21R2 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in the Vault Safety Suite 21R2 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: June 21, 2021.

Revison Date:	July 14, 2021
VIA Availability Date:	July 13, 2021
Vault Safety Help	For detailed feature descriptions, refer to the product release notes, which are available on Vault Safety Help. On August 5, we will also release the 21R2 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 21R2 Release Impact Assessment and consult Veeva Docs for Vault Platform validation details.
Feature:	Name of the feature introduced in 21R2
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	Configurable Back Reporting	High	Auto-On	Visible to Admins Only	The configurable back reporting feature, which was first released in 21R1 with Support enablement, is now available automatically in all vaults. By default, back reporting will be turned off (i.e. prevented) for all reporting destinations, except Health Canada. Please refer to the 21R1 release documentation for more information on this feature.
Safety	DSUR - Extended Definition of Death	High	Auto-On*	Visible to All Users	In Vault Safety, the List of Subjects Who Died During the Reporting Period Appendix now lists only the latest version of a fatal case received or approved during the reporting period, based on the value selected in the DSUR "Filter Case by" field. Also, the appendix table constraints have been updated to consider additional criteria for more accurate fatal case identification. Enablement Note: This feature is auto-on for customers who have DSUR appendices enabled. Previously generated DSURs need to be regenerated to see the update.
Safety	EMA Certification: Name Parts and RoA Prioritization	High	Auto-On	Visible to All Users	With this release, Vault Safety supports the import and export of EMA "Product Name Parts." New Name Parts fields are available for Case Product data entry. Additionally, EMA E2B R3 file exports now prioritize structured (G.k.4.r.10.2a/b) over unstructured (G.k.4.r.10.1) data for the Route of Administration.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Case Level Regional Validation for VAERS and EMA/MHRA E2B R3	High	Auto-On*	Visible to All Users	With this release, users can evaluate and review regional FDA VAERS and EMA E2B R3 Validation Results at the Case level. The FDA VAERS and EMA regional rules are now evaluated when the Evaluate Regulatory Conformance action runs on the Case. Regional validation results are displayed on the Case, alongside the ICH (global) validation results. Enablement Note: This feature is auto-on for customers who have the "Evaluate Regulatory Conformance" user action configured on the Case object. Otherwise, this feature can be enabled by configuring the action on the appropriate lifecycle state on the Case object.
Safety	Replace UTF Smart Quotes with ASCII Straight Quotes in FDA E2B(R2)	High	Auto-On	Visible to All Users	Vault Safety will fix an issue related to the generation of compliant FDA E2B(R2) submissions, converting "Smart Quotes" characters to "Straight Quotes" characters during ICSR generation. This will ensure the resulting ICSR is ISO 8859-1 compliant, as required for FDA E2B(R2) submissions.
Safety	VAERS Certification Enhancements	High	Auto-On	Visible to All Users	This feature, which was first released in 21R1 with Support enablement, is now available automatically in all vaults with Vaccines and VAERS Submissions enabled. Please refer to the 21R1 release documentation for more information on this feature.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Multi-Case E2B Import via API/AS2	High	Auto-On	Visible to All Users	This feature, which was first released in 21R1 with Support enablement, is now available automatically in all vaults with AS2 Gateway or API Transmissions already configured. Please refer to the 21R1 release documentation for more information on this feature.
Safety	Default Sender User by Destination	High	Configuration	Visible to Admins Only	Administrators can now configure a default sender user on all Transmission Profiles to be populated on system-generated Transmissions. For example, this allows for defaulting different QPPV contacts for EMA and MHRA.

