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**Statistics : Statistical Theory and Methods**

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# Methods and Applications of Sample Size Calculation and Recalculation in Clinical Trials

- Presents up-to-date methods for sample size calculation and recalculation in clinical trials
- Offers recommendations for application of sample size calculation and recalculation in clinical trials, taking into account regulatory guidelines and practical requirements
- Provides implementations of the methods in R software code
- Covers basic as well as more advanced and recently developed methods
- Illustrates application of the methods using numerous real clinical trial examples

This book provides an extensive overview of the principles and methods of sample size calculation and recalculation in clinical trials. Appropriate calculation of the required sample size is crucial for the success of clinical trials. At the same time, a sample size that is too small or too large is problematic due to ethical, scientific, and economic reasons. Therefore, state-of-the-art methods are required when planning clinical trials. Part I describes a general framework for deriving sample size calculation procedures. This enables an understanding of the common principles underlying the numerous methods presented in the following chapters. Part II addresses the fixed sample size design, where the required sample size is determined in the planning stage and is not changed afterwards. It covers sample size calculation methods for superiority, non-inferiority, and equivalence trials, as well as comparisons between two and more than two groups. A wide range of further topics is discussed, including sample size calculation for multiple comparisons, safety assessment, and multi-regional trials. There is often some uncertainty about the assumptions to be made when calculating the sample size upfront.

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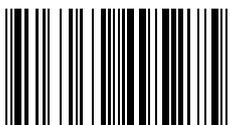
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