21R3 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in the Vault Safety Suite 21R3 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 21R2 release. We will begin tracking changes on: October 8, 2021.

Revison Date:	November 15, 2021
VIA Availability Date:	November 8, 2021
Vault Safety Help	*For detailed feature descriptions, refer to the product release notes, which are available on Vault Safety Help. On November 24, 2021 we will also release the 21R3 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 21R3 Release Impact Assessment and consult Veeva Docs for Vault Platform validation details.
Feature:	Name of the feature introduced in 21R3
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	E2B(R2) Dose Form TermIDs	High	Auto-On	Visible to All Users	In this release, the Vault Safety Dose Forms dictionary will now support the full list of nearly 400 MHRA Dose Forms, including their corresponding 1 to 3 digit codes. When Vault Safety imports an E2B(R2) file containing encoded MHRA dose forms, the system maps the data to the new Dose Form dictionary entries.
Safety	ISO 8859-1 Smart Replace and Validation for FDA E2B(R2)	High	Auto-On	Visible to All Users	Vault Safety will now validate FDA E2B(R2) submission documents for character encoding and automatically replace UTF-encoded characters with their ISO 8859-1 equivalent, or replace them with a space if there is no equivalent. FDA E2B(R2) follows the ISO 8859-1 standard, which doesn't support UTF-encoded characters. When a Case contains UTF-encoded characters, Transmissions to FDA CBER or CDER in E2B(R2) format trigger validation errors or warnings.
Safety	PMDA E2B(R3) Submission Validation	High	Auto-On*	Visible to All Users	This feature introduces full PMDA E2B(R3) conformance rules, extending the ICH E2B(R3) validation capabilities delivered in 20R3. Validation is automatic when ICSR with PMDA E2B(R3) file format is generated or regenerated for a reporting destination. PMDA E2B(R3) regional validation can be invoked at the case level using the Evaluate Regulatory Conformance action. Validation Result records are created for each evaluated Validation Criteria and can have an outcome of Pass, Fail, or Warning. **Enablement Note:** Auto-On if the E2B Case and Submission Validation feature (introduced in 20R3) is already configured in your vault. Otherwise, this feature requires configuration.
Safety	Japan PMDA E2B(R3) Export	High	Auto-On	Visible to All Users	Vault Safety now supports exporting Japan PMDA-compliant E2B(R3) files for individual cases.

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Safety	Expectedness in Periodic Reports (RSI)	High	Configuration	Visible to Admins Only	Vault Safety now supports evaluating adverse event expectedness within a specific time period, to accurately identify SUSARs in periodic reports. In a Product Datasheet, you can specify the approval date range for each term. When generating a DSUR, PBRER, or PSUR, you can select the relevant Product Datasheet version to evaluate term expectedness in periodic reports.
Safety	PMDA Gateway Submission	High	Configuration	Visible to Admins Only	Vault Safety now supports ICSR submissions to the Japan Pharmaceuticals and Medical Devices Agency (PMDA) AS2 gateway. Submissions to the PMDA follow PMDA E2B(R3) guidance and are in the PMDA E2B(R3) file format.
Safety	Most Conservative Product and Assessment Evaluation per Region Rules	High	Configuration	Visible to Admins Only	Vault Safety administrators can now optionally configure reporting rule sets to evaluate rules against the most conservative Case Product and Case Assessment. Seriousness, expectedness, relatedness, and the drug role of the related Case Products are all considered when determining the most conservative Case Product and Case Assessment. Unless configured otherwise, pre-existing rule sets, such as the FDA and EMA ICSR rule sets, continue to evaluate rules based on the primary Case Product and Case Assessment. In addition, when this feature is configured in a rule set, Vault Safety evaluates the “AE in Jurisdiction” rule parameter using the country specified on the primary Reporter Case Contact instead of the country on the primary Case Adverse Event. This is to align with ICH guidelines.

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Safety	Japan PMDA Submission Rules	High	Configuration	Visible to Admins Only	With this release, a new standard reporting Rule Set will be available for PMDA ICSR Submissions. If the system identifies a Japanese Product or Study Registration in a Case as reportable to PMDA, a submission record for PMDA will be scheduled based on the reporting rules.
Safety	Email to Vault Safety Inbox Item	High	Configuration	Visible to Admins Only	This feature enables customers to send emails to a Vault-owned email address and automatically create Inbox Items with the email and attachments. Vault Intake users will receive a notification when new Inbox Items are created from emails so they can start case intake. Customers can continue to use an existing email address by setting up an auto-redirecting rule to a Vault-owned email or Vault users can send emails directly to a Vault-owned email address. Admins can define up to 50 Vault-owned email addresses and configurations associated with each email address.
Safety	PT Aggregation in Periodic Reports	High	Support	N/A	This feature provides the option to count only unique instances of Preferred Terms (PT) per Case for summary tabulations in periodic reports. When enabled, if a Case contains multiple Case Adverse Events coded under the same PT, the report counts a single PT event instead of multiple events. This feature impacts the DSUR and PBRER Cumulative Tabulation of Serious Adverse Events From Clinical Trials; DSUR Appendix Cumulative Summary Tabulation of Serious Adverse Reactions From Clinical Trials; PBRER Summary Tabulation of Adverse Drug Reactions from Postmarketing Sources; PSUR Summary Tabulations; and PADER Summary of ADR from Postmarketing Sources. Unless this feature is enabled, the system continues to count each Case Adverse Event separately.

