TRIAL INTERACTIVE

7 Steps to a Seamless CTMS Migration

YOUR GUIDE TO EFFICIENTLY TRANSFERRING STUDY DATA WITHOUT DERAILING TIMELINES

OVERVIEW

COMMON REASONS TO MOVE TO A NEW CTMS

Whether you currently have a Clinical Trial Management System (CTMS) or your Clinical Research Organization (CRO) utilizes one, there might come a time when you decide to migrate your data to a new CTMS.

This decision could stem from dissatisfaction with your current vendor, your tracking system's limited functionality, limited storage, escalating costs, or a combination. Additionally, changes in leadership, either within your organization or at the vendor's end, can prompt a reevaluation of your current system. Whatever your reason to move to a new CTMS, this guide aims to inform your decision-making process and show you that migrating to a new system does not have to be complicated.

MIGRATING STUDY DATA TO TRIAL INTERACTIVE CTMS

The thought of migrating to a new CTMS can be daunting. You may be worried about how to mitigate risk and keep timelines on track while moving from your current system to the new CTMS. Common migration questions and concerns include:

- Are my studies in a state to be migrated into a new system?
- How can I avoid study delays due to migrating to a new system?
- Should I expect to spend time and resources on risk mitigation post data transfer?

While migrating to a new system introduces new variables, it doesn't have to introduce more risk. With Trial Interactive, migration is done in fewer steps, ensuring a smoother transition. This guide provides an overview of how we make migration painless for our clients in seven steps. With our experts at your side, you can ensure that your organization's migration process will be seamless, so you can focus on what matters most—your research.

Need assistance with your migration? Contact us.

MIGRATION DEFINITION

Your migration requires a source system, which keeps the data prior to migration, and a target system, which will receive the transferred data. In this guide, the new system is considered to be the "target" and your previous CTMS is considered to be the "source". The experts at Trial Interactive ensure that you successfully migrate data from your source to TI CTMS while keeping risk to a minimum.

Migration projects are performed through a collaboration between you, the client and the Trial Interactive team. For CTMS migrations, that includes the product manager, project manager, solutions architects, engineers, and system QA. Our operations project manager keeps everyone on task and continually provides updates on the progress directly to the client

7 STEPS FOR SUCCESSFUL CTMS MIGRATIONS

Trial Interactive helps you migrate to our CTMS in seven simple steps. With our experts at your side, you can make the switch to an easier-to-use CTMS that's part of a platform ranked #1 for sponsors, without incurring traditional migration risks.

	Milestone	Done By You	Done For You
☐	**Assess Your Need for a CTMS**	✓ Identify your vendor and sign the scope of work. ✓ Discuss what you're looking for in a CTMS.	✓ Trial Interactive builds the CTMS after understanding your requirements.
☐	**Assess Whether You Need to Migrate Your Data**	✓ Walk through pros and cons of data migration with your vendor. ✓ Understand the target system's functionality; discuss reports and system outputs.	✓ Trial Interactive continues to prepare the CTMS and sets it up to receive migration data.
☐	**Prepare for Your Data Migration**	✓ Assess the data in your current CTMS or tracking system and determine which items to migrate.	✓ Trial Interactive provides guidance on data standards to help determine if the data can be migrated to TI CTMS. ✓ Trial Interactive advises on the best timing and stage for migration.
☐	**Prepare Data for Export**	✓ Provide sample data structure or backup of database to vendor.	✓ Trial Interactive assesses data structure to determine if the data format is acceptable.
☐	**Complete Mapping Exercise**	✓ No action needed, be prepared to answer questions related to the data you provided.	✓ Trial Interactive completes the mapping exercise.
☐	**Migrate the Data**	✓ Provide the data in the format agree upon with your vendor. (API, excel, csv, etc.)	✓ Trial Interactive imports the data via sFTP, APIs, etc.
☐	**Review QC Documentation**	✓ Review the QC documentation and perform a walk-through of your new CTMS (optional).	✓ Trial Interactive provides QC documentation and an optional walk-through of the new CTMS.

