Flex Databases Platform
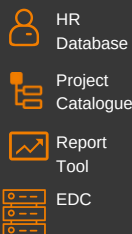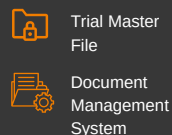
Unified eClinical platform for CRO, biotech, and pharma

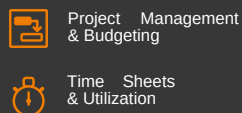**GENERAL**

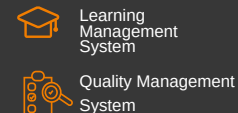- HR Database
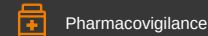- Project Catalogue
- Report Tool
- EDC

DOCUMENTS

- Trial Master File
- Document Management System

CTMS

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

PROJECT & FINANCE MANAGEMENT

- Project Management & Budgeting
- Time Sheets & Utilization

QUALITY & COMPLINCE

- Learning Management System
- Quality Management System

SAFETY

- 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
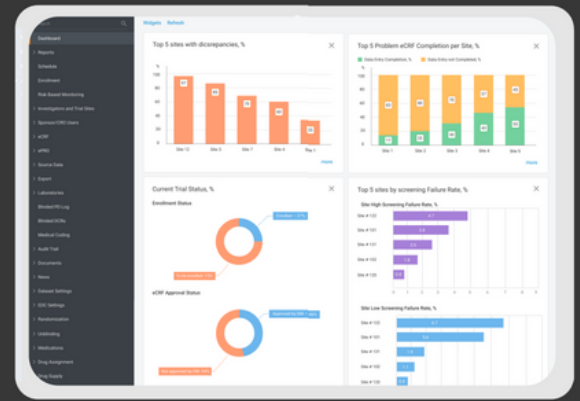
Some of our clients

Leading CROs, pharma, and biotech

Flex EDC – ensure fast capturing and reviewing data of your clinical studies in a user-friendly interface

Our Platform:

- EDC (Electronic Data Capture)
- EDC AI Medical Coding
- eCOA (ePRO and eConsent)
- RTSM Randomization
- RTSM Drug Supplies
- PACS Imaging
- RBQM Risk Based Monitoring

Trainings:

- Client training in system configuration for DM and Site users
- Client's Quality Management System setup assistance
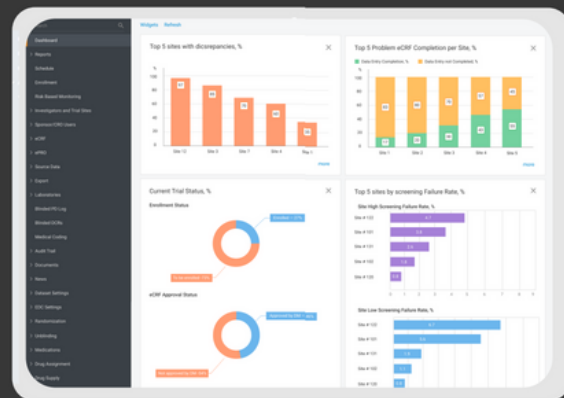- Validation assistance

Our Services:

- Study Build
- Project specific configuration
- Database Lock, Unlock and QC
- UAT support
- Data Validation
- Database archival
- Randomization / Medication lists development
- Custom reports / listings
- Data Exchange for Central Labs

Our Features:

- AI-Driven Medical Coding
- Study Builder with templates - no code approach
- Automated Query Management with auto-generation and bulk resolution using pre-configured templates, smart query tracking for faster issue resolution, and AI-driven error prediction with automatic data cleaning suggestions.
- Protocol deviations module: via Edit checks and 'Protocol Deviation' categorization in queries
- Different LNRs for different lab analytes within a single local lab form, also multiple ranges per Local Lab or per site
- Real-Time Study Monitoring & CRF Automation
- Risk Based Monitoring (RBQM) System for EDC - 26 performance parameters enabling study oversight, fraud detection, anomaly identification, trend analysis, and machine learning–driven pattern recognition.
- Full RTMS (including real-time Drug Supplies, expiration dates, lots prioritization and advanced adaptive Randomization for complex Phase III)
- SMS messages notifications

FLEX DATABASES

Flex EDC – ensure fast capturing and reviewing data of your clinical studies in a user-friendly interface

Create, manage and control your eCRFs

- Have a complete track of your study at one place
- Speed-up your study start-up timeline – only 3 weeks to set up Flex EDC for your trial
- Arrange fast and easy completion and check of your eCRFs
- Control all the visits and eCRF fulfillment in one screen – a convenient and straightforward semaphore system enables to have a glance at all patients' visits and eCRFs completion
- Use a fully validated and 21 CRF part 11 compliant system – Flex EDC is developed in compliance with all the requirements: GCP E6 R2, 21 CRF part 11, GAMP5, HIPAA, etc.

Minimize possible mistakes of sites and investigators

- Provide your sites and investigators with a separate system and an immediate data flow to your major platform
- Create mass queries in Flex EDC and use any templates you need
- Arrange automatic fulfilment of the fields with possibly calculated data, excluding any potential mistakes
- Let your investigators control visits with a calendar for every subject

Manage your stock and patient randomization with IWRS

- Save your time and money – IWRS is already a part of our Flex EDC: you will not be charged for it separately and always have access to the module
- Use one of 4 randomization types in accordance with your study design
- Randomize your patients by one click
- Control your stock and IMP distribution

Supply your patients with our ePRO

- Increase patient recruitment by simplifying patient's diaries fulfilment
- Have access to patient diaries in real-life time
- Prevent patient dropout by managing their outcomes in real time

Sprint through building your eCRFs

- An intuitive eCRF builder enables you to create forms in a few minutes
- Drag-and-drop approach for a simple eCRF building
- All the fields you might need are already in the system
- Online set-up of calculations and dates