

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault 19R1 that may affect a customer's vault. We release a version of the RIA in advance of the general release. On March 15th, the Validation Impact Assessment, which contains validation information for new features in 19R1, 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:

12 Apr 2019

This feature list is subject to change prior to the 19R1 release. We will begin tracking changes on February 25th, 2019.

Feature:

Name of the feature introduced in 19R1

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	Autocode Dictionary Exact Matches	Medium	Auto-on	Visible to Admins Only	Coding Administrators can now configure the entire application, or a specific study, to autocode exact verbatim matches directly from the Dictionary. *This setting displays automatically in Coder Tools, but a Coding Administrator must manually enable it for Vault to autocode dictionary exact matches.
Coder	Code with ATCs (WHODrug)	Medium	Auto-on	Visible to Admins Only	Users can now chose to not use ATCs for coding and autocoding decisions in WHODrug based forms. *This setting displays automatically in Coder Tools, but a Coding Administrator must manually enable it for users to code without ATCs.
Coder	Import & Export Stop Lists	Medium	Auto-on	Visible to Admins Only	Coding Administrators can now import verbatims to an existing Stop List or a new Stop List.
Coder	Import & Export Synonym Lists	Medium	Auto-on	Visible to Admins Only	Coding Administrators can now import synonyms to an existing Synonym List or a new Synonym List.
Coder	Support for Codelist Coding Properties	Medium	Auto-on	Visible to Admins Only	Both the Coder Listings page and Coder Reports now support Codelist-based coding properties, including Verbatim, Indication, and Route.
Coder	Code without Indication & Route (WHODrug)	Medium	Configuration	Visible to Admins Only	Users can now chose to not use Indication or Route fields for coding and autocoding decisions in WHODrug based forms. *Contact Veeva Services to discuss enabling this feature in your vault.
Coder	Code without Seriousness (MedDRA)	Medium	Configuration	Visible to Admins Only	Users can now choose to not include the Seriousness property in MedDRA based forms. *Contact Veeva Services to discuss enabling this feature in your vault.
Coder	Enablement Change: Code Request Data Export	Low	Auto-on	Visible to Admins Only	With this release, we changed the enablement of the Code Request Data Export feature from Support to Auto-on.
Coder	Access a Code Request's Audit Trail from the More Actions Menu	High	Auto-on	Visible to All Users	Coder users can now access the Audit Trail for each Code Request from the Code Request the Code Request's More Actions menu.
Coder	Grouping Code Requests	Medium	Auto-on	Visible to All Users	The Coder application now groups identical Code Requests and displays them in grouped

Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
					order when Group Mode is selected in the Code Request Listing table.
Coder	Query & Notes Enhancements	Medium	Auto-on	Visible to All Users	We made the following enhancements to Coding Queries and Notes: users can now close queries without entering text; users can now expand the text field to type more info, the Code Request table updates in real-time when queries are posted, re-queried, or closed.
Coder	Coder UI Enhancements	Low	Auto-on	Visible to All Users	We have made the following enhancements to the Coding panel: users can popout the Coding panel; the Dictionary tab of the Coding panel now stores user preferences for filters and columns; improvements to how MedDRA codes and WHODrug codes are displayed.
EDC, Coder	CDMS Role by Study	High	Support	Visible to Admins Only	With this release, we updated CDMS module permissions to be based on the Application Role framework.
EDC	Audit Trail Export	High	Auto-on	Visible to Admins Only	EDC Tools users can now initiate a job to export the Audit Trail for all Casebooks in their Study.
EDC	User Management Enhancements	High	Auto-on	Visible to Admins Only	We made the following enhancements to user management in EDC Tools: users can now sort the Users listing; User import is now asynchronous; users can create cross-domain and cross-vault users in EDC Tools; and the User Export CSV is now includes all columns required to re-import the file into another study.
EDC	Annotated PDFs	Medium	Auto-on	Visible to Admins Only	Studio users can export PDF versions of all case report forms (CRFs) within their study, with the option to include annotations with design details or data export information.
EDC	Import to Update In Progress Studies	Medium	Auto-on	Visible to Admins Only	Studio users can import a study XML into an in progress version. Vault checks for differences and applies updates to the current, in progress version from that import.
EDC	Prospective Casebook Amendments	Medium	Auto-on	Visible to Admins Only	EDC Tools users can now initiate prospective casebook amendments to migrate subject Casebooks from one casebook version to another, starting at a given point forward, without updating existing data.
EDC	Retrospective Casebook	Medium	Auto-on	Visible to Admins	EDC Tools users can now initiate retrospective

