




Flex Databases




eClinical platform for CROs, biotech,
pharma, and academic research



CTMS

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



DOCUMENTS

-  Trial Master File
-  Document Management System
-  Investigator Site File



EDC

-  Electronic Data Capture
-  Risk-Based Monitoring
-  Randomization and Trial Supply Management
-  Electronic Patient-Reported Outcome


PROJECT & FINANCE MANAGEMENT

-  Project Management & Budgeting
-  Time Sheets & Utilization

QUALITY & COMPLIANCE

-  Learning Management System
-  Quality Management System

SAFETY

-  Pharmacovigilance

About Flex Databases

We develop a comprehensive clinical trial management solution since 2011.

- 15+ 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.

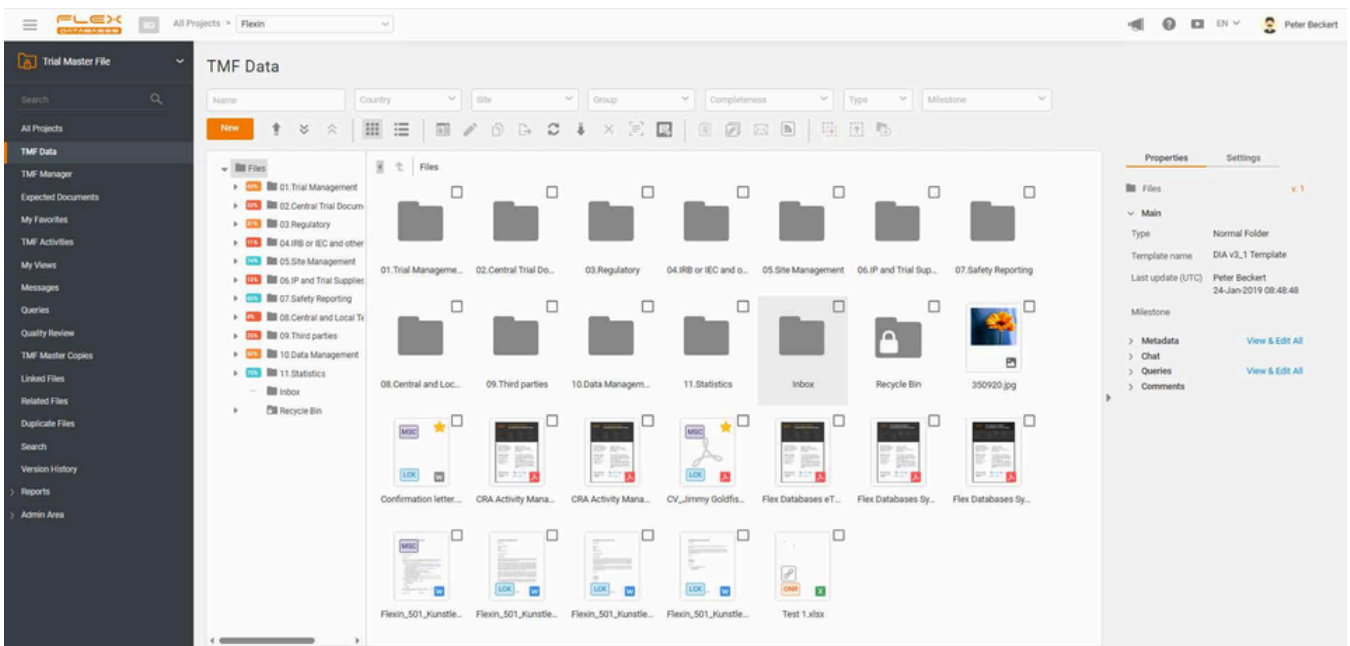
Some of our clients

Leading CROs, biotech, pharma, and academic research



Electronic Trial Master File

Module Overview



Flex eTMF keeps your Trial Master File inspection-ready every day – not just before an audit.

It continuously monitors TMF completeness, timeliness, and quality across studies and organizations, providing real-time visibility into what's missing, overdue, or at risk. With AI-assisted classification and intelligent automation, Flex eTMF reduces manual filing effort and streamlines document workflows, freeing study teams to focus on execution instead of administration.

