Flex Databases Platform

Unified eClinical platform for CRO, biotech, and pharma

GENERAL
- HR Database
- Project Catalogue
- Report Tool

DOCUMENTS
- Trial Master File
- Document Management System

CLINICAL
- CRA Activity Management
- Investigators & Sites Management
- Subject Tracking & Invoicing

PROJECT & FINANCE MANAGEMENT
- Project Management & Budgeting
- Time Sheets & Utilization

QUALITY & COMPLINCE
- Learning Management System
- Quality Management System

SAFETY
- Pharmacovigilance

About Flex Databases

We develop a comprehensive clinical trial management solution since 2011.

- **10+ years** on the market
- **4 offices** in the US, Europe, and Asia
- **All-in-one platform** from study planning to safety database

What sets us apart

Easy implementation
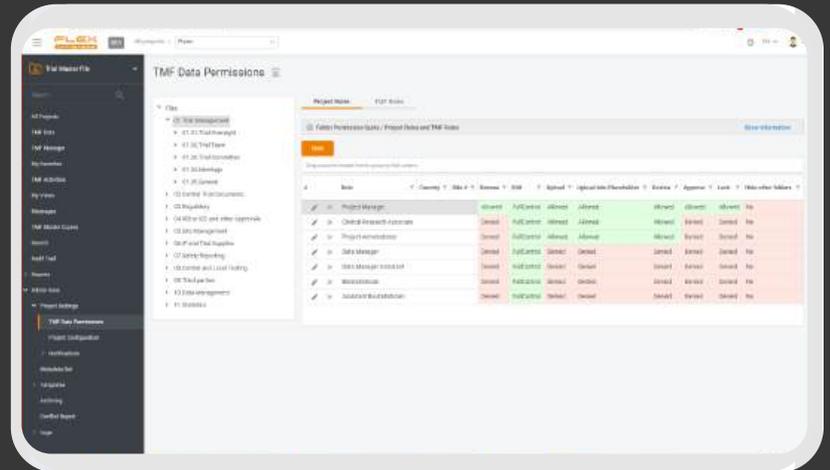
Full compliance

Complete data safety

Flexible solution

- System implementation in **3 to 10 weeks**
- A robust **backup & disaster recovery and data protection strategy**, including distributed data storages around the world
- All major **international and local regulations** covered, including FDA 21 CFR Part 11, GDPR, etc.
- Reports, workflows, trackers are under user configuration. Web-based solution, no installation required

Some of our clients

Leading CROs, pharma, and biotech

novo nordisk®   CMIC   FGK CLINICAL RESEARCH   Dr.Reddy's

ERGOMED   OPTIMAPHARM   WORLDWIDE CLINICAL TRIALS

Electronic Trial
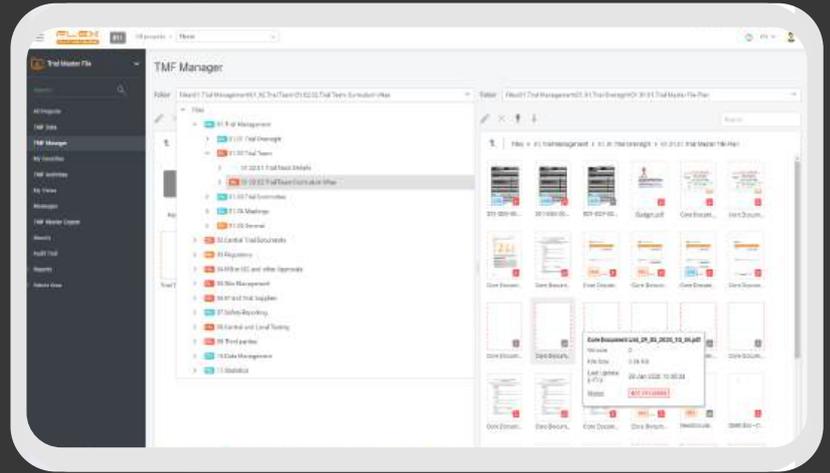# Master File
Module Overview

- Flex Databases eTMF ensures constant inspection readiness by means of automated folders completeness statistics, missing documents reports and various notifications.

