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Scientifi c factors for assessing biosimilarity and interchangeability of follow-on biologics

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Abstract

When an innovator biological product is going off patient, biopharmaceutical and/or biotech companies may file applications for regulatory approval of biosimilar products. Unlike the small molecular drug products, the complexity and heterogeneity of the molecular structure, complicated manufacturing process, different analytical methods, and possibility of severe immunogenecity reactions make evaluation of biosimilar products a great challenge for both scientific community and regulatory agencies. In this presentation, I will provide an overview of scientific/statistical factors regarding design and analysis of biosimilar products for regulatory approval of biosimilar products. These scientific/statistical issues include, but are not limited to, fundamental biosimilarity assumption, criteria, design and analysis for assessment of biosimilarity and drug interchangeability based on the concept of switching and/or alternating. In addition, a newly developed biosimilar index based on reproducibility probability of claiming bio similarity proposed by Chow et al. (2011) is discussed. The proposed bio similar index can not only address the question regarding "how similar is similar?" but also the issue of drug interchange ability in terms of the concept of switching and/or alternating under appropriate study design

.Biography

Prior to joining Duke University, Chow was the Director of TCOG (Taiwan Cooperative Oncology Group) Statistical Center and the Executive Director of National Clinical Trial Network Coordination Center. Prior to that, Chow also held various positions in the pharmaceutical industry such as Vice President, Biostatistics, Data Management, and Medical Writing at Millennium Pharmaceuticals, Inc., Cambridge, MA; Executive Director, Statistics and Clinical Programming at Covance, Inc., Director and Department Head at Bristol-Myers Squibb Company, Plansboro, NJ; Senior Statistician and Research Statistician at Parke-Davis Pharmaceutical Division, Warner-Lambert Company, Ann Arbor, MI and Wyeth-Ayerst Laboratories, Rouses Point, NY. Through these positions, Chow provided technical supervision and guidance to project teams on statistical issues and presentations before partners, regulatory agencies or scientific bodies, defending the appropriateness of statistical methods used in clinical trial design or data analyses or the validity of reported statistical inferences. Chow identifi ed the best statistical and data management practices, organizes and leads working parties for development of statistical design, analyses and presentation applications, and participated on Data Safety Monitoring Boards in clinical research and development. Chow's professional activities include playing key roles in many professional organizations such as officer, Board of Directors member, Advisory Committee member, and Executive Committee member. He has served as Program-chair, session-chair/moderator, panelist and instructor/faculty at many professional conferences, symposia, workshops, tutorials and short courses. He is the Editor-in-Chief of the Journal of Biopharmaceutical Statistics. Chow is also the Editor-in-Chief of the Biostatistics Book Series at Chapman and Hall/CRC Press of Taylor & Francis Group. He was elected Fellow of the American Statistical Association in 1995 and an elected member of the ISI (International Statistical Institute) in 1999. He was the recipient of the DIA Outstanding Service Award (1996), ICSA Extraordinary Achievement Award (1996), and Chapter Service Recognition Award of the American Statistical Association (1998). Chow was appointed Scientific Advisor to the Department of Health, Taiwan in 1999-2001 and 2006-date. Chow was President of the International Chinese Statistical Association, Chair of the Advisory Committee on Chinese Pharmaceutical Affairs, and a member of the Advisory Committee on Statistics of the DIA. As the author or co-author of more than 200 methodology papers and 19 books, Chow has contributed to titles such as Advanced Linear Models, Design and Analysis of Bioavailability and Bioequivalence Studies (1st, 2nd, and 3rd editions), Statistical Design and Analysis in Pharmaceutical Science, Design and Analysis of Clinical Trials (1st and 2nd editions), Design and Analysis of Animal Studies in Pharmaceutical Development, Encyclopedia of Biopharmaceutical Statistics (1st, 2nd, and 3rd editions), Sample Size Calculations in Clinical Research, Adaptive Design Methods in Clinical Trials, Statistical Design and Analysis of Stability Studies, Translational Medicine – Strategies and Statistical Methods, Handbook of Adaptive Design in Pharmaceutical and Clinical Development, and Controversial Issues in Clinical Trials. Chow is currently working on two book projects: Bridging Studies in Clinical Development and eDC in Pharmaceutical Development. Chow received a B.S. in mathematics from National Taiwan University, Taiwan, and a Ph.D. in statistics from the University of Wisconsin at Madison.