Veeva SiteVault Free

Getting Started Checklist
for Research Sites

Overview

Veeva SiteVault Free replaces manual, paper-based processes so you can focus on what matters - your patients. Sites can manage regulatory and source documents all in one place and collaborate remotely with study monitors.

This checklist provides a roadmap to help you get started with SiteVault Free and navigate through help resources available to you. You will be guided on how to set up users and studies, manage source documents, manage regulatory documents, and more. This checklist includes links to instructions and tips and tricks, including written help documentation, video tutorials, and more.

Actions that can only be performed by users with a Research Organization or Site Administrative Role are noted with an (A). To find out which system role you have in SiteVault Free, please navigate to the Profiles tab >select Users, select your user record, and view your system role in the Access & Permissions section. To learn more about the differences among System Roles and Permissions, please visit this page. If you need to have your System Role changed, please contact your Research Organization Administrator or Site Administrator.

A Getting Started Checklist for Monitors or CRAs can be found here.

If you have any questions, please contact our support team at sitevaultsupport@veeva.com.

MANAGING STUDIES AND USERS

SiteVault Free supports unlimited studies and users at your site.

Log In - login.veevavault.com

For instructions on logging In and logging out, please visit our Help page

- You will receive a **welcome email** with your temporary password and username. If you have not received this email or are having difficulty logging in, please check your spam/clutter folders or contact our Support Team.

Add Study Team (A)

For instructions on how to **create a user**, please visit our help page here. To learn more about the different **system roles** in SiteVault Free, see our help page here.

- Create user profiles for your team members by navigating to the **profiles > users** tab and clicking the blue create button.
- If you're adding a **site administrator or site staff** and they are an existing vault user a green checkmark will appear. **Confirm that their username includes "@sitevault.com"**. If they do not have a username ending in "@sitevault.com", select **"click here"** to add them as a new user.

Grant Monitor Access as an External User (A)

For instructions on **granting your monitor access** please visit our Help page

- Create a profile for your monitor by navigating to the **profiles > users** tab and clicking the blue create button. If they have an existing vault account, a green checkmark will appear and continue to select external as their user role at the organization and site level.

Create a Study (A)

For instructions on **creating a study**, please visit our Help page

- Create a study by navigating to the **studies** tab and clicking the blue create button. Only the **study identifier** (how your site identifies the study) and **site** are required. To select the PI, they must be added as a user first under the **profiles > users** tab.

Assign Study Team, Monitors, Partner Organizations, and Products (A)

For instructions on **assigning study team, monitors, partner organizations, or products**, please visit our Help page.

- Navigate to the **studies > study team assignments** and use the **gray create button** to assign Study Team members. Use the **action wheel to change state to active** to ensure profile documents will file to the eBinder.
- Navigate to the **studies > monitor & auditor assignments** and use the **gray create button** to assign an External role as the monitor or auditor.
- Navigate to the **studies > partner organizations** or **products** and use the **gray create button** to assign a partner organization such as a lab or IRB or a product such as IP or a device. Use the **action wheel to change state to active** to ensure associated documents will file to the eBinder.

MANAGING SOURCE DOCUMENTS

Save time preparing for monitoring visits by uploading and managing source documents electronically.

Add Participants

For instructions on how to **add participants** to studies so you can upload source documents, please visit our Help page.

Upload Source Documents

For instructions on how to **upload source documents**, please visit our Help page.

- Navigate to the **documents > source upload** tab. SiteVault Free is **HIPAA-compliant** and is capable of housing unredacted source documents.

Finalize Source Documents

For instructions on how to **finalize source documents**, please visit our Help page.

- Use the **action wheel** to **finalize source.**

Resolving Monitor Review Feedback

For instructions on how to **address issues or annotations,** please visit our Help page.

MANAGING REGULATORY DOCUMENTS

Manage an intuitive electronic regulatory binder that supports compliance with 21 CFR Part 11 and HIPAA requirements.

Viewing Documents

For instructions on how to **view documents**, please visit our Help page. You can also learn more about how to navigate within the **eBinder** on this Help page.

- Navigate to **documents > library** or **eBinder** to find documents. **All documents** can be viewed in the **library. Final or approved documents** can be viewed in the **corresponding folder within the eBinder**.

Uploading Regulatory Documents

For instructions on how to **upload regulatory documents**, please visit our Help page. To view which documents each user role can upload, please view the SiteVault Document Types Reference Spreadsheet.

- Navigate to the **documents > library** tab and click the blue create button. You can upload documents in bulk using the document inbox.

Approving Regulatory Documents

For instructions on **approving documents,** please visit our Help page. Regulatory Documents need to be **approved** for them to be added to the **eBinder** for any studies they're associated with and for a monitor that's set-up as an **external role** and assigned to the study to be able to see them.

- Use one of the options under the **action wheel** to approve the document.

Regulatory Document Approval Methods

For instructions on how to **send for eSignature** and the document types that can be eSigned, please visit our Help page here.

For instructions on how to **certify as a copy or other approval methods**, please visit our Help page here. The approval methods available on a document in SiteVault Free will depend on the document type. **Approval methods include sending for eSignature, certifying as copy, or other approval methods.**

- If eSignature is available on a document, use the **action wheel** to send a document for **eSignature**. The person signing **must be created as a user.**

Document Versioning

For instructions on how to **upload new versions**, please visit our Help page.

- To upload a new version for an existing document that is final or approved, use the **action wheel** and select **create draft.**

Other Regulatory Document Management

For instructions on how to use a **training or read & understood** workflow, please visit our Help page here.

- Use the **action wheel** to send a **final** document through a **training or read & understood workflow.**

CONNECTED STUDIES

Seamlessly connect your operations with Sponsors for better collaboration and faster trials.

Connected Studies is only applicable to studies using Veeva Site Connect through connection with a Sponsor or CRO.

Accepting or Rejecting an Agreement (A)

For instructions on accepting or rejecting an agreement on **connected studies**, please visit our Help page here.

- An agreement will be sent to all **Site Administrators** and appear as a task on the **home** screen to be accepted or rejected. **Please contact your Sponsor or CRO contact prior to rejecting an agreement**.

Regulatory Document Package (A)

For instructions on completing different types of **regulatory document requests**, please visit our Help page here.

- Navigate to the **documents > regulatory document requests** to fulfill Veeva Site Connect document requests.

eCONSENT

Consent patients electronically using a collaboration of SiteVault Free and MyVeeva for Patients.

Creating an eConsent Form

For instructions on **creating and managing eConsent forms**, please visit our Help page here.

- Navigate to **documents>library** and **create a document from template**

Editing an eConsent Form

For instructions on **editing eConsent forms**, please visit our Help page here.

- Use the **action wheel** to edit an eConsent form with the **eConsent editor**

Consenting a Participant and Countersigning an eConsent Form

For instructions on **sending and signing an eConsent form**, please visit our Help page here. The participant **must be linked to a patient profile** with contact information completed to send an eConsent form. To learn how to create a patient, please visit our help page here.

- Navigate to **studies>participant** and use the **action wheel to send eConsent**
- Once the consent has been signed by the participant, you can **countersign the document by using the action wheel.**

OTHER TABS

Vault Selector

For instructions on how to use the **vault selector**, please visit our Help page.

- If you have access to multiple sites in SiteVault Free, use the **vault selector in the upper right corner** to navigate between **different sites within your organization.**

Using Reports and Dashboards

For instructions on **reports and dashboards**, please visit our Help page.

- Navigate to the **reporting > dashboards tab** to see metrics on monitor review for sites, monitor visit prep status, expiring documents, and more.