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Safety, Safety.AI	E2B R2 and R3 Import to Inbox Item	High	Configuration*	Visible to Admins Only	Vault Safety now supports the ability to import single- and multi-case XML files in E2B(R2) and (R3) formats to Inbox Items. The system performs an E2B import upon receiving an AS2 Gateway transmission, or when a user runs the import action from an E2B document in the vault library. The Inbox Item displays the mapped E2B source data for the Case, Patient, Reporter, Adverse Events, Case Products, and Medical and Drug History in the Source Data pane. This feature also benefits from Vault Safety's existing import to AER capabilities, including Study and Product matching, data mapping, and literature and attachments import. Note: As of 21R2, AERs will enter a sunset period. No new functionality will be added to AERs. Using the new Inbox (Inbox Item) is optional in 21R2 (August 2021), recommended in 21R3 (December 2021), and mandatory in 22R1 (April 2022), when AERs will become obsolete. Enablement Note: This feature is auto-on for Safety.AI customers who are already using the Create Inbox Item action released in 21R1 for form intake.
Safety	FDA E2B R2 - Support "FDA Safety Report Type" (A.1.FDA.16) Field For Post Market	High	Support	Visible to Admins Only	Vault Safety now supports adding the FDA Safety Report Type (A.1.FDA.16) element to FDA E2B(R2) Transmissions. This feature only impacts the Transmission file format FDA E2B(R2). Only the FDA Safety Report Type tag is being added to support postmarket submissions (E2B Code=3). Other IND Safety Report tags are not yet supported. This field will only be populated for post market cases. It will not be present for study cases.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	E2B Import: Match Non-Current MedDRA in Central	Medium	Auto-On*	Visible to All Users	Vault Safety now supports coding non-current terms using central MedDRA when importing E2B files that contain non-current terms. A 'Recode' badge is displayed to remind users when a coded term is non-current. Also, the Case MedDRA Version of promoted cases from AER or Inbox Item is now set by the Active MedDRA version on user's vault. Enablement Note: This feature is auto-on for customers who are using Central MedDRA.
Safety	Support Substance Decimal Places	Medium	Auto-On	Visible to All Users	Case Product Substance Strength field now supports up to 4 decimal places of precision. During an E2B export, the value is truncated to the appropriate number of characters.
Safety	China (NMPA) Local Fields	Medium	Configuration	Visible to Admins Only	With this release, Chinese local data elements required by NMPA (China regulatory authority) become available for data entry.
Safety, Safety.AI	Local to English Language Intake	Medium	Configuration	Visible to Admins Only	Vault Safety now supports case intake from the local language to English through the Inbox Item, provided in the new Inbox. For example, the EMA requires English submissions. If an adverse event is reported from Holland in Dutch, you can enter the Inbox Item in Dutch while translating the data to English before promoting it to a Case. Note: As of 21R2, AERs will enter a sunset period. No new functionality will be added to AERs. Using the new Inbox (Inbox Item) is optional in 21R2 (August 2021), recommended in 21R3 (December 2021), and mandatory in 22R1 (April 2022), when AERs will become obsolete.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Multilingual MedDRA: Japanese	Medium	Configuration	Visible to All Users	Vault Safety Inbox Items now support the ability to browse, search and auto-code current MedDRA terms in Japanese. When the MedDRA control language is set to Japanese, the MedDRA browser filters out non-current Japanese terms by default.
Safety, Safety.AI	Multilingual MedDRA Browser and Autocode	Medium	Configuration	Visible to Admins Only	Adverse events can now be auto-coded and translated using any non-English MedDRA-supported language (except Japanese). For adverse events reported in a non-supported MedDRA language, both the native term and English translation can be manually entered; users can then auto-code the English translation. These capabilities are available on the Inbox Item screen during case intake, and the Case Adverse Event screen during subsequent case processing.
Safety	E2B Imported Case Naming and Versioning	Low	Auto-On	Visible to All Users	Imported cases created from E2B will now be named by their Unique Identifier (UID). In E2B (R3), this will map from C.1.1. Newly created Imported Cases will default to version 0.1
Safety.AI	Automatic Intake From Documents with a Viewable PDF Rendition	Medium	Auto-On	Visible to All Users	Safety.AI automatic PDF form intake feature will now be available for all file formats, including Word and image files. This will allow users to start the extraction process from any Vault Document with a Viewable PDF Rendition. Upon successful completion, an Inbox Item will be created with the case information extracted from the document text, fields, and checkboxes.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety.AI	New Checkbox Recognition from Documents	Medium	Auto-On	Visible to All Users	Safety.AI will automatically extract additional information from document checkboxes including Outcome, Report Type, Patient Gender and Age Group. Adverse Event Outcome and Seriousness will now be suggested from Case Outcome and Seriousness. The Source Data pane will show this information to facilitate human verification. Also, Safety.AI will now show a value only once in the field dropdown when it was found multiple times in the source text.
Safety.AI	Deprecate Create AER Action	Low	Auto-On	Visible to Admins Only	The Create AER action is being deprecated in 21R2. The Create AER user action was replaced in 20R2 by Create Case to allow users to promote an Inbox Item directly to a Case, without creating an AER record.
Safety.AI	AI Service with no Vault Connections	N/A	Auto-On	Visible to Admins Only	Configuration is no longer required to connect to the AI Service when setting up a new Vault with Safety.AI. Previously, an administrator had to create an External Vault Connection.

Change Log

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Date	Change	Impact
14 Jun 2021	Initial RIA Published.	N/A
22 Jun 2021	Updated the descriptions for the features "MedDRA-J" and "Non-Current in MedDRA Central". Updated the feature name for "Imported Case Name and Versioning" to "E2B Imported Case Name and Versioning".	The RIA is now up-to-date with feature names and descriptions.
25 Jun 2021	Updated the feature names for "Multilingual MedDRA: Japanese" and "E2B Import: Match Non-Current MedDRA in Central". Updated feature description for "Multilingual MedDRA: Japanese".	The RIA is now up-to-date with feature names and descriptions.
28 Jun 2021	Updated the feature name for "EMA Certification: Name Parts and RoA Prioritization."	The RIA is now up-to-date with feature names and descriptions.
29 Jun 2021	Updated the feature name for "Case Level Regional Validation for VAERS and EMA/MHRA E2B R3" and "Multilingual MedDRA Browser and Autocode". Updated feature enablement for "FDA E2B R2 - Support "FDA Safety Report Type" (A.1.FDA.16) Field For Post Market" to "Support".	The RIA is now up-to-date with feature names and descriptions.
05 Jul 2021	Removed "Inbox Item Follow-Up" feature from the RIA and updated feature description for "E2B Import: Match Non-Current MedDRA in Central".	The RIA is now up-to-date with feature names and descriptions.
14 Jul 2021	Added feature enablement links to features with configuration.	The RIA now has convenient links to the help site for any features with configuration enablement required.