The Remix: Reworking Data for Modern TMF Migrations

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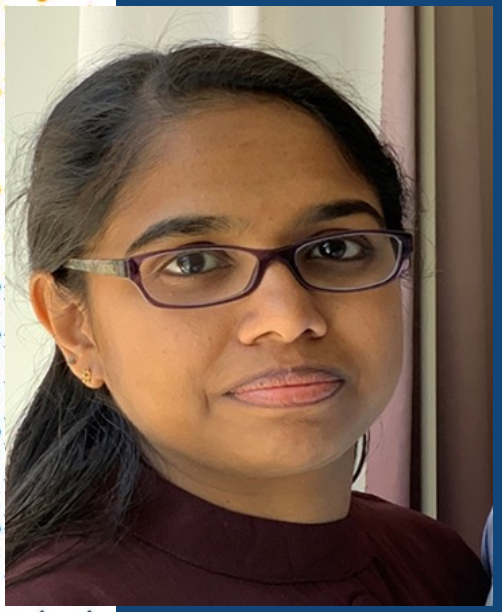


Meet the Speaker

Nisi Nazim

Title: Associate Director, Systems, Global TMF Management & Records

Organization: BeOne Medicines

15 years' experience in the Clinical Systems domain responsible for delivering system enhancements, process improvements as well as leading migrations for the electronic Trial Master File (eTMF). Prior to BeOne, at Daiichi Sankyo, has led integration project between eTMF and other systems including CTMS and was a core team member for the Master Data Management initiative and while with Accenture, contributed towards the implementation of various clinical systems for the some of the big pharmaceutical companies.

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 or the company of which the presenter is employed.*

01 INTRODUCTION

02 CHALLENGES

03 REVIEW PROCESS

04 CASE STUDY

Introduction

Data migration[1] is the process of moving stored data from one durable storage location to another. This may include changing the format of data, but not the content or meaning.

ICH E6 (R3) Section 4.2.5 Data Transfer, Exchange and Migration

Validated processes and/or other appropriate processes such as reconciliation should be in place to ensure that electronic data, including relevant metadata, transferred between computerised systems retains its integrity and preserves its confidentiality. The data exchange/transfer process or system migration should be documented to ensure traceability, and data reconciliation should be implemented as appropriate to avoid data loss and unintended modifications.

Why Migrate?

1. Trial Master File (TMF) data in one authoritative source
2. Long-term retention requirements
3. Technology advancements and changing vendor landscape
4. Regulations

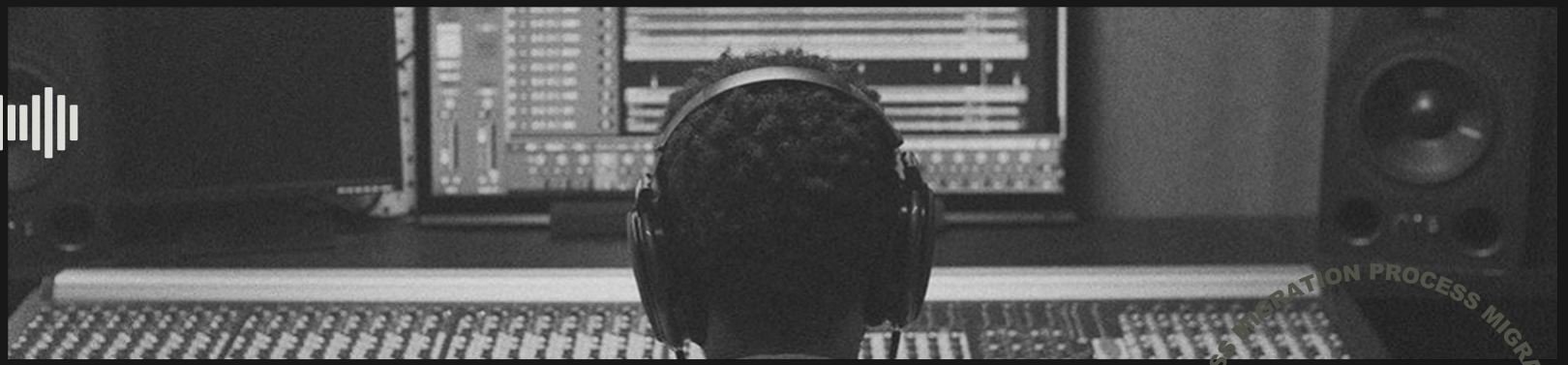
1 - MHRA GXP Data Integrity Guidance and Definitions

