

SARDAR PATEL UNIVERSITY
Programme & Subject: M.Sc (Statistics)
Semester: IV
Syllabus with Effect from: June-2013

Paper Code: PS04ESTA04	Total Credit: 4
Title Of Paper: Clinical Trials	

Unit	Description in Detail	Weightage (%)
I	Introduction to clinical trials, the need, ethics, protocol of clinical trials, Overview of phase 1 – IV and DF, SE, CTE trials, data management and case studies. Bias and random error in clinical studies, Endpoints of clinical trials and sample size estimation in SE and CTE trials.	25%
II	Design of clinical trials parallel vs. cross over designs, cross sectional vs. longitudinal designs, review of factorial designs. Randomization techniques for group allocation.	25%
III	Analysis of outcomes from Phase I- III trials, analysis of survival data from clinical trials, techniques for Interim analysis, intent to treat analysis.	25%
IV	Application areas Meta analysis, Multi-center trials, Bioequivalence trials	25%

Basic Text & Reference Books:-

- David Machin, Simon Day. Text Book Of Clinical Trials.
- Ton Cleophs, Aeilko Zwinderman. Statistics Applied To Clinical Trials.
- Stephen Senn. Cross – Over Trials In Clinical Research.
- Annpey Pong & Shein- Chung Chow. Hand Book Of Adaptive Designs In Pharmaceutical And Clinical Development.
- Effron and Marubini. Analyzing data from CT and Obs studies.
- Karl E. Peace. Design And Analysis Of Clinical Trials With Time-To-Event Endpoints.
- Geert Molenberghs & Michael G. Ken ward. Missing Data In Clinical Studies.
- Annpey Pong, Shein - Chung Chow. Handbook Of Adaptive Designs In Pharmaceutical And Clinical Development.
- Shein - Chung Chow, Mark Chang. Adaptive Design Methods In Clinical Trials.
- Umakanta Sahoo, Dipti Sawant. Clinical Trial Monitoring A Professional Hand Book.
- Diane Fair clough. Design And Analysis of Quality of Life Studies In Clinical Trials.

