MONDAY, MAY 22

MORNING
8:30 AM – 2:15 PM

WORKSHOP REGISTRATION
FEE: $215 until May 1; $910 for May 1 and after May 1; $240 after May 1
9:00 AM – 12:45 PM

SHORT COURSES (Separate Registration Fee: $95)

Presenters
Topic
HAOCA FU, Elly 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, Abby/Elly
2:15 PM – 2:30 PM
INTRODUCTION AND WELCOME
WORKSHOP CHAIR
DAVID MANNER, Elly Lilly

BALL STATE REPRESENTATIVE
JOHN EMERT, Acting Dean of College of Arts and Sciences, Ball State University
2:30 PM – 3:30 PM PLENARY SESSION

Speaker: FRANK ROCHORDL, Duke University
Title: Access Open 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

Tuesday, May 23

CONCURRENT SESSIONS
8:30 AM – 11:30 AM

CLINICAL: Emerging Applications of Model-Based Dose Escalation in Early Phase Trials
Organizers/Chairs: Mitchell Thomann, Elly Lilly
1. “Interval-Based Dose-Finding Method”, Yuan Ji, University of Chicago
2. “Model-Based Dose-Escalation Using Constrained Reference Prior”, Zachary Thomas, Elly Lilly
3. “Pharmacogenomic Implications of a Combined Phase 1/2 Escalation and Dose-Finding Trial”, Kert Viele, Bly Consultants

PRE-CLINICAL/DISCOVERY RESEARCH/BIOMARKERS: Influence of Statistics in Pharmaceutical Discovery Research
Organizer/Chair: Alan Y. Chiang, Elly Lilly
1. “Predicting Drug Safety or Drug Toxicity: Lessons Learned from Two Decades of Predicting Drug-Induced Cardiac Arrhythmias”, Derek Leshamin, Elly Lilly
2. “Statistical Thinking in Drug Discovery Science: From High Throughput Screening to a Clinical Candidate”, G. Li; Shih Tsai, University of Chicago
4. “Study Design and Statistical Data Analysis of Flow Cytometry Assays”, Shuguang Huang, Stat4ward

STATISTICAL PROGRAMMING AND DATA VISUALIZATION: Best Practice in Programming and Visualization
Organizer/Chair: Vinpin Arora, Elly Lilly
1. “Power of Visualization for Precision Medicine in Oncology”, Shuaicheng Freeman Wang, Biostats Solutions
2. “Creating Patient Profile Graphics Using Spotfire”, Zhiqun Gong, Eli Lilly
3. “Considerations Towards Collection, Storage and Utilization of Shared Data for the Pharmaceutical Industry”, Eva Bromeley, Biostats Solutions

MANUFACTURING: Bayesian Statistics in Pharmaceutical Science
Organizer/Chair: Perceval Sondar, Aralenda
1. “A Bayesian Approach to Platform Analytical Method Validation Acceptance Criteria”, Adam Rauk, Elly Lilly
2. “Risk Assessments Using a Bayesian Approach to Evaluate the Impact of Analytical Method Performance on Process Capability”, Iras Yan, Yale Dong, BMS
3. “Multivariate Variance Components Estimation: Bayesian Approach via a-vais the Frequentist Approach”, Dwaine Banton, Janssen

TUESDAY AFTERNOON, MAY 23

POSTER SESSION
12:00 PM – 1:30 PM

Statistical Innovation in Drug Development
Chair: Ying Grace Li, Elly Lilly
Posters will be accepted on any pharmaceutical statistical topic up to capacity. Abstracts must be received by April 10th, 2017.
For more information contact
Ying Grace Li at posterchair@mbeswonline.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: Yun Fei Chen, Brian Millen, and Yexi Chiang, Elly Lilly
1. “Examples of Statistical Impact in Pharmaceutical Research”
   a. “Discovery”, Yexi Chiang, Eli Lilly
   b. “Clinical Research”, J-Lin, Eli Lilly
   c. “Regulatory”, Steve Wilson, FDA
3. “Career Development”, Panel Discussion, Steve Ruberg, Elly Lilly, Steve Wilson, FDA, Ray Liu, Takeda, Yuan Ji, University of Chicago, Cindy Lee, Elly Lilly, Qi Zhang, Eli Lilly

CLINICAL: Advances in Model-Based Dose Finding Designs
Organizer/Chair: Su Chen, Abby/Elly
1. “Simulation to Support the Design of a Bayesian Dose-ranging Trial, Using Scalable Computing”, James Rogers, Dan Polhamus, Angelica Quintana, Metrum Research Group
2. “Dose Ranging Design and Analysis Methods to Identify the Minimum Effective Dose”, Hongtao Zhang, Abvy
3. “New Methodological Developments in MCP-Mod for Improved Dose Finding”, Fei Chen, John and Johnson

