Vault CDMS

20R1 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: 3/9/2020

Revision Date:	4/9/2020
VIA Available:	3/30/2020

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	Deployments, Vault Tools, Data Review, Coding Administration, Study Administration, Study Design & Configuration	All Vault CDMS Notification Emails Use Vault CDMS Logo	N/A	Auto-on	User Administrator, Data Manager, Clinical Research Associate, Clinical Coder Administrator, Vault Administrator, Lead Data Manager, Study Designer, Deployment Administrator	Yes *Users who receive notifications will see this change in any notifications received after the release.	All email notifications from Vault CDMS now use the Vault CDMS application logo.
All	Deployments, Study Administration	Automated Deployments Include Custom Study Roles & Objects	Medium	Auto-on **The new options for deployments display automatically to deployment administrators, but a Vault Owner must first create Deployment Whitelist records for those options to be useable.	Deployment Administrator	No *While the new deployment options display automatically, a Vault Owner must whitelist custom Study Roles and objects before they can be included in a deployment.	Deployment administrators can choose to include custom Study Roles and custom object configuration in their study deployments. A Vault Owner must first add Study Roles and custom objects to the Deployment Whitelist for those to be included in deployments.
All	Deployments, Study Administration	Create a Production Environment from EDC Tools after Study Creation	Medium	Auto-on *In studies using the automated deployment model	Deployment Administrator	No *If a production environment already exists, another one can't be created.	Deployment administrators can now create a production-type environment from EDC Tools.
All	Study Administration	Changes to the Manage Users Permission & CDMS User Administrator Role	High	Auto-on *In vaults where Role by Study is enabled	User Administrator	Yes	The "Manage Users" permission no longer grants the ability to edit and delete Study Countries and Sites. We then added the "Manage Study Countries" and "Manage Study Sites" permissions to the standard CDMS User Administrator study role.
All	Study Administration	New "Manage Study Role" Permission	High	Auto-on *In vaults where Role by Study is enabled	User Administrator, Lead Data Manager	Yes *Any users assigned these standard roles will have this	With this release, we added a new permission, Manage Study Roles, which provides the ability to create and edit custom Study Roles in Tools > Role Management.

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						new permission.	This permission is assigned to the CDMS Lead Data Manager and CDMS User Administrator standard roles.
All	Study Administration	New "View Coding" Permission	High	Auto-on *In vaults where Role by Study is enabled	User Administrator, Lead Data Manager, Study Designer	Yes *This permission is automatically assigned to existing standard Study Roles and any custom roles that have access to Coder tab.	This release added the new "View Coding" permission, which controls the ability to view coding progress, without impacting items that have already been coded. By default, this permissions is assigned to the CDMS Clinical Coder, CDMS Clinical Coder Administrator, and CDMS Study Designer study roles, as well as any custom Study Roles that have access to the Coder tab.
All	Study Administration	Provide Federated ID during User Creation (UI)	High	Auto-on	User Administrator	No *Records must be edited to use this new field.	When creating and editing users from EDC Tools > Users, user administrators can now provide a Federated ID. Vault uses the Federated ID to connect with a Single Sign On application.
All	Study Administration	Separated Security Profiles for Data Entry Study Roles	High	Auto-on *The new security profiles are available by default, but they are not assigned to any existing user accounts.	Vault Administrator	No *Existing users with the CDMS Data Entry security profile will still have that profile assigned.	With this release, we added separate security profiles, intended to replace the standard "Data Entry" profile: "CDMS Principal Investigator", "CDMS Sub Investigator", and "CDMS Clinical Research Coordinator".
All	Study Administration	User Activity Report	High	Auto-on	User Administrator, Lead Data Manager	Yes *Users with permission can generate this report.	EDC Tools users can track various user actions such as user logins, password resets, and users that have been created as well as study access changes like LMS training status, study/site access, and study roles, using the User Activity Report.
All	Study Administration	Veeva Learning Training Report	High	Auto-on *In Studies where the Veeva Learning Integration is enabled	User Administrator, Lead Data Manager	Yes *In Studies where the Veeva Learning Integration is enabled	Users with access to EDC Tools > Learning Systems can generate a Training Report that tracks the progress of all study users through their assigned training curricula.
All	Study Administration	Manage Custom Object Permissions in Role Management	High	Configuration *In vaults where Role by Study is enabled	User Administrator, Lead Data Manager	No *Even if there are qualifying custom objects, a Vault Owner must first	User administrators and lead data managers can now mange Read, Edit, and Delete permissions for qualifying, whitelisted, custom objects from Tools > Role Management.

