



20R3 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: 10/23/2020

Revision Date: 11/17/2020

VIA Available: 11/23/2020

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.

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|----------------------------|--|
| 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, Study Administration | Veeva Learning Integration Enhancements | High | Auto-on *In studies where the Veeva Learning Integration is enabled | Sub Investigator, User Administrator, Investigator, Lead Data Manager, Clinical Research Coordinator | Yes Studies using the Veeva Learning Integration will see these changes automatically. | Yes | Yes | No | This release includes the following enhancements to the Veeva Learning Integration: 1.) Training status is displayed on the Study listings page. 2.) Lead data managers can copy the role to curriculum mapping from another study. 3.) Lead data managers can delete learning systems from EDC Tools. |
| All | Study Administration | User Management Enhancements | High | Auto-on | User Administrator, Lead Data Manager | Yes Users with role and user management permissions will see these changes. | No | Yes | No | This release includes the following user management enhancements: 1.) We added the new API Access permission to control API access, which is assigned to the CDMS Lead Data Manager and the CDMS Data Manager roles. 2.) All study roles that are assigned the Manage Study Site permission are now automatically assigned Manage Study Countries. 3.) The Manage Review Plan Assignment permission no longer requires the Manage Study Sites permission. 4.) We added the ability to filter the Role Management table by All Roles or Active Roles. 5.) We added a new Study Role column to the user listing in EDC Tools > Users. |
| All | N/A | Upgrade a Study from Data Model Version 1 to Version 2 | High | Support | Vault Administrator | No -- | No | No | No | Organizations may work with their Veeva Services representative to upgrade their Study from Data Model Version 1 to Data Model Version 2. |
| All | System Tools | Manage the Deployment List for | Medium | Auto-on | Deployment Administrator | No -- | No | Yes | No | Deployment administrators can now add custom roles, object |



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| | | Custom Roles, Object Tabs, Reports & Dashboards from System Tools | | | | | | | | tabs, reports, and dashboards to the deployment list from within System Tools, without needing to access Business Admin. With this feature, deployments can now include custom object tabs. These no longer need to be manually configured in each vault. |
| Coder | Coding | Site & Subject Search for Coder | Medium | Auto-on | Clinical Coder, Clinical Coder Administrator | Yes Coders will see these new filters automatically. | No | Yes | Yes | Coders can now filter the Code Request listing by Site and Subject. When in Group mode, the Code Request listing no longer displays the Queries, Notes, and Age (D) columns. |
| Coder | Coding, Reports & Dashboards | Simple Autocoding Attribution | Medium | Auto-on | Clinical Coder, Clinical Coder Administrator | No -- | No | Yes | Yes | The Code Request object now stores the autocoding source, which can be either the Dictionary or the Synonym List. If the request was autocoded from the synonym list, then the Code Request record stores the name of the Synonym List and the reference to the Synonym. |
| Coder | Coding Administration | Batch Upversioning | Medium | Auto-on | Clinical Coder Administrator | No -- | No | No | Yes | A coding administrator can upversion all Forms bound to the same Synonym List with a single action, instead of one by one. |
| Coder, EDC | Coding, Coding Administration | Third Party Coding Support | Medium | Auto-on | Clinical Coder, Clinical Coder Administrator | No -- | No | Yes | Yes | CDMS now supports the clinical coding of EDC data in a third party system. Coding administrators can configure a study such that Code Requests are created both in Vault Coder and the third party system, allowing CDMS users to view requests while coders complete their work in the other system. |
| Coder, EDC | Coding Administration, Study Design & Configuration | Coding Administrators Select Dictionary Version & Coding Methods | Medium | Auto-on | Clinical Coder Administrator, Study Designer | No -- | No | Yes | Yes | While Studio will continue to be the location where we define "what to code", it's no longer where organizations define "how to code". Coding administrators must define the Dictionary Release, Synonym List, Do Not Autocode List, and Coding Method for each Form |



