# TI eTMF: Enabling Trial Collaboration and Archival in the Cloud

The eTMF platform for over 3,500 ongoing studies, processing millions of documents

Trial Interactive (TI) has been designed by clinical professionals, for clinical professionals to support studies on a global scale. TI specializes in the nuances of clinical and eTMF document management, simplifying tasks while keeping the TMF accurate and in regulatory compliance. An extremely flexible and practical solution, TI is consistently noted by clinical professionals for providing the most comprehensive yet intuitive features and workflows.

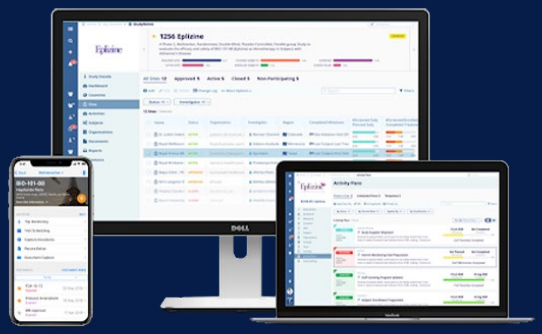
As a secure, cloud-based solution, TI enables real-time collaboration for both sponsors and CROs. Set up your eTMF in a matter of weeks, allowing access to study personnel and partners. Provide study stakeholders an easy-to-use experience with the benefits of transparency and visibility into your clinical study.

## A few of TI eTMF's practical highlights:

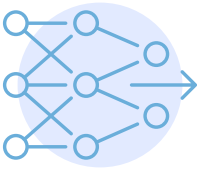
- A single access point for eTMF documentation
- Real-time eTMF Completeness view and Milestones
- Support for essential TMF workflows: document import and coding, quality review, audit and inspection, document certification, and the capture of clinical trial documentation
- A user-friendly interface supporting major browsers
- A mobile app available for phones and tablets
- A configurable document management solution for clinical, quality, and regulatory documentation
- Auto-coding and auto-naming functionality

## Other TI highlights for the compliance-focused enterprise:

- A fully hosted solution that is 21 CFR Part 11, ERES, GxP, and GDPR compliant
- Alignment with the TMF reference model
- Additional TMF support with comprehensive TransPerfect Life Sciences TMF services (paper and digital) with flexible staff augmentation
- Support for global studies with worldwide services for coding, audits, accessibility and translation



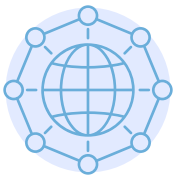
**2023 WINNER**
**Best Technology For Sponsors**
2023 Citeline Awards



Streamline Compliance with Automation

Set Up Your eTMF in a Matter Of Weeks

Improve TMF Efficiency and Collaboration



Manage Your eTMF Anytime, Anywhere

Achieve Inspection Readiness

Reduce Timelines and Increase Transparency

## FEATURES OVERVIEW

- ✓ Fast and Flexible eTMF Implementation
- ✓ Standard and Configurable TMF Reference Model Support
- ✓ Simplified Auto-Coding and Auto-Naming
- ✓ Milestone and Task Management
- ✓ CRA Mobile App (myTI)
- ✓ Corporate Directory Integration with Single Sign-On
- ✓ Out-of-the-Box CTMS Integration
- ✓ IRB Integration and Submission Support
- ✓ TMF Health Dashboard
- ✓ Ad-Hoc and Standard Reporting
- ✓ Integrated, Fully-Collaborative Document
- ✓ Active Alerts and Notifications
- ✓ FAQ and Knowledge Center
- ✓ Multilingual Translation Services
- ✓ Comprehensive TMF Services (Paper and Digital) with Flexible Staff Augmentation
- ✓ Adaptable QC Process
- ✓ Built on a Scalable, Proven Platform
- ✓ Flexible Rules and Placeholders for Required Documents by Country, Site
- ✓ Preconfigured Migration, Scanning, Certification, and Upload Processes
- ✓ 24/7 Help Desk (Email or Phone Support)
- ✓ 21 CFR Part 11, Annex 11, ERES, GxP, and GDPR Compliant
- ✓ Comprehensive Audit Trail
- ✓ Supports Dedicated and Multi-Tenant Hosting
- ✓ Email Correspondence and File Input
- ✓ Comprehensive Validation Package

# FEATURE DETAILS

## Fast and Flexible eTMF Implementation

TI is designed as a plug-and-play product. Preconfigured to the current TMF reference model and equipped with single sign-on, it is quick and pain free to implement and onboard users. Get up and running within two weeks.

