



21R2 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: 6/25/2021

Revision Date: 8/26/2021

VIA Available: 6/25/2021

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 Clinical Team</i>	If Yes, this feature is visible and available to sites, CRAs, or data managers on day 1. If No, this feature is either only visible to study designers or administrator users, or this feature requires configuration before it is visible to the clinical study team.
<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 Clinical Team	Name	Application	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
Yes	Allow Deletion of Unused Sites in Production	EDC	Study Administrators			High	Lead data managers can now delete Sites in production as long as there are no Subjects in the Site.	Lead Data Manager
Yes	CQL Improvements	CDB	CDB Users			N/A	This release adds the ALIGN and UNALIGN form modifier keywords to CQL, which control the presentation of non-repeating form data alongside repeating form data. This feature also removes the site shifting behavior for dates and datetimes.	Data Manager, Lead Data Manager
Yes	EDC General Enhancements	EDC	CRAs, Data Managers, Sites		Repeating Form Expansion	Medium	<p>This release includes the following general enhancements to the Data Entry and Review tabs:</p> <p>The "Repeating Form Expansion" feature is now enabled automatically for all Studies.</p> <p>Review tab users can click View Summary for a repeating Form in the Events & Forms panel to view a table listing all instances of the repeating Form. Clicking a Form instance in that table opens that instance in the Content panel.</p> <p>In the Review tab, repeating Form Instances display in the same layout as non-repeating Forms. Each instance is loaded as the user scrolls through the Event. The initial grid view no longer displays.</p> <p>In the Data Entry tab, if there is only one Unit Item available, Vault automatically defaults to that Unit Item, instead of requiring site users to select a Unit Item when there is only one.</p>	Clinical Research Associate, Data Manager, Investigator, Lead Data Manager, Sub Investigator

No	3rd Party Data Import Enhancements	CDB	CDB Users			Medium	<p>With this release, we made the following improvements to third party data import:</p> <p>The "site" key is now optional, and Workbench can determine subject uniqueness at the study level.</p> <p>The manifest file can define a default event, at either the package or file level, for matching, instead of matching by an event listed in the data files.</p> <p>Event matching on External ID now matches to Event execution records (EDC) instead of Event Definitions. I</p> <p>We now support these date formats: dd-MMM-yy, dd/MMM/yy, dd MMM yy, and ddMMMyy.</p> <p>Import can handle when a leading 0 isn't present for dd and MM date and datetime formats.</p> <p>Workbench now activates any ready swaps before any data exports job.</p>	Data Manager, Lead Data Manager
No	Access Current Review Plan in a Rule Expression	EDC	Librarians, Study Designers	Studio	Expression Grammar v2	Medium	<p>Users can access the Name of the currently assigned Review Plan in a rule expression using @Casebook.current_sdv_plan__v and @Casebook.current_dmr_plan__v.</p>	
No	Aggregate Identifiers & Functions	EDC	Librarians, Study Designers	Studio	Expression Grammar v2	Medium	<p>Study designers can now specify if an identifier should return an array of values, instead of distinct values. For the repeating parts of an identifier, they can use an asterisk (*) instead of a number inside the brackets to indicate that all instances of repetition should be considered in the value of the identifier. These identifiers can be referenced in the new aggregate functions.</p>	Librarian, Study Designer
No	All Listings UI Improvements	CDB	CDB Users			Low	<p>This release includes the following UI enhancements for All Listings: Each page is now sorted by Title. Sort order and filters on these pages are now sticky.</p>	Data Manager, Lead Data Manager
No	Annotated PDF Enhancements	EDC	Librarians, Study Designers			Medium	<p>This feature provides general updates to Annotated PDFs, including the ability to export annotations from listings.</p>	Librarian, Study Designer

No	Change Vault Login to Vault Selector for Diff Report	EDC	Librarians, Study Administrators, Study Designers	Studio		Medium	Diff Reports will use the Vault selector that's currently used for deployments to avoid incorrect differences showing up in the report as a result of a users various roles.	Lead Data Manager, Librarian, Study Designer
No	Cross Vault Copy	EDC	Librarians, Study Designers		Automatic Deployments	Medium	Study designers with access to multiple vaults can now copy records from one vault to another using Copy From Study.	Study Designer, Librarian
No	Delayed Execution for Query Rules	EDC	Librarians, Study Administrators, Study Designers	EDC Tools, Studio	Expression Grammar v2	Medium	Study designers can mark query-type Rules as having "delayed execution", meaning that after a Form is submitted, the rule enters a queue for processing, instead of processing immediately after form submission. In support of this feature, we added an error console to EDC Tools > Rules that displays any errors that occur during the execution of asynchronous rules.	Lead Data Manager, Librarian, Study Designer
No	Diff Report for Analyte Library, Lab Codelists & Lab Units	EDC (Labs)	Study Administrators			Medium	Lab data managers can compare Analyte Libraries, Lab Units, and Lab Codelists.	Lab Data Manager
No	Editable Grids	EDC, EDC (Labs)	Study Designers	Studio	Data Entry v2	Medium	Study Designers now have the ability to configure a repeating item group to appear in Data Entry in an Editable Grid format. Editable Grids allow for site users to efficiently enter data in a tabular, spreadsheet-like, format.	Clinical Research Coordinator, Investigator, Librarian, Study Designer, Sub Investigator
No	Enhanced System Query Closure Restrictions	EDC	Librarians, Study Designers	Studio	Query Team Restrictions	Medium	When the Query Team Restrictions feature is enabled on a Study, study designers can choose which Query Team is applied to system-generated queries via Studio's Settings page for the given Study.	Librarian, Study Designer
No	Improvements to System Listings	CDB	CDB Users			Medium	In raw exports, system listings are now one file per listing, instead of being spread across multiple files depending on the amount of data. System listing data can now also be accessed via CQL using CALL Sys_listingname, for example, CALL Sys_ILB.	Data Manager, Lead Data Manager
No	Incomplete Status for Normals	EDC (Labs)	Data Managers, Study Administrators		Labs Enabled	Low	This feature adds an "Incomplete" count for Normals that are missing units.	Lab Data Manager

