TMF Reference Model to Improve TMF Management

Presented by Jackie Morrill, Executive Director, TMF Education, LMK/TransPerfect

Meet the Speaker

Jackie Morrill

Title: Executive Director, TMF Education

Organization: LMK Clinical Research Consulting/TransPerfect

I have over 15 years of experience in clinical trial coordination and process improvement within the healthcare, biotech, and pharmaceutical industries.

Since 2013, my dedicated focus has been on all things TMF. My experience includes oversight of eTMF implementations, coordination of large migration and QC projects, development of robust TMF metrics programs, overhaul of TMF processes, extensive inspection readiness preparation for FDA, MHRA, and PDMA inspections, and the creation of LMK's accredited TMF University program.

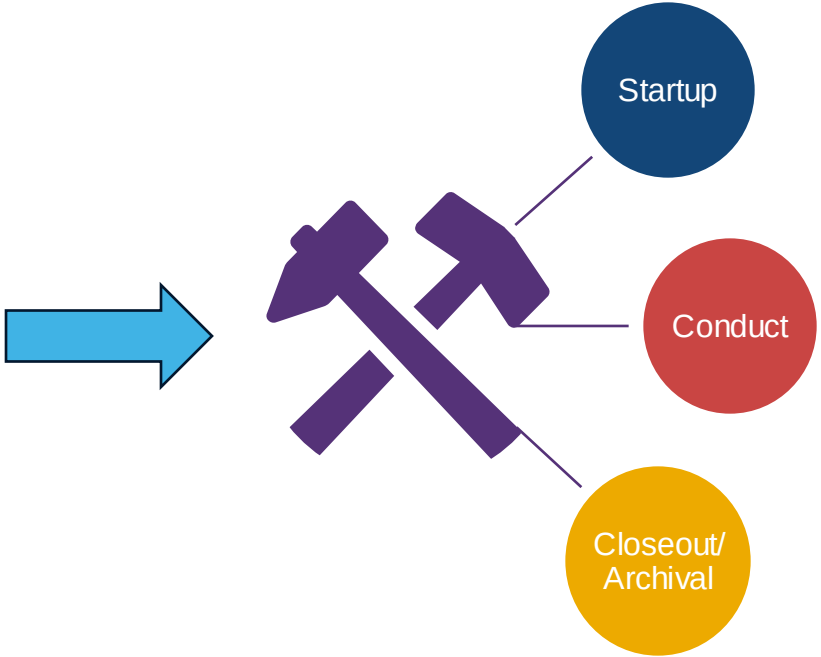
Disclaimer and Disclosures

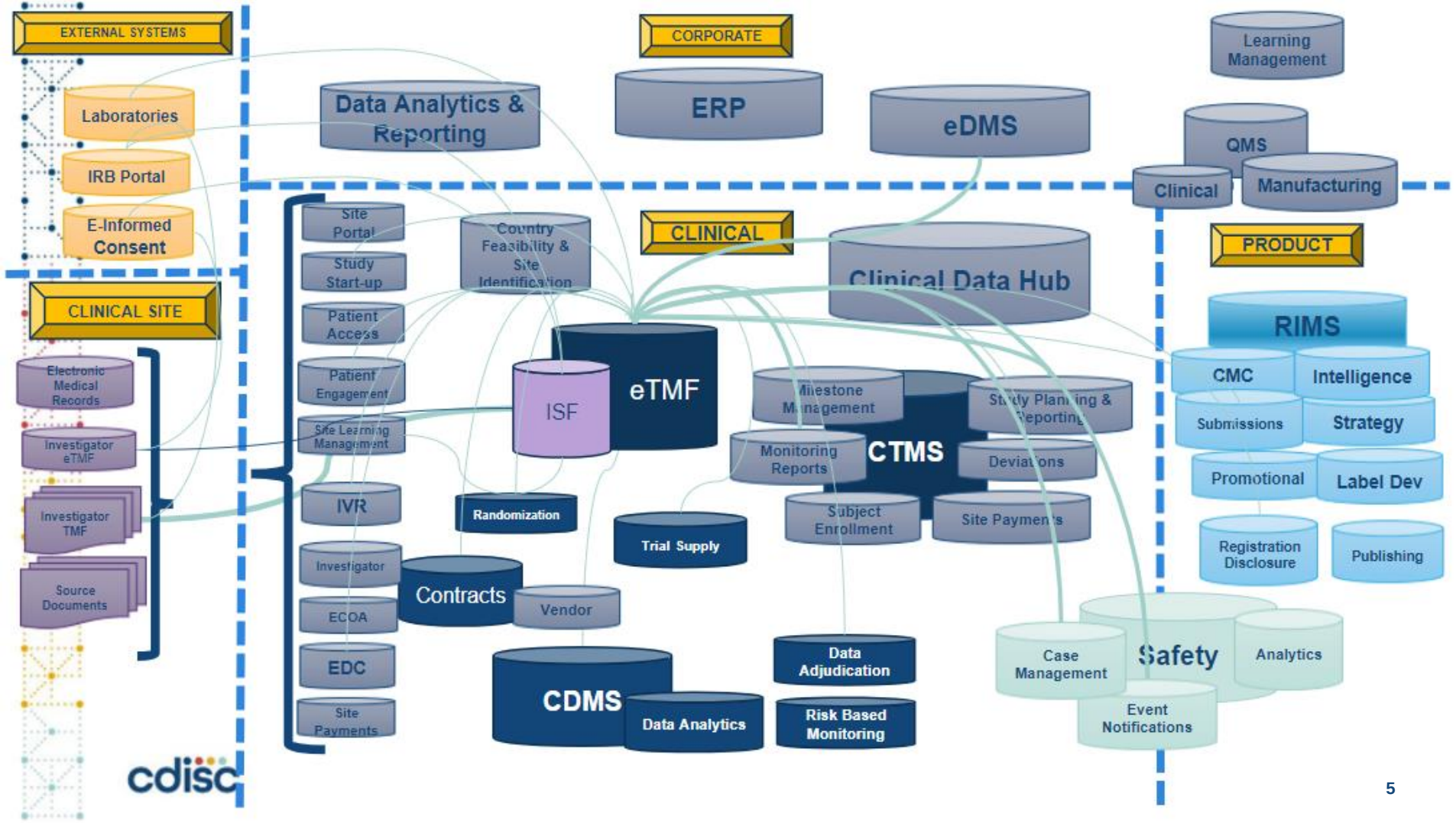
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author has no real or apparent conflicts of interest to report.*

TMF Reference Model

More than *just* a TMF Index!

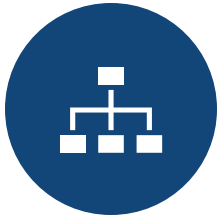



EXTERNAL SYSTEMS
