Developments in Statistical Evaluation of Clinical Trials

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Editors

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Springer

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Preface

Over the last few decades the role of statistics in the evaluation and interpretation of clinical data has become more and more important. As a result the standards of clinical study design, conduct and interpretation have been advanced. In this book statistical considerations in data analysis as a basis for deriving an accurate clinical interpretation are elaborated.

Most often it is the physician who decides whether to prescribe a specific drug for a specific patient in a specific situation. The decisions of the physicians are largely based on the interpretation of data they have read and heard. This book describes various ways of approaching and interpreting the data that result from a clinical trial study.

The book reemphasizes the essential role that biostatistics plays in clinical trials. The book contains 18 carefully reviewed chapters on recent developments in trials and statistics. The chapters in this book are generally autonomous and may be read in any order. Each chapter is written by one or more experts in the specific approach. Starting from (a) some background information about the specific approach (short history and main publications), the chapter (b) describes the type of research questions the approach is able to answer and the kind of data to be collected, (c) gives the statistical and mathematical explanation of the model(s) used in the analysis of the data, (d) discusses the input and output of the software used in the analysis, and (e) provides one or more examples with typical data sets enabling the readers to apply the programs themselves. The chapters are worked out in a homogeneous style to enhance comparability between the approaches. The data sets and the computer code for the analysis with various softwares are a very important component of the book. They are available upon request (by emailing the authors of the chapters).

Each chapter is self-contained in this edited volume. The chapters are written and reviewed by experts in the specific approach. Although an authored volume could have advantages, because of the rapid changes in the field, an edited book written by people who are in the middle of the latest developments in the specific approach

is preferable. In addition, the authors of the chapters use a shared notation to enable the reader to compare methods more easily.

The book addresses the great majority of researchers in the field of clinical trials. Included are biostatisticians, medical researchers and physicians. It is meant as a reference work for all those actually doing and using research in the field of clinical trials. To reach this vast audience, knowledge of statistics as taught at master degree level in medical and biomedical sciences is required. However, the restricted number of chapters gives each of the chapters the opportunity to go into sufficient details to enable the readers to understand and apply the methods. In addition, the book addresses biostatisticians and physicians, who are professionally dealing with research in the field of clinical trials, to provide standards for state-of-the-art practices. Furthermore, the book offers researchers new ideas about the use of biostatistical analysis in solving their research problems. Finally the book is suitable as obligated literature for courses in clinical trial evaluation given at university medical and epidemiological research schools.

We thank the authors of the chapters for their willingness to contribute to the book, the anonymous reviewers for their expertise and time invested and Springer Publishers for their decision to publish the book in their Statistics book program.

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