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Shein-Chung Chow Duke University USA - OMICS International

Dr Shein-Chung Chow Biography • Shein-Chung Chow, PhD is a Professor of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, North Carolina Prior to joining Duke University, he was Executive Director of National Clinical Trial Network Coordination Center of Taiwan Prior to that, Dr Chow held various

Analytical Similarity Assessment

Shein-Chung Chow, PhD Associate Director for Biosimilar Review Office of Biostatistics, OTS/CDER US Food and Drug Administration May 4th, 2018 Analytical Similarity Assessment Sample size 20 Sample size Title: Recent Development in BA/BE Studies Author: Shein-Chung Chow, PhD

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Title: Sample size calculations in clinical research (2nd edn) Shein-Chung Chow, Jun Shao and Hansheng Wang, Chapman & Hall/CRC, Boca Raton, FL, 2008

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Shein-Chung Chow is currently an Associate Director at Office of Biostatistics, CDER/FDA Dr Chow is the author or co-author of 300 methodology papers Sample Size Calculations in

DRUG SHELF-LIFE ESTIMATION - Semantic Scholar

Statistica Sinica 11(2001), 737-745 DRUG SHELF-LIFE ESTIMATION Jun Shao and Shein-Chung Chow University of Wisconsin and StatPlus, Inc Abstract: The shelf-life of a drug product is the time that the average drug charac- teristic (eg, potency) remains within an approved specification after manufacture

Encyclopedia oí Biopharmaceutical Statistics

- JJ Encyclopedia oí Biopharmaceutical Statistics Third Edition Revised md Expanded Volume One A-L Edited by Shein-Chung Chow Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, North Carolina, USA

DESIGN AND ANALYSIS OF CLINICAL TRIALS

DESIGN AND ANALYSIS OF CLINICAL TRIALS Concepts and Methodologies Second Edition SHEIN-CHUNG CHOW Millennium Pharmaceuticals, Inc Cambridge, MA JEN-PEI LIU

STATISTICAL TESTS FOR POPULATION BIOEQUIVALENCE

540 SHEIN-CHUNG CHOW, JUN SHAO AND HANSHENG WANG and the test formulation (eg, a new formulation or a generic copy) be provided Bioequivalence in average PK responses is referred to as average bioequivalence (ABE), which is also required in the FDA most recent guidance on …

STATISTICAL ASSESSMENT OF QT/QTc PROLONGATION ...

Bin Cheng1, Shein-Chung Chow2, David Burt3, and Dennis Cosmatos3 1Department of Biostatistics, Columbia University, New York, New York, USA In this section, we propose a small sample correction of the distribution of T and illustrate how to modify the test described in the previous section

On Sample Size Calculation in Bioequivalence Trials

Journal of Pharmacokinetics and Pharmacodynamics, Vol 28, No 2, 2001 On Sample Size Calculation in Bioequivalence Trials Shein-Chung Chow1 and Hansheng Wang2 Received August 1, 2000—Final

Duke-Industry Statistics Symposium http://sites.duke.edu ...

Shein-Chung Chow, Duke); 3) Phase II Clinical Trial Design and Dose Finding (Naitee Ting, and the sample size by varying its coefficient from small to large In extensive numerical studies, we demonstrate that required sample size heavily depends on the dispersion

STATISTICAL TESTS FOR POPULATION BIOEQUIVALENCE

540 SHEIN-CHUNG CHOW, JUN SHAO AND HANSHENG WANG and the test formulation (eg, a new formulation or a generic copy) be provided Bioequivalence in average PK responses is referred to as average bioequivalence (ABE), which is also required in the FDA most recent guidance on bioequivalence studies for orally administered drug products (FDA (2000))

Sample Size Determination Based on Rank Tests in Clinical ...

equations are usually involved when solving the required sample size In this arti-cle, we derive formulas for sample size calculation based on the three most com-monly used rank-based tests, namely, one-sample rank-sum test, two-sample rank-sum test, and test for independence We first derive the variabilities of these

Table of Contents for (9781439813584) Design and Analysis ...

Chow, Shein-Chung ISBN-13: 9781439813584 Table of Contents Preface Preliminaries Introduction History of Bioavailability Studies Formulation and Routes of Administration Pharmacokinetic Parameters Clinically Important Differences Assessment of Bioequivalence Decision Rules and Regulatory Aspects Statistical Considerations Aims and Structure of

Probability monitoring procedures for sample size ...

Probability monitoring procedures for sample size determination Zhipeng Huang a and Shein-Chung Chowb aOffice of Biostatistics, Office of Translational Science, CDER, FDA, Silver Spring, MD, USA; bDepartment of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, NC, USA

Orphanet Journal of Rare Diseases

Orphanet Journal of Rare Diseases Review Open Access Adaptive design methods in clinical trials – a review Shein-Chung Chow*1 and Mark Chang2 Address: 1Duke University School of Medici ne, Durham, North Carolina, USA and 2Millennium Pharmaceuticals, In c, Cambridge, Massachusetts, USA

- ßxj + ej, j = 1, ,n, (1.1) - JSTOR

738 JUN SHAO AND SHEIN-CHUNG CHOW at time x is a + ßx Throughout the paper, we assume that the drug charac teristic decreases as time increases, ie, ß in (11) is negative, and that the drug product expires if its average characteristic is below a given specification constant r]

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Editor-in-Chief Shein-Chung Chow, PhD Professor Department of Biostatistics and Bioinformatics Duke University School of Medicine Durham, North Carolina, USA Series Editors B

e t rics f iost r u DOI:n a l atist ournal of iometrics ...

Shein-Chung Chow1* and Fuyu Song2 1Duke University School of Medicine, Durham, North Carolina, USA Based on formulas provided in Chow, Shao, and Wang [8], sample size requirement for testing non-inferiority or equivalence for achieving an 80% power at the 5% level of significance