TMF Management of Transition (“Rescue”) Studies: Navigating Challenges and Strategies

An Effective Approach to Ensuring Study Continuity

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15 May 2025

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Presented by Georgiana Brahy, Director, TMF, Parexel

Meet the Speaker

Georgiana Brahy

Title: Director, TMF

Organization: Parexel

Georgiana Brahy is a Director of Records Management at Parexel, bringing over 12 years of Trial Master File (TMF) expertise to the role.

As a Subject Matter Expert, she excels in TMF management from document-level operations to executive-level strategic planning. Georgiana is passionate about continuous improvement and risk-based approaches in clinical research. She has led global TMF process development initiatives and coordinates leadership activities.

Outside of advancing TMF processes, Georgiana enjoys exploring new recipes, reading, and spending time with the family's cats.

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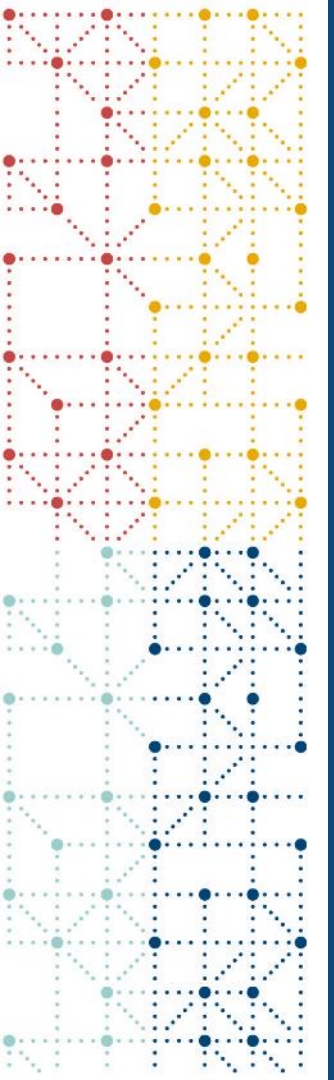
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. TMF Transition Scenarios
2. System Overview
3. Defining and Documenting the Transition
4. Risk Management
5. Lessons Learned and Final Steps

Annex - In-licensing/co-licensing in regulatory documentation management



1. TMF Transition scenarios

When could a TMF transition occur?

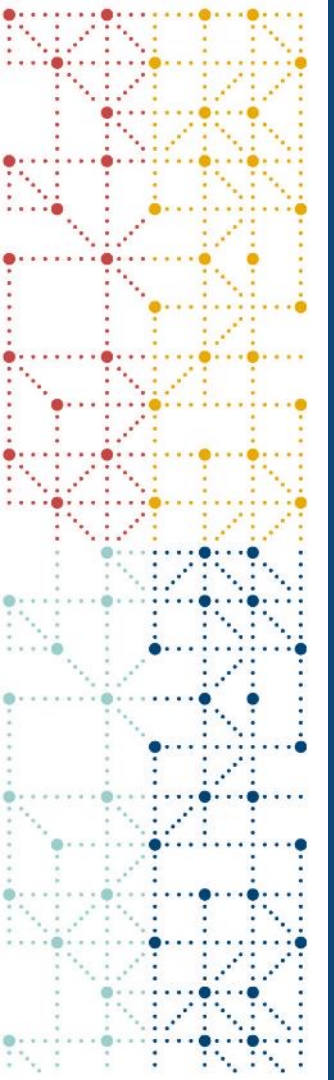
TMF Transition Scenarios

TMF Transitions may occur due to changing environments such as:

- A change in Sponsor ownership (e.g., due to mergers, acquisitions, or transfer of study rights)
- A shift in clinical research organizations (CROs)
- A Sponsor transferring activities in-house, or outsourcing TMF management
- eTMF system migration within the same organization

Types of TMF transitions:

- Full transitions, from one eTMF system to another
- Transition of services, retaining eTMF system
- Transfer of specific documentation subsets



2. System overview

How should a TMF be transferred?

