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	***Causal inference and AI/ML in pharmaceutical statistics***	**Carmel 1**
Melvin Munsaka, AbbVie	***Hands-on Short Course on Enhancing the DMC Package Using Opensource Software, AI, and LLM***	**Carmel 3**

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 Melvin 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 20

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

CMC: Commercial Process and Quality Carmel 5
Chairs: Richard Li, Eli Lilly and Jeff Gardner, DataPharm
1. "Some perspective on the use of Arrhenius model to predict drug shelf life", Kofi Adragni, Eli Lilly
2. "Adjusting for heterogeneity in nonlinear models with 2 CMC applications", Areti Manola and Stan Altan, J&J
3. "Analyzing Functional Data in a Point-and-Click User Interface", Wendy Tseng, JMP
4. "Dissolution method specification risk assessment", Sam Gardner, Eli Lilly

ARTIFICIAL INTELLIGENCE/MACHINE LEARNING: Carmel 2
Chair: Ena Bromley, Oyanalytika
1. "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
2. "LLM thinking fast and slow: knowledge extraction to facilitate phenotyping using drug records in real-world data", Haining Wang and Jing Su, Indiana University
3. "AI Assistance for R Session Based Data Exploration & Visualisation", Phil Bowsher, Posit (RStudio)
4. "Bringing Order to Clinical Data Chaos with AI", Tristan Olinger, Oyanalytika

RWE/HTA: Carmel 1
Chair: Zuoyi Zhang, AbbVie
1. "A critical assessment of matching-adjusted indirect comparisons in relation to target populations", Haitao Chu, Pfizer
2. "Decentralized Clinical Trials in the Era of Real-World Evidence Generation", Hongwei Wang, AbbVie
3. "Multi-level Network Meta-Regression with a Survival Outcome and an Application to NSCLC", Denise Yi, Servier
4. "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 Pharmaceutic Industry; Carmel 5
Chairs: Bin Liu and Yanzhu Lin, Eli Lilly
1. Examples of Statistical Impact in Pharmaceutical Research
2. Panel Discussion: Statistical Career Development in Pharmaceutic Industry

TUESDAY AFTERNOON, MAY 20

1:30 PM – 4:30 PM
CONCURRENT SESSIONS

CLINICAL: Advances in Statistical Methodologies for Dose Finding and Dose Response; Carmel 3&4
Chair: Ran Liao, Eli Lilly
1. "Implementing a two-step approach for dose response modeling in early phase clinical trials", Malik Rettiganti, Eli Lilly
2. "A Bayesian adaptive dose optimization design incorporating immune response", Yong Zang, Indiana University
3. "Dose-Response Analysis from a Quantitative Benefit-Risk Perspective", Maire Kudela, Pfizer
4. "AI-Driven Endpoint Optimization in Dose-Finding Studies", Zhen Zhang, Otsuka Pharmaceutical

CMC: Advanced Nonlinear Modeling Carmel 5
Chairs: Richard Li, Eli Lilly and Jeff Gardner, DataPharm
1. "What Exactly Is 'Stability-Indicating'? Analytical vs. Statistical Perspectives", Jeff Gardner, DataPharm
2. "Analysis of Residual Moisture During Pharmaceutical PPQ", Aotian Yang, Genentech
3. "Guard Bands: Protecting You Against Measurement Uncertainty", Steven Walfish, Iovance
4. "The current role of acceptance sampling in pharmaceutical manufacturing", Alson Look, Regeneron

Programming and Visualization; Carmel 2
Chair: Melvin Munsaka, AbbVie
1. "Interrogate Your Data with a Mouse – Using JMP's point-and-click interface to understand and seek answers of your data", Wendy Tseng, JMP
2. "Perfect Patient Profiles in SAS® using ODS Statistical Graphics", Joshua Horstman, Nested Loop Consulting, and Richann Watson, DataRich Cpnsulting
3. "Tapping the Power of SAS PRX Functions", John Labore, SAS
4. "Open-Source Software in the Analysis and Reporting of Clinical Trials Data - A Focus on Meta-Analysis", Melvin Munsaka, AbbVie

RWE/HTA: Carmel 1
Chair: Hongwei Wang, AbbVie
1. "Use on Mortality in Patients with Idiopathic Pulmonary Fibrosis", Zuoyi Zhang, AbbVie
2. "Causal approaches for the design and long-term treatment effect estimations of hybrid randomized clinical trials with longitudinal outcomes", Herbert Pang, Roche
3. "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
4. "Sensitivity Analysis in driving real-world evidence from the analysis of real-world dataYixin 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, MAY 21

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

RWE/HTA: Carmel 1
Chair: Yixin Fang, AbbVie
1. "Leveraging Large Language Models for Rare Disease Named Entity Recognition: A Comparative Study of In-Context Learning and Fine-Tuning", Miles Xi, AbbVie
2. "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
3. "Combing open-label extension studies with external controls as an alternative to traditional model extrapolation to estimate long term treatment effects", Mingyang Shan, Eli Lilly
4. "Scale-Space Inference of Causal Effects Based on Propensity Scores?", Lingsong Zhang, Purdue University

Pre-clinical and Biomarker: Carmel 5
Chair: Vipin Arora, Eli Lilly
1. "Robust Multi-Object Tracking for Home-Cage Behavioral Phenotyping Studies", Reuben Retnam, Takeda
2. "Additive Gaussian Process Models with Applications in In Vivo Digital Biomarker Studies", Carrie Li, AbbVie
3. TBD
4. TBD

11:30 AM – 1:00 PM LUNCH BUFFET; Carmel 3 & 4
12:00 PM Closing Remarks, Vipin Arora, Eli Lilly