



21R3 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: 10/18/2021

Revision Date: 12/6/2021

VIA Available: 11/8/2021

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	Actions for Repeating Item Groups	EDC	Sites			Medium	The following actions are now available for repeating Item Groups: Intentionally Left Blank, Unset Intentionally Left Blank, Reset Section/Row, and Remove Section/Unset Row.	Investigator, Sub Investigator, Clinical Research Coordinator
Yes	CQL Editor Enhancements	CDB	CDB Users			Low	With this release, we made the following enhancements to the CQL Editor: Workbench displays syntax highlighting for CQL. Users can expand or condense the CQL Editor panel. Users can open the CQL Editor in a separate browser window.	Data Manager, Lead Data Manager
Yes	Display Assigned Review Plan in the Review Tab	EDC	CRAs, Data Managers		Review Plan Assignment V1 & Later	Low	Users with permission to view SDV and DMR in the Review tab can now see which Review Plan is assigned as well as Form Review Plan overrides.	Clinical Research Associate, Data Manager, Lead Data Manager
Yes	Display Historical SDV & DMR Status when Requirement Mode is Set to No Review	EDC	CRAs, Data Managers		Review Rollup V2	Medium	Users can see the SDV or DMR review status when review is completed but then the requirement mode is set to No Review.	Clinical Research Associate, Data Manager, Lead Data Manager
Yes	Protocol Deviation Study Filter	EDC	CRAs, Data Managers, Study Administrators		Protocol Deviations	Low	Users can now filter the Protocol Deviation list by Study.	Clinical Research Associate, Data Manager, Lead Data Manager
Yes	Run Core Listings Job from the Review Tab	EDC	Study Administrators			Medium	Users with access to the Review tab and the "Manage Jobs" permission can run the Core Listings job directly from the Review tab.	Lead Data Manager
Yes	Send Long Narratives to Safety	EDC	Study Administrators			Medium	With this release, sites can enter up to 100,000 characters for the Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information (E2B ID H.1) field and 20,000 characters for the Reporter's Comments (E2B ID H.2) field on the SAE form, if those items have the appropriate lengths. Vault then includes the entirety of these field values in the XML file for transfer to the safety system.	Safety Administrator

Yes	Study Listings	EDC	Data Managers	EDC Tools		High	Users with access to EDC Tools, the "Manage Jobs" permission, and access to all sites will now be able to run the following new listings: - Subject Progress - Event Progress - Form Progress - Query Details	Lead Data Manager
Yes	Unsetting Intentionally Left Blank Restores Defaulted Data	EDC	Sites			Medium	When a user unsets the Intentionally Left Blank status of an Item, Item Group, or Form, any default data for repeating Item Groups is returned to its default state.	Clinical Research Coordinator, Investigator, Sub Investigator
No	Additional UI Filters for Listings	CDB	CDB Users			Low	Workbench users can now apply data type aware filters to listings directly from the listing grid. Data type aware filters include options to filter by the default unit for measured results, a date picker for date and datetime columns, and value selectors for both boolean and codelist defined columns.	Data Manager, Lead Data Manager
No	Allow Studio Users to Create Organizations, Studies & Collections	EDC	Librarians, Study Designers			High	Librarians or Study Designers with "All Study" access can now add their own collections or studies.	Librarian, Study Designer
No	Arms & Cohorts	EDC	Librarians, Study Designers	Studio	Expression Grammar V2	Medium	Study designers can create Subject Groups, which are used for dividing Subjects into arms and cohorts. Subjects are assigned groups via rules. This feature adds casebook variables for Arm, Cohort, and Substudy. Vault displays the subject's assigned group in EDC.	Librarian, Study Designer, Investigator, Sub Investigator, Clinical Research Coordinator
No	Audit Trail Export by Site	EDC	Study Administrators			High	Users can export the audit trail for an entire site by running the Audit Trail Export by Site job in EDC Tools.	Lead Data Manager
No	Audit Trail Export Filtering	EDC	Study Administrators			High	Audit Trail Exports generated from EDC Tools allow for optional filtering (date range and/or user filter) to limit the information included in the exported audit CSV files.	Lead Data Manager

