

# Updates to Program Book

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Monday, June 27. 10:45 AM-12:25 PM

Session 2: Statistical Challenges from Survey, Behavioral and Social Data (Invited)  
Room: Palace, 9th floor  
11:36 AM Statistical Methods in Search Engine Ranking  
will be presented by Daryl Pregibon, instead of Rachel Schutt

Monday, June 27. 2:00 PM-3:40 PM

Session 27: Challenges and Developments in Survival Analysis  
Chair: Yang Feng, Columbia University.

Monday, June 27. 3:50 PM-5:30 PM

Session 39: Next Generation Pharmacovigilance: Methodological and Policy Challenges (Invited)  
Room: Plymouth, 9th floor  
Organizer: Zhezhen Jin, Columbia University.  
Chair: Mengling Liu, New York University.

3:55 PM Approaches to Improving Safety Monitoring of Biologic Products at Food and Drug Administration/CBER  
Robert Ball. U.S. Food and Drug Administration, CBER/OBE

4:18 PM Use of Geographic Variation in Comparative Effectiveness and Pharmacovigilance Studies  
Mary Beth Landrum<sup>1</sup>, Frank Yoon<sup>1</sup>, Elizabeth Lamont<sup>1</sup>, Ellen Meara<sup>2</sup>, Amitabh Chandra<sup>3</sup> and Nancy Keating<sup>1</sup>. <sup>1</sup>Harvard Medical School <sup>2</sup>Dartmouth Medical School <sup>3</sup>Harvard Kennedy School

4:41 PM Robsert Davis Director of Research, Center for Health Research, Kaiser Permanente, Atlanta, Georgia

5:04 PM Discussion

Marianthi Markatou. IBM Thomas J. Watson Research Center and Cornell University

5:27 PM Floor Discussion.

Tuesday, June 28. 10:00 AM -11:40 AM

Session 44: Interface Between Nonparametric and Semiparametric Analysis and Genetic Epidemiology (Invited)

Room: Palace, 9th floor

Organizers: Yuanjia Wang, Columbia University; Naihua Duan, Columbia University.

Chair: Yuanjia Wang, Columbia University.

10:05 AM Statistical Methods for Rare Variant Association Testing for Sequencing Data

Xihong Lin. Harvard School of Public Health

10:28 AM A Shared-Association Model for Genetic Association Studies with Outcome Stratified Samples

Colin O. Wu, Gang Zheng and Minjung Kwak. National Heart Lung and Blood Institute

10:51 AM Bayesian Quantitative Trait Loci Mapping for Gene-Gene and Gene-Environment Interactions

Fei Zou. University of North Carolina at Chapel Hill

11:14 AM On the semiparametric case-only approach and beyond

Eric Tchetgen Tchetgen, Harvard School of Public Health

11:37 AM Floor Discussion.

On the semiparametric case-only approach and beyond

Eric Tchetgen Tchetgen, Harvard School of Public Health

Title: On the semiparametric case-only approach and beyond

Abstract: We propose a semiparametric case-only estimator of multiplicative gene-environment or gene-gene interactions, under the assumption of conditional independence of the two factors given a vector of potential confounding variables. Our estimator yields valid inferences on the interaction function if either but not necessarily both of two unknown baseline functions of the confounders is correctly modeled.

Furthermore, when both models are correct, our estimator has the smallest possible asymptotic variance for estimating the interaction parameter in a semiparametric model that assumes that at least one but not necessarily both baseline models are correct. When data on controls is available, we show how the approach can be generalized to recover more efficient estimates of G-E main effects

Session 48: The Totality of Evidence in Safety and Efficacy Evaluation of Medical Products (Invited)

Room: Nederlander, 9th floor

Organizers: Qian Li, U.S. Food and Drug Administration; Greg Soon, U.S. Food and Drug Administration.

Chair: Yijie Zhou, Merck & Co., Inc.

10:05 AM Collective Evidence

Qian Li. U.S. Food and Drug Administration

10:28 AM Adaptive Statistical Methods for Control of Type I Error Rate for Both Multiple Primary and Secondary Endpoints.

Abdul J Sankoh and Haihong Li. Vertex Pharmaceuticals Inc. Discussant: Greg Soon, U.S.

10:51 AM Collective Evidence in Medical Devices

Gregory Campbell. U.S. Food and Drug Administration.

11:14 AM Discussant: Greg Soon, U.S. Food and Drug Administration

11:37 AM Floor Discussion.

Collective Evidence in Medical Devices

Gregory Campbell. U.S. Food and Drug Administration.

Abstract: Collective evidence in medical devices can be used in a number of applications. It can be used in a premarket submission using meta-analytical techniques for multiple studies as well as for a reclassification petition to downclassify a device. Collective evidence is also of use in developing Objective Performance Criteria (OPCs) for future premarket success criterion for safety or effectiveness as well as formulating prior information from previous studies for a Bayesian analysis.

Tuesday, June 28. 1:30 PM-3:10 PM

Session 68: Theoretical Developments  
Chair: Judy Hua Zhong, New York University

Tuesday, June 28. 6:30 PM-10:00 PM

Banquet and awards ceremony.