doi: 10.4172/0975-0851.1000100

Joint Meeting

OMICS Group Conferences
Accelerating Scientific Discovery

2nd World Congress on Bioavailability & Bioequivalence: Pharmaceutical R & D Summit-2011

International Conference on Pharmaceutics & Novel Drug Delivery Systems

Quantitative evaluation of Bioequivalence/ Biosimilarity

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Biological products or medicines are therapeutic agents which are produced using a living system or organism. Access to these life-saving biological products is limited because of their expensive costs. Patents of the early biological products will be soon expired in the next few years. This allows other biopharmaceutical/biotech companies to manufacture the generic versions of the biological products, which are referred to the follow-on biological products by the United States Food and Drug Administration (FDA) or biosimilar medicinal products by the European Medicine Agency (EMA) of the European Union (EU). Competition of cost-effective follow-on biological products with equivalent efficacy and safety can cut down the costs and hence increase patients' access to the much needed biological pharmaceuticals. Unlike the conventional pharmaceuticals of small molecular, the complexity and heterogeneity of the molecular structure, complicated manufacturing process, different analytical methods, and possibility of severe immunogenecity reactions make evaluation of equivalence (similarity) between the biosimilar products and their corresponding innovator product a great challenge for both scientific community and regulatory agencies. In this paper, we will provide an overview of the current regulatory requirements for approval of biosimilar products. A review of current criteria for evaluation of bioequivalence for the traditional chemical generic products is provided. In addition, statistical considerations including design, criteria, fundamental biosimilar assumption and statistical methods are proposed. The possibility of using genomic data in evaluation of biosimilar products is also explored.

Biography

Shein-Chung Chow, Ph.D. is a Professor at the Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, North Carolina, USA. Dr. Chow is currently the Editor-in-Chief of the Journal of Biopharmaceutical Statistics and Biostatistics Book Series of Chapman and Hall/CRC Press. He is a Fellow of the American Statistical Association. Dr. Chow is the author or co-author over 200 methodology papers and 18 books, which include Design and Analysis of Bioavailability and Bioequivalence Studies and Sample Size Calculation in Clinical Research. Dr. Chow received his Ph.D. in statistics from the University of Wisconsin, Madison, Wisconsin, USA.