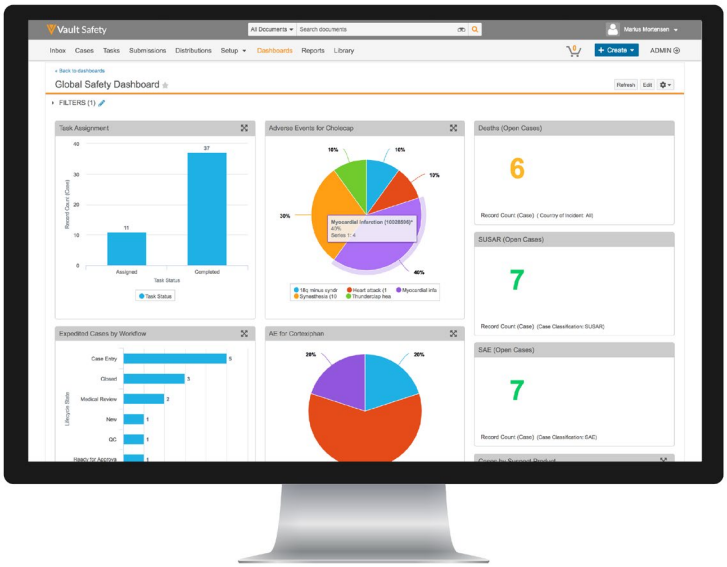
Veeva Safety

Veeva Safety is the only modern application for the collection, management, submission, 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, Veeva Safety enables sponsors to make faster, more informed decisions and improve compliance throughout the product lifecycle.



Benefits

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

Features

Global case management

Manage all adverse events in one solution while supporting regional privacy requirements, and easily process in parallel global / domestic initial and follow up cases.

Low touch case processing

Automate triaging, processing, and submissions of cases with advanced capabilities including auto-promotion, always serious lists, case qualification, expectedness, auto- calculation, pre-populations, and determined destinations.

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, E2B R2) 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 global standard World Health Organization Drug Dictionary (WHODrug C3), Medical Dictionary for Regulatory Activities (MedDRA), Unified Code for Units of Measure (UCUM), International Medical Device Regulators Forum (IMDRF), and regional requirements for Japan's Iyakuhinmei Data File (IDF) and Korea's Ministry of Food and Drug Safety (MFDS). Features automated drug code mapping via WHODrug Cross Reference Tool Japan and WHODrug Link Korea.

Health authority reporting and submissions

Provides configurable reporting rules to support electronic submission of Individual Case Safety Reports (ICSR) and periodic reports to global health authorities and partners.

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 and reports to view and track data such as case processing efficiency and ensure timely submissions.

Configurable case management workflows

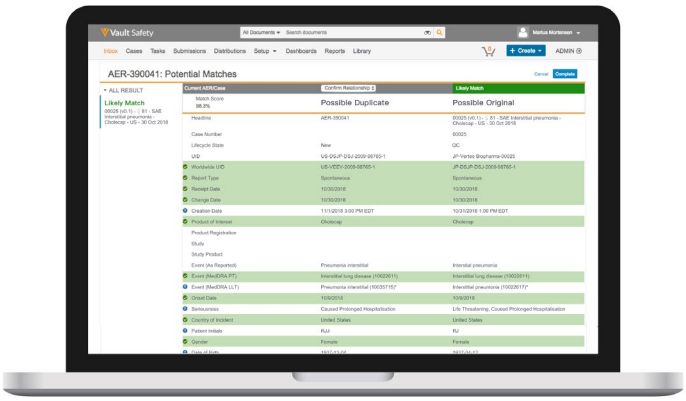
Automate and track cases with standard and configurable workflows. Provides assignment, routing, email notifications, escalation, and tracking of tasks for groups or individuals.

Literature management

Streamline literature review processes with bulk intake of literature references, reducing manual effort and speeding the time to identify possible ICSRs and safety signals. Seamlessly transfer ICSR data from a literature article to the Veeva Safety inbox for case processing.

Part of the Veeva Development Cloud

Eliminate silos and drive end-to-end safety processes with a single cloud platform for safety, clinical, regulatory, and quality.



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.

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