



19R3 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities released in this Vault CDMS release that may affect a customer's vault. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements.

This feature list is subject to change prior to the release. We will begin tracking changes on: 10/25/2019

Revision Date: 1/31/2020

VIA Available: 11/18/2019

This document does not include changes made as part of the Vault Platform release. Consult Veeva Docs for Vault Platform validation details.

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 some configuration, or must be enabled by Veeva Support.

Auto-on This feature is available automatically in its application area.

By Study Build The options to configure this feature display automatically, but it must be configured as part of a study to be visible to other users.

Study Feature Flag This feature must be enabled on each study's configuration by Veeva Services.

Support This feature must be enabled by Veeva Support.

Application	Impacted Areas	Feature Name	Feature Risk	Enablement	Training Impact	Existing Studies	Description
All	Coding, Coding Administration, Study Design & Configuration	"Other" Option for Coding Form Type	Low	By Study Build	Study Designer	No	When using "Other" for Form Type, Studio users can now select relevant Related Items based on their chosen dictionary type (WHODrug or MedDRA).
All	Deployments, Coding Administration, Study Administration, Study Design & Configuration	Automated Deployments	High	Support *Existing studies must undergo an upgrade process (via Veeva Services) to use the new deployment model.	User Administrator, Lead Data Manager, Study Designer, Deployment Administrator	No	With automated deployments, sponsors can move a study build from development to their UAT, training, and production environments without repeated exports and imports or duplicate configuration.
All	Deployments, Coding Administration, Study Design & Configuration	Ability to Change the Dictionary Type for a Form	Medium	Support *The locked configuration and Reconstitute Code Requests job display automatically, but a study designer must work with Veeva Services to use this feature.	Study Designer, Lead Data Manager	No	Studio users can now work with Veeva Services to update the Dictionary Release type, or independently update other coding configuration, for a coding Form after Code Requests already exist. Then, using the Reconstitute Code Requests job, an administrator can recreate those Code Requests referencing the updated configuration.
All	Coding Administration, Study Design & Configuration	Select Dictionary Releases from Only the Dictionary Database	Low	Auto-on	Clinical Coder Administrator, Study Designer	Yes *If a user upversions a dictionary or updates a Form's configuration	All Dictionary Release drop-down menus now only show Dictionary Releases from the Dictionary Database, instead of any dictionary release records in the vault, providing easy access to the latest dictionary release.
All	Study Administration	New Permissions Available for Role Management	Medium	Auto-on *In vaults where Role by Study is enabled	User Administrator, Lead Data Manager	Yes *These permissions are assigned to existing, standard Study Roles	With this release, we added two new permissions, "View Casebook" and "Design Study".
Coder	Coding	Dictionary Search Enhancements	Low	Auto-on	Clinical Coder, Clinical Coder Administrator	Yes	With this release, we updated Dictionary Search so that it retrieves results more quickly and with search terms in any order.
Coder	Coding	Removed Therapeutic Area from Coder	Low	Auto-on	Clinical Coder, Clinical Coder Administrator	Yes	Vault Coder no longer displays Therapeutic Area in the application as there is no way to configure this outside of Admin > Business Admin.



Application	Impacted Areas	Feature Name	Feature Risk	Enablement	Training Impact	Existing Studies	Description
Coder	Coding, Coding Administration	Extend Coding Decision to All Forms & Update the Synonym List	Medium	Auto-on	Clinical Coder, Clinical Coder Administrator	Yes *If Coders use this feature	Coders can use the new Code All Forms and Update Synonym Lists action to apply their coding decision to the current Code Request, Code Requests for all matching Forms, and any matching records in the Synonym List.
Coder	Coding, Coding Administration	Coder UI Enhancements	Low	Auto-on	Clinical Coder, Clinical Coder Administrator	Yes	With this release, we made the following UI enhancements to Vault Coder: we renamed Stop Lists as Do Not Autocode Lists; the Code Request listings page now automatically sorts Code Requests by Verbatim and coding properties; and we added a search to the Synonym List Details page in Coder Tools.
Coder	Reports & Dashboards	Enhanced Coder Metrics	Low	Auto-on	Clinical Coder Administrator, Clinical Coder	Yes *If users view these reports	We added the Last Coded By field to the Medical Coding Request object and the Last Queried By field to the Medical Coding Request Query object to allow users to create reports and dashboards related to coding progress and query status in Coder.
EDC	Assessments, Study Administration, Study Design & Configuration	Clinical Review Assessments	Medium	By Study Build *In vaults where Role by Study is enabled	Assessment Reader, Lead Data Manager, Study Designer, Assessment Editor	No	Studies can now collect additional data outside of Casebooks as "assessments".
EDC	Data Entry, Data Review	Audit Trail Enhancements	High	Auto-on	Data Manager, Auditor Read Only, Clinical Research Coordinator, Sub Investigator, Clinical Research Associate, Investigator, Lead Data Manager	Yes	With this release, we made the following enhancements to the audit trail: we updated the action labels for accessing the audit trail to "{Object} Audit Trail"; we now display the signature meaning for audit events related to signatures; and we now include seconds in the time for an audit event.
EDC	Data Entry, Data Review	Sticky Filters in the Data Entry & Review Tabs	Low	Auto-on	Data Manager, Auditor Read Only, Clinical Research Coordinator, Sub Investigator, Clinical Research Associate,	Yes	When a user applies a filter to a listing page, Vault remembers those applied filters for the duration of the user's login session.



