Date: March 27, 2024

RE: Use of Veeva SiteVault

Dear Sponsor,

Virginia Commonwealth University (VCU) implemented Veeva SiteVault in quarter 3 of fiscal year 2023. VCU identified a need to make study documents more easily accessible to sponsors, their CROs and the study teams with the ever changing work climate. As more staff are working a hybrid schedule than ever before and recognizing that sponsors and CROs were no longer coming on site to perform monitoring visits with a desire for remote monitoring, VCU recognized that keeping study records solely on paper was now causing increased burden on staff and the sponsors of our research.

Veeva SiteVault is a 21 CFR part 11 compliant electronic investigator site file system. It is able to maintain both regulatory and patient binders in a single file that complies with ICH-GCP and industry regulations. Within SiteVault, the system has the capability to allow for remote monitoring and eSignatures; this will reduce travel costs for sponsors and CROs. The system also has the capacity to do digital delegation logs if allowed by the sponsor. At the end of the study, the files can be archived virtually for the required amount of time per regulations; this will reduce archival costs for long term storage of paper records. For sponsors/CROs that have other Veeva Clinical applications, they will now have the ability to connect to our SiteVault through Study Connect to seamlessly exchange documents and information with us. A signed non-repudiation agreement has been submitted to the FDA as of January 26, 2023.

VCU's Office of the Vice President for Research and Innovation (OVPRI) is requiring that specific types of studies initiated after April 01, 2023 be started in Veeva SiteVault instead of being maintained on paper. The criteria for mandatory use of SiteVault is specified in OVPRI's compliance notice 23.002: Institutional requirement to use Veeva SiteVault for clinical trials. VCU is also asking for ongoing studies who are still actively enrolling or have participants on treatment to be maintained in SiteVault. For existing studies, study teams have been given the option to either 1) Create a note to file identifying the date when the paper will fully migrate to SiteVault. This note to file must be retained in both the paper binder and SiteVault or 2) Add note to file in both paper binders and SiteVault documenting dates where paper will no longer be maintained.

If you have any questions about the required use of Veeva SiteVault or have any concerns with how the study team is utilizing SiteVault, please don't hesitate to contact myself:

Virginia Commonwealth University

Office of the Vice President for Research and Innovation

BioTech One, Suite 3000, 3rd Floor
800 East Leigh Street
Box 980568
Richmond, Virginia 23298

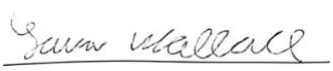
(804) 827-2262

research.vcu.edu

Lisa Richman Ballance
Associate vice president for research strategy and regulatory affairs

Lauren Wallace, MS, RAC- Drugs
Director of Clinical Research Regulatory Affairs
FDA Program Officer
Office of the Vice President for Research & Innovation
Virginia Commonwealth University
kanigherl@vcu.edu

Regards,



Lauren Wallace, MS, RAC-Drugs
Director of Clinical Research Regulatory Affairs
Office of the Vice President for Research and Innovation
Virginia Commonwealth University
kanigherl@vcu.edu

Lisa Richman Ballance, MA, CPW, CCP
Associate Vice President for Research Strategy and Regulatory Affairs
Office of the Vice President for Research and Innovation
Virginia Commonwealth University
lballanc@vcu.edu
o. (804) 827-2262