

## 22R1 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.

i nis teature list is subject to chang	e prior to the release. We will begin tracking changes on: 3/7/2022
Revision Date:	4/12/2022
VIA Available:	3/25/2022
For detailed feature descriptions, re	efer to the product release notes, which are available on Vault CDMS Help.
This document does not include ch	nanges made as part of the Vault Platform release. Consult VeevaDocs for Vault Platform validation details.
Feature Risk:	Feature risk analysis takes into account data integrity, security, and confidentiality assuming the feature is turned on (either automatically or via configuration). Veeva performs validation testing on all High and Medium risk items.
High	May affect security, patient confidentiality, application areas that support GXP functions (audit trails, eSignature, etc.) or other ERES controls data
Medium	May affect core application functions (workflows, revision history, etc.)
Low	May affect metadata/notifications
N/A	The feature is a minor UI enhancement and not a functional change. The feature has no validation impact.
Enablement Fields:	These four fields describe the availability and visibility of a feature on day 1 (if no configuration occurs), what configuration is required, and if the feature has any dependencies.
Day 1 Impact to Primary Users	This feature is visible and available tone or more primary user teams (Site Users, Clinical Team, and Coders) on day 1. If blank, this feature is either only visible to study designers or administrator users, it requires configuration before it is visible to primary users.
Users with Day 1 Visibility	This feature is visible to these users on day 1 if no configuration occurs.
Configuration	This field lists the location(s) where configuration for this feature occurs, for example, "Studio" or "EDC Tools". "Support" indicates that this feature must be enabled by Veeva Support, and "Vault Admin" indicates that configuration must be performed by a Vault Owner in the vault's Admin area.
Dependencies	This field lists any dependencies required to use this feature, for example, Labs or Expression Engine V2. The RIA assumes that the dependencies are enabled.
Training Impact:	Lists the user roles that may require updated training for this feature.

Day 1 Impact to Primary Users	Name	Application	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
Clinical Team, Site Users	Audit Trail Improvements	All	CRAs, Data Managers, Sites			High	of the audit trails has been updated	Clinical Research Associate, Data Manager, Clinical Coder, Clinical Coder Administrator, Lead Data Manager
Site Users, Clinical Team	Display Item Group Headers in Detail PDFs	EDC	CRAs, Data Managers, Sites, Study Administrators			N/A		Investigator, Sub Investigator, Clinical Research Coordinator, Clinical Research Associate, Data Manager, Lead Data Manager
Clinical Team, Coders, Site Users	Enablement Change: Action UI	Coder, EDC, EDC (Labs), EDC (Randomization)	All (EDC & Coder)			N/A	In 21R2, Vault Platform introduced Action User Interface (UI), a set of UI enhancements that give end-users an enhanced and more productive user experience by helping them perform frequently used actions in fewer clicks. With this release, this feature is enabled in Vault CDMS.	N/A

Clinical Team, Coders, Site Users	Standardize Dates in Email Notifications	All	All		Medium	With this release, Vault standardizes all dates and datetimes coming from the <i>Casebook</i> or other study-defined attributes (such as the <i>Randomization Date</i> set by the Randomization module) according to the study's specified <i>Standard Date Format</i> and selection for <i>Twelve Hour Time</i> ( <i>Yes</i> for 12-hour time, <i>No</i> for 24-hour time). Vault uses the Site's timezone.	N/A
Clinical Team	Ability to Jump to Previous/Next Instance in Expand Log Form Layout	EDC	CRAs, Data Managers, Study Administrators	Review tab. View SDV, View DMR permissions.	N/A	Users can use the up and down arrows to jump to the next or previous form instances when in the expanded log form layout in the Review tab. To use this feature, users need access to the Review tab and the <i>View SDV</i> or <i>View DMR</i> permissions.	Clinical Research Associate, Data Manager, Lead Data Manager
Clinical Team	Access Study Listing Jobs from the Review Tab	EDC	Study Administrators		Medium	With this release, CRAs and Data Managers can generate and schedule the following jobs from the Review tab:  • Form Progress Listing  • Subject Progress Listing  • Event Progress Listing  • Query Detail Listing  These listings will have the same data as the listings generated from EDC Tools, but they can be filtered by Site or by Study Country.	Lead Data Manager
	Add Analyte Name Column to Audit Trail	EDC, EDC (Labs)	Data Managers	Labs	High	The Analyte Name column was added to the Audit Trail.	Data Manager, Lead Data Manager, Lab Data Manager
	Add Initiated By Study & Initiated By Site Columns	EDC (Labs)	Data Managers	Labs	Low	Vault now displays the <i>Initiated by</i> Study and <i>Initiated by Site</i> columns for Lab Locations to indicate who created a Lab Location.	Data Manager, Lead Data Manager, Lab Data Manager
	Add Lab Name and ID to Outdated & Updated Normals Reports	EDC (Labs)	Data Managers	Labs	High	With this release, the following two columns were added to the Outdated Normals Report: Lab Name and Lab ID.	Data Manager, Lead Data Manager, Lab Data Manager

