S.S. JAIN SUBODH P.G. COLLEGE, JAIPUR

VALUE-ADDED COURSE

COURSE TITLE: CLINICAL TRIALS MANAGEMENT

NODAL DEPARTMENT: BIOTECHNOLOGY

COURSE CODE: 23VAC_6407T

MARKING SCHEME

Tutorial (Hours)	Time Allowed ESE (Hrs)	Course Credits	Total Marks	End Semester Exam (Max. Marks)	Assignment	Minimum Marks
30	2	2	50	35	15	20

COURSE OBJECTIVES:

1. This course provides an overview of the management and conduct of clinical trials, including study design, protocol development, ethical considerations, data collection and analysis, regulatory requirements, and project management.
2. This course provides a foundational understanding of clinical trials and their management, covering essential topics in a concise and accessible manner.

COURSE CONTENTS:

Clinical Trials and Protocol development process:

Introduction to Clinical Trials. Definition and types of clinical trials. Historical development of clinical trials. Ethical and legal considerations in clinical trials. Study Design and Protocol Development. Study design principles and considerations. Protocol development process and key components. Risk assessment and management. Regulatory requirements for clinical Trials. Regulatory agencies and their roles. Investigational New Drug (IND) application process. Institutional Review Board (IRB) requirements. Good Clinical Practice (GCP) guidelines.

(15 Hours)

Data Collection and Statistical Analysis:

Study Monitoring and Data Collection. Study monitoring and site management. Data collection and management strategies. Quality control and assurance. Statistical Analysis and Reporting. Statistical analysis methods and software. Clinical Trial Management and Project Planning. Project management principles and techniques. Budget planning and management. Contract negotiations and vendor management

(15 Hours)

SUGGESTED READINGS:

1. **Fundamentals of Clinical Trials.** by Lawrence M. Friedman, Curt D. Furberg, David L. DeMets, Christopher B. Granger, and David J. Machin (5th Edition, 2015).
2. **Principles and Practice of Clinical Research** edited by John I. Gallin, Frederick P. Ognibene, and Laura Lee Johnson (4th Edition, 2017).
3. **Clinical Trials: A Methodologic Perspective** by Steven Piantadosi (3rd Edition, 2017)
4. **Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines** by Tom Brody (2nd Edition, 2016).

COURSE OUTCOME:

1. This outcome equips graduates for roles such as clinical trial coordinator, regulatory affairs specialist, or clinical research associate. Understanding the regulatory and ethical aspects is essential for ensuring the safety of participants and the validity of trial data, which are critical for drug development and approval processes.
2. This outcome prepares graduates for positions such as clinical trial manager, data manager, or project manager in clinical research. Their ability to oversee trial logistics and ensure accurate data collection contributes directly to the successful execution and outcome of clinical studies.

(Prof. K. B. Sharma)
Principal

Head of the Department