No	Auto-increment Sequence Number	CDB	CDB Users			Medium	In the manifest file, the rowid key has changed from taking an array as value to taking an object with two properties called groupid and distinctid. The input for the groupid key is, as an array, user defined list of the columns from the CSV file, used to group records together in addition to Study, Site, Subject, and Event. The input for the "distinctid" key will also be an array where the input is a list of columns from the CSV file that will uniquely identify records from after the groups are defined.	Data Manager, Lead Data Manager
No	Batch Queries & Review	CDB	CDB Users			Medium	Within a listing, users can create, reply to, and close queries in batches. For review listings, users can set the status of records in bulk, including setting a new status, In Progress. All bulk actions can be applied on a per-page basis.	Data Manager, Lead Data Manager
No	Batch Upversioning Enhancements	Coder	Coder Administrators			Medium	In this release, we have made several enhancements to the Batch Upversioning experience, such as a more intuitive UI regarding the Upversioning of Forms or both Forms and Synonym Lists. If the Synonym List is Upversioning along with some but not all assigned Forms, Vault provides an option to assign a Synonym List to the assigned Forms that are not Upversioning.	Clinical Coder Administrator
No	CDB Deployments	CDB	CDB Users, Super Users	CDB		High	This feature provides the ability to deploy custom Listings and Views from a UAT environment to a production environment. Data managers and lead data managers can approve Listings and Views for deployments, and super users, or other users with the Manage Deployments permission, can create packages of listings or views and deploy them.	Data Manager, Lead Data Manager, Super User
No	CDB Usability Enhancements	CDB	CDB Users			Low	CDB users can pin columns to the left side of a listing so that those columns remain visible when scrolling horizontally. Users can resize the Query Details panel. Users can search and filter by the Source column.	Data Manager, Lead Data Manager

No	CDB Views	CDB	CDB Users			High	Workbench users can create Views, which are virtual tables based on the result set of a CQL statement. They can combine a View with other Views and Forms to create View Listings.	Data Manager, Lead Data Manager
No	Empty Form Link Indicator	EDC	Study Designers	Studio		Medium	"Warn When Empty" radio buttons have been added to the Form Link dialog so that users can choose to receive a warning if a form link is required. A "Warn When Empty" column has also been added to the Form Links grid in Studio, SDS, Diff reports, and the Link Definition object.	Clinical Research Coordinator, Investigator, Sub Investigator
No	Error Console Enhancements	EDC	Librarians, Study Administrators		Expression Grammar V2	Low	For each error listed in the Error Console, users can now view the associated rule's syntax and the entire error message in the Error Details dialog. They can also download the list of errors as a CSV file.	Lead Data Manager, Librarian
No	Extract Job Governor	EDC	Study Administrators			Medium	<p>The following rules have been implemented for running ad-hoc and scheduled extract jobs:</p> <p>An extract job can only be started if there is no other job of the same type already running</p> <p>Only two jobs of each extract type can be scheduled per study (two SDE jobs, two Form Progress Listings, etc.)</p> <p>Extract jobs of the same type have to be scheduled at least one hour apart.</p> <p>Jobs scheduled in non-production Vaults require a number of active periods to be selected, which is used to set an expiration date (ex: 5 active periods on a daily job means the job will run for 5 days). Once the scheduled job has reached its expiration date, it will no longer run and the user that scheduled the job will receive a notification.</p> <p>After a study is locked, scheduled jobs will continue running for 7 days and then expire. Ad-hoc jobs can still be run after a study is locked.</p>	Lead Data Manager

No	Include Full Hierarchy in Preview/Run Rules	EDC	Study Administrators, Study Designers, Librarians			Medium	The rule execution summary file now provides a full execution hierarchy.	Lead Data Manager, Study Designer, Librarian
No	Ingestion Audit Log	CDB	CDB Users			High	Workbench users can now access an audit log for ingestion and import from the Import > Audit Log page, where they can specify a date range and download the audit log as a CSV file. Note that the audit log begins recording events starting at the time of release.	Data Manager, Lead Data Manager
No	JDrug Suggestions & Upversioning	Coder	Coder Administrators, Coders			Medium	With this release, users are able to Upversion the JDrug dictionary to newer releases of JDrug. Users are also able to view an Impact Report, use the Propagate Code feature, and import/export a JDrug Synonym List.	Clinical Coder Administrator, Clinical Coder Manager
No	Key Manager	CDB	Super Users			Medium	Super users can now define custom key mappings of third party data points to definitions that exist in EDC. When a third party data source has different values from those in EDC in the import file, a key mapping between those two values allows import to occur without editing the source file.	Super User
No	Last Signed Date Tracking for Reports	EDC	Vault Administrators	Vault Admin	Data Model V2	Low	Vault now tracks the "Last Signed Date", which is updated to the current date and time each any time the "Sign" status field is updated to "Yes". To view this field in a report, the column must be added to a custom report.	Vault Administrator
No	Migration Environments	All		Support		High	Vault now supports the Migration environment type. Deployment administrators can deploy to Migration environments from Development.	Lead Data Manager, Librarian, Study Designer, Deployment Administrator
No	Migration UI Enhancements	Migration	Vault Administrators		Migrations	Medium	Migration users will now have a new "Post-Run Actions" menu that they can use to manage their usage of specific features in the post-run stage, such as form submission, in addition to new friction that has been added for any load/stage/run operations linked to a Production type target environment.	Vault Administrator

