Clinical Research and Data Management

Name of the Department : Department of Botany

Course Directors : Dr. T.V. Ranganathan

Course Coordinator **:** Dr. S. Rajamani

Duration of the Course : 90 hrs

Total No. of Credits : 3

Fees : **Rs.5,000/-**

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Eligibility : 1st and 2nd year UG students

Objective

- To understand the principles involved in the ethical, legal, and regulatory issues in clinical human subjects research, including the role of IRBs.
- To become familiar with the principles and issues involved in monitoring patient-oriented research.
- To understand the infrastructure required in performing clinical research and to have anunderstanding of the steps involved in developing and funding research studies.
- To become familiar with the basic Biostatistical and Epidemiologic methods involved in conducting clinical research.

Syllabus

Unit-1 Introduction to Clinical Research

- **Clinical Research:** An Overview, Different types of Clinical Research.
- **Clinical Pharmacology:** Pharmacokinetics, Pharmacodynamics, Pharmacoepidomology, Bioavailability. Bioequivalence, Terminologies and definition in Clinical Research.

- **Drug Development Process:** Preclinical trail, Human Pharmacology (Phase-I), Therapeutic Exploratory trail (Phase-II), Therapeutic Confirmatory Trail (Phase-III) and Post marketing surveillance (Phase-IV).

Unit-2 Guidelines, Regulation and Ethics in Clinical Research

- **Brief History of Clinical Research:** Sulphanilamide Tragedy, Thalidomide Disaster, Nazi Experiments, Tuskegee Study, Belmont report, Nuremberg code, Declaration of Helsinki principles.
- **Guidelines in Clinical Research-**International Conference on Harmonization (ICH), Guidelines for Good Clinical Practice, ICMR guidelines for Biomedical Research on Human Subjects,.
- **Regulation in Clinical Research-** Drug and cosmetic act, FDA, Schedule-Y- Ethics Committee and their responsibilities.
- **Clinical Research Regulatory Submission & approval Process-** IND, NDA and ANDA submission Procedure. DCGI submission procedure. Other Regulatory authorities- EMEA, MHRA, PhRMA.

Unit-3 Clinical Trial Management

- **Introduction:** Concept of Clinical Trail Management, Stake holders in Clinical Trail project.
- **Sponsors perspective:** Responsibility of Sponsors, Study Preparation Initial Documents and capability assessment, Study feasibility,Vendors/Service provider selection, Investigator selection,Budgeting in Clinical trail, Clinical Trail Agreement(CTA),Regulatory submission and approval, Sponsors obligation in Good Clinical Practice.
- **Investigator perspective:** Investigators obligation outlined in Good Clinical Practice, Recruitment, Retention and Compliance of study subjects, Ethics committee submission, adverse event and safety reporting.
- **Service provider/Vender perspective:** Contract Research Organization (CRO), Site Management Organization (SMO), Central Lab, Clinical Data Management Organization(CDMO), Medical Writing Organization, Logistic Management Organization, Pharmacovigilance Organization.
- **Clinical Research Operation, Monitoring and Clinical Evaluation:** Project management, Protocol in Clinical Research, Informed Consent, Case Report Form, Investigator's Brochure (IB), Selection of an Investigator and Site, Patient screening, Inclusion and exclusion criteria, Randomization, Blinding, Recruitment Techniques (materials and methods),Retention and

complaisance of study subjects, Ethics and Regulatory submission, Monitoring Visits, Investigator Meeting, Essential Document preparation (IB, ICF, PIS, TMF, ISF, CDA.CTA etc).

- **GMP, GLP, QA and QC (Quality Management):** International GMP regulation, Indian GMP regulation, Quality assurance in Pharmaceutical Industry, Quality control in Pharmaceutical Laboratory, GLP principles: Organizational and personal, Quality assurance program, facilities, Equipments, Reagents and Materials, Test systems, Test and Reference Items. Standard Operating Procedure, Performance of study reporting of results, storage of records and reports.
- **Responsibility of Clinical Research Professionals:**Investigator, Project Manager, Regulatory Affairs Associate, Medical Writer, Clinical Research Associate, Clinical Research Coordinator and Safety Report Associate.

Unit-4 Clinical Data Management

- **CDM Systems:** Clinical data management systems, , Electronic data capture systems, Choosing vendor products, Implementing new systems, System validation, Test procedures, Change control, Coding dictionaries, Migrating and archiving Legacy Data,
- **Clinical Data Management process-**Data management Plan, CRF design considerations, Database design considerations, Study setup, Entering Data, Tracking CRF pages, cleaning data, Managing Lab Data, Identifying and Managing the discrepancies, Collecting Adverse Event Data, Coding Reported terms, Creating report and Transferring data, Closing study, SAS in Clinical data analysis, Importing data from Excel to SAS, Statistical analysisof SAS datasets. Standard operating procedures and guidelines for data management.

Unit-5 Pharma Regulatory Affairs

- **Phamacovigilance-**Safety specification and risk management plan, Drug Hypersensitivity, Guidelines in Phamacovigilance.
- **Drug Regulatory Authorities-** Drug policy in India, Regulation on alternative system of Medicine, Safety of Herbal medicines, Medical and Scientific writing.