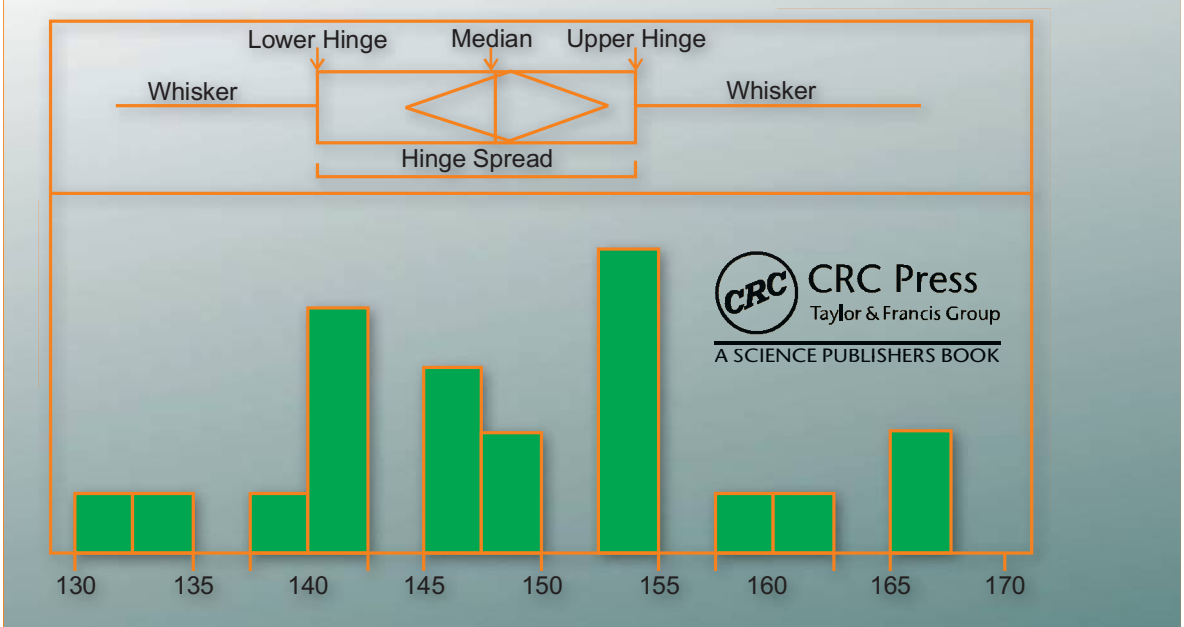
A Handbook of

Applied Statistics in Pharmacology

Katsumi Kobayashi
K. Sadasivan Pillai



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Foreword

Life expectancy has significantly increased in the last century, thanks to the discovery and development of new drugs by pharmaceutical industries. Search for new therapeutics is the primary activity of the R&D of pharmaceutical industries and it involves complex network of tasks such as synthetic chemistry, *in vitro*/*in vivo* efficacy, safety, preclinical and clinical research. Statistical analysis has always been the foundation to establish the safety and efficacy of drugs. The decision to- or not to- advance preclinical drug candidates to very expensive clinical development heavily relies on statistical analysis and the resulting significance of preclinical data. Recent reports attributed failure of certain drugs in clinical stages of development to improper conduct of preclinical studies and inappropriate application of statistical tools. Applying appropriate statistical tools is sagacious to analysis of data from any research activity. Though scientists expect computerized statistical packages to perform analyses of the data, he/she should be familiar with the underlying principles to choose the appropriate statistical tool.

'A Handbook of Applied Statistics in Pharmacology' by Katsumi Kobayashi and K. Sadasivan Pillai is a very useful book for scientists working in R&D of pharmaceuticals and contract research organizations. Most of the routine statistical tools used in pharmacology and toxicology are covered perspicuously in the book. The examples worked out in the book are from actual studies, hence do not push a reader having less or no exposure to statistics outside his/her comfort zone.

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Preface

Scientists involved in pharmacology have always felt that statistics is a difficult subject to tackle. Thus they heavily rely on statisticians to analyse their experimental data. No doubt, statisticians with some scientific knowledge can analyse the data, but their interpretation of results often perplexes the scientists.

Statistics play an important role in pharmacology and related subjects like, toxicology, and drug discovery and development. Improper statistical tool selection to analyze the data obtained from studies conducted in these subjects may result in erroneous interpretation of the performance- or safety- of drugs. There have been several incidents in pharmaceutical industries, where failure of drugs in clinical trials is attributed to improper statistical analysis of the preclinical data. In pharmaceutical Research & Development settings, where a large number of new drug entities are subjected to high-throughput *in vitro* and *in vivo* studies, use of appropriate statistical tools is quintessential.

It is not prudent for the research scientists to totally depend on statisticians to interpret the findings of their hard work. Factually, scientists with basic statistical knowledge and understanding of the underlying principles of statistical tools selected for analysing the data have an advantage over others, who shy away from statistics. Underlying principle of a statistical tool does not mean that one should learn all complicated mathematical jargons. Here, the underlying principle means only 'thinking logically' or applying 'common sense'.

The authors of this book, with decades of experience in contract research organizations and pharmaceutical industries, are fully cognizant of the extent of literacy in statistics that the research scientists working in pharmacology, toxicology, and drug discovery and development would be interested to learn. This book is written with an objective to communicate statistical tools in simple language. Utmost care has been taken to avoid complicated mathematical equations, which the readers may find difficult

to assimilate. The examples used in the book are similar to those that the scientists encounter regularly in their research. The authors have provided cognitive clues for selection of an appropriate statistical tool to analyse the data obtained from the studies and also how to interpret the result of the statistical analysis.

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