Statistical Monitoring of Clinical Trials: Fundamentals for Investigators

Lemuel A. Moy
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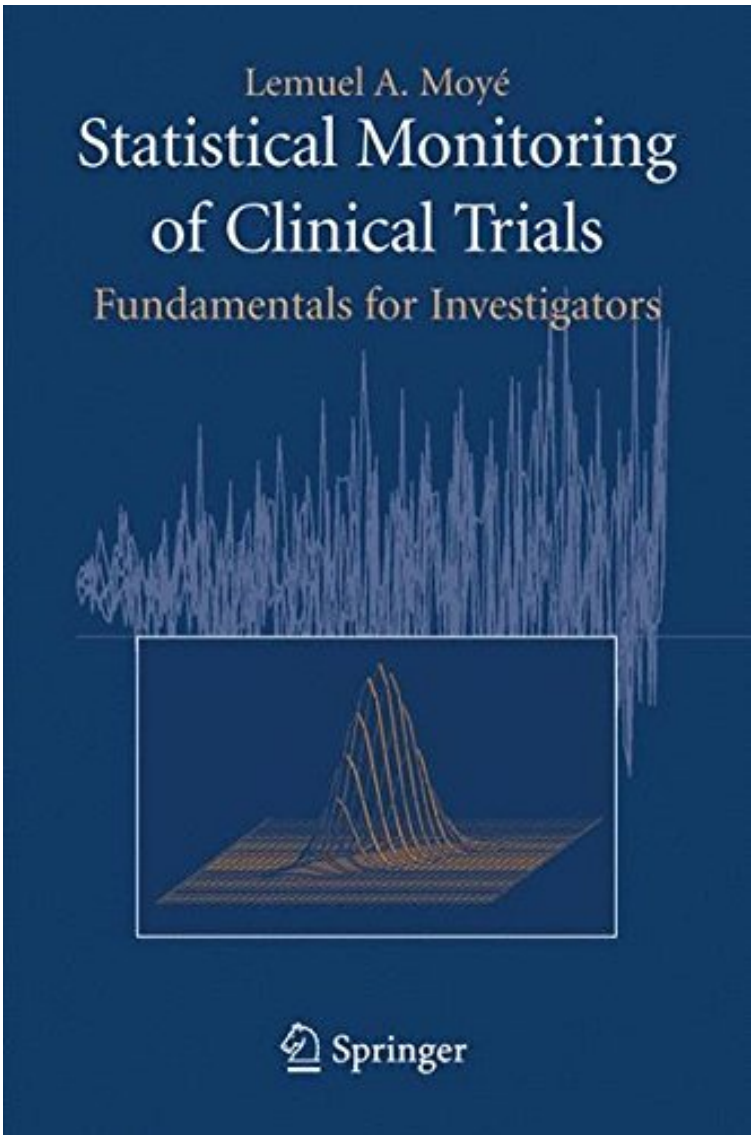

#3234995 in Books Lemuel A Moye 2005-11-16Original language:EnglishPDF # 1 9.25 x .64 x 6.10l, .89 #File Name: 0387277811254 pagesStatistical Monitoring of Clinical Trials Fundamentals for Investigators | File size: 59.Mb

Lemuel A. Moy : Statistical Monitoring of Clinical Trials: Fundamentals for Investigators before purchasing it in order to gage whether or not it would be worth my time, and all praised Statistical Monitoring of Clinical Trials: Fundamentals for Investigators:

0 of 0 people found the following review helpful. A nice good introduction to group sequential method for clinical

trialsBy W. YIPThis is a surprisingly good introductory book on group sequential method for clinical trials. There is probably better advanced textbook if you want deeper mathematical explanation. But, the author gets to the real essence without using a lot of mathematics. I like his way translating between TS, test statistics and B, Brownian Motion. Also, he gives a very intuitive explanation to stochastic curtailment and conditional power without using much mathematics at all. The last chapter is interesting - an introductory chapter to Bayesian group sequential method. I was always wondering how Bayesian approach could be applied here. Finally, he gives good and relevant examples in the book. Not too difficult to follow but relevant to common clinical trial monitoring applications.

