



22R3 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: 10/14/2022

Revision Date: 2/8/2023

VIA Available: 11/7/2022

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
Site Users	Default Settings for Data Entry	EDC		Sites			Low	The schedule tree in Data Entry is now responsive to the user's browser window, devoting more space on the screen to data entry. The width of the schedule tree will still be customizable but will take up one-third of the Data Entry screen by default. If the user chooses to customize the schedule tree width, the selected width will stick across logged in sessions. In addition, the default height of the Common Log section is higher than previous releases to provide the user with better visibility.	Clinical Research Coordinator, Investigator
Site Users	Show the Delimiter for Composite Items in Data Entry	EDC		Sites			Low	The "/" delimiter will be visible in the label for composite items in both Edit and View modes of data entry.	Clinical Research Coordinator, Investigator, Sub Investigator
Site Users	Unit Item Enhancements	EDC		Sites			Medium	<p>With this release, the error message for Unit Items has been updated for clarity and consistency with other number fields. Negative signs will no longer count as characters in a Unit Item. The default length and precision for unit items has been updated to 14 and 0.</p> <p>When an item is linked with a form with display items that are units or global lab units, the units will display in Detail PDFs, Closeout PDFs, and Assessment PDFs.</p>	Clinical Research Coordinator

Coders	Coder UI Enhancements	Coder		Coder Administrators, Coders			N/A	We have made the following UI enhancements to Coder with this release: <ul style="list-style-type: none"> - Collapsible Properties Panel: users can collapse and expand the Properties Panel as necessary while coding - Optimized white space: the Verbatims table will now occupy available white space to display more Verbatims 	Clinical Coder
Coders	Coders are Allowed to Code a Form with a Needs Synonym List Status	Coder		Coder Administrators, Coders			Medium	If a Form does not have an assigned Synonym List, then the Coder may continue to code the Form until one is assigned. Forms with the <i>Needs Synonym List</i> status will not Autocode or have Suggestions off of the Synonym List.	Clinical Coder, Clinical Coder Administrator, Clinical Coder Manager
Coders	New Upversioning Status in Coder	Coder		Coder Administrators, Coders			Medium	With this release, we've introduced a new status called <i>Failed Upversioning</i> that will display when Upversioning fails for a Form or Synonym List. This status allows Coder Administrators to easily identify which Forms and Synonym Lists failed Upversioning.	Clinical Coder, Clinical Coder Administrator, Clinical Coder Manager
Clinical Team, Site Users	Events Support Event Windows	EDC		CRAs, Data Managers, Sites			Low	The system will now calculate if an event is "Out of Window," and if so, how many days out of window. This is used in the Event Progress Listing and the Study Data Extract.	Investigator, Sub Investigator, Clinical Research Coordinator, Clinical Research Associate, Data Manager

Clinical Team, Site Users	Global Lab Units & Codelists Display in UI Grids & Detail PDF	EDC		CRAs, Data Managers, Sites, Lead Data Managers		Labs, Global Versionless Labs	Low	Lab Units and Codelists are now visible in the following grids: Repeating Form Grid, Form Linking Grid, and Item Linking Selection Dialog.	Investigator, Sub Investigator, Clinical Research Coordinator, Clinical Research Associate, Data Manager, Lead Data Manager
Clinical Team, Site Users	Show Codelist Labels in Email Notifications	EDC		All			Low	Send Email rules that contain references to codelist items now display the codelist label in addition to the backend coded value.	All
Clinical Team, Site Users	Signature History Page	EDC		CRAs, Data Managers, Lead Data Managers, Sites		Data Model V2	Medium	This feature added the Signature History page to the Data Entry and Review tabs. From this page, users can view the signature history for all signing activities, including the counts of objects signed and not signed during each signature.	Data Manager, Investigator, Lead Data Manager
Clinical Team	Ability to Specify Other Reason for Additive Review	EDC		CRAs, Data Managers, Lead Data Managers		Additive Review, Other Specify	Medium	When the "Enable Other Specify" reason for change and "Enable Additive Review" option are both set to "Yes" in Studio, reviewers can provide a custom reason for Additive Review.	Clinical Research Associate, Data Manager, Lead Data Manager
Clinical Team	Counts Include Restricted Forms & Events in the Subject Progress & Event Progress Listings	EDC		CRAs, Data Managers, Lead Data Managers			High	If the user selects Include Restricted Data, the Subject Progress Listing and Event Progress Listing will include restricted forms and events in columns that count the number of forms and events. If not selected, the listings will not include restricted forms and events.	Clinical Research Associate, Data Manager, Lead Data Manager

