

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

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
- "Super-efficient Information Borrowing in Clinical Trials via Causally-Modeled SAM Priors and Adaptive TMLE"; 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 Schuhler, 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, Genentech
- "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: Yanzhu 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"; Xiaqing 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, 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, Lilly; CMC: Richard Li, Lilly; Stat Programming: Melvin Munsaka AbbVie; RWE: Hongwei Wang, AbbVie. Preclinical/Discovery: Yanzhu Lin, Lilly; Student Session: Ann Marie Weideman, Sarah Reifeis Striker, Lilly.