
Source Document Requirements

Patty Sheehan



Objectives

- Review the source document requirements and expectations

Source Documents

- Definition: A source document is where information on a participant is first recorded.
- Allows an auditor to reconstruct the study for a participant.
- Tells the story from the consent process, determination of eligibility, and dispensation of the study pills to the last participant contact.
- Contains data that is entered into the EDC, as well as information illustrating how and when procedures were completed.

Source Document Examples

- “Originals”
- Medical records
- Progress notes
- Nurses notes
- Pharmacy records
- Study specific flow sheets
- FFQ
- IPAQ
- Local laboratory reports
- ICFs

Source Document Characteristics

- Attributable: who documented the data
- Legible
- Contemporaneous: information should be documented in the time frame that it occurred or was collected in
- Original. If not possible, the source document should be an exact copy
- Accurate



Source Document- Templates

- Template source documents will be available in the MOP
- Sites can develop their own
- CC monitoring visits will include verification of source document data to data entered in the e-CRFs