Veeva Vault Safety Suite — 20R3 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in the Vault Safety Suite in 20R3 that may affect a customer's vault. We release a version of the RIA in advance of the general release. The Validation Impact Assessment, which contains validation information for new features that have validation impact in 20R3, will be available in the Veeva Compliance Docs (VeevaDocs) vault on November 9th. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements. On November 2nd, the 20R3 Release Notes will be available. Refer to the Release Notes for additional details about each feature and data model changes in your vault. On November 26, the 20R3 Template Revisions page will be available. Refer to the Template Revisions page to learn about optional and recommended upgrades to your 20R3 vault configuration for general usability improvements, unrelated to 20R3 new features.

Vault 20R3 Release Impact Assessment

Revison Date: November 16, 2020

This feature list is subject to change prior to the 20R3 release. We will begin tracking changes on October 23rd, 2020. Updates will stop on December 11, 2020.

Feature:	Name of the feature introduced in 20R3
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
None	Not visible in Vault unless enabled by Support

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	CIOMS Enhancements	High	Auto-On	Visible to All Users	The CIOMS form will now include the following information (if available in a Case): the top priority seriousness value with each Adverse Event, Drug History, Adverse Event outcome, and the Assessment Result. Section 8-12 will now also represent the seriousness values of the whole Case and not just the primary Adverse Event.
Safety	Generate ICH E2B R2	High	Auto-On	Visible to All Users	Vault Safety now supports exporting ICH E2B R2 submission documents. This feature includes the ability to generate E2B files with ICH-specific data elements and a new user-facing option for generating an ICH E2B R2 file.
Safety	ICH E2B R3 Submission Validation	High	Auto-On	Visible to All Users	Vault Safety now provides Submission-level validation based on ICH E2B (R3) specifications. The validation includes over 150 ICH E2B (R3) validation rules and applies to EMA E2B R3, FDA VAERS E2B R3, and ICH E2B R3 file formats. This feature includes a change to remove the "Generate Transmission Document(s)" Entry Action from the Pending state in the Transmission lifecycle.
Safety	VAERS Combination Products Submission	High	Configuration	Visible to All Users	Vault Safety will now support Combination Product submissions to VAERS to ensure compliancy with upcoming January 2021 FDA regulations. This includes Case Processing with vaccine-led combination products and E2B R3 submission to VAERS with vaccine-led combination products.

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Safety	Email Distributions & Submission	High	Configuration	Visible to All Users	Vault Safety now supports a new type of Transmission Profile for sending submissions and distributions via email. A cover letter template can be configured to send as part of an email transmission, and multiple recipient email addresses can be specified for each email transmission profile. Email transmissions are tracked for delivery, opening, and error for each recipient.
Safety	MHRA Submission Setup (BREXIT)	High	Configuration	Visible to Admins Only	Administrators can now configure Vault Safety to allow submissions to the Medicines and Healthcare products Regulatory Agency (MHRA) AS2 gateway. Submissions to the MHRA follow EMA E2B (R3) guidance and are in the EMA E2B (R3) file format. In addition to the Gateway set-up, for this feature admins must perform additional configuration to move the United Kingdom out of the jurisdiction of the EMA and add it to the MHRA.
Safety	EMA/UK Vaccines Submission	High	Configuration	Visible to Admins Only	Vault Safety now allows for the capture, tracking, and submissions of Vaccines to EMA.
Safety	Auto-Submissions	High	Configuration	Visible to Admins Only	Vault Safety can now submit multiple ICSR files to the gateway and email destination directly from the Case. Once the reporting obligations are evaluated for a Case, you can submit at the Case level without navigating to each Submission/Distribution. Admins can configure, at the Transmission Profile level, which agencies and distribution partners qualify for auto-submission.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	ICH E2B R3 Case Validation	High	Configuration	Visible to Admins Only	Vault Safety now provides Case-level validation based on ICH E2B (R3) specifications. The validation includes over 150 ICH E2B (R3) validation rules and applies to EMA E2B R3, FDA VAERS E2B R3, and ICH E2B R3 file formats.
Safety	VAERS Submission	High	Configuration	Visible to Admins Only	Vault Safety now supports the capture, tracking, and submissions of ICSRs with suspect or interacting Vaccine-type products to the Food and Drug Administration (FDA). Submissions are supported through the FDA CBER VAERS Gateway, using a new FDA VAERS E2B (R3) file format. As part of this feature, Vault Safety's data model was extended to new fields to capture the data required for VAERS submissions. Additional enhancements include translation of Vaccine specific object types, conditional auto-calculation of Age at Vaccination, the prevention of creating multiple Patient Contacts or Best Doctors, and the mapping of VAERS specific acknowledgements to Vault Transmission lifecycle states.
Safety	Masked Distribution for VAERS E2B R3 File Format	High	Admin Checkbox	Visible to Admins Only	With this release, Vault Safety has extended sensitive data protection for distributions. Sensitive FDA VAERS-specific fields are now masked in addition to the pre-existing masked fields for Distributions with Patient Content Protection (PII) Masking and/or E2B Masking turned on. This enhancement applies to the FDA VAERS E2B (R3) file format. **Note**: Content protection preferences apply only to partner distributions, not reporting obligations.

