COURSE TITLE : CLINICAL RESEARCH AND DATA MANAGEMENT

HOURS : 90

CREDIT : 3

COORDINATOR : DR.S.RAJAMANI

DIRECTOR : DR.T.V.RANGANATHAN

TIME : 2.00 p.m. to 5.00 p.m. on working Saturdays
10.00 a.m. to 1.00 p.m. on holiday Saturdays

COURSE FEE : Rs. 5000/- per student

ELIGIBILITY : I, II and III Year Students of CBBT, CZBT, CEB, CBZ, MCB, MCZ, PCM, PEM, EMS, PMC and MEC.

INTRODUCTION ABOUT COURSE

A clinical trial is a research study that tests a new medical treatment or a new way of using an existing treatment to see if it will be a better way to prevent and screen for diagnose or treat a disease. For any new drug to enter in clinical trial, it must pass preclinical studies. Preclinical studies involve in vitro (i.e. test-tube or Laboratory) studies and trials on animal populations. Wide range of dosages of the study drug is given to animal subjects or to an in-vitro substrate in order to obtain preliminary efficacy, toxicity and pharmacokinetic information. Clinical trials aim to measure therapeutic effectiveness and constitute an important and highly specialized form of biological assay.

Pre-clinical studies

Pre-clinical studies involve in vitro (i.e., test tube or laboratory) studies and trials on animal populations. Wide ranging dosages of the study drug are given to the animal subjects or to an in-vitro substrate in order to obtain preliminary efficacy, toxicity and pharmacokinetic information and to assist pharmaceutical companies in deciding whether it is worthwhile to go ahead with further testing.

Phase 0

Phase 0 is a recent designation for exploratory, first-inhuman trials conducted in accordance with the U.S. Food and Drug Administration's (FDA) 2006 Guidance on Exploratory. Investigational New Drug (IND) Studies Phase 0 trials are designed to speed up the development of promising drugs or imaging agents by establishing very early on whether the drug or agent behaves in human subjects as was anticipated from preclinical studies.

Phase I

Phase I trials are the first stage of testing in human subjects. Normally, a small (20-80) group of healthy volunteers will be selected. This phase includes trials designed to assess the safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics of a drug. Phase I trials also normally include dose-ranging, also called dose escalation, studies so that the appropriate dose for therapeutic use can be found. The tested range of doses will usually be a fraction of the dose that causes harm in animal testing.

Phase II

Once the initial safety of the study drug has been confirmed in Phase I trials, Phase II trials are performed on larger groups (20-300) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients. Phase II studies are sometimes divided into Phase IIA and

Phase IIB. Phase IIA is specifically designed to assess dosing requirements (how much drug should be given), whereas Phase IIB is specifically designed to study efficacy (how well the drug works at the prescribed dose(s)). Some trials combine Phase I and Phase II, and test both efficacy and toxicity.

Phase III

Phase III studies are randomized controlled multicenter trials on large patient groups (300–3,000 or more depending upon the disease/medical condition studied) and are aimed at being the definitive assessment of how effective the drug is, in comparison with current 'gold standard' treatment. Because of their size and comparatively long duration, Phase III trials are the most expensive, time-consuming and difficult trials to design and run, especially in therapies for chronic medical conditions. It is common practice that certain Phase III trials will continue while the regulatory

submission is pending at the appropriate regulatory agency. Most drugs undergoing Phase III clinical trials can be marketed under FDA norms with proper recommendations and guidelines.

Phase IV

Phase IV trial is also known as Post Marketing Surveillance Trial. Phase IV trials involve the safety surveillance (pharmacovigilance) and ongoing technical support of a drug after it receives permission to be sold. Phase IV studies may be required by regulatory authorities or may be undertaken by the sponsoring company. The safety surveillance is designed to detect any rare or long-term adverse effects over a much larger patient population and longer time period.

Ethical conduct

Clinical trials are closely supervised by appropriate regulatory authorities. All studies that involve a medical or therapeutic intervention on patients must be approved by a supervising ethics committee before permission is granted to run the trial. The local ethics committee has discretion on how it will supervise nonintervention studies (observational studies or those using already collected data). In the U.S., this body is called the Institutional Review Board (IRB). A clinical trial for any new drug follows under the guidelines of ICH and GCP.

Good Clinical Practice (GCP)

During the clinical research and development process, most medical products will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals. In some cases, as few as 100, and rarely more than 5000 subjects will have received the product prior to its approval for marketing. Given these circumstances and because the decision to allow a new product on the market has such broad public health significance, the clinical trial process and data must conform to rigorous standards to ensure that decisions are based on data of the highest quality and integrity.

The conduct of clinical research in accordance with the principles of GCP helps to ensure that clinical research participants are not exposed to undue risk, and that data generated from the research are valid and accurate.

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 an understanding 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.

SCOPE

- India has been involved in clinical research for the past many years and is now on its way to becoming a major hub for it. The billion dollar industry is already witnessing high demand for qualified professionals.
- There is a massive need for clinical research professionals in this fast-growing field. Clinical research makes an interesting career option with a great scope for professional growth.
- With the arrival of multi-national companies establishing their research facilities in India, this industry is likely to develop exponentially. As per a report, there are over 50,000 clinical research jobs in the country. There is simply a need of qualified professionals. To build a career in clinical research, basic education in this field is necessary.
- After completion of this certificate course, one can seek work in Pharmaceutical Companies, BA/BE Centers, Clinical Contract Research Organizations, Site Management Organizations, IT Firms in Healthcare or Clinical Domain, Data Management Contract Research Organizations, EDC Service Providers, Packaging – Labeling and Contract Manufacturers, Central Laboratories, Investigator and Site Staff, and Training Centers.

CLINICAL RESEARCH AND DATA MANAGEMENT

Syllabus

Unit- 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 analysis of 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.

PROGRAM SCHEDULE

Total	**: 90 hours**
Theory (Including case studies)	**: 60 hours**
Practical	**: 30 hours**
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Fee	**: Rs.5000 per Student**
Eligibility	**: I, II and III Year Students of CBBT, CZBT, CEB, CBZ, MCB, MCZ, PCM, PEM, EMS, PMC and MEC.**
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