

**THE 43rd ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP  
MAY 18 – 20, 2020 • 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: "ENVISIONING 2020 AND BEYOND – THE FUTURE OF ANALYTICS"

**MONDAY, MAY 18**

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

8:00 AM – 2:30 PM

**WORKSHOP REGISTRATION**

FEE: \$260 until May 1 (\$130 for academia/government, \$80 for students), \$300 after May 1

8:30 AM – 12:00 PM

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

Presenters	Topic	Room
Melvin S. Munsaka, AbbVie	Using Python for Exploratory Data Analysis and Statistical Inference: A Hands-On Short Course	Carmel 3
Sukanya Dutta, GCE Solutions Wei Jin, Eli Lilly	An Introduction to Spotfire	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, 2020. For more information contact Ying Grace Li at posterchair@mbswonline.com

2:15 PM – 2:30 PM

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

**WORKSHOP CHAIRS**

VIPIN ARORA, Eli Lilly

ENA BROMLEY, BioStat Solutions

2:30 PM – 4:00 PM

**PLENARY SESSION; Carmel 3 & 4**

Speaker: SANDEEP MENON, PFIZER

Title: *Bringing 20-20 Vision into 2020: The Evolving Role of Statisticians in the Age of AI*

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 19**

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

8:30 AM – 11:30 AM

**CONCURRENT SESSIONS**

**CLINICAL: Beyond MCP-Mod: New Developments in Model-Based Phase 2 Studies; Carmel 3 & 4**

Organizer/Chair: Hongtao Zhang, Bristol-Myers Squibb

- "TBD", Jose Pinheiro, Janssen
- "TBD", Richard Payne, Eli Lilly
- "TBD", Michael McDermott, University of Rochester Medical Center
- "TBD", TBD, TBD

**BIOMARKERS/PRE-CLINICAL/DISCOVERY: Biomarker Analysis; Carmel 1**

Organizer/Chair: Lin Li, Biostat Solutions Inc.

- "Identification of potential predictive biomarkers using weighted co-expression network analysis", Hong Wang, Eli Lilly
- "Calculating the confidence interval of drug combination index using fiducial inference", Kofi Adragani, Eli Lilly
- "Design and analysis of biomarker-driven trials with master protocol", Danni Yu, Eli Lilly
- "Methods for Discovering Biomarker-Treatment Interactions with High-Dimensional Data from Randomized Clinical Trials", Abraham Apfel, BMS

**STATISTICAL PROGRAMMING AND VISUALIZATION: Visualize the Data: A Practical Session on Using Data Visualization Tools for Clinical Studies; Carmel 5 & 6**

Organizer/Chair: Ge Guo, Roche Diagnostics

- "Maximize the Impact of Statistics via Visualization", Michael Man, Eli Lilly
- "Building Automation for Generating Datasets via R and SAS for Visualizations Across Multiple Therapeutic Areas", William Martersteck, Eli Lilly
- "Effective Display of Multi-Response Clinical Data", Sanjay Matange, Independent Contractor SAS Graphics Programming and Training
- "A Critique of Data Visualizations Seen in Drug Development", Zachary Skrivaneck, Eli Lilly

**CHEMICAL MANUFACTURING CONTROL: Hands-On Bayesian Applications in CMC; Carmel 2**

Organizer/Chair: Paul Faya, Lilly

- "A Short Introduction to Bayesian Inference: Priors, Posteriors and Prediction", Paul Faya, Eli Lilly
- "Bayesian DOE with Application in CMC Development Studies", Adam Raouk, Eli Lilly
- "Leveraging Historical Batches in Vaccine Shelf Life Determination", Ji Young Kim, Merck
- "Sample Size Determination with Application in Bioequivalence Studies", Dwayne Banton, Janssen
- "Predicting shelf-life when results show no change over time or are below quantitation limits", Meng Zhao and Tim Kramer, Eli Lilly

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

**CONCURRENT STUDENT SESSION & ROUNDTABLE DISCUSSION**

**STUDENT SESSION: TBD; Carmel 5**

Organizer/Chair: Veavi Chang, Brian Millen, Eli Lilly, and Barry Katz, Indiana University

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**TUESDAY AFTERNOON, MAY 19**

1:30 PM – 4:30 PM

**CONCURRENT SESSIONS**

**CLINICAL: Digital Health; Carmel 3 & 4**

Organizer/Chair: Jennifer Schroeder, Biostat Solutions

- "TBD", Jenn Visich, Unity
  - "TBD", Melissa Pugh, Eli Lilly
  - "TBD", Albert Burgess-Hull, NIDA
  - "TBD", Caleb Grohmann, University of Illinois
- Discussant: Jennifer Schroeder, Biostat Solutions

**BIOMARKERS/PRE-CLINICAL/DISCOVERY: Bayesian Framework Approaches in Drug Discovery and Development; Carmel 1**

Organizer/Chair: Liping Hou, Biostat Solutions Inc.

