REGISTRATION FORM

2012 ASA Biopharmaceutical Section FDA–Industry Statistics Workshop

September 12–14, 2012 • Marriott Wardman Park—Washington, DC

www.amstat.org/meetings/fdaworkshop

INSTRUCTIONS

1. Print or type all information and retain a copy for your records.
2. Use a separate form for each registrant.
3. Mail form with payment to FDA–Industry Statistics Workshop Registration, 732 N. Washington Street Alexandria, VA 22314. Fax form (credit card only) to (703) 684-2037.
4. Registration form must be received by August 27, 2012, to be processed at the reduced rate. Purchase orders will not be accepted. ASA Federal ID #53-0204661.

Forms Received Without Payment Will Not Be Processed.

ATTENDEE INFORMATION

ASA ID # (if known)

Name

Preferred Name for Badge (if other than first name)

Organization

Address

City State/Province ZIP/Postal Code

Country (non-U.S.)

Phone

Email

In case of emergency, list the name and phone number of the person we should contact (remains confidential).

Emergency Contact's Name _____

Telephone Number _____

❑ Please update my ASA customer contact information with this contact information.

❑ Please exclude my name from the conference attendee roster that will appear on the conference website.

This meeting is ADA accessible.

❑ Please check here if you need special services due to a disability or have food allergies/restrictions and attach a statement regarding your needs.

CANCELLATION POLICY

Cancellations received by August 27, 2012, will be refunded, less a $25 processing fee and less a $10 processing fee for each short course. Cancellations received by September 5, 2012, will be refunded, less a $50 processing fee and less a $15 processing fee for each short course. Requests for refunds received after September 5 will not be honored. All cancellations must be made in writing to *cheryl@amstat.org*, via fax to (703) 684-2037, or mailed to FDA/Industry Statistics Workshop Registration, 732 N. Washington Street, Alexandria, VA 22314.

MEAL PREFERENCE *Lunch on Thursday, September 13 is included with your workshop registration.* Please indicate the roundtable number (see back of form) for your 1st, 2nd, and 3rd choices.

1st____ 2nd____ 3rd____ ❑ Lunch only ❑ Not attending lunch

Select one of the following menu options:

❑ Regular ❑ Vegetarian

REGISTRATION FEES **Workshop Fee (required)**

	By August 27	August 28–September 5	
❑ Registrant	$270	$295	$_____
❑ Academic (nonstudent)	$230	$255	$_____
❑ Biopharm Section Member	$230	$255	$_____
❑ Government Employee	$130	$155	$_____
❑ Student	$130	$155	$_____

Short Courses—Wednesday, September 12 *Add-ons to Workshop Fee: $100 each before August 27; $105 each August 27–September 5*

8:30 a.m.–12:00 p.m.

❑ SC1: Recent Adaptive Designs in Phase 2 and Phase 3: Theory and Implementation—*Eva Miller, Paul Gallo, and Anastasia Ivanova* $_____

❑ SC2: Utility-Based Clinical Trial Design and Analysis—*Peter Thall* $_____

❑ SC3: A Sensitivity Analysis Paradigm for Randomized Studies with Missing Data—*Daniel Scharfstein* $_____

1:30 p.m.–5:00 p.m.

❑ SC4: Classical, Adaptive and Bayesian Clinical Trial Simulations: Concepts, Execution and Implementation—*Sandeep Menon, Mark Chang, and Gheorghe Doras* $_____

❑ SC5: Statistical Evaluation of Diagnostic Performance Using ROC Analysis—*Kelly Zou, Alicia Toledano, and Gregory Campbell* $_____

❑ SC6: Meta-Analysis with Multivariate Data—*Christopher Schmid* $_____

TOTAL FEES: **$**_____

PAYMENT

❑ Check/money order payable to the **American Statistical Association** *(in U.S. dollars on U.S. bank)*

