



LMK Launches Accredited and Internationally Qualified TMF University

(Huntersville, NC and Maidenhead, United Kingdom, October 29, 2020) - The first independently accredited Trial Master File University (TMF University) is getting ready to launch its inaugural training series on January 11, 2021. TMF University engages students with a combination of high-quality virtual instruction along with standardized educational competency requirements to prepare Internationally Qualified TMF experts. Facilitated by LMK Clinical Research Consulting (LMK), TMF University received independent and internationally recognized accreditation from IAOCR, the International Accrediting Organization for Clinical Research, the world's only organization that qualifies Clinical Research Professionals to international standards.

"LMK Clinical Research Consulting is committed to partnering with organizations that parallel with our passion for quality and clinical research education. We were delighted when IAOCR agreed to work with us to provide independent accreditation for TMFU, which marks a notable step forward for the pharmaceutical and clinical research industry," says Sholeh Ehdaivand, Founder and CEO of LMK Clinical Research Consulting.

The Trial Master File (TMF) is the foundation of every clinical trial and consists of a compilation of all the necessary documents produced during the conduct of a trial. The accredited education of individuals who work on the TMF holds critical importance to the outcome of clinical trials. Considered a leader in TMF services in the clinical research industry, LMK recognized a void in the area of educational excellence and regulatory knowledge surrounding the management of the TMF in the clinical trial environment. This realization is what birthed their journey to create the TMF University curriculum and provide those in important TMF management and support roles with the required knowledge, skills, and behaviors to properly organize, assess and manage their TMFs.

"Individuals supporting the TMF play a significant part in the success of clinical trials," explains Jackie Morrill, PMP, Executive Director of Clinical Operations at LMK Clinical Research Consulting. To develop the curriculum, LMK dissected different job roles within the pharmaceutical and clinical research spaces. This allowed LMK and IAOCR to tailor the curriculum specifically to an employee's job description and responsibilities. While expert knowledge will be provided, students will also learn how to apply a broader skill set and level of expertise personalized to specific TMF case studies. There are three learning levels within the TMF University accreditation program:

Discovery level courses cover the fundamental topics concerning the TMF: **Introduction to TMF, Document Quality Control, and TMF Indexing**. These courses will ensure that Clinical Trial Assistants, Document Associates and those new to the TMF environment are well-trained to make confident TMF decisions within their roles.

Immersion level courses will cover essential topics that are critically important to TMF quality: **TMF Quality Control, Audits & Inspections, and TMF Technology**. These courses will help guarantee that individuals in more experienced roles such as Clinical Research Associate, Clinical Trial Coordinator and Functional Clinical Trial Team Member are well-equipped with a more comprehensive understanding of the TMF.

Mastery level courses will cover advanced topics of TMF Management, including **Current Regulations, TMF Process, and TMF Metrics**. These courses will give experienced TMF professionals in roles such as Clinical Project Manager, TMF Lead, TMF Project Manager or Head of Trial Master File a more in-depth understanding of complex TMF concepts and responsibilities, while also ensuring a broad understanding of how to apply their knowledge to unique TMF challenges and lifecycles.

Students have several certification/accreditation options and can choose the path that best suits their career goals:

Option 1: Accreditation by learning level (Discovery, Immersion, Mastery) by completing all course modules and corresponding competency assessments.

Option 2: Accredited Qualified TMF Professional status:

Qualified TMF Associate = Discovery + Immersion accreditation

Qualified TMF Manager = Discovery + Immersion + Mastery accreditation

Option 3: Non-Accredited certificate of completion for each class within a learning level

If you are interested in joining the first TMFU cohort, or want further information, please visit [TMF-University.com](https://tmf-university.com) or call: 980-206-3216

To learn more about LMK Clinical Research Consulting please visit: <https://lmkclinicalresearch.com/> or call: 980-206-3216

To learn more about IAOCR please visit www.iaocr.com or call:

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About IAOCR

IAOCR is the international accrediting organization for clinical research. We are the only organization in the world to qualify Clinical Research Professionals to international standards. Through robustly accrediting the competence IAOCR reduces risk—to patients, clinical research and organizations—whilst improving compliance and bring drugs to market quicker.

IAOCR business processes and accreditations have been built specifically for the clinical research industry. They provide a quality mark to organizations committed to globally consistent, high quality clinical trials workforces.

We believe that clinical trials patients anywhere in the world deserve the best protection in terms of rights and wellbeing. Therefore, in addition to providing accreditation, training and constancy guidelines and frameworks that are freely available to everyone. To find out more about the best practice initiatives visit <http://iaocr.com/resources/>

About LMK



LMK Clinical Research Consulting is a global Functional Service Provider exclusively focused on TMF consulting and services. We offer comprehensive TMF services specializing in the strategic development, project management and quality control of documents and content that supports clinical development. From study start through completion, our TMF experts deliver quality TMF document management solutions and support to ensure TMF inspection-readiness at all times. The company is eTMF agnostic and can support projects on any eTMF platform.

Our mission is to provide our clients with TMF products and services that maximize quality, compliance, efficiency and inspection-readiness. Our customized service offerings include TMF Project Management services, TMF SOP development and planning, eTMF vendor selection / implementation / configuration, TMF training (TMF University), TMF Quality Control (QC), TMF mapping, TMF Reference Model integration and document migration, all of which can be customized to meet our clients' needs.

LMK is a renowned leader in the TMF realm, providing leadership on Metrics Champion Consortium's (MCC) newly formed TMF Metrics initiative and governance as TMF Reference Model Zone leaders and reviewers. <https://lmkclinicalresearch.com/>