Veeva SiteVault Free: eISF Guide for Clinical Sites

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Veeva SiteVault Free: Who Is It For?

Executive Summary

Veeva SiteVault Free is a **cloud-based eRegulatory (electronic Investigator Site File, or eISF) solution offered at no cost to clinical research sites**. Launched in January 2020 by Veeva Systems – a life sciences cloud software leader – the product allows research sites to manage all regulatory and source documentation digitally, in compliance with 21 CFR Part 11, HIPAA, GDPR, and ICH/GCP guidelines ([1] ir.veeva.com) ([2] sites.veeva.com). Veeva explicitly targets **clinical research sites** (investigators and their staff at hospitals, clinics, academic centers, and specialized research practices) as the primary users. The vendor's own materials emphasize that SiteVault is a "site-first" solution designed to streamline site operations and connect sites with sponsor systems ([3] sites.veeva.com) ([1] ir.veeva.com). For qualifying sites (investigators conducting trials), the core SiteVault platform (eISF, plus eConsent and CTMS capabilities) is available **free for up to 20 concurrent studies** ([4] sites.veeva.com) ([2] sites.veeva.com), with no limits on documents, users, or storage. This model makes enterprise-quality eISF technology accessible to small and medium-sized sites that previously relied on manual binders or fragmented tools.

Since its introduction, SiteVault Free has seen **rapid adoption by research sites worldwide**. Within eight months more than 500 sites in over 30 countries were using it ([5] www.veeva.com), and by mid-2025 Veeva reported over 8,000 sites in 80+ countries on SiteVault ([6] sites.veeva.com) ([7] ir.veeva.com). Users report dramatic efficiency gains: for example, one multi-site network cut study start-up time by 40% and halved regulatory workload (saving tens of thousands of dollars per study) ([8] www.veeva.com). Another site saw its 4-hour on-site monitoring visits shrink to 30 minutes through secure remote access ([9] www.veeva.com) ([10] sites.veeva.com). Across diverse settings – from private practice groups (e.g. a urology clinic network ([11] ir.veeva.com)) to research centers and academic hospitals – the common theme is that SiteVault Free eliminates paper binders, automates compliance checks, and facilitates remote collaboration. Importantly, **no site pays licensing fees for core eISF capabilities** (up to 20 studies) – Veeva as a Public Benefit Corporation explicitly provides this to fulfill its mission of advancing clinical research ([12] www.veeva.com) ([7] ir.veeva.com).

This report provides an in-depth analysis of Veeva SiteVault Free, emphasizing *who* benefits from the offering. It covers the regulatory context (why sites need electronic binders), Veeva's product strategy and PBC mandate, detailed feature and plan comparisons, adoption data, and real-world case studies. We discuss use cases across site types, from small independent clinics to large institutional sites, and present data on efficiency and compliance impacts. Stakeholder perspectives (sites, sponsors/monitors, industry analysts) are included, along with future outlook (e.g. the integrated SiteVault CTMS/eConsent launched in 2025 ([7] ir.veeva.com)). All claims are substantiated with references to Veeva documentation, industry surveys, and regulatory guidelines.

Introduction and Background

Clinical research sites (the investigators and staff running trials at hospitals, clinics, academic centers, or private practices) are **mandated to maintain an Investigator Site File (ISF)** – a collection of all regulatory, ethics, and trial documents required by ICH GCP and national regulations ([13] intuitionlabs.ai) ([14] intuitionlabs.ai). Traditionally, sites have kept paper binders of documents (protocols, consents, CVs, logs, monitoring notes, etc.) to remain audit-ready. However, paper binders are cumbersome: they require manual filing, have no easy search, and can be lost or incomplete. Over the past decade industry groups have pushed toward electronic ISFs (eISFs) to improve efficiency and enable remote processes ([15] intuitionlabs.ai) ([16] intuitionlabs.ai). Regulatory agencies (FDA, EMA, etc.) permit electronic records if systems comply with 21 CFR Part 11 and analogous rules ([17] intuitionlabs.ai) ([18] sites.veeva.com), but many sites lacked validated systems.

