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Dose Finding By The Continual

As clinicians begin to realize the important role of dose-finding in the drug development process, there is an increasing openness to "novel" methods proposed in the past two decades. In particular, the Continual Reassessment Method (CRM) and its variations have drawn much attention in the medical community, though it has yet to become a commonplace tool.

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Dose Finding by the Continual Reassessment Method to become a commonplace tool dose finding by the continual reassessment method chapman as clinicians begin to realize the important role of dose finding in the the continual reassessment method crm is a model based design for phase i trials which aims to find the maximum tolerated dose mtd of a

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Abstract. The Continual Reassessment Method (CRM), along with other adaptive dose-finding study designs, has gained popularity since its proposal by O'Quigley. Several of the reasons it has been embraced by

clinical trialists is that it tends to incur fewer toxic events, and more accurately estimate the maximum tolerated dose as compared to the standard Phase I dose escalation designs.

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As clinicians begin to realize the important role of dose-finding in the drug development process, there is an increasing openness to "novel" methods proposed in the past two decades. In particular, the

Continual Reassessment Method (CRM) and its variations have drawn much attention in the medical community, though it has yet to become a commonplace tool. To overcome the status quo in phase I clinical trials, statisticians must be able to design trials using the CRM in a timely and reproducible manner. A self-contained theoretical framework of the CRM for researchers and graduate students who set out to learn and do research in the CRM and dose-finding methods in general, Dose Finding by the Continual Reassessment Method features: Real clinical trial examples that illustrate the methods and techniques throughout the book Detailed calibration techniques that enable biostatisticians to design a CRM in timely manner Limitations of the CRM are outlined to aid in correct use of method This book supplies practical, efficient dose-finding methods based on cutting edge statistical research. More than just a cookbook, it provides full, unified coverage of the CRM in addition to step-by-step guidelines to automation and parameterization of the methods used on a regular basis. A detailed exposition of the calibration of the CRM for applied statisticians working with dose-finding in phase I trials, the book focuses on the R package 'dfcrm' for the CRM and its major variants. The author recognizes clinicians' skepticism of model-based designs, and addresses their concerns that the time, professional, and computational resources necessary for accurate model-based designs can be major bottlenecks to the widespread use of appropriate dose-finding methods in phase I practice. The theoretically- and empirically-based methods in Dose Finding by the Continual Reassessment Method

will lessen the statistician's burden and encourage the continuing development and implementation of model-based dose-finding methods.

This book provides a comprehensive introduction to statistical methods for designing early phase dose-finding clinical trials. It will serve as a textbook or handbook for graduate students and practitioners in biostatistics and clinical investigators who are involved in designing, conducting, monitoring, and analyzing dose-finding trials. The book will also provide an overview of advanced topics and discussions in this field for the benefit of researchers in biostatistics and statistical science. Beginning with backgrounds and fundamental notions on dose finding in early phase clinical trials, the book then provides traditional and recent dose-finding designs of phase I trials for, e.g., cytotoxic agents in oncology, to evaluate toxicity outcome. Included are rule-based and model-based designs, such as 3 + 3 designs, accelerated titration designs, toxicity probability interval designs, continual reassessment method and related designs, and escalation overdose control designs. This book also covers more complex and updated dose-finding designs of phase I-II and I/II trials for cytotoxic agents, and cytostatic agents, focusing on both toxicity and efficacy outcomes, such as designs with covariates and drug combinations, maximum tolerated dose-schedule finding designs, and so on.

Early phase clinical trials during drug development are vital to the success of an investigational compound. In these phases, an important goal of a

dose-finding study is the determination of a dose that is safe and/or effective. Dose-finding trials based on safety outcomes are typically among the first studies conducted for any novel compound. Subsequently, another trial may be conducted to determine which dose among the range of safe doses is the most effective thereby generating a dose-effectiveness profile. When both safety and efficacy are simultaneously considered in a single trial, this is called a phase I/II trial. These trials are advantageous in that they are likely to save both time and resources. This dissertation reviews current phase I/II methods, explores key limitations of these methods, and presents an innovative approach that addresses some of these limitations. The new approaches are compared to one of the most widely known methods of this type. A common phase I/II method is the bivariate Continual Reassessment Method (bCRM; Braun, 2002). The bCRM models dichotomous safety and effectiveness outcomes for use in dose escalation and dose selection decisions. Its overall statistical model is based upon both safety and efficacy models that assume the probabilities of these outcomes increase linearly with dose. The effects of violating the linear monotonicity assumption are explored. It is shown that there are a number of scenarios in which the bCRM performs poorly, including those where effectiveness does not increase beyond a certain dose and when the most efficacious dose is not the highest dose. This indicates that an approach where linearity is not assumed could have great value. The generalized bivariate Continual Reassessment Method (gbCRM) framework is developed as an alternative to dose-finding methods with fixed models. With this

