Veeva Vault Safety 22R2 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in the Vault Safety Suite 22R2 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 22R2 release. We will begin tracking changes on June 14, 2022.

Revison Date:	August 19, 2022
VIA Availability Date:	July 15, 2022
Vault Safety Help	For detailed feature descriptions, refer to the product release notes, which are available on Vault Safety Help. On August , 2022 we will also release the 22R2 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 22R2
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	Combination Product FDA E2B(R2) Export and Case Processing Enhancements	High	Auto-On	Visible to All Users	In this release, Vault Safety provides multiple enhancements for FDA E2B(R2) generation related to drug/biologic-led combination products having device constituents. Combination Products are now exported as a single <drug> block, with the device constituent referenced within the block. In addition, device product codes and brand names are exported to FDA E2B(R2). Vault Safety will also support adding combination products during data entry after Case promotion. Finally, Vault Safety will no longer automatically generate Case Assessments or Expectedness records for device constituents, which can be error-prone and lead to unnecessary work during case processing.
Safety	Optimized BFC E2B(R2) Export	High	Auto-On	Visible to All Users	Vault Safety now supports the generation of E2B(R2) formats with optimized backward-forwards compatibility logic. This export logic enhances support for global health authorities including Health Canada.
Safety	Generate and Manage Standalone CIOMS II Line Listing	High	Configuration	Visible to Admins Only	Vault Safety now provides the ability to generate the CIOMS II Line Listing as a standalone report, independent of the PSUR aggregated report. All features available in the current PSUR line listing are also available in the standalone CIOMS II. Additionally, both masked and unmasked versions can be generated. The default version of the report contains all the data required to meet regulations. Optionally, users can add fields to the report (for example, Study ID, Patient ID, EUDRA CT number, Seriousness, Assessment Results, and Action Taken).
Safety	Domestic Case Processing for Agency Jurisdictions	High	Configuration	Visible to Admins Only	This release brings multiple enhancements to domestic case processing. Administrators can now manage a Country State/Province library with configurable support for state/province codes. You can select the Country State/Province from a picklist during intake and case processing. The system will map the domestic state codes upon E2B(R3) import and export. This enhancement is for domestic cases originating in a country, such as Spain or Italy, where the state code is required in submissions to a specific agency, such as the EMA. Administrators can also now manage the type and scope of localization for domestic case processing. The localization scope can be for all fields or specific to Narratives and/or Company Comments. If configured, the localized values for Company Comments and Narratives will also be exported in E2B formats. Additionally, this feature introduces two new Vault Settings for system administrators. One setting is to configure Inbox Item localization to default based on Reporter Country and Language. Another setting is introduced to prevent auto-submissions when a Case contains unapproved Localized Cases.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Multi-Format Submissions and Distributions	High	Configuration	Visible to Admins Only	Vault Safety now supports the automated generation of multiple document formats within a single transmission record. For example, a CIOMS I and MedWatch 3500A form can be generated within the same Distribution record to transmit to a partner or ethics committee. Additionally, Transmission Profile overrides are now considered when determining which file format validations should be run.
Safety	Receiver Information Export for E2B(R2) and PMDA E2B(R3)	High	Configuration	Visible to Admins Only	Vault Safety now supports the generation of the Receiver Block in the E2B(R2) formats. Additionally, this release updates the export logic for PMDA E2B(R3) to include recipient information in the J2.18 block.
Safety	Reporting Family Jurisdictions and Distribution List Management	High	Configuration	Visible to Admins Only	This release includes three enhancements to Reporting Families for Distributions. Vault Safety now supports specifying Reporting Family Jurisdictions on Partner Distribution Lists. When evaluating the Case, the system uses the list of countries defined to create Distributions for each Partner. In addition, you can now specify the Transmission Profile Override parameter on a reporting rule to override the standard Transmission Profile selection. Finally, MAH Distribution Lists are now automatically removed when the MAH or Reporting Organization value is deleted from all related Product or Study Registrations. The Transmission Profile override and deletion of MAH Distribution List enhancements are automatically available. However, defining jurisdictions for partner distributions requires configuration.
Safety	Improvements to WHODrug Browser and Substance Coding	Medium	Auto-On	Visible to All Users	When selecting an External Product from the WHODrug browser, the Substance information is now snapshotted to the Case, which aligns with E2B(R2) Submission requirements. Some improvements have also been made to the WHODrug Browser, such as the order of columns and filters prioritizing the most referenced product details. This makes it easier to select external products.
