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TMF Migrations and Transfers for Mergers and Acquisitions

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Meet the Speakers



Soraya Halligan

Title: Senior Manager, Development Records Management Systems

Organization: Regeneron Pharmaceuticals Inc.

Soraya heads the Development Records Management Systems team at Regeneron Pharmaceuticals, leveraging over a decade of expertise in TMF management. She oversees the global business needs and administration of CTMS and eTMF systems, leading a team responsible for the implementation and maintenance of TMF health metrics, migrations, and integrations.



Madhvi Bajaj

Title: Associate Manager, Development Records Management Systems

Organization: Regeneron Pharmaceuticals Inc.

Madhvi is the TMF Business Administrator in the Development Records Management Systems team at Regeneron Pharmaceuticals, with nine years of experience in Trial Master File (TMF) Management. She specializes in electronic Trial Master File (eTMF) systems and migrations. Her expertise ensures compliance, streamlines operations, and enhances data integrity within clinical trials.

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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 or Regeneron Pharmaceuticals.



Agenda

- Importance of a Robust Migration Strategy
- Migrations Process Map
- Pre-Migration
- Migration Execution
- Post-Migration
- Migration Case Studies



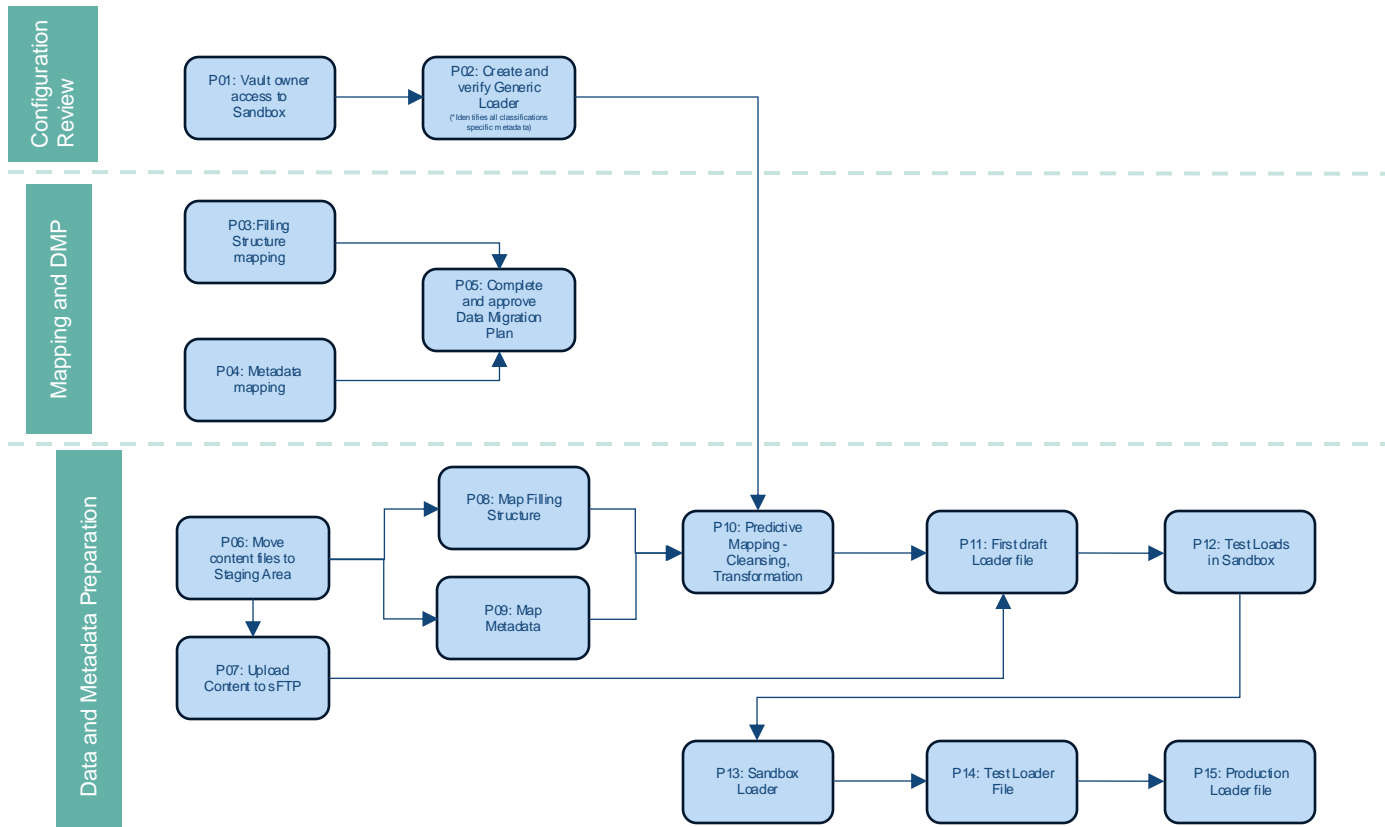
Importance of a Robust Migration Strategy



TMF Document Migration Objective : Maintain data integrity and trial timelines

- Ensures Data Security and Integrity
- Minimizes Disruption
- Compliance with Regulatory Requirements
- Enhances Efficiency
- Facilitates Better Decision-Making
- Mitigates Risks
- Improves Collaboration

