## Veeval Vault Vault 22R2 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault in 22R2 that may affect a customer's Vault. We release a version of the RIA in advance of the general release. The Validation Impact Assessment, which contains validation information for new features that have validation impact in 22R2, will be available in the Veeva Compliance Docs (VeevaDocs) Vault on July 12th. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements. On July 5th, the <u>22R2 Release Notes</u> will be available. Refer to the Release Notes for additional details about each feature and data model changes in your Vault.

## Revision Date:

02 Aug 2022

This feature list is subject to change prior to the 22R2 release. All changes after initial publication are listed in the Change Log. Updates will stop on August 6th, 2022.

Feature:	Name of the feature introduced in 22R2
GxP Risk:	GxP 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 GxP 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 in some cases, an Auto-on feature is dependent on another feature that must be enabled or configured. In other cases, individual users (not Admins) need to perform some setup, for example, with new Reporting capabilities that require creation of a new report.
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

Clinical Operations	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	CTMS	Clinical CRM Connection	Medium	Configuration	Visible to Admins Only	This feature enables Vault Clinical to transfer HCP related Activities between Vault Clinical and Medical CRM.
		Standard Content Fields on CTMS Objects	N/A	Auto-on	Visible to Admins Only	This feature adds a standard Content (blinding_v) field on select CTMS objects. Admins must activate and perform additional configurations to utilize.
	CTMS	CTMS Oversight Metrics	Medium	Auto-on	Visible to All Users	This feature adds additional Metrics Calculation methodologies to support CTMS studies where Metrics are not populated from Subject data.
		Metrics: Status Snapshot Refinements	Medium	Auto-on	Visible to All Users	Vault CTMS will now update Status Snapshot Metrics and Enrollment Status Graph data when Subject data are updated instead of a daily update.
		Recruitment Planning: Metric Over Time Expansion	Medium	Auto-on	Visible to All Users	With this feature, Vault CTMS will now evaluate both the Planned and Baseline Finish Dates for the relevant milestones and generate Metrics Over Time records for the larger date range. For example, if the Baseline Finish Date of the First Subject Screened milestone is earlier than the Planned Finish Date, CTMS will generate Metrics Over Time records starting with the Baseline Finish Date.
		Prevent Duplicate Monitored Subjects & Monitored Subject Visits	N/A	Auto-on	Visible to All Users	Users are now prevented from creating duplicate Monitored Subjects and Monitored Subject Visits for a Monitoring Event.
		Recalculate Enrollment Actuals: Notification	N/A	Auto-on	Visible to All Users	After completing the "Recalculate Enrollment Actuals" action, a notification is generated for the user who initiated the action.
		Yuzu CTN: Site Medical Department Not Required	N/A	Auto-on	Visible to All Users	This feature allows CTN Data records for sites to be included in a CTN submission without populating the Medical Department field
	CTMS, Site Connect, Study Startup, Vault Payments, eTMF	Clinical Operations Data Model Changes	N/A	Auto-on	Visible to All Users	With every release, we update the data model to better support evolving needs and new feature functionality.

CTMS, Study Startup, Vault Payments, eTMF	Reference Sites	Medium	Configuration	Visible to Admins Only	This feature will support the designation, within a study country, of a single Reference Site. Users will be able to tailou expected documents for that site, push that expected document plan out to existing sites, and use the reference site as the basis for expected documents subsequently created at sites within that country.
CTMS, Study Startup, Vault Payments, eTMF	Sync Principal Investigator Field with Study Person	Low	Admin Checkbox	Visible to Admins Only	This feature extends our clinical capabilities by introducing a bi-directional update of the Principal Investigator field on Site and Study Person. The Principal Investigator field will be updated whenever a new Study Person with the role of Principal Investigator is created.
CTMS<>CDMS	Vault Clinical Operations to CDMS Connection: Restricted Data	High	Admin Checkbox	Visible to Admins Only	Admins can control the transfer of restricted data by the Clinops to CDMS connection into CTMS for subjects visits and protocol deviations
CTMS<>CDMS	Vault Clinical Operations to CDMS Connection: Arms & Cohorts	Medium	Configuration	Visible to Admins Only	The ClinOps to CDMS Connection can now transfer the latest arm or cohort assignment for subjects
eConsent	eConsent Documents to SiteVault	Medium	Configuration	Visible to Admins Only	With this feature, eConsent customers can now exchange eConsent documents with SiteVault sites directly from Vault Clinical Operations without Site Connect.
eConsent, ePRO	Connected Studies for ePRO & eConsent	Medium	Configuration	Visible to Admins Only	With this feature, ePRO and eConsent customers will be able to automatically establish Connections to SiteVault and send Study-specific invitations to SiteVault sites.
Site Connect, ePRO, eConsent	Connected Study Types in Clinical Operations	Low	Auto-on	Visible to Admins Only	Site Connect, eConsent, and ePRO customers can now designate a Connected Study appropriately using the Connected Study Type field. This field must be populated in order to: - Send Connected Study Invitations / Agreements to SiteVault - Send Safety Distributions - Launch ePRO - Send eConsent Forms to SiteVault
ePRO	ePRO in Clinical Operations	High	Support	None	With this feature, ePRO customers can

