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Nota di contenuto	Bias and Randomization in Clinical Trials: 1980s – 2020s – 2060s -- The Markov Model for Survival Trials at 35 Years-Old -- Absolute Power Corrupts Absolutely: A Review of the Use of Unconditional Probabilities in the Planning of Clinical Trials -- Design of Clinical Trials with the Desirability of Outcome Ranking Methodology -- Benefit:Risk Assessments during Clinical Trials: A Prediction Approach Using the Desirability of Outcome Ranking (DOOR) -- The Power of Integration: How the 2-in-1 Clinical Trial Design is Changing the Future of Drug Development -- A Unified Bayesian Decision Rule-Based Approach for Bayesian Design of Clinical Trials Using Historical Data -- Group Sequential Design Under Non-proportional Hazards: Methodologies and Examples -- Multiple Testing in Group Sequential Design -- Plan

per-protocol (PP) causal inference analysis addressing intercurrent events following the targeted learning roadmap -- Maximum Tolerated Imbalance Randomization: Theory and Practice -- Response-adaptive randomization designs based on optimal allocation proportion.

Sommario/riassunto

The Deming Conference on Applied Statistics has long been deemed an influential event in the biostatistics and biopharmaceutical profession. It provides learning experience on recent developments in statistical methodologies in biopharmaceutical applications and FDA regulations. This book honors 80 years of contributions and dedication of the Deming Conference in biostatistics, and biopharmaceutical clinical trial methodology and applications. All chapters are contributed by world-class and prominent Deming speakers, who've contributed their cutting-edge research and developments to the community. Volume 1 covers Historical Milestones in Clinical Trial Design, FDA biopharmaceutical design guidance, and emerging development in Clinical Trial Design Methodology. This book aims to booster research, education, and training in biostatistics and in biopharmaceutical research and development.