Safety	Respect User Default Localization on Inbox Item	Medium	Auto-On	Visible to All Users	Inbox Item now respects the User Default Localization when displaying object reference field values. For example, when User Default Localization is set to Japanese (Japan), the Report Type field will display values in Japanese.
Safety	Partial Date Support for Dose-Level Expiration	Medium	Auto-On	Visible to All Users	Vault Safety now supports partial date entry at the Case Product Dosage-level for Expiration Date. This feature is auto-on for customers using the Case Product Dosage section control. All existing field data and security configuration will be automatically copied from the pre-existing expiration_date_v field to the new expiration_date_idate_v field.
Safety	E2B Rendition	Medium	Auto-On	Visible to All Users	Vault Safety will now automatically generate a visual E2B rendition during an import to Inbox Item, showing each E2B element ID, name, the value imported, as well as any E2B import issues.
Safety	Support for Unconstrained UCUM for Test Result Units	Medium	Auto-On	Visible to All Users	Vault Safety will now support test result units from the unconstrained (infinite) UCUM dictionary, to align with E2B(R3) specifications. This support will extend to migrations, E2B imports, E2B/CIOMS/3500A generation and case processing.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Auto-Calculations: Warnings for Overridden Values	Medium	Configuration	Visible to Admins Only	Vault Safety now provides a user option to enable or disable auto-calculation for certain fields. While editing a field on the Case, the system informs you when this field change will impact other field values. Upon saving the record, the system will also notify you when a previously manually entered field value will be overridden with a system-calculated value, if auto-calculation is enabled.
Safety	Case Data Validations and Always Evaluate Criteria	Medium	Configuration	Visible to Admins Only	Vault Safety can now validate case data without an E2B-based submission format. It can also evaluate validation criteria regardless of reportability (for example, submissions to health authorities).
Safety	EDQM Dose Forms and Routes of Administration	Medium	Admin Checkbox	Visible to Admins Only	To support mandatory EDQM standard terminology for pharmaceutical dose forms and routes of administration when reporting to EudraVigilance, Vault Safety now supports mapping those fields to the latest EDQM terms when importing and exporting E2B files.
Safety	Narrative Templates for Report Types and Studies	Medium	Configuration	Visible to Admins Only	This release enhances the administration of narrative templates. You can now configure and maintain narrative templates by Organization, Report Type, Study Type, Study, and Localization. During Case promotion, the system matches the Case to an appropriate template based on the specified fields. Also, you can now re-render a Case narrative document to refresh merge field tokens without versioning the document.
Safety	Partial Date Support for Product-Level Device Fields	Medium	Configuration	Visible to Admins Only	Vault Safety now supports partial date entry for Combination Products with device constituents for Implanted Date, Explanted Date, and Returned Date. The system will support E2B import and export of these partial dates for FDA E2B(R2). All existing field data and security configuration will be automatically copied from the pre-existing fields to the new partial date fields.
Safety	Copy Patient Information from Existing Case	Medium	Admin Checkbox	Visible to Admins Only	Upon promoting an Inbox Item, Vault Safety now supports the ability to copy patient information from previous Cases. You can select the following case information to be copied from an existing case to a new case: Patient Details (required), Medical History, Drug History, Case Contacts, Test Results, and Suspect/Interacting Products. Additionally, Adverse Events can be copied to Medical History and Concomitant Products can be copied to Drug History.
Safety	Pagination in Dose Section Control	Low	Auto-On	Visible to All Users	With this release, the Dosage section control supports paging and the manual creation of more than 10 dosages per product on a Case.
Safety	One Last Time Reporting Rule Evaluation for Downgrade Scenarios	N/A	Auto-On	Visible to All Users	Vault Safety can now accommodate downgrade scenarios when evaluating if a case qualifies for a one-last-time reporting rule to a specific destination. This enhancement was previously patched in the 22R1.0.8 maintenance release requiring Support enablement, but with 22R2 this enhancement becomes Auto-On.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Field Limit Updates for E2B (Enablement Change and Data Migration)	N/A	Auto-On	Visible to All Users	Vault Safety now supports the maximum E2B-compliant field limits for Dose Text, Transmission Reason, and Test Result Value. This feature was originally introduced in 22R1 through Support-enablement. In 22R2, this feature is automatically supported in all environments. The Case Product Dosage > Dose Text field and Case Test Result > Test Result Value fields will be automatically replaced on page layouts and available for data entry. However, the Localized Case Product Dosage > Dose Text and Transmission > Transmission Reason fields must be replaced on page layouts, if required for data entry. Existing field data and security configuration will be copied from the pre-existing Dose Text, Transmission Reason, and Test Result Value fields to the new fields.
