



24R2 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 17, 2024

Revision Date: 7/19/2024 2:31 PM PDT

VIA Available: 6/21/2024

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
	Labs: Number of Analytes per Form	EDC (Labs)	Yes		Support	Local Labs	Low	This release provides support for increasing the maximum number of lab analytes per form or lab panel from 25 to 35. This change is applied at the vault level upon request.	Lab Data Manager, Study Designer
	Queries in User Languages	EDC	No - Future Release		Support, Vault Admin		Medium	This feature allows users to see system query messages in the language associated with their user account, instead of the language associated with the Vault.	Vault Administrator
Clinical Team	Integrations: Visit Cycles for Payments	EDC				ClinOps-CDMS Connection	Medium	The definition of Event Groups, Event Labels, and Sequences for events in a repeating event group, along with any updates, will now be transferred to CTMS via the ClinOps - EDC Connection.	
	SAS Upgrade	EDC	Yes				N/A	CDMS upgraded the SAS server to the latest version 9.4 M8, which included an update to account for Mexico City ceasing to observe Daylight Savings time. The SAS server is a common server shared by both EDC and CDB applications, so any SAS extract from the two systems will be generated using this latest version.	N/A
Clinical Team, Site Users	Relabeled Form Status to "In Edit"	EDC	No - Future Release	All			Low	The "In Progress Post Submit" form status has been relabeled to "In Edit". This is reflected in all locations where the form status appears, detailed in the release notes.	All
Clinical Team, Site Users	EDC Navigation & UI Enhancements	EDC		All			Low	Usability enhancements to Data Entry and Review including: - A new, filterable column "Subject Status" appears in the Review Subjects grid. - In My Sites and My Studies, a new info icon appears next to the Ready for SDV and Ready for DMR columns with hover over messaging.	
Clinical Team, Site Users	Query Usability Enhancements	EDC		All			Medium	Query enhancements include: - Users with the Open Query permission can open queries on read only and derived items. - In the Review tab, a manual query can be canceled from a button in the top right of the query. - When closing a query, the background color of the comment area is updated to reflect an optional field. -To match the Data Entry tab UI, updates to buttons and spacing have been made to queries in the Review tab UI. - A character counter has been added to the query message textbox. - In Data Entry, item queries can now be collapsed and expanded. - Selecting Edit Value from a query in Data Entry takes site users directly to the queried item on the form. - Selecting a query from the Data Entry taskbar takes site users directly to the queried item.	

Day 1 Impact to Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
Clinical Team, Coders, Site Users	CDMS Vault Training - Sponsor and Site User Migration	EDC		All (EDC & Coder)	API, EDC Tools, System Tools		High	Training records from Absorb Learning Management System (LMS) have been migrated to Veeva's CDMS Vault Training. The "User Type" field has been added to user account details, and a type has been assigned to all existing users. End users who need to complete training modules will access CDMS Vault Training from the existing My Training link or using the direct URL, cdmstraining.veevavault.com. All site users will use VeevaID to access CDMS Vault Training, while all sponsor users will access it through the cross-domain login. Once a user is added, their email becomes read-only. Customers should include the appropriate "Site" or "Sponsor" User Type when creating users individually in System Tools, as well as in bulk via a CSV file or the Upload Users API. If the new User Type field is left blank, an algorithm will automatically determine it based on the user's email address and the sponsor's domain name. Once a User Type is saved, it becomes read-only. Warnings appear if a User Type does not match the role.	All
Clinical Team, Site Users	EDC & API: Query Source Information	EDC	Yes	API Read Only, API Read Write, CDB Users, CRAs, Data Managers, Lead Data Managers, Sites	API		Low	Query source information can now be posted to CDMS from other systems via the API. The source information is reflected in the following locations: Data Entry UI Review UI Query Detail Listings Study Data Extracts	Clinical Research Associate, Clinical Research Coordinator, Data Manager, Investigator, Lead Data Manager, Sub Investigator
Clinical Team	Studio Study Grade	EDC		API Read Write, Librarians, Study Designers, Super Users			Medium	Study Grade generates and logs a quantitative scoring to help study designers evaluate build performance, best practices and impact to data extracts within a new 'Study Grade' tab. Study Grade generates automatically on deployments from DEV to TST. A qualitative narrative is provided by Veeva Services to accompany the system evaluation. Standard CDMS roles with access to the Study Grade tab are CDMS Super User, CDMS API Read Write, CDMS Auditor Read Only, CDMS Librarian, CDMS Study Designer, and CDMS Study Designer Read Only. Note that this feature is specifically not designed to measure or evaluate a person's performance and may not be used as such.	API Read Write, Auditor Read Only, Librarian, Study Designer, Super User
Clinical Team, Site Users	PDF Enhancements - Include Organization and Site Number	EDC		Assessment Editor, Assessment Reader, CRAs, Data Managers, Lead Data Managers, Librarians, Sites, Study Designers, Super Users			Low	We've made the following updates to the generation of PDFs: - Casebook Detail, Closeout, and Assessment PDFs now include the Organization (Sponsor). The Organization in the PDF must be enabled by Support, if it's not already enabled in the Vault. - The folder name for Detail PDFs now includes the site number.	
	Listing Usability Enhancements	CDB, EDC Clinical Reporting		CDB Users, Data Managers, Lead Data Managers			Medium	In CDB Workbench and Clinical Reporting: Listing pages will now display up to 100 rows in a single page. There is an Expand / Collapse option to hide the listing header and details to provide more screen space for the listing data. The Query Panel is responsive to changes in browser size. If new data is available from incremental data imports, a message will display allowing the user to refresh the listing with the new data. There is a new Reset filter and sort option to return a listing to its original definition.	Data Manager, Lead Data Manager

