



# Sample Size Calculators for designing clinical research

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## Calculators

CI for proportion

CI for mean

Means - effect size

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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**



## **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 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 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 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 Designing Clinical Research Stephen B. Hulley, 2007 This third edition sets the standard for providing a practical guide to planning tabulating formulating and implementing clinical research with an easy to read uncomplicated presentation This edition incorporates current research methodology and offers an updated syllabus for conducting a clinical research workshop

Clinical Trials Duolao Wang, Ameet Bakhai, 2006 This book explains statistics specifically for a medically literate audience Readers gain not only an understanding of the basics of medical statistics but also a critical insight into how to review and evaluate clinical trial evidence

**Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research** Chul Ahn, Moonseoung Heo, Song Zhang, 2014-12-09 Accurate sample size calculation ensures that clinical studies have adequate power to detect clinically meaningful effects This results in the efficient use of resources and avoids exposing a disproportionate number of patients to experimental treatments caused by an overpowered study **Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research** explains how to determine sample size for studies with correlated outcomes which are widely implemented in medical epidemiological and behavioral studies The book focuses on issues specific to the two types of correlated outcomes longitudinal and clustered For clustered studies the authors provide sample size formulas that accommodate variable cluster sizes and within cluster correlation For longitudinal studies they present sample size formulas to account for within subject correlation among repeated measurements and various missing data patterns For multiple levels of clustering the level at which to perform randomization actually becomes a design

parameter The authors show how this can greatly impact trial administration analysis and sample size requirement Addressing the overarching theme of sample size determination for correlated outcomes this book provides a useful resource for biostatisticians clinical investigators epidemiologists and social scientists whose research involves trials with correlated outcomes Each chapter is self contained so readers can explore topics relevant to their research projects without having to refer to other chapters

**Sample Sizes for Clinical, Laboratory and Epidemiology Studies** David Machin, Michael J. Campbell, Say Beng Tan, Sze Huey Tan, 2018-08-20 Ein fundiertes Referenzwerk zu den statistischen Instrumenten und Softwareprogrammen die für das Design und die Planung klinischer Studien erforderlich sind Die erweiterte 4. Auflage von Sample Sizes for Clinical Laboratory and Epidemiology Studies beinhaltet eine Sample Size Software SSS Formeln und numerische Tabellen für die Gestaltung valider klinischer Studien Das Fachbuch behandelt ebenfalls Labor und epidemiologische Studien und stellt die Informationen zur Verfügung damit Studien einen wesentlichen Beitrag zur medizinischen Forschung leisten Die Autoren allesamt anerkannte Experten des Fachgebiets erläutern und untersuchen Schritt für Schritt die vielfältigen Überlegungen bei der Festlegung geeigneter Stichprobengrößen und helfen so bei der Planung von Studien Bereitgestellt werden ebenfalls Stichprobentabellen mit Erläuterungen und aussagekräftige Beispiele auf der Basis von Echtdateien Darüber hinaus enthält das Fachbuch ein Literaturverzeichnis und Angaben zu weiterführenden Referenzen zur Unterstützung der vorgestellten Prinzipien Diese bearbeitete 4. Auflage ist das bislang einzige Referenzwerk mit einem Softwareprogramm für die Gestaltung und Planung klinischer Studien enthält neue und erweiterte Kapitel mit einer Vielzahl neuer und aktualisierter Beispiele erläutern verständlich die angewandten Prinzipien und Methoden anhand von Beispielen aus der Praxis präsentiert auf nachvollziehbare Weise ein komplexes und dennoch wichtiges Thema damit die richtigen Methoden verwendet werden und fundierte Ergebnisse veröffentlicht werden können bietet Hilfestellung von einem Team international anerkannter Statistikexperten im medizinischen Bereich Sample Sizes for Clinical Laboratory and Epidemiology Studies richtet sich an medizinische Forscher aller Disziplinen sowie an Medizinstatistiker Die aktualisierte 4. Auflage ist ein wichtiges Referenzwerk für die Gestaltung und Planung verschiedener evidenzbasierter klinischer Studien

