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Chow, 2016-04-19 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 princip

Innovative Statistics in Regulatory Science Shein-Chung Chow, 2019-11-18 Statistical methods that are commonly used in the review and approval process of regulatory submissions are usually referred to as statistics in regulatory science or regulatory statistics. In a broader sense, statistics in regulatory science can be defined as valid statistics that are employed in the review and approval process of regulatory submissions of pharmaceutical products. In addition, statistics in regulatory science are involved with the development of regulatory policy, guidance, and regulatory critical clinical initiatives related research. This book is devoted to the discussion of statistics in regulatory science for pharmaceutical development. It covers practical issues that are commonly encountered in regulatory science of pharmaceutical research and development including topics related to research activities, review of regulatory submissions, recent critical clinical initiatives, and policy/guidance development in regulatory science. Devoted entirely to discussing statistics in regulatory science for pharmaceutical development. Reviews critical issues (e.g., endpoint/margin selection and complex innovative design such as adaptive trial design) in the pharmaceutical development and regulatory approval process. Clarifies controversial statistical issues (e.g., hypothesis testing versus confidence interval approach, missing data/estimands, multiplicity, and Bayesian design and approach) in review/approval of regulatory submissions. Proposes innovative thinking regarding study designs and statistical methods (e.g., n-of-1 trial design, adaptive trial design, and probability monitoring procedure for sample size) for rare disease drug development. Provides insight regarding current regulatory clinical initiatives (e.g., precision/personalized medicine, biomarker-driven target clinical trials, model informed drug development, big data analytics, and real world data/evidence). This book provides key statistical concepts, innovative designs, and analysis methods that are useful in regulatory science. Also included are some practical, challenging, and controversial issues that are commonly seen in the review and approval process of regulatory submissions. About the author Shein-Chung Chow, Ph.D. is currently a Professor at Duke University School of Medicine, Durham, NC. He was previously the Associate Director at the Office of Biostatistics, Center for Drug

Evaluation and Research, United States Food and Drug Administration (FDA). Dr. Chow has also held various positions in the pharmaceutical industry such as Vice President at Millennium, Cambridge, MA, Executive Director at Covance, Princeton, NJ, and Director and Department Head at Bristol-Myers Squibb, Plainsboro, NJ. He was elected Fellow of the American Statistical Association and an elected member of the ISI (International Statistical Institute). Dr. Chow is Editor-in-Chief of the Journal of Biopharmaceutical Statistics and Biostatistics Book Series, Chapman and Hall/CRC Press, Taylor & Francis, New York. Dr. Chow is the author or co-author of over 300 methodology papers and 30 books.

Encyclopedia of Biopharmaceutical Statistics - Four Volume Set Shein-Chung Chow, 2018-09-03 Since the publication of the first edition in 2000, there has been an explosive growth of literature in biopharmaceutical research and development of new medicines. This encyclopedia (1) provides a comprehensive and unified presentation of designs and analyses used at different stages of the drug development process, (2) gives a well-balanced summary of current regulatory requirements, and (3) describes recently developed statistical methods in the pharmaceutical sciences. Features of the Fourth Edition: 1. 78 new and revised entries have been added for a total of 308 chapters and a fourth volume has been added to encompass the increased number of chapters. 2. Revised and updated entries reflect changes and recent developments in regulatory requirements for the drug review/approval process and statistical designs and methodologies. 3. Additional topics include multiple-stage adaptive trial design in clinical research, translational medicine, design and analysis of biosimilar drug development, big data analytics, and real world evidence for clinical research and development. 4. A table of contents organized by stages of biopharmaceutical development provides easy access to relevant topics. About the Editor: Shein-Chung Chow, Ph.D. is currently an Associate Director, Office of Biostatistics, U.S. Food and Drug Administration (FDA). Dr. Chow is an Adjunct Professor at Duke University School of Medicine, as well as Adjunct Professor at Duke-NUS, Singapore and North Carolina State University. Dr. Chow is the Editor-in-Chief of the Journal of Biopharmaceutical Statistics and the Chapman & Hall/CRC Biostatistics Book Series and the author of 28 books and over 300 methodology papers. He was elected Fellow of the American Statistical Association in 1995.

Imaging Cerebrovascular Reactivity: Physiology, Physics and Therapy James Duffin, Nicholas P. Blockley, Molly G. Bright, 2021-10-01 Topic Editor Prof. James Duffin contributed to the development of an automated end-tidal targeting device, RespirAct™ and is employed by Thornhill Medical Inc. (Toronto, Canada). RespirAct™ is currently a non-commercial research tool assembled and made available by TMI to research institutions to enable CVR studies. All other Topic Editors declare no competing interests with regards to the Research Topic subject.

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