




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.

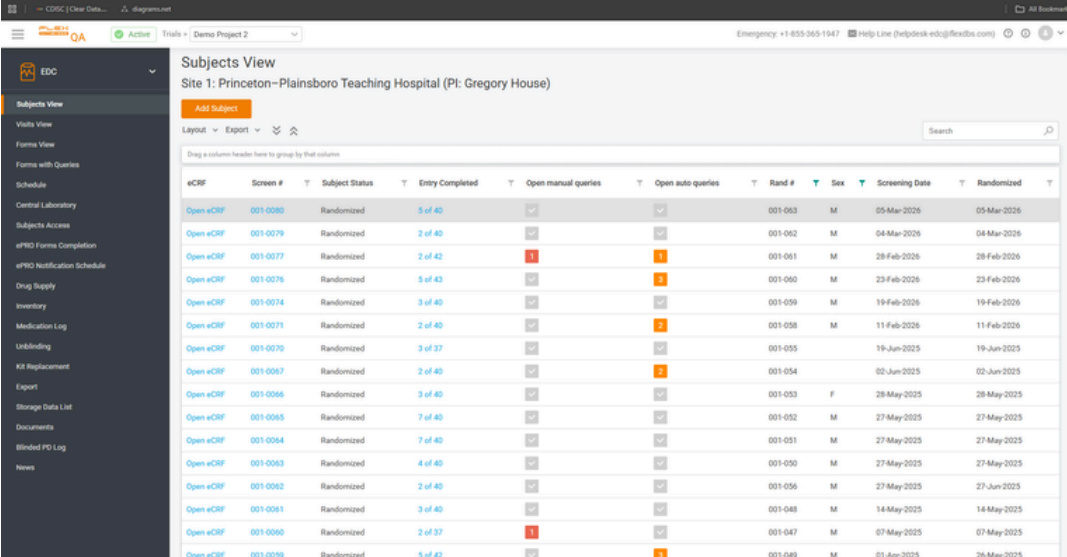
Some of our clients

Leading CROs, biotech, pharma, and academic research



Electronic Data Capture

Module Overview



The screenshot displays the 'Subjects View' interface for 'Site 1: Princeton-Plainsboro Teaching Hospital (PI: Gregory House)'. The interface includes a sidebar with navigation options like 'Subjects View', 'Visits View', 'Forms View', and 'Forms with Queries'. The main area shows a table of subjects with the following columns: eCRF, Screen #, Subject Status, Entry Completed, Open manual queries, Open auto queries, Rand #, Sex, Screening Date, and Randomized. The table contains 20 rows of data, each representing a subject's progress through the study.

eCRF	Screen #	Subject Status	Entry Completed	Open manual queries	Open auto queries	Rand #	Sex	Screening Date	Randomized
Open eCRF	001-0080	Randomized	5 of 40	0	0	001-063	M	05-Mar-2026	05-Mar-2026
Open eCRF	001-0079	Randomized	2 of 40	0	0	001-062	M	04-Mar-2026	04-Mar-2026
Open eCRF	001-0077	Randomized	2 of 42	1	1	001-061	M	28-Feb-2026	28-Feb-2026
Open eCRF	001-0076	Randomized	5 of 43	0	3	001-060	M	23-Feb-2026	23-Feb-2026
Open eCRF	001-0074	Randomized	3 of 40	0	0	001-059	M	19-Feb-2026	19-Feb-2026
Open eCRF	001-0071	Randomized	2 of 40	0	2	001-058	M	11-Feb-2026	11-Feb-2026
Open eCRF	001-0070	Randomized	3 of 37	0	0	001-055		19-Jun-2025	19-Jun-2025
Open eCRF	001-0067	Randomized	2 of 40	0	2	001-054		02-Jun-2025	02-Jun-2025
Open eCRF	001-0066	Randomized	3 of 40	0	0	001-053	F	28-May-2025	28-May-2025
Open eCRF	001-0065	Randomized	7 of 40	0	0	001-052	M	27-May-2025	27-May-2025
Open eCRF	001-0064	Randomized	7 of 40	0	0	001-051	M	27-May-2025	27-May-2025
Open eCRF	001-0063	Randomized	4 of 40	0	0	001-050	M	27-May-2025	27-May-2025
Open eCRF	001-0062	Randomized	2 of 40	0	0	001-056	M	27-May-2025	27-May-2025
Open eCRF	001-0061	Randomized	3 of 40	0	0	001-048	M	14-May-2025	14-May-2025
Open eCRF	001-0060	Randomized	2 of 37	1	0	001-047	M	07-May-2025	07-May-2025
Open eCRF	001-0059	Randomized	5 of 42	0	0	001-049	M	01-Apr-2025	26-Mar-2025