CHALLENGES

The Old Track: Legacy Data Challenges

1. Disjoined Data from multiple sources
2. Inconsistent Data Formats and Structures
3. Data Quality Issues
4. Incomplete, Missing Metadata, Lack of Metadata Standardization
5. Compliance Risk

REMIX PROCESS

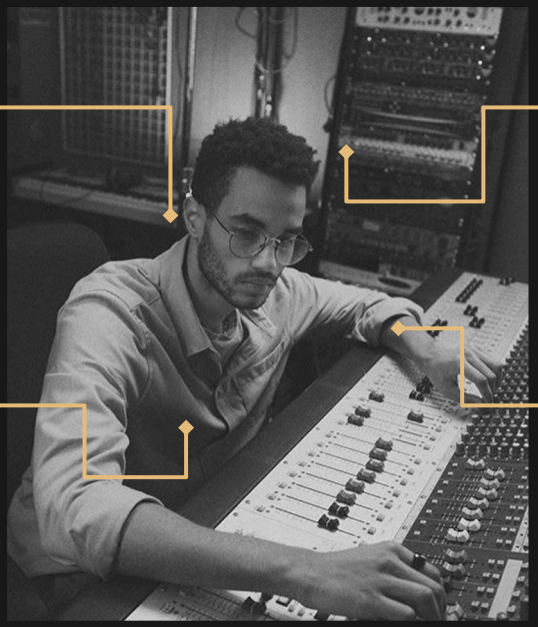


#ClearDataClearImpact

Behind The Scenes: The Remix Process

1 Pre-Migration Planning

2 Execution



3 Validation

4 Post-Migration

#ClearDataClearImpact

Pre-Migration Planning: Assessing TMF Landscape & Identifying Objectives

Analyze Existing TMF Environment

Understand the current TMF data volume, structure, and quality for effective migration planning.

Define Migration Goals

Set clear objectives such as system upgrades, compliance updates, or process improvements for migration.

Pre-Migration Planning: Risk Analysis and Mitigation Strategies

Identify Potential Risks

Recognize risks like data loss, system incompatibility, and delays to ensure thorough preparation.

Backup Strategies

Implement reliable backup plans to safeguard data and maintain continuity during migration.

Contingency and Escalation

Prepare contingency resources and escalation protocols to handle unforeseen issues effectively.

Pre-Migration Planning:
Resource Allocation & Timeline Development

Resource Identification

Identify human, technical, and financial resources essential for the successful migration project.

Timeline Creation

Develop a detailed timeline including milestones and dependencies to track progress systematically

Execution: Data Preparation

PROCESS MIGRATION

Evaluate

Review Document Inventory, Metadata File, Audit Trail. Conduct review on sample records.

Map

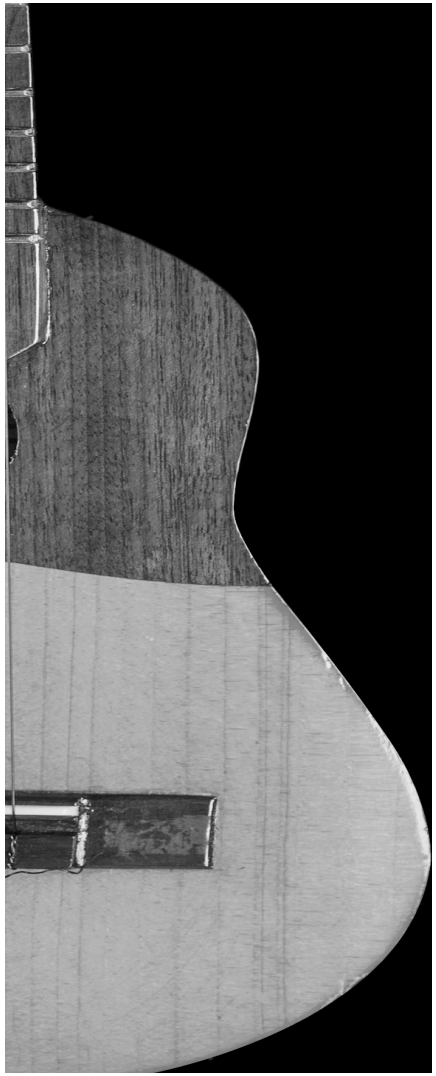
Create metadata mapping and identify dependencies.

