

ALCOA In Clinical Research

Good Documentation Practice • Data Integrity • FDA Compliance • ALCOA Acronyms • Original Data • ALCOA+ Extensions

Attributable

Every data entry linked to the responsible individual.

Legible

All records in a clear, readable format.

Contemporaneous

Data recorded in real-time during the study.

Original & Accurate

Retain originals; cross-check for errors continuously.

ALCOA Acronyms in Depth

ATTRIBUTABLE	Prevention of unauthorized disclosure of sponsor data or subject identity.
LEGIBLE	Voluntary process confirming subject willingness – written, signed, dated.
CONTEMPORANEOUS	Independent observer present when subject cannot read the ICF.
ORIGINAL	Individual authorized by law to consent on behalf of the subject.
ACCURATE	Individual participating as recipient of investigational product or control.

ALCOA+ Extensions

COMPLETE	No deletions, missing data, or undocumented changes.
CONSISTENT	Data follows logical, chronological, sequential order.
ENDURING	Preserved in durable format for full regulatory retention period.
AVAILABLE	Retrievable at any time for audits, reviews, or inspections.

Good Documentation Practice

- "What is not documented is not done!"
- Document what is done as well as what is not done
- Paper records: corrections must not obscure prior entries
- Electronic records: audit trail tracks all queries and changes

Data Integrity & Core Pillars

- Data Integrity: reliability, accuracy & consistency throughout the data lifecycle
 - Core Pillars: Rights, Safety & Wellbeing of subjects must be protected
 - Validity of clinical trial conduct per GCP & applicable regulatory requirements
 - ALCOA+ ensures high-quality, reliable data upholding all core pillars
- FDA Compliance & Audit (Form FDA 483)

FDA Compliance & Audit (Form FDA 483)

- Data must be recorded in real time (contemporaneous) – no backdating.
- Must identify who conducted the visit: initials, date, subject & visit number.
- FDA principle: "Guilty Until Proven Innocent" – submitting false data is criminal.
- Form FDA 483: issued at inspection conclusion when violations are identified.
- FDA 483 observations are public records – reviewed across pharma & biotech sectors.

Original Data & Accuracy Requirements

- Source = earliest record; first place data is documented.
- Paper: preserve original form; corrections must not obscure prior entries.
- Electronic: audit trail tracks changes; edit checks flag missing/out-of-range data.
- Accuracy requires honest, thorough representation of all study conduct facts.
- Incomplete, inconsistent, or wrong data must be corrected in a compliant manner.