Veeva

Case Study

Customer Success Story:

Exom Group Deploys Veeva Vault eTMF for Efficient Document Management and Real-time Visibility

Exom Group, a global contract research organization (CRO) for the life sciences industry, specializes in providing technology and value-added services for clinical research and personalized health. After a four-month search for an electronic trial master file (eTMF) system to manage its clinical studies and improve site collaboration, Exom deployed cloud-based Veeva Vault eTMF to streamline trial processes and achieve greater efficiency. Veeva Vault eTMF is now improving Exom collaboration with investigator sites and provides sponsors with remote document access, electronic signature capture, and real-time visibility. Veeva Vault cloud technology has transformed Exom's manual processes into automated, integrated workflows that enable high levels of efficiency, insight, and collaboration.

The Challenge

Exom was experiencing rapid growth. With each additional sponsor came more clinical trials and corresponding documents to manage. The company was using an electronic data capture (EDC) platform with limited document management functionality plus users had to waste time logging in and out of the EDC system every time they needed to access the TMF rather than being able to upload documents in process. Unfortunately, many companies are stuck in this passive TMF model where data and documents are archived at the end of a trial rather than in real time, as part of the natural workflow. Conversely, an active model for TMF management ensures all Exom TMF documents, data, and processes are managed in the system as they are being executed.

Key Highlights

The Challenge

Existing document management platform proved insufficient at managing study documents, especially with an increasing number of clinical trials. The legacy system also impeded visibility, collaboration, and audit readiness.

The Solution

Veeva Vault eTMF streamlines data and document management in the cloud to enable real-time visibility, collaboration with external partners, and greater efficiency.

Benefits

- Greater document access for site investigators and sponsors
- Faster clinical trial processes
- Enhanced regulatory compliance and audit readiness
- Flexibility to accommodate company growth

Exom was also challenged by a pattern of missing, duplicate, and unauthorized documents, while signatures and time-stamping had to be performed manually. Exom wanted to provide investigator sites and sponsors with a single access point for all clinical information to streamline collaboration and ensure TMF completeness.

"Our business was expanding rapidly, but our document management processes couldn't accommodate the increased workload," explained Luigi Visani, CEO of Exom Group. "As a high-growth company, efficiency is crucial to us. It's also imperative to provide our customers and investigators with real-time access to clinical information — the manual back-and-forth of study documents was not acceptable. We wanted a solution that would enable us to streamline content management in a single system plus provide the flexibility to evolve with our organization."

The Solution

Exom evaluated potential technology vendors based on three main criteria: a cloud-based approach; user-friendly, intuitive functionality; and software-as-a-service model. After a thorough review, Exom chose Veeva Vault eTMF for the following advantages:

- **Easy, remote access to all clinical documents in real time** allows Exom, sponsor companies, and site investigators to continuously see study status and TMF completeness. This was particularly important to Exom on the heels of the MHRA's mandate for TMF accessibility.[1]
- **Electronic functionality with electronic signatures and training logs** to eliminate manual processes and speed the clinical trial process plus enable seamless collaboration with sponsors and sites;
- **Increased visibility** in the cloud for both sponsors and investigator sites to support all stakeholders' needs for greater control when working with external partners. A full audit trail and version control also ensured reliability of all documentation to instill customer confidence;
- **Ongoing innovation** with new functionality and capabilities from Veeva delivered regularly so the system is always up to date.

Additionally, with an eye on the future, Exom turned to Veeva because Veeva Vault eTMF seamlessly integrates with Veeva's comprehensive clinical suite of document and data management applications. Veeva Vault Clinical Suite is the industry's first cloud platform that combines EDC, eSource, CTMS, eTMF, and study start-up to unify clinical data management and clinical operations. They are built on the Veeva Vault Platform, the only content management platform with the unique capability to manage both content and data, eliminating system silos and streamlining end-to-end clinical trial processes.

Exom also recognized the long-term value of Veeva Vault eTMF's natural integration with other cloud-based Veeva Vault applications. In fact, after successfully deploying Veeva Vault eTMF, Exom adopted Veeva Vault QualityDocs for a holistic approach to document management across the organization.

1. United Kingdom Medicines and Healthcare products Regulatory Agency. *Good Clinical Practice for Clinical Trials*. December 18, 2014.

The Results

Since implementing Veeva Vault eTMF, Exom has reported a number of key business benefits.

Increased Collaboration with Investigator Sites

One of the most important areas of improvement to Exom since switching to Veeva Vault eTMF has been improved collaboration with its investigator sites. They now have increased visibility and information is always available and accessible by all parties through the cloud. Sponsors feel greater confidence and benefit from more control. All document transactions to and from the site are tracked, providing a complete, reliable audit trail plus enabling the immediate filing of the final, approved document.