Additional Requirements for Migration Vault - Migrator Security Profile	Migration	Migration Users			High	With this release, we introduced new requirements for Migration Vault. These requirements aren't related to functional changes to Migration Vault in 22R1. These new requirements were only added to provide additional detail in the BRD.	Migration Users
Additive Review	EDC	Librarians, Study Designers	Studio	Review State Rollup V2	High	Additive Review allows review users to perform additional SDV and DMR tasks, with a recorded reason, on <i>Event Dates</i> and <i>Items</i> that are set to <i>Not Required</i> on the subject's assigned <i>Review Plan</i> .	Clinical Research Associate, Data Manager, Lead Data Manager, Librarian, Study Designer
Casebook Version Limit Validation	Migration	Migration Users			Medium	Migration Vault now checks that there are only two casebook versions for Sites during load operations.	Migration Users
Codelist Mapper for Safety Configuration	EDC	Study Administrators			High	Study designers can use CDASH codelist codes when designing Codelist items, and a safety administrator can configure Safety Link to map those codes to the appropriate values for the E2B XML. When Safety Link generates the E2B XML file for a Safety Case, Vault translates the CDASH codes into the appropriate E2B codes, allowing the safety system to interpret those values correctly. Also, the first study drug Treatment Form configured in the Safety Configuration page will be indicated as the Study Drug in the safety system.	Safety Administrator
Comparison Rules Enhancements	EDC	Librarians, Study Designers	Studio	Data Model V2	Medium	Study designers can now define a custom query message to use when opening a query based on a comparison rule (rule defined using the Date Comparison Configurator in Studio > Rules > Comparison Rules). Studio now also displays record counts for filter options in the Date Comparison Configurator.	Librarian, Study Designer
Configure Reveal Treatment to Require Credentials	EDC (Randomization)	Randomization Managers	Randomization	Randomization	High	Users can configure in the Randomization module whether or not a Site requires login credentials if the Site has the <i>Reveal Treatment</i> permission.	Randomization Manager

Enablement Change: Removed Ability to Opt Out of Item-level Intentionally Left Blank	EDC	Vault Administrators		N/A	With this release, we removed the ability to disable Item-level Intentionally Left Blank, to prevent issues with Item Group-level Intentionally Left Blank.	Vault Administrator
Enhancements to Medical Assessments	EDC	Assessment Editor, Assessment Reader		N/A	Assessments". Note that in this	Assessment Editor, Assessment Reader
Event Window Updates	EDC	Librarians, Study Designers		High	With this release, we made two changes to configurations of event windows:  • Study designers can choose Previous Event, Specific Event, or None for Offset Event.  • Study designers can now override the event window configuration for Events in repeating Event Groups. This is in the updated Repeating Event Overrides dialog, accessed by clicking Repeating Event Override (Labels, Windows) in the event's Properties panel (formerly labeled "Repeat Labels").	Librarian, Study Designer
Export Change Detection & Updates	CDB	CDB Users, Super Users		Medium	CDB now indicates to users when an <i>Export Listing</i> is out of sync with the parent listing. Users can choose to sync that <i>Export Listing</i> with the parent to apply those changes. Users can review CQL differences between the parent listing and the <i>Export Listing</i> before applying those changes.  *This feature is only available for <i>Export Definitions</i> created after the 21R3.5 (March 2022) release.	Data Manager, Lead Data Manager, Super User

