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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.

Controversial Statistical Issues in Clinical Trials - 1st ...

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

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(such ...

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In clinical research and development of a test treatment under investigation, commonly seen controversial issues include: 1) appropriateness of traditional statistical hypotheses for clinical evaluation of both safety and efficacy; 2) correctness of power analysis for sample size calculation based on information from a small-scale pilot study; 3) integrity of randomization and blinding for preventing potential biases; 4) post hoc endpoint selection (based on some derived endpoints); 5 ...

On controversial statistical issues in clinical research

These issues include, but are not limited to: 1) appropriateness of statistical hypotheses for clinical investigation; 2) correctness of power analysis assumptions; 3) integrity of randomization...

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Controversial Statistical Issues in Clinical Trials. DOI link for Controversial Statistical Issues in Clinical Trials. Controversial Statistical Issues in Clinical Trials book. By Shein-Chung Chow. Edition 1st Edition . First Published 2011 . eBook Published 19 April 2016 . Pub. location New York .

Controversial Statistical Issues in Clinical Trials

These issues include, but are not limited to: 1) appropriateness of statistical hypotheses for clinical investigation; 2) correctness of power analysis assumptions; 3) integrity of randomization and blinding; 4) post hoc endpoint selection; 5) impact of protocol amendments on the characteristics of the trial population; 6) multiplicity in clinical trials; 7) missing data imputation; 8) adaptive design methods; and 9) independence of a data monitoring committee.

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Controversial issues in clinical trials are referred to as debatable issues that are commonly encountered during the conduct of clinical trials. In practice, controversial issues could be raised from, but are not limited to, (1) compromises between theoretical and real/common practices, (2) miscommunication and/or misunderstanding in perception/interpretation among regulatory agencies, clinical scientists, and biostatisticians, and (3) disagreement, inconsistency, miscommunication ...

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