

TRIAL TO TRIUMPH

Achieving TMF excellence through certified accreditation.



TMF UNIVERSITY COURSE DESCRIPTION GUIDE



MASTERY LEVEL

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 in 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.

Current Regulations

New guidance and regulations are constantly emerging; at times, it can feel impossible to keep up with all of the changes! This course is constantly updated with the newest regulations, guidance, and feedback from the FDA, MHRA, EMA and ICH. This course will not only bring attendees up to speed on the current regulatory landscape, but will also teach attendees how to stay informed, up-to-date, and manage regulatory changes as they occur.

TMF Process

Active TMF management is vital to any clinical trial's success. Managing your TMF throughout a study, rather than just leaving it until the end, will promote TMF health and ensure ongoing inspection readiness. This course will explore the TMF management process from study start-up through closeout and archival, and will explain how to ensure your organization has the appropriate tools in place to support active TMF management. Attendees will learn how to develop efficient TMF processes and tools that promote inspection readiness and encourage active TMF management through stakeholder buy-in.

TMF Metrics

Measuring TMF health is increasingly important as organizations become more mature and utilize more sophisticated ways to manage their Trial Master Files. This course will define Key Performance Indicators (KPIs) for TMF, explore how to develop a TMF metrics framework, and provide examples of escalation pathways for non-compliant documents and/or studies. Attendees will receive valuable tools and resources that will enable them to establish and maintain their own customized TMF metrics program.