Managing TMF Data Migration

Richard Shore – Director, Client Solutions, Phlexglobal

John Lazenby – Technical Development Director, Phlexglobal

Bring Order, Stability, and Control to Your TMF

PHLEXGLOBAL
RAISE YOUR STANDARD

TMF TECHNOLOGY

TMF PROCESSING

TMF EXPERT SERVICES

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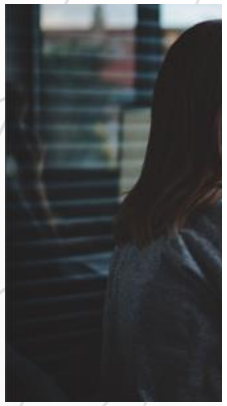
Bring Order, Stability, and Control to your Trial Master File



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RAISE YOUR STANDARD

PURPOSE-BUILT
eTMF TECHNOLOGY

HIGH-QUALITY
DOCUMENT PROCESSING

EXPERT
TMF SERVICES

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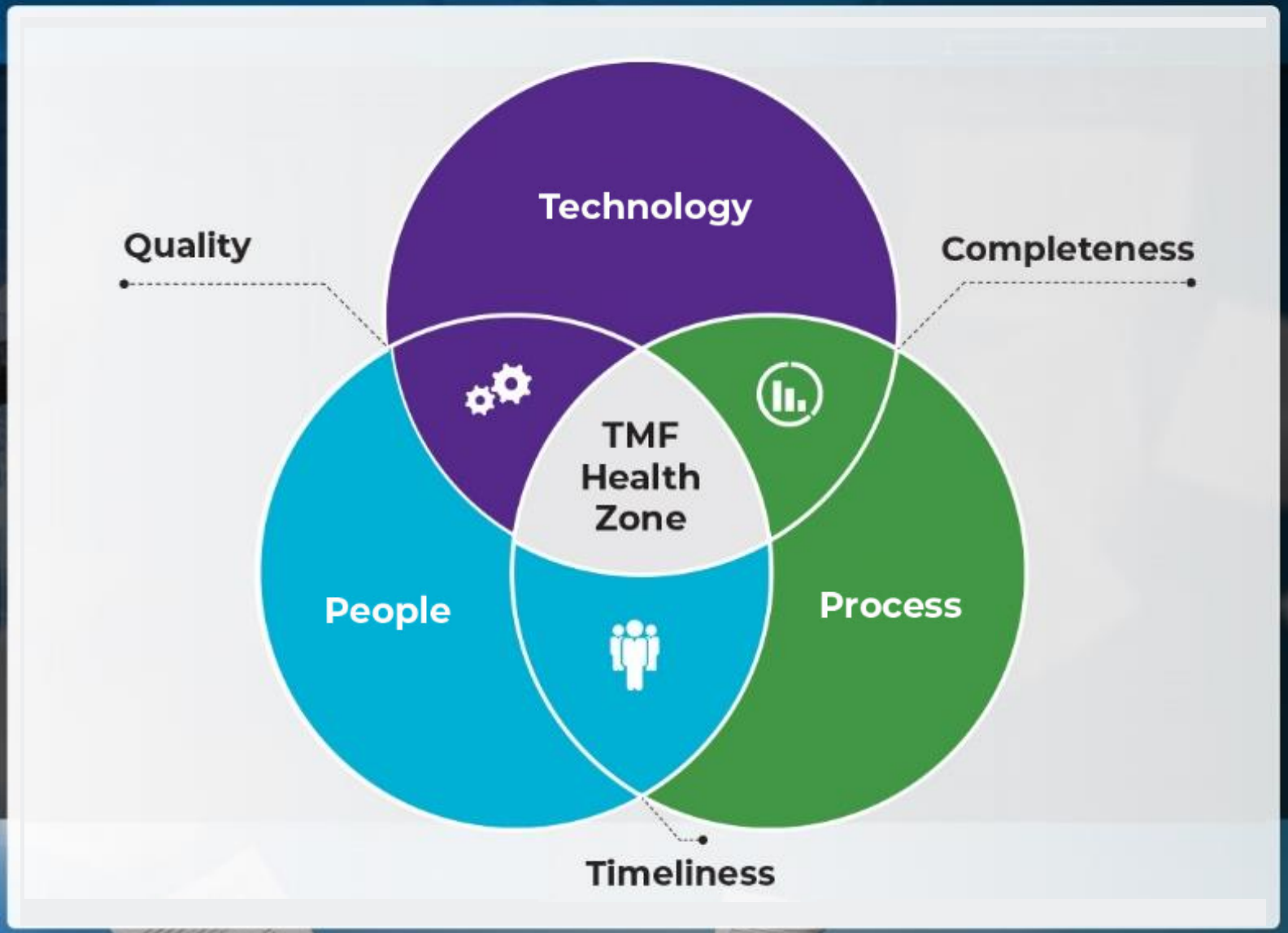
Helping you stay in the TMF Healthzone



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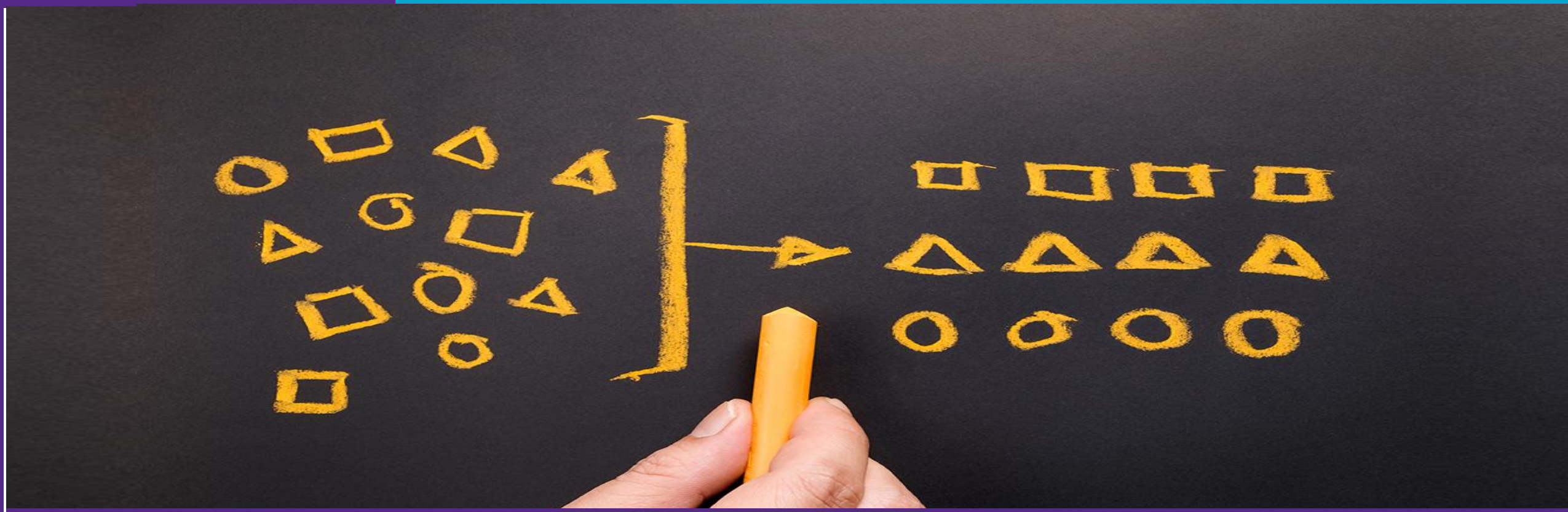