External FTPS & FTP UI Enhancements	EDC	Study Administrators	CDB, EDC Tools		Medium	This feature includes the following enhancements:  • Adds a new UI to the FTP tab in EDC	Lead Data Manager, Data Manager
						tools with 3 connection types: External FTPS, Veeva Vault, CDB Workbench	
						<ul> <li>Allows users to send export jobs to an External FTPS server, a Veeva Vault FTPS server, or a Workbench FTP or FTPS server if Workbench is enabled</li> </ul>	
						<ul> <li>Allows users to test their connection in the configuration dialog for Veeva Vault and External FTPS connection types</li> </ul>	
						Uses a new data model for external connections and migrates existing connections and scheduled jobs from Study Settings to the CDMS Outbound Connection object	
						*In order for External FTPS to work with a customer's FTPS server that has firewall ports outside of the range Veeva permits, a security process needs to occur to whitelist the customer's IP address and port range used for FTPS data transfer.	
Form Linking UI/UX Enhancements	EDC	Sites, Data Managers	Vault Admin	Form Linking V2	Medium	With Form Linking Version 2, linked forms and their data will display in a new visible group below the form data. The process for linking a form to another form remains the same, but the data entry user no longer has to navigate to another tab to add, edit or view a link. Instead, they can perform these actions while remaining on the same page as the form data.	Clinical Research Coordinator, Clinical Research Associate, Data Manager, Lead Data Manager
Import Change Approval	CDB	CDB Users, Super Users			S		Data Manager, Lead Data Manager, Super User
Import Manifest Builder	CDB	CDB Users, Super Users				The Manifest Builder tool provides a user interface for building a manifest.json file, which is required for the import of third party data.	Data Manager, Lead Data Manager, Super User

Inactivate Coding Forms	All	Study Designers, Study Administrators	Studio		Medium	, , , ,	Study Designer, Data Manager, Lead Data Manager, Clinical Coder, Clinical Coder Administrator
Item to Form Linking	EDC	Study Designers	Studio	Data Model V2	High	now link an individual item to another form. In Studio, there is a new item type, called Form Link, which study builders can add to a form. When a Form Link item is added to a form, the study builder can set up to five Display	Clinical Research Coordinator, Study Designer, Investigator, Sub Investigator, Clinical Research Associate, Data Manager, Lead Data Manager
Library Classifications	EDC	Librarians, Study Designers	Studio		High	With this release, librarians will be able to add <i>Classifications</i> to their <i>Forms</i> . The purpose of these classifications are to allow users to catalog forms by different classification types and values. These classifications will then be used by study designers (when copying from a library) to copy down forms that apply to that study. The library will come with a fixed set of classification type and pre-seeded values for certain types (like region or therapeutic area).	Librarian, Study Designer

New @HDR & @Form Attributes	CDB	CDB Users		N/A	With this release, we added the following new attributes for CQL:	Data Manager, Lead Data
						Manager, Super User
					@HDR.Subject.Cohort	0001
					@HDR.Subject.Substudy	
					@HDR.Subject.EndOfStudyDate	
					@HDR.Subject.EnrolledDate	
					@HDR.Subject.InitialConsentDate	
					@HDR.Subject.LostToFollowUpDate	
					@HDR.Subject.RandomizedDate	
					@HDR.Subject.ScreenedDate	
					@HDR.Subject.ScreenFailedDate	
					@HDR.Subject.StartedFollowUpDate	
					•	
					@HDR.Subject.StartedTreatmentDate	
					@HDR.Subject.WithdrawnDate	
					@HDR.Event.Version	
New Attributes, Functions & Usability Enhancements for Rules	EDC	Librarians, Study Designers, Super Users	Expression Grammar V2	Medium	Vault now supports the following functions for use with rules: Median, NetWorkdays, and Workday. IsBlank now supports aggregate identifiers (arrays). Users can now reference the following attributes in rule expressions: unitv (Item), translated_unitv (Item), change_reasonv (Item), and subject_namev (Casebook). When creating a rule, Vault no longer requires the selection of a Form in the Rule Details panel for rules that don't require binding to a Form, such as rules only looking at Event Dates. Vault only requires the selection of a Form when the rule expression or action contains @Form identifiers or the rule uses the Override Review Plan, Set Item Value, or Send Email rule action types.	Librarian, Study Designer, Super User