Laboratories
IRB Portal
E-Informed Consent
CLINICAL SITE
Electronic Medical Records
Investigator eTMF
Investigator TMF
Source Documents
Data Analytics & Reporting
CORPORATE
ERP
eDMS
Learning Management
QMS
Clinical
Manufacturing
PRODUCT
CLINICAL
Site Portal
Study Start-up
Patient Access
Patient Engagement
Site Learning Management
IVR
Investigator
ECOA
EDC
Site Payments
Country Feasibility & Site Identification
Clinical Data Hub
eTMF
ISF
Milestone Management
Study Planning & Reporting
Monitoring Reports
CTMS
Deviations
Subject Enrollment
Site Payments
Randomization
Trial Supply
Contracts
Vendor
CDMS
Data Analytics
Data Adjudication
Risk Based Monitoring
RIMS
CMC
Intelligence
Submissions
Strategy
Promotional
Label Dev
Registration Disclosure
Publishing
Case Management
Safety
Analytics
Event Notifications
cdisc

Life Before the TMF Reference Model

Regulatory Requirement	• To maintain clinical trial records • Limited guidance from regulators
Lack of Guidance	• No comprehensive common model • ICH GCP Section 8 provides no structure
Variability	• Content and organization • Terminology and nomenclature

What is the TMF Reference Model?