TMF Transfer Options

Overview of tailored solutions

Manual transfer	Advantages	Challenges
A manual transfer involves filing individual documents in the new reference eTMF.	Practical for small volumes of documents	Develop 1 to 1 mapping of transfer
	Document review and classification during transfer	Management of audit trails
	Ongoing sense check (e.g. reduce / manage duplicates or internal documents)	Transfer timelines

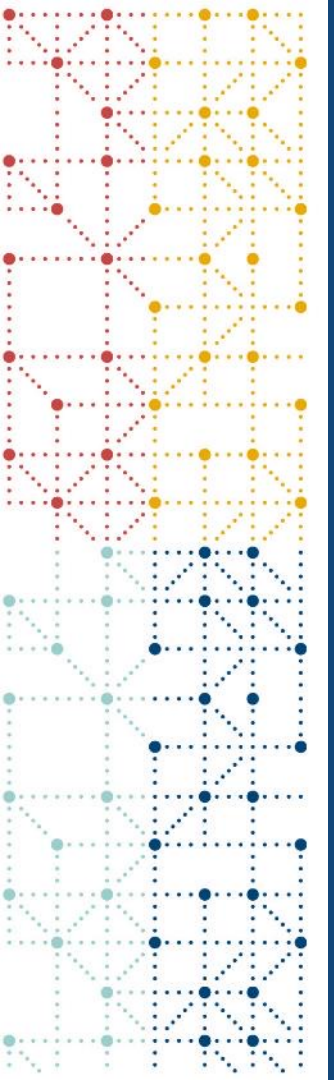
eTMF Import	Advantages	Challenges
Automated document transfer uses system functionalities / migration to transfer documents in bulk.	Can be used for large volumes of documents. Cost and time effective.	Does not account for process / document type differences
	Can map metadata and import audit trails (depending upon system set up)	Higher level mapping can have lower accuracy
	1 to 1 mapping from source to target	Document review to be completed post migration; trends may be identified later

eTMF Import – Areas of Focus

Bulk-Import: Depending on system set up, this feature can be used to import the documents in the target eTMF. After the import, expected document lists (EDLs) can be managed. In addition, document metadata can be changed or reclassified and audit trail can be mapped to each document

Steps involved in Bulk-Import:

1. **Prepare TMF Transfer Plan**
2. **Receive documents from source** (define parameters to be used)
3. **Prepare the mapping sheet** (metadata alignment)
4. **Import the documents** (audit trail can be added as supporting document)
5. **Reconciliation** (reconcile the documents between Source TMF Inventory and Target TMF inventory, using checksum values and/or VV-TMF number from source TMF system)
6. **QC check of document imports** (sampling approach)
7. **Prepare TMF Transfer summary**



3. Defining and Documenting the Transition

How do we ensure all key decisions are documented?

Transition documentation

Transition (migration) plan

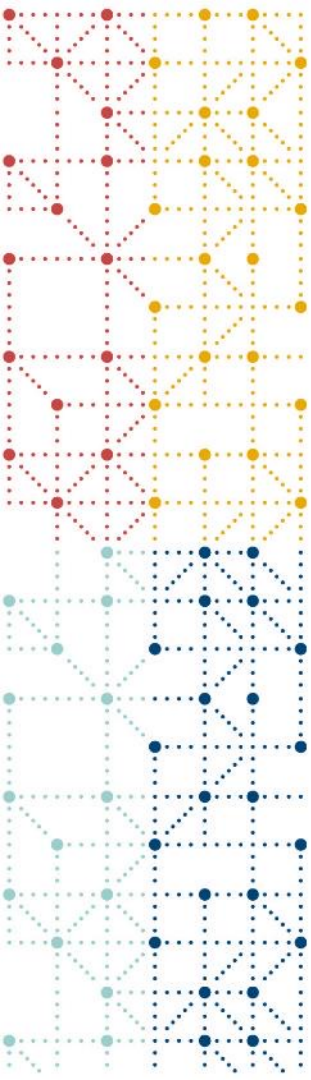
- Objectives and context of the transition
- Roles and responsibilities (including outgoing and incoming parties as applicable)
- Management of TMF Quality as related to the transition
- Management of TMF Completeness
- Strategy for managing TMF queries raised post transition
- Technical transfer specifications
- Transition schedule
- Risks and risk mitigation

Documentation attesting transition was completed

- TMF reconciliation data (attesting all documents were migrated)
- TMF transfer summary
- Sign off documentation

Key take aways

- ✓ Ensure transition process can be easily reconstructed
- ✓ Ensure that decisions are clearly tracked
- ✓ Determine document review strategies
- ✓ Develop storyboards for complex transitions
- ✓ Ensure ability to demonstrate 1 to 1 mapping to confirm transition was complete



4. Risk Management

Did we think of everything?

