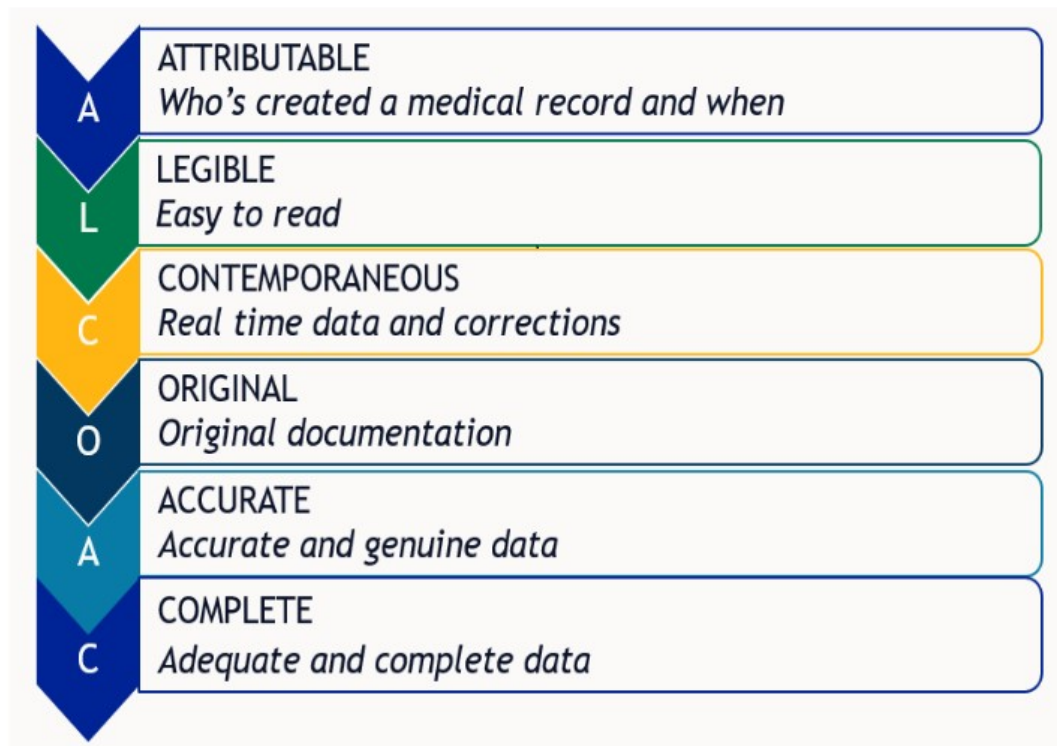## SOURCE DOCUMENTS

KEY LEARNINGS

Source documents are original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memos, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, 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).

Source Data Verification

- Requirements to create source documents

- Which documents would be considered source document

- Process for source data verification

- Understand the importance of source data verification

- Apply ALCOAC principles for source documents

ALCOA-C Principles

A	**ATTRIBUTABLE** *Who's created a medical record and when*
L	**LEGIBLE** *Easy to read*
C	**CONTEMPORANEOUS** *Real time data and corrections*
O	**ORIGINAL** *Original documentation*
A	**ACCURATE** *Accurate and genuine data*
C	**COMPLETE** *Adequate and complete data*

If it is not documented it is not done.