

PRODUCT SHEET

Veeva Safety Suite

Safety Suite of applications operate as a unified pharmacovigilance system on a single cloud platform to maximize operational efficiencies and improve patient safety.

Safety applications share a common data model which enables the end-to-end management of safety processes.

Veeva Safety is a global safety case intake, processing, and reporting system.

Veeva SafetyDocs manages safety-related content and processes including the pharmacovigilance master file, pharmacovigilance agreements, risk management plans and risk minimization measures, aggregate reports, and safety signal investigations.

Veeva Safety Workbench is an advanced reporting tool designed for handling large volumes of data and complex analyses.

Veeva Safety Signal is for signal detection using statistical methods on data from Veeva Safety and standard industry sources. Signal detection activities can be tracked and automated using alerts and workflows.

| PRODUCT | ANNOUNCED | STATUS | CUSTOMERS |
|-------------------------------|-----------|--------|-----------|
| Veeva Safety | 2019 | Mature | 51–100 |
| Veeva SafetyDocs | 2019 | Mature | 11–50 |
| Veeva Safety Workbench | 2023 | Early | 1–10 |
| Veeva Safety Signal | 2023 | Early | 1–10 |

PRODUCT SHEET

Veeva Safety

Safety is a modern individual case safety report (ICSR) management system that manages the intake, processing, and submission of adverse events for clinical and post-marketed products.

Within one system, sponsors and CROs process and manage global and domestic adverse events for drug, biologic, vaccine, device, and combination products. Built-in gateway connections and reporting rules streamline submissions to health authorities and distributions to partners.

Central coding dictionary management automates semi-annual MedDRA, WHODrug, and EDQM updates.

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|----------------------|------------------------------------------------------------------------------------------------|
| Announced | 2019 |
| Status | Mature |
| Customer type | Enterprise Pharma, Biotech, CRO |
| Customers | 51–100 |
| Platform | Veeva Vault |
| Integrations | Lives with SafetyDocs Connected with Clinical Operations, EDC, RIM, Quality, and MedInquiry |

PRODUCT SHEET

Veeva SafetyDocs

SafetyDocs manages pharmacovigilance-related content and processes. It provides solutions for the management of pharmacovigilance system master files (PSMF), pharmacovigilance agreements (PVAs), risk management plans (RMPs) and additional risk minimization measures (aRMMs), aggregate reports, and safety signal investigations.

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|----------------------|---------------------------------|
| Announced | 2019 |
| Status | Mature |
| Customer type | Enterprise Pharma, Biotech, CRO |
| Customers | 11–50 |
| Platform | Veeva Vault |
| Integrations | Lives with Safety |

PRODUCT SHEET

Veeva Safety Workbench

Safety Workbench is a reporting and analytics application that requires Veeva Safety. It is powered by Amazon Redshift and reloads the full Safety dataset nightly in a fast, consistent, and reliable way. With no complex ETL processes to manage, implementations can be completed within three months.

With over 100 standard periodic and operational reports available, users can run, extend, and dynamically filter these reports to meet compliance and operational oversight needs.

Ad-hoc reports and dashboards provide the flexibility to generate complex formats, outputs, and deep analytics insights.

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| Announced | 2023 |
| Status | Early |
| Customer type | Enterprise Pharma |
| Customers | 1–10 |
| Platform | Veeva Vault |
| Integrations | Requires Veeva Safety |

PRODUCT SHEET

Veeva Safety Signal

Safety Signal is a signal detection solution that requires Veeva Safety. It is powered by Amazon Redshift and reloads the full Safety dataset nightly in a fast, consistent, and reliable way. Common data sources such as FAERS, VAERS, and EVDAS are curated and loaded regularly.

Users can schedule or perform ad-hoc signal calculations using industry-standard disproportionality methods to detect, assess, and manage potential safety signals. Configurable alerts and automated workflows help prioritize the review of statistically significant findings.

Signal detection can also be configured directly within Veeva Safety during case processing to generate alerts when cases meet defined key criteria.

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| Announced | 2023 |
| Status | Early |
| Customer type | Enterprise Pharma |
| Customers | 1–10 |
| Platform | Veeva Vault |
| Integrations | Requires Veeva Safety |