Program Overview

Sunday, June 9

8:00AM-5:00PM

<table>
<thead>
<tr>
<th>Room</th>
<th>Session</th>
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<tbody>
<tr>
<td>White Oak Dining Room A</td>
<td>Short Course 1: Novel Approaches to Multiple Test Problems</td>
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<tr>
<td>White Oak Dining Room B</td>
<td>Short Course 2: Non-inferiority, Equivalence and Similarity Clinical Trials - The Statistical Foundations</td>
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</table>

1:00PM-5:00PM

| White Flint Amphitheater | Short Course 3: Design and Analysis of Group Sequential Trials: Recent Advances and Software |
| Forest Glen             | Short Course 4: Statistical Age-Period-Cohort Analysis Using R with Applications to Health Studies, Social Research, Economics and Finance |
| Glen Echo               | Short Course 5: Building Adaptive Clinical Trials                         |

Monday, June 10  Morning

8:05AM-9:40AM

<table>
<thead>
<tr>
<th>Salon E</th>
<th>Conference Opening Session</th>
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<tbody>
<tr>
<td>Salon E</td>
<td>Keynote Session I (Invited)</td>
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</tbody>
</table>

10:00AM-11:40AM

| Middlebrook       | Session 1: Model Based Drug Development---an Emerging Multi-disciplinary Collaborative Prognostic Tool for Drug Development (Invited) |
| Brookside A       | Session 4: Clinical Trials with Adaptive Features in Medical Product Development (Invited) |
| Brookside B       | Session 6: High-Dimensional Inference in Statistical Applications (Invited) |
| Linden Oak        | Session 8: Bayesian Methods for Big Biological Data Analysis (Invited) |
| Salon F           | Session 12: Meta-analysis in Clinical Trials: Globalization of Drug Development (Invited) |
| Salon G           | Session 13: Recent Advances in Event History Analysis (Invited) |
| Salon H           | Session 15: Handling Missing Data in Clinical Trial Design and Analysis: Applications and Practices (Invited) |
| White Flint Amphitheater | Session 30: Causal Inference in Clinical Trials (Invited) |
| White Oak Dining Room A | Session 39: 75 Years of Innovation in the Quantitative Sciences for Pharmaceutical Development (Invited) |
| White Oak Dining Room B | Session 50: The Role of Recurrent Event Data Approaches in Cardiovascular Outcome Trials (Invited) |
| Salon E           | Session 76: New Advances in Clinical Trial Design and Analysis (Invited) |
| Oakley            | Session C5: Medical Devices (Contributed) |

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### Monday, June 10 Afternoon

1:20PM-3:00PM

<table>
<thead>
<tr>
<th>Location</th>
<th>Session</th>
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<tbody>
<tr>
<td>Brookside A</td>
<td>Session ICSA3: Multidisciplinary statistics</td>
</tr>
<tr>
<td>Brookside B</td>
<td>Session ICSA4 - The Jiann-Ping Hsu Invited Session on Biostatistical and Regulatory Sciences (Invited)</td>
</tr>
<tr>
<td>Linden Oak</td>
<td>Session 10: Innovative Methods in Multivariate Analysis (Invited)</td>
</tr>
<tr>
<td>Salon F</td>
<td>Session 14: Advances in Genomic (Invited)</td>
</tr>
<tr>
<td>Salon G</td>
<td>Session 17: New Statistical Challenges for Analysis of Time to Event Data (Invited)</td>
</tr>
<tr>
<td>Salon H</td>
<td>Session 19: Statistical methods for evaluating prediction accuracy of biomarkers (Invited)</td>
</tr>
<tr>
<td>White Flint</td>
<td>Session 21: Statistics and Its Interface (Invited)</td>
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<tr>
<td>Amphitheater</td>
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</tr>
<tr>
<td>Middlebrook</td>
<td>Session 25: New Challenges in Empirical Likelihood (Invited)</td>
</tr>
<tr>
<td>Oakley</td>
<td>Session 29: Recent Statistical Methods for Interval-censored Data Analysis (Invited)</td>
</tr>
<tr>
<td>White Oak</td>
<td>Session 32: Challenges and Recent Developments in Survival Data Analysis (Invited)</td>
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<tr>
<td>Dining Room A</td>
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</tr>
<tr>
<td>White Oak</td>
<td>Session 42: Panel Discussion: Regulatory and Statistical Issues in Multi-Regional Clinical Trials (Invited)</td>
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<tr>
<td>Dining Room B</td>
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<tr>
<td>Salon E</td>
<td>Session 58: Recent Developments and Applications of Bayesian Methods in Medical device and Clinical Trials (Invited)</td>
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3:20PM-5:00PM

<table>
<thead>
<tr>
<th>Location</th>
<th>Session</th>
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</thead>
<tbody>
<tr>
<td>Middlebrook</td>
<td>Session C2: High Dimensional Regression/Machine Learning (Contributed)</td>
</tr>
<tr>
<td>Brookside A</td>
<td>Session 7: Lifetime Data Analysis (Invited)</td>
</tr>
<tr>
<td>Oakley</td>
<td>Session 9: Methods in Health Policy Research (Invited)</td>
</tr>
<tr>
<td>Brookside B</td>
<td>Session 24: Emerging Challenges in Statistical Design and Analysis for Medical Product Evaluation (Invited)</td>
</tr>
<tr>
<td>Linden Oak</td>
<td>Session 26: Statistical Methods in Disease Surveillance (Invited)</td>
</tr>
<tr>
<td>Salon F</td>
<td>Session 27: Statistical Methods in Dissecting Complex Traits (Invited)</td>
</tr>
<tr>
<td>Salon G</td>
<td>Session 31: Global Efforts to Characterize Human Genome Diversity and to Elucidate the Genetic Basis of Complex Traits (Invited)</td>
</tr>
<tr>
<td>Salon H</td>
<td>Session 49: Challenges related to treatment effect heterogeneity and subpopulations in drug development and comparative effectiveness (Invited)</td>
</tr>
<tr>
<td>White Flint</td>
<td>Session 61: Panel Discussion: Opportunities and Challenges in the Use of Recurrent Event Endpoints in Cardiovascular Outcome Trials (Invited)</td>
</tr>
<tr>
<td>Amphitheater</td>
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</tr>
<tr>
<td>White Oak</td>
<td>Session 65: Estimation and Testing for Temporally/Spatially Correlated Data in Semiparametric Models (Invited)</td>
</tr>
<tr>
<td>Dining Room A</td>
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</tr>
<tr>
<td>White Oak</td>
<td>Session 73: Opportunities and challenges: The new FDA draft guidance for accelerated approval using pCR endpoint in breast cancer areas (Invited)</td>
</tr>
<tr>
<td>Dining Room B</td>
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</tr>
<tr>
<td>Salon E</td>
<td>Session 82: Recent advances in statistical genetics and genomics (Invited)</td>
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</table>
## Tuesday, June 11 Morning

### 8:00AM-9:40AM

<table>
<thead>
<tr>
<th>Location</th>
<th>Session</th>
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<tbody>
<tr>
<td>Brookside A</td>
<td>Session ICSA2 - Celebrating 40 years of Biopharmaceutical Statistics Career: Dedication to Robert. T. O'Neill, Ph.D (ICSA Biometrics Section Special Invited Session)</td>
</tr>
<tr>
<td>Brookside B</td>
<td>Session 11: Statistical Classification Methods: Diagnostic Tests and Predictive Analyses (Invited)</td>
</tr>
<tr>
<td>Linden Oak</td>
<td>Session 16: Recent statistical developments in diagnostic studies: Multiple classes, genomic data, and beyond (Invited)</td>
</tr>
<tr>
<td>Salon F</td>
<td>Session 28: Recent advances in the analysis of prevalent cohort survival data (Invited)</td>
</tr>
<tr>
<td>Salon G</td>
<td>Session 33: Advances in Statistical Modeling of Next-Generation Sequencing (Invited)</td>
</tr>
<tr>
<td>Salon H</td>
<td>Session 34: Bridging to Statistics outside Pharmaceutical Industry: Can we be more efficient in designing and supporting Clinical Trials? (Invited)</td>
</tr>
<tr>
<td>White Flint Amphitheater</td>
<td>Session 36: Advances in Multi-Regional Clinical Trials (Invited)</td>
</tr>
<tr>
<td>White Oak Dining Room A</td>
<td>Session 37: Functional Data Analysis: Applications and New Advances (Invited)</td>
</tr>
<tr>
<td>White Oak Dining Room B</td>
<td>Session 40: Benefit-Risk Evaluation of Medical Products in Drug Development (Invited)</td>
</tr>
<tr>
<td>Salon E</td>
<td>Session 54: Planning and Implementing Clinical Trials with an Adaptive Design: Challenges in a Regulatory Setting (Invited)</td>
</tr>
<tr>
<td>Oakley</td>
<td>Session C3: Design and Analysis of Clinical Trials (Contributed)</td>
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### 10:00AM-11:40AM

<table>
<thead>
<tr>
<th>Location</th>
<th>Session</th>
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<tbody>
<tr>
<td>Brookside A</td>
<td>Session ICSA1 Student Travel Award I (Invited)</td>
</tr>
<tr>
<td>Brookside B</td>
<td>Session 23: Comparative Effectiveness Research, Inference and Applications (Invited)</td>
</tr>
<tr>
<td>Linden Oak</td>
<td>Session 41: Design and Tests of Equivalence and Biosimilar Trials (Invited)</td>
</tr>
<tr>
<td>Salon F</td>
<td>Session 45: Recent Developments in Biomarker Research and Medical Diagnosis (Invited)</td>
</tr>
<tr>
<td>Salon G</td>
<td>Session 46: Recent Developments and Applications of Bayesian Methods in Clinical Trial Design and Analysis (Invited)</td>
</tr>
<tr>
<td>Salon H</td>
<td>Session 47: Inverse Problems in Biostatistical Research (Invited)</td>
</tr>
<tr>
<td>White Flint Amphitheater</td>
<td>Session 48: Statistical inference for high-dimensional data with applications in genetics (Invited)</td>
</tr>
<tr>
<td>White Oak Dining Room A</td>
<td>Session 52: Considerations for emerging markets in multiregional clinical trials (Invited)</td>
</tr>
<tr>
<td>White Oak Dining Room B</td>
<td>Session 68: FDA Drug Safety – Regulatory and Statistical Considerations (Invited)</td>
</tr>
<tr>
<td>Salon E</td>
<td>Session 77: New Developments in Postmarketing Safety Evaluation (Invited)</td>
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<tr>
<td>Oakley</td>
<td>Session C4: Semi-Parametric/Non-Parametric Methods and Beyond (Contributed)</td>
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### Tuesday, June 11  Afternoon

