



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
- ✓ Real-time reporting
- ✓ Flexible eTMF structure
- ✓ 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 le- vel permissions for documents which are visible to multiple Organizations including Upload, Download, View, Query, Approval, and more 	

ECURITY	EFFICIENT DOCUMENT ADMINISTRATION		
1	FEATURES	DESCRIPTION	
ave access to part appropriate to nd Organization ccess rights for s, Sections, and ers for trial, country,	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 	
el documents detection of user's n for access level	Automated document indexing and categorization	The organization of documents can be optimized through automated indexing, categorization, and tagging	
edundancies and ons by only upload once one, Section, and lers to be visible for one Country or Site control document le-	Search and filter functions	 An advanced filter functionality displays relevant content depending on user-defined criteria Sort and categorize the dis- play of documents based on specific criteria 	
ons for documents risible to multiple			

REGULATORY COMPLIANCE

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 ma- nagement 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 	

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 	



