Adaptive Design Methods in Clinical Trials (Chapman & Hall/CRC Biostatistics Series)

Shein-Chung Chow, Mark Chang

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Although adaptive design methods are flexible and useful in clinical research, little or no regulatory guidelines are available. One of the first books on the topic, **Adaptive Design Methods in Clinical Trials** presents the principles and methodologies in adaptive design and analysis that pertain to adaptations made to trial or statistical procedures that are based on accrued data of ongoing clinical trials. The book also offers a well-balanced summary of current regulatory perspectives and recently developed statistical methods in this area.

After an introduction to basic concepts and statistical considerations of adaptive design methods, the book questions the impact on target patient populations as the result of protocol amendments and discusses the generalization of statistical inference. The authors also present various adaptive design methods, including where hypotheses are modified during the conduct of clinical trials, for dose selection, and commonly used adaptive group sequential design methods in clinical trials. Following a discussion of blind procedures for sample size re-estimation, the book describes statistical tests for seamless phase II/III adaptive designs and statistical inference for switching adaptively from one treatment to another. The book concludes with computer simulations and various case studies of clinical trials.

By providing theoretical and computer simulation results, method comparisons, and practical guidelines for choosing an optimal design, **Adaptive Design Methods in Clinical Trials** fills the need for a unified, comprehensive, and updated resource in the clinical research and development of adaptive design and analysis.

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