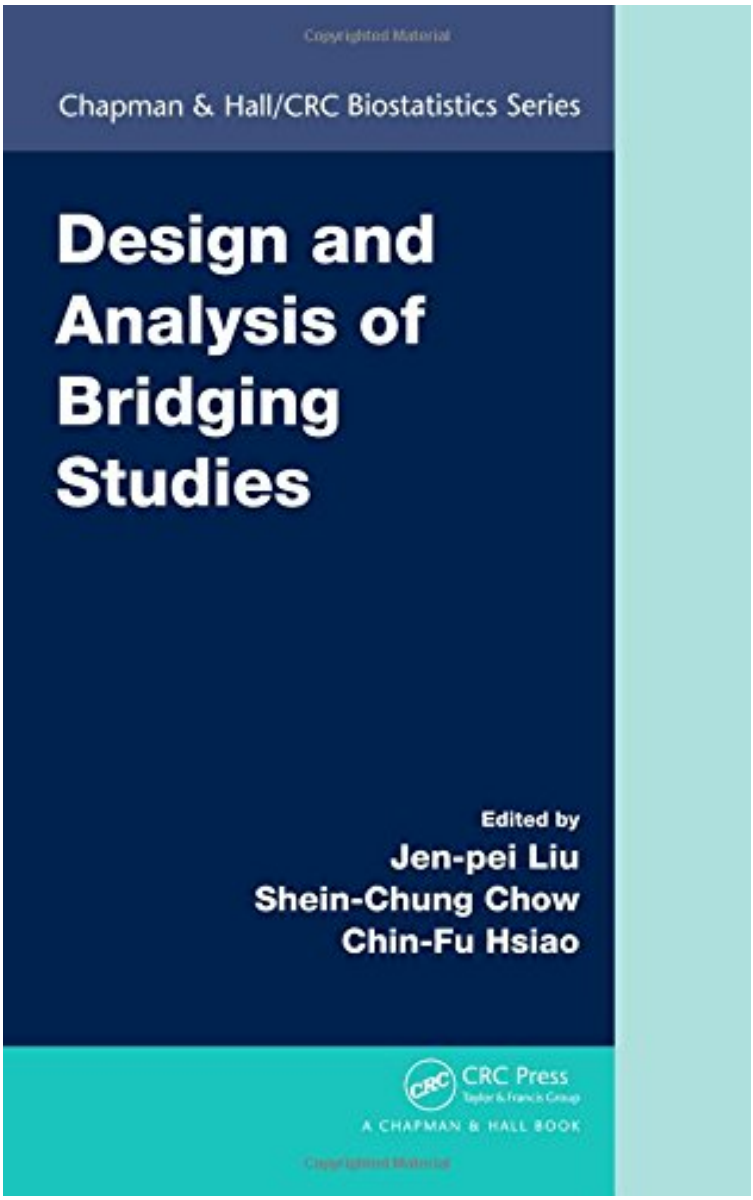
Design and Analysis of Bridging Studies (Chapman Hall/CRC Biostatistics Series)

From Chapman and Hall/CRC
**Download PDF | ePub | DOC | audiobook | ebooks*



#3765457 in Books 2012-07-26Original language:EnglishPDF # 1 9.50 x 6.50 x .75l, 1.18 #File Name: 1439846340287 pages | File size: 62.Mb

From Chapman and Hall/CRC : Design and Analysis of Bridging Studies (Chapman Hall/CRC Biostatistics Series) before purchasing it in order to gage whether or not it would be worth my time, and all praised Design and

Analysis of Bridging Studies (Chapman Hall/CRC Biostatistics Series):

As the development of medicines has become more globalized, the geographic variations in the efficacy and safety of pharmaceutical products need to be addressed. To accelerate the product development process and shorten approval time, researchers are beginning to design multiregional trials that incorporate subjects from many countries around the world under the same protocol. Design and Analysis of Bridging Studies addresses the issues arising from bridging studies and multiregional clinical trials. For bridging studies, the book explores ethnic sensitivity, the necessity of bridging studies, types of bridging studies, and the assessment of similarity between regions based on bridging evidence. For multiregional clinical trials, the text considers regional differences, assesses the consistency of treatment effect across regions, and discusses sample size determination for each region. Taking into account the International Conference Harmonisation (ICH) E5 framework for bridging studies, the book provides a unified summary of the growing literature and research activities in this area. It covers the regulatory requirements, scientific and practical issues, and statistical methodology for designing and evaluating bridging studies and multiregional clinical trials, with the goal of inspiring new research activities in the field.

" a place to start acquiring an understanding of bridging and multi-regional studies and as a supplement to ICH-E5 and local regions current regulatory implementation guidance. this book is also intended to stimulate additional research in bridging and multi-regional trials and will be of interest to those looking for research topics."Scott D. Patterson, PhD, Pfizer, Vaccines Research Development in Australian and New Zealand Journal of StatisticsAbout the AuthorJen-pei Liu is a professor in the Division of Biometry, Department of Agronomy, and Institute of Epidemiology and Preventative Medicine at National Taiwan University. He is also an adjunct investigator in the Institute of Population Health Sciences at the National Health Research Institutes in Taiwan. A fellow of the ASA, Dr. Liu is an associate editor of the Journal of Biopharmaceutical Statistics and an editor of the Chapman Hall/CRC Biostatistics Series. He has authored ten books, over 120 peer-reviewed research articles, and over 40 book chapters. His research interests include statistical methodology in bioequivalence evaluation, clinical trials, equivalence and noninferiority testing, bridging testing, statistical quality control in biopharmaceutical products, diagnostic testing, statistical QA/QC for biochip diagnostic products, and evaluation of substantial equivalence in GMO crops and food. Shein-Chung Chow is a professor in the Department of Biostatistics and Bioinformatics at Duke University School of Medicine. Dr. Chow is also a professor of clinical sciences at DukeNational University of Singapore Graduate Medical School. He is the editor-in-chief of the Journal of Biopharmaceutical Statistics and editor-in-chief of the Chapman Hall/CRC Biostatistics Series. He has authored or co-authored over 200 papers and 19 books, including Adaptive Design Methods in Clinical Trials, Second Edition, Handbook of Adaptive Designs in Pharmaceutical and Clinical Development, and Controversial Statistical Issues in Clinical Trials. A fellow of the ASA and member of the ISI, Dr. Chow has received the ASA Chapter Service Recognition Award, the DIA Outstanding Service Award, and the ICSA Extraordinary Achievement Award. Chin-Fu Hsiao is an investigator in the Institute of Population Health Sciences at the National Health Research Institutes in Taiwan. Dr. Hsiao is also an adjunct associate professor at National Chiao Tung University. His research interests encompass Bayesian analysis, clinical trials, and genetic study.