Migrating a TMF can be a massive challenge

The TMF RM Exchange Mechanism can make it easier

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Today's Presenters

Richard Shore
Director, Client Solutions, Phlexglobal

John Lazenby
Technical Development Director, Phlexglobal

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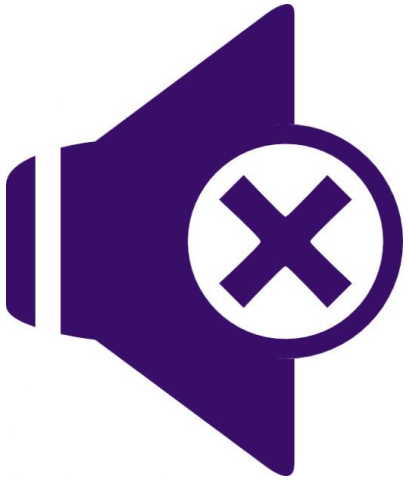
Housekeeping



LINES ARE MUTED

SEND TECHNICAL ISSUES
THROUGH THE CHAT

USE THE QUESTIONS TAB
FOR QUESTIONS

THIS PRESENTATION IS BEING RECORDED. THE SLIDES AND THE RECORDING WILL BE AVAILABLE ON DEMAND

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Managing TMF Data Migration

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Agenda

What is migration?

Why migrate?

Generalised process overview

Document deliverables

Exchange Mechanism

Summary

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Question…

Migration of content between eTMFs

Do you need to migrate eTMF documents?

YES

NO

NOT SURE

What is Data Migration?

Data Migration is:

- "….. the process of selecting, preparing, extracting and transforming data and permanently transferring it from one computer storage system to another. Additionally, the validation of migrated data for completeness and the decommissioning of legacy data storage are considered part of the entire data migration process." *(Source: Wikipedia)*

- Can also include migration from paper to electronic form

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Case Studies

Project	Client & timeline	Outcome
CRO Maturity Project	Sponsor A, 2016 – Current.	14 Studies have been migrated – most at closed status from CRO exports (media, secure transfers) Studies migrated into mapped RM 3 (Reference Model version 3) structure. Successful ongoing migration project.
Study acquisition	Sponsor B acquired 2 studies from Sponsor C. Mid 2018 – 6 week execution.	A successful migration of metadata and document content from a Veeva source system to PhlexEview 4 destination (Sponsor B eTMF)
Sponsor migrates eTMF platform	We have worked with a number of Sponsors to Map, Import and QC content 2017, 2018, 2019 to and from various eTMF platforms.	Most recent migration was a remapping – We had a small remapping need – Successful 5 week implementation.
Many more examples over the last 4 years…		

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Checklist

Key checklist points:

- Source & Destination System?
  - Name of source and destination systems.
- Transfer method (Secure file share, USB, media?)
- Study closed or open?
- Source and Destination filing structures.
  - Sub Artifact presence?
  - Site/Country naming logic
  - General metadata requirements and availability
- Document formats (source)
  - Renditions/Originals.
- Source metadata format (Excel/XML/CSV/HTML)
- Audit trail format.
- Is Paper included?
- Do the deliverables use client or PXG templates?

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Index Formats From Source Systems

- **There may be some form of Index**
  - Might not be comprehensive
  - Might not link to the files [so we need to address]
  - Having to derive metadata from folders/filenames is common
  - Have to extract from HTML/Excel sometimes also happens
  - What filing structure/version/convention used?
  - Often the index has more entries than the files supplied (or less!)
- **The Index can contain character encoding issues**
  - Think Korean/Japanese/European in one spreadsheet (can be done!)
- **The Index file name/folder path reference is a common issue area**

File Content

- **There are always files**
  - *But the formats are often inconsistent*
- **Container formats are common**
  - **Portfolio**
  - **Annotation Attachments**
  - **Document Attachments**
  - Attachments in Attachments in Attachments
  - **ZIP files**
  - Corruption is common (but less common now that a year ago)
  - PDF is good, but prone to ‘issues’
  - Duplicates?

Audit Trails From Source

- **Audit Logs**

  Formats Vary

  - XML
  - Excel
  - PDF
  - Embedded in index
  - Linking back to individual documents can be tricky
- **Regulatory Requirement!**
  - Its an inspection focus right now!
  - Some source systems provide no Audit trail at all
    - Audit begins at import!

Why Migrate?

- New eTMF system
- CRO to sponsor transfer
- CRO to CRO transfer
- Sponsor acquires/ divests an asset
- Company mergers and acquisitions
- Consolidating eTMF info (e.g. from Safety / Regulatory systems, or EDC, into core eTMF)

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Question…

Source and destination systems

Do you know your source and destination system?

