



20R2 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: 6/22/2020

Revision Date: 8/26/2020

VIA Available: 8/3/2020

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 Veeva Docs 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:	Indicates whether the feature is available automatically, requires some configuration, or must be enabled by Veeva Support.
<i>Auto-on</i>	This feature is available automatically in its application area.
<i>By Study Build</i>	The options to configure this feature display automatically, but it must be configured as part of a study to be visible to other users.
<i>Study Feature Flag</i>	This feature must be enabled on each study's configuration by Veeva Services.
<i>Support</i>	This feature must be enabled by Veeva Support.
Impact to Sites:	If Yes, depending on your vault and study configuration, this feature may impact site users (investigators and clinical research coordinators) upon release.
Impact to Sponsors:	If Yes, depending on your vault and study configuration, this feature may impact sponsor users (data managers and clinical research associates) upon release.
Impact to Coders:	If Yes, depending on your vault and study configuration, this feature may impact coding users (clinical coders and coder administrators) upon release.

Application	Impacted Areas	Name	Risk	Enablement	Training Impact	Impact to Existing Studies	Impact to Sites	Impact to Sponsors	Impact to Coders	Description
All	Data Entry, Data Review, Assessments, Study Design & Configuration, Study Administration	Restricted Data	High	By Study Build *Only in studies created after the 20R2 release	User Administrator, Data Manager, Clinical Research Coordinator, Sub Investigator, Clinical Research Associate, Assessment Reader, Investigator, Lead Data Manager, Study Designer, Assessment Editor	No Study designers must first configure restricted Forms for this feature to affect a study.	No	Yes	No	Study designers can configure certain Form Definitions as restricted. During the course of the study, these Forms will only be visible to unblinded users with permission to view restricted data.
All	Data Entry, Data Review, Study Design & Configuration	Future Date Queries on Event Dates	Medium	By Study Build	Sub Investigator, Clinical Research Associate, Data Manager, Investigator, Lead Data Manager	No A study designer must configure an Event to use the future date check.	No	Yes	No	Study designers can now choose to have Vault generate a system query when an Event Date is in the future via the Future Date property on the Event Definition.
All	Data Entry, Data Review, Study Design & Configuration	Out of Range Event Date Queries	Medium	By Study Build *In studies created after the 20R2 release	Sub Investigator, Clinical Research Associate, Data Manager, Investigator, Lead Data Manager	No A study designer must configure a Study for this feature.	No	No	No	Studio users can configure the Event Window for an Event so that Vault will create system queries if the Event is outside the window.
All	Deployments, System Tools	New System Tools Area & Enhancements to Vault-level Deployments	Medium	Auto-on *In vaults where Role by Study and Automatic Deployments are enabled	User Administrator, Deployment Administrator, Lead Data Manager	Yes Users with appropriate access will see the new System Tools area immediately.	No	Yes	No	Users can manage vault-level configurations from the new Tools > System Tools tab, including custom Study Roles (moved from Tools > Role Management), custom objects on the deployment whitelist, custom Change Reasons, and external connections. Deployment administrators can also deploy these configurations from vault to vault within System Tools, or



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										as part of a study deployment package. This feature introduces support for Change Reasons, Reports, and Dashboards to deployments.
All	Study Administration	Data and Definition Export	High	Auto-on	User Administrator	Yes The changes to this job apply immediately following the release.	No	Yes	No	This feature renamed the JReview Listing job as Data & Definition Export. The export output now includes the External ID and SDTM name, when available, and is more machine readable. The job can be configured to include restricted data if the user has the ability to access it.
All	System Tools, Study Administration, Study Design & Configuration	Template Vaults	Medium	Support *In Studies using the automatic deployment model	Vault Administrator, Deployment Administrator, Study Designer	No Organizations must work with Veeva to create a library vault.	No	No	No	Customers can request a separate vault or set of vaults to use as a “template”. In the template vault, an organization can create and manage a set of standards for study design. Then, study designers can copy from these standards when designing their own studies, without having to copy from a vault that is a part of their standard set of environments (development, UAT, training, and production).
All	System Tools	Vault Difference Report	Medium	Auto-on *In vaults where Role by Study and Automatic Deployments are enabled	Vault Administrator, Deployment Administrator, Lead Data Manager	Yes This report is available automatically.	No	Yes	No	Users with access to System Tools may compare the vault-level configuration of two vaults, including custom objects, change reasons, custom study roles, reports, dashboards, and user managed groups.
Coder	Coding	Reconstitute Code Requests Job Now Autocodes Any Updates	Medium	Auto-on	Clinical Coder Administrator, Study Designer	No Study designers must first update Coding Configuration in a way that requires the Reconstitute Code Requests job for this to apply.	No	No	Yes	When a user runs the Reconstitute Coding Job, the system will now attempt to Autocode all the Coding Requests that have been created or updated as part of the job.
Coder	Coding	Upversioning Impact Report	Medium	Auto-on	Clinical Coder Administrator	Yes This report is available automatically.	No	No	Yes	With this release, we are providing an Upversioning Impact Report so that users may preview the upversioning impact before committing to it.



