Title: Phase II Clinical Development of New Drugs

Room 1441, 25 Park Place, Georgia State University, Atlanta, GA 30303

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Abstract:

In the process of medicine discovery and development, understanding the dose-response relationship is one of the most important and challenging tasks. It is critical to identify the right range of doses in early stages of medicine development so that Phase III trials can be properly designed to confirm appropriate dose(s) for the patient. Usually in the beginning of Phase II development, there is limited information to help guide trial designs, therefore Phase II clinical trials often consist of objectives for establishing proof of concept (PoC), identifying a set of potentially safe and efficacious doses, and characterizing the dose-response relationship.

Some of the major challenges in designing these Phase II trials include the selection of dose range and frequency, clinical endpoints and/or biomarkers, and the use of control(s). Inappropriate Phase II trial designs may lead to delay of the medicine development program or waste of investment. Specifically, misleading results from poorly designed Phase II trials could force a Phase III program to confirm sub-optimal dose(s), or even stop developing a potentially useful medicine. Therefore, it is critical to consider Phase II trial designs, in the broader context of the entire medicine development plan, to make the best use of all available information, and to engage relevant experts. This short course will focus on these perspectives.

About the instructor:

Dr. Ting is a Fellow of American Statistical Association (ASA). He is currently a Director in the Department of Biostatistics and Data Sciences at BoehringerIngelheim Pharmaceuticals Inc. (BI). He joined BI in September of 2009, and before joining BI, he was at Pfizer Inc. for 22 years (1987-2009). He received his Ph.D. in 1987 from Colorado State University (major in Statistics). He has an MS degree from Mississippi State University (1979, Statistics) and a B.S. degree from the College of Chinese Culture (1976, Forestry) at Taipei, Taiwan.