Vault CDMS

23R3 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: 10/13/2023

Revision Date:	10/9/2023
VIA Available:	11/6/2023

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.
High	May affect security, patient confidentiality, application areas that support GXP functions (audit trails, eSignature, etc.) or other ERES controls data
Medium	May affect core application functions (workflows, revision history, etc.)
Low	May affect metadata/notifications
N/A	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.
Day 1 Impact to Primary Users	This feature is visible and available tone 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.
Users with Day 1 Visibility	This feature is visible to these users on day 1 if no configuration occurs.
Configuration	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.
Dependencies	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
	Migration Vault: EDC Duplicate Detection Job	Migration	Migration Users			Low	This feature identifies objects created during the *Migration Recovery* process of a failed production run. The job can only be executed by a Migrations engineer. Results are generated in batches of CSVs and shared with Migration stakeholders. This feature applies only to production loads.	N/A
	Migration Vault: Report & Log File Enhancements	Migration	Migration Users			Low	This feature is a group of enhancements that support Migration Report troubleshooting. It includes new error messaging and reports, providing users with more insight into how long each workflow step or load takes to complete based on *Study* size.	N/A
	Migration Vault: Retrying TAPIs & Runs	Migration	Migration Users			Low	Retrying TAPIs: This feature retries connection-related errors, such as client-side connection issues and read timeouts. Previously, since there were no retries, connection-related errors required a re-migration. Retrying Runs: This feature allows Migration engineers to retry the *Run*, *Med Coding*, and *Post-Run* steps for production loads should they fail in certain situations. Once data is migrated into EDC, there is no way to bulk-delete the data. This restriction is 100% intentional. If a migrated study needs to be deleted in production, the only recourse is the Migration Reset. The purpose of this feature is to provide the Migration team with additional opportunities to migrate/retry a "failed" study before having to succumb to the last resort, a Migration Reset. This feature only applies to production loads.	N/A

	Migration Vault: Separating Form Submission from Post-Run Step	Migration	Migration Users			Medium	This enhancement separates *Form Submissions* from *Post-Run,* making it a separate step within the Workflow Progress table. Having all forms submitted before applying attributes avoids concurrent, asynchronous jobs and provides more consistency across loads, preventing *Post-Run* times from varying significantly.	N/A
	Migration Vault: Setting Subject Statuses	Migration	Migration Users	EDC Tools		Low	This feature completes the automating of the Rules process by automating the setting of Subject Statuses.	N/A
	Migration Vault: Skip Step Option as part of Execute All Steps	Migration					This feature allows users to skip optional steps as part of the **Execute All Steps** workflow.	

Change Log

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Date	Description	Impact
10/9/2023	Published the initial version of the RIA.	N/A