



24R1 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: March 1, 2024

Revision Date: 4/23/2024 4:20 PM PDT

VIA Available: 3/25/2024

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.
<i>High</i>	May affect security, patient confidentiality, application areas that support GXP functions (audit trails, eSignature, etc.) or other ERES controls data
<i>Medium</i>	May affect core application functions (workflows, revision history, etc.)
<i>Low</i>	May affect metadata/notifications
<i>N/A</i>	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.
<i>Day 1 Impact to Primary Users</i>	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.
<i>Users with Day 1 Visibility</i>	This feature is visible to these users on day 1 if no configuration occurs.
<i>Configuration</i>	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.
<i>Dependencies</i>	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
	Sponsor Data Loader	EDC			Studio, Support	Data Model V2	High	With Sponsor Data Loader, users now have the ability to import data from a CSV file into forms in EDC. In Studio, study designers can create a Data Loader Configuration, which maps columns from the CSV file to Items on the destination Form. This feature adds the Data Loader tab, where data loaders can select a Study, Data Loader Configuration, and CSV file to load data into their Study.	Data Loader, Data Manager, Lead Data Manager, Study Designer	Link
Clinical Team	Visit Method	EDC	Yes	CRAs, Data Managers, Librarians, Sites, Study Designers	Studio	Data Model V2	High	<p>Visit Method is a new field in Data Entry and Review that is used to collect the type, or location, of a subject's visit. New columns have been added to the Event Progress, Subject Progress, and Query Detail listings to support this feature.</p> <p>This feature can be configured in Studio when an Event is added to an Event Group in the Schedule.</p> <p>The following minor UI updates will be visible on Day 1 as part of this feature:</p> <ul style="list-style-type: none"> - In Data Entry, Event queries are now collapsible and the Enter/Edit Event dialogs have minor cosmetic updates - In the Review tab, the Event section includes an "Event Details" header with the Event query action icon 	Assessment Reader, Clinical Research Associate, Clinical Research Coordinator, Data Manager, Lead Data Manager, Librarian, Study Designer, Super User	Link
	Refactor Progress Listing Record Updates	EDC		Vault Owners			Low	<p>To improve the performance of the Progress Listings in the Reports tab, new versions of the Progress Listing standard report templates have been created to support a new Last Run object. This new object will populate with the date and time when the progress listing data was last updated in Reports.</p> <p>The old Last Run column in the V1 versions of the reports has been deprecated and will no longer populate. Vault Owners will need to share the V2 report templates with users if they wish to use the new Last Run column.</p>	Data Manager, Lead Data Manager, Vault Administrator	Link
	Export Site Grid	EDC		Lead Data Managers, Librarians, Study Designers, Super Users, User Administrators			Low	Users with the View Study Sites permission can export the Site information from EDC Tools as an Excel™ or CSV file. Users with the Edit Study Sites permission can then import it directly into another vault, study, or environment.	Lead Data Manager, Librarian, Study Designer, Super User, User Administrator	Link
Clinical Team	Labs: Archive Lab Units, Codelists, & Analytes	EDC (Labs)		Lab Data Managers, Study Designers			Medium	Users can now archive Lab Units, Codelists, and Analytes, replacing the option to delete them.	Lab Data Manager, Study Designer	Link
	Study Progress Versioned Extracts	EDC			Support		High	This release includes the following new configurable jobs: Form Progress Versioned Extract, Event Progress Versioned Extract, Subject Progress Versioned Extract, and Query Detail Versioned Extract. These jobs allow users to export a specific version of a Study Listing in an extractable format that can be sent to an external connection. This feature is not enabled by default.	