



Noninferiority Testing in Clinical Trials: Issues and Challenges (Chapman & Hall/CRC Biostatistics Series)

Tie-Hua Ng

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Take Your NI Trial to the Next Level

Reflecting the vast research on noninferiority (NI) designs from the past 15 years, **Noninferiority Testing in Clinical Trials: Issues and Challenges** explains how to choose the NI margin as a small fraction of the therapeutic effect of the active control in a clinical trial. Requiring no prior knowledge of NI testing, the book is easily accessible to both statisticians and nonstatisticians involved in drug development.

With over 20 years of experience in this area, the author introduces the basic elements of the NI trials one at a time in a logical order. He discusses issues with estimating the effect size based on historical placebo control trials of the active control. The book covers fundamental concepts related to NI trials, such as assay sensitivity, constancy assumption, discounting, and preservation. It also describes patient populations, three-arm trials, and the equivalence of three or more groups.

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