WHAT YOUR TEAM SHOULD KNOW ABOUT MIGRATING TO A NEW CTMS

ClinOps

Top advantages of TI CTMS:

- ✓ Proactively address issues before they impact timelines
- ✓ Know the status of every task, site, and study at all times
- ✓ Schedule visits more efficiently
- ✓ View site visit reports in real time
- ✓ Manage critical processes more accurately
- ✓ Easily pull reports and view real-time, visual dashboards

You'll participate at a project level to help with the various checkpoints.
Tasks include:

- ✓ Determine what data, if any, from the source CTMS should be migrated
- ✓ Ensure that your current data is as up-to-date and accurate as possible
- ✓ Amend any mistakes or missing fields in your current data format
- ✓ Determine migration timing, when to stop tracking data in the source system, and when to enter data in the new system

IT

Top advantages of TI CTMS:

- ✓ Simplify implementation
- ✓ Experience painless employee adoption
- ✓ Relieve IT burdens with a dedicated implementation team, 24/7 technical support, and no hidden technical support fees

You'll be very involved in the migration process, as IT is an essential contributor to a successful CTMS migration. Tasks include:

- ✓ Prepare the data for transmission to TI
- ✓ Ensure data transmission to TI is successful

QA

Top advantages of TI CTMS:

- ✓ Use of our 21 CFR Part 11, Annex 11, ERES, GDPR, HIPAA, ISO 9001, and GxP compliant system
- ✓ Use of a fully validated CTMS

You'll participate at a high level to review the migration plan and complete migration from a regulatory and compliance perspective. Tasks include:

- ✓ Determine how data will be verified
- ✓ Determine how testing will be done
- ✓ Determine how the migration activities will be documented

C-Suite and Corporate Leadership

Top advantages of TI CTMS:

- ✓ Gain real-time visibility across your entire portfolio of studies in one click
- ✓ Make faster risk-based decisions
- ✓ Save over $1.2 million by reducing CRA's time populating visit reports and sending confirmation and follow up letters, $540,000 by reducing study manager's time reviewing reports, and $300,000 by eliminating manual data transfer from TMF lead responsibilities*
- ✓ Reduce the cost of ownership with built-in support services and no hidden technology costs, licensing, validation, or hosting fees

You'll provide a level of oversight during migration and beyond. Tasks include:

- ✓ Approve scope of work based on details from the ClinOps team
- ✓ Establish and maintain our long-term strategic partnership

*Savings based on average hourly rates for CRAs and Managers across 50 sites in a two-year study.

7 STEPS FOR SUCCESSFUL CTMS MIGRATIONS

STEP 1: Assess Your Need for a CTMS

Done By You:

- ✓ Identify your vendor and sign the scope of work.
- ✓ Discuss what you're looking for in a CTMS.

Done For You:

- ✓ Trial Interactive builds the CTMS after understanding your requirements.

Before diving into the migration process, it's crucial to evaluate whether you truly require a new CTMS. **Start by reflecting on your current tracking system. Are there noticeable inefficiencies hindering your operations? How satisfied are you with your existing vendor?** If you find that a change is necessary, the next step is to identify a potential vendor and engage in a detailed discussion about what you are specifically seeking in a CTMS. As you navigate this conversation, always keep your migration requirements at the forefront. Consider factors like the volume of data in your current system that you wish to transfer, anticipated timelines for the migration, and any other pertinent details.

At Trial Interactive, you will next formalize your intentions by signing a Statement of Work (SOW). This document provides a business agreement that outlines deliverables and project goals. These action items help us set a strong foundation and increase visibility throughout the migration process. By signing these documents, you can ensure that everyone is on the same page and that expectations are set from the outset.

Once the vendor has a comprehensive understanding of your needs and expectations and a signed SOW, they can commence the construction of the CTMS tailored to your specifications.

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STEP 2: Assess Whether You Need to Migrate Your Data

Done By You:

- ✓ Walk through pros and cons of data migration with your vendor.
- ✓ Understand the target system's functionality; discuss reports and system outputs.

Done For You:

- ✓ Trial Interactive continues to prepare the CTMS and sets it up to receive migration data.

When you decide on a new CTMS, the next question is: **Why should you migrate your old data?** We recommend a few considerations to guide your decision:

Resourcing: The size of your team may be a determine factor when asking if you should or should not migrate your date. For example, within a smaller organization it may be more efficient to bring in existing data for reuse saving time for future record creation.

Return on investment (ROI): Consider whether manually re-entering all the data into the new system will be a more efficient use of your team's time, or if freeing up your team for other tasks is more beneficial. Even if you have the financial flexibility to choose either option, you must weigh which is the more strategic choice.

