



Sample Size Calculators for designing clinical research

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Sample size – Conf interval for a proportion

Sample size for a descriptive study of a dichotomous variable. This calculator gives both binomial and normal approximation to the sample size.

Instructions: Enter parameters in the **green** cells. Answers will appear in the blue box below.

P = 0.075 Expected proportion

W = 0.05 Total width of confidence interval

CL 95 % Confidence level

Calculate

1. Binomial "exact" calculation

Sample size = N = 467
Expected positive results in sample = x = 35

2. Normal approximation to the binomial calculation

$\alpha = (1-CL)/2 = 0.025$
Standard normal deviate for $\alpha = Z_{\alpha} = 1.960$

Sample size = N = $4Z_{\alpha}^2 P(1-P)/W^2 = 426$
Expected positive results in sample = x = 32

Sample Size Calculation In Clinical Research

**Shein-Chung Chow, Hansheng
Wang, Jun Shao**



Sample Size Calculation In Clinical Research:

Sample Size Calculations in Clinical Research, Second Edition Shein-Chung Chow, Hansheng Wang, Jun Shao, 2007-08-22 Focusing on an integral part of pharmaceutical development *Sample Size Calculations in Clinical Research* Second Edition presents statistical procedures for performing sample size calculations during various phases of clinical research and development It provides sample size formulas and procedures for testing equality noninferiority superiority and equivalence A comprehensive and unified presentation of statistical concepts and practical applications this book highlights the interactions between clinicians and biostatisticians includes a well balanced summary of current and emerging clinical issues and explores recently developed statistical methodologies for sample size calculation Whenever possible each chapter provides a brief history or background regulatory requirements statistical designs and methods for data analysis real world examples future research developments and related references One of the few books to systematically summarize clinical research procedures this edition contains new chapters that focus on three key areas of this field Incorporating the material of this book in your work will help ensure the validity and ultimately the success of your clinical studies *Sample Size Calculations in Clinical Research* Shein-Chung Chow, Hansheng Wang, Jun Shao, 2003-03-04 Sample size calculation plays an important role in clinical research It is not uncommon however to observe discrepancies among study objectives or hypotheses study design statistical analysis or test statistic and sample size calculation Focusing on sample size calculation for studies conducted during the various phases of clinical research **Sample Size Calculations in Clinical Research** Shein-Chung Chow, Jun Shao, Hansheng Wang, Yuliya Lokhnygina, 2017-08-15 Praise for the Second Edition this is a useful comprehensive compendium of almost every possible sample size formula The strong organization and carefully defined formulae will aid any researcher designing a study Biometrics This impressive book contains formulae for computing sample size in a wide range of settings One sample studies and two sample comparisons for quantitative binary and time to event outcomes are covered comprehensively with separate sample size formulae for testing equality non inferiority and equivalence Many less familiar topics are also covered Journal of the Royal Statistical Society *Sample Size Calculations in Clinical Research* Third Edition presents statistical procedures for performing sample size calculations during various phases of clinical research and development A comprehensive and unified presentation of statistical concepts and practical applications this book includes a well balanced summary of current and emerging clinical issues regulatory requirements and recently developed statistical methodologies for sample size calculation Features Compares the relative merits and disadvantages of statistical methods for sample size calculations Explains how the formulae and procedures for sample size calculations can be used in a variety of clinical research and development stages Presents real world examples from several therapeutic areas including cardiovascular medicine the central nervous system anti infective medicine oncology and women s health Provides sample size calculations for dose response studies microarray studies and Bayesian approaches This new

edition is updated throughout includes many new sections and five new chapters on emerging topics two stage seamless adaptive designs cluster randomized trial design zero inflated Poisson distribution clinical trials with extremely low incidence rates and clinical trial simulation

Sample Sizes for Clinical Trials Steven A. Julious, 2023-06-21 Sample Sizes for Clinical Trials Second Edition is a practical book that assists researchers in their estimation of the sample size for clinical trials Throughout the book there are detailed worked examples to illustrate both how to do the calculations and how to present them to colleagues or in protocols The book also highlights some of the pitfalls in calculations as well as the key steps that lead to the final sample size calculation Features Comprehensive coverage of sample size calculations including Normal binary ordinal and survival outcome data Covers superiority equivalence non inferiority bioequivalence and precision objectives for both parallel group and crossover designs Highlights how trial objectives impact the study design with respect to both the derivation of sample formulae and the size of the study Motivated with examples of real life clinical trials showing how the calculations can be applied New edition is extended with all chapters revised some substantially and four completely new chapters on multiplicity cluster trials pilot studies and single arm trials The book is primarily aimed at researchers and practitioners of clinical trials and biostatistics and could be used to teach a course on sample size calculations The importance of a sample size calculation when designing a clinical trial is highlighted in the book It enables readers to quickly find an appropriate sample size formula with an associated worked example complemented by tables to assist in the calculations

