Course Code	Course Name	Credits
	CLINCAL RESEARCH AND PHARMACOVIGILANCE	**2**

Category: Value added Course

a. Preamble

This course provides students

- Comprehensive practical knowledge of the clinical research and drug development processes, regulatory affairs and essential documentations.
- Training on clinical research and pharmacovigilance (PV) related issues.

b. Course Outcomes

After successful completion of the course, the students will be able to

CO.No.	Course Outcome	Knowledge Level
CO1	Explain the regulatory requirements for conducting clinical trial	K2
CO2	Perform appropriate documentational requirements for Clinical trials	K3
CO3	Apply basic concepts of Pharmacovigilence	K3
CO4	Perform ADR reporting, methods and other tools used in Pharmacovigilence	K3
CO5	Analyse the adverse drug reaction and its management	K4

c. Course Syllabus **Total: 30 Hours**

CLINICAL RESEARCH **10**

Basic of clinical Research including Overview, Basic of Clinical Pharmacology, Drug Development process; Clinical Trial Design and trial Documents; Ethics, Guidelines & Regulations; Roles and Responsibilities of CR professional, Forms Filing.

CLINICAL DATA MANAGEMENT **10**

Overview of CDM; 21CFR part 11-EDC; CDISC Regulations, GCDMP; Protocol review and CRF design; Database setup, design, and validation; Data entry and

validation; Coding and dictionaries; Database lock. Good Clinical Practice (GCP), SAS® Programming.

PHARMACOVIGILANCE **10**

Aim, Roles, KPI, Databases, ICH Guidelines, Global PV Laws & Regulations, Medical coding, ICD-10, Naranjo Algorithm

d. Learning Resources

i. TEXT BOOKS

1. Friedman, Lawrence M., Curt D. Furberg, David L. DeMets, David M. Reboussin, and Christopher B. Granger. *Fundamentals of clinical trials*. springer, 2015.
2. Doan, Thao, Linda Scarazzini, Cheryl Renz, Fabio Lievano, and Mondira Bhattacharya, eds. *Pharmacovigilance: A Practical Approach*. Elsevier Health Sciences, 2018.

ii. REFERENCE BOOKS

1. Huang, Shiew-Mei, Juan JL Lertora, and Arthur J. Atkinson Jr, eds. *Principles of clinical pharmacology*. Academic Press, 2012.
2. Orleans-Lindsay, Justina. *Pharmacovigilance Medical Writing: A Good Practice Guide*. John Wiley & Sons, 2012