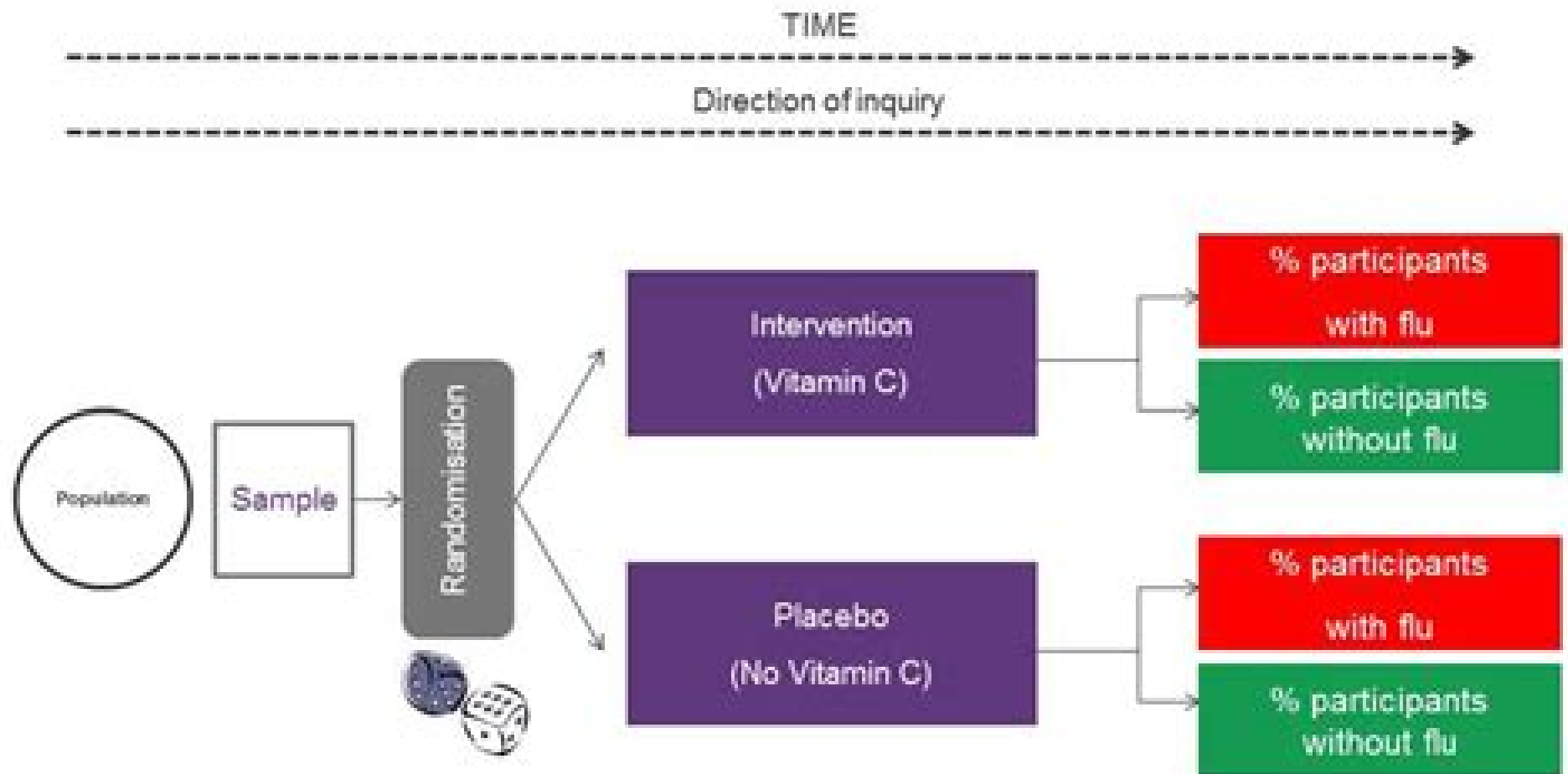


Randomised controlled trial



Randomised Controlled Clinical Trials

Kenneth Schulz, David A. Grimes



Randomised Controlled Clinical Trials:

Randomized Controlled Trials Alejandro R. Jadad, Murray W. Enkin, 2007-07-23 Randomized controlled trials are one of the most powerful and revolutionary tools of research. This book is a convenient and accessible description of the underlying principles and practice of randomized controlled trials and their role in clinical decision making. Structured in a jargon free question and answer format, each chapter provides concise and understandable information on a different aspect of randomized controlled trials, from the basics of trial design and terminology to the interpretation of results and their use in driving evidence based medicine. The authors end each chapter with their musings going beyond the evidence or citations and sometimes even beyond orthodox correctness to share their thoughts and concerns about different aspects of randomized controlled trials and their role within the health system. Updated to include insights from the last decade, this second edition challenges over reliance on randomized controlled trials by debating their strengths and limitations and discussing their optimal use in modern healthcare. It also includes a new and increasingly relevant chapter on the ethics of randomized trials. World renowned writers and thinkers Drs Jadad and Enkin bring you this invaluable book for busy health professionals who wish to understand the theory of randomized controlled trials and their influence on clinical research or policy decisions.

Randomised Controlled Clinical Trials Christopher J. Bulpitt, 2013-04-17 Bradford Hill has defined a clinical trial as 'A carefully and ethically designed experiment with the aim of answering some precisely framed question'. This definition specifies a careful design and requires the provision of adequate controls. Random allocation of treatments to subjects is important to ensure that the treated and control groups are similar. Therefore, this book 'Randomised Controlled Clinical Trials' defines a randomised controlled trial by rewriting Bradford Hill's definition as follows: 'A carefully and ethically designed experiment which includes the provision of adequate and appropriate controls by a process of randomisation so that precisely framed questions can be answered'. I am a firm advocate of Randomised Controlled Clinical Trials but intend to give a balanced view of the advantages and disadvantages of these ethical experiments. This book is directed primarily at the medical research worker, although certain chapters may find a wider application. When discussing a randomised controlled trial, it is neither practicable nor desirable to divorce theory from practice; however, the first ten chapters concentrate mainly on theory and the remainder focus on practice. The segment on trial design is followed by sections on writing the protocol, designing the forms, conducting the trial, and analysing the results. This book is meant to serve both as a reference manual and a practical guide to the design and performance of a trial.

Introduction to Randomized Controlled Clinical Trials John N.S. Matthews, 2006-06-26 Evidence from randomized controlled clinical trials is widely accepted as the only sound basis for assessing the efficacy of new medical treatments. Statistical methods play a key role in all stages of these trials, including their justification, design, and analysis. This second edition of 'Introduction to Randomized Controlled Clinical Trials' provides

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Bradford Hill has defined a clinical trial as A carefully and ethically designed experiment with the aim of answering some precisely framed question 1 This definition specifies a careful design and requires the provision of adequate controls Random allocation of treatments to subjects is important to ensure is entitled that the treated and control groups are similar Therefore this book Randomised Controlled Clinical Trials We can define a randomised controlled trial by rewriting Bradford Hill s definition as follows A carefully and ethi cally designed experiment which includes the provision of adequate and appropriate controls by a process of randomisation so that precisely framed questions can be answered I am a firm advocate of Randomised Controlled Clinical Trials but intend to give a balanced view of the advantages and disadvantages of these ethical experiments This book is directed primarily at the medical research worker although certain chapters may find a wider application When discussing a randomised controlled trial it is neither practicable nor desirable to divorce theory from practice however the first ten chapters concentrate mainly on theory and the remainder focus on practice The segment on trial design is followed by sections on writing the protocol designing the forms conducting the trial and analysing the results This book is meant to serve both as a reference manual and a practical guide to the design and performance of a trial