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Safety	System Managed Lock Object Protection (Approved, Closed, Superseded, Locked	High	Auto-On	Visible to All Users	The Vault Safety system now has mandatory edit protections on all standard Case-related objects in the Approved, Closed, and Superseded states. As before, with system-configured locking, Vault Owners are still able to edit Case-related objects in these protected states.
Safety	Atomic Security Support on App Controls	Medium	Auto-On	Visible to All Users	Vault Safety's app controls have been enhanced to fully support atomic security on a field by field basis. Fields that are logically grouped together will all respect the most stringent security of any of the underlying fields.
Safety	PBRER Unmasked Cumulative SAE from Clinical Trials and Line Listings	Medium	Auto-On	Visible to All Users	The unmasked Cumulative SAE from Clinical Trials and Line Listing reports are now available for PBRER periodic reports. Additionally, the logic to generate masked Cumulative SAE from Clinical Trials is updated to generate blind-protected unmasked versions of tabulations in addition to the masked version. **Note:** The unmasked Cumulative SAE from Clinical Trials table is automatically generated for PBRER without any configuration. However, blind protection will be applied so that only authorized users may access unmasked versions. The "Document(s) to Generate" picklist and the "Generate Masked Document" checkbox must be configured to appear on the page layout.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Local Region Submissions and Language Translation Support	Medium	Configuration	Visible to Admins Only	Vault Safety will now support the ability to translate and distribute Cases to local regions. This includes the ability to translate a global English Case to any number of languages. Many languages are available by default and additional languages can be added. This feature enables global submissions to agencies, partners, ethics committees, and other organizations. When a Case is approved, Vault Safety prepares the Case for translation with respect to reporting obligations. Localized E2B(R2) and E2B(R3) are generated, including all translated text.
Safety	Automatic Email of Case Questionnaire & Scheduled Reminders	Medium	Configuration	Visible to Admins Only	Vault Safety can now automatically send questionnaires to a reporter by email, depending on the product, country, language, and watchlist. Vault Safety will also send reminders to the reporter a specified number of times at specified intervals. Vault Safety can also track whether these emails are delivered and opened.
Safety	Add Regulatory Agencies as Standard Organizations	Medium	Admin Checkbox	Visible to Admins Only	Vault Safety is now pre-loaded with many worldwide health authorities. In addition, Vault Safety now supports gateway submissions to Health Canada.
Safety	Multilingual MedDRA	Medium	Admin Checkbox	Visible to Admins Only	Central MedDRA now supports the following MedDRA Languages: Chinese, Czech, Dutch, French, German, Hun garian, Italian, Korean, Portuguese, Brazilian Portuguese, Russian, and Spanish. This support is a backend change to serve as a foundation for future enhancements to the MedDRA Browser, Local Case Translation, and Local Case Intake.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Extended Data Model for Vaccines	Low	Configuration	Visible to All Users	Vault Safety data model was extended to better capture and track Vaccine-specific information. Data model extensions include adding the Health Care Professional object type to Case Contact, adding a new Suppress Submission to Case field, adding a new text field for Reason Received Late on Case, adding a new External System UID for integrations on Case, as well as adding the Hospital Admission Date for Patient (PHI), the Hospital Discharge Date for Patient (PHI), the Conception Date for Patient (PHI), and the Pregnancy Due Date for Patient (PHI).
Safety	E2B+ SDK Extension for Custom Distribution Formats	N/A	Configuration	None	Vault Safety now allows custom developers to extend existing E2B XML formats or create their own new text data transfer formats.
Safety	Performance and Infrastructure Enhancements	N/A	Auto-On	None	Internal infrastructure enhancements to improve scalability and performance.
Safety.AI	Inbox Item Security and Audit Trail	High	Auto-On	Visible to All Users	Safety.AI now enforces Vault security around Inbox Items including Permission Sets, Lifecycle State, and Atomic security, to ensure only authorized users can access Inbox Items. Users must be assigned the API Vault Action permission to be able to create Inbox Item records for any sponsor organizations by calling the Intake API. In addition, Safety.AI automatically compiles an audit trail that logs actions on Inbox Item records and sections as well as Create AER actions.
Safety.AI	Case Level Seriousness Detection For Inbox Priority	High	Auto-On	Visible to All Users	Safety.AI will now predict and suggest priority for new Inbox Items based on the Case-level seriousness from text if seriousness is not provided in structured data.

