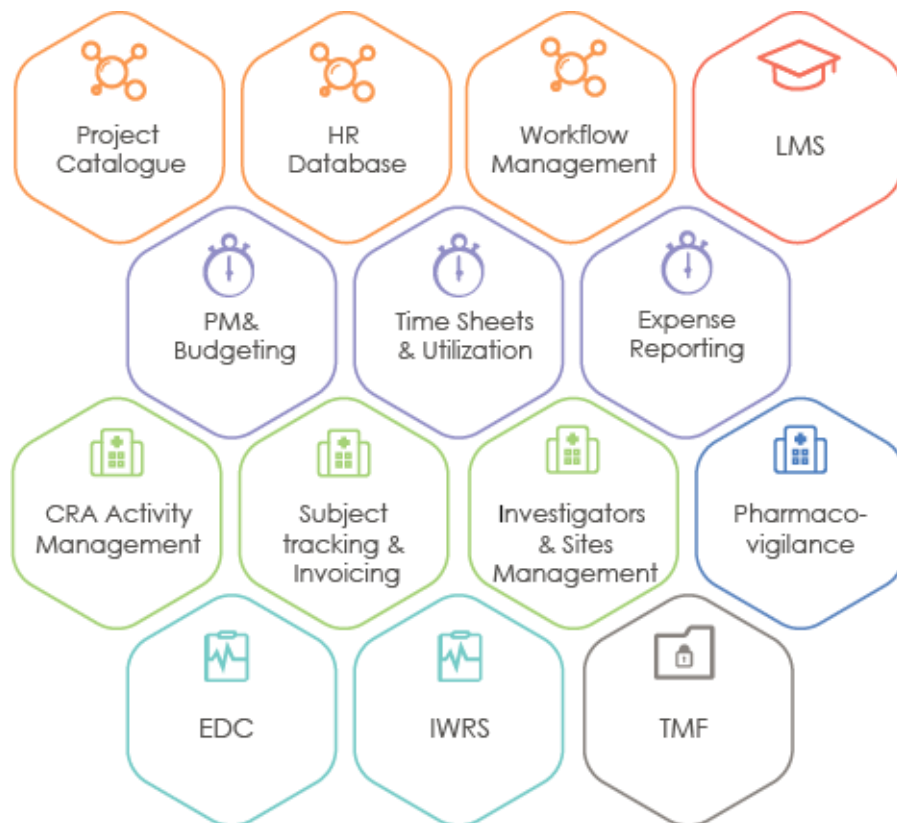


Flex Databases Modules Overview

Flex Databases is a company providing e-solutions for clinical trials. Software provided by Flex Databases helps making the processes of conducting clinical trials and managing pharma, biotech and CRO seamless and controlled. It means more effective data processing, less time required for managing data, avoiding mistakes in reports generation, endless reporting capabilities and KPI tracking.

Flex Databases platform is easily customizable, any client's requirement may be configured, it distinguishes us from many other companies. The range of modules offered by Flex Databases is very wide and covers all processes within R&D company. By choosing Flex Databases our clients win a solid, reliable IT vendor with fast feedback, flexible approach and constant client support with a focus on quality.



We offer a unique platform which allows combining traditional features related to management of clinical trials (CTMS, EDC&IWRS) with the functionality for running internal pharma companies and CRO processes as well as a capability to manage financial data, invoicing and expenses. All modules developed by Flex Databases are validated and 21 CFR Part 11 compliant.

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
- 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
- Follow-ups tracker
- Powerful data analysis tools (Information visualization, data reports and statistics)
- Possibility of multi-tenant access
- Multi-language support
- Pregnancy cases tracker

System supports you on every PV process step: what data, in what format and within what timelines should be filled in and reported.