Migrations Process Map





Comprehensive Assessment:

- Conduct thorough assessment of the existing TMF
- Identify critical documents and data
- Assess potential risks and challenges
- Consider data enrichment and data/lifecycle mapping

Define Objectives and Scope:

- Clearly outline goals and scope in a *migration plan*
- Establish timelines and milestones to track progress
- Ensure clear communication and collaboration among stakeholders
- Have a contingency plan

User Training and Support:

- Provide training sessions for new users to familiarize them with the new system, as applicable



Pre-Migration



Migration Execution

Accuracy:

- Ensure data is accurately mapped from source TMF to new TMF, including data enrichment processes when applicable
- Ensure all metadata, lifecycle states, and document attributes are correctly transferred

Validation and Testing:

- Perform validation and testing to ensure data accuracy and integrity
- *Document testing and QC of both test and production data in case of audit or inspection*

Monitoring

- Continuously monitor the migration and provide support
- Implement issue resolution and contingency planning



Migration Execution... Continued

Clear Communication:

- Maintain open lines of communication with stakeholders
- Provide regular updates on progress and any challenges encountered

Ensure Data Security:

- Ensure unblinded data remains unblinded during transfer from source to destination TMF
- Ensure unblinded data remains only accessible to unblinded individuals

Regulatory Compliance:

- Ensure the migration process complies with all relevant regulatory requirements
- Maintain thorough documentation to facilitate audits and inspections

Post-Migration

Quality Control:

- Conduct post-migration quality checks to ensure documents, metadata, and audit trails have been accurately transferred
- Address any discrepancies
 - This could include the up-versioning or stacking of documents
- Determine if additional document QC needs to occur to align with sponsor filing requirements, if applicable - in addition to migration QC
 - i.e., source TMF requirement does not include redaction of PII but destination TMF does

Documentation:

- Summarize migration activities and any discrepancies or findings in *Data Migration Report*

User Support:

- Post-migration support to address any post-migration issues or questions



Case Studies Collected from Examples Across the Industry

Case Study 1

Scenario: Acquisition where studies are closed and existing study staff *are not* being retained.

Approach: Ensure all documents are transferred from source TMF to sponsor TMF as soon as possible. Sponsor to gain access to all other transitory document repositories.

Process Alignment and Training:

- Determine if sponsor TMF QC requirements should be implemented for migrated documents, if different from source company. If so, who will resolve? If not, how will this be documented?
- Establish a process to resolve issues identified after migration after existing study team has departed.

TMF Completeness

- Sponsor to conduct completeness assessment on TMF post migration and determine how to obtain missing documents, if applicable.
- Access to transitory document repositories (i.e., SharePoint) can help

Potential Impact on Study Timelines:

- All quality issues are addressed by study team
- Content issues are resolved as per best scenario
- Study team addresses unobtainable missing documents upon identification

Case Study 2

Scenario: Acquisition from company with ongoing studies where existing study staff are being retained. Acquired company does not allow sponsor to access source TMF.

Approach: Implement strict data segregation and access control, involving restricted and separate user limited access using a migration vendor.

Training Requirements:

- Comprehensive training sessions will be necessary to ensure team is proficient in using the new system.

Process Alignment:

- Decide whose processes to follow (source company's or sponsor's?) - *may require negotiation and compromise*
- Establish a robust QC process to ensure data accuracy and completeness
- Develop a system for resolving issues with document owners promptly

Study Timelines:

- Migration process can affect the timing of ongoing studies, potentially causing delays
- Establish cut off dates for when to stop filing documents in source TMF and start in sponsor TMF

Case Study 3

Scenario: Study personnel in certain countries are not permitted to have access to certain sponsor systems, such as due to regulations or company procedures.

Approach: Implement periodic migrations or TMF transfers to ensure compliance and data integrity.

Periodic Migrations/TMF Transfers:

- Determine how often documents need to be migrated to maintain data integrity and compliance – Monthly? Quarterly?

Process Alignment and Training:

- Establish a robust QC process to ensure data accuracy and completeness
- Develop a system for resolving issues with document owners promptly

Upload Timeliness of Documents:

- Periodic migrations may affect the timeliness of document availability
- Assess the impact on study timelines and develop strategies to mitigate delays

Tracking Completeness:

- Implement tracking mechanisms to monitor the completeness of migrated documents.
- Ensure all critical documents are accounted for and accurately transferred.

Conclusion

Robust Migration Strategy

- Minimize Trial Disruption
 - Reduced impact on study timelines
- Compliance with Regulatory Requirements
- Stakeholder Collaboration

Advanced Technology

- Automate artifact and metadata mapping
- Enhanced Efficiency
- Risk Mitigation
- Data Security and Integrity
 - Ensure compliance with data protection regulations

Skilled Resources:

- Engage IT experts with experience in TMF migrations – could include using a migration vendor
- Training to ensure team members are proficient in using new system

Additional Considerations

- Document Quality Checks
- Ensuring Process Alignment
- Source TMF Company Exit Scenario



Thank You!

Q&A