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						whitelist those objects for them to appear.	
All	Study Administration	Allow Deletion of Custom Study Roles	Medium	Auto-on *In vaults where Role by Study is enabled	User Administrator, Lead Data Manager	No *A user administrator or lead data manager must initiate the deletion action to use this feature.	With this release, users with access to Tools > Role Management can delete any custom Study Roles, as long as the role is not currently assigned to any users.
All	Study Administration	Download Study Role Matrix as an Excel™ File	Low	Auto-on *In vaults where Role by Study is enabled	User Administrator, Lead Data Manager	Yes *Any user with access to Tools > Role Management can now download this file.	Role Management users can download an Excel™ file with the mappings of permissions to their custom Study Roles.
All	Study Administration, Study Design & Configuration	Study Designer Role Enhancements	High	Auto-on *In vaults where Role by Study is enabled	User Administrator, Lead Data Manager, Study Designer	Yes *For any studies using the CDMS Study Designer Role	We updated the CDMS Study Designer role to leverage Matching Sharing Rules. We added the CDMS Study Designer Read Only study role to assign to study designers in UAT, training, and production environments. The CDMS Study Designer study role is now only available in development environments.
All	Study Design & Configuration	ODM Import & Export for Automated Deployment Studies	Medium	Auto-on *In studies using automated deployments	Study Designer	No *A study designer must initiate the import or export process to use this feature.	ODM import and export functionality is available for use in automated deployment Studies.
Coder, EDC	Coding, Coding Administration, Study Administration	Automating the Autocoding and Suggestions Job	High	Auto-on	Clinical Coder, Clinical Coder Administrator, Lead Data Manager	Yes	The Autocoding & Suggestions job has been changed into an active and automated process that runs throughout the day, providing the user with Autocoding and Suggestions that are constantly up-to-date with evolving Synonym Lists. Autocoding jobs can no longer be scheduled and any currently scheduled Autocoding jobs will be cancelled with this release. Vault Coder shows an Out of Sync notification as autocoding runs in the background. Coders can click the new Refresh button to refresh the page and see the most up to date coding information. As

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							part of this feature, we removed the autoassign option.
Coder, EDC	Data Entry, Data Review, Coding, Study Design & Configuration	Form Linking & Copy from Indication	Medium	By Study Build *In studies using automated deployments and version 2 of the expression grammar	Sub Investigator, Clinical Coder, Clinical Coder Administrator, Investigator, Study Designer, Clinical Research Coordinator	No *A study designer must add form linking to a study's design.	Users can configure and associate related forms through Form Linking in the Data Entry and Studio tabs. For example, an Adverse Event form can be linked to one or more Concomitant Medication forms that are related to that Adverse Event so as to group similar or related data or indicate cause and effect. The Indication item on WHODrug-based forms can also be further configured to retrieve Indication values from other form records.
Coder, EDC	N/A	Additional Requirements for Core Listings	N/A	N/A	N/A	N/A	With this release, we introduced new BRDs for the Core Listings feature. There weren't any functional changes to Core Listings. These new requirements were only added to provide additional detail in the BRD.
Coder, EDC	N/A	Additional Requirements for the JReview® Integration	N/A	N/A	N/A	N/A	With this release, we introduced new BRDs for the JReview® feature. There weren't any functional changes to the JReview® integration. These new requirements were only added to provide additional detail in the BRD.
EDC	Data Entry	Allow Deletion of Signed, Dynamic Forms	Medium	Auto-on	Investigator	Yes *A user must delete a signed Form for these changes to be visible.	Users can now edit a controlling Item (or reset the Form containing that Item) even if their change removes a dynamically added Form that was already signed.
EDC	Data Entry	Data Entry Navigation Enhancements	Low	Study Feature Flag *Enabled by setting "Data Entry Version" in Study Config to blank	Sub Investigator, Investigator, Clinical Research Coordinator	No *This feature must be enabled for a study.	The Casebook Schedule page has been combined with the Form Display page to create a better navigational experience for the user. All Events and Forms in the Study Schedule are now displayed next to the Form panel, allowing Data Entry users to navigate to any Form within any Event. Any activities previously performed by CRAs or DMs (SDV, DMR, Freeze, Lock, etc.) will now need to be performed in the Review tab.
EDC	Data Entry, Data	Prevent Recreation of	Medium	Auto-on	Sub Investigator,	Yes *This	Vault no longer recreates system queries if

