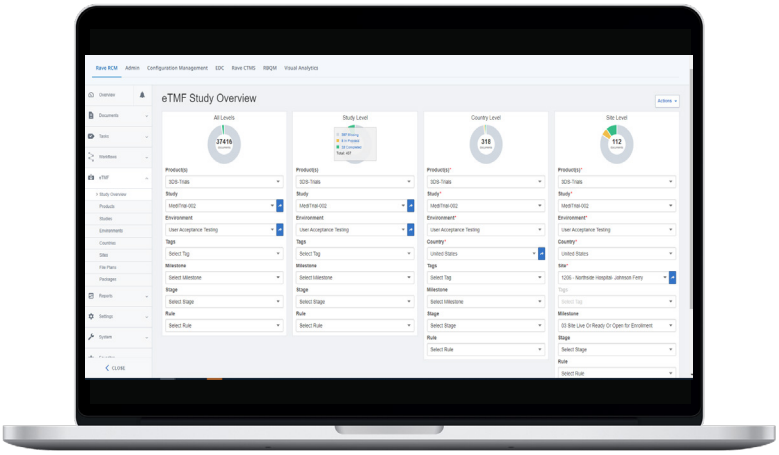
# Medidata eTMF: Simplify Trial Oversight with Unified Document Management




A robust and reliable electronic trial master file (eTMF) must be constantly inspection-ready, with accessible metrics for monitoring, that enables collaboration between sponsor, CRO, and site systems. Medidata eTMF is a global, secure collaboration platform that seamlessly manages trial master file content so it is always contemporaneous with the study. Medidata eTMF supports a risk-based QC review approach and streamlines content creation and management by automatically populating content created and updated in other applications reducing manual filing efforts providing a single source of truth. Time to create documents and the time for data reconciliation between the site file and trial master file is reduced. Medidata eTMF supports live study migrations and long term eTMF study archiving. Deployed with minimal IT involvement with implementations as short as 6 weeks for study go live all backed by superior managed services, Medidata eTMF is a perfect solution to your electronic trial master file needs.

- **Integrated with the Medidata Platform**
- **Support for complex or simple studies**
- **Quickly migrate your TMF data**
- **Fast go-live time**
- **Leverage superior managed services**
- **No hidden change fees**

# eTMF Benefits

### Reduced Complexity and Operational Efficiency

- End-to-end TMF management solution, unifying content, data, and workflows
- Simplified filing process by automatically combining content and data across the study lifecycle
- Increased error proofing and standardization via auto filing and auto naming of content

### Real-time Oversight

- Built on the Medidata Platform, content is auto-populated from Rave EDC and Medidata CTMS so your TMF is always complete
- Embedded features and functionality that provides contemporaneous metrics around quality, timeliness, and completeness

### Enhanced Site and Stakeholder Collaboration

- Tailored experience for site users to allow upload and retrieval of content
- Platform-driven permissions and role-based workflows
- Simple drag-and-drop navigation means any user can contribute regardless of familiarity with TMF structure

### Automated Document Workflows

- Tight collaboration with existing document and data workflows for Rave EDC and Medidata CTMS
- Data for study startup regarding site qualification and initiation is automatically populated in CTMS and filed to eTMF

# eTMF Features

- Advanced and robust search algorithms based on content, title, or metadata.
- Out-of-the box reports and a deployable TMF reference model is included.
- Simplified master data management to streamline study and master data setup, document filing, and reclassification.
- Flexible by design to integrate with existing systems, with bulk upload and extraction capabilities.
- Comprehensive dashboards and reports that allow you to maintain a constant state of inspection readiness.
- Powerful and flexible QC review capabilities.

# Medidata eTMF is Fast and Scalable

Organizations using Medidata eTMF have seen significant efficiencies:

**1,000s**
**OF DOCUMENTS UPLOADED PER DAY**

**6 Weeks**
**FOR THE TRIAL TO BE CONFIGURED**

# The Medidata Advantage

By taking a unified content and data management approach with Medidata eTMF, your clinical operations team can minimize risk and accelerate trial timelines surrounding the management of key artifacts. The Medidata Platform enables a single source of truth for all study-related data across your entire portfolio. The power of the platform allows you to accurately unify content, data, and workflows from study planning to study close when using Medidata EDC, CTMS, and eTMF.

Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences.
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