

THE 29th ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP
MAY 22 – 24, 2006 • BALL STATE UNIVERSITY, MUNCIE, INDIANA

Final Program

MONDAY, MAY 22

8:30 AM – 4:30 PM

WORKSHOP REGISTRATION

FEE: \$145 until May 1 (\$40 for students), \$175 after May 1

9:00 AM – 1:00 PM

SHORT COURSE (Separate Registration Fee: \$55)

Presenters: BRENDA GILLESPIE, University of Michigan
Topic: "Survival Analysis Using Cox Regression"

2:15 PM – 2:30 PM

INTRODUCTION AND WELCOME

Brian Wiens, Myogen

DR. JOHN W. EMERT, Chair, Department of Mathematical Sciences, Ball State University

2:30 PM – 4:30 PM

PLENARY SESSION

Speaker: RAYMOND CARROLL, Texas A&M

Topic: "Gene-Treatment Interactions and Their Discovery"

5:00 PM – 7:00 PM MONDAY NIGHT MIXER

TUESDAY MORNING, MAY 23

CONCURRENT SESSIONS

8:30 AM – 11:30 AM

A. Multiplicity

Organizer/Chair: Alex Dmitrienko, Eli Lilly

1. "Gatekeeping Procedures Based on Weighted Bonferroni Tests for Multiple Endpoints in Dose Finding Studies", Ajit Tamhane and Xin Cindy Wang, Northwestern University.
2. "Analysis of Multiple Endpoints: Some New Approaches", Devan V. Mehrotra and David Li, Merck
3. "Some Considerations in Testing for Multiple Endpoints in Confirmatory Clinical Trials", Mohammed Huque, FDA
4. "Cross-trial Estimation of Control Effect and False Positive Issues in Active-Control Trials", Abdul Sankoh, Sanofi-Aventis

B. Assay Validation and Optimization

Organizer/Chair: James Schwenke, Boehringer Ingelheim Pharmaceuticals

1. "Assessment of Equivalence Using a Concordance Correlation Coefficient in a Repeated Measurement Design", Jorge Quiroz, Wyeth
2. "Use and Misuse of the Gage R&R Study", Jyh-Ming Shoung, Stan Altan, and Areti Manola RW Johnson R&D
3. "Analyzing Immunoassay Data Using Nonlinear Mixed Effects Models", Brian J. Fergen, Center for Veterinary Biologics, USDA, Xia Xu, and Phillip Dixon, Iowa State University
4. "Interval Estimates for Assay Response Curves Using Nonlinear Mixed Models", Erin Blankenship, Jacqueline Wroughton, and Walter Stroup, University of Nebraska, Lincoln, and James Schwenke, Boehringer Ingelheim Pharmaceuticals

C. Assessing Safety in Drug Discovery

Organizer/Chair: Kimberly Crimin, Pfizer

1. "Integrate Metabolomics and Transcriptomics to Discover Novel Pathways and Biomarkers in Safety Assessment", Jack Liu, GSK
2. "Application of Power Spectral Analysis in Heart Rate Variability: A Marker of Autonomic Regulation of Heart Rate", Feng Liu, GSK
3. "Prediction of Adverse Drug Reaction Using In-Vitro Screening", Shijing Deng, Pfizer
4. "Flexible Longitudinal Regression Modeling of Clinical Lab Data for Early Detection of Drug Toxicity", Jonathan Schildcrout, Vanderbilt University

11:30 AM – 1:00 PM LUNCH BUFFET

TUESDAY AFTERNOON, MAY 23

POSTER SESSION

12:00 PM – 1:30 PM

Chair: Caroline Lee, Pfizer, Co-Chair: Kim Perry, Innovative Analytics
Posters will be accepted on any biopharmaceutical statistical topic.

Abstracts must be received by April 28, 2006. Students may qualify for the Charlie Sampson poster award if abstract, poster panels, and a paper briefly describing the poster are received by May 1.

