

**THE 42nd ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP
MAY 20 – 22, 2019 • Renaissance Hotel, CARMEL (Indianapolis), INDIANA**

Co-Founders

Charles B Sampson
Chairman Emeritus
Retired
Eli Lilly & Company



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

One-Page Program: **"Statistics: Making an Impact"**

MONDAY, MAY 20

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

8:00 AM – 2:30 PM

WORKSHOP REGISTRATION

FEE: \$240 until May 1 (\$120 for academia/government, \$80 for students), \$275 after May 1

8:30 AM – 12:00 PM

SHORT COURSES (Separate Registration Fee: \$100)

Presenters	Topic	Room
WEIDONG ZHANG, Pfizer, SANDEEP MENON, Pfizer/Boston University/Tufts University	Accelerating Drug Discovery Through Precision Medicine and Innovative Designs – Concepts, Rationales, and Case Studies	Carmel 3
ENA BROMLEY, LIN LI, BioStat Solutions, Inc.	An Introduction to Biomarkers for Statisticians – A Brief Guide to Utilizing the Most Appropriate Analytical Tool	Carmel 1

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

1:00 PM – 2:00 PM

POSTER SESSION; Carmel 3 & 4

Chair: Ying Grace Li, Eli Lilly

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

Abstracts must be received by April 12th, 2019. For more information contact

Ying Grace Li at posterchair@mbswonline.com

2:15 PM – 2:30 PM

INTRODUCTION AND WELCOME; Carmel 3 & 4

WORKSHOP CHAIR

VIPIN ARORA, Eli Lilly

2:30 PM – 4:00 PM

PLENARY SESSION; Carmel 3 & 4

Speaker: ALOKA CHAKRAVARTY, FDA

Title: *Statistical Leadership in The Changing Landscape of Drug Development*

Speaker: GARY SULLIVAN, Esprir Consulting

Title: *Statisticians, Leadership and Teamwork*

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, MAY 21

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

8:30 AM – 11:30 AM

CONCURRENT SESSIONS

CLINICAL: Statistical Methods for Personalized Medicine; Carmel 3 & 4

Organizer/Chair: Ilya Lipkovich, Eli Lilly

- "The Central Role of Personalized Solution in the Era of Digital Health", Haoda Fu, Eli Lilly
- "Exploratory Subgroup Identification for Biopharmaceutical Development", Xin Huang, AbbVie
- "Q-learning for Time-to-Event Data", Eric Rose, NCSU
- "Discussant", Ilya Lipkovich, Eli Lilly

BIOMARKERS/PRE-CLINICAL/DISCOVERY: Design, Analysis and Interpretation of Biomarker Studies - Challenges and Opportunities; Carmel 1

Organizer/Chair: Ena Bromley, BioStat Solutions, Inc.

- "Biomarker Analysis Strategies: Some Case Studies", Abraham Apfel, BMS
- "Ranking Biomarker Hypotheses Using Desirability Framework", Michael Man, Eli Lilly
- "Design, Analysis, and Interpretation of Biomarker Studies", Sara Hamond, Regeneron
- "Assessment of Differential Expression Methods for 10x Genomics Datasets", Jake Gagnon, Biogen

REAL WORLD EVIDENCE: Statistical Approaches to Big Data Research in EMR; Carmel 5 & 6

Organizer/Chair: Xiaochun Li, IUSM

- "Statistical Inference with Large Claims Databases: A Case Study", Changyu Shen, Harvard
- "Repurposing Statistical Tools to Improve Data Quality for Longitudinal Measurements in EHRs: a Case Study from Growth Chart", Qingxia Chen, Vanderbilt
- "Incorporation of Conditional Dependence in Record Linkage: Does it Matter?", Huiping Xu, IU, SPH/SOM
- "Estimating Treatment Effects in Electronic Health Record Data with Imperfect Phenotyped Outcomes", David Cheng, VA Boston Healthcare System

CHEMICAL MANUFACTURING CONTROL: Comparable, Similar, or Equivalent? Practical Statistical Solutions for Decision Making; Carmel 2

