CRO Outsourcing Model Implementing a New Electronic Trial Master File in 8 Weeks

The Challenge: Implementing a New Electronic Trial Master File

A mid-sized pharma company focused on inflammatory, metabolic, and affective disorders was looking for a new electronic trial master file (eTMF) solution for a number of upcoming clinical studies. Prior to adopting Medidata, the sponsor used a legacy eTMF solution and outsourced eTMF management to their CRO. The legacy eTMF solution was embedded as a module to their CTMS system. The solution was extremely difficult to navigate, required heavy manual data entry and information tracking, and ultimately caused delays in filing TMF-ready documents. The system was comprised of various file share systems that were managed by multiple people across a range of functional and geographic areas. There were additional inefficiencies from inconsistent security measures, including information storage on paper and the need for a secure location to physically store the documents. Finally, the legacy eTMF system vendor did not provide adequate customer service to meet the client's needs. The sponsor switched to **Rave eTMF** and turned to their CRO to accelerate study startup and manage the eTMF process.

The Solution: Implementation and Enablement of eTMF

Replacing legacy technology is rarely easy. But within eight weeks—through a series of collaborative workshops, out-of-the-box standard operating procedures, and effective coordination with the CRO—Medidata's Professional Services team fully delivered eTMF. As a result, the client was empowered to seamlessly manage their eTMF content and maintain inspection readiness.

Collaborative Workshops

The Medidata Professional Services team, consisting of a project manager, implementation consultant, and a client services principal began the implementation and enablement process with the CRO through a series of workshops. The first step was a pre-project initiation meeting. This meeting set expectations for the CRO and established Medidata's responsibilities. Following the initial kickoff meeting, Medidata's Professional Services team led a two-day onsite workshop to identify client requirements, provide system training, ensure functionality was enabled prior to go-live, and to configure the system. Following the initial workshop, Medidata held weekly meetings and follow-ups over webex to ensure client success.

"The Medidata Professional Services team has been really straight forward about helping and offering their resources and knowledge about the system to ensure the workflow we've laid out will be an efficient way of storing documents securely, and in a compliant, and auditable fashion."

Document Specialist at the CRO

Identify and Involve the Right Resources
The CRO identified two key personnel to manage the relationship with Medidata. In order to nurture project success and ensure timelines were met, the client identified resources in advance to help support both content ownership and IT. It was critical to involve resources with content management domain expertise to manage document contributors, while also enlisting someone with IT management who could assess the environment and user on and offboarding. These individuals were trained during the two-day onsite workshop, with the expectation they would learn to manage the content and generate studies on their own going forward. They were also provided additional video training resources.

Shared Standard Operating Procedures for Fast Implementation
Due to the validated system, Medidata provided the CRO draft standard operating procedures to manage the environment. These fully-delivered, out-of-the-box SOPs allowed the CRO to quickly understand the processes needed to use eTMF and clearly define the best path forward using the system. These SOPs act as a quick-start guide and outline what is needed for a clear understanding of the system, including how to add a user, how to capture an electronic signature, how to load content, how to migrate content into the system, and how to manage the environment efficiently. Having visibility into these SOPs also provided the CRO the time and resources to create a file structure for document loaders before document migration began, thus ensuring a very clear and straightforward process for migration and that the eTMF would be clean and done right the first time.

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including over 1,000 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 20 medical device developers— from study design and planning through execution, management and reporting.

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