

1. Overview

1.1. Process overview

The migration process describes the actions taken to deliver data to a **sponsor** and to migrate from one computing environment to another. A key point in this process is the declaration of when the “source data” location changes. This is a formal handoff of regulatory “source data” responsibilities and should occur once in the process. Another issue to manage is copies of data that must be delivered to multiple locations.

Data migration should be discussed during the requirements phase of a project in order for all parties to agree on;

- a. Needed format along with any data transformations.
- b. Appropriate query script validations.
- c. Content of any interim data transfers.
 1. With or without audit trails.
 2. Complete or incremental.
- d. Medium of data transfer.
- e. Method of data reconciliation between systems.

This process can also be used to internally migrate data from an existing legacy system to a new environment.

It does not cover the succeeding decommissioning process, which ensures that the system is inventoried, de-energized, and all elements dispositioned.

The Migration process covers:

- Requirement analysis and definition of migration.
- Development of migration tools.
- Conversion of software product and or data.
- Migration Execution.
- Migration Verification.
- Notification of migration activities.
- Appropriate documenting of the migration process

2. Data Migration Prerequisites

- 2.1. Sponsor has agreed to type and frequency of interim data transfers.
- 2.2. Sponsor has agreed to close data entry on xx days after Last Patient Last Visit.
- 2.3. Sponsor has agreed to transmit final data transfer on xx days after Last Patient Last Visit.

Note: Notify Sponsor that Company can only transmit data that has been entered into the system. At some point in time after LPLV data entry must close to allow for final data transfer.

3. Data Migration Plan (DMP)

The data migration plan (DMP) documents all activities needed to successfully transfer data to a sponsor in a validated manner and “officially” moving the source data location from Company controlled to sponsor premises. The following is the outline that should be documented using the DMP template.