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	Study Data Extract Enhancements	EDC		Lead Data Managers			Low	<p>New features in 24R1 version of the SDE include:</p> <ul style="list-style-type: none"> - Users who extract Custom Objects in the SDE will see two columns for every custom object field they have configured for their custom object: one column for the name of that field, and a secondary column for the ID of that field. - New columns in SYS_EVT for Planned Date, Event Frozen, Event Freeze Date, Event Locked, Event Locked Date, Event Signed, and Event Signed Date - New columns in SYS_FORM for Frozen, Locked, Signed, SDV Override Plan, DMR Override Plan, SDV Complete, and DMR Complete - New columns in SYS_SUB for SDV Plan, DMR Plan, Frozen, Locked, and Signed <p>The "Dataset Name" and "Column" columns in item_definitions.csv file now match the Study definitions file's respective columns, and the ordering of items matches their order in the form.</p> <ul style="list-style-type: none"> - We've fixed the following issue: previously, the returned value of the IGSEQ & FSEQ columns in the SYS_ILB dataset were returning a decimal value when they should be returning an integer. This fix impacts all SDE versions. - The datetime format for custom object files no longer includes seconds and milliseconds. This format is consistent with all other System datetimes in other SDE datasets. 	Lead Data Manager	Link
Clinical Team, Site Users	Suppress Extraneous Definition, Relationship & Façade Changes in Audit	EDC		CRAs, Data Managers, Lead Data Managers, Sites, Super Users			High	<p>The audit trail that is visible to users in EDC is derived from a more robust audit trail that previously displayed irrelevant portions of the audit to end users. The scope of the audit trail that is displayed to end users has been reduced to focus primarily on changes to data and relevant CDMS records. It will no longer show changes to definitions, relationships, or facades, particularly when a retro amendment occurs. The Casebook audit trail will still show when a casebook version changes.</p>		Link
Site Users	EDC: General Enhancements	EDC		All			N/A	<p>General UI updates to EDC, including:</p> <ul style="list-style-type: none"> - Improved spacing between Submit and Form Action Menu - Removed linking on the Auto-Save errors - Improved experience for non-editable items, hovering, and tabbing in the Editable, Read-Only, and Lab grids - Learn More link when unable to reset a form, due to item-to-form linking - For studies using Cross Form derivation version, the informational icon that shows derivation submit value and rule info will display even when the item type is also Read-only (in both Data Entry and Review). - In the subject list UI in the Data Entry and Review tabs, the logic for Last Event has been updated to match the Subject Progress Listing and will show the event with the most recent event date. 		Link
Coders	Coder: Propagate Code Final State	Coder		Coder Administrators	Coder Tools		Medium	<p>This release adds the "Final State for Propagate Code" study setting to Coder Tools > Study Settings, which gives the Coder Administrator the option to choose the final Coding Status of Code Requests impacted by the Propagate Code feature. The options are "Coded" and "Autocoded". For existing studies, the default for this study setting remains "Autocoded", and for new studies the default is "Coded". If "Coded" is selected, then the final Coding Status of the impacted Code Requests will be Coded. Additionally, when this setting is set to "Coded", if the "Enable Approval Workflow" study setting is set to "Yes", then the final Coding Status will be Pending Approval. When this study setting is set to "Autocoded", then the final Coding Status of the impacted Code Requests will be Autocoded.</p>	Clinical Coder, Clinical Coder Administrator, 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
Coders	Coder: Remapping in Upversioning	Coder		Coder Administrators			High	<p>With this release, Verbatims and Synonyms are now automatically remapped and autocoded during upversioning. The remapping process differs depending on the dictionary type and on whether the Code with ATCs study setting is enabled.</p> <p>When you upversion a Form or Synonym List, the system evaluates the full assigned code of every Code Request (for Forms) or Synonym (for Synonym Lists) to determine if it exists in the new dictionary release. If the full assigned code does not exist in the new dictionary release, then the system will attempt to remap the code starting with the lowest level of the assigned code. If it can remap the code, then the code is updated and the Coding Status remains Coded or Autocoded. If the system cannot remap the code, then the code is cleared and the Coding Status is set to Noncurrent.</p>	Clinical Coder, Clinical Coder Administrator, Clinical Coder Manager	Link