Prevent Bulk Updates to User Email	EDC	User Administrators		Medium	Vault now prevents bulk updates to the <i>Email</i> field for <i>Users</i> . To edit emails, a user administrator must edit <i>Users</i> individually. If a user administrator imports a user import file with a modified email, Vault generates an error during import. Organizations can contact Veeva Support to switch this to a warning, instead of an error, allowing for bulk email changes.	
Query Scoping for Repeating Objects	EDC	Vault Administrators	Vault Admin	Medium	repeating parts. Vault will open the	, and the second
Reconstitute Code Requests Job Enhancements	Coder	Coder Administrators, Study Administrators		Low	the Reconstitute Code Requests job on all coding Forms for the Study or on	Clinical Coder Administrator, Lead Data Manager
Restore Study Environment from File	EDC	Study Administrators, Super Users		Low		Lead Data Manager, Super User, Study Designer

SDE: Ge Enhance		Data Managers		general enhancements for the Study	Data Manager, Lead Data Manager
SDE: Inc Randomi Treatmer	zation (Randomization	Data Managers	Randomization	allow the inclusion of treatment information in the SDE SYS_RAND	Lead Data Manager, Data Manager, Randomization Manager
SDE: UI Configura	EDC	Data Managers	22R1 SDE Version		Lead Data Manager, Data Manager
SDV, ILE Locked 8 Attributes		Migration Users		Migration Vault now allows for the load of SDV, Intentionally Left Blank, Frozen, Locked, and Signed attributes for migrated data.	Migration Users

Source	Stamping	Migration	Migration Users, Vault Administrators		Medium	Vault now tracks the source as "Migrated" for migrated data in the Source Type field.	Migration Users, Vault Administrato
Studio I Improve	Usability ements	EDC	Study Designers, Librarians		Medium	This release includes two usability improvements for Studio:	Study Designer, Librarian
						The User Defined Rules page no longer lists system-generated rules, including univariate rules like Future Dates, Range Checks, Required, Progressive Display, or Comparison rules.  When executing Set Item Value rule actions, Vault no longer sets the item's value if the Item is hidden or disabled by progressive display.	

Study Role Enhancements	Study Administrators, User	High		Lead Data Manager, User Administrator
	Administrators		<ul> <li>In support of the Library Classifications feature, we added the following permissions:</li> </ul>	
			<ul> <li>View Classification, assigned to CDMS Study Designer, CDMS Study Designer Read Only, CDMS Librarian, and CDMS Super User</li> </ul>	
			<ul> <li>Edit Classification, assigned to CDMS Librarian and CDMS Super User</li> </ul>	
			• In support of the Vault Configuration Report feature, we added the Vault Configuration Report permission and assigned it to the CDMS Super User and CDMS Deployment Administrator study roles	
			• In support of the Import Change Approvals feature, we added the Approve Import permission and assigned it to the CDMS Lead Data Manager and CDMS Super User study roles	
			In support of the Unique Terms Report feature, we assigned the     Manage Jobs permission to the CDMS Clinical Coder Administrator study role	
			Assigned the Manage Jobs     permission to the CDMS API Read     Write study role	
			Assigned the View Lab Locations and Normals permission to the CDMS Clinical Research Associate study role	
			For ease of role creation, we added the following permission dependencies:	
			Data Entry automatically adds Edit Form Linking	
			View Casebook automatically adds     View Form Linking	
			<ul> <li>Vault Configuration Report automatically adds System Tools Tab, Manage Jobs, and Reports Dashboard Tab</li> </ul>	

