V Vault CDMS — 23R2 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: June 23, 2023	
Revision Date:	8/16/2023
VIA Available:	7/17/2023
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 tone 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
	Create Procedures via Rules	EDC		Study Designers	Vault Admin		Medium	This feature moves the integration configuration into Studio (from EDC Tools) for new studies and provides the ability to use logic to determine if an integration record is written to an integration object (like CDMS Procedures). All of the standard Studio functions (difference report, related objects viewer, SDS, and deployments) are included.	Study Designer	Link
Coders	Display Third-Party Coding Suggestions	Coder		Coder Administrators	API, Coder Tools	Requires a Third Party Integration for Suggestions Generation	Low	This feature displays third-party suggestions in the Coder UI to reduce time spent on locating the correct coding.	Clinical Coder, Clinical Coder Manager	Link
	Recalculate Normalized Datetime Values	EDC		Lead Data Managers			Medium	This feature includes a job that updates the normalized values for datetime items in a site based on the current site timezone. The job runs automatically when the time zone is changed for a site with existing subjects, from either EDC Tools or CTMS. Users can also run this job from EDC Tools.	Lead Data Manager	Link
Clinical Team	Snapshots: Bulk Lock & Freeze	EDC	No - Future Release	Data Managers, Lead Data Managers		Data Model V2	High	In the Review tab, Data Managers can create snapshots of clinical data for analysis during study milestones. Snapshots are a filtered subset of data that can be used over the course of the study. From the snapshot, users can view data that is ready for lock or freeze, that is already locked or frozen, or that is not yet ready (due to open queries, pending SDV, etc.). Using the snapshot, DMs & CRAs can perform lock/unlock and freeze/unfreeze actions across multiple casebooks in bulk.	Data Manager, Lead Data Manager	Link
	Screening Subjects Outside CDMS			API Read Write, Study Designers	API, Studio	Connection with CTMS or other 3rd party system	N/A	CDMS APIs now have the option to exclude subjects in CDMS until they have reached an enrolled status in CTMS. Once enrolled, the subject can be created in CDMS by the IXRS system and the connection with CTMS will check and match the corresponding subject record in CTMS. The subject's status in CDMS will be set to Enrolled per the Subject Status rules configured in Studio by the Study Designer.	API Read Write, Study Designer	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
	Review Plan Job Enhancements	EDC		Lead Data Managers, Librarians, Study Designers, Super Users			N/A	This feature confers performance enhancements to the Review Plan Reorder and SDV/DMR re-assignment jobs, particularly for complex casebook designs and large number of casebooks. In addition to these strictly performance-based enhancements, the Reorder job will now clean up Review Plan Casebook records that have become corrupted due to either a subject transfer or inadvertent deletion of manual assignments when a Review Plan Assignment record is changed. Previously these invalid records would have needed to be removed via CC before a customer could become unblocked.		Link
	Safety Integrations: New Vault Safety Inbox	EDC		Study Designers	System Tools		Medium	CDMS now has configuration to send data to Vault Safety and direct to one of two possible Inboxes.	Study Designer	Link
	Safety Integrations: Follow-up Processing Changes	EDC		Lead Data Managers, Study Designers, Super Users			Medium	We made the following changes to the follow-up model: Vault uses a job, instead of the integration task on a timer Users can run an ad hoc job for special circumstances (for example, if they change a duration rule) Form Submission Date is no longer used to get Item values. When forms are left open, but with changes, Vault passes the correct, latest values on to the safety system. This feature is automatically enabled. Veeva will contact customers to discuss this change in more detail. Each existing production Study that has the safety integration enabled will be configured to run the job once daily, at 2:00 AM UTC, and run a full scan monthly, on the 15th of the month, unless otherwise specified.		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		Lead Data Managers			Low	The following enhancements have been made to the 23R2 SDE: Sort Item columns in the Clinical Datasets by the order on the form Error logging when a job fails due to user permissions New option to configure which display label is included for clinical data items. We increased the allowed length for Short Label to 40 characters. Export File Type field is now a multi-select field Added Item External ID (ITEMEID) column to SYS_ILB, SYS_Q, SYS_PD, and SYS_LINKS Added Event Group External ID (EGROUPEID) column to clinical datasets, SYS_EVT, SYS_FORM, SYS_ILB, SYS_LINKS, SYS_Q, and SYS_PD Added columns to SYS_LINKS to clarify the Form Created Date (renamed CREATED to FORMCREATEDDT) and Link Created Date (LINKCREATEDDT) Added the Form Status (FORMSTATUS) column to the clinical datasets Added the Last Modified Date (LASTMODDT) and the Subject IXRS ID (IXRSID) columns to SYS_SUB Added the Assessment External ID	Lead Data Manager	Link