					now Launch ePRO from their Clinical
					Operations vault.
eTMF	TMF Bot: Document QC Step	Medium	Configuration	Visible to Admins Only	This feature allows customers to use TMF Bot as part of their Document Processes without using the Document Inbox. A TMF Bot QC check can be added as a step to any Document Workflow to surface possible issues within a Document.
eTMF	TMF Bot: Auto- Classification Enhancements	Low	Auto-on	Visible to All Users	Every release we target enhancements to TMF Bot Auto-classification functionality. This feature includes adding Email Ingestion support, streamlining the pipeline to maximize TMF Bot's potential, and standardizing the Report and Excel Template.
eTMF	Clinical Archival Validation Check	N/A	Auto-on	Visible to All Users	Add an additional validation check to the archival job that ensure no study documents are unclassified prior to the job initiating.
Site Connect	Site Connect: Additional Vault Clinical Docs Support	N/A	Configuration	Visible to Admins Only	This feature adds support to transfer new document types via Veeva Site Connect. - Other Submissions - Source Data Agreement
Site Connect	Site Connect Safety Distribution Update	Low	Auto-on	Visible to All Users	With this feature, Site Connect's Safety Distribution functionality has been improved to handle distributing to thousands of Study Sites in a single send action. Additionally, study site filters can now be pre-configured on the Safety Distribution Default object, allowing for automated filtering of study sites based on field criteria. Note that with this auto- filtering enhancement comes a behavior change whereby the manual filtering of study sites is no longer available during the sending flow when the 'Distribute to Sites' action is taken on a Safety Distribution.
Study Startup	Clinical Application Management	Medium	Configuration		This feature adds standard objects to support milestone-specific work and information regarding specific documents, and an action to seed those records based on documents currently linked to the milestone, in order to better manage

						clinical submissions.
	Study Startup	Email Checklists Based on Study Person Records	Medium	Configuration	Visible to Admins Only	This feature extends existing Clinical capabilities to send Checklists to non- users by also checking related Study Person records for respondents.
Commercial	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	MedComms	Alternative Response Contact for Medical Inquiry Case Response	Medium	Auto-on	Visible to All Users	Admins can add a new Response Contact field to the Case Response object page layout in MedComms, allowing users to select an alternative recipient of case response emails.
	MedComms	Data Agnostic MedComms to CRM Connection for Medical Inquiry	Medium	Support	None	A new connection to Veeva CRM in MedComms pulls Medical Inquiry information in CRM and does not require Accounts to be synced.
	MedComms	Network (OpenData) Connection to Look Up HCP Reference Data for Medical Inquiry	Low	Support	None	A new connection to Veeva Network in MedComms that allows users capturing a Medical Inquiry to search OpenData for HCP reference data when creating a Case Contact.
	MedComms, PromoMats	Auto Publish to CRM for Approved Email Fragments	Medium	Configuration	Visible to Admins Only	Vault introduces new document fields and lifecycle entry actions to automate creation and lifecycle state changes for Email Fragments. Admins can define approved Master Email Fragment Templates for combinations of Country and Product to help automate template selection.
	MedComms, PromoMats	AIR PSD Image Enhancements	Low	Admin Checkbox	Visible to Admins Only	Vault introduces a new feature to improve the image quality for some PSD images which may have imperfections in its Automated Image Rendition.
	MedComms, PromoMats	Automated Image Rendition Flattening	Low	Admin Checkbox	Visible to Admins Only	When configuring Automated Image Renditions, Admins can select the option to request the rendered image be flattened.
	MedComms, PromoMats	Packaging of CLM Content on CDN (Engage Share)	N/A	Auto-on	Visible to Admins Only	This feature adds content for CLM on staging and production CDN environments in an unzipped format alongside the zipped distribution package to support the new Engage Share feature.
	MedComms,	Commercial Data Model	N/A	Auto-on	Visible to All Users	With every release, we update the data

	PromoMats	Changes				model to better support evolving needs and new feature functionality.
	MedComms, PromoMats	OCR Pages with Images & Text	N/A	Auto-on	Visible to All Users	Vault performs OCR on PDF documents that contain both images and text.
	PromoMats	Optional Linked References for Pre Clearance Packages	Medium	Auto-on	Visible to All Users	Users can select whether to include linked references for Pre Clearance eCTD Compliance Packages.
	PromoMats, Promomats<>RIM	RIM-PM Connector Label Change in PromoMats	N/A	Auto-on	Visible to Admins Only	The label of the connector was changed from "PromoMats to RIM" to "RIM to PromoMats". This was a cosmetic change only. No changes were made to connector functionality or the API name.
Mobile	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	Station Manager	Highlight Recently Added/Updated Documents on Android	Low	Auto-on	Visible to All Users	Enhances the Station Manager mobile app to identify documents that have recently been added or updated on the device.
	Station Manager	Highlight Recently Added/Updated Documents on iOS	Low	Auto-on	Visible to All Users	Enhances the Station Manager mobile app to identify documents that have recently been added or updated on the device.
	Station Manager	Support Landscape Orientation on Android Station Manager App	Low	Auto-on	Visible to All Users	Support landscape orientation on the Android device when the physical device is flipped.
	Vault Mobile	Audit Document Views	High	Auto-on	Visible to Admins Only	Documents viewed on Vault Mobile will now be logged as a "Viewed Document" event in the Document Audit Logs. Mobile document views were not being logged previously.
	Vault Mobile	Mobile Tabs	Medium	Auto-on	Visible to Admins Only	Vault Admins can configure the permissions and order of the the mobile tabs displayed in the app.
	Vault Mobile	App Version Enforcement: Android Only	Low	Auto-on	Visible to All Users	The Android Vault Mobile app will enforce that users are on a supported version of the mobile app, and prompt users to upgrade the mobile app if needed.
	Vault Mobile	Library Named Views	Low	Auto-on	Visible to All Users	Users can now select a named view when looking for documents in the mobile app.
	Vault Mobile	Option to Open Document in Browser	Low	Auto-on	Visible to All Users	When viewing a document in the Vault Mobile app, users can now select an "Open in Browser" hyperlink from the

