Upcoming Meetings

10th Annual AdvaMed-FDA Medical Device & Diagnostics Statistical Issues Conference
April 26 - 27, 2017, Washington Marriott at Metro Center, 775 12th St NW | Washington, DC 20005

**Keynote Speaker:** Robert Califf, Former FDA Commissioner

View the conference agenda, registration, and more here!

**Poster Session:**
MDD is co-sponsoring the *poster session* at the reception following the first day of the conference. The first place winner will be announced at lunch on Day 2. The winner receives free registration to next year’s workshop. We wish the poster session to be a vibrant part of the scientific program. Please consider submitting a poster today! For more details on how to participate click here.

MDD is planning to have *mentoring event* during lunch on Day 2. The plan is to have those interested in being mentors or mentees sign up on Day 1 for a lunch table on Day 2. The ASA mentoring initiative was created by former ASA President David Morganstein. The ASA encourages sections to establish mentoring programs. Mentoring can be particularly valuable for medical devices, given their great variety, the accompanying statistical challenges, and that many device statisticians work for small device companies with few statisticians.

A good mentoring relationship has clear benefits to the mentor as well as the mentee. The transfer of information is rarely one-way. Growth as a statistician can be reciprocal. The realization that other statisticians are experiencing similar challenges as you can be encouraging and liberating. ASA recommends that a mentoring relationship have goals, objectives, activities, and guidelines, and have a finite life cycle: Establish rapport → Identify directions → Make progress → Move on. We hope you can join us at this inaugural event.
**AdvaMed “Day 0” Short Course**, co-sponsored by MDD.

**Sample Size Calculations for Statistical Testing**
April 25, 2017, Washington Marriott at Metro Center, 775 12th St NW | Washington, DC 20005

This workshop is considered "Day 0" to the 10th Annual FDA/AdvaMed Medical Devices and Diagnostics Statistical Issues Conference. Professionals often attend both the workshop and the conference. The conference will be held the day after the workshop. **MDD members receive a $200 discount off the registration fee.**

*Click here to learn more and register*

*Please note registration for this event is separate from the main Conference.*

**Speaker Abstracts**

**Sample Sizes in Acceptance Sampling**
**Dan P. Johnson, M.S., Abbott**
In this portion of the workshop, we will consider some applications of sample size calculation methods based on acceptance sampling methodologies. We will discuss sample size calculations for attribute sampling plans and variable sampling plans. We will explore how to determine sample size based on AQL, RQL, consumer’s risk (beta), producer’s risk (alpha), and a product risk assessment.

**Sample Size Calculations in Quality and Reliability Engineering**
**Paul Mathews, M.S., Mathews Malnar and Bailey, Inc.**
In this portion of the workshop, we will consider some applications of sample size calculation methods from quality engineering and reliability/survival experiments. From quality engineering, we will discuss sample size calculations for statistical process control (SPC) charts, process capability analysis including the Cp and Cpk statistics, and normal and nonparametric tolerance intervals. And from reliability engineering we will discuss sample size calculations for reliability demonstration and estimation tests, for two-sample tests, and for interference problems. The theory or source for each method’s sample size calculation will be presented and each method will be demonstrated with an applied example.

**Sample Size Requirements for Hypothesis Tests**
**Peter Costa, Ph.D., Hologic**
The first step in undertaking a clinical study is to develop a hypothesis with respect to the study outcome. As a part of the study protocol, a sample size justification is required. This section of the workshop concerns how the test statistic, significance level, and desired power are used to derive formulae for the sample size associated with a specific hypothesis test. Test of means, proportions, and variances are examined and the corresponding sample size formulas are established. Also, a look at the Bayesian approach to sample size calculation is presented. Finally, the general method for power/sample size computation is demonstrated via a particular metric. Data enhanced examples are used throughout the discussion.
Many talks related to medical devices and biomarkers will be given at the ENAR spring meeting next week. An invited session co-sponsored by MDD and other device-related session are among the attractions:

15. Evaluating Diagnosis Tests and Risk Prediction Using Clinical Utility Measures  
Sponsors: ENAR, ASA Medical Devices and Diagnostics Section  
Organizers & Chairs: Gene A. Pennello and Norberto Pantoja-Galicia, U.S. Food and Drug Administration

8:30 Decision Curve Analysis: Where are we 10 Years on?  
Andrew J. Vickers*, Memorial Sloan Kettering Cancer Center

8:55 Evaluating Markers for Risk Prediction: Decision Analysis to the Rescue  
Stuart G. Baker*, National Cancer Institute, National Institutes of Health

9:20 A Framework for Evaluating Precision Prevention  
Holly Janes*, Fred Hutchinson Cancer Research Center

9:45 Benefit-Risk Evaluation for Diagnostics: A Framework (BED-FRAME)  
Scott R. Evans* and Thuy T. Tran, Harvard University

24. CONTRIBUTED PAPERS: Medical Device Applications  
Sponsor: ENAR  
Chair: James O’Malley, Dartmouth College

9:00 Reference Database for In Vivo Diagnostic Devices  
Bipasa Biswas*, U.S. Food and Drug Administration

8:30 Passing-Bablok Regression Analysis with Rank-Transferred Data in Evaluating Hemostasis State of a Blood Sample  
Kyungsook Kim*, U.S. Food and Drug Administration

8:45 Overall Unscaled Indices for Quantifying Agreement Among Multiple Raters  
Jeong Hoon Jang*, Amita Manatunga and Qi Long, Emory University
9:00 Reference Database for In Vivo Diagnostic Devices
Bipasa Biswas*, U.S. Food and Drug Administration

