Statistical Issues in Drug Development

Stephen S. Senn
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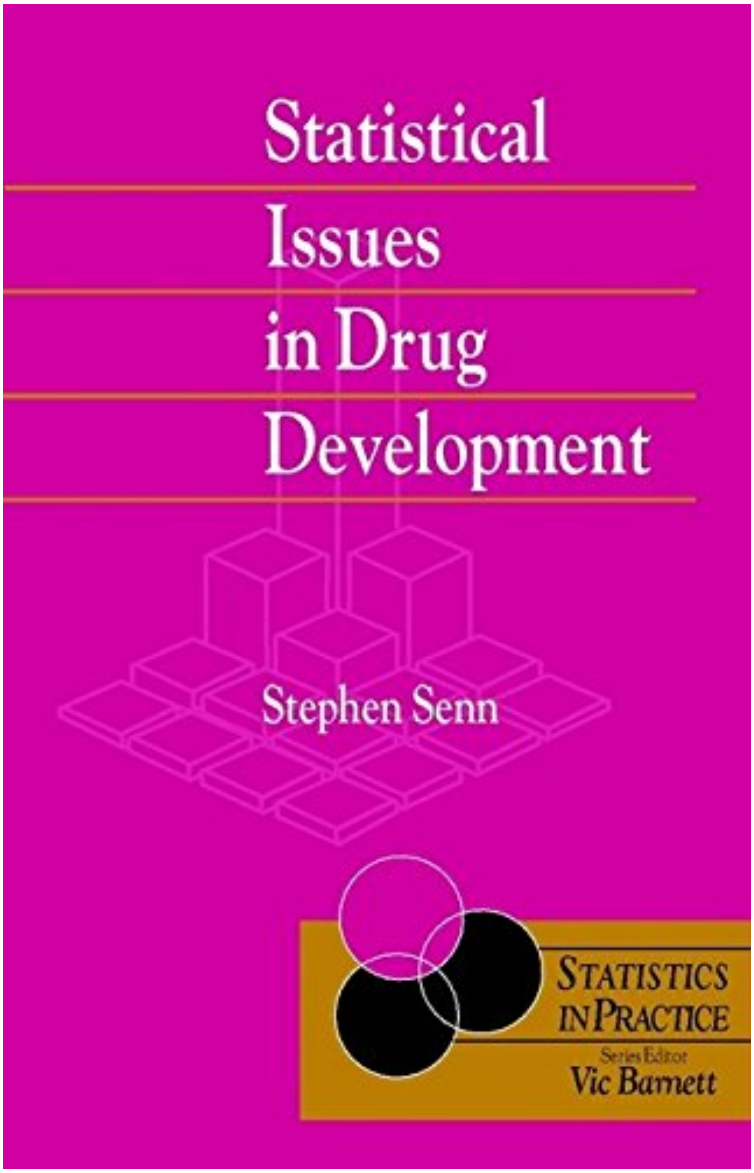

#5462481 in Books 1997-08Original language:EnglishPDF # 1 9.17 x 1.13 x 6.30l, .0 #File Name: 0471974889442 pages | File size: 17.Mb

Stephen S. Senn : Statistical Issues in Drug Development before purchasing it in order to gage whether or not it would be worth my time, and all praised Statistical Issues in Drug Development:

0 of 0 people found the following review helpful. Five StarsBy gerardo i. hurtadothank you!...34 of 34 people found the following review helpful. beautiful expository writing on key issues in drug development and clinical trialsBy Michael R. ChernickSenn is a great writer. He has written an excellent text on cross-over trials that raises many issues

