Phase I Cancer Clinical Trials A Practical Guide

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CRC Press
Now fully revised and in its fourth edition, the Oxford Handbook of Oncology has been the essential go-to guide for students and practitioners in oncology for over a decade. The scientific basis and diagnosis of cancers is covered, as well as drugs, biomarkers, and the presentation and psychosocial aspects of oncology. Concise, practical, and comprehensive, there is no better companion for both common conditions and challenging emergencies. The field of oncology has surged forward since the last edition was published and the Oxford Handbook of Oncology has been fully revised and updated to reflect these recent advances so you can be sure that the vital information you need is in your hands. This handbook incorporates changes such as the understanding of the science of cancer, novel therapies in breast, lung, renal, and melanoma, molecular sub-classification of common solid cancers, personalized therapy approaches, new agents in hard to treat cancers, the benefits of new technologies in radiotherapy, and the emerging data on the importance of the immune response. Written by

experts in the field to ensure that it is grounded in real life clinical practice, this handbook provides a concise guide to all aspects of oncology for all students, nurses, and junior faculty responsible for the care of cancer patients, while also providing further reading and highlighting areas of controversy for those who need a more detailed understanding.

Workshop Summary Demos Medical Publishing

Many new challenges have arisen in the area of oncology clinical trials. New cancer therapies are often based on cytostatic or targeted agents, which pose new challenges in the design and analysis of all phases of trials. The literature on adaptive trial designs and early stopping has been exploding. Inclusion of high-dimensional data and imaging techniques have become common practice, and statistical methods on how to analyse such data have been refined in this area. A compilation of statistical topics relevant to these new advances in cancer research, this third edition of Handbook of Statistics in Clinical Oncology focuses on the design and analysis of oncology clinical trials and translational research. Addressing the many challenges that have

arisen since the publication of its predecessor, this third edition covers the newest developments involved in the design and analysis of cancer clinical trials, incorporating updates to all four parts: Phase I trials: Updated recommendations regarding the standard $3 + 3$ and continual reassessment approaches, along with new chapters on phase 0 trials and phase I trial design for targeted agents. Phase II trials: Updates to current experience in single-arm and randomized phase II trial designs. New chapters include phase II designs with multiple strata and phase II/III designs. Phase III

trials: Many new chapters include interim analyses and early stopping considerations, phase III trial designs for targeted agents and for testing the ability of markers, adaptive trial designs, cure rate survival models, statistical methods of imaging, as well as a thorough review of software for the design and analysis of clinical trials. Exploratory and high-dimensional data analyses: All chapters in this part have been thoroughly updated since the last edition. New chapters address methods for analyzing SNP data and for developing a score based on gene expression data. In addition, chapters on risk calculators

and forensic bioinformatics have been added. Accessible to statisticians and oncologists interested in clinical trial methodology, the book is a single-source collection of up-to-date statistical approaches to research in clinical oncology.

Single-Arm Phase II Survival Trial Design
Springer
The goal of a phase I cancer clinical trial is to determine the maximum tolerated dose (MTD) or the recommended phase II dose (RP2D) of a new drug that corresponds to some given acceptable rate of dose limiting toxicity. However, a common limitation to the generalizability of phase I and phase II clinical trials is high patient heterogeneity with respect to toxicity and efficacy. A poor estimate of the MTD may put patients at unprecedented risks by assigning subtherapeutic or excessively toxic doses. Ignoring patient heterogeneity with respect to efficacy may cause phase II trials to have extremely large false positive and false negative error rates within subpopulations. In either case, the large scale phase III clinical trial conducted with an inappropriate dose may put patients in the study at high risk, and doom a potential effective and safe treatment after substantial investment in its development. It is believed that most cancer clinical trials involve a heterogeneous group of patients at the molecular level. This heterogeneity is one of the reasons that not all patients with cancer respond to a given drug. In view of this patient heterogeneity, it is clear that a "one size fits all" approach may not be suitable in the drug development process. Therefore, it is important

