



Post Graduate Diploma in Clinical Research Management

Recognized by: University of Medicine and Dentistry of New Jersey - School of Health Related Professions (UMDNJ - SHRP), USA.

Duration: 06 months with internship

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.

A Pharma Company incurs an average expenditure of 600 to 900 million dollars (approx 25,000 to 45,000 Crore Rupees) to bring new medicine to market.

The loss per day when a prospective molecule does not reach the market on time is 1 million dollars (4.5 Crore Rupees). The estimated growth in the Biopharmaceutical Industry in next 3 years is 300%.

Many Global Clinical Trials are being conducted in India, therefore the safety of the human subjects; confidentiality and protection of Human Rights are the main issues.

The Pharma / Biotech / Medical Device / Cosmetic Companies outsource their Clinical Trials to Contract Research Organizations in order to save Money and Time.

Many Clinical trials are outsourced to 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.



The Industry is in need of well-trained and skilled professionals in Clinical Research Arena.

SBRI with its proven track record in clinical data management programs has introduced post graduate diploma in clinical research management, which provides detailed understanding on all aspects of clinical research, data management, regulatory guidelines and soft skills for embarking a successful career in clinical research.

Course Coverage

The main objective of this program is to provide overall knowledge in Clinical Research, Data management and soft skills and to develop trained and skilled professionals in the area of Clinical Research Management.

This program is designed to provide a detailed understanding of drug discovery, Clinical Trials, regulatory affairs, Good Clinical Practices, study design, protocol development, Standard Operating Procedures, Adverse effects and safety monitoring, Study Closeout , clinical data management and data standards, project management, data quality, data security, clinical biostatistics, pharmacovigilance, and clinical study report generation.

Advantage

SBRI has a track record of 100% placement of its II batches in Clinical Data Management Program in ICON Clinical Research India Pvt.Ltd; encouraged by the well acceptance from the industry on our quality training we have now introduced one of its kind programs in clinical research management, in association with Helix Research Center Pvt. Ltd. The uniqueness of our program is the emphasis in On-Job Training where the participant of the program will have rare opportunity of learning by experience.



Training Methodology

The course duration is 6 Months. This includes 2 months of intensive class room Training and 4 months of on-job training.

On-line classes will be conducted on Saturday /Sunday during on-job training period.

Assignments and assessments will be given every week. This will be required to submit on or before the next contact class

Training and guest lectures by well experienced practicing professional from industries.

Unique Features

Course Recognized by UMDNJ, one of the Best Medical Universities in United States.

Credit points will be awarded to the successful candidates by UMDNJ

Assured admission for higher studies in UMDNJ to outstanding candidates & Substantial cost saving to those planning to pursue higher studies in U.S

Eligibility

Working professionals, freshers: M.Sc / B.Sc in chemical /biological sciences, BPharm / Mpharm, BTech /MTech BioTechnology, M.B.B.S / B.D.S, B.V.Sc, Degrees in alternate Medicine, Paramedical Branches.

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 Research Management, Various tasks that are performed in Clinical Research; 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.

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, good clinical practices and institutional review boards
3. Understand the protocol/study design
4. Understand the standard operating procedures
5. Gain in-depth knowledge in clinical trial design development & management
6. Gain knowledge on measuring and controlling adverse events and safety monitoring
7. Understand the database set-up
8. Perform database/procedure testing, data validation, SAE reconciliation and medical coding
9. Have a thorough insight on project management in data management domain
10. Understand the quality control tools and approaches
11. Understand how a pharmacovigilance and medical affairs team function and their dependency on data management
12. Get exposed on various case studies/live scenarios on clinical research
13. Interact with various industry experts of different areas