

The road to trial master file excellence starts here

Montrium's TMF Maturity packages provide clinical operations teams with a convenient and complete training offering to improve the knowledge of trial master file management within an organization. Carefully crafted courses, workshops, templates and exercises help augment TMF education, while giving participants with the practical tools to make positive improvements in their TMF management process.

TMF Maturity training levels

3

Courses & Workshops

24+

Hours of training & workshops

96+

TMF topics covered

88+

Templates & Deliverables

24+



ESSENTIALS



INTERMEDIATE



ADVANCED

Level up your teams trial master file maturity

01

ESSENTIALS



TMF Principles
& GCP



TMF Index +
Ref Model



The eTMF
Plan



TMF Document
Quality Check

TRAINING + WORKSHOPS

DELIVERABLES INCLUDED

eTMF Plan Template
Standard eTMF Business Rules
eTMF Connect Management SOP
WI for Trial Setup & System Admin
WI for Document Lifecycle Mgt.
eTMF Index Template
TMF Document QC Checklist
Regulatory Resource Pack

02

INTERMEDIATE



Oversight
through TMF



TMF Data
Integrity



Current TMF
Regulations



TMF Quality
Control



eTMF Processes
& Models

TRAINING + WORKSHOPS

DELIVERABLES INCLUDED

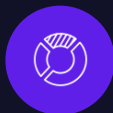
TMF Maturity Model
Email/Communication Guidance
Sample TMF QC Report
Inspection Readiness Framework
Case Studies & Articles
Regulatory Resource Pack

03

ADVANCED



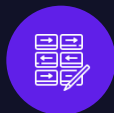
TMF Risk-based
Approach



TMF Inspection
Readiness



TMF Metrics
& KPIs



TMF
Storyboards



TMF Quality
by Design

TRAINING + WORKSHOPS

DELIVERABLES INCLUDED

Inspection Readiness Checklist
Customized QbD Process
TMF Storyboard for a study
TMF Metrics report for a study
TMF Mock Inspection
Case Studies & Articles
Regulatory Resource Pack

TMFMATURITY

ESSENTIALS

Our TMF Maturity Essentials Package has everything you need to hit the ground running with your eTMF system. This comprehensive training program will introduce your team to the TMF processes and regulatory requirements. Workshops are organized to compliment the training and allow your organization to adapt the predefined SOP, WI and TMF Plan templates.

DESIGNED FOR TEAMS

With limited internal TMF knowledge

Looking to bring TMF management in-house

Moving from paper TMF to eTMF



COURSE NAME

TMF Principles & GCP



2 - 4 hours



8 Topics



COURSE NAME

TMF Index + Reference Model



2 - 4 hours



6 Topics



WORKSHOP

TMF Reference Model Workshop



Customize TMF Index for Study



COURSE NAME

The eTMF Plan



2 - 4 hours



8 Topics



WORKSHOP

eTMF Plan Workshop



Customize TMF Plan from Template



COURSE NAME

TMF Document Quality Check



2 - 4 hours



6 Topics



WORKSHOP

Document QC Workshop



QC Review of Existing TMF

TMFMATURITY

INTERMEDIATE

The TMF Maturity Intermediate Package is a follow on from the essentials package and broadens your skillset with a focus on TMF quality, data integrity, compliance, and oversight. After learning the theory, your team will dive deeper in customized workshops targeted to truly decode the regulations impacting your TMFs, the importance of TMF quality control and understand your organization's TMF Maturity.

DESIGNED FOR TEAMS

Who completed Essentials or already have basic TMF experience

Looking to improve TMF quality and oversight



COURSE NAME

Oversight Through TMF



2 - 4 hours



8 Topics



COURSE NAME

TMF Data Integrity



2 - 4 hours



7 Topics



COURSE NAME

Current TMF Regulations



2 - 4 hours



7 Topics



WORKSHOP

TMF Regulations Workshop



TMF Inspection Readiness Framework



COURSE NAME

TMF Quality Control



2 - 4 hours



3 Topics



WORKSHOP

TMF Quality Control Workshop



Sample eTMF QC Report for given study



COURSE NAME

eTMF Process & Models



2 - 4 hours



7 Topics



WORKSHOP

TMF Maturity Workshop



TMF Maturity Model Assessment

TMFMATURITY

ADVANCED

Our TMF Maturity Advanced Package helps you and your team reach the highest TMF maturity state so that you're always ready for an inspection. This package is designed to help you truly grasp the most advanced concepts and optimize your current processes to efficiently manage winning TMFs. While the training sessions will cover the theory, the workshops are where you'll get your hands dirty and transition your team to the next level of TMF maturity.

