

THE 49th ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP
May 27-29, 2026 • Renaissance Hotel, CARMEL (Indianapolis), INDIANA

Co-Founders

Charles B Sampson
 Chairman Emeritus
 In Memory
 Eli Lilly & Company



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

"Shaping the Future of Medicine Through Data and AI"

WEDNESDAY, May 27

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

8:00 AM – 2:30 PM

WORKSHOP REGISTRATION

FEE: \$395 until May 4 (\$195 for academia/government/retiree, \$120 for students), \$445 after May 4

8:30 AM – 11:45 AM

SHORT COURSES (Separate Registration Fee: \$100)

Presenters	Topic	Room
Jiang Bian, Xing He, Haining Wang Indiana University	Practical Large Language Models (LLMs): Foundations and Applications	Carmel 5
Phil Bowsher, POSIT	RStudio & Positron Hands-on Workshop: Advancements in AI for Statistical Programming	Carmel 3

11:45 AM – 1:00 PM LUNCH BUFFET; **Carmel 3 & 4**

12:00 PM – 2:00 PM

POSTER SESSION; Carmel 3 & 4

Chair: Ann Marie Weideman, Sarah Reifeis Striker, Lilly
 Posters will be accepted on any biopharmaceutical statistical topic.

2:15 PM – 2:30 PM

INTRODUCTION AND WELCOME; Carmel 3 & 4

WORKSHOP CHAIRS

Hongwei Wang (AbbVie) and Vipin Arora

2:30 PM – 4:00 PM

PLENARY SESSION; Carmel 3 & 4

Topic 1: "Communication, Collaboration, and Critical Thinking – The Keys to Unlocking Opportunities for Statisticians in Drug Development"

Plenary Speaker 1: Kati Ramseyer, Head of Global Brand Development-Incretin NILEX, Lilly

Topic 2: "Opportunities and Challenges with AI in Regulatory Environments"

Plenary Speaker 2: Paul Schuette, PhD, Deputy Division Director, Division of Analytics and Informatics, FDA

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 Room

THURSDAY MORNING, May 28

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

8:30 AM – 11:30 AM

CONCURRENT SESSIONS

CLINICAL: Adaptive Bayesian Methods for Dose Finding and Evidence Borrowing; Carmel 3&4

Organizer/Chair: Yong Zang, Indiana University

- "Longitudinal self-adaptive borrowing", Saijun Zhao, Indiana University
- "Combination therapy dose finding", Jeremiah Jones, Eli Lilly
- "Adaptive Bayesian methods and recent topic on evidence borrowing", Zhen Zhang, Otsuka Pharmaceutical
- "Integrated Framework for Rapid Oncology Clinical Trial Evidence Synthesis", Bruno Larvol, Larvol

BIOMARKERS/PRE-CLINICAL/DISCOVERY: Analytical frameworks for assessing digital biomarkers in biomedical research; Carmel 1

Organizer/Chair: Carmen D. Tekwe, Indiana University

- "Neural network-based approaches to modeling subject-specific activity distributions from wearable devices", Caihong Qin*, Lan Xue, Roger Zoh, Carmen Tekwe, Indiana University
- "Digital health in drug development", Marta Karas, Takeda Health
- "Actigraphy-Based Assessment of Daily Rest-Activity Rhythms", Kaysen Lu, Merck
- "A neural network-based AFT model with functional covariates subject to measurement error", Roger S.Zoh*, Xiaoxin Yu, Joseph Yang, Carmen Tekwe, Indiana University

REAL WORLD EVIDENCE: RWE Strategies for Clinical and Regulatory Success; Carmel 2

Organizer/Chair: Zuoyi Zhang, AbbVie

- "Statistical Methods and AI Enabled Analytics in Real World Evidence Supporting FDA Drug Safety Labeling Changes", Miles Xi, AbbVie
- "Advances on time-to-event prediction using machine learning methods": Lingsong Zhang, Purdue University
- "Digitally Interrupted: A Difference-in-Differences Analysis of a Hospital Cyberattack and Its Impact on Operational Performance", Xiaochun Li, Indiana University
- "Pushing the Boundaries: Innovations in Indirect Treatment Comparisons and Health Technology Assessment", Haitao Chu, Pfizer

STAT PROGRAMMING/AI: Practical Use of Open-Source Tools and Infusing Statistical Programming and Visual Analytics Using Large Language Models, Carmel 5

