



Multiregional Clinical Trials for Simultaneous Global New Drug Development (Chapman & Hall/CRC Biostatistics Series)

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In a global clinical development strategy, multiregional clinical trials (MRCTs) are vital in the development of innovative medicines. **Multiregional Clinical Trials for Simultaneous Global New Drug Development** presents a comprehensive overview on the current status of conducting MRCTs in clinical development. International experts from academia, industry, and health organizations address various aspects of the important problems in global clinical development and MRCTs.

The book first provides a high-level introduction to the context, motivation, opportunities, and challenges in simultaneous global clinical development using MRCTs. It then focuses on the design, monitoring, and analysis/interpretation of MRCTs. The book concludes with an examination of the latest research topics from MRCT perspectives, such as special considerations by local health authorities, health economic evaluations, benefit-risk assessment, and medical devices.

Explaining how to design, conduct, and interpret MRCTs, this book will help biostatisticians working in the late-stage clinical development of medical products. It will also be useful for statisticians and clinicians in the biopharmaceutical industry, regulatory agencies, and medical research institutes.

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