**1:20PM-3:00PM**

<table>
<thead>
<tr>
<th>Location</th>
<th>Session</th>
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<tbody>
<tr>
<td>Brookside A</td>
<td>Session 38: Predictive Enrichment: Design, Development Strategies, and Methodological Issues (Invited)</td>
</tr>
<tr>
<td>Brookside B</td>
<td>Session 43: High dimensional Data - Modeling, Computation and Application (Invited)</td>
</tr>
<tr>
<td>Linden Oak</td>
<td>Session 51: Bayesian considerations in non-inferiority setting – Update from the DIA Bayesian Scientific Working Group (Invited))</td>
</tr>
<tr>
<td>Salon F</td>
<td>Session 59: Recent Developments in Early Clinical Development Statistics (Invited)</td>
</tr>
<tr>
<td>Salon G</td>
<td>Session 60: Statistical and Computational Challenges for Metagenomic Sequencing Data Analysis (Invited)</td>
</tr>
<tr>
<td>Salon H</td>
<td>Session 62: Trial Modeling and Simulation in New Drug Developments (Invited)</td>
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<tr>
<td>White Flint Amphitheater</td>
<td>Session 63: Markov Chains and Their Applications (Invited)</td>
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<tr>
<td>White Oak Dining Room A</td>
<td>Session 64: Accommodate Regional Regulatory Requirements Through International Collaboration (Invited)</td>
</tr>
<tr>
<td>White Oak Dining Room B</td>
<td>Session 70: Recent Advances in Genomics (Invited)</td>
</tr>
<tr>
<td>Salon E</td>
<td>Session 79: Bayesian approaches for drug safety evaluation (Invited)</td>
</tr>
<tr>
<td>Oakley</td>
<td>Session C1: Survival Analysis and Bayesian Methods (Contributed)</td>
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**3:20PM-5:00PM**

<table>
<thead>
<tr>
<th>Location</th>
<th>Session</th>
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<tbody>
<tr>
<td>Brookside A</td>
<td>Session 20: High Dimensional Statistics in Genetics and Genomics (Invited)</td>
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<tr>
<td>Brookside B</td>
<td>Session 22: Subgroup identification in clinical trials and observation studies - beyond test of interaction (Invited)</td>
</tr>
<tr>
<td>Oakley</td>
<td>Session 35: Novel development in risk predication (Invited)</td>
</tr>
<tr>
<td>Linden Oak</td>
<td>Session 57: Application of Bayesian Probability of Success (POS) in Clinical Trials (Invited)</td>
</tr>
<tr>
<td>Salon F</td>
<td>Session 66: How Adaptive Design Software can help in designing and analyzing data obtained from adaptive design trials? (Invited)</td>
</tr>
<tr>
<td>Salon G</td>
<td>Session 67: Non-clinical CMC Issues – Regulatory and Statistical (Invited)</td>
</tr>
<tr>
<td>Salon H</td>
<td>Session 69: Biomarker and Subgroup Identification for Development of Tailored Therapies (Invited)</td>
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<tr>
<td>White Flint Amphitheater</td>
<td>Session 71: Safety Analysis and Graphics Presentation (Invited)</td>
</tr>
<tr>
<td>White Oak Dining Room A</td>
<td>Session 72: Evidential Approaches to Multiplicity of Hypothesis Testing (Invited)</td>
</tr>
<tr>
<td>White Oak Dining Room B</td>
<td>Session 75: Meta-analysis and multiple comparisons in Clinical Trials (Invited)</td>
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<tr>
<td>Salon E</td>
<td>Session 84: Recent advances in longitudinal analysis (Invited)</td>
</tr>
<tr>
<td>Middlebrook</td>
<td>Session 85: Statistical Approaches in Genetic Association Studies and Related Topics</td>
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**6:30PM-10:30PM**

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<thead>
<tr>
<th>Location</th>
<th>Session</th>
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<tbody>
<tr>
<td>New Fortune Chinese</td>
<td>Session 86: Recent advances in longitudinal analysis (Invited)</td>
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Wednesday, June 12

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:20AM-9:40AM</td>
<td>Salon E: Keynote Session II (Invited)</td>
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<tr>
<td>10:20AM-12:00PM</td>
<td>Salon E: Session 5: Challenges to Multiplicity Issues in Clinical Trials with Multiple Objectives (Invited)</td>
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<td>White Flint Amphitheater: Session 53: Statistical Challenges and Recent Advances in Genomics (Invited)</td>
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<td>Glen Echo: Session 56: Recent developments in graphical modeling (Invited)</td>
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<td>White Oak Dining Room A: Session 74: Clinical Trial Data Standardization and big data analysis (Invited)</td>
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<td>White Oak Dining Room B: Session 78: New Development in Causal Inferences (Invited)</td>
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<td>Salon F: Session 80: Handling non-ignorable missing data: recent developments (Invited)</td>
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<td></td>
<td>Middlebrook: Session 83: Statistical methods of analysis for binary and time-to-event related outcomes (Invited)</td>
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</table>
Sunday, June 9, 7:30AM-8:00AM
Registration and Continental Breakfast

Full-Day Courses (8:00AM-5:00PM)
(Coffee Breaks: 9:30AM-10:00AM, 2:30PM-3:00PM; Lunch: 12:00PM-1:00PM)

SC1: “Novel Approaches to Multiple Test Problems”
Room White Oak Dining Room A
Instructor Frank Bretz, Novartis Pharma AG

SC2: “Non-inferiority, Equivalence and Similarity Clinical Trials - The Statistical Foundations”
Room White Oak Dining Room B
Instructor Yi Tsong, Food and Drug Administration

Half-Day Courses (1:00PM-5:00PM)
(Coffee Breaks: 2:30PM-3:00PM)

SC3: “Design and Analysis of Group Sequential Trials: Recent Advances and Software”
Room White Flint Amphitheater
Instructors Mei-Chiung Shih and Balasubramanan Narasimhan, Stanford University

SC4: “Statistical Age-Period-Cohort Analysis Using R with Applications to Health Studies, Social Research, Economics and Finance”
Room Forest Glen
Instructor Wenjiang Fu, Michigan State University

SC5: “Building Adaptive Clinical Trials”
Room Glen Echo
Instructor Donald Berry, The University of Texas M.D. Anderson Cancer Center

Monday, June 10, 7:00AM-8:00AM
Registration and Continental Breakfast

Monday, June 10, 8:00AM-9:40AM
Conference opening session
Room Salon E
Chair Aiyi Liu, NIH/NICHD
8:05AM Welcome
Ivan Chan, Merck
8:10AM Opening Remark
Ming-Hui Chen, U Conn & ICSA President
8:15AM Opening Remark
Jie Chen, Merck Serono & ISBS President

Keynote session I (invited)
8:20AM Keynote Lecture
The science of statistical methodology versus the art of decision-making – sound principles, best practice and when to overlook them in the interest of rationale and efficient drug development and regulation
Rob Hemmings, Statistics and Pharmacokinetics Unit Manager; Medicines and Healthcare Products Regulatory Agency (MHRA), UK CHMP member, Chair SAWP; European Medicines Agency

9:00AM Keynote Lecture
The Role of Statistics in Regulatory Decision Making
Lisa Lavange, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research (CDER), US FDA

Monday, June 10, 9:40AM-10:00AM
Morning Break

Board of Directors Meeting
5:30PM-8:00PM
Room Linden Oak
Program Schedule

**Monday, June 10, 10:00AM-11:40AM**

**Session 1: Model Based Drug Development --- An Emerging Multi-disciplinary Collaborative Prognostic Tool for Drug Development (Invited)**

Room: Middlebrook  
Organizers: Rong Liu, Merck & CO., Inc  
Chair: Rong Liu, Merck & CO., Inc

10:00AM: Assessing the Cumulative Exposure Response in Alzheimer Disease Studies  
Jianing Di, Janssen Pharmaceuticals R&D

10:25AM: Confirmation: Are we Overly Obsessed?  
Joga Gobburu, University of Maryland School of Pharmacy

10:50AM: Application of a Differential Odds Model for Ordered Efficacy Endpoints of Tofacitinib in Rheumatoid Arthritis Patients  
Bei Yang, Ann Arbor Pharmacometrics Group

11:15AM: Integrated Approach to Increase Efficiency for Back-Up Compound Development  
Rong Liu, Merk &CO, Inc.

**Session 4: Clinical Trials with Adaptive Features in Medical Product Development (Invited)**

Room: Brookside A  
Organizers: Toshimitsu Hamasaki, Osaka University Graduate School of Medicine  
Chair: Chin-Fu Hsiao, National Health Research Institutes

10:00AM: Designing an adaptive trial using a combination test for survival endpoints  
Christopher Jennison, University of Bath

10:25AM: Mid-course sample size modification in group-sequential designs with co-primary endpoints  
Toshimitsu Hamasaki, Osaka University Graduate School of Medicine

10:40AM: Simulation-Guided Design for Molecularly Targeted Therapies in Oncology  
Cryus Mehta, Cytel Inc

**Session 6: High-Dimensional Inference in Statistical Applications (Invited)**

Room: Brookside B  
Organizers: Z. John Daye, University of Arizona  
Chair: Z. John Daye, University of Arizona

10:00AM: Large scale multiple testing for clustered data  
Hongyuan Cao, University of Chicago

10:25AM: Identify Interactions for Ultra-high Dimensional Data  
Hao Helen Zhang, University of Arizona

10:50AM: Identification of Signal, Noise, and Mixed Subsets in High-Dimensional Data Analysis  
X. Jessie Jeng, North Carolina State University

11:15AM: Asymptotic Equivalence of Regularization Methods in Thresholded Parameter Space  
Jinchi Lv, University of Southern California

**Session 8: Bayesian Methods for Big Biological Data Analysis (Invited)**

Room: Linden Oak  
Organizers: Faming Liang, Texas A&M University and Kai Yu, National Cancer Institute  
Chair: Kai Yu, National Cancer Institute

10:00AM: Bayesian GP Regression Analysis for Large Functional Data  
Jianqing Shi, Newcastle University

10:25AM: Simultaneous inference of copy number variants and their association to gene expression  
Mahlet Tadesse, Georgetown University

10:50AM: Integrative Bayesian Analysis of Multi-platform Genomics Data  
Veera Baladandayuthapani, University of Texas MD Anderson Cancer Center
11:15AM Bayesian Detection of Causal Rare Variants under Posterior Consistency
Faming Liang, Texas A&M University

