**THE 41stANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP**

**MAY 14 – 16, 2018 • University Tower and Hine Hall, Indiana University-Purdue University Indianapolis, INDIANAPOLIS, 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** |
| One Page Program (FINAL) ***“The Great Adventure of Biopharmaceutical Statistics”*** |
| **MONDAY, MAY 14****8:00 am – 2:30 pm****WORKSHOP REGISTRATION**FEE: $240 until May 1 ($120 for academia/government, $80 for students), $275 after May 1**8:30 am – 12:00 pm****SHORT COURSES** (Separate Registration Fee: $100)

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| **Presenters** | **Topic** |
| *BRUNO BOULANGER, Arlenda*  | *Applied Bayesian Statistics in Drug Development*  |
| *SANJAY MATANGE, SAS* | *Clinical Graphs Using SAS* |

**12:00 PM – 1:00 PM LUNCH BUFFET****1:00 pm – 2:00 pm****POSTER SESSION****Statistical Innovation 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 9th, 2018. For more information contact Ying Grace Li at posterchair@mbswonline.com **2:15 pm – 2:30 pm****INTRODUCTION AND WELCOME (Auditorium)****WORKSHOP CHAIR**ALAN CHIANG, Eli Lilly**IUPUI REPRESENTATIVE**BARRY KATZ, Chair of Biostatistics Department, Indiana University**2:30 pm – 3:30 pm**PLENARY SESSION**Speaker:** RON WASSERSTEIN, ASA **Title:** *Doctor, It Hurts When I p***3:30 pm – 4:30 pm**Speaker: KEVIN CHARTIER, AstellasTitle: *Moving from a Sea of p to Quantitative Influence and Leadership* **4:30 pm – 6:30 pm** MONDAY NIGHT MIXER (POSTER SESSION CONTINUES)**University Tower, IUPUI**TUESDAY MORNING, MAY 15**8:30 am – 11:30 am****CONCURRENT SESSIONS**CLINICAL: Model Informed Drug Development (Auditorium)*Organizer/Chair:* Bret Musser, Regeneron; Matt Rotelli, Eli Lilly1. "Translating from Lab to Clinic: The Utility of Quantitative Pharmacology Approaches", Ronda Rippley, Regeneron
2. "Bayesian Data Analysis Using Stan/Torsten for Pharmacometric Applications", Bill Gillespie, Metrum
3. "Virtual Patients and Populations in Quantitative Systems Pharmacology Models", Richard Allen, Pfizer
4. “PKPD Approaches and Considerations in Pediatric Drug Development: Extrapolation and Dose Optimization”, William Kielbasa, Eli Lilly

PRE-CLINICAL/DISCOVERY: Omics Data (Room 206)*Organizer/Chair:* Xin Huang, Abbvie1. "Computational Approaches for Drug Target Discovery from CRISPR Functional Screens", Han Xu, MD Anderson
2. "Derive Genetic Variations at Functional Elements Directly from Target-based DNA Sequencing Assays", Tao Liu, Univ. of Buffalo
3. "Reproducible Preclinical Pharmacogenomics Analysis", Benjamin Haibe-Kains, Univ. of Toronto
4. Panel Discussion, All

VISUALIZATION/PROGRAMMING/RWE: Statistical Programming and Visualization (Room 208)*Organizer/Chair:* Mike Carniello and Donna Kowalski, Astellas1. "Trials and Tribulations of Observational Studies", Ronald Copp and Amy Boyd, ICON
2. "Programming and Visualization of Safety Data in the World of Big Data: Natural Language Processing and Machine Learning", Melvin Munsaka, AbbVie
3. "Next Generation Graphics", Suhas Sanjee, Merck
4. “Introducing R/Tidyverse to Clinical Statistical Programming”, Freeman Wang, BioStat Solutions
5. “Fitting Bayesian Pharmacokinetics Models with PROC MCMC”, Fang Chen, SAS

CHEMICAL MANUFACTURING CONTROL: Statistical Assessment in Comparability Analyses (Room 216)*Organizer/Chair:* Erik Talens, Merck 1. "Establishment of Acceptance Criteria for Comparability Studies", Rick Burdick, Elion Labs
2. "One Part of the Whole: Analytical Similarity and Totality of Evidence", Katherine Giacoletti, SynoloStats
3. "Early Phase Comparability Studies Using Platform Knowledge", Paul Faya, Eli Lilly
4. Panel Discussion, All

