Flex Databases

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

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.

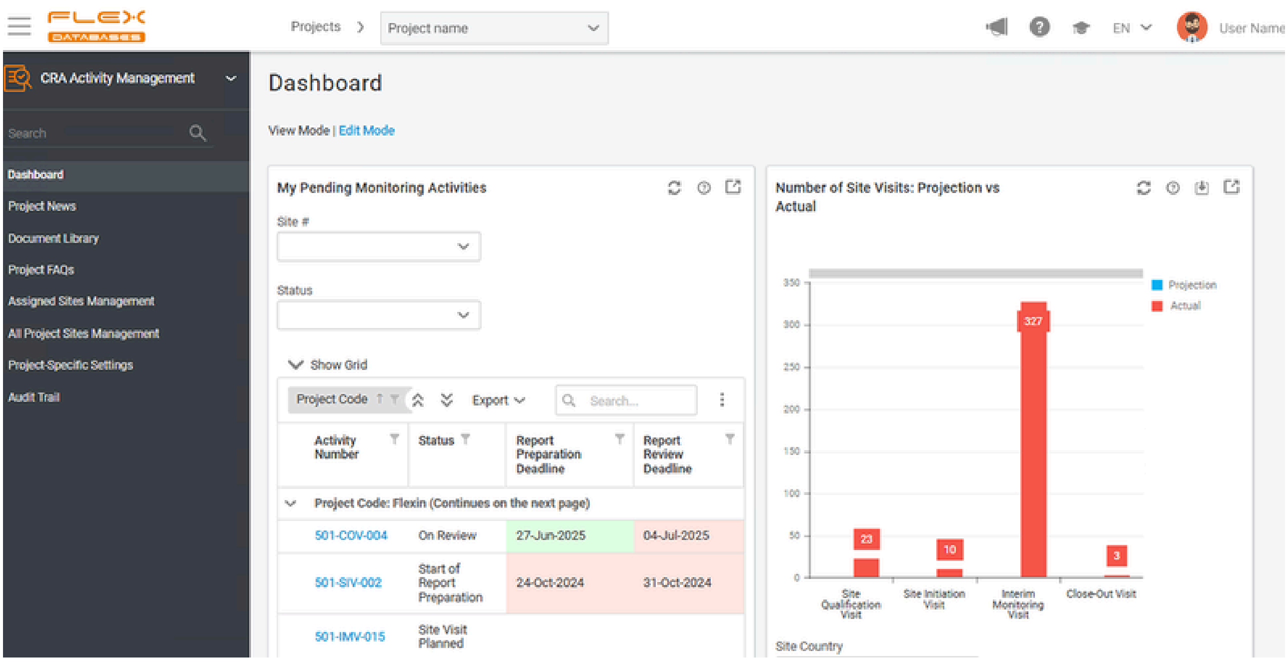
Reports, workflows, trackers are under user configuration.

Web-based solution, no installation required.

Some of our clients

Leading CROs, biotech, pharma, and academic research

CRA Activity Management
Module Overview



CRA Activity Management is an end-to-end monitoring workspace that helps Sponsors and CROs plan, execute, and document all on-site and remote visits in one place.
It provides study teams with real-time oversight of visit status, findings, and follow-up actions across the entire portfolio. Connected with other Flex modules, it keeps monitoring activities aligned with enrollment, data and documents — without extra spreadsheets and email chains.