Session 12: Meta-analysis in Clinical Trials: Globalization of Drug Development (Invited)
Room Salon F
Organizers Jessica Kim, FDA/CBER
Chair Boguang Zhen, FDA/CBER
10:00AM Impact of baseline score imbalance on systematic reviews
Rochelle Fu, Oregon Health & Preventive University
10:25AM Guidance on the implementation and reporting of a drug safety Bayesian network meta-analysis meta-analysis
David Ohlseen, Novartis Pharmaceuticals Corporation
10:50AM Meta-analysis of Observational Data
Richard Forshee, FDA/CBER
11:15AM Risk assessment using meta-analysis in the pharmaceutical regulatory setting
Mark Levenson, FDA/CDER

Session 13: Recent Advances in Event History Analysis (Invited)
Room Salon G
Organizers Xin He, University of Maryland, College Park
Chair (Tony) Jianguo Sun, University of Missouri
10:00AM Modeling and estimating terminal behavior of recurrent marker processes before failure events
Mei-Cheng Wang, Johns Hopkins University
10:25AM Parametric and Distribution-free Threshold Regression
Mei-Ling Ting Lee, University of Maryland, College Park
10:50AM Modeling Composite Degradation Processes in Lifetime Data Analysis

George Alex Whitmore, McGill University
11:15AM Empirical Likelihood Ratio Confidence Intervals for Conditional Survival Probabilities with Right Censored Data
Jian-Jian Ren, University of Maryland, College Park

Session 15: Handling Missing Data in Clinical Trial Design and Analysis: Applications and Practices (Invited)
Room Salon H
Organizers Weili He, Merck & Co., Inc.
Chair Weili He, Merck & Co., Inc.
10:00AM Testing Treatment Effect in Schizophrenia Trials with Heavy Patient Dropout
Fanhu Kong, CDER, FDA
10:20AM An Enrichment Design for Cardiovascular Drug Development
Qing Liu, Janssen R&D
10:40AM A simulation study to evaluate different analysis approaches for an outcome trial with moderate missing data
Yabing Mai, Merck & Co., Inc.
11:00AM Missing Data Strategies for Clinical Trials
Michael McIsaac, University of Waterloo
11:20AM Discussant
Fanhu Kong, FDA Qing Liu, Janssen R&D Yabing Mai, Merck & Co., Inc

Session 30: Causal Inference in Clinical Trials (Invited)
Room White Flint Amphitheater
Organizers Zhiwei Zhang, Food and Drug Administration
Chair Chenguang Wang, Johns Hopkins University
10:00AM Causal assessment of surrogacy in a meta-analysis of colorectal cancer trials
Yun Li, University of Michigan
10:25AM Statistical challenges in determining antibiotic breakpoints
Daniel B. Rubin, Food and Drug Administration

10:50AM Adjusting for observational secondary treatments in estimating the effects of randomized treatments
Min Zhang, University of Michigan

11:15AM Bayesian inference for the causal effect of mediation
Michael Daniels, University of Florida

Session 39: 75 Years of Innovation in the Quantitative Sciences for Pharmaceutical Development (Invited)

Room White Oak Dining Room A
Organizers Joshua Chen, Merck
Chair Joseph Heyse, Merck

10:00AM Deciphering Drug Effect from Brain Signals: Building a Cutting-edge Biomarker Platform with Statistical Innovation
Junshui Ma, Merck & Co., Inc

A. Lawrence Gould, Merck Investigational Research

10:40AM Clinical Trials: Doing More with Less, A Lot Less
Devan Mehrotra, Merck Early Development Statistics

11:00AM Multiplicity adjustment in seamless phase II/III trials using a biomarker for dose selection
Ivan S.F. Chan, Merck Late Development Statistics

11:20AM Discussant
Raymond P. Bain, Merck Sharp & Dohme

Session 50: The Role of Recurrent Event Data Approaches in Cardiovascular Outcome Trials (Invited)

Room White Oak Dining Room B
Organizers Byron Jones, Novartis Pharma AG
Chair Byron Jones, Novartis Pharma AG

10:00AM Recurrent event approach in CV outcome trials: opportunities and issues - from a pharmaceutical perspective
Jin Xu, East China Normal University and Novartis

10:20AM Recurrent event data approaches in cardiovascular outcome trials – A case study
Mouna Akacha, Novartis Pharma AG, Basel

10:40AM Evaluating treatment effects based on non-fatal and fatal events
Richard J Cook, University of Waterloo

11:00AM Statistical methodology for recurrent events, with application to major trials in heart failure
Stuart Pocock, London School of Hygiene and Tropical Medicine

11:20AM A Regulatory Perspective on Recurrent/Multiple Event Analyses in Cardiovascular Trials
H.M. James Hung, FDA

Session 76: New Advances in Clinical Trial Design and Analysis (Invited)

Room Salon E
Organizers Yvonne Huang, University of Maryland, Baltimore County
Chair Guoxing (Greg) Soon, FDA

10:00PM Optimal Tests of Treatment Effects for the Overall Population and Two Subpopulations in Randomized Trials, using Sparse Linear Programming
Michael Rosenblum, Johns Hopkins Bloomberg School of Public Health

10:25PM Sequential monitory of clinical trials when there are multiple primary endpoints
Peng Huang, Division of Oncology Biostatistics, Johns Hopkins University

10:50PM Imputation for Nonmonotone Nonresponse in the Survey of Industrial Research and Development
Martin Klein, U.S. Census Bureau

11:15PM Integrative genome-based drug development
Xiaogang Zhong, Georgetown University
Session C5: Medical Devices (Contributed)

Room Oakley
Chair Jack Zhou, FDA

10:00AM Method Comparison Studies Using Time Series Data in Clinical Trials of Medical Devices Chava Zibman, FDA

10:15AM Assessing Accuracy Improvement for Competing-Risk Censored Outcomes Haiwen Shi, FDA

10:30AM Hybrid robust estimators for missing data and causal inference using coarsened propensity score, with application to an observational study Jack Zhou, FDA

10:45AM The use of cure rate model in the analysis of survival time data with informative censoring Shiling Ruan, FDA

11:00AM Adaptive Design with Medical Device Trials -- A Regulatory Perspective Xiting Yang, FDA

11:15AM Multiplicity Issues in Pivotal Medical Device Trials with Testing of Superiority after Established Non-inferiority Yu Zhao, FDA

Monday, June 10, 1:20PM-3:00PM

Session ICSA3: Multidisciplinary statistics

Room Brookside A
Chair Zhezhen Jin, Columbia University

1:20PM Latent Variable Poisson models for Assessing Regularity of Circadian Patterns over Time Sung Duk Kim, NIH/NICHD

1:45PM Assessments of Condom Use in HIV-infected Patients with Generalized Partially Linear Models Hua Liang, University of Rochester

2:10PM A new class of flexible link functions with application to species co-occurrence in Cape floristic region Dipak Dey, University of Connecticut

2:35PM Analysis of a Longitudinal Quality of Life Data by Mixed Logistic Model Mounir Mesbah, University Pierre et Marie Curie

Session ICSA4 - The Jiann-Ping Hsu Invited Session on Biostatistical and Regulatory Sciences (Invited)

Room Brookside B
Chair Lili Yu, Georgia Southern University

1:20AM Bayesian Design of Superiority Clinical Trials for Recurrent Events Data with Applications to Bleeding and Transfusion Events in Myelodysplastic Syndrome Ming-Hui Chen, University of Connecticut

1:45AM Inferiority Index, Margin Function and Non-inferiority Trials with Binary Outcomes George Chi, Janssen R&D

2:10AM Predictive (Surrogate) Biomarker: Predictive of What? Sue-Jane Wang, FDA

*2:35AM Local Smoothing Support Vector Machine for Age-Dependent Classification (Jiann-Ping Hsu Pharmaceutical and Regulatory Sciences Student Paper Award) Tianle Chen, Columbia University

Monday, June 10, 11:40AM-1:20PM
Lunch on own
Session 10: Innovative Methods in Multivariate Analysis (Invited)

Room     Linden Oak
Organizers  Kelly Zou, Pfizer Inc
Chair     Kelly Zou, Pfizer Inc

1:20PM  Linear mixed models for multiple outcomes using extended multivariate skew-t distributions
Binbing Yu, National Institutes of Health

1:45PM  Evaluation of a confidence interval approach for relative inter-rater reliability in a crossed three-way random effects model
Joseph C. Cappelleri, Pfizer Inc

2:10PM  Joint confidence region estimations for area under the ROC curve and Youden index
Lili Tian, University at Buffalo

2:35PM  How to model like Bayesians without prior distributions
Samaradasa Weerahandi, Pfizer Inc

Session 14: Advances in Genomic (Invited)

Room     Salon F
Organizers  Mei-Ling Ting Lee, University of Maryland, College Park
Chair     Ruth Pfeiffer, NIH/NCI

1:20PM  Interaction-based learning in genomic analysis
Shaw-Hwa Lo, Columbia University

1:45PM  New Association Tests for Detecting Genetic Variants with Heterogeneous Effects
Kai Yu, NIH/NCI

2:10PM  Risk prediction based on hidden heritability in genome-wide association study
Nilanjan Chatterjee, NIH/NCI

2:35PM  Leveraging Local IBD Increases the Power of Case/Control GWAS with Related Individuals
Joshua Sampson, NIH/NCI

Session 17: New Statistical Challenges for Analysis of Time to Event Data (Invited)

Room     Salon G
Organizers  Lan Wang, School of Statistics, University of Minnesota
Chair     Lan Wang, School of Statistics, University of Minnesota

1:20PM  Non-Asymptotic Oracle Inequalities for the High-Dimensional Cox Regression via Lasso Data
Bin Nan, University of Michigan

1:45PM  Inference on Possibly Time-dependent Hazard Ratio While Adjusting for Confounders: The Women’s Health Initiative Data Re-analyzed
Song Yang, NIH/NHLBI

2:10PM  Recent Developments in Recurrent Event Modeling and Analysis
Edsel Pena, University of South Carolina

2:35PM  Statistical Methods for Recurrent Gap Time Data
Xianghua Luo, University of Minnesota

Session 19: Statistical methods for evaluating prediction accuracy of biomarkers (Invited)

Room     Salon H
Organizers  Eunhee Kim, Brown University
Chair     Eunhee Kim, Brown University

1:20PM  Integrative Analysis of Prognosis Data on Multiple Cancer Subtypes using Compound Group Bridge
Jin Liu, Department of Biostatistics, Yale University

1:45PM  Combination of longitudinal biomarkers in predicting binary events with application to fetal growth study
Danping Liu, Division of Epidemiology, Statistics and Prevention Research, NICHD

2:10PM  C-index for evaluating a biomarker subject to limits of detection
Lan Kong, Penn State University College of Medicine

2:35PM  Statistical issues and approaches for the evaluation of longitudinal predictive markers
Session 21: Statistics and Its Interface (Invited)

Room: White Flint Amphitheater
Organizers: Li Hsu, Fred Hutchinson Cancer Research Center
Chair: Li Hsu, Fred Hutchinson Cancer Research Center

