



QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Clinical Science Training Institute

**CLINICAL DATA
MANAGEMENT**

**Role based Projects
(CDMP)**



Self-Paced Online Training

Our Mission

Our mission is to provide the best-in-class job oriented certification and skill based courses towards Clinical research, Drug Safety, Pharmacovigilance, Clinical Data Management, Clinical SAS Data Analytics and Healthcare business. We offer Entry-Mid and Senior programs for students and professionals, looking for skills refresh or career advancement

CAREER FOCUSED PROGRAM

(Learning for Job)

ABOUT CLINICAL RESEARCH DATA MANAGEMENT

Clinical Research Data Management (CDM) is a key business process in drug discovery lifecycle. CDM refers to management of data capture and data flow process in conduct of a clinical trial. It begins with design of data capture instruments and data collection continues with data QC procedures and ends with database finalization.

ROLE BASED PROJECTS

Program was designed by industry experts for students and young professionals. The training provides in depth knowledge of roles and responsibilities of clinical research data management specialist including theoretical aspect of the field and exposure to real time scenario cases based on industry requirements.

LIST OF EXERCISES:

SINo LESSON NAME

- 1 Introduction to Clinical Trials
- 2 Protocol Design and Development
- 3 Protocol
- 4 Data Management Plan
- 5 Query Management
- 6 SAE Reconciliation
- 7 Introduction to Adverse Event Reporting and Classification
- 8 AE Coding
- 9 Clinical Trial Data Cleaning and Validation
- 10 Elements of CRF
- 11 E CRF Design and Data Tracking
- 12 Trial Master File (TMF)
- 13 Trial Master File
- 14 CTMS Track Recording
- 15 Database Lock

Main Roles and Responsibilities of Clinical Research Data Management Specialist

- Performs data entry and processing activities for assigned projects by internal or client Data Management
- Writes data management plans
- Designs clinical trial Case Report Forms (CRF) for database systems
- Creates and monitors data flow and perform quality SOP and regulatory compliance control checks
- Adapts quality assurance procedures for trial case report forms and safety / clinical database
- Assists the design of and development of databases for the studies performed
- Prepares the final archival of data and required study documentation for final study release requirements

Career path

The most common entry level positions in clinical data management field are Data Entry Specialist or Clinical Data Coordinator. Those positions are related with data handling and coordination rather than initiating and designing the trials.

Within career advancement and gaining additional skills and experience, the professional might move step further to higher positions, such as Clinical Data Coordinator I, and Clinical Data Coordinator II.

Do You Know...?

Hiring CDM professionals:

- ✓ 99% of the employers choose candidates with **clinical data management** degree
- ✓ 99% of the employers choose candidates with **clinical research** degree or experience
- ✓ 80% of the employers choose candidates with **bioinformatics** degree
- ✓ 80% of the employers choose candidates with **biotechnology** degree
- ✓ 75% of the employers choose candidates with **computer science** degree
- ✓ 40% of the employers choose candidates with **public health** degree
- ✓ 40% of the employers choose candidates with **biostatistics** degree



Contact Information

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