YES

NO

NOT SURE

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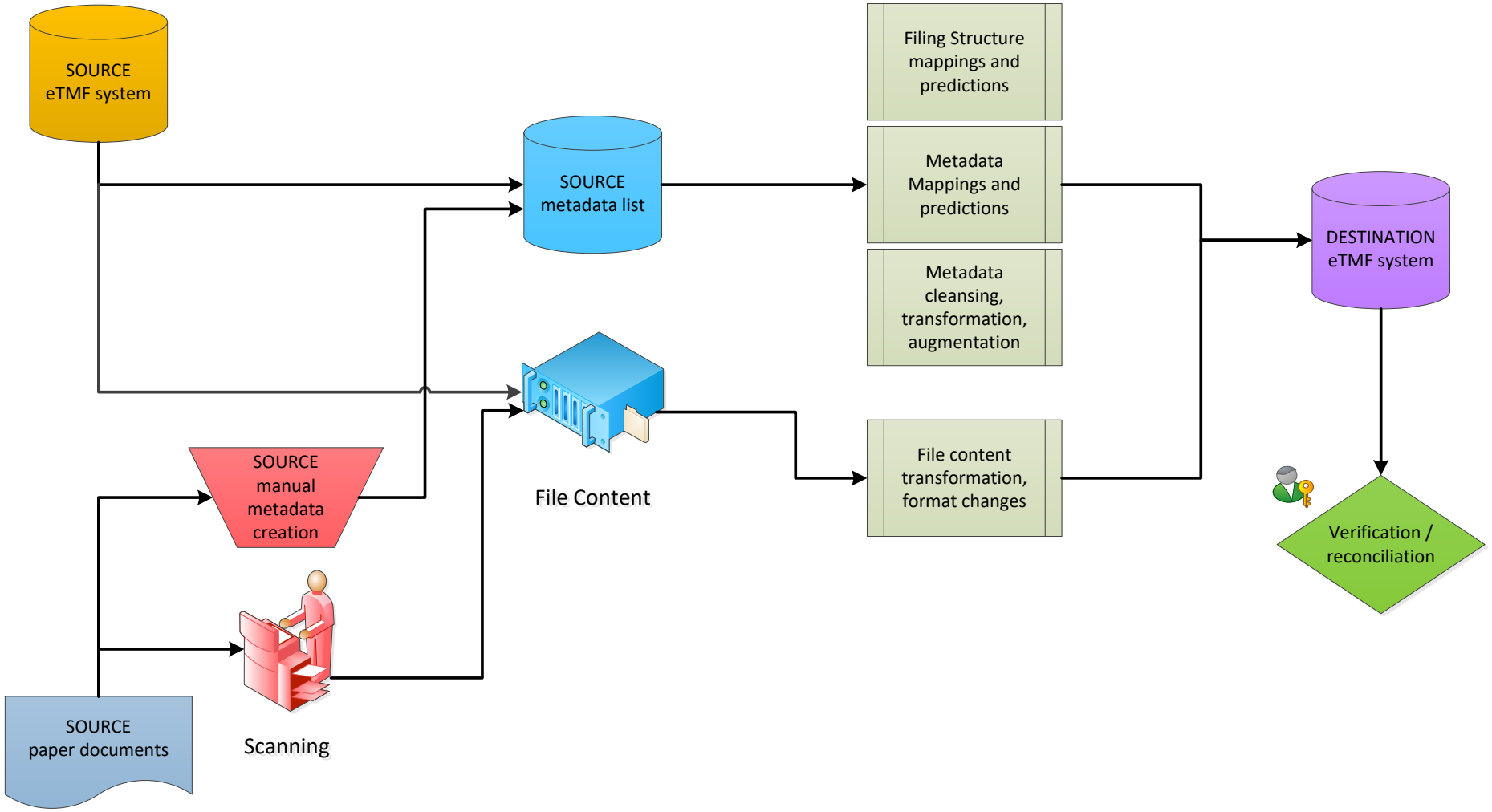
Generalised Process



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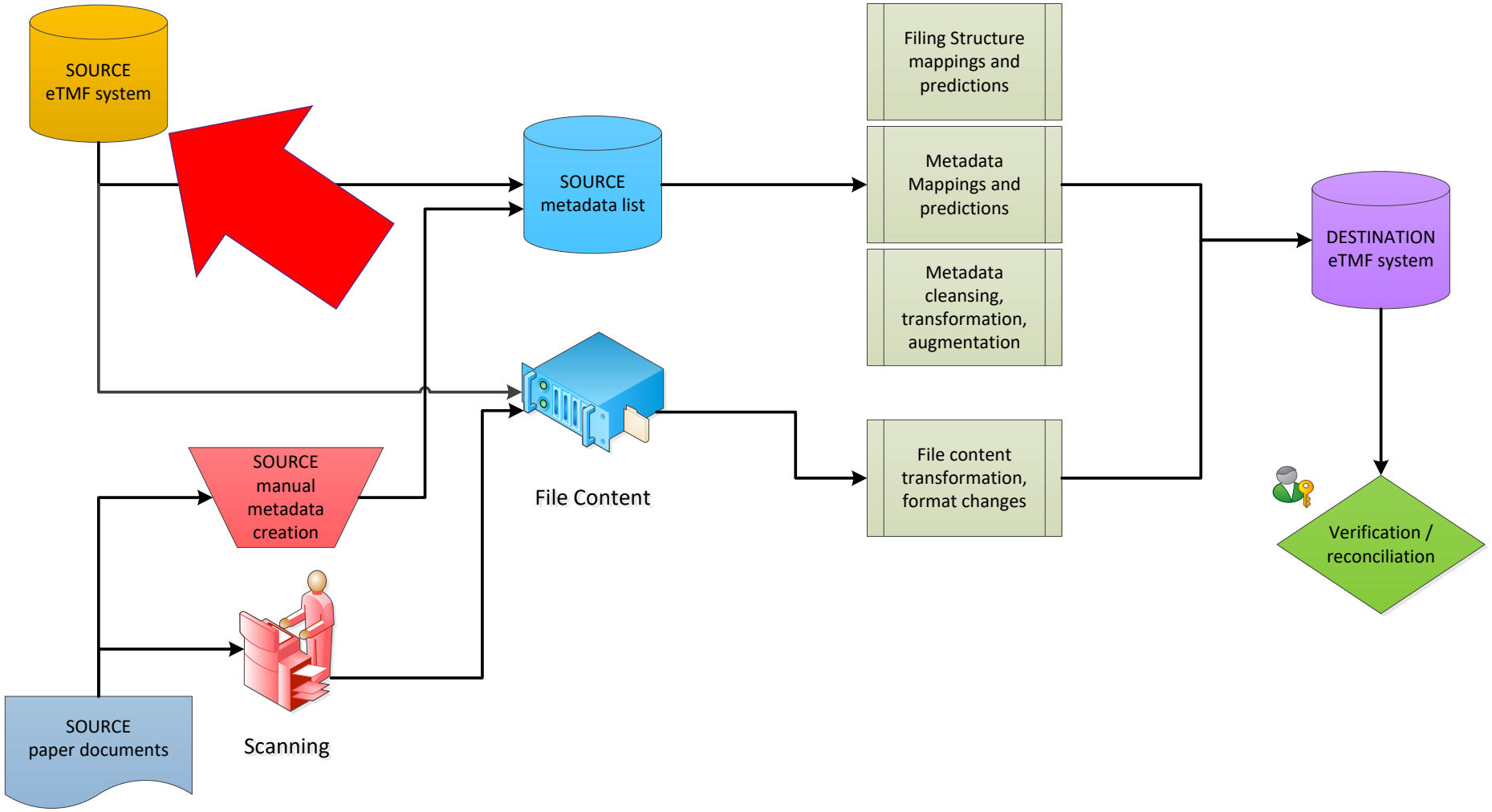
Source: Electronic



