Eight Million Documents and 5,000 Users in 11 Months:

Merck Transforms Trial Efficiency with Strategic eTMF Initiative

For many global life sciences companies, maintaining an inspection-ready trial master file (TMF), gaining insights into study processes, and collaborating with external partners requires significant time and manual intervention. Merck has embarked on a company-wide mission to update its TMF processes and technology to ensure greater quality documentation and timeliness, while making it easier for study personnel to reach critical milestones.

MERCK – AT A GLANCE

- **Corporate HQ: Kenilworth, NJ**
- **Operates in 71 countries**
- **68,000 employees worldwide**
- **Areas: Oncology, Vaccines, Diabetes, Hepatitis C, Animal Health**

A History of Innovation

Merck has a longstanding dedication to improve the health and well-being of people around the globe. Through the years, its researchers have helped to find new ways to treat and prevent illness – from the discovery of vitamin B1 to the first statins to treat high cholesterol. Merck's scientists have also helped develop many novel products to improve animal health, including vaccines and antibiotics.

The Challenge

On par with its commitment to developing innovative products, the company has a history of leveraging new technologies to drive process improvement. Merck was one of the first life sciences companies to adopt early content management tools when most global pharmaceutical companies still relied on paper. However, its once "state-of-the-art," on-premise system was now outdated, and it was increasingly difficult to find and retrieve clinical trial documents for filings and site inspections.

"We were getting by with our legacy content management system, but our capabilities were severely limited. We needed an eTMF that was easier to use, access, and search so we could improve efficiency and always be prepared for health authority site visits and audits," explained Bryan Souder, associate director of project management at Merck.

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The Solution

Merck performed a rigorous search for an eTMF solution that would transform its clinical operations and enable real-time inspection-readiness of the TMF. Merck wanted a single source of truth for all its TMF documentation, so it needed to make sure the system was accessible to thousands of users around the world and all TMF processes could be executed entirely within the application.

After a thorough market evaluation, Merck selected cloud-based Veeva Vault eTMF, part of Veeva Systems' Vault Clinical Suite of applications. "We had a high bar to meet, and Vault eTMF exceeded our expectations. It has the TMF-specific workflows and templates that our old system lacked and it is extremely easy to use. We are now confident that everyone is following study SOPs, and we can track a deeper set of metrics to improve our operational efficiency," said Souder.

Merck's decision to standardize on cloud-based Vault eTMF also aligned directly with the corporate initiative to move information technology to the cloud. With no costly infrastructure to maintain and update, Merck can effectively scale Vault eTMF across all its studies, make sure it is always using the latest functionality, and be confident it is getting the most out of its investment.

Partnership for Success

Almost immediately, Vault eTMF delivered tangible benefits to Merck worldwide. These include a fast global implementation, increased process efficiency, and real-time compliance.

Fast Global Implementation

Global implementation of Vault eTMF took less than 11 months and included training more than 5,000 users and migrating over eight million documents. "Making any kind of technology change for a company of our size and breadth is not easy and never fast," explained Souder. "Veeva stepped up, and together we delivered Vault eTMF in lightning speed."

"The collaboration and cooperation between Veeva and our whole team was incredible," added Rob Willis, director of MRL global development, IT knowledge, and portals for Merck. "In fact, we use the successful Vault eTMF implementation as an example to model internally when adopting any new technology, and it proved to non-believers that Veeva's cloud solution works in a validated environment."

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Increased Process Efficiency

Merck cites Vault eTMF's search capabilities as a huge efficiency driver. "With Vault eTMF, we estimate a 30% reduction in time to find, import, and process documents," explained Souder. "Document searches for auditors that used to take days now only take minutes in Vault eTMF. This is a major source of cost savings for us because this frees up time for users to work on higher-value tasks."

Many life sciences organizations move documents into the TMF only once they are final, making it difficult to retrieve the latest version and providing no insight into the efficiency of the process itself. In contrast, Vault eTMF ensures everyone at Merck shares, reviews, and approves documents directly in the system, recording each step along the way. Users can always find and work on the correct version, and managers can gain critical insights to reduce waste and rework.

Real-time Compliance

Vault eTMF's automated workflows ensure all stakeholders are adhering to standard operating procedures, and its ease of access guarantees users around the globe can find the documents they need when they need them. Auditors and inspectors can quickly and accurately reconstruct how a trial was run with minimal effort.

Additionally, Vault eTMF aligns with the TMF Reference Model, allowing Merck to leverage this industry standard for structuring content. "The way we structure content with Vault eTMF is much different and more consistent than before, so we expected some adjustment," continued Souder, "According to users, transitioning to the TMF Reference Model has been more of a learning curve than the switch to Vault eTMF."

Looking Ahead

Merck looks forward to providing contract research organizations, sites, and other partners direct access to Vault eTMF to further improve process efficiency. "We outsource a lot of clinical studies. Being able to add study information into Vault eTMF throughout the trial process – instead of sharing it back and forth via a hard drive or CDs or even email – is a lot faster and less risky, and it provides greater visibility," said Willis.

The company plans to continue improving document management and efficiency by leveraging Vault eTMF as a strategic asset for the entire global organization. "Having a single, authoritative source of truth in Vault eTMF is an advantage that impacts many different areas of our organization worldwide," said Souder. "We now have rich insights about our clinical processes, affording Merck the critical chance to make iterative and long-term improvements that can further increase efficiency and the clinical trial process. Vault eTMF is changing the way people think about content at Merck."