Business Case Justification for Veeva SiteVault

Clinical research sites looking to improve visibility and operating efficiency are implementing eRegulatory systems to manage regulatory documentation and processes. Securing buy-in for change is challenging, but you can demonstrate a compelling reason to change by defining a business case.

This paper provides tips and sample language to help you make a business case for Veeva SiteVault, including:

* Detailing current challenges
* Presenting a solution
* Defining the business value
* Making a financial justification

# Overview

*In this section, provide a high-level overview of the current challenges, business goals, and solution being presented.*

{organization name} is facing increasing competition to win studies and higher levels of administrative burden than ever before. Adopting an electronic regulatory (eRegulatory) system provides an opportunity to save time, cut costs, and ultimately manage more studies.

This document outlines the business reasons for implementing Veeva SiteVault, a free eRegulatory system that will enable {organization name} to complete regulatory tasks with greater speed, efficiency, and with higher quality.

# Current Challenges

*In this section, detail the challenges and risks you’re trying to solve. Below is a list of the most common challenges for regulatory teams. When creating your business case, select the issues relevant to your organization and add examples that will resonate internally. The challenges section can be a simple bulleted list or a thorough documentation of the challenges and their impact.*

As {organization name} continues to support new studies, add new team members, and expand in more locations, the administration of regulatory tasks has become more difficult. Our current method of managing regulatory documents and processes is inefficient and limits our ability to support additional studies.

Managing regulatory documentation across multiple systems (e.g. binders, local file shares, flash drives, email, portals) and in different file formats and versions (e.g. paper, PDF, draft version, track-changes versions, final versions) creates several key business challenges, including:

* **Difficulty finding information**. Decentralized storage of regulatory documents reduces efficiency and increases the likelihood of accessing the incorrect version of a document (e.g. protocol or ICF) or using outdated information. Maintaining consistent records and naming conventions is difficult and requires additional training and oversight.
* **Manual tracking and poor visibility**. Storing information in multiple systems results in duplicative tasks and workarounds. The information must be entered redundantly and manually tracked, increasing the likelihood of entry errors and reducing productivity. Spreadsheets and reports are difficult to maintain, require manual effort to reconcile, and provide no real-time insight into documents out for signature, upcoming expirations, or turnaround times.
* **Inefficient study execution**. Collecting signatures and managing staff credentials is time-consuming and cumbersome. Documents sent for signature are often emailed, printed, signed, scanned, emailed back, then printed again and saved locally. Updating the delegation log or a single CV across all active studies requires multiple versions of a CV to be printed and manually filed into each study binder. Furthermore, each version must be manually archived and tracked.
* **Too many systems and passwords to manage across sponsors**: Using multiple systems to collect and exchange information across sponsors and CROs results in increased training requirements, logins, and passwords to manage.

# Solution Overview

*Use this section to provide a high-level overview of SiteVault and highlight how it is different from alternative solutions. Be sure to call out the elements of the product or vendor that will resonate most with management.*

Moving to a centralized, web-based eRegulatory platform will enable {organization name} to improve staff efficiency, speed study activation, and increase visibility and compliance.

After reviewing multiple solutions and vendors, we have determined that Veeva SiteVault will best meet these business objectives for the following reasons:

* **System features**: SiteVault is a web-based platform and includes all of the standard features of a standard eRegulatory system including eSignatures, dashboards and reports, remote monitoring, digital delegation, version control, and automated naming and filing. SiteVault also includes Study Connect, a place to securely access and exchange trial information with sponsors and CROs using Veeva Clinical applications. Setup is easy and documents received via Study Connect are automatically filed to SiteVault eRegulatory.
* **Cost**: SiteVault is free and is fully supported by Veeva. There is no restriction on the number of users, documents or studies that can be managed in the system. Additional add-ons can be purchased, such as eConsent or enterprise Single-Sign-on, and API support for integrations.
* **Compliance**: SiteVault supports compliance with 21 CFR Part 11 and HIPAA requirements. Validation and documentation for 21 CFR Part 11 is fully-supported by Veeva.
* **Support**: System support (phone and email) is provided from Veeva at no cost. The [SiteVault Help Center](https://sites.veevavault.help/gr/) includes tutorials and self-service resources including videos, SOP templates, and live and on-demand training. In addition, their Site Success team can assist with change management and regularly lead customer workshops and community events.
* **Company and reputation**: Veeva is a public company with over 5,000 employees and serves more than 4000 sites and 1000 life sciences companies, including 49 of the top 50 largest global pharmaceutical companies. Veeva specializes in building software for the clinical research industry and is well-known among sponsors and CROs we work with.

