## New Tool Available: Veeva SiteVault Free

The Office of Research is pleased to announce that UCSF has approved use of <u>SiteVault Free</u>; below is information about this tool and what you need to do to set up an account.

#### **Product Overview**

Veeva SiteVault is a cloud-based platform that study teams can use to store regulatory documents and facilitate remote monitoring, including access to non-redacted documents such as signed informed consent forms. It is 21 CFR Part 11 and HIPAA compliant.

#### **Use Cases**

Veeva SiteVault is currently being used by study teams in the HDFCCC; their 2 main use cases for Veeva Vault are:

- 1. <u>E-regulatory binders</u> Many sponsors use this system which pulls the docs from Veeva's study eBinder into the sponsor's Trial Master File
- 2. <u>ePatient Charts</u> Study teams will be using Veeva to store <u>source documents</u> that are not found in APeX and accessible through MD Link (*examples:* patient questionnaires, disease assessment forms, and any source docs that are created specifically for study purposes and therefore not saved in the patients EMR).
  - For studies where the sponsor has declined to sign the MD Link Agreement, Veeva Vault can be used to share source docs with study monitors remotely without having to spend hours redacting the source docs.

#### **Getting Started**

Here is the information Veeva needs to set up accounts; it can be sent in a spreadsheet if there are multiple team members who need access, or just in the body of an email. Send to <u>Greyson McGrail</u>, Veeva Account Executive for UCSF.

- Parent Organization: UCSF
- Department/Site Name: e.g. Department of Otolaryngology
- Physical Address:
- Name and email of First User:

# **Training and Other Resources**

- 1. <u>Veeva Website</u> product page for Veeva SiteVault
- 2. Getting Started Checklist guide on getting started and navigating our Help section
- 3. <u>YouTube channel</u> video tutorials (can also be shared with monitors as there is a monitor specific playlist)
- 4. Regulatory Documents information on uploading and approving regulatory documents
- 5. Document Versioning all about updating documents
- 6. Source Documents all things source and RMV
- 7. Community Meetups monthly meetings where they talk about all things SiteVault
- 8. eBinder Reference Sheet guide to where each document type will file in the eBinder
- 9. Document Information MS Excel spreadsheet of document details
- 10. Template SOPs
- 11. Monitor Resources link to monitor help page

### **Product Support**

For technical support or product-related questions about Veeva SiteVault, contact SiteVaultSupport@veeva.com

For UCSF-specific questions contact <a href="mailto:research@ucsf.edu">research@ucsf.edu</a>