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
1. “FDA Biomarker Qualification Pathways and Publicly Available Resources”, Christopher Lepki, FDA
2. “Role of Real World Data to Characterize Biomarker Testing in Routine Clinical Practice and Inform Drug and Diagnostic Development”, Lisa Wang, Genentech
3. “Co-development, Approval and Utilization of a Portfolio of CDx Products to Optimize Therapeutic Selection for Cancer Patients”, Patrick Burke, Myriad Genetics
4. “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: Vinpin Arora, Elly Lilly
2. “Using Spotfire to Enable Dynamic Search of Smogs to Effectively Support Emerging Safety Signal Detections and Safety Analysis for Clinical Data”, Xiuyong Wang, Genentech

MANUFACTURING: Continued Process Verification
Organizer/Chair: Katherine Giacole, KeyStats
1. “Control Charts for CDV – A Pharma Perspective”, Maneesha Aktekar, Astra Zeneca
2. “Statistical Questions from CDV Monitoring of Bioreactor Data”, Craig Bermet, Janssen Pharmaceuticals
3. “Monitoring Versus Improving in CDV”, Jamey Crichton, Cook Pharma

TUESDAY NIGHT MIXER AND BANQUET
Alumni Center
MIXER: 4:30 PM – 5:30 PM; BANQUET: 5:00 PM – 8:00 PM
Welcome: MARILYN BUCK, Past, Ball State University; CAMILLOU 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, Abby/Elly

WEDNESDAY MORNING, MAY 24

CONCURRENT SESSIONS
8:30 AM – 11:30 AM

CLINICAL: Synthesis of Clinical Evidence for Diverse Populations
Organizer/Chair: Elly Kaysar, Ohio State University
1. “Measures of Reproducibility: Estimation via Cross-study Validation”, Lo-Bin Chang, Ohio State University
2. “Evaluating the Generalizability of an RCT to a Broader Population via Reweighting”, Chen-Yen Lin, Elly Lilly

PRE-CLINICAL/DISCOVERY RESEARCH/BIOMARKERS: Advanced and Powerful Bayesian Approaches for Early Development and Biomarkers
Organizer/Chair: Yuan Ji, Subhajit Sengupta, University of Chicago
1. “Heterogeneous Reciprocal Graphs for TCGA Cancer Biomarkers”, Peter Mueller, University of Texas at Austin
2. “Response-Adaptive Platform Designs and the Control of Type I Error Rates”, Steffen Vente, Harvard and Dana-Farber Cancer Institute
3. “Novel Bayesian Dose-Finding Designs Accounting for BMR for the Schedule Effects by Using Pharmacokinetic/Pharmacodynamic Models”, Yisheng Li, University of Texas M.D. Anderson Cancer Center
4. “BayCount: Tumor Heterogeneity as a Biomarker Using RNA-Seq Data”, Yaxuan Xu, Johns Hopkins University

BUSINESS ANALYTICS: Introduction to Business Analytics
Organizer/Chair: Todd Sanger, Elly Lilly
1. “Measuring Marketing Impact in an Environment Where Everything is on”, John Beeson, Elly Lilly
2. “Bringing 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”, Nikita Andric, Deloitte
3. “Innovative Visualization of Physicians’ Referral Network”, Rubin Wei, Eli Lilly

MANUFACTURING: Shiny/R in Pharmaceutical Sciences
Organizer/Chair: Aimee Buesen, Elly Lilly
2. “Shiny Tools for Sample Size Calculation in Process Performance Qualification of Large Molecules”, Guanqiu (Jenny) Li, Janssen Research and Development
3. “Using Shiny Tools to Establish a Stability Thermal Budget Contingency”, Aimee Buesen, Eli Lilly
4. “Panel Discussion”, All

11:30 AM – 1:30 PM LUNCH BUFFET

11:45 AM – 12:45 PM ROUNDTABLE Discussions, Shufang Wang, Elly Lilly
1. “Reflection on Connections Between Two Recent FDA Draft Guidance: Multiple Endpoints in CTs and Medical Product Communications Consistent with FDA Labeling”, Andreas Sassehey, Elly Lilly
2. “How Do You Validate an Interactive Visualization Using Tools such as Spotfire or Shiny?”, Anastasia Alexeira, Elly Lilly
3. “Statistical Topics and Ponderings in Product Performance Qualification and Routine Deployed”, Thomas Pizze, Elly Lilly
4. “Analysis Data Standards: Progress and Challenges”, Stephen Wilson, FDA

12:45 PM Closing Remarks, David Manner, Elly Lilly