Organizer/Chair: Melvin Munsaka, AbbVie

- "Leveraging Large Language Models in the R Studio and Positron Environments to Enhance Statistical Programming Activities", Phil Bowsher, Posit
- "FDA Review Experience with R Pilots", Hye Soo Cho, FDA
- "CVARS - An E2E Drug Safety Analytics Approach Using Open Source", Jiang (Jessica) Hu, FDA, Fabian (BI) (Need final confirmation)
- "A Faster Algorithm for the Finkelstein-Schoenfeld Test and Composite Outcome Measures", James Austrow, Cleveland Clinic

CMC: Process Development & Assay Stability, Carmel 6

Organizer/Chair: Richard Li, Eli Lilly

- "Monitoring Assays: Control Samples, Reference Stability, Assay Stability, Bridging References", Steven Walfish, Iovance Biotherapeutics
- "Assessing Double-Regression Estimations in Arrhenius Modeling for Time-Temperature Matrix Computation of Drug Products", Kofi Adragi, Lilly
- "Combining Bayesian Optimization and DOE to Define Design Space", Andrea Biasi Coombs, JMP
- "A Bayesian based Stability Platform Framework for Oligonucleotides", Meng John Zhao, Lilly

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

CONCURRENT STUDENT SESSION 12:15 PM-1:30 PM

STUDENT SESSION: Mock Interview and CV Feedback Session; Carmel 5, Riley, & Great Room

Organizers/Chairs: Ann Marie Weideman, Sarah Reifeis Stri, Eli Lilly

Interviewers: David Manner, Maria Kudela, Melvin Munsaka, Hongwei Wang

THURSDAY AFTERNOON, May 28

1:30 PM – 4:30 PM

CONCURRENT SESSIONS

CLINICAL: Applied Machine Learning for Clinical and Regulatory Decision-Making; Carmel 3&4

Organizer/Chair: Maria Kudela, Pfizer

- "Clinical endpoint adjudication by AI", Hiya Banerjee, Lilly
- "Comparative Effectiveness of Treatment Regimens in Moderate-to-Severe Atopic Dermatitis: Integrated Analyses Across Heterogeneous Study Designs using Causal Techniques", Prosenjit Kundu, Pfizer
- "A general, flexible, and harmonious deep-learning-assisted framework to construct interpretable functions in regression analysis", Tianyu Zhan, AbbVie
- "A Pragmatic Statistician's Case Reviews of AI Use in Drug Development", Jack Knorr, Lilly

REAL WORLD EVIDENCE: Digital twins, external control, AI; Carmel 2

Organizer/Chair: Haitao Chu, Pfizer

- "XYZ – A Unified Framework Modernizing Drug Development with Real-World Data and AI", Yong Chen, U of Pennsylvania
- "Accounting for unobserved confounders via negative control", Hongwei Wang, AbbVie
- "Adaptive Bayesian Borrowing with Prospective Specification: Ensuring Congruent Integration of Historical Controls", Saurabh Mukhopadhyay, AbbVie
- "From Averages to Individuals: Multi-task Learning for Heterogeneous Real-World Data": Satrajit Roychoudhury, Pfizer

CMC: Medical Device, Carmel 6

Organizer/Chair: Richard Li, Eli Lilly

- "Navigating Ambiguity, Complexity, and Cross-Functional Needs", Aili Cheng, Kang Liu, Ke Wang, Pfizer
- "Enhancing Patient-Centered Care: Bridging Pharma and Medical Device Technologies Through Collaborative Statistical Practices", Yenny Webb Vargas, Genetech
- "Sampling Rationale Challenges in Combination Products", Craig Bernier, J&J

Biomarker: Carmel 1

Organizer/Chair: Yanzhu Lin

- "Interpretable Deep Learning-Based Multi-biomarkers Integration Model for Response Prediction", Hong Wang, Sanofi
- "SIMBA - A Bayesian Decision Framework for the Identification of Optimal Biomarker Subgroups for Cancer Basket Clinical Trial", Yuan Ji, U. of Chicago/Bayesoft Inc.
- "A Hybrid Two-Stage Workflow Linking Biomarker Evidence to Individualized Treatment Policies", Miles Xi, AbbVie
- "To Pool or Not to Pool: Risks of Ignoring Data Structure in Regularized Biomarker Models", Yanzhu Lin, Lilly