						ellipses menu. This allows them to navigate to the document on their mobile browser in case there is functionality needed that isn't available in the mobile app.
	Vault Mobile	View Dashboards	Low	Auto-on	Visible to All Users	Users can now view their Dashboards in the Vault Mobile app. Navigating to a Report from a Dashboard chart is not supported in the mobile app.
	Vault Mobile	Mobile Task Completion	N/A	Auto-on	Visible to All Users	Users can now see and complete OneWorkflow Document Tasks in the Vault Mobile app.
Platform	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	Platform	New Operators for Workflow on Documents	Medium	Auto-on	Visible to Admins Only	This feature adds new operators for evaluating fields in Workflows on Documents. Admins may now select all blank, none blank or at least one blank in decision steps.
	Platform	Person: First Name or Last Name is Required	Medium	Auto-on	Visible to Admins Only	The First Name or Last Name field is required for a Person record when it is not associated with a User.
	Platform	Checklists: Negative Scoring	Medium	Configuration	Visible to Admins Only	Allows Admins to set a negative score for available answers to reduce the overall score for checklists.
	Platform	Document Notification Templates in Workflows on Single Documents	Medium	Configuration	Visible to Admins Only	Allows Admins to select document notification templates in their workflows on documents. In order to see document notification templates, the document workflow must be configured to only support a single document: It must have the flag "Use workflow for single document" enabled.
	Platform	Include Users Allowed in Role	Medium	Configuration	Visible to Admins Only	This feature allows Workflow on Document participant controls to expose users that are allowed in a certain document lifecycle role. Both users and groups allowed for a Dynamic Access Control enabled role as well as via role defaults and override rules are supported. Admins may enable this feature for a specific participant control by selecting the flag "Display users and groups allowed in role".

Platform	Outbound Packages: View & Add Dependencies	Low	Auto-on	Visible to Admins Only	Review and include any blocking component dependencies in an outbound package prior to exporting the VPK so that the outbound package has all the required components for a successful deployment. *Auto-on in Vaults with Outbound Packages enabled
Platform	Add Archive Option to Search Settings	Low	Admin Checkbox	Visible to Admins Only	When enabled, users can archive documents that are no longer in use.
Platform	Add CJK Indexing Option to Search Settings	Low	Admin Checkbox	Visible to Admins Only	Users can enable CJK Optimized Object Search to search for object records using a dictionary rather than whitespace to separate words. This improves matching for Chinese, Japanese, and Korean.
Platform	Add Documents to Expanded Search	Low	Configuration	Visible to Admins Only	Documents can now be added to a collection which enables expanded searches across documents and objects for the first time.
Platform	Link Records to Permalinks	Low	Configuration	Visible to Admins Only	Adds a PermalinkLink function when configuring a formula field with Return Type: Link.
Platform	Delegate Admin CSV Export Enhancement	N/A	Auto-on	Visible to Admins Only	When exporting Active Delegations (Admin > Users & Groups > Active Delegations), the limit of 1024 active delegations in the export is now lifted: all active delegations are exported.
Platform	Increase Number of Tabs Allowed	N/A	Auto-on	Visible to Admins Only	Admins are allowed to create a total of 20 custom tabs, an increase from the current limit of 10 custom tabs allowed.
Platform	Jobs: Audit Logs for External URL Call Jobs	N/A	Auto-on	Visible to Admins Only	Audit log entries for external URL call jobs now contain the username configured as the Run As user for the job. The login audit entry now includes the Job ID.
Platform	Notification Template Tab	N/A	Auto-on	Visible to Admins Only	This feature combines the Document Messages tab and the Object Messages tab into a single tab called Notification Templates.
Platform	Platform Data Model Changes	N/A	Auto-on	Visible to Admins Only	With every release, we update the data model to better support evolving needs and new feature functionality.
Platform	View Delete Warning when Deleting a Tab	N/A	Auto-on	Visible to Admins Only	When an Admin deletes a tab, all the views associated with that tab are deleted as well. To help prevent Admins from

