



An Introduction to Statistics in Early Phase Trials

Steven Julious, Say-Beng Tan, David Machin

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All new medicines and devices undergo early phase trials to assess, interpret and better understand their efficacy, tolerability and safety. *An Introduction to Statistics in Early Phase Trials* describes the practical design and analysis of these important early phase clinical trials and provides the crucial statistical basis for their interpretation. It clearly and concisely provides an overview of the most common types of trials undertaken in early phase clinical research and explains the different methodologies used. The impact of statistical technologies on clinical development and the statistical and methodological basis for making clinical and investment decisions are also explained.

- Conveys key ideas in a concise manner understandable by non-statisticians
- Explains how to optimise designs in a constrained or fixed resource setting
- Discusses decision making criteria at the end of Phase II trials
- Highlights practical day-to-day issues and reporting of early phase trials

An Introduction to Statistics in Early Phase Trials is an essential guide for all researchers working in early phase clinical trial development, from clinical pharmacologists and pharmacokineticists through to clinical investigators and medical statisticians. It is also a valuable reference for teachers and students of pharmaceutical medicine learning about the design and analysis of clinical trials.



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