

Roles in a CDM Team



A CDM (Clinical Data Management) team comprises various roles, all working together to ensure the integrity and accuracy of clinical trial data.

1. Clinical Data Manager (CDM):

- Supervises the entire data management process, ensuring data integrity and accuracy throughout the clinical trial.
- Develops and implements data management plans, including Case Report Form (CRF) design and electronic data capture (EDC) implementation.
- Oversees data quality control processes and discrepancy management.
- Collaborates with other team members and stakeholders to address data-related issues.
- May also be involved in database lock and data reporting activities.

2. Database Programmer/Designer:

- Creates and maintains the clinical trial database, ensuring it meets regulatory requirements and study needs.
- Designs data entry screens, implements edit checks, and performs data validation.
- May be involved in CRF annotation and mapping data fields to the database.

3. Medical Coder:

- Reviews and codes medical information, such as adverse events and medical history, using standardized coding dictionaries like MedDRA and WHO Drug.

- Ensures consistency and accuracy in coding practices.

4. Clinical Data Coordinator:

- Assists the Clinical Data Manager with various data management tasks.
- May be involved in CRF design, query management, data review, and database lock preparation.

5. Quality Control Associate:

- Verifies the accuracy of data entry and performs data audits to ensure data quality.
- Identifies and resolves data discrepancies.

6. Clinical Data Analyst/Biostatistician:

- Analyzes and interprets clinical trial data to draw meaningful insights.
- Uses statistical methods to assess the safety and efficacy of treatments.
- Provides statistical support for regulatory submissions and decision-making.

7. Other Potential Roles:

- **Clinical Research Associate (CRA):** Serves as a liaison between the sponsor and clinical sites, monitoring data collection and adherence to the protocol.
- **Data Entry Associate:** Enters data from paper CRFs into the database.
- **Project Supervisor/Manager:** May oversee the overall clinical trial and the CDM team's activities.