**THE 39thANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP**

**MAY 16 – 18, 2016 • BALL STATE UNIVERSITY ALUMNI CENTER, MUNCIE, INDIANA**

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| **Co-Founders** |
| **Charles B Sampson****Chairman Emeritus****Retired****Eli Lilly & Company**  | **Untitled**  | **Mir Masoom Ali** **Chairman Emeritus and George and Frances Ball Distinguished** **Professor of Statistics Emeritus** **Ball State University** |
| **Program (Version 17 April 2016)** ***“The Power and 3 I’s of Statistics : Innovation, Integrity and Impact”*** |
| **MONDAY, MAY 16****MORNING****8:30 am – 2:15 pm****WORKSHOP REGISTRATION**FEE: $215 until May 1 ($80 for students), $240 after May 1**9:00 am – 12:45 pm****SHORT COURSES** (Separate Registration Fee: $95)

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| **Presenters** | **Topic** |
| PHIL BOWSHER, RStudio | *An Introduction to Shiny, R Markdown, and HTML Widgets for R With Applications in Drug Development* |
| DONG XI, Novartis | *Graphical Approaches to Multiple Testing* |

**12:45 PM – 1:45 PM LUNCH BUFFET****Student Lunch Session –** *Networking for Success*, Soomin Park, Eli Lilly**2:15 pm – 2:30 pm****INTRODUCTION AND WELCOME****WORKSHOP CHAIR**RAY LIU, Takeda**BALL STATE REPRESENTATIVE**MUNNI BEGUM, Mathematical Sciences Department, Ball State University**2:30 pm – 3:30 pm**PLENARY SESSION**Speaker:** FRANK SHEN, ABBVIE **Title:** *Challenge. Change. Engage: Three Secret Formulae for Driving an Impactful Innovation***3:30 pm – 4:30 pm**Speaker: YI TSONG, FDA Title: *Significance Tests and confidence Interval Approaches – Where is the Duality?* MONDAY NIGHT MIXER**4:30 pm – 6:30 pm** **Alumni Center**TUESDAY MORNING, MAY 17**CONCURRENT SESSIONS****8:30 am – 11:30 am**CLINICAL: Sample Size Re-Estimation for Confirmatory Trials – Emerging Methods and Practical Guidance*Organizers/Chairs:* William Prucka, Eli Lilly1. "Sample Size Re-estimation Designs In Confirmatory Clinical Trials - Current State, Statistical Considerations, and Practical Guidance", Yili Pritchett, MedImmune
2. "Applications of Sample Size Re-Estimation in Confirmatory Clinical Trials", Jon David Sparks, Eli Lilly
3. "Emerging Methods for Estimation and Hypothesis Testing for Designs Using Sample Size Re-estimation", Cyrus Mehta, Cytel
4. "Panel Discussion", William Prucka, Lilly

DIAGNOSTICS: NGS Based Genomic Diagnostics in Precision Medicine*Organizer/Chair:* Jincao Wu & Sharon Liang, FDA1. "Regulatory Considerations for NGS-Based Tests", Sharon Liang, FDA
2. "Companion Diagnostics on an NGS-Based Assay: Methodology and Analytical Validation", James Sun, Foundation Medicine
3. "Sequence Counts as Compositional Data: Metrics for Sample Quality, Sequencing Integrity, and Batch Effects in Targeted NGS", Bonnie LaFleur, HTG Molecular Diagnostics
4. "Statistical Challenges in Genetic Diagnosis of Rare Diseases With Known Monogenic Causes", Hyun Min Kang, University of Michigan

BIOEQUIVELENCE: Bioequivalence and Biosimilar*Organizer/Chair:* Yi Tsong, FDA 1. "Equivalence Test of Analytical Biosimilarity", Yi Tsong, Xiaoyu Dong, Meiyu Shen, Yu-Ting Weng, FDA
2. "Bioequivalence evaluation of sparse sampling data using bootstrap resampling method ", Meiyu Shen, Huaixiang Li, Guoying Sun, FDA
3. "Setting Equivalence Acceptance Criteria for Demonstration of Analytical Similarity", Harry Yang, Steven Novick, Rick Burdick, MedImmune

