REGISTRATION FORM

2019 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop

September 23–25, 2019 • Marriott Wardman Park—Washington, DC • ***ww2.amstat.org/meetings/biop/2019***

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 BIOP2019 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 12, 2019, 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-US)

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 24, 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 12 will be refunded, less a $25 processing fee and less a $10 processing fee for each short course. Cancellations received from August 13 to September 3 will be refunded, less a $50 processing fee and less a $15 processing fee for each short course. Requests for refunds received after September 3 will not be honored. All cancellations must be made in writing to ***ASAInfo@amstat.org***, via fax to (703) 684-2037, or mailed to BIOP Registration, 732 N. Washington Street, Alexandria, VA 22314.

REGISTRATION FEE (required)

	By August 12	After August 12	
Registrant	$335	$360	$_____
Academic (nonstudent)	$240	$265	$_____
Biopharm Section Member	$250	$275	$_____
Government Employee	$150	$175	$_____
Students	$25	$50	$_____

SHORT COURSES Monday, September 23

$105 each through August 12; $110 each after August 12

8:30 a.m.–12:00 p.m.

❑ **SC1:** Simulation Practices for Adaptive Clinical Trial Design in Drug and Device Development, *Inna Perevozskaya, GSK* $_____

❑ **SC2:** Biomarker-Assisted Clinical Designs: Concepts, Rationale, and Case Studies, *Weidong Zhang, Pfizer, Inc.* $_____

❑ **SC3:** Designing and Integrating RCT/RWE in Safety Decision-Making, *Richard Zink, TARGET PharmaSolutions* $_____

❑ **SC4:** Methods for Causal Inference from Randomized Trials with Loss to Follow-Up or Non-Adherence, *Lucia Petito, Harvard T.H. Chan School of Public Health* $_____

❑ **SC5:** Statistical Analysis of Composite Endpoints in Clinical Trials, *Lu Mao, University of Wisconsin-Madison* $_____

1:30 p.m.–5:00 p.m.

❑ **SC6:** Smart Simulation with SAS and R, *Mehmet Kocak, The University of Tennessee Health Science Center* $_____

❑ **SC7:** New Adaptive Design Guidance, *Gregory Levin, US Food and Drug Administration* $_____

❑ **SC8:** Flexible Sample Size Designs with Applications to Improve the Efficiency and Probability of Success of Industry-Sponsored Clinical Trials, *Lanju Zhang, AbbVie* $_____

❑ **SC9:** Real-World Data and Evidence: An Interdisciplinary Approach and Applications to Precision Medicine and Health Care, *Jie Chen, Merck Research Laboratories* $_____

❑ **SC10:** Use of Historical Data in Clinical Trials: An Evidence Synthesis Approach, *Satrajit Roychoudhury, Pfizer, Inc.* $_____

TOTAL $_____

PAYMENT

❑ Check/money order payable to the American Statistical Association (in US dollars on US bank)

Credit Card: ❑ American Express ❑ Discover ❑ MasterCard ❑ VISA

Card Number

Expiration Date Security Code

Name of Cardholder

Authorizing Signature

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Roundtable Luncheon Topics—Tuesday, September 24

Bayesian Methods in Clinical Trial

TL01 Bayesian Synthetic Control Methods Using Patient-Level Historical Clinical Trials Data, *Antara Majumdar, Medidata Solutions*

TL02 Historical Data Applications in Clinical Trials, *Lanju Zhang, AbbVie*

TL03 Utilizing Historical Data in Drug Development: Opportunities and Challenges, *Yanwei Zhang, Agios Pharmaceuticals*

Big Data/ML/AI

TL04 Dimension Reduction and Pattern Detection in Medical Device Effectiveness and Safety Analysis, *Yongping Yan, FDA/CDRH*

Development of Gene Therapies

TL05 How to Utilize Data from Historical Studies in the Development of Gene Therapies? *Yimeng Lu, Vertex Pharmaceuticals*

Diagnostics and Medical Device

TL06 Bridging Strategy for Follow on Diagnostics, *Herbert Thijs, Biocartis NV*

TL07 Challenges in Evaluating In Vivo Diagnostic Devices with Quantitative and/or Qualitative Outputs, *Saryet Kucukemiroglu, FDA, and Bipasa Biswas, FDA/CDRH*

TL08 Pursuing Safety Signals in Post-Market Surveillance of Medical Devices, *Gary Chung, Johnson & Johnson*

Dose Selection in Clinical Development

TL09 Dose Escalation Method Using Two Endpoints in Combination Drug Clinical Studies Using a Bayesian Modified Continual Reassessment Method, *Kyounghwa Bae, Janssen R&D*

TL10 How to Statistically Test Up-Titration Effect on Efficacy of Binary Endpoints for Post-Randomization Dose Up-Titration in Phase 3/4 Clinical Trials: Simulation and Implementation, *Hong Ding, Novartis*

TL11 Practical Considerations of Emerging Innovative Dose-Escalation Methods in Oncology, *Wei Zhang, Eli Lilly and Company*

