**THE 46thANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP**

**MAY 22 – 24, 2023 • Renaissance Hotel, CARMEL (Indianapolis), INDIANA**

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| **Co-Founders** |
| **Charles B Sampson****In Memory****Eli Lilly and Company**  | **Untitled**  | **Mir Masoom Ali** **Chairman Emeritus and George and Frances Ball Distinguished** **Professor of Statistics Emeritus** **Ball State University** |
| One-Page Program ***“Statistical Excellence in Drug Development”*** |
| **MONDAY, MAY 22****7:30 am – 8:30 am BREAKFAST;** **Great Room****8:00 am – 2:30 pm****WORKSHOP REGISTRATION**FEE: $295 until May 1 ($148 for academia/government/retiree, $100 for students), $345 after May 1**8:30 am – 12:00 pm****SHORT COURSES** (Separate Registration Fee: $100)

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| **Presenters** | **Topic** | **Room** |
| *Bruno Boulanger and Brad Carlin, PharmaLex* | *Bayesian Approaches for Accelerating Drug and Medical Device Approvals* | **Carmel 3** |
| *Lei Liu, Washington University, Dept. of Biostatistics* | *Statistical Analysis of Zero-Inflated Continuous Data* | **Carmel 1** |

**12:00 PM – 1:00 PM LUNCH BUFFET; Carmel 3 & 4****12:00 pm – 2:00 pm****POSTER SESSION; Carmel 3 & 4***Chair*: Bing Liu, Adams Kusi Appiah, Eli LillyPosters will be accepted on any biopharmaceutical statistical topic up to capacity. Abstracts must be received by April 7th, 2023. For more information contact posterchair@mbswonline.com **2:15 pm – 2:30 pm****INTRODUCTION AND WELCOME; Carmel 3 & 4** **WORKSHOP CHAIR**VIPIN ARORA, Eli Lilly, Ena Bromley **2:30 pm – 4:00 pm**PLENARY SESSION; Carmel 3 & 4**Speaker:** JIRONG LU, Eli Lilly **Title:** How statistics and analytics are improving discovery of biotherapeuticsby accelerating the identification and optimization of clinical candidates**Speaker:** *MARGARET GAMALO*, Pfizer**Title:** Lessons learned in the application of Decentralized trials and implications on statistical analysis**4:00 pm – 4:30 pm***Curtain Raiser –* TRACK CHAIRS AND SESSIONS CHAIRS**4:30 pm – 6:30 pm** MONDAY NIGHT MIXER (POSTER SESSION CONTINUES); Great RoomTUESDAY MORNING, MAY 23**7:30 am – 8:30 am BREAKFAST;** **Great Room****8:30 am – 11:30 am****CONCURRENT SESSIONS**CLINICAL: Covariate adjustment in clinical trials; Carmel 3&4*Organizer/Chair:* Andy Wey, Eli Lilly1. “Covariate Adjustment in Bayesian Adaptive Clinical Trials”, James Willard, McGill Univ.
2. “Toward Better Practice for Covariate Adjustment in Randomized Clinical Trials”, Ying Zhang, Eli Lilly
3. “Robustly Leveraging Post-Randomization Information to Improve Precision in Randomized Trials”, Yu Du, Eli Lilly

**BIOMARKERS/PRE-CLINICAL/DISCOVERY: Statistical Approaches for Biomarker and Diagnostics; Carmel 1***Organizers/Chairs:* Lin Li, Jennifer Schroeder, PharmaLex1. “Discovering biomarker-treatment interactions with penalized regression”, Abraham Apfel, BMS
2. “Biomarkers to quantify renal decline in PKD patients”, Douglas Landsittel, IU SPH
3. “RAA:  The Development of a Robust and Automatic Annotation Procedure for Single-cell RNA Sequencing Data”, Dongyan Yan, Eli Lilly
4. “Trajectory Phenotyping for Medication for Opioid Use Disorder: Development of a Risk Stratification and Prediction Framework Using Urine Toxicology and EHR Data”, Albert Burgess-Hull, MATClinics