					deleting those views in error, Vault now displays a warning when attempting to delete a tab.
Platform	Automatically Name Envelope Records Flag Exposed in Settings	N/A	Admin Checkbox	Visible to Admins Only	This feature allows Admins to enable automatic naming of their envelope records used in workflows. Prior to this feature, this flag had to be enabled by support.
Platform	Increase in Workflow Start Step Rules	N/A	Configuration	Visible to Admins Only	Increases the limits on workflow start step rules in order to help customers move away from legacy workflows. Admins may now define up to 20 start step rules instead of 10. If Admins select the flag 'Use workflow for single document', they may define up to 30.
Platform	Notifications: Rich Text in Email Body & Notification Text	N/A	Configuration	Visible to Admins Only	This feature allows Admins to include rich text fields in the Email Body and Notification Text sections of Vault notifications and preserves the formatting specified in the rich text editor.
Platform	Enhancement to Document Multi-Value Fields in Expressions	Medium	Auto-on	Visible to All Users	Multi-value picklist and multi-select object fields on documents now return all selected values when used in lifecycle and workflow expressions.
Platform	Additional Aggregate Functions in Reports	Low	Auto-on	Visible to All Users	Vault now supports additional aggregate functions in grouped reports. Users may select the List and Distinct List functions to return a comma separated list of values in a column. Users may also now calculate standard deviation across rows.
Platform	Dashboard Exports for Large Charts	Low	Auto-on	Visible to All Users	This feature allows customers to download large chart images.
Platform	Display System-Managed Users in Search & Filters	Low	Auto-on	Visible to All Users	This feature standardizes the visibility of System-Managed users (such as Application Owner, Java SDK Service account) in search and data filters. System-managed users are not included when selecting users for the purpose of data entry (Objects, Documents, Configurations).
Platform	Drag and Drop Source File to Upload Dialog for Create New Draft, Upload New	Low	Auto-on	Visible to All Users	Users can drag and drop a file into the upload dialog when creating new draft, uploading new version, or uploading to placeholder.

	Version, and Upload to Placeholder				
Platform	Freeze Column for Related Object Sections	Low	Auto-on	Visible to All Users	Users can now freeze columns in a related object section. If enabled, users can choose how many columns to freeze (always visible) while horizontally scrolling.
Platform	Freeze Columns & Headers on Object Tabs	Low	Auto-on	Visible to All Users	Users can now freeze columns and headers on object tabs. Column headers are always visible when scrolling vertically. If enabled, users can choose how many columns to freeze (always visible) while scrolling horizontally.
Platform	Save Task Information	Low	Auto-on	Visible to All Users	This feature automatically saves information entered into a task dialog until the subsequent automatic next steps in a workflow are complete. Additionally, workflows on documents prompt for fields will now display the current value of the field if populated when the workflow contains a single document.
Platform	Support Document Roles as a Reporting Object	Low	Auto-on	Visible to All Users	Users may now add Document Roles to report types. Admins can create a Document with Document Role and User report type in order to see the details of users assigned to particular roles on documents.
Platform	Task Instruction Visibility	Low	Auto-on	Visible to All Users	This feature makes task instructions for workflows more visible. Both task instructions defined by the workflow initiator and configured on the task will now be visible on the homepage when show more is selected and by default on record or document pages.
Platform	Upload Source Files Using Vault File Manager	Low	Auto-on	Visible to All Users	When creating drafts, uploading new versions, or uploading to placeholder in vault, users now have the option to upload these files using Vault File Manager.
Platform	Action UI for Vault File Manager	N/A	Auto-on	Visible to All Users	This feature refreshes the Vault File Manager UI to align with the appearance of the Action UI in Vault.
Platform	Allow Crosslink Document Reclassification With	N/A	Auto-on	Visible to All Users	In previous releases, when attempting to reclassify a CrossLink document, Vault

		Different Rendition Types			1	validated to ensure that the rendition
						types supported on the current document type were also supported in the target document type. In this release, that validation is relaxed to allow the reclassification to occur even if a rendition type on the current document type is not supported in the target document type, as long as the document does not have any renditions of that type attached to it.
Pl	atform	Document Fields Behavior Change During Document Lifecycle State Change	N/A	Auto-on	Visible to All Users	Introduces the following behavior changes during a document lifecycle state change: 1. Any custom shared document field that is no longer associated with the document type, subtype or classification of the current document will have its value cleared. 2. Any custom document field that is disabled will continue to have its value cleared as before but will now have an audit trail entry captured for such an event
Pl	atform	Documents Viewed in Multi- Document Viewer	N/A	Auto-on	Visible to All Users	This feature makes several user experience enhancements to the multi- document viewer including indicating whether an item has been viewed or not by bolding and unbolding the name of the item.
Pl	atform	Fixed Header for Record Selection Dialog	N/A	Auto-on	Visible to All Users	Record selection dialog now has fixed header and horizontal scroll bar, that is always visible while scrolling through records.
Pla	atform	Google Drive Integration: Microsoft Office Files Check-in Enhancements	N/A	Auto-on	Visible to All Users	Enhances the Google Drive Integration feature to ensure the latest edits of any Microsoft Office files within Google Drive are always included along with a check-in to Vault.
Pl	atform	Localize Vault to Norwegian	N/A	Auto-on	Visible to All Users	Users can select Norwegian as their language and Veeva translates all static labels. Veeva does not translate any dynamic labels, but these are available for admins to translate via the Bulk Translation tool.
Pl	atform	Number Field Decimal Places Enhancement	N/A	Auto-on	Visible to All Users	Number fields with one (1) or more decimal places now display the exact value that the user entered, even if it

