

**THE 35th ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP  
MAY 21 – 23, 2012 • BALL STATE UNIVERSITY ALUMNI CENTER, MUNCIE, INDIANA**

<b>Charles B Sampson</b> Retired Eli Lilly & Company		<b>Mir Masoom Ali</b> George and Frances Ball Distinguished Professor of Statistics Emeritus Ball State University
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**Final Program  
"Strategic Use of Statistical Thinking"**

**MONDAY, MAY 21**  
8:30 AM – 4:30 PM  
**WORKSHOP REGISTRATION**  
FEE: \$195 until May 1 (\$80 for students), \$225 after May 1  
9:00 AM – 1:00 PM  
**SHORT COURSES** (Separate Registration Fee: \$90)

Presenters:	Topic
CRAIG MALLINCKRODT, Eli Lilly	<i>A Practical Guide to Preventing and Treating Missing Data</i>
PAUL FOGEL and STAN YOUNG, Consultant, Paris, France and NISS	<i>Exploring High Dimensional Data: Principal Components Analysis Versus Nonnegative Matrix Factorization</i>
THOMAS LOVE, Case Western Reserve	<i>Comparative Effectiveness Using Observational Studies</i>

2:15 PM – 2:30 PM  
**INTRODUCTION AND WELCOME**  
DOUG FARIES, Eli Lilly  
JEFFRY GRIGSBY, Associate Dean of the College of Science and Humanities, Ball State University

2:30 PM – 3:30 PM  
**PLENARY SESSION**  
**Speaker:** LEE WILKINSON, UIC and Advise Analytics  
**Topic:** A Second Opinion: Expert System for Data Analysis

3:30 PM – 4:30 PM  
**Speaker:** Lisa LaVange, CDER, FDA  
**Topic:** Current Regulatory Statistical Challenges

**MONDAY NIGHT MIXER**  
Alumni Center

4:30 PM – 6:30 PM  
**TUESDAY MORNING, MAY 22**  
**CONCURRENT SESSIONS**

**A. Decision Making in Drug Development – Can We Do Better?**

- Organizer/Chair:* Yili L. Pritchett, Abbott
- "Dysfunctional Paradigms and Stopping Rules in Clinical Trials", Peter Thall, MD Anderson
  - "The Importance of Defining and Assessing Key Success Factors for Decision-Making", David Manner, Eli Lilly
  - "Choosing Appropriate Metrics to Enable Sound Decision Making in Drug Development", Christy J. Chuang-Stein, Pfizer

**B. Current Topics in Preclinical Discovery**

- Organizer/Chair:* Imola Fodor, Genentech
- "An examination of Recurring Statistical Principles Encountered in Protein Mass Spectrometry", Richard E. Higgs, Eli Lilly
  - "Whole Genome Scans and Next Generation Sequencing", Nicholas Lewin-Koh, Genentech
  - "Imaging Platforms and Statistical Analysis of Imaging Data", Mariusz Lubomirski, Johnson and Johnson
  - "Analysis of Multiplexed Protein Lysate Microarrays", Jason R. Manro, Eli Lilly

**C. Economic Modeling and Simulation**

- Organizers/Chairs:* Lee J. Smolen, Harry J. Smolen, Medical Decision Modeling
- "Introduction to Economic Modeling and Simulation", Lee J. Smolen, Harry J. Smolen, Medical Decision Modeling
  - "An Introduction and Overview into Comparative Effectiveness Research (CER)", James Murray, Eli Lilly
  - "New Research in Economic Modeling and Simulation", Greg Samsa, Duke University

**D. Bioassay Development, Implementation, and Challenges in Practice**

- Organizer/Chair:* Kevin Guo, Eli Lilly
- "Strategic and Scientific Approaches to Developing Bioassay to Support Biologics", Darren Kamikura, Eli Lilly
  - "Opportunities for Statistical Contributions to Bioassay", David Lansky, Precision Bioassay Inc.
  - "Role of Statisticians in Implementation of USP Bioassay Chapters: Challenges and Solutions", Harry Yang, MedImmune
  - "Regulatory Challenges in Bioassay Practices", Timothy Schofield, Arlenda Inc.

11:30 AM – 1:00 PM

**LUNCH BUFFET**

**TUESDAY AFTERNOON, MAY 22**

**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 6, 2012. Students may qualify for the Charlie Sampson poster award if abstract, poster panels, and a paper briefly describing the poster are received by April 6.

For more information contact

Paul Berg at pberg@lilly.com

Phone: (317)-276-0395

**TUESDAY AFTERNOON, MAY 22**

**STUDENT SESSION SESSIONS AND CONCURRENT SESSIONS**

1:30 pm – 4:30 pm

**STUDENT SESSION**

**What You Always Wanted to Know About Statisticians in Pharma and Were Afraid to Ask**

- Organizer/Chair:* Cathie Spino, University of Michigan, Yun-Fei Chen, Eli Lilly
- "The Drug Development Process and the Role of Statisticians", Melvin Munsaka, Takeda, Jackie Reisner, PPD
  - "Common Statistical Problems Faced by Industry Statisticians", Brad Evans, Pfizer; Haoda Fu, Eli Lilly; Steve Gulyas, OptumInsight
  - "Career Path for Statisticians in the Pharmaceutical Industry", Christy Chuang-Stein, Pfizer
  - "How to Prepare Yourself for a Pharma Career?", Panel

