

TMF MANAGEMENT VENDOR OVERSIGHT CHECKLIST

Mitigate risks and control costs when working with TMF management vendors.

Initial Vendor Assessment

Perform a qualification audit using these steps:

- SOP Review
- Compliance Review
- Review Training Records
- CV Review

The Scope of Work

This section is about contracts and agreements. Establish and set expectations upfront with the vendor. Create a timeline for what will happen from start to finish.

- Define Roles and Responsibilities
- Temporary Employees and Contractors
- Clearly Defined Billing Structure

Project Plan

Establish your communication preferences and expectations for project tasks, responsibilities, and reporting.

- Establish an SOP for Communication
- Project Tasks and Responsibilities
- Project Updates and Metrics
- Audit Project Agendas and Meeting Minutes

Performance Reviews

Determine how you will track your TMF management vendor's performance and how you will deal with any challenges along the way.

- Outgoing Performance Audits
- Root Cause / Corrective Action / Preventative Action Plan

Full-Service TMF Management

Consider a vendor that provides a full suite of connected services and technology solutions to streamline TMF management from site ID to study closeout:

- TMF Consulting
- TMF Education
- Services for the Full Clinical Life Cycle
- 360 TMF Support Services
- Site and Study Team Training
- Technology for the Full Clinical Life Cycle
- Full-Service IT Support

TMF Review (Post-Hire)

After selection of a vendor, it is important to maintain a process for continual review. This review is about establishing what the vendor will allow you to see and what type of system access you will have during the process.

- Ensure Ongoing Sponsor Oversight
- Documentation
- Inspection Support
- Project Milestone Dates and Documents

Vendor Stability (Post-Hire)

Change introduces risks and creates challenges. Vendor changes can have a ripple effect on the speed and quality of customer support and services. Stay informed if your vendor announces:

- Personnel Attrition or Layoffs
- Leadership and/or Staff Changes
- Maturity of Services
- Acquisition or Merger

Initial Vendor Assessment

Perform a qualification audit using the steps below.

- A. **SOP Review** — Check your vendor's processes, especially as they relate to the essential tasks they will perform on your behalf. This is critical for TMF management. Processes must be solid and validated. The specifics of documented processes provide you with a measurable means of holding your vendor accountable.
- B. **Compliance Review** — All tasks essential to your success should be documented as measurable KPIs that determine compliance with SOPs. Measuring compliance is essential. Establish a review of key metrics like turnaround time and quality checks to allow you to see the work.
- C. **Review Training Records** — Request information on training. Training records reduce risk while showing the team's experience. What are the training expectations for the vendor? Are the teams assigned compliant training? Are they following protocol?
- D. **CV Review** — Verify the experience history and background of the staff.

Scope of Work

This section is about contracts and agreements. Establish and set expectations upfront with the vendor. Create a timeline for what will happen from start to finish.

- A. **Define Roles and Responsibilities** — Establish ownership and accountability early in the process. This allows you to understand and assess the effectiveness of the team later in the process. Who is doing what? Who is responsible for what?
- B. **Temporary Employees and Contractors** — Establish whether or not the team is internal or outsourced and if outsourced, that contracted workers have an acceptable level of experience working both in the field and with the vendor. What is the status of their employees? What percentage of their workers are temporary or contractors vs. hires? If there are a high percentage of temporary workers/contractors, do they have resumes or training records?

- C. **Clearly Defined Billing Structure** — Establish the billing breakdown to be able to hold the vendor accountable. What is the structure of payment? Is the project billed by itemization or by milestone?

Project Plans

Establish your communication preferences and expectations for project tasks, responsibilities, and reporting.

- A. **Establish an SOP for Communication** — Establish an escalation plan. How often will you meet with the vendor? How often will there be governance meetings? What are the pathways of communication when things go wrong? Are there protocols for providing positive and negative feedback? It is important to provide both positive feedback to establish what is working and negative feedback to establish what needs improvement. Have an open agenda item to discuss any ongoing concerns and issues. Ensure that you follow up with any lessons learned to ensure that future projects are defined.
- B. **Project Tasks and Responsibilities** — Create a RACI chart (Responsible, Accountable, Consulted, and Informed). Break down the individual tasks and responsibilities and establish specifically who is responsible for what. Create a means for project delegation – what are the details of the specific project tasks?
- C. **Project Updates and Metrics** — Establish a cadence and key metrics to review at specified points in the project. This is especially important at the beginning of the project. This holds both parties accountable to the established expectations and shows how you can adjust expectations and needs going forward. It can also show you red flags and pressure points if vendors are not meeting initial promises or deadlines.
- D. **Audit Project Agendas and Meeting Minutes** — Maintain comprehensive documentation of meetings and minutes. Monitor the consistency and rate of when meetings are taking place. The key is open communication with the vendor.

Performance Reviews

Determine how you will track your TMF management vendor's performance and how you will deal with any challenges along the way.

