Vault CDMS

21R1 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. The RIA serves as an early preview of the Validation Impact Assessment (VIA). Once the VIA is available on Veeva Docs, refer to it for more detailed validation information.

This feature list is subject to change prior to the release. We will begin tracking changes on: 3/5/2021

Revision Date:	4/12/2021
VIA Available:	3/29/2021

For detailed feature descriptions, refer to the product release notes, which are available on [Vault CDMS Help](#).

This document does not include changes made as part of the Vault Platform release. Consult VeevaDocs 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 Fields:	These four fields describe the availability and visibility of a feature on day 1 (if no configuration occurs), what configuration is required, and if the feature has any dependencies.
Day 1 Impact to Clinical Team	If Yes, this feature is visible and available to sites, CRAs, or data managers on day 1. If No, this feature is either only visible to study designers or administrator users, or this feature requires configuration before it is visible to the clinical study team.
Users with Day 1 Visibility	This feature is visible to these users on day 1 if no configuration occurs.
Configuration	This field lists the location(s) where configuration for this feature occurs, for example, "Studio" or "EDC Tools". "Support" indicates that this feature must be enabled by Veeva Support, and "Vault Admin" indicates that configuration must be performed by a Vault Owner in the vault's Admin area.
Dependencies	This field lists any dependencies required to use this feature, for example, Labs or Expression Engine V2. The RIA assumes that the dependencies are enabled.
Training Impact:	Lists the user roles that may require updated training for this feature.

Day 1 Impact to Clinical Team	Name	Application	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
Yes	Additional Columns for DateTime Items in Extracts	Coder, EDC	CRAs, Study Administrators, Data Managers			Low	The Core Listings, Data and Definition Export, and Study Data Extracts job outputs now show the entered datetime in the Site's timezone, UTC timezone, and the timezone of the user who ran the job, all in ISO format yyyy-MM-dd HH:mm:ss.	Clinical Research Associate, Data Manager, Lead Data Manager
Yes	Data Entry General Enhancements	EDC	Sites			Low	The Casebook Schedule panel of the Data Entry user interface no longer performs a full reload of the Schedule each time a Form or Event status updates. Vault updates the status icons as users enter data, but the scroll position remains the same. Additionally, the Expand All Events/Collapse All Events setting is now sticky, so that once a user expands or collapses the schedule, Vault maintains the selection across pages, until the session ends.	Investigator, Sub Investigator, Clinical Research Coordinator
Yes	Group Querying	Coder	Coders			Medium	Coders can now stay in Group mode to query sites. There is also an option to expand the Grouping criteria to include Query Status.	Clinical Coder, Clinical Coder Administrator
Yes	Jobs Enhancements	EDC	CRAs, Study Administrators, Data Managers			Low	Users may now cancel certain in progress jobs. The output and log files from jobs are now available from 6 months after job completion, instead of the 15 days.	Clinical Research Associate, Data Manager, Lead Data Manager
Yes	Listings UI Improvements	CDB	CDB Users			Low	Workbench users can now search and filter within the Listings page's four tabs to more easily locate listings of interest. They can also use the new View CQL action on individual listings to view the CQL statement without opening the listing.	Lead Data Manager, Data Manager
Yes	Pending Lab Location Count	EDC	Data Managers		Labs	Low	The Pending Lab Locations tab now has a number indicator to show how many Lab Locations are pending for approval.	Lab Data Manager
Yes	Recalculate Age	EDC	Sites		Labs	Medium	Users can recalculate a subject's age based upon the Lab Collection Date and the Birth Date or Birth Year item by clicking a button.	Clinical Research Coordinator, Investigator, Sub Investigator

