Multiregional Clinical Trials for Simultaneous Global New Drug Development (Chapman Hall/CRC Biostatistics Series)

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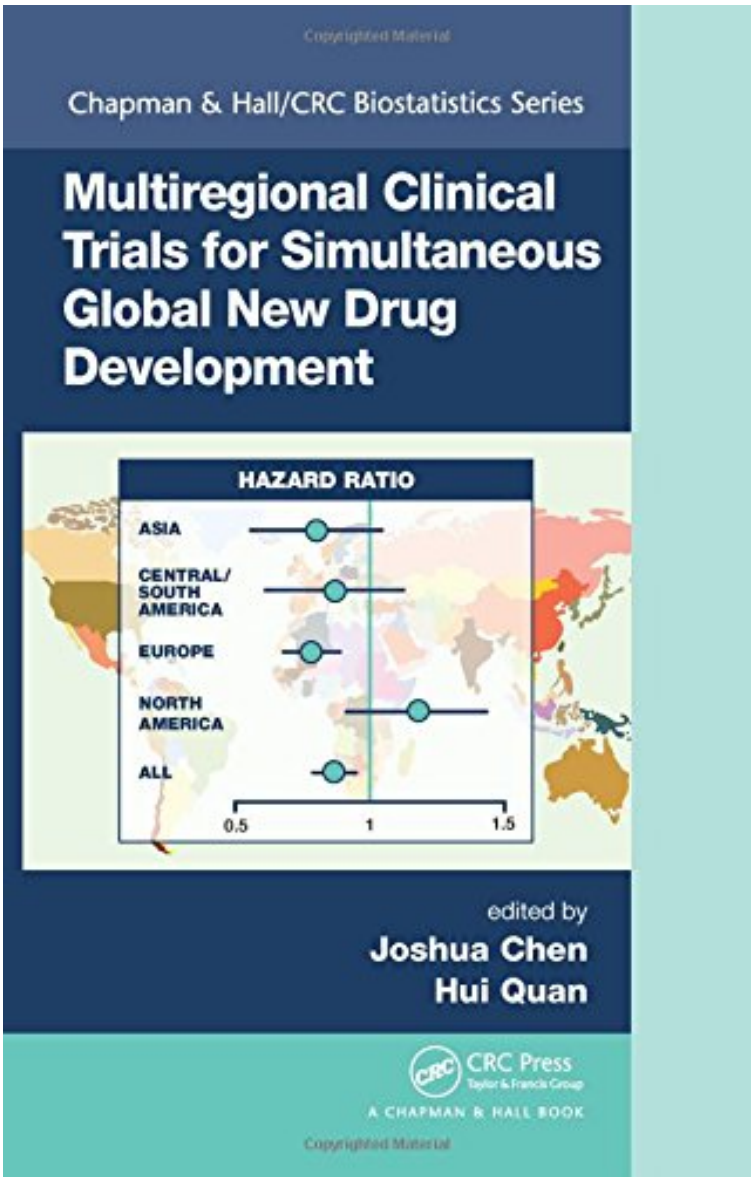

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From Chapman and Hall/CRC : Multiregional Clinical Trials for Simultaneous Global New Drug Development (Chapman Hall/CRC Biostatistics Series) before purchasing it in order to gage whether or not it would be worth my time, and all praised Multiregional Clinical Trials for Simultaneous Global New Drug Development (Chapman

Hall/CRC Biostatistics Series):

In a global clinical development strategy, multiregional clinical trials (MRCTs) are vital in the development of innovative medicines. Multiregional Clinical Trials for Simultaneous Global New Drug Development presents a comprehensive overview on the current status of conducting MRCTs in clinical development. International experts from academia, industry, and health organizations address various aspects of the important problems in global clinical development and MRCTs. The book first provides a high-level introduction to the context, motivation, opportunities, and challenges in simultaneous global clinical development using MRCTs. It then focuses on the design, monitoring, and analysis/interpretation of MRCTs. The book concludes with an examination of the latest research topics from MRCT perspectives, such as special considerations by local health authorities, health economic evaluations, benefit-risk assessment, and medical devices. Explaining how to design, conduct, and interpret MRCTs, this book will help biostatisticians working in the late-stage clinical development of medical products. It will also be useful for statisticians and clinicians in the biopharmaceutical industry, regulatory agencies, and medical research institutes.

This book consolidates current state of knowledge regarding relevant topics on MRCTs (design, operation, and analysis/interpretation) into well-organized chapters. This book should serve as a useful source of information to anyone who plans to work or is working on MRCTs. There are many on-going challenges and we also hope it will stimulate further research in MRCTs. ~Nobushige Matsuoka, PhD and Norisuke Kawai, PhD, Pfizer Japan Inc.About the AuthorJoshua Chen is the global head of biostatistics and programming at Sanofi Pasteur. He previously worked on clinical development of small molecules, biologics, and vaccines at Merck Research Laboratories. His experience spans many therapeutic areas with a major focus on human vaccines and antiviral drugs. He has extensive experience in the study, design, conducting, and reporting of international clinical trials from proof of concept through regulatory approvals and life cycle management. His primary research interest is clinical trial designs, including group sequential methods, adaptive designs, and multiregional clinical trials (MRCTs). Dr. Chen was a colead of the cross-industry MRCT Consistency Working Group under PhRMA (20082011) and the Society for Clinical Trials (20122014). He earned his PhD in statistics from the University of WisconsinMadison. Hui Quan is an associate vice president and global head of the methodology group in the Biostatistics and Programming Department of SanofiAventis. A fellow of the American Statistical Association, he has 24 years of pharmaceutical industry experience in many therapeutic areas ranging from early phase to phase IV studies. He has published 82 papers, including 59 statistical papers. His research interests include multivariate analysis, safety analysis, multiplicity adjustment, missing handling, adaptive design, integrated data analysis, modeling and simulation, benefit/risk assessment, and MRCTs. Dr. Quan was a colead of the MRCT Consistency Assessment Working Group under PhRMA (20082011) and the Society for Clinical Trials (20122014). He earned his PhD in statistics from Columbia University.