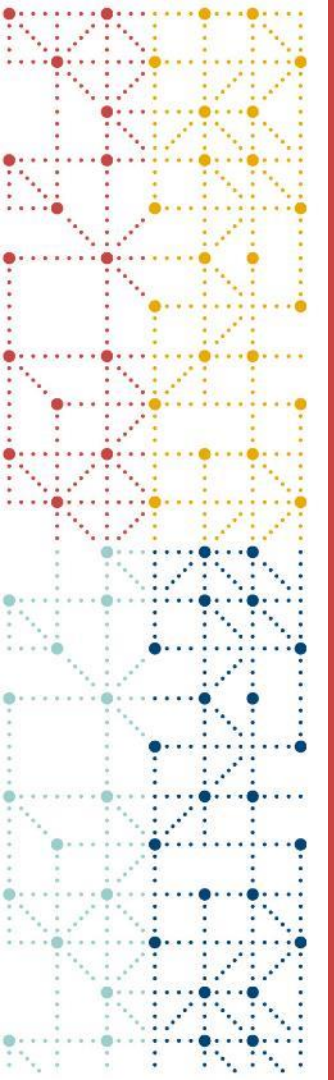


Provides a standardized taxonomy and metadata.

Outlines a reference definition of TMF records using standard nomenclature.

Single, unified interpretation of the regulations and best practices for TMF records.

Expands on ICH GCP Section 8 Essential Documents to provide a more comprehensive list of expected TMF records.



Poll Question

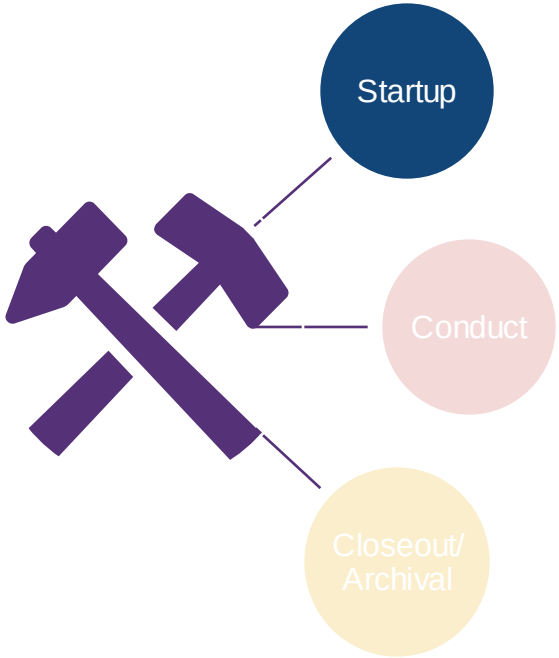
Does your organization use the TMF Reference Model?

- Yes
- Yes, with modifications
- No
- Unsure
- Unwilling to say

Startup

TMF Index

TMF Plan



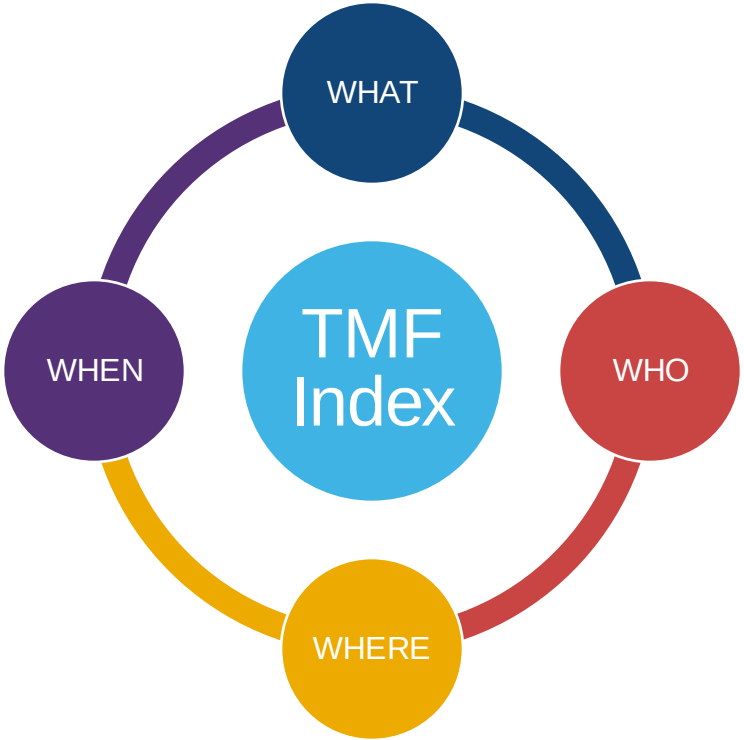
TMF Index

What records/artifacts are expected?

