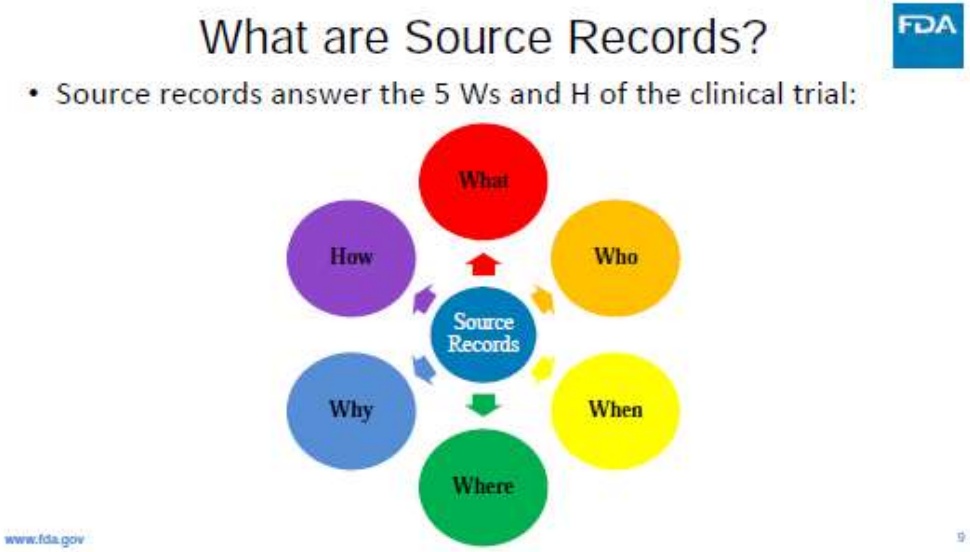
What is Source Data?

- Source data includes all information in original records of clinical findings, observations, or other activities in a clinical investigation used for reconstructing and evaluating the investigation.

- Source data are contained in source documents.

