TRIAL INTERACTIVE

TMF SERVICES
BUYERS GUIDE

Ensuring the integrity of your TMF is critical, and placing that responsibility into the hands of a third party is no small decision. Study teams are faced with myriad competing priorities throughout the lifecycle of a study and so often find it necessary to supplement resources and expertise to manage TMF processes. A vendor partner's purpose is to reduce strain on your team, enable you to scale as needed, maintain and expedite timelines, and mitigate risk. If you're looking for TMF services support but don't know where to start, the considerations below can help you ask the right questions and select a partner who understands your organization, supports your goals and objectives, and assists in maintaining constant TMF inspection readiness.

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CHECKLIST

1 ☐ **Develop a business case.**

2 ☐ **Consider your portfolio of studies.**

3 ☐ **Determine locations for document processing.**

4 ☐ **Review your current TMF standard operating procedures (SOPs).**

5 ☐ **Verify expertise with a focus on quality and inspection readiness.**

6 ☐ **Assess your in-house resources.**

7 ☐ **Check in with your CRO.**

8 ☐ **Request a proposal and perform due diligence.**

9 ☐ **Think ahead.**

☐ **Develop a business case.**

Before you begin your search for a TMF services vendor, answer this question: Why do you need to consider outsourcing your TMF services? Take the time to define your business needs, your primary objectives, and how working with a TMF services vendor can help you meet them. Once your current business needs, goals, and deliverables are established, answering the additional questions below can help you better define your business case for a vendor.

Are you outsourcing to reduce internal team costs associated with headcount, such as office facilities, IT, recruitment, human resources, and payroll? Regardless of internal costs, considering stakeholder demands without the overhead is important, as innovative studies and important study activities still need to be conducted and completed. The outsourcing model is an attractive option for companies looking for ways to cut internal costs without sacrificing study quality or timelines.

How quickly do you need to scale? Companies with large global studies produce thousands of TMF documents that must be entered into the eTMF in a timely manner. This process involves efficient, validated workflows that third-party vendors should already have in place. Working with a qualified vendor will alleviate the operational burden of scaling up rapidly to meet timelines.

Which elements require outsourcing? Processing can include paper document scanning, indexing of electronic documents into your eTMF, and quality control (QC) workflows. If you have decided to outsource your entire eTMF process, consider vendors that offer fully managed services that start with eTMF implementation and validation support, include business process reviews, and offer inspection readiness support through mock inspections or pre-inspection TMF reviews.

☐ **Consider your portfolio of studies.**

It's important to take inventory of how many studies you have completed, your current studies, your studies' phases, and your studies' sizes to determine document volumes for all your studies. Vendors need this information in order to provide you with the right proposal regarding their services, including their costs.

When reviewing your portfolio of studies, noting how many vendors and contract research organizations (CROs) you work with is important. In an outsourced model, it is possible to work with multiple third parties for specialist services; however, this impacts the number of TMF contributors. When content is being submitted from many disparate places and people, it makes a contemporaneous and complete TMF harder to achieve.

Another point of consideration is whether a migration of your studies is in scope. Migration is the process of transferring paper or electronic documents and data from one computer system to another. There can be many business cases for study migrations, including the transfer of closed studies from CROs, sponsor acquisitions, mergers, and divestitures of assets. A migration must be validated and fully documented to ensure and demonstrate there has not been any loss, change, or corruption to the migrated data, and that authenticity has been maintained.

☐ **Determine locations for document processing.**

According to the General Data Protection Regulation (GDPR) law in Europe and the United Kingdom (UK), the processing location for personal data must be in the European Union (EU). Be sure to check a vendor's processing locations to ensure there is at least one in Europe. It is also important to determine if you need strategically located processing hubs to guarantee your global studies are processed consistently and in accordance with any local regulations.

☐ **Review your current TMF standard operating procedures (SOPs).**

Conducting a review of your current SOPs is vital for ensuring that they are fit for purpose and cover all aspects of your processes. If utilizing an eTMF, your TMF SOP should cover elements such as eTMF user access and audit trail review. Take this time to look at other TMF fundamentals as well, such as your TMF plan. Be sure your plan fully details TMF expectations between sponsors and any external TMF stakeholders, and also consider whether you are using the current version of the TMF Reference Model. If your selected vendor offers consulting services, it should be able to offer an objective, expert review of your current business processes and SOPs, pinpoint and eliminate inefficiencies, suggest revisions where needed, and advise on compliance with industry regulations and best practices.