- eTMF is 24/7 securely available from anywhere in the world on any device.

- Get the most value for money and improve your productivity by using advanced Flex Databases eTMF Solution.

A helicopter view of the clinical trial processes in your laptop

- See missing documents, files uploaded statistics, folders completeness by milestone or any other parameter.
- Widgets and reports exportable and clear.
- Focus on your tasks with to-do lists automated for you.
- My favorites tab will bring you straight to what matters.
- Alerts and notifications are there to help you be up to date with expiring documents and tasks.

Electronic Trial Master File
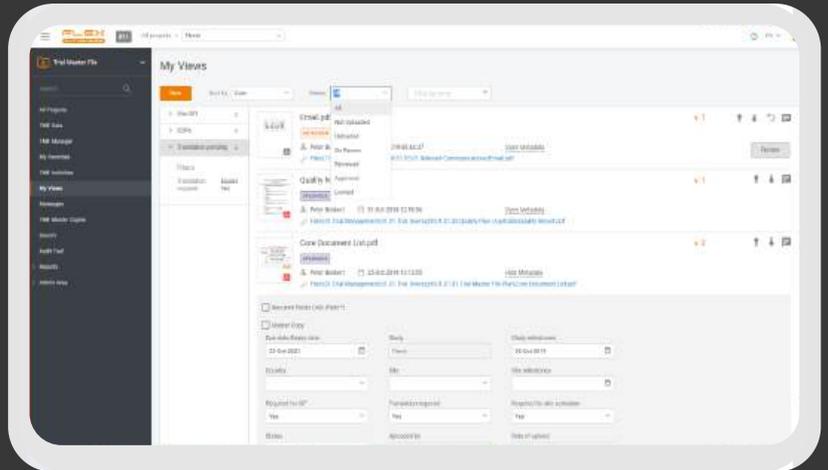# Module Overview

Tools designed for your daily activities

- Upload documents in seconds: email it directly into eTMF or through a mobile app, connect through WebDAV, drag and drop into eTMF, or just browse and upload.
- eTMF is integrated with CTMS, all the CTMS documents are filed in eTMF with zero effort.
- Need one place to review, assign metadata and distribute documents to a correct folder? We got you covered with eTMF Manager space.
- Need to send documents in bulk to sites? – email it from eTMF with a track record.
- Review, approve, lock, sign, author documents with embedded eSignature function.

Simplicity without compromising quality

- Periodic review of eTMF is finally easy with My Views tab to choose a list of documents for review and use inbuilt chat function to query and correct a document.
- Inspection readiness is not a challenge anymore – it is a daily state of your eTMF.
- Regulations are met, validation is complete, audit trail is there.
- Archiving function, logs and external access designated for inspectors, auditors, partners is there too.
- No excessive training required.

Electronic Trial Master File
List of Features

Core Features

- Centralized collaboration of study stakeholders through workflows
- Document versioning
- Configurable eSignature settings
- Connection of TMF as an external drive through WebDAV protocol
- Optical Character Recognition (OCR)
- Easy document archiving in the end of the project
- Frequently used files in My Favorites section
- Ability to send messages and leave comments for each file or folder
- E-mail blasts from TMF to the sites
- Audit Trail report
- Adjustable notifications based on folder subscriptions
- Dynamic metadata report
- Mobile app

Centralized administration

- Full TMF Reference Model Support
- Web-based access
- Configurable access control, based on project role, sites, folders, countries and for external users

Real-Time Completeness Check

- Real-time statistics on folders completeness
- Powerful Business Intelligence: widgets and reports
- Real-time changes in the Artifact Statuses

Automatic filing and batching of index documents

- Drag & Drop documents from a desktop
- Emailing to clinical sites and external partners inbox
- Automated filing of documents from CTMS

Advanced search and filtering

- User-defined lists of documents based on metadata values in My Views section
- Metadata actions (e.g. expiry date notification)
- Quality control report based on metadata values
- Export of a file batch matching several filter criteria simultaneously