyer's Guide: Considerations for Selecting Your New CTMS."*

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