



Outlined below are the key responsibilities of Clinical Data Management team:

Phase	Activities Performed
Start up	<p>Protocol Review: Assess protocol to define data needs and guide database planning</p> <p>Case Report Form (CRF) Design: Create **paper/eCRFs aligned with protocol endpoints, visits and eligibility</p> <p>Data Management Plan: Outline trial-wide data handling procedures and responsibilities</p> <p>Database Setup: Configure secure database for clinical data capture and storage</p> <p>Edit Check Specifications: Set automated checks to detect data errors and inconsistencies</p> <p>User Acceptance Testing (UAT): Validate database functionality before trial launch</p> <p>Training: Instruct teams and sites on data entry and query resolution processes</p> <p>Note: **For paper CRFs, the Clinical Data Management team is responsible for printing of CRFs</p>
During Study	<p>Discrepancy Management: Identify, query and resolve inconsistent or missing data</p> <p>Medical Coding: Apply standardized codes to medical terms, drugs for consistent analysis</p> <p>Reconciliation: Align clinical, safety and laboratory data by resolving discrepancies</p> <p>Protocol Deviations: Document and ensure consistency of all</p>

	<p>protocol deviations across data sources</p> <p>Manual Review of Data: Perform detailed checks beyond automated validations</p> <p>Data Quality Control (QC): Conduct ongoing reviews to ensure data accuracy and reliability</p>
Study Closure	<p>Final Data Cleaning: Review and correct all trial data for accuracy and completeness</p> <p>Quality Check: Verify data meets quality standards for analysis readiness</p> <p>Data Locking: Close the database as read-only for final analysis and submission</p> <p>Archival: Store trial data and documents securely per regulatory requirements</p>

Thus, the Clinical Data Management team plays a crucial role in ensuring the accuracy, completeness and integrity of clinical trial data from start to finish. Their work supports reliable analysis, regulatory submissions and ultimately the development of safe and effective medical treatments

Primary Technology / Tools used by Clinical Data Management:

- **Electronic Data Capture (EDC):** A software system used in clinical trials to collect, manage, and store clinical data electronically, improving accuracy and efficiency by replacing paper forms
- **Direct Data Capture (DDC):** A method where data is entered directly into the electronic system by site staff or patients, reducing transcription errors and speeding up data availability
- **MedDRA (Medical Dictionary for Regulatory Activities):** It is a standardized international medical terminology used in clinical trials and regulatory processes to consistently code and classify medical conditions, symptoms, adverse events, and procedures for data entry, analysis, and reporting
- **WHO-DD (World Health Organization Drug Dictionary):** It is an international classification and comprehensive dictionary of medicinal products used globally, providing standardized drug names, active ingredients, and therapeutic classifications to support consistent coding, analysis, and safety monitoring in clinical trials