ST.JOSEPH'S COLLEGEFORWOMEN (A),VISAKHAPATNAM

VII SEMESTER STATISTICS TIME: 4Hrs/Week

ST 7204(3) ANALYSIS OF CLINICAL TRIALS Max. Marks:100

SYLLABUS

Objectives:

1. Understand the fundamental principles and methodologies involved in designing clinical trials.
2. Analyze the ethical considerations and regulatory frameworks governing clinical trials.
3. Evaluate various types of clinical trial designs and their applications in different research settings.
4. Interpret statistical methods commonly used in the analysis of clinical trial data.
5. Collaborate effectively with interdisciplinary teams involved in clinical trial research.

Learning Outcomes:

1. Demonstrate a comprehensive understanding of the key concepts and methodologies involved in clinical trial design and analysis.
2. Identify and assess ethical considerations and regulatory requirements pertinent to the conduct of clinical trials.
3. Compare and contrast different types of clinical trial designs and their respective strengths and limitations.
4. Apply appropriate statistical techniques to analyze and interpret clinical trial data accurately.
5. Critically evaluate the validity and reliability of findings reported in clinical trial literature.

COURSE:

Unit I

Introduction to clinical trials: need and ethics of clinical trials, bias and random error in clinical studies, conduct of clinical trials, overview of Phase I-IV trials, multi-center trials. Data management: data definitions, case report forms, database design, data collection systems for good clinical practice.

Unit II

Determination of sample size: for two independent samples of Dichotomous Response variables, for two independent samples of Continuous Response variables and for repeated variables.

Unit III

Design of clinical trials: parallel vs. cross-over designs, cross-sectional vs. longitudinal designs, objectives and endpoints of clinical trials, design of Phase I trials, design of single-stage and multi-stage Phase II trials, design and monitoring of Phase III trials with sequential stopping, design of bioequivalence trials.

Unit IV

Reporting and analysis: analysis of categorical outcomes from Phase I - III trials, analysis of survival data from clinical trials.

Unit V

Surrogate end points: selection and design of trials with surrogate end points, analysis of surrogate end point data. Meta-analysis of clinical trials.

Books Recommended

1. S.Piantadosi(1997): Clinical Trials: A Methodological Perspective. Wiley and Sons.

2. C.Jennison and B.W.Turnbull(1999): Group Sequential Methods with Applications to Clinical Trials, CRC Press.

3. L.M.Friedman, C.Furburg,D.L. Demets(1998): Fundamentals of Clinical Trials, Springer Verlag.

4. J.L.Fleiss(1989): The Design and Analysis of Clinical Experiments. Wiley and Sons.

5. E.Marubeni and M.G.Valsecchi(1994): Analyzing Survival Data from Clinical Trials and Observational Studies, Wiley and Sons.

6. Chow S.C. and Liu J.P. (2004): Design and Analysis of Clinical Trials. 2nd Ed. Marcel Dekkar.

7. Fleiss J. L. (1989): The Design and Analysis of Clinical Experiments, Wiley