## VeeVC Vault Vault 18R2 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault 18R2 that may affect a customer's vault. We release a version of the RIA in advance of the general release. On July 9th, the Validation Impact Assessment, which contains validation information for new features in 18R2, will be available in your VeevaDocs vault. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements.

Revision Date: 8/9/2018

This feature list is subject to change prior to the 18R2 release. We will begin tracking changes on June 18th, 2018.

Feature:	Name of the feature introduced in 18R2
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 feature 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 Setting:	Indicates whether the feature is available automatically, requires configuration by an Admin (an Admin area checkbox or a more complex setup), or must be enabled by contacting Veeva Support. Note that some Auto-On features do require individual users (not Admins) to complete some set up, for example, new Reporting capabilities generally require a user to create a new report or edit an existing one.
Default Impact:	Impact to business users and processes at Day 1 if no configuration occurs
Visible to All Users	Automatically on and visible to both Admins and end users
Visible to Admins Only	Only visible to Admins, or it requires configuration by an Admin before it is available to end users
None	Not visible in Vault unless enabled by Support

Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
Platform	Secure Inbound Relationships	High	Configuration	Visible to Admins Only	This feature allows the ability to configure Atomic Security on relationships and control when related object records or documents can be assigned or unassigned to an object record.
Platform	Secure Sharing Settings	High	Configuration	Visible to Admins Only	This feature allows Admins to control and manage users' access to Sharing Settings.
Platform	Dataset Support for Configuration Migration Packages	Medium	Auto-on	Visible to Admins Only	This feature enables configuration migration specialists to add data load steps into an Outbound Migration Package.
Platform	Sandbox Vaults	Medium	Auto-on	Visible to Admins Only	Allows customers to create, refresh, or delete their own sandbox vaults from within the Vault Admin UI and APIs. Creating or refreshing a sandbox vault copies the production vault's configuration, ensuring an environment suitable for testing changes without exposing production data.
Platform	Configurable Copy Fields	Medium	Configuration	Visible to Admins Only	Admins can define which field values are included when users execute the Make a Copy action on a document.
Platform	Default Values for Standard Picklist Document Fields	Medium	Configuration	Visible to Admins Only	Allows an Admin to select default values for standard picklists, like they can do for custom document picklist fields.
Platform	Object Workflow: Update Related Record Field	Medium	Configuration	Visible to Admins Only	This feature allows users to configure an object lifecycle state entry action, or an object workflow step to automatically update a field on a related record.
Platform	Record Validation Rules	Medium	Configuration	Visible to Admins Only	This feature, which uses the same Expression Grammar as field defaulting, allows Admins to set up simple validation rules for an object field from within the object configuration.
Platform	Static Reference Constraints for Document Fields	Medium	Configuration	Visible to Admins Only	Admins can define static reference constraints on object reference document fields to filter object records by static values at runtime.
Platform	Vault File Manager: General	Medium	Configuration	Visible to Admins Only	Vault File Manager is now available to all

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	Availability				customers and no longer requires enablement from Veeva Support.
Platform	Service Availability Email	Low	Auto-on	Visible to Admins Only	A new field will be added to Admin > Settings > General where customers can provide a non-user email address that will be used by Veeva for detailed communication about service outages.
Platform	Document Type Details Label Change for Binder Options	N/A	Auto-on	Visible to Admins Only	Due to the addition of the new Document Type configuration section Binder Display Options: Unbound Documents, we relabeled the section above (previously Binder Options) to be clearer about what it allows users to configure.
Platform	Use Names for Bulk Translation	N/A	Auto-on	Visible to Admins Only	With this feature, translation files exported and imported with the Bulk Translation Tool use component names as the Object Key where possible.
Platform	Support for Object Lifecycle State in Expression Grammar	N/A	Configuration	Visible to Admins Only	Allows Admins to use the object lifecycle state when defining expressions (field defaults, record validation rules, etc.) in Vault.
Platform	User & Person Object Enhancements	High	Auto-on	Visible to All Users	This feature enhances the User & Person objects in several ways including rendering the Created By and Last Modified By fields as links, making it easier to create Person records, and adding a Vault Membership Lifecycle to User.
Platform	Add Participants to Active Object Workflows: Enhancements	Medium	Auto-on	Visible to All Users	Adding participants to an active object workflow is now more consistent with the workflow start step configuration. If a workflow start step is configured to automatically assign users based on Sharing Settings roles, users add participants to an active workflow by adding them to the Sharing Settings role directly rather than selecting "Add Participant" in the workflow Actions menu.
Platform	Binding Rule Label Changes for Binders	Medium	Auto-on	Visible to All Users	In this release, we've updated the labels for the Set Binding option to more clearly describe their behavior.
Platform	Default Single Value Reference Fields	Medium	Auto-on	Visible to All Users	This feature allows quick and easy entry of record data by defaulting object reference, self-referencing, and parent

