Flex Databases

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

FLEX DATABASES
manage all in one

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.

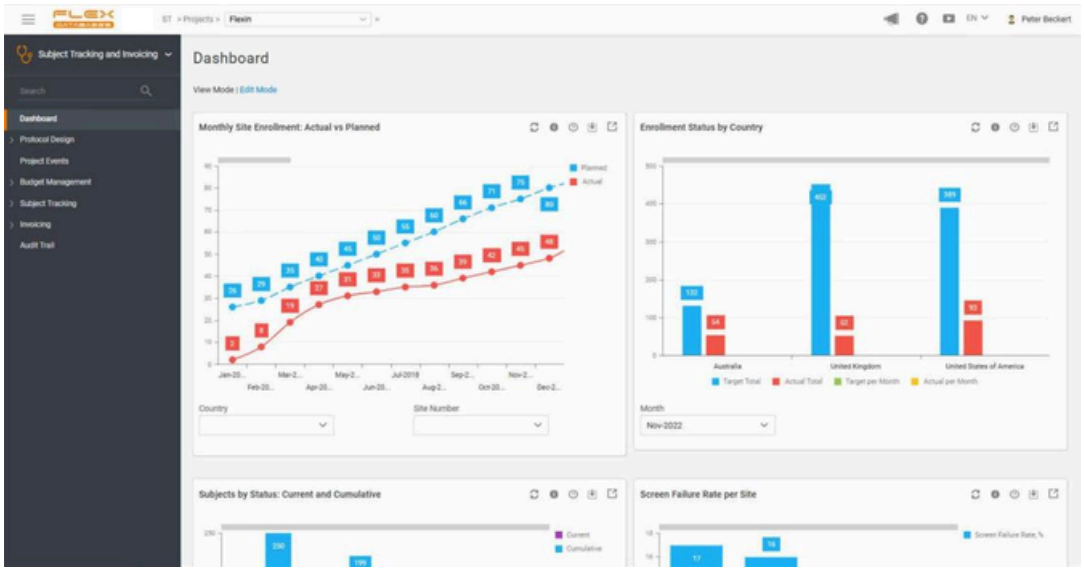
Web-based solution, no installation required.

Some of our clients

Leading CROs, biotech, pharma, and academic research

novo nordisk · BIOTRONIK excellence for life · EVEREST CLINICAL RESEARCH · Dr.Reddy's · FGK CLINICAL RESEARCH · WSG Westdeutsche Studiengruppe West German Study Group · ABX-CRO advanced pharmaceutical services · SOLTI Shaping the future of cancer research · ERGOMED

Flex Databases
Product Overview



End-to-end clinical operations: from feasibility and sites to monitoring, subjects, budgets, and payments

Flex CTMS is a clinical trial management system that brings together everything operations teams need to run studies: feasibility and start-up, investigators and sites, monitoring visits, trial participant tracking, site payments.
It centralizes operational and financial data across studies and countries, giving Sponsors and CROs a single place to plan, execute and oversee their clinical trial portfolio — instead of juggling spreadsheets and disconnected tools.

Why Flex?

- Truly end-to-end — feasibility, start-up, site and investigator management, monitoring, participant tracking, budgeting and payments in one CTMS
- One operational backbone — calendars, visits, subject data, contracts, invoices and KPIs share the same data model, improving data quality and reducing reconciliation effort
- Actionable oversight – dashboards for enrollment, visits, issues, payments and project health help spot delays, risks and profitability issues early
- Built for modern trials — supports multi-country portfolios, complex designs, outsourced studies, and integrations with EDC, eTMF, and safety systems
- Configurable, not custom-coded — visit types, trackers, workflows, budgets and reports are adjustable by business users, keeping implementation and change cost under control
- Built for inspections — audit trails, e-signatures, and “reason for change” capabilities support regulatory expectations and reduce finding rates

Contact us to learn more about Flex Databases Platform: contact@flexdatabases.com

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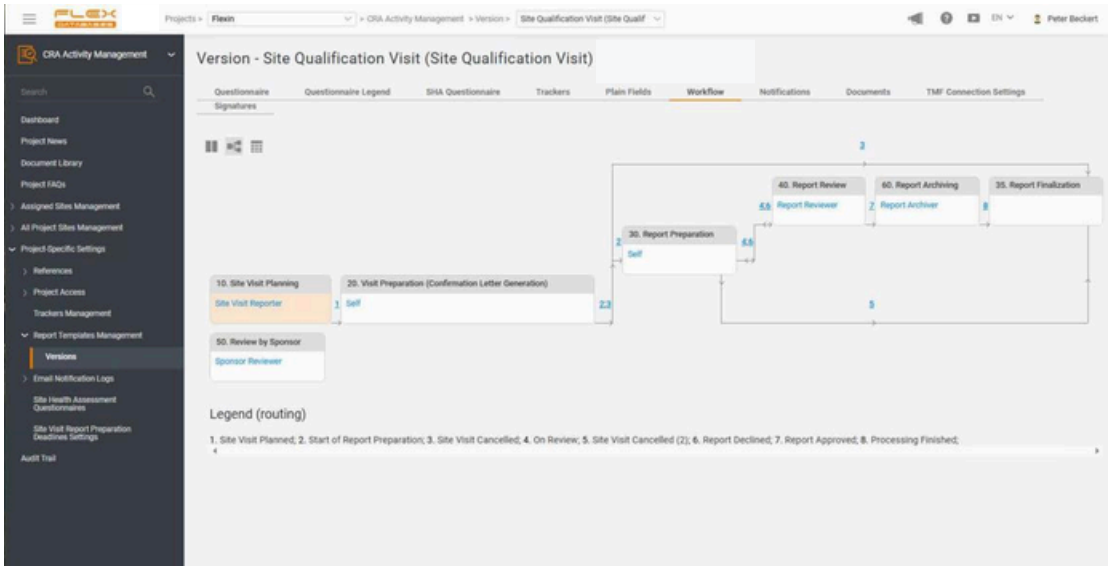

