

THE 30th ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP
MAY 21 – 23, 2007 • BALL STATE UNIVERSITY, MUNCIE, INDIANA

Final Program

MONDAY, MAY 21

8:30 AM – 4:30 PM

WORKSHOP REGISTRATION

FEE: \$150 until May 1 (\$50 for students), \$180 after May 1

9:00 AM – 1:00 PM

SHORT COURSE (Separate Registration Fee: \$55)

Presenter: PETER THALL, U. of Texas, M.D. Anderson Cancer Center

Topic: Bayesian Dose Finding

2:15 PM – 2:30 PM

INTRODUCTION AND WELCOME

MANI LAKSHMINARAYANAN, Pfizer

DR. MICHAEL MAGGIOTTO, Dean of College of Sciences and Humanities,
Ball State University

2:30 PM – 3:30 PM

MIR MASOOM ALI PLENARY SESSION

Speaker: NORMAN BRESLOW, University of Washington

Topic: Design and Analyses of Two-Phase Stratified Case-Cohort Studies

3:30 PM – 4:30 PM

MIR MASOOM ALI PLENARY SESSION

Speaker: JASON HSU, Ohio State University

Topic: All Things are Connected From Bioequivalence to Pharmacogenomics

5:00 PM – 7:00 PM MONDAY NIGHT MIXER

TUESDAY MORNING, MAY 22

CONCURRENT SESSIONS

8:30 AM – 11:30 AM

A. Statistical Considerations in Drug Development in the East and West

Organizer/Chair: Robb Muirhead, Pfizer

1. "Drug Development in Asia - Past, Present, and Future", Thomas Cook, Merck
2. "Understanding the Influence of Ethnicity on Drug Response", Michael Man, Pfizer
3. "Statistical Considerations in Pharmaceutical Development of Traditional Chinese Medicine", Shein-Chung Chow, Duke University
4. "Discussant", H. M. James Hung, FDA

B. Modeling the Relationship Between Clinical Outcome and Animal Models

Organizer/Chair: Kim Crimin, Wyeth

1. "Using Preclinical Efficacy Models to Guide Clinical Trial Simulations", Jim Rogers, Pfizer
2. "A Biomarker Approach Toward Early Detection of Efficacy in Humans", Lei Zhu, GlaxoSmithKline
3. "Improving the Quality of Clinical Candidates: A Multi-Criteria Optimization Strategy", Phil Burton, ADMETRx
4. "Discussant", Tom Vidmar, Pfizer

C. Data Mining Tools and Resources

Organizer/Chair: Jonathan Schildcrout, Vanderbilt University

1. "Using Open Source Software for Data Mining: Issues and Solutions", Gregory Warnes, University of Rochester
2. "Detecting Hepatotoxicity in Clinical Trial Data: An Anomaly Detection Approach", Sitaram Asur, Ohio State
3. "Information Mining Tools for Heterogeneous Clinical Trials Data", Fatih Altiparmak, Ohio State
4. "Making the Best of the Data You Have, Instead of the Data You Want", Andy Liaw, Merck
5. "Discussant", Ana Szarfman, FDA

11:30 AM – 1:00 PM LUNCH BUFFET

TUESDAY AFTERNOON, MAY 22

POSTER SESSION

12:00 PM – 1:30 PM

Chair: Kim Perry, Innovative Analytics

Posters will be accepted on any biopharmaceutical statistical topic.

Abstracts must be received by April 27, 2007. Students may qualify for the Charlie Sampson poster award if abstract, poster panels, and a paper briefly describing the poster are received by April 27.

