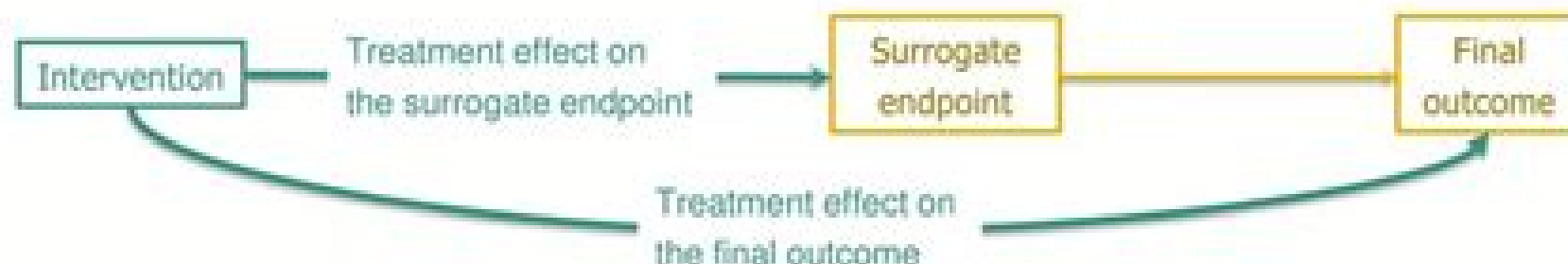


Evaluation of surrogate endpoints



Definition (Biomarker Definition Working Group, 2001)

- To **replace** the final outcome
 - At the patient level: the surrogate correlates and predicts the final outcome
 - At the trial level: the treatment effect on the surrogate correlates and predicts the treatment effect on the final outcome
- Specific to the therapeutic situation: disease, type of treatment, population,...
- Meta-analysis of RCTs using individual-patient data

Evaluation Of Surrogate Endpoints

**Institute of Medicine, Food and
Nutrition Board, Board on Health
Sciences Policy, Board on Health Care
Services, Committee on Qualification of
Biomarkers and Surrogate Endpoints
in Chronic Disease**

Evaluation Of Surrogate Endpoints:

The Evaluation of Surrogate Endpoints Tomasz Burzykowski, Geert Molenberghs, Marc Buyse, 2005-11-24 Both humanitarian and commercial considerations have spurred intensive search for methods to reduce the time and cost required to develop new therapies. The identification and use of surrogate endpoints, i.e. measures that can replace or supplement other endpoints in evaluations of experimental treatments or other interventions, is a general strategy that has stimulated both enthusiasm and skepticism. Surrogate endpoints are useful when they can be measured earlier, more conveniently or more frequently than the true endpoints of primary interest. Regulatory agencies around the globe, particularly in the United States, Europe and Japan, are introducing provisions and policies relating to the use of surrogate endpoints in registration studies. But how can one establish the adequacy of a surrogate? What kind of evidence is needed and what statistical methods portray that evidence most appropriately? This book offers a balanced account on this controversial topic. The text presents major developments of the last couple of decades together with a unified meta-analytic framework within which surrogates can be evaluated from several angles. Methodological development is coupled with perspectives on various therapeutic areas. Academic views are juxtaposed with standpoints of scientists working in the biopharmaceutical industry as well as of colleagues from the regulatory authorities. Tomasz Burzykowski is Assistant Professor of Biostatistics at the Limburgs Universitair Centrum in Belgium. Dr Burzykowski has published methodological work on the analysis of survey data, meta-analyses of clinical trials and validation of surrogate endpoints. He is a co-author of numerous papers applying statistical methods to clinical data in different disease areas: cancer, cardiovascular diseases, dermatology, orthodontics. Geert Molenberghs is Professor of Biostatistics at the Limburgs Universitair Centrum in Belgium. Dr Molenberghs published methodological work on surrogate markers in clinical trials, categorical data, longitudinal data analysis and on the analysis of non-response in clinical and epidemiological studies. He serves as Joint Editor for *Applied Statistics* (2001-2004) and is President of the International Biometric Society (2004-2005). He was elected Fellow of the American Statistical Association and received the Guy Medal in Bronze from the Royal Statistical Society. Marc Buyse founded the International Drug Development Institute in 1991. He is Past President of the International Society for Clinical Biostatistics, Past President of the Quetelet Society and Past Board Member of the Society for Clinical Trials. He is currently the Executive Director of IDDI, International Drug Development Institute, and Associate Professor of biostatistics at the Limburgs Universitair Centrum, Center for Statistics, Diepenbeek, Belgium. He has published extensively in the fields of biostatistics and oncology. His research interests include meta-analysis, surrogate endpoints, statistical detection of fraud and the design and statistical analysis of clinical trials. From the reviews: A strength of this book is its comprehensive and up-to-date presentation of issues pertinent to the evaluation of surrogate endpoints. This book makes an important contribution to the clinical trials literature. *Journal of Biopharmaceutical Statistics* (2006). Many of the chapters deal with real-life data examples and studies involving surrogate

