Bayesian Designs for Phase I-II Clinical Trials (Chapman & Hall/CRC Biostatistics Series)

Ying Yuan, Hoang Q. Nguyen, Peter F. Thall

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Reliably optimizing a new treatment in humans is a critical first step in clinical evaluation since choosing a suboptimal dose or schedule may lead to failure in later trials. At the same time, if promising preclinical results do not translate into a real treatment advance, it is important to determine this quickly and terminate the clinical evaluation process to avoid wasting resources.

Bayesian Designs for Phase I–II Clinical Trials describes how phase I–II designs can serve as a bridge or protective barrier between preclinical studies and large confirmatory clinical trials. It illustrates many of the severe drawbacks with conventional methods used for early-phase clinical trials and presents numerous Bayesian designs for human clinical trials of new experimental treatment regimes.

The first two chapters minimize the technical language to make them accessible to non-statisticians. These chapters discuss the severe drawbacks of the conventional paradigm used for early-phase clinical trials and explain the phase I–II paradigm for optimizing dose, or more general treatment regimes, based on both efficacy and toxicity. The remainder of the book covers a wide variety of clinical trial methodologies, including designs to optimize the dose pair of a two-drug combination, jointly optimize dose and schedule, identify optimal personalized doses, optimize novel molecularly targeted agents, and choose doses in two treatment cycles.

Written by research leaders from the University of Texas MD Anderson Cancer Center, this book shows how Bayesian designs for early-phase clinical trials can explore, refine, and optimize new experimental treatments. It emphasizes the importance of basing decisions on both efficacy and toxicity.

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