

TMF Acquisition Preparation: Building Success Brick by Brick

Jason Weinstein, Associate Director Trial Master File

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Meet the Speaker

Jason Weinstein

Title: Associate Director, TMF

Organization: Regeneron Pharmaceuticals

Jason is the Head of TMF Operations at Regeneron Pharmaceuticals. He has a decade of TMF experience that includes document migrations, regulatory inspections (FDA, PMDA, EMA), vendor oversight, TMF operations management, eTMF system management, and TMF health reporting. In his current role, Jason oversees document governance and processing, study team accountability and support, and the overall health of the TMF portfolio across Regeneron. Jason is also an active member of the CDISC TMF Reference Model.



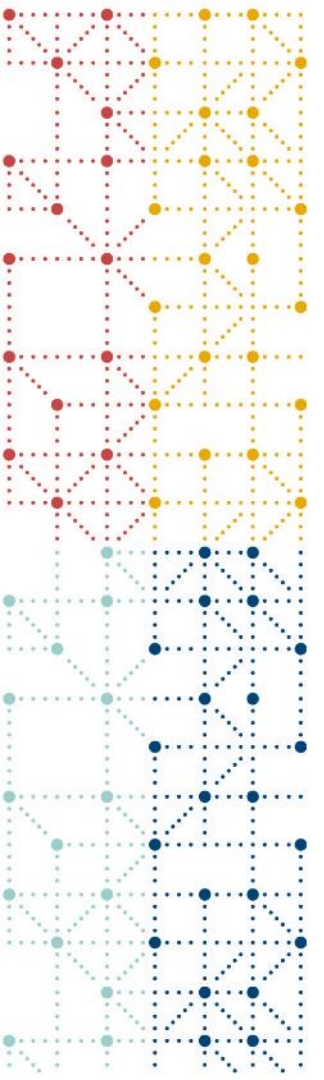
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- The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC or Regeneron*



Agenda

1. Introduction
2. Critical Stages of TMF Acquisition
 - 1.The Blueprint
 - 2.Constructing the Framework
 - 3.Connecting the Pieces
 - 4.Avoiding Structural Failures
 - 5.The Grand Finale
3. Conclusion



Introduction

Importance of the Trial Master File in Mergers and Acquisitions



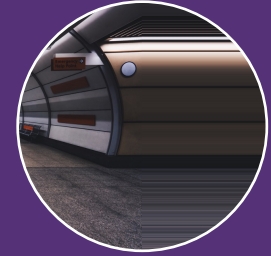
Critical
deliverable:
Both Active and
Closed Studies