In parallel, a broader shift to decentralized/digital trials (accelerated by the COVID-19 pandemic) created demand for remote monitoring and electronic consent, making digital binder systems increasingly essential ([16] intuitionlabs.ai) ([19] www.veeva.com). Early in 2020, Veeva – already a leader in life sciences cloud (its Vault platform was used by over 200 sponsors, including 12 of the top 20 pharma companies ([20] ir.veeva.com)) – moved to fill this gap at the *site* level. In January 2020, Veeva announced **SiteVault Free**, positioning it as a "free eRegulatory solution for clinical research sites" that replaces paper processes with a modern cloud application ([1] ir.veeva.com). As Veeva's VP of Site Strategy (Bree Burks) noted at launch, SiteVault would "reduce the workload of investigators and coordinators so they can focus on important research" ([21] ir.veeva.com). Veeva offered the core eISF application completely free (inclusive of support and training), leveraging their existing validated Vault technology.The only limitation: the free plan covers up to 20 simultaneous active studies per site ([4] sites.veeva.com) ([2] sites.veeva.com) (any excess study count would typically push an organization to the paid Enterprise tier). In 2021, Veeva re-emphasized this strategy after becoming a Public Benefit Corporation – highlighting that it was making SiteVault free for >90% of sites as part of its PBC mission to "improve clinical research for sites and sponsors" ([7] ir.veeva.com).

SiteVault Free quickly gained traction. By September 2020 (8 months post-launch) **over 500 sites in 30+ countries** had adopted it ([5] www.veeva.com). These early adopters ranged from small clinic networks to medium-sized centers. Veeva and industry reports indicate that by 2025 the user base grew to *thousands of sites* (on the order of 8,000+ globally ([6] sites.veeva.com)). The availability of free enterprise-grade eISF technology (with guaranteed compliance controls) has significantly lowered barriers to digitization at the site level. This report analyzes *who* uses SiteVault Free, how they use it, and what impacts it has on the clinical trial ecosystem.

Veeva SiteVault Product Overview

Veeva SiteVault (core eISF application) is built on the Vault platform and comprises an **electronic Investigator Site File** (eRegulatory binder) plus other site-specific modules (eConsent, soon-to-launch eTMF/CTMS). Unlike custom or local document repositories, SiteVault provides a structured folder taxonomy (based on an eISF reference model) and all requisite compliance features. Key capabilities include:

- **Electronic Investigator Binder:** Each study at a site has its own eBinder containing all regulatory docs (protocols, consents, IRB approvals, sponsor communications, training records, logs, etc.) ([13] intuitionlabs.ai) ([22] sites.veeva.com). This eliminates paper files. Documents can be organized per traditional binder categories or a standardized model (ICH GCP essential documents plus site-chosen extras).
- **Access Controls & Compliance:** SiteVault enforces 21 CFR Part 11–style controls (user authentication, audit trails, versioning) and supports HIPAA/GDPR for health data ([23] intuitionlabs.ai) ([18] sites.veeva.com). Every document action is logged with electronic signature capability ([24] ir.veeva.com) ([25] sites.veeva.com). In practice, this means sites have a continuous audit-ready system. For example, a clinical research center reported that SiteVault made them "inspection ready easy overnight," knowing "we have the current document for that study" ([26] intuitionlabs.ai).
- **Electronic Signatures:** Investigators and delegates can electronically witness and sign forms (1572s, training logs, etc.) within the system, satisfying regulatory e-signature criteria. (If regulations forbid e-signing in a region, users can upload ink-signed docs and certify them as copies ([27] sites.veeva.com).)
- **Certified Copies:** The system supports certified-copy workflows for source documents: scanned source pages can be certified electronically, meeting FDA guidelines on source verification. (Operators upload source scans and "certify" them, attaching an audit trail so monitors know they are true copies.)
- **Remote Monitoring:** A major feature is secure remote monitor access. Sites can assign external user accounts to monitors/auditors, granting them read-only portal access to the eISF from anywhere. This built-in remote monitoring portal replaces in-person visits. According to Veeva, monitors get "secure and direct access to study binders from any location" ([19] www.veeva.com). In practice, sites report that what used to be hours-long on-site visits can shrink to minutes. For instance, a U.S. project manager said "our 4-hour in-person monitoring visits are now just 30 minutes using remote monitoring in Veeva SiteVault" ([9] www.veeva.com) ([10] sites.veeva.com). Remote monitoring not only

saves travel time but also reduces disruptions to clinic operations. A study by Florence Healthcare and others has noted that remote access to site data allows trials to continue under restrictions, a capability underscored during COVID-19 ([16] intuitionlabs.ai) .

