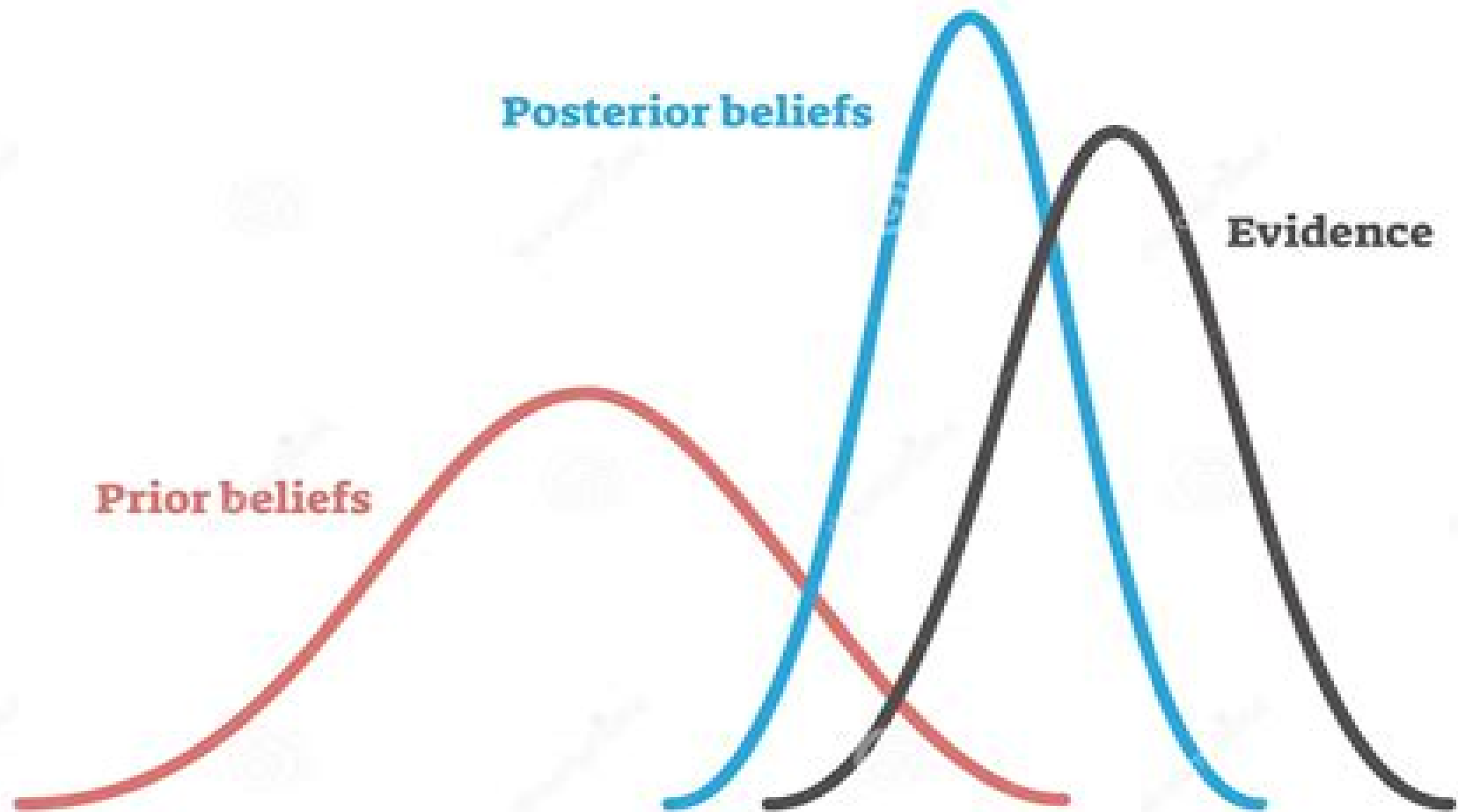


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AN Whitehead



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Paul Thomas, 2016-04-26 **Bayesian Analysis Made Simple** is aimed at those who wish to apply Bayesian methods but either are not experts or do not have the time to create WinBUGS code and ancillary files for every analysis they undertake Accessible to even those who would not routinely use Excel this book provides a custom made Excel GUI immediately useful to those users who want to be able to quickly apply Bayesian methods without being distracted by computing or mathematical issues Although the popularity of the Bayesian approach to statistics has been growing for years many still think of it as somewhat esoteric not focused on practical issues or generally too difficult to understand **Bayesian Analysis Made Simple** Eric Sanders, 2017-04-11 **Bayesian Analysis Made Simple** is aimed at those who wish to apply Bayesian methods but either are not experts or do not have the time to create WinBUGS code and ancillary files for every analysis they undertake Accessible to even those who would not routinely use Excel this book provides a custom made Excel GUI immediately useful to those users who want to be able to quickly apply Bayesian methods without being distracted by computing or mathematical issues **Benefit-Risk Assessment in Pharmaceutical Research and Development**

