

THE 33rd ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP
MAY 24 – 26, 2010 • BALL STATE UNIVERSITY ALUMNI CENTER, MUNCIE, INDIANA

Final Program

MONDAY, MAY 24
8:30 AM – 4:30 PM

WORKSHOP REGISTRATION

FEE: \$160 until May 1 (\$70 for students), \$190 after May 1

9:00 AM – 1:00 PM

SHORT COURSE (Separate Registration Fee: \$65)

Presenter: MAX KUHN, Pfizer

Topic: Predictive Modeling With R

2:15 PM – 2:30 PM

INTRODUCTION AND WELCOME

KJELL JOHNSON, Pfizer

JOHN W. EMERT, Associate Dean of the Honors College, Ball State University

2:30 PM – 3:30 PM

PLENARY SESSION

Speaker:

TOM PERMUTT, FDA

Topic: Statistics in Drug Development and Regulation: The Decade Ahead

3:30 PM – 4:30 PM

PLENARY SESSION

Speaker: RON MENTON, Pfizer

Topic: BioTherapeutics – What's the Bio about?

MONDAY NIGHT MIXER

Alumni Center

5:00 PM – 7:00 PM

TUESDAY MORNING, MAY 25

CONCURRENT SESSIONS

8:30 AM – 11:30 AM

A. Industries Respond to Change: Does it Matter Where I Work?

Organizer/Chair: Simin Baygani, Eli Lilly and Company

1. "Telecommuting: How to Work Miracles From Home", Jackie Reisner, PPD
2. "How to Broaden Your Statistical Influence Via Consulting", Thomas Peppard, Great Lakes Drug Development
3. "Statistical Thinking in an Evolving International Pharmaceutical Industry", Alan Menius, GlaxoSmithKline
4. "Panel Discussion"

B. New Frontiers in Drug-Combination Modeling

Organizer/Chair: Steve Novick, GlaxoSmithKline

1. "Quantifying Combination Drug Synergy", John Peterson, GlaxoSmithKline
2. "The Search for Synergy: A Modern Odyssey", William Greco, University at Buffalo, SUNY
3. "Evaluating the Combination Index Via Simulation", Phillip Iversen, Eli Lilly and Company, Robert Abel, Cathie Spino, University of Michigan,
4. "Nonparametric Methods for Evaluating Drug Activity and Synergy for Three Drug Combinations", Maiying Kong, University of Louisville, J. Jack Lee, Junya Fujimoto, Reuben Lotan, University of Texas M.D. Anderson Cancer Center

C. Identification of Non-Specified Conditions (Data mining in Observational Data)

Organizer/Chair: David Madigan, Columbia University

1. "Bayesian Logistic Regression for Medical Claims Data", Ivan Zorych, Columbia University
2. "Implementation and Examination of Measures of Disproportionality as Screening Tools on Longitudinal Claims Data", Andrew Bate, Pfizer
3. "Cohort Screening Methods for Identifying Unspecified Outcomes and Outcomes of Interest on Observational Databases", Steph Reisinger, ProSano
4. "Towards Real-time Safety Monitoring of Medical Products", Yoko Tanaka, Eli Lilly and Company, Xiaochun Li, Regenstrief Institute/Indiana University School of Medicine

D. Advanced Modeling and Accelerated Stability Studies

Organizer/Chair: Stan Altan, Johnson & Johnson

1. "Solid State Degradation Mechanisms", William Porter, Abbott
2. "Mathematical Modeling of Biosensor Performance for Shelf-life Prediction", Stephen Snyder, Queen's University
3. "Using an Open Bottle Accelerated Stability Experiment to Predict Degradant Behavior of a Solid Dosage Form in Moisture-Protected Packaging", Anthony Carella, Pfizer
4. "Modeling Approaches to Multiple Isothermal Stability Studies for Estimating Shelf Life", Oscar Go, Johnson & Johnson

11:30 AM – 1:00 PM

LUNCH BUFFET

TUESDAY AFTERNOON, MAY 25

POSTER SESSION

12:00 PM – 1:30 PM

Chair: Krishna Padmanabhan, Pfizer

Posters will be considered on any biopharmaceutical statistical topic.

Abstracts must be received by April 19, 2010. Students may qualify for the Charlie Sampson poster award if abstract, poster panels, and a paper briefly describing the poster are received by April 19.

