

GUJARAT TECHNOLOGICAL UNIVERSITY
PHARM.D
4th Year

Subject Name: Biostatistics & Research Methodology
Subject Code: 848804

Scope: The course is a comprehensive concepts-centric primer for the students to make them ready to conduct clinical and community-based research projects. The focus is on designing, executing, documenting and publishing the project,

Objectives:

On successful completion of the course the student will be able to :

- 1) Retrieve, read and respond to the scientific literature, including the Methods and Results sections, in public health, medicine, biological science, pharmaceutical science and related fields.
- 2) analyse a research question of choice, design a study to avail answer to this research question and summarize and analyse the data collected
- 3) understand the complex clinical trial designs
- 4) write a scientific report
- 5) use the computer technology in various hospital activities and in research

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
2	1	0	3	70	30	0	0	100

Detailed syllabus:

Sr.	Topic	Hr	% Weightage
Research Methodology			
1.	a) Types of clinical study designs: Case studies, observational studies, interventional studies, b) Designing the methodology c) Sample size determination and Power of a study Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study d) Report writing and presentation of data	10	16
Biostatistics			
2.	a) Introduction b) Types of data distribution c) Measures describing the central tendency distributions- average, median, mode d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean	5	10
3.	Data graphics Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots	5	8
4.	Basics of testing hypothesis	15	24

	a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals. b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way) c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA) d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient. e) Introduction to statistical software: SPSS, Epi Info, SAS		
5.	Statistical methods in epidemiology Incidence and prevalence, relative risk, attributable risk	7	12
6.	Computer applications in pharmacy Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics. Computer In Community Pharmacy Computerizing the Prescription Dispensing process Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system Drug Information Retrieval & Storage : Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval	18	30

Reference Books:

1. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton latest edition, publisher Marcel Dekker Inc. NewYork
2. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , latest edition, McGraw Hill Publications latest edition
3. Khanal AB. Mahajan's methods in biostatistics for medical students and research workers. Jaypee Brothers, latest edition