					fields when the referenced object only has one record. This feature is only available for empty, required fields.
Platform	OCR for Scanned Documents	Medium	Auto-on	Visible to All Users	When generating Viewable Renditions for Scanned Documents, Vault can recognize and index text within certain source files.
Platform	Vault File Manager: Enhancements	Medium	Auto-on	Visible to All Users	This feature adds enhancements to the Vault File Manager client, including new columns for Document Number and a Document Type, exact date and time of last edit, and instant deletion of local files when documents are checked back into Vault.
Platform	Viewable Renditions for Hangul Word Processor (HWP) Files	Medium	Auto-on	Visible to All Users	Vault automatically creates viewable renditions for Hangul Word Processor (HWP) source files.
Platform	Date Functions	Low	Auto-on	Visible to All Users	This feature allows users to compare a date or dateTime field to a today function, which will resolve to the current date each time the report is run.
Platform	Destination Navigation in Viewer	Low	Auto-on	Visible to All Users	Users can click the Show Destinations button in the document viewer to navigate to Destinations in PDF documents.
Platform	Domain-level User Profile Images	Low	Auto-on	Visible to All Users	Vault now manages the user profile image at the domain level as opposed to the vault level.
Platform	Populate Last Ran Field for All Reports	Low	Auto-on	Visible to All Users	Vault now populates the Last Ran field for all reports.
Platform	Vault Loader File Validation	Low	Auto-on	Visible to All Users	This feature provides up-front CSV file validation for Vault Loader.
Platform	Additional Languages for Multilingual Document Handling	N/A	Auto-on	Visible to All Users	This feature adds three (3) new languages to the list of supported languages for multilingual document handling.
Platform	Split Artist Field into Separate Author & Artist Fields	N/A	Auto-on	Visible to All Users	This feature splits the Artist document field into two separate fields: Author and Artist.
Platform	Enhanced Login Flow	High	Auto-on	None	Vault now asks for User Name and Password on different pages. We've also added a configurable ability to prevent browsers and password managers from remembering passwords types on the

					login form.
					*Note: This will be auto-on for all customers in 18R2.0.1. Customers will have the option to preview this feature by enabling it via an Admin Checkbox in Pre-Release for 18R2.0.
Platform	Action to Delete Record and Related Signatures	High	Configuration	None	This new action will be provisioned to allow the deletion of object records that have related eSignatures. It allows Admins to clean up non-production records that would otherwise have been blocked from deletion.
Platform	Related Record Audit Trail	High	Support	None	The Related Record Audit Trail allows users to include related records when retrieving the audit trail for a given object record. *This feature is Auto-on for new Quality vaults.
Platform	Unbound Document Display Options for Binders	Medium	Support	None	This feature allows users to control how unbound documents are displayed for users who are viewing a binder, or exporting from a binder.
Platform	Improved OAuth Support in Vault File Manager on Older Windows Operating Systems	N/A	Auto-on	None	This enhancement improves Vault's ability to support Vault File Manager authentication via OAuth for users on Windows™ 7, Windows™ 8, and Windows™ 8.1 environments. *Vaults that use OAuth with Vault File Manager must make a configuration update to OAuth profiles to continue using OAuth.
Platform	OAuth Configuration for Vault File Manager Supports Wildcard for Port Assignment	N/A	Auto-on	None	This enhancement improves Vault's ability to support Vault File Manager authentication via OAuth. *Vaults that use OAuth with Vault File Manager must make a configuration update to OAuth profiles to continue using OAuth.
Platform	Vault CDN Support	N/A	Support	None	Enables customers to serve regulated content directly through publicly addressable URLs generated by Vault, using the customer's own Amazon Cloudfront distributions and Amazon S3 buckets. *Note: This feature is currently only available to early adopters, and is not validated in 18R2.