Clinical Team	Include Freeze, Lock & Sign Dates in the Form Progress Listing for Data Model V1 Studies	EDC		CRAs, Data Managers, Lead Data Managers	EDC Tools	Data Model V1	Low	For studies on Data Model 1, the <i>Form Progress Listing</i> will now include values in the following columns: Freeze Date, Lock Date, and Sign Date. These columns were previously only populated for Data Model 2 studies.	Clinical Research Associate, Data Manager, Lead Data Manager
Clinical Team	Include Site Number in Study Summary Metrics Report	EDC		CRAs, Data Managers, Lead Data Managers			Low	The Study Summary Metrics Report now includes a column for Site Number.	Clinical Research Associate, Data Manager, Lead Data Manager
Clinical Team	Include User Role in Query Detail Listings for Studies Not Using Query Teams	EDC		CRAs, Data Managers, Lead Data Managers		Query Teams Disabled	Low	When a study isn't using the Query Teams feature, Vault now populates the following Query Detail Listing columns with the user's current study role: Created By Role, Answered By Role, and Closed By Role.	Clinical Research Associate, Data Manager, Lead Data Manager
Clinical Team	New Column for All Items in the Form Progress Listing	EDC		CRAs, Data Managers, Lead Data Managers			Low	A new column for All Items will now be available in the <i>Form Progress Listing</i> . This column will be included in the listing when "Include Item Counts" is selected in the job options dialog. The purpose of this column is to count the total number of items on the form, allowing users to compare this value with the number of items with data and the number of items with data change.	Clinical Research Associate, Data Manager, Lead Data Manager

Clinical Team	Protocol Deviations: Enhancements	EDC		CRAs, Data Managers		Protocol Deviations	Medium	<p>With this release, we have made various enhancements to Protocol Deviations which are detailed below.</p> <ul style="list-style-type: none"> - We have added a new column, Protocol Deviation ID, which will display in the Protocol Deviation grid and in both exports. This column allows users to find a deviation in the export by its unique ID number. - We have made improvements to the Protocol Deviation search, so that users will now be able to search on the Protocol Deviation ID or Summary. In addition, the search is more flexible and case insensitive, so users no longer need to enter an exact match. - When viewing a Protocol Deviation in the Review UI, users will now be able to see the deviation's status in the dialog. Users will only see active Protocol Deviations, such as those with an Open or Investigating status. Inactive Protocol Deviations can only be viewed in the Protocol Deviation grid. 	Clinical Research Associate, Data Manager
Clinical Team	Protocol Deviations: Export as an Excel™ File	EDC		CRAs, Data Managers		Protocol Deviations	Medium	Protocol deviations can now be exported as an Excel™ file.	Clinical Research Associate, Data Manager

Clinical Team	SDE: Enhancements	EDC		Lead Data Managers			Low	<p>In the 22R3 version of the SDE, the following changes have been made:</p> <ul style="list-style-type: none"> • <p>The SYS_PD dataset will include the Category, Subcategory, and Severity Labels along with the Form Sequence, Form VOF ID and Protocol Deviation VOF ID.</p> <ul style="list-style-type: none"> • <p>The SDE supports the use of the Lab Modifier configured for studies with Global Labs enabled through the addition of two columns for the Lab Modifier Code and its Decode. We also added the LABMODIFIER column to Core Listings and the Data and Definition Export.</p> <ul style="list-style-type: none"> • <p>The SYS_SITE dataset has been updated to support the Bulk Casebook Signature feature and includes a new column called BULKCASEBOOKSIGNATURE.</p>	Lead Data Manager
Clinical Team	SDE: Include Study Design Metadata	EDC		Lead Data Managers			Low	<p>The 22R3 version of the SDE will include the option to "Include Study Design" in the export. If checked, Vault will add a folder called "definitions" to the zip package which contains CSVs with study design information.</p>	Lead Data Manager

