



23R3 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: October 13, 2023

Revision Date: 12/06/2023

VIA Available: 11/06/2023

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 Primary Users This feature is visible and available to one or more primary user teams (Site Users, Clinical Team, and Coders) on day 1. If blank, this feature is either only visible to study designers or administrator users, it requires configuration before it is visible to primary users.

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 Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact	Release Notes
	Study Role Enhancements	EDC	Yes	API Read Only, API Read Write, Lead Data Managers, Super Users, User Administrators			Medium	<p>To support new features in the 23R3 release, we made the following changes:</p> <p>New Study Roles:CDB API Read Write: This role allows for an API user to interact with CDB to view, open, answer, and close queries from both EDC and third party data sources.</p> <p>Updates to existing Study Roles:Added the Manage Email Group Assignment permission to the CDMS API Read Write role Assigned the following permissions to the CDMS API Read Only and CDMS API Read Write roles: View Library, View Study Design, View Classification Assigned the following permissions to the CDMS API Read Write role: Design Library, Design Study, Edit Classification Assigned the Manage Jobs permission to the CDMS Safety Administrator role</p> <p>New dependencies:The Manage Safety Integrations permission now requires the Manage Jobs permission.</p>	API Read Only, API Read Write, Lead Data Manager, Super User, User Administrator	Link
	Frozen Form Support for Amendments	EDC			Support	Data Model 2	Medium	Retrospective amendments can now be applied to frozen Forms. Instead of requiring data managers to unfreeze anything, Vault adds new definitions as unfrozen, and any item type, label, short label, hint label, or override label changes will unfreeze Items.	Deployment Administrator, Lead Data Manager	Link
Clinical Team	Detail PDFs: Fast Web View	EDC		CRAs, Data Managers, Lead Data Managers, Sites			Medium	To align with FDA guidance for regulatory submissions, we have updated PDF files generated in bulk to be optimized for fast web view. This update applies to the files generated in the Detail PDF job and Site Closeout PDFs.	Clinical Research Associate, Clinical Research Coordinator, Data Manager, Investigator, Lead Data Manager, Sub Investigator	Link
	Import & Export Training Mapping	All		Lead Data Managers, Super Users, User Administrators			Medium	User administrators can now export training mapping to a file and import training mapping from a file; either exported directly from another vault or configured manually in a spreadsheet editor. In support of this feature, we moved actions on this page from buttons into the Actions menu.		Link
Clinical Team	Form Progress Listing: SDV & DMR Re-review Columns	EDC		CRAs, Data Managers, Lead Data Managers			Low	With this release, the Form Progress Listing identifies when a form that has been previously reviewed (SDV/DMR) requires re-review. The listing now includes Requires Re-SDV and Requires Re-DMR columns. These columns will only populate for studies created after 23R3.	Clinical Research Associate, Data Manager, Lead Data Manager	Link
	Fire Query when ILB Setting	EDC		Study Designers	Studio		Medium	With this feature, users in Studio have the option to choose whether or not a query will fire on a required item when it is marked as Intentionally Left Blank (ILB). Sites will receive a query in Data Entry when marking items that are configured with this setting as ILB.	Clinical Research Coordinator, Study Designer	Link
Clinical Team	Date of First Submission Columns for Extracts	EDC	No - Future Release	CRAs, Data Managers, Lead Data Managers			Low	For studies created after 23R3, the system will track the date that a form is first submitted with columns added to the Form Progress Listing, Core Listings, and Study Data Extracts.	Clinical Research Associate, Data Manager, Lead Data Manager	Link