Regulatory	Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
	RIM Publishing	RIM Submissions Publishing	High	Configuration	None	A new application within the RIM Suite, containing the following features: - Continuous Publishing - Continuous Validation - Select Leaf Target Operation - US FDA v3.3 Specification Support *Note: This feature is currently only available to early adopters. Contact: John Lawrie.
	RIM Publishing, RIM Registrations, RIM Submissions, RIM Submissions Archive	Regulatory Objective & Submissions Data Sync	Medium	Auto-on	Visible to Admins Only	Continuously synchronize data between the single-reference Regulatory Objective field and the new many-to-many Submission Regulatory Objective object until customers are ready to use the new object, ensuring all data is present in the new object when customers make the change.
	RIM Publishing, RIM Registrations, RIM Submissions, RIM Submissions Archive	Regulatory Objective Data Model Update	Medium	Auto-on	Visible to Admins Only	This feature adds new objects to RIM vaults and makes changes to the Application/Regulatory Objective relationship.
	RIM Registrations	Use Regulatory Objective Data in Manage Registered Details Wizard	Medium	Admin Checkbox	Visible to Admins Only	New Admin option controls the source of record data when updating Registrations. The new option uses Regulatory Objective to create registered details rather than Submissions joins.
	RIM Registrations	Updates to Create Related Records Wizard	Medium	Auto-on	Visible to All Users	Update the Create Related Records wizard to create data in Submission and Regulatory Objective join records based on the event data.
	RIM Registrations	Usability Updates to Manage Registered Details Wizard	Medium	Auto-on		Update UI for Manage Registered Details wizard: Default lifecycle states when possible; add hover cards to grid views; add more inline help text; support dynamic labels within the wizard pages.
	RIM Registrations, RIM Submissions, RIM Submissions Archive	RIM Component Unification	N/A	Auto-on	Visible to Admins Only	This feature deploys any standard object types, report types, notification templates, and document fields to all RIM vaults.
	RIM Submissions	Report Level Content Plans	Medium	Configuration	Visible to Admins Only	Users can create clinical and nonclinical study reports and publish the documents.

	RIM Submissions	Link Publishing	Medium	Configuration		This feature allows Admins to enable Vault link annotations as an option in RIM Submissions vaults. This allows Vault to reconcile links within published documents to become relative PDF hyperlinks.
	RIM Submissions Archive	Export Large Submissions to FTP	Medium	Auto-on	Visible to All Users	Users with appropriate permissions can export submissions to the FTP when submissions exceed Vault's file size and artifact limits for ZIP file creation.
	RIM Submissions Archive	Expand All for Single Submission	Low	Auto-on	Visible to All Users	When filtered to a single submission from within the Submissions Viewer, users can completely expand all the child nodes within a section.
Quality	Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
	QualityOne, QMS, QualityDocs	Entry Criteria Based on Related Document State Types	Medium	Configuration	Visible to Admins Only	Allows control over whether or not a record can change states, based on the record's related documents' state types.
	QualityOne, QMS	Checklist Design Loader	Medium	Configuration	Visible to Admins Only	Allows Admins to upload sections, questions, answers, and dependencies within a Checklist Design as a single, flattened CSV file.
	QualityOne, QMS	Checklists for Quality Events	Medium	Configuration	Visible to Admins Only	Checklists are a new data entry method that allows a user to input information in a question and answer format in the context of a Quality Event, for example, an Impact Assessment or Change Control. In addition to introducing a special, survey-like UI for responding to checklists, this release includes capabilities to define and manage templates called Checklist Designs. When a business process requires a checklist, Vault automatically selects the appropriate checklist design and creates an instance based on business context and matching rules.
Mobile	Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
	Veeva Snap	Veeva Snap: Support Image Uploads	Medium	Auto-on	Visible to All Users	This feature adds a new mode to the Veeva Snap application that allows users to capture and upload images to Vault from Veeva Snap as PDFs.