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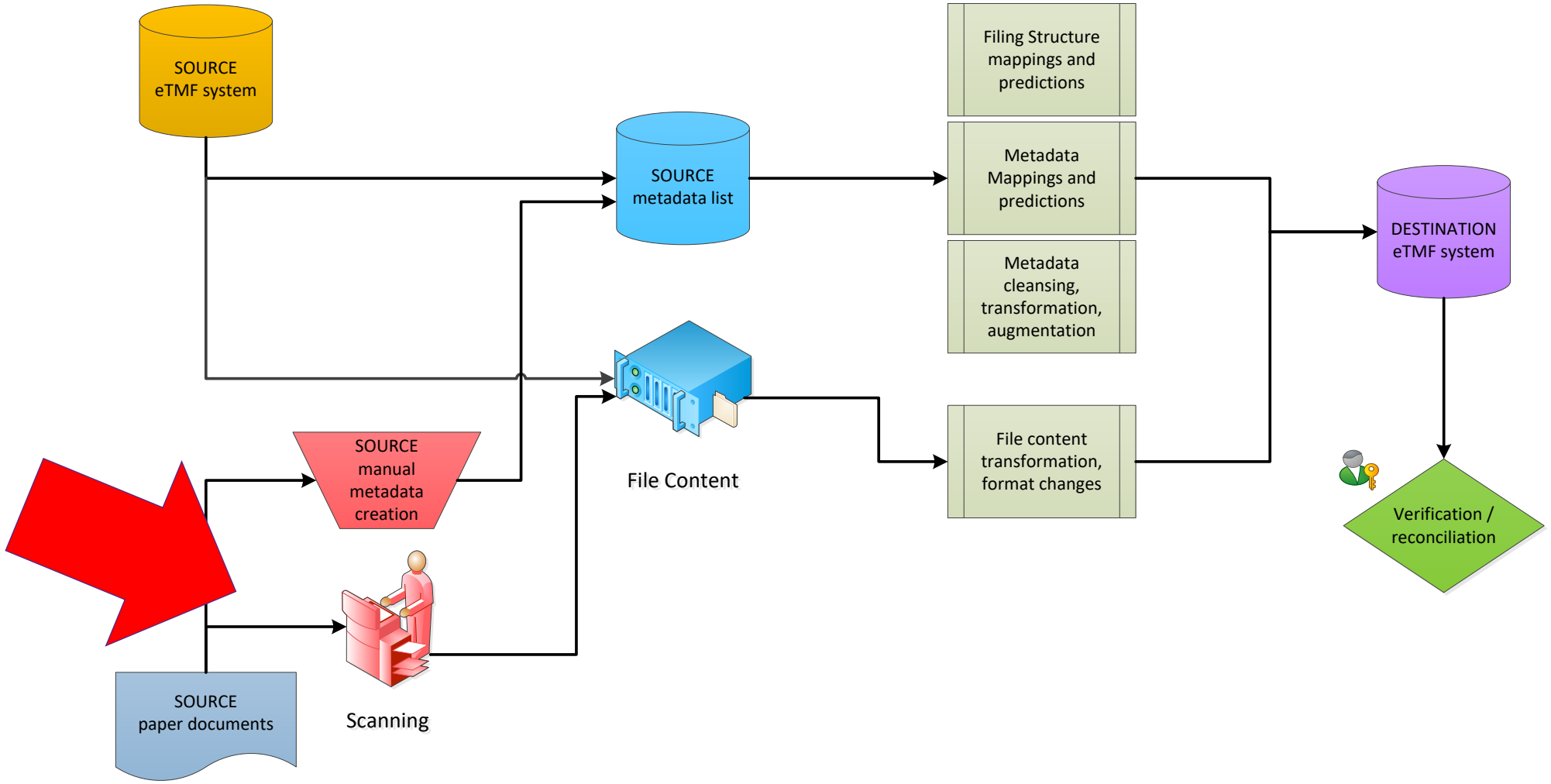
Source: Paper



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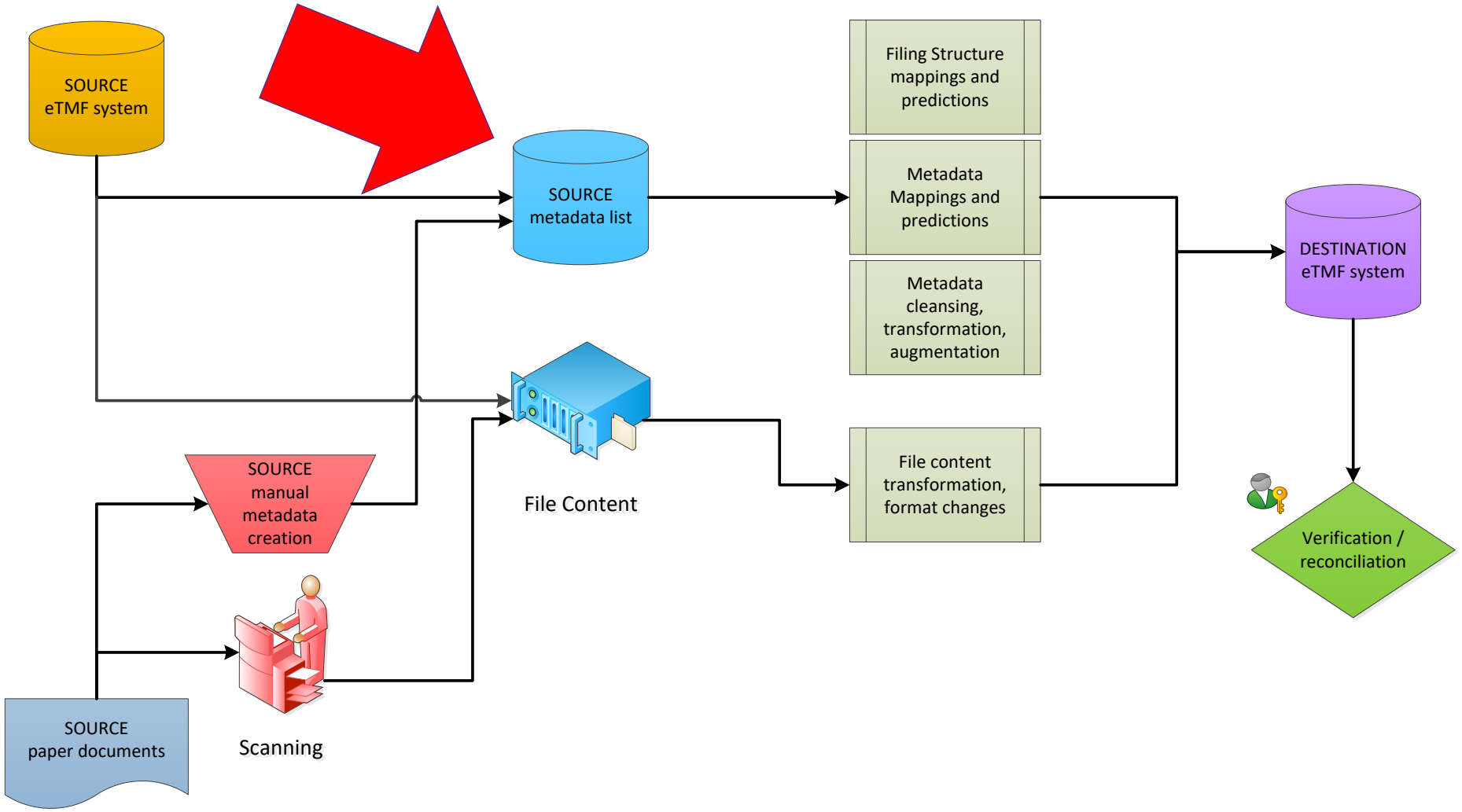
Source Metadata



