Success Story

IDDI Improves Collaboration, Control, and Audit-readiness in the Cloud with Veeva Vault eTMF

The Customer

International Drug Development Institute (IDDI) is an expert center in biostatistical and integrated eClinical services for pharmaceutical and biotechnology companies in several disease areas, including oncology and ophthalmology. IDDI optimises the clinical development of drugs, biologics, and devices thanks to proven statistical expertise and operational excellence. Founded in 1991, IDDI has offices in Belgium, Boston, Raleigh, and Cupertino.

The Challenge

Before moving to Veeva Vault eTMF, IDDI was burdened with a cumbersome hybrid system of paper-based processes supplemented with electronic shared drives and e-rooms for sharing documents with its clients. Users turned to unsecured workarounds like email, and the complexity prevented effective collaboration with sponsors, independent data monitoring committees (IDMCs), and internal teams around the world.

"As a CRO, the ability to share and collaborate on trial-related content with our clients is critical," said Linda Danielson, chief operating officer at IDDI. "For the study to progress smoothly, we need them to quickly review and approve documents. With our old system, clients had to print documents, sign and scan them, and then upload them to a shared e-room or email content back to us – not an easy or efficient process. It was also difficult to track and ensure TMF completeness."

Paper documents proved too difficult to access and track, and the organisation turned to shared drives to give sponsors access to content electronically. However, these shared drives were only accessible off-site by using a VPN. E-rooms were meant to provide more flexibility, but limitations in the e-room access control model created a new set of challenges and security vulnerabilities, leading to serious compliance concerns. Lacking true content management capabilities like workflow, reporting, and audit trails, these file shares functioned largely as document storage, and had to be cleared periodically to make room for new documents. Facing an impending audit, IDDI decided to print all electronic documents to create a paper-based TMF.

Despite the time and effort expended to compile trial master file (TMF) documents from disparate sources, audit-readiness remained challenging. "Ensuring that the TMF was complete was very difficult because many documents were filed in several different binders by department," explained Danielson. The organisation was forced to comb through multiple locations to find the right documents for audits and archiving for each of its studies. The difficulty of checking all locations where a document could reside, physically or electronically, and determining which version was most up-to-date, according to Danielson, meant the final TMFs needed extra review in order to meet inspectors' expectations.

To eliminate the inefficiencies of multiple, limited TMF sources, IDDI needed a fully paperless system that would deliver clinical trial document management capabilities, facilitate easy monitoring of TMF quality with dashboards and reports, and securely connect all parties.

The Search

IDDI sought a single digital solution that would be accessible everywhere, with versioning capabilities and audit trails for tracking content easily. As a CRO, the organisation needed a way to provide sponsors complete visibility into the TMF and enable them to load, review, and approve content directly within the system. The ideal solution would enable collaboration from any location, but would also make it easy for IDDI employees to control and configure access to TMF documents.

The Solution

IDDI searched for two years and reviewed six solutions before selecting Vault eTMF for its combination of cloud flexibility and life sciences-specific capabilities that met their most strategic areas. Crucially, as a process-driven application delivered in the cloud, Vault eTMF enables real-time collaboration between all trial stakeholders, and ensures IDDI's clients can always access the most recent versions of study documents. All users, wherever they are in the world, can review and contribute eTMF documents via a simple web login, eliminating the need for VPNs and layers of permissions.

Along with simplifying communication, Vault eTMF's document metadata allows content to be shared across studies for the same sponsor – helping IDDI better meet client needs. E-signatures in Vault eTMF have also removed the costly and time-consuming process of shipping paper documents for client approval.

With Vault eTMF, IDDI was able to streamline processes that had previously been labour and resource-intensive and close gaps that had introduced compliance risk. Automatic versioning and audit trails showing detailed document histories ensure that content is always traceable and up-to-date, replacing reams of paper and Excel tracking spreadsheets. And since Vault eTMF supports the DIA TMF Reference Model, IDDI was able to leverage a pre-validated template across its 90 studies. The organisation had found the right solution: one that delivered visibility, global access, and strong control, all while maintaining compliance.

The Implementation

IDDI was able to implement a pilot of Vault eTMF for a Phase III clinical trial in less than four weeks – defining rights, workflows, security models, and life cycles. IDDI has migrated its 34 active studies to Vault eTMF and plans to use the system for all new trials. "The Veeva project team was impressive," said Danielson. "Easy to work with and hardworking. Given the speed of cloud deployment, we were confident that Veeva would deliver within the four week deadline. Veeva's multitenant architecture also frees us from the need to maintain and update multiple systems – and we automatically benefit from ongoing innovation as they deliver new capabilities over time."

The Results - Empowering Clients with Anytime Inspection-readiness

With Vault eTMF, IDDI is improving the service it provides from start to finish, empowering its clients with greater speed, TMF quality, and ongoing inspection-readiness. Now, IDDI's TMF creation form – based on out-of-the-box templates aligned with the DIA TMF Reference Model – enables the company to set up a new trial in a single day. Using Vault's dashboards and reports, the organisation is monitoring the TMF completeness throughout the trial, allowing it to address bottlenecks early and ensure more timely delivery. Furthermore, Vault eTMF's role-based accessibility, which provides staff, sponsors, and inspectors with remote access to all the appropriate documents for review, has transformed IDDI's approach to preparing for inspections.

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> *Linda Danielson - Chief Operating Officer*
> *International Drug Development Institute*

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On the heels of new guidance from the MHRA, remote eTMF access is becoming increasingly important to sponsors and CROs alike. "Increasing demand from U.S. and European health authorities for direct access to TMF documents indicates a growing trend – a move toward in-process inspections by regulatory bodies globally," explained Jennifer Goldsmith, vice president of Veeva Vault. "The highly accessible nature of the cloud supports this need by allowing all collaborators to upload and access documents in real-time rather than having to go back and reconcile the entire TMF at study close-out."

"Life sciences companies today are increasingly looking to their research partners to streamline the clinical trial process and facilitate faster time to market," continued Goldsmith. "CROs today have a tremendous opportunity to distinguish themselves as trusted partners by enabling closer collaboration and strategic process improvements."

With Vault eTMF, IDDI has gained the foundation needed to advance its mission of improving efficiency, trial execution, and better serving its customers around the world. "At the beginning of this journey, we were looking to move from our hybrid system to a single, digital solution for TMF management to increase quality, efficiency, and control while allowing our colleagues and clients to access our data through the cloud," concluded Danielson. "Vault eTMF is enabling us to achieve our goals – supporting our global client base and long-term paperless strategy."