For more information contact

Krishna Padmanabhan at padmans@wyeth.com

Phone: (484)-865-2084

TUESDAY AFTERNOON, MAY 25

CONCURRENT SESSIONS

1:30 PM – 4:30 PM

A. Statistical Methods and Strategies for Ethnic Comparisons in Multiregional Clinical Trials

Organizer/Chair: Kyoungah See, Eli Lilly and Company

1. "Considerations in Design and Analysis of Multi-Regional Clinical Trials", James Hsien M. Hung, FDA
2. "A Posterior Predictive Inference Approach to the Analysis of a Multiregional Bridging Study", Robert Noble, GlaxoSmithKline
3. "Statistical Considerations in Multi-Regional Clinical Trials", Yoko Tanaka, Eli Lilly and Company
4. "Predicting Fracture Risks in Multiregional Observational Studies", Kyoungah See, Eli Lilly and Company
5. "Panel Discussion"

B. Immune Response and Related Antibody Assays

Organizer/Chair: Bill Pikounis, Johnson & Johnson

1. "Statistical Considerations for Defining Cut Points and Titters in Anti-Drug Antibody (ADA) Assays", Ken Goldberg, Johnson & Johnson
2. "A Gamma-Fitting Method for Anti-Drug Antibody Assays to Establish Assay Cut-Points for Non-Normal Data", Brian Schlain, Biogen Idec
3. "Statistical Comparison of Immunogenicity Cut Point Factors Using Log Transformation", Dean Li, Pfizer

C. Monitoring of Health Outcomes of Interest (Surveillance of Known Outcomes)

Organizer/Chair: Andrea Cook, Group Health Cooperative

1. "Group Sequential Methods for Observational Data Incorporating Confounding Through Estimating Equations With Application in Post-Marketing Vaccine/Drug Surveillance", Andrea Cook, Group Health Cooperative
2. "Sequential Analytic Methods for Post-Marketing Safety Surveillance Using Existing Healthcare Databases", Lingling Li, Harvard Pilgrim
3. "Evaluating new user design decisions for active surveillance", Alan Brookhart, University of North Carolina at Chapel Hill
4. "New Developments in Rapid Cycle Analysis at VA/MedSAFE", Kwan Hur, Department of Veteran's Affairs

D. Experimental Design in CMC Applications

Organizer/Chair: Brad Evans, Pfizer

1. "Application of Efficient Design and Gaussian Process Modeling in Pharmaceutical Development", Ke Wang, Pfizer
2. "Partition Experimental Designs for Sequential Process Steps: Application to Product Development", Leonard Perry, University of San Diego
3. "Application of JMP Custom DOE Platform to Optimize a Crystallization Process for Competing Responses", Roger Norris, Eli Lilly and Company
4. "Some Applications of Serially Balanced Designs to Pharmaceutical Research", Stan Altan, Johnson & Johnson

TUESDAY EVENING BANQUET

JEFFRY D. GRIGSBY, Associate Dean of the College of Sciences and Humanities
Ball State University

Announcement of Student Winner of Charlie Sampson Poster Award

Speaker: AARON BROWN, Author of *The Poker Face of Wall Street* and *A World of Chance*

Topic: The Third Financial Revolution: Statistical Money

WEDNESDAY MORNING, MAY 26

CONCURRENT SESSIONS

8:30 AM – 11:30 AM

A. Evidence Synthesis

Organizers/Chairs: Dachuang Cao, Haoda Fu, Eli Lilly and Company

1. "Models and Methods for Meta-Analysis", Ming-Hui Chen, University of Connecticut
2. "Meta-Analysis for Rare Event Studies", Dulal Bhaumik, University of Illinois at Chicago
3. "Network Meta-Analysis for Multi-Arm Trials", Thomas Lumley, University of Washington
4. "Challenges for the Future of Meta-Analysis", Larry Hedges, Northwestern University

B. Topics in Pharmacokinetic/Pharmacodynamic Modeling

Organizer/Chair: Marta Mendiondo, University of Kentucky

1. "Developing a Statistical Support Model for Research Scientists in Pharmaceutical Research", Gary Walker, Pfizer
2. "A Likelihood Approach for Fitting Nonlinear Mixed-Effects Models to Pharmacokinetic and Pharmacodynamic Data", Doug Bates, University of Wisconsin
3. "The Analysis of Pharmacokinetic Models With Repeated Dosing", David Allen, Minghua Shan, University of Kentucky

C. Comparative Effectiveness Research

Organizer/Chair: Matt Rotelli, Eli Lilly and Company

1. "Opportunities for CER Methods in Drug Discovery, Development and Commercialization", Lei Zhu, GlaxoSmithKline
2. "Strategies for Improving the Robustness of CER Estimates from Observational Data", Mary Beth Landrum, Harvard Medical School
3. "Main Effects and Interactions, Adjusted", Stan Young, National Institute of Statistical Sciences
4. "CER in Existing Observational Databases: Be Careful What You Ask For", Paul Stang, Johnson & Johnson
5. Panel Discussion, Marc Berger, Eli Lilly and Company

D. Bioassay in a Changing Regulatory Environment

Organizer/Chair: Jerry Lewis, Biogen Idec

1. "Statistical Approaches to Meeting Emerging USP Guidelines for Bioassay Development, Analysis, and Validation", David Lansky, Precision Bioassay
2. "Analysis of Bioassays: Reflections on the Approach of the European Pharmacopoeia", Rose Gaines-Das, National Institute for Biological Standards & Control (ret.)
3. "Assessing the Similarity of Bioanalytical Methods", Jason Liao, Merck
4. "Two Approaches to Potency Bioassay Analysis", Lanju Zhang, MedImmune

11:30 AM – 1:00 PM

LUNCH BUFFET

Closing Remarks

Kjell Johnson, Pfizer