Elements of a Robust Data Management System

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DM System Elements

- Regulatory Requirements
- Data Collection
- Data Entry
- Data Cleaning
- Data Set Creation
- Laboratory Data
- Web Reporting
Regulatory Requirements

- **Logical security**
  - Username/password login
  - Groups of users
  - Assign rights to groups

- **Audit trail**
  - Automatically track each change made to data

- **Record attributability**
  - Username and date/time stored on each record
GCP Definitions

1.51 Source Data

All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (1.52)
1.52 Source Documents

Original documents, data, and records (e.g., hospital records, clinical and office charts, lab notes, memos, subjects’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, etc.)
GCP Definitions

1.11 Case Report Form
- A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor and each trial subject.

1.55 Standard Operating Procedures (SOPs)
- Detailed, written instructions to achieve uniformity of the performance of a specific task.
5.1.3 Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.
Data Cleaning

- Systematically identify potential data inconsistencies or errors
- Clean all data with identical processes in order to avoid bias

Clean data:
- At data entry (embedded in structure)
- Programs running nightly
- Manual review of CRFs
Data Cleaning

- **Nightly programs**
  - Error specification document
  - Review of results
  - Reports to sites
  - Tracking
Data Cleaning

- **Updating CRFs with revised data**
  - Don’t write on CRFs after plies are separated
  - Attach data discrepancy report sheet to CRF
  - Audit trail applies to paper forms and database

- **1.9 Audit Trail (GCP)**
  - Documentation that allows reconstruction of the course of events.
GCP Principles

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.
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.
Data Set Creation

- Create read-only versions of data sets
- If data are being combined to make analysis/profile data sets, save copies of original data sets and programs
- Create audit trail data sets for final freeze
Web Reporting Systems

- Username/ password protected
- Read-only views to the data
- Summaries of database
- Post documents
- Track queries, CRF completion
- Monitor data quality
Laboratory Data

- Data must be linked with other study data
  - Participant number, center number, date,
- Will data be queried?
- How will updates be implemented?
- Will data transfers be incremental or cumulative?