21R1 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in the Vault Safety Suite 21R1 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 21R1 release. We will begin tracking changes on: March 1, 2021

Revison Date:	April 13, 2021
VIA Availability Date:	March 23, 2021
Vault Safety Help	For detailed feature descriptions, refer to the product release notes, which are available on Vault Safety Help. On April 15th, we will also release the 21R1 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 21R1 Release Impact Assessment and consult Veeva Docs for Vault Platform validation details.
Feature:	Name of the feature introduced in 21R1
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 ACK for Inbound Transmission	High	Auto-On	Visible to All Users	The system now supports the generation and transmission of Acknowledgement Message (ACK) in the E2B(R2) format for inbound single-case or multi-case E2B(R2) transmissions.
Safety	EMA E2B R3 Submission Validation	High	Auto-On*	Visible to All Users	This feature introduces full EMA E2B R3 conformance rules, extending the ICH E2B R3 validation capabilities delivered in 20R3. Validation is automatic when the EMA E2B R3 file format is generated or regenerated for a reporting destination. Validation Result records are created based on each evaluated Validation Criteria and can have an outcome of Pass, Fail, or Warning. Note: MHRA uses the EMA E2B R3 format and will be validated for EMA E2B R3 conformance. Enablement Note: If not previously configured in the 20R3 release (with the ICH Submission Validation) this features requires configuration on the Transmission (Submission and Distribution) to add the Validation Results section to the Page Layout.
Safety	Local Expedited, Downgrade, and Postmarket Study Submissions	High	Auto-On*	Visible to Admins Only	Vault Safety is extending its agency submission and distribution capabilities to configure rules-driven local expedited criteria, downgrades (aka one last time rule), and non-interventional postmarket studies. These updates have been reflected in the EMA and FDA rulesets. In addition, the FDA and EMA rule names have been refreshed to be more business-friendly names. Enablement Note: This is auto-on for customers who have enabled the "Evaluate Reporting Obligations" action (introduced in 19R3 as part of EMA submissions).

