

## **Vault V17R2 Release Impact Assessment**

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault V17R2 that may affect a customer's validation efforts. We release a version of the RIA in advance of the general release. Closer to the general release date, an updated version is released, detailing validation information. As indicated, most new features are off by default and must be configured. Any feature that is not automatically available has a Default Impact value of "None," since there is no user impact unless an Admin takes specific action.

Revision Date:	July 21st, 2017						
This feature list is subject to change prior to the V17R2 release. Please note the revision date and the change log on the last sheet. Change tracking begins two weeks prior to pre-release.							
Feature:	Name of the feature introduced in V17R2						
Enablement:	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.						
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						
Med	May affect core application functions (workflows, revision history, etc.)						
Low	May affect metadata/notifications						
Default Impact	Impact to business users and processes at Day 1 if no configuration occurs						

Application	Feature Name	Enablement	Feature Risk	Default Impact	BRD	BRD Requirement(s)	OQ Test	Trace Matrix	Comment
Clinical Operations Clinical Operations	EDL Motion Detector for Batch Update	Auto-On	Medium	Medium	Vault BRD 2017: Working with Objects (QV-08698)	VOF-06-027	Vault-OQ-VOF-06C (QV-08821)	Vault Traceability Matrix: Working with Objects (QV- 08698)	Vault identifies which Expected Document List records should be included in the daily job based on the document's Last Modified Date.
Clinical Operations	System Study Product Defaulting	Auto-On	Low	Low	Vault BRD 2017: Clinical Vault Applications (QV-08702)	CLIN-07-002	Requirement not traced to OQ script per risk classification. Please see Traceability Matrix for referenced SDLC	,	Users now don't need the View permission on Product records for the Product document field to default based on the Study.
CTMS	Streamline Monitoring Event Creation	Auto-On	Medium	Medium	Vault BRD 2017: Clinical Vault Applications (QV-08702)	CLIN-46-014	Test Scripts.  Requirement not traced to OQ script per risk classification. Please see  Traceability Matrix for referenced SDLC	Vault Traceability Matrix: Clinical Vault Applications (QV-08702)	Vault creates a related Milestone record upon creation of a Monitoring Event record.
CTMS	Clinical Data Model Public Key Cleanup	Auto-On	N/A	N/A	N/A	N/A	Test Scripts. N/A	N/A	This feature renames existing Study and Site fields and adds mirrored fields to support integrations still using old name values.
CTMS, Study Startup	Study Planning by Event	Configuration	Medium	None	Vault BRD 2017: Clinical Vault Applications (QV-08702)	CLIN-35-011 CLIN-35-012	Vault-OQ-CLIN-35B (QV-08824)	Vault Traceability Matrix: Clinical Vault Applications (QV-08702)	Admins can configure Study Events to trigger creation of milestones from a template.  "In vaults where Create Milestones from Template is enabled.
CTMS, Study Startup	Autocomplete Milestones	Configuration	Medium	None	Vault BRD 2017: Clinical Vault Applications (QV-08702)	CLIN-43-014 CLIN-43-015 CLIN-43-016 CLIN-43-017	Vault-OQ-CLIN-35B (QV-08824)	Vault Traceability Matrix: Clinical Vault Applications (QV-08702)	Admins can configure Vault to auto-populate a Milestone's Actual Finish Date field and completion status by evaluating the completion of dependencies.
CTMS, Study Startup	Milestone Date Offsets	Configuration	Medium	None	Vault BRD 2017: Clinical	CLIN-43-018 CLIN-43-020 CLIN-43-021 CLIN-43-019	Vault-OQ-CLIN-35B (QV-08824)	Vault Traceability Matrix:	Admins can configure a new workflow step, Apply Updated Dependencies, to their
eTMF, Study Startup,	Manage Multiple Milestone Template Sets	Auto-On	Medium	Medium	Vault Applications (QV-08702) Vault BRD 2017: Clinical	CLIN-35-002	Vault-OQ-CLIN-35A (QV-07620)	Clinical Vault Applications (QV-08702) Vault Traceability Matrix:	Milestone object workflows to update dependent milestone dates.  Admins can associate Milestone Template Sets from their template library to
CTMS					Vault Applications (QV-08702)	CLIN-35-003 CLIN-35-004 CLIN-35-005 CLIN-35-010		Clinical Vault Applications (QV-08702)	various master sets created for separate purposes. *In vaults where Milestone Templates is enabled.
