LMK CLINICAL RESEARCH CONSULTING
A TRANSPERFECT COMPANY

ELEVATING KNOWLEDGE

TMF CORPORATE EDUCATION PROGRAM GUIDE

Trained professionals are the foundation for maintaining an inspection ready TMF, as they have the knowledge and skills necessary to accurately and efficiently complete TMF tasks. The LMK Corporate Training & Education Program is a portfolio of non-accredited courses designed to increase knowledge and address common gaps or deficiencies amongst all TMF stakeholders. Organizations that want to elevate the knowledge and skills of their TMF stakeholders will benefit from this program, which is designed for all levels of TMF experience and contribution. Whether participants are newer to the TMF or have years of experience, whether they complete many TMF related tasks daily or only complete TMF tasks every so often, the TMF Corporate Education Program will provide valuable information to all stakeholders.

Courses can also be customized to make the learning experience relevant to the company's real world environment.

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INTRODUCTORY COURSES

Designed for those new to working with the Trial Master File who need to establish a good foundation of knowledge and understand the fundamental concepts.

TMF Overview
In this interactive course, learners will discover what the Trial Master File (TMF) is, when it's produced, and why it is the single most important aspect of the clinical trial. This course will also help learners understand who the key stakeholders are in ensuring the TMF remains inspection ready and provide. A brief overview of regulations from the FDA, MHRA, EMA and ICH.

Document Quality Control (QC)
It's imperative that every document is complete and meets all quality standards prior to being finalized in the TMF. In this course, learners are taught about Good Documentation Practices (GDocP) and how to apply those principles to perform individual document QC in a consistent and timely manner. Learners will also receive hands-on practice using proven processes and tools to perform QC on a series of sample TMF documents.

TMF Indexing
Proper document filing and indexing is a critical step in the overall continuum of the TMF. In this course, learners will come to understand how to determine what documents to file in the TMF (i.e., "TMF ready" documents), important document indexing steps, how to confirm consistency with filing, and document filing best practices. The course will also cover best practices for generating and maintaining an organizational and study specific TMF Index.

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INTERMEDIATE COURSES

Designed for those with experience in working with the Trial Master File, who understand the "basics," and are ready to take their knowledge to the next level.

TMF Quality Control

Can you imagine telling an inspector: "Apologies, but we do not know how many versions of the TMF Plan should be filed." Without ongoing TMF QC reviews, your study team may not know what's expected in the TMF or how much of that expected content has been filed. This course explores how to determine what's expected, how to use that information to perform an effective TMF QC review, and also provides learners with hands-on training, tools, and best practices for TMF QC to avoid uncomfortable inspection interactions and possible findings.

Audit and Inspection Readiness

There is no fear that compares to that of receiving a notification from a regulatory agency that your TMF will soon be inspected or that your study has been selected for an audit. Instead of panicking, it is important to rely on your organizational and study processes to help you succeed. This course is an in-depth look into audit and inspection readiness preparation for the TMF. Learners will come to understand how to get inspection ready, including activities and responsibilities to ensure preparedness, and how stay that way throughout the duration of the trial.

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ADVANCED COURSES

Designed for those with responsibilities for managing the Trial Master File or are in leadership positions where an in-depth understanding of the TMF is required.

Current Regulations
New guidance and regulations are constantly emerging in the clinical trial space and most organizations find it almost impossible to keep up with the cascade of changes. This course will cover the most recent regulations, guidance and feedback from the FDA, MHRA, EMA and ICH as it relates to incorporating expectations into organizational processes to appropriately manage the TMF. Not only will this course help to bring learners up to speed, but it will also demonstrate how to stay informed and up-to-date going forward.

TMF Process Best Practices
Your organization can only be as effective as the processes that you follow! This course will help learners to understand best practice approaches for creating and managing TMF specific processes. This interactive course features case studies, tools, and best practices that will help learners align people, process, and technology. This trifecta can be one of the most important formulas for determining TMF success and it is imperative that organizations manage each of them through a strong documented process.

TMF Metrics
Measuring TMF health becomes increasingly more important as organizations become more mature and utilize more sophisticated ways to manage their TMF. This course will explore important considerations for TMF Metrics Program development, which includes creation of Key Performance Indicators_(KPI) and reviewing examples of escalation pathways for non-compliance. Learners will receive valuable tools and resources to use in developing and/or maintaining their TMF Metrics Program.