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SOURCE DOCUMENTATION

Scenario

Apple had just started her career as a Clinical Research Coordinator (CRC). She was assigned a study on the first week into her job. There was no source document template created for the study, therefore Apple plans to create a source document template to help her collect the required study data. What should she be aware of when she creates the template?

Firstly, Apple needs to understand what constitutes a good source documentation.

ICH GCP E6 (R2) 1.52 explains what constitutes source documents . They are as follows:
Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

Secondly, Apple needs to understand what **ALCOA** is.

ICH GCP E6 (R2) 4.9.0 states, "The investigator/institution should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial subjects. Source data should be *attributable, legible, contemporaneous, original, accurate*, and complete. Changes to source data should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an audit trail)."

Each source document must pass the **ALCOA** test.

What is ALCOA?	
Attributable	Data can be traced by signature or initial to the individual who observed and recorded the data. Traceable to the subject (subject identification required on every single page of source document) and the visit date.
Legible	The data is readable and recorded in a permanent medium (e.g. non-erasable pen) or electronic records that are unalterable. Clinical reports printed on carbon paper must be backup with a photocopy (e.g. ECG reports).
Contemporaneous	Timely record of data, no pre-entry or back-date
Original	First hand record of observations, no transcription or copy. All copies of reports (e.g. ECG's photocopy reports) must be stamped with "certified true copy" and signed off by the individual who made the copy.
Accurate	Correct recording of the observation, no conflicting data recorded elsewhere. (e.g. an abnormal lab value was reviewed as non-clinically significant by the investigator but was recorded as adverse event in the source document.)

Reference:
- ICH GCP E6 (R2)
- NHG Proper Conduct of Research SOP 501-B05 Documentation

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