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Trial Master File migration

Migrate your Trial Master File (TMF) with confidence

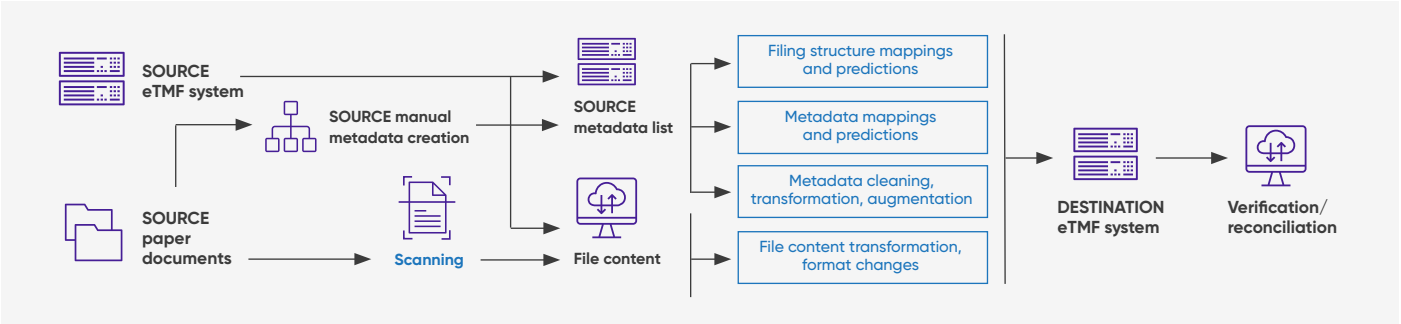
As a global authority in TMF software and services, Cencora has conducted successful TMF migrations and imports for more than 700 studies across all common scenarios, including:

- Implementing a new electronic Trial Master File (eTMF) system
- Transferring a TMF from a contract research organization (CRO) to the trial sponsor
- Consolidating eTMF information (e.g. from safety/regulatory systems or electronic data capture) intoa core eTMF
- Transferring a TMF from one CRO to another
- Acquiring or divesting a compound or molecule
- Managing TMF data through corporate mergers and acquisitions
- Customizing migration projects

Select Cencora TMF migration case studies

Project	Client	Outcome
CRO maturity project	Trial Sponsor A: Ongoing TMF migrations from their CRO	• 14 studies have been migrated, most as closed status from CRO exports (media, secure transfers) • Studies migrated into mapped CDISC Reference Model structure • Successful ongoing migraiton project
Study acquisition	Sponsor B: Acquired two studies from Sponsor C	• A successful migration of metadata and document content in six weeks from a third-party eTMF source system to the acquiring company's eTMF, PhlexTMF by Phlexglobal
eTMF system migration	Multiple trial sponsors: Map import, and QC content to and from various e TMF platforms	• Most recent migration was a remapping, successfully complted in five weeks

General flowchart of a TMF migration project



Leverage Cencora's proven TMF migration methodology

Our experts have distilled extensive TMF migration experience into a set of core best practices, with standardized processes and purpose-built technologies to optimize efficiency and accuracy. This precise, proven methodology delivers a high-quality migration of your TMF to the destination system, typically just weeks after receiving all documents from the source system.

Overview of Cencora's expert TMF migration methodology

Plan
- Identify source data within scope of migration
- Ensure access to source files in original folder structure
- Develop, finalize, and approve migration plan

Prep & map
- Extract metadata (where available) from file name and folder structures
- Review and clean data and metadata prior to migration
- Create metadata mappings, identifying any discrepancies and mismatches
- Create filing structure listings

Clean & transform
- Perform data preparation, mapping, cleaning, transformation, and augmentation activities

Test
- Perform data and file review in the context of the production environment; test the upload using test tools or a representative test environment
- Produce documented reconciliation of the number of records and record IDs

Perform migration
- Perform data upload to the production environment
- Produce final documented reconciliation of the number of records and record IDs

Report & reconcile
- Create data migration report
- Approve data migration report

Key migration planning questions:

1. What is the timeline for this migration? Is the timeline being driven by business considerations (such as a pending acquisition or New Drug Application)?
2. Are you migrating an individual study or a group of studies?
3. Is the study or group of studies open, closed, or a mix?
4. Does the study include unblinded documents?
5. What are the project deliverables?
6. What are the names/vendors of the source and destination systems?
7. Who are the originators/holders of each system: the trial sponsor, a single CRO, or multiple CROs?
8. What are the source and destination filing structures?

Have questions about TMF migration? Visit us here

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