Day 1 Impact to Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
Coders	Unique Terms Report Updates	EDC		Coder Administrators			Medium	This release makes the following enhancements to the Unique Terms Report job: - Users can select a specific date range for unique terms. Any terms that were newly coded during the selected date range will be starred in the report. - Users can now specify the coding form type when generating a Unique Terms Report. - Users can now download the Unique Terms Report in PDF as well as the current Excel file format. - The selected job options are summarized in the <u>Summary Page of the report</u> .	Clinical Coder Administrator
	Ability to Batch Assign Lists	Coder		Coder Administrators			Medium	Through the new Batch Assign Lists tab in Coder Tools, users can assign either a Synonym List or a Do Not Autocode List to multiple forms, including across different studies, at the same time.	Clinical Coder Administrator
	Coder General Enhancements	Coder		Coder Administrators			Medium	This release makes the following enhancements to Coder: - Updates to Synonym List import validation error messages - The Duplicate Synonym Warning is turned into an error that will block import. - A third option is added for Batch Upversioning Synonym List + Form allowing forms not being upversioned to be left with no assigned Synonym List. - Additional UI/Dialog enhancements	Clinical Coder Administrator
Clinical Team	Study Progress Listing Enhancements	EDC	No - Future Release	CRAs, Data Managers, Lead Data Managers			Low	We've made the following enhancements to listing jobs: In the Subject Progress Listing, the column labels for Most Recent Visit and Date of Most Recent Visit are now capitalized for consistency with other columns SDV and DMR columns in the Form Progress Listing and Event Progress Listing have been relabeled to be consistent with other listings SDV and DMR columns in the Form, Event, and Subject Progress Listings have been reordered to the following to be consistent with other listings: Required, Complete, Complete Date. The form metrics in the Subject Progress Listing have been ordered as a group, and not with the summary columns. In the Form Progress Listing, the logic for the Late column has been updated to mark forms with the statuses Blank, In Progress, and In Edit as "Late" if they are past their overdue dates to be consistent with EDC The Original Query Text column in the Query Detail Listing and the QTEXT column in the Query Detail Versioned Extract will display in the site user's language if the "Show Queries in the User Language" feature is enabled	Clinical Research Associate, Data Manager, Lead Data Manager
Clinical Team	Protocol Deviation Change Reason	EDC		CRAs, Data Managers, Lead Data Managers		Protocol Deviations	Medium	After the initial save of a Protocol Deviation record, subsequent updates will require the user to provide a Reason for Change. The most recent Change Reason for a PD record displays in the System Fields at the bottom of the record and is added to the SYS_PD dataset of the SDE. To support this feature, two new default Change Reasons of type Protocol Deviation have been added in System Tools, and enabled users can add additional change reasons.	Clinical Research Associate, Data Manager, Lead Data Manager