to be able to predict which patients are most likely to benefit from a new drug. This would not only save patients from unnecessary risk of toxicity but might facilitate their receiving beneficial treatment, and it would shorten the time required for drug development and lower associated costs. The goals of this research are two fold: (1) to investigate statistical issues involved in applying a genomic biomarker classification method to account for patient heterogeneity with respect to toxicity and efficacy response in early phase clinical trials, allowing for the possibility of differing treatment efficacy among subpopulations, and (2) developing a new design approach that incorporates high-dimensional genomic information into phase I/II clinical trials. We propose to achieve this goal by using a novel compound iterative phase I/II/I clinical trial design which may be conceptualized into three stages. The first stage consists of obtaining an overall estimate of the MTD based on an initial phase I trial under the assumption of no patient heterogeneity. A phase II study is then conducted using the preliminary estimate of the MTD to estimate efficacy. The second stage focuses on the application of the predictive classifiers in early phases of clinical trials. Supervised learning algorithms (i.e., support vector machines (SVM)) are effective classification tools in high-dimensional microarray classification problems such as the development of genomic biomarkers from microarray data. We implemented the SVM binary classification algorithm using the approach of Xu (2008) for the development of predictive classifiers based on phase II trial efficacy data by comparing the gene-expression

profiles of responders versus non-responders. Identification of patient subpopulations that might be expected to have distinct toxicity/efficacy profiles may thus be based on genomic biomarkers. The third stage of our proposed design incorporates the predictive classifier described above to estimate and refine the MTD through two key steps: (1) obtain an estimated MTD for each biomarker group by combining toxicity data from the first two stages and applying an estimation algorithm and (2) refine the MTD estimate by conducting a secondary phase I trial for each biomarker group. The secondary phase I trials account for patient heterogeneity by basing dose finding on toxicity while also accounting for each patient's genomic biomarker status. This provides a mechanism for incorporating genomic information that permits estimation of separate MTDs for the two subpopulations identified by the biomarker. We compared various MTD estimation methods, and based on the results of simulation studies recommended the use of the constrained logistic regression model to estimate biomarker group-specific MTDs prior to the secondary phase I studies. We investigated the impact of two adaptive design strategies in the secondary phase I trials across a range of dose-toxicity and dose-efficacy profiles. Our results showed that by applying predictive classifiers to determine a MTD estimate for each subpopulation we can obtain an acceptably large value of probability of efficacy (i.e., improved response rates) while also controlling the probability of toxicity (i.e., increased safety) for each subpopulation. We concluded that the MTD estimates obtained from our proposed design are more accurate

than would be expected from a single phase I trial. The results of this research provide important guidelines with respect to (1) incorporating genomic biomarker information from microarray data into early phase clinical trials to identify subpopulations and (2) use of predictive classifiers to obtain refined and improved estimates of MTDs for subpopulations.

Bayesian Designs for Phase I-II Clinical Trials
Phase I Cancer Clinical TrialsA Practical Guide This BASS book Series publishes selected high-quality papers reflecting recent advances in the design and biostatistical analysis of biopharmaceutical experiments – particularly biopharmaceutical clinical trials. The papers were selected from invited presentations at the Biopharmaceutical Applied Statistics Symposium (BASS), which was founded by the first Editor in 1994 and has since become the premier international conference in biopharmaceutical statistics. The primary aims of the BASS are: 1) to raise funding to support graduate students in biostatistics programs, and 2) to provide an opportunity for professionals engaged in pharmaceutical drug research and development to share insights into solving the problems they encounter.The BASS book series is initially divided into three volumes addressing: 1) Design of Clinical Trials; 2) Biostatistical Analysis of Clinical Trials; and 3) Pharmaceutical Applications. This book is the first of the 3-volume book series. The topics covered include: A Statistical Approach to Clinical Trial Simulations, Comparison of Statistical Analysis Methods Using Modeling and Simulation for Optimal Protocol Design, Adaptive Trial Design in Clinical Research, Best Practices and