**11:30 AM – 1:30 PM LUNCH BUFFET****CONCURRENT STUDENT SESSION (Room 206) & ROUNDTABLE DISCUSSION (Ballroom)****STUDENT SESSION: The Principal Components of a Pharmaceutical Statistics Career** *Organizer/Chair:* Veavi Chang, Brian Millen, Eli Lilly, and Barry Katz, Indiana University 1. "Influence, Innovation, and Impact: Case Examples from Current Statisticians in Pharma”,
* Kofi Adragni, Eli Lilly
* Martin King, Abbvie
1. "Career in Pharma: Personal Perspectives", Panel Discussion

Fan Liu, Notre Dame; Lin Li, BioStat Solutions; Michael Wilson, Independent Consultant; Shanthi Sethuraman, Eli Lilly; Rudolph Parrish, ELANCO; Run Zhuang, Eli Lilly**ROUNDTABLE DISCUSSION,** Shufang Wang and Josephine Asafu-Adjei, Eli LillySee [www.mbswonline.com](http://www.mbswonline.com) for a list of topics and organizers; online registration required. | TUESDAY AFTERNOON, MAY 15**1:30 Pm – 4:30 Pm****CONCURRENT SESSIONS**CLINICAL: Why Estimands Matter? (Auditorium)*Organizer/Chair:* Junxiang Luo, Eli Lilly 1. "What versus How: Estimands and Estimators", Steve Ruberg, Analytix Thinking
2. "Overview of the ICH E9 Addedndum: History, Recent Development, Key Definitions, and Content", Craig Mallinckrodt, Biogen
3. "Estimands and Sensitivity Analyses", Ilya Lipkovich, IQVIA
4. “Estimands: What Are We Missing in the Protocol/SAP versus ICH E9 Addendum?”, Bidan Huang, AbbVie

PRE-CLINICAL/DISCOVERY: Statistics for in vivo Discovery Research (Room 206)*Organizer/Chair:* Christopher Tong, Center for Veterinary Biologics, USDA1. "(Re)Randomizing Using Baseline Covariates in Animal Studies", Phil Yates, Pfizer
2. "A Bayesian Method to Analyze in vivo Combination Data with an Ordinal Categorical Response", Phil Iversen, Eli Lilly
3. “Hippocampal Place Cells Analysis via Calcium Imaging”, Zhenya Cherkas, Janssen
4. “Statistical Inference Enables Bad Science; Statistical Thinking Enables Good Science”, Christopher Tong, Center for Veterinary Biologics, USDA
5. Panel Discussion, All

VISUALIZATION/PROGRAMMING/RWE: Real World Data / Real World Evidence (Room 208)*Organizer/Chair:* Dachuang Cao, Eli Lilly1. "Overview of RWD/RWE and Their Challenges", Doug Faries, Eli Lilly
2. "Debate #1: Where is the Bigger Gap in RWE- Lack of Proper Statistical Methods vs. Lack of Proper Use of Statistical Methods”, Wei Shen, Eli Lilly, and Weili He, AbbVie
3. "Debate #2: Where to Invest More in RWE- Pragmatic Trials/Regulatory Uses vs. Artificial Intelligence/Machine Learning”, Doug Faries, and Haoda Fu, Eli Lilly

CHEMICAL MANUFACTURING CONTROL: Reduced Scale Model Qualification (Room 216)*Organizer/Chair:* Dwaine Banton, Janssen 1. "Statistical, Engineering, and Analytical Considerations for Scale-down Model (SDM) Development and Qualification", Seth Clark, Merck, et al.
2. "Scientific Approaches and Limitations to Bioreactor Reduced Scale Model Qualification", Christopher Canova, Janssen
3. "Qualification of High Throughput Micro-scale Models", Laura Pack, Seattle Genetics
4. “A Probability-based Approach to Reduced Scale Model Qualification Using Bayesian Methods”, Dwaine Banton, et al., Janssen

