



22R2 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: 6/20/2022

Revision Date: 8/5/2022

VIA Available: 7/11/2022

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	Assessments Locked when Site or Study is Locked	EDC		Assessment Editor			Medium	Users will be prevented from making changes to medical assessments when a study is locked. If the site is locked, users will be able to complete open assessments but will not be able to modify completed assignments.	Assessment Editor
Site Users	Audit Trail Enhancement: Add Reason for Invalidated Signatures	EDC		Sites		Data Model V2	High	When the legal reason of a signature definition is changed in Studio, the system will invalidate the eSignature for any objects where this signature was applied. For Data Model 2 studies, the audit trail will now include an entry when the signature was invalidated due to a change in attestation statement. This functionality is already available for DM1 studies.	N/A
Site Users	Display Columns for Event & Event Date in the Item Linking Dialog	EDC		Sites		Form Linking V2	Low	When linking an item to a form that's collected at a scheduled event, the link dialog will now include a column for Event and Event Date, making it easier to differentiate between forms collected at different events.	Clinical Research Coordinator
Site Users	Lab Header Styling Updates	EDC		Sites		Labs	Low	This feature updates the look and feel of the header section for lab forms. The fields for Collection Date Time, Lab Location, Age and Sex will be left aligned, making it easier to enter data.	Clinical Research Coordinator
Site Users	New Icon for Intentionally Left Blank	EDC		Sites			Low	A new icon for Intentionally Left Blank displays in the Form, Item Group, and Item Actions menus.	Clinical Research Coordinator, Investigator, Sub Investigator

Site Users	Recalculate Planned Date during Retrospective Amendments	EDC		Sites			Medium	When an event's planned dates are added or updated in Studio, the planned dates for the event will be recalculated in EDC for all selected events during the retrospective amendment. This will only occur when planned dates are added or updated in Studio and the affected event is selected in a retrospective amendment.	Clinical Research Coordinator, Study Designer
Coders	Dictionary Search Enhancements	Coder		Coders			Medium	Coders will be able to find more relevant results when searching phrases that include single characters such as the "E" in "Vitamin E," phrases with terms that include special characters such as "+immu boost," and phrases that include popular terms such as "carbonate" in "calcium carbonate." The Dictionary search can also return more accurate results when the search phrase includes non-relevant terms. Coders can also search for exact match results only with the use of double quotes.	Clinical Coder, Clinical Coder Administrator, Clinical Coder Manager
Clinical Team, Site Users	Audit Trail Enhancement: Additional Form Audit Entries	EDC		CRAs, Data Managers, Lead Data Managers, Sites			High	The Form Audit Trail now includes audit entries for changes relating to the following fields: <ul style="list-style-type: none"> • Study Country • Site 	Clinical Research Associate, Clinical Research Coordinator, Data Manager, Investigator, Lead Data Manager, Sub Investigator
Clinical Team, Site Users	Audit Trail Enhancements for Events	EDC		CRAs, Data Managers, Sites			High	Vault creates audit entries for changes to the following fields when a new Event is created: <ul style="list-style-type: none"> • Event Date • Planned Date • Overdue Date 	Data Manager, Clinical Research Associate, Investigator, Sub Investigator

Clinical Team, Site Users	Hint Labels in Detail and Closeout PDFs	EDC		CRAs, Data Managers, Sites			Low	When a form is configured with a hint label, that hint label will now be included in the Detail PDFs and the Closeout PDFs.	Clinical Research Coordinator, Clinical Research Associate, Data Manager
Clinical Team	Closeout PDF Enhancement: Restricted Data Warning	EDC		Data Managers			Low	When users with Restricted Data Access are generating closeout PDFs in EDC Tools, they will see a new warning that they are generating restricted PDFs.	Lead Data Manager
Clinical Team	Form Link Audit Trail in Review UI	EDC		CRAs, Data Managers			Low	Review users, like CRAs and Data Managers, will now be able to view the audit trail for form links from the Review tab. The Form Link Audit Trail will be available in the form's More Actions menu if the form is linked to another. All form link changes will be reflected in the audit trail.	Clinical Research Associate, Data Manager
Clinical Team	Form Link Items Added to SYS_LINKS	EDC		Data Managers		Form Linking V2	Medium	<p>In the 22R2 Version of the Study Data Extract, the SYS_LINKS dataset will include more "data". SYS_LINKS will include information about the form link item, including Item Group, Item Group Definition, Item Group Sequence, Item and Item Definition for the item row and information about the linked form in the form row. Both will include the link's unique Link ID.</p> <p>The Clinical Datasets and Core Listings will now also include the unique Link ID for item form links.</p>	Data Manager, Lead Data Manager
Clinical Team	Form Progress Listing Enhancement: Renamed SDV/DMR Columns to be Clearer	EDC		CRAs, Data Managers			Low	The column headers for SDV and DMR in the Form Progress Listing job have been renamed to SDV Complete and DMR Complete to more accurately describe the data in these columns.	Clinical Research Associate, Data Manager, Lead Data Manager

