

# TRIAL TO TRIUMPH

Achieving TMF excellence through certified accreditation.



TMF  
UNIVERSITY

## TMF UNIVERSITY COURSE DESCRIPTION GUIDE



### DISCOVERY LEVEL

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.

#### Introduction to TMF

In this course participants can expect to learn what the "Trial Master File" (TMF) is and why it is the single most important aspect of the clinical trial. This course 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 from this course 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 course 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 course, 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.