

Flex Databases

eClinical platform for CROs, biotech,
pharma, and academic research



CTMS

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

DOCUMENTS

- Trial Master File
- Document Management System
- Investigator Site File

EDC

- Electronic Data Capture
- Risk-Based Monitoring
- Randomization and Trial Supply Management
- Electronic Patient-Reported Outcome

PROJECT & FINANCE MANAGEMENT

- Project Management & Budgeting
- Time Sheets & Utilization

QUALITY & COMPLIANCE

- Learning Management System
- Quality Management System

SAFETY

- Pharmacovigilance

About Flex Databases

We develop a comprehensive clinical trial management solution since 2011.

- 15+ 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.

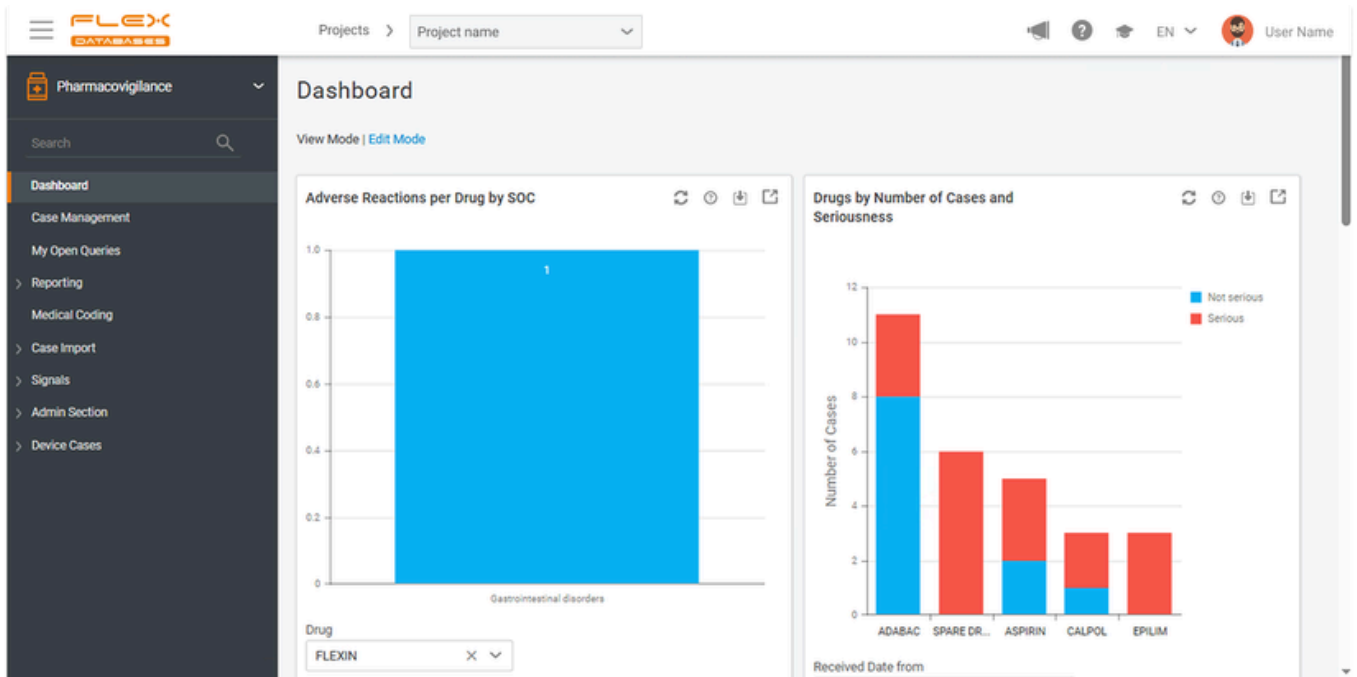
Some of our clients

Leading CROs, biotech, pharma, and academic research



Pharmacovigilance

Module Overview



Safety database and signal management for drugs, vaccines and medical devices – from intake to insight

Flex Pharmacovigilance is a unified safety platform that supports drug pharmacovigilance, medical device vigilance and vaccine safety in one validated system. It manages the full case lifecycle – from intake and triage to regulatory submissions and signal management – so safety teams can handle growing caseloads, stay compliant with changing E2B(R3) requirements, and make data-informed decisions on the safety profile of their products.

Why Flex?

