



# Modern Approaches to Clinical Trials Using SAS®

Classical, Adaptive, and Bayesian Methods

Edited by  
**Sandeep M. Menon**  
**Richard C. Zink**

# Modern Approaches To Clinical Trials Using Sas Classical Adaptive And Bayesia

**Shein-Chung Chow, Mark Chang**

## **Modern Approaches To Clinical Trials Using Sas Classical Adaptive And Bayesia:**

*Modern Approaches to Clinical Trials Using SAS: Classical, Adaptive, and Bayesian Methods* Sandeep Menon, Richard C. Zink, 2015-12-09 This book covers domains of modern clinical trial design classical group sequential adaptive and Bayesian methods applicable to and used in various phases of pharmaceutical development Written for biostatisticians pharmacometrists clinical developers and statistical programmers involved in the design analysis and interpretation of clinical trials as well as students in graduate and postgraduate programs in statistics or biostatistics it covers topics including dose response and dose escalation designs sequential methods to stop trials early for overwhelming efficacy safety or futility Bayesian designs incorporating historical data adaptive sample size re estimation and randomization to allocate subjects to effective treatments population enrichment designs Methods are illustrated using clinical trials from diverse therapeutic areas including dermatology endocrinology infectious disease neurology oncology and rheumatology

*Quantitative Decisions in Drug Development* Christy Chuang-Stein, Simon Kirby, 2021-09-03 This book focuses on important decision points and evidence needed for making decisions at these points during the development of a new drug It takes a holistic approach towards drug development by incorporating explicitly knowledge learned from the earlier part of the development and available historical information into decisions at later stages In addition the book shares lessons learned from several select examples published in the literature since the publication of the first edition The second edition reiterates the need for making evidence based Go No Go decisions in drug development discussed in the first edition It substantially expands several topics that have seen great advances since the publication of the first edition The most noticeable additions include three adaptive trials conducted in recent years that offer excellent learning opportunities the use of historical data in the design and analysis of clinical trials and extending decision criteria to the cases when the primary endpoint is binary The examples used to illustrate the additional materials all come from real trials with some post trial reflections offered by the authors The book begins with an overview of product development and regulatory approval pathways It then discusses how to incorporate prior knowledge into study design and decision making at different stages of drug development Prior knowledge includes information pertaining to historical controls To assist decision making the book discusses appropriate metrics and the formulation of go no go decisions for progressing a drug candidate to the next development stage Using the concept of the positive predictive value in the field of diagnostics the book leads readers to the assessment of the probability that an investigational product is effective given positive study outcomes Lastly the book points out common mistakes made by drug developers under the current drug development paradigm The book offers useful insights to statisticians clinicians regulatory affairs managers and decision makers in the pharmaceutical industry who have a basic understanding of the drug development process and the clinical trials conducted to support drug marketing authorization The authors provide software codes for select analytical approaches discussed in the book The book includes

enough technical details to allow statisticians to replicate the quantitative illustrations so that they can generate information to facilitate decision making themselves **Biosimilar Clinical Development: Scientific Considerations and New Methodologies** Kerry B. Barker, Sandeep M. Menon, Ralph B. D'Agostino, Sr., Siyan Xu, Bo Jin, PhD 2016-11-25 Biosimilars

have the potential to change the way we think about identify and manage health problems They are already impacting both clinical research and patient care and this impact will only grow as our understanding and technologies improve Written by a team of experienced specialists in clinical development this book discusses various potential drug development strategies the design and analysis of pharmacokinetics PK studies and the design and analysis of efficacy studies *Statistical Methods in Biomarker and Early Clinical Development* Liang Fang, Cheng Su, 2019-12-26 This contributed volume offers a much needed overview of the statistical methods in early clinical drug and biomarker development Chapters are written by expert statisticians with extensive experience in the pharmaceutical industry and regulatory agencies Because of this the data presented is often accompanied by real world case studies which will help make examples more tangible for readers The many applications of statistics in drug development are covered in detail making this volume a must have reference Biomarker development and early clinical development are the two critical areas on which the book focuses By having the two sections of the book dedicated to each of these topics readers will have a more complete understanding of how applying statistical methods to early drug development can help identify the right drug for the right patient at the right dose Also presented are exciting applications of machine learning and statistical modeling along with innovative methods and state of the art advances making this a timely and practical resource This volume is ideal for statisticians researchers and professionals interested in pharmaceutical research and development Readers should be familiar with the fundamentals of statistics and clinical trials **Adaptive Design Theory and Implementation Using SAS and R** Mark Chang, 2012-10-09

