Veeva SiteVault

A Guide to Selecting an eISF

For Clinical Research Sites

Introduction

Clinical research sites must comply with an increasing number of industry requirements to conduct clinical trials. As the number and complexity of clinical trials grow, sites are under pressure to manage more studies and to run them more efficiently.

As a result, sites are looking to an eISF to reduce the administrative workload and barriers to running more studies.

This paper provides key considerations and tips for evaluating an an eISF to help research sites choose the right solution for their needs.

eISF 101

What an eISF?

An eISF is designed to manage the documents that an investigator is required to maintain when conducting a clinical trial, otherwise known as essential documents. They replace the paper-based 'regulatory binder' by providing a secure, central location to manage electronic documents and signatures in compliance with 21 CFR Part 11 requirements.

An eISF is different from SharePoint, shared network drives, or clinical trial management systems (CTMS) because they are specifically built for the purpose of managing regulated documentation.

While some systems may allow for the storage of documents, an eISF goes above basic storage by providing system-driven workflows, role-based access controls, version control, and automation to streamline processes and improve compliance.

An eISF designed for sites are different than sponsor-provided portals in two important ways. First, the workflows support your processes and can be modified to reflect your specific business needs. Second, the system can be used across all your studies, regardless of the technology your sponsors use. Standardizing on a single system across all studies reduces training requirements and improves compliance.

Core features of an eISF

While there are a variety of solutions available, any system you evaluate should offer the following core functionality.

- Audit trails
- Version control
- Security controls
- eSignatures
- Standard naming and filing conventions
- Supports remote monitoring

Business value of an eISF

Here are a few ways the right eISF can deliver significant benefits for your site:

- **Reduces time-consuming administrative tasks** such as collecting signatures, tracking outstanding requests, and managing documentation.
- **Speeds study activation and execution** by simplifying the review processes, speeding turnaround times, and automating manual processes.
- **Streamlines access** to current study information by centralizing information and ensure appropriate access to the right documents.
- **Increases visibility** of open tasks, expirations, and study metrics.
- **Improves quality and compliance** by reducing errors and improving standardization.
- **Reduces monitoring time and costs** by providing self-serve access to regulatory documents.

Industry drivers for change

With 72% of studies falling more than one month behind schedule , regulatory authorities and clinical trial sponsors are increasingly supporting and even promoting the use of electronic documentation at the site level to improve efficiency, collaboration, and oversight.

- In January 2014, a federal mandate requiring electronic medical records took effect.
- In December 2016, the Century Cures Act was signed into law to increase use of health information technology.[2]
- In May 2018, the FDA required all eCTD submissions from sponsors to be electronic.[3]
- In March 2018, ICH GCP guidelines regarding electronic records and essential documents were updated to encourage and promote "clinical trial quality and efficiency."[4]
- In a 2019 survey, all (100%) of clinical trial sponsors reported the need for better data exchange among study partners, indicating that the industry is pushing for more streamlined processes and systems.[5]
- In March 2019, Scott Gottlieb, M.D., former FDA commissioner, stated that the clinical trials industry needs to invest in new approaches that "reward collaboration and data sharing across the clinical research enterprise."[6]

> Digital technologies are one of the most promising tools we have for making health care more efficient and more patient-focused.[7]
>
> – Scott Gottlieb, M.D., FDA Commissioner

[1] ACRP.org, February 2017, Accelerating Study Start-Up: The Key to Avoiding Trial Delays
[2] FDA.gov, March 2019, 21st Century Cures Act
[3] FDA.gov, September 2019, Electronic Common Technical Document (eCTD) guidance
[4] FDA.gov, March 2017, E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry
[5] Veeva Systems, Inc., 2019, Veeva 2019 Unified Clinical Operations Survey Report
[6] FDA.gov, March 2019, Statement by FDA Commissioner Scott Gottlieb, M.D.
[7] FDA.gov, January 2019, Breaking Down Barriers Between Clinical Trials and Clinical Care: Incorporating Real World Evidence into Regulatory Decision Making

Preparing for an evaluation

Focus on outcomes, not features

When preparing to evaluate systems, start by determining the outcomes you're looking to achieve and stack rank them in order of importance for your organization. With clear objectives in mind, you're less likely to be drawn into every 'bell and whistle' a system can offer so you can truly focus on the functionality that address the challenges you're looking to overcome.

Here are some questions to help determine what areas to focus on:

- What tasks require the most time to complete?
- What compliance risks are we looking to resolve or avoid?
- What processes require duplicate data entry or the use of multiple systems?
- What trackers or logs would we like to eliminate?
- What performance metrics are we looking to improve?
- What standards or processes are we having trouble enforcing and why?

