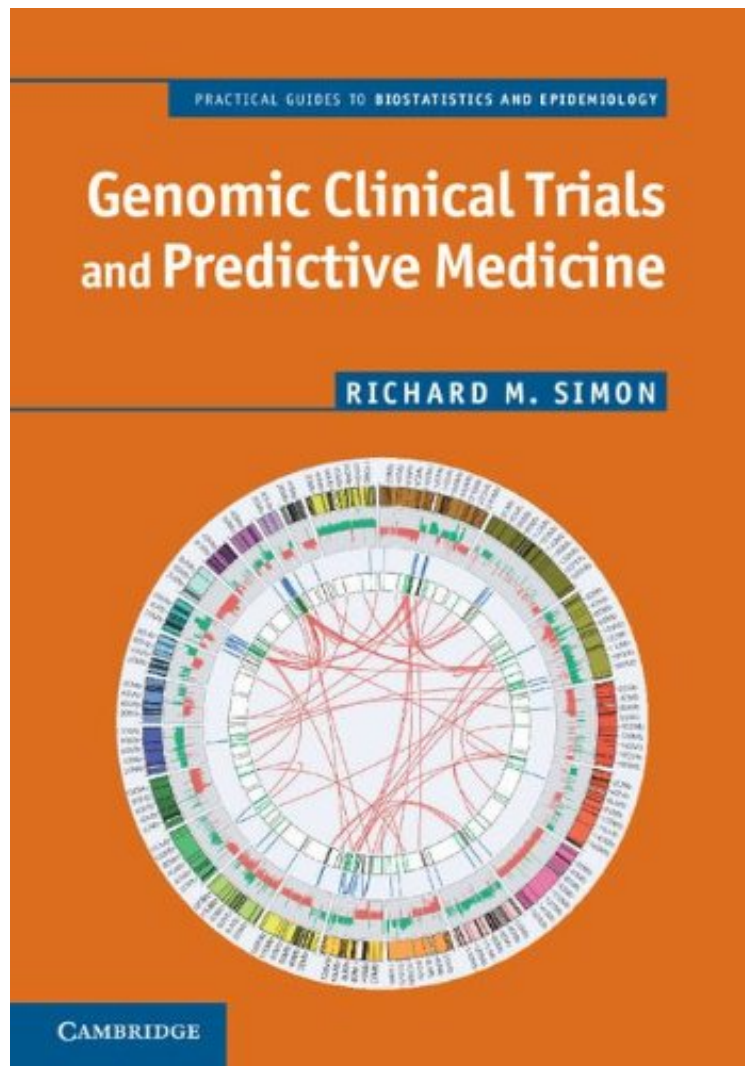


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Genomic Clinical Trials and Predictive Medicine (Practical Guides to Biostatistics and Epidemiology)

Richard M. Simon

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Genomics is majorly impacting therapeutics development in medicine. This book contains up-to-date information on the use of genomics in the design and analysis of therapeutic clinical trials with a focus on novel approaches that provide a reliable basis for identifying which patients are most likely to benefit from each treatment. It is oriented to both clinical investigators and statisticians. For clinical investigators, it includes background information on clinical trial design and statistical analysis. For statisticians and others who want to go deeper, it covers state-of-the-art adaptive designs and the development and validation of probabilistic classifiers. The author describes the development and validation of prognostic and predictive biomarkers and their integration into clinical trials that establish their clinical utility for informing treatment decisions for future patients.

"This book will be a valuable resource to those involved in genomic clinical trials. The author touches on many of the important issues in this field and provides a useful selection of approaches to handling them." Matthew Schipper, International Statistical Association
About the Author Dr Richard M. Simon is chief of the Biometric Research Branch of the National Cancer Institute, where he is chief statistician for the Division of Cancer Treatment and Diagnosis. He is the lead author of the textbook *Design and Analysis of DNA Microarray Experiments* and has more than 450 publications. Simon has been influential in promoting excellence in clinical trial design and analysis. He has served on the Oncologic Advisory Committee of the US Food and Drug Administration and is a frequent advisor to government, academic and industry organizations involved with developing improved treatments and diagnostics for patients with cancer. In 1998 Dr Simon established the Molecular Statistics and Bioinformatics Section of the National Cancer Institute, a multidisciplinary group of scientists developing and applying methods for the application of genomics to cancer therapeutics. He is the architect of BRB-ArrayTools software for the analysis of microarray expression and copy number data.