Recommendations for Trial Simulations in the Context of Designing Adaptive Clinical Trials, Designing and Analyzing Recurrent Event Data Trials, Bayesian Methodologies for Response-Adaptive Allocation, Addressing High Placebo Response in Neuroscience Clinical Trials, Phase I Cancer Clinical Trial Design: Single and Combination Agents, Sample Size and Power for the Mixed Linear Model, Crossover Designs in Clinical Trials, Data Monitoring: Structure for Clinical Trials and Sequential Monitoring Procedures, Design and Data Analysis for Multiregional Clinical Trials – Theory and Practice, Adaptive Group-Sequential Multi-regional Outcome Studies in Vaccines, Development and Validation of Patient-reported Outcomes, Interim Analysis of Survival Trials: Group Sequential Analyses, and Conditional Power – A Non-proportional Hazards Perspective.

Cancer Incidence and Survival Among Children and Adolescents CRC Press Now fully updated, the Oxford Handbook of Clinical Pharmacy remains the indispensible guide to clinical pharmacy, providing all the information needed for practising and student pharmacists. Presenting handy practical guidance in a quick-reference, bullet-point format, this handbook will supply the knowledge and confidence needed to provide a clinical pharmacy service. Complementing the current British National Formulary guidelines, the handbook givesprescribing points and linked concepts of relevance to clinical pharmacists. The contents are evidence-based and contain a wealth of

information from the authors' many years of clinical pharmacy experience. This handbook is the definitive quick-reference guide for all practising and studentpharmacists.

Harnessing Science Rutgers University Press Clinical trials are the engine of progress in the development of new drugs and devices for the detection, monitoring, prevention and treatment of cancer. A well conceived, carefully designed and efficiently conducted clinical trial can produce results that change clinical practice overnight, deliver new oncology drugs and diagnostics to the marketplace, and expand the horizon of contemporary thinking about cancer biology. A poorly done trial does little to advance the field or guide clinical practice, consumes precious clinical and financial resources and challenges the validity of the ethical contract between investigators and the volunteers who willingly give their time and effort to benefit future patients. With chapters written by oncologists, researchers, biostatisticians, clinical research administrators, and industry and FDA representatives, Oncology Clinical Trials, provides a comprehensive guide for both early-career and senior oncology investigators into the successful design, conduct and analysis of an oncology clinical trial. Oncology Clinical Trials covers how to formulate a study question, selecting a study population, study design of Phase I, II, and III trials, toxicity monitoring, data analysis and reporting, use of genomics, cost-effectiveness analysis, systemic review and meta-analysis, and many other issues. Many examples of real-life flaws in clinical trials that have been reported in the literature are included throughout. The book discusses clinical trials from start to finish focusing on real-life examples in the development, design and analysis of clinical trials. Oncology Clinical Trials features: A systematic guide to all aspects of the design, conduct, analysis, and reporting of

clinical trials in oncology Contributions from oncologists, researchers, biostatisticians, clinical research administrators, and industry and FDA representatives Hot topics in oncology trials including multi-arm trials, meta-analysis and adaptive design, use of genomics, and cost-effectiveness analysis Real-life examples from reported clinical trials included throughout

Fast Facts: Clinical Trials in Oncology
CRC Press

Praise for the First Edition "All medical statisticians involved in clinical trials should read this book..." - Controlled Clinical Trials Featuring a unique combination of the applied aspects of randomization in clinical trials with a nonparametric approach to inference, Randomization in Clinical Trials: Theory and Practice, Second Edition is the go-to guide for biostatisticians and pharmaceutical industry statisticians. Randomization in Clinical Trials: Theory and Practice, Second Edition features: Discussions on current philosophies, controversies, and new developments in the increasingly important role of randomization techniques in clinical trials A new chapter on covariate-adaptive randomization, including minimization techniques and inference New developments in restricted randomization and an increased focus on computation of randomization tests as opposed to the asymptotic theory of randomization tests Plenty of problem sets, theoretical exercises, and short computer simulations using SAS® to facilitate classroom teaching, simplify the mathematics, and ease readers'

