



The 6 Steps to an Easy eTMF Migration

HOW TO SWITCH TO
AN ETMF YOUR TEAM
WILL LOVE

OVERVIEW

Migrating to Trial Interactive eTMF

The thought of migrating to a new electronic trial master file (eTMF) system 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 eTMF.

Common migration questions and concerns include:

- Will the quality and completeness of my trial master file remain intact following field mapping and migration?
- How can I keep this transfer from disrupting our study during migration and data cleanup?
- Should I expect to spend time and resources on risk mitigation post-migration?

While migrating to a new system introduces new variables, it doesn't have to introduce more risk. With Trial Interactive, migration is easy. This guide provides an overview of how we make migration painless for our clients in six 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.

[SUBMIT A MIGRATION REQUEST](#)

Migration Definition

Migration is a data exercise. It involves moving (migrating) study documents and their associated metadata from “Source” to “Target” systems. Your old system (source eTMF) follows a structure that is inherently different from that of any new system (target eTMF). The experts at Trial Interactive ensure that you successfully get the information from one eTMF to TI eTMF without introducing risks. Migration projects are performed in collaboration with Trial Interactive (Project Manager, Solutions Architect, Solutions Engineer and Clinical Document Services Team) and your team. The Trial Interactive team will work with you to ensure the migration procedures are completed.

Note: Depending on your source eTMF vendor, Trial Interactive may have to do a full feasibility review of each migration opportunity. Migrations from certain eTMF vendors are complex and require vetting these migration opportunities in more detail, along with any specific client requirements that may differ from the standard expectations for migration.

SIX STEPS FOR SUCCESSFUL ETMF MIGRATIONS

Trial Interactive helps you migrate to our eTMF in six simple steps. With our experts at your side, you can make the switch to an easier-to-use eTMF that's rated #1 by clinical leaders, without incurring traditional eTMF migration risks.

	Milestone	Done By You	Done For You
<input type="checkbox"/>	1. Prepare for Your Migration	<ul style="list-style-type: none"> ✓ Understand and acknowledge the scope of work, meet your project team, and get onboarded to Trial Interactive. 	<ul style="list-style-type: none"> ✓ Trial Interactive defines the scope of work, organizes the kickoff meetings, delivers the migration plan and project schedule, and onboards the client to TI.
<input type="checkbox"/>	2. Export the Source Data	<ul style="list-style-type: none"> ✓ Export the index structure, configuration, audit trail, and documents from your source eTMF to Trial Interactive's secure file share. 	<ul style="list-style-type: none"> ✓ Trial Interactive monitors the secure file share as you upload your data.
<input type="checkbox"/>	3. TI Creates the Target Room	<ul style="list-style-type: none"> ✓ No action needed, but be prepared to answer questions we may have about your data. 	<ul style="list-style-type: none"> ✓ Trial Interactive builds a standard eTMF room based on the 3.2.0 TMF Reference Model (CDISC).
<input type="checkbox"/>	4. TI Completes a Mapping Exercise	<ul style="list-style-type: none"> ✓ No action needed, but be prepared to answer questions we may have about your data. 	<ul style="list-style-type: none"> ✓ Trial Interactive Solutions Architect performs a mapping exercise to align the source and target eTMF index and metadata fields.
<input type="checkbox"/>	5. TI Imports the Data	<ul style="list-style-type: none"> ✓ No action needed, but be prepared to answer questions we may have about your data. 	<ul style="list-style-type: none"> ✓ Trial Interactive imports all documents and metadata to the new TI eTMF room.
<input type="checkbox"/>	6. Review the QC Report	<ul style="list-style-type: none"> ✓ Review the post-migration report and walk-through verification of your new eTMF. 	<ul style="list-style-type: none"> ✓ Trial Interactive provides a QC verification report and a walk-through verification of the new eTMF.

WHAT SHOULD YOUR TEAM KNOW ABOUT MIGRATING YOUR ETMF?



ClinOps

Top Advantages of TI eTMF:

- ✓ Get support from on-demand TMF experts and document specialists.
- ✓ Leverage ML and AI for document processing, auto-coding, and metadata extraction.
- ✓ Maintain TMF completeness and health with real-time document processes and audit trails.
- ✓ Perform critical TMF tasks and oversight on the go with our mobile application.
- ✓ Simplify onboarding and daily use with SSO.