Clinical Team	SDE: Length Standardization	EDC		Lead Data Managers			Low	<p>In the 22R3 version of the SDE, instead of defaulting SAS text column lengths, Vault will use Vault and Studio configuration data to determine column lengths.</p> <p>For 22R3, codelist Decodes (Labels) will use 256 characters for length and 1024 bytes as the column length. In 22R2 and earlier versions, these will use 1500 characters for length and 1500 bytes as the column length.</p>	Lead Data Manager
	Automatic Removal of Invalid Event Window Configuration for First Event	EDC		Librarians, Study Designers			Medium	When the user moves an existing Event to be the first in the schedule, Vault now automatically removes the invalid window reference.	Librarian, Study Designer
	Bulk Casebook Signature	EDC			EDC Tools, Support	Data Model V2	High	Principal Investigators will now have the ability to sign multiple casebooks at once rather than signing one individual casebook at a time.	Data Manager, Investigator, Lead Data Manager
	Cross-Form Derivations	EDC	Yes	Vault Administrators	Vault Admin		Medium	<p>With this release, we've added the ability to derive values across forms in a casebook. Study Designers can add the new "Derived Items" component to forms and create <i>Set Derived Value</i> rules to set values of derived items based on criteria across a casebook. This feature is automatically enabled for Studies created after the 22R3 release. For existing Studies not yet in production, this is only available if no derivation rules exist in the <i>Study</i>.</p>	Librarian, Study Designer, Super User

	Disallow Amendments with Destructive Changes	EDC		Deployment Administrators, Lead Data Managers, Librarians, Study Designers, Super Users			Medium	Vault no longer allows retrospective amendments to casebooks that result in destructive changes (removing components that cause the removal of study data). Vault also shows a warning when Studio users remove components from the schedule or form layout and when Administrators deploy studies with destructive changes.	Deployment Administrator, Librarian, Study Designer
	E2BLink Configuration Deployments	EDC		Safety Administrators, Study Designers, Deployment Administrators			Medium	Configurations for E2BLink can now be deployed across study environments. This feature removes the ability to manually import this configuration and renames the Export action as Download Specifications.	Safety Administrator, Study Designer, Deployment Administrator
	E2BLink: Email Notifications	EDC		Safety Administrators, Study Designers	System Tools		Medium	Vault can now send email notifications when a transmission failure, an expired certificate, or an inactive connection or gateway profile. As part of this feature, we changed some UI labels in EDC Tools > Safety Configuration.	Safety Administrator, Study Designer
	Form & Item Linking Rules Allow References to Fully-qualified Identifiers	EDC		Librarians, Study Designers, Super Users	Studio	Expression Engine V2	Medium	With this release, rules containing Form and Item links will allow references to fully-qualified identifiers outside of the linked identifiers.	Librarian, Study Designer, Super User
	Global Labs Migration	EDC, EDC (Labs)		Vault Administrators	Vault Admin	Data Model V2	N/A	Existing Studies with Local Labs can be migrated to new Global Versionless Labs. Contact your Services team to schedule and execute the Migration.	Vault Administrator
	Job Execution Enhancements	All		Deployment Administrators, Lead Data Managers, Librarians, Study Designers			Medium	With this release, we updated the EDC job retention policy to 30 days, and the job governor now prevents two scheduled jobs of the same type from running at the same time.	Deployment Administrator, Lead Data Manager, Librarian, Study Designer

	Labs: Ability to Disable Pending Labs	EDC (Labs)		Data Managers, Lead Data Managers, Study Designers	Labs	Labs	Medium	Users can configure whether or not Sites can enter new lab locations and associated lab normals.	Clinical Research Associate, Clinical Research Coordinator, Data Manager, Lab Data Manager, Lead Data Manager, Study Designer
	Labs: Configurable Queries	EDC (Labs)		Data Managers, Lead Data Managers, Study Designers	Labs	Labs	Medium	Users can enable and disable system-generated Lab Queries.	Data Manager, Lab Data Manager, Lead Data Manager, Study Designer
	Labs: Support for Lab Results with Characters "<" & ">"	EDC (Labs)		Data Managers, Lab Data Managers, Lead Data Managers	Labs	Data Model V2, Labs, Global Versionless Labs	Medium	Users can use ">" and "<" when entering Lab data.	Clinical Research Associate, Clinical Research Coordinator, Data Manager, Lab Data Manager, Lead Data Manager, Study Designer
	Library: Create Library Report as CSV	EDC		Librarians			Medium	Librarians can now generate the Library Report as a CSV file. Vault now automatically uses this format if there are more than 800,000 records in the Definition Histories object and will not give users the choice to export as an Excel™ file.	Librarian
	Multi-language Support in Studio	EDC		Librarians, Study Designers			Medium	Study designers can now manage translations for their study's design components from Studio.	Librarian, Study Designer
	Notify Users when a Site is Locked from Review Plan Assignment	EDC		Lead Data Managers			Low	Vault notifies users that a site is locked from EDC Tools > Review Plan Assignment.	Lead Data Manager