					includes trailing zeros.
Platform	Preserve eSignature Page Signer Info	N/A	Auto-on	Visible to All Users	Signature pages are generated upon the first view of the page and after a new signature is captured. For signatures captured after 22R2, a regenerated page will reflect the signer's title at the time of signature. If a delegate user adds the signature, their name and title also reflect the values from the time of signing.
Platform	Vault Help: Application- Specific Help Pages	N/A	Auto-on	Visible to All Users	With this release, Vault Help is divided into application-specific URLs designed to present the information most relevant to each Application Suite. Learn more links are directed to a specific area where users will have access to the corresponding information as well as the applicable Platform features. Search is streamlined to supply results from the specific URL.
Platform	Vault Loader: Trailing Zeroes Included in Extracts for Number and Currency Fields	N/A	Auto-on	Visible to All Users	The Vault Loader UI and Command Line tool (CLI) now provide trailing zeroes in the CSV export for number and currency fields. *Auto-on in Vaults with Vault Loader enabled
Platform	Vault Java SDK Service Account	N/A	Configuration	Visible to All Users	Vault Admins can enable the "Run as Java SDK Service Account" feature in General Settings > Vault Java SDK, and custom Vault Java SDK code will execute as the new Java SDK Service Account user, rather than the System user. This setting will be available after the General Release on August 5th. The Java SDK Service Account user appears in the Users & Groups tab and audit trails and does not count against user licensing. SDK audits will be logged as "java_sdk_service@{domain} on behalf of {user}".
Platform	EDLs: Match EDL Items to Documents Job Excludes Inactive Document Types	Medium	Support	None	With this release, the EDL Item to Document Matching feature now excludes inactive document types.
Platform	Scheduled Data Exports: Update Scheduled Start Time	Low	Support	None	Admins can update the scheduled start time of the scheduled data export job.

Quality	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	LIMS	Vault LIMS	High	Configuration		A new application in the Quality Suite. This initial release provides static data management capabilities and a test execution interface for early adopters only. *This feature may not be validated in pre- release Vaults.
	LIMS, QMS, QualityDocs, Station Manager, Surveillance, Training	Quality Data Model Changes	N/A	Auto-on		With every release, we update the data model to better support evolving needs and new feature functionality.
	LIMS, QMS, Surveillance, Training, QualityDocs	Unit of Measure Object	Low	Auto-on		Unit of Measurement object introduced to Quality Suite. All Quality applications and customers may utilize this object to further describe a number or quantity with its associated unit of measure using metric or imperial units.
		Extend Recurrence Check to Support Standard Object Types on Quality Event	Medium	Configuration	-	Recurrence Checks now support all standard object types on the Quality Event object.
	QMS	External Notifications: Distribution Group Filter Fields & Membership Automation	Medium	Configuration		Admins can now define filter fields for distribution groups. These filter fields constrain person records when selecting persons during distribution group membership creation and only return records whose associated filter fields match that of the record.
	QMS	Quality Team Conditional Role Exclusivity	Medium	Configuration		Adds to the existing Quality Teams Role Exclusivity feature, enabling users to define specific role membership restrictions for each role within the Quality Team. Allows greater flexibility so that a user can be selected for more than one role on a team, while also providing exclusivity where required.
	QMS	Risk Thresholds	Medium	Configuration		Allows users to create Risk Levels for a quantitative Risk Matrix by defining Risk Thresholds.
	QMS	Support 1/2/3 Dimensions for Risk Matrix	Medium	Configuration	,	Allows Admins to configure which dimensions (Severity, Occurrence,

					Detectability) should be required for users when creating Risk Matrix records.
QMS	External Notifications: Set Reply To Email Attributes on Complaint & Medtech Emails	Low	Configuration		External Notifications sent for Complaints or Medtech Complaints on the Quality Event object now support reply to functionality.
QMS	Additional Standard Fields & Objects	Low	Auto-on		Additional standard fields and objects have been added to the QMS data model that standardize commonly utilized fields and relationships between QMS entities.
QMS	Recurrence Check Related Object UI Enhancements	Low	Auto-on		The Synchronize Columns button is now intelligent and will only display if a user has made changes to one of the related object grids in the recurrence check's related object viewer.
QMS, QualityDocs, Station Manager, Surveillance, Training	Field Display Update for Quality Error Messages	N/A	Auto-on	Visible to All Users	Updates Quality error messages to show field labels instead of public keys.
QMS, Surveillance	VPS: Data Model Updates	N/A	Auto-on		Removes several fields from the Quality Event object. If these fields are referenced in any reports in a Vault, the 22R2 Vault upgrade will fail. Customers should remove any reference to these fields in their reports.
QualityDocs	Auto-Accept Document Change Requests & Periodic Review Records into a Document Change Control	High	Configuration		Adds the ability to configure actions on the Document Change Control object to automatically link Document Change Requests and Periodic Reviews to the DCC record.
QualityDocs	Document Change Request (DCR): Send Notification to Document Owner	Low	Configuration		Allows a new event action to be configured on the Document Change Request (DCR) lifecycle, that sends a notification to the document owner when a DCR record is created for the document.
Training	Recurrence: Assign Training Assignment In Advance	Medium	Configuration		Allows a Training Assignment to be assigned a number of days or months ahead of a recurrence date.
Training	Training Record Actions: Bulk Action Support	Medium	Configuration	Visible to Admins Only	Supports executing several Training actions in bulk.
Training	View Related Training Jobs from Update Training	Low	Auto-on	Visible to Admins Only	Admin can now click a link from the Job History for the Update Training