Application	Impacted Areas	Name	Risk	Enablement	Training Impact	Impact to Existing Studies	Impact to Sites	Impact to Sponsors	Impact to Coders	Description
										Users can generate an Impact Report for any Form or Synonym List.
Coder	Coding	Coder UI Enhancements	Low	Auto-on	Study Designer	Yes These changes are automatically visible to Coder users.	No	No	No	In this release, we've added a link to the help page so that Study Designers can follow step-by-step instructions to configure the Copy Indication from Link feature. We have also added breadcrumbs to improve user coordination and navigation.
Coder	Coding	Group Mode Coding Enhancements	Low	Auto-on	Clinical Coder	Yes Coder users will see these changes immediately following the release.	No	No	Yes	Coding very large groups can take the system some time. To this end, we display in-progress indicators where needed and allow users to carry on other tasks.
Coder	Coding	Nudge User to Chrome™ Browser in Coder	Low	Auto-on	Clinical Coder, Clinical Coder Administrator	Yes Users not using Chrome™ will see this notification.	No	No	Yes	Users who use a browser other than Google Chrome™ will receive a notification recommending that they switch to the Chrome™ browser.
Coder	Reports & Dashboards	Lead Data Managers & Data Managers Can View Coding Data in Reports & Extracts	High	Auto-on	Lead Data Manager, Data Manager	Yes Users with these Study Roles will automatically see new reporting data.	No	Yes	No	Users with the CDMS Lead Data Manager, EDC Lead Data Manager, CDMS Data Manager, and EDC Data Manager study roles can now view Coding data in configured Reports and Dashboards.
Coder, EDC	Study Administration, Study Design & Configuration	Relaxed Study Update Restrictions	Medium	Auto-on	Deployment Administrator, Lead Data Manager, Study Designer	No Study designers must make these changes on a new version for this feature to affect existing studies.	No	Yes	No	We relaxed restrictions on study updates after the initial version. The following changes are now allowed: <ul style="list-style-type: none"> - Users can edit or delete Default Data for Item Groups. - Event Groups, Forms, and Item Groups can be moved non-repeating to repeating. - Events and Forms can be moved from non-dynamic to dynamic.
Coder, EDC	Study Design & Configuration	Copying a Form also Copies Coding Configuration	Medium	Auto-on	Study Designer	No Study designers must copy a Form to see this change.	No	Yes	No	When a study designer copies a Form, Vault also copies that form's Coding Configuration.
EDC, Coder	Study Design & Configuration	SDS Enhancements	Medium	Auto-on	Study Designer	Yes Study designers will see these	No	Yes	No	SDS enhancements added in this release include:



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						enhancements the next time they generate the SDS.				<ul style="list-style-type: none"> - New Review Plan tab - New Assessments tab - New columns in Rules tab - Bug fixes for length and override labels - Dynamic rules listed in Schedule tab - Item Group layout options listed on Form Definitions
Coder, EDC	Study Design & Configuration	Study Difference Report Enhancements	Medium	Auto-on	Study Designer	Yes Study designers will see these enhancements the next time they compare casebook versions.	No	Yes	No	Diff Report enhancements include adding a number of categories to the report summary, including build number and whether or not to include or exclude Event Groups and Events, Order, Rules, Views, Study Settings, Coding Configuration, and Review Plans. A UAT Validation script has also been added for Rules.
Data Workbench	Workbench	Coded Terms in Workbench	Medium	Auto-on *In vaults using the Vault Coder application	Lead Data Manager	Yes Listings for Forms using Vault Coder will show these new columns after the release.	No	Yes	No	Vault includes coded term information for EDC Forms using Vault Coder in the Workbench Export package.
Data Workbench	Workbench	Listing Cell Details Panel	Medium	Auto-on	Lead Data Manager	Yes This panel is available on all new and existing listings.	No	Yes	No	Users can open the Cell Details panel to view additional context and details about a listing cell, such as its review status and signature state, as well as open a query on that data item without leaving the listing context.
Data Workbench	Workbench	Listing Cell Highlighting	Medium	Auto-on	Lead Data Manager	Yes These highlights display automatically on all listings.	No	Yes	No	Workbench will show a visual indicator for Items and Forms marked as Intentionally Left Blank, an Item has a query, or if the Event was marked as Did Not Occur.
Data Workbench	Workbench	View & Edit Listing Properties	Medium	Auto-on	Lead Data Manager	Yes Workbench users will be able to view and edit the properties of existing listings after the release.	No	Yes	No	Workbench users can view and edit the properties of their listings.
Data Workbench	Workbench	View Import Packages in Workbench	Medium	Auto-on	Lead Data Manager	Yes Workbench users may view their import package status	No	Yes	No	With this release, users can review all import packages (both EDC and third party) and



