REGISTRATION FORM

2021 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop

September 21–24, 2021 • VIRTUAL • ***ww2.amstat.org/meetings/biop/2021***

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 16, 2021, 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 16 will be refunded, less a $25 processing fee and less a $10 processing fee for each paid short course. Cancellations received from August 17 to September 2 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 2 will not be honored. All cancellations must be made in writing and emailed to ***ASAInfo@amstat.org***; faxed to (703) 997-7299; or mailed to BIOP Registration, 732 N. Washington Street, Alexandria, VA 22314.

CODE OF CONDUCT

Meeting attendance constitutes an agreement to abide by the ASA Code of Conduct 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 16	After August 16	
Registrant	$300	$325	$_____
Academic (nonstudent)	$215	$240	$_____
Biopharm Section Member	$225	$250	$_____
Government Employee	$135	$160	$_____
Student	$20	$35	$_____

SHORT COURSES

TUESDAY, SEPTEMBER 21

10:30 a.m. – 2:00 p.m.

❑ **SC1:** Recent Development in Survival Analysis: Methods and Applications, *L.J. Wei, Harvard University; Lu Tian, Stanford University; Hajime Uno, Dana-Farber Cancer Institute/Harvard Medical School* $_____

❑ **SC2:** Bayesian Analytical Tools for Clinical Trials with Data Irregularities, *Sujit Ghosh, North Carolina State University; Amy Shi, SAS* $_____

❑ **SC3:** Utilizing Real-World Data and Real-World Evidence in Drug Development and Evaluation, *Binbing Yu, AstraZeneca, LLC; Qing Li, Takeda Pharmaceutical Company; Bo Lu, The Ohio State University* $_____

❑ **SC4:** Adaptive Seamless Design: Benefits, Challenges, and the Best Practices to Win Regulatory Approval, *Ping Gao, Innovatio Statistics, Inc; Weidong Zhang, Pfizer, Inc.* $_____

❑ **SC5:** Smart Simulations with SAS and R: Simple to More Sophisticated Applications, *Mehmet Kocak, University of Tennessee Health Science Center* $_____

2:30 p.m. – 6:00 p.m.

❑ **SC6:** Digital Health Technologies: Moving Health Care from the Clinic to the Patient, *Susan Murphy, Harvard University; Chad Gwaltney, Gwaltney Consulting; Andrew Potter, US Food and Drug Administration; Berkman Sahiner, US Food and Drug Administration; Matthew Diamond, US Food and Drug Administration* $_____

❑ **SC7:** Beyond Propensity Score Methods for Real-World Evidence: Targeted Maximum Likelihood Estimation (TMLE) with an Ensemble of Machine Learning Algorithms, *Susan Gruber, Putnam Data Sciences, LLC; Martin Ho, FDA/CBER* $_____

❑ **SC8:** Master Protocol and Its Applications, *Jingjing Ye, BeiGene; Nicole (Xiaoyun) Li, Merck; Cindy Lu, Biogen* $_____

❑ **SC9:** Multivariate and Network Meta-Analysis Methods, *Yong Chen, University of Pennsylvania; Haitao Chu, University of Minnesota; Joseph Cappelleri, Pfizer, Inc.* $_____

❑ **SC10:** Recent Statistical Advances in the Analysis of Composite Endpoints, *Lu Mao, University of Wisconsin* $_____

TOTAL $_____

ROUNDTABLE DISCUSSION

A roundtable discussion on Thursday, September 23, 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_____

PAYMENT

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

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

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2021 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop
Roundtable Discussion Topics—Thursday, September 23

Bayesian Methods in Clinical Trials

TL06 Bayesian Informative Priors, *Pablo Bonangelino, FDA/CDRH*

TL11 Portfolio Management Strategy in Clinical Development and Use of Probability of Success, *Xiaofei Bai, Boehringer Ingelheim Pharmaceuticals*

TL20 Bayesian Adaptive Clinical Trial Design with Historical Data Borrowing, *Zhong Gao, FDA*

TL27 The Benefits of Conducting Bayesian Adaptive Designs in Dose-Finding Studies for Healthy Volunteers in Non-Oncology Clinical Trials, *Carl Di Casoli, Sunovion Pharmaceuticals; HoiWun (Natalie) Au, Sunovion Pharmaceuticals*

Big Data

TL14 Application of Artificial Intelligence for Biomarker or Drug Development, *Sue-Jane Wang, FDA*