9:15 A Two-stage Model for Wearable Device Data
Jiawei Bai* #, Yifei Sun, Jennifer A. Schrack, Ciprian M. Crainiceanu and Mei-Cheng Wang,
Johns Hopkins University

9:30 Generalized Linear Mixed Models for Analysis of Cross-Correlated Binary Response in Multireader Studies of Diagnostic Accuracy
Yuvika Paliwal* and Andriy I. Bandos, University of Pittsburgh

9:45 Assessing Non-Inferiority Based on Risk Difference in Non-Randomized, One-to-Many Matched Studies
Jeremiah Perez* and Joseph Massaro, Boston University

31. Recent Developments in Optimal Treatment Regimes for Precision Medicine
Sponsors: ENAR, ASA Biometrics Section
Organizers & Chairs: Wei Zhang and Haiwen Shi, U.S. Food and Drug Administration

10:30 How Can Psychiatric Research be SMART?
Yu Cheng*, University of Pittsburgh

10:55 List-Based Treatment Regimes
Yichi Zhang, Harvard University; Eric B. Laber*; Marie Davidian and Butch Tsiatis, North Carolina State University

11:20 Some Recent Developments in Machine Learning and Precision Medicine
Michael R. Kosorok*, University of North Carolina, Chapel Hill

11:45 A Case Study in Precision Medicine: Rilpivirine Versus Efavirenz for Treatment-Naive HIV Patients
Zhiwei Zhang*, University of California

43. Innovative Group Sequential Methods for Biomarker Validation
Sponsors: ENAR, ASA Biometrics Section, ASA Medical Devices and Diagnostics Section
Organizer: Joseph Koopmeiners, University of Minnesota
Chair: Sean Devlin, Memorial Sloan Kettering Cancer Center

1:45 Identifying Optimal Approaches to Early Termination in Two-Stage Biomarker Validation Studies
Alexander M. Kaizer and Joseph S. Koopmeiners*, University of Minnesota

2:10 Two-Stage Adaptive Cutoff Design for Building and Validating a Prognostic Biomarker Signature
Mei-Yin Polley* and Eric Polley, Mayo Clinic; Erich Huang, Boris Freidlin and Richard Simon, National Cancer Institute, National Institutes of Health
2:35 Unbiased Estimation of Biomarker Panel Performance when Combining Training and Testing Data in a Group Sequential Design
Nabihah Tayob*, Kim-Anh Do and Ziding Feng, University of Texas MD Anderson Cancer Center

3:00 Discussant: Scott S. Emerson, University of Washington

88. Bringing Adaptive Trials into the Real World
Sponsor: IMS
Organizer & Chair: John A. Kairalla, University of Florida

3:45 Parametric Dose Standardization for Two-Agent Phase I-II Trials with Ordinal Efficacy and Toxicity
Peter F. Thall*, University of Texas MD Anderson Cancer Center

4:10 Bayesian and Frequentist Adaptive Designs: Experience from the World of Medical Devices
Gregory Campbell*, GCStat Consulting

4:35 Avoiding Bias in Longitudinal Internal Pilot Studies
Xinrui Zhang* and Yueh-Yun Chi, University of Florida

5:00 Increasing the Practicality of Innovative Trial Design
Christopher S. Coffey*, University of Iowa

92. Use of Real-World Evidence for Regulatory-Decision Making: Statistical Considerations and Beyond
Sponsors: ENAR, ASA Biopharmaceutical Medical Devices Section
Organizers & Chairs: Gregory Campbell, GCStat Consulting and Nelson Lu, U.S. Food and Drug Administration

3:45 Incorporating Real World Evidence for Regulatory Decision Making: Challenges and Opportunities
Lilly Q. Yue*, Nelson T. Lu and Yunling Xu, U.S. Food and Drug Administration

4:15 Synthesize Real-World Data for Establishing Performance Goals in Single-Group Medical Device Clinical Studies
Chenguang Wang*, Johns Hopkins University

4:45 Addressing Unmeasured Confounding in Comparative Effectiveness Research
Douglas E. Faries*, Wei Shen, Xiang Zhang and, Eli Lilly and Company

5:15 Discussant: Gerry W. Gray, DATA-fi
At this summer’s JSM, MDD is sponsoring or co-sponsoring 1 invited session, 2 topic contributed sessions, 3 regular contributed sessions, 2 roundtables, 1 contributed speed session, and a number of contributed poster presentations:

**Invited Session**

**Improving the Efficiency of Medical Device Clinical Trials by Combining Simulations and Experiments.**
Organizer: Rajesh Nair, FDA/CDRH

**Topic Contributed Sessions**

**Statistical Opportunities in Disease Interception – Screening, Intervening, and Evaluating Benefit-Risk Trade-Offs.** Organizer: Rachael DiSantostefano, J&J.

**Beyond Randomized Studies: Non-Randomized, Single Arm or Special Studies.**
Organizers: Shiling Ruan, Novartis, Jie (Jack) Zhou, FDA/CDRH

**Regular Contributed Sessions**

**Statistical Methods and Challenges in Diagnostic Medicine**

**Trial Design and Analysis Issues in Medical Devices**

**Diagnostics, Classification, and Agreement**

**Roundtables**

**Design Specifications of Performance for an Analytical Laboratory Method**

**Considerations in Transitioning from Proprietary to Non-Proprietary Statistical Software to Support Regulatory Submissions**

**Student Award Competition**

Our student award competition included 9 high quality applications from 3 countries. After two rounds of careful reviews by seven committee members, we have selected our 1st and 2nd place winners as well as a runner-up. All three will present their work at JSM, during the regular contributed session on diagnostics, classification and agreement on Monday, July 31st. At the MDD business meeting on Monday, the winners will be presented with the awards. Come show your support and cheer for our young statisticians!