Course Title:	**Design and Analysis of Medical Studies**
Course Code:	**BSTA-301**
Semester:	**V**
Credit Hours:	**03**

Learning Outcomes

By the end of this course, students will be able to:

1. derive a valid and meaningful scientific conclusion using appropriate statistical methods.
2. identify the terminology used in clinical trials and the several common designs used for clinical trials, such as parallel and cross-over designs.
3. evaluate new interventions to prevent or treat disease in humans.
4. identifying the risk factors that may be associated with a disease condition.

Course Outline

Unit – I

1.1 Introduction to Medical Research
Overview of Medical Research, Importance of Study Design in Medical Research, Types of Medical Studies: Experimental vs. Observational, Ethical Considerations in Medical Research.

1.2 Randomized Controlled Trials (RCTs)
Introduction to RCTs, Key Components: Randomization, Blinding, and Control Groups. Phases of Clinical Trials: I, II, III, and IV. Analysis of RCT Data.

Unit – II

1.1 Study Designs ana Analysis
Cohort Studies: Design, Size and Analytical Considerations.

Cases Control Studies: Design, Selection of Cases, Selection of Controls, Matching.
Intervention Studies: Design, Ethical considerations, Avoidance of Bias, Parallel Group Studies, Cross-over Studies, Sequential Studies. Cross-sectional Study Design. Longitudinal Study Design. Case-Studies.

2.2 Sample Size Determination and Power.
Sample Size and Power for different Medical Studies.

Unit – III

3.1 Treatment Allocation
Treatment Allocation and Randomization, Interim Analyses and Stopping Rules, Missing Data and Intent-to-Treat, Estimating Clinical Events.

3.2 Ethical and Regulatory Issues in Medical Research

Institutional Review Boards (IRBs) and Ethical Approval, Informed Consent Process, Privacy and Confidentiality in Medical Research, Reporting and Dissemination of Research Findings.

- **Teaching-learning Strategies:**

Class Lecture method, which includes seminars, discussions, assignments and projects. (Audio-visual tools are used where necessary)

- **Assignments-Types and Number with calendar:**

According to the choice of respective teacher.

- **Assessment and Examinations:**

According to the University's Semester Rules.

Sr. No.	Elements	Weightage	Details
1.	Midterm Assessment	35%	It takes place at the mid-point of the semester.
2.	Formative Assessment	25%	It is continuous assessment. It includes: Classroom participation, attendance, assignments, and presentations, homework, attitude and behavior, hands-on-activities, short tests, quizzes etc.
3.	Final Assessment	40%	It takes place at the end of the semester. It is mostly in the form of a test, but owing to the nature of the course the teacher may assess their students based on term paper, research proposal development, field work and report writing etc.

Textbook:

1. Matsui, S., Buyse, M., & Simon, R. (Eds.). (2015). *Design and analysis of clinical trials for predictive medicine*. CRC Press.

Suggested Readings:

1. Chow, S. C., & Liu, J. P. (2008). *Design and analysis of clinical trials: concepts and methodologies* (Vol. 507). John Wiley & Sons.
2. Everitt, B., & Pickles, A. (2004). *Statistical aspects of the design and analysis of clinical trials*. World Scientific.
3. Friedman, Lawrence M. (2015). *Fundamentals of Clinical Trial* (5th ed.). Springer. ISBN: 978-3-319-18538-5
4. Matsui, S., Buyse, M., & Simon, R. (Eds.). (2015). *Design and analysis of clinical trials for predictive medicine* (Vol. 72). CRC Press.
5. Shih, W. J., & Aisner, J. (2015). *Statistical design and analysis of clinical trials: principles and methods*. CRC press.

Thall, P. F., & Simon, R. M. (2012). 3. Recent developments in the design of phase II. *Recent Advances in Clinical Trial Design and Analysis*, *75*, 49.