Academic Council Meeting No. and Date : 8 / July 06, 2023

Agenda Number : 4 **Resolution Number : 32**

Vidya Prasarak Mandal's
B. N. Bandodkar College of Science (Autonomous), Thane

Syllabus for

Programme: Post Graduate Programme in Clinical Studies, Data Management & Medical Writing

Revised under Autonomy

From academic year

[2023-2024]

Preamble

To verify the safety and efficacy of particular healthcare methods and products, clinical research is required. A lot of Randomized controlled clinical trials have provided the majority of today's knowledge regarding the security and effectiveness of particular products and therapies, trials that aim to address crucial scientific and health questions care inquiries. It all starts with randomized controlled trials. “Evidence-based medicine," yet this type of study can be trusted only if it is carried out in accordance with the guidelines and standards known as "Good Clinical Research Practice" (GCP).

"Any proposal involving human subjects, including healthy volunteers, that cannot be regarded as a component of recognized clinical management or public health practice and that involves either I physical or psychological intervention or observation, or both physical and psychological intervention and observation, or collecting, storing, and disseminating data related to individuals. This definition applies to studies in which environmental factors are taken into account as well as planned experiments involving human beings are modified in a manner that can unintentionally expose people unnecessary hazards." World Health Organization governance, laws, and regulations XVII of the WHO Manual.

Medical products must pass a series of tests aimed at evaluating their safety and efficacy within the constraints of toxicity, potency, dose finding, and field conditions before being put on the market or included in public health initiatives. The therapeutic indications, the mode of administration, the dosage, the warnings, the safety precautions, the interactions, the effects on the target populations, and the safety information must all be fully disclosed in the documentation.

Most medical items will only have been examined for short-term safety and efficacy on a small number of carefully selected people during the clinical research and development process. As few as 100 people, and very rarely as many as 5000, may have received the product before it was given the all-clear for sale. The clinical trial process and data must adhere to strict requirements to guarantee that judgments are based on data of the highest quality and integrity in light of these circumstances and the fact that the decision to let a new product on the market has such broad implications for public health.

The Post Graduate Programme in Clinical Studies, data administration, and medical writing provide clinical research principles in a thorough and adequate academic to understand the entire drug development process. The practical elements of running clinical trials are emphasized, as well as theoretical and ethical issues of clinical research. For graduates with a background in life science, biotechnology, chemistry, or any biological science, the course is an excellent opportunity to acquire qualifications and skills for joining the exciting field of clinical research sector. Real-world clinical trial case studies enhance clinical trial expertise by studies that will aid people in advancing their clinical research careers.

Eligibility:
Bachelor Degree in Life Science/Biological Science/Microbiology/Biochemistry/Biotechnology or Chemistry

Duration:
One-year blended teaching weekends

Mode of Conduct:
Offline and Online Lecture

Program Specific Outcome

- The primary objective of this course is to develop specialists or trained professionals who can handle massive clinical research procedures while adhering to the proper standards, laws, and directions for clinical research.
- Participants will gain a fundamental understanding of the theories and procedures governing clinical trials in the CRO and pharmaceutical industries through the course.
- The course also seeks to give participants a better understanding of the risks and advantages of medications used in people, as well as the origin, symptoms, and impact of adverse drug reactions.
- The course's key components include the regulatory perspectives on clinical trials, pharmaco-vigilance, and project management.

Learning Outcome

1. Understanding the protocol or study design and the concept of clinical trials.
2. To evaluate databases or procedures, validate data, reconcile SAEs, and code medical information.
3. To become acquainted with how drugs are developed
4. To understand the ethical and legal stances on the operational processes of clinical research trials.
5. To understand how the Project Management and Medical Affairs teams work with various stakeholders and conduct pharmacovigilance.

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VPM's B.N.Bandodkar College of Science (Autonomous), Thane

Post Graduate Programme in Clinical Studies, Data Management and Medical Writing

Structure of Programme

SEMESTER I

Course Code	Course Title	No. of lectures	Credits
BNBPGPCS101	Clinical Pharmacology and Toxicology	**120**	**08**
BNBPGPCS102	Regulations & Good Practices	**120**	**08**
BNBPGPCS103	Clinical trial process	**120**	**08**
Total		**360**	**24**

SEMESTER II

Course Code	Course Title	No. of lectures	Credits
BNBPGPCS201	Guidelines, Regulation, and Ethics in Clinical Research	**120**	**08**
BNBPGPCS202	Pharmacovigilance and Drug Safety	**120**	**08**
BNBPGPCS203	Management of data and Medical Writing	**120**	**08**
Total		**360**	**24**

Semester I

Course Code BNBPGPCS101	Course Title Clinical Pharmacology and Toxicology	Credits 8	Lecture 120
Unit I	**Pharmaceutical Industry & globalization** Introduction to Clinical Research. Terminologies and definition in Clinical Research. Difference between Clinical Research and Clinical Practice. Types of Clinical Research. Phases of clinical research. Clinical Trials in India –The National Perspective. Pharmaceutical Industry – Global and Indian Perspective. Clinical Trial market. Career in Clinical Research. **Case Studies -** India is becoming a hot destination for clinical research		**30**
Unit II	**Pharmacology and drug development** Introduction to Pharmacology. Concept of Essential Drugs. Routes of Drug Administration. Introduction to Drug Discovery and Development. Sources of Drugs Basics of Drug Discovery & Development. Emerging technologies in Drug Discovery. Preclinical Testing. Investigation New Drug Application. Clinical trials. New Drug Application and Approval **Case study:** Siram Pharmacy drug development.		**30**
Unit III	**Therapeutics & Pharmacy** **Therapeutics** - Principles of Management & Drug Therapy and administration. **Pharmacy** - Physico-chemical properties of drugs, different drug dosage forms, Formulation development and manufacture of drugs. **Case study**		**30**
Unit IV	**Toxicology** Acute, Sub-acute and Chronic Toxicity, Mutagenicity, Teratogenicity, Oncogenicity and effects on fertility.		**30**