No	Ingestion Monitoring & Notifications	CDB	CDB Users			Medium	Workbench now only sends an email notification when data reprocessing results in changes to the issue log. Workbench also generates an import log, with general details about the import and transformation process. The Package listing now displays a Deployed date, which shows the date that the source was put into use.	Data Manager, Lead Data Manager
No	JDrug	Coder	Coder Administrators	Coder Tools		Medium	Vault Coder now offers JDrug to code and autocode Japanese medications.	Clinical Coder Administrator
No	LMS Enhancements	All	User Administrators			Medium	Vault now allows study administrators to configure curriculum and assign training before a study design is complete. Vault now also checks for enrollment twice a day, instead of once. The LMS Integration feature is now enabled using the Study Settings object, instead of the study's Study Configuration record. To enable the feature with this release, a Vault Owner must edit the "lms.enabled" record for the Study to set the Value field to "true". For any Studies where the integration was already enabled, the "lms.enabled" record automatically has the value set to "true".	User Administrator
No	MedDRAJ	Coder	Coder Administrators	Coder Tools		Medium	With this release, Vault Coder offers MedDRAJ to code and autocode Japanese Adverse Events and Medical History terms.	Clinical Coder Administrator
No	Migrations Product Toolkit: Loader (Limited Release)	EDC		Support		Medium	With this release, Veeva Services now has the ability to use the migrations Loader to perform various semi-automated study migration operations, including EDC subject creation, event creation, form creation, and item value population, along with support for basic transformations during the ingestion process.	Vault Administrator
No	Multi-role Security (Limited Release)	All		Support		High	This feature allows a single user to have multiple Study Roles in a single Study with only one user account, without the need for a custom Security Profile.	User Administrator
No	Multiple SAEs in a Single Case	EDC	Study Administrators	EDC Tools		Medium	Safety administrators can configure a Study to send multiple SAEs in a single Safety Case.	Safety Administrator

No	Override Normals Report	EDC (Labs)	Data Managers		Labs Enabled	Medium	This report gives Data Managers the opportunity to review Override normals entered by Sites and update the Normal Ranges library if necessary.	Data Manager, Lab Data Manager, Lead Data Manager
No	Pending Approval Count for Normals	EDC (Labs)	Data Managers, Study Administrators		Labs Enabled	Low	This feature adds a "Pending Approval" count for Normals, so that users can see how many normals are awaiting approval.	Lab Data Manager
No	Pop-Up Window Support for CDMS SSO Authentication	All		Vault Admin		Medium	Vault CDMS now supports pop-up windows for SSO authentication for SAML profile configurations.	Vault Administrator
No	Relabeled CDB's "View Query" Permission as "View CDB Query"	CDB, EDC	Study Administrators, User Administrators			N/A	With this release, we relabeled the "View Query" permission for CDB as "View CDB Query", so that this permission won't be confused with the new "View Query" permission for EDC.	Lead Data Manager, User Administrator
No	Safety Link Enhancements	EDC	Study Administrators	EDC Tools		Medium	Safety Configuration now includes Null Flavor settings, which control EDC's ability to send "NI" to the safety system when either the Item is null or if the E2B ID isn't mapped to an Item. This applies only to SAE and AE items with the E2B id of E.i.3.2[a-f].	Safety Administrator
No	SDS Updates	EDC	Librarians, Study Designers	Studio		Medium	The SDS has been updated for general quality improvements including the following: Schedule tree updates - like adding names for event group and form Schedule Grid updates - like adding the event group Carrying labels down through columns like the names Removing the system rules from the rules tab and adding rule bindings Adding a local lab configuration tab Adding additional information to the summary page	Librarian, Study Designer
No	Send Email when Subject is Randomized	EDC, EDC (Randomization)	Study Designers		Randomization	Medium	Users can configure an email to be sent when a subject is randomized.	Study Designer
No	Send Protocol Deviations to Vault CTMS	EDC	Study Administrators		Vault CTMS Connection Protocol Deviations	Medium	Vault CDMS sends Protocol Deviations created or updated in EDC to Vault CTMS via the CTMS connection.	Lead Data Manager

Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: 6/25/2021

Date	Description	Impact
6/21/2021	Published the initial version of the RIA.	N/A
7/8/2021	Added the "Incomplete Status for Normals" feature Updated the GxP Risk of "Pending Approval Count for Normals" from Medium to Low Updated the description of "Show Form Links in Workbench" Renamed "Multi-role Security" as "Multi-role Security (Limited Release)"	The RIA now includes an up to date list of features for release in 21R2.
7/13/2021	Updated the Configuration of Support Multiple Site Selections in Review Plan Assignment Criteria from "EDC Tools" to "Vault Admin" and the Users with Day 1 Visibility from "Study Administrators" to none. Updated the description of Support Multiple Site Selections in Review Plan Assignment Criteria.	The RIA now includes up to date enablement and impact information.
7/21/2021	Renamed the "Migrations Product Toolkit" feature as "Migrations Product Toolkit: Loader (Limited Release)" and updated its description	The RIA now includes up to date feature names and descriptions.
7/29/2021	Updated the Impacts Clinical Study Team on Day 1 of Editable Grids from "Yes" to "No".	The RIA now includes up to date impact information.
8/26/2021	Updated the description for the "LMS Enhancements" feature to better communicate the scope of the feature.	The RIA now includes representative feature descriptions.