Randomised Controlled Clinical Trials Christopher Bulpitt, 2014-01-15 **Randomised Clinical Trials** David Machin, Peter M. Fayers, Bee Choo Tai, 2021-05-12 Randomised Clinical Trials Design Practice and Reporting provides a detailed overview of the methodology for conducting clinical trials including developing protocols data capture randomisation analysis and reporting Assuming no prior background this user friendly resource describes the statistical regulatory and practical components required for conducting randomised clinical trials Numerous examples and case studies from industry academia and the research literature help readers understand each stage of the clinical trial process This second edition contains extensively revised material throughout including new chapters covering designs for repeated measures non inferiority cluster and stepped wedge trials Other new chapters describe data and safety monitoring biomarker studies and feasibility studies Updated and expanded sections discuss situations where multiple organs different body locations or competing risks are involved subgroup analysis and multiple outcomes Written by an author team with extensive experience in conducting clinical trials this book Provides comprehensive coverage of randomised clinical trials ranging from basic to advanced Features several new chapters updated case studies and examples and references to changes in regulations Explains basic randomised trials including the parallel two group controlled trial with a single outcome measure Covers paired trial designs and trials with more than two interventions Includes a chapter on miscellaneous topics such as adaptive designs large simple trials Bayesian methods for very small trials alpha spending functions and the predictive probability test Randomised Clinical Trials is essential reading for clinicians nurses data managers and medical statisticians involved in clinical trials and for health practitioners responsible for direct patient care in a clinical trial setting **Randomized Controlled Trials in Evidence-Based Dentistry** Richie Kohli, Harjit S. Sehgal, Peter Milgrom, 2024-04-16 This book reviews

the role of randomized controlled trials RCTs in clinical dentistry explains how to successfully conduct RCTs related to dentistry and provides detailed information on the use of RCTs within each of the dental specialties Although RCTs represent the gold standard in evidence based dentistry for evaluation of the effects of an intervention a textbook on the subject has to date been lacking Randomized Controlled Trials in Evidence Based Dentistry will fill this educational gap and improve the confidence of dental providers researchers and their multidisciplinary teams in conducting high quality RCTs in a variety of settings and different parts of the world In particular it will enable readers to implement a suitable step by step approach to RCTs identify possible solutions to common challenges when performing RCTs in individual dental specialties and apply these solutions to their own RCT projects

Clinical Trials Curtis L. Meinert, Susan Tonascia, 1986 The definitive reference work on clinical trials this book presents a wealth of detailed practical information on the design conduct and analysis of both single center and multicenter trials No other book on clinical trials offers as much detail as Meinert does on such issues as sample size calculation stratification and randomization data systems design consent form development publication policies preparation of funding requests and reporting procedures

Taming Randomized Controlled Trials in Education Keith Morrison, 2020-07-07 There is a recent surge in the use of randomized controlled trials RCTs within education globally with disproportionate claims being made about what they show what works and what constitutes the best evidence Drawing on up to date scholarship from across the world Taming Randomized Controlled Trials in Education critically addresses the increased use of RCTs in education exploring their benefits limits and cautions and ultimately questioning the prominence given to them While acknowledging that randomized controlled trials do have some place in education the book nevertheless argues that this place should be limited Drawing together all arguments for and against RCTs in a comprehensive and easily accessible single volume the book also adds new perspectives and insights to the conversation crucially the book considers the limits of their usefulness and applicability in education raising a range of largely unexplored concerns about their use Chapters include discussions on The impact of complexity theory and chaos theory Design issues and sampling in randomized controlled trials Learning from clinical trials Data analysis in randomized controlled trials Reporting evaluating and generalizing from randomized controlled trials Considering key issues in understanding and interrogating research evidence this book is ideal reading for all students on Research Methods modules as well as those interested in undertaking and reviewing research in the field of education

Introduction to Randomized Controlled Clinical Trials, Second Edition John N.S. Matthews, 2006-06-26 Evidence from randomized controlled clinical trials is widely accepted as the only sound basis for assessing the efficacy of new medical treatments Statistical methods play a key role in all stages of these trials including their justification design and analysis This second edition of Introduction to Randomized Controlled Clinical Trials provides a concise presentation of the principles applied in this area It details the concepts behind randomization and methods for designing and analyzing trials and also includes information on meta analysis and specialized designs such as cross over

trials cluster randomized designs and equivalence studies This latest edition features new and revised references examples exercises and a new chapter dedicated to binary outcomes and survival analysis It also presents numerous examples taken from the medical literature contains exercises at the end of each chapter and offers solutions in an appendix The author uses Minitab and R software throughout the text for implementing the methods that are presented Comprehensive and accessible Introduction to Randomized Controlled Clinical Trials is well suited for those familiar with elementary statistical ideas and methods who want to further their knowledge of the subject