Adaptive design has become an important tool in modern pharmaceutical research and development Compared to a classic trial design with static features an adaptive design allows for the modification of the characteristics of ongoing trials based on cumulative information Adaptive designs increase the probability of success reduce costs and the t *Adaptive Design Theory and Implementation Using SAS and R, Second Edition* Mark Chang, 2014-12-01 Get Up to Speed on Many Types of Adaptive Designs Since the publication of the first edition there have been remarkable advances in the methodology and application of adaptive trials Incorporating many of these new developments Adaptive Design Theory and Implementation Using SAS and R Second Edition offers a detailed framework to understand the use of various adaptive design methods in clinical trials New to the Second Edition Twelve new chapters covering blinded and semi blinded sample size reestimation design pick the winners design biomarker informed adaptive design Bayesian designs adaptive multiregional trial design SAS and R for group sequential design and much more More analytical methods for K stage adaptive designs multiple endpoint adaptive design survival modeling and adaptive treatment switching New material on sequential parallel designs with

rerandomization and the skeleton approach in adaptive dose escalation trials Twenty new SAS macros and R functions Enhanced end of chapter problems that give readers hands on practice addressing issues encountered in designing real life adaptive trials Covering even more adaptive designs this book provides biostatisticians clinical scientists and regulatory reviewers with up to date details on this innovative area in pharmaceutical research and development Practitioners will be able to improve the efficiency of their trial design thereby reducing the time and cost of drug development

**Analysis of Clinical Trials Using SAS** Alex Dmitrienko,2017-07-17 **Analysis of Clinical Trials Using SAS A Practical Guide** Second Edition bridges the gap between modern statistical methodology and real world clinical trial applications Tutorial material and step by step instructions illustrated with examples from actual trials serve to define relevant statistical approaches describe their clinical trial applications and implement the approaches rapidly and efficiently using the power of SAS Topics reflect the International Conference on Harmonization ICH guidelines for the pharmaceutical industry and address important statistical problems encountered in clinical trials Commonly used methods are covered including dose escalation and dose finding methods that are applied in Phase I and Phase II clinical trials as well as important trial designs and analysis strategies that are employed in Phase II and Phase III clinical trials such as multiplicity adjustment data monitoring and methods for handling incomplete data This book also features recommendations from clinical trial experts and a discussion of relevant regulatory guidelines This new edition includes more examples and case studies new approaches for addressing statistical problems and the following new technological updates SAS procedures used in group sequential trials PROC SEQDESIGN and PROC SEQTEST SAS procedures used in repeated measures analysis PROC GLIMMIX and PROC GEE macros for implementing a broad range of randomization based methods in clinical trials performing complex multiplicity adjustments and investigating the design and analysis of early phase trials Phase I dose escalation trials and Phase II dose finding trials Clinical statisticians research scientists and graduate students in biostatistics will greatly benefit from the decades of clinical research experience and the ready to use SAS macros compiled in this book

**Bayesian Adaptive Methods for Clinical Trials** Scott M. Berry,Bradley P. Carlin,J. Jack Lee,Peter Muller,2010-07-19 Already popular in the analysis of medical device trials adaptive Bayesian designs are increasingly being used in drug development for a wide variety of diseases and conditions from Alzheimer's disease and multiple sclerosis to obesity diabetes hepatitis C and HIV Written by leading pioneers of Bayesian clinical trial designs Bayesian Adapti [Clinical Trial Design](#) Guosheng Yin,2012-01-03 A balanced treatment of the theories methodologies and design issues involved in clinical trials using statistical methods There has been enormous interest and development in Bayesian adaptive designs especially for early phases of clinical trials However for phase III trials frequentist methods still play a dominant role through controlling type I and type II errors in the hypothesis testing framework From practical perspectives Clinical Trial Design Bayesian and Frequentist Adaptive Methods provides comprehensive coverage of both Bayesian and frequentist approaches to all phases of