## Standard and Configurable TMF Reference Model Support

TransPerfect Life Sciences is a member of the TMF Reference Model Committee and has baked that knowledge into the TI eTMF. We always know what the latest updates are to the Reference Model and keep the eTMF aligned with the most current standards. With our expert knowledge of the Reference Model, our TMF quality team can also help to configure your eTMF to custom structure requirements or train your team on how to configure on your own.

## Simplified Auto-Coding and Auto-Naming

Using Machine Learning Near Document Duplication, TI eTMF OCRs and analyzes metadata to automatically classify documents. Drag and drop documents from your desktop to assign to placeholders or required documents, and see them auto-code to that folder or artifact. Quickly apply or correct metadata fields and check the index to ensure the documents published are compliant.

## Milestone and Task Management

TI eTMF can be configured with events on your study timeline such as investigator meetings, site visits, study amendments, last subject visits, database locks, etc. Additionally, configure the associated documents for each milestone and you can quickly view right from the dashboard and assure eTMF completeness for each milestone. Tasks can be created and tracked to help your team manage TMF activity and deliverables. Get quick views from the dashboard by completion status, rejected vs. actual, team member, priority, and more. Pull milestones from your CTMS and automatically be up to date for all required documents in your eTMF. Measure eTMF health based on milestones.

## CRA Mobile App (myTI)

The myTI application is a mobile experience for the TI eTMF that ensures study teams have constant access to important eTMF processes. This accessibility saves CRAs, sites, and sponsor companies time in scanning, uploading, and publishing documents live to the eTMF. Further, CRAs can use myTI to reconcile the eTMF against the reg binder at the site.

With myTI, CRAs can quickly and securely capture, index, and publish documents to the eTMF, directly from their phone or tablet devices. CRAs can log in via Touch ID and safely capture documents with their device camera, without storing images on the device itself. Once an image is captured, CRAs can easily apply metadata, upload, and publish directly to the eTMF. Further, CRAs can use myTI to reconcile the eTMF against the reg binder at the site. myTI provides constant access to document queries and site statuses so study teams can experience key advantages of an eTMF anytime, anywhere.

## Corporate Directory Integration with Single Sign-On

Corporate directory integration makes it easy to onboard TI users. Single sign-on means study teams do not have to manage multiple passwords (one of the many reasons why the TI eTMF is quick to implement and users are able to quickly get started). Once a user has access to the TI platform, they can access any of the applications and modules.

This approach is aligned with the Framework for the Destruction of Paper and is 21 CFR Part 11 compliant.

## Out-of-the-Box CTMS Integration

Integrations with CTMS platforms like Medidata, SimpleCTMS, and BioClinica come ready to go with TI. Ensured continuity and connectedness in your systems enables streamlined management of your study.

## IRB Integration and Submission Support

Save time submitting documentation to IRBs with direct, secure integration to centralized IRBs such as Advarra (formerly Chesapeake and Schulman) and the Copernicus Group. Once documents are submitted during site activation, they go directly to the IRB review system and wait for the review board response.

## TMF Health Dashboard

Analysis of the completeness and overall health of your TMF is easy with visual "dashlets" that provide focused, intuitive views. This allows you to proactively manage the TMF health by clearly seeing where documents are missing or documents in progress that need to be completed and approved. Simplified oversight greatly reduces compliance risks and accelerates document processing.

TI eTMF facilitates gap analysis and CRA reconciliation at any point of the study with visual reporting and our robust audit module.

## Ad-Hoc and Standard Reporting

Reporting is made easy with standardized reporting views and the ability to run ad-hoc reports on your TMF to look at data that best suits your analysis. When CRAs make ongoing updates, reporting is updated so views are always current.

## Integrated, Fully Collaborative Document

Management and Authoring Only the appropriate study team members can author TMF documentation in the eTMF. Configurable permissions ensure your document authoring is controlled and there is no risk of confusion or inefficiency. Flexible workflows may be configured and enforced to take a document from a placeholder to a template through the authoring process and to final publish to the eTMF.

## Active Alerts and Notifications

Study teams work faster with alerts and notifications that ensure necessary next steps are in focus. CRAs, sponsors, and sites are alerted about events like documents uploaded to the TMF, documents needing approval, and more—to stay on top of the document work streams and maintain a complete and quality TMF.