1:20PM Model-based Inference for Subgroup Analysis
Xuming He, University of Michigan

1:45PM Clinical Trials for Personalized Medicine: New Designs and their Properties
Feifang Hu, University of Virginia

2:10PM Adaptive Procedures for Nested Processes: Application to Equal Employment
Wenjing Xu, George Washington University

2:35PM Estimation of genetic effects incorporating prior information
Ao Yuan, Howard University

Session 25: New Challenges in Empirical Likelihood (Invited)

Room: Middlebrook
Organizers: Yichuan Zhao, Georgia State University
Chair: Jing Qin, National Institute of Allergy and Infectious Diseases, NIH

1:20PM Modeling Longitudinal Data with Dropout Using Conditional Empirical Likelihood Method
Peisong Han, Department of Biostatistics, University of Michigan

1:45PM Empirical likelihood based tests for stochastic ordering under right censorship
Hsin-wen Chang, Columbia University

2:10PM Empirical Likelihood for Assessing Markov Random Field Models
Dan Nordman, Iowa State University

2:35PM Smoothed jackknife empirical likelihood method for ROC curves with missing data
Yichuan Zhao, Georgia State University

Session 29: Recent Statistical Methods for Interval-censored Data Analysis (Invited)

Room: Oakley
Organizers: Bo Cai, University of South Carolina
Chair: Xiaoyan Lin, University of South Carolina

1:20PM Weighted Logrank Tests for Interval-Censored Data when Assessment Depends on Treatment
Michael Fay, National Institute of Allergy and Infectious Diseases

1:45PM Empirical likelihood and U-statistics under interval censoring
Zhigang Zhang, Memorial Sloan-Kettering Cancer Center

2:10PM EM algorithm for regression analysis of interval-censored data under the proportional hazards model: an application to mother-to-infant HIV transmission data
Lianming Wang, University of South Carolina

2:35PM Nonparametric treatment comparison for interval-censored data
Jianguo (Tony) Sun, University of Missouri

Session 32: Challenges and Recent Developments in Survival Data Analysis (Invited)

Room: White Oak Dining Room A
Organizers: Wenbin Lu, North Carolina State University
Chair: Rui Song, North Carolina State University

1:20PM Corrected Profile Likelihood for Proportional Hazards Models with Covariate Measurement Error
Grace Y. Yi, Department of Statistics and Actuarial Science, University of Waterloo

1:45PM A New Semiparametric Estimation Method for Accelerated Hazards Mixture Cure Model
Jiajia Zhang, Department of Biostatistics, University of South Carolina
2:10PM  Semiparametric Analysis of Right-Censored Data with Temporal Covariate Effects
Guoqing Diao, George Mason University

2:35PM  Mixture cure rate model with nonparametric spline regression components
Tianlei Chen, Virginia Tech

Session 42: Panel Discussion: Regulatory and Statistical Issues in Multi-Regional Clinical Trials (Invited)
Room White Oak Dining Room B
Organizers Frank Bretz, Novartis
Chair Jie Chen, Merk Serono

Panelist:
Yuki Ando, PMDA
Lisa Lavange, FDA
Qin Huang, SFDA
Rob Hemmings, MHRA

Discussant:
Bruce Binkowitz, Paul Galo, Hui Quan and Bill Wang, various industry companies

Session 58: Recent Developments and Applications of Bayesian Methods in Medical device and Clinical Trials (Invited)
Room Salon E
Organizers Dongchu Sun, East China Normal University and University of Missouri
Chair Dongchu Sun, East China Normal University and University of Missouri

1:20PM  Analyzing safety data: A redirection of applying standard frequentist methods
Jerry Weaver, Novartis

1:45PM  Bayesian Estimate of Population size Via Capture-recapture Model with Time Variation and Behavioral Response
Xiaoyin Wang, Towson University

2:10PM  Bayesian Analysis for Binary Response Clinical Trial with Imperfect Reference Standard
Zhonggai Li, Novartis

2:35PM  A Bayesian Extension of the Hypergeometric Test for Functional Enrichment Analysis
Jing Cao, Southern Methodist University

Monday, June 10, 3:00PM-3:20PM
Afternoon Break
Monday, June 10, 3:20PM-5:00PM

Session C2: High Dimensional Regression/ Machine Learning (Contributed)

Room Middlebrook
Chair Yuping Zhang, The Jackson Laboratory for Genomic Medicine

3:20PM Stable estimation in dimension reduction by sub-sampling with random weights
Wenbo Wu, University of Georgia

3:35PM Principal trend analysis for time-course genomic data
Yuping Zhang, The Jackson Laboratory for Genomic Medicine

3:50PM On the Focused Information Criterion for Variable Selection
Binhuan Wang, New York University

4:05PM Analyzing Multivariate Longitudinal Data with Latent Variable Approach
Depeng Jiang, University of Manitoba

4:20PM Integrative Analysis of Cancer Prognosis Data with Contrasted Group Bridge Penalization
Xingjie Shi, Yale University

4:35PM Robust Statistical Analysis of RNA Seq Studies
Yuefeng Lu, Sanofi-Aventis

Session 7: Lifetime Data Analysis (Invited)

Room Brookside A
Organizers Mei-Ling Ting Lee, University of Maryland, College Park
Chair Chao A. Hsiung, National Health Research Institute, Taiwan

3:20PM On criteria for evaluating risk prediction models for public health applications
Ruth Pfeiffer, NIH/NCI

3:45AM Absorbing Markov chains and nerve impulses
Grace Yang, University of Maryland

4:10PM A model checking method for the proportional hazards model with recurrent gap time data
Chiung-Yu Huang, NIH/NIAID

4:35PM A Bayesian Approach to Genome-Wide Genetic Association Studies with Survival Time as Outcome
I-Shou Chang, National Health Research Institute, Taiwan

Session 9: Methods in Health Policy Research (Invited)

Room Oakley
Organizers Kelly Zou, Pfizer Inc
Chair Kelly Zou, Pfizer Inc

3:20PM N-of-1 Trials: A Tool for Making Patient-Centered Treatment Decisions
Christopher H. Schmid, Brown University

3:45PM The role of hospital characteristics in setting the appropriate yardstick for quality measurement: estimation, inference, and public reporting
Frank B. Yoon, Mathematica Policy Research

4:10PM Methods to jointly account for unmeasured confounding of treatment and outcome censoring with application to health services research
A. James O’Malley, Harvard Medical School

4:35PM Improving the coherence of sequential multiple imputation
Recai M. Yucel, University at Albany

Session 24: Emerging Challenges in Statistical Design and Analysis for Medical Product Evaluation (Invited)

Room Brookside B
Organizers Yunling Xu, OSB/CDRH, US Food and Drug Administration
Chair Ying Yang, OSB/CDRH, US Food and Drug Administration

3:20PM New developments in antiviral drug trial design and evaluation
Program Schedule

Monday, June 10

Guoxing (Greg) Soon, OB/CDER, US Food and Drug Administration
3:45PM  Important statistical issues encountered during the review of therapeutic cellular and blood products
Boguang Zhen, OBE/CBER, US Food and Drug Administration

4:10PM  Issues in the Use of Existing Data for Pre-market Comparative Clinical Studies
Lilly Yue, OSB/CDRH, US Food and Drug Administration

4:35PM  Statistical considerations in post approval network for medical devices
Zengri Wang, The Medtronic Inc.

Session 26: Statistical Methods in Disease Surveillance (Invited)

Room  Linden Oak
Organizers  Chong Wang, Department of Statistics, Iowa State University
Chair  Chong Wang, Department of Statistics, Iowa State University

3:20PM  Detection of Disease outbreaks with Complex Spatio-Temporal Structures Using Real Surveillance Data
Jian (Frank) Zou, Department of Mathematical Sciences, Indiana Univ.-Purdue Univ.

3:45PM  Estimating Case Fatality Ratios from Infectious Disease Surveillance Data
Nicholas G. Reich, Division of Biostatistics and Epidemiology, Univ. of Massachusetts

4:10PM  Particle learning for sequential estimation and prediction of disease outbreaks
Jarad Niemi, Department of Statistics, Iowa State University

4:35PM  Design of repeated sampling for disease detection in surveillance of PRRSv
Chong Wang, Department of Statistics, Iowa State University

Session 27: Statistical Methods in Dissecting Complex Traits (Invited)

Room  Salon F
Organizers  Ruzong Fan, National Institute of Child Health and Human Development, NIH
Chair  Zhaohai Li, The George Washington University

3:20PM  A Tree-based Approach for Gene-Gene Interaction Detection in DNA Sequencing Data
Chi Song, Yale University

3:45PM  Longitudinal methods in genetic analysis, and its application in admixed population
Mariza de Andrade, Department of Health Sciences Research, Mayo Clinic

4:10PM  A versatile omnibus test for detecting mean and variance heterogeneity for quantitative traits
Peng Wei, University of Minnesota

4:35PM  Functional Kernel Linear Models for Association Analysis of Quantitative Traits
Yifan Wang, NICHD, NIH

Session 31: Global Efforts to Characterize Human Genome Diversity and to Elucidate the Genetic Basis of Complex Traits (Invited)

Room  Salon G
Organizers  Hua Tang, Stanford University
Li Hsu, Fred Hutchinson Cancer Research Center
Chair  Marc Coram, Stanford University

3:20PM  An abundance of rare variants as a major feature of human genetic diversity: sequencing of 202 drug target genes in ^14,000 individuals
John Novembre, University of California, Los Angeles

3:45PM  The Kaiser Permanente/UCSF Genetic Epidemiology Research Study on Adult Health and Aging: Population genetic structure in a cohort of 100K subjects
Yambazi Banda, University of California, San Francisco

4:10PM  A Unified Mixed-Effects Model for rare variants association in sequencing studies
Li Hsu, Fred Hutchison Cancer Research Center
4:35PM  Combining family and twin data in association studies to estimate maternal genotype effects using the full likelihood
Jeanine Houwing-Duistermaat, Leiden University Medical Centre, the Netherlands

Session 49: Challenges related to treatment effect heterogeneity and subpopulations in drug development and comparative effectiveness (Invited)

Room   Salon H
Organizers David Ohlssen, Novartis Pharmaceuticals Corporation
Chair   David Ohlssen, Novartis Pharmaceuticals Corporation

3:20PM  Discussion on the sample size requirements for clinical trials in China and possible impacts to treatment effect homogeneity
Dejun Tang, Novartis Pharma, IIS China

3:45PM  Subgroup Without Misclassification: Some Regulatory Perspectives
Sue-Jane Wang, U.S. Food and Drug Administration

