

**THE 47th ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP  
JUNE 10 – 12, 2024 • 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  
**"Statistical Excellence in Drug Development"**

**MONDAY, JUNE 10**

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

8:00 AM – 2:30 PM

**WORKSHOP REGISTRATION**

FEE: \$345 until May 27 (\$175 for academia/government/retiree), \$395 after May 27

8:30 AM – 12:00 PM

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

Presenters	Topic	Room
David Kerr Cytel Inc.	A Statistician's Guide to DMCs – Overview, Standards, and Best Practices	Carmel 5
Phil Bowsher and Rich Iannone, RStudio	Open-Source Drug Development: ADAM, TLGs & Interactivity with R	Carmel 3

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

12:00 PM – 2:00 PM

**POSTER SESSION; Carmel 3 & 4**

Chair: Bing Liu, Eli Lilly

Posters will be accepted on any biopharmaceutical statistical topic up to capacity.

Abstracts must be received by May 10th, 2024. For more information contact

posterchair@mbswonline.com

2:15 PM – 2:30 PM

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

**WORKSHOP CHAIR**

VIPIN ARORA, Eli Lilly, Bruno Boulanger, Cencora-PharmLex

2:30 PM – 4:00 PM

**PLENARY SESSION; Carmel 3 & 4**

Speaker: JAMES TRAVIS, CDER, FDA

**Title:** My experiences with Bayesian methods and complex innovative designs as a regulator

**Speaker:** JEAN-PIERRE WERY, President & CEO, SideWinder Therapeutics

**Title:** The Critical Role of Modeling in Pre-Clinical and Translational Research

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**

**TUESDAY MORNING, JUNE 11**

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

8:30 AM – 11:30 AM

**CONCURRENT SESSIONS**

**CLINICAL: Modern Design Approaches; Carmel 3&4**

*Organizer/Chairs:* David Manner, Eli Lilly

- "Bayesian Adaptive Dual Objective Phase I-II designs for Personalized Dose-Finding with Combination Therapies", Brad Carlin, Cencora-Pharmalex
- "Advancing Pediatric Clinical Trials through Case Studies: Extrapolation, Bayesian Methods and Regulatory Perspectives" Fei Chen, Johnson & Johnson
- "Design considerations for two-stage enrichment clinical trials" Zhantao Lin, Eli Lilly
- "ENRICH: A Novel Approach to Clinical Trials in ICH", Giorgio Paulon, Berry Consultants

**COMPUTATION AND VISUALIZATION; Carmel 5**

*Organizers/Chairs:* Jing Su, Indiana University

- "Making an Interactive Shiny App with GenAI...Five Ways", Phil Bowsher, POSIT
- "Visualizing Insights, Empowering Discoveries: SAS Viya Unleashed in Biopharmaceutical Analytics", Matt Becker, SAS Institute
- "Human Perception for Information Visualization Design", Yingjie Victor Chen, Purdue University
- "Topline Results Dashboard with R Markdown & Flexdashboard", Robert Adams, Bayer AG

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

*Organizer/Chair:* Bruno Boulanger, Cencora-Pharmalex

- "A Large Language Model (LLM)-powered Workflow Applied to Pharmaceutical Informed Consent", Jacob Gagnon, Biogen
- "Navigating the Landscape: A Framework for Evaluating Large Language Models (LLMs) in Biostatistics", Sydeaka Watson, Eli Lilly
- "Exploring Bias in AI and Machine Learning", Jim Box, SAS Institute
- "Leverage AI to build end-to-end workflow for research, analysis, and reporting", Michael Man, Eli Lilly

**HTA Statistics, Benefit-Risk, HEOR; Carmel 6**

*Organizer/Chair:* Melvin Munsaka

- "Recent Developments and Innovations in Health Technology Assessment", Hongwei Wang, AbbVie
- "Novel yet Practical Bayesian Quantification of Benefit-Risk Balance of Medical Products", Saurabh Mukhopadhyay, AbbVie
- "Bayesian Benefit Risk Analysis Using the brisk R Package", Richard Payne, Eli Lilly

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

**CONCURRENT STUDENT SESSION & ROUNDTABLE DISCUSSION**

**STUDENT SESSION: Career Panel Discussion; Carmel 5**

*Organizers/Chairs:* Yan Zhu Lin, Eli Lilly; Emma Liao, Eli Lilly

- David Manner, Eli Lilly
- Wei Shen, Eli Lilly
- Ray Su, Inari Medical
- Catlin Mills, Inari Medical
- Jim Box, SAS

