

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

Final One Page Program
"Celebrating 40 years of sharing Statistical Innovation to the Biopharmaceutical Industry"

MONDAY, MAY 22
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
HAODA FU, Eli Lilly	An Introduction to Artificial Intelligence, Machine Learning and Precision Medicine
RODERICK LITTLE, University of Michigan	Missing Data in Clinical Trials

12:45 PM – 1:45 PM LUNCH BUFFET

Student Lunch Session – Advancing Influence and Career: Leadership Skills Can Be Developed by All! Walt Offen, Abbvie

2:15 PM – 2:30 PM

INTRODUCTION AND WELCOME

WORKSHOP CHAIR

DAVID MANNER, Eli Lilly

BALL STATE REPRESENTATIVE

JOHN EMERT, Acting Dean of Honors College, Ball State University

2:30 PM – 3:30 PM

PLENARY SESSION

Speaker: FRANK ROCKHOLD, Duke University

Title: Open Access and Data Sharing: Where are we on the Clinical Data Disclosure and Transparency Journey?

3:30 PM – 4:30 PM

Speaker: STEVE WILSON, FDA

Title: Biostatisticians and 21st Century Drug Development: Staying Relevant and Looking Forward

MONDAY NIGHT MIXER

4:30 PM – 6:30 PM

Alumni Center

TUESDAY MORNING, MAY 23

CONCURRENT SESSIONS

8:30 AM – 11:30 AM

CLINICAL: Emerging Applications of Model-Based Dose Escalation in Early Phase Trials

Organizer/Chair: Mitchell Thomann, Eli Lilly

- "Interval-based Dose-Finding Methods", Yuan Ji, University of Chicago
- "Model-Based Dose-Escalation using Constrained Reference Priors", Zachary Thomas, Eli Lilly
- "Program Implications of a Combined Phase 1/2 Escalation and Dose-Finding Trial", Kert Viele, Berry Consultants

PRE-CLINICAL/DISCOVERY RESEARCH/Biomarkers: Influence of Statistics in Pharmaceutical Discovery Research

Organizer/Chair: Alan Y. Chiang, Eli Lilly

- "Predicting Drug Safety or Drug Toxicity: Lessons Learned From Two Decades of Predicting Drug-Induced Cardiac Arrhythmia", Derek Leishman, Eli Lilly
- "Statistical Thinking in Drug Discovery Science: From High Throughput Screening to a Clinical Candidate", G. Sitta Sittampalam, NIH
- "Applied Bayesian Statistics and the Life Cycle Vision for Assay in Research", Bruno Boulanger, Arlenda
- "Study Design and Statistical Data Analysis of Flow Cytometry Assays", Shuguang Huang, Statward

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

Organizer/Chair: Vipin Arora, Eli Lilly

- "Power of Visualization for Precision Medicine in Oncology", Shuaicheng Freeman Wang, Biostats Solutions
- "Creating Patient Profile Graphs Using Spotfire", Zhiqun Gong, Eli Lilly
- "Considerations Towards Collection, Storage and Utilization of Shared Data for the Pharmaceutical Industry", Ena Bromley, Biostats Solutions

MANUFACTURING: Bayesian Statistics in Pharmaceutical Sciences

Organizer/Chair: Perceval Sondag, Arlenda

- "A Bayesian Approach to Platform Analytical Method Validation Acceptance Criteria", Adam Rauk, Eli Lilly
- "Risk assessments Using a Bayesian Approach to Evaluate the Impact of Analytical Method Performance on Process Capability", Yijie Dong, BMS
- "Multivariate Variance Components Estimation: Bayesian Approach vis-à-vis the Frequentist Approach", Dwaine Banton, Janssen
- "From the Garrett Two-Stage Model to the Bayesian view - A Historical Survey of Stability Modeling: 1954 to 2017", William Porter, Peak Process Performance Partners

11:30 AM – 1:00 PM LUNCH BUFFET

TUESDAY AFTERNOON, MAY 23

POSTER SESSION

12:00 PM – 1:30 PM

Statistical Innovation 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 23

CONCURRENT SESSIONS

1:30 pm – 4:30 pm

STUDENT SESSION: How to be Successful as a Pharmaceutical Statistician?

Organizer/Chair: Brian Millen, Yun-Fei Chen and Veavi Chang, Eli Lilly

- "Examples of Statistical Impact in Pharmaceutical Research"
 - "Discovery", Veavi Chang, Eli Lilly
 - "Clinical Research", Ji Lin, Eli Lilly
 - "Regulatory", Steve Wilson, FDA
- "My Life and Career in Pharmaceutical Statistics", Steve Ruberg, Eli Lilly
- "Career development", Panel Discussion, Steve Ruberg, Eli Lilly, Steve Wilson, FDA, Ray Liu, Takeda, Yuan Ji, University of Chicago, Cindy Lee, Eli Lilly, Qi Zhang, Eli Lilly

CLINICAL: Advances in Model-Based Dose Finding Designs

Organizer/Chair: Su Chen, Abbvie

- "Simulation to Support the Design of a Bayesian Dose-Ranging Trial, Using Scalable Computing", James Rogers, Metrum Research Group
- "Dose-Ranging Design and Analysis Methods to Identify the Minimum Effective Dose", Li Wang, Abbvie
- "New Methodological Developments in MCP-Mod for Improved Dose Finding", Fei Chen, Janssen

PRE-CLINICAL/DISCOVERY RESEARCH/Biomarkers: Predictive Safety Signals, Regulatory Paths to Qualification, Subgroup Identification Strategies and the Co-Development of Companion Diagnostics