4:10PM  Application of Simultaneous Confidence Interval Approach in Genetic Variant Analysis with Simulated Clinical Study Data
Ying Grace Li, Eli Lilly and Company

4:35PM  Discussant
Sue-Jane Wang, Office of Biostatistics, CDER, FDA

Session 61: Panel Discussion: Opportunities and Challenges in the Use of Recurrent Event Endpoints in Cardiovascular Outcome Trials (Invited)

Room   White Flint Amphitheater
Organizers Byron Jones, Novartis Pharma AG
Chair   Byron Jones, Novartis Pharma AG

Panelist:
Rob Hemmings, MHRA
Robert Temple, FDA
James Hung, FDA
Stuart Pocock, London School of Hygiene and Tropical Medicine
Guenther Mueller-Velten, DEV IIS Critical Care, Novartis

Session 65: Estimation and Testing for Temporally/Spatially Correlated Data in Semiparametric Models (Invited)

Room   White Oak Dining Room A
Organizers Jing Wang, University of Illinois at Chicago
Chair   Juan Du, Kansas State University

3:20PM  Simultaneous variable selection and estimation in semiparametric modeling of longitudinal/clustered data
Qiongxia Song, University of Texas at Dallas

3:45PM  Partially Linearity Testing in Generalized Additive Models
Jing Wang, University of Illinois at Chicago

4:10PM  Spectral Analysis of Quadratic Variation in the Presence of Noise
Fanfang Wang, University of Illinois at Chicago

4:35PM  Covariance Modeling of Multivariate Spatio-Temporal Data Sets
Juan Du, Kansas State University

Session 73: Opportunities and challenges: The new FDA draft guidance for accelerated approval using pCR endpoint in breast cancer areas (Invited)

Room   White Oak Dining Room B
Organizers Yijie Zhou, Merck
Chair   Lanju Zhang, Abbvie

3:20PM  Implications of recent FDA Guidance based on pCR in Early Breast Cancer
Ramachandran Suresh, GlaxoSmithKline

3:40PM  Statistical considerations for unplanned trial modification
Bo Yang, Abbvie

4:00PM  Some thoughts on the FDA draft guidance on the use of pCR as an endpoint for accelerated approval of treatment in high-risk early-stage breast cancer
Lu Cui, Abbvie

4:20PM  Implications on Design and Analysis Plan: Predictive Properties
Ming Tan, Georgetown University
Program Schedule

Monday, June 10

4:40PM Discussant
Qing Liu, Jassen Pharmaceutical Research and Development

Session 82: Recent advances in statistical genetics and genomics (Invited)
Room Salon E
Organizers Jianxin Shi, NCI
Chair Jianxin Shi, NCI

3:20PM Detect differentially expressed de novo mutations based on next-generation RNAseq data
Pei Wang, Fred Hutchinson Cancer Research Center

3:45PM Stochastic segmentation model for recurrent copy number variations in grouped array-CGH data
Haipeng Xing, State University of New York, Stony Brook

4:10PM DNA variant caller adapted to assess mitochondrial DNA variation from whole-genome sequencing data
Jun Ding, National Institute on Aging

4:35PM Discussant
Bin Zhu, NCI
Tuesday, June 11, 7:30AM-8:00AM
Registration and Continental Breakfast

Tuesday, June 11, 8:00AM-9:40AM
Session ICSA2 - Celebrating 40 years of Biopharmaceutical Statistics Career: Dedication to Robert. T. O'Neill, Ph.D (ICSA Biometrics Section Special Invited Session)

Room   Brookside A
Organizers  Yi Tsong, FDA and Aiyi Liu, NIH
Chair  Aiyi Liu, NIH

8:00AM  A life-long dedication to product safety and assessment
Christy Chuang-Stein, Pfizer Inc.

8:30AM  Efficient Logistic Regression Designs Under an Imperfect Population Identifier: Applications to Epidemiologic Studies and Clinical Trials
Paul Albert, NIH/NICHD

9:00AM  Current Controversies in Clinical Trials
Stuart Pocock, London School of Hygiene and Tropical Medicine

Session 11: Statistical Classification Methods: Diagnostic Tests and Predictive Analyses (Invited)

Room   Brookside B
Organizers  Kelly Zou, Pfizer Inc
Chair  Kelly Zou, Pfizer Inc

8:00AM  Optimal sampling ratios in diagnostic trials
Liansheng (Larry) Tang, George Mason University

8:25AM  Comparison of two correlated C indices with right-censored survival outcome: one-shot estimate of difference variance
Le Kang, U.S. Food and Drug Administration

8:50AM  Linear and Nonlinear Discriminant Analysis of Osteoarthritis Data Based on MRI Study of Cartilage
Mingyu Xi, University of Maryland, Baltimore County

9:15AM  Strategies for developing prediction models from genome-wide association studies
Jincao Wu, NIH/NCI

Session 16: Recent statistical developments in diagnostic studies: Multiple classes, genomic data, and beyond (Invited)

Room   Linden Oak
Organizers  Lili Tian, SUNY at Buffalo
Chair  Lili Tian, SUNY at Buffalo

8:00AM  Recent Developments in Diagnostic Accuracy with Multiple Classes
Jason Fine, UNC Chapel Hill

8:25AM  Confidence Intervals for the Difference in Paired Youden Indices
Gengsheng Qin, Department of Mathematics & Statistics, George State University

8:50AM  Systems Mapping toward Precision Medicine
Rongling Wu, Center for Statistical Genetics, Penn State University

9:15AM  ROC Surface/Hypersurface and Temporal Ordering of Biomarkers
Chengjie Xiong, Division of Biostatistics Washington University School of Medicine

Session 28: Recent advances in the analysis of prevalent cohort survival data (Invited)

Room   Salon F
Organizers  Chiung-Yu Huang, National Institute of Allergy and Infectious Diseases
Chair  Chiung-Yu Huang, National Institute of Allergy and Infectious Diseases

8:00AM  Length-Biased Sampling and Right Censoring: An Overview and Some Current Challenges
Masoud Asgharian, McGill University, Montreal, Quebec, Canada

8:25AM  Nonparametric estimation of the survival function for prevalent and incident cases under stationary incidence
Tuesday, June 11

Chair  Olga Marchenko, Innovation, Quintiles

8:00AM  Cross-fertilization of statistical designs and methods between biopharma and other industries
Chyi-Hung Hsu, Quantitative Decision Strategies, Janssen Research & Development, LLC

8:20AM  Data mining/machine learning methods for subgroup identification
Ilya Lipkovich, Center for Statistics in Drug Development, Quintiles

8:40AM  Improving Oncology Clinical Program by Use of Innovative Designs and Comparing Them via Simulations
Inna Perevozskaya, Statistical Research and Consulting Center, Pfizer

9:00AM  Adaptive dose-finding: from audiometry to sleep apnea
Anastasia Ivanova, UNC at Chapel Hill

9:20AM  Discussant
Thomas E Gwise, FDA/CDER

Session 34: Bridging to Statistics outside Pharmaceutical Industry: Can we be more efficient in designing and supporting Clinical Trials? (Invited)

Room  White Flint Amphitheater
Organizers  Chin-Fu Hsiao, National Health Research Institutes
Hui Quan, Sanofi-Aventis
Chair  Toshimitsu Hamasaki, Osaka University, Graduate School of Medicine

8:00AM  Regulatory and statistical issues of Multi-regional Clinical Trials: “Reference Cases” and current situation in Japan
Yuki Ando, Pharmaceuticals and Medical Devices Agency, Japan

8:25AM  Model Comparisons and Interpretations in Multi-Regional Clinical Trial Setting
Hui Quan, Sanofi-Aventis

8:50AM  Fixed and random effects models for multiregional trial design
K. K. Gordon Lan, Johnson & Johnson

9:15AM  Discussant

Session 36: Advances in Multi-Regional Clinical Trials (Invited)

Room  White Flint Amphitheater
Organizers  Chin-Fu Hsiao, National Health Research Institutes
Hui Quan, Sanofi-Aventis
Chair  Toshimitsu Hamasaki, Osaka University, Graduate School of Medicine

8:00AM  Regulatory and statistical issues of Multi-regional Clinical Trials: “Reference Cases” and current situation in Japan
Yuki Ando, Pharmaceuticals and Medical Devices Agency, Japan

8:25AM  Model Comparisons and Interpretations in Multi-Regional Clinical Trial Setting
Hui Quan, Sanofi-Aventis

8:50AM  Fixed and random effects models for multiregional trial design
K. K. Gordon Lan, Johnson & Johnson

9:15AM  Discussant
H.M. James Hung, FDA

Session 37: Functional Data Analysis: Applications and New Advances (Invited)

Room        White Oak Dining Room A
Organizers   Lily Wang, The University of Georgia
Chair        Lily Wang, The University of Georgia

8:00AM  Simultaneous Inference for Repeated Functional Data
Guanqun Cao, Auburn University

8:25AM  Partial Functional Linear Regression Using Group Adaptive LASSO and its Applications in Hyper-Acute Ischemic Stroke Study
Linglong Kong, The University of Alberta

8:50AM  Optimal Estimation for Functional Cox Model
Simeng Qu, Purdue University

9:15AM  Nested Nonnegative Cone Analysis Method
Lingsong Zhang, Purdue University

Session 40: Benefit-Risk Evaluation of Medical Products in Drug Development (Invited)

Room        White Oak Dining Room B
Organizers   Ivan S.F. Chan, Merck Research Laboratories
Chair        Ivan S.F. Chan, Merck Research Laboratories

8:00AM  Considerations for benefit:risk assessment in pharmaceutical drug development
Qi Jiang, Amgen

8:25AM  Consider the "order of operations" in benefit: risk evaluation
Scott Evans, Harvard University

8:50AM  Expected Utility of Varenicline in Smoking Cessation
Thomas Permutt, FDA

9:15AM  Discussant
Steve Snapinn, Amgen

Session 54: Planning and Implementing Clinical Trials with an Adaptive Design: Challenges in a Regulatory Setting (Invited)

Room        Salon E
Organizers   Xiting Yang, Food and Drug Administration
Yunling Xu, Food and Drug Administration
Chair        Lilly Yue, Food and Drug Administration

8:00AM  Adaptive Clinical Trials for Regulatory Device Approval: the CDRH Experience
Gerry Gray, Division of Biostatistics, Center for Devices and Radiological Health, U.S. Food and Drug Administration

8:25AM  Developing and Delivering Better Designs
Brenda Gaydos, Eli Lilly and Company

8:50AM  A Bayesian Adaptive Cardiology Device Trial Leading to Approval
Jason Connor, Berry Consultants

9:15AM  Floor discussion

Session C3: Design and Analysis of Clinical Trials (Contributed)

Room        Oakley
Chair        Gaohong Dong, Novartis

8:00AM  A varying-stage adaptive phase II/III clinical trial design
Gaohong Dong, Novartis