Application	Impacted Areas	Feature Name	Feature Risk	Enablement	Training Impact	Existing Studies	Description
					Investigator, Lead Data Manager		
EDC	Data Entry, Data Review, Study Administration	Detail PDF Enhancements	Medium	Study Feature Flag	Sub Investigator, Clinical Research Associate, Data Manager, Investigator, Lead Data Manager, Clinical Research Coordinator	No	We made the following enhancements to Detail PDFs: each page now includes a table header providing information about the form; the PDF includes bookmarks; if the PDF includes the audit trail, it now has Audit Trail by Visit and an Audit Trail by Form sections with bookmarks; and if the PDF includes queries, it now has a Queries section with a bookmark.
EDC	Data Review	Review UI Enhancements	Low	Auto-on *In vaults where the Review tab is enabled	Clinical Research Associate, Data Manager, Auditor Read Only, Lead Data Manager	Yes	We made the following enhancements to the Review tab: users can filter by Site Number in Study Sites and Queries with the Site # filter; Vault shows help content for Forms and Items in a tooltip.
EDC	Data Review, Reports & Dashboards, Study Administration	Removed SDV & DMR Propagation	Medium	Auto-on *This feature is not available for existing Studies.	Clinical Research Associate, Lead Data Manager, Data Manager	No *This feature is not available for existing Studies.	In studies created after 19R3, Vault no longer propagates the SDV and DMR status. Instead, Vault tracks review statuses using Review State records. This change does not affect studies created before 19R3.
EDC	Reports & Dashboards	Track Queries Leading to Data Changes	Medium	Auto-on	User Administrator, Data Manager, Clinical Coder, Clinical Research Associate, Clinical Coder Administrator, Lead Data Manager, Study Designer	Yes *If a user views this report	Vault EDC now tracks whether or not a query caused a user to change an Item value with the new Query Summary object. Users can reference this object in reports to gather operational data related to query efficiency.
EDC	Study Administration, Reports & Dashboards	Allow Administrator Users to Schedule Reports	Medium	Auto-on	Clinical Coder Administrator, Lead Data Manager	Yes *If these users choose to schedule reports	Lead Data Managers and Clinical Coder Administrators can now schedule flash reports with the new "Schedule Reports" permission.
EDC	Study Administration	Bulk Update the Active Version for Sites	Medium	Auto-on	Lead Data Manager	Yes *If Lead Data Managers use this feature	EDC Tools users can now update the Active Version for multiple Sites with one action.
EDC	Study Administration	Compare Casebook Versions from EDC Tools	Medium	Auto-on	Lead Data Manager	Yes *If Lead	EDC Tools users can now compare single casebook versions. The comparison report is the same report available from Studio.



