

Veeva Vault CDMS 18R3 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault 18R3 that may affect a customer's vault. We release a version of the RIA in advance of the general release. On October 19th, the Validation Impact Assessment, which contains validation information for new features in 18R3, 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: 26 Nov 2018

This feature list is subject to change prior to the 18R3 release. We will begin tracking changes on October 15th, 2018.

Feature: Name of the feature introduced in 18R3

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	Coder Tools Administration Area	Medium	Auto-on	Visible to Admins Only	A Coder Tools tab has been added under Tools to allow Coding Administrators to manage Coder settings at the Vault and Study levels.
Coder	Stop List Management	Medium	Auto-on	Visible to Admins Only	Each Code Request has a Verbatim. Autocoding looks for matching Verbatims in the Code Request list and will automatically assign codes to new Code Requests if there is a match. The stop list feature allows Coding Administrators to exclude Verbatims from the autocoding process.
Coder	Synonym List Management	Medium	Auto-on	Visible to Admins Only	Coding Administrators can create and edit Synonym Lists, and review Verbatims to add to the Synonym List.
Coder	Upversion a Study's Forms & Synonym Lists	Medium	Auto-on	Visible to Admins Only	The WhoDRUG and MedDRA medical dictionaries are imported into Coder and used in Forms and Synonym lists. Coding Administrators can now upversion the dictionaries in Coder.
Coder	Prevent Query Creation on Locked Forms	Medium	Auto-on	Visible to All Users	If a form for a Code Request is locked in EDC, Vault prevents Coder users from creating a query for the Code Request.
Coder	Code Request List Displays Query Status	Low	Auto-on	Visible to All Users	The Code Request Listing page displays a Query Status column.
Coder	Code Request Notes	Low	Auto-on	Visible to All Users	This feature allows a Coder to post a Note to a Code Request if the way they coded needs explanation. A reviewer can view the note when they select the Code Request.
Coder	Coding Panel Enhancements	Low	Auto-on	Visible to All Users	Users can drag the top margin of the Coding panel to increase or decrease its size.
Coder	Default Sorting for Code Requests	Low	Auto-on	Visible to All Users	Vault now sorts Code Requests alphabetically by Verbatim, Indication, Route, and Status (WhoDRUG) or Verbatim, Seriousness, Status (MedDRA).
Coder	Hover to Show Truncated Card Text	Low	Auto-on	Visible to All Users	In the Properties, Queries, and Notes cards, users can hover over the ellipsis to show the complete text.
Coder	Open EDC Forms from Coder	Low	Auto-on	Visible to All Users	Users can open the EDC form associated with a Code Request.
Coder	Primary Path Filter for MedDRA Dictionary Search	Low	Auto-on	Visible to All Users	Coder now provides a filter for the Dictionary search results to show only codes that are

Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
					tagged as Primary Path. This filter is selected by default.
Coder	Properties Card Displays Site & Subject	Low	Auto-on	Visible to All Users	The Properties card now displays the Site and Subject Number associated with the Code Request.
Coder	Code Request Data Export	Medium	Support	None	EDC Tools users can initiate a Code Request Export job to export a CSV file detailing all Code Requests and what those requests were coded to.
EDC	Check the Event Group Sequence in Rules	Medium	Auto-on	Visible to Admins Only	Studio users can now configure rules that reference the Event Group Sequence Number in the expression. When configured, vault now only adds a dynamic Form or Event to the Event Group sequence containing the controlling Item, and not to all sequences of the Event Group. *This option is automatically available in Studio, but a clinical programmer must create or edit a rule to use it.
EDC	Compare Study Versions	Medium	Auto-on	Visible to Admins Only	Studio users can now compare two versions of a study design from within Studio.
EDC	Copy Form Definitions across Studies	Medium	Auto-on	Visible to Admins Only	Studio users can now copy Form Definitions, and their related records, to reuse them across multiple Studies.
EDC	Edit Scheduled Jobs	Medium	Auto-on	Visible to Admins Only	EDC Tools users may now edit scheduled jobs from within EDC Tools.
EDC	Event-Level SDV and DMR Timestamps (CTMS)	Medium	Auto-on	Visible to Admins Only	Vault EDC captures a timestamp for Event-level SDV and DMR review completion.
EDC	Import Study Users	Medium	Auto-on	Visible to Admins Only	EDC Tools users can create Users and set their Study access in bulk. From EDC Tools > Users, they can upload a CSV file for import.
EDC	Manage Repeating Event Group Labels	Medium	Auto-on	Visible to Admins Only	Studio users can now set a Custom Labels property on repeating Event Groups to identify labels for each sequence of the Event Group.
EDC	Re-assign SDV or DMR Mode from EDC > Jobs	Medium	Auto-on	Visible to Admins Only	Re-assigning Source Data Verification (SDV) and Data Management Review (DMR) modes is now available as a job in EDC Tools > Jobs. As part of this feature, we relabeled "Re-evaluate Targeted SDV Mode" and "Re-evaluate Targeted DMR Mode" to "Re-assign SDV Mode" and "Re-assign DMR Mode", and removed the

