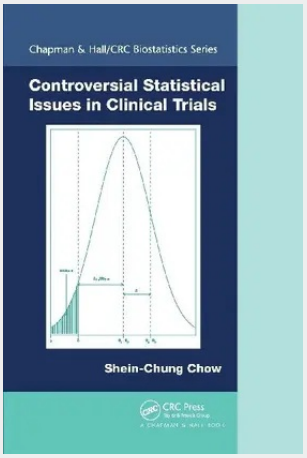
Chow

# Controversial Statistical Issues in Clinical Trials




In clinical trial practice, controversial statistical issues inevitably occur regardless of the compliance with good statistical practice and good clinical practice. But by identifying the causes of the issues and correcting them, the study objectives of clinical trials can be better achieved. Controversial Statistical Issues in Clinical Trials covers commonly encountered controversial statistical issues in clinical trials and, whenever possible, makes recommendations to resolve these problems. The book focuses on issues occurring at various stages of clinical research and development, including early-phase clinical development (such as bioavailability/bioequivalence), bench-to-bedside translational research, and late-phase clinical development. Numerous examples illustrate the impact of these issues on the evaluation of the safety and efficacy of the test treatment under investigation. The author also offers recommendations regarding possible resolutions of the problems. Written by one of the preeminent experts in the field, this book provides a useful desk reference and state-of-the art examination of problematic issues in clinical trials for scientists in the pharmaceutical industry, medical/statistical reviewers in government regulatory agencies, and researchers and students in academia.

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