SiteExchange	Site User's Homepage	Auto-On	Medium	Medium	Vault BRD 2017: Clinical Vault Applications (QV-08702)	CLIN-48	Vault-OQ-CLIN-48 (QV-08825)	Vault Traceability Matrix: Clinical Vault Applications (QV-08702)	This feature displays a customized homepage for SiteExchange site users that includes assigned tasks, links to support, and help resources for site users.
RIM Registrations	Bulk Create from Reports	Auto-On	Low	Low	Vault BRD 2017: RIM Registrations (QV-08706)	REG-03-009 REG-03-010	Vault-OQ-REG-03 (QV-08822)	Vault Traceability Matrix: RIM Registrations	Users can create related Activity and Submission records in bulk directly from the Impact Assessment Report.
Pagistrations	Manage Registered Datalle	Configuration	Modium	Modium	Vault BRD 2017: RIM	REG-03-011 REG-03-012 REG-03-013	Vault-OQ-REG-03 (QV-08822)	(QV-08706)	Users can use a user action to open a wizard for updating related Registration
Registrations	Manage Registered Details	Configuration	Medium	Medium	Registrations (QV-08706)	REG-07	,	RIM Registrations (QV-08706)	Details to reflect the latest details after approval.
Submissions	Enablement Change: Submission Content Planning	Auto-On	N/A	N/A	N/A	N/A	N/A	N/A	Submission Content Planning is now automatically available in RIM Submissions vaults.
Submissions	Cascade Review & Approval Enhancements	Configuration	Medium	None	Vault BRD 2017: RIM Submissions (QV-08708)	RSUB-10-013 RSUB-10-014 RSUB-10-016	Vault-OQ-RSUB-10 (QV-08830)	Vault Traceability Matrix: RIM Submissions (QV-08708)	Admins can now specify state types for Entry Criteria when validating that binder content is in a specific state type. Also, when configuring an Entry Action to set binder content state type, Admins can specify multiple state types that can be set to the new state.
Submissions	Content Plan Configuration Updates	Configuration	Medium	None	Vault BRD 2017: RIM Submissions (QV-08708)	RSUB-09-020 RSUB-09-021 RSUB-09-032 RSUB-09-056	Vault-OQ-RSUB-09A (QV-08827)	Vault Traceability Matrix: RIM Submissions (QV-08708)	This feature adds a workflow system action to create a content plan, content plan matching rules, and removes the Related Content Plan and Related Content Plan Item Records lifecycle entry criteria.
Submissions	Content Plan Advanced Copy	Configuration	Medium	None	Vault BRD 2017: RIM Submissions (QV-08708)	09-054	Vault-OQ-RSUB-09B (QV-08829)	Vault Traceability Matrix: RIM Submissions (QV-08708)	This feature copies the entire Content Plan hierarchy and updates the plan to reflect the target Application and Submission.
Submissions	Create Binder from Content Plan	Configuration	Medium	None	Vault BRD 2017: RIM Submissions (QV-08708)	11-020	Vault-OQ-RSUB-11 (QV-08831)	Vault Traceability Matrix: RIM Submissions (QV-08708)	Users can create a binder from a content plan section.
Submissions	Planning	Configuration	Medium	None	Vault BRD 2017: RIM Submissions (QV-08708)	09-012	Vault-OQ-RSUB-09A (QV-08827)	Vault Traceability Matrix: RIM Submissions (QV-08708)	Users can indicate if Vault should include a submission join in the Content Plan through the new Use for Content Planning field.
Submissions Archive	Submissions Archive Importing Enhancements	Auto-On	Medium	Medium	Vault BRD 2017: RIM Submissions Archive (QV-08710)	SA-03-029	Vault-OQ-SA-03B (QV-08833)	Vault Traceability Matrix: RIM Submissions Archive (QV-08710)	Vault automatically reconciles broken references when users import eCTD submissions out of order. Users can also import multiple submissions at once.
Submissions Archive	Submissions Archive Regional eCTD Support	Auto-On	Medium	Medium	Vault BRD 2017: RIM Submissions Archive (QV-08710)	SA-03-015 SA-03-024 SA-03-025 SA-03-026 SA-03-027	Vault-OQ-SA-03C (QV-08880)	Vault Traceability Matrix: RIM Submissions Archive (QV-08710)	Submissions Archive now includes eCTD import and viewing support for South Africa (ZA) 1.0 & 2.1, Thailand (TH) 0.92 & 1.0, Gulf Cooperation Council (GCC) 1.0 & 1.1, Australia (AU) 0.90 & 3.0, and European Union (EU) 1.2.1.