					Summary subtab from EDC Tools.
EDC	Study-Level Closeout Detail PDF	Medium	Auto-on	Visible to Admins Only	EDC Tools users can now download Study-level detail PDFs with a Detail PDFs job from EDC Tools > Jobs. They can choose to Export all sites or Select sites when scheduling the job.
EDC	View Set Management	Medium	Auto-on	Visible to Admins Only	Studio users can now create, edit, and delete View Set Definitions from within Studio, as well as initiate a View Set Data Coverage job to identify whether or not all Item Definitions are mapped to a Column Definition. Data export ZIP files now also include a Definitions.csv file with details about the View Set.
EDC	Views Editor Enhancements	Medium	Auto-on	Visible to Admins Only	This release includes the following enhancements to the Views Editor: support for columns with multiple types of Column Binding Definitions, support for hidden columns in views, a SAS Format Panel, CDM Keys on view-related objects, and minor usability enhancements.
EDC	Access Form Design from Studio's Browse View	Low	Auto-on	Visible to Admins Only	In Studio's Browse view, users can now click on the Form name to open the Form in Design view.
EDC	Add Investigators during Site & User Creation	Low	Auto-on	Visible to Admins Only	EDC Tools users can now add new Principal Investigators during Site creation. When creating new Users from Tools > EDC Tools > Users, administrators can now mark a user as a Principal Investigator.
EDC	Derived Data Type Validation	Low	Auto-on	Visible to Admins Only	During publishing validation, Vault checks that the data type returned by a Set Item-type rule expression matches the data type of the Item set by the expression. *This feature is auto-on in vaults where the Derived Item Values feature is enabled.
EDC	EDC Tools Usability Enhancements	Low	Auto-on	Visible to Admins Only	With this release, we made the following usability enhancements to EDC Tools: in EDC Tools > Sites, clicking into a Site now opens the Edit Study Site dialog, instead of the View Study Site dialog. When searching for a value in a picklist or drop-down menu; and users can now see results without clicking the Search icon or pressing Enter. This type ahead search is available when creating Detail PDF and Casebook Version Update jobs, as well as when managing Study Countries.

EDC	Edit Button for Properties Panel	Low	Auto-on	Visible to Admins Only	With this release, we've replaced the autosaving of properties in Studio's Properties panel with Edit and Save buttons.
EDC	Improved Validation Messages for Views	Low	Auto-on	Visible to Admins Only	We updated the validation warning messages related to Views so that the messages are more helpful and easier to read.
EDC	Increase Codelist Decode Length	Low	Auto-on	Visible to Admins Only	With this release, we extended the codelist Label property maximum length from 128 characters to 256 in order to display longer codelist decoded values in EDC.
EDC	Lock Header in Design View	Low	Auto-on	Visible to Admins Only	Studio's Design view header now scrolls with the page.
EDC	Relabeled Study Tools to EDC Tools	Low	Auto-on	Visible to Admins Only	We relabeled "Study Tools" to "EDC Tools", and placed that tab within a subtab container labeled "EDC Tools".
EDC	Set Active Casebook Version during Site Creation	Low	Auto-on	Visible to Admins Only	When creating a new Site, EDC Tools users can now assign that site an Active Casebook Version.
EDC	View Published Codelist & Unit Items	Low	Auto-on	Visible to Admins Only	Studio users can now view Unit Item Definitions and Codelist Item Definitions in published studies. Like other object definition records in Studio, these are read-only when published.
EDC	Modifying an Event Date Invalidates eSignatures	High	Auto-on	Visible to All Users	After an Event Date is edited, Vault invalidates existing eSignatures in that Event.
EDC	Ad Hoc Data Exports	Medium	Auto-on	Visible to All Users	Users with permission to create jobs can initiate a Data Export or Detail PDFs job from Review > Study Jobs. *This feature is auto-on in vaults where the Monitoring Review Tab feature is enabled.
EDC	Freeze & Unfreeze a Subject Casebook	Medium	Auto-on	Visible to All Users	Users can freeze and unfreeze all Items within a subject Casebook with a single action.
EDC	Lock & Unlock a Subject Casebook	Medium	Auto-on	Visible to All Users	Users can lock and unlock all Items within a subject Casebook with a single action.
EDC	Overdue Forms Column in Event Listing	Medium	Auto-on	Visible to All Users	In the Review tab, the Event listing now includes a column for Overdue Forms within each Event. *This feature is auto-on in vaults where the Monitoring Review Tab feature is enabled.
EDC	Reset Event	Medium	Auto-on	Visible to All Users	Users can use the Reset Event action to reset an Event to its initial state.
EDC	Add Repeating Event Group Button	Low	Auto-on	Visible to All Users	Data entry users can now add a repeating Event Group sequence to a Casebook with a button on

