# Veeva Vault Safety 20R1 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault Safety 20R1 that may affect a customer's vault. We release a version of the RIA in advance of the general release. On April 2, 2020, the Vault Safety Validation Impact Assessment, which contains validation information for new features in 20R1, will be available in your VeevaDocs vault. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements. Refer to the Vault 20R1 Release Impact Assessment for validation information for the Vault Platform.

**Revision Date:** April 14, 2020

*This feature list is subject to change prior to the 20R1 release. We will begin tracking changes on March 2, 2020.*

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| **Feature:** | Name of the feature introduced in 20R1 |
| **Feature Risk:** | Feature 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 feature 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 |
| *None* | Not visible in Vault unless enabled by Support |

| Application | Feature Name | Feature Risk | Enablement | Default Impact | Description |
|---|---|---|---|---|---|
| Safety | CIOMS I Form Update and Comprehensive Overflows | High | Auto-On | Visible to All Users | A new CIOMS I form template has been retrofitted with comprehensive field overflows (e.g. for manufacturer, country), additional organization (e.g. alphabetical sorting of Labs), and numbering for suspect products, doses, and forms. The format for all date fields has also been changed to (dd-mmm-yyyy). In addition, ISO country code and name are now present on the form. Note: The new CIOMS format will be used only for newly generated documents or re-generated documents. |
| Safety | FDA 3500A Comprehensive Overflows | High | Auto-On | Visible to All Users | The FDA MedWatch 3500A form has been retrofitted with comprehensive field overflows (e.g. for manufacturer, country), additonal organization (e.g. alphabetical sorting of Labs), and listings for conmeds with multiple doses. In addition, ISO country code and name are now present on the form. Note: The new format will be used only for newly generated documents or re-generated documents. |
| Safety | Masked Content Distributions | High | Configuration | Visible to Admins Only | This feature supports the configuration of masked PII and blinded distributions to partners while continuing to allow unblinded submissions to regulatory agencies. Admins can set masking options on the Distribution Family, and users can set masking options on the Distribution object.<br><br>This feature also adds a new Blinded narrative document template, which admins can configure for the system to use when generating the narrative document for blinded Cases. |
| Safety | Study Arms and Blinded Product Names | High | Configuration | Visible to Admins Only | Admins can now configure Study Arms under a Study and add information about whether the arms are open or blinded and which Study Products are administered in each arm. Additionally, dosage and frequency can now be configured on Study Products. For open arms, Admins can configure more granular dosage and frequency intervals. For blinded arms, Admins can configure blinded product placholder names. The Download Dosage to Case field on the Study object, in the Details section, determines when the dosage and frequency are populated on Cases.<br><br>During AER intake, users can select the appropriate Study Arm to automatically populate Study Products when a Case is opened. Admins can also configure a new type of Study Product for Standard of Care, which is never blinded. |

| Application | Feature Name | Feature Risk | Enablement | Default Impact | Description |
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| Safety | Case Level Relatedness | High | Auto-On | Visible to All Users | Users can filter for Relatedness at the Case Level. While the Relatedness Case filter is available automatically for all users, Admins must update page layouts to add the Reporter Assessment Result and Relatedness fields. |
| Safety | Automatic SUSAR/SAE Detection | High | Auto-On | Visible to All Users | Cases that meet SUSAR/SAE criteria will now automatically be tagged with the appropriate SUSAR/SAE tag. Note: This tagging will only occur for new cases/assessments or if existing assessments are re-assessed. |
| Safety | Auto-Create Assessment Results Grid | Medium | Auto-On | Visible to All Users | When a Case Assessment is created, Vault Safety now automatically generates two Case Assessment Results: one for the sponsor assessment and one for the reporter. As part of this feature, when a Case is opened, the primary adverse event is automatically designated as HCP-confirmed if the primary reporter is a qualified healthcare professional. Note: This will only occur for new cases, or active cases with new adverse events/products. |
| Safety | E2B Import - Product Matching Enhancements | Medium | Auto-On | Visible to All Users | During E2B import, the system will now map Case Products by Registration Number and Product Name. Note: This will only occur for newly imported Cases. |
| Safety | Symptom Classification for Adverse Events | Medium | Auto-On | Visible to All Users | Users can now designate adverse events as either symptoms or diagnoses, and associate adverse events with a Case Diagnosis. To support this functionality, two new fields are added to the Case Adverse Event object: the Symptom/Diagnosis field and the Diagnosis field. Depending on your vault settings, these fields will appear automatically or may need to be added to page layouts before they appear. Contact your Veeva Services representative for more information. |
| Safety | AESI and Configurable Watchlists | Medium | Configuration | Visible to Admins Only | Admins can now configure custom watchlists to monitor Adverse Events of Special Interest (AESI) and other Important Medical Events (IMEs). Watchlists can be configured for a given Product or Study and during setup, Admins can add the specific adverse events that will be monitored. Watchlists can also be configured to expedite Cases. Cases may be associated with a watchlist when they are opened and when adverse events are added or updated. As part of this feature, the Watchlist Tags field now supports a Case being tagged with multiple watchlists. |

