



## Scale your team, leverage TMF experts, reduce risks, and stay inspection-ready with a full-partner, functional service provider for all things TMF.

Manage your studies with the help of TMF experts who can assume responsibility for all components of TMF strategy and implementation to ensure completeness, quality, and timeliness. Our lead TMF consultants share nearly 100 years of collective TMF experience, industry experience, and know-how.

Whether you're moving from paper to eTMF or supporting your current eTMF, TMF Managed Services cover all needs across people, process, product, and performance. TransPerfect's global presence allows you to connect with TMF professionals in your region for accessible, responsive support. With so much at stake for quality and compliance within your TMF, you can gain an additional layer of assurance with an independent quality team dedicated exclusively to supporting TMF audit and inspection readiness.

### Solutions Highlights:

- ✔ TMF Process Development & Improvement
- ✔ TMF Processing (System Agnostic)
- ✔ TMF Study Owners
- ✔ Quality Review & Completeness Analysis
- ✔ TMF Inspection & Audit Support
- ✔ TMF Migrations & Transfers



## Pillars of TMF Success

### PEOPLE

- Experienced subject matter experts providing best practice and inspection readiness workshops
- Hands-on regulatory inspection experience
- Trained, qualified, and certified team of global document specialists for scanning, indexing, and QC
- Qualified eTMF auditor leading TMF reviews
- Service design approved by Lean Six Sigma Black Belt process specialist

### PRODUCT

- Superior metadata capabilities to capture granular detail
- Quality Review Module in TI with no extra cost
- Support the latest version of the TMF Reference Model
- Document languages captured for essential documents
- Translation capabilities for UI, document content, and full suite of modules for author-to-archive solutions
- Training documentation

### PROCESS

- Lean Six Sigma-based document workflow process management
- Risk-based, percentage/essential document QC
- Pre-indexing: machine learning auto-coding of documents through metadata extraction
- Independent eTMF pre-inspection and periodic review
- Tried and tested migration process for full program support
- Regulatory compliant archiving

### PERFORMANCE

- Custom dashboard report formats
- Reports and metrics for established KPIs
- Quality review reports with summarized analysis
- Storyboard creation and maintenance
- 24/7 service desk premium support and dedicated account team

Industry-Leading  
Language  
Services

TMF  
Reference Model  
Committee

FDA, EMA,  
MHRA, PMDA,  
GCP Inspection  
Experience

Expansive  
Global  
Footprint

## Feature Descriptions



### Process Development & Improvement

When your team is in need of resources to drive strategy, our TMF experts are here for you to establish your SOPs, TMF plan, and TMF-related work instructions. Facing legacy or overly complex processes? We can allocate our SMEs to review your current state and advise you through the development of an inspection-ready TMF strategy.



### TMF Processing

Teams with proactive TMF strategies are rapidly moving to the combination of centralized documentation (eTMF) and centralized processing for efficiency and risk reduction. A system-agnostic, centralized TMF processing model allows increased efficiency and consistent processes, regardless of CRO, country, phase, or therapeutic area. Our team of TMF experts and document specialists will ensure your quality, timeliness, and completeness.



### TMF Study Owners

Teams are challenged by competing priorities to keep the TMF a primary focus throughout the life of a trial. As such, study events get missed, study milestones aren't considered in TMF health, and, ultimately, the quality of the TMF becomes an unknown and is not properly controlled for risk mitigation. A dedicated TMF study owner makes it possible to maintain the TMF as a top priority. The study owner ensures the TMF plan is implemented and executed so TMF documentation is timely, quality-assured, and complete.



### Quality Review & Completeness Analysis

At TransPerfect, we have an independent internal quality team that is dedicated to TMF reviews, TMF health assessments, and TMF completeness. This team is leveraged across several use cases: when customers want to lean on us, to independently assess and perform TMF oversight, or during mergers and acquisitions in which companies inherit TMFs from companies they've acquired.



### TMF Inspection Support

Preparing for an inspection is often a strain on teams, as it can be time-and resource-consuming. Often, teams find it helpful to have support that not only lends resources but also lends guidance to the preparation process. A team of experts with experience navigating inspections all over the world is available upon request to help you confidently prepare for inspection.



### TMF Migrations & Transfers

Lastly, on the technical side of the house, our team performs TMF migrations to and from eTMFs in scenarios like CRO changes, system changes, or M&A, where the TMF has to move from system A to system B.

# Where Are You in Your TMF Journey?

