M.Sc. CLINICAL RESEARCH

[Syllabus Approved by Board of Studies, Medical & Health Sciences]

Programme Code	:	HLTH17
Programme Details	:	M.Sc CLINICAL RESEARCH
Programme Learning Outcomes (PLOs / PSOs)	:	ANNEXED IN THE BELOW FORMAT.
Eligibility Criteria	:	ONLY INDIAN NATIONALS CAN APPLY. GRADUATION FROM UGC RECOGNISED UNIVERSITY WITH MINIMUM 50% MARKS IN AGGREGATE IN ANY OF THE FOLLOWING SUBJECTS • B.SC. IN BIOSCIENCE/LIFE SCIENCES (BOTANY, ZOOLOGY, BIOCHEMISTRY, MICROBIOLOGY, GENETICS, BIOTECHNOLOGY) • B.SC. IN CHEMISTRY • B.SC. IN CLINICAL NUTRITION • B. SC. IN CLINICAL RESEARCH • PHARMACY OR PHARMACEUTICAL SCIENCE (B. PHARM) • GRADUATE IN MEDICINE (ALLOPATHY, HOMEOPATHY, AYURVEDA, UNANI, SIDDHA) • GRADUATION IN DENTISTRY (BDS) • OCCUPATIONAL THERAPY (B.SC) • PHYSIOTHERAPY (B.SC) • NURSING (B.SC) • PARAMEDICAL TECHNOLOGY
Duration of the Course	:	2 YEARS
Programme Structure (Credit-Based)	:	NA
Detailed Course Syllabus	:	ANNEXED IN THE BELOW FORMAT.
Teaching–Learning Methodologies	:	DIDACTIC LECTURES FOLLOWED BY HANDS-ON EXPERIENCE.

Examination & Evaluation System	**:**	ANNUAL EXAMINATION
Internship / Project / Dissertation Guidelines	**:**	1 YEAR MANDATORY INTERNSHIP
Program In Charge	**:**	PROF. PRIYA RANGANATHAN priya.ranganathan@tmc.gov.in

M.Sc. CLINICAL RESEARCH

Programme Code: HLTH17

Programme Outcome:

- To train the students in various aspects of clinical research – Ethics, Guidelines and Rules; and roles and responsibilities of a clinical research professional.
- This will also enable the individual to be a good trained knowledgeable clinical research person while supporting new drug development and clinical trials.
- To be able to participate in clinical trials management, including planning and execution of the trial and be a part of the multidisciplinary team delivering ethical clinical trials meeting all national and international norms and guidelines.

DETAILED COURSE STRUCTURE

LIST of COURSE			
	COURSE NAME	**SESSION**	**MARKS**
Module-1	Basics of Pharmacy, Drug Discovery and Development	13	800
Module-2	Ethics	13	
Module-3	Clinical Trial Design	12	
Module-4	Roles and Responsibilities of Various Stakeholders in Clinical Research.	12	
Module-5	Quality Control/Quality Assurance in Clinical Research and Pharmacovigilance.	10	
Module-6	Clinical Data Management	12	
Module-7	Epidemiological Studies	6	
Module-8	Special Module (other topics)	6	
	Total	**71**	**800**

*Each session is of 4hrs

COURSES COORDINATOR

LIST OF COURSE		
Course Code	**Course name**	**Course Coordinator**
Module-1	Basics of Pharmacy, Drug Discovery and Development	Dr. Durga Gadgil / Dr. Priya Ranganathan (durgagadgil@gmail.com / drpriyaranganathan@gmail.com)
Module-2	Ethics	
Module-3	Clinical Trial Design	
Module-4	Roles and Responsibilities of Various Stakeholders in Clinical Research.	
Module-5	Quality Control/Quality Assurance in Clinical Research and Pharmacovigilance.	
Module-6	Clinical Data Management	
Module-7	Epidemiological Studies	
Module-8	Special Module (other topics	

DETAILED SYLLABUSES

Module-1: Basics of Pharmacy, Drug Discovery and Development (13 Sessions)

