QUALITY DRIVEN

Ensuring TMF quality is the single most important part of the clinical trial process. Given the current attention to the TMF, the regulatory agencies can show up at any time to review its content. Don't be caught off guard. Make sure your study is ready by having the leaders in TMF management at LMK provide our proven TMF QC processes.

DEDICATED ELITE TMF REVIEW TEAM

The Elite TMF Review Team (ETRT) is a dedicated team who performs TMF QC and remediation (if needed) for risk-based or for 100% of the content within the TMF. The ETRT has experience in paper, electronic, and hybrid TMFs and is available to assist you onsite or remotely. With expertise in clinical trials and TMF management, the ETRT reviews your TMF content in a timely manner using an established process and tool to perform TMF QC that highlights gaps and discrepancies within the TMF.

By utilizing LMK's ETRT, you benefit from increased process effciencies and TMF compliance—saving you time and reducing your costs while increasing the quality of your TMF:

❑ Identifies and documents true discrepancies and potential gaps within the TMF. Resolves discrepancies rather than generating a long list of queries for your team to resolve.

❑ Ensures your TMF is inspection ready at all times throughout the study through routine TMF QC—providing you with another level of validation.

❑ Reduces costs and expedites timelines through "efficient" TMF content QC and remediation.

TMF REFERENCE MODEL

You haven't adapted the TMF Reference Model yet? Our team can review your SOPs to determine which document types from the TMF Reference Model are applicable to your company. We can also provide customized training on the TMF Reference Model to meet your specific needs.

TMF MIGRATION

We are an eTMF agonistic company and are fully trained in all of the major eTMF technologies currently on the market. If you need to streamline your TMF process and have your TMF content in one electronic repository we can help. Our experienced resources will migrate your TMF content quickly and efficiently ensuring prompt and accurate access to your electronic files.

RESOURCES

Is a flexible resourcing model important to you? We can provide short- and long-term resources to support your TMF activities: from TMF management through TMF QC and remediation. Depending on your needs, our resources can be onsite or virtual. We can make our flexible model work for you!

Leaders in Document Management

Contact us today!

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Website: www.lmkclinicalresearch.com

LMK CLINICAL RESEARCH CONSULTING

YOUR PARTNER IN TRIAL MASTER FILE MANAGEMENT

LMK Clinical Research Consulting is a leader in Trial Master File (TMF) management solutions to the life sciences industry.

SOLUTIONS PROVIDED. QUALITY DRIVEN.

We offer expert knowledge and experience in TMF and quality document management and provide custom and comprehensive solutions to meet the needs of pharmaceutical and biotechnology companies and clinical trial sites.

WHO WE ARE AND WHY WE DO IT?

At LMK, we believe the TMF is the foundation of every study, and a strong foundation is key to the overall health of your trial.

That is why, LMK takes a proactive approach and makes TMF quality a top priority on an ongoing basis—from study start through closeout—not just pending an inspection or at study completion.

Don't let your TMF be a document collection burden when it comes time to close your study; let it be a management tool throughout its life cycle. LMK can help you plan, collect, and maintain your clinical trial documents cost effectively without jeopardizing quality.

Give your TMF the priority it deserves and contact LMK today to discuss how we can help you with your TMF and quality document management solutions.

The LMK Advantage

Times are changing and now, more than ever, you need TMF and document management tools that help you make smarter decisions and gain the competitive advantage.

LMK can help.

TMF MANAGEMENT & PROCESS PLANNING

We are flexible and offer a full range of document services — from SOP development through file archive. Our team members are TMF experts and have extensive knowledge in clinical trial drug development. As part of your study team, we provide guidance as subject matter experts ensuring TMF compliance to guarantee quality deliverables.

LMK TMF experts will work with you throughout the life cycle of your project to effectively plan, collect, and manage your clinical trial documents on an ongoing basis. Our team performs TMF QC and remediation across Functional Lines, ensures TMF appropriateness and accuracy, and provides additional TMF support during an audit or inspection.

TMF PLANNING	Create and follow standard processes that are clear and well-defined. Develop SOPs that ensure the System of Record for all content is properly documented. Implement the TMF Reference Model (RM) based on our SOPs, not just the RM. Review the TMF RM by zone to determine which documents are applicable, create a master reference document for use by the entire company. Ensure a complete and thorough master list of possible content to file in the TMF.
TMF TRAINING	Ensure that all Functional Lines have a clear understanding of the TMF: how it is used and why it is important. Provide training on how to utilize the RM, define the zones, and understand its documents and filing structure.
TMF MAINTENANCE	Ensure documentation filed meet that criteria (prospective throughout the study or retrospectively) once the master list is built. Collect, file, and store your paper documents. Establish a process for collecting documents from Functional Lines, clinical sites, and CROs (if applicable) from study start through study completion.
TMF QUALITY CONTROL	Ensure that the TMF as a whole is complete, accurate, and inspection ready at all times. Implement a TMF QC process that can be followed by all Functional Lines regardless of the type of content that is or has been filed.
TMF CLOSEOUT	Perform final TMF QC and remediation ensuring that all discrepancies have been resolved, and properly close and archive the TMF (Paper, eTMF system or Hybrid).