Machine Learning/Artificial Intelligence: Carmel 5*Organizer/Chair:* Kyoungah See, Eli Lilly1. “Intro talk about AI for Drug Development”, Phil Bowser, RStudio
2. “Let's Deploy an AI Model”, Phil Bowser, RStudio
3. “Machine Learning for Precision Medicine”, Xin Huang, AbbVie
4. “Identify and Characterize Super-Responder Profile: Application of ML”, Kyoungah See, Eli Lilly

CMC: Control Strategies in CMC with Panel Discussion Carmel 2*Organizer/Chair:* Mark Johnson, AbbVie1. “Attribute Sampling and Acceptance Criteria Control Strategies to Assess PPQ Batches”, Mark Johnson, AbbVie
2. “Linearity of Measurement Methods, AKA, Don’t get twisted up over linearity”, Brent Harrington, Pfizer
3. “Analytical QbD – Method Development of Ion Exchange Chromatography for a Monoclonal Antibody”, Ming-Ching Hsieh and Jingming Zhang, Eli Lilly

**11:30 AM – 1:30 PM LUNCH BUFFET; Carmel 3&4****CONCURRENT STUDENT SESSION & ROUNDTABLE DISCUSSION****STUDENT SESSION: Post Pandemic of Statistical Career Development in Pharmaceutic Industry; Carmel 5** *Organizers/Chairs:* Veavi Chang, Zae Higgins, Eli Lilly 1. Examples of Statistical Impact in Pharmaceutical Research
2. “Academy path & Consultant Firm”, Abdus Sattar, Case Western
3. “Clinical Research”, Wenxian Zhou, Eli Lilly
4. Lessons learned from a career in biostatistics, Margaret Gamalo, Pfizer
5. Panel Discussion: Statistical Career Development in Pharmaceutic Industry Post Pandemic

Margaret Gamalo, Pfizer; Abdus Sattar, Case Western; Satha Thillaiampalam, Loxo; Wenxian Zhao, Eli Lilly; Dongyan Yan, Eli Lilly | TUESDAY AFTERNOON, MAY 23**1:30 Pm – 4:30 Pm****CONCURRENT SESSIONS**CLINICAL: Modern Bayesian Approaches to Using Historical, Auxillary, and Real World Data in Drug Development; Carmel 3&4*Organizer/Chair:* Brad Carlin, PharmaLex1. “Bayesian nonparametric models for early-phase clinical trials“, Yuan Ji, University of Chicago
2. “Complex Innovative Design using a Master Protocol for Chronic Pain”, Phebe Kemmer, Eli Lilly
3. “Indirect Treatment Comparisons: When Are They Needed and How Do They Work?”, Haitao Chu, Pfizer
4. “Opportunities for new estimands in clinical trials through principal stratification”, Patrick Schnell, Ohio State University

BIOMARKERS/PRE-CLINICAL/DISCOVERY: Experimental design and data analysis in discovery and developmental research; Carmel 1*Organizer/Chair:* Lin Li, PharmaLex; Hui-Rong Qian, Eli Lilly and Company1. “Whole-cage randomization for animal studies with unequal cage or group sizes”, Steven Novick, Eli Lilly
2. “Multi-parameter optimization in antibody discovery”, Suntara Cahya, Eli Lilly
3. “Non-parametric Screening and Penalized Regression for Biomarker Discovery in NGS data with Time-To-Event Outcomes”, Lira Pi, PharmaLex
4. “Assay LOD determination using probit regression”, Shuguang Huang, Stat4ward

MACHINE LEARNING / AI; Carmel 5 *Organizer/Chair:* Kyoungah See, Eli Lilly1. “Statistical versus Machine Learning and Natural Language Processing Approaches in the Assessment of Drug Induced Liver Injury”, Melvin S Munsaka, AbbVie
2. “Generative Models for Diabetic Retinopathy Images”, Linsong Zhang, Purdue University
3. “Challenges of estimating individual treatment effects using machine learning”, Ilya Lipkovich, Eli Lilly

CMC: Bayesian Applications in CMC with Panel Discussion Carmel 2*Organizer/Chair:* Jinxin (Jerry) Gao/ Chao (Richard) Li1. “A Bayesian Application in Process Monitoring – Establishing Limits for Dosage Units in Early Phase Process Control”, Man Tang, AbbVie
2. “A review of Bayesian power prior approaches to PPQ batch sample size estimation”, Stan Altan, Craig Bernier, JnJ