Clinical Team	Job Dialog Enhancements	EDC		CRAs, Data Managers, Lead Data Managers			Low	<p>With this release, we've made a few small enhancements to the New Job dialog in Review and EDC Tools. Users will no longer be able to change the scheduled job type for scheduled jobs and must delete the scheduled job and create a new one to change the job type. For consistency, we've also updated the radio buttons for several of the jobs' options to match those used elsewhere in EDC Tools. Finally, we've removed the "Restore Defaults" button for the following jobs that include the shuttle selector for job options:</p> <ul style="list-style-type: none"> • SDE (EDC Tools) • Core Listings (Review & EDC Tools) • Event Progress Listing (Review) • DMR Re-Assignment (EDC Tools) • Detail PDF (Review & EDC Tools) • Form Progress Listing (Review) • Query Detail Listing (Review) • Reconstitute Code Requests (EDC Tools) • Subject Progress Listing (Review) • SDV Re-Assignment (EDC Tools) 	Clinical Research Associate, Data Manager, Lead Data Manager
Clinical Team	Prevent Creation of Protocol Deviations in Locked Sites	EDC		CRAs, Data Managers			Medium	Vault no longer allows users to open new Protocol Deviations or edit existing Protocol Deviations in locked Sites.	Clinical Research Associate, Data Manager

Clinical Team	Protocol Deviation Audit Trail UI Enhancements	EDC		CRAs, Data Managers			Low	The audit trail for Protocol Deviations has been updated to be more user friendly. The audit trail dialog is now responsive to the user's screen size and can be closed using the X or the new Close button. The header of the audit trail grid will remain visible as the user scrolls to see more audit data.	Clinical Research Associate, Data Manager
Clinical Team	Study Summary Metrics Report	EDC		Data Managers		Review Rollup V2	High	With this new report, CRAs and Data Managers can see a summary of SDV and DMR progress in their study. The Review Metrics Report will detail how many forms, events, subjects, and sites have been reviewed at the site and country levels. With this feature, we've also made updates to the Event Progress Listing to include new columns for review data, including the number of forms SDV'd or DMR'd at the event and the SDV/DMR status of the event date.	Clinical Research Associate, Data Manager, Lead Data Manager
	Additional Fields Available in System Tools > Users	All		Super Users, User Administrators, Vault Administrators			Medium	The following fields are now available for editing in System Tools > Users: Domain Admin, Service Availability Notifications, Product Announcement Emails, and Status. These fields can also be modified via user import.	Super User, User Administrator, Vault Administrator