	Veeva Snap	Veeva Snap: Support Uploads as Attachments	Medium	Configuration	Visible to All Users	Vault Admins can configure an email message template to include a link to Veeva Snap that allows users to open the application and upload a captured document or image as an attachment to another Vault document or to an object.
	Veeva Snap	Veeva Snap: Automatic Picture Taking	Low	Auto-on	Visible to All Users	This feature adds a new mode to Veeva Snap that allows the application to take photos automatically after it detects the page edges for a certain amount of time.
	Veeva Snap	Veeva Snap: EMM Provisioning	Low	Configuration		Provides a profile attribute to denote that the application is EMM-provisioned. This attribute will be used in conjunction with the Vault permission Veeva Snap: Allow App Store Configuration.
Commercial & Medical	Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
	MedComms, PromoMats, Multichannel	Multichannel Field Updates	Medium	Auto-on	Visible to Admins Only	This feature updates the field length for two (2) text fields used for Multichannel purposes to support functionality available with the CRM 18R2 release.
	MedComms, PromoMats	Reason Selection When Making A Copy	Medium	Configuration	Visible to Admins Only	This feature extends the Make a Copy functionality for PromoMats and MedComms vaults to allow users to select a reason when copying documents and binders.
	MedComms, PromoMats	Brand Portal Editor	Low	Auto-on	Visible to All Users	The Brand Portal Editor makes creating, configuring, and removing Portals an easier, more visual, and more intuitive process, allowing Brand Managers to manage their Portals as they appear to end users.
	MedComms, PromoMats	Make a Copy from Brand Portal	Low	Auto-on	Visible to All Users	Brand Portal users can now Make a Copy directly from document hover cards and the Quick Look Viewer in the Portal Library or Portal Home Page.
	MedComms, PromoMats	My Portal Tasks	Low	Auto-on	Visible to All Users	This feature adds the My Portal Tasks pane to the Portal Home Page, allowing Portal users to see their tasks for documents in the Portal.
	MedComms, PromoMats	Automated InDesign® Component Linking	Low	Support		Vault can now automatically create and link component documents for Adobe InDesign package files. *In new

						PromoMats and MedComms vaults, Admins can enable this feature via a checkbox on the Application Settings page.
Clinical Operations	Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
·	CTMS	Upload Trip Report Questions	Medium	Configuration		Admins can download a single CSV template file that they populate and upload to create Trip Report Questions. *This feature is Auto-on for new CTMS vaults.
	CTMS	Subject Metadata & Vault CTMS/EDC Connection	Medium	Auto-on	Visible to All Users	This feature allows CTMS users to report on new and existing Subject Statuses and new Subject Status Dates integrated from Vault EDC. Users can also navigate from a Subject or Monitored Subject within CTMS to the Subject's casebook within Vault EDC.
	CTMS	Omit Unused States on Study Management Homepage Monitoring Status Widget	N/A	Auto-on	Visible to All Users	The Monitoring Status widget on the Study Manager Homepage in the CTMS application will now display only Monitoring Event Record statuses that have associated Monitoring Events.
	CTMS	Standardizing Central Monitoring and Trip Report Template Admin Tabs	N/A	Auto-on	Visible to All Users	This feature makes both the Central Monitoring tab and the Trip Report Template Admin tab, as well as their associated sub-tabs, available to all CTMS Vaults.
	CTMS	Subject Metric Updates Based on New Subject Statuses	N/A	Auto-on	Visible to All Users	This feature updates the Metrics and Monitored Metrics jobs and the Study Enrollment Status graph on both the CRA and Study Management Homepages to take the new End of Treatment and Randomized as Subject statuses into account.
	CTMS, eTMF, Study Startup	Manage EDL Bulk Update Options in Clinical Vaults	Medium	Admin Checkbox		This feature allows Admins to hide the option to "Update EDL Items for all sites in the same study" in the Update Related EDL Items dialog.
	CTMS, eTMF, Study Startup	Study Country Auto-naming	Low	Admin Checkbox	ĺ	This feature allows Admins to set a checkbox in Application Settings that enables the Study Country Name field on

					a Study Country record to be system- managed.
CTMS, eTMF, Study Startup	Milestone Hover Card	Low	Configuration	Visible to Admins Only	This feature introduces a Milestone hover card that displays a summary of the Milestone's completeness, including links to previous milestone dependencies, expected document completeness, and matched documents. *This feature is available for configuration in vaults with Milestone Autocomplete enabled.
CTMS, eTMF, Study Startup	Study Organization Role	Medium	Auto-on	Visible to All Users	This feature adds a new Study Organization object to allow for tracking an organizations role on a study. This feature also adds a new tab that will be available to any user with permissions to view all tabs.
CTMS, eTMF, Study Startup	Consolidate Organizations and Personnel Tabs	N/A	Auto-on	Visible to All Users	This feature renames the Organizations tab to organizationctms, and the Personnel tab to personnel_directoryctms, allowing tab names to be consistent across all Clinical Operations vaults.
CTMS, eTMF, Study Startup	EDL Hierarchical View: Label Update	N/A	Auto-on	Visible to All Users	This feature changes filter buttons in the EDL Hierarchical Viewer to show the field labels so that users can filter by their fields.
eTMF	Expose Global Directory and Study Personnel Tabs in eTMF	N/A	Auto-on	Visible to All Users	This feature exposes five standard tabs in eTMF vaults: Global Directory, Organizations, Personnel, Study Personnel & Communication, and Study Personnel. These tabs will be visible by any user with permissions to view all tabs.

