

THE 39th ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP
MAY 16 – 18, 2016 • BALL STATE UNIVERSITY ALUMNI CENTER, MUNCIE, 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

Program (Version 07 March 2016)
"The Power and 3 I's of Statistics : Innovation, Integrity and Impact"

MONDAY, MAY 16

MORNING

8:30 AM – 2:15 PM

WORKSHOP REGISTRATION

FEE: \$215 until May 1 (\$80 for students), \$240 after May 1

9:00 AM – 12:45 PM

SHORT COURSES (Separate Registration Fee: \$95)

Presenters	Topic
PHIL BOWSHER, RStudio	An Introduction to Shiny, R Markdown, and HTML Widgets for R With Applications in Drug Development
DONG XI, Novartis	Graphical Approaches to Multiple Testing

12:45 PM – 1:45 PM LUNCH BUFFET

Student Lunch Session – Networking for Success, Juan Camilo Zapata, Eli Lilly

2:15 PM – 2:30 PM

INTRODUCTION AND WELCOME

WORKSHOP CHAIR

RAY LIU, Takeda

BALL STATE REPRESENTATIVE

MUNNI BEGUM, Mathematical Sciences Department, Ball State University

2:30 PM – 3:30 PM

PLENARY SESSION

Speaker: FRANK SHEN, ABBVIE

Title: Challenge. Change. Engage: Three Secret Formulae for Driving an Impactful Innovation

3:30 PM – 4:30 PM

Speaker: YI TSONG, FDA

Title: Significance Tests and confidence Interval Approaches – Where is the Duality?

MONDAY NIGHT MIXER

4:30 PM – 6:30 PM

Alumni Center

TUESDAY MORNING, MAY 17

CONCURRENT SESSIONS

8:30 AM – 11:30 AM

CLINICAL: Sample Size Re-Estimation for Confirmatory Trials – Emerging Methods and Practical Guidance

Organizers/Chairs: William Prucka, Eli Lilly

- "Emerging Methods for Estimation and Hypothesis Testing for Designs Using Sample Size Re-estimation", Cyrus Mehta, Cytel
- "Applications of Sample Size Re-Estimation in Confirmatory Clinical Trials", Jon David Sparks, Eli Lilly
- "Sample Size Re-estimation Designs In Confirmatory Clinical Trials - Current State, Statistical Considerations, and Practical Guidance", Yili Pritchett, MedImmune
- "Panel Discussion", William Prucka, Lilly

DIAGNOSTICS: NGS Based Genomic Diagnostics in Precision Medicine

Organizer/Chair: Jincao Wu & Yaji Xu, FDA

- "Regulatory Considerations for NGS-Based Tests", Sharon Liang, FDA
- "Companion Diagnostics on an NGS-Based Assay: Methodology and Analytical Validation", James Sun, Foundation Medicine
- "Sequence Counts as Compositional Data: Metrics for Sample Quality, Sequencing Integrity, and Batch Effects in Targeted NGS", Bonnie LaFleur, HTG Molecular Diagnostics
- "Statistical Challenges in Genetic Diagnosis of Rare Diseases With Known Monogenic Causes", Hyun Min Kang, University of Michigan Lilly

BIOEQUIVALENCE: Bioequivalence and Biosimilar

Organizer/Chair: Yi Tsong, FDA

- "Equivalence Test of Analytical Biosimilarity", Yi Tsong, Xiaoyu Dong, Meiyu Shen, Yu-Ting Weng, FDA
- "Pharmacokinetic Bioequivalence Evaluation of Ophthalmic Products Using Bootstrap Resampling Method for Pairs of One-Point Aqueous Humor Concentrations Per Subject", Meiyu Shen, Huaixiang Li, Guoying Sun, FDA
- "Setting Equivalence Acceptance Criteria for Demonstration of Analytical Similarity", Harry Yang, Steven Novick, Rick Burdick, MedImmune