outcomes many written by authors who were directly involved in these studies The editors have written nice background sections until a more concise manuscript on this topic is written this book will remain the most important resource for biostatisticians and researchers in this area Debajyoti Sinha for the Journal of the American Statistical Association December 2006 This book is a reflection of the ongoing debate on the definition and use of surrogate markers I see the book as an invitation to join the debate There is much work to be done and reading the book might inspire many to participate It will be useful for researchers in this and related fields such as joint modeling of longitudinal and survival data and multivariate meta analysis The book is well organized is a pleasure to read and is very well documented with up to date references Hans C Van Houwelingen for Biometrics September 2006 Perspectives on Biomarker and Surrogate Endpoint Evaluation Institute of Medicine, Food and Nutrition Board, Board on Health Sciences Policy, Board on Health Care Services, Committee on Qualification of Biomarkers and Surrogate Endpoints in Chronic Disease, 2011-01-12 In 2010 the Institute of Medicine IOM recommended a framework for the evaluation of biomarkers in the chronic disease setting Published in the book Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease the framework is intended to bring consistency and transparency to the previously disparate process of biomarker evaluation Following the book's release the IOM convened a 2 day discussion forum in Washington DC in order to provide an opportunity for stakeholders to learn about react to and discuss the book Presentations reviewed the authoring committee's work process recommendations and provided perspectives on the book from the point of view of participants Thomas Fleming professor of biostatistics and statistics at the University of Washington gave a keynote presentation on the critical issues in the validation of surrogate endpoints a specific use of a biomarker The present volume recounts the discussion forum proceedings focusing in turn on each represented sector A summary of Dr Fleming's presentation then sets the committee's recommendations within the context of biomarker utilization Lastly this summary examines the main themes raised by stakeholders and the challenges and opportunities presented to stakeholders by the book's recommendations Applied Surrogate Endpoint Evaluation Methods with SAS and R Ariel Alonso, Theophile Bigirimurame, Tomasz Burzykowski, Marc Buyse, Geert Molenberghs, Leacky Muchene, Nolen Joy Perualila, Ziv Shkedy, Wim Van der Elst, 2016-11-30 An important factor that affects the duration complexity and cost of a clinical trial is the endpoint used to study the treatment's efficacy When a true endpoint is difficult to use because of such factors as long follow up times or prohibitive cost it is sometimes possible to use a surrogate endpoint that can be measured in a more convenient or cost effective way This book focuses on the use of surrogate endpoint evaluation methods in practice using SAS and R

Services,Committee on Qualification of Biomarkers and Surrogate Endpoints in Chronic Disease,2010-06-25 Many people naturally assume that the claims made for foods and nutritional supplements have the same degree of scientific grounding as those for medication but that is not always the case The IOM recommends that the FDA adopt a consistent scientific framework for biomarker evaluation in order to achieve a rigorous and transparent process **Evaluation of Potential Surrogate Endpoints** Erin E. Gabriel,2012 Valid surrogate endpoints can make clinical trials more efficient allowing for more trials to be conducted and more rapid development of effective treatments Identifying useful surrogates is a statistically challenging but extremely valuable endeavor This work develops statistical methods for the evaluation and comparison of biomarkers as correlates of protection CoP Methods herein were developed with a focus on a time to event clinical endpoint and possible time varying effects of treatment an important and thus far neglected topic is CoP evaluation We propose a novel Weibull model and three methods of estimation for use in CoP evaluation simulations and real data examples demonstrate the characteristics of these methods *Evaluation of Surrogate Endpoints Under Semi-Competing Risks* ,2020