Yes	Search & Filter for Randomization Lists	EDC (Randomization)	Randomization Managers, Data Managers		Randomization	Low	This enhancement allows users to filter their randomization lists and devices and kits by Subject Status, Site, Strata Group, Randomization Status, and more, as well as search for individual list items.	Randomization Manager
Yes	Union Behavior Changes	CDB	CDB Users			N/A	The default behavior for UNION is the same as UNION ALL, which returns all rows to all results from queries in the union. We then added the UNION DISTINCT function, which returns the results from queries in the union with duplicates removed.	Data Manager, Lead Data Manager
No	Access Data from Linked Forms with Rules	EDC	Study Designers			Medium	Study designers may now use identifiers for Forms connected to the rule's Form by a Form Link, for example, a linked Concomitant Medication form from an Adverse Events form.	Study Designer
No	Coder Approval Workflow	Coder	Coder Administrators	Coder Tools		High	Coder Administrators can enable the Approval Workflow to have Coder Managers review the coding of less experienced Coders. When enabled, all manually coded Code Requests must be approved.	Clinical Coder, Clinical Coder Administrator, Clinical Coder Manager
No	Emergency Unmasking Report	EDC (Randomization)	Data Managers		Randomization	Low	The Emergency Unmasking Report lists all instances where a user performed an unmasking on a subject in a masked study. The report also shows the user who performed the unmasking and the date and time the masking was performed.	Randomization Manager
No	Enhanced Security for CDB	CDB, EDC	User Administrators	System Tools		High	With this release, we introduced several new permissions to allow more granular access control for the CDB application. We also added a new standard role, CDB Data Provider. These new permissions aren't automatically added to custom roles. You must update your custom roles for those users to be able to use Workbench.	Lead Data Manager, User Administrator
No	Export Randomization Lists	EDC (Randomization)	Randomization Managers		Randomization	Medium	Randomization managers may now export their randomizations lists as CSV files.	Randomization Manager

No	Library Collections	EDC	Study Designers, Librarians			Medium	From the Library, librarians can create a new type of Study called a Collection. A collection allows an organization to manage a set of standards isolated from other Studies and only editable by a user with the CDMS Librarian role.	Study Designer, Librarian
No	Library Report	EDC	Librarians, Study Designers			Medium	Users can generate a Library Report to track which study design components were reused across which studies.	Librarian, Study Designer
No	Preferred Base for Extracts	Coder, EDC	Coder Administrators	Coder Tools		Medium	Coder Administrators can now have the system store Preferred Base and have it listed in all listings and extracts, including Core Listings, the Data and Definition Extract, the Code Request Extract, and Vault Reports.	Clinical Coder Administrator, Lead Data Manager
No	Procedure Notifications for Vault CTMS	EDC	Study Administrators	EDC Tools	Your organization must have a CTMS vault.	Medium	Lead data managers can use the new Integration Configuration area of EDC Tools to set up the Procedures integration with Vault CTMS, which sends a notification to CTMS when a procedure form is submitted by a data entry user in CDMS.	Lead Data Manager
No	Protocol Deviations	EDC	Study Designers	Studio		High	Organizations can track protocol deviations from within Vault CDMS. Studies can use the Create Protocol Deviation rule action to create protocol deviations programmatically, or monitoring users can create protocol deviations manually from the Review tab.	Clinical Research Associate, Data Manager, Lead Data Manager, Study Designer
No	Rules Enhancements	EDC	Study Designers			Medium	With this release, we made the following enhancements to rules: Study designers may add multiple Event Groups to the schedule with a single Add Event Group rule. Date comparison rules may now specify that two dates or datetimes must be equal.	Study Designer
No	Safety Link	EDC	Study Administrators	EDC Tools, System Tools		Medium	Safety Link is an integration between Vault CDMS and any Safety System, including Vault Safety. Enabling this integration automates the reporting of any serious adverse events (SAE) and related form data collected in Vault CDMS to the Safety System.	Vault Administrator, Safety Administrator

No	Select All Forms for Batch Upversioning	Coder	Coder Administrators			Low	Users may now select more than twenty forms to batch upversion using the new "Select All Forms on All Pages" option, instead of upversioning Forms in groups of twenty.	Clinical Coder, Clinical Coder Administrator, Clinical Coder Manager
No	SSO Authentication for eSignature	EDC	Sites		SSO must be configured for your vault.	High	With this release, Vault CDMS supports authenticating with a Single Sign-On (SSO) Provider while performing CDMS-specific activities that prompt users to authenticate after logging in.	Investigator, Lead Data Manager
No	Study Data Extracts	Coder, EDC	Study Administrators			Low	The 1:1 Study Data Extract job allows Data Managers to extract and download study execution data.	Lead Data Manager
No	Vault-level User Management	EDC	Study Administrators			High	User administrators may now manage user accounts and assign study roles from a single location in Tools > System Tools > Users. Previously, these tasks were performed in Tools > EDC Tools > Users and Admin > Users & Groups.	Lead Data Manager, User Administrator, Vault Administrator

Change Log		
This feature list is subject to change prior to the release. We will begin tracking changes on: 3/5/2021		
Date	Description	Impact
2/26/2021	Published the initial version of the RIA.	N/A
4/12/2021	Updated the Description and Users with Day 1 Visibility for the Library Report feature.	The RIA now includes up to date feature information.