MANUFACTURING: Continuous Manufacturing

Organizer/Chair: Brad Evans, Pfizer

- "Some Statistical Issues Associated With Monitoring and Control of Blend Potency at the Feed Frame Using NIR Spectroscopy", Tim Kramer, Eli Lilly
- "A Bayesian Approach to the Comparison of NIR vs HPLC Analytical Methods in Continuous Manufacturing Process Validation Studies", Areti Manola, Janssen
- "FDA/Office of Pharmaceutical Quality Updates on Statistical Reviews/Topics", Karthik Iyer, FDA (Tentative)
- "Discussant, Stan Altan, Janssen

11:30 AM – 1:00 PM LUNCH BUFFET

TUESDAY AFTERNOON, MAY 17

POSTER SESSION

12:00 PM – 1:30 PM

Statistical Applications in Drug Development

Chair: Ying Grace Li, Eli Lilly

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

Abstracts must be received by April 10th, 2015.

For more information contact

Ying Grace Li at posterchair@mbswonline.com

TUESDAY AFTERNOON, MAY 17

CONCURRENT SESSIONS

1:30 pm – 4:30 pm

STUDENT SESSION: Making a Healthy Difference as a Pharmaceutical Research Statistician

Organizer/Chair: Yun-Fei Chen, Brian Millen, Han Wu, Eli Lilly

- "Statistical Innovation and Patient Outcomes", Craig Mallinckrodt, Eli Lilly
- "Reflections on my Pharma Career", Naitee Ting, Boehringer-Ingelheim
- "How to Prepare for Your Job Interview", Russell Reeve, Naitee Ting, Quintiles, Boehringer-Ingelheim

CLINICAL: Modeling and Simulation in the Pharmaceutical Industry

Organizer/Chair: Jose Pinheiro, Janssen

- "Synergistic Opportunities with Pharmacometricians and Statisticians", Alan Hartford, Abbvie
- "Precision in Model Prediction", Matt Rotelli, Eli Lilly
- "Application of Dose Scaling Method in Similarity Assessment", Yaning Wang, FDA
- "Panel Discussion", Jose Pinheiro, Janssen

BIOMARKERS: Precision Medicine, Biomarker, and Subgroup Identification in Drug Development

Organizer/Chair: Michael Man, Eli Lilly

- "The VG (Virtual Twins and GUIDE) Method for Subgroup Identification", Qi Tang, Abbvie
- "Subgroup Identification in a Learn-and-Confirm Paradigm", Lei Shen, Eli Lilly
- "Statistical Issues in Co-Developing Drug Therapy and Diagnostic Test Using Biomarker Enrichment Design", Hong Tian, Janssen
- "Future horizon for Precision Cancer Medicine - A Clinical Trials Design Perspective", Sameera Wijayawardana, Eli Lilly

STATISTICAL PROGRAMMING AND DATA VISUALIZATION: Best Practice in Programming and Visualization

Organizer/Chair: Vipin Arora, Eli Lilly

- "A Shiny New World of Programming and Visualization", Michael Man, Lilly
- "Moving from Data Collection to Data Visualization and Analytics: Leveraging CDISC SDTM Standards to Support Data Marts", Steve Kirby, Chiltern International
- "Good Practices and Implementation Methods for Optimally Stratified Randomization", Jonathan Chipman, Vanderbilt University
- "Concepts and Strategies for Developing Effective Data Visuals", Becky Bates, GCE Solutions
- "Data Visualization by Various Software Tools in Pharmaceutical Industry Settings", Jiayan Huang, Eli Lilly

MANUFACTURING: Comparability and Biosimilarity

Organizer/Chair: Yanbing Zheng, Abbvie

- "A Further Look at the Current Equivalence Test for Analytical Similarity Assessment", Aili Cheng, Pfizer
- "Using the Confidence Interval on Effect Size to Demonstrate Analytical Similarity Between Reference and Biosimilar Products", Rick Burdick, Elion Labs
- "Statistical Methods for Comparability Assessment in Drug Development", Yuanyuan Duan, Abbvie
- "Analytical Similarity Assessment: Practical Challenges and Statistical Perspectives", Richard O. Montes, Pfizer
- "Discussant", Yi Tsong, FDA