TUESDAY NIGHT MIXER AND BANQUET; Carmel 3 & 4**4:30 pm – 5:15 pm** **Dinner and Banquet****5:15 pm – 8:00 pm****Welcome**: SHANTHI SATHURAMAN, Chief R&D Analytics Officer & SVP - Statistics, Eli LillyAnnouncement of Winner(s) of MBSW Student Poster Award**Banquet Speaker**: BRUNO BOULANGER, Senior Director of Global Head Statistics and Data Science, PharmaLex, Belgium**Title:** Reshaping Pharmaceutical Drug Development and Approvals by using Bayesian ApproachesWEDNESDAY MORNING, MAY 24**7:30 am – 8:30 am BREAKFAST;** **Great Room****8:30 am – 10:30 am****CONCURRENT SESSIONS**CLINICAL: Statistical Challenges and Solutions for Decentralized Clinical Trials; Carmel 3&4*Organizers/Chairs*: Karen Liu, Eli Lilly1. “Impact of Using A Mixed Data Collection Modality on Statistical Inferences in Decentralized Clinical Trials”, Alex Curtis and Yongming Qu, Eli Lilly
2. “Evaluation of the effect of centralized reader on Alzheimer's Trials”, Melissa Williamson and Dunlei Cheng, Eli Lilly
3. “Remote Data Collection using Digital Health Technologies in Clinical Development“, Jie Shen, AbbVie

**BIOMARKERS/PRE-CLINICAL/DISCOVERY; Statistical Approaches for Discovery and Preclinical Research;** **Carmel 1***Organizer/Chair:* Lin Li/Erin Wagner, PharmaLex1. “Bayesian Order Constrained Adaptive (BOCA) Design for Phase II Clinical Trials Evaluating Subgroup-Specific Treatment Effect”, Mu Shan, IU
2. "Virtual Control Group for Preclinical Drug Safety Assessment”, Dean Li, Pfizer
3. “Dynamic Bayesian Causal Network Analysis”, Ixavier Alonzo Higgins, Eli Lilly

**Epidemiology/RWE;** **Carmel 5***Organizer/Chair:* Vipin Arora, Eli Lilly1. “Methylation Quantitative Trait Loci and the Risk of Congenital Heart Diseases”, Ming Li, IU
2. “Data Driven Infectious disease modeling”, Maria Litvinova, IU
3. “Molecular Epidemiology: Identifying biomarkers predictive of gestational age and neonatal morbidity”, Kelli Ryckman, IU
4. “Validation of real-world data-based outcomes: Concepts and applications”, Sangmi Kim, Eli Lilly

 **10:30 AM – 11:30 AM CLOSING FORUM; Carmel 3 & 4***Organizer/Chair:* Ena Bromley, Oyanalytika*A discussion of cutting-edge topics regarding the future of biopharmaceutical statistical design and analysis, raised by participants both before and during the meeting. Conferees are encouraged to submit topics for discussion to the organizer/chair by email and in person during the meeting.* **Panelists: Lin Li, PharmaLex** **Yuan Ji, University of Chicago** **Kang Liu, Pfizer** **Tracy Follansbee, Elsevier** **11:30 AM – 1:00 PM LUNCH BUFFET; Carmel 3 & 4****12:00 PM Closing Remarks**, Vipin Arora, Eli Lilly |

**FOR MORE INFORMATION ON THE WORKSHOP**, please contact **Workshop Chair** VIPIN ARORA or ENA BROMLEY at varora@lilly.com, or **Registrar** Cindy Lee @c\_lee@lilly.com, **Publicity Chair** MELVIN MUNSAKA at melvin.munsaka@abbvie.com. The program and workshop logistics will be updated periodically at the web site as the workshop approaches: **https://www.mbswonline.com**/. The track co-chairs are: **Clinical**:David Manner, Lilly; **CMC**: Mark Johnson, AbbVie; **Machine Learning/AI**: Kyoungah See**,** Lilly; **Preclinical/Discovery**: Lin Li, PharmaLex; **Student Session**: Veavi Chang, Zae Higgins, Lilly.