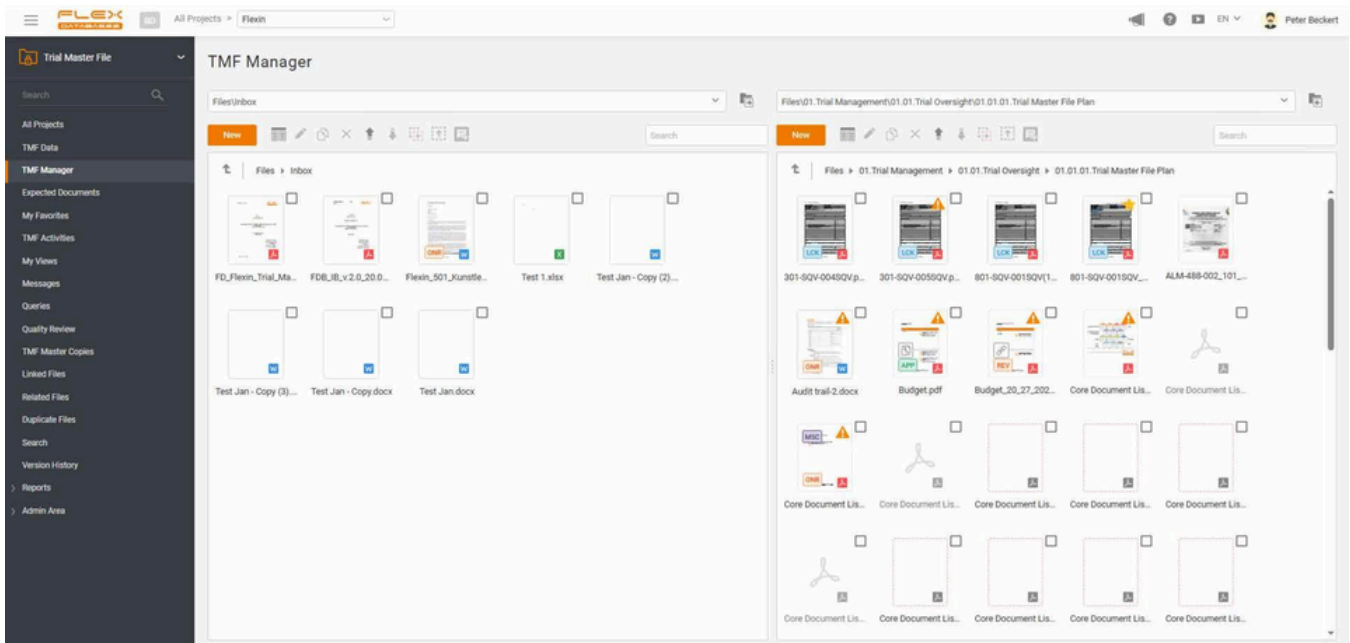
The Three Pillars of TMF Health

- **Completeness** – Are all expected documents in place for each study, country, site, and milestone?
- **Timeliness** – Are documents created, submitted and approved within required timelines?
- **Quality** – Are documents final, approved, legible, consistent and correctly classified?

Flex eTMF tracks these three dimensions continuously and presents them in clear visual dashboards and reports.

Electronic Trial Master File

Module Overview



Tools designed for your daily activities

- Capture documents in seconds – email directly into the eTMF, connect via WebDAV, drag & drop, or upload through the browser
- Zero-effort CTMS filing – documents created in CTMS are automatically filed into the correct eTMF folders
- One workspace for bulk actions – review documents, assign metadata and distribute them to the right folders in one click
- Easy distribution to sites – send document packages to sites straight from the eTMF with a complete, auditable track record
- In-place review and sign-off – review, approve, author, lock and sign documents with embedded e-signature functionality

