

**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<br>Indiana University | Practical Large Language Models (LLMs):<br>Foundations and Applications                    | Carmel 5 |
| Phil Bowsher, POSIT                                     | RStudio & Positron Hands-on Workshop:<br>Advancements in AI for Statistical<br>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**

**WEDNESDAY 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:* Ran Liao and Indrajit Ghosh, Lilly

- "Longitudinal self-adaptive borrowing"; Saijun Zhao, Indiana University
- "Combination therapy dose finding"; Jeremiah Jones, 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, Judith Perez Granado, 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
- "Improved Phenotyping Between Narcolepsy Type 1, Type 2 and Idiopathic Hypersomnia Through Classification and Clustering Methods Applied to Polysomnography"; Marta Karas, Takeda Health
- "Actigraphy-Based Assessment of Daily Rest-Activity Rhythms"; Kaysen Lu, Merck
- "A Functional Accelerated Failure-Time Model with Varying Effects Correcting for Measurement Error"; Joseph Yang, 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
- "Robust Causal Inference for Skewed and Outlier-Prone Data: A Doubly Robust Rank-Based Approach"; Ruohui (Matt) Chen, Northwestern University

**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

- "FDA Experience with R Pilots"; Hye Soo Cho, FDA
- "Beyond the Keyboard: Voice-Driven Analysis for Clinical Data Science"; Phil Bowsher, Posit
- "{pmrm}: an R package for fitting progression models for repeated measures"; Will Landau, Lilly
- "cVARS - Transforming Drug Safety Analytics and Deliverables for Enhanced and Comprehensive E2E Review, Analysis, Signal Detection, Reporting, and Regulatory Submissions with the Aid of AI and LLMs"; Michael Schuher, AbbVie

**CMC: Process Development & Assay Stability; Carmel 6**

*Organizer/Chair:* Richard Li, Lilly

- "Monitoring Assays: Control Samples, Reference Stability, Assay Stability, Bridging References"; Steven Walfish, Iovance Biotherapeutics
- "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; Carmel 5, Riley, & Great Room**

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

**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"; Zhili Qiao, 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, 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
- "Closing the Quality Loop: Integrating Statistics and Data Science Within Quality Assurance for Medical Device Lifecycle Improvement"; AJ McKechnie, Cook Medical

**Biomarker; Carmel 1**

*Organizer/Chair:* Yanzhuo Lin, Lilly

- "Interpretable Deep Learning-Based Multi-biomarkers Integration Model for Response Prediction"; Hong Wang, Sanofi
- "A Hybrid Two-Stage Workflow Linking Biomarker Evidence to Individualized Treatment Policies"; Miles Xi, AbbVie
- "Next-generation AI for Ki67 Image Analysis: Foundation Models, Synthetic Images, and Knowledge Transfer"; Xuhong Zhang, Indiana University

**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, Lilly

Winners of MBSW Student Poster Award Announcement: AnnMarie Weideman and Sarah Striker, Lilly

**Banquet Speaker:** Claude Petit, AVP-Statistics, Lilly

**Title:** "AI: Another Revolution, or the Last One?"

**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 and Xi Shen, Lilly

- "Advancing the Analysis of Daily Digital Health Data in Clinical Trials Using Two-Level MMRM and Functional Data Analysis Methods"; Liuqing (Jasmine) Yang, AbbVie
- "Decentralized clinical trial"; Wenjia Wang and Tuo Wang, Lilly
- "A Faster Algorithm for the Finkelstein-Schoenfeld Test and Composite Outcome Measures"; James Austrow, Cleveland Clinic
- "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

- "Retrieval-Augmented Generation in Regulated Biopharmaceutical Environments: A Perspective on Knowledge-Grounded AI"; DJ Penix, Pinnacle Solutions and John LaBore, SAS
- "Hepatotox Tool for Analysis and Displays Associated with Hepatotoxicity"; Peigang Li, AbbVie
- "Rebooting Independent Data Monitoring Committee Decision-Making Through Targeted Data Visualization Strategies"; Lava Timsina, IDDI
- "An Overview of the SASSY System of R Packages"; David Bosak, Archytas Clinical Solutions

**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"; Xiaoqing Huang, Indiana University
- "An LLM-Powered Virtual Agent for Genomics Analysis to Accelerate Drug Discovery"; Keela Dai, Lilly
- "Detecting Precise Adverse Drug Events from Real-world Data"; Pengyue Zhang, Indiana University
- "AdmixSuSIE: Local Ancestry-Aware Fine-Mapping for Biomarker and Target Discovery in Admixed Populations"; Boran Gao, Purdue University

**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 Dang, Amgen

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

**12:45 PM Closing Remarks, Vipin Arora and Hongwei Wang**

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