REGISTRATION FORM

2017 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop

September 25–27, 2017 • Marriott Wardman Park—Washington DC • ***ww2.amstat.org/meetings/biopharmworkshop/2017***

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 BIOP2017 Registration, 732 N. Washington Street, Alexandria, VA 22314. Fax form (credit card payment only) to (703) 684-2037.
4. Registration form must be received by August 30, 2017, 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

❑ 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.

MEAL PREFERENCE

Lunch on Tuesday, September 26, is included with your workshop registration.

Please indicate the table 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*

IN CASE OF EMERGENCY, list the name and phone number of the person we should contact (remains confidential).

Emergency Contact's Name _____

Telephone Number _____

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 30 will be refunded, less a $25 processing fee and less a $10 processing fee for each short course. Cancellations received from August 31 to September 15 will be refunded, less a $50 processing fee and less a $15 processing fee for each short course. Requests for refunds received after September 15 will not be honored. All cancellations must be made in writing to ***ASAInfo@amstat.org***, via fax to (703) 684-2037, or mailed to BIOP2017 Registration, 732 N. Washington Street, Alexandria, VA 22314.

REGISTRATION FEE (required)

	By August 30	August 31 –September 15	
Registrant	$335	$360	$_____
Academic (nonstudent)	$240	$265	$_____
Biopharm Section Member	$250	$275	$_____
Government Employee	$150	$175	$_____
Student	$130	$155	$_____

SHORT COURSES Monday, September 25

$105 each through August 30; $110 each August 31–September 15

8:30 a.m.–12:00 p.m.

❑ **SC1:** Introduction to Generalized Linear Mixed Models with Applications to Clinical Pharmacology and Personalized Medicine, Francisco Diaz, The University of Kansas Medical Center $_____

❑ **SC2**: Data Visualization in the Life Sciences, Kelci Miclaus, JMP Life Sciences, SAS Institute; Richard Zink, JMP Life Sciences, SAS Institute $_____

❑ **SC3:** Futility Analyses in Confirmatory Clinical Trials: Methods and Procedures, Scott Evans, Harvard University; Paul Gallo, Novartis Pharmaceutical; Satrajit Roychoudhury, Novartis Pharmaceutical $_____

❑ **SC4:** Multi-Regional Clinical Trials and the ICH E17, Aloka Chakravarty, FDA/CDER; Lisa LaVange, FDA/CDER; William Wang, Merck & Co Inc. $_____

1:30 p.m.–5:00 p.m.

❑ **SC5:** Bayesian Adaptive Designs for Immunotherapy and Drug Combination Trials, Ying Yuan, MD Anderson Cancer Center $_____

❑ **SC6:** Patient-Reported Outcomes: Measurement, Implementation, and Interpretation, Joseph Cappelleri, Pfizer Inc. $_____

❑ **SC7:** Advancing Drug Development Through Precision Medicine and Innovative Clinical Designs: Concepts, Rationale, and Case Studies, Bo Huang, Pfizer Inc.; Jing Wang, Pfizer, Inc.; Weidong Zhang, Pfizer, Inc. $_____

❑ **SC8:** Defining Treatment Effects in Randomized Trials, Tom Permutt, FDA/CDER $_____

TOTAL $_____

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

2017 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop
Roundtable Luncheon Topics—Tuesday, September 26

All roundtable discussions will include up to 10 people at a table, except **TL21**, which will be a speaker with lunch and include everyone in the room.

Bayesian Design

TL1 Use Bayesian Methods to Make Better Use of Historical Data: A Regulatory Perspective and Some Empirical Examples, Lingling Li, Sanofi Genzyme

TL2 What Does a Regulatory Reviewer Expect to See in Bayesian Trials? Xin Fang, FDA/CDRH; Xiting Yang, FDA

TL3 Application of Bayesian Models in Basket Trials, Na Hu, Boehringer Ingelheim China

Big Data

TL4 Data Integration with the Changing Landscape of Technology, Dong Wang, FDA/NCTR

Comparative Effectiveness

TL5 Pragmatic Trials: How Did/Do They Work for You? Andrei Breazna, Pfizer Inc.