	Additive Review Listing	EDC		Lead Data Managers		Review Rollup V2, Additive Review	High	The Additive Review Listing will provide CRAs and data managers with a report on items additively reviewed in the study. It will include a summary report to give a high-level view of items additively reviewed by sites. Additionally, it will include a detailed report at the item or event-date level, which will include the user who performed the additive review, the datetime when the item or event date was reviewed and the additive reason why.	Lead Data Manager
	Allow Vault-level Deployment from UAT to Template Vaults	All		Deployment Administrators, Super Users, User Administrators	System Tools		Medium	With this release, CDMS supports vault-level deployments from UAT vaults to Template (Library) vaults.	Deployment Administrator, Super User, User Administrator
	Amendment Preview: Copy Study Data	EDC			Support	Data Model V2	High	Study data, like execution data and restricted data if applicable, can be copied from Production by users with the Copy Study Data to PPT permission. Does not include CDB or custom object data. Data copied to the Post Production Test (PPT) environment cannot be merged; subsequent Copy Study Data actions will first remove any existing data.	Deployment Administrator, Lead Data Manager, Super User, Vault Administrator
	Audit Trail Export Includes Assessments & Protocol Deviations	EDC		Lead Data Managers			High	The Audit Trail Export now includes audit entries for Medical Assessments and Protocol Deviations.	Data Manager, Lead Data Manager
	Course Progress Training Report	All			Support	LMS Integration	High	This feature introduces a new version of the Training Report that includes details about course progress (Course Status column).	Super User, User Administrator
	Deployment Enhancement: HVO Custom Objects Filtered from Deployment List	EDC		Deployment Administrators, Super Users, User Administrators			Low	Vault no longer allows the deployment of high-volume objects in Vault-level deployments.	Deployment Administrator, Super User, User Administrator

	Dynamic Rule Enhancement: Better Support for PPC Changes	EDC		Study Designers, Librarians			Low	<p>Vault now ignores the results of inactive dynamic rule definitions. If a rule is marked as Inactive after it has been run, and another dynamic rule attempts to add or remove the same targeted objects, Vault is now able to execute the new rule without interference from the inactive rule's results.</p> <p>Study designers should be aware of this change, but there is no visible change or action required. This enhancement helps improve performance and prevent issues during rule execution.</p>	Study Designer, Librarian
	Max Length for Codelist Items	EDC	Yes	Librarians, Study Designers			Medium	This feature allows users to set a Length on Items using Codelists so that SAS extracts from EDC and CDB can be generated using exact lengths.	Librarian, Study Designer
	Medical Assessments: Data Changes & Reassessment	EDC	No - Future Release	Study Designers	Studio		High	Items can now be selected to trigger a Reassessment when data changes for the item. When this happens, a new Medical Assessment is created and is marked as a Reassessment. If there is a previously completed Assessment on the form, that Assessment is marked as Obsolete.	Assessment Editor, Assessment Reader, Study Designer
	My Training Tab	All				LMS Integration	Medium	With this release, Vault now shows assigned training in the My Training tab, listing assigned curricula, statuses, and completion dates. This removes the My Access column from the Study Listings page in the Data Entry tab.	All

	New Navigation Pattern for EDC Tools	EDC		Librarians, Study Administrators, Study Designers, Super Users, User Administrators, Vault Administrators, Deployment Administrators			Low	With this release, we updated the navigation pattern for EDC Tools. This included moving the navigation to a side panel, displaying the environment type, build version, and lock status throughout EDC Tools, tab stickiness, and enhancing the layout of the Jobs, Casebook Versions, Review Plans and Rules subtabs.	Deployment Administrator, User Administrator, Super User, Lead Data Manager, Vault Administrator, Safety Administrator
	New Safety Link E2B Element: E.i.9	EDC		Safety Administrators	EDC Tools		Medium	The E2B ID E.i.9 'Identification of the Country Where the Reaction / Event Occurred' is now mappable by Safety Link	Safety Administrator
	Object Usage Report	EDC		Librarians, Study Designers			Low	The Object Usage Report allows study designers to see where a definition is in use and what other definitions are related to it. They can use this information to ensure their changes won't have unintended effects.	
	Safety Link: Updates Labeled as "Follow-Ups"	EDC		Safety Administrators			Low	All Follow-Up generated by Safety Link will be labeled as Follow-Up and not Amendment. Specifically it will be labeled as Follow-Up in Reports and in the E2B XML the E2B ID C.1.11.1 'Report Nullification / Amendment' will be null and will no longer have the value 2 which is reserved for Amendments.	Safety Administrator
	Show "Include Randomization Treatment" in the SDE Job Information Tooltip	EDC		Lead Data Managers		Randomization	Low	When a user selects "Include Randomization Treatment" in the SDE for versions 22R1 and later, they will see that option reflected in the information icon in the Job History as well as for scheduled jobs if they schedule an SDE with that option.	Lead Data Manager

