



# Statistical Issues in Drug Development

By Stephen S. Senn

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Drug development is the process of finding and producing therapeutically useful pharmaceuticals, turning them into safe and effective medicine, and producing reliable information regarding the appropriate dosage and dosing intervals. With regulatory authorities demanding increasingly higher standards in such developments, statistics has become an intrinsic and critical element in the design and conduct of drug development programmes.

*Statistical Issues in Drug Development* presents an essential and thought provoking guide to the statistical issues and controversies involved in drug development.

This highly readable second edition has been updated to include:

- Comprehensive coverage of the design and interpretation of clinical trials.
- Expanded sections on missing data, equivalence, meta-analysis and dose finding.
- An examination of both Bayesian and frequentist methods.
- A new chapter on pharmacogenomics and expanded coverage of pharmaco-epidemiology and pharmaco-economics.
- Coverage of the ICH guidelines, in particular ICH E9, Statistical Principles for Clinical Trials.

It is hoped that the book will stimulate dialogue between statisticians and life scientists working within the pharmaceutical industry. The accessible and wide-ranging coverage make it essential reading for both statisticians and non-statisticians working in the pharmaceutical industry, regulatory bodies and medical research institutes. There is also much to benefit undergraduate and postgraduate students whose courses include a medical statistics component.

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## Editorial Review

### Review

For all his contributions to the development and exposition of medical statistics Stephen Senn is awarded the **2009 Bradford Hill Medal** by the Royal Statistical Society.

"This book is a thought provoking, intriguing, and often challenging read. The author is unafraid to tackle weighty philosophical and paradigmatic issues, and he generally does so with great skill and insight. ...this excellent book should serve to inspire both statisticians and life scientists." (*Journal of the American Statistical Association*, September 2009)

"For statisticians, this should be required reading for anyone considering or starting out on a career in clinical drug development. I am also quite sure that most experienced statisticians would find this a useful book to dip into on occasion ... . This book will not disappoint." (*Journal of the Royal Statistical Society: Series A (Statistics in Society)*, April 2009)

"This book is an outstanding effort from a statistician of heroic proportions. Someone like me is only capable of sitting on the curb and applauding wildly." (*Journal of Biopharmaceutical Statistics*, Volume 19, Issue 1, 2009)

### From the Publisher

This book for non-statisticians explains the statistical issues in drug development to help them plan, analyze and interpret clinical trials. It also examines the commercial pressures, regulatory standards and high scrutiny that accompany this field.

### From the Back Cover

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## **Users Review**

### **From reader reviews:**

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