Submissions Archive	Submissions Archive Harmonization Job	Configuration	Medium	None	Vault BRD 2017: RIM Submissions Archive (QV-08710)	SA-03-030 SA-03-031	Vault-OQ-SA-03B (QV-08833)	Vault Traceability Matrix: RIM Submissions Archive (QV-08710)	Admins can schedule the Submissions Archive Harmonization Job to reconcile any broken references that result from submissions imported out of order.
Submissions Archive	Submissions Archive Import Unreferenced	Configuration	Medium	None	Vault BRD 2017: RIM Submissions Archive (QV-08710)	SA-03-028	Vault-OQ-SA-03B (QV-08833)	Vault Traceability Matrix: RIM Submissions Archive (QV-08710)	Users can now choose to import files not referenced by the eCTD XML backbone.
EDC EDC	Casebook Schedule Audit Trail	Auto-On	High	Low	Vault BRD: EDC (QV-08066)	EDC-04-011	Vault-OQ-EDC-04 (QV-09002)	Vault Traceability Matrix: EDC (QV-08066)	Users can view an audit trail of all activity in the casebook schedule.
EDC	Event-Level Electronic Signature	Auto-On	High	Low	Vault BRD: EDC (QV-08066)	EDC-14-006	Vault-OQ-EDC-14 (QV-09005)	Vault Traceability Matrix: EDC (QV-08066)	Users can now sign all submitted forms in an Event at once.
EDC	Subject-Level Electronic Signature	Auto-On	High	Low	Vault BRD: EDC (QV-08066)	EDC-04-012	Vault-OQ-EDC-04 (QV-09002)	Vault Traceability Matrix: EDC (QV-08066)	Users can now sign all submitted forms in a Casebook at once.
EDC	Mark a Form as Intentionally Left Blank	Auto-On	Medium	Low	Vault BRD: EDC (QV-08066)	EDC-09-004	Vault-OQ-EDC-09 (QV-09003)	Vault Traceability Matrix: EDC (QV-08066)	Users can mark a form as Intentionally Left Blank.
EDC	Mark an Event as Did Not Occur	Auto-On	Medium	Low	Vault BRD: EDC (QV-08066)	EDC-04-010	Vault-OQ-EDC-04 (QV-09002)	Vault Traceability Matrix: EDC (QV-08066)	Users can now indicate that an event did not occur.
EDC	Remove Empty Unscheduled Events	Auto-On	Medium	Low	Vault BRD: EDC (QV-08066)	EDC-04-013	Vault-OQ-EDC-04 (QV-09002)	Vault Traceability Matrix: EDC (QV-08066)	Users can remove unscheduled events as long as all forms are blank.
EDC	Source Data Review & Verification Enhancements	Auto-On	Medium	Low	Vault BRD: EDC (QV-08066)	EDC-21-004 EDC-21-005 EDC-22-004 EDC-22-005	Vault-OQ-EDC-21 (QV-09006) Vault-OQ-EDC-22 (QV-09007)	Vault Traceability Matrix: EDC (QV-08066)	This feature introduces a shaded icon to indicate required SDV and SDR tasks. Users can see what percentage of SDR and SDV tasks they have completed for a form. Users can also perform SDV and SDR at the form-level.
EDC	Updated Date, DateTime & Time Controls	Auto-On	Medium	Low	Vault BRD: EDC (QV-08066)	EDC-02-001 EDC-02-013	Vault-OQ-EDC-02 (QV-08389)	Vault Traceability Matrix: EDC (QV-08066)	Users can now input dates and times into a free text field for Date, DateTime, and Time item controls.
EDC	Enrollment on Site Listing Page	Auto-On	Low	Low	Vault BRD: EDC (QV-08066)	EDC-06-002	Requirement not traced to OQ script per risk classification. Please see Traceability Matrix for referenced SDLC Test Scripts.	Vault Traceability Matrix: EDC (QV-08066)	The Site listing page now includes an enrollment column.
EDC	Event-Level More Actions Menu	Auto-On	Low	Low	Vault BRD: EDC (QV-08066)	EDC-04-014	Requirement not traced to OQ script per risk classification. Please see Traceability Matrix for referenced SDLC Test Scripts.	Vault Traceability Matrix: EDC (QV-08066)	Users can perform event-level actions using the More Actions menu.
