

Book Review

Fundamentals of Clinical Research

Bridging Medicine, Statistics and Operations

Antonella Bacchieri, Giovanni Della Cioppa,
Springer - Verlag Berlin Heidelberg
ISBN: 978-81-8489-485-1



Fundamentals of Clinical Research is one of the few books that has attempted to integrate clinical trial methodology with other components of clinical research such as statistics. The authors deserve rich compliments for bringing out a well researched book covering different aspects of clinical developments.

In a simple lucid language, the book begins by stressing the complexity of assessment of treatment outcomes due to variability of biological phenomena. The sources of biological and measurement related variability / errors is covered in Chapter 1 which emphasizes the importance of recognizing and overcoming the background noise in order to separate and measure the 'signal' resulting

from treatment. Chapter 2 delves on the characteristics that define a clinical study and its distinction from an observational (epidemiological) study; giving details about the study protocol. Chapter 3 provides a brief introduction to the prospective and retrospective aspects of observational studies. Although, this chapter discusses various aspects from 'control of bias in epidemiology' to 'control of phenomenon of confounding' along with the advantages and disadvantages of the different types of observational studies, it somehow stands out alone in the overall coverage of various aspects of clinical research such as planning and implementation along with analysis, interpretation and publication of results.

Chapters 4, 5, 6 and 7 are dedicated to the definition and quantification of the treatment effects being studied, the logical foundations of the statistical analysis and the study sample and choice of study treatments (including placebo, blinded and concomitant treatments) respectively. Chapters 8, 9, 10 and 11 give an overview of the most common experimental designs with emphasis on common methodological errors.

Chapter 12, one of the most important chapters, is entirely devoted to the drug development process and to the various phases and their importance in clinical

development. Genuine efforts are made to give details about the goals of each phase, planning, conduct, analysis and reporting including registration dossier.

The book elaborates not only on the drug development process from discovery to post marketing surveillance but also covers less common topics such as the sources of variability, comparison between frequentist and Bayesian approach to statistical testing and various study designs.

Importantly, the language has a logical flow of reasoning making it useful to biomedical researchers, physicians and statisticians alike. The book no doubt has a practical approach, emphasizing on study protocols that are not only scientifically correct but also feasible in real life settings. Methods proposed to accelerate clinical development and strategies to reduce time and costs of clinical development are also commendable. Addition of a detailed coverage of the logistic and legal aspects of clinical research could immensely benefit researchers working in diverse areas of clinical development.

Reviewed by:

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Statement about the ownership and other particulars about the newspaper entitled "Pharma Times" as required to be published ever year after the last day to February.

FORM - IV (Rule 8)

1. Place of Publication : Mumbai
2. Periodicity : Monthly
3. Printer's Name : **Mr. Anil Daniel**
C.E.O.
Anitha Art Printers
Whether Citizen of India : Yes
Address : 29-30, Oasis Industrial Estate, Vakola, Santacruz (East), Mumbai 400 055.
4. Publisher's Name : **Kaushhik Desai on behalf of Indian Pharmaceutical Association**
Whether Citizen of India : Yes
Address : Same as above
5. Editor's Name : **Kaushhik Desai**
Whether Citizen of India : Yes
Address : Indian Pharmaceutical Association, Kalina, Santacruz (East), Mumbai 400 098.
6. Names & Addresses of individual who won the Newspaper and holding more than one per cent of the total Capital ; **Indian Pharmaceutical Association**

I, Mr. Kaushik Desai hereby declare that the particulars given above are true to the best of my knowledge and belief.

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Kaushhik Desai
Editor

Date: 01.04.2010