THE 36th ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP
MAY 20 – 22, 2013 • BALL STATE UNIVERSITY ALUMNI CENTER, MUNCIE, INDIANA

Co-Founders

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

Program (Version 6 May 2013)
"Sharing Statistical Solutions"

MONDAY, MAY 20
8:30 AM – 2:15 PM
WORKSHOP REGISTRATION
FEE: $205 until May 1 ($80 for students), $230 after May 1

12:45 PM – 1:45 PM LUNCH BUFFET

9:00 AM – 12:45 PM
SHORT COURSES (Separate Registration Fee: $95)

Presenters:	**Topic**
TERRY THERNEAU, Mayo Clinic	*Using Multiple Outcomes in Survival Models*
DIANE FAIRCLOUGH, University of Colorado Denver	*Analysis Methods for Informative Censoring*

2:15 PM – 2:30 PM
WORKSHOP CHAIR INTRODUCTION AND WELCOME
BILL PIKOUNIS, Johnson and Johnson
2:30 PM – 3:30 PM
PLENARY SESSION
Speaker: FRANK HARRELL, Vanderbilt University
Title: *Information Allergy*
3:30 PM – 4:30 PM
Speaker: LEE WILKINSON, Skytree, University of Illinois at Chicago
Title: *Expert Systems and Predictions for the Future*

MONDAY NIGHT MIXER
DAVID OWSLEY MUSEUM OF ART, Ball State University Campus
4:30 PM – 6:30 PM

TUESDAY MORNING, MAY 21
CONCURRENT SESSIONS
8:30 AM – 11:30 AM

CLINICAL: Safety in Drug Development: A Panoramic View of New Solutions and Statistical Approaches
Organizer/Chair: Cristiana Gassmann-Mayer, Johnson and Johnson
1. "Meta-Analysis of Clinical Trial Safety Data in a Drug Development Program: Answers to Frequently Asked Questions", Brenda Crowe, Eli Lilly
2. "Simulation-Based Designs for Safety Monitoring in Clinical Trials: Two Case Studies", Fei Chen, Johnson and Johnson
3. "Evaluating Change in Hazard in Clinical Trials With Time-to-Event Safety Endpoints", Rafia Bhore, Novartis
4. "Recommendations on integrated safety summaries from Phase 1 studies", Sveta Weiner, Johnson and Johnson

DISCOVERY/PRECLINICAL: Current Statistical Issues in Assay Development and Validation
Organizer/Chair: Aili Cheng, GlaxoSmithKline
1. "Directly Testing the Linearity Assumption for Assay Validation", Steven Novick, GlaxoSmithKline and Harry Yang, MedImmune
2. "Development and Validation in the World of Quality by Design", Tim Schofield, MedImmune
3. "Statistical Issues in Development and Validation of Functional Assays", Tsai-Lien Lin, FDA

OBSERVATIONAL: Econometric Methods in Pharmaceutical Research
Organizer/Chair: John Horowitz, Ball State University
1. "Discrete Choice Methods applied to Prescribing Decisions ", Mariana Carrera, Case Western Reserve University
2. "Limited Dependent Variables in Health Research: Some Examples From Smoking", Erik Nesson, Ball State University
3. "Using Claims Data to Analyze Adherence to Pharmaceutical Therapies: Initial Treatment and Time to Discontinuation", John Bowblis, Miami University

MANUFACTURING: Stability Analyses: Beyond ICH Q1E
Organizer/Chair: Rebecca Elliott, Eli Lilly
1. "On the Shelf-Life of Pharmaceutical Products", Jim Schwenke, PQRI, Applied Research Consultants
2. "Statistical Considerations for Mitigating the Risk of Individual OOS Results on Stability", Jeff Gardner, DataPharm Statistical and Data Management Services
3. "Change During Patient Use - Questions and Challenges", Rebecca Elliott, Senior Research Scientist, Eli Lilly

STUDENT: How to Nurture Your Statistics Degree into a Profession in Pharma
Organizer/Chair: Yun-Fei Chen, Eli Lilly, Cathie Spino, U. Michigan
1. "The Drug Development Process and the Role of Statisticians", Yun-Fei Chen, Eli Lilly, Cathie Spino, U. Michigan
2. "From Courses to Careers: A View From the Pharmaceutical Industry", Brad Evans, Pfizer, Haoda Fu, Eli Lilly, Jackie Reisner, PPD
3. "Leadership Skills for Statisticians: Why it is Important and How to Develop Them", Gary Sullivan, Eli Lilly
4. "How to Prepare Yourself for a Pharma Career", Panel Discussion

11:30 AM – 1:00 PM LUNCH BUFFET

TUESDAY AFTERNOON, MAY 21
POSTER SESSION
12:00 PM – 1:30 PM
Chair: Fangyi Zhao, Eli Lilly
Posters will be accepted on any biopharmaceutical statistical topic up to capacity.
Abstracts must be received by April 8th, 2013.
For more information contact
Fangyi Zhao at posterchair@mbswonline.com

TUESDAY AFTERNOON, MAY 21
CONCURRENT SESSIONS
1:30 pm – 4:30 pm

CLINICAL: Quantitative Methods for Decision Making
Organizer/Chair: Alan Chiang, Eli Lilly
1. "The Use of Global Benefit -Risk Assessment in Drug Development", Yili Pritchett, Astellas
2. "Evaluation of Benefit-Risk in Clinical Programs", Freda Cooner, FDA
3. "Benefit-and-Risk Evaluation of Treatment of Arterial Disease in the Lower Limbs", Justin Recknor, Gore
4. "Predicting Phase III Success Using a Combination of Phase II Results and Historical Reference Data", David Burt, GlaxoSmithKline