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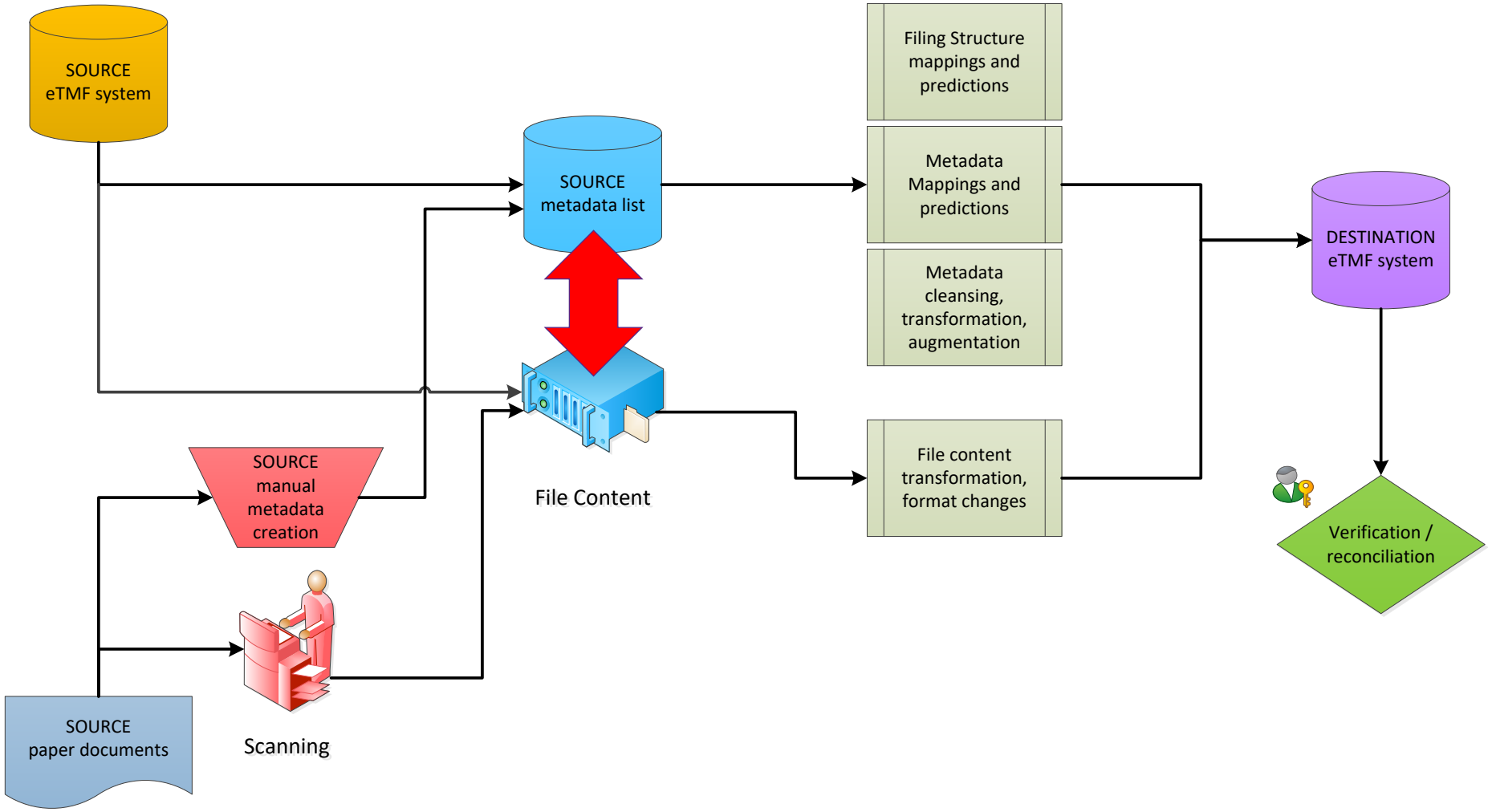
Metadata and Files