Organizer/Chair: Aili Cheng, Pfizer

- "Statistical Approaches for Demonstrating Analytical Similarity in the Presence of Correlation", Harry Yang, Medimmune
- "Process Comparability: How to Set Appropriate Acceptance Criteria for Limited 3 or 4 Batches at Late Stage/Post-Approval", Aili Cheng, Pfizer
- "Limitations of Statistical Comparability Limits (Working subtitle for fans of The Princess Bride: "I don't think <that word> means what you think it means")", Katherine Giacoletti, SynoloStats
- "A Comparative Study of Confidence Intervals to Assess Biosimilarity from Analytical Data", Leon (Heliang) Shi, Pfizer
- "Max – Min: A Cautionary Tale", Jose Ramirez, Amgen

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

CONCURRENT STUDENT SESSION & ROUNDTABLE DISCUSSION

STUDENT SESSION: Impactful and Credible Communication and Collaboration With Stakeholders – Some Challenges and How to Overcome Them; Carmel 5

Organizers/Chairs: Veavi Chang, Brian Millen, Eli Lilly, and Barry Katz, Indiana University

- "From the World of Nonclinical Statistics", Yushi Liu, Eli Lilly
- "From the World of Pharmacokinetics Analysis", Zoey (Ziyi) Jin, AbbVie
- "From the World of Efficacy Analysis", Tim Clough, Novartis
- "From the World of Safety Analysis", Junfang Chen, Meng Liu, AbbVie
- "From the World of Post Marketing Analysis", Xiang Zhang, Eli Lilly

TUESDAY AFTERNOON, MAY 21

1:30 PM – 4:30 PM

CONCURRENT SESSIONS

CLINICAL: Master Protocols; Carmel 3 & 4

Organizer/Chair: Melissa Spann, Eli Lilly

- "Pros and Cons of Concurrent vs Historical Controls and Modeling Information Over Time for into the Trial", Kert Viele, Berry Consultants
- "Treatment Allocation and Using Time-Based Cohorts to Make Indirect Comparisons", Christopher Kaiser, Eli Lilly
- "Flexible Bayesian Semiparametric Hierarchical Model for Platform Trial with Non-Exchangeability", Jianchang Lin, Takeda
- "A Multi-Source Adaptive Platform Design for Testing Sequential Combinatorial Therapeutic Strategies", Alex Kaizer, University of Colorado

BIOMARKERS/PRE-CLINICAL/DISCOVERY: Preclinical Developments; Carmel 1

Organizer/Chair: Erin Wagner, BioStat Solutions, Inc.

- "Optimal Study Formats for Preclinical Studies to Control the False Discovery Rate (FDR)", Eric Rozet, Milana Filatenkova, Bruno Boulanger, PharmaLex
- "Two-Stage Sequential Procedure to Test Pathway Effects and Gene Effects Using Semiparametric Bayesian Kernel Survival Model", Lin Zhang, Eli Lilly
- "Data Processing and Analysis Integrator (dPAL) Shiny App for Biomarker and Discovery Analysis", Shuaicheng Wang, BioStat Solutions, Inc.

VISUALIZATION/PROGRAMMING: Visualization of Clinical Trial Data - Taking it to the Next Level Using New Tools and Promoting Cross-Functional Collaboration; Carmel 5 & 6

Organizer/Chair: Melvin Munsaka, AbbVie

- "Use of a Heat Map to Visualize the Benefits and Risks of a Study Treatment", Junfang Chen, Chery Renz, William Palo, Anthony Oladipo, and Yumi Kubo, AbbVie
- "SafetyGraphics R Library – An Open-Source Tool and Clinical Workflow for Assessing Hepatotoxicity in Clinical Trials", Zachary Skrivaneck, Eli Lilly
- "Visualizing Tables in Spotfire", Jianfei Jiang, Jeanhee Pak, Eli Lilly
- "Combining Novel Graphics and Statistical Analysis in Clinical Safety Data – Some Open-Source Tools", Meng Liu, AbbVie
- "R for Deep Learning with TensorFlow with Applications in Cancer Immunotherapy", Phil Bowsher, RStudio

