

Media Reviews

Cross-over Trials in Clinical Research, 2nd ed.

Stephen Senn, Wiley (Chichester, UK, 2002) 345 pp., \$85.00.

The intended audience for this text is both statisticians and medical researchers. Professor Stephen Senn serves both these audiences well by striking an excellent balance between appropriate technical details and discussion, while simultaneously providing useful alternative references for those wishing to discover the delights of the technical details. Sections of the book focusing more on the technical aspects are highlighted, enabling the reader to avoid these parts if so desired.

The cross-over design in which subjects either receive treatment A followed by B or treatment B followed by A (the "AB/BA" design) is extensively discussed in this book (pages 35 through 156). At first glance, dedicating 121 pages to the discussion of this one study design in a book that has a total of 322 pages (excluding references) might appear to be a little excessive. What should be noted is that this extensive discussion is used to develop an understanding of the analytic methods for different data types (normal, binary, ordered categorical, frequency, and survival). Textual discussion is provided on how to calculate relevant statistics by hand and how to perform such analyses using the packages SAS, S-plus, Genstat, StatXact, and the Excel add-in StatPlus. In many cases, example computer code is given.

Clinical trial designs involving three or more treatments are then discussed, building on the

concepts detailed in the chapters concerning the AB/BA design. Limited specific discussion is given for "special designs," such as factorial designs, incomplete block designs, n of 1 trials, and bioequivalence trials. Following this, a chapter is dedicated to appropriate graphical and tabular presentations of data. To me, the content of this chapter has the potential to be greatly underestimated and should be carefully reviewed by those needing to summarize data from cross-over trials, using either graphical or tabular formats. Remaining aspects in the design of cross-over trials are contained in the penultimate chapter, "various

design issues," which discusses the issues surrounding sample size, dropout, and length of the wash-out period.

This text is well structured and easy to read. Inclusion of software packages other than SAS is a useful contribution. I felt that some of the textual discussion of the "hand calculations" could have been made more concise, but in general found that these descriptions added clarity. The inclusion of more detailed methods for non-normally distributed data is useful, but I was left a little disappointed with the extent of these discussions and would like to have seen more detailed discussion of methods

across the board. In particular, an increase in the aspects of modeling these alternative types of data rather than a focus on how to generate a p-value would be useful. I would also have preferred to see a greater discussion of incomplete block designs rather than suggestions of alternative reading material. The inclusion of such additional material would raise this book from being incredibly useful to being invaluable.

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