Hindi Vidya Prachar Samiti's

RamniranjanJhunjhunwala College

Of Arts, Science & Commerce

(Autonomous College)

Affiliated to
UNIVERSITY OF MUMBAI

Syllabus for the Post Graduate Diploma

Program: Post Graduate Diploma in Clinical Studies, Data Management and Medical Writing

Program Code: RJSPGDCSDMMW

(Revised Syllabus Academic year 2020-2021)

Post Graduate Diploma in

Clinical Studies, Data Management and Medical Writing

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Preamble:

Clinical research has led to medical advances benefiting mankind. Clinical research is performed on human beings to evaluate safety and efficacy of a new treatment or a new drug. Clinical trial is aimed to evaluate if the medical intervention is more effective and less harmful than the standard treatment. Regulatory authorities approve or reject the marketing of the drug depending on the data obtained from clinical trial. Professional in the specialized industry of clinical research need to have good knowledge of International Conference on Harmonization Good Clinical Practices guidelines. Different level of training is needed at different functional levels of clinical research due to the complexity of overall drug development process. Clinical data management focuses on clinical trial data collection and data management. Methodical and scientific knowledge with good basic writing skills is essential for medical writing. In additional to technical skills, good interpersonal skills and excellent communication is essential for clinical research professional.

Post Graduate Diploma in Clinical Studies, data management and medical writing offers essentials of clinical research in a profound and concise manner to understand the overall process of drug development. The course emphasizes the theoretical and ethical clinical research and practical aspects of conducting clinical trials. The course is ideal for Graduates with the background of Life Science / Biotechnology / Chemistry / Statistics to build qualification and expertise to enter into the exciting world of clinical research. Real-world clinical trial case studies reinforce the knowledge of clinical studies that will help individuals accelerate their career in clinical research.

Program Objectives and Outcomes:

This course is based on systematic teaching, learning and evaluation techniques. Quality based training, comprehensive coaching by experts from industry professionals and dynamic mentoring will fulfill following objectives.

- To understand the overall drug development process in compliance with ICH GCP, regulatory guidelines and ethics
- To identify and differentiate designs and phases of clinical trial and comprehend about the responsibilities of different stakeholders
- To consider the process of monitoring and managing a clinical trial conducted at the study site
- To understand the basics of clinical data management
- To contemplate the rationale of pharmacovigilance and medical writing

Title: Post Graduate Diploma in Clinical Studies, Data Management and Medical Writing

Eligibility: Bachelor's Degree in Life Science / Biotechnology / Chemistry / Statistics

Duration of the course: One Year (Part time) Blended teaching weekends

Fee Structure:

Tuition Fee	:	35,000.00
RFID	:	150.00
Examination Fees	:	500.00
Application form fees	:	Rs 100.00

Intake capacity: 40 students

Faculty: Industry and Academia Professional in area of Clinical research, Pharmacy, Clinical Data Management, Pharmacovigilance and Medical writing

Standard of Passing:

a. Candidate who secures minimum 50% marks in each paper be declared to have passed the examination in that subject.
b. A candidate who fails to secure 50% marks in a paper will be allowed to reappear in that paper.
c. Candidate can carry forward at his/her option the marks in the paper in which he/she has passed, in such a case student is entitled for award of class.
d. Candidate who secures a minimum of 50% marks in each paper and an aggregate of 60% and above marks on the whole shall be declared to have passed the examination in the First Class.
e. Candidate who secures a minimum of 50% marks in each paper and an aggregate of 70% and above marks on the whole shall be declared to have passed the examination in First Class with Distinction.

Medium of Instruction: English

Scheme of Evaluation: There would be continuous evaluation

- Internal assessment: 40% weightage - multiple choice questions, quiz, assignments, case studies
- External assessment: 60% weightage - subjective questions

SEMESTER I

PAPER	TITLE OF PAPER	INTERNAL		EXTERNAL		CREDITS	COURSE CODE
		Maximum	Minimum	Maximum	Minimum		
I	Clinical Pharmacology and Toxicology	40	16	60	24	8	RJSPGDCSDMMW101
II	Good Practices & Ethics	40	16	60	24	8	RJSPGDCSDMMW102
III	Clinical Trial Processes	40	16	60	24	8	RJSPGDCSDMMW103
	Total	**120**	**48**	**180**	**72**	**24**	

SEMESTER II

PAPER	TITLE OF PAPER	INTERNAL		EXTERNAL		CREDITS	COURSE CODE
		Maximum	Minimum	Maximum	Minimum		
I	Regulations	40	16	60	24	8	RJSPGDCSDMMW201
II	Pharmacovigilance	40	16	60	24	8	RJSPGDCSDMMW202
III	Clinical Data Management & Medical Writing	40	16	60	24	8	RJSPGDCSDMMW203
	Total	**120**	**48**	**180**	**72**	**24**	

Total (600) = Internal (240) + External (360) **Total Credits =** 48

SEMESTER I

Paper I: Clinical Pharmacology and Toxicology **8 Credits**

UNIT – 1:

Pharmaceutical Industry & globalization –Overview, Opportunities & Career options in Clinical Research

UNIT – 2:

Pharmacy - Physico-Chemical properties of drugs, different drug dosage forms, Formulation development and manufacture of drugs.

