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Good Documentation Practice

Good Clinical Practice (GCP) and ALCOA-C principles play a pivotal role in documentation. This includes all essential information regarding the trial, such as informed consent process, source data for case report forms (CRFs), etc. Accurate and complete documentation is crucial for transparency, traceability, and accountability of the trial process.

ALCOA-C Principles

- **Attributable:** Who wrote or did this? All documentation should be traceable to the person who made them. This ensures accountability and transparency.
- **Legible:** Can it be read? Documentation must be clear and easy to read to avoid misinterpretation or errors. Illegible handwriting can lead to data discrepancies.
- **Contemporaneous:** Documentation must be created at the time the events occur. Delayed or backdated entries affects data integrity.
- **Original:** When possible, only original documents should be used. Photocopies or scans can introduce errors and inaccuracies. Photocopied document should be certified true copy.
- **Accurate:** Documentation must be accurate and truthful. Are there conflicting data elsewhere? Corrections or amendments should have explanations for the changes.
- **Complete:** Documentation should cover all relevant details, including deviations, adverse events, and participant responses. Gaps can lead to inconsistencies.

General Practice

- Maintain all data and observations of patient. Records should be identifiable to a particular participant.
- Source document - where information is first recorded.
- Study documentation should be able to recreate the study for any reviewer.
- All entries are to be signed and dated in real time.
- Corrections are made by drawing a single line through the incorrect entry, initial and date.
- Never obliterate entries that require correction.
- Subject records need to be secure but accessible.
- Use dark ink pen, no pencils. Never use whiteout.
- If the source data is incomplete or deficient, it may be completed or corrected using an addendum. This late entry must be signed and dated at the time it is created.

Note to File

- May be used to correct errors, or to explain protocol deviation. Reasons for any deviation should be documented and attempts to correct or prevent it in the future should be included.

Medical Records from External Source

- Copies of records from external source can be used to support endpoints, inclusion/exclusion criteria, adverse events, etc. Attempts to obtain these documents should be recorded accordingly.

Questionnaires

- Documentation must reflect who completed the questionnaire, in compliance with the protocol.
- Questionnaires completed by a staff should reflect how the information was obtained - direct interview, phone call, chart abstraction, etc.

Good documentation practice has a profound impact on the quality and credibility of clinical trial data. When documentation is consistent and adheres to these principles, it becomes a reliable source of information as a cornerstone of scientific integrity and patient safety.

Potatoes, Eggs, or Coffee?

A daughter complained to her father about her miserable life. The father boiled three pots of water, and put potatoes, eggs, and coffee beans in them. After simmering, he asked her what she saw.

"Potatoes, eggs, and coffee," she replied.

He urged her to look closer and touch them. The potatoes had softened, the eggs hardened, and the coffee filled the air with a pleasant aroma.

He explained that all three faced the same adversity in boiling water but reacted differently. The potato went in strong but became weak. The egg, fragile, turned hard. The coffee beans transformed the water, creating something new.

He asked, "Which are you? When adversity strikes, do you become like the potato, egg, or coffee bean?"

Challenges and adversity can drain our energy both physically and mentally. But it is up to us how we decide to face it and use the adversity to turn us into a better version of ourselves.