

**25 Key Assessments for Accurate Case Histories
(Source Document Key Traits)**

Case History Assessments	
1.	Data provided is accurate
2.	Data is legible
3.	Investigator's involvement and oversight documented
4.	Investigator does not over delegate control of study and general responsibilities
5.	Investigator does not delegate medical task to nonmedically qualified individuals
6.	Entries are attributable
7.	Entries are dated
8.	Person dating entries is the originator of the entry
9.	Entries are written concurrently/contemporaneous
10.	Entries are written in indelible (permanent) ink
11.	Corrections to entries are explained
12.	Entries are corrected by the originator of the entry
13.	Corrections are single-lined through; dated; initialed; and explained
14.	Medical risk, the protocol, and medical options are documented as discussed by the investigator
15.	Complete observations of adverse events are documented by the investigator
16.	Adverse events are discussed with the subject by the investigator or a medical doctor subinvestigator
17.	Documentation supports that subjects meet inclusion and not exclusion criteria
18.	Investigator documents that subject is proper candidate for study
19.	Documentation is present verifying when source data was completed
20.	Deviations are approved prospectively and not reactively by the sponsor, investigator and IRB
21.	Repeated deviations are limited in occurrence – corrective actions work to prevent reoccurrences
22.	Positive and negative (complete) medical histories are documented in source – the absence of information does not document the medical criteria was actually discussed
23.	Original documents are available
24.	Documentation is present that no study procedure was performed prior to informed consent
25.	Credentials and licensures for the study team are present, current, and approved for current state in which research is being performed