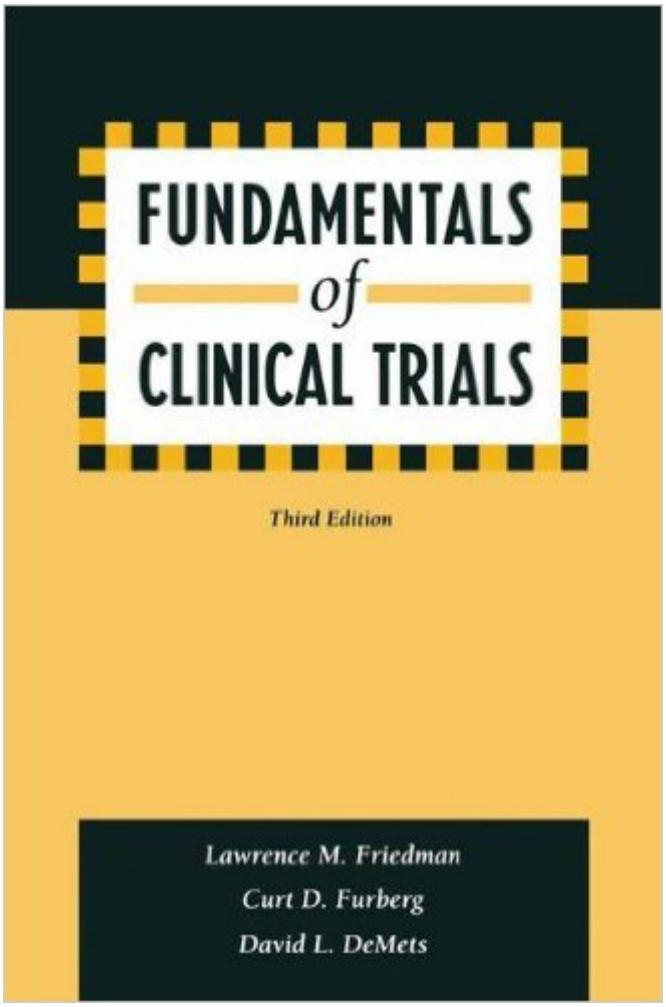
Fundamentals Of Clinical Trials



Synopsis

The randomized control clinical trial has become the gold standard scientific method for the evaluation of pharmaceuticals, biologics, devices, procedures and diagnostic tests. This trial design has been successfully used in both therapeutic and disease prevention trials. It is superior to alternative designs by eliminating several sources of bias which exist in those designs. This role has evolved over the past three decades in a number of disease areas including cardiology, opthalmology, cancer and AIDS. While the specifics of using the randomized control design for a specific intervention and disease may differ, the basic fundamentals still apply in developing the study protocol and operational procedures. These fundamentals still apply in developing the study protocol and operational procedures. These fundamentals include identifying the specific questions to be tested and appropriate outcome measures, determining an adequate sample size, specifying the randomization procedure, detailing the intervention with visit schedules for subject evaluation, establishing an interim data and safety monitoring plan, detailing the final analysis plan and determining the organizational structure. This text is structured to address the fundamentals as the protocol for a clinical trial is being developed. A chapter is devoted to each of the critical areas of a protocol to aid the clinical trial researcher. The fundamentals described in this text are based on sound scientific methodology, statistical principles and years of accumulated experience by the three authors. Collectively, the authors have been active researchers in a broad area of clinical trials including cardiology, cancer, opthalmology, diabetes, osteoporosis, AIDS, women's health and screening tests. In these studies, the authors have served as members of the steering committee responsible for developing the protocol and as members of data and safety monitoring committees. The fundamentals were proposed in the first edition published in 1981 and have not changed substantially in the later editions. However, the number of examples illustrating the fundamentals has greatly expanded base on the collective experience of the authors. This text is intended for the clinical researcher who is interested in designing a clinical trial and developing a protocol. It is also of value to researchers and practitioners who must critically evaluate the literature of published clinical trials and assess the merits of each trial and the implications for the care and treatment of patients. The test uses numerous examples of published clinical trials from a variety of medical disciples to meaningfully illustrate the fundamentals. Technical design issues such as sample size are considered but the technical details have been suppressed as much as possible through the use of graphs and tables. While the technical material has been kept to a minimum, the statistician may still find the principles and fundamentals presented in this text useful both in a consulting and teaching capacity. The text assumes that the readers have only a modest formal statistical

background. A basic introductory statistics course is helpful in maximizing the benefit of the text. However, a researcher or practitioner with no statistical background would still find most, if not all the chapters understandable and useful.