- A. **Outgoing Performance Audits — Spot check.** Conduct remote or on-site sponsor-run audits to verify how the vendor is completing the project. It isn't always about if the work is getting done, but how it is getting done and whether or not it is the way you have agreed/established.
- B. **Root Cause / Corrective Action / Preventative Action Plan —** Determine ahead of time how you will deal with any challenges along the way, particularly if corrective action is required. It is important to prevent any potential problems, but should they occur, your CAPA (Corrective and Preventive Action) is mission critical. Do you have a defined plan? Is your vendor in charge of the plans? Is the vendor working to develop improvements for their systems and processes? How are you holding the vendor accountable?

Full-Service TMF Management

Consider a vendor who provides technology and services from site ID to study closeout to streamline TMF management:

- A. **TMF Consulting —** Support for your TMF health is mission critical. Does your vendor have best-practice TMF consulting services? Consider if your vendor provides TMF analysis, evaluation and recommendation for improvements. Determine if they offer: best practice workshops, inspection readiness workshops, process development and review, SOP creation and review, TMF Reference Model implementation, TMF plan creation, metrics development, and more.
- B. **TMF Education —** What resources does your vendor offer to train and certify your team on TMF best practices? Do they offer corporate training and education programs to bridge TMF knowledge gaps? Do they provide instructor-led courses on TMF management with professional certification and credentials?

- C. **Services for the Full Clinical Life Cycle —** Determine if your vendor provides dedicated support for TMF Services, validation, implementation, medical writing, and more. Consider the continuity of their support and whether they have a 24/7, global, multilingual help desk.
- D. **360 TMF Support Services —** How will your vendor alleviate the burden of TMF maintenance? Determine if they provide TMF services such as paper scanning, document transfer, quality review and completeness analysis, TMF migrations, document processing in any system, TMF audits, secure archiving, and more.
- E. **Site and Study Team Training —** Do your vendors help mitigate regulatory compliance risks by training personnel in SOPs & protocols? Consider the training resources and modules that your vendor provides and whether they support the full life cycle.
- F. **Technology for the Full Clinical Life Cycle —** Worried about content and data spread across different systems? A seamlessly connected technology platform simplifies and automates clinical processes for sponsors, CROs, and sites around the world.
- G. **Full-Service IT Support —** How does your vendor reduce IT burdens from implementation to your fully deployed production system? Consider whether your vendor outsources their IT support to various partners, or if they provide in-house implementation, configuration, migration, and validation.

TMF Review (Post-Hire)

After selection of a vendor, it is important to maintain a process for continual review. This review is about establishing what the vendor will allow you to see and what type of system access you will have during the process.

- A. Ensure Ongoing Sponsor Oversight — Perform co-monitoring visits when applicable. Go on-site with a CRA to verify how they work.

Documentation

- i. Plans — Ensure that all plans are approved and signed off on by a contracting company. For example: data management plan and monitoring plan.
 - ii. Monitoring Visit Reports — Are you reviewing these reports and are you aware of the trends that are being established? What is the process for how they are performed?
 - iii. Audit Reports — Sponsor oversight is one of the biggest inspection findings. Are you being provided audit summaries and final audit reports for what the vendor is doing for QC? What access did the vendor give you? How are you performing your quality review?
- B. Inspection Support — Are your vendors helping you establish a culture of inspection readiness? Do they offer support for mock inspections? Are they providing best practice TMF workshops?

Project Milestone Dates and Documents —

- Are you aware of the vendor's expected document list? All versions of documents? Do you have a procedural understanding of your TMF? It is important to know the answer to these questions as they are the most common questions from auditors to sponsors.
- i. How is the TMF managed?
 - ii. How is the TMF organized?
 - iii. What is the story of the TMF?
 - iv. What is the story of each document?
For example: revisions, corresponding documentation, and business justification on filing.

Vendor Stability (Post-Hire)

Change introduces risks and creates challenges. Any of the following vendor changes can have a ripple effect on the speed and quality of customer support and services.

- A. Personnel Attrition or Layoffs — Any event that affects company staffing impacts the resourcing of your projects. Staff changes due to mergers, acquisitions, financial issues, or negative corporate culture create instability, knowledge transfer issues, and broken workstreams. It's important to pay attention to staff interruptions as they introduce risk to your TMF services.
- B. Leadership and/or Staff Changes — You've put a lot of trust in your vendor's leadership. If the leaders who you expected to oversee your work leave the company or move to other roles, how can you trust the new leadership to be as focused on your projects? Changes in leadership often change up organizational priorities, and it's important to consider how it can affect your TMF management and timelines.
- C. Maturity of Services — Is your service provider truly experienced in delivering reliable TMF services? Do they have the infrastructure that scales and meets the complexity of your global studies? If your TMF vendor is new in the TMF services industry, they may lack the experience to streamline your TMF management.
- D. Acquisition or Merger — In our industry, many solutions providers ultimately merge with large corporations. When changes in ownership take place, vendors may not resemble the company that you invested in and trusted with your work. You may also experience operational disruption, quality issues, and a permanent change in the collaborative relationship with your vendor.