

**THE 31<sup>ST</sup> ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP**  
**MAY 19 – 21, 2008 • BALL STATE UNIVERSITY ALUMNI CENTER AND HORIZON CENTER, MUNCIE, INDIANA**  
**Preliminary Program**

**MONDAY, MAY 19**

**8:30 AM – 4:30 PM**

**WORKSHOP REGISTRATION**

FEE: \$165 until May 1 (\$65 for students), \$195 after May 1

**9:00 AM – 1:00 PM**

**SHORT COURSE** (Separate Registration Fee: \$60)

Presenters: MICHAEL PROSCHAN, National Institute of Allergy and Infectious Diseases

Topic: Statistical Monitoring of Clinical Trials: A Unified Approach

**2:15 PM – 2:30 PM**

**INTRODUCTION AND WELCOME**

KIMBERLY CRIMIN, Wyeth

MICHAEL MAGGIOTTO, Dean of College of Sciences and Humanities, Ball State University

**2:30 PM – 3:30 PM**

**PLENARY SESSION**

Speaker: JEROME FRIEDMAN, Stanford University

Topic: Generalized Boosting Algorithms for Regularized Regression and Classification

**3:30 PM – 4:30 PM**

**PLENARY SESSION**

Speaker: ROD LITTLE, University of Michigan

Topic: Missing Data in Clinical Trials

**MONDAY NIGHT MIXER**

Alumni Center

**5:00 PM – 7:00 PM**

**TUESDAY MORNING, MAY 20**

**CONCURRENT SESSIONS**

**8:30 AM – 11:30 AM**

**A. Adaptive Designs in Dose-Ranging Studies**

*Organizer/Chair:* Jose Pinheiro, Novartis

1. "Challenges of Designing and Running Adaptive Dose Ranging Trials", Tom Parke, Tessella
2. "Evaluating Dose-Exposure-Response Modeling in Adaptive Dose-Ranging", Chyi-Hung Hsu, Novartis
3. "Bayesian Adaptive Dose-Ranging Trials", Inna Perevozskaya, Merck
4. "Disease Progression Modeling and Its Use in Dose Finding Trials", Hao Zhu, FDA

**B. Toxicogenomics**

*Organizer/Chair:* Nandini Raghavan, Johnson & Johnson

1. "Qualification of Markers for Nephrotoxicity", Dan Holder, Merck
2. "Identification of Differentially Expressed Gene Categories in Microarray Studies Using Nonparametric Multivariate Analysis", Justin Recknor, Eli Lilly
3. "Developing Genomic Hepatotoxicity Markers", Edit Kurali, GSK
4. "Developing Genomic Biomarkers for Early Safety Screens for Non-genotoxic Carcinogenicity", Nandini Raghavan, Johnson and Johnson

**C. Pharmacovigilance**

*Organizer/Chair:* Paul Stang, Johnson & Johnson

1. "Data Everywhere But is There Enough to Analyze?", Mark Overhage, Regenstrief Institute
2. "To Shrink or Not to Shrink: the Dilemmas of Signal Detection", Charles Gerrits, Takeda
3. "Modeling Rare Adverse Events in Health Record Data Requires Purposeful Covariate Selection", Ron Pearson, Prosanos
4. "Safety Surveillance of Medical Products with Automated Data", Arnold Chan, I3

**D. Quality by Design (QbD)**

*Organizer/Chair:* Stan Altan, Johnson & Johnson

1. "Practical Application of QbD for Process Scale-Up and Definition of Design Space", Sean Mackey, Abbott
2. "QbD From a Statistical Perspective", PhRMA CMC Statistics Expert Team Design Space Subteam
3. "Implementation of QbD – An FDA Perspective", Chiwan Chen, FDA
4. "Discussant", David LeBlond, Abbott

**11:30 AM – 1:00 PM**

**LUNCH BUFFET**

**TUESDAY AFTERNOON, MAY 20**

**POSTER SESSION**

**12:00 PM – 1:30 PM**

*Chair:* Krishna Padmanabhan, Wyeth

Posters will be accepted on any biopharmaceutical statistical topic.

Abstracts must be received by April 21, 2008. Students may qualify for the Charlie Sampson poster award if abstract, poster panels, and a paper briefly describing the poster are received by April 21.

