

Veeva Vault CDMS 19R2 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault 19R2 that may affect a customer's vault. We release a version of the RIA in advance of the general release. On July 23rd, the Validation Impact Assessment, which contains validation information for new features in 19R2, 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:

19 Jul 2019

This feature list is subject to change prior to the 19R2 release. We will begin tracking changes on July 1st, 2019.

Feature:

Name of the feature introduced in 19R2

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 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:

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 some Auto-on features do require individual users (not Admins) to complete some set up. For example, new Reporting capabilities generally require a user to create a new report or edit an existing one.

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	Feature Risk	Enablement	Default Impact	Description
Coder	Code WHODrug Forms on Indication & Route	Medium	Auto-on	Visible to Admins Only	If a WHODrug form is configured to collect Indication and Route values, a Coding Administrator can configure a form to either use or not use Indication and Route for coding and autocoding.
Coder	Prioritize MedDRA Coding by Displaying a Seriousness Column	Medium	Auto-on	Visible to Admins Only	If a MedDRA form is configured to collect a Seriousness value, a Coding Administrator can configure a form to either use or not use Seriousness to prioritize coding.
Coder	Coder UI Enhancements	Low	Auto-on	Visible to All Users	With this release Coder offers the following UI enhancements: filtering by Query Status; Master Checkbox Control in Code Request Listing table; visual outline around the Code & Code + Next buttons.
Coder	New Dictionary Search with Enhancements	Medium	Support	None	Now that dictionary records are available in the new Dictionary Database, we built the Dictionary Search algorithms in SQL. In this effort, we also unlocked several enhancements. The enhancements include displaying only unique records in the Dictionary Search results, capturing all Preferred Name varieties of the same Drug Name, search phrases can have up to 10 search terms, and the ability to search all special characters.
Coder	Coder Dashboard	Low	Support	None	Vault Coder users can view high level metrics for code assignments and coding progress from the new, standard Coder Dashboard.
Coder	Dictionary Database	N/A	Support	None	Coder now uses a new infrastructure which allows any CDMS Vault or Safety Vault to remotely access MedDRA or WHODrug (B3 and C3) dictionary records. Vault Coder can pull dictionary search results, perform upversioning, and dictionary based autocoding directly from the Dictionary Database.
EDC, Coder	Custom Role Management	High	Auto-on	Visible to Admins Only	User administrators can now create custom Application Role from a new Roles Management area. Vault now maps Application Roles to Security Profiles so that users only need to assign a Study Role (Application Role) to assign all permissions. *This feature is auto-on in vaults

Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
					where Role by Study is enabled.
EDC, Coder	Enable Forms for Coding from Studio	Medium	Auto-on	Visible to Admins Only	Studio users can now identify coding forms and configure them so that they are enabled and integrated for coding within Coder.
Coder, EDC	ODM Import & Export Includes Coder Study Settings	Medium	Auto-on	Visible to Admins Only	The ODM XML file for export and import in Studio now includes Coder Study Settings.
EDC	Amendment History	High	Auto-on	Visible to Admins Only	EDC Tools > Casebook Versions now includes the Amendment History subtab, which lists all amendments within a Study.
EDC	EDC Tools Enhancements	High	Auto-on	Visible to Admins Only	This feature includes the following enhancements: users can edit cross-domain users from EDC Tools; users can bulk import cross-domain users; users can run the Query Rules job in Preview mode; and we relabeled the "Country" column as "Study Country" in EDC Tools > Sites.
EDC	Include Record Deletion in Audit Export	High	Auto-on	Visible to Admins Only	Vault includes record deletion, such as deletion due to a retrospective amendment removing a Form, in the Audit Trail Export job's output.
EDC	Transfer Subjects between Sites	High	Auto-on	Visible to Admins Only	Lead data managers can transfer a Subject from one Site to another.
EDC	Subject Deletion	High	Configuration	Visible to Admins Only	Users with the "Delete Casebook" permission can delete subject Casebooks from the casebook-level Actions menu. *This feature is available in vaults where Role by Study is enabled. *The Delete Casebook application role function is available automatically. By default, no roles have the Delete Casebook permission. A Vault Owner must edit or create a role that includes this permission.
EDC	Allow Unknown Times	Medium	Auto-on	Visible to Admins Only	DateTime controls can now be configured to accept Unknown times. *The option to allow unknown times is available automatically in Studio, but a study designer must add unknown time configuration to the study design for it to be visible to data entry users.
EDC	Ignore Casebook Versions in Import File	Medium	Auto-on	Visible to Admins Only	Studio users can choose to ignore the version numbering during import and instead import the Casebook Definition as the current version.