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Safety.AI	Calculated Inbox Item Priority	High	Auto-On	Visible to All Users	Safety.AI automatically suggests the priority for new Inbox Items based on Adverse Event seriousness. You can verify the suggested priority while verifying the data in each Inbox Item, and use priority to quickly sort and filter Inbox Items in order to find and process the highest priority items first.
Safety.AI	Send AER to External System	High	Configuration	Visible to Admins Only	Prior to sending the AER to an external system or promoting it to a Vault Safety Case, Safety.AI compares the current AER against all other AERs in the system to find all potential matches. Safety.AI integrates seamlessly with Vault Safety. Customers with the full Vault Safety Suite can promote their AER to a Vault Safety Case and continue with case processing. For customers using an external system for case processing, Safety.AI transmits AERs through an AS2 Gateway using the ICH-compliant E2B (R3) format.
Safety.AI	Record Ranking and Unstructured Text in Source Data UI Panel	Medium	Auto-On	Visible to All Users	The user interface has been designed for Safety.AI to streamline high-volume case intake. Safety.AI guides users to review and verify information extracted from unstructured data such as case narratives. To provide context during data verification, the system shows a snippet of the relevant unstructured data and highlights the extracted value. You can expand and collapse blocks of unstructured data for additional context. During data verification, users can assign ranks to repeated sections (Case Adverse Event, Product, and Reporter). Sections assigned a rank are listed in descending order.