For more information contact

Krishna Padmanabhan at padmans@wyeth.com

Phone: (484)-865-2084

**TUESDAY AFTERNOON, MAY 20**

**CONCURRENT SESSIONS**

**1:30 PM – 4:30 PM**

**A. Meta-Analysis of Clinical Trial Data**

*Organizer/Chair:* Brenda Crowe, Eli Lilly

1. "Meta-Analysis: To Believe or Not to Believe, That is the Question", Karen Price, Eli Lilly
2. "Meta-Analysis With Zero Cells", Ingram Olkin, Stanford University
3. "Using Hierarchical Models to Design Prospective Studies From Positive Subsets", Scott Berry, Berry Consultants
4. "Random-Effects Meta-Analyses for Outcomes With Three or More Mutually Exclusive Categorical Responses", Chris Schmidt, Tufts University

**B. Proteomics: Statistical Methods for an Emerging Technology**

*Organizer/Chair:* Jared Lunceford, Merck

1. "Proteomics and Statistical Analysis", Qinghua Song, Merck
2. "Using Statistical Concepts to Enhance the Production and Analysis of Proteomic Data", Doug Robinson, BMS
3. "Statistical Analysis Issues in Global Proteomic Studies", Ann Oberg, Mayo Clinic
4. "Estimating the Statistical Significance of MS/MS Peptide Identifications", Richard Higgs, Eli Lilly

**C. Finding the Balance: Integrating and Evaluating the Benefits and Risks of Medicines**

*Organizer/Chair:* Patrick Ryan, GSK

1. "Benefit-Risk Subgroup Analysis Using Patient Rule Induction Method", Dan Parks, GSK
2. "A Multiattribute Model for Benefit-Risk Assessment and Representation", Jim Felli, Eli Lilly
3. "Nonidentifiability of the Numbers Needed to Treat to Benefit (NNTB) and Harm (NNTH) One Patient: Some Implications for Benefit-Risk Analysis", Charlie Poole, UNC
4. "No Free Lunches: Quantifying Benefit-Risk Tradeoffs for New Pharmaceuticals", Reed Johnson, RTI

**D. Critical Process Parameters, Critical Quality Attributes and Control Strategies**

*Organizer/Chair:* Tom Parks, Eli Lilly

1. "Sequential Development of a Control Strategy for the Chromatographic Purification of a Biotechnology Product Using Statistically Designed Experiments", Jonathan Lawrence, Eli Lilly
2. "A Science and Risk-Based Approach to Establish Criticality of Process Parameters and Quality Attributes", Guillermo Miroquesada, Eli Lilly
3. "The Use of Routine Process Capability in the Determination of PARs, CPPs, and Mapping of the Design Space for an API Process", Kevin Seibert, Eli Lilly
4. "Measuring and Applying Operational Capability in Manufacturing", Bernard McGarvey, Jerry Mitchell, Eli Lilly

**TUESDAY EVENING BANQUET**

TERRY KING, Provost and Vice President for Academic Affairs  
Ball State University

Announcement of Student Winner of Charlie Sampson Poster Award

Speaker: PETER LACHENBRUCH, Oregon State University and President, ASA

Topic: Communicating Statistics: Speaking Out and Reaching Out

**WEDNESDAY MORNING, MAY 21**

**CONCURRENT SESSIONS**

**8:30 AM – 11:30 AM**

**A. Experimental Medicine and Biomarker Use in Clinical Trials**

*Organizer/Chair:* Viswanath Devanarayan, Abbott

1. "Use of Tolerance Intervals and Fit-for-Purpose Limits: Connecting the Biomarker Assay Performance to the Size of Trials", Bruno Boulanger, UCB Pharma
2. "Use of a Biomarker Endpoint for Proof of Concept Trials in Early Clinical Development", Jens Praestgaard, Novartis
3. "Role of Biomarker Data in Model Based Drug Development", Yaning Wang, FDA
4. "Bayesian Adaptive Designs Based on Biomarkers", Ming-Dauh Wang and Alan Chiang, Eli Lilly

**B. Statistical Issues and Analyses of Metabolomics Data**

*Organizer/Chair:* Matthew Mitchell, Metabolon Inc.

1. "Statistical Issues in Metabolomics", Matthew Mitchell, Metabolon Inc.
2. "Inferring Patterns From Metabolomics Data: A Case Study", Jyotsna Kasturi, Johnson and Johnson
3. "Variable Selection Using Random Forests", Costel Chirila, Metabolon Inc.
4. "Discussant", Max Kuhn, Pfizer

**C. Drug Safety, Observational Studies**

*Organizer/Chair:* Stan Young, NISS

1. "Aprotinin: Background and Introduction", Stan Young, NISS
2. "Aprotinin: Statisticians View of Observational Studies", Robert Obenchain, SoftRx
3. "Aprotinin: New Data About an Old Drug", Andrew Shaw, Duke University
4. "Analysis of an Observational Study", George Rochester, CEDR FDA
5. "Discussant", Gerhart Phol, Lilly

**D. Stability Analysis Methods**

*Organizer/Chair:* Seth Clark, Merck

1. "Issues With Multifactor Stability Studies", Roswitha Kelly, FDA
2. "Bayesian Model Averaging for Multifactor Stability Studies", Robert Noble, GSK and Miami University
3. "Questions and Controversies Related to Stability Modeling", Stan Altan, Johnson and Johnson
4. "Reconsidering Shelf Life: An Update From the PQRI Stability Shelf Life Working Group", Jim Schwenke, BIPI

**11:30 AM – 1:00 PM**

**LUNCH BUFFET**

*Closing Remarks*

Kimberly Crimin, Wyeth