**Alternative Analysis (Optional)**

*If desired, include a brief summary of considered alternatives - one of which should be the status quo, or doing nothing. The reasons for not selecting the alternatives should also be included.*

The following alternative options have been considered to address the business problem, but were not selected for the following reasons:

|  |  |
| --- | --- |
| **Alternative option** | **Reason for not selecting alternative** |
| Keep the current system in place | * Requires increased staffing * Manual and untimely reporting * Lack of automation * Increase risk of non-compliance |
| Develop software internally | * Lack of qualified resources * Significant cost associated with software design * Timeframe required is too long |
| {list other product(s) explored} | * Significantly higher cost * Lack of familiarity among sponsors and CROs * Difficult to learn and use |

# Business Value

*This section should define how the system will help achieve your organization's goals. The following are common goals you can use to help define the business objectives.*

Utilizing SiteVault will help {organization name} meet several strategic goals, including:

* **Save time and reduce administrative burden**. Centralizing and automating regulatory processes will reduce time spent collecting signatures, allow investigators to sign documents from anywhere, and make it easier to locate the correct version of a document. Automated reporting eliminates manual record-keeping and makes it easy to quickly see the status of a document due for signature, an expiring CV, or a list of documents added since our last monitoring visit.
* **Work more easily with sponsors and CROs:** An eRegulatory system that is connected to sponsors and CROs will reduce redundant requests for information, reduce training and system fatigue, and enable us to retain full visibility of historical data after study close-out.
* **Speed study activation**. The ability to create a new study binder and add people to a study in a few clicks will improve study activation timelines. Startup documents can be routed for eSignature and reporting will improve visibility into the status of open study tasks. Documents, such as CVs, can be updated once across all locations.
* **Reduce monitoring time and costs**. Providing study monitors with ‘self-service’ access to information will reduce redundant requests, time spent preparing for monitor visits, and the need to use multiple portals across different study sponsors. Monitors can easily identify and review new documents and will enjoy spending less time on-site. Since many monitors are already familiar with Veeva, the learning curve will be minimal.
* **Improve quality and compliance**. Maintaining a single system to manage all master versions of a file eliminates duplicate documents, reduces the risk of errors, and ensures all files are easily accessible and up-to-date.

# Financial Justification

*When making purchasing decisions, sites should consider the cost savings associated with material costs and staff time. In this section, identify the current regulatory costs to your organization and how the system will reduce the costs. This section can include a simple list of tasks that will be streamlined or a detailed chart showing a full time and cost analysis. Below is an example of how you might breakdown the anticipated savings in the first year. Alternatively, you may want to show the number of additional studies that can be managed, or other metrics that are more meaningful to management.*

The following table captures the potential savings associated with the system for the first year.

|  |  |  |
| --- | --- | --- |
| **Type** | **Description** | **First year costs and anticipated savings** |
| Cost | Product and licensing fees | $0.00 |
| Cost | Direct costs for software installation, support, and training | $0.00 |
| Savings | Material savings for reduction of paper, ink, storage space  *Calculate the anticipated savings for paper, binders, printer ink, and storage of active study binders and documents.* | $ |
| Savings | Archival fee savings for storing documents electronically  *Calculate the anticipated savings for long term archival / storage of study documents.* | $ |
| Savings | Time savings for collecting signatures  *Calculate the anticipated time / costs saved collecting and tracking signatures. For example: 1 full-time regulatory coordinator currently spends about 5 hours per week routing and tracking signatures. It is anticipated that this number will be reduced to no more than 1 hour per week. With 3 full time staff at an average of $30 per hour, this results in ($30 x 4 / week reduced time x 3 regulatory staff x 52 weeks) $18,720 in savings annually.* | $ |
| Savings | Time savings for managing staff profile documents  *Calculate the anticipated time / costs saved with the ability to update staff profile documents one across all studies. If your site is paper based, consider the time involved with printing, re-printing, and manually filing medical licenses and CVs into your regulatory binder. If your site utilizes a shared drive, consider the time spent updating and copying documents to different folders or shared drives.* | $ |
| Savings | Time savings for monitor preparation and access  *Calculate the anticipated time / costs saved by providing monitors with self-serve access before, during, or after a visit. For example: Consider the time spent sending and resending documents to monitors, or the time spent sitting with monitors during a visit to review documents together.* | $ |
| Savings | Time savings for reporting  *Calculate the anticipated time / costs saved by eliminating the need to build and manage reports showing upcoming expiring documents and signature turnaround times*. |  |
| **Net First Year Anticipated Savings** | | **$** |

Based on the cost benefit analysis above we see that by authorizing the use of Veeva SiteVault, {organization name} will save $XX,XXX in the first year alone. This represents a significant improvement in our operating costs and is a clear indicator of the benefits the system will have on the company.

Additional Resources

* Learn more about Veeva SiteVault or to sign up for SiteVault: [Visit website >](https://sites.veeva.com/)
* Watch this on-demand webinar to see a demonstration: [Watch video >](https://go.veeva.com/SiteVault_Free_eRegulatory_Demo)
* Download an overview of Veeva SiteVault: [Download >](https://www.veeva.com/resources/veeva-sitevault-product-brief/)

**About Veeva Systems**

Veeva is the global leader in cloud software for the life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 1,000 customers, ranging from the world’s largest pharmaceutical companies to emerging biotechs. As a Public Benefit Corporation, Veeva is committed to balancing the interests of all stakeholders, including customers, employees, shareholders, and the industries it serves. For more information, visit veeva.com.

**Veeva Systems**

Global Headquarters

Pleasanton, California, USA

4280 Hacienda Drive

Pleasanton, California 94588