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AI & DIGITAL

SafetyDrugs

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Manage drug safety with control, compliance, and traceability.



DIGITAL PRODUCTS

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Solution Brief

SafetyDrugs

SafetyDrugs is a pharmacovigilance software platform designed to support pharmaceutical companies and regulated organizations in the end-to-end management of drug safety processes..
The system enables organizations to collect, manage, analyze, and submit adverse event data in compliance with international pharmacovigilance standards.

The Challenge

Pharmaceutical organizations must manage large volumes of safety reports while complying with increasingly stringent international regulations.

Typical challenges include:

- Complex management of Individual Case Safety Reports (ICSRs)
- Timely submission of reports to regulatory authorities
- Need for auditability and operational traceability
- Risk of manual errors in case management processes
- Submission of safety reports supported by reliable data analysis

Without a specialized platform, pharmacovigilance processes become difficult to manage and expose organizations to compliance risks.

The Solution

SafetyDrugs is a pharmacovigilance database designed to manage the entire lifecycle of ICSRs and adverse events, from collection to submission to regulatory authorities.
The platform supports both clinical trial and post-marketing activities, enabling organizations to maintain control, compliance, and traceability across pharmacovigilance operations.

Key Features

- End-to-end ICSR management
- Case management and classification workflows
- Regulatory submission gateway
- Regulatory reporting and line listing
- Pharmacovigilance data analytics

Regulatory Compliance

SafetyDrugs supports major international standards including:

- ICH E2B (R3)
- Good Pharmacovigilance Practices (GVP)
- Good Clinical Practice (GCP)
- GDPR
- CFR 21 part 11

Business Impact

- Optimized pharmacovigilance processes
- Reduced manual errors
- Improved regulatory compliance
- Enhanced safety monitoring operations

Case Study

Pharmacovigilance Data Management

A mid-sized European pharmaceutical company needed to modernize its systems by implementing a pharmacovigilance safety database to manage the growing volume of adverse event reports more efficiently.

The Challenge

- Manual and fragmented case management
- Difficulty meeting regulatory submission timelines
- Lack of integration across information systems

The Solution

The organization implemented SafetyDrugs as a centralized platform for adverse event management.
The system enabled end-to-end ICSR lifecycle management, integrating customized case management workflows, regulatory submissions, and pharmacovigilance reporting to monitor product risk profiles more effectively.

Implementation

- **SafetyDrugs** platform configuration
- Migration of historical data
- Training for pharmacovigilance teams
- System validation



Results

- Improved case traceability
- Reduced ICSR processing times
- Simplified pharmacovigilance data analysis
- Greater compliance with regulatory requirements
- Improved data integrity and data security
- Increased protection during audits and regulatory inspections

Architecture

Architecture Overview

SafetyDrugs is a safety database designed for the management of Individual Case Safety Reports (ICSRs). The platform uses an architecture designed to ensure operational stability, data security, and regulatory compliance.

Core Layers

Data Import Management Layer

The system includes a selective import tool enabling incoming case triage, duplicate detection, and follow-up management.

Workflow & Case Management Layer

The platform supports structured pharmacovigilance case processing through configurable workflows, status transition alerts, compliance checks during workflows, and validation before submission.

Analytics & Reporting Layer

The system enables extraction of standard regulatory reports and submission to regulatory authorities (EMA, FDA, and MHRA) and partners through XML files compliant with ICH E2B (R3). The Business Intelligence module supports aggregated data analysis and signal detection based on disproportionality analysis indicators.

Security Layer

The platform supports two-factor authentication and encrypted data management.
Every database access and case modification is tracked through a complete audit trail.

Core Components

- Duplicate search
- Selective Import
- ICSR processing
- Reporting
- Gateway services
- Business Intelligence Data Analysis



Security & Operational Continuity

The platform is designed to ensure data security, integrity, auditability, and regulatory operational continuity.

Deployment

SafetyDrugs can be deployed in on-premises or SaaS environments, enabling organizations to choose the model best aligned with their security and governance requirements.

One Abacus.
Many Minds.
One Vision.

Discover how **SafetyDrugs** can support pharmacovigilance management across your organization.

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