**TUESDAY AFTERNOON, JUNE 11**

1:30 PM – 4:30 PM

**CONCURRENT SESSIONS**

**CLINICAL: Meta-analyses and indirect treatment comparisons; Carmel 3&4**

*Organizer/Chair:* Brad Carlin, Cencora-Pharmalex

- "Alternatives to Normal-Normal Meta Analysis", Tim Hanson, Medtronic
- "Network Meta Analysis to Predict the Efficacy of an Approved Treatment in a New Indication", Jennifer Proper, Eli Lilly
- "A comprehensive review and shiny application on the matching-adjusted indirect comparison", Haitao Chu, Pfizer Inc.
- "Tipping point analyses for the between-group correlation in an arm-based evidence synthesis", Wenshan Han, Florida State University

**Real World Evidence; Carmel 6**

*Organizer/Chair:* Melvin Munsaka, AbbVie

- "Revolutionizing Infectious Disease Management through Real World Evidence", Gene Olinger, Oyanalitika
- "Real-world evidence for pharmacovigilance and drug repurposing", Pengyue Zhang, Indiana University
- "Sensitivity analysis for evaluating treatment effects from real world data", Mingyang Shan, Eli Lilly
- "Historical data borrowing for predictive biomarker identification", Adam Luo, Abbvie

**Biomarkers and Pre-Clinical; Carmel 5**

*Organizer/Chair:* Lira Pi, Cencora-Pharmalex

- "Bayesian-frequentist hybrid inference framework for single cell RNA-seq analyses", Dongyan Yan, Eli Lilly
- "Leveraging Generative AI Technology for Accelerated Analysis of Scientific Publications in Pre-clinical Medical Research", Steven Silva, Cencora-Pharmalex
- "Amyloid Reduction as a Surrogate Biomarker in Alzheimer's Disease Clinical Trials: Exploring the Path Forward Following FDA Guidelines", Guoqiao Wang, Washington Univ.

**CMC; Carmel 2**

*Organizer/Chair:* Richard Li, Eli Lilly

- "Frequentist and Bayesian tolerance intervals for setting specification limits for left-censored gamma distributed drug quality attributes", Richard Montes, Alnylam Pharmaceuticals
- "OMARS designs, bridging the gap between screening and optimization experimental designs", José Núñez Ares, EFFEX
- "Reliably Assessing Comparability in Autologous Cell Therapy Change Protocols: A Compliance Perspective", Bruno Boulanger, Cencora-Pharmalex
- "An Overview of Statistical Approaches for Classifying Product Quality Attributes as "Stability-Indicating"", Jeff Gardner, Data Pharm
- "Low Correlation Designs for Demonstrating Proven Acceptable Ranges and Informing Design Spaces", Tim Kramer, Eli Lilly

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

4:30 PM – 5:15 PM

**DINNER AND BANQUET**

5:15 PM – 8:00 PM

**Welcome:**

SHANTHI SATHURAMAN, Chief R&D Analytics Officer & SVP - Statistics, Eli Lilly

Announcement of Winner(s) of MBSW Student Poster Award

**Banquet Speaker:** Scott Clark, PhD ASA Fellow Retired, Eli Lilly and Company

**Title:** Reflections and Projections on Statistical Leadership

**WEDNESDAY MORNING, JUNE 12**

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

8:30 AM – 11:30 AM

**CONCURRENT SESSIONS**

**CLINICAL: Advanced Questions; Carmel 3&4**

*Organizers/Chairs:* David Manner, Eli Lilly

- "Power Performance for Testing a Composite Outcome with Correlated Endpoints using the Finkelstein-Schoenfeld Test", Ray Su, Inari Medical
- "Two basic statistical strategies of conducting causal inference in real-world studies", Yixin Fang, AbbVie
- "Optimal treatment regimes for behavioral interventions using multiple surrogate outcomes", Eric Laber, Duke University
- "Causal Inference in treatment effect estimation using longitudinal real-world data for precision medicine", Jing Su, Indiana University School of Medicine

**COMPUTATION AND VISUALIZATION; Carmel 5**

*Organizer/Chair:* Melvin Munsaka, AbbVie

- "R-shiny application for visualizing cough count data collected from a wearable device", Richard Vinisko, Boehringer Ingelheim
- "Going from SAS v9 Programming to SAS Viya Programming: What's the Same, What's Different", John LaBore, SAS Institute; Josh Horstman, Nested Loop
- "Why Do I Have Missing Data and How Do I Fix it?", Melodie Rush, SAS Institute
- "Leveraging Visual Analytics in Drug Safety and Benefit-Risk in Multi-Regional Clinical Trials", Melvin Munsaka, AbbVie

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

12:00 PM Closing Remarks, Vipin Arora, Eli Lilly, Bruno Boulanger, Cencora-PharmLex