

What is ALCOA++

Upholding data integrity means following principles like ALCOA++ standards which ensure data is reliable from the moment it's created until it is submitted.

Let's explore each attribute on ALCOA++:

- **Attributable:** Data must be linked to the person or system who generated or recorded it, with a clear date and time
Example: Study nurse logs a participant's vital signs in the electronic medical record. The entry automatically records the nurse's username and timestamp.
- **Legible:** Data must be readable and understandable
Example: Study coordinator writes participant data in source notes using permanent ink. The handwriting is clear enough for another person to understand without any explanation .
- **Contemporaneous:** Data should be recorded at the time the event occurs i.e. on a real time basis
Example: Investigator administers an investigational drug at 9:00 AM and immediately records the administration time and drug details in the source notes and dosing log, rather than entering it later from memory.
- **Original:** The original source of the data or a certified copy must be maintained
Example: Study coordinator files original signed and dated laboratory reports received from the laboratory in source file (source file contains the original documents where trial data is first recorded, such as medical charts, laboratory reports, participant diaries etc.)
- **Accurate:** Data must correctly reflect the reality, with no errors or alterations
Example: When a study nurse records a dose, it shows the exact amount given, not an estimate
- **Complete:** All data must be fully recorded without omissions i.e. no missing data
Example: Study coordinator ensures that for each adverse event (AE) corresponding details required by the protocol such as severity, onset date, resolution date, relationship to study drug and outcome are mentioned and there is no missing data
- **Consistent:** Data should be uniform and follow logical order
Example: A participant's visits are documented in the correct order (Visit 1 → Visit 2 → Visit 3) and the visit dates align with the protocol schedule
- **Enduring:** Data must remain intact and accessible for the entire retention period in accordance with applicable local regulations and guidelines (e.g. Under US

FDA guidelines, the retention period extends to two years after marketing approval of the drug/device, or two years after the investigation is formally discontinued and the FDA is notified, whichever date is later)

Example: Electronic data is stored securely, backed up to prevent any loss and remains accessible for regulatory inspections, if any

- **Available:** Data should be readily retrievable and accessible when needed

Example: During an FDA audit, the site is immediately able to provide the requested source records and Case Report Forms because they are stored in a structured and easily accessible system

- **Traceable:** Changes to data must be recorded so the history of edits is clear and transparent

Example: Audit trail is showing who corrected a laboratory value and why