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Statistical approaches in oncology clinical development: Current paradigm and methodological advancement

Satrajit Roychoudhury and Soumi Lahiri

Boca Raton: Chapman and Hall/CRC.

This book is an excellent compilation of chapters from a variety of authors coming from pharmaceutical companies, academia, and even one from the food and drug administration (FDA) to inform readers about the current paradigm in oncology clinical trials. The chapters dive much deeper than the standard, parallel, randomized, controlled trials that we may expect in phase III and instead start with phase I development, move into phases II and III, and then consider quality of life (QOL) and regulatory concerns. Thus, reading chronologically, the book offers a generous overview spanning oncology drug development; each chapter, however, could be read in isolation to understand that particular phase of trial design or subject matter.

After a short introduction, chapters 2 and 3 focus on dose-finding, specifically through model-based approaches. Practical advice and specific guidance for a rigorous protocol of a small (ie, 15-30 patients) expansion cohort is provided at the end of chapter 2, which fills a gap in the literature as expansion cohorts are increasingly popular in phase I studies, but often proposed without rigor. The fourth chapter presents methods to evaluate an interaction between a (binary) biomarker and (binary) treatment for binary and time-to-event outcomes. The fifth chapter considers phase II designs ranging from single-arm historical control trials to biomarker-based designs including umbrella and basket trials. A brief fifth chapter expands on mid-to-late phase adaptive, Bayesian trial design, discussing the BATTLE and I-SPY trials as examples. The seventh chapter discusses adaptive design in late-stage trials including seamless designs and sample size re-estimation. Safety monitoring and analyses across all phases of study are the topics in chapter 8 where Frequentists and Bayesian stopping boundaries and multistage designs are discussed. Recommendations for safety reporting, transparent details on subgroup analyses, and meta-analytic methods for combining information from multiple trials are also presented.

Where most books would have ended, this book continues with two important chapters. The ninth chapter addresses including QOL as an endpoint in oncology trials and how to address numerous statistical challenges from these data including the role of QOL data, multiplicity issues, and missingness of the data. The last chapter presents regulatory pathways for drug approval, with necessary information for anyone involved in trial design and analysis, but one that is often ignored by those not working directly with regulators.

While the writing is generally clear, the chapters are greatly enhanced by including case studies or specific examples of trials that have been implemented to illustrate the design and/or methods discussed in the chapters. Additionally, R code is available at the end of two chapters (chapter 2 for a single-agent model for dose escalation and a meta-analytic model and in chapter 4 for evaluating biomarkers and the relative excess risk due to interaction) for direct translation of the methods.

Overall, this book is an admirable compilation of statistical design and methods addressing all phases of oncological drug development. While much focus is on model-based, Bayesian analyses, the book still presents more classical and Frequentist designs and methods with ample references, thus allowing readers from many backgrounds and preferred styles to learn more about trial design and statistical methods in oncology.

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Statistical analysis with measurement error or misclassification: Strategy, method and application

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New York: Springer-Verlag.

Measurement error is an important and challenging topic affecting all areas in biostatistics, including survival analysis, longitudinal data analysis, and causal inference, among others. Even though there are many journal articles, which focus on measurement error, fewer textbooks are available that contain summaries or comprehensive discussions of the impact and approaches to address measurement error. Existing textbooks (eg, Fuller, 1987; Gustafson, 2004; Carroll et al., 2006; Buonaccorsi, 2010) generally aim to introduce general methods to deal with measurement error but pay less attention on the discussion of measurement error in specific datasets or particular statistical models.

Yi's book *Statistical Analysis with Measurement Error or Misclassification: Strategy, Method and Application* fills important gaps in the available literature. First, this book not only reviews several methods to deal with measurement error, but also comprehensively discusses strategies of correcting measurement error effect in different types of data and model structures. Second, this book contains supplementary problems in each chapter, which motivate readers to brainstorm approaches to address potential research problems. In addition to the presentation of methodologies, this book also illustrates applications through data analysis in each chapter, as reviewed below.

Chapter 1 mainly reviews concepts and introduces several fundamental methods and frameworks in statistical inference, including modeling, discussions of parameter identifiability, and estimation methods (including likelihood method, estimating equations, generalized method of moments, and profiling method). Moreover, the idea of model misspecification, which is also a concern in statistical analysis, is also briefly discussed.

In chapter 2, Yi introduces the definitions and concepts in the measurement error literature. First, Yi emphasizes that measurement error is a term used for continuous variables, while misclassification is for binary variable. In addition, Yi describes the scope of analysis of measurement error, including modeling strategies (structural method and functional method), measurement error mechanism (nondifferential and differential), measurement error models (classical error model, Berkson additive model, and multiplicative model), and data requirements (validation subsample, repeated measurements, instrumental data, and sensitivity analyses). Finally, Yi presents an overview of general strategies to handle measurement error. These methods include likelihood-based correction method, unbiased estimating functions method, and method of correcting naive estimators (eg, simulation extrapolation and regression calibration).

The impact of measurement error in covariates for different types of outcome data and model structures is discussed in chapters 3 to 7. Throughout these chapters, Yi first introduces notation, models, and the assumed modeling framework, and then provides strategies to correct the effect of measurement error. Chapters 3 and 4 discuss survival data analysis with measurement error, focusing on the Cox proportional hazards model and the additive hazards model, including recurrent event data. Chapter 3 first discusses feasible methods in this context for continuous covariates, including regression calibration, SIMEX methods, and insertion correction of the likelihood function, followed by methods to correct bias due to misclassification and methods for multivariate survival data with covariate measurement error. One of methods for recurrent event data, in chapter 4, is called the naive