understanding Randomization in Clinical Trials: Theory and Practice, Second Edition is an excellent reference for researchers as well as applied statisticians and biostatisticians. The Second Edition is also an ideal textbook for upper-undergraduate and graduate-level courses in biostatistics and applied statistics. William F. Rosenberger, PhD, is University Professor and Chairman of the Department of Statistics at George Mason University. He is a Fellow of the American Statistical Association and the Institute of Mathematical Statistics, and author of over 80 refereed journal articles, as well as The Theory of Response-Adaptive Randomization in Clinical Trials, also published by Wiley. John M. Lachin, ScD, is Research Professor in the Department of Epidemiology and Biostatistics as well as in the Department of Statistics at The George Washington University. A Fellow of the American Statistical Association and the Society for Clinical Trials, Dr. Lachin is actively involved in coordinating center activities for clinical trials of diabetes. He is the author of Biostatistical Methods: The Assessment of Relative Risks, Second Edition, also published by Wiley.

Oncology Clinical Trials John Wiley & Sons A collection of poems to reach hurting hearts and minds."I have digested the bitternessFrom every "I love you"You never meant So I can watch the honey drip from my wounds"

Randomized Phase II Cancer Clinical Trials National Academies Press Phase I trials are a critical first step in the study of

novel cancer therapeutic approaches. Their primary goals are to identify the recommended dose, schedule and pharmacologic behavior of new agents or new combinations of agents and to describe the adverse effects of treatment. In cancer therapeutics, such studies have particular challenges. Due to the nature of the effects of treatment, most such studies are conducted in patients with advanced malignancy, rather than in healthy volunteers. Further, the endpoints of these trials are usually measures adverse effects rather than molecular target or anti-tumor effects. These factors render the design, conduct, analysis and ethical aspects of phase I cancer trials unique. As the only comprehensive book on this topic, Phase I Cancer Clinical Trials is a useful resource for oncology trainees or specialists interested in understanding cancer drug development. New to this edition are chapters on Phase 0 Trials and Immunotherapeutics, and updated information on the process, pitfalls, and logistics of Phase I Trials

Biopharmaceutical Applied Statistics Symposium Springer Nature Reliably optimizing a new treatment in humans is a critical first step in clinical evaluation since choosing a suboptimal dose or schedule may lead to failure in later trials. At the same time, if promising preclinical results do not translate into a real treatment advance, it is important to determine this quickly and terminate the clinical evaluation process to avoid wasting resources. Bayesian Designs for Phase I– II Clinical Trials describes how phase I– II designs can serve as a bridge or protective barrier between preclinical studies and large confirmatory clinical trials. It illustrates many of the severe drawbacks with conventional methods used for early-phase

clinical trials and presents numerous Bayesian designs for human clinical trials of new experimental treatment regimes. Written by research leaders from the University of Texas MD Anderson Cancer Center, this book shows how Bayesian designs for early-phase clinical trials can explore, refine, and optimize new experimental treatments. It emphasizes the importance of basing decisions on both efficacy and toxicity.

Clinical Trials National Academies Press Traditional preclinical mouse models of cancer have been very useful for studying the biology of cancer, however they often lack key characteristics of human cancers. As a result, many novel drug candidates fail in human clinical trials despite evidence of drug efficacy in those preclinical models. Thus, researchers are seeking new approaches to augment preclinical knowledge before undertaking clinical trials for human patients. Recently, there has been renewed interest in comparative oncology - the study of naturally developing cancers in animals as models for human disease - as one way to improve cancer drug development and reduce attrition of investigational agents. Tumors that spontaneously develop in pet dogs and other companion animals as a result of normal aging share many characteristics with human cancers, such as histological appearance, tumor genetics, biological behavior, molecular targets, and therapeutic response. In June 2015 the Institute of

Medicine hosted a workshop to examine the rationale and potential for integrating clinical trials for pet patients with naturally occurring cancers into translational cancer research and development. Participants discussed the research needs, strategies, and resources to support greater integration of clinical trials for pets with cancer into translational research pathways, and challenges and potential solutions for facilitating that integration. This report summarizes the presentations and discussions from the workshop.