Essential Concepts in Clinical Research Kenneth Schulz, David A. Grimes, 2018-07-19 This practical guide speaks to two audiences those who read and those who conduct research Clinicians are medical detectives by training For each patient they assemble clinical clues to establish causes of signs and symptoms The task involves both clinical acumen and knowledge of medical research This book helps guide clinicians through this detective work by enabling them to make sense of research and to review medical literature critically It will also be invaluable to researchers who conduct clinical research particularly randomized controlled trials Building on previously published peer reviewed articles from The Lancet this handbook is essential for busy clinicians and active researchers interested in research methods Written by leaders in the field of clinical research who have published extensively with authorship of hundreds of articles in medical journals The authorship includes one of the three authors of the CONSORT guidelines for the reporting of randomized controlled trials The book presents the essential concepts to a wide array of topics including randomized control trials descriptive studies cohort studies case control studies bias and screening tests The book utilises a readable and humorous prose style lightening what can be a difficult area for clinical readers Derived from decades of teaching clinical research in seminar settings the book will empower clinicians to make sense of and critically appraise current medical research and will enable researchers to enrich the quality of their work For this Second Edition the authors have revised and updated the original 16 chapters and added six new chapters For busy clinicians and active researchers interested in research methods this book provides helpful tools to derive satisfaction indeed fun from clinical science

Pragmatic Randomized Clinical Trials Cynthia J. Girman, Mary E. Ritchey, 2021-04-08 Pragmatic Randomized Clinical Trials Using Primary Data Collection and Electronic Health Records addresses the practical aspects and challenges of the design implementation and dissemination of pragmatic randomized trials also sometimes referred to as practical or hybrid randomized trials While less restrictive and more generalizable than traditional randomized controlled trials such trials have specific challenges which are addressed in this book The book contains chapters encompassing common designs along with advantages and limitations of such designs analytic aspects in planning trials and estimating sample size and how to use patient partners to help design and operationalize pragmatic randomized trials Pragmatic trials conducted using primary data collection and trials embedded in electronic health records including electronic medical records and administrative insurance claims are addressed This comprehensive resource is valuable not only for

pharmacoepidemiologists biostatisticians and clinical researchers but also across the biomedical field for those who are interested in applying pragmatic randomized clinical trials in their research Addresses typical designs and challenges of pragmatic randomized clinical trials pRCTs Encompasses analytic aspects of such trials Discusses real cases on operational challenges in launching and conducting pRCTs in electronic health records A Medical Educator's Guide to Thinking Critically about Randomised Controlled Trials: Deconstructing the "Gold Standard" Margaret MacDougall,2024-05-30 Drawing on the statistical and philosophical expertise of its authors this book is designed to improve understanding and use of randomised controlled trials RCTs among health professionals It is intended for use primarily by medical educators involved in teaching statistics and evidence based medicine EBM to medical students junior doctors and other health professionals However each of the chapters serves a wider range of interests including the practical needs of physicians in interpreting research evidence to support clinical decision making and the teaching needs of philosophers of medicine who want to more fully appreciate how RCTs work in practice and provide engaging examples for their students Rather than compete with the proliferating methodological literature on RCT designs this book focuses on cultivating a healthy skepticism among developing health professionals to support critical appraisal of their own and published work on RCTs at a fundamental level including through a more informed understanding of the place of subgroup analyses in sound statistical inference Management of the positive predictive value in the statistical analysis of RCT findings is included as an important topic for contemporary medical curricula In comparing RCTs with non randomised studies a search for empirical evidence for the superiority of RCTs is initiated pointing to the need for further work to confirm what form this evidence should take Medical educators will find a wealth of reasons to encourage their students to think more critically about how the RCT operates in practice as a gold standard **Journal of the Royal Army Medical Corps** ,1999 Immunotherapies Against Infectious Diseases Saba Tufail, Mohammad Asif Sherwani ,Najmul Islam,2024-11-08 Infectious diseases have jeopardized human health significantly as evidenced by the ongoing Covid 19 pandemic In recent years the world has witnessed outbreaks of many emerging and re emerging infections such as SARS most recent by SARS CoV 2 Ebola Zika MERS dengue which in addition to taking millions of lives have posed major health issues in recovered individuals Moreover several infectious agents like hepatitis B and C viruses human papillomavirus human immunodeficiency virus type 1 Epstein Barr virus human T cell leukemia lymphoma virus type 1 Kaposi sarcoma associated herpesvirus Helicobacter pylori and Streptococcus bovis have been found to cause different types of cancers since the action mechanism of these agents sometimes transforms an infected cell into a cancer cell As these infections are difficult to treat with available drugs owing to their lower efficacy toxicity and emergence of drug resistance immunotherapy is viewed as a viable option Immunotherapy is manipulating body s defense mechanism to treat manage disease Threats of emerging and reemerging infectious diseases in addition to dangers of developing cancer due to cancer causing infectious agents combined with lack of effective treatment