Insights into
study quality
and compliance

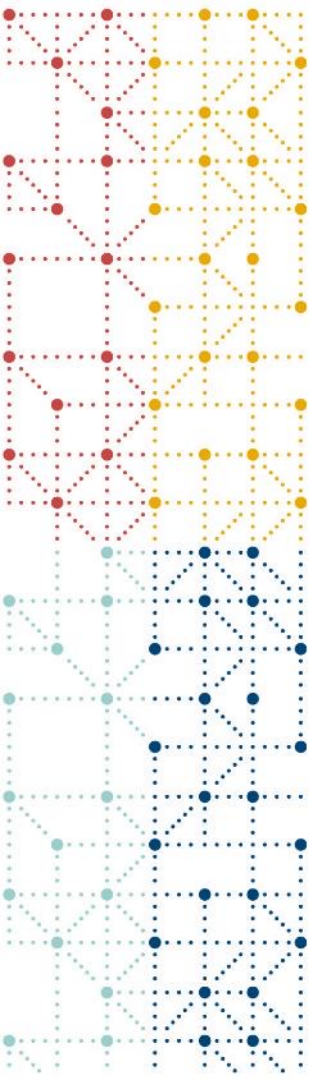


Cost and Time
Efficiency



Facilitates
Transition

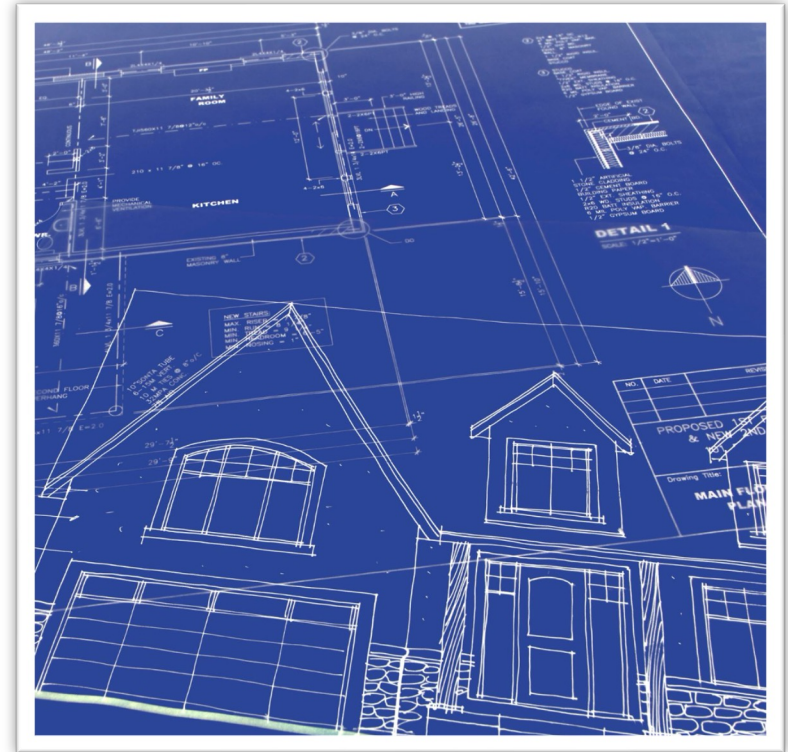




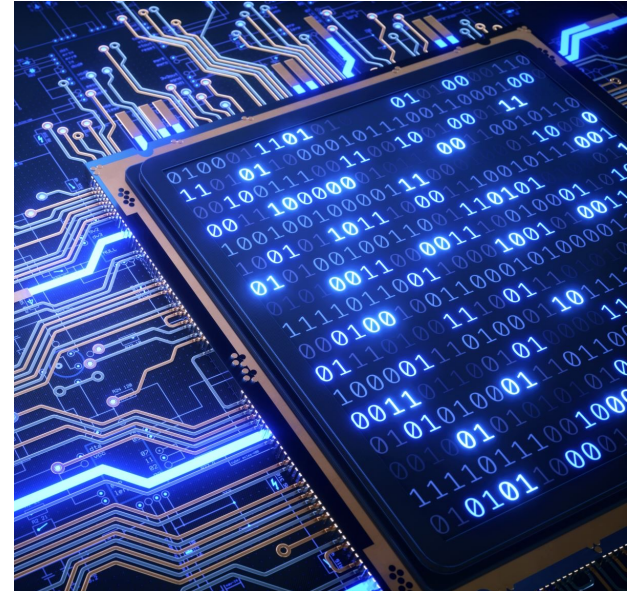
Critical Stages of TMF Acquisition

The Blueprint: Creating a Plan

- How many studies? What are their status?
- Is there an eTMF?
- What other systems are part of the TMF? Are those already in scope of this M&A?
- Is there a TMF SOP and/or TMF Plan?
- Do they follow the CDISC TMF Reference Model?

