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Bayesian Analysis with R for Drug Development Harry Yang, Steven Novick, 2019-06-26 Drug development is an iterative process. The recent publications of regulatory guidelines further entail a lifecycle approach. Blending data from disparate sources, the Bayesian approach provides a flexible framework for drug development. Despite its advantages, the uptake of Bayesian methodologies is lagging behind in the field of pharmaceutical development. Written specifically for pharmaceutical practitioners, *Bayesian Analysis with R for Drug Development: Concepts, Algorithms, and Case Studies* describes a wide range of Bayesian applications to problems throughout pre-clinical, clinical, and Chemistry, Manufacturing, and Control (CMC) development. Authored by two seasoned statisticians in the pharmaceutical industry, the book provides detailed Bayesian solutions to a broad array of pharmaceutical problems. Features: Provides a single source of information on Bayesian statistics for drug development. Covers a wide spectrum of pre-clinical, clinical, and CMC topics. Demonstrates proper Bayesian applications using real-life examples. Includes easy-to-follow R code with Bayesian Markov Chain Monte Carlo performed in both JAGS and Stan. Bayesian software platforms. Offers sufficient background for each problem and detailed description of solutions suitable for practitioners with limited Bayesian knowledge. Harry Yang, Ph.D., is Senior Director and Head of Statistical Sciences at AstraZeneca. He has 24 years of experience across all aspects of drug research and development and extensive global regulatory experiences. He has published 6 statistical books, 15 book chapters, and over 90 peer-reviewed papers on diverse scientific and statistical subjects, including 15 joint statistical works with Dr. Novick. He is a frequent invited speaker at national and international conferences. He also developed statistical courses and conducted training at the FDA and USP, as well as Peking University. Steven Novick, Ph.D., is Director of Statistical Sciences at AstraZeneca. He has extensively contributed statistical methods to the biopharmaceutical literature. Novick is a skilled Bayesian computer programmer and is frequently invited to speak at conferences, having developed and taught courses in several areas, including drug combination analysis and Bayesian methods in clinical areas. Novick served on IPAC RS and has chaired several national statistical conferences.

Big Data Parvati Mishra, 2025-01-07 The illustrations in this book are created by Team EducOHack. *Big Data: Revolutionizing the Future* delves into how big data has become a dominant paradigm transforming various sectors and reshaping society. This book, divided into 13 chapters, provides a thorough examination of big data, discussing its applications, growth, and potential. We explore how big data approaches can revolutionize both business and health sectors while also addressing the risks associated with datafication. Chapters 11 to 13 focus on the growth of big data in different sectors, detailing the expanding market and advancements in big data analytics. Chapters 5 to 10 offer insightful examples of big data's transformative potential. This book emphasizes the importance of grounding these perspectives in existing scientific methods to enhance their practical applicability. We also discuss the comprehensive understanding that comes from analyzing all available data, illustrating this with empirical examples. *Big Data: Revolutionizing*

the Future presents a clear accessible narrative enriched with a wide range of examples to help readers grasp the full implications and opportunities of big data

Specification of Drug Substances and Products Christopher M. Riley, K. Lien Nguyen, 2024-09-22 Specification of Drug Substances and Drug Products is a fully comprehensive reference on Specification Setting for Pharmaceuticals There have been several recent developments in the ICH Guidelines which were not captured in previous editions notably the new guideline on Development of Analytical Procedure and the revisions to the validation guidelines and the specification guidelines This edition contains chapters discussing the unique requirements for the universal critical quality attributes as well as the specific tests required to characterize and control different types of products ranging in complexity from small molecules in immediate release oral dosage forms to complex products such as drug antibody conjugates and mRNA based products This substantially expanded revision of the 2nd edition will serve as practical comprehensive reference for scientists managers educators and consultants involved in the development and regulation of pharmaceutical products Presents critical assessment potential impact and application of the recent revisions to ICH guidelines on method validation Q2 as well as the latest guideline on Analytical Method Development Q14 and the special regional requirements in non ICH regions Addresses comprehensive treatment of the development and validation of analytical methodologies used in the analysis control and specification of a variety of different types of dosage forms ranging from traditional oral solid dosage forms to proteins nRNA based drugs vaccines and gene therapy This book will also address drug device combination products such as digital drug delivery systems transdermal systems and inhalation products Presents detailed treatment of latest statistical approaches including new approaches to the treatment of validation data method specification setting and shelf life prediction based on stability data

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