Veeva Vault Safety — 23R1 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in the Vault Safety Suite 23R1 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 23R1 release. We will begin tracking changes on February 27, 2023.	
Revison Date:	March 24, 2023
VIA Availability Date:	March 31, 2023
Vault Safety Help	For detailed feature descriptions, refer to the product release notes, which are available on Vault Safety Help. On April 20, 2023 we will also release the 23R1 Template Revisions page on Safety Help about optional or recommended upgrades to your Vault configuration for general usability improvements, unrelated to configuration changes for new features introduced in this release.
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 23R1
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 administrator.
Admin Checkbox	An administrator 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	Automatic MedDRA Hierarchy Updates	High	Auto-On	Visible to All Users	Vault Safety now enables downloading the latest central MedDRA dictionary version as soon as it becomes available. With the download complete, when you update the active version in your Vault all of the global and localized terms, as well as any hierarchy changes, are automatically applied to MedDRA terms referenced on Cases. This means that you can immediately start the required verifications. In addition, it reduces the manual effort of bulk recoding, enabling MedDRA Admins and Medical Coders to focus on currency status changes, policy, and best practices.
Safety	CIOMS II Line Listing Expectedness	High	Auto-On	Visible to All Users	The CIOMS II standalone report in Vault Safety now supports different expectedness logic for Clinical Trial and Postmarketing Cases in the same report. Clinical Trial expectedness will be based on the Investigational Brochure (IB)/Study datasheets, while Postmarketing Cases will use the Product datasheet.
Safety	PMDA Multi-Submission with Localized Case	High	Auto-On	Visible to All Users	With this release, Vault Safety supports multiple PMDA Submissions from a single Case.
Safety	Case Access Group Security	High	Configuration	Visible to Admins Only	With Case Access Groups, Vault Safety significantly simplifies security around access to Cases based on Case data including Sponsor, Report Type, Country, and Market Segment. In addition, this feature provides more granular control over unblinded information and personally identifiable information (PII) at the object and field levels. For example, Admins can manage access to non-sensitive data for specified open and non-Study Products, Drug Roles, and Study Product Roles.
Safety	Support for New Company Products Type in Safety Data Exchange	High	Configuration	Visible to Admins Only	Vault Safety Data Exchange now supports the new Company Product product types, such as Cosmetics and Nutritional. In addition, the Vault Safety rule engine now supports rules based on product type. For example, you can configure FDA Submission rules specific to OTC Drugs so that this product type won't be subject to the same Submission rules as prescription drugs.
Safety	PII Masking on Potential Matches Page	High	Admin Checkbox	Visible to Admins Only	With this release, Admins can enable personally identifiable information (PII) masking on the Potential Matches page where Atomic Security is not enforced.
Safety	Enhanced Eligible Products Selection for Cross Reporting	High	Support	Visible to Admins Only	With this release, Vault Safety uses improved logic to determine the product driving ICSR reporting requirements in cross reporting scenarios. Contact Veeva Support to enable this feature in your Vault.

Additionally, Admins can modify the behavior of the Product and Study rule parameters when evaluating cross reporting scenarios. Admins can configure this behavior only after Support has enabled the improved logic feature. |
| Safety | All Product Types Available for FDA 3500A and CIOMS I Generation | High | Support | None | With this release, Vault Safety supports generating MedWatch 3500A and CIOMS I forms for device-only Cases. To accommodate reporting on additional classes of Products (for example, Over the Counter and Cosmetics), exporting Company Product types is also supported. |

