Veeva SiteVault

Sponsor Information

System Description and Architecture

Veeva SiteVault is a eRegulatory / Investigator Site File (ISF) solution licensed to and built specifically for clinical research sites.

SiteVault is provided as a service that customers may access and use per the Terms of Service (ToS). Veeva hosts and retains physical control over the SiteVault application and makes the Software available through the Internet via a web-browser. SiteVault is a non-configurable system with and does not support single sign-on, custom workflows or APIs. The SiteVault application consists of the following core capabilities:

- eRegulatory: Manage regulatory and source documents
- Study Connect: Seamlessly exchange documents and study information with sponsors and CROs
- Remote Monitoring: Provide monitors with secure, direct access to review regulatory and source documents to assist with source data review (SDR) and source data verification (SDV).

Veeva controls the configuration and management of SiteVault on behalf of sites. The binder structure (1) in SiteVault cannot be changed due to system requirements and sites are not required to file documents in a specific order to match sponsor filing.

Contractual Obligations

Veeva Site Vault is provided at no cost to the site and does not require a signed contract. Sites are required to accept the Veeva SiteVault ToS (2) with Veeva prior to implementation and receive approval before they are granted the right to access and use SiteVault and the associated software documentation for their internal business purposes until the expiration or termination of the Terms of Service Agreement.

Vendor Evaluation

Most clinical research sites using SiteVault are small, independent research organizations or small site networks, who generally will not conduct a formal evaluation of Veeva SiteVault prior to signing up for SiteVault. Contact sitesuccess@veeva.com for additional information if a site does not have a vendor evaluation on file.

Larger research organizations, who may have more stringent requirements, may request, and maintain vendor evaluation documentation to ensure SiteVault meets their internal policies and procedures. Veeva provides a tool for these organizations to evaluate the security and compliance of SiteVault (3)

System Validation

SiteVault is a fully validated solution and is built on Veeva Vault which has been validated by Veeva Systems in accordance with industry-standard validation guidelines and regulations (e.g., 21 CFR 820.75, 21 CFR 211.68, 21 CFR 11, EU Annex 11). SiteVault Technical & Operational Security Whitepaper covers how the security works for Veeva SiteVault (4).

SiteVault Validation is performed by Veeva on behalf of the user community to confirm that user needs have been met. The site therefore will not provide their own URS and UAT documentation.

A current UAT/PQ Validation Package is made available to sites and updated each time we do a "release"/change. The current validation package for SiteVault can be downloaded in the UAT/PQ section of the help page and describes the validation process, plan, deliverables, and resources required for the validation of Veeva SiteVault (5). This UAT/PQ verifies that SiteVault successfully satisfies all the configuration requirements as defined in the User Requirements Specification (URS).

Access Control

Veeva creates the site's first regulatory user in SiteVault. Additional user accounts are set up and maintained by the site's regulatory user(s). Veeva recommends that sites create SOPs surrounding access, use and maintenance of SiteVault. Veeva provides template SOPs (6) that cover the core areas of GCP compliance for implementing an eISF. These resources serve as reference tools only. Laws, rules, and regulations vary by country and jurisdiction, and Veeva cannot provide the site legal advice regarding their legal or regulatory obligations. It is the responsibility of the site to maintain the appropriate SOPs based on their specific use of SiteVault.

Sites are responsible for managing any changes to their practices, policies, and procedures with their own legal, privacy, and compliance resources. Sites should describe in their own SOPs which documents are kept as back up in case of a system failure (e.g., protocol, IB). Sites can also obtain documents from Veeva in the event of system failure by contacting sitesuccess@veeva.com.

System Support Access

Only Veeva administrators providing support or addressing technical issues, and handpicked members of the Veeva product development team can access select customer data. Access is only granted in accordance with the Veeva Terms of Service (ToS) and is limited by policy to allow the least access necessary to provide support or measure product performance, following the principle of least privilege.

Who to contact?

If you would like to discuss the details of this memo further or have additional questions, please contact sitesuccess@veeva.com.

References

(1) eBinder Reference Card link
(2) Veeva SiteVault Terms of Service link
(3) Higher Education Cloud Vendor Assessment Tool link
(4) SiteVault Technical & Operational Security Whitepaper link
(5) Veeva SiteVault Validation Documents link
(6) SiteVault SOP Templates link