8:15AM  Bayesian Seamless Phase I/II Adaptive Design for Molecularly Targeted Agents
Yong Zang, UT MD Anderson Cancer Center

8:30AM  Evaluating the Active Control Effect for Non-inferiority Trials
Mark Rotmann, FDA

8:45AM  Balance continuous covariates based on kernel densities
Zhenjun Ma, Sanofi-Aventi
Tuesday, June 11, 9:00AM-10:00AM
Session ICSA1 Student Travel Award I (Invited)
Room Brookside A
Chair Zhezhen Jin, Columbia University

10:00AM Assessing Model Fit in Joint Models of Longitudinal and Survival Data with Applications to Cancer Clinical Trials (ASA Biopharmaceutical Section Student Paper Award at the ICSA/ISBS 2013 Joint Conference)
Danjie Zhang, University of Connecticut

10:25AM Optimal Sparse Principal Component Analysis in High Dimensional Elliptical Model
Fang Han, John Hopkins University

10:50AM Semiparametric Odds Rate Model for Modeling Short-term and Long-term Effects with Application to a Breast Cancer Genetic Study
Mengdie Yuan, George Mason University

11:15AM Non-identifiability, equivalence classes, and attribute-specific classification in Q-matrix based Cognitive Diagnosis Models
Stephanie S. Zhang, Columbia University

Tuesday, June 11, 10:00AM-11:40AM
Session 23: Comparative Effectiveness Research, Inference and Applications (Invited)
Room Brookside B
Organizers Min-ge Xie, Department of Statistics and Biostatistics, Rutgers University
Chair Min-ge Xie, Department of Statistics and Biostatistics, Rutgers University

10:00AM Bayesian Meta-Analysis Approaches to Evidence Synthesis in Clinical Practice Guideline Development
Yulei He, Department of Health Care Policy, Harvard Medical School

10:25AM Applications of ROC Analysis in Medical Research: Recent Developments and Future Directions
Kelly Zou, Statistics, Pfizer Inc., Specialty Care Business Unit
10:50AM Bayesian Network Meta-Analysis for Health Technology Assessment and Evaluation for Investigative Treatment
Wei Shen, Global Statistical Sciences, Eli Lilly and Company

11:15AM Combining nonparametric inferences using data depth and confidence distribution
Dungang Liu, Department of Biostatistics, Yale University School of Public Health

Session 41: Design and Tests of Equivalence and Biosimilar Trials (Invited)

Room Linden Oak
Organizers Yi Tsong, FDA/CDER
Chair Yi Tsong, FDA/CDER

10:00AM Statistical considerations on analytical equivalence assessment
Yi Tsong, CDER, FDA

10:25AM Sample Size Determination for Equivalence Trial of Continuous Responses
Yu-Wei Chang, Temple University

10:50AM Establishing a biosimilarity index based on a tolerance interval approach for assessing biosimilar products
Hsiao-Hui Tsou, National Health Research Institutes, Miaoli, Taiwan

11:15AM Equivalence tests for exchangeability based on two-sided probability
Xiaoyu Dong, FDA/CDER

Session 45: Recent Developments in Biomarker Research and Medical Diagnosis (Invited)

Room Salon F
Organizers Danping Liu, National Institute of Health
Chair Danping Liu, National Institute of Health

10:00AM Comparing Diagnostic Accuracies in a Multi-Reader, Multi-Test Design
Eunhee Kim, Brown University

10:25AM Combining biomarkers to maximize treatment selection benefit
Ying Huang, Fred Hutchinson Cancer Research Center

10:50AM A Crossed Random Effects Modeling Approach for Estimating Diagnostic Accuracy from Ordinal Ratings without a Gold Standard
Zhen Chen, NIH/NICHD

11:15AM Early Termination of a Two-stage Study to Develop and Validate a Panel of Biomarkers
Joseph Koopmeiners, University of Minnesota

Session 46: Recent Developments and Applications of Bayesian Methods in Clinical Trial Design and Analysis (Invited)

Room Salon G
Organizers Dejun Tang, Novartis Pharmaceuticals
Chair Dejun Tang, Novartis Pharmaceuticals

10:00AM Bayesian Approach to the Design and Analysis of Non-inferiority Trials for Anti-infective Products
Meg Gamalo, FDA

10:25AM Objective Bayesian Analysis for Some Biomedical Models
Dongchu Sun, University of Missouri

10:50AM Bayesian Probit Model to Handle Missing Binary Data in Clinical Trials
Robert Wan, Novartis Pharmaceuticals

11:15AM A Bayesian Survival Model Based on Additive Regression Tree to Predict the Readmission Risk of Heart Failure Patients
Song Zhang, University of Texas Southwestern Medical Center

Session 47: Inverse Problems in Biostatistical Research (Invited)

Room Salon H
Organizers Krishna Saha, Central CT State University

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Chair: Dipak Dey, University of Connecticut

10:00AM Joint modeling of multivariate ordinal medication adherence data
Abdus S. Wahed, University of Pittsburgh

10:25AM Semiparametric Analysis of Linear Transformation Models with Covariate Measurement Errors
Samiran Sinha, Texas A&M University

10:50AM Approximation of Computationally Expensive Posterior Densities arising in Inverse Problems
Nikolay Bliznyuk, University of Florida

11:15AM Empirical likelihood-based inference for partially linear models
Haiyan Su, Montclair State University

Session 48: Statistical inference for high-dimensional data with applications in genetics (Invited)

Room: White Flint Amphitheater
Organizers: Pingshou Zhong, Michigan State University
Chair: Pingshou Zhong, Michigan State University

10:00AM Sparse covariance matrix. How sparse is sparse?
Wenjiang Fu, Michigan State University

10:25AM High-Dimensional Statistical Testing with Confounding Effects
Z. John Daye, University of Arizona

10:50AM A Method for Detection and Inference of Low-dimensional Linear Dependency
Kai Zhang, University of North Carolina

*11:15PM Sparse Projection Regression Model For High-dimensional Linear Regression (ICSA Student Paper Award)
Qiang Sun, University of North Carolina-Chapel Hill

Session 52: Considerations for emerging markets in multiregional clinical trials (Invited)

Room: White Oak Dining Room A
Organizers: Joshua Chen, Merck
Chair: Joshua Chen, Merck

10:00AM Consistency Assessment with Global and Bridging Trial Strategies in Emerging Markets
Shentu Yue, Merck

10:20AM Some Experience in Considering Emerging Markets in Planning and Conducting Clinical Trials
Xiaolong Luo, Celgene

10:40AM Emerging markets in multiregional clinical trials: Implementation of quality by design
Daphne Tsae-Yun Lin, CDER, FDA

11:00AM A Statistical Decision Framework for Use of OUS Data in PMA: a Regulatory Reviewer’s Perspective
Yunling Xu, U.S. Food and Drug Administration

11:20AM Discussant
William Wang, Merck

Session 68: FDA Drug Safety – Regulatory and Statistical Considerations (Invited)

Room: White Oak Dining Room B
Organizers: Yi Tsong, FDA
Chair: Min Min, FDA

10:00AM Finding Appropriate Method for Heart Rate Correction in TQT Studies
Qianyu Dang, CDER, FDA

10:20AM Multiple Contrast Tests for the Evaluation of Animal Carcinogenicity Studies
Mohammad Atiarr Rahman, FDA

10:40AM Bayesian techniques in animal carcinogenicity studies
Steven Thomson, FDA

11:00AM Sample Size Determination for Bioequivalence Trial Adjusted for Multiple Comparisons
Anna Sun, University of Maryland at Baltimore County

11:20AM Discussant
Jie Chen, Merck Serono

Session 77: New Developments in Postmarketing Safety Evaluation (Invited)

Room  Salon E
Organizers  Yi Huang, Department of Mathematics and Statistics University of Maryland
Chair  Yi Huang, Department of Mathematics and Statistics University of Maryland

10:00AM  Marginal Meta Analysis for binary outcomes in Postmarketing Safety Study
Elande Baro, Department of Mathematics and Statistics, UMBC

10:25AM  Marginal Structural Models for Multi-State Outcomes
Wei Yang, Assistant Professor, University of Pennsylvania

10:50AM  Statistical and Epidemiological Challenges in Post-Marketing Observational Studies
Yun Lu, Food and Drug Administration

11:15AM  Discussant
Ram Tiwari, FDA

Session C4: Semi-Parametric/Non-Parametric Methods and Beyond (Contributed)

Room  Oakley
Chair  Senniang Chen, Iowa State University

10:00AM  Quantile Regression Imputation of Missing Values for General Estimating Equations
Senniang Chen, Iowa State University

10:20AM  A Note on Power and Sample Size Calculations for the Kruskal-Wallis Test for Ordered Categorical Data
Chunpeng Fan, Sanofi US Inc.

10:40AM  Modeling Compositional Data: A Comparison of Two Methods
Bingzhi Zhang, Sanofi

11:00AM  Functional Sparsity for Nonparametric Regression
Bo Kai, College of Charleston

Tuesday, June 11, 11:40AM-1:20PM
Lunch on own

11:20AM  A Novel Age-Standardization Method Minimizes the Bias in Cancer Mortality Rate Estimations
Martina Fu, Okemos High School
Program Schedule

Tuesday, June 11, 1:20PM-3:00PM

Poster Presentation
1:20-3:00PM Trends and Hot Spots in Mortality from Drug Poisoning in U.S.
Diba Khan, Centers for Disease Control and Prevention

Session 38: Predictive Enrichment: Design, Development Strategies, and Methodological Issues (Invited)
Room Brookside A
Organizers Zoran Antonijevic, Cytel, Inc.
Chair Sue-Jane Wang, CDER, FDA
1:20PM Overview of current designs for biomarker strategies
Olga Marchenko, Quintiles, Inc.
1:45PM Emerging statistical issues in development of personalized medicines
Cong Chen, Merck & Co., Inc.
2:10PM Adaptive enrichment design strategies, including a case study
Zoran Antonijevic, Cytel, Inc.
2:35PM Regulatory experience of predictive enrichment in oncology clinical trials
Rajeshwari Sridhara, FDA

Session 43: High dimensional Data - Modeling, Computation and Application (Invited)
Room Brookside B
Organizers Wenjiang Fu, Michigan State University
Chair Wenjiang Fu, Michigan State University
1:20PM Fast stagewise algorithms for approximate regularization paths
Ryan Tibshirani, Carnegie-Mellon University, Statistics

