SiteVault Free

# Time and Cost Savings of Veeva SiteVault Free

## Transform your Clinical Research Operations

Clinical research sites receive long-term material cost savings and time efficiencies with SiteVault Free. Sites can expect a 30-50% reduction in staff time collecting signatures, filing staff credential, tracking expirations, preparing and conducting monitor visits, and reviewing correspondence and documentation.

> When I calculate the amount of manual time it takes to receive a regulatory document and process it to the point of being monitored and filed away, I estimate we save at least 50% of time per document using Veeva SiteVault.
>
> – **William Chrvala,** CCRC Managing Director, Mid Hudson Medical Research, PLLC

## Save on study costs by reducing resources and staff time spent

*In this model, based on a 24-month study, the site saves 45% of the original cost.*

| | Paper-based Estimated Costs Per Study[3] | Potential Savings Per Study | Potential Final Cost |
|---|---|---|---|
| Paper, ink, storage space, archive fees | $1,126 | 100% | 0 |
| Staff time: *Collecting signatures; Filing staff credentials; Tracking expirations; Preparing and conducting monitor visits; Reviewing correspondence and documentation* | $12,755 | 40%[2] | $7,653 |
| **Total cost per study[3]** | **$13,881** | | **$7,653** |

[1] Based on customer feedback including Mid Hudson Medical Research and Tilda Research.

[2] Average of customer-reported reduction in staff time of 30-50%

[3] A CenterWatch survey reports the actual costs of regulatory tasks for a 24-month study—from startup to database lock—took an estimated at 255.5 hours of staff time per study (at $50 per hour based on fair market value per hour for a Study Coordinator), for a cost of $12,755. Added to an estimated $1,226 in materials—paper, folders, binders, storage boxes, document storage and regulatory software—the total cost is $13,901.

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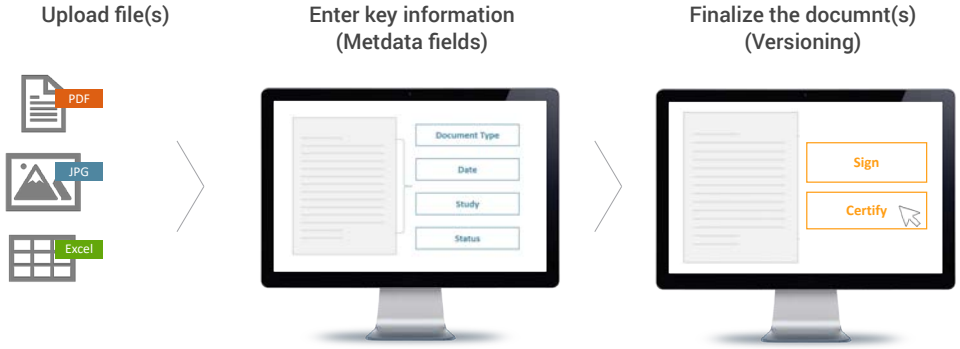
## Reduce time spent with bulk documentation upload

Moving to an electronic, paperless eRegulatory system like SiteVault Free enables sites to save time throughout the lifecycle of the trial.




**50 Documents** x **20 Seconds** = **16 Minutes**

Average number of documents in initial reg packet

Average time to classify a document

Total time to add a reg packet

## The need for efficient management of essential documents

Investigative sites are responsible for maintaining essential documents or an investigator Trial Master File (TMF). This is often referred to as the investigator site file (ISF) or regulatory binder. Per industry regulations:

- Sites must maintain adequate and accurate records, per 21 CFR 312.62, and make them available for inspection in accordance with 21 CFR 312.68.
- A complete investigator TMF should be available before, during and after the trial, and accessible under the control of the investigator/institution, independent from the sponsor.

## How are sites doing this today?

Today, many sites manage their ISF in paper format since many electronic systems are not compliant with 21 CFR Part 11, HIPAA requirements, or other industry regulations. Further, many sites can't afford to purchase their own solution.

## How can SiteVault Free help?

SiteVault Free is a free eRegulatory solution designed for clinical sites or research sites that replaces manual and paper-based processes. Sites can manage study documentation in a modern system that supports compliance with 21 CFR Part 11 and HIPAA requirements.

SiteVault Free reduces the need to maintain paper binders, upload documents to different sponsor portals, and email and fax paper copies to monitors. It is owned and managed by the site. It can be used to manage all regulatory and source documentation, including final inspectable documents and active files.

[4] European Medicines Agency, 2018.