**Sample Size Determination and Power** Thomas P. Ryan, 2013-05-28 A comprehensive approach to sample size determination and power with applications for a variety of fields Sample Size Determination and Power features a modern introduction to the applicability of sample size determination and provides a variety of discussions on broad topics including epidemiology microarrays survival analysis and reliability design of experiments regression and confidence intervals The book distinctively merges applications from numerous fields such as statistics biostatistics the health sciences and engineering in order to provide a complete introduction to the general statistical use of sample size determination Advanced topics including multivariate analysis clinical trials and quality improvement are addressed and in addition the book provides considerable guidance on available software for sample size determination Written by a well known author who has extensively class

tested the material Sample Size Determination and Power Highlights the applicability of sample size determination and provides extensive literature coverage Presents a modern general approach to relevant software to guide sample size determination including CATD computer aided trial design Addresses the use of sample size determination in grant proposals and provides up to date references for grant investigators An appealing reference book for scientific researchers in a variety of fields such as statistics biostatistics the health sciences mathematics ecology and geology who use sampling and estimation methods in their work Sample Size Determination and Power is also an ideal supplementary text for upper level undergraduate and graduate level courses in statistical sampling

Sample Size Determination in Clinical Trials with Multiple Objectives Takashi Sozu,Tomoyuki Sugimoto,Toshimitsu Hamasaki,Scott R. Evans,2015-12-06 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

**Innovative Statistics in Regulatory Science** Shein-Chung Chow,2019-11-14 Statistical methods that are commonly used in the review and approval process of regulatory submissions are usually referred to as statistics in regulatory science or regulatory statistics In a broader sense statistics in regulatory science can be defined as valid statistics that are employed in the review and approval process of regulatory submissions of pharmaceutical products In addition statistics in regulatory science are involved with the development of regulatory policy guidance and regulatory critical clinical initiatives related research This book is devoted to the discussion of statistics in regulatory science for pharmaceutical development It covers practical issues that are commonly encountered in regulatory science of pharmaceutical research and development including topics related to research activities review of regulatory submissions recent critical clinical initiatives and policy guidance development in regulatory science Devoted entirely to discussing statistics in regulatory science for pharmaceutical development Reviews critical issues e g endpoint margin selection and complex innovative design such as adaptive trial design in the pharmaceutical development and regulatory approval process Clarifies controversial statistical issues e g hypothesis testing versus confidence interval approach missing data estimands



multiplicity and Bayesian design and approach in review approval of regulatory submissions Proposes innovative thinking regarding study designs and statistical methods e g n of 1 trial design adaptive trial design and probability monitoring procedure for sample size for rare disease drug development Provides insight regarding current regulatory clinical initiatives e g precision personalized medicine biomarker driven target clinical trials model informed drug development big data analytics and real world data evidence This book provides key statistical concepts innovative designs and analysis methods that are useful in regulatory science Also included are some practical challenging and controversial issues that are commonly seen in the review and approval process of regulatory submissions About the author Shein Chung Chow Ph D is currently a Professor at Duke University School of Medicine Durham NC He was previously the Associate Director at the Office of Biostatistics Center for Drug Evaluation and Research United States Food and Drug Administration FDA Dr Chow has also held various positions in the pharmaceutical industry such as Vice President at Millennium Cambridge MA Executive Director at Covance Princeton NJ and Director and Department Head at Bristol Myers Squibb Plainsboro NJ He was elected Fellow of the American Statistical Association and an elected member of the ISI International Statistical Institute Dr Chow is Editor in Chief of the Journal of Biopharmaceutical Statistics and Biostatistics Book Series Chapman and Hall CRC Press Taylor Francis New York Dr Chow is the author or co author of over 300 methodology papers and 30 books      Fundamentals of Clinical Trials Lawrence M. Friedman, Curt D. Furberg, David L. DeMets, 2010-09-09 The clinical trial is the most definitive tool for evaluation of the applicability of clinical research It represents a key research activity with the potential to improve the quality of health care and control costs through careful comparison of alternative treatments 1 It has been called on many occasions the gold st dard against which all other clinical research is measured Although many clinical trials are of high quality a careful reader of the medical literature will notice that a large number have deficiencies in design conduct analysis presentation and or interpretation of results Improvements have occurred over the past few decades but too many trials are still conducted without adequate attention to its fundamental principles Certainly numerous studies could have been upgraded if the authors had had a better understanding of the fundamentals Since the publication of the first edition of this book a large number of other texts on clinical trials have appeared most of which are indicated here 2 21 Several of them however discuss only specific issues involved in clinical trials Additionally many are no longer current The purpose of this fourth edition is to update areas in which major progress has been made since the publication of the third edition We have revised most chapters considerably and added one on ethical issues      **Design and Analysis of Clinical Trials** Shein-Chung Chow, Jen-Pei Liu, 2008-12-04 Praise for the First Edition of Design and Analysis of Clinical Trials An excellent book providing a discussion of the clinical trial process from designing the study through analyzing the data and to regulatory requirement could easily be used as a classroom text to understand the process in the new drug development area Statistical Methods in Medicine A complete and balanced presentation now revised updated and expanded As the field of

