Discipline Specific Elective (DSE) Course 1c: Biostatistics

Course Title & Code	Credits	Credit Distribution of the Course			Eligibility Criteria	Prerequisite of the course (if any)
		Lecture (45 Hours)	Tutorial (00 Hours)	Practical (30 Hours)		
DSE 1c: Biostatistics	**4**	**3**	**0**	**1**	**NIL**	**NIL**

Course Objectives:

- To illustrate modelling approach for analysis of survival data in order to meet need of Statisticians in Pharmaceutical and bio-medical research sector.
- To guide scientists, clinicians and students for analysing their own data.

Course Learning Outcomes: After successful completion of this course, student will be able to:

- Develop understanding of time-to-event data in Biomedical Sciences.
- Summarizing clinical data using displays, parametric and non- parametric approaches.
- Understanding concepts of conditional and inverse probabilities as applied to survival data.
- Establishing meaningful relationships for causative and consequential health factors.
- Understand survival patterns in presence and in absence of censoring.
- Account for censored patterns and their implications.
- Estimation of failure and hazard forms based on patient data records.
- Formulate and interpret stochastic models for specific-disease data sets.
- Comprehend basis and construction of clinical trials for different stages.
- Analyze concept of Biometric genetics.

Unit I (11 Hours)

Analysis of Medical, Epidemiologic and Clinical Data: Studying association between a disease and a characteristic: (a) Types of studies in Epidemiology and Clinical Research (i) Prospective study (ii) Retrospective study (iii) Cross-sectional data, (b) Dichotomous Response and Dichotomous Risk Factor: 2x2 Tables (c) Expressing relationship between a risk factor and a disease (d) Inference for relative risk and odds ratio for 2x2 table, Sensitivity, specificity and predictivities. Clinical Trials: Its Planning and its Four Phases.

Unit II (11 Hours)

Special Survival Features: Censoring and its types. Study time and Patient time. Survival Analysis: Survival Distributions and their Properties *viz.* Exponential, Weibull, Gamma, Rayleigh and Lognormal. Estimation of Survivor and Hazard Functions: Life Table, Kaplan-Meier and Nelson-Aalen Estimates. Estimating Median and Survival Times. Estimation of Mean survival time and variance for Type I and Type II Censored data with examples.

Unit III (11 Hours)

Cox-Proportional Hazards Model: Its Linear Component, Fitting, Hypothesis Tests. Estimating Hazard and Survivor Function. Kaplan Meier Estimate, Hazard and Cumulative Incidence Functions, Modelling. Cause Specific Hazard and Incidence, Model Checking. Sample Size Requirements for a Survival Study.

Unit IV (12 Hours)

Multiple Factor Hypothesis for Process of Heredity. Medelian Population: Gene Frequency and Genotype Frequency. Hardy Weinberg Law: Multiple Alleles, Two or More Pairs of Genes, Linkage of Genes, Sex Linked Genes. Influence of Gene Frequencies on Population Mean. Breeding Value of Genotypes. Dominance Deviation.

Essential Readings:

1. Biswas, S. (1995). *Applied Stochastic Processes: A Biostatistical and Population Oriented Approach*, Wiley Eastern Ltd.
2. Cox, D.R. and Oakes, D. (1984). *Analysis of Survival Data*, Chapman and Hall.
3. Dabholkar A.R. (1999). *Elements of Bio Metrical Genetics*. Concept Publishing Co., New Delhi.
4. Indrayan, A. and Malhotra, R.K. (2018). *Medical Biostatistics*. Chapman & Hall/CRC Press.
5. Kestenbaum, B. (2019). *Epidemiology and Biostatistics: An Introduction to Clinical Research*, Springer.
6. Robert F. Woolson (1987). *Statistical Methods for the analysis of biomedical data*, John Wiley & Sons.

Suggested Readings:

1. Collett, D. (2003). *Modelling Survival Data in Medical Research*, Chapman & Hall/CRC.
2. Elandt Johnson R.C. (1971). *Probability Models and Statistical Methods in Genetics*, John Wiley & Sons.
3. Ewens, W. J. (1979). *Mathematics of Population Genetics*, Springer Verlag.
4. Ewens, W.J. and Grant, G.R. (2001). *Statistical methods in Bio informatics: An Introduction*, Springer.
5. Friedman, L.M., Furburg, C. and DeMets, D.L. (1998). *Fundamentals of Clinical Trials*, Springer Verlag.
6. Gross, A.J. And Clark V.A. (1975). *Survival Distribution; Reliability Applications in Biomedical Sciences*, John Wiley & Sons.
7. Indrayan, A. (2008). *Medical Biostatistics*, Chapman & Hall/CRC.
8. Lee, Elisa, T. (1992). *Statistical Methods for Survival Data Analysis*, John Wiley & Sons.
9. Li, C.C. (1976). *First Course of Population Genetics*, Boxwood Press.
10. Liu Xian. (2012). *Survival Analysis: Model and Applications.* Wiley.
11. Miller, R.G. (1981). *Survival Analysis*, John Wiley & Sons.
12. Tattar P.N and Vaman H.J. (2023). *Survival Analysis*. CRC Press.

List of Practicals:

1. Interpreting clinical Trial data.
2. Sample size estimation in clinical Trials.
3. Plotting Survival and Hazard Curves for different parameter combinations in respect of some life time distributions.
4. Computing Kaplan-Meier estimates based on recorded surviving times with and without censoring.
5. Fitting of Cox-Proportional Hazard Model.
6. Hypothesis Formulation and their Testing for Cox-Proportional Hazard Model.
7. Estimation of Mean Survival Time and its variance for complete and survival data.
8. Random union among gametes.
9. Gene effect on population mean.