

eTMF IMPLEMENTATION QUICK GUIDE



Implementing an eTMF for the first time can feel like a daunting process. This checklist will help you focus on some primary considerations to reduce risks, maintain compliance, and establish effective processes in your eTMF so that your team embodies a culture of inspection readiness from the start.

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Establish your TMF team.

Many study teams need both internal and external resources to support the success of the TMF implementation. To build a strong internal team you'll first need executive support to ensure the TMF and inspection readiness are organizational priorities. You'll need to specify your key decision makers so it is clear who will be steering which aspects of the effort, as well as identifying if all of the expertise is available for effective implementation.

Your external TMF team will include your eTMF/eClinical and TMF services vendors, or your CRO. Does your external team understand your needs, and can they meet them? Does your external team align with your internal team with key points of contact on both sides? Lastly, do all your internal and external team members have proper access to the eTMF?

Set clear expectations with your vendor.

What does your vendor need from you to configure and implement your eTMF and get it live? As soon as you sign the contract with your vendor, set your timeline. Consider if you will be implementing your eTMF for a single study or for multiple, ongoing studies within a program. This will play a major factor in the length of your implementation. Piloting your implementation with one study, then scaling up allows you to identify the best approach to move forward. Starting with one study gives you and your team a chance to learn and understand your eTMF system.

Have a TMF plan.

Does each functional area understand their requirements and expectations? For example, does your data management group know which documents they're responsible for, and why? Are some documents in other clinical systems? Ensure your plan indicates who is responsible for each document and where it can be mapped to if located elsewhere. Your plan should be the overarching plan for the TMF, including the TMF filing structure to be used, chain of custody records, and all study-specific processes for archiving and paper destruction.

Leverage the TMF Reference Model.

There are two ways you can use the TMF Reference Model: out-of-the-box or customized. Ask these questions to determine which is right for you:

- What do you need to go into a conversation with vendors?
- What will inspectors require of you for documentation?
- If you're a sponsor, are there more documents you require?

Establish clear processing guidelines.

How do you want your documents processed? How do you want your documents submitted? Who is submitting your documents? Make sure you discuss this with your study team.

As part of your document processing guidelines, establish standard naming conventions. This makes it easy to file documents in good order, prevent duplicates, and find documents quickly. Your naming conventions should include the protocol number, site number, document or artifact type, and date. Educate your users on your naming conventions and why it's important to use them when submitting documents to your TMF.

Make sure your eTMF is validated and enables appropriate security and reliability.

eTMF systems should ensure that no loss, alteration, or corruption of data and documents can occur. Focus on your new system's security, and ensure that your eTMF is validated to determine that the functionality is fit for purpose and follows all Good Clinical Practice (GCP) principles, relevant regional/international regulatory guidelines, and 21 CFR Part 11 compliance.

Determine each user's role and access.

Who is providing you with documents? What level of system access do they need to submit documents? Your functional groups and CROs may not need full access to the system to complete their activities. If you have team members who are just completing oversight of their section in the TMF, give them reader access. If you have data managers who need to upload and enter metadata for their documents, give them editor access. What you don't want are too many administrators in your TMF. Administrator access only should be granted to your system owner, and whoever provides reports to your leadership. If you need to designate a team of administrators, you must have alignment on who owns which tasks, and monitor your audit trails accordingly.

Keep close track of each user's access and training. What type of access do they have? When did their access start and end? Know the access rights the eTMF can provide in the event of a regulatory inspection and establish an access timeframe. For example, Trial Interactive sets system access for inspectors to 14 days.

Make sure your site contact list is accurate.

Keep in mind that a site contact list isn't just the principal investigator and study coordinator; it includes anyone associated with your site, and anyone listed on the delegation of authority log. Make sure you know what information you still need for each site contact if you don't already have it. When sub-investigators or study coordinators leave or come into your study, make sure you update your list, and indicate when they started and ended on the study as well.

Thoroughly review your TMF process documents.

Are all of your SOPs current? Which SOPs need revision? If you are moving from a paper TMF to an eTMF, do your SOPs cover both environments? Can all of your documents live in the same platform? Answering these questions will help you identify any gaps in your SOPs and address them during your document review. Check with your vendor to see if it offers services for SOP development and gap analysis.

Plan to scale in case you expand your studies.

Perhaps your study is starting in just a few countries, but you have plans to eventually carry out the study in five more. What are those additional countries? What are the languages?

Let your team know that this is a possibility up front. When your study's documents come in, whoever reviews them will know to capture a translation/back translation, other required documents, and a certificate of translation. This is valuable information to have ahead of time and will help your document review process run more efficiently.

Establish an inspection readiness strategy at implementation.

Your TMF team should understand an inspection-ready TMF must start from setup and what the value and importance of the eTMF is in inspection readiness. Ensure you set some cadence for regular TMF reviews and updates, and know how to leverage eTMF reports and metrics for oversight and to ensure completeness, quality, and timeliness.

Although this checklist is not completely exhaustive, you'll be on your way to a successful eTMF implementation by ensuring you consider the above questions and considerations before getting started.