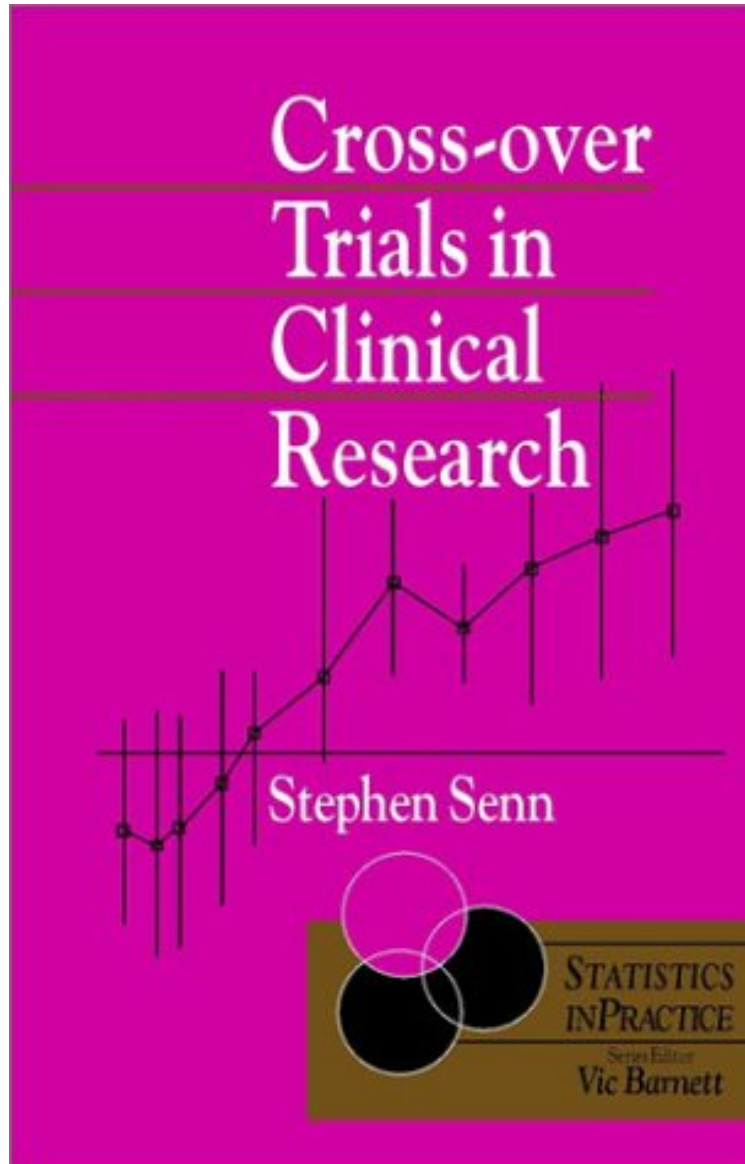


Cross-over Trials in Clinical Research

Stephen S. Senn

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Stephen S. Senn : Cross-over Trials in Clinical Research before purchasing it in order to gage whether or not it would be worth my time, and all praised Cross-over Trials in Clinical Research:

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book with cross-over trials very useful when testing equivalence. By Michael R. Chernick. Stephen Senn is a great writer and an excellent applied statistician. He has written a number of excellent books related to the conduct of clinical trials. This is the second edition of the book and it is even an improvement of the first which was also excellent and often consulted! A nice thing about Senn with all of his books is that he does not shy away from controversy. He also is very careful in his presentation and he avoids common mistakes and points out the mistakes of others. I recently got a deeper appreciation for this book when I had to design a crossover equivalence trial while I was employed at Auxilium about 10 months ago. Senn does a very thorough job of explaining the AB/BA design which although simpler than many of the others is commonly used. Most of the important concepts in cross-over designs such as the washout period and the within subject variability can be addressed in this simplest of cross-over designs. This book is an excellent reference for any statistician that gets involved in cross-over trials. It is clear, concise and strong on concepts but also detailed enough to make the correct mathematics clear. Cross-over trials have the advantage of potentially reducing variability since each subject acts as his own control. But to avoid confounding, a washout period with the subject off treatment is required so that the effect of the earlier treatment is not influencing the results for the next treatment. Sometimes this constraint can make recruiting difficult and there can be other logistic issues that can make it infeasible.

Statistics in Practice A new series of practical books outlining the use of statistical techniques in a wide range of application areas: Human and Biological Sciences Earth and Environmental Sciences Industry, Commerce and Finance Cross-over Trials in Clinical Research Stephen Senn Biometrics, Medical Department, CIBA-Geigy Ltd, Basle, Switzerland Cross-over Trials in Clinical Research provides a practical introduction to this important tool within the pharmaceutical industry. Aimed at guiding practitioners in the methods of using cross-over designs efficiently, this book presents a fresh insight into how such trials may be designed and analysed. Key features of this comprehensive treatment are: A focus on the two-period AB/BA design, including the most up-to-date developments in this topic. Important aspects of special design graphical and tabular presentation of trials, robust approaches to analysis, and practical issues in planning. Direct relevance to drug development with an approach rooted firmly in biology and pharmacokinetics rather than stressing the mathematical aspects. All techniques included are discussed and illustrated in detail with many practical examples drawn from the authors wide-ranging experience. This book will prove an invaluable reference to all statisticians and researchers in the pharmaceutical industry. It will also appeal to physicians involved in clinical research.

"clearly written mode of presentation is very effective I recommend this book as a useful resource" (Journal of the American Statistical Association, December 2004) "The book by Senn was the very first volume in Wiley's excellent series, "Statistics in Practice". Here, 10 years later, it is now the first of the books in that series to reappear in a second addition. (Technometrics, May 2004) "...well structured and easy to read...incredibly useful..." (Applied Clinical Trials, December 2002) "...an excellent reference source and is easily readable." (The Statistician) "...explanation are kept as non-technical as possible, although they do not lack statistical rigour...well worth reading..." (Pharmaceutical Statistics, Vol 2, 2003) the main additions can be seen as adding to the arguments for the authors view on carryover affects... (Clinical Trials, No.1 2004) From the Publisher Few issues in clinical trials are as controversial as the cross-over variety. Contains pertinent information on the usefulness of cross-over trials, their disadvantages, the two-stage analysis of AB/BA design and the recent revolution in attitudes to it, sequences for trials with three or more treatments, Hodges-Lehmann type estimators, various design concepts and much more. Features a significant amount of tested, practical and worked examples. From the Back Cover Cross-over trials are an important class of design used in the pharmaceutical industry and medical research, and their use continues to grow. Cross-over Trials in Clinical Research, Second Edition has been fully updated to include the latest methodology used in the design and analysis of cross-over trials. It includes more background material, greater coverage of important statistical techniques, including Bayesian methods, and discussion of analysis using a number of statistical software packages. * Comprehensive coverage of the design and analysis of cross-over trials. * Each technique is carefully explained and the mathematics is kept to a minimum. * Features many real and original examples, taken from the author's vast experience. * Includes discussion of analysis using SAS, S-Plus and, GenStat, StatXact and Excel. * Written in a style suitable for statisticians and physicians alike. Primarily aimed at statisticians and researchers working in the pharmaceutical industry, the book will also appeal to physicians involved in clinical research and students of medical statistics.