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

Tasks include:

- ✓ Identify what data from the source eTMF should be migrated.
- ✓ Quality check the data imported to Trial Interactive's SFTP server is accurate.
- ✓ Help with the sites and site details.
- ✓ Communicate when to pause the clinical trial during migration and then when to resume.
- ✓ Review our QC evidence.



IT

Top Advantages of TI eTMF:

- ✓ Relieve IT burdens with a dedicated implementation team, 24/7 technical support, and no hidden technical support fees.

You'll participate at a high level without too much involvement in day-to-day procedures.



QA

Top Advantages of TI eTMF:

- ✓ Use our 21 CFR Part 11, Annex 11, ERES, GDPR, HIPAA, and GxP compliant system.
- ✓ Mitigate regulatory compliance risks by training personnel in SOPs and protocols.
- ✓ Gain full visibility into each site's regulatory documents, ensuring that they are always inspection ready.

You'll participate at a high level to review the migration plan and completed migration from a regulatory and compliance perspective.

Tasks include:

- ✓ Review the migration plan and migration summary.
- ✓ Review the evidence from the QC verification report that everything was migrated properly.



C-Suite and Corporate Leadership

Top Advantages of TI eTMF:

- ✓ Join over 250 sponsors who use TI 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.
- ✓ 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.

Note: Your Source eTMF Vendor might need to provide assistance during the process to help you export everything that is in scope for migration onto our SFTP server.



STEP 1: PREPARE FOR YOUR MIGRATION

When starting the migration process from your source eTMF to your target eTMF, there are a few prerequisites we'll complete together.

Done By You:

- ✓ Understand and acknowledge the scope of work, meet your project team, and get onboarded to Trial Interactive.

Done For You:

- ✓ Trial Interactive defines the scope of work, organizes the kickoff meetings, delivers the migration plan and project schedule, and onboards you to TI.

One of the first steps in the eTMF migration process is to define the scope of work with Trial Interactive. This is an essential step in understanding the migration checkpoints. By working with Trial Interactive, you can ensure that the migration process aligns with your organizational goals.

Once you have defined the scope of work, the next step is to sign the Scope of Work (SOW) and Standard Operating Procedure (SOP) documents. These documents provide a detailed overview of the migration process, outlining the specific steps involved, timelines, and key deliverables. By signing these documents, you can ensure that everyone is on the same page and that expectations are set from the outset.

Next, you will attend a kickoff meeting with your project manager, solutions architect, solutions engineer, and clinical document services team. Following the kickoff meeting, you will receive your migration plan and project schedule. These documents detail the processes in place, the scope of the migration, and the responsibilities of each team member involved in the migration process.

Finally, as part of the onboarding process, you will be introduced to the Trial Interactive system and will receive training on how to use the system, as well as any necessary support to ensure a smooth transition to the new system.

These action items help us set a strong foundation and increase visibility throughout the migration process.



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STEP 2: EXPORT YOUR SOURCE DATA

Export the Index Structure, Configuration, Audit Trail, and Documents from your source eTMF to a secure TI file share.

Done By You:

- ✓ Export the index structure, configuration, audit trail, and documents from your source eTMF to Trial Interactive's secure file share.

Done For You:

- ✓ Trial Interactive monitors the secure file share as you upload your data.

After you have defined and signed your SOW, attended your kickoff meeting, received your migration plan and project schedule, and onboarded to the TI system, it's time to start the migration process. The second milestone of eTMF migrations is critical. It involves providing the source export of your current eTMF system to Trial Interactive. This source export typically includes the index structure, configuration, audit trail, and documents from your previous eTMF system.

The purpose of providing the source export is to ensure that Trial Interactive's migration team has all the necessary information to configure the new eTMF system to meet your study's requirements. This includes understanding your previous index structure, document types, and metadata fields.

Once you export your source data, you will upload it to our secure file share, (TI Secure File Transfer Protocol, SFTP), where it is securely stored and can be accessed by the solutions architects and engineers throughout the migration process. At this time, Trial Interactive's team will also conduct an initial analysis of the export. This analysis helps identify any potential challenges that may arise during the migration process.

Overall, providing your export allows for a smooth transition to a new eTMF system, ensuring that all the necessary information is available to configure the new system accurately.

Questions about this milestone? [Contact us](#) to discuss the process.



