Pre Ph.D. (Clinical Research)

School of Pharmaceutical & Population Health Informatics

DIT University Dehradun

Course Structure
for
Pre Ph.D. (Clinical Research)
Course Work
Session: 2020-21

Approved by the Board of Governors

Pre Ph.D. (Clinical Research)

DIT UNIVERSITY, SCHOOL OF PHARMACEUTICAL & POPULATION HELATH INFORMATICS & INSTITUTE OF CLINICAL RESEARCH (INDIA)
PhD CLINICAL RESEARCH
PROGRAM STRUCTURE

ACADEMIC YEAR 2020-2023

SEMESTER -I						
Papers		**Total Marks**	**Credits**			
Course Code	**Title**		**L**	**T**	**P**	**Total**
MB901	Research Methodology	100	4	0	0	4
PH711	Seminar	75	1	0	0	1
CPE-RPE	Research Publication Ethics	100	2	0	0	2
Electives (Any Two)						
CR701	Basics in clinical research	100	4	0	0	4
CR702	Bioethics in clinical Research	100	4	0	0	4
CR703	Regulatory Aspects of Clinical Research	100	4	0	0	4
Total		**475**	**15**			

B) Thesis work

Pre Ph.D. (Clinical Research)

Subject Code	MB901	Subject Title	Research Methodology						
LTP	4 0 0	Credit	4	Subject Category	UC	Year	1st	Semester	I

Contents

Unit I: Introduction to Research

Methodology and Method, Types of research- Descriptive vs. Analytical, Applied vs. Fundamental, Quantitative vs. Qualitative, Conceptual vs. Empirical, Concept of Interdisciplinary Research, Procedures in research, Identification of the problem-Literature survey, Experimental methods, Quasi-experimental studies- Survey, Types of surveys- CATI, CAPI, Mail, Email, Face-to-face, Questionnaire

Unit II: Sampling and Analysis

Discourse analysis, Biographical Data Analysis, Primary and secondary data, Collection and validation, Methods of sampling- Simple random sampling, Stratified random sampling and Systematic sampling, Attitude Measurement- land Scales, Scaling of attitude , Deterministic attitudes, Measurement models, Summative models.

Unit III : Experimental design and Hypothesis

Factorial experimental design,Designing experiments, Basic principles- replication,randomization, blocking. Single Factor Experiment: Hypothesis design, Hypothesis testing using z- test, t-test, ANOVA etc., Analysis of Variance Components (ANOVA) for
fixed effect model, Sum of squares of treatments (SST), Sum of squares of error (SSE),Degrees of freedom, Confidence interval, ANOVA for random effects model, Model adequacy checking.

Unit IV: Computer Application

Introduction to spread sheet application, Features and functions, Using formulas and functions, Data storing, Features for Statistical data analysis, Generating charts/ graph and other features, Power point presentation, Use of software for statistical analysis such as SPSS.

Unit V: Research Report

Type of research report- contents, Steps in drafting, Editing and evaluating the final draft,Styles for figures, tables, text, quoting of reference and bibliography, Use and format of appendices- Indexing, Structure and presentation of research report, Research ethics,plagiarism.

Reference Books

1. Research Methodology: Methods and Techniques, CR Kothari
2. Research Methodology, D K Bhattacharyya
3. Research Methodology, P. Sam Daniel

Pre Ph.D. (Clinical Research)

Subject Code	CR701	Subject Title	Basics in Clinical Research						
LTP	4 0 0	Credit	4	Subject Category	UC	Year	1st	Semester	I

UNIT 1: Introduction to Clinical Research

Definition and need of Clinical research, Areas of Clinical research, Phases of Drug Discovery and development. Overview of preclinical and clinical trials.

UNIT 2: Phases and Types of Clinical Trials

Introduction to Clinical Trials, Phases of Clinical Trials Phase I –aims of phase I – selection of volunteers-informed consent-protocol –design of study, Phase II- Therapeutic exploratory –objectives of phase II-Phase IIa; Phase IIb- regulatory requirements. Phase III- Therapeutics confirmatory – Objectives of phase III- design of Phase III-protocol-regulatory requirements, Phase IV – Post marketing Studies- Aims ,Objectives and Procedures, Types of Clinical Trials: Randomized/Non randomized Clinical Trial, Observational studies: Prospective and Retrospective Studies, E-clinical trials- introduction-advancement in drug discovery and development – cutting costs in clinical trial.

