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.

Overview of the Curriculum

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 TOPICS:
THEORETICAL ASPECT OF THE FIELD

1. Introduction to Clinical Trials
2. Phase I Clinical Trials.
3. Phase II Clinical Trials.
4. Phase III Clinical Trials.
5. Phase IV Clinical Trials.
6. Good Clinical Practice And ICH Guidelines
7. SOP Development
8. Communication With Cross Functional Team
9. Introduction to Clinical protocol
10. Foundation of Clinical Data Management
11. Good Clinical Data Management Practices (GCDMP)
12. Data Management Plan
13. Clinical Trial Data and Its Quality
14. Clinical Data Management System
15. Clinical Data Repository
16. Loading the external data into the CDM system
17. Exporting Data to DMC
18. Clinical trial data cleaning and validation
19. Query Management
20. Data Clarification Form
21. Patient Diaries & Patient Reported Outcome
22. Remote Data Entry
23. Clinical Data Entry - I
    SAE Reconciliation - II
24. Elements of CRF
25. e-CRF Design & Data Tracking
26. Types of Reports Generated
27. Database Locking
28. Clinical Data Archiving

LIST OF EXERCISES:

CASE 1. Introduction to Clinical Trials

CASE 2. Protocol Design and Development

CASE 3. Data Management Plan

CASE 4. Data Cleaning and Data Validation.

CASE 5. Query Management.

CASE 6. Coding of Adverse Events.

CASE 7. SAE Reconciliation.

CASE 8. Elements of CRF.

CASE 9. e-CRF designing, Data tracking from CRF.

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