Statistical Monitoring of Clinical Trials: Fundamentals for Investigators introduces the investigator and statistician to monitoring procedures in clinical research. Clearly presenting the necessary background with limited use of mathematics, this book increases the knowledge, experience, and intuition of investigations in the use of these important procedures now required by the many clinical research efforts. The author provides motivated clinical investigators the background, correct use, and interpretation of these monitoring procedures at an elementary statistical level. He defines terms commonly used such as group sequential procedures and stochastic curtailment in non-mathematical language and discusses the commonly used procedures of Pocock, OBrienFleming, and LanDeMets. He discusses the notions of conditional power, monitoring for safety and futility, and monitoring multiple endpoints in the study. The use of monitoring clinical trials is introduced in the context of the evolution of clinical research and one chapter is devoted to the more recent Bayesian procedures. From the reviews: "The author has a wealth of experience in this area and this is demonstrated throughout the text with relevant poignant examples." Short Book Reviews of the ISI, June 2006

From the Back CoverStatistical Monitoring of Clinical Trials: Fundamentals for Investigators introduces the investigator and statistician to monitoring procedures in clinical research. Clearly presenting the necessary background with limited use of mathematics, this book increases the knowledge, experience, and intuition of investigations in the use of these important procedures now required by the many clinical research efforts. The author provides motivated clinical investigators the background, correct use, and interpretation of these monitoring procedures at an elementary statistical level. He defines terms commonly used such as group sequential procedures and stochastic curtailment in non-mathematical language and discusses the commonly used procedures of Pocock, OBrienFleming, and LanDeMets. He discusses the notions of conditional power, monitoring for safety and futility, and monitoring multiple endpoints in the study. The use of monitoring clinical trials is introduced in the context of the evolution of clinical research and one chapter is devoted to the more recent Bayesian procedures. Dr. Lemuel A. Moy, M.D., Ph.D. is a physician and a biostatistician at the University of Texas School of Public Health. He is a diplomat of the National Board of Medical Examiners and is currently Professor of Biostatistics at the University of Texas School of Public Health in Houston where he holds a full time faculty position. Dr. Moy has carried out cardiovascular research for twenty years and continues to be involved in the design, execution and analysis of clinical trials, both reporting to and serving on many Data Monitoring Committees. He has served in several clinical trials sponsored by both the U.S. government and private industry. In addition, Dr. Moy has served as statistician/epidemiologist for six years on both the Cardiovascular and Renal Drug Advisory Committee to the Food and Drug Administration and the Pharmacy Sciences Advisory Committee to the FDA. He has published over 120 manuscripts in peer-reviewed literature that discuss the design, execution and analysis of clinical research. He authored Statistical Reasoning in Medicine: The Intuitive P-value Primer (Springer, 2000) and Multiple Analysis in Clinical Trials: Fundamentals for Investigators (Springer, 2003). From the reviews: "This book is aimed at helping clinical researchers, who have little or no quantitative background and who have difficulty in communicating with biostatisticians or experienced trial methodologists. The author has a wealth of experience in this area and this is demonstrated throughout the text with relevant poignant examples. Each chapter has a comprehensive reference list and a set of problems . A book to recommend for students/researchers who need to be able to apply correct use and monitor procedures for clinical investigations." (S. Starkings, Short Book s, Vol. 26 (1), 2006) "The present book is designed to provide a useful presentation of eight detailed, well written parts of statistical techniques in clinical research, a useful tool in statistical monitoring of clinical trials. In particular, the aim of the present book is to give a consistent and self-contained overview on important fundamental and modern procedures used by clinical investigators . The book is of great interest to research workers in the design, execution and analysis of clinical research." (Cryssoula Ganatsiou, Zentralblatt MATH, Vol. 1094 (20), 2006) "This book is written such that it can be understood without a sophisticated mathematical background....[It] is highly recommended for clinical researchers who start to serve on a DMC, but also for healthcare graduate students and junior physician-scientists....[and] is also enjoyable reading for statisticians." (Iris Pigeot, Biometrics, December 2007) "This book seems to be a successful attempt to introduce group sequential monitoring of clinical trials to a larger audience than well-trained statisticians working in the conduct of such trials. It is an important book that came on time and very much recommended for nonstatistician clinical investigators and members of the Data Monitoring Committees (DMCs) as well as statisticians who are not familiar with group

sequential methodologies in clinical trials. The book is self-containing and avoids mathematical complications as much as possible." (Abdulkadir Hussein, Technometrics, Vol. 50 (1), 2008) "This book has been written to inform and help investigators understand the complex mathematical procedures and monitoring guidelines in clinical trials. useful for researchers and investigators who would like to understand the application of statistical principles in clinical trials. I have greatly benefited by reading this book providing a concise overview of such a diverse and complex field in a relatively simple and easy to understand format. This is a well-written book . I strongly recommend it for all academic libraries." (Faisel Yunus, Journal of Applied Statistics, Vol. 23 (10), 2007)