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Sommario/riassunto	This BASS book Series publishes selected high-quality papers reflecting recent advances in the design and biostatistical analysis of biopharmaceutical experiments – particularly biopharmaceutical clinical trials. The papers were selected from invited presentations at the Biopharmaceutical Applied Statistics Symposium (BASS), which was

founded by the first Editor in 1994 and has since become the premier international conference in biopharmaceutical statistics. The primary aims of the BASS are: 1) to raise funding to support graduate students in biostatistics programs, and 2) to provide an opportunity for professionals engaged in pharmaceutical drug research and development to share insights into solving the problems they encounter. The BASS book series is initially divided into three volumes addressing: 1) Design of Clinical Trials; 2) Biostatistical Analysis of Clinical Trials; and 3) Pharmaceutical Applications. This book is the first of the 3-vol ume book series. The topics covered include: A Statistical Approach to Clinical Trial Simulations, Comparison of Statistical Analysis Methods Using Modeling and Simulation for Optimal Protocol Design, Adaptive Trial Design in Clinical Research, Best Practices and Recommendations for Trial Simulations in the Context of Designing Adaptive Clinical Trials, Designing and Analyzing Recurrent Event Data Trials, Bayesian Methodologies for Response-Adaptive Allocation, Addressing High Placebo Response in Neuroscience Clinical Trials, Phase I Cancer Clinical Trial Design: Single and Combination Agents, Sample Size and Power for the Mixed Linear Model, Crossover Designs in Clinical Trials, Data Monitoring: Structure for Clinical Trials and Sequential Monitoring Procedures, Design and Data Analysis for Multiregional Clinical Trials – Theory and Practice, Adaptive Group-Sequential Multi-regional Outcome Studies in Vaccines, Development and Validation of Patient-reported Outcomes, Interim Analysis of Survival Trials: Group Sequential Analyses, and Conditional Power – A Non-proportional Hazards Perspective.