Theory of Drug Development (Chapman & Hall/CRC Biostatistics Series)

Eric B. Holmgren

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Theory of Drug Development presents a formal quantitative framework for understanding drug development that goes beyond simply describing the properties of the statistics in individual studies. It examines the drug development process from the perspectives of drug companies and regulatory agencies.

By quantifying various ideas underlying drug development, the book shows how to systematically address problems, such as:

- Sizing a phase 2 trial and choosing the range of p-values that will trigger a follow-up phase 3 trial
- Deciding whether a drug should receive marketing approval based on its phase 2/3 development program and recent experience with other drugs in the same clinical area
- Determining the impact of adaptive designs on the quality of drugs that receive marketing approval
- Designing a phase 3 pivotal study that permits the data-driven adjustment of the treatment effect estimate
- Knowing when enough information has been gathered to show that a drug improves the survival time for the whole patient population

Drawing on his extensive work as a statistician in the pharmaceutical industry, the author focuses on the efficient development of drugs and the quantification of evidence in drug development. He provides a rationale for underpowered phase 2 trials based on the notion of efficiency, which leads to the identification of an admissible family of phase 2 designs. He also develops a framework for evaluating the strength of evidence generated by clinical trials. This approach is based on the ratio of power to type 1 error and transcends typical Bayesian and frequentist statistical analyses.

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