

**THE 48th ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP**  
**May 19 – 21, 2025 • Renaissance Hotel, CARMEL (Indianapolis), INDIANA**

Co-Founders

Charles B Sampson  
 In Memory  
 Eli Lilly and Company



Mir Masoom Ali  
 Chairman Emeritus and George and Frances Ball Distinguished  
 Professor of Statistics Emeritus  
 Ball State University

One-Page Program  
 "Data and Beyond – A Deeper Dive"

**MONDAY, MAY 19**

7:30 AM – 8:30 AM BREAKFAST; **Great Room**

8:00 AM – 2:30 PM

**WORKSHOP REGISTRATION**

FEE: \$375 until May 2 (\$190 for academia/government/retiree, \$100 for students), \$425 after May 1

8:30 AM – 12:00 PM

**SHORT COURSES (Separate Registration Fee: \$100)**

Presenters	Topic	Room
Yixin Fang, AbbVie	<i>Causal inference and AI/ML in pharmaceutical statistics</i>	<b>Carmel 1</b>
Melvin Munsaka, AbbVie	<i>Hands-on Short Course on Enhancing the DMC Package Using OpenSource Software, AI, and LLM</i>	<b>Carmel 3</b>

12:00 PM – 1:00 PM LUNCH BUFFET; **Carmel 3 & 4**

12:00 PM – 2:00 PM

**POSTER DISPLAY; Carmel 3 & 4**

Chair: Bing Liu, Yanzhu Lin, Eli Lilly  
 Posters will be accepted on any biopharmaceutical statistical topics.

2:15 PM – 2:30 PM

**INTRODUCTION AND WELCOME; Carmel 3 & 4**

**WORKSHOP CHAIR**

VIPIN ARORA, Eli Lilly and Meovin Munsaka, AbbVie

2:30 PM – 4:00 PM

**PLENARY SESSION; Carmel 3 & 4**

Speaker (Virtual): WEN ZENG, CDER, FDA

**Title: Immunobridging Approach for Recent COVID-19 Pre-exposure Prophylaxis (PrEP) EUA Application**

**Speaker: ALOKA CHAKRAVARTY**, VP-Clinical Data Insights and Advanced Analytics, Eli Lilly

**Title: Innovations in Real World Data and AI in Drug Development**

**Speaker: ABIE EKANGAKI**, Sr. VP & Global Head of Biometrics, Premier Research

**Title: Reshaping the Role of Statisticians in the Era of Evolving AI/ML Approaches in Clinical Trials**

4:00 PM – 4:30 PM

*Curtain Raiser* – TRACK CHAIRS AND SESSIONS CHAIRS

4:30 PM – 6:30 PM

**MONDAY NIGHT MIXER (POSTER SESSION); Great Room**

**TUESDAY MORNING, MAY 21**

7:30 AM – 8:30 AM BREAKFAST; **Great Room**

8:30 AM – 11:30 AM

**CONCURRENT SESSIONS**

**CLINICAL: Applications of simulation-informed trial design Carmel 3&4**

Organizer/Chair: Mitch Thomann, Boehringer Ingelheim

- "Evaluation of Outcomes of Bayesian Simulations with Informative Priors", Mitch Thomann, Boehringer Ingelheim
- "Harnessing the Power of Combining East with R", Kyle Wathen, Cytel
- "A Simulation Study to Evaluate the Statistical Efficiency of Different Endpoint Strategies for Multi-System Diseases", Kristine Meyer, Boehringer Ingelheim
- "Accelerating clinical trial simulation in R with {targets}", Will Landau, Eli Lilly

**CMC: Commercial Process and Quality Carmel 5**

Organizers/Chairs: Richard Li, Eli Lilly and Jeff Gardner, DataPharm

- "Some perspective on the use of Arrhenius model to predict drug shelf life", Kofi Adragini, Eli Lilly
- "Adjusting for heterogeneity in nonlinear models with 2 CMC applications", Areti Manola and Stan Altan, J&J
- "Analyzing Functional Data in a Point-and-Click User Interface", Wendy Tseng, JMP
- "Dissolution method specification risk assessment", Sam Gardner, Eli Lilly