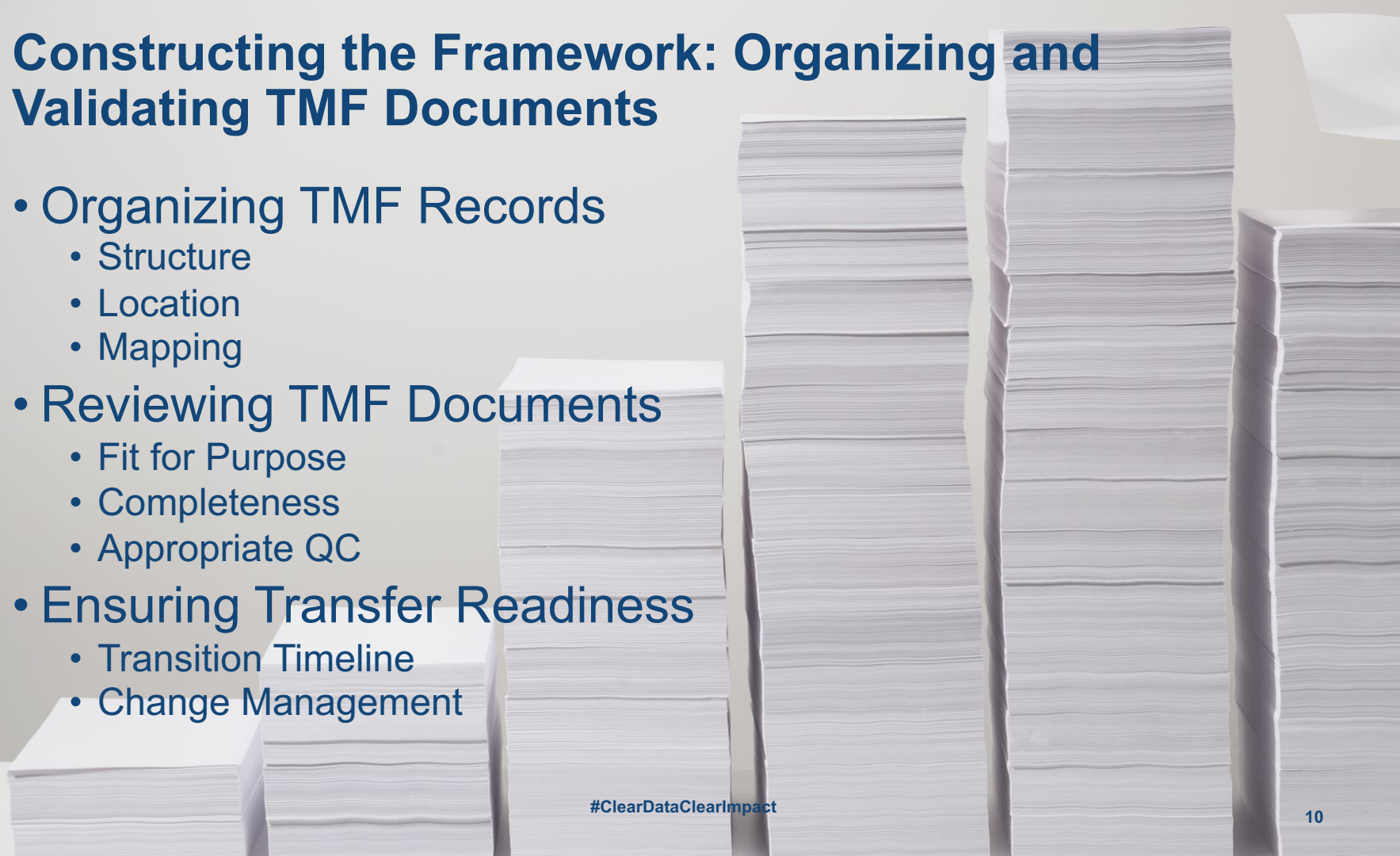


Fit for Purpose





Constructing the Framework: Organizing and Validating TMF Documents

- Organizing TMF Records
 - Structure
 - Location
 - Mapping
 - Reviewing TMF Documents
 - Fit for Purpose
 - Completeness
 - Appropriate QC
 - Ensuring Transfer Readiness
 - Transition Timeline
 - Change Management
- 

Connecting the Pieces: Communication and Collaboration



- Effective Communication is Critical
 - Establish clear channels of communication
 - Regular updates and meetings – Core Team
- Facilitating Smooth TMF Handover
 - Documenting processes and procedures
 - Ensuring all team members are informed
- Creating a Unified Structure
 - Aligning goals and objectives
 - Building trust and cooperation

Avoiding Structural Failures:

Common Challenges

Missing Documents

Missing Metadata

Vendor Transition

Location
Location
Location



Avoiding Structural Failures:

Strategies

Have a plan

Be prepared
to change the
plan

Document
Decisions

Over
Communicate



The Grand Finale: Successful Integration and Future Leverage

- Successful Integration of TMF
 - Documents Migrated
 - Update the TMF Plan and supporting documents
 - Ensuring all supporting components are in place (e.g. CTMS)
- Exploring Future Opportunities
 - Leveraging the acquired TMF
 - Identifying new trends
 - Lesson's Learned
- Celebration of Achievement
 - Recognizing the effort and dedication
 - Appreciating the final masterpiece



Wrap Up

- You've seen the blueprints and understand why the TMF is an important part of M&A
- You've learned about constructing the framework and prepping your TMF for migration
- You've learned about connecting the pieces and why communication is important
- You're aware of possible M&A structural failures and how to avoid them
- You've learned how to celebrate your success and prepare for future projects

Get out there and build some new M&A towers!!

Questions





Thank You!

