



# 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



# Pharmacovigilance

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

Case Code	Batch Name	Status	Country	Domestic / Foreign	Case Received Date	Days Waiting	Due Date	Send Date	Case Validity	Case Type	Responsible Person	CAP
Case Code GB-202-27 (5)	Latvia P10-2	Reported	Latvia	Foreign	20-Aug-2020	7	27-Aug-2020	28-Aug-2020	Valid	Spontaneous	Polly Byrd	
	Latvia P10-12	Not Reported	Latvia	Foreign	20-Aug-2020	7	27-Aug-2020	27-Aug-2020	Valid	Spontaneous	George Clark	
	Austria P10-27	Cancelled	Austria	Domestic	20-Aug-2020	7	27-Aug-2020	27-Aug-2020	Valid	Spontaneous	Dina Mason	
	Russia P10-41	Not Reported	Russia	Foreign	20-Aug-2020	7	27-Aug-2020	27-Aug-2020	Not Valid	Report from Study	John Doe	
	Austria P10-70	Reported	Austria	Foreign	20-Aug-2020	7	27-Aug-2020	27-Aug-2020	Valid	Report from Study	Polly Byrd	
	Germany P10-144	Cancelled	Germany	Foreign	20-Aug-2020	7	27-Aug-2020	27-Aug-2020	Valid	Report from Study	Jane Doe	
	Italy P10-151	Not Reported	Italy	Foreign	20-Aug-2020	7	27-Aug-2020	27-Aug-2020	Valid	Report from Study	Dina Mason	
	France P10-48	Reported	France	Foreign	20-Aug-2020	7	27-Aug-2020	27-Aug-2020	Valid	Spontaneous	Molly Andrews	
	Poland P10-68	Cancelled	Poland	Foreign	20-Aug-2020	7	27-Aug-2020	27-Aug-2020	Valid	Spontaneous	Molly Andrews	

**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.

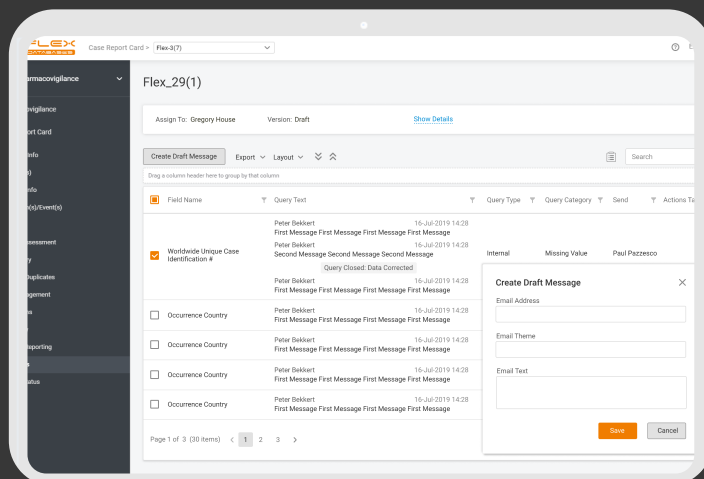
**Data-informed decisions on drug safety profile**

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.

# 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

### Data import & export

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

### 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

**Contact us to learn more about  
Flex Databases Platform:  
[contact@flexdatabases.com](mailto:contact@flexdatabases.com)**

# Pharmacovigilance Signal Management

The screenshot displays the 'Signal Constructor' interface within the Flex Databases Pharmacovigilance system. It features a sidebar with navigation options like Dashboard, Case Management, My Open Queries, Reporting, Medical Coding, Case Import, Signals, Signal Constructor, Signal Management, and Admin section. The main area shows a table of adverse events with columns for Include, Case Code, Medicinal Product, Reaction/Event MedDRA, PT Term, and Primary Source Reaction. The table lists several cases, including 'AF FLEX 1(1)' and 'SE Spare M44-401 (5)', with associated MedDRA codes and terms like 'Cardiac arrest' and 'Diarrhoea'.

Include	Case Code	Medicinal Product	Reaction/Event MedDRA	PT Term	Primary Source Reaction
<input type="checkbox"/>	AF FLEX 1(1)	ASPIRIN	SMQ LLT PT HLT HLGT SOC Dictionary	Tension headache (10043269)	Headache
<input type="checkbox"/>	SE Spare M44-401 (5)	SPARE DRUG	SMQ LLT PT HLT HLGT SOC Dictionary	Cardiac arrest (10007515)	Cardiac arrest (10007515)
<input type="checkbox"/>	SE Spare M44-401 (5)	CALPOL	SMQ LLT PT HLT HLGT SOC Dictionary	Cardiac arrest (10007515)	Cardiac arrest (10007515)
<input type="checkbox"/>	US Spare	COLEST FOL 10	SMQ LLT PT HLT HLGT SOC Dictionary	Diarrhoea	Explosive

## 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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