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

Eric B. Holmgren
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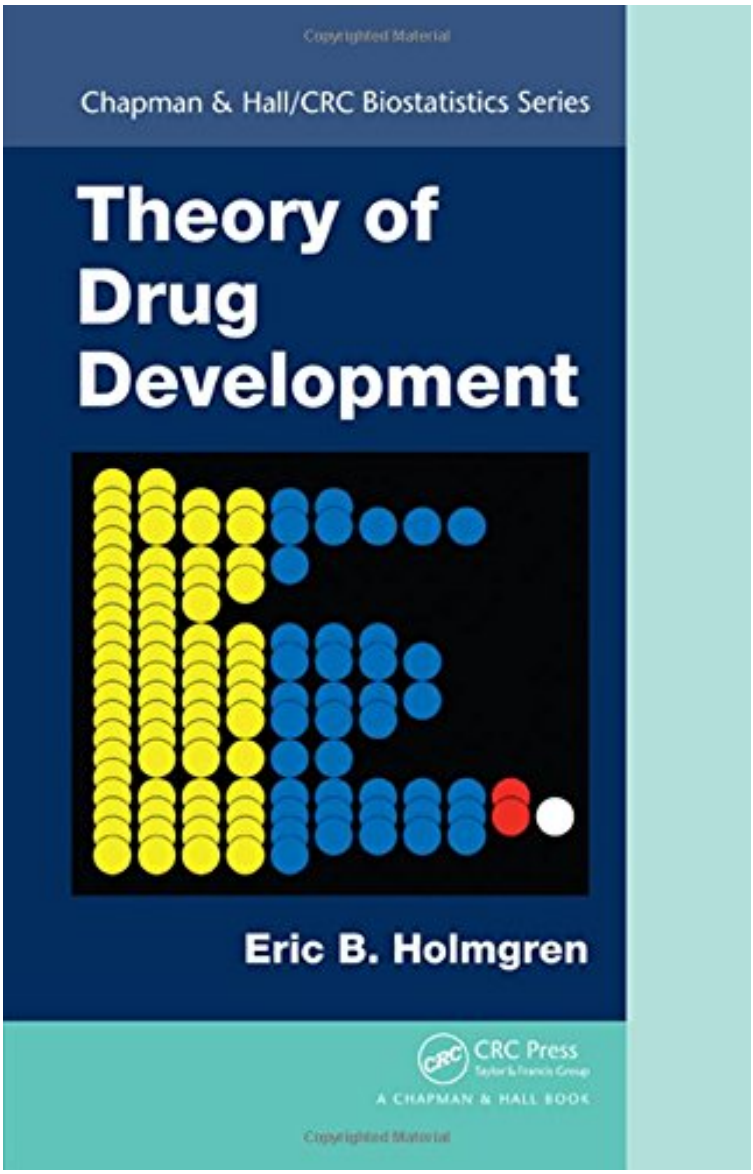

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Eric B. Holmgren : Theory of Drug Development (Chapman Hall/CRC Biostatistics Series) before purchasing it in order to gage whether or not it would be worth my time, and all praised Theory of Drug Development (Chapman Hall/CRC Biostatistics Series):

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.

"In each chapter, author provides appropriate statistical formulas that readers can actually utilize. Since this book handles many mathematical formulas, and contains many real good examples, this book would be very useful for statisticians who work at pharmaceutical companies and are deeply involved with drug development Overall, this book covers necessary and important aspects for drug development, and would be quite useful to clinical statisticians."Byung-Ho Nam, PhD, Department of Cancer Control and Policy, Graduate School of Cancer Science and Policy, National Cancer Center, Korea, in Biometrics "The given book presents a theory of drug development that is based on maximizing the efficiency with which drugs that truly provide clinical benefits are identified. The author shows how to optimize the drug development process at its three main stages (Phases 1, 2, 3), and at some transitional sub-stages, so that the number of molecules that result in a positive final Phase 3 clinical trial per investment is maximized."Fatima T. Adylova in Zentralblatt MATHAbout the AuthorEric B. Holmgren is a consultant and statistical scientist. He previously worked at Genentech and Hoechst Roussel Pharmaceuticals. He received a Ph.D. in mathematical statistics from Stanford University.