EDC	Import Sites	Medium	Auto-on	Visible to Admins Only	EDC Tools users can create Sites in bulk by importing them as a CSV file.
EDC	Manage Study Settings from Studio	Medium	Auto-on	Visible to Admins Only	Studio users can now manage settings from the Study Configuration object, as well as Signature Definitions, from within Studio.
EDC	Retrospective Amendment Enhancements	Medium	Auto-on	Visible to Admins Only	This feature updates what changes are disallowed between casebook versions.
EDC	Review Plan Editor	Medium	Auto-on	Visible to Admins Only	Studio now includes a specialized Review Plan Editor to easily create and manage Review Plans for a study.
EDC	Set Label in Creation Dialog	Medium	Auto-on	Visible to Admins Only	Studio users can enter a Label for a new design definition in the creation dialog. Vault generates a Name value based on the entered label.
EDC	Site Review Plan Assignment	Medium	Configuration	Visible to Admins Only	EDC Tools users can now assign Review Plans to individual Sites from EDC Tools > Review Plan Assignments.
EDC	Compare Versions Enhancements	Low	Auto-on	Visible to Admins Only	This release improves the readability of the Compare Versions report's Excel™ output and adds new include options to the report.
EDC	Manual Save for SDV & DMR in the Review Tab	Medium	Auto-on	Visible to All Users	With this release, we made several enhancements to the Review tab to improve performance and prevent errors during review tasks, including manual save for SDV and DMR reviews.
EDC	Review Tab Enhancements	Medium	Auto-on	Visible to All Users	This release includes the following enhancements to the Review tab: Last Event and Next Event columns for the Subject listing; highlighting for the currently selected Event and Form; and the ability to view Subject and Site details by hovering over the Name for the subject and site. *In vaults where the Review tab is enabled.
EDC	Casebook Creation Confirmation	Low	Auto-on	Visible to All Users	Users must now click through a confirmation dialog when creating new subject Casebooks.
EDC	Repeating Item Group Tabular View	Low	Configuration	Visible to All Users	Vault can now display repeating Item Groups in a tabular view where the data entry user will be able to view queries on Items within the group, see information about those queries, and open a dialog to interact all queries within the Item Group. *This feature is available in vaults where the Review tab is enabled. *The Display Format

					property is automatically available in Studio, but a study designer must add the configuration into a study design for this feature to display for data entry users.
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Change Log

This feature list is subject to change prior to the 19R2 release. We will begin tracking changes on July 1st, 2019.

Date	Change	Impact
19 Jul 2019	Updated the description of the "Subject Deletion" to include that this feature is only available in vaults where the Role by Study is enabled.	The RIA now includes up to date feature descriptions.
18 Jul 2019	Updated the description for "Repeating Item Group Tabular View" to include that this feature is only available in vaults where the Review tab is enabled.	The RIA now includes up to date feature descriptions.
10 Jul 2019	Added the Manual Save for SDV & DMR in the Review Tab feature	The RIA now includes an up to date list of features for release with 19R2.
09 Jul 2019	Updated the availability date for the Validation Impact Assessment to July 23rd	The RIA now includes current dates for document availability.
10 Jun 2019	Published the initial version of the RIA	N/A