**ARTIFICIAL INTELLIGENCE/MACHINE LEARNING: Carmel 2**

Organizer/Chair: Ena Bromley, Oyanalytika

- "A machine learning early warning system for diarrhoeal disease to combat health threats of climate change in the Asia-Pacific region", Raul Cruz, Indiana University
- "LLM thinking fast and slow: knowledge extraction to facilitate phenotyping using drug records in real-world data", Haining Wang and Jing Su, Indiana University
- "AI Assistance for R Session Based Data Exploration & Visualisation", Phil Bowsher, Post (RStudio)
- "Bringing Order to Clinical Data Chaos with AI", Tristan Olinger, Oyanalytika

**RWE/HTA: Carmel 1**

Organizer/Chair: Zuoyi Zhang, AbbVie

- "A critical assessment of matching-adjusted indirect comparisons in relation to target populations", Haitao Chu, Pfizer
- "Decentralized Clinical Trials in the Era of Real-World Evidence Generation", Hongwei Wang, AbbVie
- "Multi-level Network Meta-Regression with a Survival Outcome and an Application to NSCLC", Denise Yi, Servier
- "A Doubly Robust Instrumental Variable Approach for Estimating Average Treatment Effects in Time-to-Event Data with Unmeasured Confounding: Application to Real-World Data on ICU Patients with Septic Shock", Runjia Li, Eli Lilly

11:30 AM – 1:30 PM LUNCH BUFFET; **Carmel 3&4**

**CONCURRENT STUDENT SESSION & ROUNDTABLE DISCUSSION**

**STUDENT SESSION: Statistical Career Development in Pharmaceutical Industry; Carmel 5**

Organizers/Chairs: Bin Liu and Yanzhu Lin, Eli Lilly

- Examples of Statistical Impact in Pharmaceutical Research
- Panel Discussion: Statistical Career Development in Pharmaceutical Industry

**TUESDAY AFTERNOON, MAY 21**

1:30 PM – 4:30 PM

**CONCURRENT SESSIONS**

**CLINICAL: Advances in Statistical Methodologies for Dose Finding and Dose Response; Carmel 3&4**

Organizer/Chair: Ran Liao, Eli Lilly

- "Implementing a two-step approach for dose response modeling in early phase clinical trials", Malik Rettiganti, Eli Lilly
- "A Bayesian adaptive dose optimization design incorporating immune response", Yong Yang, Indiana University
- "Dose-Response Analysis from a Quantitative Benefit-Risk Perspective", Maire Kudela, Pfizer
- "AI-Driven Endpoint Optimization in Dose-Finding Studies", Zhen Zhang, Otsuka Pharmaceutical

**CMC: Advanced Nonlinear Modeling Carmel 5**

Organizers/Chairs: Richard Li, Eli Lilly and Jeff Gardner, DataPharm

- "What Exactly Is 'Stability-Indicating'? Analytical vs. Statistical Perspectives", Jeff Gardner, DataPharm
- "Analysis of Residual Moisture During Pharmaceutical PPQ", Aotian Yang, Genentech
- "Guard Bands: Protecting You Against Measurement Uncertainty", Steven Walflsh, Iovance
- "The current role of acceptance sampling in pharmaceutical manufacturing", Alson Look, Regeneron

**Programming and Visualization; Carmel 2**

Organizer/Chair: Melvin Munsaka, AbbVie

- "Interrogate Your Data with a Mouse – Using JMP's point-and-click interface to understand and seek answers of your data", Wendy Tseng, JMP
- "Perfect Patient Profiles in SAS® using ODS Statistical Graphics", Joshua Horstman, Nested Loop Consulting, and Richann Watson, DataRich Consulting
- "Tapping the Power of SAS PRX Functions", John Labore, SAS
- "Open-Source Software in the Analysis and Reporting of Clinical Trials Data - A Focus on Meta-Analysis", Melvin Munsaka, AbbVie

