

24R2 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.

Validation Impact Assessment (VIA). C	Once the VIA is available on Veeva Docs, refer to it for more detailed validation information.					
This feature list is subject to chang	e prior to the release. We will begin tracking changes on: June 17, 2024					
Revision Date:	6/17/2024 12:16 PM PDT					
VIA Available:	6/21/2024					
	efer to the product release notes, which are available on <u>Vault CDMS Help</u> . nanges 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	CDB Support	Users with Day 1 Visibility	Configuration	Dependencies	GxP Risk	Description	Training Impact
	YAML Builder for Migration Vault	Migration	Yes	Migration Users	Migration Vault		Low	This release adds a YAML Builder within Migration Vault to support the creation of mapping files for study migrations. The YAML Builder generates a single YAML mapping file for each Form definition from the target study in Vault EDC. This only applies to Forms that do not include repeating Item Groups. All users with Migrator, System Administrator, or Vault Owner access to Migration Vault can access the YAML Builder, if enabled.	Migration Users
	Support for DMR in Migration Vault	Migration	Yes	Migration Users	Migration Vault		Low	Migration Vault now manages the migration of Data Management Review (DMR) attributes from the Legacy EDC System.	Migration Users

Change Log						
This feature list is subject to change prior to the release. We will begin tracking changes on: March 1, 2024.						
Date	Change	Impact				
6/17/2024	Published the initial version of the RIA	N/A				