	Study Data Extract: Data Type & SAS Type Changes in the 22R2 Version	EDC		Lead Data Managers			Low	<p>In the 22R2 Version of the Study Data Extract, the following changes were made to fix incorrect data types:</p> <ul style="list-style-type: none"> • The column CASEBDEF has a SAS Type of numeric in the SYS_EVT, SYS_SITE, and SYS_SUB datasets. • The column MANUAL has a Data Type of boolean in the SYS_Q dataset. • The column NSUBMITS has a Data Type of integer and a SAS Type of numeric in the SYS_ASM dataset. • The column IGSEQ has a Data Type of integer and a SAS Type of numeric, the column INACBYSYS has a Data Type of boolean, and the column LASTINACDT has a Data Type of datetime and a SAS Type of numeric in the SYS_PD dataset. • The column LABMODIFIER has a Data Type of boolean in the SYS_LABRANGES dataset. • The columns LABMODIFIER and LABSYSMANAGED have Data Types of boolean, and the column LABPREC has a Data Type of integer and a SAS Type of numeric in SYS_ANALYTES 	Lead Data Manager
--	--	-----	--	--------------------	--	--	-----	--	-------------------

	Study Role Enhancements	All		Super Users, User Administrators	System Tools		Medium	With this release, we made the following changes to standard study roles: CDMS API Read Only and CDMS API Read Write now have the View Study Design and View Library permissions; CDMS Super User now has the Copy Study Data to PPT permission; CDMS Super User, CDMS Lead Data Manager, CDMS Study Designer, CDMS Librarian, and CDMS User Administrator now have the Manage Study Settings permission. The CDMS Super User now has the Configure Query permission, which was added to support features in a later release.	Lead Data Manager, Super User, User Administrator
	Study Settings Tab in EDC Tools	EDC		Lead Data Managers, Librarians, Study Designers, Super Users, User Administrators			High	We added the Study Settings tab to EDC Tools, where study administrators with the new Edit Study Settings permission can manage the following settings: Enable Absorb Learning System, Include Absorb Course Details in the Training Report, Connect to Vault CTMS, and CTMS Study Link ID.	Lead Data Manager, Librarian, Study Designer, Super User, User Administrator
	Updated Handling for Dynamic Event Group Deletion	EDC	N/A	Librarians, Study Designers			N/A	With this release, Vault no longer deletes a dynamic <i>Event Group</i> when the only dynamic <i>Event</i> present in it is deleted.	Librarian, Study Designer

	Updated Studio Properties Panel	EDC		Librarians, Study Designers			Low	<p>We updated the Properties panel in Studio to meet new standards and use the new UI framework. These changes are visual, and there is no change to functionality. We moved actions out of the Properties panel and into the Actions menu. Vault no longer displays the Properties panel for Codelists, Units, or Rules.</p> <p>As part of this enhancement, we removed the "Mandatory" field from the properties for Events and Forms.</p>	Librarian, Study Designer
	Versionless Unit & Codelist Definitions for Labs	EDC, EDC (Labs)	Yes		Labs, Vault Admin	Data Model V2	High	<p>Local Labs Unit and Codelists are now versionless, and Lab Forms point to Lab module for Units and Codelists instead of Studio. This enhancement exposes translated values in the Audit Trail for both lab and non-lab forms. Existing Studies must undergo a migration process in Business Admin to move to this new model.</p> <p>Vault CDMS Utilities does not support the new Global Versionless Local Labs.</p>	Data Manager, Lab Data Manager, Lead Data Manager, Study Designer
	Warn when Locking a Site with Open Assessments	EDC		Lead Data Managers			Low	Users will be shown a warning message when attempting to lock sites with open assessments.	Lead Data Manager

