Communicate. Accelerate. Deliver. Electronic Trial Master File (eTMF) Case Study

A small biotech company engaged Covance to conduct a Phase II study for an innovative new oncology drug.

Understanding the Challenge

- Providing streamlined document management workflow, storage and access
- Delivering high-quality, audit-ready reports and documentation
- Communicating with and coordinating activities among geographically dispersed sites
- Adhering to study timelines

Electronic System Transforms Results

To help set our client up for success, our operations team and project managers used a cost-effective eTMF system instead of a traditional paper-based document management and storage system to support the quality, integrity and validity of the clinical trial data and to provide the speed and accuracy required to meet our client's timelines. The eTMF system provided near real-time access to reports and data generated from all the sites, helping our project managers answer client questions on study progress and coordinate activities across locations. This immediate access to reports and documents also enabled our project managers to proactively identify mistakes and potential problems, addressing issues before they impacted study performance. Internal assistance and staff training were then provided as needed.

Always anticipating tomorrow's needs, our eTMF system assured our client that all documentation, including the final trial master file, would be completely accurate and audit-ready without delay. This required meticulous, regulatory-compliant data recording and document management. Project managers received alerts of new monitoring reports, which were automatically loaded into the system after approval. Outputs were then incorporated into a high-quality, audit-ready final study document. To further gain a competitive advantage, we championed adherence to study timelines, deliverables and critical milestones.

Finally, based on insight leveraged from years of experience running clinical trials, the Covance eTMF system was designed with ease of use in mind – benefiting both our internal team and our client. To locate and review documents quickly – no matter where in the world they were generated and uploaded – we created an easy-to-navigate user interface and site library. This improved the quality control process, reducing and eliminating errors and delays in document approval. Thus, we were able to provide consistent feedback and information that enabled faster decision making at each critical point.

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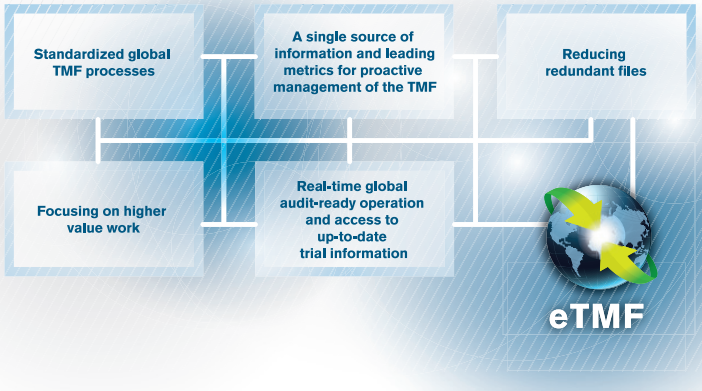
Here is what you can expect from Covance **eTMF**



Producing high-quality, audit-ready reports and documents is essential for any clinical trial – but it means getting involved with myriad details. Partner with Covance and let us manage your document workflow, storage and access so you can focus on the big picture – bringing your drug to market.

Learn more about our drug development solutions at **www.covance.com**

Covance Inc., headquartered in Princeton, NJ, is the drug development business of Laboratory Corporation of America® Holdings (LabCorp®). Covance is the marketing name for Covance Inc. and its subsidiaries around the world.

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