

How To Create and Maintain an Inspection-Ready Culture

Preparing for a regulatory inspection can be daunting – but it doesn't have to be. The best approach to reduce the stress of an inspection is to create a culture of compliance by building inspection-readiness practices into daily operations.

The truth is inspection readiness begins and ends with your TMF. Below are some tips to help you achieve an inspection-ready TMF at all times, and sustain a culture of compliance in your organization.

Gain executive buy-in and support

Leadership endorsement is essential to build and maintain an inspection-ready culture. Ongoing and consistent communication from executives is critical in making sure that everyone is aware of the benefits of incorporating inspection-readiness practices into daily operations.

Involve and get feedback from sites and study teams

Make it a practice to gather feedback from internal and external study teams. This can be done during study planning, training sessions, or pre-defined times throughout the study. Involving all stakeholders regularly in the process will increase trust, improve collaboration, and maintain high-quality documentation practices throughout the study.

Take appropriate care in creating your TMF plan

A well-developed TMF plan includes the roles and responsibilities of internal and external partners across the study, document content requirements, instructions for inspections, and the type and frequency of quality checks. It is a living document that should be reviewed and updated on a regular basis to ensure the TMF is fully leveraged to enable a constant state of inspection readiness for your organization.

An excellent TMF plan template can be downloaded from the [TMF Reference Model](#) website.

Actively manage your TMF to keep it up-to-date at all times

An active TMF operating model ensures a constant state of inspection readiness by managing all TMF documents, related information, and processes in the same system, in real-time, as they are executed.

Incorporate active TMF management practices into daily operations by submitting all TMF documents in a timely and contemporaneous manner. Apply quality control checks to ensure they are accurate and complete. Each action should be traceable and auditable for inspectors to review.

Train (and retrain) employees on how to stay compliant

Training should include regulations, the company's processes, and information about the construct of the TMF, such as how documents are to be filed, TMF user roles and responsibilities, etc. All new team members should receive this training as part of their onboarding process. Review training materials regularly, revise as needed, and retrain all current team members when changes occur.

 Leverage governance and oversight processes to ensure compliance

Good Clinical Practice (GCP) requires that the sponsor demonstrate ongoing oversight throughout the trial for studies conducted in-house and those outsourced to vendors. Clearly define your oversight activities, detail how performance will be measured, and provide evidence-based documentation within your TMF.

 Use reports and KPIs to maintain compliance

Organizations that use operational metrics and key performance indicators (KPIs) have greater visibility into TMF status than those not using metrics.¹ Establish and monitor key performance indicators to drive inspection readiness and inform proactive decision-making. Design reports to help identify issues before they become problems, and use KPIs to assess TMF timeliness, accuracy, and completeness. Checking these on a regularly scheduled basis will enable your organization to identify and resolve TMF issues proactively, before an inspection occurs.

 Conduct regular QA audits and/or “mock inspections” periodically

Just as a “fire drill” helps everyone in a building prepare for an emergency, conducting internal audits and mock inspections ensures your organization is ready for an inspection. Leverage these activities to identify areas where processes and/or performance can be enhanced or improved.

 Plan for change

Be prepared to modify your TMF and TMF plan to accommodate any necessary regulatory changes in a timely manner. It is better to incorporate changes when needed rather than risk citation for failure to comply during an inspection.

“An ounce of prevention is worth a pound of cure.” -Benjamin Franklin

¹ Veeva 2018 Unified Clinical Operations Survey