



Advanced Diploma- Clinical Data Management

Recognized by University of Medicine and Dentistry of New Jersey, USA

Duration: 06 months (4 hrs/ day)

Rationale for Course

Clinical Research has been one of the important facets in the drug development chain/process and it is of paramount importance to understand this growing science in a methodical manner and Of late, it has assumed more significance specifically in India due to wide variety of patient population and many of the Indian Pharmaceutical industries are in search of new chemical entities to bring them into market. Clinical data management is one of the major arms of Clinical Research. High-quality clinical data are at the heart of a successful clinical trial. If the data are not complete or do not reflect the actual reported results, the analysis and the conclusions drawn from that analysis may not be reliable. This diploma in clinical data management course provides detailed understanding on data management in the life cycle of drug development with practical exposure on data collection from investigator sites, validation, analysis and submission of clinical trial data to regulatory agencies.

Who Must Attend

Pharmacy, Medical and Life Science graduates, Graduates with medical knowledge.

Course Benefits

Upon the completion of the course, the participants would gain pragmatic knowledge on drug discovery & pre-clinical research concepts at a macro level; how clinical research would be setup; Understanding of various phases in Clinical Research; Importance of Clinical Data Management, Various tasks that are performed in Clinical Data Management; data standards; regulatory perspectives involved in clinical research and how a trial data/report is being submitted to various regulatory bodies/agencies. This understanding would be of great value addition while performing clinical data management/clinical research tasks.



Brief Description

This course is designed to provide students a detailed understanding on drug discovery, development & regulatory affairs, study design and protocol development with a special emphasis on clinical data management & data standards, Project management, data quality, data security and this course also provide an overview on, clinical biostatistics, pharmacovigilance, protocol writing and clinical study report generation. Live exercises and guest lectures from various pharmaceutical industries would be imparted during this program.

Course Objectives and Outcome

The main objective of this curriculum is to develop experts/skilled resources to perform clinical data management tasks by having a correct spatial orientation of other disciplines of clinical research.

Upon successful completion of this program, Students should be able to:

1. Understand the drug discovery and pre-clinical development
2. Understand the regulatory perspectives on clinical research activities
3. Understand the protocol/study design
4. Understand the database set-up
5. Perform database/procedure testing, data validation, SAE reconciliation and medical coding
6. Have a thorough insight on project management in data management domain
7. Understand the importance of quality in data management and quality control tools/approaches
8. Understand how a pharmacovigilance and medical affairs team function and their dependency on data management
9. Get exposed on various case studies/live scenarios on clinical research
10. Interact with various industry experts of different areas