

Factors affecting Data Integrity:

Maintaining data integrity is essential for credible clinical trial outcomes. Various human, technical and procedural factors as mentioned below can influence the accuracy and reliability of trial data:

- **Human error:** Mistakes during data entry, transcription or recording can compromise accuracy and reliability
- **Poor documentation:** Missing, incomplete or inconsistent records reduce transparency and the ability to confirm results
- **Inadequate training:** Staff who are not adequately trained in trial-specific procedures, systems, applicable guidelines/regulations may unintentionally introduce errors
- **System failures:** Malfunctions in electronic data capture systems, laboratory equipment or software can lead to data loss or alteration
- **Protocol deviations:** Failure to adhere strictly to the approved trial protocol compromises consistency and comparability of results
- **Intentional misconduct:** Intentional falsification, selective reporting or fabrication of data weakens trust and validity
- **Weak Oversight and Monitoring:** Insufficient quality checks or monitoring processes allow errors to persist undetected
- **Data Security Risks:** Unauthorized access, breaches or inadequate backup systems can compromise confidentiality and integrity of trial data