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| | | | | | | | | | | in Coder Tools. As part of this feature, we renamed the Application Settings subtab as Default Study Settings in Coder Tools. |
| CDB | Workbench | Enhancements to 3rd Party Data Import | Medium | Auto-on | Lead Data Manager, Data Manager | No -- | No | Yes | No | Third party data import supports the ordering of Item Groups in resulting core listings, includes headers as columns in core listings, and additional ISO8601 date formats. |
| CDB | Workbench | Export Definition Status Enhancements | Medium | Auto-on | Lead Data Manager, Data Manager | Yes Users will see the new status indicators right away. | No | Yes | No | Users can now mark an export listing as ready. Once all listings within an export definition are in the Ready status, Workbench moves the Export Definition from Draft into the Published status. |
| CDB | Workbench | Raw Export Type | Medium | Auto-on | Lead Data Manager, Data Manager | No -- | No | Yes | No | This feature adds the Raw type for Export Definitions, which exports listings and system data sets in a raw format. |
| CDB | Workbench | Review Data from Listings | Medium | Auto-on | Lead Data Manager, Data Manager | Yes Users will see these new options on listings right away. | No | Yes | No | Users can mark forms as reviewed from listings and add comments to indicate when there is a known issue. Users can then filter their listings on Review status, as well as queries, ILB, Did Not Occur, Overdue visits, and data not entered. |
| CDB | Workbench | Schedule & Deliver Export Packages | Medium | Auto-on | Lead Data Manager, Data Manager | No -- | No | Yes | No | Users can schedule the recurring generation of an export package. |
| CDB | Workbench | Support Queries as Listings | Medium | Auto-on | Lead Data Manager, Data Manager | No -- | No | Yes | No | Workbench users may now create listings to display query information. These listings can be used in export packages. |
| CDB | Workbench | CDB Support for Data Model Version 2 | Medium | Configuration | Lead Data Manager, Data Manager | No -- | No | Yes | No | Vault CDB now supports Data Model Version 2. |
| CDB | Workbench | Email Notifications for 3rd Party Data Import | Low | Auto-on | Lead Data Manager, Data Manager | Yes Users will receive a notification the next | No | No | No | Workbench now sends an email notification when third party data import finishes. |



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| | | | | | | time they import data. | | | | |
| CDB | Workbench | Manifest File for Export Packages | Low | Auto-on | Lead Data Manager, Data Manager | Yes Any export packages generated after the release will contain a manifest file. | No | Yes | No | Export packages now include a manifest file (manifest.json) that describes the contents of the package. |
| CDB | Workbench | Open a Query in EDC's Review Tab | Low | Auto-on | Lead Data Manager, Data Manager | Yes Users will see the link on queries after the release. | No | Yes | No | For each query on EDC data, CDB now displays a link to view the query in EDC's Review tab. |
| EDC | Data Review, Study Administration, Study Design & Configuration | Query Team Restrictions | Medium | By Study Build | Clinical Research Associate, Data Manager, Lead Data Manager, Study Designer | No -- | No | Yes | No | Lead data managers can define groups of roles, or query teams, that can interact with certain types of queries. This feature introduces the Close All Queries permission, which controls the ability to close queries regardless of team. This permission is automatically assigned to the CDMS Lead Data Manager study role. |
| EDC | Study Administration | Audit Trail Export by Study or Subject | High | Auto-on | Lead Data Manager | No -- | No | Yes | No | We replaced the Audit Trail Export job with Audit Trail Export by Study. Then, we added the Audit Trail Export by Subject job, which allows users to select subjects, including deleted subjects, to include in the export. |
| EDC | Study Administration | Review Plan Assignment Enhancements | Medium | Auto-on *In studies using Review Plan Assignment V2 | Lead Data Manager | Yes Lead data managers must delete criteria or manually assign plans to see these changes. | No | Yes | No | This release includes the following enhancements to review plan assignment: deletion of assignment criteria is allowed in studies containing casebooks and manual assignment to sites now includes a confirmation dialog. |
| EDC | Study Administration | Rules Execution Enhancements | Medium | Auto-on | Lead Data Manager | Yes Lead data managers will see these changes upon release. | No | Yes | No | This release replaced the Query Rules tab in EDC Tools with a Rules tab, which includes additional filters, viewing options, and rules of all action types, not only query creation rules. |
| EDC | Study Administration | Send SDV Requiredness to | Medium | Auto-on *In studies using | Lead Data Manager | Yes CTMS begins sending this information | No | Yes | No | CDMS now sends SDV requiredness to CTMS via the |