No	New Aggregate Functions	EDC	Librarians, Study Designers		Expression Grammar V2	Medium	With this release, we added the following functions for use with aggregate identifiers: IsAnyBlank Count CountIf NoBlanks AllEqual GetAllMatches	Librarian, Study Designer
No	New Subject Statuses to Align with CTMS	All	Study Designers, Librarians			Medium	In this release, we've added new subject statuses to align with Vault CTMS. These statuses are available for use in CDMS and will export on the SYS_SUB dataset in the SDE. The new statuses include the following: Consented Started Treatment Started Follow Up Lost to Follow Up	Librarian, Study Designer
No	Post-load Form Status Selection	Migration	Vault Administrators		Migrations	Medium	Migration users can now select a Form Status to apply to Forms when those Forms are fully migrated into EDC.	Vault Administrator
No	Previous/Next Identifiers for Repeating Event Groups, Forms & Item Groups	EDC	Study Designers, Librarians		Expression Grammar V2	Medium	Studio now supports using [-1] (previous) and [+1] (next) to indicate that an identifier should resolve to the previous or next value of that identifier, for repeating Event Groups, Forms, and Item Groups.	Librarian, Study Designer
No	Progressive Display Enhancements	EDC	Librarians, Study Designers		Rules V2	Medium	Studio users can configure the progressive display of multiple Items or Item Groups from a single dialog on the controlling Item. Vault now also indicates whether an Item is the controlling Item and displays both controlling and dependent definitions in the Properties panel.	Librarian, Study Designer
No	Review & Query Dashboards	CDB	CDB Users			Medium	The new Dashboards page displays summary information for each review listing, including record counts and status summaries. The query charts display status and subject summary information for all queries in the study. Each grid and chart provides the user the ability to drill down and take action on any outstanding review issue or query.	Data Manager, Lead Data Manager

No	Rule Syntax Enhancements	EDC	Librarians, Study Designers		Expression Grammar V2	Medium	<p>This release includes the following enhancements to rule syntax:</p> <p>For Send Email rules, Vault now supports the <code>has_value_changed__v</code> attribute on the Item identifier. This attribute returns true if the value of the identified Item has changed since the previous form submission.</p> <p>Vault now supports the <code>submit_counter__v</code> attribute on <code>@Form</code> identifiers and fully-qualified form identifiers. This attribute returns the number of times the identified Form has been submitted.</p> <p>Vault now supports the <code>previous_submit_value__v</code> attribute on fully-qualified item identifiers.</p> <p>Vault now supports the <code>intentionally_left_blank__v</code> and <code>change_reason__v</code> attributes on fully-qualified identifiers. The <code>intentionally_left_blank__v</code> attribute returns true if the identifier was marked as intentionally left blank. The <code>change_reason__v</code> attribute returns the Change Reason applied to the most recent modification of the identifier.</p>	Librarian, Study Designer
No	Safety Link Support for External Labs	EDC	Study Administrators	EDC Tools		Medium	Users can map an external, unscheduled Labs Form Definition in Safety Configuration and have it included in the E2B XML.	Safety Administrator
No	SDE: Add Additional Columns to System Datasets	EDC	Study Administrators	EDC Tools	Available to users with access to EDC Tools and the "Manage Jobs" permission.	Low	In this release, additional columns will be added to the following System Datasets: SYS_EVT, SYS_FORM, SYS_ILB, SYS_Q.	