**RWE/HTA: Carmel 1**

Organizer/Chair: Hongwei Wang, AbbVie

- "Use on Mortality in Patients with Idiopathic Pulmonary Fibrosis", Zuoyi Zhang, AbbVie
- "Causal approaches for the design and long-term treatment effect estimations of hybrid randomized clinical trials with longitudinal outcomes", Herbert Pang, Roche
- "Health disparity in alcohol-associated hepatitis in the post-pandemic era: Real-world evidence from Optum claims and All of Us EMR data", Jiangqiong Li, Indiana University
- "Sensitivity Analysis in driving real-world evidence from the analysis of real-world data" Yixin Fang, AbbVie,

**TUESDAY NIGHT MIXER AND BANQUET; Carmel 3 & 4**

4:30 PM – 5:15 PM

**DINNER AND BANQUET**

5:15 PM – 8:00 PM

**Welcome:**

Lei Shen, Sr. Vice President, Research-Statistics, Eli Lilly

Announcement of Winner(s) of MBSW Student Poster Award

**Banquet Speaker:** Robert Rachford, Founder, Better Biostatistics

**Title:** Biostatisticians in an AI-filled world: How to Ensure We Thrive in an Evolving Landscape

**WEDNESDAY MORNING, JUNE 12**

7:30 AM – 8:30 AM BREAKFAST; **Great Room**

8:30 AM – 10:30 AM

**CONCURRENT SESSIONS**

**CLINICAL: Borrowing control information from historical studies in clinical trials Carmel 3&4**

Organizers/Chairs: Indrajit Ghosh, Eli Lilly

- "Precision and bias of common methods for augmenting control arms in clinical trials", Kristine Broglio, AstraZeneca
- "Could borrowing in interim futility analyses allow us a more efficient trial design without inflating type 1 error?", Lily Haine, Eli Lilly
- "Optimizing External Data Borrowing in Clinical Trials: A Bayesian Perspective with Weight Constraints", Leon Shi, Pfizer
- Panel Discussion

**RWE/HTA: Carmel 1**

Organizer/Chair: Yixin Fang, AbbVie

- "Debiased Trial Emulation: Negative Control Outcomes guided Causal Machine Learning for Evidence Generation and Drug Discovery using Real-world Data", Iris (Yiwen) Lu, University of Pennsylvania
- "Combining open-label extension studies with external controls as an alternative to traditional model extrapolation to estimate long term treatment effects", Mingyang Shan, Eli Lilly
- "Scale-Space Inference of Causal Effects Based on Propensity Scores?", Lingsong Zhang, Purdue University
- Panel Discussion

**Pre-clinical and Biomarker: Carmel 5**

Organizers/Chairs: Vipin Arora, Eli Lilly

- "Robust Multi-Object Tracking for Home-Cage Behavioral Phenotyping Studies", Reuben Retnam, Takeda
- "Additive Gaussian Process Models with Applications in In Vivo Digital Biomarker Studies", Carrie Li, AbbVie
- TBD
- TBD

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 MELVIN MUNSAKA at [varora@lilly.com](mailto:varora@lilly.com), [melvin.munsaka@abbvie.com](mailto:melvin.munsaka@abbvie.com), or **Registrar** Cindy Lee @c\_lee@lilly.com, **Publicity Chair** MELVIN MUNSAKA at [melvin.munsaka@abbvie.com](mailto: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 Committee Members are: David Manner [manner\\_david\\_h@lilly.com](mailto:manner_david_h@lilly.com), Yixin Fang [yixin.fang@abbvie.com](mailto:yixin.fang@abbvie.com), Hongwei Wang [hongwei.wang@abbvie.com](mailto:hongwei.wang@abbvie.com), Bing Liu [liu\\_bing@lilly.com](mailto:liu_bing@lilly.com), Richard Li [rj\\_chao1@lilly.com](mailto:rj_chao1@lilly.com), Wanzhu Tu [wutu1@iu.edu](mailto:wutu1@iu.edu), Ena Bromley [ena.bromley@gmail.com](mailto:ena.bromley@gmail.com).