Pediatric Drug Development Andrew E. Mulberg,Steven A. Silber,John N. van den Anker,2011-09-20 Pediatric Drug Development Concepts and Applications is designed as a reference and textbook and is meant to address the science of differences between the pediatric and adult subject in the development of pharmaceutical products Considered are the ethics and medical needs of proper understanding the pediatric and adult differences the business case for proper development of drugs for children as well as the technical feasibility studies and processes that are necessary for a proper pediatric drug development program The applications of these approaches will benefit all stakeholders and ultimately not only educate but also provide better and safer drugs for pediatric patients Biostatistics in Biopharmaceutical Research and Development Ding-Geng Chen,2024-12-24 The Deming Conference on Applied Statistics has long been deemed an influential event in the biostatistics and biopharmaceutical profession It provides learning experience on recent developments in statistical methodologies in biopharmaceutical applications and FDA regulations This book honors 80 years of contributions and dedication of the Deming Conference in biostatistics and biopharmaceutical clinical trial methodology and applications All chapters are contributed by world class and prominent Deming speakers who ve contributed their cutting edge research and developments to the community Volume 2 covers Biomarkers in Drug Development Time To Event Data Analysis and Methods and emerging development in biopharmaceutical biostatistics This book aims to booster research education and training in biostatistics and in biopharmaceutical research and development **Cancer** Vincent T. DeVita,Theodore S. Lawrence,Steven A. Rosenberg,2010 Introducing the first volume of a new series Cancer Principles Practice of Oncology Annual Advances in Oncology This series of annual volumes will focus on the most significant changes in oncologic research and practice that have taken place during the preceding year Each volume identifies scientific and clinical areas in oncology that are rapidly changing and show a high potential for affecting the management of cancer patients in the future These

areas may reflect current controversies in oncology and every effort is made to provide clear direction for the practicing oncologist

Biomarker Analysis in Clinical Trials with R Nusrat Rabbee, 2020-03-11 The world is awash in data This volume of data will continue to increase In the pharmaceutical industry much of this data explosion has happened around biomarker data Great statisticians are needed to derive understanding from these data This book will guide you as you begin the journey into communicating understanding and synthesizing biomarker data From the Foreword Jared Christensen Vice President Biostatistics Early Clinical Development Pfizer Inc Biomarker Analysis in Clinical Trials with R offers practical guidance to statisticians in the pharmaceutical industry on how to incorporate biomarker data analysis in clinical trial studies The book discusses the appropriate statistical methods for evaluating pharmacodynamic predictive and surrogate biomarkers for delivering increased value in the drug development process The topic of combining multiple biomarkers to predict drug response using machine learning is covered Featuring copious reproducible code and examples in R the book helps students researchers and biostatisticians get started in tackling the hard problems of designing and analyzing trials with biomarkers Features Analysis of pharmacodynamic biomarkers for lending evidence target modulation Design and analysis of trials with a predictive biomarker Framework for analyzing surrogate biomarkers Methods for combining multiple biomarkers to predict treatment response Offers a biomarker statistical analysis plan R code data and models are given for each part including regression models for survival and longitudinal data as well as statistical learning models such as graphical models and penalized regression models

Frontiers of Biostatistical Methods and Applications in Clinical Oncology Shigeyuki Matsui, John Crowley, 2017-10-03 This book presents the state of the art of biostatistical methods and their applications in clinical oncology Many methodologies established today in biostatistics have been brought about through its applications to the design and analysis of oncology clinical studies This field of oncology now in the midst of evolution owing to rapid advances in biotechnologies and cancer genomics is becoming one of the most promising disease fields in the shift toward personalized medicine Modern developments of diagnosis and therapeutics of cancer have also been continuously fueled by recent progress in establishing the infrastructure for conducting more complex large scale clinical trials and observational studies The field of cancer clinical studies therefore will continue to provide many new statistical challenges that warrant further progress in the methodology and practice of biostatistics This book provides a systematic coverage of various stages of cancer clinical studies Topics from modern cancer clinical trials include phase I clinical trials for combination therapies exploratory phase II trials with multiple endpoints treatments and confirmative biomarker based phase III trials with interim monitoring and adaptation It also covers important areas of cancer screening prognostic analysis and the analysis of large scale molecular data in the era of big data

