

Data Quality Management

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GCP Requirements: Data Management

GCP Definition:
Good Clinical Practice is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve participation of human subjects

GCP Requirements: Data Management

Case Report Form:

E6 1.11 CRF is “a printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.”

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Purpose of CRF:

- To capture all protocol-required information
- To capture the data consistently across ALL study staff and sites
- Must be accurate and verifiable!

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- Data from all CRFs are entered into a centralized database
- Database is protected—only designated staff may enter, change, or view data.
 - Data computer should not be used for general purposes
- Data is analyzed to determine if the endpoints of the protocol have been met, Hence timely delivery is crucial.

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ICH E6 5.5.1

- The sponsor is responsible for ensuring that there are qualified people to:
- Handle and verify the data
- Conduct the statistical analyses and prepare trial reports

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- Only individuals who have been properly trained in GCP, research ethics and CRF completion and have been authorized by the PI can complete the CRFs
- The Staff Responsibility Log will list those persons authorized to complete the CRFs



GCP Requirements: Data Management

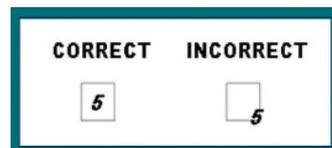
STAFF ARE KEY

- Consistent, well-organized staff with clear job responsibilities are vital to achieve this.
- Standardized instructions for all: Train, practice, re-train until it is perfected.

GCP Requirements: Data Management

- ICH E6 2.10
- All trial data should be recorded, handled and stored in a way that ensures its accurate reporting, interpretation and verification
- Record data correctly

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Record Data Correctly - Use leading zeros

INCORRECT

This entry is incorrect and will result in a query

1 MAR 07
dd - MON - yy

CORRECT

01 MAR 07
dd - MON - yy

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**GCP Requirements:
Data Management**

ICH E6 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
 - All data entries should be reviewed and reviewer sections of the data forms signed.

**GCP Requirements:
Data Management**

- ICH E6 4.9
- Investigator’s responsibility to ensure that all data reported to the sponsor on CRFs and in other reports are accurate, complete and legible
- Data intended for patient care should be submitted to clinicians in a timely manner.

**GCP Requirements:
Data Management**

- PI or designee must review all **CRFs-Usually a monitor.**
- All items are answered (unless blank due to a skip pattern)
- Only one response per item is recorded
- Entries are legible
- Use leading zeroes
- Header information is complete (Identifiers)

**GCP Requirements:
Data Management**

ICH E6 4.9.2

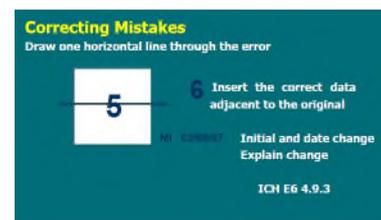
- Certain data on CRFs are derived from source
- CRF Documents must be consistent with the source documents
- Role of source data verification: If copy of original please verify with date and signature

**GCP Requirements:
Data Management**

- Correcting Mistakes
- NEVER use correction fluid
- NEVER erase or obscure original entry
Ensures an audit trail exist for all entries

ICH E6 4.9.3

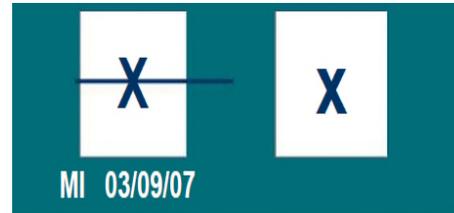
**GCP Requirements:
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GCP Requirements: Data Management

- Correcting Mistakes
- X is marked in the wrong box
- Draw a single line through the incorrectly marked box
- Initial and date it
- Mark the correct box

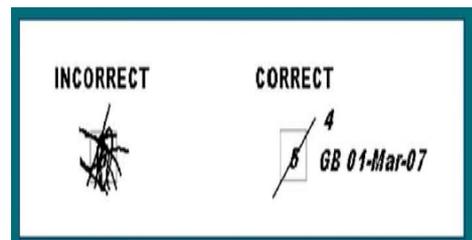
GCP Requirements: Data Management



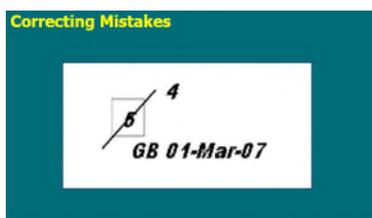
GCP Requirements: Data Management

- Correcting Mistakes
- NEVER scribble out an entry
- Draw one horizontal line through the error
- Insert the correct data adjacent to the original Initial and date the change (never past date or future date - always use today's date)

GCP Requirements: Data Management



GCP Requirements: Data Management



GCP Requirements: Data Management

ICH E6 5.5.3

- For electronic data handling, sponsor has several responsibilities - must maintain :
 - A security system that prevents unauthorized access to the data
 - A list of the names of those who are authorized to make changes to the data

GCP Requirements: Data Management

- Backups of the data
- A system that is designed to allow for changes to the data without deletion of entered data (for an audit trail)



GCP Requirements: Data Management

Data is the reason we are all here.....

- provided it is accurately, timely
- recorded, analyzed, and reported

Data fax Reports

- These are sent periodically to the sites by the data collection centers.
 - Solve these on time
 - Send responses in real time
 - Initial and date refaxes
 - Keep the data fax in good shape

Lessons

- It was noted in some site for untrained staff to fill EMBLEM CRFs
- Data computer is used for general purposes e.g emails, meeting minutes, games, internet
- Delay or failure to submit data to clinicians for patient care
- GCP Errors e.g over writing, not dating, incomplete data
- Varied understanding of study questions e.g what is a Swamp?

Lessons

- Failure to review data at the sites
- No verification of electronic data entry
- Delayed filling of forms common with control enrolment
- Not all patient forms are kept in one folder
- Loose placement of forms instead of filing
- Distortion of the EMBLEM folder arrangement of forms