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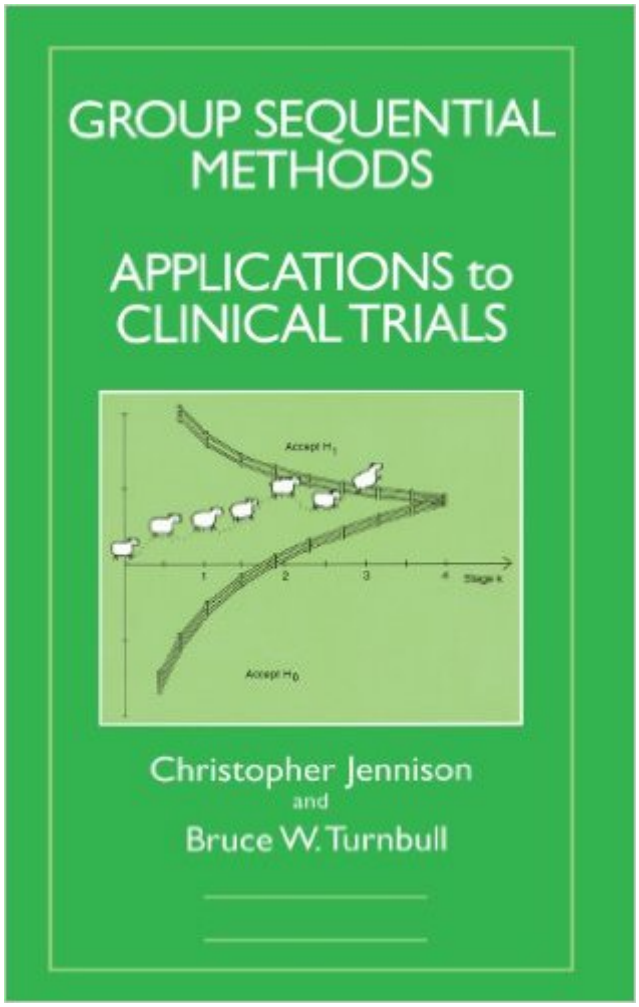
Group Sequential Methods With Applications To Clinical Trials (Chapman & Hall/CRC Interdisciplinary Statistics)



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Synopsis

Group sequential methods answer the needs of clinical trial monitoring committees who must assess the data available at an interim analysis. These interim results may provide grounds for terminating the study-effectively reducing costs-or may benefit the general patient population by allowing early dissemination of its findings. Group sequential methods provide a means to balance the ethical and financial advantages of stopping a study early against the risk of an incorrect conclusion.Group Sequential Methods with Applications to Clinical Trials describes group sequential stopping rules designed to reduce average study length and control Type I and II error probabilities. The authors present one-sided and two-sided tests, introduce several families of group sequential tests, and explain how to choose the most appropriate test and interim analysis schedule. Their topics include placebo-controlled randomized trials, bio-equivalence testing, crossover and longitudinal studies, and linear and generalized linear models.Research in group sequential analysis has progressed rapidly over the past 20 years. Group Sequential Methods with Applications to Clinical Trials surveys and extends current methods for planning and conducting interim analyses. It provides straightforward descriptions of group sequential hypothesis tests in a form suited for direct application to a wide variety of clinical trials. Medical statisticians engaged in any investigations planned with interim analyses will find this book a useful and important tool.

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Customer Reviews

Advances in the theory of repeated significance testing in the 1980s and 1990s has made

sequential methods practical by identifying stopping rules for data collected sequentially but in groups. This material is now used to plan interim analyses and both safety and efficacy group sequential trials for clinical trials. This text provides for the first time thorough coverage of these advances with suitable references to the literature.It should be on the bookshelf of any biostatistician who conducts clinical trials for pharmaceutical or medical device companies.

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