



## 23R1 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: 3/3/2023*

**Revision Date:** 2/27/2023

**VIA Available:** 3/27/2023

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.

<b>Feature Risk:</b>	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.
<b>Enablement Fields:</b>	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.
<b>Training Impact:</b>	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
Clinical Team, Site Users	Audit Event for Item Change Reason on Create	EDC	Migration Users	Migration Vault	Migrated Studies Only	High	To support data migrations, Vault now supports setting a change reason when an item is created. The migrated change reason will appear in the audit trail after the item is created.	Migration Users
Clinical Team, Site Users	Create Repaired Forms as Facades	EDC, Migration	CRAs, Data Managers, Lead Data Managers, Migration Users, Sites			Low	Forms created via repair are now created as blank forms (facades), rather than the <i>In Progress</i> status.	Clinical Research Associate, Clinical Research Coordinator, Data Manager, Investigator, Lead Data Manager, Migration Users, Sub Investigator
	Notify Users after Step Completion	Migration	Migration Users			Low	Migration Vault now sends users a notification, both in application and via email, after completing a migration workflow step.	Migration Users
	UI Redesign: New Rules Steps	Migration	Migration Users			Medium	Users are no longer required to execute rules in batches. This feature automates the rules execution process. The Deactivating Rules, Dynamic Rules, and Reactivate Rules steps display in the Workflow Progress table.	Migration Users
	UI Redesign: Validation & Stage, Run, Post-Run	Migration	Migration Users			Medium	This feature introduced a new design for the migration workflow and its UI to make it more user friendly. This removed unnecessary steps and actions from the workflow to streamline it. The Workflow Progress table shows a load's progress through the migration workflow. Users can download the Workflow Progress table as a CSV file at any time.	Migration Users

## Change Log

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Date	Description	Impact
2/27/2023	Published the initial version of the RIA	N/A

