

Source Documentation in Clinical Research

Introduction • Purpose • ALCOA+ • Common Findings & Discrepancies • Quality Enhancement • Conclusions

Accuracy

All data recorded in source documents must be accurate.

Compliance

Adhere to regulatory standards and GCP guidelines.

Consistency

Use standardized formats and terminology across all docs.

Timeliness

Complete and verify documentation promptly after events.

Purpose of Source Documentation

RECONSTRUCT THE TRIAL	Enables an independent observer (CRA, Auditor) to reconfirm data and reconstruct events as they happened.
AUDIT TRAIL	Provides complete audit trail to permit investigation when required by sponsors or regulators.
ELIGIBILITY EVIDENCE	Confirms subject eligibility (Inclusion/Exclusion), documenting progress from consent to study completion.
IP ACCOUNTABILITY	Records IP dispensed, consumed and returned; serves as complete medical record for the treating physician.
CRF FOUNDATION	Forms the foundation for data transcribed into CRF, ultimately translated into the clinical study report.

Core Pillars Supported by Source Docs

- Regulatory Compliance – GCP and applicable regulatory requirements.
- Data Integrity – accuracy, consistency, and completeness of trial data.
- Participant Safety – tracks AEs, patient history, and treatment outcomes.
- Audit & Monitoring – primary reference for sponsors, auditors & regulators.

Core Pillars Supported by Source Docs

MISSING SIGNATURES	Signatures omitted from essential clinical trial documents.
INCONSISTENT DATA	Data entries show discrepancies across multiple documents.
INCOMPLETE RECORDS	Records not fully documented – gaps in key information.
DELAYED ENTRIES	Data recorded long after the event, impacting study integrity.

Frequent Discrepancies in Documentation

- Missing dates, unsigned documents & mismatched patient identifiers (IDs).
- Inconsistent entries – variations causing confusion and data integrity issues.
- Delayed documentation – timeliness gaps compromise study reconstruction.
- Unclear communication – ambiguous notes difficult for subsequent reviewers.

Enhancing & Evaluating Documentation Quality

- Regular audits & real-time verification during data entry to reduce errors.
- Standardized templates and ongoing staff training on documentation best practices.
- Audit trails – detailed records of all documentation changes and updates.
- Utilize electronic systems (EDC) to streamline and safeguard documentation.

Conclusion

Source docs must demonstrate ALCOA+ per GCP. PI commitment, site training, and continuous monitoring are key. The source document narrates the patient's medical journey for any independent observer – the foundation of credible clinical research.