Plan & schedule every visit

- Full lifecycle of monitoring visits in one place — plan, schedule, and track all visit types (qualification, initiation, interim, close-out, for-cause and any custom type)
- Central and personal calendars — keep all planned, due and rescheduled visits under control
- Visit portfolios across studies — see all assigned visits by study, country, site and CRA, including overdue and at-risk visits
- Configurable visit templates — standardize what needs to be checked and documented per visit type

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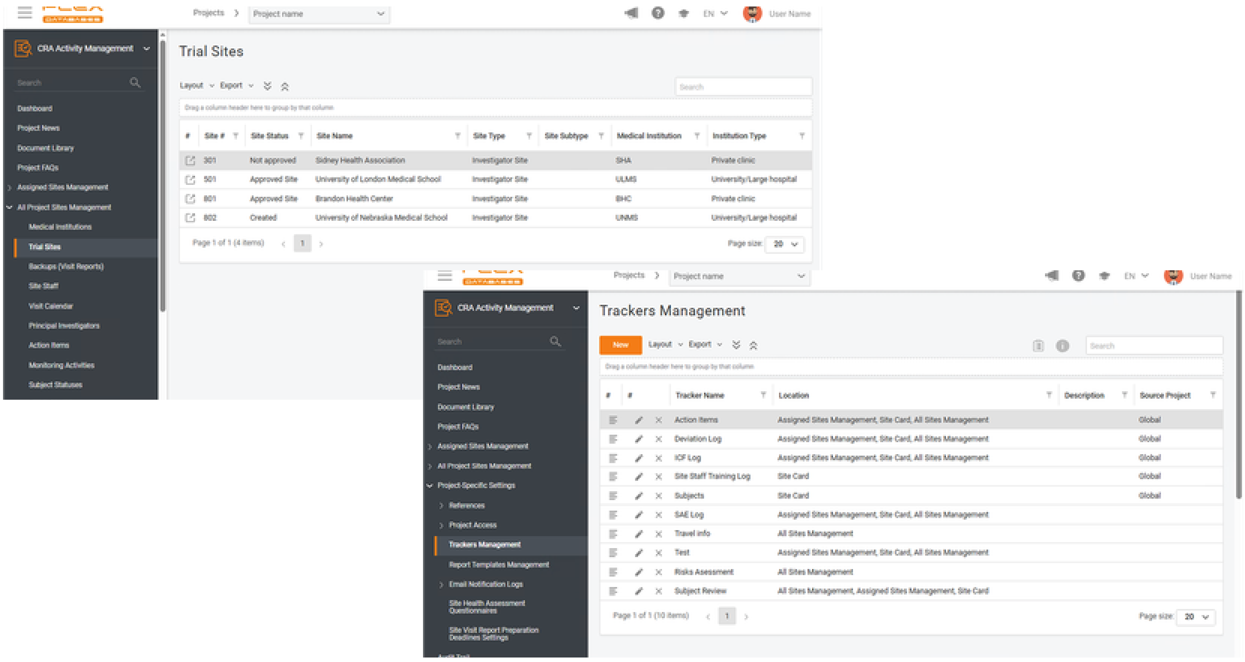

Execute, document & follow up

- One monitoring workspace for CRAs — consolidates upcoming visits, open actions, pending reports and follow-up tasks per monitor
- Structured trip reports — monitoring visit reports generated from customer templates with auto-populated study, site, enrollment and deviation data, minimizing manual typing
- Confirmation & follow-up letters in one click — automatically generate with embedded action items and issues, linked back to the visit
- Offline site visit reports — CRAs can draft and finalize visit reports offline and sync them when connection is restored, so poor site internet is no longer a blocker
- Integrated issue & deviation tracking — log issues, protocol deviations and action items directly from the visit, route them through resolution workflows and ensure closure

On-site, remote & centralized monitoring

- Support for on-site,remote and hybrid visits — manage classic on-site visits and remote monitoring activities in the same workspace and with the same trackers.
- Link to eTMF and site systems — automatically file approved visit reports, letters and key monitoring documents into eTMF; keep links to source systems for SDV/SDR where applicable.
- Always-on access to site documentation — combined with Flex eTMF and site-facing tools, CRAs can review essential documents remotely between on-site visits instead of waiting for the next trip.
- Monitoring checklists & questionnaires — configurable checklists for remote and on-site assessments to make sure nothing is missed at the site or in the eTMF