Safety	Import to Inbox Item for Receive E2B API and Safety Link	N/A	Configuration	Visible to Admins Only	Admin users will now be able to switch the import of E2B via the Receive E2B API and via Safety Link to the Inbox Item using the Transmission Profile "Import to Inbox Item". The field is now available on all Transmission Profile types including Partner Exchange Transmission Profile type.
Safety	Enable Configurable Deletion Rules for Standard Case Grandchildren, Localization, Transmission, Inbox Item Objects	N/A	Configuration	Visible to Admins Only	The Vault platform capability for configurable object Deletion Rules is now available for Case Assessment children (Assessment Results, Assessment Expectedness), Case Product children (Case Product Dosage, Indication, Substance), Localized Case children (e.g. Localized Case Assessment), Transmission children (Transmission Message), and Inbox item children (Inbox Item Control). Administrators can configure the Deletion Rules for these objects to "Cascade delete children records" for easier object record maintenance.
Safety	Safety Suite Manifest Update and Tabs	N/A	Configuration	Visible to Admins Only	Vault SafetyDocs has an increased number of standard objects available. Tabs have been added to the application manifest. Appropriate tabs will appear as Safety applications are enabled and disabled.

Change Log

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Date	Change	Impact
13 Jun 2022	Initial RIA Published.	N/A
14 Jun 2022	Updated the GxP Risk analysis from Medium to High for the features "Multi-Format Submissions and Distributions", "Receiver Information Export for E2B(R2) and PMDA E2B(R3)", and "Reporting Family Jurisdictions and Distribution List Management". Updated the GxP Risk analysis from Medium to Low for the feature "Pagination in Dose Section Control". Updated the feature name of "Generate CIOMS II Line Listing (Standalone)" to "Generate and Manage Standalone CIOMS II Line Listing", of "Patient Copy" to "Copy Patient Information from Existing Case", and of "Non-BFC E2B(R2) Export" to "Optimized BFC E2B(R2) Export". Updated the description of the features "Domestic Case Processing for Agency Jurisdictions (i.e. Spain / Italy)", "Import to Inbox Item for Receive E2B API and Safety Link", "Narrative Templates for Report Types and Studies", and "Support for Unconstrained UCUM for Test Result Units".	The RIA has up-to-date GxP Risk analysis, feature names, and descriptions.
15 Jun 2022	Updated the description of the feature "Optimized BFC E2B(R2) Export". Updated the name of the "Combination Product FDA E2B(R2) Export and Case Processing Enhancements" feature, previously named "Combination Products: Compliance Fixes and Efficiency Improvements". Updated the name and description of the "Domestic Case Processing for Agency Jurisdictions" feature, previously named "Domestic Case Processing for Agency Jurisdictions (i.e. Spain / Italy)".	The RIA has up-to-date feature names and descriptions.
16 Jun 2022	Updated the description of the features "Partial Date Support for Product-Level Device Fields" and "Partial Date Support for Dose-Level Expiration".	The RIA has up-to-date feature descriptions.
17 Jun 2022	Updated the description of the feature "Pagination in Dose Section Control".	The RIA has up-to-date feature descriptions.
23 Jun 2022	Updated the description of the feature "Combination Product FDA E2B(R2) Export and Case Processing Enhancements".	The RIA has up-to-date feature descriptions.
24 Jun 2022	Updated the name of the "Improvements to WHODrug Browser and Substance Coding" feature, previously named "Improvements to WHODrug Coding Control".	The RIA has up-to-date feature names.
28 Jun 2022	Added two features to the RIA, including "One Last Time Reporting Rule Evaluation for Downgrade Scenarios" and "Enable Configurable Deletion Rules for Standard Case Grandchildren, Localization, Transmission, Inbox Item Objects".	The RIA has an up-to-date list of features.
29 Jun 2022	Updated the description of the feature "Domestic Case Processing for Agency Jurisdictions". Updated the Enablement and Default Impact of the feature "Support for Unconstrained UCUM for Test Result Units".	The RIA has up-to-date feature descriptions, enablement, and default impact.
20 Jul 2022	Updated the Enablement and Default Impact of the feature "E2B Rendition".	The RIA has up-to-date enablement and default impact.
19 Aug 2022	Added the "Safety Suite Manifest Update and Tabs" feature to the RIA.	The RIA has an up-to-date list of features.