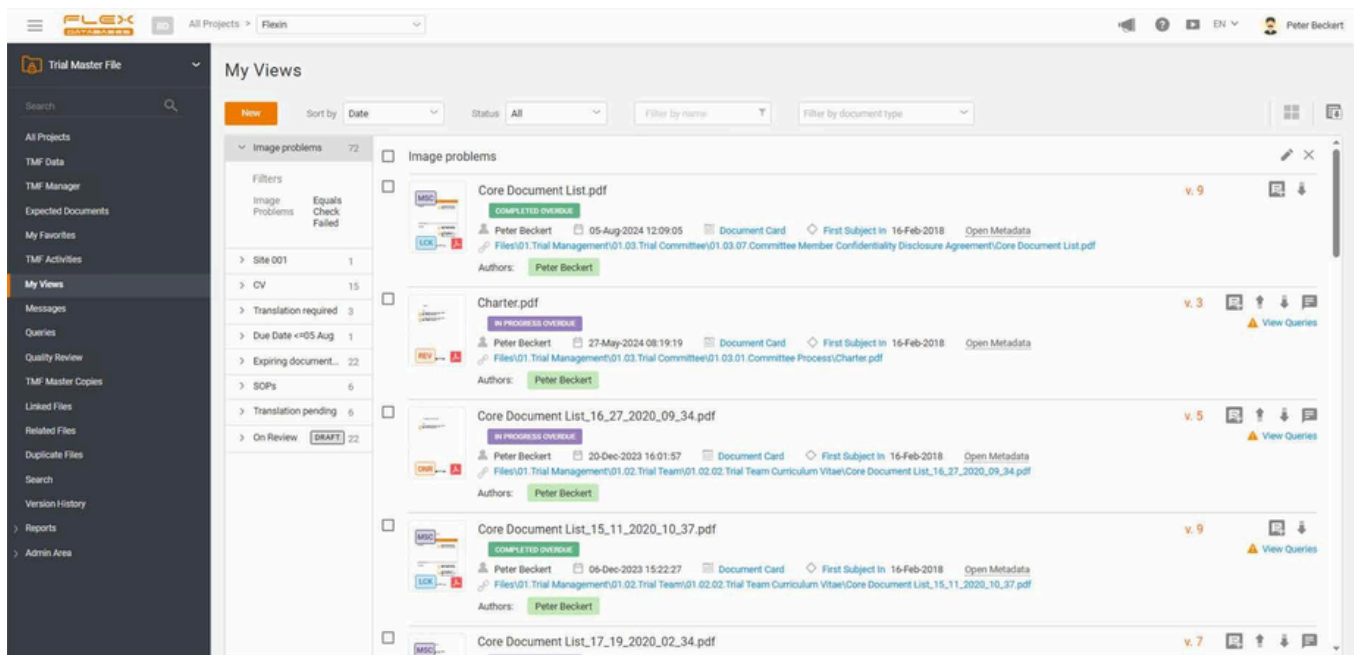
Simplicity without compromising quality

- Effortless periodic review – use quality review tool to build checklists, run structured quality audits, and resolve findings via in-built chat and comments
- Inspection readiness as a default state – completeness, timeliness and quality are monitored continuously, not just before an audit
- Regulatory and validation confidence – regulations are met, validation is documented, and a full audit trail is available at any time
- Controlled access and archiving – dedicated archiving functions, logs and secure external access for inspectors, auditors and partners
- Minimal training required – intuitive web interface and consistent UX across the Flex Databases platform



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Real-Time Completeness Check

- Real-time statistics on folder and artifact completeness across studies, countries and sites.
- Powerful business intelligence widgets and reports for TMF KPIs
- Real-time changes in artifact statuses reflected immediately in dashboards
- Dynamic metadata reports to monitor expiry dates, missing attributes and other risk indicators

Filing & Daily Work

- 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

Centralized Administration

- Full TMF Reference Model support with configurable structures.
- Web-based access with no local installation required.
- Configurable access control based on project role, sites, folders, countries and external user profiles
- Advanced Search and Filtering
- User-defined lists and saved views (My Views) based on metadata values and filters.
- Expiry date notifications
- Quality control and structured quality review
- Export of file batches matching multiple filter criteria simultaneously for audits, inspections or migrations



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Actions	Project	File Name	Path	Linked By	Date	Info
	Flexion	Flex_M1_Kunster_SIV CL_14042019 (1).docx	Files\01.Trial Management\01.01.Trial Oversight	Peter Becker	12-Mar-2025 15:12:04	
	Flexion	Flex_M1_Kunster_SIV CL_14042019 (1).docx	Files\01.Trial Management\01.03.Trial Compliance\01.03.02.Com. Member List	Peter Becker	12-Mar-2025 15:12:04	
	Flexion	Flex_M1_Kunster_SIV CL_14042019 (1).docx	Files\01.Trial Management\01.01.Trial Oversight	Peter Becker	12-Mar-2025 15:12:30	
	Flexion	Flex_M1_Kunster_SIV CL_14042019 (1).docx	Files\11.Statistics\11.01.S. Oversight\11.01.01.Statistics Analysis Plan	Peter Becker	12-Mar-2025 15:12:30	
	Flexion	Budget_20_17_2021_01_24.pdf	Files\01.Trial Management\01.01.Trial Oversight\01.01.01.Trial Master File Plan	Peter Becker	12-Mar-2025 15:25:01	
	Flexion	TMF Setup Request.pdf	Files\01.Trial Management\01.01.Trial Oversight\01.01.01.Trial Master File Plan	Peter Becker	12-Mar-2025 15:25:01	
	Flexion	Flex_M1_Kunster_SIV CL_02062019.docx	Files\01.Trial Management	Peter Becker	12-Mar-2025 15:31:50	
X	Flexion	Flex_M1_Kunster_SIV CL_02062019.docx	Files\01.Trial Management\01.01.Trial Oversight\01.01.01.Trial Master File Plan	Peter Becker	12-Mar-2025 15:31:50	
X	Flexion	Flex_M1_Kunster_SIV CL_02062019_12_23_2019_15_3_4860.docx	Files\01.Trial Management\01.01.Trial Oversight\01.01.01.Trial Master File Plan	Peter Becker	12-Mar-2025 15:33:03	

Actions	Project	File Name	Path	Related By	Date	Reason for Relation
	Flexion	Budget.pdf	Files\01.Trial Management\01.01.Trial Oversight\01.01.01.Trial Master File Plan			
X	Flexion	Flex_M1_Kunster_SIV CL_02062019.docx	Files\01.Trial Management	Peter Becker	12-Mar-2025 15:30:50	

Core Features

- Centralized collaboration of study stakeholders through configurable workflows and task lists
- Granular, role- and attribute-based permissions (by project, country, site, folder and external user type)
- Document versioning with clear “current vs superseded” status, duplicate detection and side-by-side version comparison for QC and inspections
- Configurable e-signature settings aligned with your SOPs and roles
- Connection of eTMF as an external drive via WebDAV, enabling work with files directly from the desktop
- Linked and related documents (core vs country/site versions, correspondence vs decisions) to keep context connected across TMF sections
- Collaborative authoring and review via Office 365 (online co-authoring, comments, track changes) with seamless filing of final versions into the eTMF



manage all in one