

STAT-811 Medical Statistics (3 Credit Hours)

1. Objectives

This course aims to introduce students to the data structures used in medical sciences, data management, designing, analysis and modeling.

2. Course Contents

Designs in epidemiology, Defining and assessing heterogeneity of effects, interaction. Sensitivity and specificity of the diagnostic test, Cohort Study designs, statistical power and sample size computations. Log-linear models, Survival data, Proportional hazards model, multivariate survival data. Causal Inference, Longitudinal data. Communicating results of epidemiological studies. Introduction to clinical trials, bias and random error in clinical studies, Data management, database design, data collection systems for good clinical practice, Design of clinical trials: parallel vs. cross-over designs, cross-sectional vs. longitudinal designs, objectives and endpoints of clinical trials, Surrogate endpoints, selection and design of trials with surrogate endpoints, analysis of surrogate endpoint data. A meta-analysis of clinical trials. Related applications/computations with R.

3. Recommended Books

- i. Piantadosi S., Clinical Trials: A Methodological Perspective. Wiley and Sons. (2013)
- ii. Jennison C and Turnbull B. W., Group Sequential Methods with Applications to Clinical Trials, CRC Press. (1999).
- iii. Friedman, L. M., Furberg, C. and Demets D. L., Fundamentals of Clinical Trials, Springer Verlag. (2015).
- iv. Fleiss, J. L., The Design and Analysis of Clinical Experiments. Wiley and Sons (2011).
- v. Tang, W. Tu, X., Modern Clinical Trial Analysis. Springer Sci. & Bus. Media. (2012).
- vi. Geller, N.L., Advances in Clinical Trial Biostatistics. CRC Press. (2015).

4. Outcomes

On successful completion of this course, students will be able to collect data and study designs and models in epidemiology and clinical trials. The design comparison will include the parallel, cross-over designs, cross-sectional and longitudinal designs.