Flex Databases Platform

Unified eClinical platform for CRO, biotech, and pharma

GENERAL	CTMS	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.

- **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

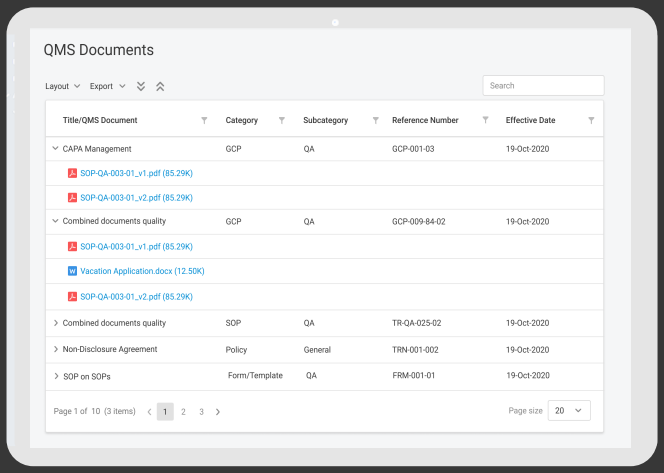
Leading CROs, pharma, and biotech

novo nordisk®
CMIC
FGK CLINICAL RESEARCH
Dr.Reddy's
ERGOMED
OPTIMAPHARM
WORLDWIDE CLINICAL TRIALS

FLEX DATABASES

Quality Management System

Manage SOPs, audits, incidents, CAPA, and all the quality-related activities across company and projects within a single module



CAPA management

- CAPA initiating, review, resolution, and follow up
- Assigning responsible team members to tasks and process steps;
- Tracking all the responses and progress of CAPA;
- CAPA observation period scheduling and tracking;
- CAPA effectiveness tracking and evaluation;
- Documents generation and sign-off;
- Actions implementation evidence;
- Various KPIs tracked, performance measured on company level and per project.

Audit management

- Audits planning and scheduling;
- Any type of audits: internal, external, vendor, etc;
- Full audit lifecycle from planning to CAPA tasks resolution and observation period.

Incident management

- Any incident is registered and tracked;
- Incident severity and impact evaluation;
- Tracking the incident resolution, including actions, and timelines;
- Making decisions about the necessity of CAPA based on assessment.

SOPs and other QMS documents

- Create a new QMS document or initiate review;
- Review cycle of documents with comments, revision history and electronic signatures;
- Get notifications regarding periodic review;
- Transparency in review process with reporting on steps of review, responsible employees, and timelines.