

**Location**

Saratoga Springs,
New York

**Industry**

Contract Research



etmf
connect

Overview

Before making the switch to an electronic trial master file (eTMF), the Criterium team had to reconcile TMF documents from two distinct locations; on a fileshare and on paper. Even with a successful working system for many years, it was a growing challenge with new sponsor partnerships and additional studies coming onboard. Looking to improve their IT environment and keep ahead as a technology-driven CRO, Criterium selected Montrium's user-friendly eTMF tool, eTMF Connect, to better support R&D activities.

Challenge

The amount of both regulated and non-regulated content grows quickly in a hybrid fileshare and paper TMF environment. Over time, this arrangement made it more time-consuming for the Criterium team to reconcile documents, obtain study metrics and track overall study progress. With numerous trackers maintaining the inventory of documents and activity, the team had to manually ensure that each tracker would have matching data both in the fileshare and paper versions. In planning for future growth, Criterium was looking for a solution that could keep up with their expanded efforts to scale up, as they were outgrowing the hybrid TMF model. Criterium then began the search for a consolidated eTMF tool that was easy to manage while providing the core functionalities users needed.

Highlights

The customer: Criterium Inc. is a leading full-service contract research organization (CRO) with headquarters in Saratoga Springs, New York. Their research activities follow ICH-GCP standards to support the pharmaceutical, biotech, and medical device industries.

Challenge: A hybrid fileshare and paper model made TMF reconciliation and measuring metrics time-consuming, requiring extensive Excel-based tracking.

Solution: The transition to a compliant and validated eTMF system for improved traceability, oversight and control, internal collaboration, allowing for productivity in a central environment.

"I have already recommended Montrium to others working in clinical research. This is in large part due to their outstanding support throughout our implementation of the product and demonstrated knowledge of both the clinical and regulatory environments."

Nicole Palmer
Clinical Trial Administrator Manager
Criterium

Solution

Criterium thoroughly researched seven of the leading solutions available, carefully weighed the pros and cons of each and viewed numerous product demonstrations before choosing Montrium's eTMF Connect. Considering that the system chosen would need to follow industry good clinical practice and global regulatory requirements, Criterium's first choice was eTMF Connect due to its intuitive, user-friendly features and robust filing system. Montrium's product came within budget for Criterium's new eTMF solution.

Montrium Product Implementation & Support teams facilitated Criterium through the implementation, training, and migration phases. Criterium's use of eTMF Connect allows its users to operate in all capacities, within a secure and globally compliant environment that adheres to study requirements from various sponsors.

Key Achievements

- Criterium now operates within a consolidated eTMF to manage files from one central location, eliminating the need for external trackers
- Compliance is maintained with built-in features that meet requirements for electronic records (e.g. granular permissions controls) and electronic signatures
- TMF planning is made easier with the ability to track ongoing study metrics in real-time
- Internal teams work from a collaborative, secure environment anytime, anywhere

"eTMF Connect has changed the way we approach trial management and interact with our TMF. We've already noticed efficiency improvements and in the long term, this will keep us innovative and competitive."

Nicole Palmer
Clinical Trial Administrator Manager
Criterium

Results

Business Development and Collaboration

- eTMF Connect has improved visibility, collaboration and control between employees, sponsors and sites. This has also given Criterium the competitive edge needed to create winning bids for new studies.
- Criterium projects considerable growth and with several new studies onboarding this year, eTMF Connect will allow more users to easily contribute to the system.

Compliance with 21 CFR Part 11

- eTMF Connect maintains compliance with built-in features that meet requirements for electronic records (e.g. permissions management) and electronic signatures.

Productivity and Time Saved

- Criterium can quickly file, compile and sort through thousands of documents as organized by site, study, folder, etc. The process is faster than with a hybrid fileshare-paper TMF.
- Being able to export the docs into an Excel spreadsheet or zip file at the push of a button saves a considerable amount of time and labor.
- eTMF planning features (e.g. identifying expected, incomplete, overdue documents) allows Criterium to visualize the completeness of trial content and quickly gain an overview of study progress.
- No longer needing to ship files between sites or to obtain a wet signature, Criterium employees can work in parallel and now experience reduced waiting times on external document approvals.

Continued Support and Training

- New employees can easily get up-to-date on the system using eTMF Connect product videos to facilitate training, a faster process compared to training on the hybrid system.
- An open line of communication with Montrium means that Criterium's suggestions for improvement are accounted for and results are produced in a timely manner by Montrium.