
Preface

The development of cancer drugs, from the preclinical studies to final randomized clinical trial is a science per se. The process involves multiples distinct steps and requires the participation of multiple individuals with unique expertise such as toxicologist, pharmacologists, pathologists, statisticians, clinicians and ethics and regulatory experts. In addition, it involves several different organizations such as academic center, pharmaceutical industry and governmental organizations. Teaching and learning this process is not a simple task. The editors are seasoned clinical investigators with different backgrounds who spend considerable time teaching student and junior colleagues the nuts and bolts of drug development both at their own institutions but also through active participations in workshops and seminars on the topic. It became apparent to us that there are no sources in which the basis and principles of drug development are concisely summarize. This book has been written to fill that gap and to provide a guide for the beginners of drug development as well as a consultation manual for more advance drug developers. It is intended to provide a practical tool for the design, conduction, analysis and reporting of a clinical trial as well as to establish a developmental plan for a new agent.

The book is organized into five parts – all of them written by experts and renowned authors who have done a great job putting the chapters together. Part I summarizes basic concepts in biostatistics and in clinical and analytical pharmacology that are needed to understand the clinical drug development process. Part II provides a comprehensive summary of preclinical studies that are required before a medical agent can be tested in humans. Part III deals with clinical trial design from phase I to phase III as well as with correlative studies in clinical trials including the more classic pharmacokinetics and the newer molecular imaging and tissue biomarkers. Part IV is an important section that outlines the FDA requirement for testing and approving a drug for cancer treatment. Part V focuses on more specific descriptions of developmental strategies for the different classes of anti-cancer agents ranging from conventional cytotoxic agents to molecularly targeted agents. The final section outlines the resources and perspective of the National Cancer Institute.

We expect this book to be a night table manual and guide for those interested in the complex but rewarding field of anticancer drug development and the place to get started when training in this field. We also hope that this text book would be useful to our peer teachers in drug development.

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