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Nota di contenuto	Part I: Specification and Sampling Acceptance Tests -- Statistical Considerations in Setting Quality Specification Limits Using Quality Data -- Counting Test and Parametric Two One-Sided Tolerance Interval Test for Content Uniformity Using Large Sample Sizes -- Part II: Analytical Biosimilar and Process Validation -- Sample Size Consideration for Equivalent Test of Tier-1 Quality Attributes for Analytical Biosimilarity Assessment -- A Probability Based Equivalence Test of NIR Versus HPLC Analytical Methods in a Continuous Manufacturing Process Validation Study -- A Further Look at the Current Equivalence Test for Analytical Similarity Assessment -- Shiny Tools for Sample Size Calculation in Process Performance Qualification of Large Molecules -- Part III: Continuous Process -- Risk Evaluation of Registered Specifications and Internal Release Limits Using a Bayesian Approach -- Development of Statistical Computational Tools Through Pharmaceutical Drug Development and Manufacturing Life Cycle -- Application of Advanced Statistical Tools to Achieve Continuous Analytical Verification: A Risk Assessment Case of the Impact of

Analytical Method Performance on Process Performance Using a Bayesian Approach -- Part IV: Clinical Trial Design and Analysis -- Exact Inference for Adaptive Group Sequential Designs -- A Novel Framework for Bayesian Response-Adaptive Randomization -- Sample Size Determination Under Non-proportional Hazards -- Adaptive Three-Stage Clinical Trial Design for a Binary Endpoint in the Rare Disease Setting -- Part V: Biomarker-Driven Trial Design -- Clinical Trial Designs to Evaluate Predictive Biomarkers: What's Being Estimated? -- Biomarker Enrichment Design Considerations in Oncology Single Arm Studies -- Challenges of Bridging Studies in Biomarker Driven Clinical Trials: The Impact of Companion Diagnostic Device Performance on Clinical Efficacy -- Part VI: Application of Novel Data Modality -- Parallel-Tempered Feature Allocation for Large-Scale Tumor Heterogeneity with Deep Sequencing Data -- Analysis of T-Cell Immune Responses as Measured by Intracellular Cytokine Staining with Application to Vaccine Clinical Trials -- Project Data Sphere and the Applications of Historical Patient Level Clinical Trial Data in Oncology Drug Development -- Novel Test for the Equality of Continuous Curves with Homoscedastic or Heteroscedastic Measurement Errors -- Quality Control Metrics for Extraction-Free Targeted RNA-Seq Under a Compositional Framework -- Part VII: Omics Data Analysis -- Leveraging Omics Biomarker Data in Drug Development: With a GWAS Case Study -- A Simulation Study Comparing SNP Based Prediction Models of Drug Response.

Sommario/riassunto

This book presents the proceedings of the 39th annual Midwest Biopharmaceutical Statistics Workshop (MBSW), held in Muncie, Indiana on May 16–18, 2016. It consists of selected peer- reviewed and revised papers on topics ranging from statistical applications in drug discovery and CMC to biomarkers, clinical trials, and statistical programming. All contributions feature original research, and together they cover the full spectrum of pharmaceutical R&D – with a special focus on emergent topics such as biosimilarity, bioequivalence, clinical trial design, and subgroup identification. Founded in 1978, the MBSW has provided a forum for statisticians to share knowledge, research, and applications on key statistical topics in pharmaceutical R&D for almost forty years, with the 2016 conference theme being "The Power and 3 I's of Statistics: Innovation, Impact and Integrity." The papers gathered here will be of interest to all researchers whose work involves the quantitative aspects of pharmaceutical research and development, including pharmaceutical statisticians who want to keep up-to-date with the latest trends, as well as academic statistics researchers looking for areas of application.