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						immediately.				their import progress from the new Import > Packages page
Data Workbench	Workbench	Workbench Data Export	Medium	Auto-on	Lead Data Manager	No Workbench users must create Export Definitions to use this feature.	No	Yes	No	Workbench users can create Export Definitions, which represent a collection of listings for export. Then, they can generate and download these export packages (ZIP).
Data Workbench	Workbench	Enhanced Scheduling for 3rd Party Import	Low	Auto-on	Lead Data Manager	No A Workbench user must update their import manifest file to use this feature.	No	Yes	No	Workbench users can now choose to match on External ID, Name, or Event Date when importing third party data. They can also choose to not match to any EDC Events and have Workbench create new Event Definitions for each Event in the import package.
Data Workbench	Workbench	New Functions for CQL	N/A	Auto-on	Lead Data Manager	No A Workbench user must create or edit a CQL statement to use these new functions.	No	Yes	No	Clinical Query Language (CQL) now supports the following functions: Union(), UnionAll(), Pivot(), and UnPivot(). As part of this feature, repeating Item Groups are now supported within all CQL functions.
Data Workbench	Workbench	Wide & Compact CQL Results	N/A	Auto-on	Lead Data Manager	No Workbench users must create or edit custom listings using the new CQL keywords.	No	Yes	No	Users can arrange data items in a wide or compact format. Wide format means that every data item is returned in its own column for every form or item group it was collected in (in the context of the CQL statement). Compact format means that a data item's results are presented in a single column, regardless of which form or item group it was collected in. This can be useful for comparing item values.
EDC	Data Entry, Data Review, Assessments, Study Design & Configuration, Study Administration	Translatable PDFs	Medium	Auto-on	N/A	Yes The next PDF exported for a Study will be translatable.	No	No	No	With this release, all PDF strings generated by Vault are translatable and include translation support for CJK characters. PDFs included in this feature include Detail PDFs, Blank PDFs, Annotated PDFs, and Clinical Assessment PDFs.
EDC	Data Entry	Changed Handling	Medium	Auto-on *In	Sub	No This change only	Yes	No	No	If a dynamic Form contains