## FAQ and Knowledge Center

A comprehensive FAQ provides helpful information for day-to-day operations like vendor contacts and document-specific details. A Q&A feature allows you to send requests to subject-matter experts, and responses can be added to your general knowledge base for future reference to help other team members. Context-sensitive online help, quick reference training videos, and job aids are available to easily guide users through the TI eTMF experience.

## Multilingual Translation Services

Study teams benefit from TransPerfect's leading translation services and capabilities, as well as global locations around the world. As the world's largest translations company, we are able to support clinical trials that include considerations for multiple languages.

## Comprehensive TMF Services (Paper and Digital) with Flexible Staff Augmentation

The TransPerfect Life Sciences TMF quality team has a full suite of services to help study teams prevent inspection findings with compliant documentation. TransPerfect Life Sciences has a 25-year history of clinical services and is an influencer of the TMF Reference Model. Combined with our global capabilities, our TMF services are uniquely designed to help your study teams scale to emerging needs.

## Adaptable QC Process

The Audit Module allows auditors to perform quality and timely audits throughout the study and keep the TMF healthy. TI eTMF provides configurable selection criteria for published documents to be included into the audit pool.

When performing an audit, the auditor performs tasks such as cross-checking the metadata with each document, checking for absence of PHI, ensuring that the document is filed under the appropriate folder, etc. If issues arise, the auditor can route the document along with the findings to be resolved by an audit responder.

If no issues are found, the auditor approves the document (with or without comments). Audit reports include all the audited documents along with any findings/issues and resolutions.

## Built on a Scalable, Proven Platform

TI has powered tens of thousands of studies, publishing millions of documents over our 15 year lifespan. With global hosting and availability, the system is built to scale for both storage capacity and number of users, so there are never any limitations to the size of your study team, or quantity of documents or data that can be uploaded to the system. TI will not slow down due to concurrent users, number of documents uploaded, or other system activity. You can run your study without concern for your activity impacting the system.

## Flexible Rules and Placeholders for Required Documents by Country, Site

TI eTMF is designed so that clinical teams can custom fit the experience to their requirements and was built to handle many standards, including but not limited to the DIA TMF Reference Model. Configure rules for your document processes to ensure compliance to your standards, and set up document placeholders for all of your required documents so you can easily determine the completeness of your TMF. Once a site milestone is reached, for example, new required document rules are activated and placeholders are created throughout the eTMF, triggering document alerts to study, sponsor, and site personnel.

## Preconfigured Migration, Scanning, Certification, and Upload Processes

Moving documents and data into (or out of) your eTMF is painless with preconfigured processes. Flexible staffing augmentation and support for scanning, certifying, and publishing documents by TransPerfect can allow your study team to focus on what's important: managing the trial.

## 24/7 Help Desk (Email or Phone Support)

TransPerfect's global presence enables us to provide responsive support on a 24-hour basis with a full-time service desk and network operations center. TransPerfect supplies a world-class SLA to our customers for both response time and uptime.

## 21 CFR Part 11, Annex 11, ERES, GxP, and GDPR Compliant

TI maintains compliance with all current and emerging regulations critical to clinical operations. We are a privacy-by-design platform with established best practices and SOPs by which all personnel are trained and held accountable. TI is 21 CFR Part 11, Annex 11, ERES, GxP, GDPR, and HIPAA compliant, ensuring that your TMF documents are hosted within regulatory standards. A powerful and flexible native eSignature solution is supported alongside best-of-breed solutions such as DocuSign and AdobeSign.

## Comprehensive Audit Trail

All activity and e-signature data in the eTMF is logged and preserved in a 21 CFR Part 11, Annex 11, and ERES compliant fashion for an accurate and detailed history of the changes and updates made to eTMF documentation and data.

## Supports Dedicated and Multi-Tenant Hosting

Trial Interactive is hosted worldwide in multiple global hosting locations including Europe and the US. TI can be hosted in two different ways depending on your organizational needs. Multi-tenant hosting supports a single application layer across all studies, always ensures you have the latest version of the software, and guarantees your study is always in a validated state. Dedicated hosting gives you control of when you upgrade and provides for a more flexible, integrated solution that is fashioned to your specific IT needs.