Oncology Clinical Trials Oxford University Press, USA

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.

Volume 1 Design of Clinical Trials Academic Press

An ideal health care system relies on efficiently

generating timely, accurate evidence to deliver on its promise of diminishing the divide between clinical practice and research. There are growing indications, however, that the current health care system and the clinical research that guides medical decisions in the United States falls far short of this vision. The process of generating medical evidence through clinical trials in the United States is expensive and lengthy, includes a number of regulatory hurdles, and is based on a limited infrastructure. The link between clinical research and medical progress is also frequently misunderstood or unsupported by both patients and providers. The focus of clinical research changes as diseases emerge and new treatments create cures for old conditions. As diseases evolve, the ultimate goal remains to speed new and improved medical treatments to patients throughout the world. To keep pace with rapidly changing health care demands, clinical research resources need to be organized and on hand to address the numerous health care questions that continually emerge. Improving the overall capacity of the clinical research enterprise will depend on ensuring that there is an adequate infrastructure in place to support the investigators who conduct research, the patients with real diseases who volunteer to participate in experimental research, and the institutions that organize and carry out the trials. To address these issues and better understand the current state of clinical research in the United States, the Institute of Medicine's (IOM) Forum on Drug Discovery, Development, and Translation held a 2-day workshop entitled Transforming Clinical Research in the United States. The workshop, summarized in this volume, laid the foundation for a broader initiative of the Forum addressing different aspects of clinical research. Future Forum plans include further examining regulatory, administrative, and structural barriers to the effective conduct of clinical research; developing a vision for a stable, continuously funded clinical

research infrastructure in the United States; and considering strategies and collaborative activities to facilitate more robust public engagement in the clinical research enterprise.

The Prevention and Treatment of Missing Data in Clinical Trials Karger Medical and Scientific Publishers

When a patient is diagnosed with a gynecological malignancy, she and her doctors must make urgent, high-risk decisions about her course of treatment. In selecting an appropriate plan of care, physicians must weigh the patient's individual needs, the tumor's specific characteristics, and the treatment's potential side effects. Because there is no one-size-fits-all treatment solution, a plethora of clinical trials have been performed on ovarian cancer patients, but clinicians may struggle to keep up with this ever-growing body of research. Collecting and synthesizing research findings from a wide array of medical journal articles and book chapters, Clinical Trials in Ovarian Cancer provides physicians with an invaluable resource. Gynecologic oncologist Christine S. Walsh systematically outlines each of the seminal Phase III trials that have shaped the treatment of ovarian cancers, detailing the rationale for the trial, the patient population studied, treatment delivery methods, efficacy, toxicity, and trial conclusions. She provides a clear overview of established treatments, as well as still-controversial experimental approaches. The first book to organize this cutting-edge research into an easy-to-use reference, Clinical Trials in Ovarian Cancer should help medical personnel at all levels provide their patients with the highest standard of care.

Oxford University Press

Phase I trials are the first step in the study of novel therapeutic approaches. They aim to identify the recommended dose, schedule and pharamcologic behaviour of new drugs, and to describe the adverse effects of

treatment. This practical guide discusses the design, conduct, analysis and ethical aspects of Phase I cancer trials.