## **Change Log**

This feature list is subject to change prior to the 18R2 release. We will begin tracking changes on June 18th.

Date	Change	Impact
8/9/2018	Updated the Application of the following features to include "RIM Publishing": - Regulatory Objective & Submissions Data Sync - Regulatory Objective Data Model Update	The RIA now includes up to date application information.
8/6/2018	Renamed "Subject Metadata & Vault CTMS/EDC Integration" to "Subject Metadata & Vault CTMS/EDC Connection" to better reflect the feature's functionality.	The RIA now includes up to date feature names.
7/27/2018	Added the "RIM Submissions Publishing" feature.  Updated the Feature Risk of the following features: - "Split Artist Field into Separate Author & Artist Fields" from "Low" to "N/A" - "Vault File Manager: Enhancements" from "Low" to "Medium"	The RIA now includes a list of all features in 18R2 and contains up to date feature risk information.
7/24/2018	Updated the Description of the "Vault CDN Support" feature to clarify that this feature is not validated in 18R2.  Updated the Feature Risk of the following features: - "Document Type Details Label Change for Binder Options" from "Medium" to "N/A" - "Additional Languages for Multilingual Document Handling" from "Low" to "N/A" - "RIM Component Unification" from "Low" to "N/A" - "Vault CDN Support" from "Medium" to "N/A"	The RIA now includes up to date feature descriptions and feature risk.
7/3/2018	Updated the Enablement of "Advanced Login Flow" from "Admin Checkbox" to "Auto-on".  Updated the Description of "Advanced Login Flow" to clarify that customers can enable this feature via an Admin Checkbox in prerelease for 18R2.0.  Renamed "Action to Cascade Delete eSignatures" to "Action to Delete Record and Related Signatures".	The RIA now includes up to date enablement information, feature descriptions, and feature names.

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6/29/2018	Updated the Feature Name of "Support for Object Lifecycle & State in Expression Grammar" to "Support for Object Lifecycle State in Expression Grammar".  Updated the Description of "Add Participants to Active Object Workflows: Enhancements" to clarify the enhancements this feature provides.	The RIA now includes up to date feature names, descriptions, and enablement information.	
	Updated the Enablement of "Configurable Copy Fields" from "Autoon" to "Configuration".		
	Updated the Default Impact for the following: - "Usability Updates to Manage Registered Details Wizard" from "Visible to Admins Only" to "Visible to All Users" - "Updates to Create Related Records Wizard" from "Visible to Admins Only" to "Visible to All Users"		
6/26/2018	Updated the Application for the following:  - "Regulatory Objective & Submissions Data Sync" from "RIM Registrations" to "RIM Registrations, RIM Submissions, RIM Submissions Archive"  - "Regulatory Objective Data Model Update" from "RIM Registrations" to "RIM Registrations, RIM Submissions, RIM Submissions Archive"	The RIA now includes up to date default impact and application information.	
6/22/2018	Updated the Feature Risk of the following features: - "Static Reference Constraints for Document Fields" from "Low" to "Medium" - "Reason Selection When Making a Copy" from "Low" to "Medium" - "Multichannel Field Updates" from "Low" to "Medium" - "Standardizing Central Monitoring and Trip Report Template Admin Tabs" from "Low" to "N/A" - "EDL Hierarchical View: Label Update" from "Low" to "N/A" - "Default Values for Standard Picklist Document Fields" from "Low" to "Medium"  Updated the Application Family and Application for the "Related Record Audit Trail" from "Quality/Platform, QMS" to "All/Platform".  Added the "Action to Cascade Delete eSignatures" feature.	The RIA now includes a list of all features in 18R2 and contains up to date Feature Risk, Application Family, and Application information.	
	Updated the Description of the "Vault CDN Support" feature to clarify that this feature is currently only available to early adopters.		
6/19/2018	Updated the Description of the "Automated InDesign® Component Linking" feature to clarify that Admins can enable this feature via a checkbox in new PromoMats and MedComms vaults.	The RIA now contains up to date feature descriptions.	

6/11/2018	Initial RIA published	N/A
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