DESIGNED FOR TEAMS

That completed TMF Maturity Intermediate or have established TMF management processes and want to be at the top of their TMF game



COURSE NAME

TMF Risk-Based Approach



2 - 4 hours



4 Topics



COURSE NAME

TMF Inspection Readiness



2 - 4 hours



5 Topics



COURSE NAME

TMF Metrics & KPIs



2 - 4 hours



8 Topics



COURSE NAME

TMF Storyboards



2 - 4 hours



6 Topics



COURSE NAME

TMF Quality by Design



2 - 4 hours



5 Topics



WORKSHOP

Inspection Readiness Workshop



Perform a mock TMF inspection



WORKSHOP

TMF Metrics Workshop



Create a Metrics Report for a study



WORKSHOP

Storyboarding Workshop



Draft a Storyboard for a given study



WORKSHOP

TMF Quality by Design Workshop



Design & document a new QbD process



Powerful templates and tools to accelerate TMF maturity



eTMF Plan template



Standard eTMF Business Rules



eTMF Management SOP



WI for Trial Setup & System Admin



WI for Document Lifecycle Mgt.



eTMF Index Template



TMF Document QC Checklist



Regulatory Resource Package



TMF Maturity Model



Email/Communication Guidance



Sample TMF QC Report



Inspection Readiness Framework



Case Studies & Reference Articles



Inspection Readiness Checklist



Customized QbD Process



TMF Storyboard for a study



TMF Metrics Report for a study



TMF Mock Inspection



FREQUENTLY ASKED QUESTIONS

Who is the TMF Maturity Essentials Package for?

Smaller CROs/sponsor organizations who have little experience with TMF, or CROs/sponsor organizations who are moving from a paper TMF to an eTMF.

How long will each training session be?

We schedule half a day for each training session. Depending on the questions and discussion of each topic, we usually see the trainings last 2-4 hours each.

How many people can attend each session?

Up to 10 trainees per trainer. If you have a larger team, we are happy to discuss what will be best for your team.

Are materials provided?

Yes, all materials like SOP, WI, and eTMF Plan templates will be provided alongside the guidelines, regulations, and any interesting articles to further your knowledge.

Can I get access to the recordings?

Absolutely! We understand that some members of your team may have other commitments and will need to watch the recordings at a later time. Recordings will be available through a link for a limited time after training.

Are the trainings and workshops remote or in-person?

Due to the volatile situation with the global pandemic and typically working with decentralized clinical teams, we usually conduct remote training at times that are convenient for you. Let us know if you are interested in any in-person sessions.

Do I need to subscribe to eTMF Connect first?

No, these packages have been designed with both eTMF Connect and other eTMF subscribers in mind. We do include demonstrations of the Connect system during trainings that usually help to solidify the theory—even if your eTMF system is not Connect. Our trainers have experience with other common eTMF systems and would be happy to give examples of how it relates to your TMF technology.

FREQUENTLY ASKED QUESTIONS

Can I choose the order of the sessions?

We recommend following the order of the training sessions as listed and either conducting the corresponding workshops after each training or at the very end when all the training is complete. We will work with you on the schedule and flow if you prefer to reorder how the sessions are presented.

I already have some eTMF knowledge. Can I do the TMF Maturity Intermediate first?

Of course! The essentials package is really built for those that have either never used an eTMF or have very little TMF knowledge. We can chat about your knowledge gaps and recommend either the intermediate or advanced package.

Will you issue a training certificate?

Great question! Trainees will receive a training certificate after completion of the final training quiz of each package. The training quiz score will be mentioned on the certificate.

Do you help us customize the templates provided?

Yes! During the workshops, we will go into the details of each template and suggest areas for customization. We will take the time to understand your current process and make some optimization proposals. At the end, we can review your finalized WIs, SOPs, and eTMF Plan.

When can I start?

Now! Send us your availabilities and we can confirm the training bookings on signature of the contract.

Any questions we haven't answered here?

No problem, please get in touch with your Montrium representative so we can provide you with an answer.
