SiteVault Compliance Attestation

02 May 2022

Re: SiteVault 21CFR11 & HIPAA Compliance

The SiteVault application was designed for clinical research sites to manage their regulatory documentation (e.g., Investigator Site File) and exchange information with Sponsors. SiteVault provides investigators and staff with easy access to study documents through an intuitive electronic regulatory binder that supports compliance with 21 CFR Part 11 and HIPAA requirements. With SiteVault, remote monitoring allows monitors a secure, direct access to study binders from any location. Monitors can perform source data review (SDR) and source data verification (SDV). Electronic signature functionality simplifies approvals and replaces printing, faxing, and scanning with fully electronic signature workflows.

SiteVault has been designed to conform to the technical controls defined in the following regulations:

- 21CFR11 Electronic Records; Electronic Signatures; Final Rule
- Health Insurance Portability and Accountability Act: Combined Text of All Rules

These technical controls include security access (e.g., 21CFR11.10d), audit trails (e.g., 21CFR11.10e), electronic signatures (e.g., 21CFR11.100), and data encryption (e.g., 45CFR164). Details of these controls are defined in the following compliance assessments (available upon request):

- Digital Trials Platform – Regulatory Assessment (QV-21574)
- 21CFR11 Compliance Assessment (QV-00503)
- HIPAA Security Rule Compliance Assessment (QV-05382)
- Vault Data Integrity Controls Assessment (QV-04400)

Veeva has validated (21CFR11.10a) the technical controls of *SiteVault* in alignment with industry recognized frameworks including:

- ISPE GAMP 5 A Risk-Based Approach to Compliant GxP Computerized Systems
- PIC/S Good Practices for Computerised Systems in Regulated “GXP” Environments
- EMA GCP/467532/2019 Notice to sponsors on validation and qualification of computerised systems used in clinical trials
- FDA General Principles of Software Validation

Jacques Mourrain, PhD
VP, Quality Regulatory & Compliance

Loren Smith
Regulatory Liaison Officer