approach, the model could be modified to fit a variety of trends that typically arise during dose-finding. It is shown that there are scenarios where the gbCRM provides major advantages when the proper models are used. However, there also exist a number of scenarios where there is an increased risk of choosing an unsafe dose when improper models are used. This study indicates that the use of statistical model selection procedures is likely to improve the performance of the gbCRM by gaining the benefits of proper model selection while avoiding some of the consequences of improper model selection. To address these concerns, an extension of the gbCRM, called the flexible bivariate Continual Reassessment Method (fbCRM), is developed. The fbCRM incorporates model selection and averaging to help make statistical decisions within the gbCRM framework. A simulation study shows that, under many scenarios, the fbCRM is vastly superior to methods with fixed models. Finally, the bCRM, gbCRM and fbCRM are applied to data from a small clinical trial whose goal was to describe the dose-response relationship of the colonization of the Haemophilus influenzae bacterium. These methods are used to define the dose-colonization of this bacterium when applied to human subjects, and to explore how the dose escalation scheme of this trial might have differed if the fbCRM had been used.

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Initially, our method assigns dose to patients using the aforementioned two-stage CRM ignoring any patient heterogeneity, and tests the risk effect as trial proceeds. It then transitions to a risk-adjusting stage only if sufficient risk effect on toxicity outcome is observed. The performance of this multi-stage design is evaluated under various scenarios, using dosing accuracy measures calculated based on the final model estimate at the end of a trial and on the intra-trial dose allocation. The results are compared to the conventional two-stage CRM without considering patient heterogeneity. Simulation results demonstrate a substantial improvement in dosing accuracy in scenarios where there are true risk effects on toxicity probability; and in situations where risk factors do not have an effect, the performance of the proposed method is also comparable to that of the conventional design.

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

Handbook of Methods for Designing, Monitoring, and Analyzing Dose-Finding Trials gives a thorough presentation of state-of-the-art methods for early phase clinical trials. The methodology of clinical trials has advanced greatly over the last 20 years and, arguably, nowhere greater than that of early phase studies. The need to accelerate drug development in a rapidly evolving context of targeted therapies, immunotherapy, combination treatments and complex group structures has provided the stimulus to these advances. Typically, we deal with very small samples, sequential methods that need to be efficient, while, at the same time adhering to ethical principles due to the involvement of human subjects. Statistical inference is difficult since the standard techniques of maximum likelihood do not usually apply as a result of model misspecification and parameter estimates lying on the boundary of the parameter space. Bayesian methods play an important part in overcoming these difficulties, but nonetheless, require special consideration in this

particular context. The purpose of this handbook is to provide an expanded summary of the field as it stands and also, through discussion, provide insights into the thinking of leaders in the field as to the potential developments of the years ahead. With this goal in mind we present: An introduction to the field for graduate students and novices A basis for more established researchers from which to build A collection of material for an advanced course in early phase clinical trials A comprehensive guide to available methodology for practicing statisticians on the design and analysis of dose-finding experiments An extensive guide for the multiple comparison and modeling (MCP-Mod) dose-finding approach, adaptive two-stage designs for dose finding, as well as dose–time–response models and multiple testing in the context of confirmatory dose-finding studies. John O'Quigley is a professor of mathematics and research director at the French National Institute for Health and Medical Research based at the Faculty of Mathematics, University Pierre and Marie Curie in Paris, France. He is author of Proportional Hazards Regression and has published extensively in the field of dose finding. Alexia Iasonos is an associate attending biostatistician at the Memorial Sloan Kettering Cancer Center in New York. She has over one hundred publications in the leading statistical and clinical journals on the methodology and design of early phase clinical trials. Dr. Iasonos has wide experience in the actual implementation of model based early phase trials and has given courses in scientific meetings internationally. Björn Bornkamp is a statistical methodologist at Novartis in Basel, Switzerland, researching and implementing dose-

finding designs in Phase II clinical trials. He is one of the co-developers of the MCP-Mod methodology for dose finding and main author of the DoseFinding R package. He has published numerous papers on dose finding, nonlinear models and Bayesian statistics, and in 2013 won the Royal Statistical Society award for statistical excellence in the pharmaceutical industry.

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Dose-finding experiments define the safe dosage of a drug in development, in terms of the quantity given to a patient. Statistical methods play a crucial role in identifying optimal dosage. Used appropriately, these methods provide reliable results and reduce trial duration and costs. In practice, however, dose-finding is often done poorly, with widely used conventional methods frequently being unreliable, leading to inaccurate results. However, there have been many advances in recent years, with new statistical techniques being developed and it is important that these new techniques are utilized correctly. Statistical Methods for Dose-Finding Experiments reviews the main statistical approaches for dose-finding in phase I/II clinical trials and presents practical guidance on their correct use. Includes an introductory section, summarizing the essential concepts in dose-finding. Contains a section on algorithm-based approaches, such as the traditional 3+3 design, and a section on model-based approaches, such as the continual reassessment method. Explains fundamental issues, such as how to stop trials early and how to cope with delayed or ordinal outcomes. Discusses in detail the main websites and software used to implement the methods. Features numerous worked examples making use of real data. Statistical Methods for Dose-Finding Experiments is an important collaboration from the leading experts in the area. Primarily aimed at statisticians and clinicians working in clinical trials and medical research, there is also much to benefit graduate students of biostatistics.