Data Management Plan

Module 10 Topic 2

Data Management Plan

WHAT-

- Data Management Plan is document which defines and documents
  - Data management tasks
  - Responsibilities
  - Deliverables
- It Outlines -
  - How every step would be performed
  - What all documents needs to be created
  - What all documents to be collected
- DMP is based on
  - Protocol
  - Study specific instructions

Data Management Plan (contd)

WHY-

- Clinical Data Management (CDM) involves complex interplay of activities. Also CDM involves interaction with many groups like Clinical operations team, Medical writing team, Monitors and Statisticians. Lack of planning will only lead to confusion, thus writing a Data Management Plan is an important first step in CDM activities. DMP is a living document, which orchestrates the conduct of Clinical Data Management project.

Data Management Plan (contd)

Objective of project

- Regulatory
- Post Marketing Survey
- Scientific Publication

Deliverables

- Clinical Statistical Report
- Final Tables and Listings
- Analysis Datasets
- Clean Database

Data Management Plan (contd)

Planning of CDM activities

- What is the work to be performed
- Task ownership matrix
- Risk involved and Business Continuity Plan (BCP)
- SOPs or guidelines that will apply
- What document or output to collect or produce
- How it will be collected
- Archival

Factors that Affect Plan

- Number of investigative sites.
- Rate of arrival of CRFs.
- Type of CRF (Paper/ electronic).
- Type and extent of external data.
- Number of patients (enrolled/screened/dropouts/completers).
- Anticipated number of Univariate and Multivariate edit checks.

Factors that Affect Plan (contd)

- Duration of patient enrollment period.
- Date of database lock.
- Duration of project Time to review one unit of Data (page/ visit/ patient).
- Number of unique CRF pages/ modules/ screens.

Factors that Affect Plan (contd)

Additionally we also need to consider some important timelines that are not under direct control of Data Management group but effect final deliverable. They need to assumed and discussed with Clinical department in advance. They include availability of final protocol, First site initiation, FSFV and LSLV…etc.

Steps in CDM Process

- Study Setup
- Database setup
- Tracking CRF Data
- Data Entry (in paper studies)
- Lab Data and external data
- Discrepancies
- Coding
- Reports
- Transfers
- Closure

Level of detail

- Which team will be doing what activities.
- When the tasks will be accomplished.
- Identifying coding dictionaries & methodology to be used.
- Turn-around time for resolution of queries.
- Timeframes for completion of tasks.

Study Start-up

- Clinical Data Management System (CDMS) and its version number
- Site setup
- List of all software
- Physical hardware

Database Set-up

- Step-by-step process for creating the database.
- Testing and validation of Database.
- Procedure for handling database modifications.

CRF Review

- How CRFs will be reviewed
- How CRFs are prepared prior to data entry
- CRF completion Guidelines.
- Details of transmittal & receipt process of CRFs, DCFs & external data e.g. laboratory reports, ECG data, paper diaries etc.
  - Timing of transmittal
  - Volume of each shipment

Data Entry/ Verification

- Double data entry process
- Method of reconciling discrepancies
- Data entry guidelines
  - Acceptability of abbreviations
  - How symbols should be entered

External Data Reconciliation

- Process
- Contacts e.g. Specific department/ CRO
- Study-specific Guidelines

Data Validation

- How & when study data will be cleaned
- Study-specific edit checks
  - Acceptable values for each data point
- Edit checks should be run to ensure data
  - Completeness
  - Consistency
  - Sensibility
  - Accuracy

Coding Procedures

- Which data points will be coded.
- How they will be coded.
- Dictionary name & version.
- Coding guidelines.
- Process for dictionaries updates.

Electronic Data Integration

- Data to be received from where & whom.
- Quality control processes.
- Process of integration.
- Details of how electronic file will be integrated with CRF based data.

QC Audit

- Percentage of patients to be audited.
- Data points that will be audited.
- Level of auditing needed prior to interim analyses or data transfers.
- Acceptable error rate.
- Action plan for resolution of audit issues.

Archival

- Process & timing for archiving of CRFs, DCFs (paper studies) & electronic data.
- Archival of study related documents.
- Archival of electronic data.

Data Management Plan

- Defines both needs & expectations of data management team.
- Serves as a communication tool for entire project team.
- Serves as a reference for DM team members and other study team members.

Abbreviations

- DMP- Data Management Plan
- CDM- Clinical Data Management
- BCP- Business Continuity Plan
- SOP- Standard Operating Procedures
- CRF- Case Report Form
- FSFV- First Subject First Visit
- LSLV- Last Subject Last Visit
- CDMS- Clinical Data Management System
- DCF- Data Clarification Forms
- ECG- Electrocardiograph
- CRO- Clinical research Organization