

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault 18R2 that may affect a customer's vault. We release a version of the RIA in advance of the general release. On July 29th, the Validation Impact Assessment, which contains validation information for new features in 18R2, 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:

8/8/2018

This feature list is subject to change prior to the 18R2 release. We will begin tracking changes on July 5th, 2018.

Feature:

Name of the feature introduced in 18R2

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	Vault Coder	High	Support	None	Users can perform clinical coding activities with the new Vault Coder application.
EDC	Automatic Creation of Study Data Extraction View Set	High	Auto-on	Visible to Admins Only	Studio users can now auto-generate a View Set Definition containing a View Definition for each Form in the Study.
EDC	User Administration UI Enhancements	High	Auto-on	Visible to Admins Only	This feature includes the following UI enhancements for Study Tools > Users, allowing administrators to search for existing users and updating the Study Access step with simplified options.
EDC	Enhanced Views Editor for Clinical Data Mapping	Medium	Auto-on	Visible to Admins Only	This feature provides an updated Views area in Studio where clinical programmers can more easily create and manage their View Definitions.
EDC	Export Files to Configurable FTP Location	Medium	Auto-on	Visible to Admins Only	Study Tools users can create and manage connections to an FTP from Study Tools > Connections, as well as choose to send the results of data export jobs to a configured FTP location.
EDC	Inactivate Reasons for Change	Medium	Auto-on	Visible to Admins Only	Admins can now inactivate Reason for Change records using the Change Reason Status field.
EDC	Job Scheduling	Medium	Auto-on	Visible to Admins Only	Study Tools users can now schedule recurring jobs from Study Tools > Jobs.
EDC	Site Administration	Medium	Auto-on	Visible to Admins Only	Study Tools users can now create and manage Study Sites from Study Tools > Sites.
EDC	Study Country Administration	Medium	Auto-on	Visible to Admins Only	Study Tools users can now view and create Study Country records from Study Tools > Study Countries.
EDC	Clinical Data Export in SAS Format	Medium	Configuration	Visible to Admins Only	Study Tools users can now choose to export study data using a View Set and then convert that data into SAS format in a single job.
EDC	Reason for Change & Intentionally Left Blank Support Comments	Medium	Configuration	Visible to Admins Only	An administrator can now configure a Study to allow data entry users to free text type a reason for Intentionally Left Blank or Reason for Change
EDC	Require Data for Row Export	Medium	Configuration	Visible to Admins Only	This feature allows Studio users to specify if a column is "Required" for data export. When the Required checkbox is selected on a column mapping, Vault EDC exports all data for a row if there is any data for that column, even if other columns on that row would be blank. *The new

Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
					Required checkbox displays automatically, but a clinical programmer must update or create new Column Binding Definition records to use this feature.
EDC	Site-Specific Review Plans	Medium	Configuration	Visible to Admins Only	Study administrators can now assign Review Plans on a site-by-site basis, using the Review Plan Site object.
EDC	Subject Milestones & Veeva CTMS Connection	Medium	Configuration	Visible to Admins Only	With this feature, clinical programmers can now define subject milestone exports in Vault EDC that update subject information in the associated CTMS vault.
EDC	URL Item Control	Medium	Configuration	Visible to Admins Only	This feature introduces the new URL control type for Item fields. Data entry users enter a URL on a Form, and Vault EDC validates that it is a working URL. *A clinical programmer must add an Item Definition of the URL data type to the Casebook Definition for this feature to display in Vault EDC's data entry area.
EDC	Added Study Tools Tab	Low	Auto-on	Visible to Admins Only	Users with the correct permissions now access Study Tools from a standard tab. This feature replaces the Study Tools button within the Casebooks tab.
EDC	Export Study Users into CSV	Low	Auto-on	Visible to Admins Only	Study Tools users can export Users in a Study as a CSV file from Study Tools > Users.
EDC	Prevent Reuse of a Single Form Across Multiple Log Events	Low	Auto-on	Visible to Admins Only	Vault EDC now prevents Studio users from using a single Form Definition in multiple Log Events.
EDC	Remove Component Study Selection	Low	Auto-on	Visible to Admins Only	Users can no longer select a Study to add components from in Studio Design view's Components panel.
EDC	Skip Inactive Rules during Publishing Validation	Low	Auto-on	Visible to Admins Only	During publishing validation, any errors on Rule Definitions that are Inactive are downgraded to warnings.
EDC	Detail PDF Export Options	High	Auto-on	Visible to All Users	Users can now choose whether or not to include Audit Trail information in their PDF exports.
EDC	Freeze at the Item Level	Medium	Auto-on	Visible to All Users	Users can now freeze data at the Item field level.
EDC	Default Repeating Item Group Records	Medium	Configuration	Visible to All Users	Study designers can configure repeating Item Group Definition so that when a data entry user