CHEMICAL MANUFACTURING CONTROL: Non-Similarity Criteria for Bioassays, Reference Standards Qualification, and Shiny Accelerated Stability Analysis; Carmel 2

Organizer/Chair: Chuck Miller, Merck

- "Beyond Linearity: An Integrative Approach to Accelerated Stability Analysis Using R Shiny", Zhenguo JD Gao, AbbVie
- "Risks of Sequential Qualification of Reference Standards", Ji Young Kim, Merck
- "Challenges in Potency Assignment for Monoclonal Antibody Reference Standards", Paul Faya, Eli Lilly
- "Using the Total Error Profile to Select the Calibration Model in Bio and Binding Assays", Perceval Sondag, PharmaLex
- "Recent Results on Equivalence Test Bounds to Limit Non-Similarity-Induced Bias in Potency with Additional Discussion about Power", David Lansky, Precision Bioassay

TUESDAY NIGHT MIXER AND BANQUET; Carmel 3 & 4

4:30 PM – 5:30 PM

DINNER AND BANQUET

5:30 PM – 8:00 PM

PANDURANG KULKARNI, Chief Analytics Officer and Vice-President Biometrics, Eli Lilly

Announcement of Winner(s) of MBSW Student Poster Award

Banquet Speaker: STEPHEN RUBERG, Analytix Thinking, LLC

Title: *The Need for Analytical Science*

WEDNESDAY MORNING, MAY 22

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

8:30 AM – 11:30 AM

CONCURRENT SESSIONS

CLINICAL: Statistical Methods with Network Meta-Analysis and Survival Data; Carmel 3 & 4

Organizers/Chairs: James Stamey and Jack Tubbs, Baylor University

- "Simple Network Meta-Analysis with Mixture Finite Polya Trees", Johanna van Zyl and Jack Tubbs, Baylor University
- "A Bayesian Approach to Modeling Indirect Comparisons of Covariate-Adjusted ROC Curves", Sarah Stanley, Eli Lilly
- "An Introduction to the Lehmann Family of ROC Curves with Extensions to Covariate-Adjusted and Longitudinal Data Cases", Melissa Innerst, Baylor University
- "Comparison of Bayesian Network Meta-Analysis Models for Survival Data", Purvi Prajapati, Baylor University
- "Variable Selection in Semiparametric Survival Models for Correlated Failure-Time Data with Long-Term Survivors", Abdullah Al Masud, AbbVie

BIOMARKERS/PRE-CLINICAL/DISCOVERY: Discovery; Carmel 1

Organizer/Chair: Lin Li, BioStat Solutions, Inc.

- "A Multivariate Method for Efficient Biomarker Discovery", Kofi Adragi, Eli Lilly
- "System Biology Approach to Drug Discovery", Yushi Liu, Eli Lilly
- "Drug Discovery in the Age of Open Data", Erin Wagner, BioStat Solutions, Inc.

REAL WORLD EVIDENCE: The Role of Real World Evidence in Decision Making: Current Thinking and Practice; Carmel 5 & 6

Organizer/Chair: Li-An Lin, Merck

- "Real-World Evidence for Economic Modeling", Hongwei Wang, AbbVie
- "Integration of Continuum Safety Evidence for Decision Making", Li-An Lin, Merck
- "Are X-Confounders Ignorable?", Bob Obenchain, Risk Benefit Statistics LLC
- "Discussant", Melvin Munsaka, AbbVie

CHEMICAL MANUFACTURING CONTROL: Product Sampling and Assessment During Process Performance Qualification (PPQ) and Continued Process Verification (CPV) Stages of the Product Life Cycle; Carmel 2

Organizer/Chair: Mark Johnson, AbbVie

- "Product Sampling and Acceptance Criteria for Continued Process Verification and Process Performance Qualification Activities", Mark Johnson, AbbVie
- "Some Thoughts on Developing Economically Sustainable Manufacturing Control Strategies", Jeff Gardner, DataPharm
- "It's Not Just about Statistics: Lean, Patient-Centered Statistical Sampling and Evaluations in PPQ and CPV", Katherine Giacoletti, SynoloStats
- Panel Discussion, All

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

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