Day 1 Impact to Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
Clinical Team	Query Team Enhancements	EDC		CRAs, Data Managers, Lead Data Managers		Query Teams	Medium	Enhancements to Query Teams include: - "Query Team" is added as a filterable column to the Queries grid. - Users with multiple roles which are part of more than one query team can select the query team when answering or closing a query. - Reopening a query is reserved for users within the query's selected Query Team. - The Query Team tag is moved to the query message header.	
	Form Performance Enhancements	EDC		CRAs, Data Managers, Lead Data Managers, Sites			N/A	In 23R3, Veeva released some performance enhancements related to form-level activities. These enhancements were gradually rolled out across CDMS Vaults. With the 24R2 release, this feature is enabled automatically in all Vaults.	
Clinical Team	PDF Memory Optimization Enabled for All Vaults	EDC		Data Managers, Lead Data Managers			N/A	In 24R1, Veeva improved the job performance for generating large Closeout and Detail PDF through memory optimization. Initially, this update required enablement by Veeva Support at the vault level. In 24R2, this feature will be applied to all vaults.	
	Frozen Form Support for Amendments Enabled on All Vaults	EDC		Deployment Administrators, Lead Data Managers		Data Model 2	Medium	In 23R3, Veeva released Frozen Form Support for Amendments to streamline the Retrospective Amendment process. This feature was initially enabled upon request to Veeva Support. With the 24R2 release, this feature is enabled automatically in all vaults.	Deployment Administrator, Lead Data Manager
	Delete Empty Production Environments	EDC	No - Future Release	Deployment Administrators, Super Users, User Administrators	Support		High	With this release, an empty Production instance can be removed using the "Delete Environment" action in EDC Tools > My Studies. This is only possible for empty Production instances that have no data.	Deployment Administrator, Super User, User Administrator
	Ability to Rename Studies	EDC	No - Future Release	Deployment Administrators, Super Users, User Administrators	Support		Medium	With this release, users can rename a study from the My Studies page in EDC Tools. Users must have the Manage Deployments permission and access to all environments and sites in order to utilize this feature. The previously existing "Rename" dropdown option in My Studies has been updated to "Rename Environment." Users can select the Edit icon next to a study to rename it. A Study Rename job will run automatically when a study is renamed, the results of which can be viewed in Deployment History. For non-ELA customers, full study renames must be coordinated with their Veeva contact so that Licensing can be updated concurrently.	Deployment Administrator, Super User, User Administrator
	Study Data Extract Enhancements	EDC		Lead Data Managers			Low	This release includes the following enhancements made to the Study Data Extracts job: - A new file in the definitions folder called study_definitions.csv that includes the metadata for a Study - The QTEXT column in the SYS_Q and SYS_QT datasets will display system queries in the user's language if the "Show Queries in the User Language" feature is enabled - The "In Progress Post Submit" form status label has been changed to "In Edit" for SDE Version 24R2. Previous versions will still use "In Progress Post Submit"	Lead Data Manager
	Extract Job Governor Enhancements	EDC		Lead Data Managers			Medium	With this release, we've added Audit Trail Export Jobs to the total scheduled job count for the Vault.	Lead Data Manager

Day 1 Impact to Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
	External Connection Enhancements	All		Lead Data Managers			Medium	Users can send a test data file to validate testing of External Connections that are utilized in jobs/extracts. This new option sends the data file while testing the connection, and will alert the user whether the test was successful or not. The test data file will attempt to be removed from the user's FTPS server after it has been sent. If the destination path doesn't already exist when the test file is sent, the system will create a folder. This only applies to the "Veeva Vault" and "External FTPS" connection types.	
	Safety Integration Enhancements & Additional E2B Standard Fields	EDC		Librarians, Safety Administrators, Study Designers			Medium	For both Safety Integrations, the Datetime Value Behavior for datetime field transfer can now be configured (sent in site time or UTC). The E2B Link has been enhanced to allow the configuration of additional Safety Settings, including the Study Name and Sponsor Study Number Value, as well as the Action Taken with the Study Drug and the Acknowledgement File late behavior for the Integration Setup. New E2B fields can be mapped and added to the safety case transfer, including C.5.3, C.5.2, E.i.1.2, D.3, D.4, D.6, H.4, D.7.1.r.1a, D.7.1.r.1b, G.k.9.i.4, G.k.9.i.2.r.3, G.k.8.	Librarian, Safety Administrator, Study Designer
	Vault Safety - EDC Connection Transfers Local Lab Test Results	EDC		Librarians, Safety Administrators, Study Designers	Studio		Medium	Local lab test results can be transferred via the Vault Safety-EDC connection in a configurable time frame of given days before and after the SAE start date	Librarian, Safety Administrator, Study Designer
	Vault Safety - EDC Connection Configurations in the SDS	EDC		Librarians, Study Designers			Low	To support the study build and review, the Safety Integration configurations of the Vault Safety - EDC Connection are now traceable in the Study Design Specifications (SDS).	Librarian, Study Designer
Clinical Team	Ability to Run Casebook Design Export (CDE) from Studio	EDC		Librarians, Study Designers	Studio		Low	The Casebook Design Export (CDE) is a JSON representation of the study's design at a specific casebook version. With this feature, the CDE can be retrieved from the Studio UI.	Librarian, Study Designer
	Copy Form Designs with Safety Integration Configuration	EDC		Librarians, Study Designers			Medium	Copying a Form from another Study or Library now includes the Safety Integration configurations.	Librarian, Study Designer
	Relabeled Floating Rule Action Identifiers	EDC		Librarians, Study Designers, Super Users		Rules Engine V2	N/A	The 'floating' parts of the Action Identifiers within User Defined Rules have been relabeled to say "this" and "all" as appropriate per the selected Action and Dynamic Action Scope of the rule.	Librarian, Study Designer
	Vault Safety - EDC Connection Supports Subject Deletion	EDC		Safety Administrators			Medium	The deletion of a subject is supported as a nullification via the Vault Safety - EDC Connection.	Safety Administrator

