



23R2 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: 6/23/2023

Revision Date: 6/19/2023

VIA Available: 7/17/2023

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 Primary Users</i>	This feature is visible and available to one 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.
<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 Primary Users	Name	Application	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
	Altered Workflow for Medical Coding	Migration	Migration Users		Coder	Medium	<p>This feature reorders the migration workflow for medical coding. The new step order is as follows:</p> <ol style="list-style-type: none"> 1. Items are created as part of Run step 2. After Run, Medical Coding runs as its own step. 3. After Medical Coding. existing Post-Run and additional steps are executed. 	Migration Users
	Migration Vault: Abandoning Loads	Migration	Migration Users			Low	This feature allows users to stop a step mid-step from within the Migration Vault. Once this happens, the Load is abandoned and a new Load is required.	Migration Users
	Migration Vault: Reconcile Listings	Migration	Migration Users			Low	There is an existing defect in CDMS in which the database records can get out-of-synch after a successful migration due to the large amount of data processed during the migration process. When this occurs in Production, there is a synchronization job that repairs any discrepancies, but there is no such job that synchronizes the data in UAT and DEV environments. This synchronization can only be kicked off after the Load is finished.	Migration Users
	Migration Vault: Study Decommissioning & Database Clean-up	Migration	Migration Users			Low	After a Study has finished migrating or after a release, there is no formal process in place that removes a Study's data from the applicable databases, which can lead to performance issues. After a Study has successfully migrated and after a release, this process ensures the appropriate environments and databases are cleaned up and that the migrated study is decommissioned.	Migration Users

Change Log

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Date	Description	Impact
6/19/2023	Published the initial version of the RIA	N/A