Veeva Vault Safety 22R1 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in the Vault Safety Suite 22R1 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 22R1 release. We will begin tracking changes on March 1, 2022.

Revison Date:	April 25, 2022
VIA Availability Date:	March 25, 2022
Vault Safety Help	For detailed feature descriptions, refer to the product release notes, which are available on Vault Safety Help. On April 14, 2022 we will also release the 22R1 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 22R1
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	Reporter Masking for Post-Market Non-Literature Cases	High	Admin	Visible to Admins Only	Vault Safety provides a system-level setting to support masking reporter information in all outbound Submissions and Distribution for post-market non-literature Cases (E2B(R2), E2B(R3), CIOMS I, MedWatch3500A). If an admin enables this setting, reporter masking applies to all post-market non-literature Cases.
Safety	E2B(R2) Enhancements	High	Auto-On	Visible to All Users	This release includes multiple E2B(R2) enhancements for all E2B(R2) report formats (ICH, FDA, HC). When "Drug Not Administered" is selected for a Product Drug Role, the system will map the suspect code to B.4.k.1. Import and export of the <safetyreportversion> tag are now supported. When masking is applied to a Transmission, E2B(R2) elements are now masked with “PRIVACY” or left blank if an element does not support nullFlavors. Finally, seriousness is now collated from all Case Adverse Events when transmitting Case Seriousness criteria (A.1.5.2).
Safety	FDA Submission Automation: Relatedness Assessment Source Parameter	High	Auto-On	Visible to Admins Only	The FDA does not require a study submission if a sponsor assesses a case as Not Related while the investigator assesses the case as Related for a SUSAR in a clinical trial. With this release, users will no longer have to inactivate the submission to the FDA, as it will not be generated due to now evaluating the relatedness for FDA SUSAR cases based on the Sponsor’s Assessment. Additionally, the Assessment Source parameter will be introduced for use in Custom Rulesets.
Safety	Generate Assessment Results With Clinical and Post Market Source Defaults	High	Auto-On	Visible to All Users	This release enhances EMA E2B(R3) file generation by ensuring that the Source Type on system-generated Case Assessment Results is accurately set for postmarket submissions to the EMA EVHUMAN module. Table constraints for the DSUR Interval Line Listings of Serious Adverse Reactions have also been updated with further protections to ensure only related adverse events are listed. Additionally, administrators can now edit the name of system-provided Controlled Vocabulary records, if required.
Safety	Health Canada Transmission Profiles and Message Types	High	Auto-On	Visible to All Users	Vault Safety now supports the Health Canada gateway for electronic submissions of clinical and post-market cases. A valid Health Canada E2B(R2) file with correct header information is also generated.

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Safety	Precise Inclusion of Age-Related and Medically Confirmed E2B Elements	High	Auto-On	Visible to All Users	This release includes enhancements to E2B generation for precise inclusion of age-related elements and medical confirmation by a health professional. This change impacts all standard E2B(R2) and (R3) formats that Vault Safety generates. Medically Confirmed by Healthcare Professional (A.1.14/E.i.8) is now only transmitted when the primary Reporter is not a health professional; Patient Date of Birth (B.1.2.1/D.2.1) is now only transmitted when a full date is provided (CCYYMMDD); Age at Time of Onset (B.1.2.2/D.2.2) is now only transmitted if the Date of Birth is not transmitted; and Age Group (B.1.2.3/D.2.3) is now only transmitted when both the Date of Birth and Age at Onset are not transmitted. Parent Date of Birth for E2B(R2) (B.1.10.2.1) is now only transmitted when a full date is provided (CCYYMMDD); Parent Age (B.1.10.2.2/D.10.2.2) is now only transmitted if the Date of Birth is not transmitted, and "Year" is always used as the unit of the Parent Age.
Safety	Always Serious and Product or Study-Independent Watchlists	High	Configuration	Visible to Admins Only	You can now create watchlists without specifying a Study or Product. Further, watchlists can be configured to exclude clinical trial studies. Additionally, you can set Seriousness criteria for adverse events on a watchlist. If a Case contains a matching adverse event(s), the Seriousness will automatically be assigned to the Case Adverse Event, if Seriousness is not already specified.
Safety	Auto-Listedness Using Core Datasheets	High	Configuration	Visible to Admins Only	To support listedness calculations during case processing, expectedness records will now generate for product's core datasheet (CCDS) and a new field will be available for core datasheet rollup on Assessment and Case level. Also, Vault Safety expectedness can now be run off a product's core datasheet without additional configuration of local datasheets (if they are not needed by customer's product/organization).
Safety	Automated Cross Reporting	High	Configuration	Visible to Admins Only	In this release, Vault Safety extends the evaluation of reporting obligations to include cross-reporting (investigational to marketing registration) scenarios. Vault Safety evaluates the investigational and marketing registrations of study products, then identifies any additional reporting destinations for products and studies. Administrators can also specify destination overrides on product licenses.

