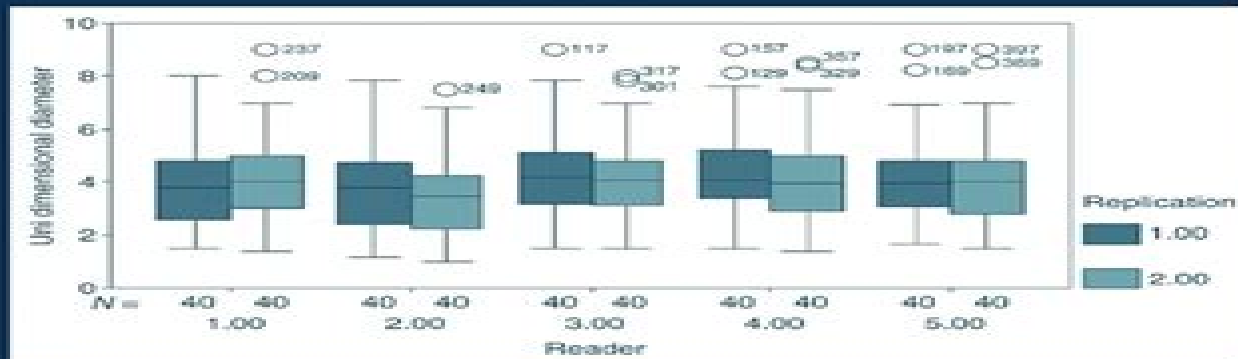


Bayesian Methods for Measures of Agreement



Lyle D. Broemeling



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Data and Safety Monitoring Committees in Clinical Trials Jay Herson, 2016-12-19 Praise for the first edition Given the author's years of experience as a statistician and as a founder of the first DMC in pharmaceutical industry trials I highly recommend this book not only for experts because of its cogent and organized presentation but more importantly for young investigators who are seeking information about the logistical and philosophical aspects of a DMC S T Ounpraseuth The American Statistician In the first edition of this well regarded book the author provided a groundbreaking and definitive guide to best practices in pharmaceutical industry data monitoring committees DMCs Maintaining all the material from the first edition and adding substantial new material Data and Safety Monitoring Committees in Clinical Trials Second Edition is ideal for training professionals to serve on their first DMC as well as for experienced clinical and biostatistical DMC members sponsor and regulatory agency staff The second edition guides the reader through newly emerging DMC responsibilities brought about by regulations emphasizing risk vs benefit and the emergence of risk based monitoring It also provides the reader with many new statistical methods clinical trial designs and clinical terminology that have emerged since the first edition The references have been updated and the very popular end of chapter Q A section has been supplemented with many new experiences since the first edition New to the Second Edition Presents statistical methods tables listings and graphs appropriate for safety review efficacy analysis and risk vs benefit analysis SPERT and PRISMA initiatives Newly added interim analysis for efficacy and futility section DMC responsibilities in SUSARs Serious Unexpected Serious Adverse Reactions basket trials umbrella trials dynamic treatment strategies SMART trials pragmatic trials biosimilar trials companion diagnostics etc DMC

responsibilities for data quality and fraud detection Fraud Recovery Plan Use of patient reported outcomes of safety Use of meta analysis and data outside the trial New ideas for training and compensation of DMC members Jay Herson is Senior Associate Biostatistics Johns Hopkins Bloomberg School of Public Health where he teaches courses on clinical trials and drug development based on his many years experience in clinical trials in academia and the pharmaceutical industry

Randomization, Masking, and Allocation Concealment Vance Berger, 2017-10-30 Randomization Masking and Allocation Concealment is indispensable for any trial researcher who wants to use state of the art randomization methods and also wants to be able to describe these methods correctly Far too often the subtle nuances that distinguish proper randomization from flawed randomization are completely ignored in trial reports that state only that randomization was used with no additional information Experience has shown that in many cases the type of randomization that was used was flawed It is only a matter of time before medical journals and regulatory agencies come to realize that we can no longer rely on or publish flawed trials and that flawed randomization in and of itself disqualifies a trial from being robust or high quality even if that trial is of high quality otherwise This book will help to clarify the role randomization plays in ensuring internal validity and in drawing valid inferences from the data The various chapters cover a variety of randomization methods and are not limited to the most common and most flawed ones Readers will come away with a profound understanding of what constitutes a valid randomization procedure so that they can distinguish the valid from the flawed among not only existing methods but also methods yet to be developed

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Essentials of a Successful Biostatistical Collaboration Arul Earnest, 2016-10-14 The aim of this book is to equip biostatisticians and other quantitative scientists with the necessary skills knowledge and habits to collaborate effectively with clinicians in the healthcare field The book provides valuable insight on where to look for information and material on sample size and statistical techniques commonly used in clinical research and on how best to communicate with clinicians It also covers the

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