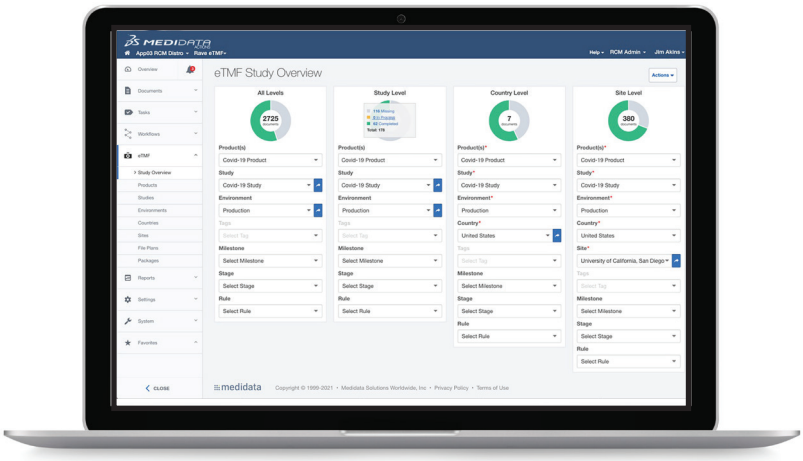
Rave eTMF - Simplify Trial Oversight with Unified Document Management



Your Trial Master File (TMF) complexity is growing. It's not uncommon to upload thousands of documents per day, subject to strict regulatory requirements for filing, and under aggressive timelines. It is paramount that a robust and reliable electronic TMF (eTMF) is constantly inspection-ready, provides accessible metrics for monitoring, and favors collaboration between sponsor, CRO, and site systems.

Rave eTMF is a global, secure collaboration platform to seamlessly manage Trial Master File content so it is always contemporaneous with the study. Rave eTMF streamlines content creation and management by automatically populating content created and updated in other applications. This reduces manual filing efforts and provides a single source of truth resulting in significant efficiencies for teams, including reductions in time to create documents and time for data reconciliation between the site file and trial master file. Rave eTMF is also easily deployed with minimal IT involvement, with an implementation timeline as short as 8 weeks.

Rave 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 Clinical Cloud™, content is auto-populated from Rave EDC and Rave 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

- Site landing page for easy 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 CTMS
- Data for study startup regarding site qualification and initiation is automatically populated in CTMS and filed to eTMF
- Documents required for regulatory submissions that are tracked in CTMS are automatically tagged in eTMF

Rave eTMF Features

Advanced and robust search algorithms based on content, title, or metadata.

Simplified master data management to streamline study and master data setup, document filing, and reclassification.

Comprehensive dashboards and reports that allow you to maintain a constant state of inspection readiness.

Out-of-the box deployable DIA reference model is included.

Flexible by design to integrate with existing systems, with bulk upload and extraction capabilities.

Rave eTMF is Fast and Scalable

Organizations using Rave eTMF have seen significant efficiencies:

1000s
DOCUMENTS UPLOADED PER DAY

8 Weeks
FOR TRIAL TO BE CONFIGURED

*Medidata internal data

The Medidata Advantage

By taking a unified content and data management approach with Rave eTMF, your clinical operations team can minimize risk and accelerate trial timelines surrounding the management of key artifacts. The Medidata Clinical Cloud 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 Rave EDC, CTMS, and eTMF.