

Statistical Design and Analysis of Clinical Trials: Principles and Methods (Chapman & Hall/CRC Biostatistics Series)

By Weichung Joe Shih, Joseph Aisner

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Statistical Design and Analysis of Clinical Trials: Principles and Methods concentrates on the biostatistics component of clinical trials. Developed from the authors' courses taught to public health and medical students, residents, and fellows during the past 15 years, the text shows how biostatistics in clinical trials is an integration of many fundamental scientific principles and statistical methods.

Teach Your Students How to Design, Monitor, and Analyze Clinical Trials

The book begins with ethical and safety principles, core trial design concepts, the principles and methods of sample size and power calculation, and analysis of covariance and stratified analysis. It then focuses on sequential designs and methods for two-stage Phase II cancer trials to Phase III group sequential trials, covering monitoring safety, futility, and efficacy. The authors also discuss the development of sample size reestimation and adaptive group sequential procedures, explain the concept of different missing data processes, and describe how to analyze incomplete data by proper multiple imputations.

Turn Your Students into Better Clinical Trial Investigators

This text reflects the academic research, commercial development, and public health aspects of clinical trials. It gives students a multidisciplinary understanding of the concepts and techniques involved in designing and analyzing various types of trials. The book's balanced set of homework assignments and in-class exercises are appropriate for students in (bio)statistics, epidemiology, medicine, pharmacy, and public health.

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Editorial Review

About the Author

Weichung Joe Shih, PhD, is professor and chair of the Department of Biostatistics in the Rutgers School of Public Health at Rutgers University, and director of the Biometrics Division at the Rutgers Cancer Institute of New Jersey. He is an elected fellow of the American Statistical Association and an elected member of the International Statistical Institute. He served on the advisory board of the U.S. FDA for reviewing new drug applications and was associate editor of professional journals, including *Statistics in Medicine, Controlled Clinical Trials, Clinical Cancer Research, Statistics in Biopharmaceutical Research,* and *Statistics in Bioscience*. His research interests include adaptive designs and missing data issues.

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