Session 51: Bayesian considerations in non-inferiority setting – Update from the DIA Bayesian Scientific Working Group (Invited)
Room Linden Oak
Organizers Fanni Natanegara, Eli Lilly
Chair Mani Lakshminarayanan, Merck
1:20PM Current state of Bayesian noninferiority trials in medical product development
Fanni Natanegara, Eli Lilly
1:45PM Order Restricted Dirichlet Meta-analysis (ORDM) and its applications to non-inferiority margin determination
Ram Tiwari, FDA/CDER/OTS/OB
2:10PM An application of Bayesian approach for testing non-inferiority: case studies in vaccine trials
G. Frank Liu, Merck
2:35PM The network meta-analytic-predictive approach to non-inferiority trials
Beat Neuenschwander, Novartis

Session 59: Recent Developments in Early Clinical Development Statistics (Invited)
Room Salon F
Organizers Richardus Vonk, Bayer Pharma AG
Chair Richardus Vonk, Bayer Pharma AG
1:20PM Overview on Adaptive Designs in Oncology phase I Trials
Chenghua Xia, Bayer Healthcare

1:45PM Biomarker-Informed Adaptive Design using Mixed Effects Model
Mark Chang, Boston University

2:10PM Trial predictions vs. trial simulations in early clinical development: a Bayesian framework to evaluate the predictive probability of success
Bruno Boulanger, Arlenda SA, Belgium

2:35PM Discussant
Richardus Vonk, Bayer Pharma AG, Germany

Session 60: Statistical and Computational Challenges for Metagenomic Sequencing Data Analysis (Invited)

Room Salon G
Organizers Lingling An, University of Arizona
Chair Hongmei Jiang, Northwestern University

1:20PM Hypothesis Testing and Power Calculations for Taxonomic-Based Human Microbiome Data
Bill Shannon, Washington University School of Medicine

1:45PM metaGeMS: Detection of SNPs from Metagenome Using Model Selection on High-Throughput Sequencing Data
Xinping Cui, University of California-Riverside

2:10PM Analysis of 16S rRNA Microbiome Data
Paul Brooks, Virginia Commonwealth University

2:35PM Discussant
John Daye, University of Arizona.

Session 62: Trial Modeling and Simulation in New Drug Developments (Invited)

Room Salon H
Organizers Zhaoling Meng, Sanofi and Hui Quan, Sanofi

Session 63: Markov Chains and Their Applications (Invited)

Room White Flint Amphitheater
Organizers Wendy Lou, University of Toronto
Chair James C. Fu, University of Manitoba

1:20PM A Spatial Scan Test Based on the Compound Poisson Model for Cluster Detection of ER Visits
Hsing-Ming Chang, University of Alberta, Canada

1:45PM Joint Distribution of Rank Statistics considering Location and Scale Parameters via Finite Markov Chain Imbedding Technique and its Power Study
Wanchen Lee, University of Manitoba, Canada

2:10PM An Adaptive Procedure for Multiple Window Scan Statistics
Tung-Lung Wu, University of Connecticut

2:35PM Methods for Flexible Sample-Size Design in Clinical Trials
Gang Li, Johnson and Johnson

Session 64: Accommodate Regional Regulatory Requirements Through International Collaboration (Invited)

Room White Oak Dining Room A
Organizers  Tai Xie, Brightech International LLC
Chair  Wei Li, National Center for Cardiovascular Diseases, Fuwai Hospital, China

1:20PM  Regional (statistical) needs of global research
Laurent Billot, The George Institute for Global Health, Australia

1:45PM  N-of-1 Design and Its Applications to TCM Clinical Trials
Tai Xie, Brightech International LLC

2:10PM  Statistical Considerations on Medical Device Trial Design and Evaluation in China
Wei Li, National Center for Cardiovascular Diseases, Fuwai Hospital, China

2:35PM  Statistical Evaluations for Multi-Regional Clinical Trial in China
Yang Wang, National Center for Cardiovascular Diseases, Fuwai Hospital, China

Session 70: Recent Advances in Genomics (Invited)
Room  White Oak Dining Room B
Organizers  Lynn Kuo, University of Connecticut, Department of Statistics
Chair  Lynn Kuo, University of Connecticut, Department of Statistics

1:20PM  Nonparametric Bayesian Functional Clustering on Time-Course Microarray Data
Ziwen Wei, Merck & Co., Inc

1:45PM  Statistical Reconstruction of RNA Secondary Structure from High-Throughput Sequencing Data
Zhengqing Ouyang, The Jackson Laboratory for Genomic Medicine

2:10PM  Weighted Pseudolikelihood for Analysis of Multiple Secondary Outcomes in Genetic Association Studies
Elizabeth Schifano, University of Connecticut, Department of Statistics

2:35PM  Stochastic Models For Genetic Analysis of Longitudinal Phenotypes
Ruzong Fan, NICHD/NIH

Session 79: Bayesian approaches for drug safety evaluation (Invited)
Room  Salon E
Organizers  Lan Huang, FDA/CDER
Chair  Jyoti Zalkikar, FDA/CDER

1:20PM  Statistical Heterogeneity in Multi-arm Clinical trials: A Meta Analysis Approach
Saman Muthukumarana, University of Manitoba, Canada

1:45PM  Bayesian applications in drug safety evaluation
Amy Xia, Amgen, Inc.

2:10PM  Signal Detection in FDA AERS Database Using Dirichlet Process
Na Hu, University of Missouri

2:35PM  Analyzing multiple safety endpoints using Bayesian variable selection
Bradley W. McEvoy, FDA

Session C1: Survival Analysis and Bayesian Methods (Contributed)
Room  Oakley
Chair  Yuanye (Vickie) Zhang, Novartis

1:20PM  Bayesian Models for Survival Data with a Cure Fraction and Semi-Competing Risks
Yuanye (Vickie) Zhang, Novartis

1:40PM  Revisit Kaplan-Meier Estimator in Estimating QAL Survival Distributions
Jiantian Wang, Kean University

2:00PM  Regression analysis of bivariate current status data under the Gamma-frailty proportional hazards model using EM algorithm
Naichen Wang, University of South Carolina

2:20PM  Evaluations of model-based methods in analyzing complex survey data: a simulation study using data from the National Health Interview Survey
Rong Wei, National Center for Health Statistics, CDC, USA
2:40PM  Bayesian Predictive Approach to Early Termination for Enriched Enrollment Randomized Withdrawal Trials
Yang Ge, Merck Research Laboratories

Tuesday, June 11, 3:00PM-3:20PM
Afternoon Break

Tuesday, June 11, 3:20PM-5:00PM
Session 20: High Dimensional Statistics in Genetics and Genomics (Invited)
Room  Brookside A
Organizers  Hongzhe Li, Department of Biostatistics and Epidemiology; University of Pennsylvania
Chair  Ao Yuan, Howard University

3:20PM  Simultaneous reconstruction of copy number variations in families
Jianxin Shi, National Cancer Institute

3:45PM  Regularization Methods for High-Dimensional Instrumental Variables Regression with an Application to Genetical Genomics
Wei Lin, University of Pennsylvania

4:10PM  Concordant integrative analysis of multi-sample large-scale expression data sets
Yinglei Lai, George Washington University

4:35PM  Optimal High Dimensional Multiple Testing Under Linear Models
Jichun Xie, Temple University

Session 22: Subgroup identification in clinical trials and observation studies - beyond test of interaction (Invited)
Room  Brookside B
Organizers  Yue Wang, Gilead Sciences
Chair  Yue Wang, Gilead Sciences

3:20PM  Identifying simple subgroups of enhanced treatment effect from randomized clinical trial data
Jeremy Taylor, Biostatistics, University of Michigan

3:45PM  A Robust Method for Estimating Optimal Treatment Regimes
Anastasios A. Tsiatis, NC State University

4:10PM  Targeted subgroup identification for treatment selection
Menggang Yu, Biostatistics & Medical Informatics, U. of Wisconsin
4:35PM  A general boosting algorithm for personalized medicine  
Lu Tian, Health Research & Policy – Biostatistics, Stanford Univ

Session 35: Novel development in risk prediction (Invited)

Room  Oakley  
Organizers  Huilin Li, New York University  
Chair  Ruth Pfeiffer, NIH/NCI

3:20PM  Developing, evaluating, and validating risk prediction models in survey cohort studies  
Stephanie Kovalchik, National Cancer Institute

3:45PM  Multiple testing methods for analyzing rare genetic variants  
Marinela Capanu, Memorial Sloan-Kettering Cancer Center

4:10PM  Estimation and Selection of Complex Covariate Effects in Pooled Nested Case-Control Studies with Heterogeneity  
Mengling Liu, New York University School of Medicine

4:35PM  Floor Discussion

Session 57: Application of Bayesian Probability of Success (POS) in Clinical Trials (Invited)

Room  Linden Oak  
Organizers  G. Frank Liu, Merck & Co. Inc  
Chair  G. Frank Liu, Merck & Co. Inc

3:20PM  What is POS and why is it important for late-stage clinical trials?  
Christy Chuang-Stein, Pfizer Inc.

3:45PM  Expected shrinkage in treatment effect from phase II to III given a prior distribution of phase II portfolio  
Jianliang Zhang, Medimmune LLC.

4:10PM  Applications of Probability of Study Success in clinical drug development at Eli Lilly and Company  
Ming-Dauh Wang, Eli Lilly and Company.

4:35PM  A Bayesian View to Predicting Future Directions in Clinical Trials  
Mani Lakshminarayanan, Merck Research Laboratories

Session 66: How Adaptive Design Software can help in designing and analyzing data obtained from adaptive design trials? (Invited)

Room  Salon F  
Organizers  Sue-Jane Wang, U.S. Food and Drug Administration  
Chair  Sue-Jane Wang, U.S. Food and Drug Administration

The session will give four presentations in response to four adaptive design scenarios covering the various phases of a drug development program. The software includes ADDPLAN, EAST, FACTS, and gsDESIGN.

Keaven Anderson (gsDESIGN): exploratory vs confirmatory sample size re-estimation: an open source option  
Scott Berry (FACTS): exploratory adaptive dose-ranging  
Yannie Jemiai (EAST): confirmatory adaptive sample size planning  
Gernot Wassmer (ADDPLAN): confirmatory adaptive treatment selection

Session 67: Non-clinical CMC Issues – Regulatory and Statistical (Invited)

Room  Salon G  
Organizers  Yi Tsong, FDA/CDER  
Chair  Xiaoyu Dong, FDA/CDER

3:20PM  An Equivalence QbD Approach to Robustness test in Analytical method validation  
Lanju Zhang, Abbvie

3:40PM  Use of acceptance sampling plan for stability study  
Frank Ye, Amgen

4:00PM  Determination of bioassay cut point  
Meiyu Shen, FDA
4:20PM  Linearity testing for analytical methods
Harry Yang, MedImmune

4:40PM  Discussant
Yi Tsong, FDA/CDER

Session  69:  Biomarker and Subgroup Identification for Development of Tailored Therapies (Invited)

Room  Salon H
Organizers  Lei Shen, Eli Lilly and Company
Chair  Joshua Chen, Merck Research Laboratories

3:20PM  Rigorous and Consistent Assessment of Methods to Identify Subgroups with Enhanced Treatment Response
Richard C. Zink, SAS Institute, Inc.