STEP 3: TARGET ROOM CREATION

Trial Interactive's Certified Experts build a standard TI eTMF Room based on a standard eTMF template.

Done By You:

- ✓ **No action needed**, but be prepared to answer questions TI may have about your data.

Done For You:

- ✓ Trial Interactive builds a standard eTMF room based on the 3.2.0 TMF Reference Model (CDISC).

In Step Three, Trial Interactive builds a standard eTMF room based on the 3.2.0 TMF Reference Model. **While our team builds the eTMF room, there is no action needed on your end.**

During this step, you'll have open lines of communication with your project manager, who will keep you updated on the progress of the eTMF room build and if we have any questions about your data.

To speed eTMF migrations, Trial Interactive uses the out-of-the-box eTMF room, which is based on the 3.2.0 TMF Reference Model that is affiliated with the Clinical Data Interchange Standards Consortium (CDISC). According to the TMF Reference Model, "Version 3.2.0 of the Reference Model reflects updated regulatory guidance and current industry best practices – making it easier for organizations to configure the TMF Reference Model to their processes, and to further improve TMF quality, completeness, and timeliness."¹

Should your study require a more customized eTMF room, we can build the target room based on your study requirements to accommodate the migration. However, this option comes with an increased risk of timeline extensions and higher costs than the standard out-of-the-box configuration.

¹ <https://tmfrefmodel.com/version-3-2-0-of-the-tmf-reference-model-launched>



STEP 4: MAPPING EXERCISE

Trial Interactive Solutions Architect performs a mapping exercise to align the source and target eTMF index and metadata fields.

Done By You:

- ✓ **No action needed**, but be prepared to answer questions TI may have about your data.

Done For You:

- ✓ Trial Interactive Solutions Architect performs a mapping exercise to align the source and target eTMF index and metadata fields.

Step Four is a critical preparation step that reduces the risks associated with switching eTMF systems, such as missing documents or misaligned fields. During this step, **there is no action needed on your end**. The mapping exercise will be completed by Trial Interactive solutions architects. The purpose of this step is to ensure that the eTMF room has a field for every document and file that exists. To do this, the solutions architect notes and compares the source and target eTMF index and metadata fields on an Excel sheet and aligns them.

From this exercise, we create a Master Mapping File, which serves as a load file to automate migration. By automating the data upload, which happens during Step Five, we speed migration and reduce the risk of human error, which can lead to significant consequences such as delays in regulatory submission and inspection findings. The Master Mapping File also serves as a reference point, ensuring that the source and target eTMF are aligned.

If you have any questions about the mapping process, reach out to your project manager.



STEP 5: DOCUMENT AND METADATA IMPORT

Trial Interactive imports all documents and metadata to the new TI eTMF Room.

Done By You:

- ✓ **No action needed**, but be prepared to answer questions TI may have about your data.

Done For You:

- ✓ Trial Interactive imports all documents and metadata to the new TI eTMF room.

By Step Five, your eTMF room is fully prepared for our team to import the data and documents. **No action is required on your end**, but there may be specific scenarios that require discussion. For instance, not all source metadata may be applicable or mapped, which your project manager will address if it applies to your migration.

Trial Interactive imports all documents to the new TI eTMF room. Once the documents are loaded into the new eTMF, the metadata associated with each document is also migrated. Metadata can include information such as document name, version, date, author, and other relevant information. The data loading process is a crucial step in eTMF migration, as it ensures that documents and metadata are accurately and securely transferred to the new system.

We prioritize a seamless migration process for our clients and welcome your input, should you have any concerns.



STEP 6: MIGRATION QC VERIFICATION REPORT

TI provides a QC verification report and a walk-through verification of the new eTMF.

Done By You:

- ✓ Review the post-migration report and walk-through verification of your new eTMF.

Done For You:

- ✓ Trial Interactive provides a QC verification report and a walk-through verification of the new eTMF.

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

The final step, Step Six, provides evidence of the successful migration. You'll receive a migration summary report detailing everything that was migrated, along with a quality control (QC) verification report that compares source and target eTMFs. Additionally, the QC report outlines the steps our team took to ensure top-quality results. These reports provide peace of mind that all files, documents, metadata, and other elements are in their proper place.