| Application | Feature Name | Feature Risk | Enablement | Default Impact | Description |
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| Safety | Study Site Reporters | Medium | Configuration | Visible to Admins Only | Admins can now configure Study Contacts for Study Sites to enable more efficient data entry. During intake, users can select the Study Site and reporter (Site Contact) to automatically populate information about the Primary Reporter when the Case is opened. |
| Safety | xEVMPD Dosage Forms | Medium | Configuration | Visible to Admins Only | A controlled vocabulary has been added for the xEVMPD, which allows users to select a dosage form from the dictionary. |
| Safety | Non-Standard Dose Units | Medium | Auto-On | Visible to All Users | When entering dosage information on the Case Product object, users will now have more data entry flexibility. Users can now enter dosage with non-standard custom Units of Measurement (e.g. "GC/eye"), and still be able to generate compliant regulatory reports. Generated forms, such as FDA 3500A and CIOMS I, will show custom UoM. The system will continue to generate compliant E2Bs, whether dosage information was entered custom or selected from a controlled vocabulary. |
| Safety | Standardised and Custom MedDRA Queries (SMQs / CMQs) | Medium | Configuration | Visible to Admins Only | This feature supports MedDRA SMQs and CMQs through the new MedDRA Query object. When an Admin imports a MedDRA dictionary, Vault Safety imports the full SMQ hierarchy. Admins can also configure CMQs to meet their organization's adverse event monitoring needs, including hierarchical CMQs. Users can run reports to find Cases matching one or more SMQs/CMQs. |
| Safety | Controlled Vocabulary: Extended Configurability | Medium | Configuration | Visible to Admins Only | Admins now have more control over standard and custom Controlled Vocabularies to match their internal protocols and safety management processes. Standard controlled vocabularies are still protected to prevent editing fields which would interfere with E2B mappings or Vault Safety functionality. |
| Safety | MedDRA Auto-Coding | Medium | Configuration | Visible to Admins Only | This enhancement features a new MedDRA Auto-Code control, which allows users to automatically code the MedDRA term after entering a reported term. |
| Safety | Frequency: Multi-Option Control | Low | Auto-On | Visible to All Users | The enhanced Frequency control now allows users to choose between three frequency data entry options, each with more user-friendly, everyday terms. Vault Safety automatically calculates and enters the respective E2B frequency value. |

| Application | Feature Name | Feature Risk | Enablement | Default Impact | Description |
|---|---|---|---|---|---|
| Safety | Blinded Case Previews | Low | Auto-On | Visible to All Users | Vault Safety now supports the ability to generate blinded previews of Individual Case Safety Reports (ICSRs) during case processing with sensitive study data hidden for blinded studies. This feature only impacts new Cases when generating FDA 3500A, CIOMS I, or E2B previews. Unblinded Previews will continue to be blind-protected and restricted to authorized users. Note: This will only occur for newly generated or re-generated existing documents. |
| Safety | Precise Naming for Assessment Matrix, Case Product, and Adverse Event | Low | Auto-On | Visible to All Users | New naming conventions will provide better context to the user when navigating through Case Assessments. Product Name and Adverse Event Name will now be populated based on their corresponding Reported fields. Similarly, the Case Assessment Name will be updated with the new Product and Adverse Event naming convention. Note: This will only occur for new cases or active cases with new adverse events/products. |
| Safety | Import Narratives API Endpoint | Low | Auto-On | None | The narrative import API endpoint imports narrative text into a Case Narrative document. This API completes the set for Vault Safety to allow full data migrations without the use of E2B intermediaries. |
| Safety | E2B Notification Links | Low | Auto-On | Visible to All Users | E2B notifications now contain links to the relevant Case, Object Record, or document being referenced in the notification. Note: These links will appear in new notifications only. |
| Safety | Performance and Infrastructure Enhancements | Low | Auto-On | None | Internal infrastructure enhancements to improve scalability and performance. |
| Safety | Case Product Dose and Indication Sections | Low | Configuration | Visible to Admins Only | Users can now enter product indications and dosages on the Case Product page directly. This enhancement will ensure faster data entry and provide better context to the user when navigating through the Case. |
| Safety | Uniform Control Enhancements | Low | Auto-On | Visible to All Users | User interface controls will now better adapt to screen resolutions and look more uniform. |
| Safety | Case Product Drug Role: Treatment | Low | Support | None | 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 (E2B, CIOMS I, MedWatch 3500A, etc.) |

# Change Log

*This feature list is subject to change prior to the 20R1 release. We will begin tracking changes on March 2, 2020.*

| Date | Change | Impact |
|---|---|---|
| February 14, 2020 | Published the initial version of the RIA | N/A |
| March 5, 2020 | Fixed a typo in the description of the E2B Notification Links feature. | N/A |
| March 19, 2020 | Updated the name of the Blinded Case Previews feature and added the Case Product Dose and Indication Sections feature. | The RIA now includes up-to-date feature naming, and a list of all features in 20R1. |
| March 26, 2020 | Added the Case Product Drug Role: Treatment feature.<br>Updated the Default Impact column for Case Product Dose and Indications Sections, and MedDRA Auto-Coding.<br>Split the Case Level Relatedness and Automatic SUSAR/SAE Detection feature into two separate line items. | The RIA now includes up-to-date feature information, and a complete list of features in 20R1. |
| April 14, 2020 | Updated the enablement, impact, and description of the Case Level Relatedness Feature.<br>Updated the description of the AESI and Configurable Watchlists feature.<br>Updated the enablement and impact of the Symptom Classification for Adverse Events feature.<br>Split the xEVMPD Dosage Forms and Non-Standard Dose Units feature into separate line items and updated the enablement and impact. | The RIA now includes up-to-date feature information, and a complete list of features in 20R1. |
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