

Controversial Statistical Issues in Clinical Trials: A Comprehensive Guide for Researchers and Practitioners

Clinical trials play a pivotal role in the development and evaluation of new medical treatments. However, the design, analysis, and interpretation of clinical trials often involve complex statistical issues that can lead to controversy. This book, "Controversial Statistical Issues in Clinical Trials," provides a comprehensive overview of these issues, offering a unique perspective from both sides of the debate.



Controversial Statistical Issues in Clinical Trials (Chapman & Hall/CRC Biostatistics Series Book 42)

by Shein-Chung Chow

★★★★★ 5 out of 5

Language : English

File size : 19713 KB

Print length : 611 pages



Understanding Controversial Statistical Issues

The book begins by examining the fundamental principles of clinical trial design, including randomization, blinding, and sample size calculation. It then delves into specific statistical methods that have been the subject of controversy, such as:

- **P-values and statistical significance:** The overuse and misuse of p-values has been widely criticized, leading to calls for alternative approaches to hypothesis testing.
- **Multiple hypothesis testing:** The problem of multiple comparisons arises when multiple statistical tests are performed on the same data, increasing the risk of false positive findings.
- **Intention-to-treat analysis:** This approach to analyzing clinical trial data assumes that all participants should be included in the analysis, regardless of whether they adhered to the study protocol.
- **Adaptive designs:** These designs allow for modifications to the trial design based on interim data, raising concerns about the validity of the results.
- **Bayesian statistics:** This alternative statistical approach uses prior information to inform the analysis and interpretation of clinical trial data.

Exploring Perspectives and Controversies

The book presents diverse perspectives on these controversial issues, showcasing the arguments and evidence supporting each side of the debate. It includes contributions from leading statisticians, clinical researchers, and regulatory agencies, providing a balanced and well-rounded analysis.

The authors carefully examine the strengths and weaknesses of different statistical methods and approaches, providing readers with a deeper understanding of the underlying assumptions and potential pitfalls. They also discuss the ethical and practical implications of these controversies,

highlighting the impact they have on the development and approval of new treatments.

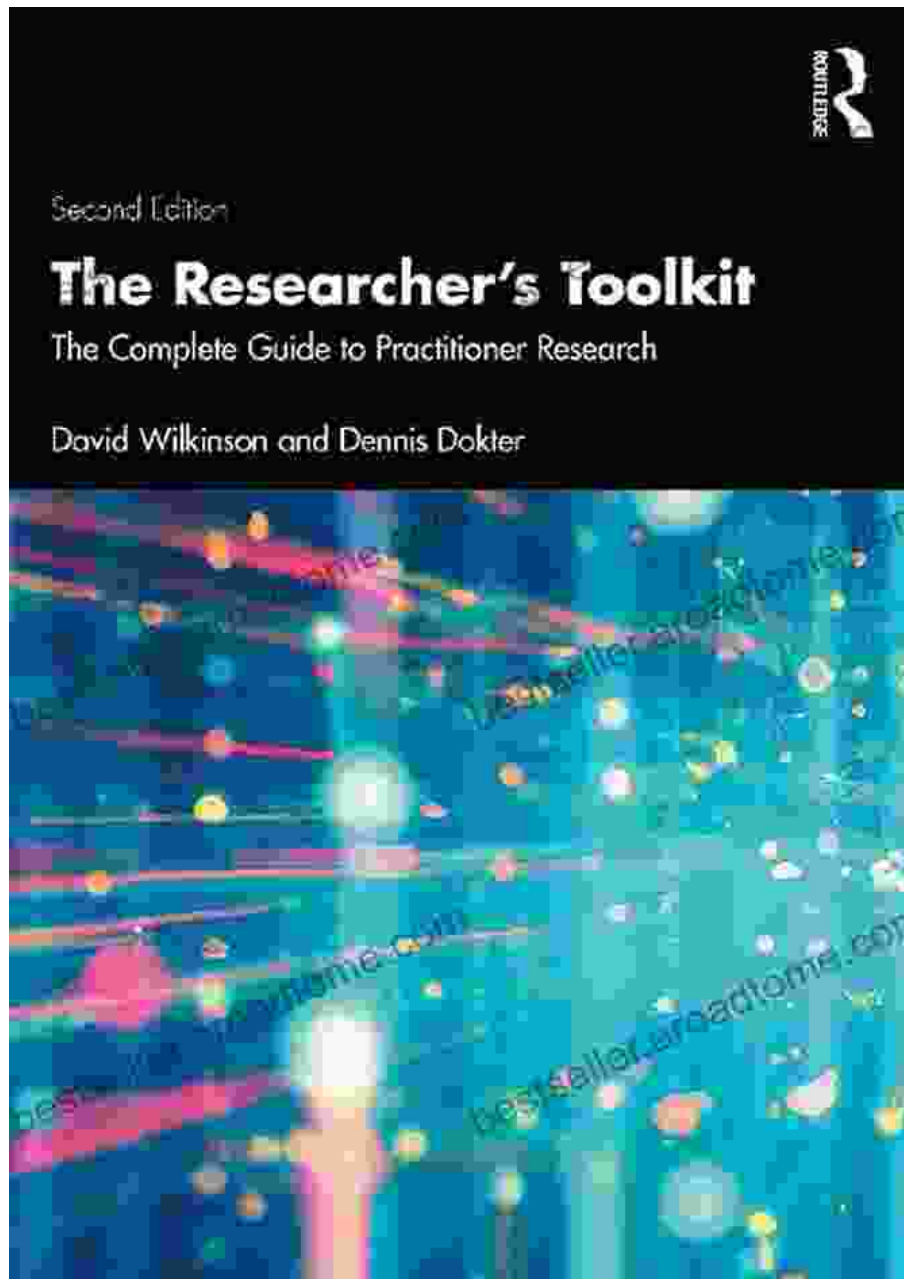
Practical Guidance for Researchers and Practitioners

In addition to its theoretical and philosophical discussions, the book offers practical guidance for researchers and practitioners involved in clinical trials. It provides clear recommendations on how to address controversial statistical issues in the design, analysis, and interpretation of clinical trials.

The authors emphasize the importance of transparency and reproducibility, urging researchers to fully disclose their statistical methods and assumptions. They also provide tips for communicating statistical results clearly and effectively, ensuring that stakeholders can make informed decisions based on the trial findings.

"Controversial Statistical Issues in Clinical Trials" is an essential resource for anyone involved in the design, analysis, or interpretation of clinical trials. It provides a comprehensive and balanced overview of the most pressing statistical controversies, offering insights from both sides of the debate.

By providing practical guidance and promoting informed decision-making, this book empowers researchers and practitioners to navigate the complexities of clinical trial statistics and contribute to the advancement of medical research.



Key Features

- In-depth coverage of controversial statistical methods and approaches
- Balanced perspectives from leading statisticians, clinical researchers, and regulatory agencies
- Practical guidance for addressing statistical issues in clinical trials

- Emphasis on transparency, reproducibility, and clear communication
- Essential resource for researchers, practitioners, and anyone involved in clinical trials



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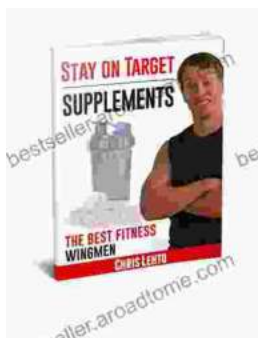
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