Fundamental Concepts for New Clinical Trialists (Chapman & Hall/CRC Biostatistics Series)

Scott Evans, Naitee Ting

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Fundamental Concepts for New Clinical Trialists describes the core scientific concepts of designing, data monitoring, analyzing, and reporting clinical trials as well as the practical aspects of trials not typically discussed in statistical methodology textbooks.

The first section of the book provides background information about clinical trials. It defines and compares clinical trials to other types of research studies and discusses clinical trial phases, registration, the protocol document, ethical issues, product development, and regulatory processes. It also includes a special chapter outlining the valuable attributes that statisticians can develop to maximize their contributions to a clinical trial.

The second section examines scientific issues faced in each progressive step of a clinical trial. It covers issues in trial design, such as randomization, blinding, control-group selection, endpoint selection, superiority versus noninferiority, and parallel group versus crossover designs; data monitoring; analyses of efficacy, safety, and benefit-risk; and the reporting/publication of clinical trial results.

As clinical trials remain the gold standard research studies for evaluating the effects of a medical intervention, newcomers to the field must have a fundamental understanding of the concepts to tackle real-world issues in all stages of trials. Drawing on their experiences in academia and industry, the authors provide a foundation for understanding the fundamental concepts necessary for working in clinical trials.

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