	General Processing Updates	EDC		Librarians, Study Designers	Vault Admin		High	<p>We made several general processing updates to avoid errors and ensure successful processing when removing or copying design configurations and where record keys are unable to be reconciled from within studies or across products.</p> <ul style="list-style-type: none"> - Async errors and CDB job failures will no longer occur in cases where a form is deleted in Studio and that form had been linked to another form - Deleting Forms, ItemGroups, or Items will no longer cause errors when copying review plans that had previously included them - Vault hides Studies which have no active instances from Studio > Libraries and Studio > Studies. An "empty" study can occur due to a study copy failure. This feature allows a study to be removed or the study design to be re-started using the same study name, as long as the prior environment instances are removed, and no Prod instance was created. 	Librarian, Study Designer	Link
	Include Sponsor Organization in PDFs	EDC			Support		Medium	When generating the Blank and Annotated PDFs from Studio the Sponsor (Organization) can now be included in the cover page. This setting applies to the Blank and Annotated PDFs in Studio.	Librarian, Study Designer	Link
	Admin General Enhancements	EDC		Lead Data Managers, Vault Owners			Medium	<p>When implementing a new Retrospective Amendment, Vault will no longer default the "Status for Changed Forms" setting. As such, users will need to explicitly select "Set to In Progress" or "Leave as Submitted."</p> <p>The "External Connections" tab in System Tools was renamed to "Connections".</p>	Lead Data Manager, Vault Administrator	Link
	Rule Editor Enhancements	EDC		Librarians, Study Designers, Super Users	Studio	Rules v2	Medium	This feature includes general UI changes made to the rule editor, including button relabels.	Librarian, Study Designer, Super User	Link
	PDF Memory Optimization	EDC			Support		N/A	The Closeout and Detail PDFs with audit trail will now complete successfully with individual casebooks that have over 20k data points.		Link
Coders	Auto Close Queries when Coded or Autocoded	Coder		Coder Administrators	Coder Tools		Medium	This release adds the "Autoclose Query when Coded or Autocoded" study setting, which allows the Coder Administrator to choose whether to have coding queries autoclose when the Coding Status of the queried Code Request is changed to Coded or Autocoded.	Clinical Coder, Clinical Coder Administrator, 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
Coders	Coder Minor Enhancements	Coder		Coder Administrators, Coders			Medium	This release adds validations to Coder Tools and Jobs that validate each assigned code in a Synonym List before importing it. If an assigned code does not exist in the target dictionary, then an error is displayed on the import log and the Synonym is not imported. This release also makes the following changes: When the Code with ATCs study setting is set to Yes, only Synonym Lists that are configured to include coding with ATCs can be assigned to forms. When the Code with ATCs study setting is set to No, only Synonym Lists that are configured to not include coding with ATCs can be assigned to forms.	Clinical Coder Administrator, Clinical Coder Manager	Link
	Show Safety Configuration in the SDS	EDC		Study Designers			Low	The Studio Study Design Specification now includes safety configuration details. If a study isn't using the safety integration, those tabs won't show in the SDS. In the current release, the SDS doesn't include those tabs for Vault Safety-EDC Connection studies.	Study Designer	Link
Clinical Team	EDC Clinical Reporting	EDC	Yes	Data Managers, Lead Data Managers		Clinical Reporting tab permission and basic CDB permissions will need to be added to custom data management roles.	Medium	The new EDC Clinical Reporting application allows for reporting on clinical data from Vault EDC, with the ability to view core data listings, create custom listings, and extract data. This functionality is a subset of functionality already available to CDB Workbench users. EDC Clinical Reporting is not available for testing in pre-release. It will be available with the 24R1 general release.	Data Manager, Lead Data Manager, Super User	Link