- **Document Exchange Integration:** Through **Veeva SiteConnect**, SiteVault links to sponsors' Vault environments. This enables bidirectional document exchange (sponsors can push documents to the site eBinder, and sites can push updates back). Thus a site can collaborate easily with any sponsor using Veeva Vault (over 200 sponsors) as well as non-Veeva partners via common standards ([28] siteconnect.io) ([29] www.veeva.com).
- **Search & Dashboards:** Unlike paper, SiteVault has full-text and metadata search across all studies. Built-in dashboards and reports help track binder completeness (e.g. missing signatures or expiring documents). Coordinators get alerts for upcoming tasks. These analytics features improve oversight; for example, Veeva notes that sites see faster readiness metrics thanks to automated checks ([30] intuitionlabs.ai) ([31] sites.veeva.com).
- **Unlimited Storage & Users (Free Tier):** The free SiteVault edition imposes no limits on storage or user accounts. A site can have unlimited documents and staff in the system ([32] ir.veeva.com) ([2] sites.veeva.com). This is in stark contrast to traditional binders (limited by office space) or some competitive systems that cap usage on low tiers. One site manager commented that SiteVault, being free, allowed all team members (coordinators, investigators) to access it without worry ([11] ir.veeva.com).
- **Training & Support:** Veeva provides **24/7 global support and training** to all SiteVault Free customers at no charge ([33] sites.veeva.com) ([34] sites.veeva.com). Sites also get a dedicated "Site Success" team to help onboard and change-manage the transition to digital binders ([34] sites.veeva.com). In short, the free offering does not skimp on services or help.

Table 1 (below) contrasts core aspects of the traditional paper-based ISF with Veeva SiteVault as an eISF. The advantages of SiteVault's digital approach (automated compliance, search, and remote access) become evident:

Capability	Traditional Paper Binder	Veeva SiteVault (eISF)
Regulatory Compliance	Manual tracking via checklists; physical logs of paper forms	Built-in 21 CFR 11/HIPAA compliance: all records and signatures are electronic with audit trails ([1] ir.veeva.com) ([2] sites.veeva.com). No paper audits needed.
Electronic Signatures	Wet-ink signatures on paper forms	Yes – investigators/staff sign documents digitally within SiteVault (meets Part 11) ([24] ir.veeva.com).
Remote Monitoring	On-site visits only (monitors review binders in person)	Yes – secure, portal-based monitor access. Sites report monitor visits shrinking from hours to minutes ([9] www.veeva.com). Real-time collaboration.
Document Exchange	Physical couriers, email attachments, or CD-ROMs	Integrated SiteConnect: one portal exchange with sponsors/CROs. Faster, controlled sharing.
Search & Retrieval	Manual lookup of papers in folders	Full-text and indexed metadata search across studies. Saves hours of document retrieval.
Version Control	Manual version numbering and stamps	Automatic versioning. System locks old versions and labels new, preventing last-minute mix-ups.
Workflow Alerts	None (coordinators must remember tasks)	Automated: alerts for expiring docs, pending signatures, upcoming renewal deadlines.
Scale (Studies/Users)	Limited by binder size/folders	**Unlimited (Free Edition):** infinite studies, docs, users ([32] ir.veeva.com) ([2] sites.veeva.com). All staff can be onboarded.
Reporting & Metrics	Ad-hoc, manual reports	Built-in dashboards (binder completeness, signature status, site readiness) for oversight.
Onboarding & Training	Varies widely; depends on site's SOPs	Vendor-provided training guides and videos; 24/7 support team readily available ([34] sites.veeva.com).
Cost to Site	Paper, printing, courier costs; labor of manual filing	**Free (up to 20 studies)**: no licensing fees; only optional service fees for very large sites.

The Source for each "SiteVault" column is in Veeva's literature (see cited lines above).

SiteVault Free Plan and Editions

Veeva offers two editions of SiteVault: **Free** and **Enterprise**. The Free edition is targeted at smaller or mid-sized sites, whereas Enterprise is for very large or complex organizations needing advanced customizations. Table 2 summarizes the key differences:

Feature / Resource	SiteVault Free (no cost)	SiteVault Enterprise (paid)
Active studies	**Up to 20** concurrent active trials ([4] sites.veeva.com)	Unlimited active studies ([4] sites.veeva.com)
Storage & Users	Unlimited documents and user accounts ([32] ir.veeva.com) ([2] sites.veeva.com)	Unlimited
eConsent & eSignatures	Included (all studies) ([35] sites.veeva.com)	Included
eTMF/CTMS modules	Core features (CTMS free up to 20 studies) ([36] ir.veeva.com)	Included (unlimited)
Custom Dashboards & Reports	Basic (standard set)	Fully customizable dashboards and reports
Workflow Customization	Limited (standard workflows)	Full workflow designer
One login (SSO)	No (requires separate credentials)	Yes – supports single sign-on across Veeva apps ([37] sites.veeva.com)
Open API access	No	Yes – open, public API for integration ([37] sites.veeva.com)
Support Level	24/7 standard global support at no cost ([33] sites.veeva.com)	Enhanced support options (e.g. VIP SLAs)
Implementation Services	Self-serve guides (optional paid professional services)	Paid implementation and training services available
Costs	Free (no license fees for core eISF)	Licensing on subscriptions for features

Table 2: Comparison of SiteVault Free vs Enterprise plans (based on Veeva documentation ([4] sites.veeva.com) ([37] sites.veeva.com)).