UNIT 3: BA/BE Studies

Bioavailability and Bioequivalence – Definition, Needs, Methods and Procedures, factors affecting Bioavailability Bioequivalence/ Therapeutic Equivalence, Study parameters: Tmax, Cmax, AUC, t1/2, Test method to assess Bioequivalence, Steady State studies, Regulatory requirements, planning & design, Protocol/ CRF outline, QA & QC, Drug accountability, Elements of BE study

Unit 4: Clinical Trial Design

Different types of trial design , Prospective Trials , Retrospective Clinical Trials, Cross- Sectional vs Longitudinal trials, Parallel Designs, Cross Over designs , Factorial Designs, Observational Studies , Quality of Life Studies , Future of QoL Trials, Multicentre Trials-Advantages and Disadvantages ,Golden Rules, Administrative Considerations, Single Patient Clinical Trials, Purpose of Single Clinical Trials, Types of Single Patient trial designs, Trials in Special Population- Elderly , Children, Surgical Trials, Types of Surgical Trials

Unit 5: Clinical Measurements

Types of Efficacy Criteria, Efficacy Endpoints, Clinical Scales, Visual Analog Scales ,Patient Diaries, , Safety Endpoints, No control , Sources of Bias-Subject Bias , Investigator bias , Selection Bias , Instrument bias , Instrument Bias, Publication Bias

Unit 6 : Blinding and Randomization

Simple , Block , Stratified, Cluster, Unequal Minimization , Blinding – Open Label , Single , Double and Triple Blinding, Breaking the code/Blind in Clinical Trials. Fraud and Misconduct in Clinical trials.

Pre Ph.D. (Clinical Research)

Unit 7: Drug safety in Clinical Trials and Pharmacovigilance

Introduction of Pharmacovigilance, Adverse Events, Causality assessment, Data safety monitoring boards, Types of Survillence , Spontaneous reporting, ICH E2A Guidelines

Reference Books

1. Conducting Clinical Research- A practical guide, Judy Ann Stone
2. Fundamentals of Clinical Research: Bridging Medicine, Statistics and Operations, Antonella Bacchieri, Giovanni Della Cioppa
3. Manual of Drug Safety and Pharmacovigilance, Barton L. Cobert
4. Statistics at Square One by MJ Campbell and TDV Swinscow
5. Statistics at Square Two by MJ Campbell
6. Designing Clinical Research by Stephen Hulley , Steven Cummings , Warren Browner ,Deborah Grady and Thomas Newman

Pre Ph.D. (Clinical Research)

Subject Code	CR702	Subject Title	Bioethics in Clinical Research						
LTP	4 0 0	Credit	4	Subject Category	UC	Year	1st	Semester	I

Unit 1: Background of ethics in CR

a historical overview; Codes related to ethics: highlights of Nuremberg code, Declarations: contents of Declaration of Helsinki and its importance Ethical Guidelines: the Belmont Report, C.I.O.M.S (W.H.O) guidelines

Unit 2: Ethical Issues & Special ethical considerations in Clinical Trial Design

Ethical Issues in RCT. Use of Placebo, Vulnerable Subjects; Ethics in Stem Cell Research, Transplantation, Assisted Reproductive Technologies; Biotech products and Medical devices.

Unit 3: Institutional Review Board & Independent Ethics Committee

Composition, Power and Review procedure; Ethics Committee: Role and responsibilities in a clinical trial, Conflict of interest in Clinical research: types of conflicts of interest and its avoidance

Unit 4 : Informed consent

Historical overview, protection of subjects, Informed consent process, Patient Information Sheet, Informed Consent form, HIPAA.

Unit 5: Insurance and Indemnity

Types of insurance, contractual agreements, Human volunteers & Compensation, Privacy and confidentiality in clinical research, Consumer Protection Act.

Unit 6- ICMR

ICMR Guidelines for Biomedical Research, CTRI (India)- WHO ICTRP.

Reference Books:

1. The Oxford Textbook of Clinical Research Ethics, Ezekiel J. Emanuel
2. Reviewing Clinical Trials: A Guide for the Ethics Committee, Johan Petter Einar Karlberg
3. Ethics in Clinical Research, Dr. Jane Barrett

Pre Ph.D. (Clinical Research)

Subject Code	CR703	Subject Title	Regulatory Aspects of Clinical Research						
LTP	4 0 0	Credit	4	Subject Category	UC	Year	1st	Semester	I

Unit 1 – Schedule Y

History and Background of Regulations, Food drug and cosmetic Act/ Rules of 1938, Drugs and Cosmetic Act 1945 , CDSCO Structure and Functions , Schedule Y and Appendices to Schedule Y and recent amendments.

UNIT 2– ICH-GCP Regulations

Background of drug regulations, International Conference on Harmonization, history of ICH, ICH Structure ICH Guidelines, Good Clinical Practice- Elements and principle of GCP

UNIT 3 - Other Country Regulations

Regulatory Requirements in USA, Europe,Australia

Unit 4– Medical Devices and Orphan drugs

Global Regulations for Medical Devices, Classification of medical Devices, Regulatory agencies and regulations, Clinical Trials of Medical Devices.Drug Development for orphan's diseases and Drug legislation

Unit 5: Herbal Regulations

Regulations for Herbal Drugs in India, USA,UKMHRA and EUROPE

Unit 6- Patents and TRIPS

Patent, Intellectual Property Rights, Trademarks, Copyright, Infringement of patents, Claim for Patent, USPTO, Indian Patent Laws, TRIPS-GATT/WTO, Doha Declaration.

Reference Books:

1. Ethical and Regulatory Aspects of Clinical Research, Ezekiel J. Emanuel
2. Principles of Good Clinical Practice, Michael J. McGraw, Adam N. George, Shawn P. Shearn, Thomas F. Haws, Jr., Rigel L. Hall
3. Drug Discovery and Clinical Research, S. K. Gupta