Clinical Team	DDE Retirement	EDC		Lead Data Managers			Low	The Data and Definition Export (DDE) job is now deprecated and any existing scheduled jobs will be removed. The associated DDE permission and role will be deprecated in an upcoming release.	Lead Data Manager	Link
	Safety: EDC Connection	EDC	No - Future Release		Support		High	EDC studies can now transfer safety case data to Vault Safety over a Vault Connection.	Clinical Research Associate, Clinical Research Coordinator, Data Manager, Investigator, Lead Data Manager, Safety Administrator, Study Designer, Sub Investigator, Super User	Link
	Detail PDF Job Supports Site Deletion	EDC		Data Managers, Lead Data Managers			Medium	Scheduled Detail PDF jobs will be updated to remove a site if that site is deleted. If all sites referenced in the scheduled job are deleted, then the Detail PDF will run on all remaining sites in the study.		Link
	Support for All Timezones, Study Countries and Site Addresses	EDC		API Read Only, API Read Write, Lead Data Managers, Librarians, Study Designers, Super Users, User Administrators			Low	Study Sites now provide fields to save Site Address, Site City, Site Postal Code, and Site State/Province. The list of available time zones and countries has been updated to align with the IANA, and ISO standards, respectively.	API Read Write, Lead Data Manager, Librarian, Study Designer, Super User, User 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
	Roles, Permissions and Security Enhancements	All	Yes	API Read Only, API Read Write, Data Managers, Lead Data Managers, Librarians, Randomization Managers, Safety Administrators, Study Designers, Super Users			Medium	<p>With this release, we provide a new role, CDB Administrator, which has access to the respective Workbench or Clinical Reporting tabs, as well as privileges to View Admin, Migrate Reviews, and Delete Data Sources. Migrate Reviews and Delete Data Sources permissions are features for future releases and don't provide additional capabilities in 24R1.</p> <p>In addition, we have introduced the 'View Safety Cases' permission which provides the ability to see safety case banners. This new View Safety Cases permission has been granted to the following roles: CDMS Auditor Read Only, CDMS API Read Write, CDMS API Read Only, CDMS Clinical Research Associate, CDMS Clinical Research Coordinator, CDMS Data Manager, CDMS Lead Data Manager, CDMS Librarian, CDMS Randomization Manager, CDMS Safety Administrator, CDMS Principal Investigator, CDMS Study Designer, CDMS Study Designer Read Only, CDMS Sub Investigator, and CDMS Super User.</p> <p>We also added the CDMS Data Loader role, which is available to customers using the Sponsor Data Loader feature. In support of that feature, we added the following permissions: Data Loader Tab (granted to the CDMS Super User, CDMS User Administrator, CDMS Data Loader, CDMS Data Manager, and CDMS Lead Data Manager study roles), Load Data (granted to the CDMS Super User and CDMS Data Loader), and View Import History (CDMS Super User, CDMS Data Loader, CDMS Data Manager, and CDMS Lead Data Manager).</p>	API Read Only, API Read Write, Auditor Read Only, Clinical Research Associate, Clinical Research Coordinator, Data Loader, Data Manager, Investigator, Lead Data Manager, Librarian, Randomization Manager, Safety Administrator, Study Designer, Sub Investigator, Super User	Link
Clinical Team, Site Users	Study Progress Listing Enhancements	EDC		CRAs, Data Managers, Sites			Low	<p>This release includes the following enhancements made to Study Progress Listing jobs:</p> <ul style="list-style-type: none"> - Subject Progress Listing - the logic in the Most Recent Visit column has been updated to display the event with the most recent event date. Previously, this column displayed the latest event in the schedule with an event date. - Event Progress Listing - the Event Date SDV column has been relabeled to "Event Date SDV Complete." - In Review, the Job Type list is now ordered alphabetically - In Job History, the information icon will now be available for Progress Listings generated from EDC Tools, which will detail the options included in the job 		Link
Clinical Team	Rules Job Enhancements	EDC		Lead Data Managers, Librarians			N/A	The Rule job output file will show "Created" and "Deleted" actions for dynamic repeating forms	N/A	Link
	Safety Message Status Enhancements	EDC		Safety Administrators			N/A	We added new Safety Messages to reflect failed E2B XML generation, transmission profile issues, or failed file send.	Safety Administrator	Link