Cleanse

Perform data cleansing to ensure data is of good quality.

Augment

Transform and / or augment the source data to match the target systems requirements.



Validation: Migration Verification

Proof of Concept

Test the process in a non-Production environment.

Risk-Based Approach

Conduct spot check on certain zones or record types. Define sampling criteria

User Acceptance Testing

Engage stakeholders in testing

Data Completeness Verification

Ensure all expected data is present before and after migration

Documentation

Keep records of migration activities

Data Integrity Checks

Conduct accuracy and consistency checks

Post Migration: Additional Activities

Inspection Readiness Checks

Spot Checks and risk-based reviews to assess completeness, metadata accuracy as it relates to the study.

Decommissioning of legacy systems

Ensuring the migrated data is the source of truth. Securely archive any retained elements, like historical audit logs, and confirm all access is revoked.

Conduct Lessons Learned

Capture what went well and identify areas for improvement.

THE
COLLABORATION

The Collaboration: Teams and Technology in Harmony

- Maintain **regular communication** and updates throughout the process.
- **Clear documentation** of migration plan.
- **Implement feedback** channels to capture stakeholder input and **encourage feedback** to address concerns and improve collaboration.

THE BEAT
DROPS:
TECHNOLOGY
& STANDARDS

The Beat Drops: Efficient Migration with Technology

Key Benefits:

1. Speed and Efficiency
2. Consistency
3. Scalability

The Remix Artist:
Automation and AI Tools

Automated Data Mapping

Tag relevant metadata

Migration Workflow Automation

Automate repetitive tasks such as document upload, metadata tagging, as well performing metadata transformations.

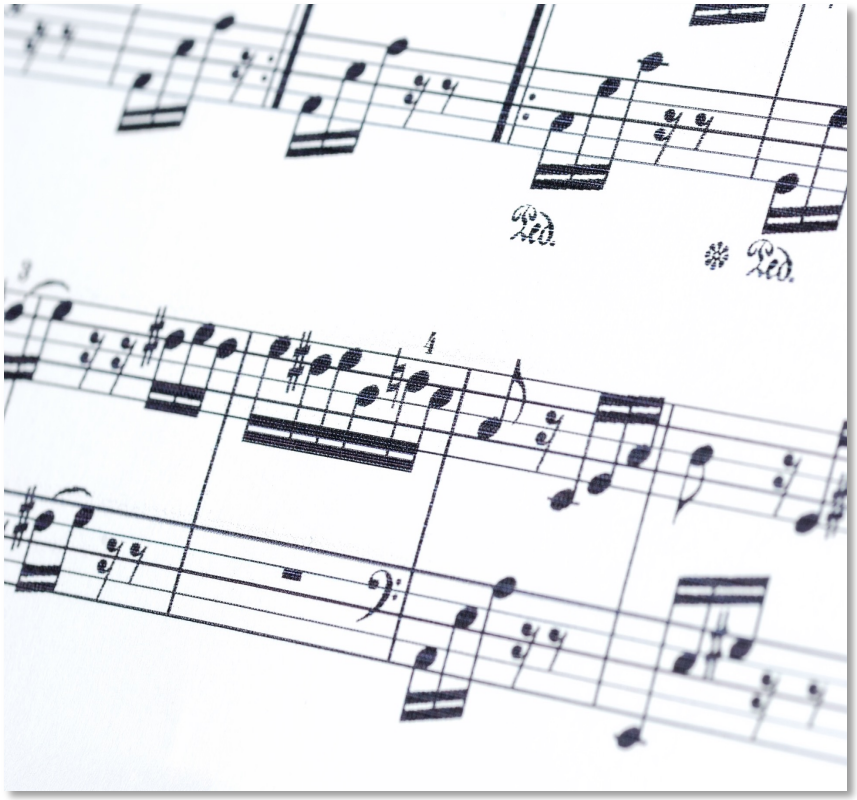
Automated Data Validation

Automating validation scripts, flagging missing metadata, duplicates, or misfiled documents.

