Veeva Vault eTMF

Manage Outsourced Clinical Trial Oversight with Veeva Vault eTMF

Sponsors that outsource clinical trial management activities to contract research organizations (CROs) retain the regulatory responsibility for the quality and integrity of trial data and conduct. Adherence requires sponsors to have systems and processes in place to ensure adequate sponsor oversight, as well as document and demonstrate how the trial master file (TMF) is set up and maintained.

Yet sponsors may lose oversight of the TMF in outsourced studies because the TMF structure lacks consistency across multiple systems and partners, increasing the risk of inspection findings, delayed trials, and unexpected costs.

Veeva Vault eTMF gives sponsors real-time and secure access to clinical documentation at every point throughout a trial's setup, execution, and archival. It provides the visibility, transparency, and control to oversee trials more effectively, while removing the need for costly end-of-study migrations.

Benefits

- **Increase Oversight and Control:** Gain real-time visibility into TMF status, track CRO activity, and gain the transparency needed to ensure effective oversight.
- **Stay Inspection Ready:** Ensure a constant state of inspection readiness by managing all TMF documents and processes in a unified eTMF system.
- **Streamline Collaboration:** Give study teams a real-time view of TMF completeness to help sponsors, CROs, and sites work together to accelerate trials.

Active TMF

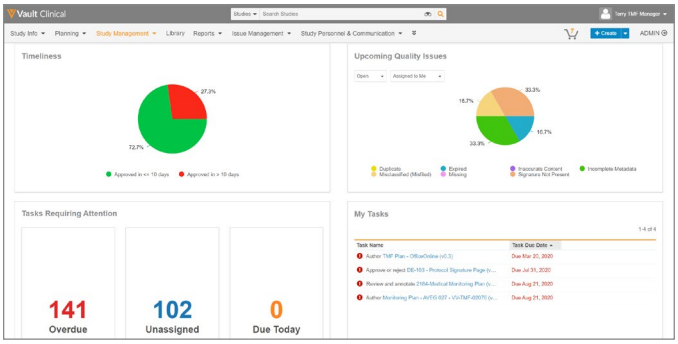
An eTMF becomes a strategic asset to your organization when all TMF stakeholders (sponsor, sites, and CROs) are brought into one system, and both TMF processes and documents are actively managed in real-time. The entire document lifecycle can be tracked, providing access to a greater set of metrics and 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.

Features

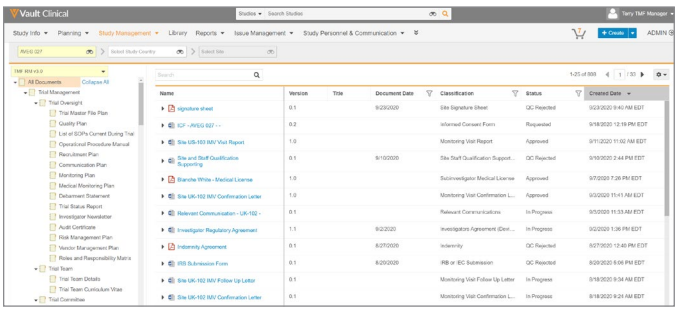
TMF Homepage

The TMF Homepage provides a high-level overview of your TMF milestones and completeness to support proactive decisions during a clinical trial. Trial managers and partners will know what is required, what has been completed, and what is missing. The Quality Issues chart helps quickly identify and examine data about a given study, country, or site's performance and management. Drill down through real-time dashboards and reports to answer questions about progress, monitor completeness, or remedy process bottlenecks.



TMF Viewer

The TMF Viewer allows you to easily search and access all document versions and supports an ongoing state of audit and inspection readiness. You can also filter results, navigate documents, and export data to Microsoft Excel. The TMF Viewer provides a real-time view of documents during a study, and a full historical picture of the progress of the study after completion.



Timeliness Tracking

Timeliness is a core metric for inspection readiness and overall TMF health. Calculate the amount of time it takes between two different actions, such as "document date" to "approval date", or "created date" to "approval date", etc. The Timeliness Field shows how quickly departments and partners are getting documents into your TMF. It also enables you to review and act on areas of concern. Whichever metric is most meaningful to your organization, you can keep tabs and utilize results as a KPI on reports and dashboards on the TMF Homepage.

Multi-Document Workflows (MDW)

With multi-document workflows, users can send one or more documents out for review and approval on a single workflow instance. When configured, users can add a document or group of documents to an envelope and start a workflow controlled by the envelope. This is an efficient way to allow users to review
one or more documents with a single workflow task.

Milestones and Expected Document Lists (EDL)

Vault eTMF shows the state of the milestone at a glance – complete, in progress, or not started. An EDL is a checklist of all the documents collected to reach the milestone. As with milestones, Vault eTMF reveals the state of progress for documents within each EDL. These capabilities improve inspection readiness and support active management of documents throughout the clinical study. Direct uploading, where on-site CRO monitors upload documents directly into the TMF, makes receiving documents more streamlined by eliminating the need to send documents to a central team for uploading. Direct loading has been shown to dramatically increase completeness rates for studies that utilize it with their CROs.

Document Quality Control Workflow

Intitiate quality check workflows at the appropriate time to improve the accuracy of the eTMF on an ongoing basis. Drilling into the details view of a document allows users to review document content and metadata simultaneously, making the process easier and more efficient.

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