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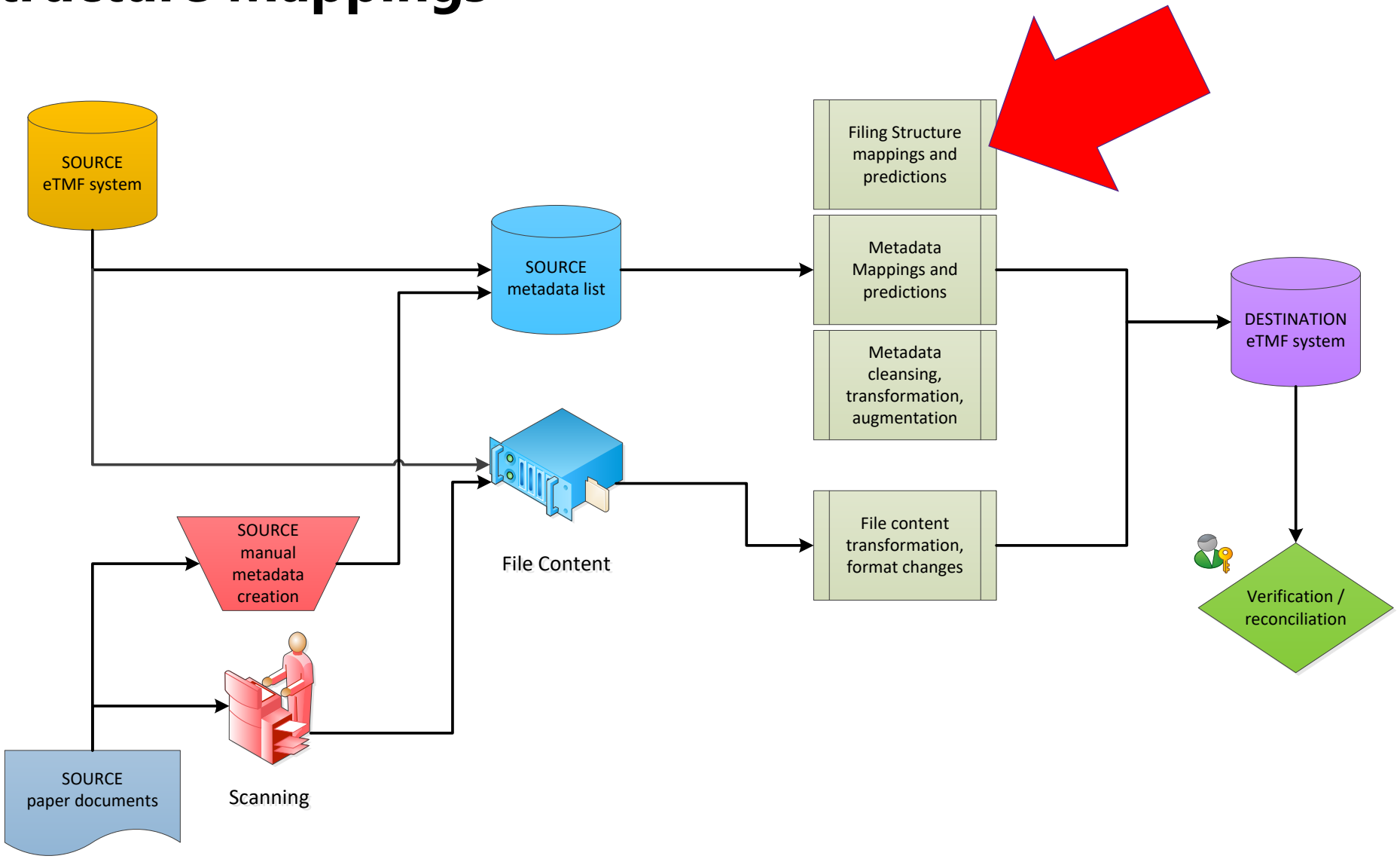
Filing Structure Mappings



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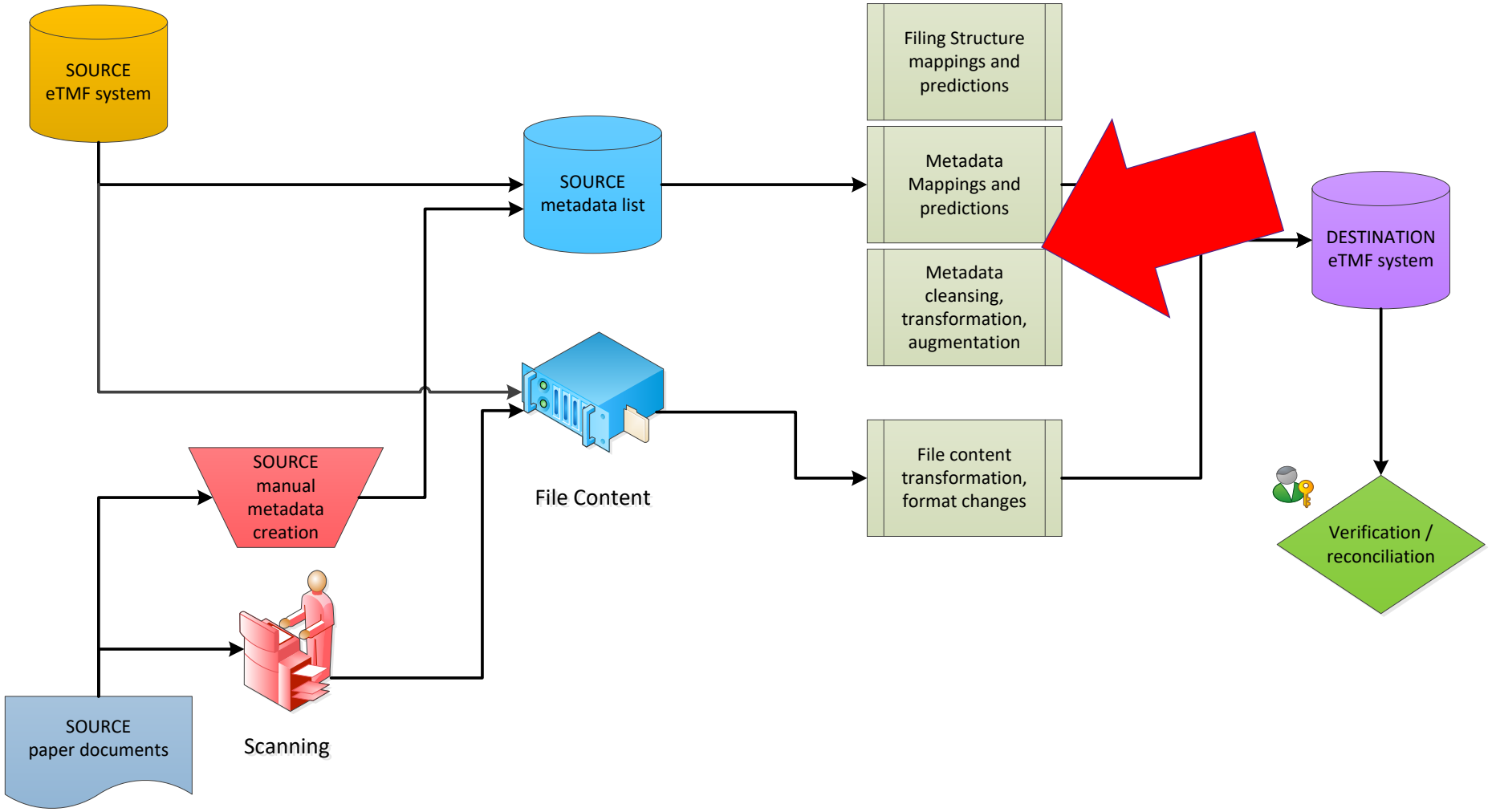
Metadata Mappings



