Veeva Vault Safety — 23R2 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in the Vault Safety Suite 23R2 release that may affect a customer's Vault. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements. The RIA serves as an early preview of the Validation Impact Assessment (VIA). Once the VIA is available on Veeva Docs, refer to it for more detailed validation information.

This feature list is subject to change prior to the 23R2 release. We will begin tracking changes on June 27, 2023.

Revison Date:	August 4, 2023
VIA Availability Date:	July 21, 2023
Vault Safety Help	For detailed feature descriptions, refer to the product release notes, which will be available on Vault Safety Help on July 10, 2023.
Vault Platform RIA	This document does not include changes introduced as part of the Vault Platform release. See the Vault Release Impact Assessment and consult Veeva Docs for Vault Platform validation details.
Feature:	Name of the feature introduced in 23R2
GxP Risk:	GxP risk analysis takes into account data integrity, security, and confidentiality assuming the feature is turned on (either automatically or via configuration). Veeva performs validation testing on all High and Medium GxP risk items.
High	May affect security, patient confidentiality, application areas that support GxP functions (audit trails, eSignature, etc.) or other ERES controls data
Medium	May affect core application functions (workflows, revision history, etc.)
Low	May affect metadata/notifications
N/A	The feature is a minor UI enhancement and not a functional change. The feature has no validation impact.
Enablement Setting:	Indicates whether the feature is available automatically, requires some configuration, or must be enabled by Veeva Support
Auto-On	This feature is available automatically. Note that in some cases, an Auto-on feature is dependent on another feature that must be enabled or configured.
Config	This feature requires configuration by an Admin.
Admin Checkbox	An Admin must use a checkbox or field in the Admin area to make this feature available.
Support	This feature must be enabled by Veeva Support.
Default Impact:	Impact to business users and processes at Day 1 if no configuration occurs
Visible to All Users	Automatically on and visible to both Admins and end users
Visible to Admins Only	Only visible to Admins, or it requires configuration by an Admin before it is available to end users
None	Not visible in Vault unless enabled by Support

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Clinical Trials: Blinded Field and Product Reported Field Updates	High	Auto-On	Visible to All Users	With this release, for Clinical Trial Cases, Vault Safety automatically updates the Case-level Blinded field when all Study Products are unblinded. In addition, the Study Product (Reported) field is automatically populated when non-blinded Study Products are added to Cases.
Safety	DSUR and PBRER List All Suspect Products	High	Auto-On	Visible to All Users	With this release, all suspect Case Products are listed on the DSUR and PBRER Interval Line Listings of Serious Adverse Reactions and List of Subjects Who Died During Reporting Period.
Safety	FDA MedWatch 3500A Support for OTC and Additional Device Fields	High	Auto-On	Visible to All Users	With this release, Vault Safety supports more mappings for Device-specific fields and Combination Product scenarios when exporting FDA MedWatch 3500A forms.
Safety	OTC Carton Attachment Export for FDA E2B(R2)	High	Auto-On	Visible to All Users	With this release, OTC Carton images can be included in FDA ESG Submissions for Cases with OTC Products.
Safety	PMDA Local Case Processing Automations	High	Auto-On	Visible to All Users	With this release, reportable Japanese Product Registrations and Assessments are automatically populated based on Case Product selection.
Safety	DSUR and PBRER Drug Role Filtering	High	Configuration	Visible to Admins Only	With this release, DSUR and PBRER reports offer a Drug Roles to Include parameter, which affects the Interval Line Listings of Serious Adverse Reactions, the List of Subjects Who Died During the Reporting Period, and the Cumulative Tabulations of Serious Adverse Reactions and Serious Adverse Events.
Safety	Non-E2B Case Identifiers Entry and Duplicate Search	High	Configuration	Visible to Admins Only	With this release, Vault Safety enhances Case Identifier capabilities to improve duplicate search.
Safety	PMDA Submission Rule Parameter Updates	High	Configuration	Visible to Admins Only	This release includes new and updated PMDA Rule Parameters to support more efficient Case processing.
Safety	Study Product Expectedness	High	Configuration	Visible to Admins Only	This release includes multiple improvements to Clinical Trial Study Case Expectedness calculations.
Safety	DSUR and PBRER Investigational Product Causality	High	Admin Checkbox	Visible to Admins Only	With this release, Vault Safety includes the option to consider only Assessment Results related to Investigational, Placebo, Active Comparator, and Blinded Study Products in the Serious Adverse Reaction reports for the DSUR and PBRER.
Safety	IMDRF on FDA MedWatch 3500A	High	Admin Checkbox	Visible to Admins Only	With this release, Admins can configure the FDA MedWatch 3500A to export IMDRF Codes instead of FDA Device Codes.
Safety	Logically Delete Non-Submittable Transmissions on Subsequent Evaluation	High	Admin Checkbox	Visible to Admins Only	With this release, the Vault Safety reporting rules engine reevaluates reporting obligations on all Case data modifications, updating previously created Transmission Due Dates and including only Transmissions that meet reporting obligations.
Safety	One Last Time Reporting for Reportability Changes	High	Admin Checkbox	Visible to Admins Only	With this release, One Last Time Transmission generation is extended for reportability changes, such as changes to Case Product, Drug Role, or Study, for all reporting destinations, regardless of rule set configuration.
Safety	Gateway Connection IP Management	High	Support	None	With this release, Admins can manage the IP list for Gateway Connections. In addition, Vault Safety now supports more legacy features when setting up AS2 Gateways and offers enhanced troubleshooting.
Safety	Upgrade/Downgrade Transmission State Evaluation	High	Support	None	With this release, Vault Safety includes an option to ignore Transmission lifecycle states when evaluating upgrade and downgrade reporting for specific destinations.