Human Error: Migrating data significantly reduces the risk of human error. Manually entering data always carries the risk of mistakes. By migrating, you not only preserve the continuity of your data but also centralize it in one location, minimizing the chances of errors and ensuring data integrity. In essence, migration offers a streamlined, efficient, and error-free approach to transitioning to a new CTMS.

As you assess whether you need to migrate your data, walk through the pros and cons with your vendor. Understand how the system captures data. Discuss report and system outputs. During this step, Trial Interactive will continue to prepare the CTMS to meet your requirements.

STEP 3: Prepare for Data Migration

Done By You:

- ✓ Assess the data in your current CTMS or tracking system and determine which items to migrate.

Done For You:

- ✓ Trial Interactive provides guidance on data standards to help determine if the data can be migrated to TI CTMS.
- ✓ Trial Interactive advises on the best timing and stage for migration.

When preparing for migration, thoroughly assess the data housed in your source CTMS or tracking system. **This involves determining which specific items are crucial to transfer to the new system.** A CTMS typically contains a myriad of data points, including milestone data, organization and personnel data, monitoring visit data, subject visits, and more. Key data to consider for migration encompasses historical study performance, details about personnel (such as study personnel, site personnel, and investigators), and organizational data (like institutions and site information). Given the vast amount of data, the migration process can be intricate and multifaceted.

During the assessment, the team will also need to determine each study's suitability for migration. Study status, size, the amount of data involved, and study team resources should all be considered. Small studies are often easier to migrate than larger studies, and it is often simpler to migrate a study during the planning or feasibility phases as fewer data points will be involved and it may be easier for the team to transition to a new CTMS. However, if your new CTMS includes functionality that will simplify the study team's ability to enter data and manage study progress, there may be benefits to migrating studies that are ongoing or even nearing close-out. It is vital to ensure all of the above when determining which studies will be part of the migration.

When multiple studies are involved, migration is often phased. During the assessment for migration suitability, many teams find it beneficial to group their studies into three categories: those to migrate now, those to migrate later, and those not to migrate at all. Resource balancing for a migration is key; one common approach is to set a date at which time all studies will be started in the new CTMS. This helps to ensure a smooth transition from one CTMS to another without further complicating the migration process or overwhelming the study team.

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STEP 4: Prepare Data for Export

Done By You:

- ✓ Provide sample data structure or backup of database to vendor.

Done For You:

- ✓ Trial Interactive assesses data structure to determine if the data format is acceptable.

As you advance to the fourth step of the migration process, the focus shifts to readying your data for export. **Provide your vendor with example or sample data, which can serve as a reference point for the migration.** As you prepare your datasets, bear in mind that the migration process is seldom straightforward. Instead of transferring a singular set of data, the process is often more intricate, involving multiple moving parts. This could encompass data from multiple studies or data that's system-wide.

To give your vendor a clearer picture of the data structure, provide a backup of your database. This not only aids in understanding the data's structure but also ensures that all parties are aligned in their expectations. Proper preparation at this stage sets the foundation for a successful migration.

STEP 5: Complete Mapping Exercise

Done By You:

- ✓ No action needed, be prepared to answer questions related to the data you provided.

Done For You:

- ✓ Trial Interactive completes the mapping exercise.

This step is a critical preparation step that reduces the risks associated with switching your CTMS, such as missing data. **During this step, there is no action needed on your end. The mapping exercise will be completed by Trial Interactive solutions architects.** The architects will review sample files and technical documents for your current CTMS for the purpose of determining which data points will be included in the migration and where those data points will go in the new CTMS. A target location will be identified for each data point involved, and the architect will document this in a mapping document. The mapping document includes the following information: the name of the data point's field in the source CTMS, the name of the proposed target field in the new CTMS, and any additional information or logic/rules needed to ensure a smooth migration. For example, if a protocol number is captured in the source CTMS in a field called "Study Number", but the applicable field is called "Protocol Number" in the target CTMS, the mapping document will show that the data will flow from the Study Number field in the source CTMS to the Protocol Number field in the target CTMS.

