Essential Document Collection Made Easy by XClinical

ELECTRONIC TRIAL MASTER FILE

marvin eTMF

Managing your TMF documents and processes on paper is outdated. While document management systems, such as Share Point, can help to collect documents, these are not compliant and are lacking required features and workflows required in clinical trial execution. Marvin eTMF is a compliant, validated and budget friendly eClinical solution for managing all your essential trial documentation and processes. The software incorporates fine-grained role-based access and ensures your TMF to stay inspection ready.

Key features:

- Simple and intuitive user interface
- Customizable eTMF Reference Model folder structure
- **Affordable to deploy, No per user fees!**
- Digital document placeholders (PHs)
- Secure anytime, anywhere access
- Multi-level & fine-grained access control
- Full audit trail and versioning
- **Completeness, Quality and Timeliness reporting**
- Metadata recording
- Search and retrieval for audit readiness
- e-approval submission workflow
- **Fully compliant and validated**

Key benefits:

- Easy and timely document collection
- Compliance with FDA and EMA regulations
- Direct secure access, visible 24/7
- Notifications increase TMF oversight

Marvin eTMF offers the opportunity to:

- Enable sponsor oversight in an easy and cost-effective way
- Increase inspection readiness through management of timeliness, quality and completeness
- Provide a compliant and affordable eTMF offering
- Focus on the clinical trials process and less on cumbersome manual preparation in the face of an audit

Simple and Intuitive Interface Get up to speed in no time

Marvin eTMF makes daily work easier and more efficient. The simple and intuitive web-based interface reduces training time and increases **efficiency**. With minimal training users can create, exchange, and update TMF documents. CROs, Site personnel, monitors, auditors and sponsors can be trained within a few hours.

Full support of your own TMF structure or the DIA Reference model

Trial master files are not one size fits all. Marvin eTMF gives you the **flexibility** to use your own TMF structure and has a built Reference Model for identifying and classifying trial documents. Improve inspection readiness and reduce time to set up a new site by adherence to the TMF reference model to bring order, structure, and lineage to your eTMF And helping you segment and organize any large data volume in the most efficient way.

Marvin eTMF supports better project management through real-time access to study documentation. It offers clear workflows, reporting, search and retrieval, audit-readiness at each point in time, and many other valuable features. Marvin eTMF is a powerful and intuitive system answering our client's needs for managing documentation in a secure and regulatory compliant manner. It is a cloud-based, highly configurable eTMF system with quality-focused workflows.

Easy Uploading and Filing

Marvin eTMF allows you to easily file the documents in the correct location in the TMF reference model and add metadata by **drag and dropping** documents individually or as a set.

Intuitive Search Capabilities

Marvin eTMF leverages the metadata related to your document to help locate the relevant document in a search. Metadata is the information attached to an item and captures details like the document author, file type, size, time of creation, upload time, your own comment and so on. Marvin eTMF's search algorithms—based on file-name, location, or metadata—makes searching TMF artifacts simple, **accurate**, and robust.

Flat Rate
Cost effective

The software has a very cost friendly and effective way of managing users and sites. When accepting a fair use policy the software allows for **unlimited** users and storage.
Deploys in days, not months

Compliance with FDA and EMA Regulations

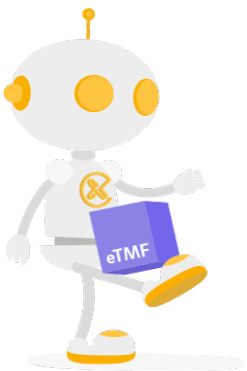
Marvin eTMF contains all components, controls and policies that are required according to 21 CFR Part 11, ICH-GCP E6 and GDPR (General Data Protection Regulation). The system is specified and **validated** according to the regulatory and data protection requirements.

Fine-grained Role Based Controlled Access

Accommodate Site, Sponsor, CRO, External Users, Inspectors and auditors within one environment. Designate certain users as QC reviewers, to finalize documents as TMF-ready. The content is maintained in a **secure**, compliant environment with controlled access, configurable user roles, and a complete audit trail providing direct eTMF access for all study stake-holders.

Plotting Your Course from filling to Inspection Readiness

Marvin eTMF leverages digital placeholders (PHs) to **automatically** generate the folder structure according to a predefined file plan. A file plan specifies the expected documents in each filing area and allows for up-to-the-moment accuracy on the compliance documentation status. Notifications for overdue files keep everybody in sync.



Real-Time Dashboards

Get a quick oversight and identify problems into the eTMF status and progress. Dashboards display the health of the eTMF, including overdue reporting and **review status**, listing new uploads and last activities

Secured Anytime, Anywhere 24/7 Access

Marvin eTMF is a user-friendly application that can be accessed using a modern browser such as Edge, Chrome, Firefox and Safari. It offers easy and secured access for viewing, sharing, and retrieving any file from anywhere, anytime with **customizable** access levels.

Essential Document Collection Made Easy

*„We are delighted to announce the eTMF as response to our customers' needs for digital document management. The team and I are looking forward to working with you on the **integration of the Marvin eTMF** into your eClinical solutions as well as its future improvements."*

Dr. Elisabeth Frank
Product Manager Marvin eTMF

About us

XClinical is an international eClinical vendor headquartered in Germany, founded in 2002. Its software platform Marvin provides solutions for Clinical Data Management, such as EDC (including IWRS/Drug Supply Management, WebPRO, reporting, etc.), Coding, study build (CDISC ODM-based study design including SDTM mapping and visualization), Clinical Document Management (eTMF) and a mobile application for direct communication between Investigators & Patients. Our software and technical services accelerate clinical trials worldwide. We are experts in clinical research, project management, software development, data privacy and data security. XClinical was founded with a vision to build standards-based solutions to simplify and speed up the clinical trial process.

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