☐ **Verify expertise with a focus on quality and inspection readiness.**

When selecting a vendor, be sure to confirm that it is composed of TMF experts that can focus on and prioritize your TMF management. These experts can provide services such as independent periodic quality reviews to ensure good TMF health or provision of TMF study owner resources as an extension of an internal team. These subject matter experts (SMEs) can alleviate resource risk by collaborating with your teams to assist with the burden of the day-to-day management of the TMF. TMF study owners can show you how to best utilize your eTMF, owning important aspects like eTMF user management and analysis of metrics and key performance indicators (KPIs).

For inspection readiness, choose a vendor that promotes this as a culture right from the start of any engagement and offers solutions like mock TMF audits, inspection readiness workshops, pre-inspection reviews, and full inspection support throughout any live Good Clinical Practice (GCP) inspection.

☐ **Assess your in-house resources.**

Do you have internal team members who can handle some of your TMF services needs, or do you need to outsource all your TMF activities? Regardless of your approach to outsourcing, it's important to establish one of your internal team members as the main point of contact for your TMF services vendor who can hold your vendor accountable to KPIs, service-level agreements (SLAs), budgets, and timelines.

When considering your in-house resources, it is also important to identify who will contribute documents to

your TMF. Although clinical operations will contribute many documents, consider other teams that will contribute documents as well, such as data management, pharmacovigilance, and statistics. Don't forget to also consider contributors like sites, CROs, home-based clinical research associates (CRAs), and third-party vendors.

Confirm the vendor has a workflow that makes it easy to submit documents for processing to an eTMF with features such as communication inboxes and drag-and-drop functionality. For paper, ensure your vendor has a robust chain of custody for document submissions. It is important for all TMF contributors to have proper training, so your vendor should have a training group that offers solutions like face-to-face training, webinars, bite-size functionality videos, or quick reference guides. These solutions should be complemented by document submission best practices, including standard naming conventions, to ensure thorough training.

☐ Check in with your CRO.

It's a good idea to consider whether your preferred CRO or strategic partner provides services in addition to managing your studies. Most large CROs can do both, so it may be better to pay just one price for TMF management. However, using a CRO for TMF services often means using the CRO's process developed for its own eTMF system. CRO staff are only trained on the in-house process, so they may not be familiar with other systems and processes. In addition, CROs often are not transparent with charges for TMF management. Specialist TMF vendors will break down charges, so typically there is better oversight on what you're paying for in terms of deliverables and resources. If you have your own eTMF and work with multiple CROs, a specialist services vendor is more than likely the better option for all your studies, from author to archive.

☐ Request a proposal and perform due diligence.

Selecting a TMF services vendor is no different than selecting a vendor for any other outsourcing needs. Using a template request for proposal (RFP) makes it easier to compare different responses and ask the right questions of vendors. Inquiring how long projects take to implement and finding out each vendor's scanning capacity are both important questions to include if you have a high volume of paper documents. Asking about the steps taken to QC a document, and ensuring those steps are in alignment with best practices like ALCOA principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available when needed) will help you find the right TMF services vendor for you. Qualified vendors have robust SOPs in place to document their process and train their staff consistently and regularly.

Be sure to also ask vendors for references from clients similar in size to you. Good, reputable vendors can easily provide these.

While it's a standard process to liaise with your outsourcing group for RFPs and vendor selection, be sure to include other stakeholders from IT, clinical, and quality assurance (QA) to form a well-rounded team that can collaborate to make the final selection.

☐ Think ahead.

Finally, start thinking ahead to next steps such as contracts, ensuring tasks and responsibilities are clear and all involved parties agree on service levels. Include SLAs in your contracts to hold your vendor accountable for high performance. Advise your QA group to perform a vendor audit, and insist on a robust governance structure early with your vendor to cover escalations, performance assessments that tie into service levels, and continuous improvement programs. An experienced TMF services vendor will already have a framework in place and will be able to recommend the cadence for governance meetings, content, and updates, as well as which key stakeholders to include.

While there is a lot of planning that goes into the buying process for TMF services, knowing what questions to ask can help ease the transition and better prepare you and your study for streamlined TMF management. Refer to this guide to help you focus on the most important factors to your business and business needs as you evaluate potential TMF services vendors.

For any questions or assistance with TMF services, contact us at info@trialinteractive.com.

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