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	Review	Manually Closed System Queries			Clinical Research Associate, Data Manager, Investigator, Lead Data Manager, Clinical Research Coordinator	change applies to all existing and future queries upon the release.	the same system query (same Rule and data point) was previously opened and then manually closed.
EDC	Data Entry, Data Review, Study Design & Configuration	Item Indentation	Low	By Study Build	Data Manager, Clinical Research Coordinator, Sub Investigator, Clinical Research Associate, Investigator, Lead Data Manager, Study Designer	No *A study designer must add this configuration to a study.	Study designers can indent Items on a Form using the new Indent Level property.
EDC	Data Entry, Study Design & Configuration	Prevent Creation of First Instance for Repeating Forms Added by an Add Form or Add Event Rule	Medium	Auto-on	Sub Investigator, Investigator, Study Designer, Clinical Research Coordinator	Yes	With this release, Vault no longer automatically creates the first instance of a repeating Form if the Form is added by an Add Form or Add Event rule. For existing Studies that want to continue with the original behavior or adding the first instance, a Vault Administrator can set the Dynamic Repeating Form Instance field on the Study Configuration object to "No".
EDC	Data Entry, Study Design & Configuration	Progressive Display	Medium	Study Feature Flag *In studies using automated deployments and version 2 of the expression grammar	Sub Investigator, Investigator, Study Designer, Clinical Research Coordinator	No *A study designer must add this configuration to a study.	Study designers can design a form such that data collection items are dynamically displayed or hidden as a user progresses through a form.
EDC	Data Review, Study Administration	Site-level SDV & DMR Re-assignment	Medium	Auto-on	Lead Data Manager	Yes *A lead data manager can run the job immediately after the release.	EDC Tools users can now run the SDV and DMR Re-assignment jobs at the Site level.
EDC	Study Administration	Removed "Manage Study Lock" Permission from CDMS Deployment Administrator	High	Auto-on *In vaults where Role by Study is enabled	User Administrator, Deployment Administrator, Lead Data Manager	Yes *This feature removes a permission from a standard Study Role.	With this release, we removed the Manage Study Lock permission from the standard CDMS Deployment Administrator study role.

