OPY751 CLINICAL TRIALS

DETAILED SYLLABUS

OBJECTIVES:

- To highlight the epidemiologic methods, study design, protocol preparation
- To gain knowledge in the basic bio-statistical techniques involved in clinical research.
- To describe the principals involved in ethical, legal and regulatory issues in clinical trials.

UNIT I ROLE OF CLINICAL TRIALS IN NEW DRUG DEVELOPMENT

Drug Discovery, regulatory guidance and governance, pharmaceutical manufacturing, nonclinical research, clinical trials, post-marketing surveillance, ethical conduct during clinical trials.

UNIT II FUNDAMENTALS OF TRIAL DESIGN

Randomised clinical trials, uncontrolled trials. Protocol development, endpoints, patient selection, source and control of bias, randomization, blinding, sample size and power.

UNIT III ALTERNATE TRIAL DESIGNS

Crossover design, factorial design, equivalence trials, bioequivalence trials, non-inferiority trials, cluster randomized trials, multi-center trials.

UNIT IV BASICS OF STATISTICAL ANALYSIS

Types of data and normal distribution, significance tests and confidence intervals, comparison of means, comparison of proportions, analysis of survival data, subgroup analysis, regression analysis, missing data.

UNIT V REPORTING OF TRIALS

Overview of reporting, trial profile, presenting baseline data, use of tables, figures, critical appraisal of report, meta-analysis.

OUTCOMES:

The student will be able to

- Explain key concepts in the design of clinical trials.

- Describe study designs used, identify key issues in data management for clinical trials.
- Describe the roles of regulatory affairs in clinical trials.

TEXT BOOKS:

1. Fundamentals of Clinical Trials, Lawrence M. Friedman, Springer Science & Business Media, 2010

2. Textbook of Clinical Trials, David Machin, Simon Day, Sylvan Green, John Wiley & Sons, 2007

3. Clinical Trials: A Practical Approach, Stuart J. Pocock, John Wiley & Sons, 17-Jul-2013

REFERENCES:

1. Clinical trials, A practical guide to design, analysis and reporting. Duolao Wang and Ameet Bakhai. Remedica. 2006.

2. Introduction to statistics in pharmaceutical clinical trials. T.A. Durham and J Rick Turner. Pharmaceutical Press.

3. Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines, Tom Brody, Academic Press, 2016.