- "A Bayesian gene network reveal insight into the JAK-STAT pathway in systemic lupus erythematosus", Yushi Liu, Eli Lilly
- "Bayesian hierarchical modeling for the establishment of Pharmacodynamic (PD) biomarker threshold", Ran Wei, Eli Lilly
- "TBD", Timothy Mutsvari, PharmaLex

**REAL WORLD EVIDENCE: TBD; Carmel 5 & 6**

Organizer/Chair: TBD, TBD

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**CHEMICAL MANUFACTURING CONTROL: Statistical Applications in Pharmaceutical Manufacturing & Development; Carmel 2**

Organizer/Chair: Heliang Shi, Pfizer

- "Multivariate Analysis of Cell Culture Bioprocess Data", Jinxin Gao, Eli Lilly
- "QbD: A Predictive Distribution Approach", John Peterson, GlaxoSmithKline
- "The Evaluation of PLS Models on Coated Tablets Weight Gains", Yong Mei, Pfizer
- "A Manufacturing Paradigm for Establishing Dissolution Profile Similarity Criteria", Stan Altan, Janssen R&D
- "The Application of Restricted Maximum Likelihood (REML) Analysis to Analytical Method Development for Combination Products", Mark D. Johnson, AbbVie

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

4:30 PM – 5:30 PM

**DINNER AND BANQUET**

5:30 PM – 8:00 PM

Announcement of Winner(s) of MBSW Student Poster Award

**Banquet Panel Discussion: Xiaochun Li, Indiana School of Medicine, TBD, TBD, TBD**

Title: *Real World Evidence – Challenges, Opportunities, and Regulatory Perspective*

**WEDNESDAY MORNING, MAY 20**

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

**8:30 AM – 9:30 AM Keynote Speaker Presentation**

Speaker: Sanjiv Chopra, MBBS, MACP, Harvard Medical School

Title: *Two Most Important Days: Reflections on Lasting Happiness and Living with Purpose*

<https://sanjivchopra.com>

9:30 AM – 9:45 AM Break

9:45 AM – 12:00 PM Parallel Sessions (CMC Session will start at 9:45 AM)

**CONCURRENT SESSIONS**

**CLINICAL: Model Informed Drug Development; Carmel 3 & 4**

Organizer/Chair: Jack Knorr, Eli Lilly

- "TBD", Mannie Chigusta, Eli Lilly
- "TBD", Veavi Ching-Yun Chang, Eli Lilly
- "TBD", TBD, TBD
- "TBD", TBD, TBD

**BIOMARKERS/PRE-CLINICAL/DISCOVERY: "Omic data in Drug Target Discovery"; Carmel 1**

Organizer/Chair: Erin Wagner, Biostat Solutions Inc.

- "Comparisons of DEG approaches for multi-sample sc/sn RNAseq datasets", Jake Gagnon, Biogen
- "Biobanks for drug target identification and evaluation", Liping Hou, Biostat Solutions
- "Serum Neurofilament Light (sNFL) for Disease Prognosis in Multiple Sclerosis", Ray Su, Biogen

**STATISTICAL PROGRAMMING AND VISUALIZATION: Open Source Technology for Life Science Data Visualization; Carmel 5 & 6**

Organizer/Chair: Freeman Wang, Biostat Solutions

- "R and Python for Clinical Workflows", Phil Bowsher, RStudio
- "Supercharging Shiny Apps in Life Sciences – Highlights and Best Practices", Eric Nantz, Eli Lilly
- "Spotfire versus R/Shiny: Dawn of Dashboard Visualization", Freeman Wang, Biostat Solutions

**CHEMICAL MANUFACTURING CONTROL: TBD; Carmel 2**

Organizer/Chair: Angel Lu, PharmaLex

- "Comparison of Frequentist and Bayesian methods when comparing process", Angel Lu, PharmaLex
- "Bayesian Solutions in Action, including examples of the Beta Distribution", Bill Pikounis, Janssen
- "Improved Dissolution Acceptance Limits", Rick Lewis, GlaxoSmithKline
- "Introduction of Bayesian Assurance for Sample Size Determination in CMC", Timothy Mutsvari, PharmaLex

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

12:45 PM Closing Remarks, Vipin Arora, Eli Lilly, ENA BROMLEY, BioStat Solutions