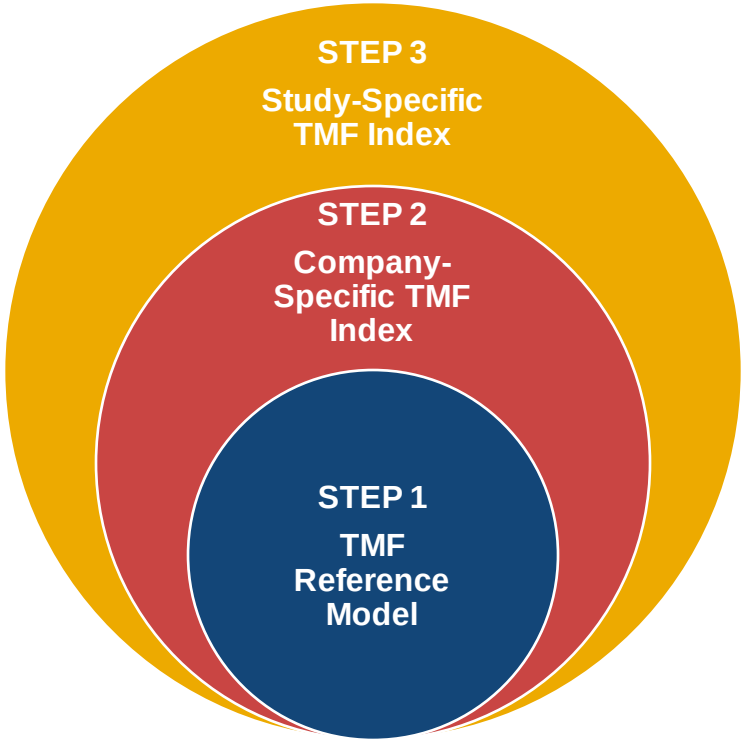
Who is the artifact owner?

Where is the artifact located?

When is the artifact expected?



TMF Index

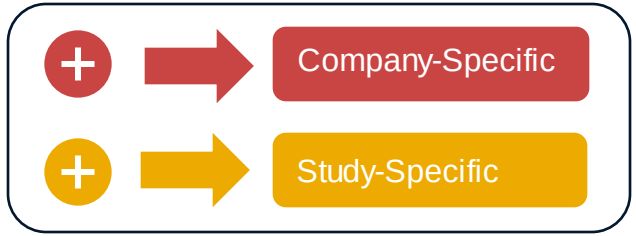


Document study-specific expectations – applicable artifacts, artifact owner, artifact location

Addition of company-specific artifacts (forms, templates), process details, expectations (translations, metadata, naming and dating conventions)

Starting point for a TMF Index

TMF Index



Artifact name	Definition / Purpose	Recommended Subartifacts - Documents/documentation recommended to be filed to the artifact.

TMF Level					
Trial Level Document	Trial Level MILESTONE/ EVENT	Country/ Region Level Document	Country Level MILESTONE/ EVENT	Site Level Document	Site Level MILESTONE/ EVENT

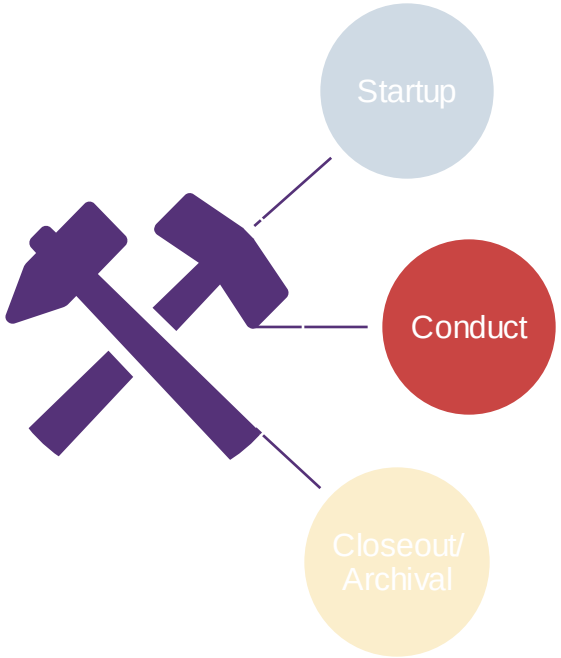
Suggested Columns for Implementing the TMF Reference Model							
Dating Convention	Artifact Owner	Artifact Location	Wet Ink Signature	SOP Reference	Translation Required	Current Artifact Name	Additional Metadata

TMF Plan

Key Concepts

Conduct

- TMF Health
- Quality Reviews
- Outsourcing
- Oversight



Pillars of TMF Health

Driving Quality with the TMF Reference Model

Establish expected records (Completeness)

Drive functional responsibilities/ review (Artifact Owner)

Understand where records are located (Artifact Location)

Align reviews with milestones and events (Timeliness, Completeness)

Naming and dating conventions, metadata requirements (Quality)

TMF Outsourcing

The sponsor is responsible for ensuring that the TMF is inspection ready regardless of who “holds” or manages the TMF on their behalf.