		Assignment Job History				Assignments job to see related jobs that started and completed.
	Training	Classroom Training: Cancel Training Assignments Part Of Class If No Valid Path Exists	Medium	Auto-on	Visible to All Users	A Classroom Training Assignment that is part of class (part of Roster) will now be cancelled in the following cases: 1) Learner Role/Curriculum/Training Requirement/Person is Ineligible/Retired 2) The Classroom Training Requirement is removed from the Curriculum, or the Curriculum is removed from the Learner Role.
	Training	Updatable Quiz Design for Individual Training Assignment	Medium	Auto-on	Visible to All Users	Quiz Design can be updated on an individual Training Assignment, in addition to updating it for a Training Requirement
	Training	Vault Training: Data Model Updates	N/A	Auto-on	Visible to All Users	The LearnerRole-Person join object was made a complex join to support the new Study Training application.
Regulatory	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	RIM, RIM Registrations	Country-Language Enhancement	N/A	Auto-on	Visible to Admins Only	A new Country Language object field, Use for XEVMPD/IDMP (use_for_xevmpdidmpv), identifies records that must be considered for XEVMPD and IDMP. The XEVMPD and IDMP data aggregation algorithms also reference the field when identifying attachments for inclusion.
	RIM Publishing	Health Canada Validation Criteria v5.1 Support	High	Configuration	Visible to Admins Only	Vault Submissions Publishing supports validating Canadian submissions against Health Canada's v5.1 Validation Criteria specification.
	RIM Publishing	Support US 4.3 Validation Criteria	High	Configuration	Visible to Admins Only	With this release, US FDA submissions can be validated using US 4.3 Validation Criteria.
	RIM Publishing	Merge & Publish Submission Content Plan	Medium	Configuration	Visible to Admins Only	Users can merge all contents of a Submission Content Plan to publish into a single file within Submissions Archive.
	RIM Publishing	Japanese Validation Criteria Item 7 Support	N/A	Auto-on	Visible to All Users	Vault Submissions Publishing supports the Japanese Validation Criteria update to Item 7, allowing for up to 500MB file sizes.
	RIM Publishing	Publishing Progress Indicator Enhancements	N/A	Auto-on	Visible to All Users	The publishing process indicator includes all continuous publishing jobs, and the

					indicator's downloaded CSV includes the current stage in the publishing process.
RIM Publishing, RIM Registrations, RIM Submissions, RIM Submissions Archive	22R2 RIM Data Model Changes	N/A	Auto-on	Visible to All Users	With every release, we update the data model to better support evolving needs and new feature functionality.
RIM Submissions, RIM Publishing, RIM Registrations, RIM Submissions Archive	Application Indication Data Model Harmonization	N/A	Auto-on	Visible to All Users	The following data model changes were made to harmonize inconsistencies in the data model for select RIM Vaults. 1) For Vaults where the indication field on Application Indication is named indicationrim, the field is relabeled to therapeutic_indicationrim 2) For Vaults where the outbound relationship name for Application Indication is indicationrimr, the name is changed to therapeutic_indicationrimr Any existing customizations/integrations involving this object field should be assessed and updated appropriately to use the new field name and/or outbound relationship name.
RIM Publishing, RIM Submissions	RIM PDF Standardization	Medium	Configuration	Visible to Admins Only	Vault can preprocess Submission Publishing documents to produce PDFs compliant with common health authority validation criteria when configured within a Rendition Profile.
RIM Publishing, RIM Submissions	Publishing Completeness Check on State Change	Low	Configuration	Visible to Admins Only	A new checkbox is available within the configuration of the Content Plan Hierarchy State Change workflow system action and user action. When configured, the state change will be prevented when publishing is ongoing.
RIM Publishing, RIM Submissions	Open Validation Results Behavior Updates	N/A	Auto-on	Visible to All Users	Open Validation Results are updated to show a count of the Validation Results records, rather than a sum of the occurrences. Additionally, Informational validation results for bookmark and hyperlink counts are excluded from the count.
RIM Registrations	EUDAMED UDI XML Generation Updates	High	Auto-on	Visible to Admins Only	EU UDI submissions are generated using the EUDAMED XML Schema v2.0.2. Also, the XML always includes required

					elements, improving troubleshooting when they do not have a value.
RIM Registrations	EU UDI Submission Viewer	High	Configuration		A new Registrations wizard will be provided to review the data quality of UDI submissions that have been generated for EUDAMED.
RIM Registrations	Multiple Gateway Support	High	Configuration	Visible to Admins Only	Users can create and apply multiple health authority gateway profiles for XEVMPD and publishing submissions.
RIM Registrations	Labeling Change Management Automation	Low	Admin Checkbox	Visible to Admins Only	Automation applied to the labeling change management process includes: creating Labeling Deviation records based on the outcome of workflows and lifecycles, automatically associating Labeling Concepts with Activities to allow for market-specific dispositioning, and calculating Safety Category and Lead Reference Market Due Date to assist with market-specific due date calculation.
RIM Registrations	Registrations Wizards Harmonization: Application Relationships	Low	Admin Checkbox	Visible to Admins Only	When the Submission Wizard is enabled, Registrations wizards can reference Application relationship records as the primary data source when creating records in bulk, bundling Activities or Regulatory Objectives, or pulling Regulatory Objective data to a submission.
RIM Registrations	Bundling & Splitting Enhancements	Medium	Auto-on	Visible to All Users	The bundling and splitting wizards can bundle and split Regulatory Objective and Submission details for medical device- and shelf life-related information, in addition to creating bundled or split Regulatory Objective and Submission details with a mix of object types when the internal names of the source and target object types match.
RIM Submissions, RIM Registrations	Global Content Plan Object Type Support	Medium	Auto-on		Name-based object type mapping now applies to the Submission relationship records created during creation and dispatch of Global Content Plan. This means the object type of the created Submission relationship records are set with the matching object type of the source Event relationship object type instead of the default object type that is

