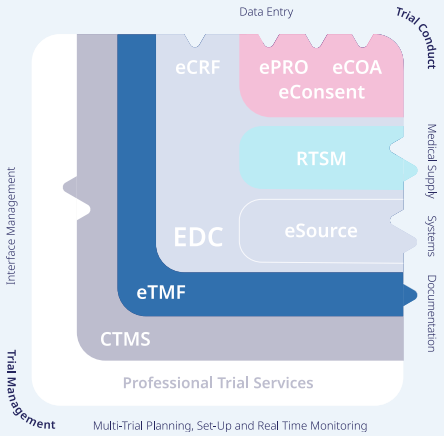
oomnia eTMF



STREAMLINED TRIAL MASTER FILE MANAGEMENT WITH OOMNIA eTMF

Manage your documents efficiently and be inspection-ready at any time

oomnia eTMF is an integral part of our unified clinical trial software. Digitally capture, store, manage, approve, and share trial documentation with ease while remaining compliant with regulatory guidelines and requirements. oomnia quickly customizes every form to trial-specific requirements, which is 3-5 times faster than the competition, leading to faster trial start-up times.

- ✓ Enhanced oversight
- ✓ Flexible eTMF structure
- ✓ Real-time reporting
- ✓ Increased collaboration

BENEFITS OF OUR UNIFIED eTMF

Boost your clinical trial success

EXCEPTIONAL QUALITY

Real-time integrated graphical reports ensure that the eTMF is completely inspection ready, and changes are traceable. A full audit trail ensures enhanced transparency and traceability.

ENHANCED FLEXIBILITY

The eTMF structure can be adapted to match trial-specific demands. Moreover, oomnia eTMF accelerates setup by 3-5 times, boosting efficiency and easily adjusts to changes.

ERROR REDUCTION

Pre-created placeholders provide users with a clear framework, reducing the likelihood of errors when uploading documents. Integrated graphical reports allow for the easy detection of missing documents.

TIME SAVINGS

An eTMF can be set up for a new study by reusing eTMF index and structure from previous trials. Furthermore, training time is reduced by reusing roles and permissions.

COST SAVINGS

The system is able to run multiple trials on a single instance, reuse eTMF structures, as well as user roles and permissions.

ADVANCED FEATURES OF OOMNIA eTMF

Unlock the full potential of your clinical trials

RELIABLE ACCESS CONTROL AND SECURITY

FEATURES	DESCRIPTION
Automatic access level control	• User only have access to part of the eTMF appropriate to their Role and Organization • Easily set access rights for eTMF Zones, Sections, and Artifact folders for trial, country, and site-level documents • Automatic detection of user's organization for access level control
Transparent document access	• Eliminate redundancies and reconciliations by only upload documents once • Easily set Zone, Section, and Artifact folders to be visible for more than one Country or Site • Granularly control document level permissions for documents which are visible to multiple Organizations including Upload, Download, View, Query, Approval, and more

ENHANCED VERSIONING AND CHANGE TRACKING

FEATURES	DESCRIPTION
Integrated query and discrepancy resolution	• User directed queries communicate and highlight document discrepancies • Enhanced document accuracy and integrity, with streamlined resolution of documentation issues
Dynamic document management and reporting	• Comprehensive management of document progress and status, real-time insights on uploads, approvals, and timeliness • Real-time monitoring integrated graphical reports is included for eTMF completion tracking
Real-time change tracking	• Full audit trail, including modifications to eTMF structure and specific documents or placeholders
Automated version control and audit trails	• Automatic versioning of uploaded documents • Preview and approval are provided at the document version level

EFFICIENT DOCUMENT ADMINISTRATION

FEATURES	DESCRIPTION
Simplified file and data upload, approval, and storage	• Pre-created placeholders provide users with a clear framework, reducing the likelihood of errors when uploading documents
Automated document indexing and categorization	• The organization of documents can be optimized through automated indexing, categorization, and tagging
Search and filter functions	• An advanced filter functionality displays relevant content depending on user-defined criteria • Sort and categorize the display of documents based on specific criteria

REGULATORY COMPLIANCE

FEATURES	DESCRIPTION
Flexible TMF Reference model implementation	• Based on the CDISC TMF refence model out of the box • Easily implement ISO14155:2020 reference model for medical device investigations • Flexible enough to adapt to any Sponsor- or CRO-specific TMF structure that may be in use.
Reporting	• Real-time integrated eTMF reports ensure compliance with regulatory requirements by enabling comprehensive document management and oversight of TMF progress, quality, and completeness
Audit Trails	• Export human readable audit trails in .csv and .xlsx formats with the capability to filter for required data

AUDIT AND INSPECTION READINESS

FEATURES	DESCRIPTION
Versatile export options	• CSV and XLSX export facilitates efficient data handling and report generation • Batch document export options