MANUFACTURING: Continuous Manufacturing*Organizer/Chair:* Brad Evans, Pfizer 1. "Some Statistical Issues Associated With Monitoring and Control of Blend Potency at the Feed Frame Using NIR Spectroscopy", Tim Kramer, Eli Lilly
2. "A Probability Based Equivalence Test of NIR vs HPLC Analytical Methods in a Continuous Manufacturing Process", Areti Manola, Janssen
3. "Sampling Considerations for UDU Release Testing in Continuous Manufacturing", Plinio De los Santos, Merck
4. "Discussant, Stan Altan, Janssen

**11:30 AM – 1:00 PM LUNCH BUFFET**TUESDAY AFTERNOON, MAY 17**POSTER SESSION****12:00 pm – 1:30 pm****Statistical Applications in Drug Development***Chair*: Ying Grace Li, Eli LillyPosters will be accepted on any biopharmaceutical statistical topic up to capacity. Abstracts must be received by April 10th, 2015.For more information contact Ying Grace Li at posterchair@mbswonline.com **TUESDAY AFTERNOON, MAY 17****CONCURRENT SESSIONS** **1:30 pm – 4:30 pm****STUDENT SESSION: Making a Healthy Difference as a Pharmaceutical Research Statistician** *Organizer/Chair:* Yun-Fei Chen, Brian Millen, Han Wu, Eli Lilly 1. "Statistical Innovation and Patient Outcomes", Craig Mallinckrodt, Eli Lilly
2. "Reflections on my Pharma Career", Naitee Ting, Boehringer-Ingelheim
3. "How to Prepare for Your Job Interview", Russell Reeve, Quintiles, Naitee Ting, Boehringer-Ingelheim

**WEDNESDAY MORNING, MAY 18** **10:00 AM – NOON****Special Session on Statistical Programming**“Leadership of Statisticians and Programmers in the Future of Big Data and Computing” | CLINICAL: Modeling and Simulation in the Pharmaceutical Industry *Organizer/Chair:* Jose Pinheiro, Janssen 1. "Synergistic Opportunities with Pharmacometricians and Statisticians", Alan Hartford, Abbvie
2. "Precision in Model Prediction", Matt Rotelli, Eli Lilly
3. "Application of Dose Scaling Method in Similarity Assessment", Yaning Wang, FDA
4. "Panel Discussion", Jose Pinheiro, Janssen"

BIOMARKERS: Precision Medicine, Biomarker, and Subgroup Identification in Drug Development *Organizer/Chair:* Tuan Stevon Nguyen, Eli Lilly1. "The VG (Virtual Twins and GUIDE) Method for Subgroup Identification", Qi Tang, Abbvie
2. "Subgroup Identification in a Learn-and-Confirm Paradigm", Lei Shen, Eli Lilly
3. "Statistical Issues in Co-Developing Drug Therapy and Diagnostic Test Using Biomarker Enrichment Design", Hong Tian, Janssen
4. "Cross-Validated STEPP Analysis for Biomarker Subgroup Determination Problems", Gu Mi, Eli Lilly

STATISTICAL PROGRAMMING AND DATA VISUALIZATION: Best Practice in Programming and Visualization *Organizer/Chair:* Vipin Arora, Eli Lilly1. "Good Practices and Implementation Methods for Optimally Stratified Randomization", Jonathan Chipman, Vanderbilt University.
2. "Zero-Inflated Models for RNA-Seq Count Data", Munni Begum, Ball State University
3. "Moving from Data Collection to Data Visualization and Analytics: Leveraging CDISC SDTM Standards to Support Data Marts", Steve Kirby, Chiltern International
4. "Concepts and Strategies for Developing Effective Data Visuals", Becky Bates, GCE Solutions
5. "A Shiny New World of Programming and Visualization", Michael Man, Eli Lilly