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Safety	Bulk Unblind	High	Configuration	Visible to Admins Only	Vault Safety can now bulk unblind multiple cases in a given study. This includes both the removal of blind protection for previously unblinded cases and snapshotting study arm product information for blinded cases. Cases currently in workflow will not be modified by this action.
Safety	Case Nullification	High	Configuration	Visible to Admins Only	Vault Safety now supports the ability to void a case, including the option to nullify previous Transmissions using a configurable user action at the Case-level. You must specify a reason for nullification when you run the action, which will auto-populate in new system-generated transmission records related to the case. Additionally, upon initiating the voiding process, the system automatically cancels any in-progress workflows.
Safety	Conditional Expectedness	High	Configuration	Visible to Admins Only	This feature brings multiple enhancements to the configuration and evaluation of Datasheets for auto-expectedness. When configuring Datasheets, administrators can now specify seriousness criteria conditions, which define when a listed term is unexpected. Seriousness criteria can be configured at both the Datasheet and MedDRA Criteria (listed term) level. Admins can also now configure precise expectedness on Datasheets, which prevents the system from marking terms as unexpected if they are not listed on the Datasheet. Additionally, a new Expectedness MedDRA Criteria setting allows you to specify unexpected terms on a Datasheet.
Safety	Expectedness from Core Datasheets	High	Configuration	Visible to Admins Only	When generating a submission, evaluate expectedness for a study case using its Investigational Brochure (IB) datasheet
Safety	Follow-up with Any Matching UID	High	Configuration	Visible to Admins Only	Admins can now configure Vault Safety to allow Inbox Items to be promoted to a Follow-Up Case when the Worldwide UID does not match but matches another UID, such as an External System UID or a Case Identifier.
Safety	Identifiable Patient Definition Ruleset Parameter	High	Configuration	Visible to Admins Only	In this release, Vault Safety allows submission rules to evaluate the Identifiable Patient Definition ruleset parameter to determine whether or not a case contains an Identifiable Patient as defined by E2D (ICH standard), or less strict "Patient Known to Exists" - a newly introduced case field. This allows greater specificity in submission to health authority and partners with less strict definitions of patient (i.e. FDA) while minimizing the potential for over reporting to destinations that have more strict definitions of patient (i.e. EMA).

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Safety	Organized Data Collection of Reports from Patient Support Programs and Market Research Programs	High	Configuration	Visible to Admins Only	Vault Safety now supports organized data collection of reports from PSPs (Patient Support Programs) and MRPs (Market Research Programs). Admins can create Study placeholders for Studies with unspecified products and intake users can select Company Products as Suspect Products. Upon case promotion, reporting obligations are evaluated using Product Registrations for the suspect Company Products.
Safety	PHI Masking on Foreign Submissions	High	Configuration	Visible to Admins Only	Vault Safety can now generate safety reports with PHI masking for Submissions. Masking can be configured at the reporting rule level to apply to all cases or only foreign cases.
Safety	Submission Automation: Upgrade and Downgrade Parameters	High	Configuration	Visible to Admins Only	Vault Safety will introduce new parameters to calculate whether a Case is an upgrade or a downgrade in order to support additional submissions scenarios for the FDA, EMA, ROW, and custom rule sets. This feature will also support the one-last-time and one-more-time reporting rules, while considering the appropriate due date and local expedited criteria.
Safety	Submission Rules: Support for MedDRA Queries (SMQs and CMQs)	High	Configuration	Visible to Admins Only	With this release, Vault Safety will extend the Safety Rule Engine to allow greater configurability for Custom Rule Sets. New rule parameters will be introduced to support the selection of specific Products and/or Studies when deciding if a rule should be executed. Additionally, MedDRA Queries (SMQs and CMQs) can be used to determine if a case should be reportable in order to support situations such as "Lack of Efficacy" or customer-managed lists of non-reportable terms.
Safety	Merge Inbox Item to In-Flight Case	Medium	Admin	Visible to Admins Only	Vault Safety now supports merging information received in Inbox Item into the latest Case version. When merged, source documents will also be added to the latest Case version. To facilitate parallel processing, Intake users can now alert the case processor that there is new case information by marking an Inbox Item as a follow-up to the latest case. Inbox Items marked as follow-up can either be merged into the latest Case version or can be used to create a Follow-Up Case.
Safety	Strict Case Locking	Medium	Admin	Visible to Admins Only	Administrators can now enable a system setting to enforce strict case locking, which prevents users from making changes to a Case unless that user had locked the Case themselves.
Safety	Case UID Manual Intake on Inbox Item	Medium	Auto-On	Visible to All Users	Users can now manually enter the Worldwide UID and an External System UID on the Inbox Item page to facilitate case intake and duplicate search.