For more information contact

Caroline Lee at (734) 622-3085 or Kim Perry at (269) 327-8511

TUESDAY AFTERNOON, MAY 23

CONCURRENT SESSIONS

1:30 PM – 4:30 PM

A. Survival Analysis

Organizer/Chair: Alexandra Carides, Merck

1. "Adventures in the Simulation of Clinical Trials With Time-to-Event Endpoints", Brent Blumenstein, TriArc Consulting
2. "Informative Noncompliance: An Overlooked Issue in the Calculation of Sample Size for Survival Trials", Qi Jiang, Amgen
3. "Analysis of Recurrent Episodes Data: the Length-Frequency Tradeoff", Jason Fine, University of Wisconsin, Madison
4. "Discussant", Steve Snapinn, Amgen

B. High Throughput Screening of Drug Candidates

Organizer/Chair: Ferdous Gheyas, Schering Plough

1. "Virtual Screening with QSAR: Fishing Expedition?", Andy Liaw, Merck
2. "Find that Hidden Treasure - Smooth the Data", Brad Evans, Pfizer
3. "OBSTree: a New Method of Recursive Partitioning", S. Stanley Young, NISS, Ke Zhang, GSK, and Jacqueline M. Hughes-Oliver, NCSU
4. "Testing for Excess Over Highest Single Agent With an Application to High Throughput Screening of Pairs of Compounds", John Peterson, GSK

C. Current Issues in Traditional Drug Safety Studies

Organizer/Chair: Wherly Hoffman, Eli Lilly

1. "Respiratory Safety Pharmacology Studies", Lori Mixson, Merck
2. "Cardiovascular Safety Pharmacology Studies", Ron Menton, Wyeth
3. "Central Nervous System Safety Pharmacology Studies", Lonnie Grantham, Pfizer
4. "Non-Clinical Safety Pharmacology and the Regulatory Decision", Aisar Atrakchi, FDA
5. "Challenges and Opportunities in Outsourcing Safety Pharmacology Studies", Wherly Hoffman, Eli Lilly

TUESDAY EVENING BANQUET

Announcement of Student Winner of Charlie Sampson Poster Award

Speaker: Bruce Rodda, University of Texas SPH

Topic: Natural Selection or Intelligent Design: The Evolution of the Statistician in the Pharmaceutical Industry

WEDNESDAY MORNING, MAY 24

CONCURRENT SESSIONS

8:30 AM – 11:30 AM

A. Post-Randomization Events

Organizer/Chair: Robb Muirhead, Pfizer

1. "Treatment Effect Estimators in Longitudinal Clinical Trials With Concomitant Medication", Neal Thomas and Naitee Ting, Pfizer, Sam Dickson, NC State, and Donald Rubin, Harvard
2. "Evaluating Dose Response From Flexible Dose Trials", Ilya Lipkovich, Eli Lilly
3. "Tackling Selection Bias in HIV Immunotherapy Trials", Robin Mogg and Devan V. Mehrotra, Merck
4. "Discussant", Jeremy Taylor, University of Michigan

B. Statistical Issues in Combination Drug Discovery

Organizer/Chair: John Peterson, GSK

1. "Mixture-Amount Experiments with Applications to Combination Drug Studies", Qing (Kathy) Liu, Wyeth
2. "A Semiparametric Model for Assessing Drug Interaction for Combination Therapy *in vitro* and *in vivo* Studies", Maiyong Kong, MD Anderson Cancer Center, University of Texas
3. "An Application of Response Surface Methodology in Drug Combination Oncology Phase I Studies", Kathryn Dawson, PPD
4. Discussant, John Peterson, GSK

C. Understanding Post-Marketing Safety Data

Organizer/Chair: Alan Menius, GSK

1. "Assessing Safety Signals in Spontaneous Event Databases", Robertino Mera, GSK
2. "Identifying Meaningful Patient Subgroups Via Clustering: Sensitivity Graphics", Bob Obenchain, Eli Lilly
3. "Using Health Care Claims Data for Safety Signal Detection", K. Arnold Chan, i3 Drug Safety

11:30 AM – 1:00 PM

LUNCH BUFFET

Brian Wiens, Myogen