Therapeutics - Principles of Management & Drug Therapy

UNIT – 3:

Pharmacokinetics - Absorption, bioavailability, distribution, metabolism protein binding, excretion, placental and blood brain barrier

Pharmacodynamics - Mechanism of drug action, receptors, agonists, antagonists, side effects and adverse events

UNIT – 4:

Toxicology - Acute, Sub-acute and Chronic Toxicity, Mutagenicity, Teratogenecity, Oncogenicity and effects on **fertility; pre-clinical studies**

Paper ll: Good Practices & Ethics **8 Credits**

UNIT – 1:

Good Manufacturing Practices, Good Laboratory Practices

UNIT – 2:

International Conference on Harmonization, Good Clinical Practices

UNIT – 3:

History of Ethics in Clinical Research and Ethics Committee

UNIT – 4:

Belmont Report, Nuremberg Codes, Declaration of Helsinki

Paper lll: Clinical Trial Processes **8 Credits**

UNIT - 1:

Responsibilities of Stakeholders: Sponsors, Investigators, CROs, Monitors; Clinical Trial Designs

UNIT – 2:

Clinical Trial Phase I, Phase II, Phase III, Phase IV

UNIT – 3: Essential Documents in Clinical Trials:

SOP, Protocol, Investigator Brochure, Master Files, Informed Consent Forms, Case Record Form

UNIT – 4:

Managements of Clinical Trials - Investigator's Meeting, Project management, Patient Recruitment & Retention, Trial Monitoring, Drug Resource and supplies; Trial Budget, Audit and Inspection

SEMESTER II

Paper I: Regulations **8 Credits**

UNIT – 1:

BA/BE Studies - Bioavailability and Bioequivalence - Methods and Procedures, regulatory requirements, planning & design, Protocol/ CRF outline, QA & QC, Drug accountability

UNIT – 2:

Regulation in India: Drugs and Cosmetics Act, Schedule 'Y', Quality in Regulatory Context, Patent laws; **ICMR**

UNIT – 3:

USFDA: History, Structure & Function, Code of Federal Regulation

UNIT – 4:

EMEA: History, Structure & Function, Regulations;

JAPAN :History, Structure & Function

Paper II: Pharmacovigilance **8 Credits**

UNIT – 1:

Overview of Pharmacovigilance: Importance; National & International Programs; Methods

UNIT – 2:

Principles of Pharmacovigilance: ADR; Assessment; Medication errors, Signal detection; Risk assessments

UNIT – 3:

Drug Dictionaries: Coding & Tools; **Drug Safety**: PSURs; Package inserts

UNIT – 4:

Regulatory Guidelines: ICH, EMEA, USFDA, Sch. 'Y'

Paper lll: Clinical Data Management & Medical Writing **8 Credits**

UNIT – 1:

Biostatistics: Descriptive Statistics - Data Types; Collection; Sampling, Compilation; Tables & Graphs, Measures of Central Tendency, Measures of variation

UNIT – 2:

Clinical Data Management: Overview, scope, terminologies; Principles of CDM

UNIT – 3:

Clinical Data Management: Data Entry, Queries & Data Clarification, Electronic Data Capture, Software in CDM

UNIT – 4:

Medical Writing: Literature Search & Medical Articles, Contract writing, Publication, Abstracts, Bibliography, Clinical Study Reports

List of Reference Books:

1. Research in education by J W Best and J V Khan Prentice Hall of India, New Delhi (1995).
2. Pharmaceutical Statistics by Sanford Bolton, Marcel Dekker, New York, USA, Informa Healthcare; 4 edition (October 17, 2003).
3. Elementary Statistical Quality Control, Volume 25, Burr, I. W. (1979), New York: Marcel Dekker, Inc.
4. Managing the clinical drug development process, C. Nardi, Marcel Dekker, New York, USA (1991).
5. Basic managerial skills for all by E H Mcgrath, Prentice Hall of India, N.Delhi (2002).
6. Clinical Research Environment in India by Umakanta Sahoo, Faiz Kermani, ICFAI University Press (2008).
7. Clinical Trials. Lelia Duley and Barbara Farrell (eds), BMJ Books, London, 2002.
8. Handbook for good clinical research practice WHO Library Catalogue.
9. Articles: ICH-GCP, Schedule Y, US FDA guidelines, WHO Guidelines.
10. Bioavailability and Bioequivalence in pharmaceutical technology by Tapan Kumar and Ganeshan M, CBS publishers and distributers(2006).
11. Design of experiments. A realistic approach by V L Anderson and Robert Mclean, Marcel Dekker, New York, USA (1974).
12. Fundamentals of Clinical Research: Bridging Medicine, Statistics and Operations, Antonella Bacchieri and Giovanni Della Cioppa, Springer (2007)