Short Course of the 2019 Workshop on Biostatistics and Bioinformatics

Title: Phase II Clinical Development of New Drugs

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

1:30pm-5:30pm, May 10, 2019

Naitee Ting, Biostatistics & Data Sciences, Boehringer and Ingelheim Pharmaceuticals Inc.

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 consists 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.

Dr. Ting published articles in Technometrics, Statistics in Medicine, Drug Information Journal, Journal of Statistical Planning and Inference, Journal of Biopharmaceutical Statistics, Biometrical Journal, Statistics and Probability Letters, and Journal of Statistical Computation and Simulation. His book "Dose Finding in Drug Development" was published in 2006 by Springer, and is considered as the leading reference in the field of dose response clinical trials. The book "Fundamental Concepts for New Clinical Trialists", co-authored with Scott Evans, was published by CRC in 2015. Another book "Phase II Clinical Development of New Drugs", co-authored with Chen, Ho, and Cappelleri was published in 2017 (Springer). He is an adjunct professor of Columbia University and University of Connecticut. He has been an active member of both the ASA and the International Chinese Statistical Association (ICSA).