modalities has shifted focus of scientific community to immunotherapy Advancements in immunotherapies comprising vaccines monoclonal antibodies cytokines T cells and checkpoint inhibitors have shown immense promise in combating not only cancer but infectious diseases as well Through this Research Topic we aim to discuss recent advances in immunotherapy based treatment management of infectious diseases We aim to include studies that evaluate how different forms of immunotherapies including vaccines have been can be exploited for preventing treating managing infectious diseases We welcome Original Research Articles Reviews and Mini reviews discussing the following main themes Vaccines against emerging re emerging diseases Vaccine design components technologies such as adjuvants delivery systems administration route dosage Targeted therapy Cancer immunotherapy using but not limited to monoclonal antibodies cytokines T cells and checkpoint inhibitors Monoclonal antibodies including nanobodies against SARS COV 2 for the treatment and prevention of COVID 19 Immunotherapies for infectious diseases using but not limited to monoclonal antibodies cytokines T cells and checkpoint inhibitors Authors are encouraged to submit manuscripts elaborating the use of delivery systems nanoparticles nanomaterials for the aforementioned theme themes Clinical Trials, Practice and Design in Gastrointestinal Cancers

Alberto Puccini,Edouard Auclin,Jorg Kleeff,2023-11-07

Systematic Reviews in Health Care Matthias Egger,George

Davey-Smith,Douglas Altman,2008-04-15 The second edition of this best selling book has been thoroughly revised and expanded to reflect the significant changes and advances made in systematic reviewing New features include discussion on the rationale meta analyses of prognostic and diagnostic studies and software and the use of systematic reviews in practice

Translational Surgery Adam E.M. Eltorai,2023-03-22 Translational Surgery covers the principles of evidence based medicine and applies these principles to the design of translational investigations The reader will come to fully understand important concepts including case control studies prospective cohort studies randomized trials and reliability studies Investigators will benefit from greater confidence in their ability to initiate and execute their own investigations avoid common pitfalls in surgical research and know what is needed for collaboration Further this title is an indispensable tool in grant writing and funding efforts The practical straightforward approach helps the translational research navigate challenging considerations in study design and implementation The book provides valuable discussions of the critical appraisal of published studies in surgery allowing the reader to learn how to evaluate the quality of such studies Thus they will improve at measuring outcomes making effective use of all types of evidence in patient care In short this practical guidebook will be of interest to every surgeon or surgical researcher who has ever had a good clinical idea but not the knowledge of how to test it Focuses on translational research in Surgery covering the principles of evidence based medicine and applying those principles to the design of translational investigations Provides a practical straightforward approach to help surgeons and researchers navigate challenging aspects of study design and implementation Details valuable discussions on the critical appraisal of published studies in Surgery allowing the reader to effectively use all types of evidence for patient