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Multi-Case E2B Import via API/AS2	High	Auto-On*	Visible to All Users	Vault Safety now supports the ability to import multi-case XML files in E2B(R2) and (R3) format via AS2 Gateway or API. Additionally, multi-case E2B(R2) files can be imported manually through the UI. Enablement note: Auto-on if the customer already has AS2/API set up.
Safety	Multiple Case E2B Import	High	Auto-On	Visible to All Users	Vault Safety now supports the import of EMA E2B(R3) files that contain multiple cases.
Safety	PADER Transmission Date Filter	High	Auto-On*	Visible to All Users	Vault Safety now filters PADER reports based on Transmission Date by default, which allows a firm cutoff date for including cases in the report. Cases with multiple versions for initial, follow-up or amendment reasons within the same reporting period are counted as initial in the PADER. In the 15 Day Summary Reports, the system considers additional criteria to identify fatal cases. Enablement Note: Feature is auto-on for customers who have configured PADER. This will not impact previously generated reports; they must be re-generated to take effect.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Postmarket Studies and Literature enhancements for PADER, PBRER, PSUR, CIOMS and 3500A	High	Auto-On*	Visible to All Users	PADER, PBRER, PSUR, CIOMS I, and 3500A have been enhanced to leverage Study Type to account for Post Market studies. To improve the data entry experience, administrators can now configure Study Type on Studies so that new study cases can automatically default the Study Type. A new literature flag has been added to Report Type to classify literature. This will be automatically turned on for our standard Literature Report type and can be configured on custom report types to drive literature classification in PADER, PBRER, PSUR, CIOMS I, and 3500A. Enablement Note: Feature is auto-on for customers who are using PADER, PBRER, PSUR, CIOMS I, or 3500A. This will not impact previously generated reports; they must be re-generated to take effect.
Safety	Promote to Case Follow-up: Set Follow-up Receipt Date to Initial Receipt Date	High	Auto-On*	Visible to All Users	With this release, when an AER is promoted to a Follow-Up Case, the receipt date on the Follow-Up defaults to the Initial Receipt Date. This change in behavior resolves an issue where the New Information Date (C.1.5 in E2B R3) was possibly earlier than the Receipt Date (C.1.4 in E2B R3) if the Receipt Date was incorrectly entered on the AER. Enablement Note: This takes effect for new cases when they are created from an AER. This does not update existing cases.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	VAERS Certification Enhancements	High	Auto-On*	Visible to All Users	Vault Safety has enhanced VAERS E2B (R3) collection, verification and generation as part of VAERS certification scenarios. Enablement Note: Auto-on for customers who have enabled VAERS data collection.
Safety	VAERS E2B R3 Submission Validation	High	Auto-On*	Visible to All Users	This feature introduces full VAERS E2B R3 conformance rules, extending the ICH E2B R3 validation capabilities delivered in 20R3. Validation is automatic when the VAERS E2B R3 file format is generated or regenerated for a reporting destination. Validation Result records are created based on each evaluated Validation Criteria and can have an outcome of Pass, Fail, or Warning. Additionally, at the case level, an extra safeguard has been added for Vaccines to display a warning if the most severe adverse event is not set as the primary. Enablement Note: If not previously configured in the 20R3 release (with the ICH Validation) this features requires configuration on the Transmission (Submission and Distribution) and Case to add the Validation Results section to the Page Layout.
Safety	PADER Subtotal/Grand Total and New Appendices	High	Configuration*	Visible to All Users	PADER now includes two new appendices: Non-Primary Suspect Product Report, and List of Death Cases. Additionally, Subtotals and Grand totals are now displayed in the Summary Tabulation of ADRs. Enablement Note: Templates for the new appendices and the existing Summary Tabulation of ADRs are *required* to be configured prior to report generation.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	PBRER, PSUR, DSUR Case Approval Date Filter	High	Configuration	Visible to Admins Only	Vault Safety now provides the option to filter PBRER, PSUR, and DSUR reports by Case Approval Date, this allows a firm cutoff date for including cases in the report. The system will continue to use the Case Receipt Date / New Info Date by default. Enablement Note: This will not impact previously generated reports, they must be re-generated to take effect.
Safety	FDA E2B R2 - Support "FDA Safety Report Type" (A.1.FDA.16) Field	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. Enablement Note: This feature won't take effect until the FDA E2B (R2) mandated date requiring the new regional data element A.1.FDA.16 (FDA Safety Report Type). After this date, FDA E2B (R2) files generated from Vault Safety will include this field automatically.
Safety	Tracking Non-Submittable Cases (Suppress Submission)	High	Configuration	Visible to Admins Only	When enabled this feature prevents automatic ICSR submission record generation for cases designated as non-submittable (i.e. Invalid, Pregnancy cases, etc). These cases will also be excluded in aggregate reports.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Configurable Back Reporting	High	Support	Visible to Admins Only	Vault Safety now supports configurable back reporting for agencies, licensed partners and other reporting destinations. Back reporting means that a report will be sent back to the original sender. By default, back reporting will be turned off (i.e. prevented) for all reporting destinations, except Health Canada. Enabling back reporting for specific destinations can be done via Transmission Profiles. For an example, after importing an E2B downloaded from EVWEB, if that case is further processed and approved, a submission to the EMA isn't generated (unless back reporting is enabled for EMA).
Safety	Use Adverse Event PT on CIOMS and MedWatch 3500A	High	Support*	N/A	Vault Safety now supports the option to display adverse events using the MedDRA Preferred Term (PT) on CIOMS I and MedWatch 3500A forms. Enablement Note: Contact Veeva Support to request this feature be enabled. Once enabled all new CIOMS I and MedWatch 3500A forms will use the MedDRA PT. This will not impact previously generated reports, they must be re-rendered to take effect.
Safety, Safety.AI	Duplicate Detection Using External System UID	Medium	Auto-On*	Visible to All Users	Vault Safety will now use the External System UID for duplication detection. It will return potential matches for cases that have only this field matching the Inbox Item or AER. Enablement Note: Feature is auto-on, but customers must configure External System UID to capture this on AER/Case (if they did not in 20R3)