Organizer/Chair: Todd Townsend, Merck

- "FDA Biomarker Qualification Pathways and Publically Available Resources", Christopher Leptak, FDA
- "Role of Real World Data to Characterize Biomarker Testing in Routine Clinical Practice and Inform Drug and Diagnostic Development", Lisa Wang, Genentech
- "Co-development, Approval and Utilization of a Portfolio of CDx Products to Optimize Therapeutic Selection for Cancer Patients", Patrick Burke, Myriad Genetics
- "Novel Assay Development and the Application of Potential Predictive Clinical Safety Biomarkers in Nonclinical Models to Guide Research Efforts", Todd Townsend, Merck
- "Panel Discussion: Additional Mechanisms for Building and Extending a Collaborative Community to Increase Value of Generated Data", Presenters

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

Organizer/Chair: Vipin Arora, Eli Lilly

- "Facilitating Efficient Review with a Graphics-Driven Approach to Interim Safety Reporting", Kevin Buhr, University of Wisconsin, Madison
- "Using Spotfire to Enable Dynamic Search of SMQs to Effectively Support Emerging Safety Signal Detections and Safety Analysis for Clinical Data", "Xiangyun Wang", Genetech
- "Visual Analytics in Safety Monitoring – Beyond the Usual Graphs and Available Tools", Melvin Munsaka, Takeda

MANUFACTURING: Continued Process Verification

Organizer/Chair: Katherine Giacoletti, SynoloStats

- "Control Charts for CPV – A Pharma Perspective", Maneesha Altekhar, Astra Zeneca
- "Statistical Questions from CPV Monitoring of Bioreactor Data", Craig Bernier, Janssen Pharmaceuticals
- "Monitoring Versus Improving in CPV", Jamey Crichton, Cook Pharmica

TUESDAY NIGHT MIXER AND BANQUET

Alumni Center

MIXER: 4:30 PM – 5:00 PM; BANQUET: 5:00 PM – 8:00 PM

Welcome: Marilyn Buck, Provost, Ball State University and Pandurang Kulkarni, Chief Analytics Officer and Vice-President Biometrics, Eli Lilly

Announcement of Student Winner of Charlie Sampson Poster Award

Title: "Celebrating 40 Years of Sharing Statistical Innovation to the Biopharmaceutical Industry" – Chaired by
WALT OFFEN, Abbvie

WEDNESDAY MORNING, MAY 24

CONCURRENT SESSIONS

8:30 AM – 11:30 AM

CLINICAL: Synthesis of Clinical Evidence for Diverse Populations

Organizer/Chair: Elyl Kaiser, Ohio State University

- "Measures of Reproducibility: Estimation via Cross-study Validation", Lo-Bin Chang, Ohio State University
- "Evaluating the Generalizability of an RCT to a Broader Population via Reweighting", Chen-Yen Lin, Eli Lilly
- "Hierarchical Random-Effect Meta-Analysis of Binary Events Investigating Relation Between Treatment Effect and Underlying Risk", Jingjing Yan, Amgen

PRE-CLINICAL/DISCOVERY RESEARCH/Biomarkers: Advanced and Powerful Bayesian Approaches for Early Development and Biomarkers

Organizer/Chair: Yuan Ji, University of Chicago

- "Heterogeneous Reciprocal Graphs for TCGA Cancer Biomarkers", Peter Mueller, University of Texas at Austin
- "Response-Adaptive Platform Designs and the Control of Type I Error Rates", Steffen Ventz, Harvard and Dana-Farber Cancer Institute
- "Novel Bayesian Dose-Finding Designs Accounting for the Schedule Effects by Using Pharmacokinetic/Pharmacodynamic Markers", Yisheng Li, University of Texas M.D. Anderson Cancer Center
- "BayCancer: Tumor Heterogeneity as a Biomarker using RNA-Seq Data", Yanxun Xu, Johns Hopkins University

BUSINESS ANALYTICS: Introduction to Business Analytics

Organizer/Chair: Todd Sanger, Eli Lilly

- "Measuring marketing impact in an environment where everything is "on", John Beeson, Eli Lilly
- "Bridging the gap from insight to action: engaging a traditional business team (rooted in field experience and market research) with the results of complex advanced analytics", Nikola Andric, Deloitte
- "Innovative Visualization of Physicians' Referral Network", Rubin Wei, Eli Lilly

MANUFACTURING: Shiny/R in Pharmaceutical Sciences

Organizer/Chair: Aimee Buesgen, Eli Lilly

- "Statistical Computation Tools in Pharmaceutical Drug Development and Manufacturing Life Cycle", Fasheng Li, Pfizer
- "Shiny Tools for Sample Size Calculation in Process Performance Qualification of Large Molecules", Qianqiu (Jenny) Li, Janssen Research and Development
- "Using Shiny Tools to Establish a Stability Thermal Budget Contingency", Aimee Buesgen, Eli Lilly
- "Panel Discussion", All

11:30 AM – 1:00 PM LUNCH BUFFET

11:45 AM – 12:45 PM ROUNDTABLE Discussions, Shufang Wang, Eli Lilly

- "Reflection on Connections Between Two Recent FDA Draft Guidances: Multiple Endpoints in CTs and Medical Product Communications Consistent with FDA Labeling", Andreas Sashegyi, Eli Lilly
- "How Do You Validate an Interactive Visualization Using Tools Such as Spotfire or Shiny?", Anastasia Alexeeva, Eli Lilly
- "Statistical Topics and Ponderings in Product Performance Qualification and Routine Release", Thomas Parks, Eli Lilly
- "Analysis Data Standards: Progress and Challenges", Stephen Wilson, FDA
- "Big Data in Translational Research – Leveraging Data to Retrieve Meaningful Action", Ray Liu, Takeda

12:45 AM Closing Remarks, David Manner, Eli Lilly