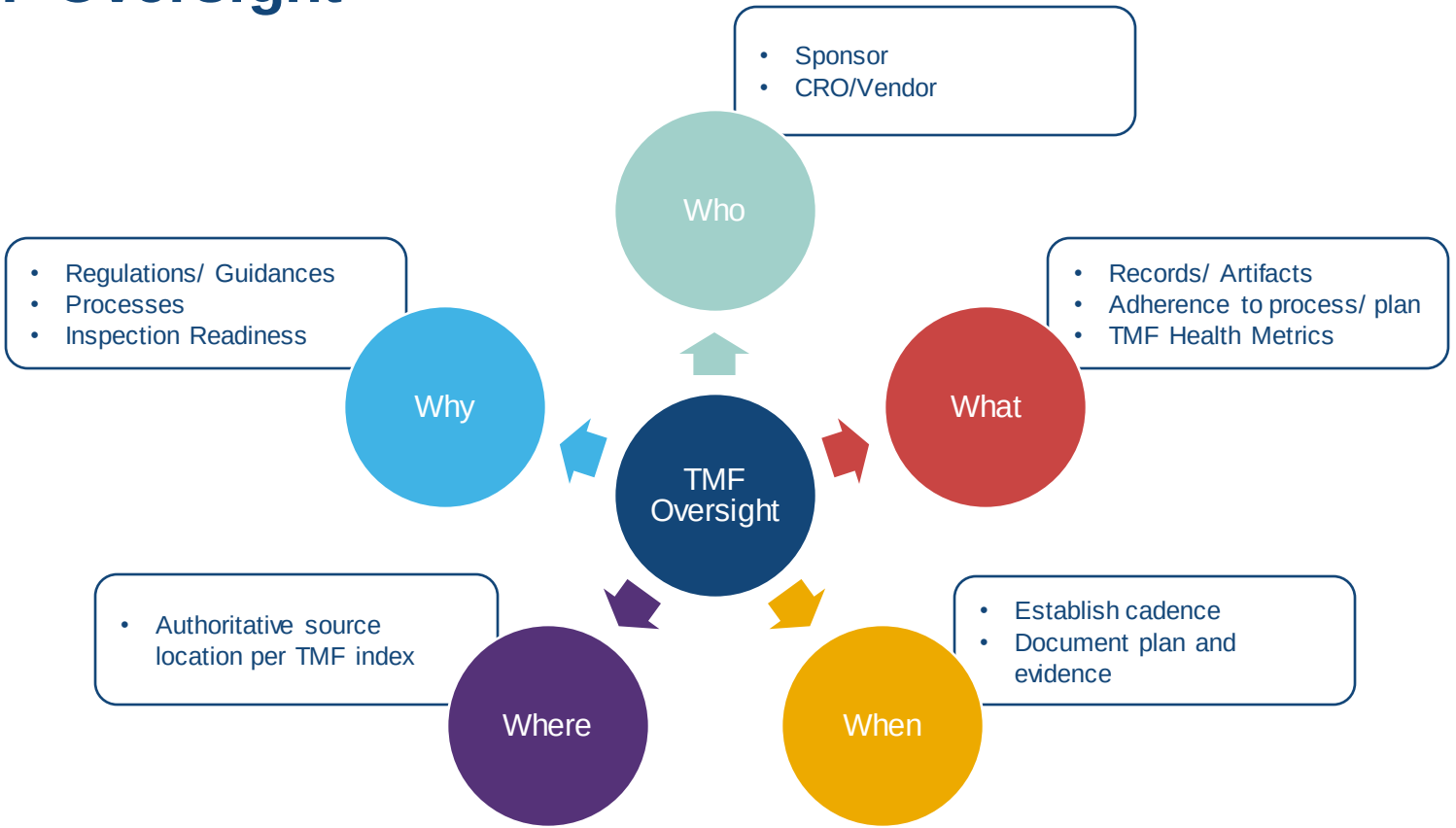
Third Parties can be contracted to provide oversight.

