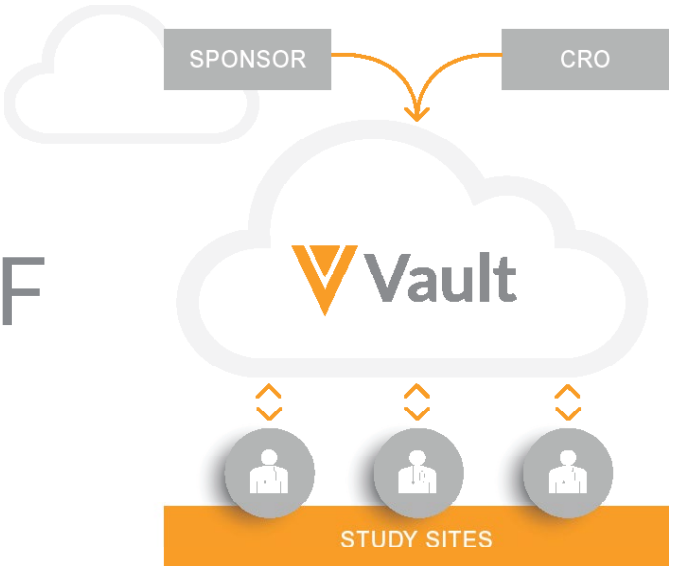
Datasheet

Veeva Vault eTMF



Veeva Vault eTMF provides real-time inspection readiness, full visibility into TMF status, and access for all study partners. Sponsors get the clarity they need to oversee trials more effectively. CROs gain the flexibility and control required to operationalize their SOPs and efficiently populate the eTMF. Auditors get easy online access with a dedicated role. And sites receive a simple and efficient means to interact with CROs and sponsors.

Veeva Vault eTMF promotes the highest levels of TMF quality, access, visibility, and control.

Real-time Inspection Readiness

Business-specific workflows ensure TMF content gets managed in real-time, enabling accurate reporting and better decision-making. Organizations can feel confident that their TMFs are complete at all times, eliminating the need for rework at the end of a study.

Full Visibility

Comprehensive reports and dashboards provide full visibility into TMF completeness, timeliness, and quality. Managers have the insight to identify and remedy process bottlenecks, and users can drill down through interactive reports to answer questions about trial progress, team performance, and TMF quality.

Always Accessible

The Veeva Vault cloud platform allows users to access Veeva Vault eTMF via any device from any location, making it simple to author, upload, review, and approve documents. Mobile optimization provides the ideal user experience when out of the office.

Easy to Use

Veeva Vault eTMF's simple-to-use functionality and intuitive user interface promotes adoption and use. With minimal training, users can create, exchange, and update TMF documents.

Fast Implementation

Veeva Vault's flexible configuration and cloud deployment allows companies to be up and running in weeks. With full support of all versions of the TMF Reference model, roles, reports, and workflows are ready to use.

Veeva Vault eTMF supports the TMF Reference Model and includes roles, reports, and workflows.

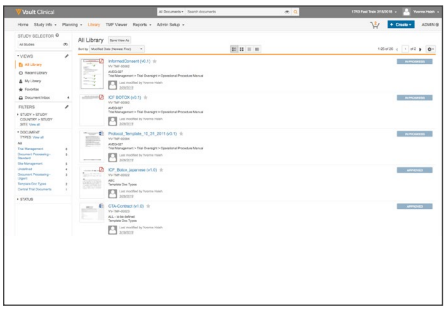
Learn more at veeva.com

Veeva Vault eTMF

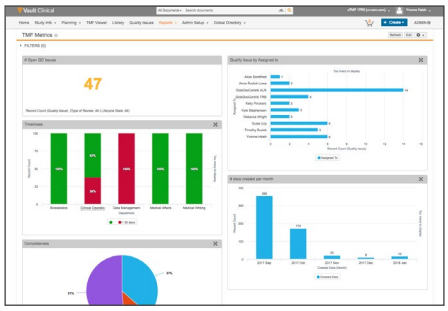
Active TMF

Your eTMF becomes a strategic asset to your organization when all TMF stakeholders – site, sponsor, CRO – are brought into one system, and both your TMF processes and documents are actively managed in real-time with your eTMF. The entire document lifecycle can be tracked, providing access to a greater set of metrics and data to inform business decisions. Challenges and bottlenecks can be corrected during the course of the study, and manual rework at the end is eliminated.

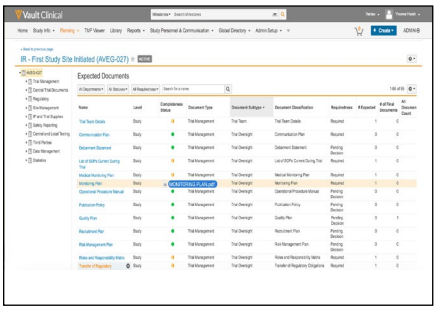
With an active TMF, adherence to study SOPs and regulatory requirements is not an afterthought, but an ongoing process to ensure your TMF is always inspection-ready. Veeva Vault eTMF is the only electronic trial master file that enables an active TMF operating model.



Find documents fast with dynamic filters



Interactive dashboards translate insights into action



The Expected Document List provides insights into TMF completeness status

Visibility into Trial Status

Trial managers and partners will know what's required, what completed, and what's missing. Drill down through real-time dashboards and reports to answer questions about progress and completeness, or remedy process bottlenecks.

Completeness Reporting

The Expected Document List (EDL) provides insights into what documents need to be collected for a given study. This functionality empowers users to identify what documents are still missing, and then to take action to upload files directly via drag and drop.

Document QC Workflow

Intitiate quality check workflows at the appropriate time to improve the accuracy of the eTMF on an ongoing basis. Veeva Vault's DocInfo layout allows users to review document content and metadata simultaneously, making the process easier and more efficient.

TMF Reference Model Support

Veeva Vault eTMF has full support for the documents, properties, relationships, and hierarchies of the TMF Reference Model Version 3.0 for both core and recommended documents.

Dynamic Security

Security and access controls determine level of access based on study team or role. Users can only interact with the documents pertinent to them, reducing overall risk and improving quality.

Real-time Collaborative Authoring

Seamless integration between Veeva Vault and Microsoft Office Online provides real-time collaborative authoring on all clinical documents and does so in a compliant way.

Study Binders

Multiple pieces of content can be bundled into a single binder, which can then be set as active or inactive for TMF archiving purposes. Final documents are protected and easily retrieved when needed.

Global Health Authority Submission Support

Veeva Vault eTMF automatically creates submission-ready files and captures details relevant for submissions processing. This feature eliminates significant downstream processing and removes unnecessary time and expense.

Scan Documents on the Go

Veeva Snap allows users to easily scan documents directly into Vault from an iPhone or iPad. With the snap of a button, documents are encrypted, secured, and automatically uploaded to your Vault.

Vault Clinical Suite

Veeva Vault Clinical Suite is the first eClinical suite offering EDC, coding, data management, CTMS, eTMF, study startup, payments, and site connect on one enterprise-class cloud platform. For the first time, life sciences companies can unify clinical operations and data management with a single platform to create a single source of truth and streamline clinical trials from study start-up to close.

Veeva's suite of clinical applications is built on the Veeva Vault Platform, the first cloud platform built from the ground up to meet the rigorous usability, scalability, performance, validation, and security requirements of the life sciences industry. With a modern user experience and cloud pace of innovation, Vault Clinical Suite transforms clinical operations and clinical data management.