Current Paradigm and Methodological Advancement OUP Oxford

Randomized clinical trials are the primary tool for evaluating new medical interventions. Randomization provides for a fair comparison between treatment and control groups, balancing out, on average, distributions of known and unknown factors among the participants. Unfortunately, these studies often lack a substantial percentage of data. This missing data reduces the benefit provided by the randomization and introduces potential biases in the comparison of the treatment groups. Missing data can arise for a variety of reasons, including the inability or unwillingness of participants to meet appointments for evaluation. And in some studies, some or all of data collection ceases when participants discontinue study treatment. Existing guidelines for the design and conduct of clinical trials, and the analysis of the resulting data, provide only limited advice on how to handle missing data. Thus, approaches to the analysis of data with an appreciable amount of missing values tend to be ad hoc and variable. The Prevention and Treatment of Missing Data in Clinical Trials concludes that a more principled approach to design and analysis in the presence of missing data is both needed and possible. Such an approach needs to focus on two critical elements: (1) careful design and conduct to limit the amount and impact of missing data and (2) analysis that makes full use of information on all randomized participants and is based on careful attention to the assumptions about the nature of the missing data underlying estimates of treatment effects. In addition to the highest priority recommendations, the book offers more detailed recommendations on the conduct of clinical trials and techniques for analysis of trial data.

Clinical Trials in Oncology Academic Press
Phase I trials are a critical first step in the study of novel cancer therapeutic approaches. Their primary goals are to identify the recommended dose, schedule and pharmacologic behaviour of new agents or new combinations of agents and to describe the adverse effects of treatment. This comprehensive resource for oncology trainees and specialists explains cancer drug development and includes information on Phase 0 trials and immunotherapeutics, as well as updated information on the process, pitfalls and logistics of Phase I trials.

Statistical Methods for Survival Trial Design
National Academies Press
Scientists and clinicians seek a new paradigm that could improve the efficiency, cost-effectiveness, and overall success rate of cancer clinical trials, while maintaining the highest standards of quality. To explore innovative paradigms for cancer clinical trials and other ways to improve their quality, the National Cancer Policy Forum held a workshop, Improving the Quality of Cancer Clinical Trials, in Washington, DC. The main goals of the workshop were to examine new approaches to clinical trial design and execution that would: (1) better inform decisions and plans of those responsible for developing new cancer therapies (2) more rapidly move new diagnostic tests and treatments toward regulatory approval and use in the clinic (3) be less costly than current trials The resulting workshop summary will serve as input to the deliberations of an Institute of Medicine committee that will develop consensus-based recommendations for moving the field of cancer clinical trials forward.

A Practical Guide CRC Press
Phase I Cancer Clinical TrialsA Practical GuideOxford University Press
Oxford Handbook of Clinical Pharmacy CRC Press
This book provides a detailed review of how

oncology drug development has changed over the past decade, and serves as a comprehensive guide for the practicalities in setting up phase I trials. The book covers strategies to accelerate the development of novel antitumor compounds from the laboratory to clinical trials and beyond through the use of innovative mechanism-of-action pharmacodynamic biomarkers and pharmacokinetic studies. The reader will learn about all aspects of modern phase I trial designs, including the incorporation of precision medicine strategies, and approaches for rational patient allocation to novel anticancer therapies. Circulating biomarkers to assess mechanisms of response and resistance are changing the way we are assessing patient selection and are also covered in this book. The development of the different classes of antitumor agents are discussed, including chemotherapy, molecularly targeted agents, immunotherapies and also radiotherapy. The authors also discuss the lessons that the oncology field has learnt from the development of hematology-oncology drugs and how such strategies can be carried over into therapies for solid tumors. There is a dedicated chapter that covers the specialized statistical approaches necessary for phase I trial designs, including novel Bayesian strategies for dose escalation. This volume is designed to help clinicians better understand phase I clinical trials, but would also be of use to translational researchers (MDs and PhDs), and drug developers from academia

and industry interested in cancer drug development. It could also be of use to phase I trial study coordinators, oncology nurses and advanced practice providers. Other health professionals interested in the treatment of cancer will also find this book of great value.