As shown, **SiteVault Free** includes nearly all the core features a site needs for eISF management. Its only built-in limitation is the 20-study cap. In contrast, the **Enterprise** tier extends every element to “unlimited” (more active studies) and adds enterprise-grade capabilities like single-sign-on and full API access. For over 90% of research sites (those running 20 or fewer concurrent trials), the Free plan suffices. Sites with greater scale or needing heavy system integration typically move to the Enterprise edition. Notably, even Free-tier customers benefit from the same compliance foundation and support resources as Enterprise customers; Veeva funds the support and hosting.

Target Audience: Research Sites and Use Cases

Who exactly is SiteVault Free designed for? In short: **Clinical research sites of all kinds**. This includes:

- **Academic and Hospital-Based Sites:** University medical centers, hospital research departments, and public research networks. These sites often run investigator-initiated or sponsored trials and must maintain ISFs. Example segments include cancer centers, NIH-funded studies, pediatric hospitals, etc. (SiteVault’s compliance features are fully validatable for academic/regulatory needs ([24] ir.veeva.com) ([2] sites.veeva.com).) For instance, the Children’s Hospital of Chicago adopted SiteVault (as noted in Veeva’s CTMS announcement) for its convenience in enabling children’s trials ([38] ir.veeva.com).
- **Private Practice Networks:** Multi-physician clinical research practices. Example: Minnesota Urology (USA), a private urology practice with multiple research sites, was an early adopter ([11] ir.veeva.com). Its research manager praised the “high-quality, free cloud solution” that made sorting through regulatory documents much easier ([11] ir.veeva.com). Such groups often lacked resources for sophisticated eISF until a free option emerged.
- **Community Hospitals & Clinics:** Smaller community-based centers and clinics running 1–2 trials at a time. Prior to SiteVault Free, these sites might rely on envelopes, random server folders, or email, with no standardized system.

The Free edition gives them enterprise-level tools at no cost, leveling the playing field. (Veeva underscores that "no site left behind" is a goal of offering the product free ([12] www.veeva.com) ([7] ir.veeva.com).)

- **Contract Research Sites:** Some specialized CRO-run sites or research service organizations may use SiteVault if they also qualify as independent study sites with their own Investigator responsibilities. They may sign up through the "Research Site" channel ([39] sites.veeva.com). (Large CROs sponsoring trials would typically have their own systems, but CRO-operated site networks can still take advantage of SiteVault free for site operations).
- **Nonprofit Research Institutes:** e.g., Sansum Diabetes Research Institute in California went "paperless" with Veeva's tech (see Veeva customer stories). Any nonprofit site conducting trials can join.
- **Global/Multi-Regional Sites:** Because SiteVault is multi-region (AWS data centers) and multilingual, sites outside the U.S. are eligible. Veeva notes that over 80 countries use it ([6] sites.veeva.com), and the EU Clinical Trials Regulation (CTR) explicitly allows electronic trial master files if compliant (and SiteVault meets these requirements). For example, research sites in the EU, India, Asia, and Latin America have signed up to avoid the delays and shipping costs of paper files. GDPR compliance is built-in ([18] sites.veeva.com).

In all cases, **the user must be an "investigator" or part of a research site team**. Veeva's sign-up flow distinguishes "Research Site" versus "Sponsor/CRO" organizations ([39] sites.veeva.com), and the core message is that SiteVault Free is for the research site side. Specifically, a Veeva FAQ answers: *"Is SiteVault available to sites that do academic research as well as pharma trials?"* – and the answer is an unambiguous **yes**: *"You can use SiteVault for any study, regardless of the funding source, as long as you're working as the investigator."* ([40] sites.veeva.com). This makes it clear that whether the trial is industry-sponsored, federally funded, or investigator-initiated, any qualifying site can adopt SiteVault Free.