For more information contact

Kim Perry at (269)-488-3204

TUESDAY AFTERNOON, MAY 22

CONCURRENT SESSIONS

1:30 PM – 4:30 PM

A. Modeling and Simulation

Organizer/Chair: Alan Hartford, Merck

1. "Sample Size and Power Calculations for a Longitudinal Endpoint in Clinical Trials: A Case Study of Using Modeling and Simulation", Jose Pinheiro, Novartis
2. "Examining Clinical Utility: A New Formulation for an Old Drug", Kevin Dykstra, Pharsight
3. "PhysioPD™ Modeling and Statistics", Jim Bosley, Rosa Pharmaceuticals

B. Specification Setting

Organizer/Chair: Kim Vukovinsky, Pfizer

1. "Setting Specifications for Bioassays", Tim Schofield, Merck
2. "Considerations in Stability Data Analysis for Specification Setting", Suntura Cahya, Jeff Hofer, Eli Lilly
3. "Setting CU Acceptance Criteria for Moderate Sample Sizes", Greg Lerner, Kim Vukovinsky, Pfizer, Soren Andersen, Novo Nordisk, Myron Diener, sanofi-aventis, Jim Pazdan, Novartis, Lori Pfahler, Merck, Dennis Sandell, Siegfried, Helen Strickland, GSK
4. "Specification Setting for Combination Products: Achieving Maximum Regulatory Compliance While Minimizing Manufacturing Loss", Greg Steeno, Wenqing Li, Lenny Margulis, Pfizer
5. "Specification Setting in Parenterals", Brent Harrington, Wyeth

C. Data Mining Methods in Genomics and Proteomics

Organizer/Chair: Scott Chasalow, BMS

1. "Linking Metabolic Profiles to Biological Outcome", Stanley Young, NISS
2. "Multiplicity and Meta-Analysis in Genetic Association Studies", Katy L. Simonsen, BMS.
3. "Developing Predictive Classifiers and Their Use in the Design of Pivotal Trials", Richard Simon, NIH
4. "Discussant", Scott Chasalow, BMS

TUESDAY EVENING BANQUET

DR. TERRY KING, Provost and Vice President for Academic Affairs
Ball State University

Announcement of Student Winner of Charlie Sampson Poster Award
Speaker: MARY ELLEN BOCK, Purdue University and President, ASA
Topic: Directions in Statistics

WEDNESDAY MORNING, MAY 23

CONCURRENT SESSIONS

8:30 AM – 11:30 AM

A. Nonparametric/Rank-Based Methods

Organizer/Chair: Donna Kowalski, Astellas

1. "Rank-Based Analysis of Crossover Trials for Classic and Novel Designs", Mary Putt, University of Pennsylvania
2. "Efficient Rank-Based Inference for Stratified Trials", Devan Mehrotra, Merck
3. "Adjusting for Ordinal Covariates by Inducing a Partial Ordering", Vance Berger, National Cancer Institute
4. "Discussant", John Spurrier, University of South Carolina

B. Bayesian Approaches in Stability, QbD, Random Effects Modeling, and Dose Finding

Organizer/Chair: David LeBlond, Abbott

1. "Bayesian Hierarchical Modeling of Drug Stability Data", Jie Chen, Merck
2. "Posterior Predictive Approach to Pharmaceutical Process Optimization for Quality by Design", Gregory Stockdale, GSK
3. "Bayesian Approach to Constructing Tolerance Intervals for the 1-Way Random Effects Model", Stan Altan, Johnson & Johnson
4. "Bayesian Continuous Reassessment Method in Phase 1 Dose Finding Studies", Yi-Lin Chiu, David LeBlond, Abbott
5. "Bayesian Specification Setting", Shea Watrin, Amgen

C. Data Mining Methods in Drug Safety and Post-Marketing

Organizer/Chair: Alan Menius, GSK

1. "Large-Scale Logistic Regression for Pharmacovigilance", David Madigan, Rutgers University
2. "Statistical Modeling of Pre- and Post-Marketing Safety Data", Michael O'Connell, Insightful
3. "Safety Case-Studies Using Propensity Adjustments for Bias", Bob Obenchain, Eli Lilly
4. "Leveraging Observational Data for Pharmacovigilance", Patrick Ryan, GSK

11:30 AM – 1:00 PM LUNCH BUFFET

Closing Remarks

Mani Lakshminarayanan, Pfizer