Book Information

Paperback: 361 pages

Publisher: Springer; 3rd edition (October 10, 2008)

Language: English

ISBN-10: 0387985867

ISBN-13: 978-0387985862

Product Dimensions: 6.1 x 0.9 x 9.2 inches

Shipping Weight: 1.2 pounds

Average Customer Review: 4.1 out of 5 starsÂ Â See all reviewsÂ (17 customer reviews)

Best Sellers Rank: #417,087 in Books (See Top 100 in Books) #90 inÂ Books > Textbooks > Medicine & Health Sciences > Research > Biostatistics #170 inÂ Books > Medical Books > Basic Sciences > Biostatistics #299 inÂ Books > Medical Books > Research

Customer Reviews

POST-SCRIPT. I am adding this sentence and the next few sentences, four years after I originally posted my review. My new book, CLINICAL TRIALS," recently published by ELSEVIER/ACADEMIC PRESS. My book is more detailed on "specifics" than is Dr. Friedman’s book. My new book provides real-life examples from about 100 clinical trials, mostly in oncology. My new book provides examples of real consent forms, a real DMC charter, and excerpts from a dozen real Clinical Study Protocols. My book takes an unusual approach in the chapters on CONSENT FORMS and PACKAGE INSERTS in that I provides excerpts from a dozen lawsuits that centered around disputed information in consent forms and package inserts. As is well known, it is a fact that the outcome of lawsuits is a primary driver for many of the activities of companies, including pharmaceutical companies, corporations, manufacturers, and so on. My book is also unusual, in that it includes an entire chapter on PLACEBOS, and an entire chapter on INTENT TO TREAT analysis, and an entire chapter on the STUDY SCHEMA. These three topics are grossly ignored by most or perhaps all other books on clinical trials. Too bad! My book corrects these deficiencies.FUNDAMENTALS OF CLINICAL TRIALS, 3rd ed., by Lawrence M. Friedman, et al, is 360 pages long. The book contains 19 chapters, each concluding with a carefully chosen collection of 30 to 100 references. One of Lawrence Friedman’s other books, the informative and lucid, "DATA

MONITORING IN CLINICAL TRIALS," is centered around case histories. In contrast, this book is not focused on case histories. FUNDAMENTALS OF CLINCAL TRIALS was a source of inspiration for me, shortly before I started writing my book, CLINICAL TRIALS. My book is a bit longer (over 600 pages).

Fundamentals of Clinical Trials Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics, 7e (Fundamentals of Clinical Chemistry (Tietz)) Clinical Trials; Your Key to Building a 7 Figure Practice Bayesian Designs for Phase I-II Clinical Trials (Chapman & Hall/CRC Biostatistics Series) Surviving "Terminal" Cancer: Clinical Trials, Drug Cocktails, and Other Treatments Your Oncologist Won't Tell You About Clinical Trials in Cardiovascular Disease: A Companion to Braunwald's Heart Disease, 1e Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines Conducting Clinical Trials Dictionary for Clinical Trials Group Sequential Methods with Applications to Clinical Trials (Chapman & Hall/CRC Interdisciplinary Statistics) Simulation for Designing Clinical Trials: A Pharmacokinetic-Pharmacodynamic Modeling Perspective (Drugs and the Pharmaceutical Sciences) Intelligent Drug Development: Trials and Errors in Clinical Research Fundamentals of Nursing: Human Health and Function (Craven, Fundamentals of Nursing: Human Health and Functionraven, Fundamentals of Nurs) Clinical Companion to Medical-Surgical Nursing: Assessment and Management of Clinical Problems, 9e (Lewis, Clinical Companion to Medical-Surgical Nursing: Assessment and Management of C) How to Let God Solve Your Problems: 12 Keys for Finding Clear Guidance in Life's Trials Everything in Its Place: My Trials and Triumphs with Obsessive Compulsive Disorder Feeding Eden: The Trials and Triumphs of a Food Allergy Family O'Connor's Texas Rules * Civil Trials 2014 Your Time Is Done Now: Slavery, Resistance, and Defeat: The Maroon Trials of Dominica (1813-1814) Wolves at the Door: The Trials of Fatty Arbuckle