TUESDAY NIGHT MIXER AND BANQUET

Alumni Center

MIXER

4:30 PM – 5:00 PM

BANQUET

5:00 PM – 8:00 PM

Welcome: MIR MASOOM ALI, Chairman Emeritus and George and Frances Ball Distinguished Professor of Statistics Emeritus
Announcement of Student Winner of Charlie Sampson Poster Award

Speaker: CHARLIE SCHICK, Atigeo

Title: "Accelerating Analytics With External Data"

WEDNESDAY MORNING, MAY 18

CONCURRENT SESSIONS

8:30 AM – 11:30 AM

CLINICAL: Statistical Approaches to Address Multiplicity Testing in Clinical Trials

Organizer/Chair: Chakib Battoui, Eli Lilly

- "Confident Biomarker Identification by Assessing Efficacy in Subgroups and Their Mixtures", Jason Hsu, Ohio State, Eli Lilly
- "Multiple Error Rates in Assessing Efficacy in Subgroups and Their Mixtures", Xu Haiyan, Janssen
- "Panel Discussion", All

BIOMARKERS: Unleashing the Power of Statistics in Drug Discovery Research

Organizer/Chair: Shihong Deng, Pfizer

- "Leveraging Omics Data in Drug Development – Get Ready for the Show!", Weidong Zhang, Pfizer
- "Statistical modeling for Tumor Regrowth Experiments in Xenograft Studies", Cong Li, Takeda
- "Bayesian Inference of Tumor Heterogeneity in Human Cancers", Yuan Ji, University of Chicago
- "Transcriptomic Biomarkers Research at Eli Lilly With Applications in Autoimmune Conditions", Guilherme V. Rocha, Eli Lilly

ANALYTICAL METHODS: Continued Validation and Verification of Analytical Methods

Organizer/Chair: Harry Yang, MedImmune

- "Analytical Development Using Quality by Design", Tim Schofield, MedImmune
- "Statistical Approaches for Assessment of Parallelism for Bioassays", Xiaoyu (Cassie) Dong, FDA
- "Method Validation Based on Total Error", Jason Zhang, MedImmune

MANUFACTURING: Internal Release Limit and Control Limit

Organizer/Chair: Mary Ann Gorko, AstraZeneca

- "Setting Release Limits: A comparison of Frequentist and Bayesian Approaches", Niels Væver Hartvig, Novo Nordisk
- "Risk Evaluation of Shelf-Life Specifications and Internal Release Control Using a Bayesian Approach", Yijie Dong, BMS
- "Setting Control Limits Using Bayesian Methods When Most Observations Are Below the Limit of Quantitation", Steve Novick, MedImmune
- "Effective use of Release and Control Limits to Manage Manufacturing and Patient Risks", Tim Schofield, MedImmune

11:30 AM – 1:00 PM LUNCH BUFFET and Closing Remarks: Ray Liu, Takeda

FOR MORE INFORMATION ON THE WORKSHOP, please contact RAY LIU, Takeda, e-mail: ray.liu@takeda.com or Publicity Chair Melvin Munsaka at melvin.munsaka@takeda.com or Munni Begum at mbegum@bsu.edu. The program and workshop logistics will be updated periodically at the web site as the workshop date approaches, see <http://www.mbswonline.com/>. The track co-chairs are: CLINICAL: David Manner, Eli Lilly; BIOMARKERS: Fen Gao, Takeda; DATA VISUALIZATION: Vipin Arora, Cindy Lee, Eli Lilly; MANUFACTURING: Jyh-Ming Shoung, Johnson and Johnson; DIAGNOSTICS: Jingjing Ye, FDA; BIOEQUIVALENCE, Yi Tsong, FDA.