EDC	Submit Button Rename	Auto-On	Low	Low	Vault BRD: EDC (QV-08066)	EDC-03-010	Requirement not traced to OQ script per risk classification. Please see Traceability Matrix for referenced SDLC Test Scripts.	EDC (QV-08066)	The Submit button is now the Complete button.
EDC	Task Bar Displays Applied Filters	Auto-On	Low	Low	Vault BRD: EDC (QV-08066)	EDC-08-011	Requirement not traced to OQ script per risk classification. Please see Traceability Matrix for referenced SDLC Test Scripts.	Vault Traceability Matrix: EDC (QV-08066)	The Task Bar displays automatically applied filters.
EDC	Pagination for Common Log Forms	Auto-On	Low	Low	Vault BRD: EDC (QV-08066)	EDC-16-004	Requirement not traced to OQ script per risk classification. Please see Traceability Matrix for referenced SDLC Test Scripts.	Vault Traceability Matrix: EDC (QV-08066)	This feature adds pagination for common log forms. Users can page through all common log forms of a certain type without returning to the table view.
EDC	Repeating Item Groups	Support	Medium	None	Vault BRD: EDC (QV-08066)	EDC-24	Vault-OQ-EDC-24 (QV-09029)	Vault Traceability Matrix: EDC (QV-08066)	Users capture repeating sets of questions while on a single form.
Multichannel Multichannel	Single Document Multichannel Publishing	Configuration	Low	None	Vault BRD 2017: Commercial Applications (QV-08700)	COM-17-001 > COM-17-008	Requirement not traced to OQ script per risk classification. Please see Traceability Matrix for referenced SDLC	Vault Traceability Matrix: Commercial Applications (QV-08700)	This feature allows users to easily manage the creation, versioning, and withdrawal of multichannel content from a single document.
All							Test Scripts.		

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Cart containing binders, the ZIP file now includes ruments for those binders and their nested binders.
reference fields on objects for XFA forms. Mapping is enabled.
in the multi-document viewer.
ct-specific message templates, including custom object
re now ordered by A-Z by document number.  Mapping is enabled.
o from a record's Details page to see a list of related
onliguration of two vaults.
vimage and link annotations on video files.
es bookmarks for captions and displays them beneath ngs.
es a document name after any metadata updates or
om actions for objects. Document and object custom nsmission of the user's session ID via a post message
cord data, including its fields, related record fields, and
o a downloadable template file.
out's Related Object section by object type.
and it is set to be an account to the contract of the contract

Change Log							
This feature list is subject to change prior to the V17R2 release. Please note the following changes:							
Date	Changes	Impact					
June 8 <sup>th</sup> , 2017	Initial RIA published.	N/A					
June 27 <sup>th</sup> , 2017	17R1.4 features updated and finalized in the RIA.	RIA includes all features for release in 17R2.					
June 29 <sup>th</sup> , 2017	Updated the enablement of "Manage Registered Details" from Auto- On to Configuration.	RIA includes up to date enablement information.					
June 30 <sup>th</sup> , 2017	Updated the enablement of "Create Binder from Content Plan" from Support to Configuration.	RIA includes up to date enablement information.					
July 6 <sup>th</sup> , 2017	Updated the feature risk and default impact of "Pagination for Common Log Forms", "System Study Product Defaulting", and "Date Calculations with +0 Days Use Vault Time Zone"  Updated the enablement of "User Task Object Class" to Auto-On, updated the default impact to "Medium", and added a note to this feature's description defining the impact on Clinical Operations vaults.	RIA includes up to date enablement, feature risk, and default impact information.					
July 6 <sup>th</sup> , 2017	Removed the "Date Calculations with +0 Days Use Vault Time Zone" line item. This feature was classified as a Fixed Issue, not a feature.	RIA includes only features for release in 17R2.					
July 10 <sup>th</sup> , 2017	Added the "EDL Motion Detector for Batch Update" feature.	RIA includes all features for release in 17R2.					
July 14 <sup>th</sup> , 2017	Added the Validation Guide to the RIA.	RIA includes the Validation Guide.					
July 21 <sup>st</sup> , 2017	Added updated risk and validation information for EDC to the RIA.	RIA with Validation Guide includes up to date risk and validation information for EDC in 17R2.					