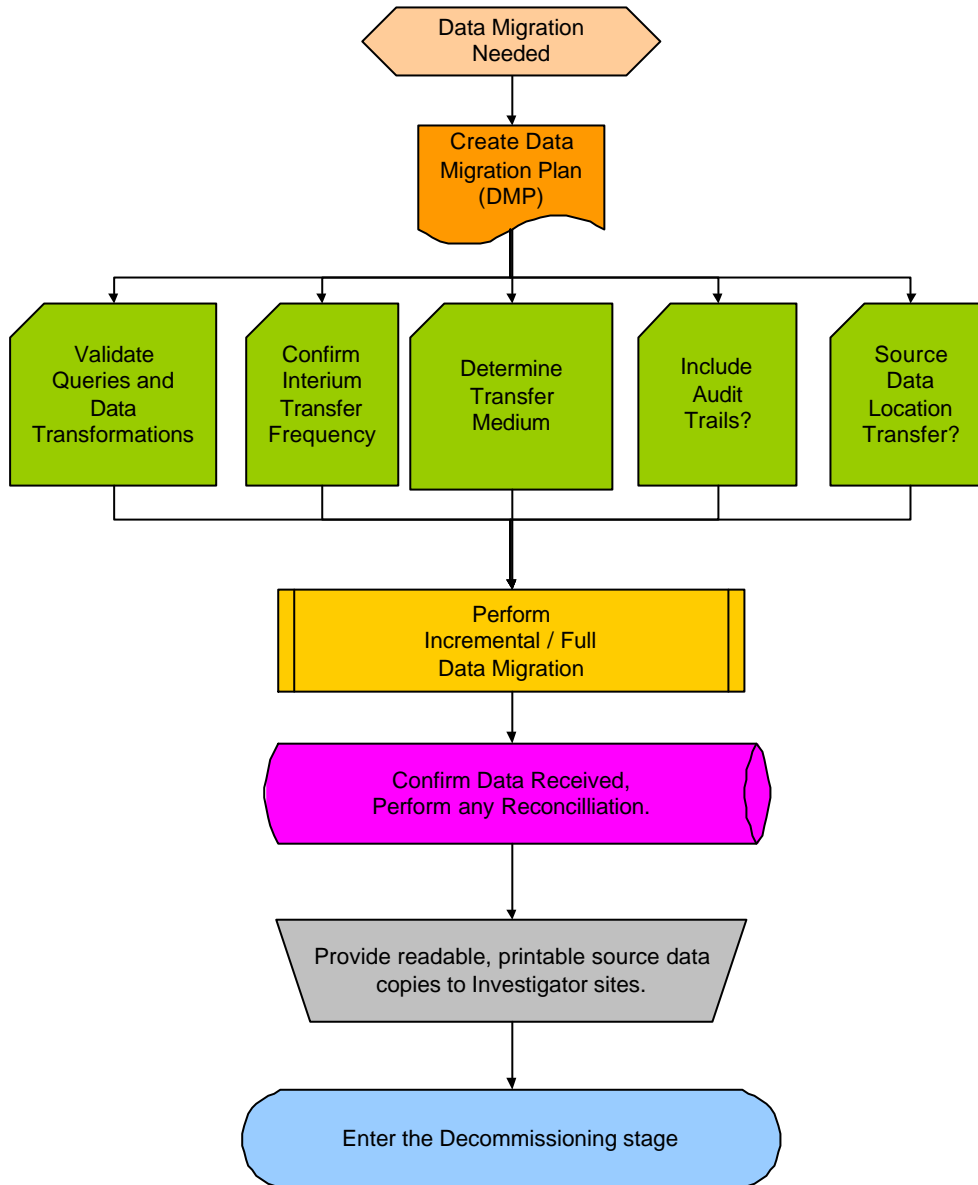
- 3.1. Purpose of the Migration
 - 3.1.1. A general purpose of the plan is discussed here outlining sponsor agreements.
- 3.2. Interim data transfers
 - 3.2.1. Discuss what type of interim data transfers will occur. This includes complete or incremental, with or without audit trails.
 - 3.2.2. Discuss the medium by which to transfer data. This can be CD, SSL, or persistent connection. Floppies are not to be used as they can be modified in transit unless encrypted.
 - 3.2.3. Discuss the frequency of data transfer along with appropriate confirmations that transfer has occurred.
- 3.3. Final data transfers
 - 3.3.1. Discuss what is to be included in a final data transfer. Discuss that one may not be required as the accumulation of interim transfers would suffice.
 - 3.3.2. Discuss what data reconciliations are necessary to ensure the sponsor has the final dataset.
 - 3.3.3. Discuss inclusion of full audit trail information.
 - 3.3.4. Discuss the medium of data transfer.
 - 3.3.5. State that the source data ownership is transferred to the sponsor during this stage.
 - 3.3.6. Discuss how copies of source data will be available at investigator locations available for inspection by regulatory authorities in both paper and electronic format.
- 3.4. Data transfer validations
 - 3.4.1. All interim and final data transfers need to be queried, transformed, and transmitted in a validated manner. This means that a set of requirements, designs, and code need to be documented and tested to ensure that the correct data is being transmitted with correct formatting.
 - 3.4.2. Validation evidence can either be included in the DMP or as separate references.

4. Migration Process

- 4.1. Periodic Basis
 - 4.1.1. Initiate predetermined interim data transfers.
- 4.2. Near Last Patient Last Visit (LPLV)
 - 4.2.1. Coordinate with the sponsor to ensure that all outstanding data is transmitted in a timely manner.
 - 4.2.2. On LPLV notify sponsor that the database will close in xx hours.
 - 4.2.3. At LPLV+xx hours, close data entry.
 - 4.2.4. Compile final output data file.

5. Data Migration Flow

5.1. The following flowchart outlines the Data Migration activities.



6. Internal System Migration Process

Company internal systems over time will need to be retired in favor of new hardware/software environments but might still need the same or replacement application(s) available. In order to accomplish this task similar processes as in sponsor data migration should occur. The data migration plan shall be used to document the activities necessary to migrate systems.