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		of Dynamic Form Removal		studies created after the 20R2 release	Investigator, Investigator, Clinical Research Coordinator	applies to studies created after the 20R2 release.				data, and the controlling Item is edited in such a way that the Form should be removed, Vault now shows a banner on the Form indicating that it isn't required. Upon reset, Vault automatically removes the Form from the Casebook.
EDC	Data Entry, Data Review	Updates to Subject Deletion	High	Auto-on *This applies to all existing and new studies.	N/A	Yes Users will see these changes the next time they delete a subject.	Yes	Yes	No	When deleting subjects, users no longer need to reset all events prior to deletion, as Vault automatically deletes all data alongside the Subject. Users must now also type "DELETE" following reason selection.
EDC	Data Entry, Data Review	Enablement Change: Removed Review Functionality from Data Entry	Low	Auto-on	Clinical Research Associate, Lead Data Manager, Data Manager	Yes All Studies now have the Review tab enabled and can no longer perform review tasks in the Data Entry tab.	No	Yes	No	With this release, we enabled the Review UI for all vaults and removed all data review functionality from the Data Entry tab.
EDC	Data Entry, Data Review, Reports & Dashboards	Freeze/Lock/Sign Propagation Updates	High	Auto-on *Only in studies created after the 20R2 release	Clinical Research Associate, Data Manager, Investigator, Lead Data Manager	Yes Users will see these status propagation changes the next time they freeze, lock, or sign a record.	Yes	Yes	No	This feature completes the migration of the rest of the Review tasks (e.g. Freeze, Lock and Signature) off of the execution objects (e.g. Item, Item Group, Form, Event, Casebook) and to the Review State objects. The signature status of Forms and Event Dates will be stored on the Signature State object which will eliminate the need to propagate the signature up and down the execution record hierarchy. This feature also introduced several new standard report templates.
EDC	Data Entry, Reports & Dashboards, Study Administration, Study Design & Configuration	Study Closeout PDFs	High	By Study Build *In vaults where Role by Study is enabled	Investigator, Lead Data Manager, Study Designer, Clinical Research Coordinator	No A study designer must create a new Signature Definition and a lead data managers must initiate the closeout process from EDC Tools.	Yes	Yes	No	Lead data managers can generate closeout PDFs for locked sites, send them to a site for review, and track the review status. Site users can download the closeout PDF and either accept or reject it.
EDC	Data Entry, System Tools	Change Reasons for Event Reset	Medium	Auto-on	Sub Investigator,	Yes Users will be prompted to select a	Yes	Yes	No	Data entry users must now select a Change Reason when



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					Investigator, Lead Data Manager, Clinical Research Coordinator	reason during event reset, but an organization must configure custom reasons to use them.				resetting an Event. An organization can define custom reasons for this action from System Tools > Change Reasons. As part of this feature, when resetting an Event, the user must type "RESET" in an additional confirmation dialog.
EDC	Data Review	Enhanced SDV/DMR Review Plans	Medium	By Study Build *In studies created after the 20R2 release	Lead Data Manager	No A lead data manager must configure assignment criteria.	No	Yes	No	Source Data Verification will be driven by Subject Status and can be applied to a subset of subjects. You can provide multiple parameters for identifying subjects for verification. For a given Review Task, Review Plan Assignment criteria can be defined by Study Country, Study Site, Subject Status, or any combination of the three. You can also specify a minimum number of subjects or minimum percentage of subjects for assignment.
EDC	Data Review	Improved Review Navigation	Low	Auto-on	Clinical Research Associate, Lead Data Manager, Data Manager	Yes The changes to the Review tab display automatically to all users who can access it.	No	Yes	No	In this release, the Review is divided into two tabs: "Review > My Studies" and "Review > My Study Sites".
EDC	Data Review, Study Design & Configuration	Data-driven Review Plans	Medium	By Study Build *In studies using version 2 of the expression grammar	Clinical Research Associate, Data Manager, Lead Data Manager, Study Designer	No Study designers must create a new rule using the Override Review Plan action.	No	Yes	No	Studies can use the new Override Review Plan rule action type to assign a chosen Review Plan to a Form based on user-entered data.
EDC	Study Administration	Study Role Enhancements	High	Auto-on *In vaults where Role by Study is enabled	User Administrator, Lead Data Manager	Yes Changes to standard Study Roles apply automatically in all vaults where Role by Study is enabled.	No	Yes	No	Functional enhancements to Study Roles include the following: - Manage Review Plan grants the ability to execute jobs. - The Assign Code, Design Study, Manage Sites, or Manage Review Plan Assignment permissions automatically grant access to all Study Sites. - Standard Study Roles that are



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										assigned the Edit Form Linking permission are now assigned the View Form Linking permission automatically.
EDC	Study Administration	Allow for Deletion of Sites	Low	Auto-on	Lead Data Manager	No Lead data managers must delete a Site for this change to apply.	No	Yes	No	This feature allows the user to delete sites in EDC Tools in environments other than production.
EDC	Study Design & Configuration	Date Comparison Configurator	High	By Study Build	Study Designer	No Study designers must create new rules using this feature.	No	Yes	No	Study designers can easily create Rules that compare two values using the new Comparison Rules editor, without having to write a rule expression.
EDC	Study Design & Configuration	Cascade Delete for Forms	Medium	Auto-on	Study Designer	No Study designers must delete a Form to see this change.	No	Yes	No	When deleting a Form, study designers can choose to delete the form's related design definitions (item groups, items, codelists, and units).
EDC	Study Design & Configuration	Copy Codelists & Units from Another Study	Medium	Auto-on	Study Designer	No Study designers must initiate the copy process to copy any records.	No	Yes	No	Study designers can copy Codelists and Units from other studies they have access to, instead of creating them in each study.
EDC	Study Design & Configuration	Casebook Variables for Rules	Medium	By Study Build	Study Designer	No Study designers must edit existing rules or create new ones	No	Yes	No	Study designers can reference certain casebook-level variables when writing rule expressions.
EDC	Study Design & Configuration	Reference Sequence Number in Rule Expressions	Medium	By Study Build *In studies using version 2 of the expression grammar	Study Designer	No Study designers must edit existing rules or create new ones to utilize this feature.	No	Yes	No	With this release, study designers can reference the Sequence Number of a repeating Event Group, Form, or Item Group when writing a rule expression. This allows rules to only evaluate on certain instances of an Event Group, Form, or Item Group.



Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: 6/22/2020

Date	Description	Impact
6/22/2020	Published the initial version of the RIA.	N/A
7/2/2020	Removed the "Disable Vault Create Button on CDMS Application Pages" feature and added the "Listing Cell Highlighting" and "View & Edit Listing Properties" features.	The RIA now includes an up to date list of features for 20R2.
7/8/2020	<p>Updated the name and description of the "Library Vaults" feature to "Template Vaults"</p> <p>Updated the enablement notes related to new study availability limitations and data model 2.0 to "Only in studies created after the 20R2 release" on the "Restricted Data", "Remove Frozen & Locked Status Propagation", "Remove Signature Propagation", "Casebook Variables for Rules", and "Comparison Rules". The enablement settings for these features are unchanged.</p> <p>Updated the Impacted Application Areas and Descriptions of the "Remove Signature Propagation" and "Remove Frozen & Locked Status Propagation" features to include that these features introduced new standard report templates.</p>	The RIA now includes up to date feature names, enablement notes, and information about impacted application areas.
7/9/2020	Renamed the following features: "Site Review Plan by Subject Percentage" to "Enhanced SDV/DMR Review Plans", "Review UI Enhancements" to "Improved Review Navigation", "Override the Review Plan for a Form Using Rules" to "Data-driven Review Plans", and "Comparison Rules" to "Date Comparison Configurator"	The RIA now includes up to date feature names.
7/14/2020	Added the "Change Reasons for Event Reset", "Changed Handling of Dynamic Form Removal", and "Updates to Subject Deletion" features. Renamed the "Event Matching on External ID for 3rd Party Import" feature as "Enhanced Scheduling for 3rd Party Import" and updated its description.	The RIA now includes an up to date list of features for 20R2.
7/20/2020	Consolidated the Removed Frozen & Locked Status Propagation and Removed Signature Propagation features into Freeze/Lock/Sign Propagation Updates.	The RIA now includes an up to date list of features for 20R2.



7/23/2020	Added the "Coded Terms in Workbench " feature and updated the VIA Availability Date from 7/27 to 8/10.	The RIA now includes an up to date list of features and up to date availability dates.
7/24/2020	Updated the VIA Availability Date from "8/10" to "8/3"	The RIA now includes the latest date for VIA availability.
7/30/2020	<p>Updated the enablement and impact to existing studies of Study Closeout PDFs from "Auto-on" to "By Study Build". Updated the enablement of Casebook Variables for Rules and Date Comparison Configurator to remove the note that these features are only available for new studies.</p> <p>Split the Event Date Query Enhancements feature into two separate items, Out of Range Event Date Queries and Future Event Date Queries, as the Out of Range Event Date Queries feature is only available to studies created after 20R2.</p>	The RIA now includes up to date availability and enablement settings for 20R2.
8/5/2020	Updated the enablement of "Enhanced SDV/DMR Review Plans" from "Study Feature Flag" to "By Study Build *In studies created after the 20R2 release", as well as its impact on existing studies. This feature is not available for studies created after the 20R2 release.	The RIA now includes up to date availability and enablement settings for 20R2.
8/17/2020	Added the "Listing Cell Details Panel" feature and updated the description of the "Coded Terms in Workbench" feature.	The RIA now includes an up to date list of features and descriptions for 20R2.
8/21/2020	Updated the Training Impact of "Updates to Subject Deletion" to "N/A", as no standard Study Roles have permission to delete subjects.	The RIA now includes up to date Training Impact.
8/26/2020	Updated the description for the "Coded Terms in Workbench" feature to clarify the scope of the feature.	The RIA now includes up to date feature descriptions.