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Safety	Inbox Item Follow-Up: Pre-calculations	Medium	Admin	Visible to Admins Only	Vault Safety now pre-calculates and displays automatic field calculations, Combination Product Constituents, and Study Products when merging an Inbox Item to a follow-up Case version. This behavior ensures that automatically calculated fields are always up-to-date on the new follow-up Case version. This feature also introduces the Case Promotion Settings Page, where admins can enable and configure settings for Inbox Item Follow-up.
Safety	Inbox Item Follow Up	Medium	Admin	Visible to Admins Only	When promoting an Inbox Item, duplicate detection now presents an option to create a Follow-Up Case that compares all the data on the previous Case version with the new data on the Inbox Item. Users can select which information they want to keep or ignore based on the Inbox Item. Upon Case promotion, the system merges the data from the previous Case version and the Inbox Item to create a Follow-Up Case version. This feature supports Inbox Item passthrough fields received through the API and atomic security on fields from the previous Case version.
Safety	Auto-Expectedness Roll Up Override	Medium	Auto-On	Visible to All Users	This enhancement delivers updated logic to ensure that overriding expectedness on a Case Assessment does not prevent the Case-level Expectedness field from updating to match the primary Case Assessment, unless the Case-level Expectedness field has been explicitly overridden.

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Safety	Inbox Item Intake Enhancements	Medium	Auto-On*	Visible to All Users	Manual intake and verification on Inbox Items is made easier with several new enhancements. Firstly, the New Info Date will now be available in the Inbox grid to sort new Inbox Items by date and easily identify late Cases. Secondly, the display for imported long text fields (such as Case Narratives) is now wider to facilitate the verification using the Source Pane. Thirdly, the Inbox Item sections will now show a Save button instead of Verify for manual entry to differentiate that from verification of imported or extracted data. Fourthly, all the required fields will be highlighted in yellow and will not have a blank option. **Enablement Note:** Auto-enabled when using Inbox Item.
Safety	MedDRA Synonyms	Medium	Configuration	Visible to Admins Only	Vault Safety can now capture company-specific MedDRA coding preferences and speed up coding with a MedDRA Synonym list. You can manually create and edit synonyms in Vault Safety, or bulk import synonyms from an external source. When auto-coding a MedDRA field from a reported term, Vault Safety will first search for an exact match to an active MedDRA Synonym. If no exact match is found, the system will search the MedDRA dictionary for a matching term.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Configurable Field Exceptions for Masked Distributions: Blank, Sex, Country	Medium	Configuration	Visible to Admins Only	With this release, when turning on Patient Content Protection, Vault Safety now supports configuration to leave certain fields unmasked in masked Distributions. You can choose to unmask one or more of the following fields: blank fields, Reporter Country, Parent Sex, and Patient Sex. You can now pre-configure which of these PII/maskable E2B fields should be unmasked, while the remaining fields stay masked. Also, when the Date of Birth field is masked, the system now populates the Age and Age Group field values during ICSR report generation, if available. This enhancement is supported for all ICSR output formats, including E2B and PDF forms.
Safety	Domestic Case Processing	Medium	Configuration	Visible to Admins Only	Vault Safety now supports domestic case processing for region-specific data collection. For example, for cases reportable to Japan, the PMDA has specific requirements for domestic case data collection. You can complete data entry and case processing in the local language, from intake through the medical review stage.
Safety.AI	Automatic Case Intake from Uploaded Email	Medium	Configuration*	Visible to Admins Only	Vault Safety.AI will now automatically extract case information from EML and MSG email files. Intake users to start the extraction process from an email file and attachments with Viewable PDF Renditions. Upon successful completion, the system creates a single Inbox Item linked to the email and attachments. **Enablement Note:** Auto-on for Safety.AI customers who have configured the "Create Inbox Item" action and enabled Attachments on the Document Type.
Safety, Safety.AI	Intake via API using JSON Object	N/A		N/A	The Intake Json API will now accept Json text as intake_json parameter so that Inbox Item data can be passed in as a Json object.

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Safety	Intake JSON API for Safety Customers	N/A		N/A	Vault Safety can now ingest cases using the Safety.AI Intake JSON REST API (/api/\{version}/app/safety/ai/intake) to receive an Inbox Item from a JSON file. Vaults no longer require Safety.AI to receive calls from this endpoint. Vaults without Safety.AI only support processing structured data (JSON) and unstructured data will be ignored. Besides, the Vault Retrieve Job Status endpoint should be used to determine the status of the request: GET {{/api/\{version}/services/jobs/\{job_id}.}}

Change Log

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Date	Change	Impact
08 Oct 2021	Initial RIA Published.	N/A
15 Nov 2021	Configuration enablement links added.	The RIA is now updated with links to enablement artricles for features with configuration tasks.