



21R1 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities in this MyVeeva for Patients release that may affect customers' experiences. Refer to each feature's Enablement and Impact Notes to determine the configuration requirements, and refer to the Users Impacted, Staff Action Required, and Impact Notes to determine what users are affected and whether those users must perform actions to implement the capability. The RIA is an early preview of the Validation Impact Assessment (VIA).

Note: This feature list is subject to change prior to the 21R1 release. We will begin tracking changes on March 26, 2021.

Revision Date:	March 26, 2021
Additional Resources:	For detailed feature descriptions, refer to the release notes on the help website linked below. This document does not include changes made as part of the Vault Platform release or SiteVault outside of integrations with MyVeeva for Patients. Consult VeevaDocs for Vault Platform validation details.
MyVeeva for Patients Help	Help documentation and release notes for participants using MyVeeva for Patients.
SiteVault Free Help	Help documentation and release notes for site staff using SiteVault Free and the Veeva eConsent editor.
Vault Help	Help documentation and release notes for site staff using SiteVault Enterprise.
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.
<i>High</i>	May affect security, patient confidentiality, application areas that support GxP functions (multifactor authentication, eSignature, etc.) or other ERES controls data
<i>Medium</i>	May affect core application functions (formatting text in the eConsent editor, viewing eConsent forms in MyVeeva for Patients, etc.)
<i>Low</i>	May affect metadata/notifications
<i>N/A</i>	The feature is a minor UI enhancement and not a functional change. The feature has no validation impact.
Enablement:	Indicates whether the feature is available automatically, requires some configuration, or must be enabled by Veeva Support
<i>Auto-On</i>	This feature is available automatically. In some cases, an Auto-On feature is dependent on another feature that must be enabled or configured.
<i>Configuration</i>	This feature requires configuration by an administrator to be visible to end users.
<i>Support</i>	This feature must be enabled by Veeva Support.
Staff Action Required:	Indicates whether the affected staff members can perform an action (for example, edit an eConsent form) to implement new capabilities (for example, to update the form's content or formatting for participants in MyVeeva for Patients).
<i>Yes</i>	A staff member can perform an action to implement the capability. See the Impact Notes for more information.
<i>No</i>	No action is required by a staff member for the feature. The functionality is either configured by an admin or is a more minor or automatic update (for example, a change to the UI that does not require the site staff to update an eConsent form).

Feature Name	Users Impacted	Enablement	Staff Action Required	GxP Risk	Feature Description	Impact Notes
Question Blocks	Site Staff, Participants	Auto-On	Yes	High	This feature allows site staff to add question blocks and their response options to eConsent forms in the Veeva eConsent editor and participants to answer questions in MyVeeva for Patients. Site staff can add up to 12 response options and can specify whether the question is required. If they make a question required, participants can't sign the eConsent form in MyVeeva for Patients until they answer the question.	Site staff can add question blocks to the blank ICFs in SiteVault to enable participants to answer questions in MyVeeva for Patients.
Signature Date Based on Time Zone	Site Staff, Participants	Configuration	No	High	With this feature, the signature date and time on signed ICFs includes the time and time zone. The time zone is based on the site's time zone in SiteVault and the participant's device settings in MyVeeva for Patients. If no time zone is specified, the dates and times are displayed in Coordinated Universal Time (UTC). Additionally, action dates in MyVeeva for Patients are now displayed as how long ago the participant completed the action.	The time zone must be set on the site record in SiteVault. Veeva will update the settings for early adopters and SiteVault Free. SiteVault Enterprise customers must also configure the site's time zone. Participants don't need to update settings.
Editing Template ICFs	Site Staff	Configuration	Yes	Medium	This feature allows site staff for SiteVault Enterprise customers to use SiteVault and the Veeva eConsent editor to create controlled templates for their organization's eConsent forms.	Veeva eConsent must be enabled and configured for the vault. Additionally, SiteVault Enterprise is required to edit template ICFs.
Participant Declines to Sign	Site Staff, Participants	Auto-On	No	Medium	This feature allows participants to decline eConsent forms in MyVeeva for Patients. When they do so, the document's Veeva eConsent status is updated to Patient Declined in SiteVault and a notification is sent to the approver.	Veeva will configure the notification for SiteVault Free. We recommend that SiteVault Enterprise customers also configure the notification.
Editor UI Redesign	Site Staff	Auto-On	Yes	Low	This feature allows site staff to select whether titles in all block types and text content in signature and question blocks are displayed in MyVeeva for Patients and included in .PDF files. Additionally, they can now include text content in signature and question content blocks as well as text content blocks. Additional updates are made to the editor UI for ease-of-use.	If site staff want to include text content in a signature or question block, they can edit the eConsent form in the Veeva eConsent editor.
Spanish UI for Participants	Participants	Auto-On	No	Low	This feature allows participants to view application text in Spanish. This applies to only the application text and not eConsent forms. Site staff select the language of the eConsent form.	Participants can set Spanish as the first preferred language in their browser settings. If Spanish is already set, this functionality is automatically on for the user.

Feature Name	Users Impacted	Enablement	Staff Action Required	GxP Risk	Feature Description	Impact Notes
Split Content Block	Site Staff	Auto-On	No	Low	This feature allows site staff to select the Split Content button on the text content toolbar to split the text into a new content block. This enables users to paste an entire document or a large portion of a document into the editor then split it into content blocks instead of manually copying and pasting each part of a source document into a new content block.	None

Change Log

This feature list is subject to change prior to the 21R1 release. We will begin tracking changes on March 26, 2021.

Date	Change	Impact
13 Apr 2021	For the Participant Declines to Sign feature, updated the description and notes to indicate that the notification is available in 21R1.	The RIA now includes up-to-date GxP risks, descriptions, and impact notes.
	Updated the GxP risk of the Split Content Block feature from Medium to Low.	
26 Mar 2021	Initial RIA Published	N/A