TRANSPERFECT LIFE SCIENCES | TMF UNIVERSITY

Developing qualified TMF professionals through certified accreditation.

Trial TO Triumph

LEVEL 1: DISCOVERY — Achieving TMF Excellence — TMF UNIVERSITY

LEVEL 2: IMMERSION — Achieving TMF Excellence — TMF UNIVERSITY

LEVEL 3: MASTERY — Achieving TMF Excellence — TMF UNIVERSITY

TMF UNIVERSITY COURSE DESCRIPTION GUIDE

Course Length Per Level: **3 Modules, 3 Hours Each**
Competency Assessments: **2/3 Hours Per Module**

TMF University (TMFU) is the first and *only* internationally recognized certification program for TMF Professionals. It is accredited by IAOCR, the International Accrediting Organization for Clinical Research – the world's only organization that qualifies Clinical Research Professionals to international standards. Geared toward individual learners, TMFU engages students with a combination of high-quality, virtual instruction in a live setting along with standardized educational competency requirements to prepare Internationally Qualified TMF experts.

The TMFU curriculum equips individuals in important TMF management and support roles with the required knowledge, skills, and behaviors to properly organize, assess and manage their TMFs. The program also creates a pathway to accredited certification and internationally recognized credentials for those who desire to be trained and recognized as a *true* TMF Professional.

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Recommended TMF Experience: 6 Months

DISCOVERY LEVEL

Discovery course modules cover the fundamental topics concerning the TMF: **Introduction to TMF, Document Quality Control, and TMF Indexing**. These modules 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.

Introduction to TMF

Participants can expect to learn what the "Trial Master File" (TMF) is in this module and why it is the single most important aspect of the clinical trial. This module will explore the key components of the TMF, identify TMF contributors, define where and how TMF content may be stored and organized, and when content is expected. Attendees will walk away with a solid understanding of the who, what, where, when and why of the TMF.

Document Quality Control

It is imperative that every document is complete and accurate prior to filing in the TMF. This module is an introduction to the world of document quality control (QC) within the Trial Master File. Attendees can expect to learn how to perform QC in a consistent and timely manner, and will also receive hands-on training in the proven processes and tools one should know in order to perform a thorough document QC review.

TMF Indexing

TMFs contain a large volume of documents that must be properly organized to ensure inspection readiness. Establishing a filing structure for expected documents through the life of the study will ensure consistent document indexing and is imperative to TMF health. In this module, attendees will review different TMF filing structures, learn how to properly file and index documents into the TMF, how to confirm consistency with filing, and discover filing best practices.

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Recommended TMF Experience: 1 Year

IMMERSION LEVEL

Immersion course modules cover essential topics that are critically important to TMF quality: **TMF Quality Control, Audits & Inspections, and TMF Technology**. These modules 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.

TMF Quality Control

Can you imagine telling an inspector, “Apologies, but we don’t know how many versions of the project management plan should be filed?” This module explores what TMF Quality Control (QC) is, why it is important for TMF inspection readiness, and how to conduct effective TMF QC reviews by breaking the TMF QC process down into six key elements. To avoid uncomfortable inspection interactions and possible findings in the future, attendees will receive hands-on training, tools, and best practices for TMF QC.

Audits & Inspections

There is no fear that compares to that of receiving an inspection notification from a regulatory agency or an audit request from a sponsor. Instead of panicking, try preparing. This module is an in-depth look into inspection readiness and audit preparation for the TMF. Attendees will learn best practices that will help them get inspection ready and stay that way, as well as how to prepare, conduct themselves, and respond appropriately to regulatory inspection or audit findings when the inevitable occurs.

TMF Technology

With so many different eTMF products/vendors on the market, it can be difficult selecting the system that is right for your organization. This module reviews when and how to know you are ready for an eTMF system, what to look for during the selection process, how to make the right decision, and once you’ve made the decision, how to implement your new eTMF to maximize its return on your investment. Attendees will receive tools, resources, and best practices that will help them introduce technology into their TMF environment and benefit from the advantages and efficiencies that eTMF systems offer.

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Recommended TMF Experience: 2 Years

MASTERY LEVEL

Mastery course modules cover advanced topics of TMF Management, including **Current Regulations, TMF Process**, and **TMF Metrics**. These modules 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.

Current Regulations

New guidance and regulations are constantly emerging; at times, it can feel impossible to keep up with all of the changes! This module 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 module 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 module will define Key Performance Indicators (KPIs) for the 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.

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Certification & Accreditation Options

Students can choose to take individual courses or combine two or more learning levels to attain International Accreditation status. These options allow them to choose the path that best suits their career goals:

Option 1 **Certificate of Participation**: Earned for each course module attended within a learning level without the completion of the related competency assessment.

Option 2 **International Accreditation by learning level (Discovery, Immersion, Mastery)**: Completion of all course modules and related competency assessments within the learning level.

Option 3 **Internationally Qualified TMF Professional Status**: Completion of all required course modules and related competency assessments for Qualified TMF Associate (Silver) and/or Qualified TMF Manager (Gold) qualifications.

QUALIFIED TMF ASSOCIATE

Discovery + Immersion Accreditation

6 modules plus successful completion of competency assessments

QUALIFIED TMF MANAGER

Discovery + Immersion + Mastery Accreditation

9 modules plus successful completion of competency assessments

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FREQUENTLY ASKED Questions

Are TMF University courses offered on-demand?

No. TMF University is a synchronous learning program. Each module is presented in a live setting via Zoom to registered learners on designated dates.

How long is each course?

Each interactive, instructor-led course is 3 hours long. Each learning level consists of three, 3-hour modules for a total of 9 hours of course instruction within the learning level.

How much time do the assessments take to complete each week?

Most learners spend 2-3 hours each week (in addition to attending the class) completing the competency assessments that are required for the learning level accreditation and the TMF Associate and TMF Manager Qualifications.

Can I turn in all of my assessments at the same time at the end of the program?

No. Assessments are due within one week of the live course presentation.

How long do I have to respond to the assessor's feedback for each assessment?

Feedback to the assessor is due within 72 hours of receipt, even if the 72-hour window falls on a weekend. All assessment portfolios must be finalized within 14 calendar days of the initial submission.

Will I have access to the course content after the course is delivered?

Yes. Course content and recordings are available for review in the TMF University ShareFile portal. You will receive instructions on how to set up your ShareFile account following the first module of the course in which you are enrolled.

Do I have to pay for the program at time of registration?

Yes. Payment is due with the registration to secure your seat in the cohort.

Are cohort sizes limited?

Yes. Each cohort is limited to 12 learners.

Do I need experience working in the TMF in order to register for the class?

Yes. A minimum of 6 months of experience working with a TMF is recommended. Please reference the "Recommended TMF Experience" information for each learning level.

Who can I contact for answers to other questions I have?

For more information about TMF University, registration or payment, please contact:

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