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Safety	Case Compare Limit Increase	Medium	Auto-On	Visible to All Users	When creating a Follow-up Case or merging to an In-flight Case, Vault Safety now supports a maximum of 10,000 records for up to three (3) objects and 500 records for the remaining objects on Case Compare.
Safety	Domestic Local Awareness Date Synchronization	Medium	Auto-On	Visible to All Users	With this release, the Local Awareness Date on Domestic Localized Cases is now populated with the New Info Date from Global Cases.
Safety	Enhanced Product Matching Support for Intake	Medium	Auto-On	Visible to All Users	This release introduces enhanced Product matching when using the Intake API (JSON).
Safety	Fast Verify for Imported Inbox Items	Medium	Auto-On	Visible to All Users	With this release, Vault Safety validates Inbox Item data after importing a Case to Inbox Item through E2B or API integration.
Safety	Smart MedDRA Coding on Import	Medium	Auto-On	Visible to All Users	With this release, Smart MedDRA Coding extends to E2B and JSON import for Inbox Item creation and facilitates Automated Case Promotion. *Auto-on in Vaults with Smart MedDRA Coding enabled.
Safety	Safety Rule Set Config Report	Medium	Auto-On	Visible to Admins Only	With this release, Admins can export a configuration report for Reporting Rules and Safety Rulesets.
Safety	Aggregate Report Interval Case Listing	Medium	Configuration	Visible to Admins Only	With this release, Vault Safety provides the ability to view a list of all Cases included in the interval reporting period for Aggregate Reports.
Safety	Asynchronous Activity Indicators - Validation Results	Medium	Configuration	Visible to Admins Only	This release includes UI improvements around communicating the progress of generating validation results.
Safety	Automated Case Promotion Action	Medium	Configuration	Visible to Admins Only	This release expands Automated Case Promotion availability with both a user action and an entry action.
Safety	Company Product Match Verification	Medium	Configuration	Visible to Admins Only	With this release, Vault Safety supports Generic Product matching and improves general Product matching accuracy by verifying against the Product Registration library.
Safety	Faster Company Product Selection on Inbox Item	Medium	Configuration	Visible to Admins Only	This release streamlines the Product coding process during intake.
Safety	Multi-Product Selector for Study Products on Inbox Item	Medium	Configuration	Visible to Admins Only	With this release, Vault Safety supports adding multiple Study Products to Inbox Items in one action.
Safety	New Substance Name Field in Product Library	Medium	Configuration	Visible to Admins Only	To match E2B guidance, the Vault Safety Product Library includes a new Substance Name field that supports up to 250 characters.
Safety	PMDA Local Receipt Date Overrides	Medium	Configuration	Visible to Admins Only	This release includes multiple features for recording New Info Dates and Receipt Dates on Localized Cases and including them on PMDA Submissions.
Safety	PMDA Special Report Classification for Case Processing	Medium	Configuration	Visible to Admins Only	Vault Safety now supports PMDA Special Report Classification for Case Processing, including promoting values set on Inbox Items to Cases, Follow-up Cases, and In-flight Cases.
Safety	Simplified Case Access Group Security Setup	Medium	Configuration	Visible to Admins Only	This release optimizes matching logic for Case Access Group security and includes a Country field on User Access Group Assignment records to make setup more flexible.
Safety	Auto-Generate Serious and Non-Serious Assessments	Medium	Admin Checkbox	Visible to Admins Only	In this release, Vault Safety supports automatic generation of Assessments, Assessment Expectedness, and Assessment Results for both serious and non-serious Adverse Events.