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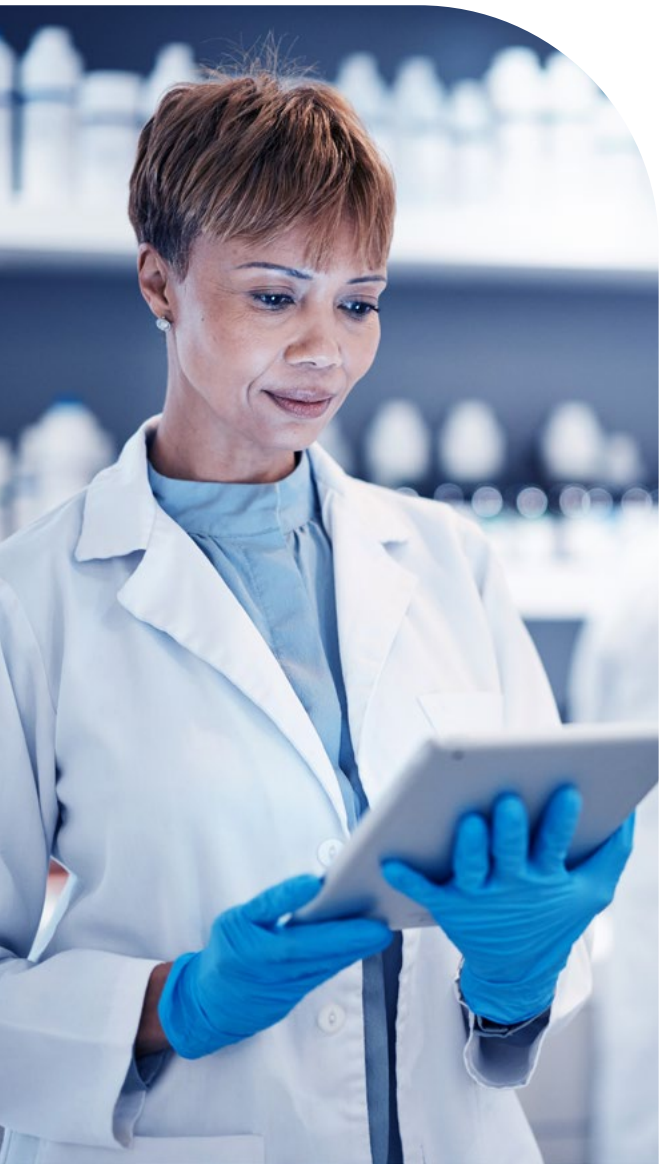
STEP 6: Migrate the Data

Done By You:

- ✓ Provide the data in the format agree upon with your vendor. (API, excel, csv, etc.)

Done For You:

- ✓ Trial Interactive imports the data via an sFTP, APIs, etc.



In this step, migration of data from your old CTMS to the new CTMS begins. The method of data transfer will need to be confirmed prior to this step – will you use Application Programming Interfaces (APIs), or upload dataset files to a target location so the new CTMS can process and ingest them? The technical teams will discuss and provide feedback so the ideal solution can be used.

While migration is ongoing, you will need to decide how to track ongoing study activities. **Our migration process tries not to interrupt your work as much as possible, but we recognize that study management activities do not pause while a migration is occurring.** Each organization must determine how to continue work during the migration phase.