Coordinators: Dr. Durga Gadgil (durgagadgil@gmail.com),
Dr. Priya Ranganathan (drpriyaranganathan@gmail.com)

Course Details:

- Process of drug development and narrowing down to few molecules
- Pre-clinical testing
- Phases of trials
- Basic principles – Bioavailability, Bioequivalence, Pharmacokinetics

Course Outcomes:

- To gain basic knowledge about general medicine, various cancers and its management, how drugs are discovered in the laboratory and in the clinics, what is the importance of conducting research, how clinical research is conducted. Students also learn of important medical terminologies and are introduced to treatment modalities and pharmacological concepts in treatment and management of various diseases.

Module-2: ETHICS (13 Sessions

Coordinators: Dr. Durga Gadgil (durgagadgil@gmail.com), Dr. Priya Ranganathan (drpriyaranganathan@gmail.com)

Course Details:

- **Ethics Part A (Regulations)**
    - History of Ethics and Evolution of Laws
    - Declaration of Helsinki
    - Good Clinical Practice – ICH, Indian GCP, ICMR guidelines, NDCT rules 2019
    - Brief overview of US-FDA and EMEA

- **Ethics Part B (Informed consent)**
    - Informed consent process
    - Informed consent form

Course Outcomes:

- This topic introduces the events in history that led to evolution of Ethics in Clinical Research. It also trains the students on various ethical principles and guidelines which are mandatory to be followed by every clinical research professional.
- It trains the students about rules and regulations to be followed in India and also international guidelines for conducting ethical research, including the informed consent process.
- This module prepares the background knowledge base for becoming a trained clinical research person who can support all types of research activities.
- Students are also taught the Indian regulations and some international regulations in the conduct of clinical trials.

Module-3: Clinical Trial Design (12 Sessions)

Coordinators: Dr. Durga Gadgil (durgagadgil@gmail.com),
Dr. Priya Ranganathan (drpriyaranganathan@gmail.com)

Course Details:

- **Phases of trials – Review**
- **Clinical trials**
  - Study design
  - Randomization
  - Blinding
  - Placebo
  - To cover breaking of blind, simultaneous use of blinded and unblinded groups
  - Basic statistics
- **Elements of a protocol**
  - To cover protocol violation and deviation

Course Outcomes:

- This module introduces the students to the study protocol and how to write a protocol, what are the elements of a good protocol.
- The sessions on statistics prepares the students with basic knowledge of statistical designs and tests which are applied while generating clinical trial data.
- Sessions are devoted to evaluation of safety parameters in a clinical trial.
- Students are assigned protocols for which they have to design the Informed Consent Documents, in the format which meets the guidelines and regulations.
- To understand and apply the knowledge of biostatistics to clinical work
- To understand and interpret available literature relevant to the clinical trials.

Module-4: Roles and Responsibilities of Various Stakeholders in Clinical Research (13 Sessions)

Coordinators: Dr. Durga Gadgil (durgagadgil@gmail.com), Dr. Priya Ranganathan (drpriyaranganathan@gmail.com)

Course Details:

- **Roles and Responsibilities**
  - IRB (Ethics committee)
    - To cover compensation policy
  - Investigator
  - Sponsor
  - CRA/CRC/Monitor
- **Safety Reporting**
  - Adverse event / SAE reporting
  - Data Monitoring and Interim Analysis

Course Outcomes:

- To understand the roles of Ethics Committee members and their responsibilities while reviewing the protocol proposals. The need to have SOPs for their functioning and how to document minutes of the meeting and responses to Investigators.
- To understand the role and responsibilities for Good Clinical Practices while being an Investigator for a clinical trial.
- To understand the role and responsibilities of the Clinical Research Coordinator.
- How to initiate a study at a site, how to monitor the clinical trials, document their findings of the activities and take corrective and preventive actions.
- To understand how to write a monitoring visit report.