Day 1 Impact to Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact	Release Notes
	Standard Version of Coding Reports & Dashboard	Coder		Vault Owners			Low	Coding reports are now available in the Veeva Standard report format. There are also new custom dashboard components and a dashboard available to users. All CDMS vaults (new and existing) will have access to the following reports: MedDRA standard report V3, which supports MedDRA and MedDRAJ. WHODrug standard report V3, which supports both B3 and C3. JDrug standard report	Clinical Coder, Clinical Coder Administrator, Clinical Coder Manager	Link
Clinical Team	Date of First Review Columns for Extracts	EDC	No - Future Release	CRAs, Data Managers, Lead Data Managers			Low	For studies created after 23R3, the date of the first SDV and DMR review for a Form or Event Date will display as columns in the Form Progress Listing, Event Progress Listing, and the SYS_FORM dataset in the Study Data Extract job.	Clinical Research Associate, Data Manager, Lead Data Manager	Link
Coders	Route Coding Reports to Coder	Coder		Coder Administrators, Coders			Medium	Links for the Name columns in Vault Coding reports now lead directly to the related Code Request pages in Vault Coder. When routed to the respective Code Request page, the page is filtered for that specific Code Request record. A new filter for Name will also be displayed. If the user clicks the Name link for a coding query, coding note, or coding property, that name will be in focus on the Code Request page. The same applies when the user clicks the Name link for a Grouped Code Request. If the user clicks the Name link for a Medical Coding Item Definition, the respective Code Request page will load showing all the respective Coding Requests. Name filters on the Code Request page can be removed at any time.	Clinical Coder, Clinical Coder Administrator, Clinical Coder Manager	Link
Clinical Team	Study Progress Listing Enhancements	EDC		CRAs, Data Managers, Lead Data Managers			Low	This release includes the following Study Progress Listing job enhancements: Query Detail Listing: Renamed the Created Date column to Query Created Date, and the Created By column to Query Created By Form Progress Listing: Updated the SDV Required and DMR Required fields to support Data Model 1 studies when the Form Progress Listing is sent to Vault Reports	Clinical Research Associate, Data Manager, Lead Data Manager	Link

Day 1 Impact to Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact	Release Notes
Clinical Team	SDE: Enhancements	EDC	Yes	Lead Data Managers			Low	For SDE Sent to CDB, starting with this release, users can only include SYS datasets and Custom Objects when sending SDE data to CDB. The option to include clinical datasets is disabled. This applies to both the 23R2 and 23R3 versions of the SDE. For SAS, we increased the compression for SDE jobs being exported as a SAS file to minimize processing time, and we've changed the way XPT files are generated so that they can be opened with the SAS Universal Viewer. The 23R3 version of the SDE includes the following changes: Clinical Datasets now include columns for Date of First Submission (FIRSTSUBMITDT), Form Created Date (CREATEDT), and Form (Latest) Submission Date (LASTSUBMITDT); SYS_FORM now includes the Date of First SDV (FIRSTSDVDT) and the Date of First DMR (FIRSTDMRDT); the column header for the Last Submit Date column in SYS_FORM dataset has been changed from SUBMITDT to LASTSUBMITDT for consistency; the SYS_SUB dataset automatically includes columns for Latest Arm (LATESTARM), Latest Cohort (LATESTCOHORT), and Latest Substudy (LATESTSUBSTUDY) if the study includes these subject group definitions; the SYS_PD dataset has been updated with 4 new columns: Protocol Deviation Restricted (RESTRICTED) - visible only when user select the option to "Include Restricted Data", Event External Id (EVENTEID), and Form External ID (FORMEID), and Item Group External ID (IGROUPEID); Item Group External ID (IGROUPEID) has also been added to the following datasets: SYS_LINKS (if item to form linking is enabled), SYS_ILB, SYS_Q, and Clinical Lab datasets; the SYS_ASM and SYS_ASMR datasets have been updated to include several new columns: Event Group (EGROUP), Event Group Definition (EGROUPDEF), Event Group External ID (EGROUPEID), Event (EVENT), Event Definition (EVENTDEF), Event External ID (EVENTEID), Event Group Sequence (ESEQ), Form External ID (SOURCEFEID), and Form Sequence (FSEQ); the SYS_ASMR dataset additionally includes: Form (SOURCEF), Form Definition (SOURCEFDEF), Question Number (QUESNUM), and Question External ID (QUESEID); For studies using a Safety configuration, the 23R3 version of the SDE includes 2 new SYS datasets for Safety Cases (SYS_SAFEC) and Safety Messages (SYS_SAFM), and a full list of columns in these new datasets can be found in CDMS Help.	Lead Data Manager	Link
Clinical Team, Site Users	EDC General Enhancements	EDC		CRAs, Data Managers, Sites			Low	We've made the following enhancements to EDC: Snapshots: We've removed the refresh/sync icon from the snapshots results page. Users should refresh their browser to view updated results. Small Screen Size Warning: We've updated the warning message window to more prominently guide the user. The "Test My Setup" option has been relabeled "Help Me Fix It" and is the primary action.	Clinical Research Associate, Clinical Research Coordinator, Data Manager, Investigator, Lead Data Manager, Sub Investigator	Link
	Standard Version of Operational Reports & Dashboards	EDC		Vault Owners			Low	With this release, Vault Report templates are available in the new standard version V3. Some report templates have been updated from previous versions to include new columns, filters, or report types. Vault owners will automatically have access to the new report templates and they can be shared with other users.	Clinical Research Associate, Data Manager, Lead Data Manager, Vault Administrator	Link