"With Veeva Vault eTMF, we save so much time by removing the tedious back-and-forth of documents throughout the trial, saving our company hundreds of hours per year" explained Visani. "In fact, we estimate an annual saving of at least one full-time employee."

Exom isn't alone. Research shows that one in four (23%) trial sponsors now use their eTMF application to share documents with CROs, up from 14% in 2014.[2] Similarly, more sponsors use eTMF applications to exchange documents with sites (16%, up from 11% in 2014) signaling the benefit of such systems for document collaboration. In addition, organizations that have adopted advanced eTMF solutions report significant improvements in efficiency, compliance and control, and collaboration.

Active TMF Management Increases Control, Compliance, Speed

Before implementing Veeva Vault eTMF, Exom had been operating under a passive TMF model. In a passive TMF, documents are uploaded into the system only after they are finalized. The underlying processes are still paper-based, even though the documents are now in electronic format. Often, documents are also saved in multiple locations or systems, making it difficult for users to track trial progress and stay inspection-ready at all times. With active TMF management enabled by Veeva Vault eTMF, documents and processes are managed in real time, as the TMF is being generated, and in one easily accessible place.

A 2016 global research study reveals significant change is underway as the industry shifts from passive to active TMF management and adopts advanced eTMF applications to improve inspection readiness and shorten clinical trials.[2]

> *Instead of a passive approach to managing clinical trial documents, where we file them days after their collection and complete QC at the end of a study, we can now take an active approach in which we enter documents into Veeva Vault eTMF and QC them continuously throughout the trial.*
>
> — ***Luigi Visani,*** *CEO, Exom Group*

2. "How eTMFs Are Transforming the Pharma Industry," *Pharmaceutical Executive*, by Rik van Mol, July 2016. For more: www.pharmexec.com/how-etmfs-are-transforming-pharma-industry.

"Instead of a passive approach to managing clinical trial documents in which we file them days after their collection and then complete quality control (QC) at the end of a study, we can now take an active approach where we enter documents into Veeva Vault eTMF on a daily basis," said Visani. "Doing so ensures all study documents are complete, current, and accurate, and sponsors have clear visibility into the status of a study at all times. This also helps us prepare for regulatory audits and inspections."

According to the same study, two-thirds (65%) of CROs and 67% of sponsors cite improved inspection readiness as the key driver to move to an advanced eTMF solution.[3] Like Exom, CROs leveraging these eTMFs report improvements across all major inspection categories, noting significantly fewer duplicate documents, incomplete documents, and expired documents.

Streamlined Clinical Trials Enhances Efficiency

Exom determined that Veeva Vault eTMF is the only application that enables active TMF management for real-time visibility, control, and inspection readiness. "Innovation hinges on how efficiently organizations like ours collaborate with clinical trial investigators and sponsor companies," said Visani. "It is critical that we can interact quickly so clinical trials are conducted at a fast pace and medicines get to patients as soon as possible. Veeva Vault eTMF gives us an integrated, single source of real-time data that streamlines the clinical trial process and raises efficiency to a very high level."

After its first deployment at 50 clinical sites across two studies, Exom realized between 30% and 40% efficiency gains in document management over its prior paper-based approach. The company also saved approximately 80% in courier costs for collecting and delivering documents with sites.

Exom clients like Sanofi now have direct access to clinical trial documentation through Veeva Vault eTMF. "We are very impressed by Veeva Vault eTMF," said the director of clinical operations for Sanofi Italy, Silvia Michelagnoli. "We plan to share our positive experiences of working in Vault eTMF in two national clinical studies with our international colleagues."

Looking Ahead

Recently, Exom deployed another product in the Vault product line – Veeva Vault QualityDocs, to facilitate the sharing of Good Clinical Practices (GCPs) related documents among employees and partners. Veeva Vault QualityDocs provides Exom with increased visibility into content status and processes, which enables the company to better control the quality procedures, the trainings logs, and to timely manage any possible quality issue. Now, with a single platform, Exom has also accelerated review and approval workflows to speed standard operating procedure document development, as well as the corrective and preventive action (CAPA) resolution process.

"Lower global costs and increased efficiency were key drivers for implementing Veeva Vault QualityDocs, as well as the fact that the application provides quality assurance," explained Visani. "The ability to prepare, track, and finalize documents within a shared, single platform gives us visibility into content status and lets us mitigate issues proactively to improve external audit processes and reduce risk."

Exom expects additional benefits from Veeva Vault eTMF and Veeva Vault QualityDocs as it leverages more of each application's features. The company is also considering adopting additional Veeva Vault applications in regulatory and commercial.

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3. *Veeva 2016 Paperless TMF Survey: CRO Report*.

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