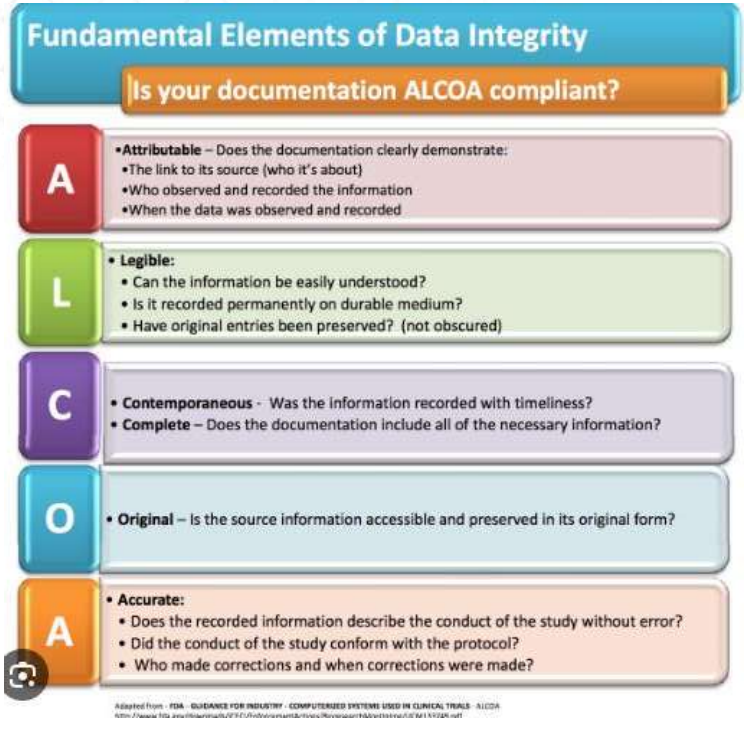
Source Documentation

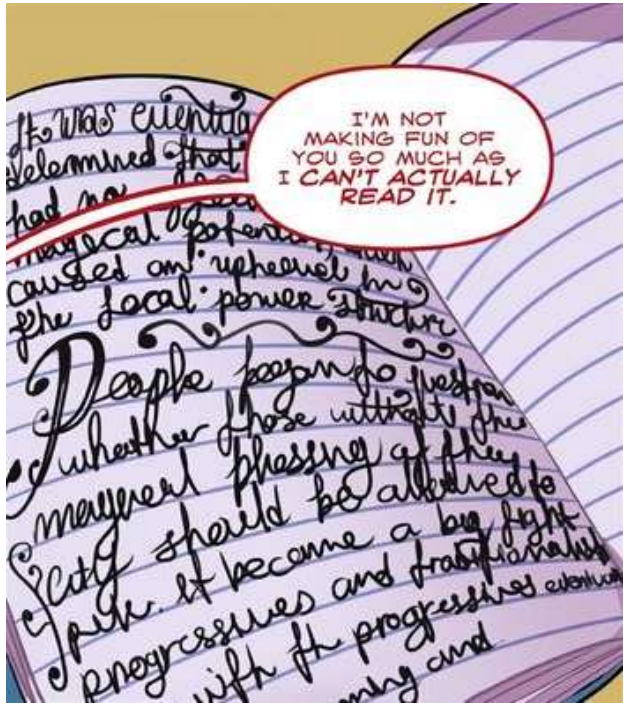
- A **complete** source record should answer the What, Who, When, Where, Why, and How



Good Clinical Practice for Documentation

Source data should meet ALCOA principles and must meet the regulatory requirements for recordkeeping.





Examples of Source Documents

- Participant medical records including electronic medical records (EMR)
- Phone encounters or notes
- Lab and diagnostic test results
- The paper or electronic informed consent document
- If data are directly observed and directly entered into an electronic system (e.g., WebDCU), the electronic record is considered the source.
- Specific research worksheets (CRFs) used to document key research data elements

Source Types

- **Electronic Medical Record (EMR)** as source
  - No need for paper source document if monitor can access EMR to verify information
  - Over the shoulder EMR verification is allowed (coordinator should be available for the entirety of the visit)
- **Paper Medical Record** as source
  - If EMR access is not available to monitors, print information from EMR and file in subject binder (eBinder should follow the same flow as a physical binder)
- **Paper Case Report Forms (CRFs)** as source (most common)
  - Paper document is used to collect information that gets entered to WebDCU
  - File paper source in subject binder
  - *Example:* Printed CRF from WebDCU
- **Electronic Case Report Forms** (eCRF)
  - Information obtained in **real time** and entered directly to WebDCU
    - Should ***ONLY*** be used as source from a ***contemporaneous observation***
  - Add "direct data entry" to general comments section
  - This practice may reduce DCRs
  - There will be no other source
  - Check local institutional policy to ensure direct data entry is permitted
- **Note To Files (NTF)** can be used for documentation of out of ordinary occurrences that need further clarification and file with source documentation.
  - Can be paper (stored in subject research binder) or electronic (stored in the subject's EMR)

Example of Note to File

Note-To-File Template

A note to file should:

- Be generated on a case-by-case basis
- Include the subject and protocol it refers to
- Be signed and dated by the individual who is writing it
- Be legible if handwritten
- Explain clearly and *specifically* the reason for the error/omission/discrepancy or process/policy it aims to address.
- Should include any corrective action or follow-up when applicable.
- Be filed with the document, subject file or behind the study binder tab to which it applies

Sample Note To File:

PROTOCOL #: 2010-01000

TITLE: The Effect of 'Investigational Product' on XYZ Levels in Healthy Controls

From: research coordinator
[Insert staff name, include role on study}

To: Subject File

Re: Subject# 015-SAW
[insert subject identification]

Date: October 31, 2011

Dr. Smith consented the subject on January 20, 2010. Dr. Smith, in error dated the consent form January 22, 2010. The dating discrepancy is not representative of an inappropriate consent process, but the result of a typo. Dr. Wolf has been reminded to confirm the correct date in the future.

Signature:

Important things to note about Source Documents/Data

- All data reported in WebDCU should match the source.
- Source documents should be retained, and the site should make records available to monitors, auditors, and inspectors.
- When multiple valid sources for a data item are available, the decision regarding which values will be considered as source must be documented.
  - *Example:* If multiple labs are drawn in a day and the protocol does not specify, the PI could circle and date the source. The site could also compose a memo to specify what the source is for that site in particular circumstances.
- Know if your StrokeNet trial requires the use of the Study book, or if using CRFs alone will suffice (e.g. VERIFY requires study book).