THURSDAY NIGHT MIXER AND BANQUET; Carmel 3 & 4

4:30 PM – 5:15 PM

DINNER AND BANQUET

5:15 PM – 8:00 PM

Welcome: David Manner, Eli Lilly

Announcement of Winner(s) of MBSW Student Poster Award

Banquet Speaker: Yuan Luo, Northwestern University

Title: EPIC Multi-Modal AI for Drug Discovery

FRIDAY MORNING, May 29

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

8:30 AM – 11:30 AM

CONCURRENT SESSIONS

CLINICAL: Innovations in Clinical Trial Methodology: From Digital Health to AI-Enhanced Analysis; Carmel 3&4

Organizer/Chair: Ran Liao, Lilly

- "Advancing the Analysis of Daily Digital Health Data in Clinical Trials Using Two-Level MMFM and Functional Data Analysis Methods", Luqing (Jasmine) Yang, AbbVie
- "Decentralized clinical trial", Ruitao Lin, MD Anderson, Tuo Wang, Lilly
- "Dealing with Messy Data: Clinical and Biomedical Examples", Hui Zhang, Northwestern University
- "Med-ICE: Enhancing Factual Accuracy in Medical AI through Autonomous Multi-Agent Consensus", Tom (Zhiyuan) Chen, Hill Research

STAT PROGRAMMING/AI: Practical Use of Open-Source Tools and Infusing Statistical Programming and Visual Analytics Using Large Language Models, Carmel 5

Organizer/Chair: Melvin Munsaka, AbbVie

- "Dynamic Risk Prediction with Deep Neural Network", Lihui Zhao, Northwestern University
- "Retrieval-Augmented Generation in Regulated Biopharmaceutical Environments: A Perspective on Knowledge-Grounded AI", DJ Penix and John LaBore, Pinnacle Solution
- "Recurrence: An Analysis of Adverse Events Whose Time Has Come in the Evaluation of Patient Safety in Clinical Trials", Richard Zink, JMP
- "Generating Interactive Drug Clinical Reports Using Large Language Models and Quarto", Mai Duong, AbbVie

BIOMARKERS/PRE-CLINICAL/DISCOVERY; Carmel 1

Organizers/Chairs: Miles Xi, AbbVie

- "Change Point Mixed-Effect Model Identifies Early Plasma Proteomic Changes in Alzheimer's Disease", Xiaoping Huang, Indiana University
- "Addressing the Small-n, Large-p Challenge in Sparse Learning", Vinamrata Sharma, Indiana University
- "Transfer learning from mouse to human using trVAE and scGPT", Dongyan Yan, Eli Lilly
- "An LLM-Powered Virtual Agent for Genomics Analysis to Accelerate Drug Discovery", Keela Dai, Lilly

EPIDEMIOLOGY: Unresolved Issues and Methodological Challenges in the Analysis of Real-World Evidence, Carmel 6 (Special Invited in-person and Virtual Session)

Organizer/Chair: Simone Pinheiro, AbbVie

- In-person:** "Target Trial Emulation for Real-World Evidence: A Bridge Between Observational Studies and Randomized Trials", Tianming Gao, AbbVie
- "Integrating Target Trial Emulation and the Estimand Framework", Gerd Rippen, IQVIA Germany
- "Regulatory Perspectives on Methodological Frameworks for Real-World Evidence", Hana Lee, FDA
- "Targeted Learning Approaches for Causal Inference in Real-World Data", Lauren Deng, Amgen

11:30 AM – 1:00 PM LUNCH BUFFET; **Carmel 3 & 4**

12:45 PM Closing Remarks, Vipin Arora, Eli Lilly

FOR MORE INFORMATION ON THE WORKSHOP, please contact Workshop Co-Chairs Vipin Arora at vipin.arora@gmail.com, Hongwei Wang at hongwei.wang@abbvie.com, or 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: <http://www.mbswonline.com>. The track co-chairs are: **Clinical:** David Manner, Ran Liao, Eli Lilly; **CMC:** Richard Li, Eli Lilly; **Stat Programming:** Melvin Munsaka, AbbVie; **RWE:** Hongwei Wang, AbbVie. **Precinical/Discovery:** Yanzhu Lin, Eli Lilly **Student Session:** Ann Marie Weideman, Sarah Reifeis Striker, Eli Lilly.