	Show Sponsor in the My Vaults Page	EDC		All	System Tools, Vault Admin	My Vaults Page	Low	From System Tools, an administrator can define the Sponsor for a Study, which then shows in the Sponsor column of the My Vaults page. This supports CRO users who have access to multiple sponsor vaults.	All	Link
Clinical Team	SDE: Send Extract to CDB	CDB, EDC	Yes	Lead Data Managers	CDB		Low	Users running SDE Version 23R2 with Workbench enabled can include datasets in CSV format to send to CDB Workbench for review and analysis.	Lead Data Manager	Link
	Deploy from Template Vault	All			Support		Medium	With this feature, CROs can build and test custom roles and other vault-level configuration in one central location and push them out to multiple vaults at a time. Once this feature is enabled by Support, there are migration tasks that Veeva will work with customers to perform.	Deployment Administrator, Super User	Link
Coders	Coder: Display Verbatims and Related Items in ALL CAPS	Coder		Coder Administrators	Coder Tools		Medium	With this release, Verbatims are displayed and grouped in all caps in List View, Group View, and the Properties Panel when the respective study setting is set to "Yes."	Clinical Coder 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	Study Progress Listing Enhancements	EDC		CRAs, Data Managers, Lead Data Managers		Review Rollup V2	Low	We've added various columns to the following listing jobs. These changes will be available when accessing listings from Review, EDC Tools, and Reports. Event Progress Listing changes:New columns to count the number of submitted forms where SDV & DMR are required Subject Progress Listing changes: New columns to count the number of forms where SDV is required and completed New columns to count the number of forms where DMR is required and completed We've also enabled the Study Progress Listings in the Reports tab feature for all Vaults. Users will still need to schedule listing jobs to populate the corresponding listing reports in the Reports tab. Finally, we relabeled the columns in the Study Summary Metrics report to include "Forms".	Clinical Research Associate, Data Manager, Lead Data Manager	Link
Clinical Team	Query Team Selection Enhancements	EDC		CRAs, Data Managers, Lead Data Managers		Multi-role Security	Medium	This release includes the following updates to the options for assigning a query team in multi-role security vaults: If a user has multiple roles on different query teams and creates a query, the query team dropdown list will only contain teams associated with the roles with the query permission. If a role does not have a query permission, the associated team will not display in the query team dropdown list If a user with multiple roles only has one role with a query permission, the query team will default to that role's team	Clinical Research Associate, Data Manager, Lead Data Manager	Link
	CDMS Billing Status Support	All		Lead Data Managers			Low	With this feature, an organization can now track their study's Billing Status. They can set it to indicate On Hold, Locked, or Archived. As part of this feature, we renamed the Manage Study Lock permission to Manage Study Milestones.	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	Event Window Reporting Enhancements	EDC		CRAs, Data Managers, Lead Data Managers			Low	Additional Event Window Statuses have been added with this release, which will be visible in the Event Progress Listing and event reports. When an event does not yet have an event date, its window status will be "Planned". If an event window has not been defined for an event, its window status will be "No Defined Window". In the Event Progress Listing, Days Out of Window will only calculate for events with an event date and an event window definition. Otherwise, this will be blank.	Clinical Research Associate, Data Manager, Lead Data Manager	Link
Clinical Team	All Bookmarks in Detail PDFs are Clickable	EDC		Data Managers, Lead Data Managers			N/A	In the Detail PDF, all bookmarks are hyperlinks.	Data Manager, Lead Data Manager	Link
Clinical Team, Site Users	Small Screen Size Warning	All		Assessment Editor, Assessment Reader, CRAs, Data Managers, Lead Data Managers, Sites, Study Designers			N/A	Vault presents users with a warning dialog in cases where a user's screen resolution is less than the minimum supported setting of 1280 x 720. The dialog displays to impacted users upon entering the Data Entry, Review, Protocol Deviations, and Assessments tabs for the first time in a session. As part of this change, we made small changes to the shades of some colors in the application.	Assessment Editor, Assessment Reader, Clinical Research Associate, Clinical Research Coordinator, Data Manager, Investigator, Lead Data Manager, Study Designer, Sub Investigator	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
