Collibra

USE CASE

Rock solid data and AI governance for clinical safety and Pharmacovigilance

Building a defensible Pharmacovigilance (PV) drug safety and risk management plan (RMP) for a robust future of patient safety in life sciences.

Drug and treatment safety data is among the most regulated data in the world. For data security professionals, data demands on pharma and life sciences were already high. But the reality is they will get higher. Much higher.

Life Sciences regulatory agencies expect a complete, traceable record of Adverse Events (AEs): every governance decision and every downstream transformation of safety data, from source system to health authority submission. The consequences of compliance failures aren't theoretical: inspection findings, delayed approvals, financial penalties and eroded trust with regulators and patients are at real risk.

For many pharmaceutical companies, however, the governance of clinical safety and pharmacovigilance data remains fragmented. Where validated source systems like Argus may be controlled, everything that happens after data extraction isn't. That includes pivots, analysis files, aggregate reports, data sharing and safety governance decisions documented in meeting minutes. These actions are not as well documented, governed, sourced or retrievable for regulatory examination.

Where Pharma and Life Sciences organizations face real governance risk.

- **No formal global governance structure:** Safety governance is fragmented across regions, often with no enterprise-wide data governance, charter or RACI. Ownership and stewardship are inconsistent. And, in many cases, undefined.
- **Decisions buried in unstructured documents:** Safety governance councils document decisions and change rationale in meeting minutes stored as PDF files. Decision-making outcomes are manually recorded, segmented and difficult to reconstruct for audit.
- **Downstream data is ungoverned:** Data extracted from safety databases are routinely consumed, transformed and analyzed outside controlled environments (in Excel, pivot files, SharePoint, and email) with limited visibility into what changed, who approved it and why.
- **Audit trail and traceability are manually reconstructed:** Approvals and changes are not consistently captured in systems. When regulators ask for evidence, teams must piece together a trail from emails, spreadsheets and meeting notes; it's a process that is expensive, slow, error-prone and difficult to defend.
- **Cross-functional handoffs lack accountability:** Upstream controls across clinical, Electronic Data Capture (EDC), regulatory, vendor and partner data are unclear. Data flows downstream without consistent governance, documentation or approval records.
- **MedDRA version management is manual:** Product-to-preferred-term mappings are managed in Excel, with no automated change impact analysis, no version control and no audit trail for who mapped what and when.

You can't reconstruct an audit trail that never existed.
You can't govern downstream data without visibility and controls.

The gap between safety governance policy and safety governance reality in pharma and life sciences is a data traceability and accountability problem.

- No centralized inventory of datasets, systems, reports or external data sources
- Safety governance decisions stored as unstructured PDFs with no catalog or audit workflow
- No end-to-end lineage from source systems through transformations to aggregate reporting and associated reconciliations
- Inconsistent controls over data requests, approvals and downstream consumption
- No structured mechanism for mapping regulatory requirements to data, processes and evidence

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Collibra Life Sciences solution

- **Regulatory and compliance traceability:** Collibra maps regulatory requirements and policies to the data, processes, owners and supporting evidence behind them (including time-sensitive health authority communications) reducing manual investigation effort and improving inspection readiness.
- **Clinical Safety and Pharmacovigilance (CSPV) data and system catalog:** Collibra creates a centralized inventory of priority CSPV datasets, systems, reports and external data sources (with ownership, metadata, and business glossary definitions) establishing the discoverability and governance coverage that audit readiness requires.
- **Automated audit trail for safety governance decisions:** Collibra catalogs and audits safety governance group minutes and decision records, replacing manually maintained PDFs with a governed, searchable and version-controlled workflow.
- **End-to-end data lineage from source to regulatory submission:** Collibra traces priority aggregate reports from Argus and other validated source systems through every transformation, approval and downstream output, providing the impact analysis and audit evidence regulators expect which manual reconstruction cannot reliably deliver.
- **Governed MedDRA version control:** Collibra loads MedDRA releases as a controlled version, automates the derivation of new, updated and obsolete preferred terms, and maintains a complete audit trail for every product-to-preferred-term mapping, eliminating Excel-based manual processes and enabling CSPV CoE oversight at scale.
- **Controlled downstream data use:** Collibra standardizes data requests, approvals, change justification and cross-functional handoffs, enforcing consistent controls from clinical and EDC through to safety reporting, partner data exchange and regulatory submissions.
- **Unstructured safety document governance with Deasy Labs:** Safety governance minutes, case narratives, regulatory correspondence and audit files stored as PDFs and documents are surfaced, classified, and enriched with metadata, making previously ungoverned content part of the governed data estate for the first time.

Key outcomes

A trusted, traceable, audit-ready CSPV data foundation.

Collibra moves clinical safety and pharmacovigilance governance from fragmented, manual and reactive to centralized, automated and defensible. Every dataset is inventoried. Every decision is traced. Every downstream transformation is governed. You don't just experience better compliance. Collibra provides a safe, trusted, AI-ready platform for context and control, which is what pharmacovigilance actually requires.

Collibra + Deasy Labs

Extend governance to unstructured safety documents that Clinical Safety & Pharmacovigilance operations rely on: meeting minutes, audit files, case narratives and regulatory correspondence. Machine Learning (ML) and Natural Language Processing (NLP) surface governed content in document repositories where manual review is impractical, turning previously invisible safety records into cataloged, traceable, audit-ready assets.

Learn more:
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