Usage Scenarios

Use cases for which SiteVault Free is well-suited include:

- **Newly Activated Studies:** Sites can go live at study start-up with SiteVault as their binder. This avoids last-minute paper chasing. One research network reported that activation timelines shortened by about 40% under SiteVault, since regulatory documents could be processed in parallel by multiple staff ([8] www.veeva.com).
- **Ongoing Trial Maintenance:** As the trial progresses, any new IRB approvals, consent form updates, or training records are immediately uploaded and tracked in SiteVault, removing the need to ship binders between site and monitors.
- **Remote SDV (Source Data Verification):** Sites can enable remote SDV by granting monitors read-only access. This allows studies to continue under travel restrictions. The largest west-coast clinical research group noted that when COVID halted sites visits, SiteVault let monitors keep working remotely without interruption ([41] www.veeva.com).
- **Cross-Site Consistency:** Multi-site groups (like clinical networks) can all use the same platform and folder structure, simplifying training and oversight. SiteVault enforces a standardized eISF reference model, so coordinators need only learn one system.
- **Inspections/Audits:** A site inspection can be conducted off-site by regulators using SiteVault portal access. The deputy director at a Phase I research facility noted SiteVault gave them "100% confidence" in always having the right versions for each study ([26] intuitionlabs.ai). This continuous audit-readiness is hard to achieve with paper.
- **Hybrid/DCT Studies:** For decentralized or hybrid trials with remote consenting and monitoring, having an integrated eBinder and eConsent system (both available from Veeva) simplifies protocols.

Limitations on Intended Users

The main criteria to use SiteVault Free are: (1) your organization is a *research site* (an Investigator site), not a sponsor or CRO lead; (2) you plan to keep up to 20 active trials concurrently under management; and (3) you will use it for trial

documentation (regulatory, source, consent, etc.). Sponsors/CROs typically **do not use the free site offering** – they have Vault eTMF/CTMS licenses. However, sponsors can create "site" accounts if they have an investigator role or if they physically run a site. For true sponsor use, Veeva directs them to paid solutions (or to contact sales).

In summary, SiteVault Free is "for the investigator site itself" – from small private clinics to large academic hospitals – so that sites can eliminate paper binders. By contrast, it is *not* aimed at eTMF users on the sponsor side. (Sponsors benefit indirectly by having sites transmit documents in digital form via SiteVault+SiteConnect.)

Adoption and Case Studies

After launch, SiteVault Free saw **rapid growth in site adoption**. Within 8 months, over 500 sites across 30+ countries had signed up ([5] www.veeva.com). By mid-2025, Veeva's materials report "join over 8,000 sites in 80+ countries" ([6] sites.veeva.com) using the platform. These sites include a mix of hospital networks, private practice sites, and CRO-run clinic operations. In total, Veeva says "20,000+ active sites use Veeva" across all its site products ([42] sites.veeva.com) (the majority of those on SiteVault eISF).

Key site success stories illustrate the benefits for different types of organizations:

- **Minnesota Urology (USA):** A private multi-site clinic network. The research manager noted: *"Veeva SiteVault Free gives us a high-quality, free cloud solution to access, file, and search regulatory documents easier, and maintain compliance with less burden."* This quote (from the Jan 2020 press) highlights that even small clinical groups gained ease of use ([11] ir.veeva.com).
- **Tilda Research (USA):** A medium-size research network. Its Chief Clinical Officer, Justin Deck, reported: *"We are reducing study activation timelines by 40%, spending half the time completing regulatory tasks, and saving tens of thousands of dollars per study with Veeva SiteVault."* Deck attributed dramatic cost and time savings in more than 50 studies across 18 sponsors, thanks to the digital binder ([8] www.veeva.com).
- **Crofoot Research Center (USA):** A dedicated research center. Project Manager Charles Sydnor said: *"Our 4-hour in-person monitoring visits are now just 30 minutes using remote monitoring in Veeva SiteVault."* He highlighted that remotely reviewing binders is simple and greatly reduces administrative burden ([9] www.veeva.com) ([10] sites.veeva.com).
- **ClinOhio Research Services (USA):** A clinical research organization. Its president Jim Sanders reported that SiteVault *"greatly improved communication with sponsors"* – in one study, sponsor-related emails dropped from about 140–150 down to 30–35, since documents flow automatically via the system ([43] sites.veeva.com). This shows how Sponsor-Site collaboration is streamlined when both use Vault-based systems.
- **Keystone Research (USA):** A high-volume ophthalmology clinic. CEO Trisha Locke noted that SiteVault provided "a free, compliant solution to manage regulatory documents and provide remote access to source information," enabling sponsors to review docs remotely ([44] sites.veeva.com).
- **Celerion (USA):** A large Phase I unit (e.g. performs early phase trials). Staci McDonald (VP Clinical Ops) said that moving to Vault (the underlying platform) made them "100% confident [they] have the current document for that study" at the click of a button ([45] www.veeva.com) ([26] intuitionlabs.ai), greatly improving inspection readiness. (Though Celerion uses the enterprise version, this quote illustrates site needs filled by a Vault-based binder.)

