Veeva Vault Safety 20R2 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault Safety 20R2 that may affect a customer's vault. We release a version of the RIA in advance of the general release. On July 24th, 2020, the Validation Impact Assessment, which contains validation information for new features in 20R2, will be available in your VeevaDocs vault. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements.

This feature list is subject to change prior to the 20R2 release. We will begin tracking changes on June 26th, 2020.

Revision Date: July 23, 2020

The Vault Platform RIA provides validation information about the Vault Platform. Auto-on features will appear automatically in Vault Safety. Access the Vault Platform with the following link:
Vault Platform RIA

Feature:	Name of the feature introduced in 20R2
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 configuration by an Admin (an Admin area checkbox or a more complex setup), or must be enabled by contacting Veeva Support. Note that in some cases, an Auto-on feature is dependent on another feature that must be enabled or configured. In other cases, individual users (not Admins) need to perform some setup, for example, with new Reporting capabilities that require creation of a new report.
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

Applications	Summary	Feature Risk	Enablement	Default Impact	Description
Safety	Health Canada E2B R2 Export	High	Auto-On	Visible to All Users	Vault Safety now supports the ability to export ICSRs in the Health Canada compliant E2B(R2) .xml format. This format will be selectable when creating new Submissions and configuring Transmission Profiles.
Safety	Optimized Submissions: Local Datasheets & Primary Expectedness	High	Auto-On*	Visible to All Users	Vault Safety will now generate submissions based on local expectedness (based on a product registration's country, product and local datasheet). Auto-expectedness will also now calculate only the primary case assessment. *Auto-On in vaults with Product Datasheets configured. In vaults that do not have Product Datasheets, administrators must perform configuration to make this feature available to end-users.
Safety	E2B R2 & R3 Validation	High	Auto-On	Visible to All Users	With this release, we've made various enhancements around informing users of validation errors when entering data and submitting E2B messages. Below highlights some of these enhancements. At the time of creation, a Submission E2B file (EMA E2B R3, FDA E2B R2, and FDA Combination Products) is validated against the XML schema, and errors reported, so that the user can address validation errors before attempting to submit to the Health Authority. Vault also validates specific nullFlavour values, as well as Value/Unit pair controls and displays an icon for the invalid selections. The Reason Omitted picklist is validated to catch errors in existing or imported data and also is now limited to show only the valid values when creating new records in Vault Note that pre-configured field Validation Rules are no longer displayed when the invalid icon is displayed. Users can now add Reason Omitted (Nullflavor) values of UNK & ASKU to the Batch/Lot Number on Case Product Dosage. Enhancements to the way E, G, F, C sections are formatted in the XML based on special scenarios. For E2B/EMA R3 Submissions, corresponding comments are no longer exported when Gender is not entered. An actionable and user friendly error message is displayed when a rule engine could not evaluate rules due to missing or invalid Transmission Profile details.

Applications	Summary	Feature Risk	Enablement	Default Impact	Description
Safety	E2B R2 Product Import Converter and other E2B Enhancements	High	Auto-On	Visible to All Users	When importing E2B(R2) files, Vault Safety now merges drug duplicates (B.4.k section) and creates a single Case Product, including all of its dosages and substances. A drug is considered a duplicate when the proprietary medicinal product name (B.4.k.2.1), all active substance names (B.4.k.2.2), and the country where the drug was obtained (B.4.k.2.3) match. The system sends a warning notification if conflicting information is found under drug duplicates. With this feature the Medical History (D.7.1.r) section is mapped to the Case Medical History. This feature also fixes optimistic locking issues on import.
Safety	PSUR Cumulative Tabulations and CIOMS II Line Listings	High	Configuration	Visible to Admins Only	Vault Safety now supports generating Periodic Safety Update Reports (PSURs) cumulative tabulations along with CIOMS II line listings. Reports can be generated based on drugs, studies, and/or active substances.
Safety	Drug ⇄ Biologic Combination Products	High	Configuration	Visible to Admins Only	Vault Safety now supports end-to-end case processing for post-marketing combination products having multiple drug and biologic constituents. When a combination product case is opened, its pre-configured constituents are downloaded to the case, and assessment records are auto-generated for them. Furthermore, watchlists created for the combination product (e.g. AESI, IME) are applied to the case. Finally, if the combination product is marketed in the US, an FDA-bound E2B(R2) submission is generated, along with the new FDA regional fields for combination products. Leverage these capabilities to remain compliant with the FDA's PMSR requirements for combination products (21 CFR Part 4), which take effect July 21, 2020.
Safety	DSUR Appendices (Cumulative SAR, Death Cases), DSUR Masked Distribution	High	Configuration	Visible to Admins Only	**DSUR Masked Distribution** In this release, to facilitate both DSUR submissions to health authorities and distributions to partners/committees, customers will be able to generate both masked and unmasked versions of the Cumulative Tabulation of SAEs and Interval Line Listings. **DSUR Appendices (Cumulative SAR, Death Cases)** Customers will also be able to generate Appendix R1 Cumulative Tabulation of SARs, and Appendix R2 List of Subjects Who Died During the Reporting Period.
Safety	XLSX Report Templates	High	Configuration	Visible to Admins Only	This release adds support for Vault Merge Fields with the use of .XLSX Aggregate templates. This allows administrators to configure additional aggregate details (product family, date, etc.) on the templates that will render on generated Aggregate Line Listings and Cumulative reports.