Credit Card ❑ American Express ❑ Discover ❑ MasterCard ❑ VISA

Card Number

Expiration Date Security Code

Name of Cardholder

Authorizing Signature

Roundtable Luncheon Topics
Thursday, September 13

Adaptive and Other Study Designs

TL1: Practical Issues with Non-Randomized Study Designs, Pablo Bonangelino, FDA/CDRH

TL2: Logistics and Implementation of Adaptive Trial Designs, Eva Miller, ICON Clinical Research

TL3: Sample Size Re-estimation: Concepts and Applications, Emelita Wong, PPDI

TL4: Innovated Design for First-Time in Human Study, Yu Lou, GlaxoSmithKline

TL5: Randomized Withdrawal Design, Ha Nguyen, Pfizer Inc.

Bayesian Methods and Designs

TL6: Evaluation of Type 1 Error in Bayesian Medical Device Trials with Informative Priors, Greg Maislin, Biomedical Statistical Consulting

TL7: Bayesian Application in Registration Trials with Confirmatory Secondary Endpoints, Yi-wen Ma, Janssen Pharmaceutical Companies of Johnson & Johnson

TL8: Bayesian Method, Adaptive Design, and Enhanced Quantitative Decision in Early Drug Development, Tianhui Zhou, Pfizer Inc.

Biomarkers/Biosimilars

TL9: Biomarker Qualification in Drug Safety, Aloka Chakravarty, U.S. Food and Drug Administration

TL10: Evaluation of the Risk Prediction Performance of Biomarkers and Tests, Yuying Jin, FDA/CDRH

TL11: Selection and Validation of Biomarkers and Surrogate Endpoints, Abel Eshete, FDA

TL12: Statistical Issues in the Approval of Biosimilars, Eric Chi, Amgen Inc.

Collaboration/Guidelines

TL13: Awareness and Implementation of CDISC Standards, Vipin Arora, Abbott Laboratories

TL14: PhD, MS Statisticians: Roles and Responsibilities in the Pharmaceutical Industry, Nfii Ndikintum, PharmaNet/i3

TL15: Application of EMA Bioequivalence Guidelines (2010) in a Global Setting, James Lee, Daiichi Sankyo Pharma Development

TL16: New FDA cUTI Draft Guidance and Design Implications, Prasanna Ambati, PPD, Inc.

Comparative Effectiveness/PROs

TL17: How Can Quantitative Methods and Tools Be Applied by Industry and Regulators to Determine a Medicine's Value to Payers, Providers, and Patients?, Amit Bhattacharyya, GlaxoSmithKline

TL18: Industry Perspective on Practical Issues of PROs, Sheryl McCoy, Amgen

Diagnostics/Devices

TL19: Statistical Issues in Companion Diagnostics, Estelle Russek-Cohen, FDA CBER/OBE Division of Biostatistics

TL20: Statistical Design and Analysis Issues for Cardiovascular Medical Device Studies, Gary Kamer, FDA/CDRH/OSB/DBS

TL21: Evaluating Performance Measures Where Patients Contribute a Measure in a Temporal Sequence, Bipasa Biswas, FDA

TL22: Methods for Developing and Validating Diagnostic Tests, Lori Christman, STATKING Clinical Services

TL23: Design Considerations for Pivotal Clinical Investigations for Medical Devices, Alicia Toledano, Statistics Collaborative, Inc.

TL24: Diagnostic Imaging Studies, Lakshmi Vishnuvajjala, FDA/CDRH

TL25: Missing Data Due to the Lack of a Reference Standard in Evaluation of Diagnostic Medical Devices, Qin Li, FDA/CDRH

TL26: Clinical Trials for Devices with Aesthetic Indications, Phyllis Silverman, FDA/CDRH

Drug Development

TL27: Innovation Session: Redesigning the Pharmaceutical R&D Process, Dennis Cosmatos, ReSearch Pharmaceutical Services, Inc.