Flex EDC: Integrated EDC with RTSM, RBM & ePRO for any study, any phase, any scale.

Flex EDC is an integrated Electronic Data Capture solution with built-in RTSM, RBM capabilities and ePRO/eCOA. It helps sponsors, CROs, and sites design, run, and monitor clinical trials faster – without adding extra vendors or interfaces.

Key Benefits

- Built for any trial portfolio – from early phase and pivotal studies to large observational programs, registries, and decentralized / hybrid trials
- From protocol to go-live in 3-10 weeks
- No-code Study Builder, reusable visit/CRF templates, predefined edit checks
- One unified platform instead of multiple tools
- Easy for sites and patients
- EDC, RTSM, RBM, ePRO/eCOA in a single validated environment – fewer integrations, fewer contracts, fewer points of failure
- Lower data management workload
- AI-assisted medical coding, automated checks and queries, smart error prediction
- Actionable oversight, not just data grids
- RBM dashboards with KRIs across site performance enabling informed decision-making on SDV percentage
- Intuitive UI, clear workflows, multilingual support – minimal training, better adherence

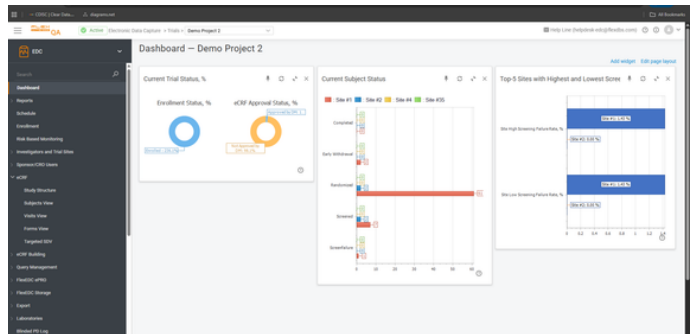


Electronic Data Capture

Module Overview

Full interconnection across all the parts of Flex Databases system:

- Get the data captured in EDC, analyzed in RBM, processed in CTMS, and finalized in TMF
- Have adverse reactions initiated in EDC and managed in Pharmacovigilance.



Study Design & Build

- Drag-and-drop design of forms, visits and schedules
- Support for complex, adaptive and decentralized designs (multi-arm, cohorts, hybrid / DCT setups)
- Controlled mid-study amendments with versioning and impact analysis

Data Capture & Data Management

- Browser-based entry with real-time validation
- Configurable edit checks, cross-form logic
- Advanced laboratory data handling and LIMS integration
- Full query lifecycle management and audit trail

Compliance, Security

- Designed to support ICH GCP E6(R2/R3), 21 CFR Part 11, GAMP 5, HIPAA, GDPR.
- Role-based access control, configurable electronic signatures, and complete audit trail
- Validated SDLC and data encryption in transit and at rest, with secure cloud / on-premises hosting options

Risk-Based Monitoring (RBM)

- Effective data analytics and reporting tools
- Risk-based monitoring (RBM) dashboards to help prioritize sites and focus on critical data and processes
- Configurable risk indicators and visual alerts to support timely decisions and targeted oversight

Patient-Facing (ePRO/eCOA)

- Web and mobile access for patients
- Configurable questionnaires and reminders
- Patient-reported data stored in the same database as site-entered data

Services & Implementation

- Portfolio- and program-level rollouts for Sponsors and CROs with global operations
- End-to-end study build and configuration, including randomization schemes and lab/LIMS workflows
- UAT and validation support with documentation and training for all user roles
- Assistance with migration from legacy EDC solutions and ongoing customer support