DESCRIPTION

Presents elements of clinical trial methods that are essential in planning, designing, conducting, analyzing, and interpreting clinical trials with the goal of improving the evidence derived from these important studies

This Third Edition builds on the text’s reputation as a straightforward, detailed, and authoritative presentation of quantitative methods for clinical trials. Readers will encounter the principles of design for various types of clinical trials, and are then skillfully guided through the complete process of planning the experiment, assembling a study cohort, assessing data, and reporting results. Throughout the process, the author alerts readers to problems that may arise during the course of the trial and provides common sense solutions. All stages of therapeutic development are discussed in detail, and the methods are not restricted to a single clinical application area.

The authors bases current revisions and updates on his own experience, classroom instruction, and feedback from teachers and medical and statistical professionals involved in clinical trials. The Third Edition greatly expands its coverage, ranging from statistical principles to new and provocative topics, including alternative medicine and ethics, middle development, comparative studies, and adaptive designs. At the same time, it offers more pragmatic advice for issues such as selecting outcomes, sample size, analysis, reporting, and handling allegations of misconduct. Readers familiar with the First and Second Editions will discover revamped exercise sets; an updated and extensive reference section; new material on endpoints and the developmental pipeline, among others; and revisions of numerous sections.
In addition, this book:

• Features accessible and broad coverage of statistical design methods—the crucial building blocks of clinical trials and medical research -- now complete with new chapters on overall development, middle development, comparative studies, and adaptive designs

• Teaches readers to design clinical trials that produce valid qualitative results backed by rigorous statistical methods

• Contains an introduction and summary in each chapter to reinforce key points

• Includes discussion questions to stimulate critical thinking and help readers understand how they can apply their newfound knowledge

• Provides extensive references to direct readers to the most recent literature, and there are numerous new or revised exercises throughout the book

*Clinical Trials: A Methodologic Perspective, Third Edition* is a textbook accessible to advanced undergraduate students in the quantitative sciences, graduate students in public health and the life sciences, physicians training in clinical research methods, and biostatisticians and epidemiologists.

This book is accompanied by downloadable files available below under the **DOWNLOADS** tab.

These files include:

• **MATHEMATICA** program – A set of downloadable files that tracks the chapters, containing code pertaining to each.

• **SAS PROGRAMS and DATA FILES** used in the book.

The following software programs, included in the downloadables, were developed by the author, Steven Piantadosi, M.D., Ph.D:

• **RANDOMIZATION** – This program generates treatment assignments for a clinical trial using blocked stratified randomization.

• **CRM** – Implements the continual reassessment methods for dose finding clinical trials.

• **OPTIMAL** – Calculates two-stage optimal phase II designs using the Simon method.

• **POWER** – This is a power and sample size program for clinical trials.

Executables for installing these programs can also be found at https://risccweb.csmc.edu/biostats/.

**Steven Piantadosi, MD, PhD**, is the Phase One Foundation Distinguished Chair and Director of the Samuel Oschin Cancer Institute, and Professor of Medicine at Cedars-Sinai Medical Center in Los Angeles, California. Dr. Piantadosi is one of the world’s leading
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