MONDAY, MAY 18
6:30 AM – 7:15 AM
Walk/Jog Around Ball State Campus – See Map on the website for details

8:30 AM – 2:15 PM
WORKSHOP REGISTRATION
FEE: $215 until May 1 ($40 for students), $240 after May 1
9:00 AM – 12:45 PM
SHORT COURSES
( Separate Registration Fee: $95

12:45 PM – 1:45 PM LUNCH BUFFET

STUDENT SESSION: A Significant Career: The Pharmaceutical Statistician
Organizer/Chair: Yun-Fei Chen, Brian Miller, Eli Lilly

1. “Example Contributions”
   a. “Discovery”, Veeyi Chang, Lilly
   b. “Clinical”, Li Xie, Lilly
   c. “Utility”, Melvin Munaska, Takeda

2. “How to Prepare Yourself for a Clinical Career?”
   Panel Discussion, Wali Offen, AbbVie

3. “Using Clinical Trials Data to Inform the Lifecycle of a Product”, Dang Xia, Pfizer

CLINICAL: Discovering Enriched Populations and Enrichment Designs in an Era of Personalized Medicine
Organizer/Chair: Neby Bekele, Gilead
1. “Enrichment Design with Patient Augmentation”, Bo Yang, AbbVie
2. “Using Statistics to Bridge Translation and Clinical Science: Building a Binary Classifier from Multiple Biomarkers”, Nusrat RBabbee, Gilead
3. “Tailoring Therapies in Adaptive Platform Clinical Trials”, Scott Berry, Berry Consultants

DIAGNOSTICS: Statistical Challenges in Personalized Medicine Bridging Studies
Organizer/Chair: Tinghui Yu, FDA/Jingye Ye, FDA
1. “Personalized Treatment Rule - What Best We Can Do”, Haoda Fu, Eli Lilly
2. “Combining Survival Trials Using Aggregate Data Based on Misspecified Models”, Tinghui Yu, Ying Bai, Sherry Liu, Xiaofei Hu, FDA
3. “Bridging Clinical Efficacy Results from a Laboratory Assay to a Validated IVID Kit - a Case Study”, Jonathan Denne, Leping Zhao, Eli Lilly


DISCOVERY/PRECLINICAL: Methods to Integrate Different Types of Genomic Data and its Applications to Pharmaceutical Industry
Organizer/Chair: Caiyan Li, Takeda
2. “Sparse Simultaneous Signal Detection and Its Applications in Genomics”, Hongzhe Li, University of Pennsylvania
3. “A Comprehensive Description of Genetic Interactions in Cancer by Integrating TCGA Data”, Yuan J, North Shore University Health System

MANUFACTURING: Measurements and Their Uncertainties in an Analytical Process
Organizer/Chair: Yuanxuan Duan, AbbVie Life Inc. and Lanru Zhang, Eli Lilly
1. “A Hypothetical Test Approach to Content Uniformity Test”, Luan Zhang, AbbVie
2. “Large Volume Dose Content Uniformity Test: Parametric Versus Nonparametric (counting)”, Meiyu Shen, FDA
3. “Analysis and Visualization Approaches to Assess UDU Capability”, Jeff Hofer, Eli Lilly
4. “Quality Assurance Test of Dosing Dose Uniformity of Multiple-Dose Inhaler and Dry Powder Inhaler Drug Products”, Xiaoyu Dong, FDA
5. “Discusant”, Steve Novick, GlaxoSmithKline

TUESDAY NIGHT MIXER AND BANQUET
Alumni Center
MIXER 4:30 PM – 6:30 PM
BANQUET 6:30 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: WOODY CARTER, University of Chicago
Title: Ring the Bells That Still Can Ring/Forget Your Perfect Offering/There is a Crack, a Crack in Everything/That's how the Light gets in

WEDNESDAY, MAY 20
8:30 AM – 11:30 AM
CONCURRENT SESSIONS

CLINICAL: Statistical Methods for Comparing Categorical and Survival Outcomes at a Fixed Point Time
Organizer/Chair: Kyunghae See, Eli Lilly
1. “Restricted Mean Event Time Analysis with an Application to Diabetes Cardiovascular Studies”, Haoda Fu, Eli Lilly
2. “Bayesian Modeling Averaging Approach to Model a Binary Outcome for a Dose Ranging Trial”, Robert Noble, AbbVie
3. “Comparison of Statistical Methods for Power and Error Rates Using the Survival Analyses at Fixed Time Points – Simulation Approach”, Tim Costigan, Eli Lilly
4. “Panel Discussion”, All

OBSERVATIONAL: Recent Developments in Observational Studies
Organizer/Chair: Haoda Fu, Dingfeng Jiang, Eli Lilly
1. “A Unified Approach for Subgroup Identification and Individualized Treatment Recommendation With Applications To Randomized Control Trials and Observational Studies”, Haoda Fu, Eli Lilly
2. “Bayesian Modeling Averaging Approach to Model a Binary Outcome for a Dose Ranging Trial”, Robert Noble, AbbVie
3. “Comparison of Statistical Methods for Power and Error Rates Using the Survival Analyses at Fixed Time Points – Simulation Approach”, Tim Costigan, Eli Lilly
4. “Panel Discussion”, All

MATERIALS AND THEIR UNCERTAINTIES IN AN ANALYTICAL PROCESS
Organizer/Chair: Yan Shen and Stan Altan, Johnson and Johnson
2. “Useful Block Designs for Gage R&R Studies for Measuring Total Analytical Variability”, Jyh-Ming Shoung, Johnson and Johnson
3. “A GUM/Metropolitan Perspective on the Analysis of a Gage R&R study of an Analytical Test when a New Clinical Trial Investigator Takes Over”, Abha Sharma, Roche

MANUFACTURING: Statistical Measurements and Their Uncertainties in an Analytical Process
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FOR MORE INFORMATION ON THE WORKSHOP, please contact RAY LUI, Takeda. Email: ray.liu@takeda.com or Publicity Chair Marvin Munaska at marvin.munaska@takeda.com or Munni Bogum at mbogum@nd.edu. The program and workshop logistics will be updated periodically on the website. For details on topics presented, see http://www.mbswonline.com. The program co-chairs are: CLINICAL: David Mannier, Eli Lilly; DISCOVERY/PRECLINICAL: Fan Gao, Takeda; OBSERVATIONAL: Haoda Fu, Eli Lilly; MANUFACTURING: Jyh-Ming Shoung, Johnson and Johnson; DIAGNOSTICS Tinghui Yu, FDA; BIOEQUIVALENTICITY: Yi Tang, Mark Sweet, FDA; STATISTICAL APPLICATIONS IN DRUG DEVELOPMENT: Li Xie, Eli Lilly; INDUSTRY SESSIONS: RAY LIU – posterchair@mbswonline.com.