Captivate® eTMF

Connected,Inspection-ReadyTrial Master File Management

Captivate eTMF is a secure, standards-aligned electronic Trial Master File solution designed to help sponsors, CROs, and study teams manage essential trial documentation in a consistent, transparent, and inspection-ready manner. Built to integrate with the broader Captivate clinical data platform, Captivate eTMF supports centralized oversight of regulatory and administrative artifacts while preserving traceability, compliance, and workflow flexibility.

Designed for real-world study operations, Captivate eTMF enables structured document organization, custom structure, automated lifecycle tracking, and controlled access helping teams reduce administrative burden, improve oversight, and support audits and inspections with confidence.

Structured Document Organization Across the Study

Captivate eTMF provides a framework for organizing and storing essential regulatory and operational documents throughout the clinical lifecycle.

Standards-Aligned Filing and Indexing

Study documents are captured and indexed according to recognized industry standards to support consistency, clarity, and regulatory expectations.

Key capabilities include:

- Support for global TMF Reference Model indexing or custom taxonomy
- Consistent document metadata capture for reliable classification
- Configurable folders, categories, and subcategories aligned to study needs
- Full search and filter capabilities across documents and metadata

Structured organization ensures study content is accessible, traceable, and aligned with inspection readiness objectives.

Controlled Document Lifecycle and Versioning

Captivate eTMF tracks documents and their evolution through clear lifecycle states to maintain accountability and integrity.

Version History and Traceability

Each document stored in Captivate eTMF includes a complete history of changes, versions, and actions.

Key capabilities include:

- Automated versioning with timestamped history
- Audit trails for uploads, revisions, approvals, and access
- Clear differentiation between draft, final, and archived content
- Comprehensive version history supports compliance, reduces ambiguity, and simplifies audit responses.

Workflow Support Across Teams

Captivate eTMF supports structured processes for document creation, review, approval, and distribution while giving teams flexibility where protocols differ.

Configurable Review and Approval Paths

Study teams can define and automate document workflows that reflect their SOPs and operational cadence.

Key capabilities include:

- Configurable review and approval routing
- Alerts and reminders for pending actions
- Role-based access to review, approve, or annotate documents
- Support for collaborative review without version conflicts

These workflows help reduce bottlenecks, ensure transparency, and drive accountability across functional teams.

Security, Compliance, and Inspection Readiness

Captivate eTMF is designed to meet regulatory and privacy expectations across global trials while supporting audits without unnecessary friction.

Key capabilities include:

- Compliance with 21 CFR Part 11, Annex 11, GDPR, and applicable privacy standards
- Role-based access control with detailed permission levels
- Secure document storage and transmission
- Comprehensive audit trails for uploads, changes, approvals, and access log
- Inspection-ready documentation and traceability support sponsors and CROs through regulatory submissions and inspections.

Integration With the Captivate Clinical Data Platform

Captivate eTMF is integrated into the broader Captivate ecosystem, enabling aligned workflows across documents, clinical data, and operational artifacts.

Key capabilities include:

- Centralized visibility into document status relative to clinical milestones
- Unified export capability for archived trial packages Consistent
- metadata and audit trails across systems

This integration reduces the need for disconnected document filing systems and supports more coherent study oversight.

Who Uses Captivate eTMF

Captivate eTMF is used by sponsors, CROs, and clinical operations teams responsible for regulatory and essential trial documentation.

Common use cases include:

- Document organization for Phase I–IV studies
- Centralized oversight for multi-site and global programs
- Inspection readiness and regulatory submissions
- Collaborative review and approval workflows across functional teams

Why Study Teams Choose Captivate eTMF

- Standards-aligned document organization and indexing
- Comprehensive version tracking and audit trails
- Configurable workflows that reflect real-world SOPs
- Integrated clinical and operational context across the Captivate platform
- Built-in compliance and inspection readiness