MANUFACTURING: Comparability and Biosimilarity *Organizer/Chair:* Yanbing Zheng, Abbvie 1. "A Further Look at the Current Equivalence Test for Analytical Similarity Assessment", Aili Cheng, Pfizer
2. "Using the Confidence Interval on Effect Size to Demonstrate Analytical Similarity Between Reference and Biosimilar Products", Rick Burdick, Elion Labs
3. "Statistical Methods for Comparability Assessment in Drug Development", Yuanyuan Duan, Abbvie
4. "Analytical Similarity Assessment: Practical Challenges and Statistical Perspectives", Richard O. Montes, Hospira, a Pfizer company
5. "Discussant", Yi Tsong, FDA

TUESDAY NIGHT MIXER AND BANQUET**Alumni Center****MIXER****4:30 pm – 5:00 pm**BANQUET**5:00 pm – 8:00 pm**Welcome: MIR MASOOM ALI, Chairman Emeritus and George and Frances Ball Distinguished Professor of Statistics EmeritusAnnouncement of Student Winner of Charlie Sampson Poster Award**Speaker:** CHARLIE SCHICK, Atigeo **Title:** "*Accelerating Analytics With External Data*"WEDNESDAY MORNING, MAY 18**CONCURRENT SESSIONS****8:30 am – 11:30 am**CLINICAL: Statistical Approaches to Address Multiplicity Testing in Clinical Trials*Organizer/Chair:* Chakib Battioui, Eli Lilly1. "Confident Biomarker Identification by Assessing Efficacy in Subgroups and Their Mixtures", Jason Hsu, Ohio State, Eli Lilly
2. "Multiple Error Rates in Assessing Efficacy in Subgroups and Their Mixtures", Haiyan Xu, Janssen
3. "The Closure Principle Revisited: Looking Back at a 40 Years Old (and Wise) Principle With Special Reference to Multiple Endpoints in Clinical Trials", Dror Rom, ProsoftClinical
4. "Panel Discussion", All

BIOMARKERS: Unleashing the Power of Statistics in Drug Discovery Research*Organizer/Chair:* Shibing Deng, Pfizer1. "Leveraging Omics Data in Drug Development – Get Ready for the Show! ", Weidong Zhang, Pfizer
2. "Statistical modeling for Tumor Regrowth Experiments in Xenograft Studies", Cong Li, Takeda
3. "Bayesian Inference of Tumor Heterogeneity in Human Cancers", Yuan Ji, University of Chicago
4. "Transcriptomic Biomarkers Research at Eli Lilly With Applications in Autoimmune Conditions", Guilherme V. Rocha, Eli Lilly

ANALYTICAL METHODS: Continued Validation and Verification of Analytical Methods*Organizer/Chair:* Harry Yang, MedImmune 1. "Analytical Development Using Quality by Design", Tim Schofield, GSK
2. "Statistical Approaches for Assessment of Parallelism for Bioassays", Xiaoyu (Cassie) Dong, FDA
3. "Method Validation Based on Total Error", Jason Zhang, MedImmune

MANUFACTURING: Internal Release Limit and Control Limit *Organizer/Chair:* Mary Ann Gorko, AstraZeneca 1. "Setting Release Limits: A comparison of Frequentist and Bayesian Approaches", Niels Væver Hartvig, Novo Nordisk
2. "Risk Evaluation of Shelf-Life Specifications and Internal Release Control Using a Bayesian Approach", Yijie Dong, BMS
3. "Setting Control Limits Using Bayesian Methods When Most Observations Are Below the Limit of Quantitation", Steve Novick, MedImmune
4. "Effective use of Release and Control Limits to Manage Manufacturing and Patient Risks", Tim Schofield, GSK

**11:30 AM – 1:00 PM LUNCH BUFFET and Closing Remarks**: Ray Liu, Takeda |

**FOR MORE INFORMATION ON THE WORKSHOP**, please contact **RAY LIU**, Takeda, e-mail: ray.liu@takeda.com or Publicity Chair Melvin Munsaka at melvin.munsaka@takeda.com or Munni Begum at  mbegum@bsu.edu . 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: David Manner, Eli Lilly; BIOMARKERS: Fen Gao, Takeda; DATA VISUALIZATION: Vipin Arora, Cindy Lee, Eli Lilly; MANUFACTURING: Jyh-Ming Shoung, Johnson and Johnson; DIAGNOSTICS Jingjing Ye, FDA; BIOEQUIVALENCE, Yi Tsong, FDA.