Preace

The ultimate purpose of the results from a clinical trial is not to tell us precisely what happened in that trial, but, in combination with results from other trials in the drug’s clinical development program, to gain insight into likely drug responses in patients who would be prescribed the drug should it be approved for marketing. The discipline of Statistics enables us to do this.

This book discusses key statistical concepts that facilitate the analysis of data collected from a group of individuals participating in a biopharmaceutical clinical trial, the estimation of their clinical significance in the general population of individuals likely to be prescribed the drug if approved, and the related decision making that occurs at both the public health level (by regulatory agencies when deciding whether or not to approve a new drug for marketing) and the individual patient level (by physicians and their patients when deciding whether or not the patient should be prescribed a drug that is on the market).

These key concepts include drug safety and efficacy, clinical significance, statistical significance, and benefit-risk estimation. All of these facilitate decision making during drug development, and also during pharmacotherapy once the drug is marketed.
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