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

FLEX DATABASES

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CRA Activity Management

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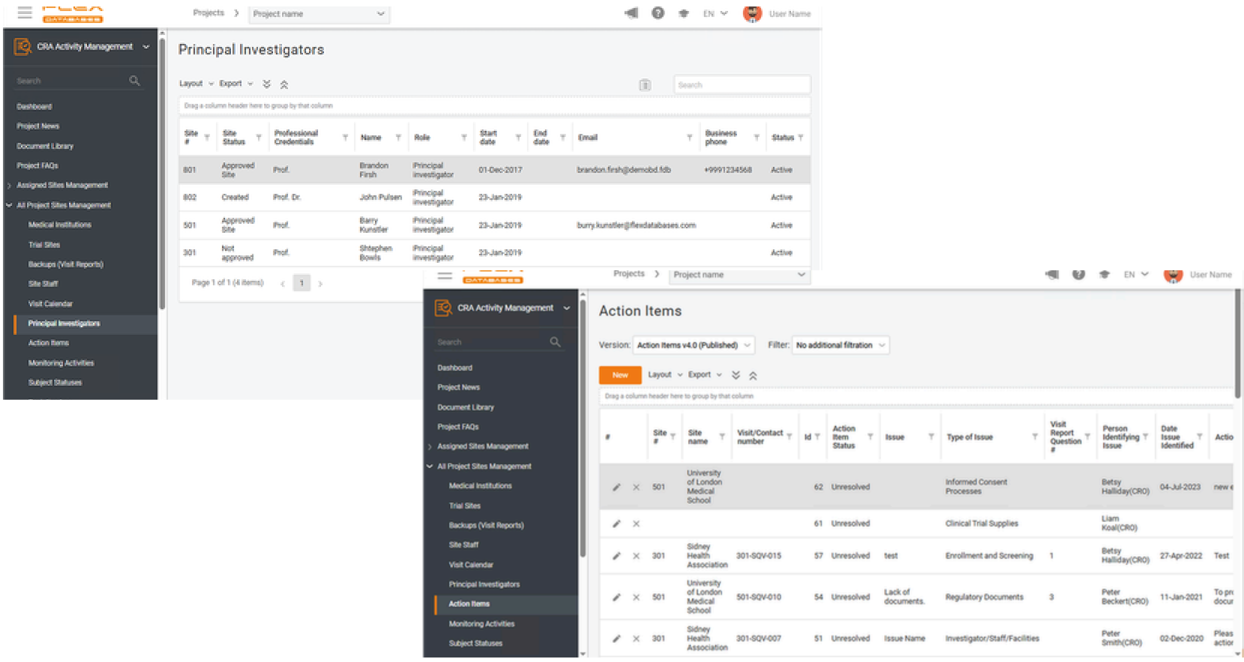

Flexibility, configuration & integrations

- Fully configurable trackers — action items, issues, deviations, subject enrolment and any other logs are configurable without custom development or extra fees.
- Template designer — maintain your own templates for visit reports, confirmation and follow-up letters, questionnaires and monitoring checklists.
- Configurable workflows — monitoring visit and report workflows can be tailored to reflect your exact SOPs, roles and QA steps.
- Smart notifications & alerts — automated reminders for upcoming and overdue visits, late reports, unresolved issues and pending signatures.
- Must-have controls & APIs — 21 CFR Part 11-ready electronic signatures, study role-based permissions, and interconnection of CRA Activity Management with eTMF, EDC or even beyond with an open API

KPIs, analytics & oversight

- Cross-project monitoring dashboards — real-time view of visit status, overdue visits, report cycle times, open actions and issues across studies and countries.
- CRA performance metrics — track workload and performance for each CRA (e.g. time from visit to report submission, number and age of unresolved actions, follow-up completion).
- Risk-based oversight — use site health assessment seamlessly integrated in monitoring visits along with deviations and issue trends as operational KRIs to support risk-based monitoring and targeted SDV/SDR.
- Self-service reporting & exports — build ad-hoc reports with graphs, widgets and grids, then export them for governance meetings, audits, inspections or sponsor reviews.

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