Handbook of Adaptive Designs in Pharmaceutical and Clinical Development

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In response to the US FDA's *Critical Path Initiative*, innovative adaptive designs are being used more and more in clinical trials due to their flexibility and efficiency, especially during early phase development. **Handbook of Adaptive Designs in Pharmaceutical and Clinical Development** provides a comprehensive and unified presentation of the principles and latest statistical methodologies used when modifying trial procedures based on accrued data of ongoing clinical trials. The book also gives a well-balanced summary of current regulatory perspectives.

The first several chapters focus on the fundamental theory behind adaptive trial design, the application of the Bayesian approach to adaptive designs, and the impact of potential population shift due to protocol amendments. The book then presents a variety of statistical methods for group sequential design, classical design, dose-finding trials, Phase I/II and Phase II/III seamless adaptive designs, multiple stage seamless adaptive trial design, adaptive randomization trials, hypotheses-adaptive design, and treatment-adaptive design. It also covers predictive biomarker diagnostics for new drug development, clinical strategies for endpoint selection in translational research, the role of independent data monitoring committees in adaptive clinical trials, the enrichment process in targeted clinical trials for personalized medicine, applications of adaptive designs that use genomic or genetic information, adaptive trial simulation, and the efficiency of adaptive design. The final chapters discuss case studies as well as standard operating procedures for good adaptive practices.

With contributions from leading clinical researchers in the pharmaceutical industry, academia, and regulatory agencies, this handbook offers an up-to-date, complete treatment of the principles and methods of adaptive design and analysis. Along with reviewing recent developments, it examines issues commonly encountered when applying adaptive design methods in clinical trials.

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