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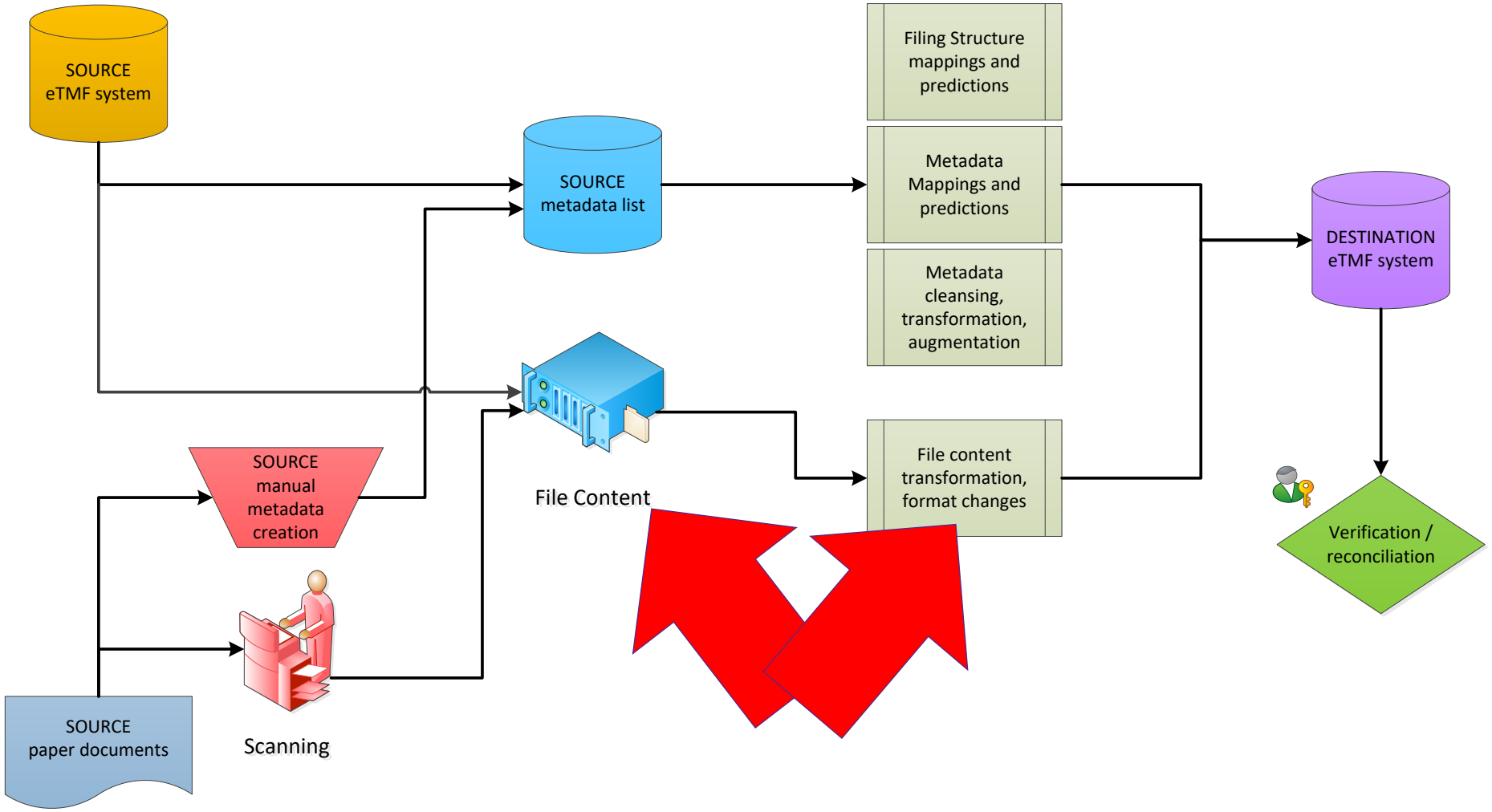
File Content



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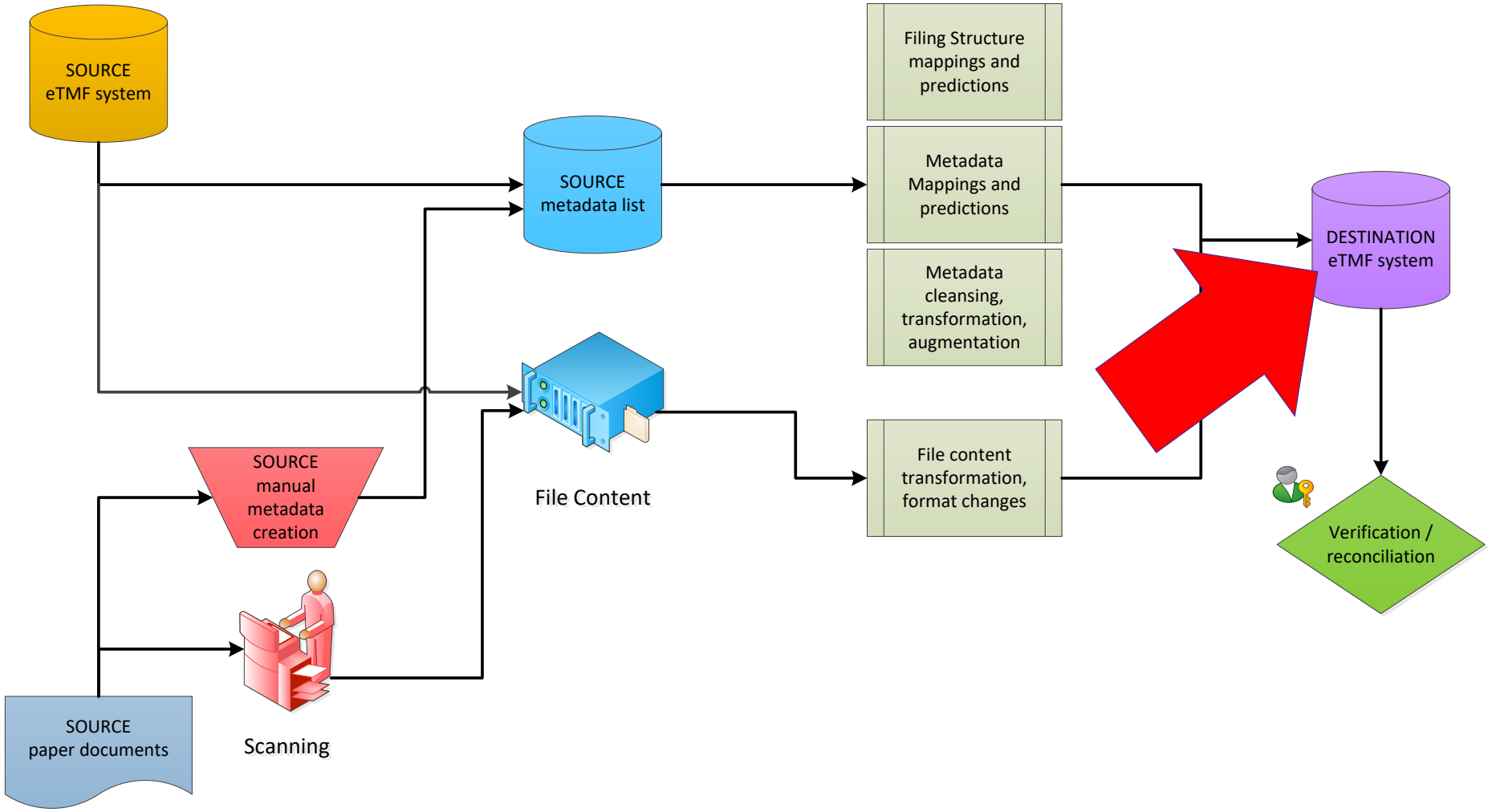
Performing Migration