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Safety	Duplicate Detection by Case Identifiers	Medium	Auto-On	Visible to All Users	Vault Safety will now search for duplicates using Case Identifiers. Inbox Item UIDs and Case Identifiers will be cross compared with Case UIDs and Identifiers during duplicate detection.
Safety	Identifiable Reporter and Patient Per ICH E2D on Inbox Item	Medium	Auto-On	Visible to All Users	Vault Safety will now evaluate the Identifiable Patient and Identifiable Reporter fields on the Inbox Item based on the ICH Guideline "Post-approval safety data management: definitions and standards for expedited reporting E2D," which looks at certain fields from the Patient and Case Contacts section. In addition, if you mark one or more of these fields as Masked, the patient or reporter will qualify as identifiable.
Safety	Ignore Validation Rule	Medium	Auto-On	Visible to All Users	Validation Results on a Case or Transmission can now be changed to the Ignored state. This allows users to proceed with case processing and submissions while ignoring certain validation failures. Subsequent validation evaluations will not execute on ignored results.
Safety	Inbox Item Global Actions for Manual Intake	Medium	Auto-On	Visible to All Users	Vault Safety now supports global actions to create, edit, and save all Inbox Item records in a single click during manual Inbox Item intake. The system warns users when navigating away from an Inbox Item with unsaved data.
Safety	Rank Suggestion and Validation for E2B-Imported Blinded Products	Medium	Auto-On	Visible to All Users	Vault Safety will now suggest Rank 1 for Investigational Blinded Products (G.k.2.5 = Yes) on E2B R3 import to Inbox Item. These Case Products won't need a Study Product or Company Product to be a primary suspect (rank 1).
Safety	Automated Case Promotion to Initial and Follow-Up Case	Medium	Configuration	Visible to Admins Only	Vault Safety now supports automated Inbox Item promotion to an Initial or Follow-Up Case for E2B transmissions received via AS2 Gateway from external systems that have their own case processing workflows. The system verifies whether Case promotion is valid, leverages Case Identifier matching, and has selectable merging methods based on seriousness.
Safety	Case Validations: Control Workflow Transitions	Medium	Configuration	Visible to Admins Only	Vault Safety can now calculate the worst validation result for a case and transmission to be used in entry criteria and prevent lifecycle state changes. The system will also prevent gateway submissions for any transmissions with Hard Failures.
Safety	Configurable Validation Criteria	Medium	Configuration	Visible to Admins Only	Vault Safety now supports additional custom validation criteria using the standard validation criteria syntax, which will run as part of the Case validations. In addition, the Vault Safety validation engine now supports E2B(R2) formats.