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	New Info Date for PADER Line Listings	High	Support	None	For PADER Line Listings, previously, the Initial Report Date and a Transmission Date represented the date the FDA first received the Case. With this release, a New Info Date column will be added to the Interval Line Listings and to the Non-Primary Suspect Drug Report, which will be populated from the Case. When you filter the PADER data on the New Info/Receipt Date, you can see what date was used as the inclusion criteria for the report. The Transmission Date has been added to the log of the 15-Day and Non-15 Day report and the log of the Summary of Adverse Events Report to assist in troubleshooting. Essentially, all four (4) PADER reports now have both the Receipt/New Info Date and the Transmission Date.
Safety	Parameter Driven Assessment Selection for Rules Engine	High	Support	None	Previously, the most conservative product and assessment rule parameter evaluation strictly relied on Case Seriousness, Expectedness, and Relatedness being defined in the Distribution Rules. This can lead to under-reporting for common rule sets. Vault Safety can now employ a more tolerant rule parameter evaluation based on the configuration of relevant reporting rules.
Safety	Case Access Groups: Workflow Participants by Role	Medium	Auto-On	Visible to All Users	When using Case Access Groups, Vault Safety can now assign workflow tasks by role on the Case, Localized Case, and Transmission. Note: This feature is auto-on only after you have enabled Case Access Group Security.
Safety	Domestic Case Edit Enhancements	Medium	Auto-On	Visible to All Users	With this release, global Case Processors can view and edit global information in dual-text app controls, even while the localized Case is still generating.
Safety	Generate E2B Formats for Migrated Cases	Medium	Auto-On	Visible to All Users	With this release, preview generation of E2B(R3) files and Transmission generation of all E2B formats are now available for migrated Cases.
Safety	Simplified Case Intake for Studies	Medium	Auto-On	Visible to All Users	Inbox Items now support manual intake for unarmed studies. Based on the selected Study, Study Product selection will use either Study Arms or Study Products. In addition, Case Products can now be marked as Blinded, Unblinded, or Open-Label when a blinded Study is selected.
Safety	Configurable Inbox Item Sections and Custom Case Fields for Manual Intake	Medium	Configuration	Visible to Admins Only	Admins can now configure the list and order of Inbox Item fields for the Details, Patient, Contact, Medical Events, and Products sections. Admins can also hide Medical History and Drug History in the Medical Event and Products sections. Finally, Admins can select custom Case fields for the Inbox Item Details and Patient sections. Users can then manually enter values for the selected fields during intake and the system can copy these values to Case upon promotion.

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Safety	IMDRF Bulk Snapshotting	Medium	Configuration	Visible to Admins Only	With this release, when an IMDRF Dictionary version is updated, the system now downloads the full dictionary. Admins can choose when to transition to a new version and receive notifications when updating and downloading are complete.
Safety	Partner AS2 Gateway Connections	Medium	Support	None	This release introduces a number of enhancements for Vault Safety gateway connections administration to facilitate managing allowlists and certificates, as well as testing gateway connections.
Safety	Pregnancy Case Intake	Medium	Configuration	Visible to Admins Only	Intake users can now mark an Inbox Item as Pregnancy Case to track pregnancy exposure or to report an Adverse Event suffered by the mother. Upon Case promotion, Child Information placeholders and Case Test Results will be automatically created to facilitate data entry.
Safety	Smart MedDRA Coding	Medium	Configuration	Visible to Admins Only	Vault Safety Smart MedDRA Coding offers advanced coding of MedDRA terms that aren't an exact match to the active dictionary or your synonym list. Using AI and automation, this feature overcomes common problems such as alternate and incorrect spelling, abbreviations, and multiple reported terms. For Case Processors, this means less time spent on manual MedDRA coding. For Admins, configuring Smart MedDRA Coding reduces the manual effort of maintaining the MedDRA Synonym list. As terms are coded, they are automatically added to the synonym candidate list, making coding more streamlined and consistent over time.
Safety	Indexing of New Migrated Cases for Duplicate Search	Medium	Admin Checkbox	Visible to Admins Only	With this release, Admins can initiate indexing of newly migrated Cases to include them in duplicate detection.
Safety	Local Case Import to Inbox Item	Medium	Admin Checkbox	Visible to Admins Only	Vault Safety can now import local language text to the Inbox Item localized fields to facilitate translation to English in the global fields. When enabled, the system imports the text values to the localized or global fields based on the set Localization.
Safety	Generate Assessments Record Action	Medium	Support	None	Vault Safety now gives Case Processors the ability to generate Assessments, Assessment Results, and Expectedness records for all serious and non-serious Adverse Events on a Case. Completed in a single action, this feature improves Case processing efficiency by removing the need to generate each required record manually.
Safety	Case Compare: Descriptive Error Messages	Low	Auto-On	Visible to All Users	This feature introduces more descriptive error messages on the Case Compare page. These enhanced messages help users understand issues that may occur when merging an Inbox Item to an in-flight Case or creating a Follow-Up Case.
Safety	Case Locking User Interface Enhancements	Low	Auto-On	Visible to All Users	This feature introduces enhancements to manual and strict Case locking. If another user applies manual or strict Case locking, the relevant user actions will not be displayed or available for you to run in the All Actions menu. This improvement affects only the user interface and contains no functionality changes.
Safety	Record Selection Usability Enhancements For Case	Low	Auto-On	Visible to All Users	With this release, searching and selecting records from picklist fields during Case data entry is made easier by displaying exact matches at the top as you type.