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Safety.AI	Inbox Item Date Validations	Medium	Auto-On	Visible to All Users	Inbox Item dates will be validated during verification and on promotion.
Safety.AI	Suggestion Generation and Verification	Medium	Auto-On	Visible to All Users	When Safety.AI infers case data from indirect mentions in the source text, it clearly identifies suggestions for the user to consider during data verification, along with their confidence level and rationale to make verification easy. The system can make suggestions for the Drug role and rank, Patient Gender, and Event Country fields if the data cannot be directly extracted from the intake source. For example, if the Event Country is not stated but the text includes the Reporter's country, the system infers that the Reporter's country may also be the Event Country and makes a suggestion based on this data.
Safety.AI	Product Dosage Intake	Medium	Auto-On	Visible to All Users	Safety.AI will support Product Dosage intake. The Intake API will accept dosage information in the JSON structured data that will be presented in Product sections of the Inbox Item user interface. Up to 10 dosages will be supported and users will be able to verify, edit, add, and delete product dosages for each product record.
Safety.AI	Case Contact Intake and Classification	Medium	Auto-On	Visible to All Users	Vault Safety.AI API will ingest structured contact information for reporters, patients, and other contacts. While entering and verifying data, Safety.AI allows users to classify Case Contact types, including differentiating between reporters and the patient.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety.AI	Simple Conflict Resolution for Text and Age Fields	Medium	Auto-On	Visible to All Users	To make data verification easier, Safety.AI shows the confidence score for values extracted from the source text. This feature helps reduce the effort to resolve information conflicts when multiple potential values are inferred from the source text by showing the options ranked with the highest confidence score first. Safety.AI automatically populates high confidence level predictions, while medium confidence level data is available in a drop-down menu.
Safety.AI	Intake and Verification for New Product and Reporter Fields	Medium	Auto-On	Visible to All Users	Safety.AI will support Product Indication and Lot Number intake. The Intake API will accept these fields in the JSON structured data that will be presented in Product sections of the Inbox Item user interface. Users will be able to edit and save these fields. Additionally, vaccine company products on the AER will create Vaccine Case Products on the AER once verification is complete.
Safety.AI	Manual AER Intake	Medium	Auto-On	Visible to All Users	Users can manually create Inbox items as an alternative to automated intake through the API.
Safety.AI	Vaccine Administration Facility and Cause of Death Intake	Medium	Auto-On	Visible to All Users	Safety.AI Intake API will validate and ingest Vaccine Administration Facility and Cause of Death information. Case Contact and Cause of Death records will be generated upon promoting to Case.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety.AI	Data Extraction for Patient Information and Event Dates	Medium	Auto-On	Visible to All Users	Safety.AI uses Natural Language Processing and rule-based algorithms to automatically extract case information from unstructured data (text) sent through the API. This feature adds support to extract the Patient Age unit, Date of Birth, and Date of Death.
Safety.AI	AI Service - Intake Assembly Service	Medium	Auto-On	None	Safety.AI uses Natural Language Processing and rule-based algorithms to automatically extract case information from unstructured data (text) sent through the API. This epic aims to merge this information with other unstructured and structured data to create a Sparse AER.
Safety.AI	AI Service - Product and Event Classification, Dates and Addresses Extraction	Medium	Auto-On	None	Safety.AI uses Natural Language Processing and rule-based algorithms to automatically extract case information from unstructured data (text) sent through the API. This epic adds some AI service capabilities for product and adverse event classification, as well as dates and address extraction.
Safety.AI	AI Service - Data Extraction for Products, Medical Terms, Reporters and Patient Age	Medium	Auto-On	None	Safety.AI uses Natural Language Processing and rule-based algorithms to automatically extract case information from unstructured data (text) sent through the API. This epic adds some AI service capabilities leveraging AWS Comprehend Medical for extraction of Products, Medical Terms, Reporters, Test Results, and Patient Age.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety.AI	Product And Medical Event Classification	Medium	Auto-On	Visible to All Users	Safety.AI attempts to classify products (Case Product or Drug History) and medical events (Adverse Event or Medical History) to help intake users triage and verify product and event information. The system can classify the product drug role as drug history, suspect, interacting, concomitant, treatment, or not administered. The system can classify the medical event type as concurrent condition, adverse event, or medical history. Users can verify and edit the product and event type when they verify the Inbox Item. When the Inbox Item is promoted to an AER, the system creates the appropriate Case Product or Drug History records and Adverse Event or Medical History records based on the drug role and event type respectively.
Safety.AI	Promote to Case from Inbox Item	Medium	Configuration	Visible to All Users	Case Validity will now be checked on the Inbox Item form. After verifying the data of an inbox item, users will be able to check duplicates and promote to Case directly. The user will automatically be redirected to the Case.
Safety.AI	Data Validation and Promote to AER	Medium	Configuration	Visible to Admins Only	After verifying the data of an Inbox Item, users can create an AER to proceed with case processing. This feature includes section validation to ensure field values are E2B (R3) compliant.
Safety.AI	Safety Inbox	Low	Auto-On	Visible to All Users	Safety Inbox is the core object and hub of activity for Safety.AI