Core Areas & Capabilities

Feasibility, Investigators, Sites & Start-Up

- Investigator and site universe — central repository of investigators, institutions, sites, regulators and vendors with experience, capabilities and contact details
- Feasibility support — capture and reuse site and investigator attributes to make smarter selection decisions
- Study start-up & submissions — track contracts, regulatory and ethics submissions, approvals and site activation across all countries and sites
- Linked documents & TMF — just upload documents into CTMS and get them in finalized and locked status in eTMF

CRA Activity Management & Monitoring

- End-to-end visit lifecycle — plan, schedule and track all monitoring visit types
- On-site and remote monitoring — manage classic on-site visits and remote monitoring activities with customized workflows, trackers and reporting rules
- CRA workspace — dedicated CRA home with visit calendar, to do list, pending reports and follow-up tasks across assigned studies and sites
- Automated visit documentation — monitoring visit reports plus confirmation and follow-up letters generated from templates
- Automated issues & deviations — log and track issues, protocol deviations and action items directly from the visit

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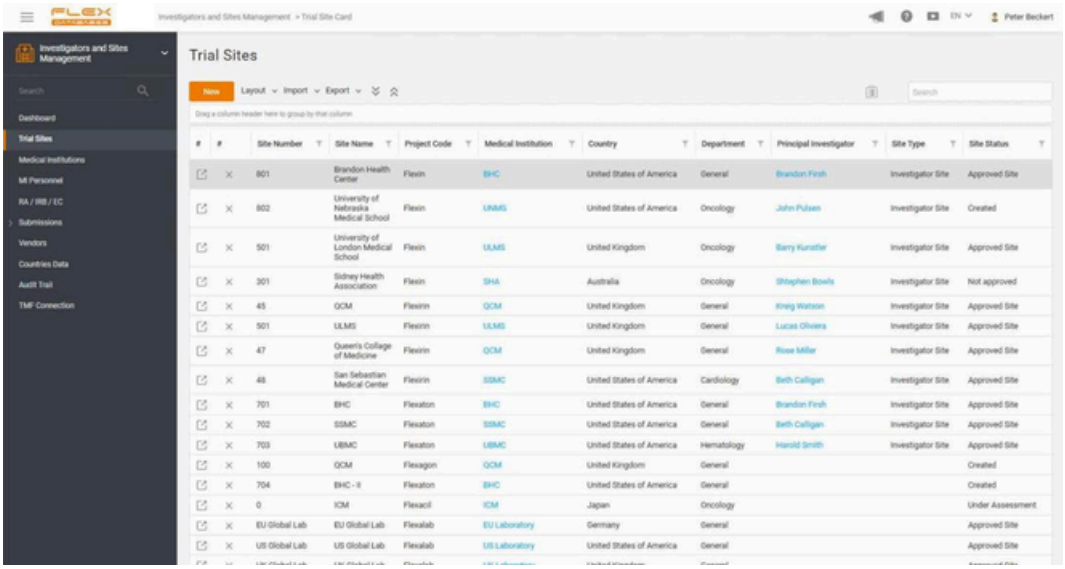

Reporting, Analytics & Oversight

- Real-time dashboards — enrollment, visits, issues, payments, and project health presented in configurable dashboards for operations, finance, and leadership
- Ad-hoc reporting — build complicated reports without IT involvement
- Portfolio-level KPIs — drill from portfolio down to study, country, site or CRA to understand where risks and bottlenecks are emerging
- Exports & integrations — export to BI tools and connect via APIs to EDC, eTMF and ERP systems for broader analytics

Compliance, Security & Platform Integration

- Cloud-based, validated CTMS aligned with ICH GCP, 21 CFR Part 11 and data protection requirements, with full audit trails across key processes
- Role-based permissions by project, country, site, role, and Sponsor/CRO/site/vendor
- Part of the Flex Databases platform together with EDC, eTMF, PV, QMS & Learning, DMS, and Project/Finance modules, so clinical, quality and financial data share a consistent backbone instead of living in silos

Trial Subject Tracking & Site Payments

- Subject journey tracking — monitor each trial subject from screening to last visit, including status, visit completion, windows, screen failures and withdrawals
- Enrollment oversight — enrollment curves and KPIs by study, country, site, and investigator help identify under- and over-performing sites
- Rules-based payment engine — site payments and invoices are generated automatically from subject and visit data
- Multi-currency, multi-beneficiary — support for complex financial arrangements
- Planned vs actual financials — compare forecasted vs real payments and costs per study, country and site, and export data for finance or ERP systems

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