Textbook of Clinical Trials in Oncology Susan Halabi, Stefan Michiels, 2019-04-24 There is an increasing need for educational resources for statisticians and investigators Reflecting this the goal of this book is to provide readers with a sound foundation in the statistical design conduct and analysis of clinical

trials Furthermore it is intended as a guide for statisticians and investigators with minimal clinical trial experience who are interested in pursuing a career in this area The advancement in genetic and molecular technologies have revolutionized drug development In recent years clinical trials have become increasingly sophisticated as they incorporate genomic studies and efficient designs such as basket and umbrella trials have permeated the field This book offers the requisite background and expert guidance for the innovative statistical design and analysis of clinical trials in oncology Key Features Cutting edge topics with appropriate technical background Built around case studies which give the work a hands on approach Real examples of flaws in previously reported clinical trials and how to avoid them Access to statistical code on the book s website Chapters written by internationally recognized statisticians from academia and pharmaceutical companies Carefully edited to ensure consistency in style level and approach Topics covered include innovating phase I and II designs trials in immune oncology and rare diseases among many others

Plotkin's Vaccines,E-Book Walter A. Orenstein,Paul A. Offit,Kathryn M. Edwards,Stanley A. Plotkin,2022-12-21 From the latest vaccination evidence recommendations and protocols to new vaccine development and the use of vaccines in reducing disease Plotkin s Vaccines 8th Edition covers every aspect of vaccination Now completely revised and updated from cover to cover this award winning text continues to provide reliable information from global authorities offering a complete understanding of each disease as well as the latest knowledge of both existing vaccines and those currently in research and development Described by Bill Gates as an indispensable guide to the enhancement of the well being of our world Plotkin s Vaccines is a must have reference for current authoritative information in this fast moving field Contains all new chapters on COVID 19 vaccine hesitancy and non specific effects of vaccines as well as significantly revised content on new vaccine technologies such as mRNA vaccines emerging vaccines and technologies to improve immunization Presents exciting new data on evolution of adjuvants across the centuries dengue vaccines human papillomavirus vaccines respiratory syncytial virus vaccines tuberculosis vaccines and zoster vaccines Provides up to date authoritative information on vaccine production available preparations efficacy and safety and recommendations for vaccine use with rationales and data on the impact of vaccination programs on morbidity and mortality Provides complete coverage of each disease including clinical characteristics microbiology pathogenesis diagnosis and treatment as well as epidemiology and public health and regulatory issues Keeps you up to date with information on each vaccine including its stability immunogenicity efficacy duration of immunity adverse events indications contraindications precautions administration with other vaccines and disease control strategies Covers vaccine preventable diseases vaccine science and licensed vaccine products as well as product technologies and global regulatory and public health issues Analyzes the cost benefit and cost effectiveness of different vaccine options Helps you clearly visualize concepts and objective data through an abundance of tables and figures Enhanced eBook version included with purchase Your enhanced eBook allows you to access all of the text figures and references from the book on a variety of devices

Encyclopaedic Companion to Medical Statistics Brian S.

Everitt, Christopher R. Palmer, 2011-06-20 Statistical methodology is of great importance to medical research and clinical practice The Encyclopaedic Companion to Medical Statistics contains readable accounts of the key topics central to current research and practice Each entry has been written by an individual chosen for both their expertise in the field and their ability to communicate statistical concepts successfully to medical researchers Real examples from the biomedical literature and relevant illustrations feature in many entries and extensive cross referencing signposts the reader to related entries Key Features Contains accounts of over 400 statistical topics central to current medical research 80% of first edition entries updated and revised Presents the latest techniques used at the cutting edge of medical research Covers common errors in statistical analyses in medicine Real examples from the biomedical literature and relevant illustrations feature throughout Contains contributions from over 70 experts in the field Medical researchers researchers and practitioners in medical research and statistics will benefit greatly from this book *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 **Oncology Clinical Trials** William Kevin Kelly, Susan Halabi, 2018-03-28 The second edition of Oncology Clinical Trials has been thoroughly revised and updated and now contains the latest designs and methods of conducting and analyzing cancer clinical trials in the era of precision medicine with biologic agents including trials investigating the safety and efficacy of targeted therapies immunotherapies and combination therapies as well as novel radiation therapy modalities Now divided into six sections this revamped book provides the necessary background and expert guidance from the principles governing oncology clinical trials to the innovative statistical design methods permeating the