Application	Impacted Areas	Feature Name	Feature Risk	Enablement	Training Impact	Existing Studies	Description
						Data Managers use this feature	
EDC	Study Administration	Core Listings	Low	Auto-on	Lead Data Manager	Yes *If a Lead Data Manager runs the job	EDC Tools users can export a formatted CSV of execution data for selected Forms and Sites with the new "Data Listing" job.
EDC	Study Administration	Display the Number of Users Assigned a Study Role	Low	Auto-on *In vaults where the Role by Study feature is enabled	User Administrator, Lead Data Manager	Yes	Vault now displays the number of Users assigned a Study Role in Tools > Role Management.
EDC	Study Administration	Relabeled Connections as FTPs	Low	Auto-on	Lead Data Manager	Yes *The label change is visible to all EDC Tools users	With this release, we relabeled the Connections tab in EDC Tools as FTPs.
EDC	Study Administration	Enablement Change: Prospective Amendments	Low	Support	Lead Data Manager	No	With this release, we updated the enablement of prospective amendments from auto-on to support. Organizations must now contact Veeva Support and request that prospective amendments be enabled in their vault. This change applies to existing vaults.
EDC	Study Design & Configuration	Compare All Versions in Studio	Medium	Auto-on	Study Designer	Yes *If Study Designers use this feature	Studio users can now compare all existing versions of a Study to all versions of another Study, instead of comparing versions one by one.
EDC	Study Design & Configuration	Compare Forms Across Studies	Medium	Auto-on	Study Designer	Yes *If Study Designers use this feature	Users can now compare only the Forms in a Study to the Forms in another Study.
EDC	Study Design & Configuration	New Studio Navigation Pattern	Medium	Auto-on	Study Designer	Yes *If an organization is using Studio	With this release, we refreshed and rearranged the Studio user interface to make it smoother and easier to use. Users can now immediately select a Study upon opening Studio, and the original Studio subs have been moved into a side navigation panel.
EDC	Study Design & Configuration	Set Blank Handling from Rule Editor	Medium	Auto-on *This field displays automatically, but it isn't populated for existing Rules	Study Designer	No	Studio users can now determine how a rule handles blank values from the Rule Editor. Previously, this setting was only available in Admin > Business Admin.
EDC	Study Design & Configuration	Studio Usability Enhancements	Medium	Auto-on	Study Designer	Yes *If an organization is using Studio	We updated the New Event Group, New Event, and New Form dialogs, updated default property values, and moved the Data



Application	Impacted Areas	Feature Name	Feature Risk	Enablement	Training Impact	Existing Studies	Description
							Type property to ease design definition creation in Studio.
EDC	Study Design & Configuration	Study Documentation Enhancements	Medium	Auto-on	Study Designer	Yes *If a Study Designer uses this feature	We added new annotations for annotated PDFs and new values to the Study Design Specification to show more information about a study design in these documents.
EDC	Study Design & Configuration	Set Subject Status with Rules	Medium	By Study Build *In Studies using Version 2 of the expression grammar	Study Designer	No	Studio users can create rules to change a subject's Status based on entered data.
EDC	Study Design & Configuration	Send Emails with Rules	Low	By Study Build	Study Designer	No	Studio users can create a rule to send a configured email notification to a group of study users. Note that in the current release, rule configuration for Send Email rules must be performed primarily in Admin > Business Admin by a Veeva Services team member.



Change Log

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Date	Description	Impact
10/21/2019	Published the initial version of the RIA	N/A
10/26/2019	Removed the "Enablement Change: Vault Coder Dashboards & Reports" feature	The RIA now has an up to date list of features for release in 19R3.
10/29/2019	Renamed the "Simple Listings" feature as "Core Listings"	The RIA now includes up to date feature names.
10/30/2019	Removed the "JReview® Integration" and "Veeva Learning Integration" features. These features were postponed to a later release.	The RIA now includes an up to date list of features for release in 19R3.
11/5/2019	Updated the enablement of "Clinical Assessments" from "By Study Build" to "By Study Build *In vaults where Role by Study is enabled"	The RIA now has up to date enablement information.
11/11/2019	Updated the name of "Ability to Change the Dictionary for a Form" to "Ability to Change the Dictionary Type for a Form"	The RIA now includes up to date feature names.
11/18/2019	Updated the description for the "'Other" Option for Coding Form Type' feature	The RIA now includes up to date feature descriptions.
11/20/2019	Updated the description for the "Track Queries Leading to Data Changes" feature	The RIA now includes up to date feature descriptions.
11/20/2019	Updated the description for the "Send Emails with Rules" feature	The RIA now includes up to date feature descriptions.
1/31/2020	Updated the name of "Clinical Assessments" to "Clinical Review Assessments"	The RIA now includes up to date feature names.