care **Evidence-based Practice in Nursing & Healthcare** Bernadette Mazurek Melnyk, Ellen Fineout-Overholt, 2011
 Bernadette Mazurek Melnyk and Ellen Fineout Overholt are creators of the ARCC Advancing Research and Clinical practice through close Collaboration Model an innovative strategy for implementing and sustaining evidence based practice in healthcare systems The ARCC Model is cited as an exemplar of education in evidence based practice in the Board on Health Care Services and the Institute of Medicine's book Health Professions Education A Bridge to Quality Melnyk and Fineout Overholt's book should be required reading in all graduate programs Their text has provided a blueprint for the future of nursing practice and a rigorously substantiated and clearly described means for clinicians educators and administrators to participate in improving quality of care Janet D Allan PhD RN FAAN Dean and Professor University of Maryland School of Nursing Evidence based Practice in Nursing Healthcare A Guide to Best Practice has been instrumental in developing a culture of evidence based practice at Barnes Jewish Hospital It is fundamental to our curriculum provided to all levels of staff from new graduate nurses to the highest levels of hospital leadership Dr Patricia Potter RN PhD FAAN Dr Gail Rea RN PhD CNE Dr Karen Balakas RN PhD CNE Jennifer Williams MSN RN ACNS BC Elizabeth Pratt MSN RN ACNS BC Evidence Equals Excellence group at Barnes Jewish Hospital and Barnes Jewish School of Nursing at Goldfarb Evidence based Practice in Nursing Healthcare A Guide to Best Practice is an exemplary text that spans the continuum of nursing evidence to support best practice Utilizing this text with undergraduate RN to BSN and graduate nursing students it is the ONLY text that demonstrates how to retrieve read and analyze evidence whether it is published as an individual study systematic review meta analysis best practice guideline or outcomes management report Students learn how to utilize multiple complex databases and websites as they move through each chapter And they experience dissemination of evidence through the development of presentations publications posters and grants This is truly a remarkable book that embraces evidence as the basis for nursing practice and patient centered care and safety Having used this text with more than 1000 students over the past five years I can honestly say that I have found no other text that facilitates learning and development of clinical judgment that is grounded in valid reliable and applicable evidence This is a keeper Alice E Dupler JD APRN BC Clinical Associate Professor Washington State University College of Nursing I have used the book since I developed the Evidence based Practice course for our College of Nursing in Fall 2007 It was the first course of its kind at Indiana State University It has been well received and the preferred course for all nursing graduate students for completion of their final scholarly projects The text was essential in developing the course and provides the foundation and guidance that the students need to develop their Evidence Based Practice projects the students love the text Susan Eley PhD RN FNP BC Assistant Professor Director FNP Program Indiana State University **Handbook of Statistical Methods for Randomized Controlled Trials** KyungMann Kim, Frank Bretz, Ying Kuen K. Cheung, Lisa V. Hampson, 2021-08-23 Statistical concepts provide scientific framework in experimental studies including randomized controlled trials In order to design monitor analyze and draw

conclusions scientifically from such clinical trials clinical investigators and statisticians should have a firm grasp of the requisite statistical concepts The Handbook of Statistical Methods for Randomized Controlled Trials presents these statistical concepts in a logical sequence from beginning to end and can be used as a textbook in a course or as a reference on statistical methods for randomized controlled trials Part I provides a brief historical background on modern randomized controlled trials and introduces statistical concepts central to planning monitoring and analysis of randomized controlled trials Part II describes statistical methods for analysis of different types of outcomes and the associated statistical distributions used in testing the statistical hypotheses regarding the clinical questions Part III describes some of the most used experimental designs for randomized controlled trials including the sample size estimation necessary in planning Part IV describe statistical methods used in interim analysis for monitoring of efficacy and safety data Part V describe important issues in statistical analyses such as multiple testing subgroup analysis competing risks and joint models for longitudinal markers and clinical outcomes Part VI addresses selected miscellaneous topics in design and analysis including multiple assignment randomization trials analysis of safety outcomes non inferiority trials incorporating historical data and validation of surrogate outcomes

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