VaultConnections

Veeva Vault RIM to Clinical Operations Connection FAQ

Which Vault RIM applications are required for the Vault RIM to Clinical Operations Connection?

This connection facilitates data transfers between the Vault Clinical Operations Suite and the Vault Submissions application within the Vault RIM Suite.

Which direction do documents flow—from Vault Clinical Operations to RIM or vice versa? How does one evaluate the 'right' source Vault based on Document Types? Documents and data records can be sent from Vault Clinical Operations to Vault RIM and the other way around.

Which documents and data records will be transferred depends on the customer's business process. Still, Veeva can provide a list of standard documents exchanged between Vault Clinical Operations and Vault RIM to use as a starting point.

Generally, we recommend considering the Vault where a document is authored as the Source Vault.

What amount of effort is required to establish and configure the connection? Is written help available to customers to integrate the Vault connections, or can integration configuration only be managed by Veeva?

While an Administrator with deep technical knowledge could complete the configurations independently, Veeva strongly recommends engaging our Professional Services team to implement the Vault Connection.

The connection requires significant effort in mapping data across environments, which our team supports as part of a services engagement.

What process should be followed if a data transfer error occurs? Is there a notification to System Admin or Veeva?

Currently, there is no automatic notification. However, it is possible to run a flash report on error messages.

A System Admin should triage this regularly and research/repair the root cause of any errors.

What happens if the target Vault has additional mandatory Document Fields not found in the source Vault?

If the Target Vault has additional mandatory Document Fields, there are three options for each Field:

1) Configure the connection so the Target Vault Field is populated by an existing Field



within the Source Vault

2) Make the Field in the Target Vault optional

3) Select a default value for the Field in the Target Vault

Does mapping between Vaults need to be done each time a new product is created? No. The configuration mapping of Document Types and Data Records is completed once during the Design and Build phase. Based on this mapping, when a user creates a new Product Family in Vault RIM, the connection automatically creates a Product record in Vault Clinical Operations.

Will Crosslinks work across Veeva domains (e.g., could we link to our CRO's Vault)? No, crosslinks are not currently supported across domains.

Do you suggest implementing the connection once both Vaults are already configured and active, or can the connection be established as part of the initial RIM implementation?

The Vault Connection can be established either during the implementation of the systems or once the systems are already in use. There is no specific timeline.

Is there a way to transfer only specific document versions from Vault RIM to Vault Clinical operations and the other way around?

All Steady State versions will be shared for documents within the identified Document Types.

Today, there is no way to limit the scope, though this is an area the Veeva Product Team is evaluating for future enhancement. However, the configuration is specific by Document Type.

When a document is crosslinked from Vault Clinical Operations to Vault RIM, does it appear only in Library? Is there a way to auto-file the document in a specific Binder section or Submission Content Plan?

If the Document Fields specified in the auto-matching criteria are populated, the autofilling will be available. Additional configuration may be required.

How do you deal with further versions of a document during the crosslinking process? Are documents compiled on top of the previous version or copied as individual documents in the Target Vault?

All steady state versions are stacked on top of the prior version. So, there will be a single document with multiple versions in the target Vault.

Is there a way to track in the system how the Vault connection is used? Yes, you can leverage reports and dashboards in both Vault Clinical Operations and Vault RIM that track the number of created/updated Crosslink documents and data

records on an ongoing basis. A number of crosslinked documents by type per week or a total number of created Site records are examples.



What is the process of maintaining the Vault RIM to Clinical Operations connection?

Once the connection is configured, Administrators should monitor the User Exception Message and User Exception Item records. As Veeva has new releases three times a year, it is important to also establish a process that includes assessing the impact of the new features related to the connection.

Administrators should be aware that certain changes to data or configuration in the RIM or Clinical Operations Vaults may impact the connection, so it is important to fully assess any changes for impact.

Need help navigating these questions and answers?

Reach out to the Veeva Team: rd_csm@veeva.com You can also find additional resources on the <u>Vault Connections Resource Hub</u>.