



Statistical Issues in Drug Development

Stephen S. Senn

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Statistical Issues in Drug Development Stephen Senn Professor of Pharmaceutical & Health Statistics, University College, London Statistical Issues in Drug Development provides an accessible text for those working directly in drug development, regulatory and marketing departments within the pharmaceutical industry. As a consequence of regulatory authorities demanding increasingly higher standards, statistics has become a critical element in the design and conduct of drug development programmes. The concepts covered in this volume guide the non-statistician through the most pressing statistical issues and controversies in drug development. Key issues covered include:

- * Design & interpretation of clinical trials
- * Bayesian & frequentist methods
- * Sequential & cross-over trials
- * Drug monitoring & pharmaco-economics

The book has been prepared in two sections. The first section considers the role of statistics in drug development from four different perspectives: historical, philosophical, technical and professional. The second section covers a series of controversial topics such as fixed versus random effects for meta-analysis, one-sided versus two-sided tests and the ethics of placebo run-ins. The approachable and wide-ranging coverage of this book will make it invaluable to all those working in drug development and regulation.

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