BOOK REVIEWS

TAL, J. *Strategy and Statistics in Clinical Trials: A Non-Statistician's Guide to Thinking, Designing, and Executing*. Waltham, MA: Academic Press; 2011, 267pp, \$69.95 (hardcover), ISBN 9780123869098.

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Strategy and Statistics in Clinical Trials: A Non-Statistician's Guide to Thinking, Designing, and Executing is not your typical statistics book. Many academics who see the word "statistics" in a textbook title immediately anticipate seeing mathematical formulas, Greek letters representing key statistical parameters, and sometimes even matrix algebra. You won't find any of those in this book, at least not in the first half; even in the second half, the most complex mathematics you will find is the formula for standard deviation.^{p164} Readers should heed the subtitle of the book, "a non-statistician's guide. . ." As described in the author's foreword, this book is much more about the theoretical issues surrounding the design of clinical trials and the interpretation of data from those trials. The author's goals and vision for this text are to provide just enough background information (again, to non-statisticians) to allow for more informed and comprehensible dialogue between the many different parties involved with clinical trial design, especially with biostatisticians.

In the book, the author introduces many of the fundamental issues of basic statistical theory, including sampling from a larger population, hypothesis testing, drawing inferences, sensitivity, specificity, paired-testing, and Type I and Type II errors. Interwoven with these concepts are key issues of clinical trials, such as discussion of clinical trial phases and their goals, needs for interim analyses, human subjects and research ethical issues, and theoretical consideration for study endpoints - both single and composite endpoints. Each chapter begins with one or

more applied situations taken from actual clinical trials (some may be mildly disguised fictitious drugs). In each case, the author describes the trial design issues and how one of more relevant statistical concepts may be applied to the situation. For example, the chapter describing sampling from a larger population (Chapter 6) is an eloquently prepared chapter discussing how parameter estimation with absolute certainty is impossible (and therefore sampling requires the language of "probabilities").

As mentioned, the book is highly theoretical and conceptual in its nature, but that should not be construed to mean being overly complex in its language. Anyone with the most basic knowledge of statistics will be able to read, comprehend, and even enjoy the situations that unfold in each chapter. The book is also written in a conversational, first-person style. Large sections of the text read more like a personal journal than an instructional textbook. The conceptual nature of the book, however, may also be one of its limitations. Whenever the book introduces statistical concepts (eg, sample size, effect size), the discussion stops just short of presenting the reader with the equations and an example of "here's how to calculate this yourself." Some readers may find this disappointing. Indeed, readers will not find any of the usual cookbook equations for sample size estimation, effect size, analysis of variance, etc. In retrospect, as the author intends, he takes readers just to the point where they should engage a statistician to help them do it right, but no further.

This book is easy to read and will appeal to a wide audience with diverse backgrounds in health care. Anyone with the most basic exposure to statistics will be able to follow the concepts introduced throughout its chapters. This book would be of greatest value to non-statisticians engaged in some aspect of clinical trials but who do not need to actually compute any statistics for themselves, ie, this is not your typical statistics book!

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