					configured for the Submission relationship.
RIM Submissions	Bulk Update Tokens Action	Medium	Configuration	Visible to Admins Only	When configured and initiated on a Content Plan record, the Update Toker in Fields action resolves tokens on all descendant Content Plan Items.
RIM Submissions	XML Element Name Tokenization Support	Medium	Auto-on	Visible to All Users	Content Plan tokens within the XML Element Name field on the Content Pla Template are resolved during the actio which currently support Content Plan token resolution, reducing manual effo for non-eCTD submission publishing.
RIM Submissions	Content Plan Bulk Actions on Matched Documents	Low	Auto-on	Visible to All Users	Users can initiate bulk document action on matched documents in the viewer when applying the Type = Matched Document filter. Additionally, filtering th Content Plan Hierarchy Viewer is now available for two additional matched document fields: Lifecycle State (Statu and Ready for Publishing.
RIM Submissions	Content Plan Viewer Indicator Update	Low	Auto-on	Visible to All Users	The Content Plan Viewer indicator and pre-validation locking functionality are updated to include all asynchronous st changes.
RIM Submissions	Content Plan Creation Refactoring & Harmonization	N/A	Auto-on	Visible to All Users	Content Plan creation, update, and cop processes are refactored for efficiency Vaults using the Submission Wizard, th Copy Content Plan and Copy Into Content Plan actions leverage Applica relationship records as source data wh copying Submission relationships.
RIM Submissions	Create Binder from Content Plan: Allow Document to be Linked Multiple Times in the Same Binder Section	N/A	Auto-on	Visible to All Users	Multiple instances of a document matched under the same parent Conte Plan are now successfully linked withir single binder section in binders create from a Content Plan. Previously, only o instance of the document could be link in the same binder section.
RIM Submissions Archive, RIM Submissions	Active Dossier Hovercard Update	N/A	Auto-on	Visible to All Users	The Active Dossier hovercard displays source document, translation, and submitted document information, along with their language and status.
RIM Submissions Archive	Submissions Archive Harmonization Job to	Medium	Auto-on	Visible to All Users	RIM Submissions Archive Harmonizat Job is enhanced to fix the eCTD

	RIM Submissions Archive	Correct eCTD Submission Placeholder Files Restrict Submissions Archive Access to Full User Licensed Vault Users	N/A	Auto-on	Visible to All Users	Submission Placeholder Files created in error due to the out-of-order Submission imports. Vault enforces Submissions Archive application licensing, blocking RIM Vault users without a Full User application license from accessing any Submissions Archive functionality.
	RIM Submissions Archive	Submissions Archive Binder Import Behavior Update	N/A	Auto-on	Visible to All Users	With this release, to improve import performance, the Submissions Archive binder node ordering is no longer calculated during the import process. The binder node ordering calculation during view time remains unchanged.
SiteVault	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	Site Connect, SiteVault Enterprise, SiteVault Free	Connected Study Type on Study	N/A	Configuration	Visible to Admins Only	This feature adds a new Connected Study Type field on the Study object and page layout. The system-managed Connected Study Type field indicates which Connected Study components have been enabled by the Sponsor.
	Site Connect, SiteVault Enterprise, SiteVault Free	New Exchangeable Document Types on Connected Studies	N/A	Configuration	Visible to Admins Only	This feature adds support to transfer documents of type Ancillary Committee Submission and Source Data Agreement to a Sponsor/CRO's vault for a Connected Study.
	SiteVault Enterprise, SiteVault Free	Site Viewer System Role	High	Auto-on	Visible to Admins Only	With this feature, the Site Viewer site- level system role is available. This system role provides users limited view-only access to SiteVault.
	SiteVault Enterprise, SiteVault Free	User Administration for Large Research Organizations	N/A	Auto-on	Visible to Admins Only	This feature enhances user creation to support large multi-site Research Organizations. When a Research Organization Administrator user in a Research Organization with more than three Sites creates a new user, all of the site-level system roles default to No Access.
	SiteVault Enterprise, SiteVault Free	Digital Delegation: Usability Optimizations	High	Auto-on	Visible to All Users	This feature introduces various enhancements to the Digital Delegation functionality: * Easy Enablement and Disablement: Additional automated triggers are in place