DISCOVERY/PRECLINICAL: Next Generation Sequencing and Its Statistical Issues
Organizer/Chair: Yuefeng Lu, Sanofi, and Xiwen Ma, Eli Lilly
1. "Next-Generation Sequencing - Opportunities and Challenges", Phil Ebert, Eli Lilly
2. "Statistical Considerations for NGS Study", Ray Liu, Millennium
3. "Variation Discovery From Heterogeneous Tumor-Normal Paired DNA Samples Using Exome Sequencing", Hyonho Chun, Purdue University

OBSERVATIONAL: FDA Sentinel/Mini-Sentinel and OMOP Initiatives: Status Update
Organizer/Chair: Kenneth Hornbuckle and Stephen Paul Motsko, Eli Lilly
1. "FDA Sentinel/Mini-Sentinel: Developing a National Active Surveillance System", Azadeh Shoaibi, FDA
2. "OMOP Overview and Scientific Results", Bill Dumouchel, Oracle
3. "High-Dimensional Propensity Score: Lessons Learned", Jeremy Rassen, Brigham and Women's Hospital and Harvard Medical School
4. "Evolution of Active Surveillance: Industry Perspective", Stephen Motsko and Kenneth Hornbuckle, Eli Lilly

MANUFACTURING: Accelerated Testing for Biologics
Organizer/Chair: Leslie Sidor, Amgen
1. "Physical Biochemistry, Metrology, and Accelerated Degradation Experiments", William R. Porter, Peak Process Performance Partners
2. "Accelerated Stability Modeling for Bioproducts", Kevin Guo, Eli Lilly
3. "Modeling Sub-Visible Particle Data With Product Held at Accelerated Stability Conditions", Jose Ramirez, Amgen
4. "Determining Equivalence Acceptance Criteria With Accelerated Stability Data", Leslie Sidor, Amgen

TUESDAY NIGHT MIXER AND BANQUET
Alumni Center
MIXER
4:30 PM – 5:00 PM
BANQUET
5:00 PM – 8:00 PM
Welcome: SUDIPTA SAHA, Ball State University
Announcement of Student Winner of Charlie Sampson Poster Award
Speaker: PAUL MCKENZIE, Vice-President, Johnson and Johnson
Title: *Leadership and Career Development*

WEDNESDAY MORNING, MAY 22
CONCURRENT SESSIONS
8:30 AM – 11:30 AM

CLINICAL: Contributions of Statisticians in Clinical Trials: From Design to Analysis
Organizer/Chair: Edmund Luo, Bausch and Lomb
1. "The Role of Statistics Innovation in Improving the Productivity of Pharma R&D", Haoda Fu, Eli Lilly
2. "New Insights in Use of Baseline Covariates in Clinical Trial Design and Data Analysis", Yongming Qu, Eli Lilly
3. "Examination of Analysis Methods for Positive Continuous Dependent Variables: Model Fit and Cost Saving Implications", Brian Smith, Amgen
4. "Detection of Outliers in Biomedical Data", Rahmatullah Imon, Ball State University

DISCOVERY/PRECLINICAL: Reproducible Research
Organizer/Chair: Jason Manro, Eli Lilly
1. "The Reproducibility Initiative: a potential solution to the irreproducibility problem", Elizabeth Iorns, Science Exchange
2. "Barriers to Reproducible Research and a Web-Based Solution", Matt Shotwell, Vanderbilt University
3. "Doing Reproducible Research Unconsciously: Higher Standard But Less Work", Yihui Xie, Iowa State

OBSERVATIONAL: Methods for Missing Data
Organizer/Chair: Shaila Ballal, ImClone
1. "Towards a Complete Solution for Cost/Effectiveness in Oncology: Handling Heterogeneity, Variability and Censoring", Gerhardt Pohl, Eli Lilly
2. "Notes on Joint Analysis of Longitudinal and Time-to-Event Data by Random Effects Models", Lei Liu, Northwestern University
3. "Summarizing Longitudinal PRO's in the Presence of Limited Survival", Li Li and Gerhardt Pohl, Eli Lilly

MANUFACTURING: Spec Setting: What Does it Mean/What Goes Into it?
Organizer/Chair: Helen Strickland, GlaxoSmithKline
1. "Drug Product Specifications: Considerations for Developing Product Quality Demonstration Methods", Helen Strickland, GlaxoSmithKline
2. "Clinical Considerations for Developing Product Quality Requirements for Uniformity of Dosage Units", Tim Kramer, Eli Lilly
3. "Challenges in Process Comparison Studies", Seth Clark, Merck
4. "Futuristic Approaches to Determining Product Quality Requirements that are Related to Patient Needs", Open Discussion

11:30 AM – 1:00 PM LUNCH BUFFET & *Closing Remarks*: Bill Pikounis, Johnson and Johnson

FOR MORE INFORMATION ON THE WORKSHOP, please contact **BILL PIKOUNIS**, Johnson and Johnson, Email: chair@mbswonline.com . The program and workshop logistics will be updated periodically at the web site as the workshop date approaches, see http://www.mbswonline.com/ . The track co-chairs are: CLINICAL: Bret Musser, Merck; DISCOVERY/PRECLINICAL: Steve Novick, GlaxoSmithKline; OBSERVATIONAL: Gerhardt Pohl, Eli Lilly; MANUFACTURING: Brad Evans, Pfizer; STUDENT: Yun-Fei Chen, Eli Lilly, and Cathie Spino, University of Michigan.