REGISTRATION FORM

2022 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop

September 20–22, 2022 • Bethesda North Marriott Hotel & Conference Center—Rockville, MD | ***ww2.amstat.org/meetings/biop/2022***

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, 2022, to be processed at the reduced rate.
5. Purchase orders will not be accepted.
6. 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.

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.

PAYMENT

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

❑ Cash Amount Paid $_____

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

Card Number

Expiration Date Security Code

Name of Cardholder

Authorizing Signature

REGISTRATION FEE (required)

	Through August 16	After August 16	
Registrant	$335	$360	$_____
Academic (nonstudent)	$240	$265	$_____
Biopharm Section Member	$250	$275	$_____
Government Employee	$150	$175	$_____
Student	$25	$50	$_____

ROUNDTABLE LUNCHEON *(Included; please make a selection.)*

Wednesday, September 21

List the table number (see back of form) for your 1st, 2nd, and 3rd choices.

1st_____ 2nd_____ 3rd_____ Menu choice: ❑ Regular ❑ Vegetarian

❑ Box lunch only, no roundtable ❑ No lunch

SHORT COURSES *($105 each through August 16; $110 each after August 16)*

Tuesday, September 20

8:30 a.m.–12:00 p.m.

❑ **SC1:** Nuts and Bolts About Defining Estimands and Constructing Estimators Based on ICH E9 Addendum (R1), *Yongming Qu, Eli Lilly and Company; Ilya Lipkovich, Eli Lilly and Company* $_____

❑ **SC2:** Leveraging External DataThrough Bayesian Methods in Clinical Trials, *Ying Yuan, MD Anderson Cancer Center; James Travis, FDA/CDER* $_____

❑ **SC3:** Improving Precision and Power in Randomized Trials by Leveraging Baseline Variables, *Michael Rosenblum, Johns Hopkins Bloomberg School of Public Health; Kelly Van Lancker, Johns Hopkins Bloomberg School of Public Health; Josh Betz, Johns Hopkins Bloomberg School of Public Health* $_____

❑ **SC4:** Design Considerations and Statistical Methods for Vaccine Clinical Trials, *Wenji Pu, GSK Plc.; Ivan Chan, AbbVie Inc.; Jonathan Hartzel, Merck & Co., Inc.; Fabian Tibaldi, GSK* $_____

❑ **SC5:** R for Clinical Study Reports and Submission, *Yilong Zhang, Merck & Co., Inc.; Nan Xiao, Merck & Co., Inc.; Keaven Anderson, Merck & Co., Inc.* $_____

1:30 p.m.–5:00 p.m.

❑ **SC6:** Estimand Framework Implementation, *Gregory Levin, US Food and Drug Administration; John Scott, US Food and Drug Administration; Susan Mayo, CDER* $_____

❑ **SC7:** Use of External Data in Clinical Trial: Unleashing the Power of Information, *Satrajit Roychoudhury, Pfizer Inc.; Ram Tiwari, Bristol Myers Squibb* $_____

❑ **SC8:** Leveraging Real-World Data in Medical Product Clinical Trials Design and Analysis, *Chenguang Wang, Johns Hopkins University; Nelson Lu, FDA/CDRH; Wei-chen Chen, FDA/CDRH* $_____

❑ **SC9:** Estimating Treatment Effect in a Principal Stratum: Applications of Causal Inference to the Tripartite Estimand Approach (TEA) and Early Biomarker Response, *Stephen Ruberg, Analytix Thinking, Purdue University; Arman Sabbaghi, Purdue University*

❑ **SC10:** Cell and Gene Therapy: Concepts, Rationale, Statistical Issues, and Regulatory Considerations, *Weidong Zhang, Jounce Therapeutics, Inc.; Srinand Ponnathapura Nandakumar, Nurix Therapeutics; Lynn Navale, Allogene Therapeutics* $_____

ADDITIONAL OPPORTUNITIES

❑ 40+1 BIOP Section Celebratory Reception
Wednesday, September 21, 5:45 p.m.–6:30 p.m. $ FREE!

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

TOTAL

$_____

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Roundtable Luncheon Topics—Wednesday, September 21

RL01 The Applications of Artificial Intelligence in Multiple Drug Development Procedures, *Bochao Jia, Eli Lilly and Company*

RL02 Jointly Assessing the Overall Treatment Effects Across Multiple Timepoints by a Global Test in the Paradigm of Longitudinal Analysis, *Hong Li, AbbVie*

RL03 Challenges in Digital Health Products: Development, Validation, and Regulatory Concerns, *Feiming Chen, FDA/CDRH*

RL04 Evidentiary Roadmap for Use of ctDNA in Cancer Drug Development and as an Early Endpoint, *Hillary Stires, Friends of Cancer Research*

RL05 Challenges and Strategies to Properly Utilize Historical or Real-World Data in Clinical Trials, *Huan Wang, FDA/CDER/OTS/OB/DB9*

R06 Innovative Statistical Strategies and Challenges in Oncology Drug Development, *Olga Marchenko, Bayer*

RL07 The Symbiosis Between Statistics and Pharmacometrics for Model-Informed Drug Development, *Luke Fostvedt, Pfizer, Inc.*

RL08 Number of Repetitions in Re-Randomization Tests, *Yujie Zhao, Merck & Co., Inc.*

RL09 Is More Always Better? Dose Optimization in Oncology, *Ji Lin, Sanofi*

RL10 RTOR (Real-Time Oncology Review) Experiences, *Brent Burger, Jazz Pharmaceuticals*

