



KEY CONSIDERATIONS WHEN PLANNING FOR YOUR CLINICAL TRIAL DATA MIGRATION

Planning, executing, and tracking [clinical trials](#) is a significant endeavor for any company conducting drug research. Often trials, or the materials collected for the trials, can linger for years. This means systems that are used to monitor these trials and inventories over time can become obsolete or in need of a significant upgrade.

With this challenge also comes the need to determine whether data associated with legacy trial management systems needs to be migrated to a new system or version. Before looking into planning and implementing clinical trial data migration, it's necessary to understand the processes and types of data that might be involved.

This piece focuses on the critical aspects of planning and executing data migration when clinical trial management systems (CTMS) or similar systems are upgraded or replaced. It highlights the complexities involved due to the nature and volume of [clinical trial data](#), the necessity of a well-defined migration strategy, and the key elements that contribute to a successful data migration project.



8 KEY CONSIDERATIONS WHEN PLANNING TO MIGRATE YOUR CLINICAL TRIAL DATA

1. Understand the Necessity for Migrating Clinical Trial Data

- Clinical trials are long-term endeavors, and the data collected within their associated management systems can have significant longevity. Obsolete systems or the need for upgrades necessitate consideration for migrating data to newer platforms. The data generated across the different phases of a clinical trial (*design, biospecimen management, implementation*) is crucial for future studies and ongoing processes.

2. Identify the Variety of Data Across the Phases of Clinical Trials

It's important to acknowledge the variety of data generated across the three main phases of a clinical trial:

- **Design Phase:** Study setup, visit schedules, patient data (*potentially*), test plans, specimen collection plans, inventory of kits, and accessioning items
- **Biospecimen Management Phase:** Patient markers (e.g., *consent*), specimen biomarkers, and inventory information (*storage location, volume, container details*)

- **Implementation Phase:** Sample data, test results, status updates, audit trails

Each of these phases brings a [different amount and varying types of data](#). Some of this data may be necessary in future studies or evolve over several years, making it a prime candidate for migration between systems.

3. Define the Key Components of the Data Migration Plan

There are several crucial inputs to planning a clinical trial data migration project:

- **Scope and Assumptions:** Defining the boundaries of the migration and underlying assumptions
- **Resourcing and Timelines:** Estimating the necessary resources and project duration.
- **Data Mapping and Requirements Collection:** Understanding the structure and content of both source and target systems, identifying data differences, and defining necessary translations and transformations
- **Overall Migration Strategy:** Determining the approach (*manual, automated, hybrid*) for migrating each data object

4. Align on a Data Migration Strategy

Given the volume and variability in data that could be collected and needing management for clinical trials, it becomes easy to see the importance of a well-defined migration strategy to ensure the seamless continuation of any trial that may not end or finalize reporting during a system change. The migration strategy should align with overall project goals and other related workstreams and consider different approaches: manual or direct entry, the use of automated tools, or a hybrid of both.

Each data object needs to be assessed to determine the best approach based on resources, timelines, effort (*complexity and data availability*), and risks to testing and validation.



5. Criticality of Data Assessment

An initial assessment of the data is crucial to confirm assumptions and gain a clearer understanding of the scope. The assessment provides a detailed look at the main sources of the data as well as a deep understanding of the targets. This helps to scope the amount of data to be migrated, identify gaps in the target system, and gauge the complexity of the migration.

Key things to look for during the assessment include data volumes per data type, data cleanliness, and data availability.

6. The Significance of Data Mapping

Data mapping is a detailed process of aligning source and target systems at the table and field level and is fundamental to defining requirements for translations and transformations. By mapping the source data objects at a table and field level, it is easier to see where records may need to be restructured into new or different tables or objects. It is also easy to see where certain field anomalies may exist, especially at the data type or size constraints.

In these types of systems, record level mapping becomes essential as the data context or the combination of multiple fields within an object define the entity relationship and possibly the structure of the object itself.

7. Plan for Translations (XREFs) and Transformations (XFRMs)

Data values that need to be redefined to conform to the target standards are said to be translated or cross-referenced. These are often simpler but volume dependent.

In comparison, data that need to be restructured, rebuilt, or even manufactured to support the target standards, are said to be transformed. These are more complex, carry higher validation risks, and increase migration costs. Defining XREFs and XFRMs based on data mapping is crucial for assembling requirements and assessing risk, effort, and automation potential.

8. The Data Migration Plan

The comprehensive [data migration](#) plan is a critical project deliverable, especially for systems managing laboratory or clinical information (*i.e.* [LIMS](#), [CTMS](#)). It clearly defines the data migration goals and objectives; summarizes the strategic approach for each data object; identifies roles, stakeholders, and impactful workstreams required; and outlines the validation/testing approach, milestones, contingencies, and associated risks.





LOOKING AHEAD

It's significantly important to understand the complexities and critical importance of thorough planning for clinical trial data migration projects. These key insights emphasize the need to understand the diverse types of data involved, conduct comprehensive assessments and data mapping exercises, define clear requirements for data translations and transformations, and develop a well-considered migration strategy and plan.

By addressing these key elements in planning, organizations can effectively migrate their valuable clinical trial data to new systems, ensuring data continuity, accessibility, and the ongoing success of their laboratory or clinical information management endeavors.

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