> **Chapter 1**

Introduction to Biostatistics

Biostatistics

Biostatistics is that branch of statistics which deals with problems in biological sciences. In other words, application of statistical methods to biological sciences is said to be biostatistics.

Biostatistics broadly deals with statistical applications in the context of biological problems including medicine, pharmacy and public health. Biostatistics is developed during the period of Sir Francis Galton (1822-1910) who is known as father of biometry. Measurement of biological aspects is known as biometrics and hence the terms biostatistics and biometry are synonymously used. Sir Francis Galton while examining the relationship between height of fathers and their sons based on heredity concept proposed concept of regression. Karl Pearson, basically a statiscian tried to apply statistical methods to biological problems. Later, R. A. Fischer was also attracted towards the application of statistics in biology and made significant contribution to the development of biostatistics.

LEARNING OBJECTIVES

To know Biostatistics, its significance and applications in pharmacy.

Applications of Biostatistics in Pharmacy

1. Biostatistics has been applied to a wide variety of problems in pharmacy, medicine and other health sciences.

2. Government organizations, research institutes and industry have been extensively using statistics and biostatistics. The census wing of the government extensively uses biostatistics in the analysis of data. In the interpretation of population characteristics such as birth rates, death rates, population growth rates, infant mortality rate, gross reproduction rate, age specific fertility, life expectancy etc. biostatistics is very much helpful. The ministry of health and family welfare also makes use of biostatistics while formulating policies related to medical care for child and women development, family planning, health and sanitation programs. The ministry of agriculture also depends much on biostatistics in planning for production of food grains and other commercial crops based on trends and projections.

3. Agricultural scientists depend on design of experiments and analysis of variance in the study of crop variations and soil fertility.

4. Biostatistics provides a lot of input to the research institutes such as Indian Institute of Chemical Technology (IICT), Central Drug Research Institute (CDRI), Indian Council of Medical Research (ICMR), Indian Council of Agricultural Research (ICAR) and others. For example, the study of growth and trends in the incidence of various diseases, growth and spread of various organs causing cancer etc. helps the scientist in the invention of new treatments and new drugs.

5. Pharmaceutical industry makes use of biostatistics in Drug discovery and development process, design of new drug delivery systems and formulation development, testing hypothesis in developing new drugs, formulations and for assessing the effectiveness of a drug in curing a disease.

6. The pharmaceutical industry also uses the tools of statistical control and theory of sampling for quality control and quality assurance of drugs and pharmaceuticals.

Specific Applications of Biostatistics in Pharmacy Research

(i) Provides methods of data collection and presentation and analysis of results for better understanding and for drawing valid conclusions.

(ii) During the stage of planning the experiments, design of experiments (DOE) provides inputs for planning experiments to get the relevant information.

(iii) Provide methods to reduce experimental error in the investigation

(iv) Provide methods to estimate sample size (n) or replication needed for the given accuracy in the results

(v) Provides standard designs and methods of analysis suitable for various experimental and observational studies.

(vi) Provides a variety of "tests of significance" to test the significance of the observed results and to make comparisons.

(vii) Provides methods of analysis of bivariate population and to evaluate the correlation between two variables.

(viii) Provides methods of regression and multiple regression for establishing mathematical relationship between two or more variables.

(ix) Provides methods of Probit analysis for estimating LD_{50} and ED_{50} of new drug substances.

(x) Provides statistical optimization techniques for drug development, formulation development and analytical method development.