All you have to do is review the report and walk through your new eTMF with your project team. Rest assured knowing that as a Trial Interactive customer, you now have a dedicated support team to provide TMF support and education to streamline TMF compliance and remove the friction from day-to-day clinical operations.

CONCLUSION

Trial Interactive takes the pain out of migration. Our six steps provide visibility into the migration process to alleviate the common concerns that accompany migration. Don't let the fear of switching hold you back.

Once you've made the switch, you'll experience all the benefits of Trial Interactive eTMF: cost-efficiency, dedicated expert support, and the best platform of connected solutions for growing pharma and biotech companies.

If you have any questions, please [submit a migration request](#).

Customer Experiences with Switching to TI eTMF

Simple, Customizable Workflows

"I am very familiar with Veeva Vault and Trial Interactive is more simple [to use]."

— TMF Administrator, Eidos

Clean, Intuitive UI

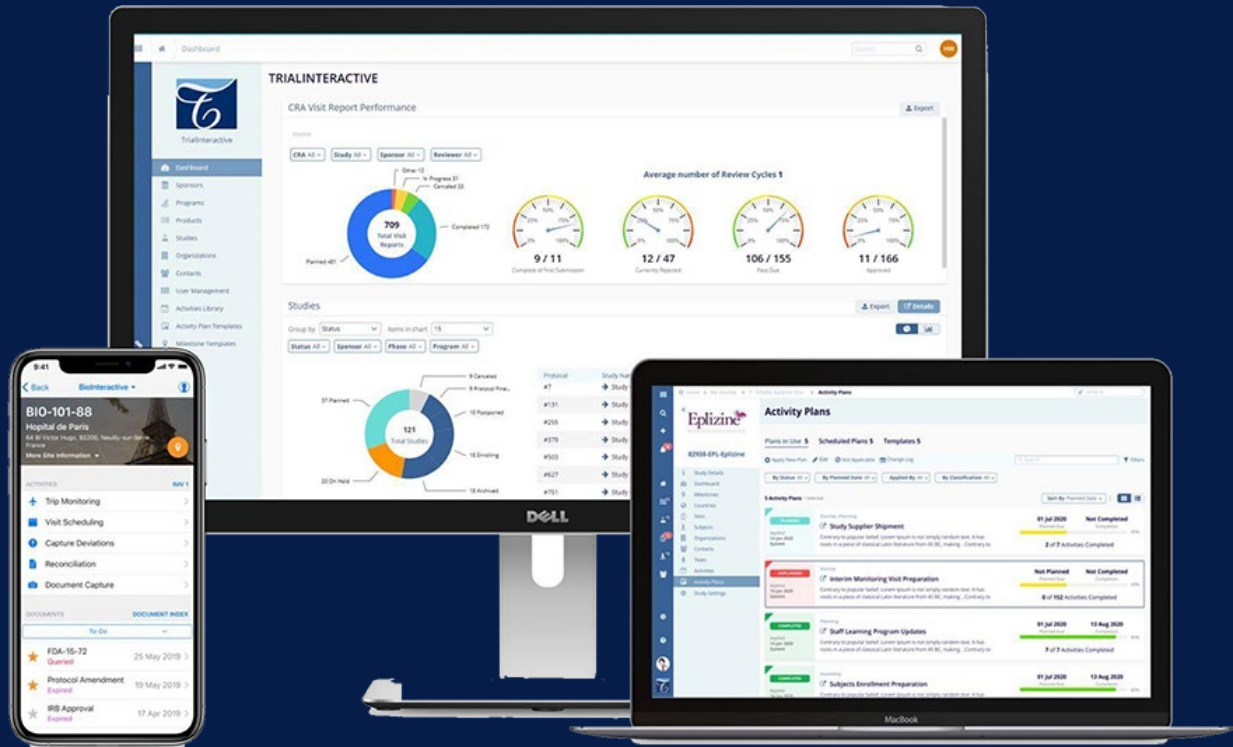
"Our business users like yours best, your UI is clean and intuitive, and you have a lot of great features that other systems don't offer. Seems super configurable and flexible and easy to deploy."

— CRO, Tech-Res

Support for Clinical Professionals

"Having a great core team with the expertise we needed was critical to our success. It truly was a refreshing experience working with you on this project, looking forward to future collaborations."

— Clinical Trial Assistant, Westat



Take the Next Step

Get a demo of the eTMF rated #1 by clinical leaders.

Schedule a Demo