No	SDE: General Enhancements	EDC	Study Administrators	EDC Tools	Available to users with access to EDC Tools and the "Manage Jobs" permission.	Low	This feature provides the following general enhancements to the SDE: Included information in the Job History grid about which SDE version and options were selected Improved naming consistency across the key clinical data columns and system dataset columns Added arms and cohorts fields to the SYS_SUB dataset Added new subject statuses date columns to the SYS_SUB dataset Added Item Definition Name and Analyte Name columns to the SYS_ILB dataset Added Last Signature Date to the SYS_FORM dataset Improved consistency in coding column headers by removing spaces Sanitized the SDE and Study Listings default file name to replace non alpha-numeric characters with an underscore	
No	SDE: Versioning	EDC	Study Administrators	EDC Tools	Available to users with access to EDC Tools and the "Manage Jobs" permission.	Low	This feature allows users to select which version of the SDE they want to run. Each version may contain a different set of datasets, columns, or other changes.	
No	Send Coding to Safety	Coder, EDC	Study Administrators			Medium	Vault CDMS includes the assigned code's LLT in the E2B XML to the safety system.	Safety Administrator
No	Send Treatment Form to Safety	EDC	Study Administrators	EDC Tools		Medium	Safety administrators can configure their Study to send any linked Treatment Forms with the Safety Case to the safety system. If a Treatment Form of each Treatment Form Definition is marked as Administered to Subject and the Start Date is before the SAE's Start Date, then Vault includes it in the Safety Case.	Safety Administrator
No	Set Subject Status Date to Randomization Date	EDC, EDC (Randomization)	Study Designers	Studio	Randomization is enabled.	Medium	Users now have the option to set the subject status change date to "Randomize Date" in the Set Subject Status actions section in the Rule Editor.	Study Designer
No	Show Course Completion in the Training Report	All	Vault Administrators	Vault Admin	Veeva Learning Integration	High	Vault now tracks the individual training courses associated with training curricula. The completion of these courses is shown in the training report.	Lead Data Manager, User Administrator, Vault Administrator

No	Study Role Enhancements	All	Study Administrators, User Administrators			High	<p>With this release, we made the following permissions to standard Study Roles:</p> <p>Added the Browse View (CDB) permission (assigned to the CDMS Data Manager, CDMS Lead Data Manager, and CDMS Super User roles)</p> <p>Added the Create View, Modify View, Delete View, and Manage Key Mappings (CDB) permissions (assigned to the CDMS Super User role)</p> <p>Added the Manage Study Priority permission (assigned to the CDMS Super User and CDMS Lead Data Manager roles)</p> <p>Assigned the View Casebook permission to the CDMS Clinical Research Associate role</p> <p>Renamed Manage Study Deployments as Manage Deployments</p> <p>The Manage Randomization List permission now requires All Sites access</p>	Lead Data Manager, User Administrator
No	Support for Migration of Restricted Data	Migration	Vault Administrators		Migrations	High	The Migrations module now supports the migration of restricted data into EDC. Migrated data uses the same restricted data functionality as restricted data collected in EDC.	Vault Administrator
No	Validate YAML for UTF-8 Character Set	Migration	Vault Administrators		Migrations	Low	The Migration tool will have additional automated checks to determine whether the source files are UTF-8 compliant and will let users know of any issues via the validation statuses.	Vault Administrator
No	Validation Environments	All	Study Administrators, Study Designers, Librarians			High	Vault now supports the Validation environment type. Deployment administrators can deploy to Validation environments from UAT.	Deployment Administrator, Lead Data Manager, Study Designer, Librarian

No	Veeva Learning Integration Enhancements	All	Study Administrators, User Administrators		Veeva Learning Integration	High	<p>This release includes the following enhancements to the Veeva Learning integration:</p> <p>User administrators can now assign training to users with Access to All Studies (vault-wide users) and users with Access to All Study Environments (study-wide users).</p> <p>When updating the Curriculum to Role Mapping for a Study Environment, users can now copy their changes to the mapping to one or more Studies.</p> <p>Users can now generate the training report across one or more Studies from System Tools > Users. The training report has been updated with additional columns to provide a more complete picture of training progression.</p>	Lead Data Manager, User Administrator
----	---	-----	---	--	----------------------------	------	---	---------------------------------------

Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: 10/18/2021

Date	Description	Impact
10/11/2021	Published the initial version of the RIA.	N/A
10/25/2021	Renamed "Progressive Display of Forms" as "Progressive Display Enhancements" Updated the Description for "Study Role Enhancements" and "Progressive Display Enhancements" Added the "Rule Syntax Enhancements" feature	The RIA now includes an up to date list of features for release in 21R3.
11/2/2021	Renamed "Pin Columns in Listings" as "CDB Usability Enhancements" and updated its description Updated the description for "Study Role Enhancements" Added Dependencies for "Display Historical SDV & DMR Status when Requirement Mode is Set to No Review" and "Last Signed Date Tracking for Reports"	The RIA now includes up to date feature names, descriptions, and dependencies.
11/18/2021	Added the "Protocol Deviations Study Filter" and "Migration UI Enhancements" features Updated the "Impacts Clinical Study Team on Day 1" for "Run Core Listings Job from the Review Tab" Updated the "Training Impact", "Users with Day 1 Visibility", and "Impacts Clinical Study Team on Day 1" for "Extract Job Governor" Updated the "Description" for "Ingestion Audit Log"	The RIA now includes an up to date list of features for release in 21R3.
11/22/2021	Updated the "Description", "Users with Day 1 Visibility", and "Training Impact" for the "CDB Deployments" feature	The RIA now includes up to date information about this feature's visibility.