Day 1 Impact to Primary Users	Name	Application	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
Clinical Team, Site Users	VeevaID for CDMS Vault Training	EDC		Sites, User Administrators	System Tools		High	<p>Site users with a Veeva ID account will access Vault CDMS Training using their VeevaID login or will be prompted to create a Veeva ID account as they access training.</p> <p>For existing CDMS vaults, user administrators will still add site users in the UI or through the import using the site user's EDC account. Veeva will coordinate with customers to schedule and migrate existing CDMS site users to VeevaID. Migrations will occur over a scheduled weekend, with approximately eight weeks' notice. Sponsors with a very large number of users will coordinate migrations directly with the Veeva product team. For new customer vaults, user administrators can add site users with their Veeva ID and receive prompts to invite new site users to VeevaID when the user's email does not have a corresponding VeevaID account.</p> <p>Once the VeevaID user is added, the corresponding fields become read-only and are managed by the user in their VeevaID. These fields include: First Name, Last Name, Username, Email, Security Policy, User Type, Language, Locale, and Timezone.</p> <p>Full native VeevaID support for all site users will initially be enabled only for customers onboarded after 24R2. Existing customers will coordinate with CDMS product teams to schedule a bulk migration of their site users to VeevaID. After the migration, their vaults will be enabled for full VeevaID support and integration.</p> <p>This feature will not be available for testing in pre-release.</p>	Clinical Research Coordinator, Investigator, Sub Investigator, User Administrator
	Ability to Update Analyte Length/Precision Value on the SDS	EDC, EDC (Labs)		Study Designers			Medium	If a study is on global labs, the precision/length values should be pulled from the analyte definition in the analyte library for any item definition that has an associated analyte definition and a Number or Unit data type.	
	Standard Reports for Items on Data Model V2	EDC		Vault Owners	Vault Admin	Data Model 2	Low	<p>We are introducing two new standard reports with item-level information:</p> <p>Items Intentionally Left Blank (V3): This report provides a listing of items marked intentionally left blank, filtered by study and grouped by site and subject for studies on Data Model V2.</p> <p>Item Reason for Change Report (V3): This report provides a count of items per site per change reason entered by the site for studies on Data Model V2. It excludes system-managed changed reasons.</p>	Clinical Research Associate, Data Manager, Lead Data Manager, Vault Administrator
	Vault Safety - EDC Connection Supports Vault Safety Custom Fields	EDC		Vault Owners	Studio, Vault Admin		Medium	The Vault Safety - EDC Connection supports both Vault Safety standard and custom fields for item configurations and safety data transfer to Vault Safety.	Librarian, Safety Administrator, Study Designer, Vault Administrator

