



Clinical Trial Simulations: Applications and Trends: 1 (AAPS Advances in the Pharmaceutical Sciences Series)

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This edition includes both updates and new uses and issues concerning CTS, along with case studies of how clinical trial simulations are being applied in various therapeutic and application areas. Importantly, the book expands on the utility of CTS for informing decisions during drug development and regulatory review. Each chapter author was selected on the basis of demonstrated expertise in state-of-the-art application of CTS.

The target audience for this volume includes researchers and scientists who wish to consider use of simulations in the design, analysis, or regulatory review and guidance of clinical trials. This book does not embrace all aspects of trial design, nor is it intended as a complete recipe for using computers to design trials. Rather, it is an information source that enables the reader to gain understanding of essential background and knowledge for practical applications of simulation for clinical trial design and analysis. It is assumed that the reader has a working understanding of pharmacokinetics and pharmacodynamics, modeling, pharmacometric analyses, and/or the drug development and regulatory processes.

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