

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault Safety 19R3 that may affect a customer's vault. We release a version of the RIA in advance of the general release. Closer to the 19R3 release date, the Validation Impact Assessment, which contains validation information for new features in 19R3, will be available in your VeevaDocs vault. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements.

Revision Date: November 20, 2019

This feature list is subject to change prior to the 19R3 release. We will begin tracking changes on November 4, 2019.

Feature:	Name of the feature introduced in 19R3
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.
<i>High</i>	May affect security, patient confidentiality, application areas that support GXP functions (audit trails, eSignature, etc.) or other ERES controls data
<i>Medium</i>	May affect core application functions (workflows, revision history, etc.)
<i>Low</i>	May affect metadata/notifications
<i>N/A</i>	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
<i>Visible to All Users</i>	Automatically on and visible to both Admins and end users
<i>Visible to Admins Only</i>	Only visible to Admins, or it requires configuration by an Admin before it is available to end users
<i>None</i>	Not visible in Vault unless enabled by Support

Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
Safety	Auto-Expectedness	High	Configuration	Visible to Admins Only	Vault Safety auto-calculates expectedness at the Case and Case Assessment levels using Product Datasheets. Admins can configure Core and Local Product Datasheets that list expected adverse events. Users can override auto-calculated fields.
Safety	Auto-Calculations for Cumulative Dose, Latency, and Duration	Medium	Auto-On	Visible to All Users	Vault Safety now auto-calculates the following fields during case processing: Duration of Reaction, Duration of Drug Administration, First Dose Latency, Last Dose Latency, and Cumulative Dose. This feature is limited to new data. Auto-calculation will not override existing data. Users can override auto-calculated fields.
Safety	Case Information Ranking	Medium	Configuration	Visible to Admins Only	Case-related information can now be ranked: Case Adverse Events, Case Products, Case Reporters, and Case Assessments. Ranking is respected during generation of FDA MedWatch 3500A reports. Admins must configure page layouts for the Rank field to appear.
Safety	Common Terminology Criteria for Adverse Events Grades	N/A	Auto-On	Visible to All Users	The Case Adverse Event object supports a new field to select the Common Terminology Criteria for Adverse Events (CTCAE) grade.
Safety	Configurable AS2 Gateway	High	Support	None	Vault Safety now supports configurable AS2 Gateway profiles, which allows customers to exchange cases and information with external organizations. Once Veeva Support enables this feature on a vault and whitelists corresponding partner or agency , an Admin can configure the Transmission Profile and Gateway Profile.



Safety	Create Follow-Up Case from Potential Match	Low	Auto-On	Visible to All Users	The Potential Match page now contains an option to create a Follow-Up Case when promoting an Adverse Event Report.
Safety	Designated Medical Events	High	Configuration	Visible to Admins Only	Vault Safety now includes a Veeva-managed DME watchlist, defined using MedDRA terms. A Case is tagged as a DME and expedited if it involves a DME and a suspect product registered in the EU. Admins must configure page layouts to add the Case>Watchlist Tags field and the Case Adverse Event>DME field.
Safety	E2B Case Migration	Low	Configuration	Visible to Admins Only	Users can now migrate Cases to Vault Safety from a source E2B file, bypassing the Adverse Event Report intake process. Vault Safety disables all case processing features on Imported E2B Cases created by migration. Admins must configure a User Action on the AER Document Lifecycle to allow the Migrate E2B action.
Safety	EMA Submissions	High	Configuration	Visible to Admins Only	Vault Safety now supports direct Submissions of compliant E2B (R3) to the EMA EudraVigilance Gateway. Admins can configure an EMA Gateway Profile and Transmission Profiles. Users can select the appropriate EMA Transmission Profile when they set up Submissions.
Safety	FDA Submissions	Medium	Configuration	Visible to Admins Only	Vault Safety FDA reporting rules now support a special scenario in which cases downgraded to non-serious generate a follow-up Transmission. The enhanced rules also ensure that non-serious ICSRs generate an FDA Submission only when they occur within FDA jurisdiction.

Safety	Custom Agency Submissions	High	Configuration	Visible to Admins Only	Vault Safety now supports partner distributions based on EMA or FDA reporting rules.
Safety	Partner Distributions	Medium	Configuration	Visible to Admins Only	Vault Safety now supports custom Agency submissions based on EMA or FDA reporting rules.
Safety	MedDRA Auto-Coding for Imported Cases	Low	Auto-On	Visible to Admins Only	When a case is opened or imported from a source E2B file, Vault Safety initiates MedDRA auto-coding. MedDRA auto-coding extends to all MedDRA fields on a Case with corresponding verbatim ("as reported") fields. Auto-coding is based on an exact match (case insensitive) search across all MedDRA PTs/LLTs.
Safety	PADER Aggregate Reports	Medium	Configuration	Visible to Admins Only	Vault Safety now supports the creation of PADER aggregate reports, including generating PADER tabulations and report templates.
Safety	Receive and Acknowledge E2B Transmissions	Medium	Configuration	Visible to Admins Only	Vault Safety now supports receiving E2B files from other organizations and automatically importing received files to AERs. Vault Safety can receive E2B files from incoming AS2 Gateway Transmissions or through the Vault Safety REST API. Once an E2B Transmission is received, the system generates an E2B(R3) ACK which is automatically sent back via the AS2 Gateway or made available through the Vault Safety REST API.



Safety	WHODrug UI Enhancements	Low	Auto-On	Visible to All Users	The WHODrug dictionary user interface has been updated to comply with WHODrug certification requirements. A new WHODrug app control is also available on page layouts.
Safety	WHODrug Search Criteria Auto-Fill	Low	Auto-On	Visible to All Users	When a user opens the WHODrug browser, Vault Safety now automatically searches the WHODrug Dictionary with the reported product name and country. The browser searches across drug names and preferred names. The user must manually select the product from the results. This feature is available only for External Product and Drug History records.
Safety	Device on MedWatch 3500A	High	Configuration	Visible to Admins Only	FDA MedWatch 3500A report generation now includes Section D ("Suspect Medical Device"). Vault Safety supports entry of device-related information in the Product library and on Case Products.
Safety, SafetyDocs	Merge PDF Files	High	Configuration	Visible to Admins Only	Users can now merge multiple documents within a binder to a single downloadable PDF.

Change Log

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Date	Change	Impact
November 4, 2019	Published the initial version of the RIA	N/A
November 20, 2019	Updated the entry for "MedDRA Auto-Coding for Imported Cases"	The RIA now includes current information for the MedDRA Auto-Coding for Imported Cases feature