Risk assessment

Understand the context

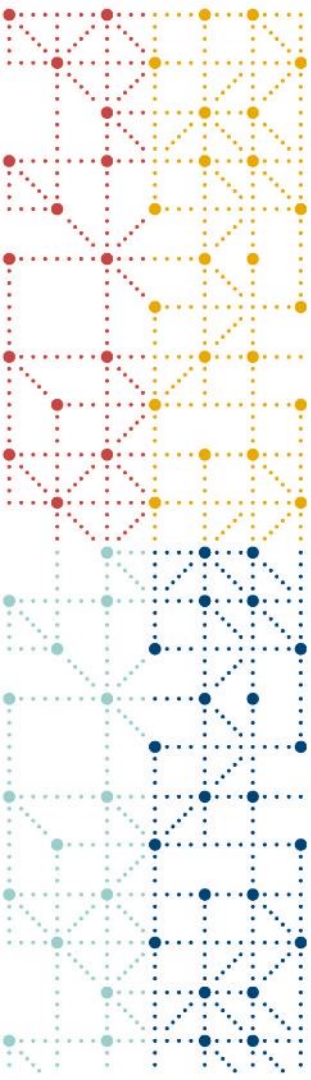
- If other services / tasks are being transitioned, ensure a clear overview is available
- Clarify list of sites / countries and their status (active, closed, etc.)

Risk assessment

- Actively identify and raise questions
- Assess technical challenges (e.g document formats, metadata issues)
- Assess documentation risks (e.g unblinded documents)
- Consider access and training requirements
- Ensure study team awareness of migration specifics
- Determine impact that process and SOP changes may have on TMF
- Consider issues that could arise post-transition requiring support of transferring sponsor/vendor
- Ensure roles and responsibilities are well defined
- Consider impact of transition on other deliverables (e.g black-out period)
- Consider whether documents can be modified / deleted post transition

Risk mitigation

- Ensure identified risks are evaluated and mitigation actions are implemented



5. Lessons Learned and Final Steps

Leveraging transition knowledge

Lessons learned and conclusions

It is recommended to leverage and further refine scenarios arising during each transition.

Building a lessons learned database complemented by associated process templates and FAQs can enable faster and more effective TMF transitions.

The transition documentation should stand the test of time – it should be readily available for regulatory inspections, maintaining clear end to end history.

Conclusion:

eTMF transitions can be incredible learning experiences. Adaptability, a general understanding of TMF processes, and a thorough assessment of all possible facets of this important change in a trial's lifecycle are key for a successful transition.

Thank You!

Annex-> In-licensing/co-licensing in regulatory documentation management

When multiple sponsors are involved in licensing deals, clear agreements on document ownership, access, and responsibilities are essential. Typically, the regulatory sponsor (Sponsor A in this case) would maintain overall responsibility for the Trial Master File (TMF) and regulatory submissions. However, they may delegate preparation of certain documents or dossier sections to the co-sponsor (Sponsor B).

Key considerations may include:

- ✓ Establishing clear roles and responsibilities for document creation, review, and approval between the sponsors.
- ✓ Implementing secure document sharing platforms or systems to allow controlled access for both parties.
- ✓ Defining processes for version control and change management of shared documents.
- ✓ Outlining quality control and oversight procedures to ensure consistency and compliance across documents prepared by different sponsors.
- ✓ Addressing how confidential information will be handled and protected when shared between sponsors.
- ✓ Planning for long-term document retention and access rights after the collaboration ends.
- ✓ Ensuring alignment on submission strategies and timelines.

The specific arrangements would typically be detailed in licensing agreements and quality agreements between the sponsors. Regular communication and coordination between sponsors is essential for smooth document management in these complex scenarios.

References: EU CTR (536/2014): Article 71 Sponsor; Article 72 Co-sponsorship; EU - Complex clinical trials – Questions and answers; CTR Q&A documents