	Rules Enhancements	EDC		Librarians, Study Designers			Medium	The following enhancements have been made to rules: Subject status rules now allow users to use repeating Event Groups, Forms, and Item Groups in the Rule Action, so long as a sequence number is specified. Added functions: HasDuplicates(), SiteDateTime(), and SiteDateValue() The Rule Preview job now shows all rules from the job in the rule_details file, to provide clarity for job results where a rule resulted in no changes Relabeled the Query action to Open Query and the Ready to Randomize action to Set as Ready to Randomize Updated the order of the Rule Action list Added the Create Integration Entry rule action has been added to support new Procedures features When changing the Evaluate Rule When property for a rule, the rule editor no longer clears Rule Actions if a valid action has already been set In the SDS, the Date Comparisons tab has been relabeled to Comparison Rules to match Studio New publishing validations: Derivation rules where the result	Librarian, Study Designer	Link
Clinical Team	Job Governor Enhancements	EDC		Lead Data Managers			Medium	The following enhancements have been made to the job governor: Users cannot start any identical extract job covered by the job governor if the job is in the "Queued" or "In Progress" status. The Audit Trail Export jobs now fall under the job governor, and no more than one Audit Trail Export job of the same type can be started at the same time within a study	Lead Data Manager	Link
	Safety Integrations: Handle Adverse Events with no Term Item Value	EDC		Safety Administrators, Study Designers			Low	For follow-up/nullification sends, Vault detects an empty Adverse Event term and notes it with a default reason text. Some external safety systems have issues with the re-import of a case where an event term is empty, despite that being valid in the CDMS system.	Safety Administrator, Study Designer	Link
	Safety Integrations: Nullification Reason Mapping	EDC		Safety Administrators, Study Designers	EDC Tools		Medium	Vault now allows the mapping of a nullification reason as part of a follow-up where the adverse events of the case no longer apply. When not mapped, Vault also inserts a default reason text instead of missing a reason.	Safety Administrator, Study Designer	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
	Safety Integrations: Study Drug Level Blinding	EDC		Safety Administrators, Study Designers	EDC Tools		Low	Blinding is now set at the study drug level, to accommodate studies where some study drugs or treatments are blinded, while others aren't.	Safety Administrator, Study Designer	Link
	Safety Integrations: Enhanced Reporting	EDC		Safety Administrators, Study Designers			N/A	We added additional fields to the safety case and safety message are now in place to make these listings and reviews more informative.	Safety Administrator, Study Designer	Link

Day 1 Impact to Primary Users	Name	Application	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact	Release Notes
	Advanced Joins in CQL	CDB	CDB Users			N/A	CQL now supports the definition of direction and criteria for table joins. CQL allows multiple joins within a single CQL statement.	Data Manager, Lead Data Manager	Link
	Mask Blinded Data	CDB	CDB Users	CDB		High	Users with access to the Configurations page in CDB will have the ability to configure settings for masking blinded data either in the UI, in the Exports, or in both areas for all Vaults in CDB. Masking appears for users without Restricted Data access, and applies to non-EDC data column-level blinding.	Super User, Vault Administrator	Link
	Conditional Unblinding	CDB	CDB Users	CDB	Masking	High	Organizations can define conditions where data can selectively be unblinded in the system.	Data Manager, Lead Data Manager	Link
	OpenEDC: Support for Non-Veeva EDC Studies	CDB, EDC		Support		Medium	OpenEDC allows customers to load data from other EDC systems into CDB, without managing the study in Vault CDMS. With OpenEDC, CDMS is only used to manage user roles and access to the Study in CDB. All other actions on study data occur in CDB.	Data Manager, Lead Data Manager, Study Designer	Link
	Import In Progress Post Submit Data from EDC	CDB	CDB Users			Medium	The Workbench Export job now includes data from Forms in the In Progress Post Submit status.	Data Manager, Lead Data Manager	Link
	CDB Product Naming	CDB				N/A	CDB now uses the application names "CDB Workbench" and "CDB Manifest Builder" throughout. As part of this feature, we also updated the URL for CDB Manifest Builder. The URL from the previous release will redirect to the new URL.		Link
Clinical Team	SDE: Send Extract to CDB	CDB, EDC	Lead Data Managers	CDB		Low	Users running SDE Version 23R2 with Workbench enabled can include datasets in CSV format to send to CDB Workbench for review and analysis.	Lead Data Manager	Link

Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: June 23, 2023

Date	Change	Impact
6/19/2023	Published the initial version of the RIA	N/A
7/15/2023	Updated the Description for "CDMS Billing Status Support", "SDE: Enhancements", and "Rules Enhancements" Updated the Dependencies for "Snapshots: Bulk Lock & Freeze" and "Study Progress Listings Enhancements" Updated the Users with Day 1 Visibility for "Study Progress Listings Enhancements"	The RIA has up to date descriptions and dependency information.
7/17/2023	Added a Release Notes column with links to that feature in the What's New in 23R2	The RIA now has links to release notes.
8/16/2023	Moved the "OpenEDC: Support for Non-Veeva EDC Studies" feature from the CDMS RIA worksheet back into the CDB RIA worksheet. Moved the "Screening Subjects Outside CDMS" feature from the CDB RIA back into the CDMS RIA.	Features are now in the appropriate application worksheet.