Source Documents

Source Data is defined as all information in original records and certified copies of original records of clinical findings, observations, or other activities (in a clinical investigation) used for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

Source Documents are those documents where data regarding study subjects are first recorded and serve as the basis for the information submitted to the Sponsor on the case report forms. Any form of documentation may be used as a source document and is subject to review when validating the integrity of data collection and analysis. Common source documents are participant medical records, phone encounters or notes, lab and diagnostic test results, participant diaries and specific research worksheets used to document key research data elements.

If data are entered directly into a computer system, the electronic record is considered the source. A computerized system should ensure that the methods for record keeping and retention afford at least the same degree of confidence as that provided with paper systems. For example, each entry, including any change, should be made under the electronic signature of the individual making the entry, and any changes that are made to data stored on electronic media should be maintained in an audit trail to protect the authenticity and integrity of the electronic records.

The following principles of source documentation apply in clinical trials:

- Each data point necessary to reconstruct and evaluate the conduct of the trial is supported by and traceable to a previously recorded entry in a primary source document.
- Source documentation is signed and dated and indicates who performed the various study tasks. If worksheets are developed to collect study data (or if a copy of a CRF is used as a worksheet), they must be labeled “Source” and signed/dated by the person completing the worksheet.
- Data should not be entered directly onto a case report form (CRF) unless the CRF calls for data not normally recorded on a primary source document (e.g., forms self-administered by patients) or unless the protocol or operations manual contains instructions to do so.
- Every patient contact is documented (all clinic visits, phone contacts that require action or contain clinically significant information, etc.).
- Source documentation is timely, i.e., completed as close to the time of observation as possible. Late additions are identified as such.
- When recording the times for a series of study-related activities, use the same clock for all events to assure that they were completed in the required order.

Source documentation should meet the ALCOA standard for data quality:

- Attributable to the person collecting and recording the data
- Legible
- Contemporaneous (dated and signed/initialed at the same time)
- Original (the first recording)
- Accurate

References:

1. 1. Good Documentation Practice in Clinical Research, Perspectives in Clinical Research, 2011 Apr-Jun; 2(2): 59-63.
2. Guidance for Industry: Electronic Source Data in Clinical Investigations, U.S. Department of Health and Human Services, September 2013.