15 questions to ask a vendor

Use these questions to determine the best solution for your needs and ensure long-term return on investment.

Company history and reputation

1. **Is the vendor widely known and trusted by industry sponsors and CROs?**
   Clinical research sites operate in a larger ecosystem of life sciences companies. Choosing a vendor that is well known and trusted by the partners you collaborate with will help speed acceptance of new systems and set you apart from the competition.

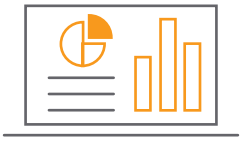
2. **Is the company profitable or cash flow positive?**
   A software vendor in good financial standing has the means to invest more in ongoing innovation or R&D than those that are not.

3. **What is the ownership profile of the company?**
   Are they public, VC-backed, or private equity owned? Private equity is risky because a banker is the one really captaining the ship based on return on investment. Public companies are safer as their financial standing and missions are transparent.

4. **What countries does the vendor have customers in?**
   The more the better as this speaks to scale and global performance.

5. **How many paying customers do they have, and what is their collective volume of data/content?**
   A higher number of paying customers and volume of information managed demonstrates the vendor's ability to scale and execute.

6. **Does the company have a history of successful products?**
   A company's track record of products, innovations and satisfied customers in an indicator of experience, resources, and longevity.



End-user system functionality

7. **Can non-technical users build reports and dashboards, without relying on the vendor?**
   Enabling end-users to build their own reports improves visibility, saves time, and puts you in control of your information. Inquire about specific metrics you want to see and whether the system can support and automate the delivery of reports.

8. **Are documents scanned and converted to searchable text?**
   Built in optical character recognition (OCR) technology ensures you can always find what you are looking for since everything contained within the document itself can be identified in a search.

9. **How does the system control different versions of a document?**
   Managing changes to documents is daunting. Rather than repeatedly uploading and re-saving new documents, the system should automate versioning and allow you to quickly and easily see changes between two versions of a document. Differences in text between two versions should be highlighted and noticeable, eliminating the need for line by line comparison and reducing the likelihood of missing a change.

10. **Can non-technical staff create or modify workflows and users groups?**
    Consider the unique roles within your organization, how different departments or areas may have varying processes, and how more complex studies can require additional layers of approval. A system with the capabilities to route documents on workflows that you design and manage will help support the unique needs of more complex studies and departments within your organization.

11. **Can teams easily review and collaborate on documents within the system?**
The ability to annotate, edit, or track feedback on documents without moving documents out of the system is crucial to streamlining reviews and ensuring long-term adoption. If users can't perform work within the system, old habits will take over and you'll be back to square one.

Approach to building software

12. **Is the software built on an application platform or is it a point solution?**
Many vendors will refer to their system as a 'platform.' The quick test is to ask how many applications are on the same platform. Don't let a vendor call a module or add-on an application. A true platform will have multiple applications running on the same code base that can interact with each other.

13. **How many integration partners does the vendor actively support?**
A vendor that supports integrations with multiple systems and third parties is apt to have a better understanding of business processes and the ability to support your needs in the long run.

14. **Does the vendor have an open, public API?**
System integrators and other research systems can play a significant role in the tuning of a software solution. Don't be trapped by your vendor. Ask whether your vendor offers an open API (application protocol interface). A public API is even better as it eliminates barriers to integration and demonstrates code quality.

15. **Does the company outsource their development?**
Communication is integral to successful software companies. Needs come from customers then go to product designers, which go to architects, which then get coded by developers, which are then tested by QA teams and implemented into the system. This relay can lose fidelity if communication is not crystal clear. Furthermore, outsourcing might be an indicator that a company is not planning to provide their product long term since it does not value investing in in-house developers.

The right partner to ensure long-term success

The long term success of any business software implementation is dependent on the partner you choose. In this highly regulated industry, finding a partner you can trust and who is committed to your success is key. Look for a company that is well-known and respected across the broader life sciences industry, has a track record of innovation, and will be around for the foreseeable future.

Next Steps

Contact Veeva to explore how an eISF can benefit your site: **sites.veeva.com/contact**

Watch a demo of SiteVault >

Veeva

About Veeva Systems
Veeva is the global leader in cloud software for the life sciences industry, serving more than 1,000 biopharma companies — including 18 of the top 20 pharmas — 6,000 clinical research sites, and 20,000 patients. We also provide free software and global support to research sites as part of our mission as a Public Benefit Corporation (PBC). Our goal is to reduce the technology burden among sites and make clinical trials more accessible to patients. Learn more at sites.veeva.com.