

A panoramic view of the Berlin skyline at sunrise or sunset, featuring the TV Tower (Fernsehturm) and various city buildings under a clear blue sky.

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How to migrate study data (and how not to!)

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Meet the Speakers

Frederik Soerensen

Title: Manager, Technology Consulting

Organization: Base life science

Frederik, with a DPhil in Statistics from Oxford, leads complex GxP migration projects. At Base life science, he's in charge of Migration Delivery Excellence.



Pawel Rucki

Title: Manager, Business Consulting

Organization: Base life science

Pawel brings a robust 15-year background in clinical operations to the table, with a specialized focus on Trial Master File (TMF) systems over the past 7 years. His expertise includes facilitating multiple migrations from a business perspective. Currently, at Base Life Science, Pawel leads the GxP Records Management Excellence.



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Agenda

1. Introduction to TMF migrations
2. Effort drivers in migration – A Data Scientists viewpoint
3. Case studies
4. Lessons Learned



Introduction to TMF migrations

What is a successful TMF migration



What is data migration?

Wikipedia's Perspective:

- Data migration involves a series of steps: selection, preparation, extraction, and transformation of data.
- It culminates in the permanent transfer of data to a new storage system.
- Validation of migrated data and decommissioning of old storage are integral parts of the process.

FDA's Viewpoint:

- Migration refers to the translation or transfer of data/documents between validated systems.
- Compliance with CFR21 Part 11 is crucial, ensuring records are accurate and complete post-migration.

MHRA's Approach:

- Data migration to new media/formats requires validation and thorough documentation.
- The process must be auditable to confirm no loss or corruption of data and metadata, preserving authenticity.



TMF Migrations in numbers

Adoption of the eTMF:

- 2014: 13%, 2017: 31%, 2018: 65%

Data Migration Research Study 2017:

- 31% of migrations were classed as unsuccessful
- 54% of migrations not completed on time
- 64% of migrations not completed within a budget
- 50% of migrations needed more efficient management and oversight

72% of data migrations exhibit quality issues post migration activity

Source: Clinical trial master file migration: A preordained step for a centralized electronic trial master file, *Perspect Clin Res.* 2020 Oct-Dec; 11(4): 139–143. Published online 2020 May 7. doi: 10.4103/picr.PICR_106_19



Successful Migration

Robust planning and scoping (records & metadata):

- Identify assets and studies that need migration
- Analyse source (quality of the TMF):
 - TMF Index, file structure and metadata
 - File content: missing data, unsupported file extensions and corrupted files
 - Source files, renditions and audit trail

Robust monitoring and governance:

- Verify the progress at key milestones (mapping, dry runs)
- Agile approach to execution

Quality and completeness of the migration:

- Key focus: completeness and correctness of the TMF
- Execute pre-defined QC Plan



Effort drivers in migrations

A Data Scientists viewpoint

Migration Effort Drivers

High effort drivers

These increase the migration workload for both LoB and migration team significantly and should be clarified as early as possible



Data governance



Number of data sources



Unavailability of data



Source/target complexity gap

Medium effort drivers

These are important and should be considered but only after analysis of high effort driver have been exhausted



Number of metadata fields



System usage variance

Low effort drivers

These have very little impact on effort required for migration to be successful compared to other drivers



Number of object records



Number of documents



Case Studies

Case 1: Lift-and-shift



Rationale

- Lower implementation cost
- Less impact on key LoB



Project experience

- LoB not heavily involved in project
- All document and records migrated successfully



Impact

- Unharmonized business process
- LoB frustration post-migration
- New project for data remediation

Case 2: Everything is important



Rationale

- Ensure high data quality
- Avoid separate business process for migrated records & documents



Project experience

- Extremely heavy for both migration team and LoB to enrich/clean metadata
- Timeline consistently not met due to data complexity live source data



Impact

- Extended project budget & timeline
- Ultimately, delta was addresses by shift to “lift-and-shift”-strategy

Case 3: Too much focus on in-scope content



Rationale

- Ensure quality of migrated data
- Don't spend time on documents and data not in scope for migration



Project experience

- In-scope content migrated successfully in SBX, VAL, and PROD
- Late realization that document scope was not complete



Impact

- Delta migration required to not affect overall project timelines
- Incomplete study data at go-live



Lessons Learned

Three migration recommendations

Focus on to-be process

- Enrich metadata crucial for to-be process – defer less critical information to post-migration
- Avoid manual enrichment as much as possible

Early eyes-on from LoB

- Get LoB involved early in the process - don't go for a “let's get everything right first” approach
- Align expectations to avoid frustration
- Empower LoB to provide feedback efficiently

Verify scope as early as possible

- Verify completeness of source system extract – either completely or using a sampling approach
- For live source systems, lock scoping criteria in the early stages of the project



Thank You!