about when such design can be used and what their limitations are. This book covers the gamut of issues in drug development concentrating on important and sometimes subtle issues in clinical trials including design and analysis, intention to treat principle, multiple testing, Bayesian and frequentist approaches and interpretations, meta analysis, regulatory issues and ethics. It also covers cross-over designs, pharmacokinetics, pharmacodynamics and pharmacoeconomics.The introduction gives you a feeling for the approach in the book and how it splits into two parts. Part I, consisting of chapters 2-5, provides some history of the development of statistical methods and some introductory topics that are fundamental to the discussion in Part II.Part II is the heart of the book where the practical statistical issues in clinical trials are raised. The text is intended for non-statisticians who work in the pharmaceutical industry but to quote part of Senn's preface he states "Although addressed to the life-scientist it is my hope that many statisticians, in particular those studying medical statistics or embarking on a career in drug development, will also find it useful. Above all I hope that it will help communication between the disciplines: a process by which the statistician stands to benefit as much as any other professional in drug development."I can really appreciate what Senn has done. He explains the issues of intention-to-treat, washout, multiplicity and other problems that I have had to wrestle with and try to explain to MDs and clinical managers. But even more importantly to me than helping me communicate the many issues that I was aware of, he also raises many subtle issues that I was not aware of. This includes questions of bioequivalence, the use of baseline information and particularly percentage change from baseline versus covariate adjustment, problems of inference regarding measurements taken after titration and issuesw in N of 1 trials. I even learned a few new techniques (e.g. Taves minimiization and Atkinson's generalization of it for allocating patients to treatment groups).The only complaint I can see is that there is not enough detail. However, remember the text was not designed for statisticians and so much of the mathematics and technicalities are deliberately left out.But Senn does provides a detailed list of relevant references at the end of each chapter that allows the reader to find in texts and journal articles all the detail one might need. Also to aid with communication there is a large glossary of terms at teh back of the book.This is a great reference for scientists and statisticians as well!

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 Statistical Issues in Drug Development Stephen Senn Professor of Pharmaceutical Health Statistics, University College, London Statistical Issues in Drug Development provides an accessible text for those working directly in drug development, regulatory and marketing departments within the pharmaceutical industry. As a consequence of regulatory authorities demanding increasingly higher standards, statistics has become a critical element in the design and conduct of drug development programmes. The concepts covered in this volume guide the non-statistician through the most pressing statistical issues and controversies in drug development. Key issues covered include: * Design interpretation of clinical trials * Bayesian frequentist methods * Sequential cross-over trials * Drug monitoring pharmaco-economics The book has been prepared in two sections. The first section considers the role of statistics in drug development from four different perspectives: historical, philosophical, technical and professional. The second section covers a series of controversial topics such as fixed versus random effects for meta-analysis, one-sided versus two-sided tests and the ethics of placebo run-ins. The approachable and wide-ranging coverage of this book will make it invaluable to all those working in drug development and regulation.

For all his contributions to the development and exposition of medical statistics Stephen Senn is awarded the 2009 Bradford Hill Medal by the Royal Statistical Society. ?This book is a thought provoking, intriguing, and often challenging read. The author is unafraid to tackle weighty philosophical and paradigmatic issues, and he generally does so with great skill and insight. ...this excellent book should serve to inspire both statisticians and life scientists.? (Journal of the American Statistical Association, September 2009) "For statisticians, this should be required reading for anyone considering or starting out on a career in clinical drug development. I am also quite sure that most experienced statisticians would find this a useful book to dip into on occasion ... . This book will not disappoint." (Journal of the Royal Statistical Society: Series A (Statistics in Society), April 2009) "This book is an outstanding effort from a statistician of heroic proportions. Someone like me is only capable of sitting on the curb and applauding wildly." (Journal of Biopharmaceutical Statistics, Volume 19, Issue 1, 2009)From the PublisherThis book for non-statisticians explains the statistical issues in drug development to help them plan, analyze and interpret clinical trials. It also examines the commercial pressures, regulatory standards and high scrutiny that accompany this field.From the Back CoverStatistics 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 Statistical Issues in Drug Development Stephen Senn Professor of Pharmaceutical Health Statistics, University College, London Statistical Issues in Drug Development provides an accessible text for those working directly in drug development, regulatory and marketing departments within the pharmaceutical industry. As a consequence of regulatory authorities demanding increasingly higher standards, statistics has become a critical element in the design and conduct of drug development programmes. The concepts covered in this volume guide the

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