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EDC	Study Administration	Vault EDC/CTMS Connection with Spark	High	Configuration	Lead Data Manager	No *This feature must be enabled for the vault.	This feature allows customers using both Vault EDC and Vault CTMS applications to connect those vaults for the purpose of transferring Studies, Study Countries and Sites from Vault CTMS to Vault EDC and Subjects, Subject Visits and Visit Definitions from Vault EDC to Vault CTMS using Veeva Vault Spark Messaging.
EDC	Study Administration	Add Study Countries during Site Creation	Low	Auto-on	Lead Data Manager	No *Users must create a new Site to see this change.	EDC Tools users can now add Study Countries when creating a new Site without leaving the New Study Site dialog.
EDC	Study Administration, Study Design & Configuration	Send Email Rule Configuration	Medium	By Study Build *Send Email rules are only available in vaults using Role by Study and studies using the automated deployment model.	Lead Data Manager, Study Designer	No *A study designer and lead data manager must configure a Send Email rule and Email Group.	With this release, Send Email rules and Email Groups can now be fully configured from Studio and EDC Tools. This feature added the Manage Email Group Assignments permission, which is automatically assigned to the CDMS Lead Data Manager study role.
EDC	Study Design & Configuration	Choose Study Template Review Plans in Studio	Medium	Auto-on	Study Designer	Yes *Study designers can see the new options right away.	Study Designers can select which review plans should be used as a default template to override SDV and DMR plans at the study level.
EDC	Study Design & Configuration	Copy Rules from Another Study	Medium	Auto-on	Study Designer	No *A Studio user must initiate the copy process to use this feature.	Studio users can copy rules from another Study. Vault validates all identifiers in the copied rules and shows an indicator when a rule contains an invalid identifier.
EDC	Study Design & Configuration	New Functions in the Formula Expression Grammar	Medium	Auto-on *In studies using version 2 of the expression grammar	Study Designer	No *Study designers must create rules using these new functions.	This feature (1) introduces new functions: Power(), Sum(), Average(), and StartOfDay() to Vault Formulas, and (2) enhances Today() to take an optional timezone parameter.
EDC	Study Design & Configuration	Reciprocal Rules	Medium	Auto-on	Study Designer	Yes *This change applies to all Rules. Organizations can work with	Rules created after 20R1 are considered "reciprocal", and so rules for any Items referenced as part of an @Form identifier now apply to any use of the Form in a Casebook, even if that form isn't repeating.

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						Veeva Services to return individual rules to their previous state if required.	
EDC	Study Design & Configuration	Status Change Date for Set Subject Status Rules	Medium	By Study Build	Study Designer	No *Existing Set Subject Status rules will continue to function without a date.	Study designers can configure a Set Subject Status rule action to set the date for the status change to an Event Date or date from a date-type Item.
EDC	Study Design & Configuration	Support for the Optional Requirement Mode in the Review Plan Editor	Medium	By Study Build	Study Designer	No *Study designers must create or edit a Review Plan using the Optional requirement mode.	The Review Plan Editor now supports the Optional Requirement Mode for Event Dates and Items.
EDC	Study Design & Configuration	Rule Editor Enhancements	Low	Auto-on	Study Designer	Yes *Study designers can see and use these changes upon accessing the Rule Editor.	Instead of typing in the path for identifiers directly in the Rule Editor, users can search for identifiers and insert them with #define statements. As part of this feature, users can also collapse and expand the Rule Details panel.
EDC	Study Design & Configuration	Select All for Assessments Item Group Visibility	Low	Auto-on	Study Designer	Yes *Study designers can see these changes right away.	Users now have the option to select all Items under an Item Group in addition to the ability to select Items independently.

Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: *3/9/2020*

Date	Description	Impact
3/2/2020	Published the initial version of the RIA	N/A
3/9/2020	Updated the description for "Automating the Autocoding and Suggestions Job" to provide more detail about the changes associated with this feature.	The RIA now includes up to date feature descriptions.
3/12/2020	Updated the risk of "Automating the Autocoding and Suggestions Job" from "High" to "Low"	The RIA now includes up to date feature risk.
3/18/2020	Updated the RIA format by adding new columns to provide information about end user impact	The RIA now includes additional information.
3/23/2020	Removed the 'New "Workbench Tab" Permission in Role Management ' feature from the RIA, as this feature was removed from the VIA. Updated the risk of "Automating the Autocoding and Suggestions Job" from Low to High	The RIA now includes an up to date list of features with up to date feature risk.
4/6/2020	Updated the Training Impact for the New "View Coding" Permission and Study Designer Role Enhancements features Updated the Description and Impacts Existing Studies comment for the New "View Coding" Permission feature	The RIA now includes up to date training impact, feature descriptions, and study impact information.
4/9/2020	Updated the Enablement, Affect on Existing Studies, and Description for the "Automated Deployments Include Custom Study Roles & Objects" and "Manage Custom Object Permissions in Role Management" features	The RIA now includes up to date information about features for release in 20R1.