Veeva SiteVault

Digital Delegation Vision and Design

A Better Way to Delegate

Veeva SiteVault's Digital Delegation feature enables Principal Investigators (PIs) and their staff to manage the delegation of study responsibilities electronically rather than on a paper; the feature provides monitors and auditors the ability to understand and see evidence of these delegations.

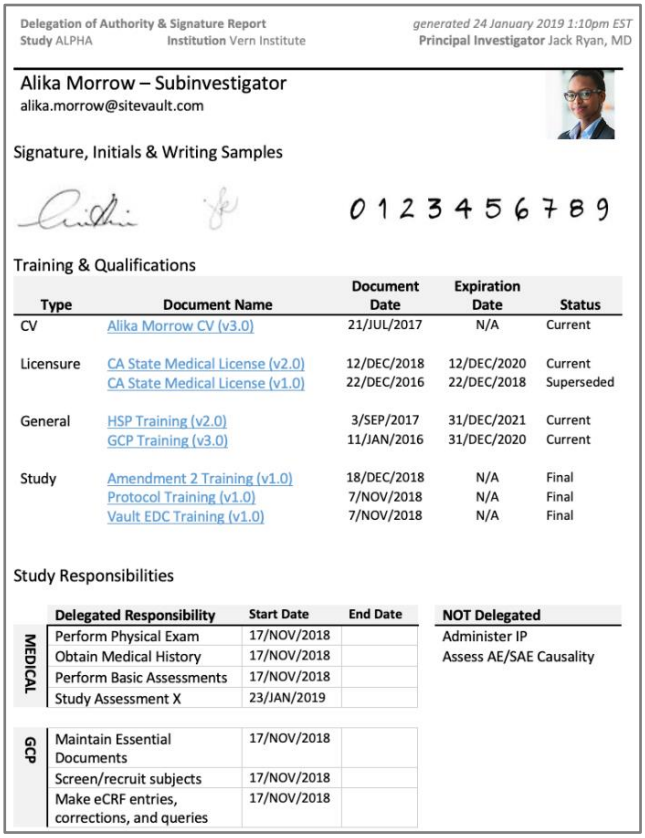
Veeva developed Digital Delegation in SiteVault to overcome many of the paper-based challenges that our customers experience. To better support our customers' frequently asked questions, this paper explains Veeva's vision and key design choices.

Rethinking the DOA Log

Sites, sponsors, and auditors told us there was significant room for improvement in their experiences with delegation logs. These discussions formed the basis for our vision of what the log could become if it were digitally transformed:

- **Easier to manage for staff and PIs**, no matter where they are located
- **Providing clearer information** and richer context to monitors/auditors
- **Unable to be lost or destroyed**…or run out of space on a page

The image to the right [Figure 1] is a mockup of a delegation of authority document which merges the content of two separate records, "Delegation of Authority" and "Signature & Initials," into one.



Delegation of Authority & Signature Report — *generated 24 January 2019 1:10pm EST*
Study ALPHA **Institution** Vern Institute **Principal Investigator** Jack Ryan, MD

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Signature, Initials & Writing Samples

0 1 2 3 4 5 6 7 8 9

Training & Qualifications

Type	Document Name	Document Date	Expiration Date	Status
CV	Alika Morrow CV (v3.0)	21/JUL/2017	N/A	Current
Licensure	CA State Medical License (v2.0)	12/DEC/2018	12/DEC/2020	Current
	CA State Medical License (v1.0)	22/DEC/2016	22/DEC/2018	Superseded
General	HSP Training (v2.0)	3/SEP/2017	31/DEC/2021	Current
	GCP Training (v3.0)	11/JAN/2016	31/DEC/2020	Current
Study	Amendment 2 Training (v1.0)	18/DEC/2018	N/A	Final
	Protocol Training (v1.0)	7/NOV/2018	N/A	Final
	Vault EDC Training (v1.0)	7/NOV/2018	N/A	Final

Study Responsibilities

	Delegated Responsibility	Start Date	End Date
MEDICAL	Perform Physical Exam	17/NOV/2018	
	Obtain Medical History	17/NOV/2018	
	Perform Basic Assessments	17/NOV/2018	
	Study Assessment X	23/JAN/2019	
GCP	Maintain Essential Documents	17/NOV/2018	
	Screen/recruit subjects	17/NOV/2018	
	Make eCRF entries, corrections, and queries	17/NOV/2018	

NOT Delegated
Administer IP
Assess AE/SAE Causality

Figure 1

Key Design Decisions and Rationale

1 Do not require signatures or initials

There is no GCP requirement for signatures or initials on a delegation log; Requiring signatures would be an additional burden on sites without any benefit to security or validity of the delegation log information

The primary regulatory basis for a delegation log comes from ICH GCP (ref 4.1.5): "The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties." There is no mention of investigator delegation in FDA's Code of Federal Regulations (Title 21, Parts 312 and 812). Regulation (EU) No 536/2014 (Article 73) mentions that "The principal investigator shall assign tasks among the members of the team…" but does not use the term delegation in this context.

When managing delegation logs on paper, the purpose of obtaining signatures and/or initials at certain time points is to provide evidence that staff or a PI acknowledged, reviewed, or approved certain decisions. In SiteVault, such activities are recorded in the system audit trail and can **only be completed in the system by a logged in user**. Requiring a signature or initials would increase the burden on PIs and site staff and would not make these system acknowledgements, reviews, or approvals more secure or valid.

When a monitor or auditor reviews delegation information, they do so by reviewing a PDF document generated by SiteVault. **All versions of document are automatically generated, with a new major version created each time the PI approves any delegation changes for the study**[1]. Monitors and auditors can view and download the audit trail for Delegation of Authority documents to confirm that only the SiteVault System has edited or changed the document.

2 Do not list specific responsibilities for PIs

Doing so would conflict with the primary purpose of the delegation log

Per ICH GCP (4.2.5), "The investigator is responsible for supervising any individual or party to whom the investigator delegates trial-related duties and functions conducted at the trial site." Regardless of how many or how few study responsibilities that the PI personally executes during conduct of a study, the PI is responsible for all study conduct at their site. If the log were to list specific responsibilities "delegated" to the PI, it would make the log less clear.

In certain blind or double-blind scenarios in which the PI does not personally execute a given study responsibility, GCP is clear that the PI remains accountable to delegate those responsibilities to others.

3 Do not create an end of study declaration page

Requiring signatures is an additional burden on sites and does not improve the security or validity of the delegation log information

TransCelerate's delegation log template includes an End of Study Declaration page which is "signed by the PI at the conclusion of the study (Close Out Visit) to attest that the PI acknowledges the delegation and training of staff throughout the trial."2

This additional signature/task is redundant with all previous PI-attested updates to site staff delegations (which are required at every revision of the document). Adding another round of PI attestation at study close provides no additional value to sites, monitors, or auditors regarding the accuracy or validity of information already displayed on the final version of a log.

1 These requirements (reference SiteVault Business Requirements section SV-E.12-BR-005) are validated by Veeva as part of each major release.
2 Information and Guidance Document for the Completion of the Site Signature and Delegation of Responsibilities (DOR) Log, TransCelerate (October 2022 v3).