Flex Databases Platform

Unified eClinical platform for CRO, biotech, and pharma

GENERAL

- eTMF
- EDC
- Workflow Management

CTMS

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

PM & BUDGETING

- Project Management & Budgeting
- Expense Reporting
- Time Sheets & Utilization

COMPLIANCE & SAFETY

- Learning Management System
- Quality Management System
- 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

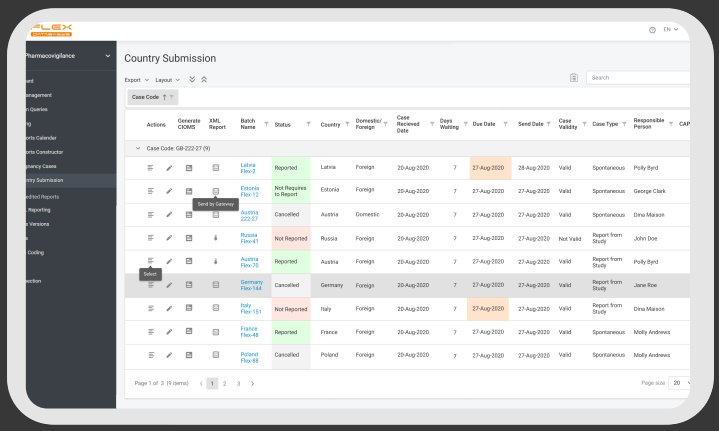
Leading CROs, pharma, and biotech

novo nordisk®
CMIC
FGK CLINICAL RESEARCH
Dr.Reddy's
ERGOMED
OPTIMAPHARM
WORLDWIDE CLINICAL TRIALS

FLEX DATABASES

Pharmacovigilance

Safety database with automated gateway for direct submissions to the authorities.



Drug pharmacovigilance. Medical device vigilance. Vaccine pharmacovigilance.

Manage full-cycle pharmacovigilance process with the system by utilizing the embedded, fully configurable workflow.

Communicate with partners and regulatory authorities directly via gateway.

Make reports in formats, required by regulatory authorities.

Data-informed decisions on drug safety profile

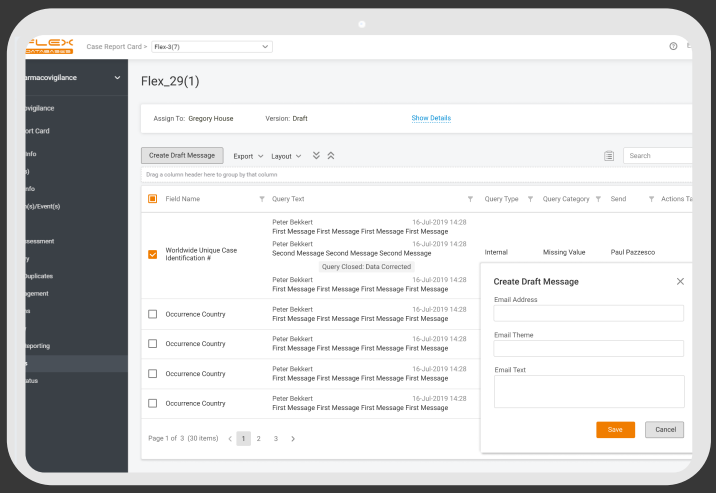
We leverage the latest technologies for advanced safety data analysis and evaluation.

Our reporting tool is designed to build reports based on any data point available in the system and provide instant data accessibility for further interpretation and actions.

FLEX DATABASES

Pharmacovigilance

Main Features



Advanced Safety Case Processing

- Configurable case processing workflow
- Direct gateway connections for case submissions
- Case version management with follow-ups and amendments
- Automatic duplicate search on configurable criteria
- Automatic validity check
- Queries management tool for all case data
- Multi-language capabilities
- Pregnancy and Literature cases tracker
- Auto-narrative generation on any template

MedDRA support

- Built-in MedDRA coding tool with a possibility of automatic coding
- Different MedDRA versions support

Reporting and submissions

- Periodic reports constructor: line listings, Cumulative and Summary tabulations
- CIOMS and MedWatch 3500A/3500 forms
- Multi-country submissions report

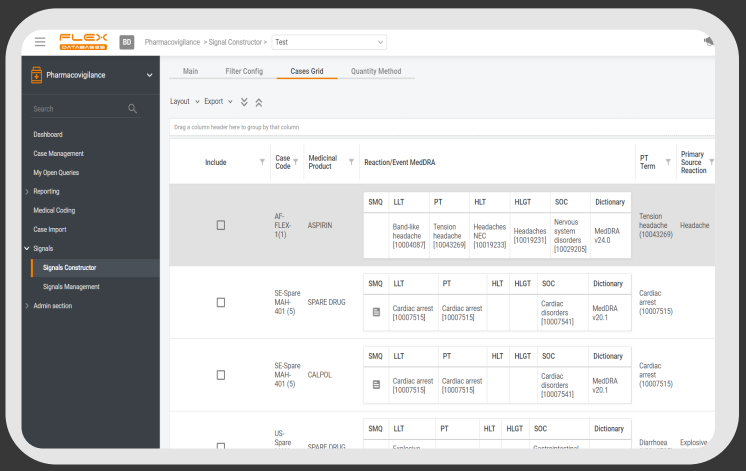
Data import & export

- E2B R3 XML import/export, both manual and automatic
- Data export in Excel, Word, XML, and PDF

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

Pharmacovigilance

Signal Management



Comprehensive signal management

- Validation, prioritization, assessment, and case series generation as a proof for a suspect signal

Unified and compliant system

- All safety processes in one PV management system. Validation documents and safe storage provided and covered for you

Flexible solution to support you scaling business and processes

- Configurable workflows and templates throughout the system. System is there to guide you and provide compliance, but not to limit your business workflows

In-depth quantitative and qualitative signal detection

- Disproportional analysis;
- Multi-item Gamma Poisson Shrinker (MGPS) scores;
- Empirical Bayesian Geometric Mean (EGBM) scores.

Complete transparency

in your safety data processing

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