	Labels in Studio Added to Definition Records	EDC	No - Future Release	Vault Owners			Medium	In Business Admin, Studio created labels are now stored along with their study definition names.	Vault Administrator	Link
Clinical Team	Study Priority and Job Governor Enhancements	EDC		Lead Data Managers			Medium	<p>This feature includes the following updates to Study Priority and Job Governance:</p> <p>Study priority icons have been updated for consistency</p> <p>The priority expiration has been updated to a predefined picklist of values: 7 days, 30 days, 90 days, or Until Study Lock</p> <p>Job governance has been updated to properly account for different users' timezones when scheduling jobs</p>	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
	Review Listing Enhancements	CDB	Yes	Data Managers, Lead Data Managers			Medium	Performance improvements ensure long running listings will be flagged and possibly disabled to allow for a more performant listing to be created. This ensures no listings are using workbench resources and timing out. With this release, Data Filters from Review Listings (filters on metadata in the first column) have been removed to improve performance.	Data Manager, Lead Data Manager	Link
	CDB Ingestion Improvements	CDB	Yes	Data Managers, Lead Data Managers			Medium	CDB data ingestion now allows blank spaces to exist in the import filename, as well as in the manifest defining the file. Upon ingestion, CDB will replace blank spaces with underscore. Import logs will only capture up to 10,000 warnings and errors and will stop recording when this threshold is met.	Data Manager, Lead Data Manager	Link
	Data Review Enhancements	CDB	Yes	Data Managers, Lead Data Managers			Medium	CDB users can now use comparison filters and search for form items in the Listing Builder. Users can now download a Listing Definition and copy a single Listing to another Study.	Data Manager, Lead Data Manager	Link
	CDB Support for Visit Method	CDB	Yes	Data Managers, Lead Data Managers			Medium	CDB now supports the Visit Method feature from EDC. Custom listings can reference visit method by adding the new header attribute to the CQL SELECT statement: @HDR.Event.VisitMethod. The Clean Patient Tracker now includes visit method in calculations for the Incomplete SDV and Clean columns.	Data Manager, Lead Data Manager	Link

Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: March 1, 2024.

Date	Change	Impact
2/26/2024	Published the initial version of the RIA	N/A
3/1/2024	Updated the GxP Risk for "CDB Support for Visit Method" from "N/A" to "Medium" and updated the Description to cover changes to the Clean Patient Tracker. Updated the Description for "Data Review Enhancements" to clarify that this feature isn't an enablement change. Added additional information to the "Visit Method" feature description regarding listings columns. Added the "Study Priority and Job Governor Enhancements" feature. These changes were previous part of the "SDE Enhancements" feature.	The RIA now includes an up to date list of features with up to date GxP risk and feature descriptions.
3/8/2024	Updated the name of "Show Safety Configuration in the SDS & Annotated PDF" to "Show Safety Configuration in the SDS" and updated its description to exclude the Annotated PDF. Updated the name of "Safety: EDC Connection (VSEC)" to "Safety: EDC Connection"	The RIA now has up to date feature descriptions and names.
3/18/2024	Added a bullet point to the EDC General Enhancements feature that addresses the Last Event column UI in Data Entry.	The RIA now has up to date feature descriptions.
4/5/2024	Updated feature description for SDE Enhancements to clarify the ordering of items.	The RIA now has up to date feature records.
4/9/2024	Added information about Data Filters to the Review Listing Enhancements feature. Edited feature description for the CDB Ingestion Improvements feature.	The RIA now has up to date feature descriptions.
4/12/2024	Added a Release Notes column and fixed the order of the Change Log	The RIA now has links to the release notes.
4/15/2024	Corrected the Change Log from the previous version to begin with change tracking on March 1	The RIA Change Log now shows changes from the tracking period.
4/17/2024	Updated feature description to correct the roles listed for the Roles, Permissions, and Security Enhancements feature.	The RIA now has up to date feature descriptions.
4/23/2024	Added datetime specification updates regarding custom objects in the Study Data Extracts Enhancements feature.	The RIA now has up to date feature descriptions.