	Option to Include Keys & Origins in SDS	EDC		Librarians, Study Designers			Medium	Studio users can choose to include the Private Key, Cross Vault Unique ID, Origin Name, Origin Type, Origin Definition Name, and Origin Key in their Study Design Specifications.	Librarian, Study Designer
	Principal Investigator No Longer Required for Site Creation	EDC		Lead Data Managers			Low	The Site Principal Investigator field is no longer required when creating a new Site. In addition, the Add as PI field now includes an explanatory tooltip in System Tools > Users.	Lead Data Manager
	Retrospective Amendment Start Event Requires the First Event	EDC		Lead Data Managers			Medium	Users can now only select the first Event in the Study for the Start Event on a retrospective amendment.	Lead Data Manager
	Rule Execution Enhancements	All		Deployment Administrators, Librarians			Medium	With this release, we have removed the casebook limitation in the <i>Run Rules</i> job and doubled the amount of rules that can be run within one job.	Lead Data Manager, Librarian
	Rules: Referencing the Previous Value of an Object with @PreviousEvent	EDC		Librarians, Study Designers	Studio	Expression Engine V2	Medium	Users can now reference the previous value of an identifier in a rule based on the previous Event in the Casebook, sorted by Event Date.	Librarian, Study Designer
	Select Sites Across Multiple Pages when Running a Retrospective Amendment	EDC		Lead Data Managers			Low	Users can select multiple Sites across pages when selecting Sites for a Retrospective Amendment.	Lead Data Manager
	Show Progress Percentage for In Progress Jobs			Deployment Administrators, Lead Data Managers, Librarians, Study Designers	EDC Tools		Medium	Users can see the progress completion percentage of In Progress jobs as the job runs.	Deployment Administrator, Lead Data Manager, Librarian, Study Designer
	Sign with Open Queries	EDC			EDC Tools, Support	Data Model V2	High	Principal Investigators can apply their signatures to forms and event dates that have open queries.	Investigator, Lead Data Manager

	Study Progress Listings in the Reports Tab	EDC			Vault Admin		High	The <i>Study Progress Listing</i> job will now be available in the Reports tab. Once the job is scheduled, the listing data will be pushed to the Reports tab. In Reports, Standard Templates are available and will match the output of the listing from EDC Tools. Users with access to Reports can create their own version of the report based on the standard template, which they can customize by adding filters or by adding or removing columns. This feature is only available to certain early adopters. Contact your Veeva Services representative for details.	Clinical Research Associate, Data Manager, Lead Data Manager
	User Import Enhancements	All		User Administrators			Low	With this release, we made the following enhancements to user import: <ul style="list-style-type: none"> • Vault warns users when they edit an existing user's details with an import. • Vault warns users when they specify overlapping site and country access for a user during import. 	User Administrator
	User Training Report Shows Users with All Sites Access	All		User Administrators			Low	The User Training Report now shows Users with All Sites access.	User Administrator
	Vault Diff Report Support for Multi-Role Security	All		Deployment Administrators		Multi-Role Security	Medium	The Vault Diff Report now compares custom Study Roles between vaults using multi-role security.	Deployment Administrator

Veeva CDB Features								
Day 1 Impact to Primary Users	Name	Application	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
	3rd Party Data Load Error Rollback	CDB	Data Managers, Lead Data Managers			Medium	When there is an error for a source package, CDB now reverts back to the last successful package so that the swap can be made active.	Lead Data Manager, Data Manager
	Automated Checks Re-query	CDB	Data Managers, Lead Data Managers			Medium	Checks will now re-query when records reappear on a check.	Data Manager, Lead Data Manager
	CDB Data Provider Query Access	CDB	Vault Administrators			Medium	Administrators can now define a user's source access (for data providers) to answering queries within CDB > Admin > Users. Once given access, data providers can access select listings in CDB to answer queries associated with their specific data source. This feature added the View Selected Listings, View Selected CDB Query Listings, and Answer 3rd Party Queries permissions, assigned to the CDB Data Provider, CDMS Super User, and CDMS Data Manager standard study roles. This feature also renamed the View Listings permission as View All Listings and the View CDB Queries permission as View All CDB Query Listings.	Data Providers, Vault Administrator
	CDB Support for Item to Form Linking	CDB	Data Managers, Lead Data Managers, Super Users			N/A	CDB now supports the Item to Form Linking feature in EDC. Users can access these links using the @FormLink notation.	Data Manager, Lead Data Manager, Super User
	Hide Columns in Listings, Views & Checks	CDB	Data Managers, Lead Data Managers, Data Providers, Super Users			Low	Users can now hide columns in listing, views, and checks from the Sort & Filter menu. Hidden columns persist across the user, study, and object. CDB represents hidden columns with a dotted orange line. Users can unhide all columns at any time. As part of this enhancement, users no longer need to click OK in the Sort & Filter menu to apply a sort order.	Data Manager, Lead Data Manager, Super User, Data Providers
	Multiple Schedules per Export Definition	CDB	Lead Data Managers, Data Managers	CDB		Medium	CDB now supports multiple, unique, scheduled exports (up to 5) per <i>Export Definition</i> .	Data Manager, Lead Data Manager

