

**Location**

La Jolla, California

**Industry**

Biotechnology

etmf
connect

Overview

To meet patients' critical unmet needs and provide innovative drug solutions, the EpicentRx team was looking for alternative ways to be more efficient with their trial master file (TMF) management. Since working with Montrium's eTMF Connect for over one year, EpicentRx has seen heightened efficiency and productivity with the increased organization of data and records, the use of TMF data reporting features, and enhanced collaboration amongst sites and study teams.

Challenge

Previously, the EpicentRx team utilized a paper-based TMF which challenged the existing team and prevented scalability. As stated by Gina Varner, Director of Regulatory Affairs at EpicentRx, "Managing and filing in the paper TMF was too slow-moving, and it was also difficult to have a real-time assessment of completeness of TMF." The EpicentRx team was looking for a different way to increase efficiency while remaining compliant with the requirements of 21 CFR Part 11.

Highlights

The customer: EpicentRx is a patient-driven immuno-oncology company with headquarters in La Jolla, California. Their research and development activities surround drug candidates that work effectively and broadly across diverse patient populations and tumor types, and are minimally toxic to preserve the patient's quality of life.

Challenge: Working in a paper-based TMF made collaboration, review of documents, and measuring performance and compliance difficult, requiring a significant amount of time and resources to maintain.

Solution: The transition to Montrium's eTMF Connect improved collaboration and accurate reporting, allowing for increased productivity and efficiency within a central application.

"When initially uploading documents and comparing them to the system's placeholders aligned with the DIA's TMF Reference Model, right away we could see in the eTMF Connect Navigator what was effectively complete, any documents we were missing, and any titles that needed to be named differently."

Gina Varner

Director of Regulatory Affairs**EpicentRx**

Solution

EpicentRx went through a full vendor selection process and evaluated several other software platforms. Montrium stood out compared to other products as eTMF Connect was cost-effective and provided a user-friendly interface with powerful TMF capabilities.

Gina Varner, Director of Regulatory Affairs at EpicentRx shares, “The product came with a good support team that could work with our particular needs to implement the software in a way that would work best for us,” adding, “eTMF Connect has been worth the financial investment, we have become more efficient with our staff resources and maintaining the TMF, and can take on new projects without adding significant time and costs.”

Key Achievements

- EpicentRx now operates within a consolidated eTMF to manage files from one central location
- eTMF planning and strategy is now possible by tracking ongoing study metrics with added Excel exporting capabilities
- Internal teams can now collaborate in an environment and see changes in real-time
- The new eTMF platform has created new efficiencies, providing the ability to manage a larger volume of studies as well as studies that are larger in size

“The Montrium Support team is very attentive and willing to make changes to make the system more user-friendly. We frequently make use of the customer webinars and in-application support with the Help Center.”

Gina Varner

**Director of Regulatory Affairs
EpicentRx**

Results

Collaboration and Organization

- eTMF Connect enhances visibility and collaboration between all trial stakeholders while maintaining control.
- By spending less time filing paper documents, and providing real-time tracking and viewing of documents, the EpicentRx team is more efficient, using fewer resources to manage studies.
- With EpicentRx’s projected growth and increasing number of new studies coming in, Montrium’s eTMF has prepared the organization to have better handling of the increased intake of documents and data.

Productivity and Efficient Use of Resources

- Before a process that could take hours or days, EpicentRx can quickly file, compile and sort through thousands of documents as organized by site, study, folder, etc. eTMF Connect’s search and filtering features reduce the amount of time required to locate TMF content.
- The export to Excel function helps with more advanced reporting of TMF content, helping to gauge overall TMF health in different areas of the business. Exporting data at the push of a button saves a considerable amount of time and effort for the EpicentRx team.
- eTMF Connect provides real-time updates and reporting so that project teams, monitors and study sites can work concurrently and obtain a clear understanding of study progress.

Training and Ongoing Support

- New hires can promptly catch-up and learn the system using product videos and articles in the Connect Help Center to facilitate training. This is a much faster process for EpicentRx compared to training with a paper TMF.
- Working with a designated Product Specialist and Customer Success Manager means that EpicentRx suggestions for product improvement are valued and acted on. Results are produced on time to improve the user experience continually.