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	PBRER, PSUR, DSUR, PADER Timezone Awareness and Enhancements	Medium	Auto-On*	Visible to All Users	PBRER, PSUR, DSUR and PADER report filters have been enhanced to recognize timezones for more precise case inclusion. In addition, the ability to run PADER reports based on the Case Receipt Date / New Info Date has been replaced by running the reports solely based on Transmission Date. Also, the Non-Primary Suspect Product Report will now be generated by default. Lastly, the PBRER Cumulative ADRs from Postmarketing "Interval" column has been enhanced to respect the Case Approval Date when that option is selected in the PBRER "Filter Case By" field. Enablement Note: Feature is auto-on for customers who have configured the corresponding aggregate report (PBRER, PSUR, DSUR, and PADER). This will not impact previously generated reports; they must be re-generated to take effect.
Safety	PSUR Time to Onset and Group by PT	Medium	Auto-On*	Visible to All Users	PSUR reports have been updated to use MedDRA Preferred Terms (PT) for grouping adverse events, this replaces the previous verbatim term grouping mechanic. Additionally, the PSUR Line Listing now includes Time to Onset information. Enablement Note: This feature is auto-on, however, it will not impact previously generated reports; they must be re-generated for this update to take effect.
Safety	Recode Badge for MedDRA Terms	Medium	Auto-On	Visible to All Users	Users are now made aware with a visible indicator if a coded term's MedDRA Version is not in sync with the Case MedDRA Version

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Safety	Show Assessment Results on CIOMS I	Medium	Auto-On*	Visible to All Users	This feature reintroduces Case Assessment Results on the CIOMS I form, replacing the system-generated identifiers for Product names with readable names. As always, this section respects study masking and will show the blinded name on blinded forms. Enablement Note: This will take effect for any newly generated CIOMS I form. This will not impact previously generated reports; they must be re-generated to take effect.
Safety	Support VAERS Reason Omitted "Other"	Medium	Auto-On	Visible to All Users	With this feature, customers can select "Other" as a reason omitted value for the Race (FDA.D.11) and Vaccination Facility (FDA.G.k.4.r.14.8) fields. Nullflavor "OTH" is also mapped to reason omitted "Other" as part of the FDA VAERS E2B R3 export.
Safety	Japan (PMDA) Local Fields	Medium	Configuration	Visible to Admins Only	With this release, Japanese local data elements required by PMDA (Japan regulatory authority) become available for data entry.
Safety	Korea (MFDS) Local Fields	Medium	Configuration	Visible to Admins Only	With this release, Korean local data elements required by MFDS (Korean regulatory authority) become available for data entry.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Pregnancy and Parent-Child Case Data Collection Enhancements	Medium	Configuration	Visible to Admins Only	Pregnancy and Parent-Child cases have been enhanced for the collection of child information with the introduction of the new Child Information object type for cases. This allows non-submittable pregnancy cases to be more easily tracked. To improve data entry for follow-ups to collect pregnancy outcomes, Child Information records will automatically generate test result placeholders for APGAR scores (1, 5, and 10-minute), Birth Outcome, and Head Circumference. In the event that the pregnancy outcome results in an adverse event in the neonate, the information is captured as a regular Case with a reference to the Parental (Pregnancy) Information.
Safety	Case Version and Transmission Sequence Numbers	Low	Auto-On*	Visible to All Users	Vault Safety will now stamp every new case and transmission with a sequence number. The sequence number can be used in conjunction with Vault platform capabilities to create a custom report to retrieve the latest version of a case or transmission for a period. Enablement Note: This will not stamp previously created cases or transmissions. A buffer of 10,000 unused numbers has been provided for previously created cases; however, this is not automatically applied.
Safety.AI	Inbox Item PHI/PII Encryption	High	Auto-On	N/A	This feature adds an extra layer of protection for standard personal identifiable Information (PII) on the Inbox Item. This prevents Veeva from viewing encrypted fields unless they are assigned Delegate Access for 20+ Inbox Item fields and 20+ Case fields when received via API pass-through.

