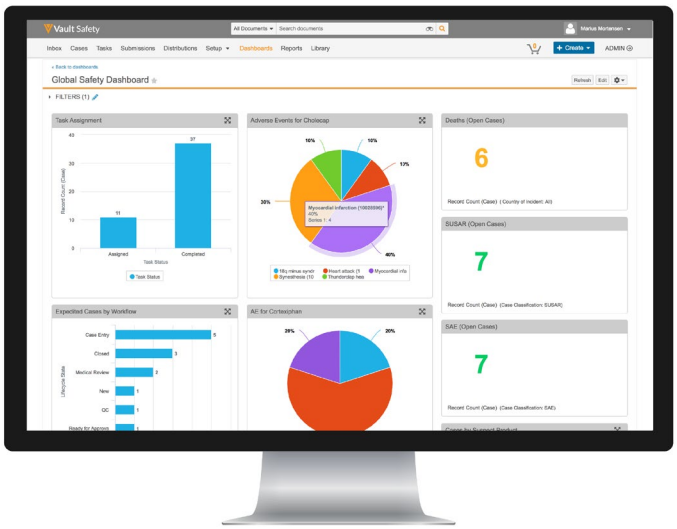
Veeva Vault Safety



Veeva Vault Safety is the only modern application for the collection, management, and real-time oversight of adverse events.

Outsourcing with legacy systems behind corporate firewalls has left organizations with insufficient visibility, fragmented data, and ineffective access to safety information.

With the ability to manage adverse event information and documentation in a single system, Vault Safety enables sponsors to make faster, more informed decisions and improve compliance throughout the product lifecycle.

Benefits

- **Improve oversight to reduce risk:** Real-time reports and dashboards and seamless collaboration with partners provides the necessary visibility for risk mitigation and compliance.
- **Streamline case management:** Gain efficiencies with a modern safety application built for today's regulations and best practices.
- **Stay current:** Access new capabilities and the latest regulatory requirements with easy and automatic upgrades.
- **Unified:** A single cloud platform for safety, clinical, regulatory, and quality eliminates silos and drives end-to-end safety processes.

Single source of truth

Improve collaboration, safety information and document quality. Sponsors and CROs leverage the same files across Vault Quality, Vault Clinical, Vault RIM, and Vault MedComms to author, review, and approve safety information and documentation.

Case processing

Streamline adverse event management with role-based assignment and routing of cases for follow-up and medical review, parallel case processing, and intelligent duplicate detection and follow-up.

Built on modern industry standards

Based on the latest International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Efficacy Guidelines (E2B R3, E2C R2, E2F) and International Organization for Standardization for the Identification of Medicinal Products (ISO IDMP) standards to align with Good Pharmacovigilance Practices (GVP) in the European Union.

Dictionary support

Supports the industry-standard World Health Organization Drug Dictionary (WHODrug C3), the Medical Dictionary for Regulatory Activities (MedDRA), and the Unified Code for Units of Measure (UCUM).

Health authority reporting and submissions

Provides full electronic submission of Individual Case Safety Reports (ICSR) and periodic reports throughout the entire product lifecycle.

Active monitoring and notifications

Active monitoring with automated notification of issue detection for Adverse Events of Special Interest (AESI), Designated Medical Event (DMI's), and Watchlists.

Interactive dashboards and reports

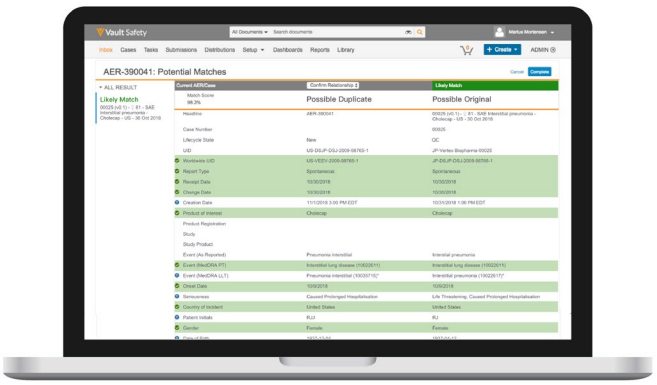
Drill down through real-time, interactive dashboards to narrow in on the exact source of processing and reporting delays. Take action directly from the reports to address hold-ups and stay on track for submission deadlines.

Configurable case management workflows

Automate and track cases with standard and configurable workflows. Provides assignment, routing, email notifications, escalation, and tracking of tasks for groups or individuals.

Part of the Veeva Development Cloud

A single cloud platform for safety, clinical, regulatory, and quality eliminates silos and drives end-to-end safety processes.



Vault Platform

Veeva Vault is the first cloud platform built from the ground up to meet the rigorous content management requirements of the life sciences industry. With a modern user experience and uniquely designed for both content and data on a single platform, organizations can seamlessly manage end-to-end processes.

The Vault Platform leverages the latest in cloud technology and is delivered and accessed through the web for greater ease-of-use. Hosted at SOC I Type II and ISO 27001 certified global data centers, every release is IQ and OQ qualified reducing the validation efforts.