The Future of Data Remixing:
Continuous Evolution

AI and Machine Learning

Using AI algorithms for document classification, deduplication, and predictive analytics. Machine learning improves accuracy over time by learning from migration patterns.



Industry Standards for Seamless Migration

Standards:

- Simplifies data mapping.
- Specifies metadata fields that are required.
- Promote interoperability across systems.
- Ensures consistency in record organization.
- Reduces errors.
- Ensures compliance with regulations.

The New Track: A Clean, Structured eTMF

Standardized Structure

Documents are consistently classified ensuring every piece of record follows the same universal framework

Data Integrity & Compliance

Every record is validated, tracked, and audit-ready, reducing risk.

Single Source of Truth

Authoritative source and centralized hub. Streamlined system to locate the information quickly.

Enhanced Oversight

Enables real-time monitoring and governance

CASE STUDY

Case Study: Remixing in Action

CASE STUDY#1

Background: Sponsor received transfer of multiple studies from CRO. The TMF structure is custom and does not follow CDISC TMF Reference Model. Each study has its own structure and with variations in artifact names even though they are the same.

Approach

1. Review and build a centralized mapping specification for the CRO.
2. Include all possible variations of the artifacts including sub-artifacts.
3. Continuous communications.

Lessons Learned

1. Request CRO to provide the Index template versions being followed as part of transfer process.

Case Study: Remixing in Action

CASE STUDY#2

Background: Sponsor received transfer of study from CRO. The source eTMF system cannot generate metadata or audit trails. In addition to not following any industry standards on record structuring, the document inventory and record filenames transferred were in non-English.

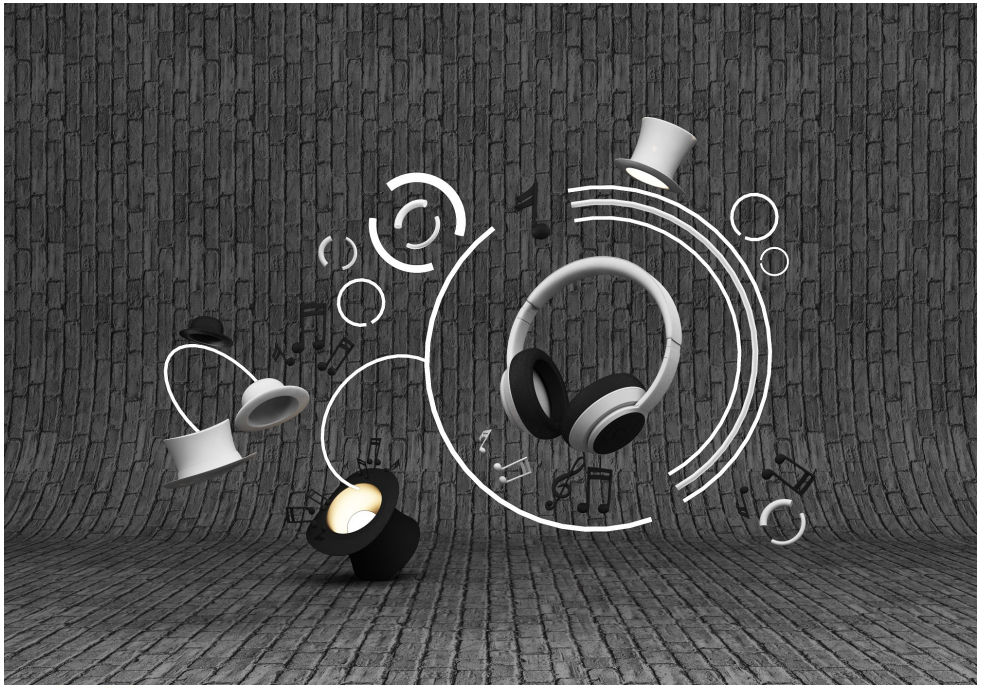
Approach

1. Note in Data Migration Plans the inability to generate audit trails or metadata file.
2. Translate the document inventory file to English.
3. Address metadata gaps by reviewing the translated document inventory.

Lessons Learned

1. Engage with Study Teams to review and confirm the translated document inventory.

Key Takeaways:
Your Next Hit Remix



- Plan Thoroughly
- Leverage Technology
- Prioritize Compliance
- Engage Stakeholders
- Test and Validate
- Maintain Documentation

Thank You!