					the casebook schedule, instead of from within the New Event dialog.
EDC	Display Locked & Frozen Status for Forms & Events	Low	Auto-on	Visible to All Users	In the Review tab, Vault now displays Frozen and Locked icons for Forms, Events, and Casebooks in those statuses. *This feature is auto-on in vaults where the Monitoring Review Tab feature is enabled.
EDC	Review Tab Filtering Enhancements	Low	Auto-on	Visible to All Users	In the Review tab, users can filter a Form to display only Items with incomplete tasks. Task-related filters now also continue to apply throughout the Review tab, including switching between Event and Form listings, until the user ends the browser session. *This feature is auto-on in vaults where the Monitoring Review Tab feature is enabled.
EDC	Review Tab Navigation Enhancements	Low	Auto-on	Visible to All Users	With this release, we made the following navigation enhancements to the Review tab: replaced the Actions (gear) menu at the Event-level with a More Actions (ellipsis) menu. This feature did not change the actions included in the menu; added an Actions menu at the Casebook level; and added Next and Previous task navigation buttons. *This feature is auto-on in vaults where the Monitoring Review Tab feature is enabled.
EDC	Persona-Based Dashboards	Low	Support	Visible to All Users	Vault EDC now includes three (3) standard dashboards that are specific to certain user personas: Study Design Review Dashboard for Clinical Programmers, Vault EDC Data Manager Review Dashboard, and Vault EDC CRA Dashboard. *To enable this feature, contact your Veeva Services representative.

Change Log

This feature list is subject to change prior to the 18R3 release. We will begin tracking changes on Monday, October 15th.

Date	Change	Impact
26 Nov 2018	Removed the "Access Coding Request Audit Trail from More Actions Menu" feature. This feature was postponed to a later release. Updated the description of the "Coding Panel Enhancements" feature to include only in scope enhancements.	The RIA includes an up to date list of features for release in 18R3.
15 Nov 2018	Removed the "CDMS Permissions by Application Role" feature. This feature was postponed to a later release.	The RIA now includes an up to date list of features for release in 18R3.
08 Nov 2018	Updated the Enablement of "Code Request Data Export" from "Auto-on" to "Support" and its Default Impact from "Visible to Admins Only" to "None"	The RIA now includes up to date enablement and default impact information.
06 Nov 2018	Added the "Code Request Data Export" feature.	The RIA now includes an up to date list of features for release in 18R3.
23 Oct 2018	Updated the Feature Risk of "Check Event Group Sequence in Rules" from "Low" to "Medium" Removed "Views Support for Medical Coding Requests". This feature was postponed to a later release.	The RIA now includes an up to date list of features and up to date risk assessments.
22 Oct 2018	Updated the following Feature Descriptions to include up to date enablement notes: Check Event Group Sequence in Rules, Derived Data Type Validation, Overdue Forms Column in Event Listing, Review Tab Filtering Enhancements, Review Tab Navigation Enhancements, and Display Locked & Frozen Status for Forms & Events. Updated the Feature Name of "Access Code Request EDC Forms" to "Open EDC Forms from Coder".	The RIA now includes up to date names and enablement information for each feature.
18 Oct 2018	Added the "Views Support for Medical Coding Requests" feature	The RIA now includes an up to date list of features.
17 Oct 2018	Updated the Feature Risk of "Event-Level SDV and DMR Timestamps (CTMS)" from Low to Medium.	The RIA now includes up to date risk assessments.
16 Oct 2018	Updated the Feature Risk of "Check Event Group Sequence in Rules" feature from Medium to Low. Consolidated "Hidden Columns in Views" into "Views Editor Enhancements"	The RIA now includes an up to date list of features with up to date risk assessments.
24 Sep 2018	Published initial version of the RIA.	N/A

