



Design and Analysis of Clinical Trials with Time-to-Event Endpoints (Chapman & Hall/CRC Biostatistics Series)

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Using time-to-event analysis methodology requires careful definition of the event, censored observation, provision of adequate follow-up, number of events, and independence or "noninformativeness" of the censoring mechanisms relative to the event. **Design and Analysis of Clinical Trials with Time-to-Event Endpoints** provides a thorough presentation of the design, monitoring, analysis, and interpretation of clinical trials in which time-to-event is of critical interest.

After reviewing time-to-event endpoint methodology, clinical trial issues, and the design and monitoring of clinical trials, the book focuses on inferential analysis methods, including parametric, semiparametric, categorical, and Bayesian methods; an alternative to the Cox model for small samples; and estimation and testing for change in hazard. It then presents descriptive and graphical methods useful in the analysis of time-to-event endpoints. The next several chapters explore a variety of clinical trials, from analgesic, antibiotic, and antiviral trials to cardiovascular and cancer prevention, prostate cancer, astrocytoma brain tumor, and chronic myelogenous leukemia trials. The book then covers areas of drug development, medical practice, and safety assessment. It concludes with the design and analysis of clinical trials of animals required by the FDA for new drug applications.

Drawing on the expert contributors' experiences working in biomedical research and clinical drug development, this comprehensive resource covers an array of time-to-event methods and explores an assortment of real-world applications.

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