Day 1 Impact to Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact	Release Notes
Site Users	Rules: Usability Improvements	EDC		Librarians, Study Designers	Studio	Rules V2	Medium	<p>This release includes the following updates to improve rule usability:</p> <ul style="list-style-type: none"> @PreviousEvent identifiers can now be used with Set Derived Value rules We've updated how rules are evaluated when they contain multiple Item to Form links (such as from a repeating Item Group, for example) and Item to Form links to the same Form. Previously, the link identifiers were grouped at the Form level and evaluated once. With this release, individual link identifiers will be evaluated separately to ensure that linked information from a specific Item Group is correctly associated in rule processing. Vault will no longer prevent users from submitting a form when submission would result in a query being opened on a locked object (Form, Event). With this release, Vault will allow form submission but skip opening a query on a locked object. 	Librarian, Study Designer	Link
Clinical Team	Labs: Import Lab Units & Codelists	EDC (Labs)		Lab Data Managers			Medium	With this release, users can import multiple Lab units and codelists at once.	Lab Data Manager	Link
Clinical Team	Safety Configuration Moved to Studio	EDC		Librarians, Safety Administrators, Study Designers, Super Users	EDC Tools, Studio		Medium	We moved Safety Configuration from EDC Tools to Studio, including a wizard for form configuration and inclusion criteria. As part of this feature, we added the following functions: all safety Form Types can be mapped to multiple EDC Forms, NullFlavors for coded fields have the 10067482 code, Safety Case entries can reference repeating Item Groups, and Study Drug Inclusion Criteria can reference First Dispense Closest On/Before SAE Start/End Date.	Librarian, Safety Administrator, Study Designer, Super User	Link
	Clinical Data Change Extract	EDC		Lead Data Managers		Data Model V2	High	This feature includes a new Data Change Extract in EDC Tools, where users with the Manage Jobs permission can view changes made to Item and Event Date data during a specific time period. Users can include up to 90 days of data in the extract and specify which forms to include. The extract can be run on ad-hoc or scheduled on a daily, weekly, or monthly basis. The extract is separated into columns so that changes are easily identifiable.	Lead Data Manager	Link
Site Users	ILB Enhancements	EDC		Sites		Form Linking V2, Data Entry V2	Medium	<p>This feature includes the following changes made to the Intentionally Left Blank functionality, which apply to standard and lab forms:</p> <ul style="list-style-type: none"> The option to mark a form as Intentionally Left Blank will now be displayed as a button at the top of the form instead of an action in the action menu. In Lab forms, the button will replace the Lab Tests Not Performed checkbox. The ILB button will be disabled in cases when ILB is not allowed because the study or site is locked, the form is locked, frozen, or marked for removal, or there are existing item links. The task bar will include blank forms <p>These changes will affect form linking functionality accordingly: Forms marked as ILB cannot be included in form to form or item to form linking - marking a form as ILB after it has been linked will remove form links.</p> <p>When a linked form is reset, existing form links for that form are removed. The Reset Form option will be disabled if there are existing item links.</p>	Clinical Research Coordinator	Link
	Review Plan Assignment V3 Enhancements	EDC		Lead Data Managers, Librarians, Study Designers, Super Users			Medium	<p>This feature includes the following new option in the Assignment Criteria section when creating a Review Plan Assignment: "Apply assessment criteria to each site within selected country individually."</p> <p>This setting will respect the assigned ordinals and percentages individually for each site within the selected country.</p> <p>In addition, the Reorder Assignment job has been renamed to Reevaluate Plan Assignment for clarity, as the job runs through the history of each subject and applies Review Plans based on the current/updated criteria. A downloadable report and log file are provided in the Job History tab that detail the subjects whose review plans were changed as a result of the job. Options to select Specific Sites and Preview the job's output are also available with this release.</p>		Link