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| | | CTMS | | the CTMS spark connection | | upon the release. | | | | CTMS spark connection. |
| EDC | Study Administration | Set the Form Status for Impacted Forms during Retrospective Amendments | Medium | Auto-on | Lead Data Manager | No -- | No | Yes | No | Users can now select a Form Status when initiating a retrospective amendment and choose to set the impacted Forms to the In Progress Post Submit or Submitted statuses. |
| EDC | Study Administration | Status for After-Deploy Job | Medium | Auto-on | Deployment Administrator | No -- | No | Yes | No | We added new statuses to the deployment job, Import Completed and Completed with Documentation Errors. This lets users identify when a deployment is complete but Vault hasn't yet generated or failed to generate the SDS and comparison report. |
| EDC | Study Administration | Study Administration Functional Enhancements | Medium | Auto-on | Vault Administrator, Deployment Administrator, Lead Data Manager | Yes Users with permission to access these areas will see these changes. | No | Yes | No | With this release, we made the following functional enhancements: 1.) Site Name is no longer requires uniqueness within the Study. 2.) We added hover text for the Delete Study Data and Delete Site Data job in EDC Tools > Job History. 3.) System Tools > External Connections now only displays the Absorb connection, and not the vault connections required for automatic deployments. |
| EDC | Study Design & Configuration | Reference Change Reason and Did Not Occur for Events in Rules | Medium | Auto-on *This feature should be automatically available for all studies on grammar version 2. | Study Designer | No -- | No | Yes | No | Study designers may now reference the Change Reason and Did Not Occur status of an Event in rule expressions, using @Event.change_reason__v and @Event.did_not_occur__v. These two properties are also available as tokens for Send Email rules. |
| EDC | Study Design & Configuration | Time & Events Schedule | Medium | Auto-on *Auto-on in studies created after | Study Designer | No -- | No | Yes | No | Studio now includes a Time & Events Schedule Editor, which displays the study schedule in |



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| | | | | 20R3 | | | | | | a grid, and allows users to order events and assign forms. |
| EDC, Labs | Data Entry, Lab Tools, Study Design & Configuration | Labs | Medium | By Study Build | Sub Investigator, Investigator, Lead Data Manager, Study Designer, Clinical Research Coordinator | Yes Studio see lab configuration options upon release. | No | Yes | No | <p>The Labs module provides a seamless data integration into EDC and easy access to centralized lab locations, normal ranges, and an Analyte Library.</p> <p>This feature also allows users to enter data in one centralized location so that data entry errors can be avoided. Site users can select from lab locations in order to pull normal ranges and data that can benefit all studies.</p> <p>From the site perspective, users are able to select a lab location and pull normal ranges using analytes from the Analyte Library. Analytes and normal ranges can be edited and added in the Labs tab.</p> |
| EDC, Randomization | Data Entry, Study Design & Configuration | Randomization | High | Support | Lead Data Manager, Study Designer | No -- | No | No | No | <p>The Randomization module supports simple randomization in clinical trials that use randomization types such as blocking and stratification.</p> <p>Through this module, the user can download a Randomization list template, fill in the data, and re-upload the template in order to begin the randomization process.</p> <p>With the Randomization module, users can easily configure various randomization settings such as randomization type, data masking, and strata variables.</p> |

Change Log

This feature list is subject to change prior to the release. We will begin tracking changes on: 10/23/2020

| Date | Description | Impact |
|------------|--|---|
| 10/19/2020 | Published the initial version of the RIA. | N/A |
| 10/23/2020 | <p>Removed the "Safety Clinical Data Link" feature. This feature was postponed to a later release.</p> <p>Updated the Feature Risk of "Audit Trail Export by Study or Subject" from "Medium" to "High".</p> | The RIA now includes an up to date list of features and risk information. |
| 10/26/2020 | <p>Updated the feature name of "'How to Code" Configuration Moved from Studio to Coder Tools' to "Coding Administrators Select Dictionary Version & Coding Methods".</p> <p>Removed the comments on features where "Impact to Existing Studies" is "No".</p> | The RIA now includes an up to date list of feature names. |
| 11/5/2020 | <p>Updated the enablement of the "Time & Events Schedule" feature from "Study Feature Flag" to "Auto-on".</p> <p>Removed the "Join by Subject" feature, as it was released with a maintenance release.</p> <p>Removed the "Manage Listing Columns without CQL Editor" feature, as this feature was postponed to a later release.</p> <p>Added the "Schedule & Deliver Export Packages" and "Export Definition Status Enhancements" features.</p> | The RIA now includes an up to date list of features. |