	ClinOps<>RIM	Rim-ClinOps: Transferring All Document Versions (RIM Side)	Medium	Admin Checkbox	Visible to Admins Only	When creating CrossLinks in a RIM vault the System shall transfer all SteadyState versions of a document instead of the latest version.
Vault Connections	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	SiteVault Enterprise, SiteVault Free	SiteVault Data Model Changes	N/A	Auto-on	Visible to All Users	With every release, we update the SiteVault data model to better support evolving needs and new feature functionality.
	SiteVault Enterprise, SiteVault Free	Support Microsoft Word Documents for eConsent Forms	Medium	Auto-on	Visible to All Users	With this feature, users can upload Microsoft WordTM informed consent forms (ICFs) to SiteVault and transform them into electronic consent (eConsent) forms using the Veeva eConsent editor.
	SiteVault Enterprise, SiteVault Free	Veeva ePRO in SiteVault	High	Auto-on	Visible to All Users	This features introduces Veeva ePro in SiteVault allowing users to do the following tasks: * Use electronic patient reported outcomes (ePro) in conjunction with a study * Establish approved ePro documents for use in a study * Assign and distribute ePro documents to study participants * Monitor and analyze the outcomes reported by participants
	SiteVault Enterprise, SiteVault Free	Filter User Profiles by Site	High	Auto-on	Visible to All Users	With this feature, when a SiteVault user has a site selected in the Vault Selector and views a list of User Profile records, only the records relevant to the currently selected site are displayed.
						to simplify the enablement process. * Data Validation: Enhanced logic is applied to eliminate unnecessary workflows and tasks. * Bulk Edit Staff Delegations: Users will now have the ability to add/remove multiple delegations from a staff member at once, simultaneously add/remove multiple staff delegations, and edit delegations without leaving the study person details page.

						*This feature may not be validated in pre- release Vaults.
	CTMS<>CDMS, ClinOps<>RIM, Promomats<>RIM	Protect Vault Connection Performance and Scalability (All Connections)	N/A	Auto-on		The RIM to Clinops Connection will have one Inbound Job and multiple Job Workers for each run (one per active Integration) on the RIM Vault instead of just one Job. The Job Logs will present multiple Job Tasks.
Training	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description

	Change Log							
	This feature list is subject to change prior to the 22R2 release. Change tracking is effective as of June 13th, 2022.							
Date	Change	Impact						
02 Aug 2022	Updated the GxP Risk of the following feature: - "Scheduled Data Exports: Update Scheduled Start Time"	The RIA now includes up to date GxP Risks.						
29 Jul 2022	Updated the Description and Enablement of the following feature: - "Vault Java SDK Service Account" Updated the Default Impact of the following feature: - "Scheduled Data Exports: Update Scheduled Start Time" Added the following feature: - "Submissions Archive Binder Import Behavior Update" Removed the following feature: - "Vault Platform HTTP/2 Support"	The RIA now includes a list of all features in 22R2 and up to date Feature Descriptions, Enablements, and Default Impacts.						
22 Jul 2022	Updated the Enablement and Default Impact of the following feature: - "EDLs: Match EDL Items to Documents Job Excludes Inactive Document Types"	The RIA now includes up to date Enablements and Default Impacts.						
15 Jul 2022	Updated the Description of the following feature: - "Document Fields Behavior Change During Document Lifecycle State Change"	The RIA now includes up to date Descriptions.						
08 Jul 2022	Updated the Description of the following feature: - "Document Fields Behavior Change During Document Lifecycle State Change"	The RIA now includes up to date Descriptions.						
05 Jul 2022	Added link to the 22R2 release notes.	The RIA now includes a link to the 22R2 release notes.						

01 Jul 2022	Updated the Default Impact of the following feature: - "New Operators for Workflow on Documents" - "Additional Standard Fields & Objects" Updated the Description of the following features: - "New Operators for Workflow on Documents" - "VPS: Data Model Updates" - "VPS: Data Model Updates" - "Support US 4.3 Validation Criteria" Updated the name of the "Link Records to Annotations and Permalinks" feature to "Link Records to Permalinks" Added the following feature: - "Documents Viewed in Multi-Document Viewer"	The RIA now includes a list of all features included in 22R2 and up to date Default Impacts, Feature Names, and Descriptions.
28 Jun 2022	Added the following feature: - "Drag and Drop Source File to Upload Dialog for Create New Draft, Upload New Version, and Upload to Placeholder"	The RIA now includes a list of all features in 22R2.
24 Jun 2022	Added the following feature: - "Link Records to Annotations and Permalinks"	The RIA now includes a list of all features in 22R2.
21 Jun 2022	Updated the GxP Risk of the following feature: - "Vault Java SDK Service Account" Updated the Enablement and Default Impact of the following feature: - "Rim-ClinOps: Transferring All Document Versions (RIM Side)"	The RIA now includes up to date GxP Risks, Enablements, and Default Impacts.

17 Jun 2022	Updated the GxP Risk of the following features: - "Allow Crosslink Document Reclassification With Different Rendition Types" - "Connected Study Types in Clinical Operations" - "Digital Delegation: Usability Optimizations" - "Document Fields Behavior Change During Document Lifecycle State Change" - "Google Drive Integration: Microsoft Office Files Check-in Enhancements" - "RIM-PM Connector Label Change in PromoMats" - "Site Connect Safety Distribution Update" - "Site Viewer System Role" Updated the Feature Description of the following features: - "Digital Delegation: Usability Optimizations" - "Rim-ClinOps: Transferring All Document Versions (RIM Side)" Updated the Enablement of the following features: - "AIR PSD Image Enhancements" - "Digital Delegation: Usability Optimizations" - "AIR PSD Image Enhancements" - "AIR PSD Image Enhancements" - "AIR PSD Image Enhancements" Added the following feature: - "AIR PSD Image Enhancements" Added the following feature: - "Preserve eSignature Page Signer Info"	The RIA now includes a list of all features in 22R2 and up to date GxP Risks, Feature Descriptions, Enablements, and Default Impacts.
13 Jun 2022	Initial RIA published	N/A