THE 34th ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP
MAY 23 – 25, 2011 • BALL STATE UNIVERSITY ALUMNI CENTER, MUNCIE, INDIANA

Co-Founders

Charles B Sampson **Retired** **Eli Lilly & Company**	**Mir Masoom Ali** **George and Frances Ball Distinguished** **Professor of Statistics Emeritus** **Ball State University**

Preliminary Program

MONDAY, MAY 23

8:30 AM – 4:30 PM
WORKSHOP REGISTRATION
FEE: $170 until May 1 ($80 for students), $200 after May 1

9:00 AM – 1:00 PM
SHORT COURSE (Separate Registration Fee: $75)
Presenter: SHEIN-CHUNG CHOW, Duke University School of Medicine
Topic: Adaptive Clinical Trial Design

2:15 PM – 2:30 PM
INTRODUCTION AND WELCOME
WHERLY HOFFMAN, Elan
MARILYN BUCK, Associate Provost and Dean of University College, Ball State University

2:30 PM – 3:30 PM
PLENARY SESSION
Speakers: ABRAHAM WYNER, the University of Pennsylvania, and
Blakeley McShane, Northwestern University
Topic: A Statistical Analysis of Multiple Temperature Proxies: Are Reconstructions of Surface Temperatures Over the Last 1000 Years Reliable?"

3:30 PM – 4:30 PM
PLENARY SESSION
Speaker: KEITH BAGGERLY, University of Texas MD Anderson Cancer Center
Topic: Case Studies in Forensic Bioinformatics - The Need for Simple Tests in High-Throughput Biology

MONDAY NIGHT MIXER
Alumni Center
5:00 PM – 7:00 PM

TUESDAY MORNING, MAY 24

CONCURRENT SESSIONS
8:30 AM – 11:30 AM

A. Controversies in Active-Controlled Clinical Trial Designs

Organizer/Chair: Alan Hopkins, Theravance, Inc.

1. "Overview: Science, Politics and Non-inferiority Designs, Alan Hopkins, Theravance, Inc.
2. "FDA Draft Guidance on Non-Inferiority Trials and the Challenge for Pharmaceutical Development: An Overview of Fundamental issues and Concerns", Patrick Peterson, Eli Lilly
3. "Non-Inferiority Trials and Historical Evidence of Treatment Effect for Severe Infections", Thamban Valappil, FDA
4. "Issues in Noninferiority Analyses: Handling of Missing Data and Selection of Analysis Groups", Brian Wiens, Alcon Laboratories
5. "Ethics, Inferiority Index and Margin – An Attempt to Minimize Controversies", George Chi, Johnson & Johnson
6. "Panel Discussion", Session Speakers

B. Reducing Drug Attrition Rates

Organizer/Chair: Katja Remlinger, GlaxoSmithKline

1. "Introduction", Katja Remlinger, GlaxoSmithKline
2. "Hit Scoring in High Throughput Screening - What Have We Learned?", Andy Liaw, Merck
3. "Modeling to Fail", Mandy Bergquist, GlaxoSmithKline
4. "Decision-Making Methods for Prioritizing Drug Candidates", Tom Vidmar, Biostat Consultants and Brad Evans, Pfizer

C. Uncontrolled Confounding

Organizer/Chair: John Seaman, Baylor University

1. "Sensitivity Analysis for Unmeasured Confounding in Principal Stratification in Settings Using Binary Variables", Scott Schwartz, Texas A&M
2. "Graphical and Likelihood-Based Approaches to Bias Analysis", Sander Greenland, UCLA
3. "Accounting for Unmeasured Confounding in Cost-Effectiveness Analyses", James Stamey, Baylor University.

D. Univariate and Multivariate Process Monitoring

Organizer/Chair: Peter Sprinz, Eli Lilly

1. "Change Point Analysis and Applications", Peter Sprinz, Eli Lilly
2. "Applying Change Point Detection in Vaccine Manufacturing", Hesham M. Fahmy, Merck
3. "A Non-parametric Change Point Model for Multivariate Phase-II Statistical Process Control", Mark Holland, University of Minnesota

11:30 AM – 1:00 PM LUNCH BUFFET

TUESDAY AFTERNOON, MAY 24

POSTER SESSION
12:00 PM – 1:30 PM
Chair: Paul Berg, Eli Lilly

Posters will be accepted on any biopharmaceutical statistical topic.
Abstracts must be received by April 18, 2011. Students may qualify for the Charlie Sampson poster award if abstract, poster panels, and a paper briefly describing the poster are received by April 18.
For more information contact
Paul Berg at pberg@lilly.com
Phone: (317)-276-0395

TUESDAY AFTERNOON, MAY 24

CONCURRENT SESSIONS
1:30 pm – 4:30 pm

A. Predictive Biomarkers and Oncology Trials

Organizer/Chair: Peter Slasor, Amgen

1. "Overview of Drug/Diagnostic Co-Development", Gracie Lieberman, Genentech
2. "What Happens When You Let Up on the Brakes: Exploring Biomarkers of Ipilimumab Activity", Scott Chasalow, BMS
3. "Searching for Predictive Biomarkers in Clinical Trials: Successful and Unsuccessful Stories", Li-An Xu, BMS
4. "Evaluating Predictive Markers - Design and Analysis Considerations", Yuan-Li Shen, FDA