clinical trial design Before underpinning various adaptive methods the book establishes an overview of the fundamentals of clinical trials as well as a comparison of Bayesian and frequentist statistics Recognizing that clinical trial design is one of the most important and useful skills in the pharmaceutical industry this book provides detailed discussions on a variety of statistical designs their properties and operating characteristics for phase I II and III clinical trials as well as an introduction to phase IV trials Many practical issues and challenges arising in clinical trials are addressed Additional topics of coverage include Risk and benefit analysis for toxicity and efficacy trade offs Bayesian predictive probability trial monitoring Bayesian adaptive randomization Late onset toxicity and response Dose finding in drug combination trials Targeted therapy designs The author utilizes cutting edge clinical trial designs and statistical methods that have been employed at the world's leading medical centers as well as in the pharmaceutical industry The software used throughout the book is freely available on the book's related website equipping readers with the necessary tools for designing clinical trials Clinical Trial Design is an excellent book for courses on the topic at the graduate level The book also serves as a valuable reference for statisticians and biostatisticians in the pharmaceutical industry as well as for researchers and practitioners who design conduct and monitor clinical trials in their everyday work

**Innovative Strategies, Statistical Solutions and Simulations for Modern Clinical Trials** Mark Chang, John Balser, Jim Roach, Robin Bliss, 2019-03-20 This is truly an outstanding book It brings together all of the latest research in clinical trials methodology and how it can be applied to drug development Chang et al provide applications to industry supported trials This will allow statisticians in the industry community to take these methods seriously Jay Herson Johns Hopkins University The pharmaceutical industry's approach to drug discovery and development has rapidly transformed in the last decade from the more traditional Research and Development R D approach to a more innovative approach in which strategies are employed to compress and optimize the clinical development plan and associated timelines However these strategies are generally being considered on an individual trial basis and not as part of a fully integrated overall development program Such optimization at the trial level is somewhat near sighted and does not ensure cost time or development efficiency of the overall program This book seeks to address this imbalance by establishing a statistical framework for overall global clinical development optimization and providing tactics and techniques to support such optimization including clinical trial simulations Provides a statistical framework for achieve global optimization in each phase of the drug development process Describes specific techniques to support optimization including adaptive designs precision medicine survival endpoints dose finding and multiple testing Gives practical approaches to handling missing data in clinical trials using SAS Looks at key controversial issues from both a clinical and statistical perspective Presents a generous number of case studies from multiple therapeutic areas that help motivate and illustrate the statistical methods introduced in the book Puts great emphasis on software implementation of the statistical methods with multiple examples of software code both SAS and R It is important for statisticians to possess a deep knowledge of the drug development process

beyond statistical considerations For these reasons this book incorporates both statistical and clinical medical perspectives

*Current Index to Statistics, Applications, Methods and Theory*, 1994 The Current Index to Statistics CIS is a bibliographic index of publications in statistics probability and related fields [Adaptive Design Methods in Clinical Trials](#) Shein-Chung Chow, Mark Chang, 2011-12-01 With new statistical and scientific issues arising in adaptive clinical trial design including the U S FDA's recent draft guidance a new edition of one of the first books on the topic is needed Adaptive Design Methods in Clinical Trials Second Edition reflects recent developments and regulatory positions on the use of adaptive designs in clinical trials

