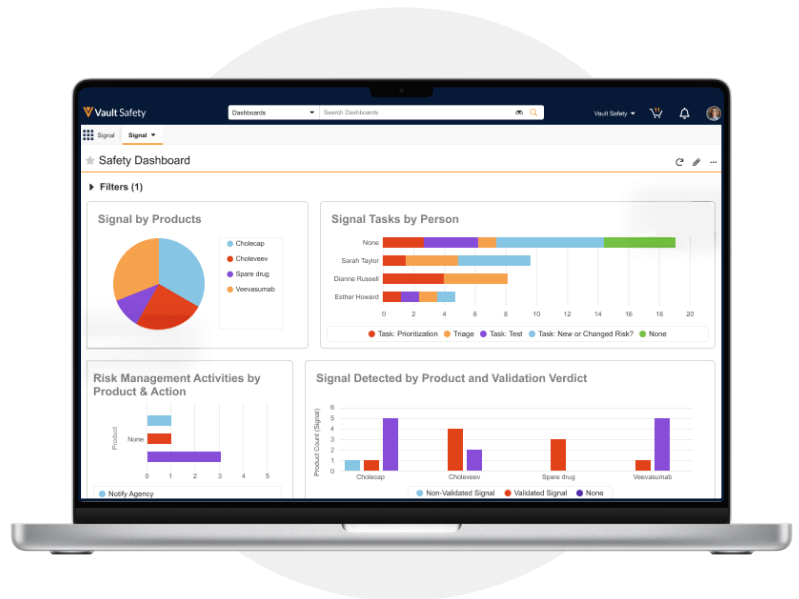


Seamlessly Manage Signals from Detection through Evaluation

Veeva Safety Signal provides signal detection, analysis, and management. Automate or perform ad hoc analysis using industry-standard methods on Veeva Safety case data and common data sources such as FAERS, VAERS, and EVDAS.

With automatic daily transfer of safety data from Veeva Safety to Veeva Safety Signal, safety teams eliminate complex ETL processes while gaining faster and more reliable insights.

Veeva Safety Signal is part of Veeva Safety, operating as a unified safety solution on a single cloud platform to maximize operational efficiencies and improve patient safety.



Business Benefits

Faster Signal Detection

Accelerate signal identification with automated analysis and flexibility to start signal review—in parallel—during case processing.

Streamlined Compliance

Full visibility and traceability from signal identification to recommended actions and outcome tracking.

Greater Business Alignment

Configurable workflows to align signal management with business processes while meeting compliance requirements.

End-to-end Signal Management

Manage signals from detection through evaluation with integrated documentation management for investigations.

Features

- ✔ **Daily Data Refresh**

All Veeva Safety data, including all case versions, is automatically imported nightly into Veeva Safety Signal and shares a common data model.
- ✔ **Alerts**

Initiate and configure business rules to automatically identify potential signals based on the results of calculations.
- ✔ **Integrated Documentation Management**

Seamlessly document signal-related activities, such as investigations, for traceability and to reduce risk and improve inspection-readiness.
- ✔ **Powerful OLAP Database**

A high-performance database optimized for complex queries on billions of rows, enabling faster and more efficient execution of detailed queries and calculations.
- ✔ **Case Series**

Drill down into a case series behind each Signal Calculation to explore the case series in Veeva Safety Workbench Dashboards and Veeva Safety Workbench Reports.
- ✔ **Application Validation**

All elements of infrastructure qualification (IQ) and operational qualification (OQ) are performed and documented for each major release. A sandbox/test environment and user acceptance testing (UAT) scripts are also provided that can be leveraged and adapted for performance qualification (PQ).
- ✔ **Data Sources**

Automatically brings together data and de-duplicates adverse events from multiple sources including FAERS, VAERS, EVDAS, and Veeva Safety.
- ✔ **Configurable Workflows**

Easily configure workflows to align with your business processes, automatically routing signal management activities or recommended mitigation actions to a specific person or team. Manage EMA GVP Module IX compliance.
- ✔ **Part of Veeva Development Cloud**

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

Out-of-the-box disproportionality calculations, such as EBGm with stratification, and case counts with fully configurable filtering. Perform calculations at MedDRA PT level or MedDRA Query level and create advanced subgroups. New calculations with results permanently can be stored in Veeva Safety.
- ✔ **Unified with Veeva Safety**

Directly integrate signal individual case reviews into safety case processing to create a unified signal detection process.