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BOOK REVIEW

Sample Size Calculations in Clinical Research, Second Edition, by S.-C. Chow, J. Shao, and H. Wang, Boca Raton, FL: Chapman & Hall/CRC, 2007, ISBN 1-58488-982-9, xiv + 465 pp., $89.95.

The specific goal of this (2nd edition) book continues to be to provide a comprehensive and unified presentation regarding sample size calculations in a variety of clinical research and development phases and to serve as a solid reference for researchers in academia, industry, and government. The book has been expanded, by around 100 pages, from its original 12 chapters to its current 15 chapters. All original material from the 1st edition exists (and appears to be completely unchanged) in this 2nd edition. New material has been added as follows: (i) Two entirely new chapters have been added, Chapters 12—Microarray Studies, and Chapter 13—Bayesian Sample Size Calculation; (ii) a section from the 1st edition has been expanded into its own chapter, Chapter 11—Dose Response Studies; and (iii) two new sections have been added to the last chapter, Chapter 15—Sample Size Calculations in Other Areas. It's two new sections are entitled, respectively, "QT/QTc Studies with Time-Dependent Replicates" and "Propensity Analysis in Nonrandomized Studies".

Hence, for a review of Chapters 1 through 10, 14 (11 in 1st edition), and Sections 3 through 6 of Chapter 15 (Chapter 12, Sections 2–5 in 1st edition), one should refer to the original book review (Filloon, 2004). A review of the new material in this 2nd edition follows, including summary comments of which some are carried over from the original book review.

Chapter 11 provides sample size calculations for dose-response studies under a variety of scenarios. Whereas the 1st edition discusses only the two topics of linear contrast testing and minimum effective dose (MED) estimation for continuous responses, the 2nd edition extends linear contrast testing to include binary and time-to-event (i.e., survival) responses also. Furthermore, Cochran-Armitage trend testing for proportions is now addressed as well as extensive discussion of several types of phase 1 dose-escalation trials for toxicity estimation (i.e., maximum tolerable dose, MTD).

In Chapter 12, microarray studies are addressed with emphasis on the issues associated with multiplicity. Specific direction per sample size is given on how to deal appropriately with false detection rate (FDR) and family-wise error rate (FWER). Hence, guidance is given on how to effectively deal with multiplicity adjustment at the design (i.e., sample sizing) stage.

Chapter 13 shows how to determine sample size requirements when addressing one- and two-sample problems from a Bayesian perspective. Both confidence

interval (i.e., posterior credible interval) and misclassification (i.e., posterior error) approaches are outlined. Depending on whether one is concerned with interval coverage, length or worst case, one is shown the respective posterior credible interval approach for various cases of the one- and two-sample problems with known or unknown precision.

The last chapter (Chapter 15) includes two new sections regarding QT/QTc studies and propensity analysis. The section on QT/QTc studies (Section 1) addresses the issue of sample size determination when multiple repeated measurements are present, under both parallel and crossover design settings. The topic of propensity analysis in nonrandomized studies (Section 2) revolves around the stratified Mantel-Haenszel test statistic and how sample sizes can be determined for this scenario. The rest of the chapter is unchanged from the 1st edition.

This book continues to provide an exhaustive algebraic derivation of sample size formulae for a wide variety of statistical testing scenarios, reference tables for select topics, and numerous worked examples to show how to use said formulae. It has been expanded by adding the emerging topics of microarray and QTc studies respectively and by offering the Bayesian perspective of sample sizing also. However, as stated in the book review of the 1st edition (and still currently true), (i) one needs to be careful because a significant number of typographical errors exist, (ii) one should take caution in moving between chapters as notation changes between them, and (iii) one should be aware that there is no reference or comparison to existing sample size software.

This book can be a helpful resource in a departmental library to the extent that it collates sample size information from many different clinical research topics into a single location. Additionally, it could reduce literature searching and help with evaluation for those sample size problems that are not incorporated into existing software.

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REFERENCE

Filloon, T. G. (2004). Book review of Chow, S.-C., Shao, J., Wang, H., 2003. Sample size calculations in clinical research. *Journal of Biopharmaceutical Statistics* 14:839–841.

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