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N	Support for Migration of Code Requests	Coder, Migration	Migration Users			Medium	Migration Vault is now able to migrate Code Requests from third party systems into Vault CDMS.	Migration Users
N S	Support for Migration of Studies with Safety Systems		Vault Administrators, Migration Users			Medium	New Studies that are migrating from a third party EDC system and have an automated solution for the transfer of safety data can now enable Safety Link after the migration to Vault CDMS. Vault administrators can use Vault Loader to load Safety Cases and Safety Messages from the originating system into Vault CDMS. Then, the organization can enable Safety Link. After the CDMS vault and safety system are connected, Vault automates all new and existing Safety Cases for the life of the Study.	N/A
c	Suspected Concomitant Medication		Study Administrators	EDC Tools	Form Linking V2	Medium		Safety Administrator
a F U	Track Removal of a Child from the Parent as an Update on the Parent	EDC	Librarians, Study Designers, Super Users			Medium	The Library Report now records the removal of a child from a parent, such as an <i>Item</i> from an <i>Item Group</i> , as an update to the parent record with the "Updated" action. This extends up to the <i>Form</i> level.	Librarian, Study Designer, Super User

Unique Terms Report	Coder	Coder Administrators		High	With this feature, coders will be able to generate the Unique Terms Report (UTR) to view all unique Code Requests across multiple Studies. This report will be available in the new Jobs section of Coder Tools to Coder Administrators with the Manage Jobs permission. When creating a new UTR job request, the user will select the dictionary and study they wish to include in the report. The following dictionaries are available: MedDRA, WHODrug, MedDRAJ, and JDrug.	Clinical Coder, Clinical Coder Administrator
Use Destination as Origin When Copying into a Library	EDC	Librarians		Medium	When a user copies a <i>Study</i> or <i>Collection</i> into a library <i>Collection</i> , Vault assigns the destination library as the origin for all copied object records. The copy operation now also places the object records in a created state to allow the tracking of changes for that record within the <i>Collection</i> .	Librarian
Vault Configuration Report	All	Super Users, Deployment Administrators		Medium		Super User, Deployment Administrator

## **Change Log**

This feature list is subject to change prior to the release. We will begin tracking changes on: 3/7/2022

Date	Description	Impact
2/28/2022	Published the initial version of the RIA.	N/A
3/9/2022	Updated the "Day 1 Impact to Primary Users" for "Configure Reveal Treatment to Require Credentials", "Inactivate Coding Forms", "Reconstitute Code Requests Job Enhancements", "Unique Terms Report", and "Access Study Listing Jobs from the Review Tab"  Updated the "Users with Day 1 Visibility" for "Inactivate Coding Forms" and "External FTPS & FTP UI Enhancements"  Updated the "Configuration" for "Reconstitute Code Requests Job Enhancements", "Unique Terms Report", "Library Classifications", and "Configure Reveal Treatment to Require Credentials"  Updated the "Dependencies" for "Reconstitute Code Requests Job Enhancements", "Access Study Listing Jobs from the Review Tab", and "Audit Trail Improvements"  Updated the "Application" for "Restore Study Environment from File"  Updated the "Description" for "Standardize Dates in Email Notifications"  Updated the "Training Impact" for "Access Study Listing Jobs from the Review Tab"	The RIA now has an up to date representation of features for release in 22R1.
3/20/2022	Added the "Prevent Bulk Updates to User Email" and "Renamed Clinical Assessments as Medical Assessments" features Updated the description for the "Study Role Enhancements" feature	The RIA now includes an up to date list of features for 22R1.

3/21/2022	Added the "Enablement Change: Action UI", "Display Item Group Headers in Detail PDFs", and "Ability to Jump to Previous/Next Instance in Expand Log Form Layout" features Updated Dependencies for the "Additive Review" feature Renamed "Safety Migrated Studies" to "Support for Migration of Studies with Safety Systems"  Updated the Users with Day 1 Visibility and Training Impact for the "Vault Configuration Report" feature  Updated the Description for the "Codelist Mapper for Safety Configuration", "Suspected Concomitant Medication", and "New Attributes, Functions & Usability Enhancements for Rules" features Updated "Enhancements to Medical Assessments" (formerly known as Renamed "Clinical Assessments" as "Medical Assessments") to include all enhancements to Medical Assessments in this release	The RIA includes an up to date list of features for release in 22R1.		
4/1/2022	Renamed "Additional Requirements for Migration Vault" as "Additional Requirements for Migration Vault - Migrator Security Profile"	The RIA includes up to date feature descriptions.		
4/12/2022	Updated the Description and Training Impact for "Item to Form Linking"	The RIA now includes up to date descriptions and training impacts.		