CRO/Vendor may conduct internal oversight activities.

TMF Plan should address the management and oversight of the TMF.

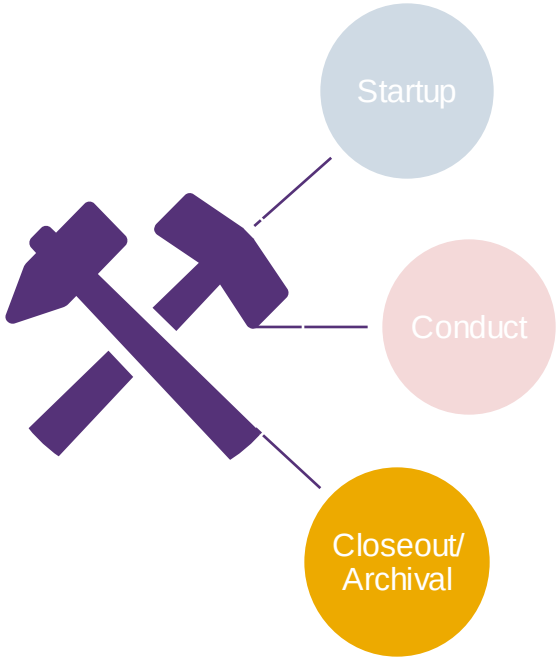
Ensure the TMF Plan/Index reflects who is responsible (sponsor and/or delegate) and where the record resides.

TMF Oversight



Closeout and Archival

TMF Transfer Planning



TMF Transfer Planning: Index Mapping

Listing of Records | Original Classification | Mapping Location

Record Name	Record Number	Zone	Section	Artifact	Classification Confirmed?	New Zone	New Section	New Artifact
Clinical Trial Material Request Form_v2.0	VV-TMF-55194	01	01.01	01.01.05 Operational Procedure Manual		06	06.01	06.01.02 IP Instructions for Handling
Clinical Trial Material Resupply Request Form	VV-TMF-55195	01	01.01	01.01.05 Operational Procedure Manual		06	06.01	06.01.02 IP Instructions for Handling
Delegation of Authority Log Form_v1.0	VV-TMF-55196	01	01.01	01.01.05 Operational Procedure Manual	Yes			
Drug Destruction Documentation Log Template_v1.0	VV-TMF-55197	01	01.01	01.01.05 Operational Procedure Manual		06	06.01	06.01.02 IP Instructions for Handling
Drug Return Form	VV-TMF-55198	01	01.01	01.01.05 Operational Procedure Manual		06	06.01	06.01.02 IP Instructions for Handling
I P Accountability Log 100mg Tablet Form_v1.0	VV-TMF-55201	01	01.01	01.01.05 Operational Procedure Manual		06	06.01	06.01.02 IP Instructions for Handling
IP Accountability Log 50mg Tablet Form_v1.0	VV-TMF-55199	01	01.01	01.01.05 Operational Procedure Manual		06	06.01	06.01.02 IP Instructions for Handling
IP Accountability Log 75mg Tablet Form_v1.0	VV-TMF-55200	01	01.01	01.01.05 Operational Procedure Manual		06	06.01	06.01.02 IP Instructions for Handling
IP Temperature Excursion Form Template_v2.0	VV-TMF-55202	01	01.01	01.01.05 Operational Procedure Manual		06	06.01	06.01.02 IP Instructions for Handling

If it is not documented, it did not happen!

CDISC Training Course: Fundamentals of the TMF Reference Model

This training will focus on how the TMF Reference Model can be utilized to improve TMF Management. Starting with the basics of the TMF Reference Model itself, the training will walk through the importance of people, process, and technology, setting up a TMF, performing QC, developing oversight approaches, and finally, surviving the dreaded inspections!

Module 1: What Is a TMF?

Module 2: How Will the TMF Be Managed?

Module 3: TMF Repositories, the TMF Index, and the TMF Plan

Module 4: Assessing TMF Health

Module 5: Archiving, Transfers, and Paper Destruction

Module 6: TMF Oversight

Thank You!