Seventy Fourth Annual Deming Conference on Applied Statistics Tropicana Casino and Resort, Havana Tower, Atlantic City, NJ Sponsored by the Biopharmaceutical Section of the ASA and the Metropolitan Section of the ASQ

Monday December 3, 2018 Registration: $6:30 \Rightarrow 8$ AM Hot Breakfast $7 \Rightarrow 8$ AM

8 ⇒ 9 AM: Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Drugs in China Dr. Ruyi He, MD, Chief Scientist, Center for Drug Evaluation, Chinese Food and Drug Administration

Session A

Recent Development on Bayesian Clinical Trial Designs Using Historical Data Professor: Ming-Hui Chen, University of Connecticut Moderator: Naitee Ting

Session B

Subgroup Identification: A Comparative Review Professor Wei-Yin Loh, University of Wisconsin - Madison Moderator: Ivan S. F. Chan

Lunch (On Your Own) 12 ⇒ 1:30 PM

Session C &

Statistical Challenges in the Analysis of Biomarker Data Professor Stephen W. Looney, Augusta University Moderator: Kalyan Ghosh

Session D .

Bayesian Nonlinear Models for Bactericidal Activity of Tuberculosis Drugs Dr. Divan A. Burger, University of Pretoria Prof. Ding-Geng Chen, University of North Carolina – Chapel Hill (UNC) Moderator: Walter R. Young

7:00 PM Speaker's and Awards Dinner (Optional Added Fee Event)

Tuesday December 4. 2018 Registration: $6:30 \Rightarrow 8$ AM Hot Breakfast $7 \Rightarrow 8$ AM

8 ⇒ 9 AM: Recent Advances in Regulatory Statistics in Cardio-Renal and CNS Clinical Trials Dr. Hsien-Ming James Hung, FDA

Session E .

Experiences in Designing and Analyzing Vaccine Outcome Studies Dr. Scott Paterson, Sanofi-Pasteur Moderator: Fred Balch

Session F &

Advanced Visual Analytics of Safety Data from Different Data Sources –
Approaches and Available Tools
Drs. Melvin Munsaka (AbbVie), Kefei Zhou (Jazz Pharmaceuticals)
Krishan P. Singh (GSK)

Moderator: Ivan S. F. Chan

Lunch (On Your Own) 12:15 ⇒ 1:45 PM

Session G 🕮

Text Mining with R: A Tidy Approach
Dr. Julia Silge, Stack Overflow
Moderator: Fred Balch

Session H 🕮

Statistical Topics in Health Economics and Outcomes Research:
Patient-Reported Outcomes, Meta-Analysis, and Health Economics
Dr. Joseph C. Cappelleri, Pfizer

Professor Thomas Mathew, University of Maryland, Baltimore County Moderator: Wenjin Wang

Wednesday December 5, 2018 Registration: $6:30 \Rightarrow 8$ AM Hot Breakfast $7 \Rightarrow 8$ AM

Session I .

Risk Factor Identification & Comparative Effectiveness Research Using Electronic Health Records: Challenges, Analytical Strategies & Recent Developments Drs. Rebecca Hubbard and Yong Chen, University of Pennsylvania Bin Huang, Cincinnati Children's Hospital Medical Center Moderator: Kalyan Ghosh

Session J 🌲

Designing and Integrating the RCT/RWE in Safety Decision Making
Drs. Rima Izem, FDA
Richard C. Zink, TARGET PharmaSolutions Inc.
William Wang, Merck

Lunch (On Your Own) 12:15 ⇒ 1:15 PM

Session K

Overview Of Non-Inferiority Trial Design, Analysis and Reporting Drs. Susan Wang and Gang Cheng, Boehringer Inglelheim China Moderator: Naitee Ting

Session L

Moderator: Ivan S. F. Chan

FDA Advisory Committee Meeting and Non-inferiority Case Study
Drs. Bob Powell (UNC), Steve Wilson (Consultant), & William Wang (Merck)
Moderator: Ivan S. F. Chan

♣ Sessions will have their breaks extended by 15 minutes for Poster Presentations

Thursday December 6, 2018 Short Course Registration and Hot Breakfast: 6:30 ⇒ 8 AM

8:00⇒9:30 Lecture / 9:30⇒9:50 Break / 9:50⇒11:20 Lecture / 11:20⇒12:40 Lunch on Your Own / 12:40⇒2:10 Lecture / 2:10⇒2:30 Break / 2:30⇒4:00 Lecture) / 4:00⇒4:20 Break / 4:20⇒5:50 Lecture

Fundamental Concepts for New Clinical Trialists Dr. Naitee Ting, Boehringer Inglelheim
Professor Scott R. Evans, Harvard School of Public Health
Moderator: Xiaoming Li

Text: Fundamental Concepts for New Clinical Trialists

Design, Data Monitoring & Analysis of Clinical Trials With Multiple Outcomes Dr. Toshimitsu Hamasaki, Osaka University and National Cerebral and Cardiovascular Center, Japan Dr. Hsien-Ming James Hung, FDA

Dr. Hsien-Ming James Hung, FDA Moderator: Alfred H. Balch

Texts: Group-Sequential Clinical Trials with Multiple Co-Objectives Sample Size Determination in Clinical Trials with Multiple Endpoints

Friday December 7, 2018

Hot Breakfast 7⇒8 / 8:00⇒9:30 Lecture / 9:30⇒9:50: Break / 9:50⇒11:20: Lecture / 11:20⇒11:40 / Break / 11:40⇒1:10: Lecture