TUESDAY NIGHT MIXER AND BANQUET**University Tower, IUPUI****4:30 pm – 5:30 pm MIXER****5:30 pm – 8:00 pm BANQUET (Ballroom)****Welcome**: KATHY JOHNSON, Vice Chancellor, IUPUIPANDURANG KULKARNI, Chief Analytics Officer and Vice-President Biometrics, Eli LillyAnnouncement of Winner(s) of MBSW Student Poster Award**Banquet Speaker**: GREG ENAS, Innovatov**Title:** *BigDataTruth.com – Virtual Insight Within Artificially Intelligent Augmented Reality*WEDNESDAY MORNING, MAY 16**8:30 am – 11:30 am****CONCURRENT SESSIONS**CLINICAL: Bayesian Monitoring and Benefit-Risk Assessment of Safety Data (Auditorium)*Organizer/Chair:* Melvin Munsaka, AbbVie1. "Bayesian Detection of Potential Risk Using Inference on Blinded Safety Data", Brian Waterhouse, AbbVie
2. "A Simple Bayesian Approach to Quantifying Confidence Level of Adverse Event Incidence Proportion in Small Samples", Fang Liu, Univ. of Notre Dame
3. “The Case for Bayesian Methods in Benefit-Risk Assessment: Overview and Future Directions”, Carl Di Casoli, Halozyme
4. "Bayesian Approaches to Benefit-Risk Assessment Leveraging External Data", Fanni Natanegara and Michael Sonksen, Eli Lilly
5. “Hierarchical Bayes Modeling in Benefit-Risk Assessment Using Choice Based Conjoint”, Saurabh Mukhopadhyay, AbbVie

PRE-CLINICAL/DISCOVERY: Improving Safety and Immunogenicity Assessment (Room 206)*Organizer/Chair:* Jianchun (Jason) Zhang, MedImmune1. "Statistical Evaluation of Several Methods for Cut-point Determination of Immunogenicity Screening Assay", Meiyu Shen, FDA
2. "Statistical Issues for In-study Cut-point Factors for Immunogenicity Assays", Jochen Brumm, Genentech
3. "Dose Adjustment with Consideration of Drug-Drug Interaction and Patient Variation", Junshan Qiu, FDA
4. "Exposure Adjusted Analysis of Adverse Events Data”, Peigang Li, AbbVie

VISUALIZATION/PROGRAMMING/RWE: Data Visualization in the Pharmaceutical Industry: New Developments and Challenges (Room 208)*Organizer/Chair:* Spencer Laurens, Indiana University 1. "Data Visualization: Taking it to the Next Step”, Vipin Arora, Eli Lilly
2. "Visualizing and Comparing Nonlinear Curves and Surfaces", Heather (Shi) Zhao, Indiana University
3. "Dash: A Pythonic Web Application Framework for Advanced Visualizations", Rob Williams, Plotly
4. “Creating and Deploying Interactive Adverse Events through Visualizations, Dashboards and Shiny Apps”, Phil Bowsher, RStudio

CHEMICAL MANUFACTURING CONTROL: Lifecycle Approach to Bioassay (Room 216)*Organizer/Chair:* Perceval Sondag and Bruno Boulanger, Arlenda 1. "The USP Bioassay Chapters - The Honeymoon’s Over", Steven Walfish, USP
2. "Bioanalytical Method Validation with Bayesian Informative Prior Information: Case Study", Steven Novick, MedImmune
3. "The Total Error Concept Applied to Bioassay Transfer", Bruno Boulanger, Arlenda
4. Panel Discussion, All

**11:30 AM – 1:00 PM LUNCH BUFFET (Ballroom)****12:45 PM Closing Remarks**, Alan Chiang, Eli Lilly |

**FOR MORE INFORMATION ON THE WORKSHOP**, please contact **ALAN CHIANG** at chiangay@lilly.com, or **Publicity co-chair** VICTORIA SIDES at victoria\_sides@lilly.com and MELVIN MUNSAKA at melvin.munsaka@abbvie.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**:SAURABH MUKHOPADHYAY, Abbvie; **CMC**: KATHERINE GIACOLETTI, SynoloStats; **Visualization/Programming/RWE**: DONNA KOWALSKI**,** Astellas; **Preclinical/Discovery**: KATJA REMLINGER, GSK; **Student Session**: VEAVI CHANG, BRIAN MILLEN, Eli Lilly and BARRY KATZ, Indiana University.