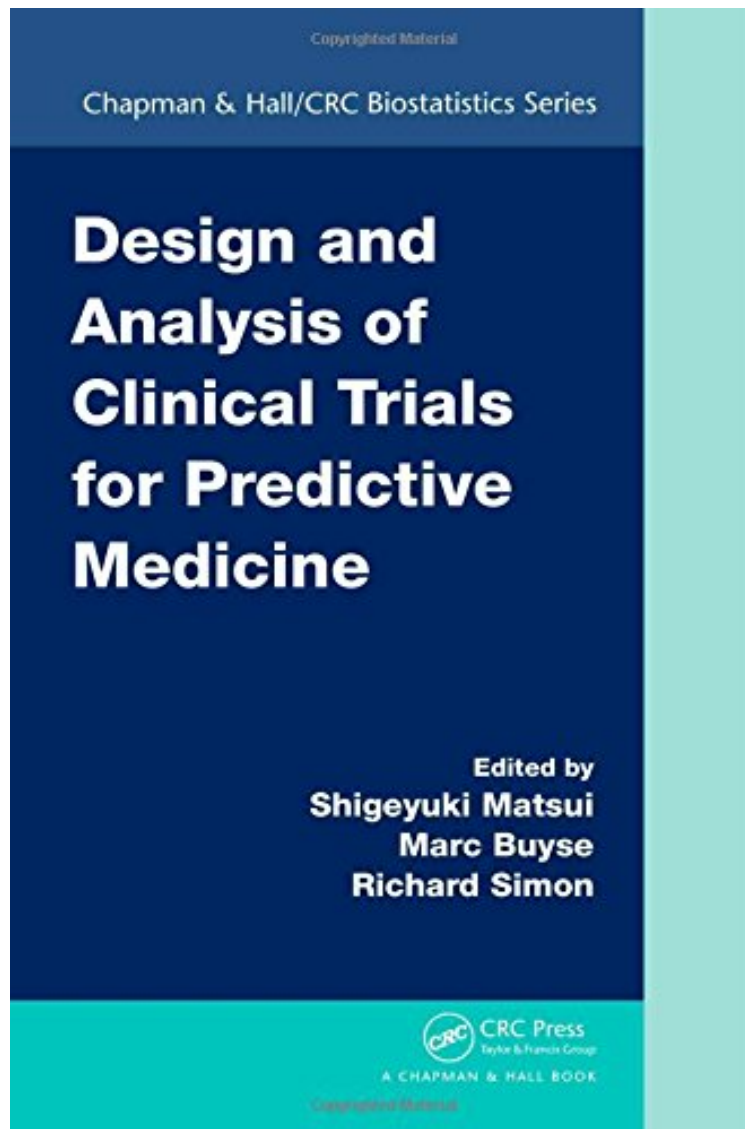


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Design and Analysis of Clinical Trials for Predictive Medicine provides statistical guidance on conducting clinical trials for predictive medicine. It covers statistical topics relevant to the main clinical research phases for developing molecular diagnostics and therapeutics from identifying molecular biomarkers using DNA microarrays to confirming their clinical utility in randomized clinical trials. The foundation of modern clinical trials was laid many years before modern developments in biotechnology and genomics. Drug development in many diseases is now shifting to molecularly targeted treatment. Confronted with such a major break in the evolution toward personalized or predictive medicine, the methodologies for design and analysis of clinical trials is now evolving. This book is one of the first attempts to contribute to this evolution by laying a foundation for the use of appropriate statistical designs and methods in future clinical trials for predictive medicine. It is a useful resource for clinical biostatisticians, researchers focusing on predictive medicine, clinical investigators, translational scientists, and graduate biostatistics students.

"To say this is an extremely timely book would be a gross understatement. The editors have assembled an impressive series of articles that address many of the major methodological issues confronting researchers who are attempting to not only identify valuable medical treatments but to determine which subsets of patients will benefit from these treatments. These issues are particularly important in cancer research, where treatments are often burdensome, toxic, and expensive; one does not want to treat large numbers of patients when only a few will benefit [this] would be a very valuable resource for anyone in, or moving into, the area of clinical trials for developing targeted therapies. Because the chapters steer away from highly technical discussions, I would recommend this book to clinicians as well as statisticians who are working in this challenging and developing area of research." -Susan Ellenberg, Journal of the American Statistical Association "Design and Analysis of Clinical Trials for Predictive Medicine addresses a necessity for precision medicine: identifying and testing molecular biomarkers for their ability to predict the effect of treatments on specific patient populations." Journal of Clinical Research Best Practices, December 2015 " a very good collection of relevant topics and methods, which have been published and applied in the field of personalized medicine from a clinical development perspective. The editors of this book are experts in the field and have published extensively on these topics. a useful reference for biostatisticians and researchers involved in the design and analyses of biomarker integrated clinical trials." Arunava Chakravartty, Journal of Biopharmaceutical Statistics " a useful resource for clinical biostatisticians, researchers focusing on predictive medicine, clinical investigators, translational scientists, and graduate biostatistics students." Zentralblatt MATH About the Author Shigeyuki Matsui is a professor in the Department of Biostatistics at Nagoya University Graduate School of Medicine in Japan. He is also a visiting professor at the Institute of Statistical Mathematics. Dr. Matsui has served as council and nominating committee member of the International Biometric Society. He is currently council of the Biometric Society of Japan (BSJ) and editor-in-chief of the Japanese Journal of Biometrics. He is the recipient of the 2014 Award from the BSJ. Dr. Matsui is also a frequent reviewer commissioned by government and advisor to pharmaceutical companies in Japan. He holds degrees in engineering from the Tokyo University of Science in Japan. Marc E. Buyse is the founder of the International Drug Development Institute in Louvain-la-Neuve, Belgium and of CluePoints Inc. in Cambridge, Massachusetts. He is also an associate professor of biostatistics at Hasselt University in Belgium. He was president of the International Society for Clinical Biostatistics, president of the Quetelet Society, and fellow of the Society for Clinical Trials. He worked at the European Organization for Research and Treatment of Cancer in Brussels and at the Dana Farber Cancer Institute in Boston. He holds degrees in engineering and statistics from Brussels University, management from the Cranfield School of Management in the UK, and a doctorate in biostatistics from Harvard University. Richard M. Simon is chief of the Biometric Research Branch at the National Cancer Institute in Bethesda, Maryland. He leads a multidisciplinary group of scientists developing and applying methods for the application of genomics to cancer therapeutics. Dr. Simon is the architect of BRB-ArrayTools software used for the analysis of microarray and digital expression, copy number, and methylation data. He is the recipient of the 2013 Karl E. Peace Award for Outstanding Statistical Contributions for the Betterment of Society and is the author or coauthor of more than 450 publications.