	Reduce Header & Unit SAS Lengths	CDB	Data Managers, Lead Data Managers			Low	This release reduces the SAS length for @HDR (6000 bytes to 512 bytes, except ILBReason, which was reduced to 1020 bytes) and unit text columns (from 6000 bytes to 512 bytes) in Export Listings to lower space allocation requirements.	Data Manager, Lead Data Manager
	Reference Objects	CDB	Data Managers, Lead Data Managers, Super Users			Medium	CDB now supports reference objects, which are like Forms, in that they contain a limited set of Items, but they are different in that a reference object must define how it relates to other header or form data. This relationship is defined upon ingestion. Once the data has been defined and ingested, CQL can use it like any other Form. Reference objects are defined in the manifest file for an import package. Then, the data for the reference object is imported as a CSV file in that import package. This feature introduces a new CQL function, KEYMATCH, which is only available for use with reference objects.	Data Manager, Lead Data Manager, Super User
	Route 3rd Party Packages to the Right Vault in the Domain	CDB	Data Managers, Lead Data Managers			Medium	To provide an easier way to upload 3PD packages for customers who have multiple vaults in a domain, CDB now checks for the Study specified in the package across all the vaults in the domain that the uploader can access.	Lead Data Manager, Data Manager
	Support for Queries on CDB Derived Fields	CDB	Data Managers, Lead Data Managers, Super Users			Medium	Users can now view the cell details for a CDB univariate, derived field. From the Cell Details panel, they can now open and close queries on the underlying EDC or third party data Item.	Data Manager, Lead Data Manager, Super User

Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: 10/14/2022

Date	Description	Impact
10/10/2022	Published the initial version of the RIA	N/A
10/14/2022	Added the "Other Specify Reason for Additive Review" and "Global Labs Migration" features.	The RIA now contains an up to date list of features for release in 22R3.
10/27/2022	Added the "3rd Party Data Load Error Rollback" and "Route 3rd Party Packages to the Right Vault in the Domain" features Updated the description for "CDB Data Provider Query Access"	The RIA now includes an up to date list of features for release in 22R3.
10/17/2022	Renamed "Other Specify Reason for Additive Review" as "Ability to Specify Other Reason for Additive Review"	The RIA now includes up to date feature names.
10/18/2022	Updated the description for "Job Execution Enhancements", "CDB Data Provider Query Access", "Unit Item Enhancements", "Reduce Header, Codelist & Unit SAS Lengths", and "Global Lab Migration"	The RIA now includes up to date feature descriptions.
10/20/2022	Updated the GxP risk on "Global Labs Migration" from "Low" to "N/A"	The RIA now includes up to date GxP Risk.
10/28/2022	Updated the Dependencies for "Rules: Referencing the Previous Value of an Object with @PreviousEvent", Updated the Label for the dependency in "Form & Item Linking Rules Allow References to Fully-qualified Identifiers" Updated the Description of "SDE: Enhancements" Updated the Name of "Reduce Header & Unit SAS Lengths" to "Reduce Header & Unit SAS Lengths" Updated the Name of "Support for Migration of Code Requests with ATC4 Values" to "Support for Migration of Code Requests with ATC4 Level Matches" and updated its Description and Configuration	The RIA now includes up to date names, descriptions, and dependencies;
10/26/2022	Updated the Configuration field for "SDE: Include Study Design Metadata" and "SDE: Enhancements"	The RIA now includes up to date enablement information.



11/1/2022	Added the "Signature History" feature, which was split from the "Bulk Casebook Signature" feature, and removed the related description text from "Bulk Casebook Signature" Updated the description for "Events Support Event Windows"	The RIA has an up to date list of features with descriptions.
11/10/2022	Updated the Description for "Cross-Form Derivations"	The RIA now includes up to date descriptions.
11/11/2022	Updated the Description for "SDE: Length Standardization"	The RIA now includes up to date feature descriptions.
2/8/2023	Updated the description for "Cross-Form Derivations"	The RIA now includes up to date descriptions.