1 2 3 4 5 6 7

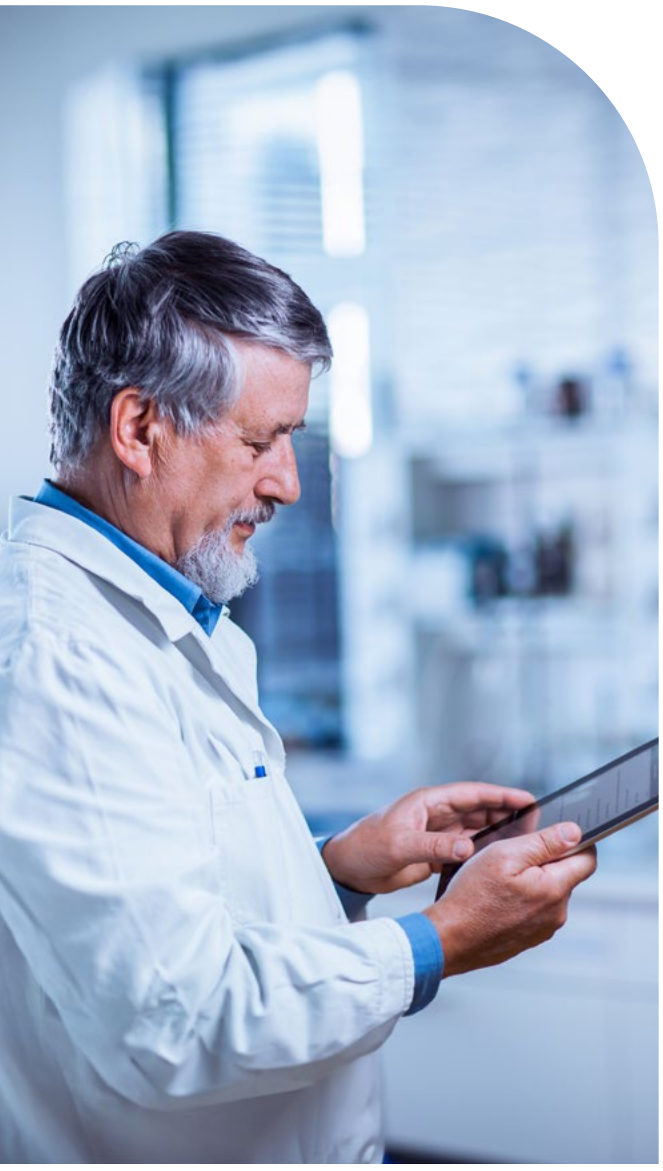
STEP 7: Review QC Documentation

Done By You:

- ✓ Review the QC documentation and perform a walk-through of your new CTMS (optional).

Done For You:

- ✓ Trial Interactive provides QC documentation and an optional walk through of the new CTMS.



You've successfully migrated to Trial Interactive CTMS and will soon experience all the benefits of our industry-leading CTMS. With TI CTMS, you'll achieve that goal of efficiency and productivity, with no major headaches.

The final step provides evidence of the successful migration. You will receive QC documentation that includes screenshots comparing source and target data, and that migration was done correctly. These reports provide peace of mind that all data is in their proper place. The purpose of this step is to make sure everything went where it was supposed to and the values were not changed.

All you have to do is review the report. If you have specific questions, members of the team can walk you through the system. Rest assured knowing that as a Trial Interactive customer, you now have a dedicated support team to provide support and training to remove the friction from day-to-day clinical operations.

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Trial Interactive takes the pain out of migration. Our seven steps provide visibility into the migration process to alleviate the common concerns that accompany migration. By choosing to migrate to TI CTMS you ensure a seamless flow and preservation of your valuable study data. You will also have access to a dedicated migration team and CTMS team, who have extensive experience with eClinical technology. Trial Interactive is at the forefront of innovation and regularly updates product features as part of our commitment to simplify complex processes.

If you have any questions, please submit a migration request.

Once you switch, you'll experience all the benefits of Trial Interactive CTMS: unmatched process visibility, real-time insights, and the best platform of connected solutions for growing pharma, medical device, and biotech companies.

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.

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.

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

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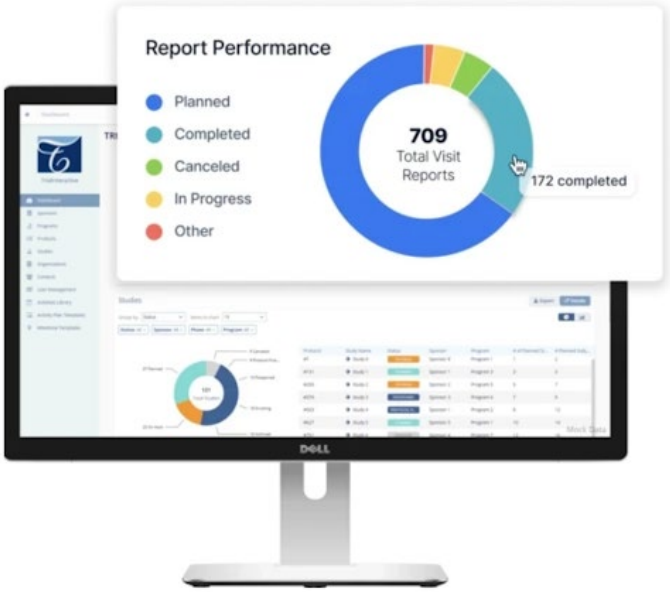

Take the Next Step

Get a demo of the CTMS that's part of the platform ranked #1 for sponsors by the 2023 Citeline Awards.

Schedule a Demo

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