Course Code BNBPGPCS102	Course Title Regulations & Good Practices	Credits 8	Lecture 120
Unit I	**BA/BE Studies** Methods and Procedures for Bioavailability and Bioequivalence, Regulatory Requirement, Planning & Design, Protocol/ CRF Outline, QA & QC, and Drug Accountability		**30**
Unit II	**Regulation in India** Drug and cosmetic act, FDA, Schedule-Y- Ethics Committee and their responsibilities, patent laws & ICMR Overview.		**30**
Unit III	**USFDA** History, Structure & Function, Code of Federal Regulation.		**30**
Unit IV	**EMEA & JAPAN** **EMEA:** Introduction, Organizational & Function, and Regulations. **JAPAN**: History, structure, and function.		**30**

Course Code BNBPGPCS103	Course Title Clinical Trial Process	Credits 8	Lecture 120
Unit I	**Responsibilities of Stakeholders** Sponsors, Investigators, CROs, Monitors.		**30**
Unit II	**Clinical Trial Phase** Preclinical trail, Human Pharmacology (Phase-I), Therapeutic Exploratory trail (Phase-II), Therapeutic Confirmatory Trail (Phase-III) and Post marketing surveillance (Phase-IV).		**30**
Unit III	**Essential Documents in Clinical Trials** SOP, Protocol, Investigator Brochure, Master Files, Informed Consent Forms, Case Record Form		**30**
Unit IV	**Managements of Clinical Trials, Budget & Audit** Investigator's Meeting, Project management, Patient Recruitment & Retention, Trial Monitoring, Drug Resource and supplies. Trial Budget, Audit and Inspection		**30**

Semester II

Course Code BNBPGPCS201	Course Title Guidelines, Regulation and Ethics in Clinical Research	Credits 8	Lecture 120
Unit I	**Brief History of Clinical Research** Sulphanilamide Tragedy, Thalidomide Disaster, Nazi Experiments, Tuskegee Study, Belmont report, Nuremberg code, Declaration of Helsinki principles.		**30**
Unit II	**Guidelines in Clinical Research** International Conference on Harmonization (ICH), Guidelines for Good Clinical Practice, ICMR guidelines for Biomedical Research on Human Subjects.		**30**
Unit III	**Regulation in Clinical Research** Drug and cosmetic act, FDA, Schedule-Y- Ethics Committee and their responsibilities.		**30**
Unit IV	**Clinical Research Regulatory Submission & approval Process** IND, NDA and ANDA submission Procedure. DCGI submission procedure. Other Regulatory authorities- EMEA, MHRA, PhRMA.		**30**

Course Code BNBPGPCS202	Course Title Pharmacovigilance and Drug Safety	Credits 8	Lecture 120
Unit I	**Pharmacovigilance** Importance; National & International Programs; Methods.		**30**
Unit II	**Principles of Pharmacovigilance** ADR; Assessment; Medication errors, Signal detection; Risk assessments.		**30**
Unit III	**Dictionary of Drugs** Drug Safety: PSURs; Coding & Tools; Package Inserts		**30**
Unit IV	**Regulatory Requirements** Sch. 'Y', ICH, EMEA, and USFDA		**30**

Course Code BNBPGPCS203	Course Title Management of data and Medical Writing	Credits 8	Lecture 120
Unit I	**Bio-Statistics and Descriptive Statistics** Types of data; Collection; Sampling, Compilation; Measures of Central Tendency, Measures of variation.		**30**
Unit II	**Basic Excel for Data Entry** Basics of Excel, Tables & Graphs, Basic Excel Formulas, Data Entry in Excel		**30**
Unit III	**Clinical Data Management**: Principles of CDM, Data Entry, Queries & Data Clarification, Software's in CDM.		**30**
Unit IV	**Medical Writing:** Searching the literature and medical articles, drafting contracts, publishing, abstracts, bibliographies, and clinical study reports.		**30**

List of Reference Books:

1. An Introduction to Pharmacovigilance Kindle Edition
2. Articles: ICH-GCP, Schedule Y, US FDA guidelines, WHO Guidelines.
3. Basic managerial skills for all by E H Mcgrath, Prentice Hall of India, N.Delhi (2002).
4. Bioavailability and Bioequivalence in pharmaceutical technology by Tapan Kumar and Ganeshan M, CBS publishers and distributers (2006).
5. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
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. Design of experiments. A realistic approach by V L Anderson and Robert Mclean, Marcel Dekker, New York, USA (1974).
9. Elementary Statistical Quality Control, Volume 25, Burr, I. W. (1979), New York: Marcel Dekker, Inc.
10. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
11. Fundamentals of Clinical Research: Bridging Medicine, Statistics and Operations, Antonella Bacchieri and Giovanni Della Cioppa, Springer (2007) .
12. Handbook for good clinical research practice WHO Library Catalogue.
13. Managing the clinical drug development process, C. Nardi, Marcel Dekker, New York, USA (1991).
14. Organizational Behavior, John W Newstrom, Keith Davis, Tata McGraw Hill, New Delhi (2002) 7.
15. Pharmaceutical Statistics by Sanford Bolton, Marcel Dekker, New York, USA, Informa Healthcare; 4 edition (October 17, 2003).
16. Pharmacovigilance: A Practical Approach Kindle Edition
17. Research in education by J W Best and J V Khan Prentice Hall of India, New Delhi (1995).
18. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green,March 2005, John Wiley and Sons.
19. Textbook of Pharmacovigilance (India) [Print Replica] Kindle Edition.

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