## Email Correspondence and File Input

TI eTMF has email inboxes to capture all email correspondence for each study. Once a correspondence email is sent in, it is rendered to PDF and may be selected for inclusion in a separate interface by study staff. Attachments are checked for duplicates and are linked back to the original email.

## Comprehensive Validation Package

TI has been fully tested internally according to our own software development life cycle (SDLC) procedures. We conduct a formal QA verification and documentation process before the product releases. We recommend performing validation in accordance with FDA guidance and/or GAMP 5 guidance for configurable, off-the-shelf applications.*

TransPerfect offers an optional TI validation package to streamline the validation activities required by customers prior to going live, as required by the FDA. Incorporating the TI validation package into your Trial Interactive validation activities allows for a rapid validation for the initial deployment and minimized validation activities associated with future enhancements and configuration changes.

**Please note that TI has already been validated in all of our FDA-regulated life sciences customers.*


"Our search for an eTMF solution required that we find a product that met DIA requirements and was designed and backed by people who truly understand the world of clinical trials. The claims made by the Trial Interactive team during our evaluation process were proven overwhelmingly true; it's easy to use, provides us with significant insight into TMF completeness, and reporting on key data is simple and comprehensive. Trial Interactive has without question improved ARCA's ability to complete trials in the most efficient manner possible."

*Eric Negrey, Senior Director of IT and Facilities at ARCA Biopharma*

# The eClinical Platform for Global Product Development

## STREAMLINE SITE ACTIVATION AND CLINICAL MANAGEMENT LIFE CYCLES. ACCELERATE TIMELINES FROM SITE ID TO CLOSEOUT.

- Flexible and Configurable to Requirements
- Expedites Site Activation and Document Work Streams
- Comprehensive, Easy-to-Use Workflows, Mobile eTMF
- Fast Implementation and User Onboarding / Adoption
- 21 CFR Part 11, Annex 11, ERES, GxP, and GDPR Compliant

### TI eTMF

A practical, secure, compliant, single access point for TMF documentation, supporting all essential document processes and reducing time, costs, and risks of TMF management.

### myTI

Enable site document capture and key eClinical workstreams anytime, anywhere with a mobile eTMF. Save CRAs weeks of time processing documents.

### CTMS

Get important actions and information at your fingertips with a single source of truth for you clinical operations. TI CTMS provides mobile-first trial management for planning and tracking, with specific attention to monitoring requirements.

### Study Start-Up

Accelerate site activation by simplifying the collection, completion, and finalization of critical regulatory documentation necessary for approval to bring a site online.

### GlobalLearn

Train site personnel and study teams, orchestrate virtual investigator meetings, and ensure SOP compliance to reduce risks and increase team efficiency with a compliance-focused learning management system.

### eFeasibility

Speed site selection with a configurable survey module to contact, assess, and prequalify sites. Screen sites for inclusion and save surveys and collected data for future use.

### Site Portal & eISF

Reduce administration and improve speed and compliance for site personnel and study teams with an investigator site solution that facilitates digital investigative site binder processes.

### Collaborate

Collaborate on clinical and R&D documentation with shared workspaces for sponsors, CROs, and sites. Enforce project workflows to build and finalize study documentation such as TMF and eISF with remote monitoring and mobile document processes.

### Quality Management

Handle your SOPs, CAPAs, and deviations, as well as clinical trial and R&D documentation, with an EDMS focused on quality and R&D document workflows.

### Safety

Simplify safety letter communication between sponsor, CRO, countries, and sites with a shared investigator site and safety team solution. Enforce safety reporting deadlines with a database of regulatory requirements.

## TRIAL INTERACTIVE

TransPerfect's Trial Interactive solution provides a collaborative, web-based platform for study start-up and eTMF that enables sponsors, CROs, IRBs, central laboratories, and other vendors to maintain and update clinical trial documentation in a secure online environment. Trial Interactive streamlines study timelines and reduces the administrative burdens of global clinical trials.

As part of TransPerfect's Life Sciences division, Trial Interactive is dedicated to working collaboratively with clients on a global scale, supporting the clinical trial life cycle with platform offerings including investigator database, e-feasibility, study start-up, eTMF and TMF management services, mobile eTMF, clinical document management and collaboration, compliance-focused learning management, pharmacovigilance and safety management, endpoint adjudication, and product licensing and alliance management.

For more information, please contact **info@trialinteractive.com** or **+1 212.400.8848**, or visit **www.trialinteractive.com**.

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