Complex and Innovative Study

TL05 Practical Challenges in Implementation of Adaptive Design, *Qiqi Deng, Boehringer Ingelheim Pharmaceuticals*

COVID-19

TL03 Regulations During a Pandemic: EUA and Its Future, *Hope Knuckles, Abbott*

TL32 Design Challenges for Trials for Prevention of COVID-19 After Emergency Use Authorization of First Two Vaccines, *Gosford Aki Sawyerr, Syneos Health*

Decision Analysis

TL15 Quantitative Decision Under Unequal Covariances and Post-Treatment Variances, *Macaulay Okwuokenye, Brio Dexteri Pharmaceutical Consultant*

Diagnostics and Medical Device

TL22 Evaluation of Diagnostic Tests of Infectious Diseases for the Purposes of Mass Testing, *Chava Zibman, FDA*

TL28 Issues and Challenges in Leveraging Moderate/Small-Sized External Data: Propensity Score Approach and Beyond, *Sutan Wu, FDA/CDRH; Lei Li, FDA*

Early-Phase/Pre-Clinical Trials

TL10 Efficacy-Driven Dose-Finding with Toxicity Control in Phase I Oncology Studies with Moderate Treatment Effect, *Junxian Geng, Boehringer Ingelheim Pharmaceuticals*

TL31 Early-Phase Clinical Trials – Time to Change Conversation to Beyond *P*-Values, Multiplicity Adjustment, Multiple Imputations, *Veena Somayaji, Pfizer*

Estimands

TL13 The Tripartite Estimand Approach: When Is It Useful?, *Stephen Ruberg, Analytix Thinking, Purdue University*

TL17 What Is the Purpose, What Are We Trying to Achieve with the Estimand Framework?, *Susan Mayo, FDA Office of Biostatistics; Yongman Kim, FDA*

Evidence Synthesis

TL12 Considerations for Using Real-World Data for Effectiveness in Regulatory Decision-Making, *Prashni Paliwal, Flatiron Health*

TL25 How to Leverage Phase 2 Control Data with Historical Control Data to Predict the Success of Phase 3 Study?, *Guoqin Su, Novartis; Frank Fan, Novartis*

TL26 Use of Historical Trial Data to Expedite Drug Development, *Matthew Gribbin, Amgen*

Innovations in Animal Drug Development

TL19 Introduction to CVM Biostatistics, *Laura Stets, FDA/CVM*

Modeling and Simulation

TL21 An Arithmetically Progressed Poisson Process and Its Application in Bio-Sciences, *Mian Adnan, Bowling Green State University*

TL23 New Perspectives on Randomization Tests for Co-Primary and Secondary Endpoints in Phase III Clinical Trials, *Arman Sabbaghi, Purdue University*

TL30 Computation Modeling and Regulatory Science: Where Are We Now?, *Yazmin San Miguel, Abbott Laboratories*

Noninferiority, Bioequivalence, and Biosimilars

TL24 A General Testing Approach for Bioequivalence in Multivariate Settings, *Younes Boulaguiem, University of Geneva*

Oncology

TL07 Cancer Immunotherapy Trials: Where Are We and Where Are We Going?, *Jingjing Ye, BeiGene*

Other

TL01 Concentration QTc Modeling for Assessing QT Interval Prolongation, *Jerry Zhang, Jazz Pharmaceuticals*

TL02 Have Lunch with the 2021 and 2022 Biopharmaceutical Section Chairs and Learn About the Section, *Weili He, AbbVie*

TL04 Student and Young Professional Mentoring Roundtable, *Richard Zink, Lexitas Pharma Services; H.M. James Hung, FDA*

TL16 Tips on How to Conduct a Successful Interview, *Joseph Cappelleri, Pfizer*

TL29 Increasing Justice, Equity, Diversity, and Inclusion (JEDI) in the Biopharmaceutical Industry: Why and How?, *Godwin Yung, Genentech; Dooti Roy, Boehringer Ingelheim*

Precision Medicine

TL18 Challenges in Bridging Study Evaluating the Performance of a Market-Ready Companion Diagnostic Test, *Sunghee Kim, FDA/CDRH*

Real-World Evidence

TL09 Harnessing Real-World Data for Decision-Making in Early-Phase Oncology Trials, *Arnab Maity, Pfizer*

Time-to-Event Analysis

TL08 Characterizing a Survival Curve from Clinical Trials, *Jason Liao, Incyte Corporation*

For additional information, please visit *ww2.amstat.org/meetings/biop/2021*.