REGISTRATION FORM

2020 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop

September 22–25, 2020 • VIRTUAL • ***ww2.amstat.org/meetings/biop/2020***

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 BIOP Registration, 732 N. Washington Street, Alexandria, VA 22314. Fax form (credit card payment only) to (703) 997-7299.
4. Registration form must be received by August 13, 2020, 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 (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.

❑ Yes! I would like to volunteer to assist during the virtual conference.

CANCELLATION POLICY

Cancellations received by August 13 will be refunded, less a $25 processing fee and less a $10 processing fee for each paid short course. Cancellations received from August 14 to September 3 will be refunded, less a $50 processing fee and less a $15 processing fee for each paid 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.

CONDUCT POLICY

Meeting attendance constitutes an agreement to abide by the ASA Activities Conduct Policy found at *www.amstat.org/conductpolicy.*

DISCLAIMER AND WAIVER

The American Statistical Association (ASA) intends to capture images and record portions of this event for future access and for use in ASA print and electronic (including the ASA website) news and promotional material. By participating in this event, you grant the ASA the right to use any image, photograph, voice, or likeness without limitation and without compensation. All media become the property of the ASA. Media may be displayed, distributed, or used by the ASA for any purpose.

REGISTRATION FEE (required)

	Through August 13	After August 13	
Registrant	$300	$325	$_____
Academic (nonstudent)	$215	$240	$_____
Biopharm Section Member	$225	$250	$_____
Government Employee	$135	$160	$_____
Students	$20	$35	$_____

SHORT COURSES

You may select ONE FREE short course each day. Additional short courses are $75 each.

TUESDAY, SEPTEMBER 22

10:00 a.m. – 1:30 p.m.

❑ **SC1:** A Gentle Introduction to Causal Inference in View of the ICH E9 Addendum on Estimands, *Dong Xi, Novartis Pharmaceuticals; Heinz Schmidli, Novartis Pharma AG; Björn Bornkamp, Novartis Pharma AG* $_____

2:00 p.m. – 5:30 p.m.

❑ **SC2:** Artificial Intelligence for Drug Development, Precision Medicine, and Health Care, *Mark Chang, Boston University; Sandeep Menon, Pfizer Inc.* $_____

❑ **SC3:** Bayesian Designs for Phase I-II Clinical Trials, *Peter Thall, The University of Texas MD Anderson Cancer Center; Ying Yuan, The University of Texas MD Anderson Cancer Center* $_____

❑ **SC4:** Causal Inference for Real-World Evidence: Propensity Score Methods and Case Study, *Hana Lee, US Food and Drug Administration; Joo-Yeon Lee, US Food and Drug Administration* $_____

❑ **SC5:** Robust Design and Analysis of Clinical Trials with Nonproportional Hazards: Methodology and Implementation with R, *Satrajit Roychoudhury, Pfizer Inc.; Keaven Anderson, Merck & Co., Inc.* $_____

❑ **SC6:** Statistical Leadership: From Concepts to Practice, *Rakhi Kilaru, PPD; Lisa Lupinacci, Merck and Co., Inc.* $_____

WEDNESDAY, SEPTEMBER 23

3:00 p.m. – 6:30 p.m.

❑ **SC7:** Adaptive, Bayesian, and Complex Clinical Trials: What, Why, and How, *Scott Berry, Berry Consultants, LLC* $_____

❑ **SC8:** Leadership for Statisticians: The Bridge from Innovation to Practice, *Gary Sullivan, Espirer Consulting LLC* $_____

❑ **SC9:** Machine Learning for Statisticians, *Junshui Ma, Merck & Co., Inc.; Andy Liaw, Merck & Co., Inc.* $_____

❑ **SC10:** Statistical Designs and Strategies for Oncology Drug Development, *Cong Chen, Merck & Co., Inc.* $_____

ROUNDTABLE DISCUSSION

A roundtable discussion on Thursday, September 24, is included with your workshop registration. Please indicate the function number (see back of form) for your 1st, 2nd, and 3rd choices. 1st_____ 2nd_____ 3rd_____

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

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2020 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop
Roundtable Discussion Topics—Thursday, September 24

Bayesian Methods in Clinical Trials

TL26 Continuous Clinical Trial Oversight via Automated Bayesian Data Modeling and Probabilistic Programming, *Ulrich Schaechtle, MIT*