Veeva CDB Features								
Day 1 Impact to Primary Users	Name	Application	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
Clinical Team	Automated Checks	CDB	CDB Users	CDB		High	CDB users with the Create Listings permission can create checks. Within a check, a user can define a query action on each event date and/or a form item that exists on the check. CDB will open a query against new records as they are captured by the check. When a row is no longer captured by the check (indicating that the issue has been resolved), CDB closes the query.	Data Manager, Lead Data Manager
	3rd Party Data Import Enhancements	CDB	CDB Users			Medium	This feature includes the following enhancements: <ul style="list-style-type: none"> • When a file contains a column without a header name, CDB generates the F-016 warning. • If a third party data package doesn't contain any data (CSV files only have a header row), CDB creates a blank Core Listing for the source. 	Data Manager, Lead Data Manager
	Additional Attributes to the Sys_Forms Listing	CDB	CDB Users			N/A	With this release, we added the following attributes to the Sys_Forms system listing: Site.PI, Event.Date, Event.Status, Subject.Status, Site.Country, Site.Name, Form.ILB, Form.ILBReason, Form.SDV, Form.DMR, Form.Frozen, Form.Locked, Form.Signed, Form.LastModifiedDate, Form.Version, and Form.ExternalID.	Data Manager, Lead Data Manager, Super User
	CDB Usability Enhancements	CDB	CDB Users	CDB		Low	Users will now be able to filter Listings and checks with case insensitivity via contains, doesn't not contain, starts with and ends with operators for string fields.	Data Manager, Lead Data Manager

	Export Package Audit Log	CDB	Data Managers, Lead Data Managers	CDB		Medium	CDB will provide log of exports, export packages, and export listings. Users can download logs for a specific date range to see what has been exported, when the exports ran, and who generated the exports. As part of this feature, the Export > Packages page now shows a Created On column, whether the SDTM export type uses SDTM or External Names, and the datetime that the package finished processing or was completed.	Lead Data Manager
	Export Package Blinding	CDB	CDB Users	CDB		High	With this release, CDB now applies blinding to generated export packages by default. If the export owner or Vault Owner chooses, they can set the Type as Unblinded. For unblinded export definitions, CDB generates the unblinded export package.	Data Manager, Lead Data Manager
	Export Package Notifications	CDB	Vault Administrators	CDB		High	CDB can be configured to send notifications to subscribed users when export package generation succeeds, fails, and when the package is delivered to an FTP destination. This feature also adds the new "Delivery Failed" status to capture when an export package is successfully generated but CDB fails to send it to the configured FTP destination. This feature allows users to download the export log from the package drop-down, see when the package finished processing, and see when the export definition was created. Users who create an export definition of type SDTM will be able to see whether the column labels were created with the EDC SDTM Name or the EDC External Name in the export definition properties dialog.	Data Manager, Lead Data Manager, Vault Administrator

Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: 6/20/2022

Date	Description	Impact
6/13/2022	Published the initial version of the RIA	N/A
6/21/2022	Updated the description for "Versionless Unit & Codelist Definitions for Labs", "Updated Studio Properties Panel", and "Study Settings Tab in EDC Tools"	The RIA now includes up to date feature descriptions.
7/1/2022	Added the "Source Stamping for Migrated Code Requests", "Migration Submits Forms with Derived Items Created by Repair", and "Allow Vault-level Deployment from UAT to Template Vaults" features Updated the description for "Versionless Unit & Codelist Definitions for Labs", "Updated Studio Properties Panel", and "Export Package Audit Log"	The RIA now includes an up to date list of features for release in 22R2.
7/15/2022	Renamed "Event Group Names based on Multiple Columns" as "Derived Columns" Updated the configuration of "My Training Tab" Updated the description of "Audit Trail Enhancement: Additional Form Audit Entries"	The RIA now includes an up to date list of feature scope and enablement.
7/20/2022	Updated the description for "Additional Attributes to the Sys_Forms Listing" and "Additional Fields Available in System Tools > Users"	The RIA now includes up to date feature descriptions.
7/28/2022	Updated the description for the "Study Role Enhancements" feature	The RIA now includes an up to date list of permissions changes.
7/27/2022	Updated Training Impact and Users with Day 1 Visibility for "Updated Handling for Dynamic Event Group Deletion"	The RIA now includes up to date information for feature impact.
8/5/2022	Updated the description for "Dictionary Search Enhancements"	The RIA now includes up to date feature descriptions.