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Safety.AI	Dosage Extraction	Medium	Auto-On	Visible to All Users	Safety.AI will now automatically extract the dose and administration dates from unstructured text and PDF forms, and link them to their associated Case Products. The dosage information will be populated with a confidence icon and the source text will show in the Source Data pane to facilitate human verification.
Safety.AI	Inbox Item Manual Study Intake	Medium	Auto-On	Visible to All Users	Users are now able to select the Study and Study Arm on the Inbox Item to perform manual study case intake. On case promotion, Study and Study Arm information will be downloaded from the Vault Safety Library, including the Study Registration and Study Products, to reduce data entry effort. This enhancements supports open and blinded studies.
Safety.AI	MedDRA Auto-Coding For Intake API and PDF Forms	Medium	Auto-On	Visible to All Users	When an Inbox Item is created from data received through the Intake API or extracted from a PDF form, Safety.AI initiates MedDRA auto-coding. MedDRA auto-coding extends to all MedDRA fields on an Inbox Item with corresponding verbatim ("as reported") fields. Auto-coding is based on an exact match (case insensitive) search across all MedDRA PTs/LLTs.
Safety.AI	Multiple Candidates for Date and Country Fields	Medium	Auto-On	Visible to All Users	Safety.AI will now show up to 4 candidates for Date and Country fields supported for extraction from text. Safety.AI will show the confidence level icon for each value and populate the one with the highest confidence score.

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Safety.AI	Automatic PDF Form Intake	Medium	Configuration	Visible to Admins Only	Safety.AI will automate intake from PDF forms using Artificial Intelligence and Machine Learning. A new User Action on Vault library documents will allow users to start the extraction process from the document text. Upon successful completion, an Inbox Item will be created with the extracted case information for the Reporter, Patient, Adverse Events, and Products and prioritized (P1 to P3) based on the detected seriousness.
Safety.AI	Checkboxes and Fields Recognition and Verification from PDF Forms	Medium	Configuration*	Visible to Admins Only	Safety.AI will automatically extract and map Seriousness checkboxes from a source PDF document to suggest the Inbox Item Priority. The Source Data pane will show this information to facilitate human verification. Also, Safety.AI will now extract document field labels for values found in the document text and will show them the Source Data pane along with the source text. Enablement Note: "Automatic PDF Form Intake" configuration enables this feature.
Safety.AI	Inbox Item Manual Data Entry Enhancements	Low	Auto-On	Visible to All Users	Manual Inbox Item intake has been enhanced for better usability. When a user manually creates an Inbox Item, by default the record will now have sections for the Primary Reporter, Suspect Product, and Adverse Event. When a user creates additional Case Contacts, Products, or Medical Events, the new section will be opened at creation. Additionally, when viewing a section with multiple products, events, or contacts, the first item will be expanded by default.

Change Log

This feature list is subject to change prior to the 21R1 release. We will begin tracking changes on March 1, 2021.

Date	Change	Impact
22 Feb 2021	Initial RIA Published.	N/A
01 Mar 2021	Updated descriptions for "VAERS E2B R3 Submission Validation" and "PADER Enhancements and Transmission Date Filter." Added feature "PADER Subtotal/Grand Total and New Appendices."	The RIA now includes up to date information about features in 21R1.
01 Mar 2021	Removed "Inbox Item Translations" feature because it is an internal issue.	No Impact.
08 Mar 2021	Added feature "FDA E2B R2 - Support "FDA Safety Report Type" (A.1.FDA.16) Field."	The RIA now includes up to date information about features in 21R1.
12 Mar 2021	Updated feature descriptions for "PBRER, PSUR, DSUR, PADER Enhancements and Timezone Awareness," "FDA E2B R2 - Support "FDA Safety Report Type" (A.1.FDA.16) Field," and "Case Number Stamping - Optimization to Retrieve Latest Case for a Period." Removed the "China Local Fields" feature.	The RIA now includes up to date information about features in 21R1.
16 Mar 2021	Udated feature names to accurately reflect the name of the feature instead of the name of the epic.	The RIA now includes up to date information about features in 21R1.
17 Mar 2021	Updated "Case Version and Transmission Sequence Numbers" feature name.	The RIA now includes up to date information about features in 21R1.
12 Apr 2021	Added features, "Configurable Back Reporting," "E2B R2 ACK for Inbound Transmission," and "Multi-Case E2B Import via API/AS2"	The RIA now includes up to date information about features in 21R1.
13 Apr 2021	Changed "FDA E2B R2 - Support "FDA Safety Report Type" (A.1.FDA.16) Field" feature enablement to Support.	The RIA now includes up to date information about features in 21R1.