Diagnostics

TL6 Comparison of Devices with Quantitative Output, Bipasa Biswas, FDA/CDRH

Dose Selection

TL7 Dose-Escalation Methods Using Two Endpoints in Oncology Studies, Kyounghwa Bae, Janssen R&D

TL8 Dose-Finding/Selection/Optimization in Oncology, Lisa Hendricks, Novartis

TL9 Challenges in Dose Response Modeling, Jared Christensen, Pfizer Inc.

High-Dimensional Data

TL10 Applications of Multidimensional Time Model for Probability Cumulative Function and Multi-Scale Time Analysis to Noise Models for Single-Cell Transcriptomics and DNA Analyses, Michael Fundator, DBASSE of National Academy of Sciences

Meta-Analysis

TL11 Meta-Analysis for Regulatory Decision-Making, Zhiheng Xu, FDA/CDRH; Qin Li, FDA/CDRH

Methodologies

TL12 Statistical Data Analysis in Human Abuse Potential Studies: New Chemical Entities vs. Abuse-Deterrent Formulations, Beatrice Setnik, INC Research, Early Phase; Ling Chen, FDA; Catherine Mills, INC Research, Early Phase

TL13 Dose Titration Algorithm Tuning (DTAT) Supersedes 'the' MTD. What Next? David Carl Norris, Precision Methodologies, LLC

Modeling and Simulation

TL14 Data Augmentation Method for Two-Sample Binomial Data with False-Positive Misclassification, Dewi Gabriela Rahardja, DHS

Oncology

TL15 A Challenge in Oncology Trial Design: Understanding the Relationship Between PFS and OS, Ke Zhang, Janssen R&D

TL16 Maintenance Trials in Oncology: Challenges and Opportunities, Suddhasatta Acharyya, Novartis; Allison Florance, Novartis

TL17 Adaptive Population Selections in Biomarker-Driven Phase III Oncology Trials, Yue Shentu, Merck

TL18 Consideration of Clinical Aspects in Oncology Trial Design, Sabrina Wan, Merck; Keaven Anderson, Merck

Patient-Reported Outcomes

TL19 Developing Standards for Clinical Outcome Assessment (COA) Data Collected in Clinical Trials: Experiences, Considerations, and Potential Solutions, Marian Mullin Strazzeri, FDA/CDER

Real-World Evidence

TL20 Translate Real-World Data into Real-World Evidence to Support Regulatory Decision-Making, Jianxiong Chu, FDA/CDRH

TL21 TOWNHALL ROUNDTABLE
Use of Real-World Evidence and Real-World Data for FDA Approval and Clearance, Terri Johnson, FDA

TL22 Cluster-Randomized Trials: Considerations for Power and Analysis, Todd Durham, QuintilesIMS; William Hawkes, QuintilesIMS

Role of Statisticians

TL23 Chat with the Publications Officer of the Biopharmaceutical Section, Richard Zink, JMP Life Sciences, SAS Institute

Safety

TL24 Blinded Safety Signal Monitoring for the FDA IND Safety Reporting Final Rule, Greg Ball, Merck

TL25 Patient Support Program Data: How Can We Leverage This Data for Safety Surveillance? Karolyn Kracht, AbbVie

Study Design, Study Endpoints, and Estimands

TL26 Should Phase III Randomized Clinical Trial (RCT) Designs Remain as the Gold Standard in the Current Era of Precision Medicines? Deepak Khatry, MedImmune

TL27 Making Real-World Inferences from Clinical Trials: Design, Conduct, and Analysis, Gregory Levin, FDA; Mark Rothmann, FDA

TL28 Sample Size Estimations for Special Cases in Clinical Trial Designs, Aijun Gao, Chiltern

Therapeutic Area-Specific Topic

TL29 Alzheimer's Disease Scientific Working Group Updates, Stephen Wilson, FDA; Hong Liu-Seifert, Eli Lilly and Company

Vaccines

TL30 Emergency! Don't Send That Patient Home! George Habek, SAS

Other

TL31 Standard Analyses and Displays for Clinical Trial Data: Recommendations from a PhUSE Industry-Regulatory Collaboration, Mercidita Navarro, Genentech

For additional information, please visit *ww2.amstat.org/meetings/biopharmworkshop/2017*