

## **Flex Databases Platform**

Unified eClinical platform for CRO, biotech, and pharma

GENERAL	стмѕ	PM & BUDGETING	COMPLIANCE & SAFETY
eTMF	CRA Activity Management	Project Management & Budgeting	Learning Management System
EDC	Investigators & Sites Management	Expense Reporting	Quality Management System
Workflow Management	Subject Tracking & Invoicing	Time Sheets & Utilization	Pharmacovigilance

### **About Flex Databases**

We develop a comprehensive clinical trial management solution since 2011.

### What sets us apart

- Easy implementation
- Full compliance

Complete data safety

Flexible solution

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





# Electronic Trial Master File

**Module Overview** 

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- 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** 

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#### 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

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#### **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