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Safety	Import Product Matching by Company Product Substance, Trade Name, and Alias	Medium	Configuration	Visible to Admins Only	This release enhances product matching when importing Inbox Items or AERs from E2B and JSON files by supporting product generic names, trade names, product aliases, and substance aliases.
Safety	MedDRA Hierarchy for CMQ and Vault Reporting	Medium	Configuration	Visible to Admins Only	Admins can now download the full active MedDRA version from the central dictionary to your vault instead of uploading dictionary .zip files. Admins can also perform a deep copy of MedDRA queries and associated records, as well as update the MedDRA hierarchy with higher-level terms associated with all LLT terms in your vault. Additionally, Vault Safety now supports creating Custom MedDRA Queries (CMQs) using any level of the MedDRA hierarchy (SOCs, HLGTs, HLTs, PTs, and LLTs). Previously, MedDRA Queries could only be constructed using LLTs. The MedDRA Queries with non-LLTs will be supported through standard Vault Reporting and Dashboarding.
Safety	Promote to Multiple Cases	Medium	Configuration	Visible to Admins Only	Vault Safety can now promote a single Inbox Item to up to 100 cases. The cases will be related and contain all the information from the Inbox Item, including source documents. This functionality is primarily intended for the intake of literature and legal cases. This feature is not supported for E2B imported Inbox Items.
Safety	Safety Rule Version Management	Medium	Configuration	Visible to Admins Only	Admins can now configure an Active Version of the system-provided standard rulesets. When new rules are introduced into a standard ruleset (for example, FDA, EMA, and PMDA) as part of a release, admins can set the rule version to allow for adoption of the most recent version of a standard ruleset on a configurable basis.
Safety	Transmission Product Types	Medium	Configuration	Visible to Admins Only	This feature enables products to be registered as different product types in different markets. For example, a product may be registered as a combination product with the FDA, and a drug with the EMA. This feature is controlled by a new Transmission Product Type setting, which can be set at the Product or Study Registration level by an admin. One scenario this feature supports is omitting device constituents from combination product E2B Reports. Because certain jurisdictions do not accept combination product submissions, you can exclude Device-type product constituents from E2B files generated for Combination Product reports. Unless this feature is enabled, E2B files generated for a Combination Product Case continue to include both Device-type and Drug-type Product Constituents.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Blind Protection Relatedness Override - CIOMS I and E2B	Medium	Support	N/A	Vault Safety now provides the ability to blind protect unblinded double-blinded study cases in generated CIOMS I and E2B documents. Users can select an override for Case Assessment Results, if different from the blinded Assessment, to be displayed in the unblinded CIOMS I and unmasked E2B documents.
Safety	Deep Duplicate Search	Medium	Support	N/A	Vault Safety will now search for potential matches using all Case Adverse Events and Company or Study Products, including non-primary records. Additionally, users will be able to confirm new case creation when no potential match is found.
Safety	FDA E2B(R2) Partial Dates for Combination Product Expiration Date	Medium	Support	N/A	Vault Safety now accepts partial dates in the Case Product “Expiration Date” field. For FDA E2B(R2) combination product reports, partial dates are exported to Expiration Date elements B.4.k.2.4.FDA.1a-b using the appropriate date format code.
Safety	Field Limit Updates for E2B	Medium	Support	N/A	Vault Safety will now support the maximum E2B length for Dose Text, Reason Text, Result Value and Age value. First, Dose Text will now accept up to 2,000 characters (E2B limit for G.K.4.r.8 / B.4.k.6) on Inbox Item, Case Product Dosage and Localized Case Product Dosage. Second, Reason Text will now accept up to 2,000 characters (E2B limit for C.1.11.2 / A.1.13.1) on Transmission. Third, Result Value on Case Test Result will now accept up to 50 digits (E2B limit for F.r.3.2 / B.3.1d). Lastly, Age Value will accept up to 5 digits (E2B limit for D.2.2a).
Safety	Foreign Localized Case Synching	Medium	Support	N/A	On a follow-up Localized case, Vault Safety now performs a one-time data sync from the global case to the localized case when the associated transmission record is created. System also prevents user edits to the follow-up Localized Case until transmission it is ready for transmission evaluation.
Safety	Attach Custom Child Objects to Case on Follow-Up From Inbox Item	Low	Auto-On	Visible to All Users	When promoting an Inbox Item to a Follow-Up Case, custom child object records will now be added to the new Case version.
Safety	Provision Standard Verbatim Fields for Case Drug History and Case Diagnosis	Low	Configuration	Visible to Admins Only	In this release, Vault will allow for standard fields to support migration of verbatim values for Case Drug History and Case Diagnosis records.

Change Log

This feature list is subject to change prior to the 22R1 release. We will begin tracking changes on March 1, 2022.

Date	Change	Impact
22 Feb 2022	Initial RIA Published.	N/A
01 Mar 2022	Updated the description of the "Inbox Item Global Actions for Manual Intake" feature and updated the name of the "FDA E2B(R2) Partial Dates for Combination Product Expiration Date" feature.	The RIA has up-to-date feature names and descriptions.
02 Mar 2022	Updated the description of the "Rank Suggestion and Validation for E2B-Imported Blinded Products" feature.	The RIA has up-to-date feature descriptions.
04 Mar 2022	Updated the name and description of the "Generate Assessment Results With Clinical and Post Market Source Defaults" feature, previously named "Generate Assessment Results Compliant With EMA E2B(R3)"	The RIA has up-to-date feature names and descriptions.
10 Mar 2022	Added new feature "Case UID Manual Intake on Inbox Item" and updated the description of the "Transmission Product Types" feature.	The RIA has up-to-date features and descriptions.
22 Mar 2022	Added two Suppport-enablement features: "Blind Protection Relatedness Override - CIOMS I and E2B" and "Foreign Localized Case Synching"	The RIA has an up-to-date listing of new features.
12 Apr 2022	Added an "Application" column and updated the description of "Automated Case Promotion to Initial and Follow-Up Case"	The RIA reflects the relevant application for each feature and includes up-to-date feature descriptions.
25 Apr 2022	Updated the Enablement and Default Impact of the "Deep Duplicate Search" feature, which was previously labelled Auto-On but now requires Support enablement.	The RIA has up-to-date information about feature enablement and impact.