

Clinical Data Management Process

Data Validation and Query Management

Data Validation & Query Management

- Data Validation refers to systematic checks and procedures used to detect errors, inconsistencies, and missing data in clinical trial datasets.
- Query Management involves identifying, resolving, and tracking data discrepancies through formal queries with study sites.
- Both processes ensure high-quality data that meets regulatory standards, such as ICH-GCP (E6 R2), FDA 21 CFR Part 11, and CDISC guidelines.

Data Validation

- Data validation facilitates identification of data entry errors, outliers, and missing values. It helps maintain audit trails and data traceability which help with regulatory compliance. It reduces the risk of incorrect study conclusions.
- There are two types:
- Automated Validations: these are pre-programmed edit checks which flag discrepancies in real-time and reduces manual workload and improves efficiency.
- Manual Validations: these are performed through visual review and logical assessment of pre entered data. They are required for complex cases where automated checks fail.

Query Management

- Query Management facilitates communication between data managers, site personnel, and monitors. It helps maintain regulatory compliance (ICH-GCP, FDA, GDPR).
- Steps for query resolution:
- Discrepancy Identification: Automated system or data reviewer detects an error.
- Query Generation: A formal query is raised in the EDC system or communicated to the site. The query describes the issue and requests correction or confirmation.
- Site Response & Data Correction: The study site reviews the query and provides a response.
- Query Closure: The data manager verifies the correction. Once resolved, the query is closed in the system.