Day 1 Impact to Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact	Release Notes
	VeevaID Support	EDC	Yes		Support		High	With this release, Vault CDMS now supports the VeevaID feature from Vault. When a new user is created, including during import, Vault can check if that user has an existing VeevaID account. If the user does have a VeevaID account, CDMS creates that user as a cross-domain user associated with their Veeva ID. A user administrator can also opt out of creating a VeevaID during import.	API Read Write, Super User, User Administrator	Link
Clinical Team	Study Priority and Job Governor Enhancements	EDC		Lead Data Managers			Medium	We've made the following enhancements regarding extract job governance and study priority: Users can now set and edit the study priority expiration date when setting a study to be priority When a user goes to lock a study after the priority is set, the system will inform the user that the priority expiration date will change to the time of study lock plus the number of days set based on the "Number of days before scheduled job cleanup after study lock" setting. Users are allowed to run one Unique Terms Report at a time The Audit Trail Export jobs fall under the job governor for scheduled jobs, and users cannot schedule more than the maximum number of scheduled jobs allowed for that job type within the study	Lead Data Manager	Link

Day 1 Impact to Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact	Release Notes
	CDB Listing Builder	CDB	Yes	CDB Users, Data Managers, Lead Data Managers, Super Users			Medium	The Listing Builder is a user interface for creating listings, checks, and views without using CQL.	Data Manager, Lead Data Manager, Super User	Link

Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: October 13, 2023

Date	Change	Impact
10/9/2023	Published the initial version of the RIA.	N/A
10/20/2023	<p>Updated the "Users with Day 1 Visibility" for "Study Role Enhancements" from "Lead Data Managers, Super Users, User Administrators" to "API Read Only, API Read Write, Lead Data Managers, Super Users, User Administrators"</p> <p>Updated the "Users with Day 1 Visibility" for "VeevaID Support" from "Super Users, User Administrators" to "API Read Write, Super User, User Administrator"</p> <p>Updated the "Training Impact" for "Study Role Enhancements" from "Lead Data Managers, Super Users, User Administrators" to "API Read Only, API Read Write, Lead Data Manager, Super User, User Administrator"</p> <p>Updated the "Training Impact" for "VeevaID Support" from "Super Users, User Administrator" to "API Read Write, Super User, User Administrator"</p> <p>Updated the "Description" for "Rules: Usability Improvements", replacing the paragraph "With this release, identifiers will no longer permute against each other for the same form2 instance. They will instead be processed as one evaluation and the Item Groups and Items will permute independently rather than being grouped at the form level." with "We have updated how rules are evaluated when they contain multiple item to form links (for example, from a repeating item group) or item and form links to the same form. Previously, the linked form was evaluated as a whole. With this release, the individual link identifiers are evaluated separately, which ensures the linked information from the specific item group is correctly associated in the rule processing."</p>	The RIA includes up to date impact information and clearer descriptions.
10/25/2023	<p>Updated the "Name" of "Clinical Data Change Report" to "Clinical Data Change Extract" and updated the "Description" to reflect this name change. This change applies with the 23R3.0 release.</p> <p>Updated the "Configuration" for "Labs: Import Lab Units & Codelists" from "Labs" to "Blank", as this feature is automatically enabled.</p>	The RIA has up to date feature names and enablement.

11/1/2023	Updated the "Name" of "SDE: Study Priority and Job Governor Enhancements" to "Study Priority and Job Governor Enhancements". Updated the "Description" of "Review Plan Assignment V3 Enhancements" to correct the option label from "Apply Review Plan Assignment to all sites within selected countries individually" to "Apply assignment criteria to each site within each selected country individually". Updated the RIA's spacing so that longer descriptions are visible in all file formats, which include changes to the list formatting in the "SDE: Enhancements" feature description.	The RIA has up to date names and descriptions.
11/6/2023	Added the "Release Notes" column with links to the What's New in 23R3	The RIA now includes links to the release notes.
11/9/2023	Removed the "PPT Environment Restricted to PPT Vaults" feature. This feature has been postponed to a later release.	The RIA now contains an up to date list of features.
11/14/2023	Added "Data Model V2" to "Dependencies" for "Clinical Data Change Extract"	The RIA now contains up to date dependencies.
11/22/2023	Updated the "Description" for "Review Plan Assignment V3 Enhancements" to list "Apply assessment criteria to each site within selected country individually" instead of "Apply assignment criteria to each site within each selected country individually" for the field label.	The RIA now includes up to date descriptions.
11/28/2023	Updated the "Configuration" for "VeevaID Support" from "Blank" to "Support" and updated the "Users with Day 1 Visibility" from "API Read Write, Super User, User Administrator" to "Blank"	The RIA now contains up to date enablement information.
12/6/2023	Added missing new values to the 10/20/2023 Change Log entry	The RIA Change Log now contains both old and new values for 10/20/2023.