Andreas Sashegyi, James Felli, Rebecca Noel, 2013-11-27 Many practitioners in the pharmaceutical industry are still largely unfamiliar with benefit risk assessment despite its growing prominence in drug development and commercialization Helping to alleviate this knowledge gap **Benefit Risk Assessment in Pharmaceutical Research and Development** provides a succinct overview of the key considerations relevant to benefit risk assessment across the pharmaceutical R D spectrum from early clinical development to late stage development to regulatory review to post launch assessment The book first presents interpretations of benefit and risk in the context of a molecule moving from preclinical evaluation into its early testing in

humans It next considers benefit and risk characterization and assessment during a molecule's journey from its clinical evaluation in humans through its submission to regulators for marketing approval Throughout these sections the book offers insight into the role of benefit risk assessment in heightening understanding among key stakeholders by shaping questions and guiding discussions among scientists physicians developers and regulatory agencies The book also focuses on a molecule's entry into the marketplace as a drug available for consumption by people It explores the role of benefit risk assessment as the relevance of carefully collected clinical efficacy and safety metrics fades in the wake of real world use and evidence of effectiveness and safety Bringing together the expertise of 15 contributors from academia and the industry this book offers an easy to read guide to the various facets of benefit risk assessment in the major stages of pharmaceutical R D Suitable for those in both technical and managerial roles it enables readers to communicate more effectively across their development chain as well as rationally and thoughtfully embed benefit risk assessment into their R D processes

Theory of Drug Development Eric B. Holmgren, 2013-10-24 Theory of Drug Development presents a formal quantitative framework for understanding drug development that goes beyond simply describing the properties of the statistics in individual studies It examines the drug development process from the perspectives of drug companies and regulatory agencies By quantifying various ideas underlying drug development the book shows how to systematically address problems such as Sizing a phase 2 trial and choosing the range of p values that will trigger a follow up phase 3 trial Deciding whether a drug should receive marketing approval based on its phase 2/3 development program and recent experience with other drugs in the same clinical area Determining the impact of adaptive designs on the quality of drugs that receive marketing approval Designing a phase 3 pivotal study that permits the data driven adjustment of the treatment effect estimate Knowing when enough information has been gathered to show that a drug improves the survival time for the whole patient population Drawing on his extensive work as a statistician in the pharmaceutical industry the author focuses on the efficient development of drugs and the quantification of evidence in drug development He provides a rationale for underpowered phase 2 trials based on the notion of efficiency which leads to the identification of an admissible family of phase 2 designs He also develops a framework for evaluating the strength of evidence generated by clinical trials This approach is based on the ratio of power to type 1 error and transcends typical Bayesian and frequentist statistical analyses

Biosimilars Shein-Chung Chow, 2013-07-29 As many biological products face losing their patents in the next decade the pharmaceutical industry needs an abbreviated regulatory pathway for approval of biosimilar drug products which are cost effective follow on subsequent versions of the innovator's biologic products But scientific challenges remain due to the complexity of both the manufacture and testing of these products

Optimal Design for Nonlinear Response Models Valerii V. Fedorov, Sergei L. Leonov, 2013-07-15 Optimal Design for Nonlinear Response Models discusses the theory and applications of model based experimental design with a strong emphasis on biopharmaceutical studies The book draws on the authors many years of experience in academia and the pharmaceutical industry

industry While the focus is on nonlinear models the book begins with an explanation of the key ideas using linear models as examples Applying the linearization in the parameter space it then covers nonlinear models and locally optimal designs as well as minimax optimal on average and Bayesian designs The authors also discuss adaptive designs focusing on procedures with non informative stopping The common goals of experimental design such as reducing costs supporting efficient decision making and gaining maximum information under various constraints are often the same across diverse applied areas Ethical and regulatory aspects play a much more prominent role in biological medical and pharmaceutical research The authors address all of these issues through many examples in the book Statistical Topics in Health Economics and Outcomes Research Demissie Alemayehu, Joseph C. Cappelleri, Birol Emir, Kelly H. Zou, 2017-11-22 With ever rising healthcare costs evidence generation through Health Economics and Outcomes Research HEOR plays an increasingly important role in decision making about the allocation of resources Accordingly it is now customary for health technology assessment and reimbursement agencies to request for HEOR evidence in addition to data from clinical trials to inform decisions about patient access to new treatment options While there is a great deal of literature on HEOR there is a need for a volume that presents a coherent and unified review of the major issues that arise in application especially from a statistical perspective Statistical Topics in Health Economics and Outcomes Research fulfils that need by presenting an overview of the key analytical issues and best practice Special attention is paid to key assumptions and other salient features of statistical methods customarily used in the area and appropriate and relatively comprehensive references are made to emerging trends The content of the book is purposefully designed to be accessible to readers with basic quantitative backgrounds while providing an in depth coverage of relatively complex statistical issues The book will make a very useful reference for researchers in the pharmaceutical industry academia and research institutions involved with HEOR studies The targeted readers may include statisticians data scientists epidemiologists outcomes researchers health economists and healthcare policy and decision makers Adaptive Design Methods in Clinical Trials Shein-Chung Chow, Mark Chang, 2011-12-01 With new statistical and scientific issues arising in adaptive clinical trial design including the U S FDA s recent draft guidance a new edition of one of the first books on the topic is needed Adaptive Design Methods in Clinical Trials Second Edition reflects recent developments and regulatory positions on the use of adaptive designs in clini

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