**Bayesian Adaptive Methods for Clinical Trials** Scott M. Berry, Bradley P. Carlin, J. Jack Lee, Peter Muller, 2010-07-19 Already popular in the analysis of medical device trials adaptive Bayesian designs are increasingly being used in drug development for a wide variety of diseases and conditions from Alzheimer's disease and multiple sclerosis to obesity diabetes hepatitis C and HIV Written by leading pioneers of Bayesian clinical trial designs Bayesian Adaptive Methods for Clinical Trials explores the growing role of Bayesian thinking in the rapidly changing world of clinical trial analysis The book first summarizes the current state of clinical trial design and analysis and introduces the main ideas and potential benefits of a Bayesian alternative It then gives an overview of basic Bayesian methodological and computational tools needed for Bayesian clinical trials With a focus on Bayesian designs that achieve good power and Type I error the next chapters present Bayesian tools useful in early Phase I and middle Phase II clinical trials as well as two recent Bayesian adaptive Phase II studies the BATTLE and ISPY 2 trials In the following chapter on late Phase III studies the authors emphasize modern adaptive methods and seamless Phase II III trials for maximizing information usage and minimizing trial duration They also describe a case study of a recently approved medical device to treat atrial fibrillation The concluding chapter covers key special topics such as the proper use of historical data equivalence studies and subgroup analysis For readers involved in clinical trials research this book significantly updates and expands their statistical toolkits The authors provide many detailed examples drawing on real data sets The R and WinBUGS codes used throughout are available on supporting websites Scott Berry talks about the book on the CRC Press YouTube Channel [Bayesian Approaches to Clinical Trials and Health-Care Evaluation](#) David J.

Spiegelhalter, Keith R. Abrams, Jonathan P. Myles, 2004-01-16 READ ALL ABOUT IT David Spiegelhalter has recently joined the ranks of Isaac Newton Charles Darwin and Stephen Hawking by becoming a fellow of the Royal Society Originating from the Medical Research Council's biostatistics unit David has played a leading role in the Bristol heart surgery and Harold Shipman inquiries Order a copy of this author's comprehensive text TODAY The Bayesian approach involves synthesising data and judgement in order to reach conclusions about unknown quantities and make predictions Bayesian methods have become increasingly popular in recent years notably in medical research and although there are a number of books on Bayesian analysis few cover clinical trials and biostatistical applications in any detail Bayesian Approaches to Clinical Trials and Health Care Evaluation provides a valuable overview of this rapidly evolving field including basic Bayesian ideas prior

distributions clinical trials observational studies evidence synthesis and cost effectiveness analysis Covers a broad array of essential topics building from the basics to more advanced techniques Illustrated throughout by detailed case studies and worked examples Includes exercises in all chapters Accessible to anyone with a basic knowledge of statistics Authors are at the forefront of research into Bayesian methods in medical research Accompanied by a Web site featuring data sets and worked examples using Excel and WinBUGS the most widely used Bayesian modelling package Bayesian Approaches to Clinical Trials and Health Care Evaluation is suitable for students and researchers in medical statistics statisticians in the pharmaceutical industry and anyone involved in conducting clinical trials and assessment of health care technology

### Case

**Studies in Innovative Clinical Trials** Kristine Broglio, Binbing Yu, 2023-11-27 Drug development is a strictly regulated area As such marketing approval of a new drug depends heavily if not exclusively on evidence generated from clinical trials Drug development has seen tremendous innovation in science and technology that has revolutionized the treatment of some diseases And yet the statistical design and practical conduct of the clinical trials used to test new therapeutics for safety and efficacy have changed very little over the decades Our approach to clinical trials is steeped in convention and tradition The large fixed randomized controlled trial methods that have been the gold standard are well understood and expected by many trial stakeholders However this approach is not well suited to all aspects of modern drug development and the current competitive landscape We now see new therapies that target a small fraction of the patient population rare diseases with high unmet medical needs and pediatric populations that must wait for years for new drug approvals from the time that therapies are approved in adults Large randomized clinical trials are at best inefficient and at worst completely infeasible in many modern clinical settings Advances in technology and data infrastructure call for innovations in clinical trial design Despite advances in statistical methods the availability of information and computing power the actual experience with innovative design in clinical trials across industry and academia is limited This book will be an important showcase of the potential for these innovative designs in modern drug development and will be an important resource to guide those who wish to undertake them for themselves This book is ideal for professionals in the pharmaceutical industry and regulatory agencies but it will also be useful to academic researchers faculty members and graduate students in statistics biostatistics public health and epidemiology due to its focus on innovation Key Features Is written by pharmaceutical industry experts academic researchers and regulatory reviewers this is the first book providing a comprehensive set of case studies related to statistical methodology implementation regulatory considerations and communication of complex innovative trial design Has a broad appeal to a multitude of readers across academia industry and regulatory agencies Each contribution is a practical case study that can speak to the benefits of an innovative approach but also balance that with the real life challenges encountered A complete understanding of what is actually being done in modern clinical trials will broaden the reader's capabilities and provide examples to first mimic and then customize and expand upon when exploring these ideas on their

own *Journal of the American Statistical Association*, 2006 A scientific and educational journal not only for professional statisticians but also for economists business executives research directors government officials university professors and others who are seriously interested in the application of statistical methods to practical problems in the development of more useful methods and in the improvement of basic statistical data **AMSTAT News** American Statistical Association, 1999