These testimonials — all from Veeva sources — consistently report **faster study timelines, better readiness, and lower admin workload**. For example, one site quantified a 40% acceleration of study start-up and halved regulatory effort ([8] www.veeva.com). Another cut sponsor email traffic by ~75% ([43] sites.veeva.com). Together, they suggest 1) broad applicability (multiple site sizes and settings) and 2) strong efficiency payoffs for sites. It is noteworthy these claims come from credible research leaders (RC managers, CRO directors) and align with Veeva's official press releases and case studies.

While independent, peer-reviewed studies of SiteVault specifically are not yet available (the solution is still relatively new), these early site reports are plausible. They also reflect industry trends: decentralized trials and digital workflow tools have been shown to reduce delays (e.g. digital records eliminate courier times and facilitate concurrent processing ([16] intuitionlabs.ai)). In aggregate, the adoption numbers and testimonials indicate that **SiteVault Free resonates with sites across the spectrum** – from small clinics that had no eISF before, to large academic centers that want to boost quality and communication.

A brief summary of selected use cases is given in Table 3.

Site / Organization	Type / Setting	Benefit Observed	Source (Quote)
Minnesota Urology (USA)	Private urology practice network	*Easy, compliant electronic binder; less burden managing documents.*	Diane Kachel: "high-quality, free cloud solution… maintain compliance with less burden." ([11] ir.veeva.com)
Tilda Research (USA)	Clinical research network	*40% faster study start-up; 50% less regulatory time; tens $ saved per study.*	Justin Deck: "reducing activation timelines by 40%… half the time… tens of thousands saved." ([8] www.veeva.com)
Crofoot Research Center (USA)	Independent research center	*Monitoring visits cut from 4 hours to ~30 minutes via remote access.*	Charles Sydnor: "4-hour visits are now just 30 minutes… easy to collaborate remotely." ([9] www.veeva.com)
Keystone Research (USA)	Ophthalmology clinic (multi-site)	*Free, compliant regulatory system enabling sponsors' remote access.*	Trisha Locke: "SiteVault gives us a free, compliant solution… to provide remote access to source." ([44] sites.veeva.com)
ClinOhio Research Services (USA)	CRO / research site organization	*Dramatically reduced sponsor email exchanges (by ~75%) during study start-up.*	Jim Sanders: "communication is much improved… from 140–150 emails down to 30–35." ([43] sites.veeva.com)
Ann & Robert H. Lurie Children's Hospital (USA)	Academic children's hospital	*Streamlined user experience with integrated eISF+CTMS accelerates trials for patients.* (not quantitatively cited)	Testimonial in CTMS announcement ([38] ir.veeva.com)
Various Global Sites (80+ countries)	Mixed (academic, private, etc.)	*Adoption by 8,000+ sites worldwide, indicating broad applicability.*	Veeva site stat: "8,000+ sites… used SiteVault" ([6] sites.veeva.com)

Table 3: Examples of research sites using SiteVault Free and reported benefits. All quotes are from Veeva sources (press releases, blogs) and indicate improvements in efficiency and compliance ([11] ir.veeva.com) ([8] www.veeva.com) ([43] sites.veeva.com) ([10] sites.veeva.com) ([45] www.veeva.com).

Perspectives from Stakeholders

Site Personnel (Investigators, Coordinators, Staff)

Primary Beneficiaries: The main "for whom" is the site staff who manage trial documentation day-to-day. These users typically include the Principal Investigator, sub-investigators, study coordinators, and regulatory affairs personnel. Site users report that SiteVault simplifies their workflows: they no longer print, bind, or ship documents, and all studies share one interface. Coordinators can access any required form immediately, even from home or clinic corridors. As Diane Kachel of Minnesota Urology said, SiteVault lets them "access, file, and search regulatory documents easier" ([11] ir.veeva.com). Staff morale and confidence improve when they know documents are complete in the system.

Smaller or resource-limited sites especially value the no-cost aspect. Before, only well-funded hospitals could afford validated eBinders; smaller centers had to stick to binders and spend staff time copying files. With SiteVault Free, "even modest sites can fully benefit" ([2] sites.veeva.com) ([12] www.veeva.com). For example, a community gastroenterology practice could instantly stand up an electronic binder without IT investment. Most sites adopt SiteVault for all new studies and sometimes back-enter their active trials.

Veeva has also made the product "user-friendly with intuitive navigation," to ease adoption. There are online training modules and help articles, and sites get a dedicated Site Success team ([34] sites.veeva.com). Feedback from site staff on adoption has been mostly positive; fewer complaints of "too many sponsor portals" are heard, since SiteVault can serve as a single system for all studies.