RL11 Defining and Evaluating Estimands for Health-Related Quality of Life Time-to-Event Endpoints, *Libby Floden, Clinical Outcomes Solutions*

R12 Leveraging the Estimand Framework to Support Benefit-Risk Assessments, *Rebecca D. Taha, ICON PLC*

RL13 Benefit-Risk Assessment Planning and Tool Suite, *Brian Waterhouse, Merck*

RL14 Use of Q-TWiST Analysis in Benefit-Risk Assessment, *Ugochinyere Emeribe, AstraZeneca*

RL15 Dose Optimization – Paradigm-Shift to Find Optimal Dose for New Generations of Anti-Cancer Drugs: Statistical Designs and Considerations for a Randomized Dose-Ranging Phase II Trial, *Kathy Zhang, BeiGene*

RL16 Connecting Statisticians in Early Clinical Development, *Michael Kunz, Bayer AG*

RL17 Cohort-Based Dose Finding and Rolling-Based Dose Finding in Phase I Oncology Trials, *Ray Li, Pfizer, Inc.*

RL18 Meet and Greet with the Biopharmaceutical Section Chairs, *Alan H. Hartford, Takeda Pharmaceuticals*

RL19 Win Ratio for Composite Endpoints, *Martha Cao, Eidos Therapeutics*

RL20 Estimands in Neuroscience Clinical Trials, *Jing Dai, Jazz Pharmaceuticals*

RL21 Estimands for Safety Assessments, *Shanti V. Gomatam, FDA*

RL22 Impact of Missing or Alternative Tumor Assessments on the Validity of PFS Results, *Ray Lin, Genentech/Roche*

RL23 Assessing Missing Data Mechanisms for Unspecified Diabetic Retinopathy Disease Severity Encounters in the Electronic Health Record: An IRIS® Registry Analysis, *Meghan Hatfield, Verana Health*

RL24 Multiple Imputation in Clinical Trials, *Chenjia Xu, Eli Lilly and Company*

RL25 The Treatment and Handling of Missing Data in the Analysis of Real-World Data, *Gosford Aki Sawyerr, Syneos Health LLC*

RL26 Assessing Concordance or Agreement for Nominal Data in Medical Device, *Ying Wang, Johnson & Johnson*

RL27 Statistical Methods and Challenges in Multiparameter Quantitative Imaging Biomarkers, *Xiaofeng Wang, Cleveland Clinic Lerner Research Institute*

RL28 Bayesian vs. Frequentist Approaches to Analyze Carryover Effect in a 2x2 Crossover Study, *Chung-Kai Sun, Johnson and Johnson Vision Care*

RL29 Issues and Solutions in Statistical Implementation of Cellular and Gene Therapy Studies, *Patricia Fox Anderson, ICON PLC*

RL30 Increasing Justice, Equity, Diversity, and Inclusion (JEDI) in the Biopharmaceutical Industry: Role of Statisticians, *Dooti Roy, Boehringer Ingelheim Pharmaceuticals, Inc.*

RL31 Integrating AI-Based Software as Medical Device (SaMD) in Drug Development, *Natalia Muhlemann, Cytel, Inc.*

RL32 Statistical Considerations for Endpoint Adjudication, *Jennifer Bogert, Janssen R&D*

RL33 Harnessing the Power of Centralized Statistical Monitoring in Post-Pandemic Trial Conduct, *Rakhi Kilaru, PPD*

RL34 Harnessing Real-World Data for Decision-Making in Early-Phase Oncology Trials, *Arnab Kumar Maity, Pfizer Inc.*

RL35 Leveraging Real-World Evidence (RWE) in the Vaccine Clinical Research & Development (VCRD), *Veena Somayaji, Pfizer, Inc.*

RL36 Pharmacogenomics Polygenic Risk Score for Drug Response Prediction Using PRS-PGx Methods, *Song Zhai, Merck & Co., Inc.*

RL37 Principal Stratification: Misunderstood and Underutilized?, *Ahmad Hakeem Abdul Wahab, Janssen Pharmaceuticals*

RL38 Reinforcing Results of Adjusted Analyses of Overall Survival in Oncology Trials with Treatment Switching, *Macaulay Okwuokenye, Brio Dexteri Pharmaceutical Consultants*

RL39 Clinical Validation and Clinical Outcome Studies for Adjunctive Diagnostic Devices, *Terry Liao, FDA*

RL40 The Use of Non-Concurrent Randomized Controls in Multi-Arm Adaptive Platforms Trials, *Ben Caleb Saville, Berry Consultants*

RL41 Sample Size Re-estimation and Interim Analyses with Different Information Fractions for Time-to-Event Trials, *Juliana Ianus, Alexion, AstraZeneca Rare Disease*

RL42 The Type I Error Control and Multiplicity Issue in Interim Analysis in Rare Disease, *Yuqian Shen, Sanofi*

RL43 Diagnostic Tests' Accuracy Goal, *Dandan Xu, US Food and Drug Administration*

CANCELATION POLICY: Cancelations received by August 16 will be refunded, less a $25 processing fee and $10 processing fee for each short course. Cancelations received from August 17 to September 2 will be refunded, less a $50 processing fee and $15 processing fee for each short course. Requests for refunds received after September 2 will not be honored. All cancelations 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*.

COVID RESTRICTIONS: Meeting attendance constitutes an agreement to abide by currently prevailing requirements outlined by Montgomery County, Maryland, at the time of the conference (*www.montgomerycountymd.gov/covid19*). These may include, but are not limited to, wearing a mask, social distancing, and showing proof of COVID vaccination or negative PCR/antigen test.

For additional information, please visit *ww2.amstat.org/meetings/biop/2022*.