TL28: Bridging to Bridges in Vaccine Development: Managing the Drift in Multi-Serotype Vaccines, Jonathan Hartzel, Merck & Co., Inc.

TL29: Challenges and Opportunities in Small to Mid-Size Pharmaceutical Companies, Mike Colopy, UCB Pharma

TL30: First-Time-in-Human Trials: Everything but the Kitchen Sink?, Jennifer Gauvin, GlaxoSmithKline

Futility

TL31: Role of Futility Analysis in an Unblinded Interim Analysis, Peter Hu, Janssen Pharmaceutical Companies of Johnson & Johnson

TL32: Futility Analyses, Anthony Rodgers, Merck & Co., Inc.

Methodology

TL33: Practices on Benefit-Risk Assessment, Hong Laura Lu, FDA/CDRH

TL34: Missing Data: Bridging the Gap Between Industry and Academia, Herbert Thijs, Hasselt University

TL35: Statistical Issues in Oncology Clinical Trials: Progression-Free Survival and Overall Survival, Ying Wan, Janssen Research & Development LLC, Johnson & Johnson

TL36: Agreement Assessment Among Medical Devices or Raters, Lawrence Lin, Baxter International Inc.

TL37: The Actual Practice of Randomization Management, Michael Collins, ICON Clinical Research

TL38: Assessment of the Dose Proportionality of PK Parameters in SRD or MRD Trials and the Evaluation of the Steady State: What Is the Common Practice?, Jingtao Wu, TAKEDA Global Development and Research Center

TL39: Analysis of change from baseline data in the presence of covariate-by-treatment interaction, Jihao Zhou, Allegan Pharmaceuticals Inc.

TL40: Meta-Analysis Based on Post-Hoc Selected Subgroups in Evaluating Overall Treatment Effect, Jagadish Gogate, Symbiance, Inc.

TL41: Experiences with Zero-Inflated Poisson or Negative Binomial Models in Clinical Trials or Other Types of Studies for Regulatory Submission Purposes, Stan Lin, FDA/CBER; Samir Lababidi, FDA/CBER; Ross Pierce, FDA/OBRR

TL42: What Do We Do When the Sites Are Not Poolable?, Jack Zhou, FDA/CDRH

TL43: Covariate Adjustment: Should Study Center Be Included?, Caiyan Li, Baxter Healthcare

TL44: Statistical Modeling to Evaluate Long-Term Persistence, Jason Martin, Merck & Co., Inc.

TL45: Mediators and Moderators in Randomized Clinical Trials, Christine Blasey, Corcept Therapeutics and Stanford University

TL46: Issues in Clinical Trials with a Time Lag Between Randomization and Initiation of Treatment, Chunrong Cheng, FDA/CBER

TL47: Precision Study for a Qualitative Assay, Tie-Hua Ng, FDA/CBER

TL48: Sensitivity Analyses for Progression-Free Survival in Supporting Labeling Claim, Yun Wang, HHS/FDA

Noninferiority

TL49: Challenges in the Designs of Noninferiority and Equivalence Trials with Clinical Endpoints, Madhuja Mallick, Merck Research Laboratories

TL50: Considerations in Defining the Primary Analysis Population for Noninferiority Studies, Ralph DeMasi, Janssen R&D, Johnson & Johnson

Propensity Scores

TL51: Subgroup Matching by Propensity Score in Randomized Trials, Xuena Wang, Amgen Inc.

TL52: Safety Assessment Using Propensity Score Methods in Observational Database Cohort Studies, Janelle Charles, U.S. Food and Drug Administration

Safety

TL53: QT/QTc Evaluation in Early Development Studies, Jaya Natarajan, Janssen R&D, Johnson & Johnson

TL54: Analysis of Safety Events of Interest in Placebo-Controlled Clinical Trials, Elena Polverejan, Janssen R&D, Johnson & Johnson

Veterinary

TL55: Using R in Veterinary Medicine Research, Louis Luempert, Novartis Animal Health