BioInformatics –
A Roadmap To Success

Data Management Plans

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What is a Data Management Plan?

• A document that describes how clinical data will be handled during the course of the study

• Similar in nature and scope to a statistical analysis plan or a clinical monitoring plan.
Guidance Relating to Data Management Plans

• There are no specific documents or guidance related to data management plans

• The Society for Clinical Data Management has a document titled Good Clinical Data Management Practices

• We have a detailed example for you.
DM Plan – Why?

- To comply with Good Clinical Practice (ICH Guideline E6)

- A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
How is a DM Plan Related to GCP?

• Section 4.9 Records and Reports

  – 4.9.2 Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained
How is a DM Plan Related to GCP? (continued)

- Section 4.9 Records and Reports
  - 4.9.3 Any change or correction to a CRF should be dated, initialed, and explained and should not obscure the original entry. That is, an audit trail should be maintained. This applies to both written and electronic changes or corrections.

- Describe the process for changing CRF data and the audit trail that documents the change.
How is a DM Plan Related to GCP? (continued)

- Section 5.5 Trial Management, Data Handling, and Record Keeping
  - 5.5.3 (c) Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e., maintain an audit trail, data trail, edit trail).
What Information Should be Reviewed to Write A DM Plan

• **Study Protocol**
  – The study protocol defines how and why the study is being conducted. This document is key to understanding the study.

• **Study Manual/Monitoring Plan**

• **CRFs**

• **Data coming from external sources, e.g., laboratory data**
What Information Should be Contained in a DM Plan?

- Data Capture
- Data Transcription
- Data Transfer
- Storage of Clinical Data
- Data Processing
Data Capture

• Traditional Paper Case Report Forms (CRFs)
• Remote Data Entry
  – Use paper CRFs but have data entry and storage done at the site or central location for multiple sites within a geographic region
• Electronic Data Capture (EDC)
  – Study information entered directly into a computer; not paper trail
Data Transcription

• CRF completion guidelines
  – Paper CRFs may have a separate document describing the process
  – Electronic Data Capture may have on-line help and documentation

• Example guidance for paper CRF
  – Complete form with blue ink
  – Date and initial any changes made to the form
Data Transfer

- How will the CRFs be transferred from the sites to the data entry office?
- Will lab data be provided in Excel files or other data structure?
- Which data will be considered Source Documents?
- Sponsor should always retain the original CRF data.
Storage of Clinical Data (Paper and Electronic)

- Original documents (CRFs) should be stored in a secure (locked) room or file cabinet.
- Document procedures for granting access to database servers.
  - System controls
  - Username/Passwords
- It is important that the clinical data and audit trail are easily accessible for audit.
**Data Processing**

- **Data entry, cleaning, coding and transfer.**
- **Goal:** Efficiently provide quality data for analysis.
- **How?**
  - Have current Standard Operating Procedures and Work Instructions available to staff
  - Quality control checks, i.e., data audits
Who is the Target Audience of a DM Plan?

- Data managers
- Data programmers
- Query/Discrepancy staff
- Project Leader
- Clinical Monitors
- Statisticians
- Clinic site staff
When Should a DM Plan be Updated?

- When the Protocol is amended
  - Addition or removal of a site
  - New CRF added to the study

- When data handling process changes

- Yearly review by data manager; only need sign-off if major changes have occurred
Data Plan Conclusions

- A Data Management Plan helps define the process and document your procedures
- Have SOPs and WIs to support the DM Plan
- Review the study protocol
- Communicate with the study team
- Encourage data audits