Big Data/Machine Learning/Artificial Intelligence

TL04 An Analytical Discussion of Impact of the "Era of Big Data" on Clinical Drug Development, *Natasha Sahr, Novartis*

Diagnostics and Medical Device

TL13 Analytical and Statistical Challenges with IHC Assays as Companion Diagnostics, *Yaji Xu, FDA*

TL17 Study Design and Statistical Evaluation of Pan-Cancer Screening Tests, *Gene Anthony Pennello, FDA*

TL22 Sensitivity Specificity or Reliability Validity or Real-World Evidence & COVID-19 Testing, *Carolyn Carroll, Stat Tech, Inc.*

Endpoint and Validation

TL08 Statistical Issues of Using EGFR as Efficacy Endpoint in Chronic Kidney Disease Clinical Trials, *Fanny Ki Wong, AstraZeneca*

Estimand

TL10 Aligning Statistical Estimands with Clinical Objectives, *Robert Abugov, FDA/CDER*

TL12 Analyzing Recurrent Events in Cardiovascular Outcome Trials, *Samvel Gasparyan, AstraZeneca R&D*

TL18 ICH E9(R1) Addendum on Estimands and Sensitivity Analysis in Clinical Trials, *Sharon E. McDermott, Covance*

TL19 Practical Aspects of Sensitivity Analysis for Estimand in Trial with Treatment Switching, *Macaulay Okwuokenye, Brio Dexteri Pharmaceutical Consultants*

TL28 Design and Analysis Considerations for COVID-19 Trials, *Larry Leon, Bristol Myers Squibb*

Evidence Synthesis

TL05 Empowerment of Performance Goal (PG) Study in Pivotal Clinical Investigations, Methodology, and Framework, *Yongping Yan, FDA/CDRH*

Innovative Study Designs

TL24 Adaptive Platform Trials – Vision for Future Clinical Trial Design, *Wei Wang, Covance*

TL29 Using Multi-Arm Multi-Stage Designs in Oncology Clinical Trials, *Priyam Mitra, Bristol Myers Squibb*

Modeling and Simulation

TL23 Measurement Errors in VAS Pain Measurements, *Bin Wang, FDA*

Noninferiority, Bioequivalence, and Biosimilars

TL21 Bioequivalence Trials as a Reliable Source of Pharmacological Relevant Data: Experiences and Perspectives from Clinical Research Organizations (CRO), *Carlos Alejandro Díaz-Tufinio, UNAM*

Oncology

TL01 Phase I Oncology Trials, *Andrei Breazna, Quartesian*

Other

TL07 Student and Young Professional Mentoring Roundtable, *H.M. James Hung, FDA; Richard C. Zink, TARGET PharmaSolutions, Inc.*

TL14 Covariate Analysis and Propensity Scores Adjustment, *Pablo E. Bonangelino, FDA/CDRH*

TL16 Have Lunch with the 2020 and 2021 Biopharmaceutical Section Chairs and Learn About the Section, *Bruce Binkowitz, Shionogi, Inc.*

TL20 How Data Visualization Can Help the Exploration of Clinical Trial Data, *Meijing Wu, AbbVie*

Quantitative Decision-Making

TL25 Practical Considerations in Quantitative Decision-Making, *Xinyan Zhang, Sanofi*

Real-World Evidence

TL03 Use of RWE in Regulatory Decision-Making: Ready for Prime Time?, *Isaac Nuamah, Janssen R&D*

Safety

TL02 How to Analyze and Present Long-Term Safety Data in an Informative and Appropriate Way, *Yunxia Sui, AbbVie*

TL11 Blinded and Unblinded Ongoing Aggregate Safety Monitoring and Evaluation for Clinical Trial Program, *Li-An Lin, Merck & Co., Inc.*

Scientific Working Group

TL15 Scientific Collaboration: Developing and Supporting Successful SWGs, *William Wang, Merck & Co., Inc.*

Small Populations

TL06 Issues and Challenges Regulators and Sponsors Face with Rare Disease Programs, Including Gene Therapy and Cell Therapy Programs, *Michelle Casey, Pfizer Inc.*

TL09 Statistical Approaches for Design and Analysis of Composite or Multi-Component Endpoints in Rare Disease, *Qi Zhang, Sanofi*

TL27 Use of Real-World Evidence in Regulatory Decisions for Rare Diseases, *Ran Duan, Alexion Pharmaceuticals*

For additional information, please visit *ww2.amstat.org/meetings/biop/2020.*