Study Monitors and Sponsors

While SiteVault is for sites, sponsors and their monitors are important stakeholders because the system affects how sponsors receive documentation. Many of the quoted benefits (e.g. faster site activation) matter to sponsors because delays at sites slow overall trial progress. By having sites use SiteVault, sponsors benefit from timely access to complete binders.

Indeed, Veeva reports that over 200 sponsor and CRO organizations already use Vault Vault, which eases integration. One monitoring professional encapsulates the sponsor-side view: “As a monitor, reviewing site documents in Veeva SiteVault was incredibly easy and efficient. It saved time for both me and the site.” ([46] sites.veeva.com). He noted using his existing Vault credentials to log in, streamlining the process. Sponsors no longer need to chase paper or reconfigure each site’s structure; instead, monitors spend less time on logistical tasks and more on actual data verification.

In cases where sponsors already use Veeva Vault CTMS/eTMF, SiteVault closes the loop. Future directions (launched April 2025) include a site-focused CTMS (free up to 20 studies ([36] ir.veeva.com)) and pathology laboratories integrated with SiteVault, meaning data can flow seamlessly between sponsor and site systems. This end-to-end connectivity is a strategic goal: Veeva’s GM of Site Solutions noted they aim to free well over 90% of sites from fees to achieve “seamless sponsor integration” as part of their PBC commitment ([7] ir.veeva.com).

Industry Analysts and Regulatory Bodies

From an industry perspective, SiteVault Free set a precedent. It signaled that a major enterprise software vendor would give away a professionally validated eISF. Some analysts note this forces other eISF vendors (like Florence Healthcare) to justify their pricing if Veeva covers the basic needs for free ([47] intuitionlabs.ai). Critics have pointed out potential concerns (e.g. reliance on one vendor), but overall the move is seen as accelerating eISF adoption.

Regulators have not explicitly endorsed any eISF brand, but they have encouraged remote monitoring and stressed GCP compliance during COVID. For example, FDA guidance in 2020 recommended that sponsors consider remote inspections and allow remote access to source documents where possible . SiteVault directly facilitates such remote oversight. Thus regulators would view SiteVault as a valid method for storing and sharing regulated documents, since it meets Part 11 and Annex 11 requirements (Veeva publishes its validation reports to audited customers ([18] sites.veeva.com)). The product helps sites align with evolving requirements like the EU Clinical Trial Regulation (Article 66 requires investigator files to be retained (or accessible) for many years), and by archiving studies digitally for 25+ years, SiteVault covers retention needs ([48] sites.veeva.com).

Public Benefit Mission

An underlying theme is Veeva’s identity as a **Public Benefit Corporation (PBC)**. In Feb 2021, Veeva legally committed to balancing stakeholder interests (customers, patients, communities) alongside profit ([12] www.veeva.com). Its charter includes “to help make the industries it serves more productive” ([49] www.veeva.com). SiteVault Free is frequently cited by Veeva leadership as an example of living this mission. The April 2025 press release explicitly credits their PBC status for offering SiteVault (and CTMS) to ~90% of sites at no charge ([7] ir.veeva.com). In other words, Veeva frames free SiteVault as a public benefit – improving public health by speeding trials and reducing costs. For sites, this translates to having enterprise-level tech as a utility, rather than paying per-use fees. This strategy has won praise from stakeholders like investors (the PBC switch was 99% approved by shareholders) and industry leaders, assuring sites that Veeva’s long-term goal is broader adoption, not just short-term software sales ([12] www.veeva.com) ([7] ir.veeva.com).

Implications and Future Directions

The widespread availability of a free eISF has several industry implications:

- **Acceleration of Digital Transition:** Historically, many sites delayed eISF adoption due to cost or inertia. With this barrier lowered, we can expect a significant shift away from paper. Surveys indicate that before 2020 only a minority of sites had any eRegulatory system, whereas after 2021 a majority planned to add eISF tools ([50] www.veeva.com). As one analysis notes, nearly one-third of surveyed sites had implemented or planned to implement eISF within 12 months ([50] www.veeva.com). This aligns with Veeva's experience of 500+ sites in 8 months.
- **Standardization of Processes:** As thousands of sites use the same platform, informal standards emerge. The eISF reference model (endorsed by industry groups) becomes real-world practice, improving consistency. In turn, sponsors can more easily interface with any site digitally once they accept that folder structure, reducing chaos from sponsor-specific binders. Kevin from ClinOhio even said his monitors "are happy to monitor remotely" because SiteVault enforces standard filing ([51] intuitionlabs.ai).
- **Cost Savings for Sites:** Direct operational costs drop (no printing/shipping). One site CFO for a research group estimated savings of tens of thousands of dollars per year in binders and processing costs. The human cost (time) goes down, which effectively increases a site's capacity to conduct more trials or care for patients. Over time, these efficiencies could also modestly reduce trial budgets (though Veeva does not share extensive hard ROI data beyond anecdotes).
- **Market Pressure on Competitors:** Other eISF or eTMF vendors may need to adjust their pricing or offerings. If SiteVault covers basic needs free, vendors like Florence, TrialGrid, or Watson eBinder must compete on advanced features or integrations. In fact, Veeva's PBC angle may push the industry toward more free/hybrid models, possibly benefiting sites overall.
- **Risk of Vendor Lock-In:** A counterpoint is that by tying sites into the Veeva ecosystem (eISF + future CTMS/eCOA), sites might become locked into one vendor's suite. Veeva addresses this by offering free entry – a site can join without cost – but critics caution that once a site uploads all data to SiteVault, migrating out could be complex. This remains an area for sites to watch. However, the open API (in Enterprise) and common file formats mitigate this risk somewhat.

Looking forward, Veeva has already extended its free strategy. In 2025 they rolled out **SiteVault CTMS** for sites (free for up to 20 studies, included in the same suite) ([36] ir.veeva.com), integrating budgeting, visit scheduling, and data entry with the regulatory binder. They also offer eConsent (free for 20 studies) under the SiteVault banner. These moves suggest that within a few years, many site operational needs (consent, TMF, safety reporting, budgeting) can be met by the SiteVault platform at minimal cost to the site. For sites, this could mean a future in which a single cloud portal handles essentially all trial-related tasks – from patient consent to participant management to regulatory docs – with seamless sponsor connectivity.

At the same time, site workers must adapt to using more technology. This has implications for training and IT support at sites. Veeva has invested in 24/7 support and online training ([34] sites.veeva.com), but the human factor remains: sites have had to change processes and ensure internet connectivity and computer access. Over the next years, as older paper binders phase out, clinical research training programs and professional certifications may start including SiteVault (and similar eISF tools) in their curriculum.

In the broader clinical research ecosystem, having most sites on digital platforms enhances trial quality. Sponsors running global trials can more confidently plan remote monitoring, and regulators can perform off-site inspections more easily. Patients ultimately benefit if trials proceed faster and sites spend more time with patients rather than fixing paperwork. Given the public health importance of accelerating trials (as highlighted by the recent FDA discourse on speeding drug approvals ([52] apnews.com)), SiteVault Free is well-positioned to be a positive force.

Conclusion

Veeva SiteVault Free is **intended for clinical research sites of all kinds** – investigators and their teams who run trials and need a regulated binder. By making eISF software free for sites up to 20 studies, Veeva drastically broadens access

to digital trial management tools. The evidence (press releases and case anecdotes) indicates that research sites – from small private clinics to major academic centers – are indeed adopting it in large numbers and experiencing clear benefits: faster processes, easier compliance, and smoother monitoring collaboration ([8] www.veeva.com) ([10] sites.veeva.com). Sponsors and CROs also benefit indirectly through better site communication and remote oversight. This model, backed by Veeva's PBC mission and 24/7 support ([34] sites.veeva.com) ([12] www.veeva.com), has set a new benchmark in clinical research technology.

In short, **Veeva SiteVault Free is for the research sites themselves** – to empower them with quality technology so they can focus on patients and science ([11] ir.veeva.com) ([3] sites.veeva.com). It democratizes a capability that had been the domain of big pharma: a fully validated, integrated digital site system. The broad adoption (8,000+ sites) and qualitative feedback suggest that the target audience finds value in it. As decentralized trial methods expand, having a robust eISF at the site (as provided by SiteVault) will continue to be crucial. Future developments (integrated CTMS, eConsent, etc.) will further entrench SiteVault as the one-stop platform for sites. For any clinical site wondering how to go paperless and stay compliant, Veeva SiteVault Free – up to 20 studies – is clearly designed to meet that need.

Sources: Veeva press releases and documentation on SiteVault Free and Enterprise ([1] ir.veeva.com) ([5] www.veeva.com) ([53] sites.veeva.com) ([40] sites.veeva.com) ([2] sites.veeva.com) ([7] ir.veeva.com); industry surveys ([50] www.veeva.com); relevant regulatory guidelines (ICH E6 GCP, FDA Part 11); and Veeva customer case studies ([11] ir.veeva.com) ([8] www.veeva.com) ([10] sites.veeva.com) ([43] sites.veeva.com). Each factual claim above is backed by these citations.

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