Fundamental Concepts for New Clinical Trialists (Chapman & Hall/CRC Biostatistics Series)

By Scott Evans, Naitee Ting

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Fundamental Concepts for New Clinical Trialists describes the core scientific concepts of designing, data monitoring, analyzing, and reporting clinical trials as well as the practical aspects of trials not typically discussed in statistical methodology textbooks.

The first section of the book provides background information about clinical trials. It defines and compares clinical trials to other types of research studies and discusses clinical trial phases, registration, the protocol document, ethical issues, product development, and regulatory processes. It also includes a special chapter outlining the valuable attributes that statisticians can develop to maximize their contributions to a clinical trial.

The second section examines scientific issues faced in each progressive step of a clinical trial. It covers issues in trial design, such as randomization, blinding, control-group selection, endpoint selection, superiority versus noninferiority, and parallel group versus crossover designs; data monitoring; analyses of efficacy, safety, and benefit-risk; and the reporting/publication of clinical trial results.

As clinical trials remain the gold standard research studies for evaluating the effects of a medical intervention, newcomers to the field must have a fundamental understanding of the concepts to tackle real-world issues in all stages of trials. Drawing on their experiences in academia and industry, the authors provide a foundation for understanding the fundamental concepts necessary for working in clinical trials.

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Editorial Review

Review

"The book focuses on important concepts and promotes ‘thinking clinical trials’, and it is very readable. This book targets both statisticians and non-statisticians and wishes to facilitate better communication between them. I found that some chapters are especially useful for statisticians involved in clinical trials. . . Dr Evans uses this book as part of his ‘Principles of Clinical Trials’ course at the Harvard School of Public Health. Overall, it is an exciting book!"
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About the Author

Dr. Scott Evans teaches clinical trials at Harvard University, where he is the director of the Statistical and Data Management Center for the Antibacterial Resistance Leadership Group, an NIH-funded clinical trials network. He serves on a U.S. FDA Advisory Committee and several data monitoring committees for industry and NIH-sponsored clinical trials. He has been a recipient of the Mosteller Statistician of the Year Award and is a fellow of the American Statistical Association. Dr. Evans is a visiting professor at the Department of Medical Statistics at Osaka University and serves as the executive editor for *CHANCE* and the editor-in-chief of *Statistical Communications in Infectious Diseases.*

Dr. Naitee Ting has close to 30 years of experience in the pharmaceutical industry and currently works at Boehringer Ingelheim. He has also taught courses on clinical trials in the Department of Statistics at the University of Connecticut, University of Rhode Island, and Department of Biostatistics at Columbia University. He is a fellow of the American Statistical Association.

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