**CONCURRENT SESSIONS**

**A. Joint Modeling of Longitudinal Measurement and Time-to-event Data**

- Organizer/Chair:* Jane Qian, Abbott Laboratories
- "Joint Modeling of Multiple Outcomes in Clinical Trials", Wei Shen, Eli Lilly
  - "Sample Size and Power Determination in Joint Modeling of Longitudinal and Survival Data", Haitao Chu, University of Minnesota
  - "Joint Modeling of Time-to-Event and Incomplete Longitudinal Data", Abdus Sattar, Case Western Reserve University
  - "Joint Modeling of Clinical Efficacy and Safety With an Application to Diabetes Studies", Haoda Fu, Eli Lilly

**B. Working Towards Success in Translational Medicine**

- Organizer/Chair:* Maha Karnoub, Pfizer
- "Novel Methods for Discovery and Replication in Large Scale Genomic Studies with Sparse Signals", Dmitri Zaykin, NIEHS
  - "Integration of Genetics and Genomics in Drug Discovery", Judy Zhong, NYU School of Medicine
  - "Clinicopathologic and Gene Expression Parameters Predict Liver Cancer Prognosis", Ke Hao, ScD., Mount Sinai School of Medicine
  - "Building to Clinical Efficacy: A Statistician's Role in a Case-Study of Translational Imaging", Eve Pickering, Pfizer

**C. PRO Development**

- Organizers/Chairs:* Laura Lee Johnson, NCCAM-NIH, Clarice Hayes, Eli Lilly
- "FDA Approach", Clarice Hayes, Co-director of the PRO Consortium
  - "PROMIS Approach", Nan Rothrock, Northwestern University
  - "Application of Item Response Theory to PRO Development", Michael Kallen, Northwestern University
  - "Assessment Center® as a Data Collection Tool", Nan Rothrock, Northwestern University

**D. Statistical Approaches to Addressing the Requirements of the New FDA Process Validation Guidance**

- Organizer/Chair:* Jason Marlin, Eli Lilly
- "Statistical Methods for Process Validation Acceptance Criteria", Mark Varney
  - "Small Molecule Approaches to Addressing the Requirements of the New FDA Process Validation Guidance", Jason Marlin, Eli Lilly
  - "Capability Assessments and Process Validation Stage 3 Implementation: 1.33 and Beyond", Krista Witkowski, Merck
  - "A Qualitative Decision Making Tool to Aid in Defining the Number of Lots for a Process Validation Campaign", Leslie Sidor, Amgen

**TUESDAY NIGHT MIXER AND BANQUET**

Alumni Center

**MIXER**

4:30 PM – 5:00 PM

**BANQUET**

5:00 PM – 8:00 PM

MICHAEL MAGGIOTTO, Dean of the College of Science and Humanities, Ball State University  
Announcement of Student Winner of Charlie Sampson Poster Award

**Speaker:** RUSSELL LYONS, Indiana University

**Topic:** *Fat Chance: Adventures in Debunking*

**WEDNESDAY MORNING, MAY 23**

**CONCURRENT SESSIONS**

8:30 AM – 11:30 AM

**A. Multiple Endpoints – Regulatory Guidance, Statistical Advances and their Applications in Clinical Trials**

- Organizer/Chair:* Frank Bretz, Novartis, Lingyun Liu, Cytel
- "Addressing Multiplicity Issues in Clinical Trials: Regulatory Guidance and Recent Advances", Mohamed Alosch, FDA
  - "Fallback and Related Testing Procedures for Clinical Trials", Brian Wiens, Alcon
  - "Testing Multiple Families of Hypotheses: A Review of Recent Developments", Brian Millen, Eli Lilly
  - "Multiple Testing Procedures Using Graphical Approaches", Jeff Maca, Novartis

**B. Metabolomics, Biomarkers, and Matrix Factorization**

- Organizer/Chair:* S. Stanley Young, NISS
- "Metabolic Profiling: Opportunities and Challenges", Chris Beecher, NextGenMetabolomics
  - "Matrix Factorization for Biomarker Discovery", Paul Fogel, Consultant, Paris
  - "Using Metabolic Profiling to Explore Horse Fitness", Stan Young, NISS

**C. Recent Developments in Comparative Effectiveness**

- Organizer/Chair:* Karen Lynn Price, Eli Lilly
- "Comparative Effectiveness Research: Perspectives and Developments from DIA Working Group", Matthew D. Rotelli, Eli Lilly
  - "Applying Bayesian Evidence Synthesis in Comparative Effectiveness Research", David Ohlssen, Novartis
  - "A Flexible Model for the Mean and Variance Functions, with Application to Medical Cost Data", Lei Liu, Northwestern University
  - "Approaches for Assessing the Impact of Unmeasured Confounding with Internal Validation Data: An Example in Type 2 Diabetes", Doug Faries, Eli Lilly

**D. Release Limit Calculations and Stability Studies**

- Organizer/Chair:* Jyh-Ming Shoung, Johnson and Johnson
- "A Bayesian Approach to the Calculation of Release Limits", Areti Manola, Janssen Pharmaceutical Research and Development
  - "Stability Across Multiple Storage Conditions: Accumulating Uncertainty", Brad Evans, Pfizer
  - "Impact of Stability on Setting and Meeting Specifications in an Uncertain World", William R. Porter, Peak Process Performance Partners
  - "Discussant", Stan Altan, GSK

11:30 AM – 1:00 PM

**LUNCH BUFFET**

**Closing Remarks**

Doug Faries, Eli Lilly