B. Statistical Considerations in Immunogenicity Testing

Organizer/Chair: Lei Zhou, Amgen

1. "Statistical Perspectives Based on a Decade of Immunogenicity Cutpoint Assessments", Wendell C. Smith, B2S Consulting
2. "Development of Fit-for-Purpose Customized Assay Statistical Tools (CAST) for Immunogenicity Assays", Cheng Su, Amgen Inc.
3. "Characterization and Optimization Using Design of Experiments", Martin Kane, Human Genome Science, Inc.
4. "Sample Size Determination for Cutpoint Estimation of Immunogenicity Assay", Lanju Zhang, MedImmune

C. Advanced Bias Adjustment Techniques

Organizer/Chair: Bo Lu, Ohio State University

1. "The Hidden Role of the Propensity Score in Matching for Inference about Causal Effects", Ben Hansen, University of Michigan
2. "Using the Propensity Score as a Regression Predictor or Matching: A Comparative Study of Treatment Effect Estimation Bias", Bo Lu, Ohio State University
3. "Near/Far Matching: Overcoming Unobserved Selection Bias", Mike Baiocchi, University of Pennsylvania

D. Statistical Mitigation of Out-of-Specification/Out-of-Trend in a Quality-by-Design World

Organizer/Chair: Yan Shen, Johnson & Johnson

1. "Design of Experiments to Establish Temperature and Humidity Limits for Temperature Excursions during Product Distribution", Bill Porter, Abbott
2. "Statistical Challenges in Projecting Stability OOT/OOS in a QbD World", Jason Martin, Eli Lilly
3. "Regression to the Mean as a Tool to Understand "Out-of-Specifications (OOS)", Jyh-Ming Shoung, Johnson & Johnson
4. "TBA", Abbie Gentry, McNeil Consumer

TUESDAY EVENING BANQUET
ROBERT MORRIS, Associate Provost for Research and Dean of the Graduate School
Ball State University
Announcement of Student Winner of Charlie Sampson Poster Award
Speaker: SASTRY PANTULA, Past ASA President
Topic: Surfing the Data Waves

WEDNESDAY MORNING, MAY 25

CONCURRENT SESSIONS
8:30 AM – 11:30 AM

A. What Can Statisticians do to Help Others Better Understand Safety?

Organizer/Chair: Whedy Wang, Orexigen

1. "Hiding Safety Signals: 5 Easy Lessons", Janet Wittes, Statistics Collaborative, Inc.
2. "The Current Regulatory Environment and Its Impact on the Analysis of Safety Data", Susan Harris, AstraZeneca
3. "Statistical Assessments of Suicidal Ideation and Behavior in Clinical Trials and the Historic and Regulatory Consideration", Cristiana Gassmann-Mayer, J&J
4. "The Expectation of a Rare Adverse Event", Laura J Meyerson, Biogen Idec
5. "The Role of Statisticians During Clinical Development: Some Thoughts on Possible Technical Contributions and Helpful Non-Technical Skills", Jesse A. Berlin, Johnson & Johnson
6. "Panel Discussion", Session Speakers

B. New Development of Bioassay and Bioprocess Comparability Analysis

Organizer/Chair: Harry Yang, MedImmune

1. "A Bayesian Approach to Parallelism Testing in Bioassay", Steven Novick, GlaxoSmithKline
2. "Establishing Equivalence of Biopharmaceuticals through Indirect Assays", Michael Li, MedImmune
3. "The Posterior Probability of Dissolution Equivalence", David LeBlond, Abbott

C. Patient Heterogeneity in Observational Research: Response Challenge

Organizer/Chair: Robert Obenchain, Risk Benefit Statistics LLC

1. "Introduction to the Simulated Dataset", Robert Obenchain, Risk Benefit Statistics LLC
2. "Some Relatively Simple Ways to Get Good Answers", Xiaochun Li, IUPUI
3. "Lessons Learned", Stan Young, NISS
4. "Discussant", Patrick Ryan, Johnson & Johnson (Tentative)

D. Delivery of Content Uniformity

Organizer/Chair: Yoonjin Cho, GlaxoSmithKline

1. "Construction of Tolerance Intervals with Censored Samples", Kris Krishnamoorthy, University of Louisiana-Lafayette
2. "A Proposed Content-Uniformity Test for Large Sample Sizes", Kim Vukovinsky, Pfizer
3. "Parametric Tolerance Interval Testing", Rick Lewis & Steve Novick, GlaxoSmithKline

11:30 AM – 1:00 PM LUNCH BUFFET
Closing Remarks
Wherly Hoffman, Elan

FOR MORE INFORMATION ON THE WORKSHOP, please contact **MIR MASOOM ALI**, Ball State University, (765)-284-7495, Email: mali@bsu.edu or **MELVIN MUNSAKA**, Takeda Global Research & Development, (224)-554-2846, Email: mmunsaka@tgrd.com. The preliminary program will be updated periodically at the web site http://www.mbswonline.com. Registration will be available on the website in February.