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety.AI	Structured Case Data Intake and New Inbox Item Fields	Low	Auto-On	Visible to All Users	Safety.AI Intake API will validate and ingest case information that is not editable on the Inbox Item form, including Case Contact, Adverse Event, Case Products, Product Dosage, and Product Indication fields. These fields will be snapshot to the Case upon promoting to Case. Safety.AI will support two new fields, Product Patient Route of Administration (RoA) and Adverse Event Outcome for structured data API intake and for verification on the Inbox Item form.
Safety.AI	Case Detail and Patient Intake	Low	Auto-On	Visible to All Users	The user interface has been designed for Safety.AI to streamline high-volume case intake. The system seamlessly guides users through their verification and data entry tasks on the Inbox Item page, with the ability to verify data extracted through the API while reviewing source data side-by-side. This epic covers the following non-repeater sections: Details and Patient.
Safety.AI	Human Verification Enhancements For Predictions	Low	Auto-On	Visible to All Users	Dropdown fields will be searchable to make selection easier, especially from long lists (e.g. country). In addition, Safety.AI will now automatically populate medium confidence level predictions in addition to high-level ones.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety.AI	Reporters, Products and Adverse Events Intake	Low	Auto-On	Visible to All Users	The user interface has been designed for Safety.AI to streamline high-volume case intake. The system seamlessly guides users through their verification and data entry tasks on the Inbox Item page, with the ability to verify data extracted through the API while reviewing source data side-by-side. Users can also manually create and remove Reporter, Case Product, and Case Adverse Event child records from Inbox Items. This epic covers the following repeater sections: Reporters, Products, and Adverse Events.
Safety.AI	Safety.AI Intake Limits	Low	Auto-On	None	Safety.AI enforces limits on the Intake API input data and Inbox Item child records (e.g. number of products) to ensure the system remains stable at all times. The maximum number of records and other limits are configurable and can be adjusted by Support upon request within predefined limits.
Safety.AI	Inbox Item Document Linking	Low	Auto-On	Visible to All Users	Source Documents will be linked to their Inbox Items for better visibility and navigation.

Change Log

This feature list is subject to change prior to the 20R3 release. We will begin tracking changes on October 23rd, 2020.

Date	Change	Impact
16 Oct 2020	Initial RIA Published	N/A
23 Oct 2020	Updated "Configuration for Product and Medical Event Classification"	The RIA now includes up to date GxP Risk.
28 Oct 2020	Updated "Add Regulatory Agencies as Standard Organizations"	The RIA now includes up to date descriptions.
02 Nov 2020	Updated Descriptions for: "VAERS Submission", "Extended Data Model for Vaccines", "MHRA Submission Setup (BREXIT)"	The RIA now includes up to date descriptions.
09 Nov 2020	Added new feature "PBRER Unmasked Cumulative SAE from Clinical Trials and Line Listings" and updated description for "ICH E2B R3 Submission Validation"	The RIA now includes up to date features and descriptions.
16 Nov 2020	Added new features "System Managed Lock Object Protection (Approved, Closed, Superseded, Locked)" and "Atomic Security Support on App Controls"	The RIA now includes up to date features and descriptions.