					creates a new Form, the system creates the configured Item Groups automatically, including setting the configured default values on the new Items. *While the settings for this feature display automatically in Studio, a clinical programmer must configure this as part of their study design before this feature will display in Vault EDC's data entry area.
EDC	Edit Value Button in Query Dialog	Low	Auto-on	Visible to All Users	This feature adds an Edit Value button to the query dialog. The Edit Value button allows the user to open the Form in Edit mode, and automatically scrolls to the queried Item field, so that the user can update the queried value.
EDC	Event & Form Icon Tooltips	Low	Auto-on	Visible to All Users	EDC users can now hover over an icon with their mouse and see a description of what that icon represents.
EDC	Event Operational Summary Metrics & Reports	Low	Auto-on	Visible to All Users	This feature adds two new standard template Reports: "Template: Event with Event Operational Summary" and "Template: Event Operational Summary", as well as several new fields to track operational metrics on Events.
EDC	Filtering on Study, Site & Casebook Listing Pages	Low	Auto-on	Visible to All Users	Users may now apply filters to the Study, Site, and Casebook listing pages.
EDC	Global Search for a Subject Casebook	Low	Auto-on	Visible to All Users	All Vault EDC users may now search for Subjects using the new global search.
EDC	Navigation & Data Entry UI Enhancements	Low	Auto-on	Visible to All Users	This feature includes the following UI enhancements: the Site name now displays in the breadcrumb menu for all users, the Event Date for a Form now displays when viewing the Form, and a tooltip now displays for the Pencil button.
EDC	New Standard Template Reports	Low	Auto-on	Visible to All Users	This feature adds the following standard report templates: Query Aging by Site, Subject Progression, Schedule Deviation, Overdue Data Entry by Event, Form SDV Monitoring Activity per Week, and Comprehensive Form Summary.
EDC	Reviews on Event Date	Medium	Support	None	Users may now perform SDV and DMR on Event Dates. *This feature is available on a limited basis until a future release. Contact your Veeva services representative for details.
EDC	Specialized Application Area for Site Review & Monitoring	Medium	Support	None	Vault EDC now includes a new Review tab for site monitoring activities, including SDV, DMR, and more. *This feature is available on a limited

					basis until a future release. Contact your Veeva services representative for details.
--	--	--	--	--	---------------------------------------------------------------------------------------



Change Log

This feature list is subject to change prior to the 18R2 release. We will begin tracking changes on Thursday, July 5th.

Date	Change	Impact
8/8/2018	Added the "Specialized Application Area for Site Review & Monitoring" and "Reviews on Event Dates" features.	The RIA now includes an up to date list of features.
8/6/2018	Updated the "Subject Milestones & Veeva CTMS Integration" feature name to "Subject Milestones & Veeva CTMS Connection" to better reflect the feature's functionality.	The RIA now includes up to date feature names.
7/6/2018	Removed the "Specialized Application Area for Site Review & Monitoring" and "Reviews on Event Dates" features. These features were postponed to a later release.	The RIA now includes an up to date list of features for release in 18R2.
6/25/2018	Published initial version of the RIA.	N/A