Day 1 Impact to Primary Users	Name	Application	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
	CDB Incremental Import	CDB		Support		Medium	Data from Vault EDC will no longer be ingested from a job in EDC Tools. Incremental data exports every 15 minutes will update all CDB studies. A full extract of data will occur once per day, and used if there are study design changes. We redesigned the EDC Import page to show data imports by source, with the ability to drill down to see previous imports from that source and delete the source for users with the Delete Data Sources permission.	CDB Administrator, Data Manager, Lead Data Manager
	Reprocess Third Party Data	CDB	CDB Users		CDB Incremental Import	Medium	For studies using Incremental EDC loads, third party sources will automatically be reprocessed once per day, and not on EDC ingestion. A job will run every hour to reprocess data that has not been reprocessed in the past 24 hours.	Data Manager, Lead Data Manager
Clinical Team	Clean Patient Tracker Enhancements	CDB	CDB Users, Data Managers, Lead Data Managers		CDB Incremental Import (with the exception of showing incomplete reviews by Subject).	Medium	The Clean Patient Tracker now includes counts by Subject of Incomplete Reviews, Overdue Forms, and In-Progress Log Forms. Incomplete Reviews are counted in the definition of a Clean Subject. Users can download Subject, Event, and Form Progress Reports from the Clean Patient Tracker.	Data Manager, Lead Data Manager
	Listing Usability Enhancements	CDB, EDC Clinical Reporting	CDB Users, Data Managers, Lead Data Managers			Medium	In CDB Workbench and Clinical Reporting: Listing pages will now display up to 100 rows in a single page. There is an Expand / Collapse option to hide the listing header and details to provide more screen space for the listing data. The Query Panel is responsive to changes in browser size. If new data is available from incremental data imports, a message will display allowing the user to refresh the listing with the new data. There is a new Reset filter and sort option to return a listing to its original definition.	Data Manager, Lead Data Manager
	Ability to Download Log Files from the Dashboard	CDB	CDB Users, Data Managers, Lead Data Managers			Medium	The Object Summary and Deletion Logs are now accessible from the Dashboard.	Data Manager, Lead Data Manager
	CDB API: Query Source Information	CDB, EDC Clinical Reporting	Data Managers, Lead Data Managers	CDB		Low	CDB Workbench will now ingest EDC Query Source Information for Queries and Query Messages. The following fields will be populated with the source information: Origination System Origination ID The fields can be set by EDC, CDB, or an external system. Fields are also visible in CDB through the Queries application.	

	Incremental Ingestion Study Activation	CDB	Lead Data Managers, Study Designers	EDC Tools	CDB Incremental Import	Medium	To ensure performant ingestion, not all studies on a vault will be enabled for incremental import. In EDC Tools, users with the Edit Study Settings permission will be able to set up to two (2) test study environments, one training, one validation, and one production environment for incremental ingestion.	Lead Data Manager, Study Designer
	New Set Review Permission	CDB	User Administrators			Medium	The new Set Review permission defines which roles can update the status of a review listing row. The permission is available to custom roles, and is assigned to the standard CDMS Lead Data Manager, CDMS Data Manager, and CDMS Super User roles automatically.	User Administrator

Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: June 17, 2024.

Date	Change	Impact
6/17/2024	Published the initial version of the RIA.	N/A
6/17/2024	Added the Form Performance Enhancements feature.	The RIA now has up to date features.
6/19/2024	Updated multiple feature descriptions, added the Delete Empty Production Environments feature, and updated the CDB support column for the Ability to Rename Studies feature.	The RIA now has up to date features and feature descriptions.
6/20/2024	Updated the wording for several feature descriptions.	The RIA now has up to date feature descriptions.
6/21/2024	Added "CDB Administrator" to the Training Impact for CDB Incremental Impact. Updated the Description for CDB Incremental Impact to include the ability to delete data sources. Updated the descriptions for SDE Enhancements and Queries in User Languages.	The RIA now has up to date feature information.
6/24/2024	Updated several feature descriptions for clarity.	The RIA now has up to date feature descriptions.
6/26/2024	Updated wording for several feature descriptions to increase clarity.	The RIA now has up to date feature descriptions.
7/1/2024	Added the SAS Upgrade feature, updated wording of several feature descriptions, updated the configuration for the Ability to Rename Studies and Delete Empty Production Environments features	The RIA now has up to date features and feature information.
7/3/2024	Updated several feature descriptions.	The RIA now has up to date feature descriptions.
7/11/2024	Updated the feature description for the EDC Navigation & UI Enhancements feature and added an additional sentence to the Studio Study Grade feature description.	The RIA now has up to date feature descriptions.
7/15/2024	Added the "Incremental Ingestion Study Activation" feature for CDB Updated the description of "Safety Integration Enhancements & Additional E2B Standard Fields" to include the updates to acknowledgement file handling.	The RIA has an up to date list of features.
7/19/2024	Updated the description for the Study Progress Listing Enhancements feature.	The RIA now has up to date feature descriptions.