TL12 Statistics Considerations in CAR-T and Cell Therapy Dose-Finding Studies, *Xiaoling Wu*

DSMB/IA/AC

TL13 Approaches to Data Summarization to Help Facilitate Decision-Making During Trials, *Patricia Feeney, PROMETRIKA, LLC*

TL14 Best Practices for DMCs, *David Kerr, Axio Research*

Endpoint and Validation

TL15 Evaluating the Influence of Outliers on Efficacy Conclusions, *Asli Memisoglu, Alkermes Inc.*

Estimand

TL16 Estimands for Use in Pulmonary-Allergy US FDA Regulatory Submissions, *Yongman Kim, FDA*

TL17 Experience Sharing in Defining Primary Estimand in Psychiatric Clinical Trials Following the Release of the Draft ICH E9(R1) Addendum, *Peiling Yang, FDA*

TL18 Implications and Opportunities for the Implementation of Safety Estimands in Clinical Trials, *Rebecca Taha, Eli Lilly and Company*

Evidence Synthesis

TL19 Clinical Efficacy vs. Treatment Effectiveness: Average Group Benefit vs. Probability of Clinically Meaningful Benefit to an Individual Patient, *Deepak Khatry, MedImmune/AstraZeneca*

TL20 Structured Subgroup Identification Using the SOS Software and Discussion Around a Case Study, *Xiaoqiang Xue, IQVIA*

Master Protocols

TL21 Master Protocols: When and How Should They Be Used? *Yingwen Dong, Sanofi*

TL22 Use of Master Protocol Designs Within Oncology Clinical Drug Development, *Swarna Reddy, Covance, and Feng Liu, AstraZeneca*

Multiple Tests

TL23 Cascading Hypotheses Tests for IFU Modification and Validation, *Feiming Chen, FDA*

Noninferiority, Bioequivalence, and Biosimilars

TL24 Pharmacogenetics Applied to Comparative Bioavailability Studies for Variability Assessment, *Carlos Díaz Tufinio, National Institute of Genomic Medicine, and Jose Antonio Palma Aguirre, Axis Clinicals Latina*

Oncology

TL25 Oncology Novel Phase I Dose-Escalation Design in the Real Trial Setting, *Wei Zhong, Pfizer, Inc.*

TL26 Use of Propensity Score (PS) Methods to Build Synthetic Control Arm (SCA) from Historical Clinical Trials Data for Assessing Treatment Effects When a Randomized Control Is Not Feasible or Compromised, *Xiang Yin, Medidata Solutions*

Precision Medicine

TL27 Statisticians Impact to Patients: Novel Drug Development for Regulators and Developers, *Melanie Poulin-Costello, Roche, and Catherine Njue, Health Canada*

Real-World Evidence

TL28 Case Studies in the Use of Real-World Evidence to Improve Regulatory Decision-Making, *Brian Segal, Flatiron Health, and Rebecca Hubbard, University of Pennsylvania*

TL29 Opportunities and Challenges of Using Real-World Data for Regulatory Decision-Making, *Changming (Sherman) Xia, FDA*

TL30 Pros and Cons of Integrating Prospective Observational Study in CLL Patients with Contemporaneous Real-World CLL Patients Data Obtained from EMR and Claims Database, *David Ipe, Pharamcyclics; Mei Cheng, Pharamcyclics; and Sandhya Upasani, Pharamcyclics*

Scientific Working Group

TL31 Statistical Challenges in Drug Development in Oncology, *Olga Marchenko, Bayer, and Qi Jiang, Seattle Genetics*

Small Populations

TL32 Determining the Appropriate Settings for Pediatric Drug Development Approaches, *Rebecca Rothwell, FDA*

TL33 Innovative Designs and Advanced Statistical Methodologies for Rare Disease Clinical Trials, *Yeh-Fong Chen, FDA, and George Kordzakhia, FDA*

TL34 Modern Pediatric HIV Drug Development: A Statistical Perspective, *Ralph DeMasi, ViiV Healthcare*

TL35 Use of Historical Data or Natural History of Disease for Drug Development in Rare Disease, *Meilin Huang, Regeneron, and Michelle DeVeaux, Regeneron*

Vaccines

TL36 Analyses for Validation of Biomarkers, *Ivan Ordonez, Sanofi Pasteur*

Other

TL37 Balancing Study Enrollment from the Statistical Perspective, *Katie Everett, QST Consultations, Ltd.*

TL38 Creating a Statistical Community with the Biopharmaceutical Section, *Richard Zink, TARGET PharmaSolutions*

TL39 Have Lunch with the Biopharmaceutical Section's 2020 Chair, *Bruce Binkowitz, Shionogi Inc.*

TL40 Making Use of Outcome Data in Propensity Scores Analysis, *Pablo Bonangelino, FDA/CDRH*

TL41 Some Thoughts on Section 14 of Prescription Drug Labeling, *Mingyu Xi, FDA*

TL42 Strategies for Maintaining the Blind When Analyzing Randomized Open-Label Studies, *Neil Wohlford, PROMETRIKA, LLC*

For additional information, please visit *ww2.amstat.org/meetings/biop/2019*.