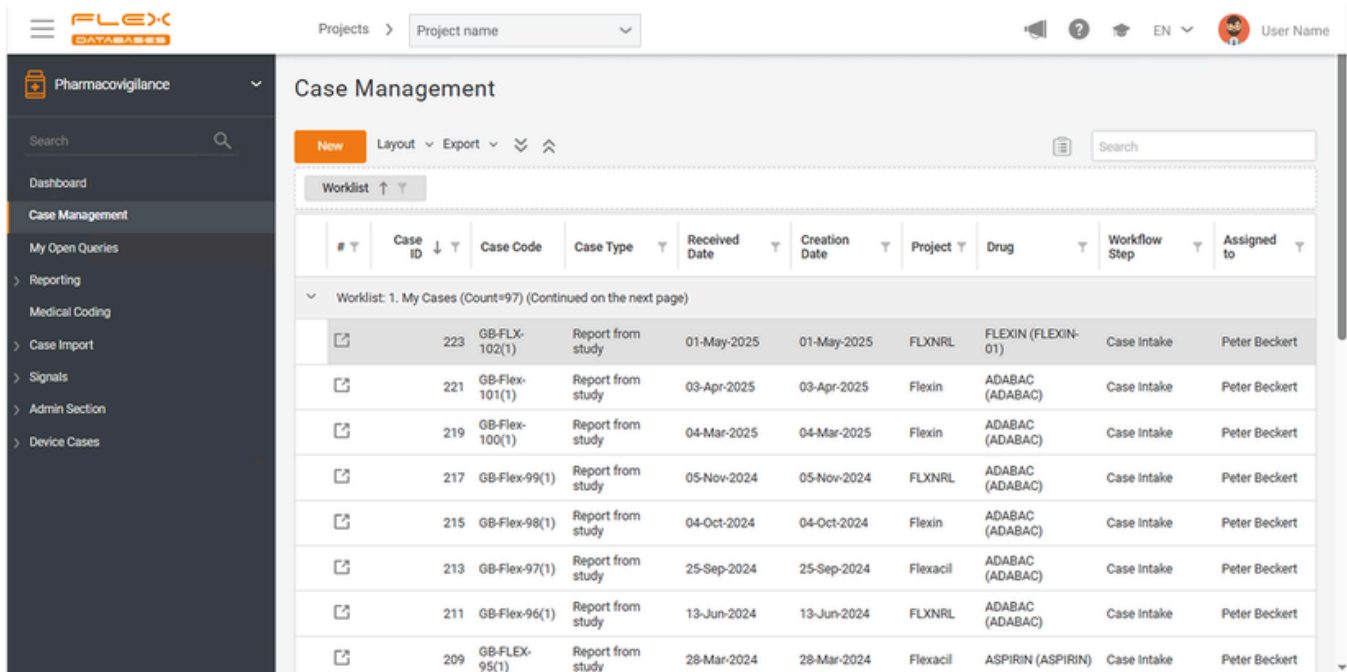
- End-to-end PV workflows in one system – intake, case processing, quality checks, submissions, follow-up and signal management on a single platform instead of scattered tools
- Built for global E2B(R3) compliance – automated gateway for direct case submissions and E2B(R3) import/export help you keep pace with EMA, FDA, and other authority requirements
- Designed for high case volumes – automation, configurable workflows, and duplicate checks reduce manual work and support sustainable case throughput as volumes grow
- From raw data to safety insights – advanced quantitative and qualitative signal detection, dashboards and reports let you see trends and support risk-benefit decisions



manage all in one

Pharmacovigilance

Module Overview



The screenshot displays the 'Case Management' module in the Flex Databases platform. The interface includes a sidebar with navigation options like 'Dashboard', 'Case Management', and 'Reporting'. The main area shows a table of cases with columns for Case ID, Case Code, Case Type, Received Date, Creation Date, Project, Drug, Workflow Step, and Assigned to. The table lists several cases, all of which are 'Report from study' and 'Case Intake'.

#	Case ID	Case Code	Case Type	Received Date	Creation Date	Project	Drug	Workflow Step	Assigned to
223	GB-FLX-102(1)	Report from study	01-May-2025	01-May-2025	FLXNRL	FLEXIN (FLEXIN-01)	Case Intake	Peter Beckert	
221	GB-Flex-101(1)	Report from study	03-Apr-2025	03-Apr-2025	Flexin	ADABAC (ADABAC)	Case Intake	Peter Beckert	
219	GB-Flex-100(1)	Report from study	04-Mar-2025	04-Mar-2025	Flexin	ADABAC (ADABAC)	Case Intake	Peter Beckert	
217	GB-Flex-99(1)	Report from study	05-Nov-2024	05-Nov-2024	FLXNRL	ADABAC (ADABAC)	Case Intake	Peter Beckert	
215	GB-Flex-98(1)	Report from study	04-Oct-2024	04-Oct-2024	Flexin	ADABAC (ADABAC)	Case Intake	Peter Beckert	
213	GB-Flex-97(1)	Report from study	25-Sep-2024	25-Sep-2024	Flexacil	ADABAC (ADABAC)	Case Intake	Peter Beckert	
211	GB-Flex-96(1)	Report from study	13-Jun-2024	13-Jun-2024	FLXNRL	ADABAC (ADABAC)	Case Intake	Peter Beckert	
209	GB-FLEX-95(1)	Report from study	28-Mar-2024	28-Mar-2024	Flexacil	ASPIRIN (ASPIRIN)	Case Intake	Peter Beckert	