Module-5: Quality Control/Quality Assurance in Clinical Research and Pharmacovigilance (10 Sessions)

Coordinators: Dr. Durga Gadgil (durgagadgil@gmail.com), Dr. Priya Ranganathan (drpriyaranganathan@gmail.com)

Course Details:

- **Quality control and Quality Assessment**
  - Overview
  - Essential documents
  - Study files
  - Source documentation
  - Monitoring
  - Audits and Inspections including preparation
  - Training records
  - Standard Operating Procedures
  - CAPA

- **Investigational Product Management**
  - Storage
  - Temperature
  - Accountability
  - Destruction

Course Outcomes:

- To understand what is a study Audit. How audits are conducted and reported.
- To understand how to Audit all study related documents, including study files, essential documents, and informed consents.
- To understand and learn how to take corrective and preventive actions on findings of an Audit (CAPA process)
- To understand how to plan for an inspection and actions needed to facilitate the inspection.

- To learn and understand how to conduct Pharmacovigilance (PV) during clinical trials and in the post-marketing period of a new drug. To learn how to evaluate various adverse events which get reported in clinical trials and after marketing of a drug. Management of reporting timelines for serious adverse events, as per Indian Regulations.

Module-6: Clinical Data Management (12 Sessions)

Coordinators: Dr. Durga Gadgil (durgagadgil@gmail.com),
Dr. Priya Ranganathan (drpriyaranganathan@gmail.com)

Course Details:

- **Data Management**
  - Methods of Data Collection
  - CRF design and types

- **Project Management**
  - Putting it all together – including laboratory management, investigations, processes, recruitment potential, patient recruitment and retention

Course Outcomes:

- To understand various aspects of data management after clinical trial data is generated.
- They learn of the various standards to be applied for data management, quality controls and assurance of the data that is generated.
- How to write a study report after data is generated .
- How to prepare a report for publication in journals or poster presentations or conference presentations

Module-7: ModuleEpidemiological Studies (6 Sessions)

Coordinators: Dr. Durga Gadgil (durgagadgil@gmail.com),
Dr. Priya Ranganathan (drpriyaranganathan@gmail.com)

Course Details:

- Basic concepts
- Surveillance systems to understand disease burden
- Design and planning of Epidemiological studies including field intervention trial
- Quality control and good Epidemiological practices
- Epidemiology field work in Population Based studies
- Ethical aspects of Epidemiological research

Course Outcomes:

- To understand various types of Epidemiological studies.
- To learn how the data helps in disease prevention.
- To understand the importance of screening and public health studies

Special Module: Other topics

Coordinators: Dr. Durga Gadgil (durgagadgil@gmail.com),
Dr. Priya Ranganathan (drpriyaranganathan@gmail.com)

- Newer techniques in Clinical research (1 Session) (09-HLTHI7-608-C)

- Clinical Research in Vaccines, Medical Devices (2 Sessions) (09-HLTHI7-610-C)

- Investigator-initiated studies – special issues (1 Session) (09-HLTHI7-611-C)

- Epidemiological Studies (1 Session) (09-HLTHI7-612-C)

- Communication skills (1 Session) (09-HLTHI7-609-C)

Course Outcomes:

- Students get to know of newer developments in clinical research tools that can be used
- Clinical research professionals require skills in verbal and written communications. They also need to learn how to present themselves at hospitals and with site study team members.
- To learn how to present at conferences by using various techniques for making a presentation, e.g. power-point presentations.
- Clinical Research professionals learn how to interact with peers, juniors, doctors and other site staff. Some skills are required while interacting with patients too. All this is covered in this class.
- To learn and understand how academic studies are conducted.
- How to conduct multi-centre academic studies.
- How to manage such investigator-initiated studies, including planning for adequate funds for such studies.

- To appraise and sensitize students of how clinical research needs to be conducted with Vaccines, Medical Devices.
- To learn what rules and regulations and guidelines govern studies with vaccines and medical devices.
- To appraise and sensitize students of how clinical research needs to be conducted with Herbal/Ayurvedic medicines.
- To learn what rules and regulations and guidelines govern studies with herbal and Ayurvedic drugs.