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Safety	Record Selection Usability Enhancements For Inbox Item	Low	Auto-On	Visible to All Users	With this release, searching and selecting records from the Study, Country, and Product Registration dropdown fields during Inbox Item data entry is made easier by displaying recently used values at the top of the list. These fields also now include a binoculars icon for browsing and filtering the available options. In addition, searching and selecting records in picklist fields (for example, Dose Form and Patient RoA) is made easier by displaying exact matches at the top as you type.
Safety	Local Intake Auto-Translation Framework	Low	Configuration	Visible to Admins Only	With this release, Vault Safety can now use the Amazon Translate Connection to translate local text fields to English to allow for global Case processing. In other words, you can now use a third-party service to translate Inbox Item text fields from the reporter's local language to English during Case intake. Admins can enable translations at the Transmission Profile level and by configuring a user action. Admins can also configure the localizations, fields, and volume limits for translations.
Safety	EDQM Dose Forms and Routes of Administration Enablement Update	N/A	Auto-On	Visible to All Users	With this release, the EDQM Dose Forms and Routes of Administration feature is Auto-On. This feature was originally introduced in 22R2 with Admin Checkbox-enablement.
Safety	MedWatch 3500A and CIOMS I Preview Generation for Open Label Study Arms	N/A	Auto-On	Visible to All Users	With this release, Vault Safety supports generating MedWatch 3500A and CIOMS I preview forms for Cases that use an Open Label Arm from a Blinded Study.
Safety	New Duplicate Search Algorithm Enablement Update	N/A	Auto-On	Visible to All Users	With this release, the New Duplicate Search Algorithm feature is Auto-On. This feature was originally introduced in 22R3 with Support-enablement. Although the feature is Auto-On in Vaults with Inbox Items enabled, Admins still control the deep duplicate search options through Case Promotion settings. This feature is available for Inbox Items only, and is not supported for AERs.
Safety	PADER Date Filtering Criteria Enablement Update	N/A	Auto-On	Visible to All Users	With this release, the PADER Date Filtering Criteria feature is Auto-On. This feature was originally introduced in 22R3 with Support-enablement.
Safety	23R1 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.
Safety	External Connection SDK Support for Custom E2B Export	N/A	Configuration	None	With this release, Vault Safety introduces faster exports of custom E2B formats. This makes generating E2B files for large Cases more efficient.
SafetyDocs	PSMF Logbook Format Enhancements	Medium	Auto-On	Visible to All Users	The PSMF Logbook in SafetyDocs has been enhanced to have a clearer format. The new Excel template is automatically available in all Vaults. To use this feature, you must first remove any previously generated logbooks in your existing PSMF binders.
SafetyDocs	PSMF Binder Approvals	Medium	Auto-On	Visible to All Users	Vault SafetyDocs can now manifest approval pages on generated PSMF PDFs.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
SafetyDocs	Literature Process Management	Medium	Configuration	Visible to Admins Only	Vault SafetyDocs now supports the management of literature articles and article reviews. This feature includes the data structure and document types necessary for Literature Management. Future enhancements will leverage this data structure.
SafetyDocs	PSMF Binder Table of Contents	Medium	Configuration	Visible to Admins Only	Vault SafetyDocs can now automatically generate a table of contents for PSMF Binders when merging to PDF.
SafetyDocs	PVA Document and Obligation Management	Medium	Configuration	Visible to Admins Only	Vault SafetyDocs now supports the management of pharmacovigilance (PVA) agreements and Safety Data Exchange agreements. This feature includes the data structure and document types necessary for PVA Management. Future enhancements will leverage this data structure.

Change Log		
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Date	**Change**	**Impact**
27 Feb 2023	Initial RIA Published.	N/A
17 Mar 2023	Updated the Enablement and Default Impact of the feature "PADER Date Filtering Criteria Enablement Update".	The RIA has up-to-date enablement and default impact.
24 Mar 2023	Updated the GxP Risk of the feature "Support for New Company Products Type in Safety Data Exchange".	The RIA has up-to-date GxP Risk analysis.