field from conducting trials in a safe and effective manner analyzing and interpreting the data to a forward looking assessment and discussion of regulatory issues impacting domestic international and global clinical trials Considered by many as the gold standard reference on oncology clinical trials in the field the second edition continues to provide examples of real life flaws and real world examples for how to successfully design conduct and analyze quality clinical trials and interpret them With chapters written by oncologists researchers biostatisticians clinical research administrators and industry and FDA representatives this volume provides a comprehensive guide in the design conduct monitoring analysis and reporting of clinical trials in oncology NEW TO THIS EDITION Outlines how to design clinical trials with and without biomarker testing including genomics based basket trials and adaptive trials for all phases during treatment and quality of life trials Includes new chapters on immunotherapy trials radiation therapy trials multi arm trials meta analysis and adaptive design use of genomics dose modifications and use of ancillary treatments in investigational studies establishing surrogate endpoints practical issues with correlative studies cost effectiveness analysis and more Comprehensively covers all regulatory aspects in the pursuit of global oncology trials Digital access to the ebook included

The Textbook of Pharmaceutical Medicine John P. Griffin, John O'Grady, 2008-04-15 New edition of successful standard reference book for the pharmaceutical industry and pharmaceutical physicians The Textbook of Pharmaceutical Medicine is the coursebook for the Diploma in Pharmaceutical Medicine and is used as a standard reference throughout the pharmaceutical industry The new edition includes greater coverage of good clinical practice a completely revised statistics chapter and more on safety Covers the course information for the Diploma in Pharmaceutical Medicine Fully updated with new authors Greater coverage of good clinical practice and safety New chapters on regulation of medical devices in Europe and regulation of therapeutic products in Australia

Clinical Trial Biostatistics and Biopharmaceutical Applications Walter R. Young, Ding-Geng (Din) Chen, 2014-11-20 Since 1945 The Annual Deming Conference on Applied Statistics has been an important event in the statistics profession In Clinical Trial Biostatistics and Biopharmaceutical Applications prominent speakers from past Deming conferences present novel biostatistical methodologies in clinical trials as well as up to date biostatistical applications from the pharmaceutical industry Divided into five sections the book begins with emerging issues in clinical trial design and analysis including the roles of modeling and simulation the pros and cons of randomization procedures the design of Phase II dose ranging trials thorough QT QTc clinical trials and assay sensitivity and the constancy assumption in noninferiority trials The second section examines adaptive designs in drug development discusses the consequences of group sequential and adaptive designs and illustrates group sequential design in R The third section focuses on oncology clinical trials covering competing risks escalation with overdose control EWOC dose finding and interval censored time to event data In the fourth section the book describes multiple test problems with applications to adaptive designs graphical approaches to multiple testing the estimation of simultaneous confidence intervals for multiple comparisons and weighted parametric multiple

testing methods The final section discusses the statistical analysis of biomarkers from omics technologies biomarker strategies applicable to clinical development and the statistical evaluation of surrogate endpoints This book clarifies important issues when designing and analyzing clinical trials including several misunderstood and unresolved challenges It will help readers choose the right method for their biostatistical application Each chapter is self contained with references

Cancer Clinical Trials Stephen L. George,Xiaofei Wang,Herbert Pang,2016-08-19 *Cancer Clinical Trials* Current and Controversial Issues in Design and Analysis provides statisticians with an understanding of the critical challenges currently encountered in oncology trials Well known statisticians from academic institutions regulatory and government agencies such as the U S FDA and National Cancer Institute and the pharmaceutical industry share their extensive experiences in cancer clinical trials and present examples taken from actual trials The book covers topics that are often perplexing and sometimes controversial in cancer clinical trials Most of the issues addressed are also important for clinical trials in other settings After discussing general topics the book focuses on aspects of early and late phase clinical trials It also explores personalized medicine including biomarker based clinical trials adaptive clinical trial designs and dynamic treatment regimes

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