

# Welcome to Flex Databases platform

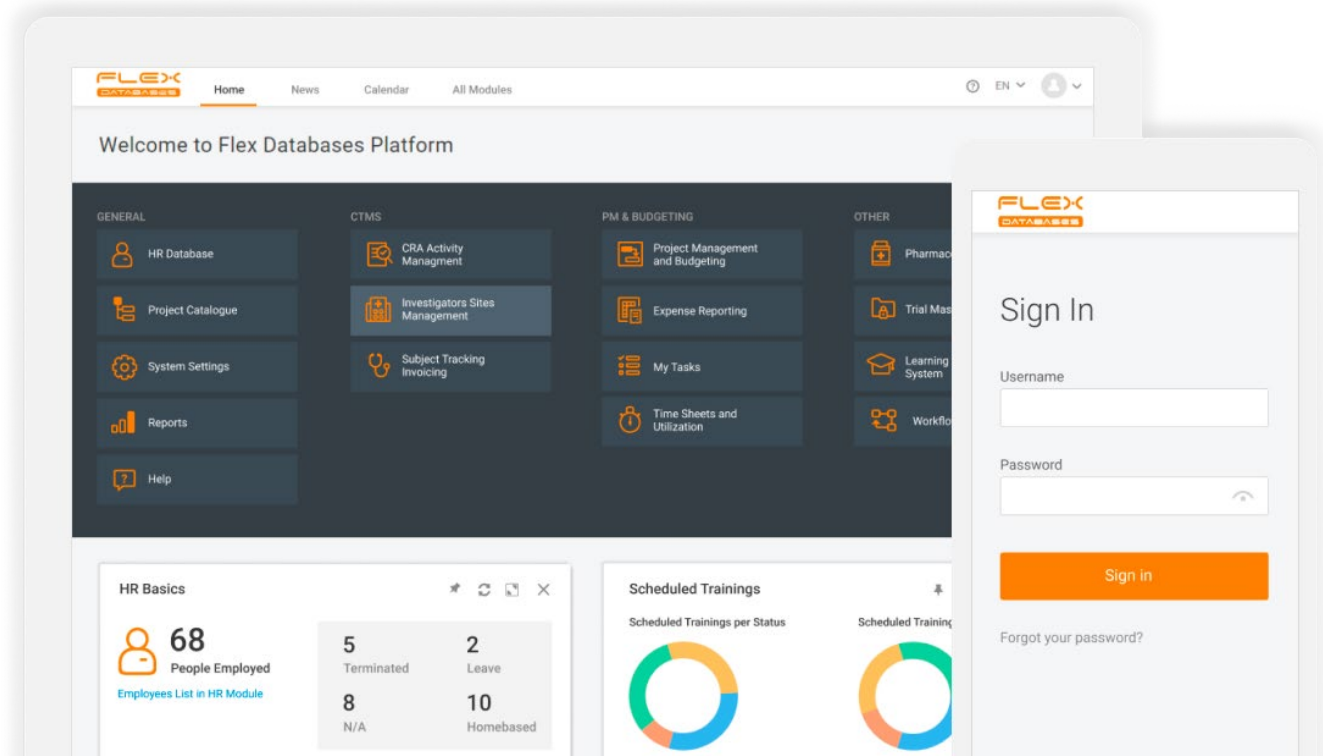
GENERAL	CTMS	PM & BUDGETING	OTHER
HR Database	CRA Activity Management	Project Management & Budgeting	Pharmacovigilance
Project Catalogue	Investigators & Sites Management	Expense Reporting	Trial Master File
Workflow Management	Subject Tracking & Invoicing	Time Sheets & Utilization	Learning Management System

Flex Databases is a software development company. We develop e-Clinical systems for CROs and pharmaceutical companies.

Our platform consists of 12 modules that cover every aspect of clinical trials, from project startup to pharmacovigilance. We offer both single modules and a unified solution to maintain all processes - you can cover all existing software needs with only one vendor.

All modules developed by Flex Databases are validated and compliant with 21 CFR Part 11 and other global regulations. We provide flexible and configurable baseline system versions with free updates, perform customizations and development for client-specific needs.

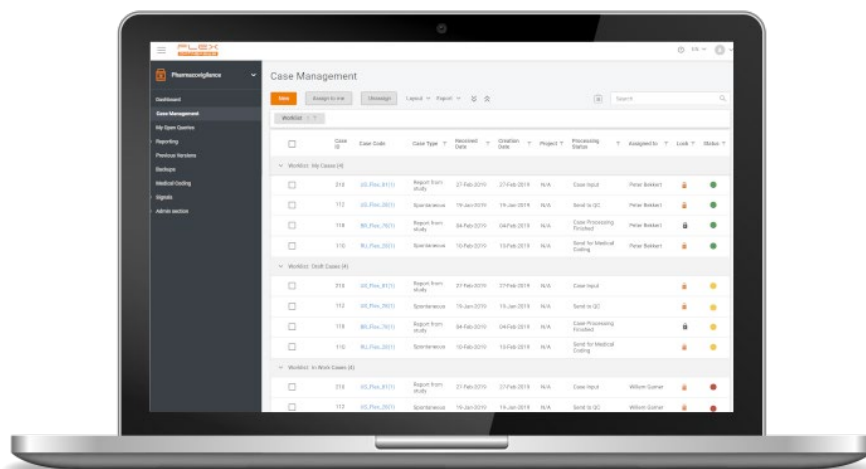
Unlike traditional e-Systems developer, Flex Databases provides a combination of flexibility, fair prices, and go-the-extra-mile service and support.





# Pharmacovigilance

Flex Databases Pharmacovigilance software is a secure and validated PV system which serves as a single point of entry, assessment and reporting of safety data. It's aligned with global regulations and provides more accurate information to authorities. Flex Databases PV software leverages your existing investments, helping you improve the efficiency of your work.



## Main features and advantages

- Managing all PV processes within one system
- E2B R2/R3 compliant XML export
- Built-in MedDRA coding tool with embedded automated search of SMQ terms by coded values and possibility of automatic coding
- Periodic reports constructor: line listings, summary tabulations, calendar
- Customizable workflow
- Automatic duplicate search
- Signal detection and management using modern qualitative and quantitative (statistical, machine learning, neural network) methods
- Automatic AEs data validation such as checks and queries
- Fully integrated Drug/Project Catalogue
- Data export in SAS, Excel, Word and PDF
- Queries management tool for overall control of queries reported by all users involved into PV processes
- Notifications to users about actions to be taken and approaching deadlines
- Data collection control in the right format within correct timelines
- Auto-narrative generation
- Support for CIOMS, generate CIOMS reports and/or local forms
- Follow-ups tracker
- Powerful data analysis tools (Information visualization, data reports and statistics)
- Possibility of multi-tenant access
- Multi-language support
- Pregnancy and Literature cases tracker
- Ad-hoc reporting tool for cross-project and cross-module reporting (graphs, widgets)