Advanced Safety Case Processing

- Configurable case processing workflow covering intake, triage, data entry, coding, medical review, QA, reporting and archiving – tailored to your SOPs
- Direct gateway connections for electronic submissions to health authorities and partners, based on configurable reporting rules and schedules
- Case version management with support for follow-ups and amendments, preserving a full history of changes
- Automatic duplicate search using configurable criteria to prevent double-counting and data quality issues
- Automatic validity checks to ensure minimum criteria are met before cases move forward in the workflow
- Queries management for any case data field with tracking of questions and answers
- Auto-narrative generation based on configurable templates to speed up consistent case narratives while keeping medical reviewers in control



Pharmacovigilance

Module Overview

Projects > Project name

Submissions Tracker

To track submissions, add Submission Rules, reportable Drugs, or Projects in the Agency for Reporting settings section.

Case Code	Agency Short Name	Due Date (Agency)	Days Left (Agency)	Send Date (Agency)	Days Overdue	Status	Submission Type	Case Class	Submission Format	St M
Case Code: AO-Flex-2773(1)	SeAg	30-Jul-2025	8			Not reported	Initial	Other		Di
Case Code: AO-Flex-2774(1)	AZ	10-Jul-2025	0		12	Not reported	Initial	Other		Di
Case Code: AO-Flex-2779(1)	Akit	13-Jul-2025	0		9	Not reported	Initial	AR/ADR		Di
Case Code: AO-Flex-2784(1)	SAg	25-Jul-2025	3			Not reported	Initial	Other	XML R2, CIOMS, MedWatch	Vi

Data Import, Exchange & Dictionaries

- E2B(R3) and R2 XML import/export, both manual and automatic, to exchange ICSRs with authorities and partners
- Export of safety data to Excel, Word, XML, and PDF for local analysis, QC or sharing with stakeholders
- Built-in MedDRA and WHODrug coding tool with support for different MedDRA versions and options for automatic or assisted coding
- Version management to keep historical cases consistent when dictionaries are updated

Reporting & Regulatory Submissions

- Periodic report constructor – build line listings, cumulative and summary tabulations directly from data in the system
- Support for CIOMS and MedWatch 3500A/3500 forms and other standard formats used by regulators
- Multi-country submissions reports to see, at a glance, which cases and periodic reports are submitted, due or overdue per region
- Configurable reporting rules for expedited and periodic reporting to global health authorities (e.g. EudraVigilance, FDA FAERS) and partners
- Complete audit trail for case changes, submissions, acknowledgements and corrections



Pharmacovigilance

Module Overview

The screenshot shows the Flex Databases Pharmacovigilance Signal Card interface. The top navigation bar includes the Flex Databases logo, the breadcrumb 'Pharmacovigilance > Signal Card > Test(1)', and user information 'Peter Beckert'. The left sidebar lists the navigation menu: Pharmacovigilance, Signal Card, 1. General, 2. Case Series, 3. Validation, 4. Prioritization, 5. Reporting, 6. Evaluation, 7. Measures, 8. Actions, and Versions. The main content area is titled 'Test(1)' and contains a 'Step: Open' indicator, 'Change Date: 12-Oct-2022 15:56', and 'Assign to: Unassigned'. There are 'Save' and 'Cancel' buttons at the top right, and a 'Finish' button below the step information. A 'Workflow Scheme' link is also present. The 'General' section includes fields for 'Record Name *' (Test), 'Record Description', 'Reviewer', 'Active Substance Name', and 'Drug'. Below these is a section for 'MedDRA Terms for the Signal' with an 'Add Term' button and a table with columns: SMQ, LLT, PT, HLT, HLGT, SOC, and Dictionary. The table currently displays 'No data to display'.

Signal Detection & Risk Management

- Comprehensive signal management— validation, prioritization, assessment and case series generation as supporting evidence for potential signals
- In-depth quantitative and qualitative signal detection using disproportionality methods and structured medical review
- Built-in support for advanced metrics such as Multi-item Gamma Poisson Shrinker (MGPS) and Empirical Bayesian Geometric Mean (EBGM) scores to highlight product–event combinations that may require attention

Services & Implementation

- End-to-end implementation of the safety database, including gateway setup, configuration of workflows, and validation package delivery
- Migration from legacy PV systems or in-house databases with data mapping & reconciliation
- Training and ongoing support for safety operations, medical reviewers, QPPVs and affiliates

Unified, Compliant & Scalable

- All safety processes in one PV management system – case processing, reporting, signal management and documentation in a single validated environment
- Web-based architecture with role-based access, supporting internal teams and external partners with configurable permissions
- Designed to support ICH E2B(R3), GVP, 21 CFR Part 11, GDPR and other regional PV regulations, with full auditability of data and workflows
- Configurable workflows, templates and rule sets so the system can scale with your business and evolving regulatory requirements