research possibilities expands the need for a working understanding of how to carry out clinical trials only increases New developments in the theory and practice of clinical research include a growing body of literature on the subject new technologies and methodologies and new guidelines from the International Conference on Harmonization ICH Design and Analysis of Clinical Trials Second Edition provides both a comprehensive unified presentation of principles and methodologies for various clinical trials and a well balanced summary of current regulatory requirements This unique resource bridges the gap between clinical and statistical disciplines covering both fields in a lucid and accessible manner Thoroughly updated from its first edition the Second Edition of Design and Analysis of Clinical Trials features new topics such as Clinical trials and regulations especially those of the ICH Clinical significance reproducibility and generalizability Goals of clinical trials and target population New study designs and trial types Sample size determination on equivalence and noninferiority trials as well as comparing variabilities Also three entirely new chapters cover Designs for cancer clinical trials Preparation and implementation of a clinical protocol Data management of a clinical trial Written with the practitioner in mind the presentation assumes only a minimal mathematical and statistical background for its reader Instead the writing emphasizes real life examples and illustrations from clinical case studies as well as numerous references 280 of them new to the Second Edition to the literature Design and Analysis of Clinical Trials Second Edition will benefit academic pharmaceutical medical and regulatory scientists researchers statisticians and graduate level students in these areas by serving as a useful thorough reference source for clinical research

**Small Clinical Trials** Institute of Medicine, Board on Health Sciences Policy, Committee on Strategies for Small-Number-Participant Clinical Research Trials, 2001-02-01 Clinical trials are used to elucidate the most appropriate preventive diagnostic or treatment options for individuals with a given medical condition Perhaps the most essential feature of a clinical trial is that it aims to use results based on a limited sample of research participants to see if the intervention is safe and effective or if it is comparable to a comparison treatment Sample size is a crucial component of any clinical trial A trial with a small number of research participants is more prone to variability and carries a considerable risk of failing to demonstrate the effectiveness of a given intervention when one really is present This may occur in phase I safety and pharmacologic profiles II pilot efficacy evaluation and III extensive assessment of safety and efficacy trials Although phase I and II studies may have smaller sample sizes they usually have adequate statistical power which is the committee's definition of a large trial Sometimes a trial with eight participants may have adequate statistical power statistical power being the probability of rejecting the null hypothesis when the hypothesis is false Small Clinical Trials assesses the current methodologies and the appropriate situations for the conduct of clinical trials with small sample sizes This report assesses the published literature on various strategies such as 1 meta analysis to combine disparate information from several studies including Bayesian techniques as in the confidence profile method and 2 other alternatives such as assessing therapeutic results in a single treated population e g astronauts by sequentially measuring

whether the intervention is falling above or below a preestablished probability outcome range and meeting predesigned specifications as opposed to incremental improvement

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