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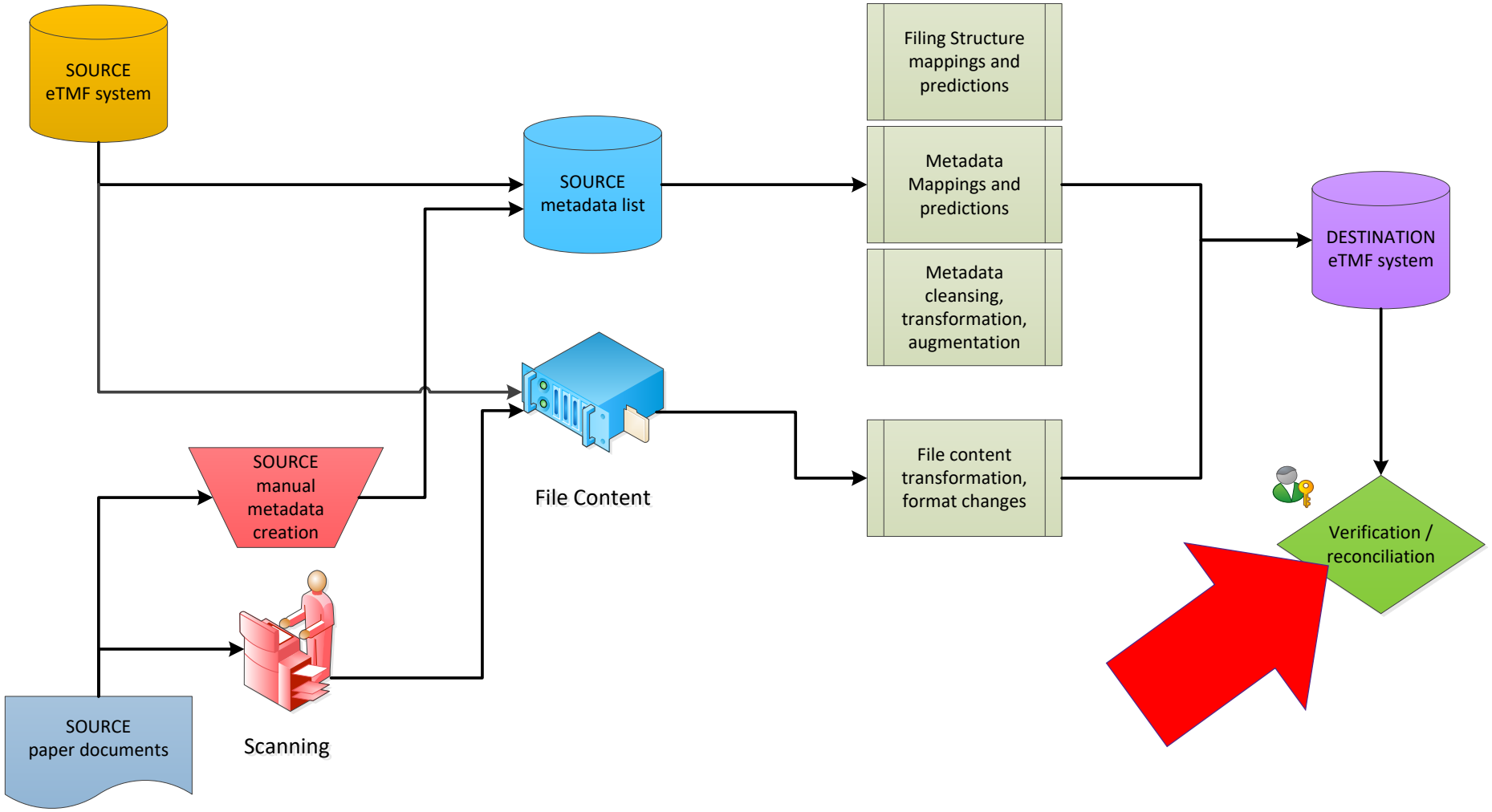
Verification and Reconciliation



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Document Deliverables

- **Data Migration Plan**
  - includes metadata and filing structure mappings
  - approved before any formal activities start

- **Reconciliation Document**
  - including clear summary

- **Data Migration Report**
  - approved by client as completion of migration

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Responsible / Accountable / Consulted / Informed

ROLES AND RESPONSIBILITIES

Responsible / Accountable / Consulted / Informed:

Activity	Phlexglobal	Client
Phase: IDENTIFY AND PLAN		
Identify Source data within scope of migration	I	R, A
Provide access to Source files in original folder structure	C, I	R, A
Finalize and approve Data Migration Plan	R, A	I
Phase: PREPARE AND MAP *(for each study or group of studies)*		
Extract metadata, where available, from filename and folder structure	R, A	I
Review and cleanse data and metadata prior to migration	R, A	I
Create metadata mappings, identifying any discrepancies and mismatches	R, A	C
Create filing structure listings	R, A	C
Phase: CLEAN, TRANSFORM, AUGMENT		
Perform data preparation, mapping, cleansing, transformation, augmentation activities	R, A	I
Phase: TEST MIGRATION		
Perform data upload to production environment in test location	R, A	C
Produce documented reconciliation of numbers of records, and document ID's	R, A	-
Phase: PRODUCTION MIGRATION		
Perform data upload to production environment	R, A	C
Produce final documented reconciliation of numbers of records, and document ID's	R, A	-
Phase: REPORT AND RECONCILE		
Create Data Migration Report	R, A	-
Approve Data Migration Report	-	R, A
Cross-Phase Activities		
Project planning & management arrange project meetings, progress reports	R, A	C

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Transferring the TMF

TMF RM EM v1.0 is now available

- Support for core TMF RM EM v1.0 is going to help
  - Reliant on both Source and Destination System support

- Doesn't consider the document format/content (only metadata) – so all those previous points on document format are important!

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Summary

- **We have a mature process for migration of content between systems**
  - EMS will make this simpler and less labour intensive at a future date
  - Document and Index format can currently be a challenge
  - Audit trail content is important

- **Comprehensive migration reporting and evidence is key**
  - Included in the final migrated study

- **eTMF systems are now beginning to offer mature migration options**
  - It's a key evolution element in the eTMF world in 2019

- **RM adoption (to Sub Artifact level) is a big advantage for study migration**
  - We can migrate anything, but RM offers a comprehensive metadata standard
  - Be wary of versions (RM2 -> RM3.1 can be done, but needs transformation)
  - Non RM -> RM often needs detailed index review and transformation

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THANK YOU

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