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Safety	Study Site Reporter on Inbox Item	Medium	Support	None	Admins can now configure Study Contacts for use as Site Reporters during the initial intake of Inbox Item Study Cases.
Safety	Clear Radio Button Selection for Submittable Fields	Low	Configuration	Visible to Admins Only	With this release, Vault Safety supports clearing radio button selections on submittable fields.
Safety	Product Masking Selection for Study Products	Low	Configuration	Visible to Admins Only	With this release, Blinded field values for Case Study Products, Studies, and Study Arms are now consistently Open Label, Unblinded, and Blinded.
Safety	Rule Engine Destination Evaluation Log	Low	Configuration	Visible to Admins Only	With this release, Vault Safety logs Destinations that were evaluated as part of Evaluate Reporting Obligations to enhance transparency around Destinations that were evaluated, but did not qualify, for a reporting rule.
Safety	Enhanced Eligible Products Selection for Cross Reporting Enablement Update	N/A	Auto-On	Visible to All Users	With this release, the Enhanced Eligible Products Selection for Cross Reporting feature is Auto-On. This feature was originally introduced with Support-enablement.
Safety	Manual Transmission Creation Automation	N/A	Auto-On	Visible to All Users	With this release, Vault Safety maps more Transmission Profile fields to manually created Transmission records.
Safety	Parameter Driven Assessment Selection for Rules Engine Enablement Update	N/A	Auto-On	Visible to All Users	With this release, the Parameter Driven Assessment Selection for Rules Engine feature is Auto-On. This feature was originally introduced with Support-enablement.
Safety	Prioritize Seriousness for Downgrades	N/A	Auto-On	Visible to All Users	This release enhances Most Conservative Product evaluations for Downgrade and Upgrade reports.
Safety	All Product Types Available for FDA 3500A and CIOMS I Generation Enablement Update	N/A	Configuration	Visible to Admins Only	With this release, the All Product Types Available for FDA 3500A and CIOMS I Generation feature is Configuration-enablement. This feature was originally introduced in 23R1 with Support-enablement.
Safety	Custom Rulesets and Rules Configuration	N/A	Configuration	Visible to Admins Only	Vault Owners can now configure custom Reporting Rule Sets and Rules for global agencies and trading partners.
Safety	External E2B+ Builder SDK Event Type	N/A	Configuration	Visible to Admins Only	With this release, the Vault Safety Java SDK provides the E2BOutboundEventType attribute, which indicates whether request types are "Regenerate" or "Submit".
Safety	Generate Assessments Record Action Enablement Update	N/A	Configuration	Visible to Admins Only	With this release, the Generate Assessments Record Action feature is Configuration-enablement. This feature was originally introduced in 23R1 with Support-enablement.
Safety	Full Case Data Import to Inbox Item Through API	N/A	Auto-On	None	With this release, the public JSON Intake API now supports the import of all Case data to Inbox Items.
Safety, SafetyDocs	23R2 Data Model Changes	N/A	Auto-On	Visible to Admins Only	We've updated the Vault Safety data model to better support evolving needs and new functionality.
SafetyDocs	Aggregate Report Authoring	Medium	Configuration	Visible to Admins Only	This release introduces Aggregate Report authoring.
SafetyDocs	PSMF Automated Vault Report Annexes	Medium	Configuration	Visible to Admins Only	With this release, Vault SafetyDocs enhances PSMF Annex generation.
SafetyDocs	PSMF Periodic Review	Medium	Configuration	Visible to Admins Only	Vault SafetyDocs can now automatically trigger a periodic review of PSMF Documents
SafetyDocs	PSMF Version Binding	Medium	Configuration	Visible to Admins Only	With this release, Vault SafetyDocs automatically selects the correct PSMF document version when starting a PSMF review workflow for PSMF Binders.
SafetyDocs	Signal Management	Medium	Configuration	Visible to Admins Only	With this release, customers can perform Signal Management activities as part of the SafetyDocs application.

Change Log		
This feature list is subject to change prior to the 23R2 release. We will begin tracking changes on June 27, 2023.		
Date	**Change**	**Impact**
26 Jun 2023	Initial RIA Published.	N/A
18 Jul 2023	Added the feature "One Last Time Reporting for Reportability Changes".	The RIA has an up-to-date list of features.
04 Aug 2023	Updated the description of the feature "All Product Types Available for FDA 3500A and CIOMS I Generation Enablement Update".	The RIA has up-to-date feature descriptions.