3:45PM  Emerging Biomarker and Subgroup Identification Methods: Review and Comparisons
Ying Ding, University of Pittsburgh

4:10PM  A Bayesian Approach to Subgroup Identification using Tree-Based Models
Xiaojing Wang, University of Connecticut

4:35PM  Optimized Subgroup Identification for Tailored Therapies
Lei Shen, Eli Lilly and Company

Session  71:  Safety Analysis and Graphics Presentation (Invited)

Room  White Flint Amphitheater
Organizers  Qi Jiang, Amgen
Chair  Qi Jiang, Amgen

3:20PM  Graphs are statistical methods too! The case for graphics in safety analysis.
Brenda Crowe, Eli Lilly and Company

3:45PM  Using Graphical Approaches to Identify and Describe Complex Relationships
Kenneth Koury, Merck Research Laboratories

4:10PM  Time-to-Event Analysis with Partial Adjudication of Potential Events Using Fractional Imputation
Haijun Ma, Amgen

4:35PM  Discussant
Brenda Crowe, Kenneth Koury, Haijun Ma, Qi Jiang

Session  72:  Evidential Approaches to Multiplicity of Hypothesis Testing (Invited)

Room  White Oak Dining Room A
Organizers  Yanming Yin, FDA
Chair  Yanming Yin, FDA

3:20PM  A Fisherian Evidential Approach to Testing Multiple Hypotheses
Haiyan Xu, Jassen Pharmaceutical Research and Development

3:45PM  Totality Evidence in Drug Evaluation
Qian Li, NIH, National Center for Complimentary Medicine

4:10PM  Unmet Medical Need: Use of Nested-Hybrid Trial Design for demonstrating Treatment Efficacy of New Antibacterial Drugs
Mohammad Huque, FDA

4:35PM  Discussant
Guoxing (Greg) Soon, FDA

Session  75:  Meta-analysis and multiple comparisons in Clinical Trials (Invited)

Room  White Oak Dining Room B
Organizers  Xiao Ding, Gilead
Chair  Xiao Ding, Gilead

3:20PM  Privacy-maintaining statistical analysis in multi-site public health surveillance
Darren Toh, Harvard University

3:45PM  Application of mixture gatekeeping procedure with logical restriction
Xiao Ding, Gilead Sciences

4:10PM  Difference by age for women’s response to initial highly active antiretroviral therapy: Meta-analysis of clinical trials submitted to FDA (2000-2010)
Jin Yan, U.S. Food and Drug Administration
Program Schedule

4:35PM  Multiplicity Issues in Human Drug Abuse Potential Studies
Ling Chen, FDA/CDER

Session 84: Recent advances in longitudinal analysis (Invited)
Room  Salon E
Organizers  Colin Wu, NIH/NHLBI
Chair  Colin Wu, NIH/NHLBI

3:20PM  Joint Latent Class Model of Survival and Longitudinal Data: An Application to CPCRA Study
Lei Liu, Northwestern University

3:45PM  Longitudinal Clinical Trials with Adaptive Choice of Follow-up Time
Neal Jeffries, National Heart, Lung, and Blood Institute

4:10PM  Nonparametric estimation of conditional distributions and rank-tracking probabilities with time-varying transformation models in longitudinal studies
Xin Tian, National Institutes of Health

4:35PM  Approaches to retrospective sampling for longitudinal transition regression models
Sally Hunsberger, NCI, BRB

Session 85: Statistical Approaches in Genetic Association Studies and Related Topics (Invited)
Room  Middlebrook
Organizers  Zhaohai Li, George Washington University
Chair  Zhaohai Li, George Washington University

3:20PM  Rank-based Robust Tests for Quantitative-trait Genetic Association Studies
Qizhai Li, Academy of Mathematics and Systems Science, CAS

3:45PM  Estimation and empirical likelihood for single-index models with missing data in the covariates
Liugen Xue, College of Applied Sciences, Beijing University of Technology

4:10PM  Rank-Based Tests for Comparison of Multiple Endpoints among Several Populations
Zhengbang Li, Central China Normal University

4:35PM  Floor Discussion

Tuesday, June 11, 6:30PM-10:30PM

Social Event: ICSA/ISBS Banquet
Location: New Fortune Chinese Seafood Restaurant

Bus leaves  5:00PM, 5:50PM
Featured Speaker:  Prof. Xiao-Li Meng, Harvard University
Karaoke/dancing/entertaining
Wednesday, June 12, 7:30AM-8:20AM
Registration and continental breakfast

Wednesday, June 12, 8:20AM-9:40AM
Keynote Session II (invited)

Room   Salon E  
Chair   Yi Tsong, FDA

8:20AM   Keynote Lecture
Enhancing the Visibility of the Statistics Profession: The International Year of Statistics and You
Marie Davidian, Professor of Statistics, North Carolina State University

9:00AM  Keynote Lecture
Has the time come to give up blinding in clinical trials?
Nancy Geller, Director, Office of Biostatistics Research National Heart, Lung and Blood Institute National Institutes of Health

Wednesday, June 12, 10:00AM-10:20AM
Morning Break

Wednesday, June 12, 10:20AM-12:00PM
Session 5: Challenges to Multiplicity Issues in Clinical Trials with Multiple Objectives (Invited)

Room   Salon E  
Organizers Toshimitsu Hamasaki, Osaka University Graduate School of Medicine  
Chair   Toshimitsu Hamasaki, Osaka University Graduate School of Medicine

10:20AM Addressing multiplicity issues in complex clinical trial designs
Frank Bretz, Novartis Pharma

10:45AM Flexible multivariate methods for design and analysis of binary-event composite endpoint trials
Edward Mascha, Cleveland Clinic

11:10AM Partition testing in confirmatory adaptive designs with structured objectives
Toshifumi Sugitani, Osaka University Graduate School of Medicine

11:35AM Discussant
Mohammad Huque, FDA/CDER

Session 53: Statistical Challenges and Recent Advances in Genomics (Invited)

Room   White Flint Amphitheater Foyer  
Organizers Xueying Chen, Vertex Pharmaceuticals  
Chair   Yi Wu, Vertex Pharmaceuticals

10:20AM JOINT ANALYSIS OF SNP AND GENOME EXPRESSION DATA IN GENETIC ASSOCIATION STUDIES OF COMPLEX DISEASES
Xihong Lin, Harvard School of Public Health

10:45AM Analysis of omics data from heterogeneous samples: pitfalls and solutions
Xi Kathy Zhou, Weill Cornell Medical College

11:10AM Efficient sequential Monte Carlo with multiple proposals and control variates
Wentao Li, Rutgers University

11:35AM Discussant
Challenges in incorporating ‘omics’ data in clinical trials
Na (Michael) Li, Emergent BioSolutions

Session 56: Recent developments in graphical modeling (Invited)

Room   Glen Echo  
Organizers Hua (Judy) Zhong and Yixin Fang, NYU School of Medicine  
Chair   Yixin Fang, NYU School of Medicine

10:20AM Consistent Cross-Validation for Tuning Parameter Selection in High-Dimensional Variable Selection
Yang Feng, Assistant Professor Department of Statistics, Columbia University

10:45PM Estimation of sparse directed acyclic graphs through a penalized likelihood method for gene network inference
Sung Won Han, Hoffmann-La Roche Inc.
11:10AM A penalized multi-attribute exponential random graph model for supervised link prediction in biological networks
Ali Shojaie, Assistant Professor of Biostatistics, University of Washington

11:35AM High dimensional graphical models of non-Gaussian data
Hua Tang, Associate Professor, Genetics, Stanford University School of Medicine

Session 74: Clinical Trial Data Standardization and big data analysis (Invited)

Room White Oak Dining Room A
Organizers Guoxing (Greg) Soon, FDA
Chair Guoxing (Greg) Soon, FDA

10:20AM FDA Analysis Data Standardization
Wen Zeng, FDA

10:45AM Achieving Standardized Data
Rong Ye, MedImmune

11:10AM Anti-viral Drug Data Conversion, Validation and Analysis
Jing (Jerry) Li, University of Maryland,

11:35AM Floor Discussion

Session 78: New Development in Causal Inferences (Invited)

Room White Oak Dining Room B
Organizers Wei Yang, University of Pennsylvania
Chair Wei Yang, University of Pennsylvania

10:20AM Matching weight as an analogue to pair matching in propensity score analysis
Liang Li, MD Anderson Cancer Center

10:40AM Estimating Post-Treatment Effect Modification with Generalized Structural Mean Models
Alisa Stephens, University of Pennsylvania

11:00AM Latent Propensity Score for Average Causal Effect Estimation Allowing Covariate Measurement Error

Yi Huang, University of Maryland, Batimore County

Taki Shinohara, Johns Hopkins University

*11:40AM Large Sample Randomization Inference of Causal Effects in the Presence of Interference (ICSA Student Paper Award)
Lan Liu, University of North Carolina

Session 80: Handling non-ignorable missing data: recent developments (Invited)

Room Salon F
Organizers David Li, Pfizer
Chair David Li, Pfizer

10:20AM A simulation study to compare multiple imputation methods under missing not at random assumption
David Li, Pfizer

10:45PM An analytic method for the placebo-based pattern-mixture model
Kaifeng Lu, Forest Laboratories, Inc

11:10PM Bivariate penalized smoothing spline method of imputation using survey design-related variables and the propensity of response
Guangyu Zhang, National Center for Health Statistics

11:35M Evaluation of Sensitivity to Missing Data in Longitudinal Clinical Trials
Dustin Ruff, Eli Lilly and Company

Session 83: Statistical methods of analysis for binary and time-to-event related outcomes (Invited)

Room Middlebrook
Organizers Kyoungah See, Eli Lilly
Chair Jing Zhang, Miami University

10:20AM EM algorithm for Generalized odds-rate hazard models with interval-censored data
Bin Zhang, Cincinnati Children’s Hospital Medical Center
10:45AM  Treatment effect estimation in adaptive clinical trials: a regulatory perspective  
Ying Yang, OSB/CDRH, US Food and Drug Administration

11:10AM  Bayesian Modeling Averaging approach to model a binary outcome for a dose ranging trial  
Bob Noble, GlaxoSmithkline

*11:35AM  Marginalizable conditional model for clustered binary data (ASA Biopharmaceutical Section Student Paper Award at the ICSA/ISBS 2013 Joint Conference)  
Rui Zhang, University of Washington
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