Preface

This new edition of *New Drug Development* has retained the sections that were particularly well received in the first edition, added chapters discussing the latest developments in the realm of drug safety, and expanded its coverage of clinical trials considerably. The book still adopts a lifecycle approach to drug development, since an understanding of the research that precedes and follows clinical trials is extremely helpful in placing these trials in the larger framework of integrated pharmaceutical medicine. Accordingly, overviews of medicinal chemistry, drug discovery and design, and nonclinical research precede the coverage of clinical trials, and an overview of postmarketing surveillance follows them. Drug manufacturing is also considered, since clinical trials require the drug products being tested. However, this edition is first and foremost a book about clinical trials that are conducted to bring a new drug to market.

A different presentation style has been adopted in this edition. While still reader-friendly, the first edition was more academic in nature, written as a scholarly textbook and therefore containing several hundred references throughout the text. In contrast, this edition presents factual knowledge with a minimum of referencing, thereby improving the flow of ideas and concepts and making it even more reader-friendly. The primary target audience is entry-level professionals in the pharmaceutical, biopharmaceutical, and contract research organization (CRO) industries, along with seasoned clinical research professionals who wish to refresh their knowledge in areas outside their immediate area of expertise. The book prepares you for discussions with many members of study teams, including statisticians and biomedical data scientists, clinical research associates, clinical monitors, clinical trial investigators, clinical trial administrators, managers, and coordinators, project managers, data managers, clinical scientists, regulatory affairs professionals, clinical operations specialists, medical writers, nurses, pharmacists, and medical safety officers. You will benefit considerably from being able to converse with all of these colleagues, and you will therefore become a more valuable employee to your company. This edition is also well suited for students of medicine, pharmacy, and nursing, and for physician assistants and allied health professionals. Further readings are suggested at the end of chapters for those who wish to pursue individual topics in more detail.
Numerical information utilized in the drug development process takes many forms. Its collection and analysis vary from context to context, and its interpretation facilitates informed decision-making. Study design, experimental methodology, and operational execution are concerned with the collection of optimum quality data. Analysis and interpretation are concerned with producing results and interpreting their meaning. Since the discipline of Statistics (notated with a capital S) is concerned with both design and analysis, the book provides a conceptual introduction to Statistics and illustrates its important role in the new drug development process. For readers who may start to feel a little queasy at the very mention of the word Statistics, please rest assured that this is absolutely not a traditional Statistics book. It adopts a conceptual approach, not a computational one, explaining the statistical thinking that goes into the successful planning of clinical trials.

Of course, once a clinical trial has been planned, it must be executed (run) successfully too. The operational complexities of running clinical trials are immense, and the well-coordinated participation of many clinical research professionals is critical. The roles and responsibilities of these individuals are introduced in the following chapters.

Throughout the discussions of the various topics included, I have focused on three key messages. First, optimum quality study design is fundamental to good trials. If studies are designed well, the data acquired can be analyzed in a straightforward manner. Second, optimum quality operational execution is necessary to run good trials and to collect optimum quality data for analysis: poor quality data can still be analyzed, but the answers provided to the research questions asked will also be of poor quality. Third, the purpose of new drug development is to produce drugs that can be used safely and effectively to treat patients. We are privileged to be engaged in an endeavor that makes a huge difference to the health and well-being of millions of people.

Thank you for your interest in this edition: I very much hope that you enjoy reading it.

Chapel Hill, NC

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New Drug Development
An Introduction to Clinical Trials: Second Edition
Turner, J.R.
2010, XXV, 256 p., Hardcover