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Safety	Drug / Biologic Combination Products with Device Constituents	High	Configuration	Visible to Admins Only	Vault Safety now supports end-to-end case processing for post-marketing drug/biologic combination products having device constituents. Auto-expectedness is calculated using the combination product's datasheets. Additional device information can be entered during data entry, including device event problem codes, device evaluation codes, and remedial action information. Finally, if the combination product is marketed in the US, an FDA-bound E2B(R2) submission is generated, along with the new FDA regional fields for combination products and their device constituents. This includes Malfunction (30-Day) and Public Health Risk (5-Day) reports. Leverage these capabilities to remain compliant with the FDA's PMSR requirements for combination products and their device constituents (21 CFR Part 4), which take effect July 21, 2020.
Safety	Copy Report Type and Receipt Date from AER Source Document Vault Metadata	Medium	Auto-On	Visible to All Users	Users can now capture the report type and receipt date to an AER created from a document in the library.
Safety	Duplicate Detection Enhancements	Medium	Auto-On	Visible to All Users	Vault Safety will now use Study Arm and Site Reporter information for duplication detection. It will return potential matches for cases that have only one MRN field matching for Patient information. Additionally, the Potential Matches page will show the Lifecycle state for the promoted AER and selected match to facilitate the review.
Safety	MedDRA Auto-Coding Control	Medium	Auto-On	Visible to All Users	The MedDRA auto-code feature is now automatically available. Previously, this feature required configuration. Vault Safety 20R2 automatically updates all MedDRA fields to use the auto-code control. In addition, the Case Diagnoses and Case Drug History records now support the MedDRA auto-code control.
Safety	Manual Case Lock	Medium	Configuration	Visible to Admins Only	Individual users can now more easily lock Cases and their related records, including Case Adverse Events, Products, Medical History, and Assessments, to prevent other users from editing them. Privileged users can unlock and reassign.
Safety	Case Product Drug Role: Treatment	Medium	Configuration	Visible to Admins Only	Users can now assign the drug role of a Case Product to be a treatment of the adverse event. Case Products designated as a treatment will not be included in any standard generated reports (aggregates, E2B, CIOMS I, MedWatch 3500A, etc.). Note this feature was first introduced in 20R1 but could be enabled by Veeva Support only. In 20R2, this feature can be made available through Configuration.
Safety	Medical Review Timeline	Medium	Configuration	Visible to Admins Only	Medical Review timeline empowers users with a highly visual, interactive timeline of the cases adverse events, products, doses, test results, and history.

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Safety	Deprecated Controlled Vocabularies	Medium	Configuration	Visible to Admins Only	Administrators can now deprecate non-system controlled vocabularies without impacting imports and follow-ups. Users will not be able to select deprecated controlled vocabularies for new cases, but not be blocked when processing older ones. This is particularly useful for migration data.
Safety	Substances	Medium	Configuration	Visible to Admins Only	Vault Safety can now track substances and their use in individual products. When adding a product to a case that is associated with a substance, the substance is snapshotted to the case product.
Safety	MedDRA: Centralization	Medium	Admin Checkbox	Visible to Admins Only	Vault Safety now offers access to a centralized Veeva-managed MedDRA dictionary. This greatly simplifies the ongoing management of MedDRA, alleviating customers from having to manually update the dictionary in their own vaults. When a new dictionary version becomes available in the centralized repository, customers individually choose when to transition to it. A new configuration option provides greater flexibility on how to code follow-up cases, by choosing to always use the currently active MedDRA version instead of the same MedDRA version as the initial case and visually notifying users of non-current terms. Simplify your operations by transitioning to our centralized MedDRA dictionary. **Note**: Customers must still maintain a valid MedDRA license with MedDRA to use this service.
Safety	Case Locked Icon in Approved, Closed, and Superseded State	Low	Auto-On	Visible to All Users	A new Case Locked icon will be automatically available with no configuration needed. The lock icon will appear by default on Cases in the Approved, Closed, Superseded, and Rejected states.
Safety	MedDRA Browser Hierarchy Tree View	Low	Auto-On	Visible to All Users	Vault Safety now allows users to browse through MedDRA in the Tree View hierarchy and to refine their searches to a specific MedDRA level to find terms. The updated browswer appears automatically for all MedDRA fields.
Safety	Performance Optimization: Promote to Case	Low	Auto-On	None	Updated framework to enhance Promote to Case performance speed.
Safety	WHODrug Version Selection from Central Database	Low	Configuration	Visible to Admins Only	While selecting the active WHODrug dictionary, administrators can now see when the list of releases in their vault is out of sync and fetch the latest WHODrug versions.

Change Log		
This feature list is subject to change prior to the 20R2 release. We will begin tracking changes on June 22nd, 2020.		
Date	**Change**	**Impact**
June 19, 2020	Initial RIA Published	N/A
July 6, 2020	Updated descriptions of multiple features	The RIA now includes up-to-date Feature Descriptions
July 10, 2020	Added a line item for MedDRA Auto-Coding and updated the description for Manual Case Lock feature enablement.	The RIA now includes up-to-date feature information.
July 17, 2020	Added a separate line item for the Case Locked Icon in Approved, Closed, and Superseded State, which was previously bundled with the Manual Case Lock feature; and updated the enablement for the Deprecated Controlled Vocabularies feature from "Admin Checkbox" to "Config."	The RIA now includes up-to-date feature information.
July 22, 2020	Updated the description of the E2B R2 & R3 Validation feature.	The RIA now includes up-to-date feature information.
July 23, 2020	Updated the Feature Risk from "Medium" to "Low" for the Case Locked Icon in Approved, Closed, and Superseded State feature.	The RIA now includes up-to-date feature information.