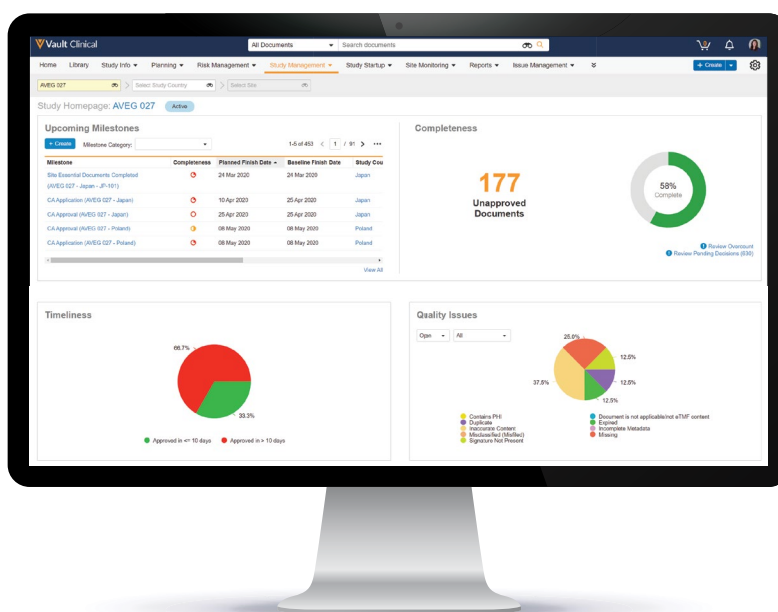# Veeva Vault eTMF

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.

Benefits

• **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.

• **Streamline Collaboration.** Give study teams a real-time view of TMF completeness to help sponsors, CROs, and sites work together to accelerate trials.

• **Unify Clinical Operations.** Speed trial execution by leveraging the most comprehensive suite of clinical applications on a single cloud platform.

Active TMF

Active TMF management ensures all TMF documents, related information, and processes are managed in the same system, in real-time, as they are being executed. As a result, TMF management is automated and in a constant state of inspection readiness.

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 are not afterthoughts but instead part of 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.

TMF Reference Model Support

Veeva Vault eTMF supports the TMF Reference Model for the documents, properties, relationships, and hierarchies for both core and recommended documents.

TMF Homepage

Get a high-level overview of your TMF milestones and completeness with the TMF Homepage. Use real-time dashboards and reports to answer questions about progress and completeness, make proactive decisions, and remedy process bottlenecks.

TMF Viewer

Search and access all document versions, as well as export data to Microsoft Excel, with the TMF Viewer. It provides a real-time view of documents during a study and a full historical picture after study completion.

Timeliness Tracking

Calculate the amount of time it takes between two different actions, such as document creation date and document approval date. Timeliness metrics show how quickly departments and partners get documents into your TMF and enable you to review and act on areas of concern.

Completeness Reporting

Identify the documents that need to be collected for a given study with the Expected Document List (EDL). This functionality empowers users to identify missing documents and take action to upload files directly via drag and drop.

Document Quality Check Workflow

Initiate quality checks at the appropriate time to improve accuracy on an ongoing basis. Users can review document content and metadata simultaneously for each document, making the process easier and more efficient.

TMF Bot

Process documents more quickly and increase TMF compliance with the TMF Bot, an artificial intelligence feature that automatically classifies uploaded and mobile-scanned documents.

Connectivity with LMS

Streamline and automate training and reconciliation with the seamless connection between Vault eTMF and Vault Study Training.

TMF Transfer

Enable study teams to quickly and accurately transfer TMF documents without manual end-of-study migrations. With a single click, completed study country, study site, associated TMF documents, and audit trail information are seamlessly transferred between sponsor and CRO Vaults.

Real-time Collaborative Authoring

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

Global Health Authority Submission Support

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

Vault Clinical Suite

Veeva Vault Clinical Suite is the first eClinical suite offering EDC, coding, data management, CTMS, eTMF, study start up, payments, study training, 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.