



THIRD EDITION

# Statistical Issues in Drug Development

STEPHEN SENN

STATISTICS IN PRACTICE

WILEY Blackwell

# Statistical Issues In Drug Development

**Demissie Alemayehu, Birol  
Emir, Michael Gaffney**

## **Statistical Issues In Drug Development:**

*Statistical Issues in Drug Development* Stephen S. Senn, 2008-02-28 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.

*Statistical Issues in Drug Research and Development* Karl E. Peace, 2017-09-19 This book is a compilation of topics addressed by the ASA Biopharmaceutical Section work groups including the etiology and evolution of the work groups, the work group guidelines and structure and the statistical issues associated with clinical trials in clinical drug development programs.

**Statistical Issues in Drug Development** Stephen S. Senn, 2021 This will be the third edition of *Statistical Issues in Drug Development* and will be fully revised and updated to include information on the latest industry standards and guidelines. Both the first 1997 and second 2007 editions were very well received and the book has become a standard. This book is unique in providing a thorough and critical discussion of the most important and controversial issues encountered by statisticians and their life scientist colleagues on both sides of the regulatory divide in drug development. The primary purpose of the book is to encourage and facilitate discussion between statisticians and their colleagues of the many complex statistical issues that arise in drug development. The book will be suitable as a course of self-instruction for statisticians who are new to the pharmaceutical industry either because of recent graduation or change of career. It will also act as an authoritative reference for those working in drug development and provide possible topics for discussion in journal forums.

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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 **BOOK JACKET** Interface between Regulation and Statistics in Drug Development Demissie Alemayehu,Birol Emir,Michael Gaffney,2020-11-11 With the critical role of statistics in the design conduct analysis and reporting of clinical trials or observational studies intended for regulatory purposes numerous guidelines have been issued by regulatory authorities around the world focusing on statistical issues related to drug development However the available literature on this important topic is sporadic and often not readily accessible to drug developers or regulatory personnel This book provides a systematic exposition of the interplay between the two disciplines including emerging themes pertaining to the acceleration of the development of pharmaceutical medicines to serve patients with unmet needs Features Regulatory and statistical interactions throughout the drug development continuum The critical role of the statistician in relation to the changing regulatory and healthcare landscapes Statistical issues that commonly arise in the course of drug development and regulatory interactions Trending topics in drug development with emphasis on current regulatory thinking and the associated challenges and opportunities The book is designed to be accessible to readers with an intermediate knowledge of statistics and can be a useful resource to statisticians medical researchers and regulatory personnel in drug development as well as graduate students in the health sciences The authors decades of experience in the pharmaceutical industry and academia and extensive regulatory experience comes through in the many examples throughout the book **Statistical issues in pharmaceutical industry** Gary G. Koch,1990

Statistical Issues in Oncologic Clinical Drug Development Kevin Carroll,2013 Statistical Issues in Pharmaceutical Development Gary G. Koch,1993 **Controversial Statistical Issues in Clinical Trials** Shein-Chung Chow,2016-04-19 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 cov **Statistical Issues in Detection of Biological Signals in the Analysis of Microarray Gene Expression Data** Ruixiao Lu,2008

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*Proceedings of the Section on Statistical Education* American Statistical Association. Section on Statistical Education,1998    *Health Research Methodology* ,1992    **Journal of Statistical Planning and Inference** ,1994  
**Statistical Issues in the Design and Analysis of Clinical Trials** Yanning Liu,2017-01-11    **Antiepileptic Drug Development** Jacqueline A. French,Marc A. Dichter,Ilo E. Leppik,1998 Among the key issues addressed are new drug discovery current trial methodology innovative trial designs antiepileptic drug evaluation procedures and criteria and global drug development The book highlights methods for the extension of clinical trials to pediatric patients women of childbearing age the elderly and patients with new onset epilepsy In addition it provides a timely update on newly released drugs in the United States    *AMSTAT News* American Statistical Association,2004    *Journal of the Royal Statistical Society* ,2002

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