Sample Size Calculations in Clinical Research Shein-Chung Chow, Hansheng Wang, Jun Shao, 2003-03-04 Sample size calculation plays an important role in clinical research It is not uncommon however to observe discrepancies among study objectives or hypotheses study design statistical analysis or test statistic and sample size calculation Focusing on sample size calculation for studies conducted during the various phases of clinical research and development Sample Size Calculation in Clinical Research explores the causes of discrepancies and how to avoid them This volume provides formulas and procedures for determination of sample size required not only for testing equality but also for testing non inferiority superiority and equivalence similarity based on both untransformed raw data and log transformed data under a parallel group design or a crossover design with equal or unequal ratio of treatment allocations It contains a comprehensive and unified presentation of statistical procedures for sample size calculation that are commonly employed at various phases of clinical development Each chapter includes whenever possible real examples of clinical studies from therapeutic areas such as cardiovascular central nervous system anti infective oncology and women s health to demonstrate the clinical and statistical concepts interpretations and their relationships and interactions The book highlights statistical procedures for sample size calculation and justification that are commonly employed in clinical research and development It provides clear illustrated explanations of how the derived formulas and or statistical procedures can be used

Sample Size Tables for Clinical Studies David Machin, Michael J. Campbell, Say Beng Tan, Sze Huey Tan, 2011-08-26 This book provides statisticians

and researchers with the statistical tools equations formulae and numerical tables to design and plan clinical studies and carry out accurate reliable and reproducible analysis of the data so obtained There is no way around this as incorrect procedure in clinical studies means that the researcher s paper will not be accepted by a peer reviewed journal Planning and analysing clinical studies is a very complicated business and this book provides indispensable factual information Please go to <http://booksupport.wiley.com> and enter 9781405146500 to easily download the supporting materials *Sample Size*

Calculations for Clustered and Longitudinal Outcomes in Clinical Research Chul Ahn, Moonseoung Heo, Song Zhang, 2014-12-09 This book explains how to determine sample size for studies with correlated outcomes which are widely implemented in medical epidemiological and behavioral studies For clustered studies the authors provide sample size formulas that account for variable cluster sizes and within cluster correlation For longitudinal studies they present sample size formulas that account for within subject correlation among repeated measurements and various missing data patterns For multiple levels of clustering the authors describe how randomization impacts trial administration analysis and sample size requirement *Sample Size Determination in Clinical Trials with Multiple Endpoints* Takashi Sozu, Tomoyuki

Sugimoto, Toshimitsu Hamasaki, Scott R. Evans, 2015-08-20 This book integrates recent methodological developments for calculating the sample size and power in trials with more than one endpoint considered as multiple primary or co primary offering an important reference work for statisticians working in this area The determination of sample size and the evaluation of power are fundamental and critical elements in the design of clinical trials If the sample size is too small important effects may go unnoticed if the sample size is too large it represents a waste of resources and unethically puts more participants at risk than necessary Recently many clinical trials have been designed with more than one endpoint considered as multiple primary or co primary creating a need for new approaches to the design and analysis of these clinical trials The book focuses on the evaluation of power and sample size determination when comparing the effects of two interventions in superiority clinical trials with multiple endpoints Methods for sample size calculation in clinical trials where the alternative hypothesis is that there are effects on ALL endpoints are discussed in detail The book also briefly examines trials designed with an alternative hypothesis of an effect on AT LEAST ONE endpoint with a prespecified non ordering of endpoints **Methods and Applications of Sample Size Calculation and Recalculation in Clinical Trials** Meinhard

Kieser, 2020-11-19 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. Part III presents methods that allow to modify the initially specified sample size based on new information that becomes available during the ongoing trial. Blinded sample size recalculation procedures for internal pilot study designs are considered, as well as methods for sample size reassessment in adaptive designs that use unblinded data from interim analyses. The application is illustrated using numerous clinical trial examples, and software code implementing the methods is provided. The book offers theoretical background and practical advice for biostatisticians and clinicians from the pharmaceutical industry and academia who are involved in clinical trials. Covering basic as well as more advanced and recently developed methods, it is suitable for beginners, experienced applied statisticians, and practitioners. To gain maximum benefit, readers should be familiar with introductory statistics. The content of this book has been successfully used for courses on the topic.

Sample Sizes for Clinical Trials Steven A. Julious, 2009-08-26. Drawing on various real-world applications, Sample Sizes for Clinical Trials takes readers through the process of calculating sample sizes for many types of clinical trials. It provides descriptions of the calculations with a practical emphasis. Focusing on normal, binary, ordinal, and survival data, the book explores a range of trials, including su

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