

STATISTICAL ISSUES IN DRUG RESEARCH AND DEVELOPMENT

edited by
KARL E. PEACE



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Statistical Issues In Drug Research And Development

AN Whitehead



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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

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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

Pharmaceutical Statistics Sanford Bolton, 1990 **Calcutta Statistical Association Bulletin**, 1991 *Design and Analysis of Clinical Trials* Shein-Chung Chow, Jen-Pei Liu, 2004 Presentation of principles and methodologies for various clinical trials and a well balanced summary of current regulatory requirements Emphasizes real life examples and illustrations from clinical case studies as well as numerous references Statistical issues in pharmaceutical industry Gary G. Koch, 1990 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 *Health Research Methodology*, 1992 *Nonparametric Statistical Inference* Jean Dickinson Gibbons, Subhabrata Chakraborti, 1992 **Multivariate Statistical Analysis** Narayan C. Giri, 1996 Vector and matrix algebra Groups and Jacobian of some transformations Multivariate distributions and Invariance Properties of multivariate distributions Estimators of parameters and their functions Basic multivariate sampling distributions Tests of hypotheses of mean vectors Tests concerning covariance matrices and mean vectors Discriminant analysis Principal components Canonical correlations Factor analysis **Technometrics**, 1991 Controversial Statistical Issues in Clinical Trials Shein-Chung Chow, 2016-04-19 In clinical trial practice controversial statistical issues inevitably

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