Introductory Adaptive Trial Designs Mark Chang, 2015-05-21 All the Essentials to Start Using Adaptive Designs in No Time Compared to traditional clinical trial designs adaptive designs often lead to increased success rates in drug development at reduced costs and time Introductory Adaptive Trial Designs A Practical Guide with R motivates newcomers to quickly and easily grasp the essence of adaptive design Classical and Adaptive Clinical Trial Designs Using ExpDesign Studio Mark Chang, 2010-06-15 ExpDesign Studio facilitates more efficient clinical trial design This book introduces pharmaceutical statisticians scientists researchers and others to ExpDesign Studio software for classical and adaptive designs of clinical trials It includes the Professional Version 5.0 of ExpDesign Studio software that frees pharmaceutical professionals to focus on drug development and related challenges while the software handles the essential calculations and computations After a hands on introduction to the software and an overview of clinical trial designs encompassing numerous variations Classical and Adaptive Clinical Trial Designs Using ExpDesign Studio Covers both classical and adaptive clinical trial designs monitoring and analyses Explains various classical and adaptive designs including groupsequential sample size reestimation dropping loser biomarker adaptive and response adaptive randomization designs Includes instructions for over 100 design methods that have been implemented in ExpDesign Studio and step by step demos as well as real world examples Emphasizes applications yet covers key mathematical formulations Introduces readers to additional toolkits in ExpDesign Studio that help in designing monitoring and analyzing trials such as the adaptive monitor graphical calculator the probability calculator the confidence interval calculator and more Presents comprehensive technique notes for sample size calculation methods grouped by the number of arms the trial endpoint and the analysis basis Written with practitioners in mind this is an ideal self study guide for not only statisticians but also scientists researchers and professionals in the pharmaceutical industry contract research organizations CROs and regulatory bodies It's also a go to reference for biostatisticians pharmacokinetic specialists and principal investigators involved in clinical trials **ERRATUM Classical and Adaptive Clinical Trial Designs Using ExpDesign Studio** By Mark Chang The license for the ExpDesign Studio software on the CD included with this book is good for one year after installation of the software Prior to the expiration of this period the software will generate a reminder about renewal for the license The user should contact CTriSoft International the owners of ExpDesign Studio at [www.CTriSoft.net](http://www.CTriSoft.net) or by email at [license@ctrisoft.net](mailto:license@ctrisoft.net) about renewal for the license This should have been made clear in the first printing of this book We apologize for this error **Adaptive Design Methods in Clinical Trials** Shein-Chung Chow, Mark Chang, 2006-11-16 Although adaptive design methods are flexible and useful in clinical research

little or no regulatory guidelines are available One of the first books on the topic Adaptive Design Methods in Clinical Trials presents the principles and methodologies in adaptive design and analysis that pertain to adaptations made to trial or statistical procedures that are based on accrued data of ongoing clinical trials The book also offers a well balanced summary of current regulatory perspectives and recently developed statistical methods in this area After an introduction to basic concepts and statistical considerations of adaptive design methods the book questions the impact on target patient populations as the result of protocol amendments and discusses the generalization of statistical inference The authors also present various adaptive design methods including where hypotheses are modified during the conduct of clinical trials for dose selection and commonly used adaptive group sequential design methods in clinical trials Following a discussion of blind procedures for sample size re estimation the book describes statistical tests for seamless phase II III adaptive designs and statistical inference for switching adaptively from one treatment to another The book concludes with computer simulations and various case studies of clinical trials By providing theoretical and computer simulation results method comparisons and practical guidelines for choosing an optimal design Adaptive Design Methods in Clinical Trials fills the need for a unified comprehensive and updated resource in the clinical research and development of adaptive design and analysis

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