	Amendments			Only	casebook amendments to migrate existing subject data from one casebook version to another.
EDC	Select a Casebook Version	Medium	Auto-on	Visible to Admins Only	Studio users can select earlier versions of a study's Casebook Definition from the Studio Actions menu to view that version and edit version properties.
EDC	Study Design Specification	Medium	Auto-on	Visible to Admins Only	Studio users can now export a Study Design Specification, a structured Microsoft Excel™ file with details about each included design component.
EDC	Study Update Restrictions	Medium	Auto-on	Visible to Admins Only	Vault now prevents users from making certain design changes to a Study after the initial version has been published.
EDC	Text-Based Rule Editor	Medium	Auto-on	Visible to Admins Only	Studio users can access a new rule editor when creating a new rule or accessing an existing one.
EDC	Freeze & Lock Event Dates	Medium	Configuration	Visible to Admins Only	Users can now freeze or lock the Event Date. Users can now freeze or lock an Event from the Event's More Actions menu. As part of this enhancement, we updated the enablement of eSignature, SDV, and DMR for Event Dates from Auto-on (in vaults with the Review tab enabled) with a Review Plan referencing Event Dates, to Configuration.
EDC	Column Display Property on Column Definitions	Low	Auto-on	Visible to Admins Only	Clinical programmers can use Column Display to add names for their columns that include spaces and special characters to use during data export. With the release of Enhanced Vault Formulas, the column's Name can no longer contain spaces.
EDC	Data Export includes CodelistLabels.csv	Low	Auto-on	Visible to Admins Only	Data Export job outputs now include a "CodelistLabels.csv", listing the Code and Decode values for Codelist Items in the Study.
EDC	Delete Study Data in Development Vaults	Low	Auto-on	Visible to Admins Only	EDC Tools users can now delete study execution data in their development and UAT vaults. This feature is not available in production vaults.
EDC	Select Object & Field Values for Column Mappings	Low	Auto-on	Visible to Admins Only	Clinical programmers can now select clinical objects and field values from within the Views Editor.

EDC	Study Data Extract Notifications	Low	Auto-on	Visible to Admins Only	Studio users now receive notifications when the Study Data Extract job begins and finishes.
EDC	Clear Signature Action	High	Auto-on	Visible to All Users	Users can now use the Clear Signature action in the Actions Menu to clear a signature for a Form, Event, or Casebook, if a mistake was made in signing.
EDC	eSignature Enhancements	High	Auto-on	Visible to All Users	There is now a Sign button at the Form level. From the Casebook Schedule, users can now sign multiple events at once, or the entire Casebook. Event Dates now have an object record to track if their signature status.
EDC	Intentionally Left Blank Enhancements	Medium	Auto-on	Visible to All Users	We have made the following enhancements to Intentionally Left Blank: Item status rolls up to the Item Group or Form; when user marks a Form as Intentionally Left Blank, all Items on the form become Intentionally Left Blank; and marking anything as Intentionally Left Blank now removes completed DMR and SDV.
EDC	Continuous Form Panel	Low	Auto-on	Visible to All Users	The Review tab's Form panel now displays all Forms within an Event at once. Users can scroll through all Forms in an Event without clicking to open each Form. *In vaults where the Review tab is enabled.
EDC	Data Entry UI Enhancements	Low	Auto-on	Visible to All Users	When no Repeating Item Groups exist, Vault now displays the message: "No records to display". When user adds or removes dynamic Events or Forms, Vault now displays a status message along with a loading spinner.
EDC	Enablement Change: Persona-Based Dashboards	Low	Auto-on	Visible to All Users	With this release, we changed the enablement of the Persona-Based Dashboards feature from Support to Auto-on.
EDC	Event & Form Tree Panel	Low	Auto-on	Visible to All Users	Review tab users can now view all the Events and Forms for a Subject in a single tree view, similar to the casebook schedule in the Data Entry tab. *In vaults where the Review tab is enabled.
EDC	Query Enhancements	Low	Auto-on	Visible to All Users	We have made the following enhancements to Queries: the query comment maximum length has been extended from 255 to 500 characters;

					system queries now indicate which rule created the query.
EDC	Renamed "Casebooks" Tab as "Data Entry"	Low	Auto-on	Visible to All Users	We relabeled the "Casebooks" tab as "Data Entry" to better reflect the purpose of this tab.
EDC	Service Announcements	Low	Auto-on	Visible to All Users	Service announcements allow users to receive a banner notification in the application when there is an upcoming change or service status that requires attention. *Service announcements display automatically in your vault as assigned by Veeva. There is no configuration required for Vault users. Contact your Veeva representative for additional details.
EDC	CTMS Users Open Casebooks in the Review Tab	Low	Configuration	Visible to All Users	CTMS users of the Vault CTMS & Vault EDC integration open a Casebook from their CTMS vault, the Casebook now opens in the Review tab of Vault EDC. *This feature is available automatically when the Vault CTMS integration is configured.
EDC	Casebook Schedule UI Enhancements	N/A	Auto-on	Visible to All Users	The Casebook Schedule filter buttons, Schedule and Event Date, are now radio buttons. The New Event Button is now gray.
EDC	Enhanced Vault Formulas	Medium	Support	None	This feature improves Vault Formula capabilities, usability, and performance. By utilizing new operators, new functions, and new system variables, customers can streamline formulas and perform new calculations.

Change Log

This feature list is subject to change prior to the 19R1 release. We will begin tracking changes on Monday, February 25th.

Date	Change	Impact
12 Apr 2019	Updated the "Query Enhancements" feature description to indicate that the updated character limit is 500.	The RIA now includes up to date feature descriptions.
18 Mar 2019	Updated the enablement of "Freeze & Lock Event Dates" from "Support" to "Configuration" and its default impact from "None" to "Visible to Admins Only". Updated the description for "Freeze & Lock Event Dates" to clarify its impact.	The RIA now includes up to date enablement information for 19R1.
11 Mar 2019	Added the "Import to Update In Progress Studies" feature. Updated the description of "Freeze & Lock Event Dates" to communicate that this feature changes the enablement of eSignature, SDV, and DMR at the Event Date level.	The RIA now includes an up to date list of features for release in 19R1.
19 Feb 2019	Updated the date that the Validation Impact Assessment will be available from March 18 to March 15	The RIA now includes the up-to-date publication date for the Validation Impact Assessment.
15 Feb 2019	Published the initial version of the RIA.	N/A

