REGISTRATION FORM

2024 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop

September 25–27, 2024 • Bethesda North Marriott Hotel & Conference Center—Rockville, MD | ***ww2.amstat.org/meetings/biop/2024***

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 14, 2024, 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.

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 14	After August 14	
Registrant	$365	$390	$_____
Academic (nonstudent)	$260	$285	$_____
Biopharm Section Member	$280	$305	$_____
Government Employee	$170	$195	$_____
Students	$25	$50	$_____

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

Thursday, September 26

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

$120 each through August 14; $125 each after August 14

8:30 a.m.–12:00 p.m.

❑ **SC1:** Adaptive and Complex Innovative Designs Across Trial Phases for Accelerated Approval $_____

❑ **SC2:** Striving for PROgress: Lessons in Trial Design, Analysis, and Reporting of Patient-Reported Outcome (PRO)-Based Endpoints in Cancer Clinical Trials $_____

❑ **SC3:** Statistical Considerations and Design Strategies for Dose Optimization $_____

❑ **SC4:** Unleashing the Power of Machine Learning and Deep Learning to Accelerate Clinical Development $_____

❑ **SC5:** A Deep Dive into Matching, Stratification, and Weighting for Leveraging Real-World Data in Clinical Trials: Methods, Applications, and Regulations $_____

1:30 p.m.–5:00 p.m.

❑ **SC6:** A Practical Guide to Estimand Thinking $_____

❑ **SC7:** Cell and Gene Therapy: Introduction and Overview of Important Regulatory, Statistical, and Operational Considerations $_____

❑ **SC8:** Practical Considerations for Transforming Real-World Data (RWD) into Real-World Evidence (RWE) $_____

❑ **SC9:** Bayesian Statistics and Bayesian Models for Practical Dose Finding and Dose Optimization Oncology Clinical Trials $_____

❑ **SC10:** Overall Survival Analysis Methods Correcting for Treatment Switching Effects in Oncology Trials: Theory and SAS/R Code $_____

OTHER

❑ Workshop Mixer, Thursday, September 26, 5:45 p.m. – 6:30 p.m.

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

TOTAL

$_____

CANCELATION POLICY: Cancelations received by 5:00 p.m. ET on August 14 will be refunded, less a $25 processing fee and $10 processing fee for each short course. Cancelations received from August 15 to September 2 at 5:00 p.m. ET will be refunded, less a $50 processing fee and $15 processing fee for each short course. Requests for refunds received after 5:00 p.m. ET on 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 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop 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 take photographs and video of this event for use in ASA news and promotional material, in print, electronic, and other media, including the ASA website. By participating in this event, you grant the ASA the right to use any image, photograph, voice, or likeness, without limitation, in its promotional materials and publicity efforts without compensation. All media become the property of the ASA. Media may be displayed, distributed, or used by the ASA for any purpose.

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Roundtable Luncheon Topics—Thursday, September 26

TL01 Application of Tipping Point Analysis in Clinical Trials Using the Multiple Imputation Procedure in SAS
Xianwei Bu, AbbVie

TL02 Artificial Intelligence and Bayesian Methods for Decision-Making in Drug Development
Alyssa Vanderbeek

TL03 Bayesian Approaches to Facilitate Rapid Development of Cell and Gene Therapy for Rare Diseases
Yue Wang, Astellas Pharma Global Development, Inc.

TL04 Comparison of Current Early Phase Dose Optimization Methods
Hao Sun, Iowa State University

TL05 Considerations on Controls
Vatsala Karwe

TL06 How Can Statisticians Influence Clinical Trials to Be More Representative?
Ning Leng

TL07 Operational Challenges for Conducting Open-Label Clinical Trials That Are Sponsor-Blinded
Lisa Macpherson, Eli Lilly and Company

TL08 Time to Move Beyond Simple Tabulations of Adverse Events for Evaluating and Comparing the Safety Profile of Oncology Compounds?
Ellen Snyder, Merck

TL09 Enhancing Endpoints Development Through Clinical Outcome Assessments
Steven Sun

TL10 Assessments of Treatment Effects in Post-Treatment Subgroup
Madhuja Mallick, AbbVie

TL11 Master Protocols in Clinical Trials: How Will the FDA's Guidance Facilitate the Implementation of Master Protocols?
Chenjia Xu, Eli Lilly and Company

TL12 Regulatory Considerations for Open-Source Coding in the Biopharmaceutical Industry in the Age of Machine Learning and Cloud Computing
Boaz Adler, Cytel Inc.

TL13 Quantitative Go-No Go Decision-Making in Gene Therapy Development Programs for Rare Diseases
Cong Han

TL14 The Statistician's Role in Quantitative Drug Development (QDD): A Roundtable Discussion
Luke Hickey

TL15 The Role of Statisticians in Generating Patient Preference Information to Support Regulatory Decisions
Mo Zhou, Novartis

TL16 The Novel Criterion for the Efficiency of the Group Predictions for Imbalanced Data
Gueorgui Mersov, Basis Technologies Inc.

TL17 Statistical Analysis and Challenges of AI & M[illegible]ntegrated Digital Pathology Devices
WITHDRAWN
Ji Hye Park, FDA/CDRH

TL18 Evaluation of Artificial Intelligence–B[illegible] Digital Pathology Device to Mark or Detect Targets
WITHDRAWN
Elisavet Sofikitou, US Food and Drug Administration

TL19 All Things Consider About Progression-Free Survival (PFS)
Ruiyun Jiang, Bristol-Myers Squibb

TL20 Biomarkers as Surrogate Endpoints in Neurodegenerative Disease
Haoyan Hu, Eli Lilly and Company

TL21 Statistical Assessment for Analytical Comparability Between Pre-Change and Post-Change Processes
Aili Cheng, Pfizer

TL22 Advancing Pediatric Clinical Trials Through Case Studies: Extrapolation, Bayesian Methods, and Regulatory Perspectives
Robert Nelson

TL23 What Have We Learned Since the FDA/NCI 2014 Meeting Highlighting Challenges in Evaluating Cancer as an Outcome in Non-Cancer Post-Approval Safety Studies?
Melissa Moore-Clingenpeel, CorEvitas

TL24 Nurturing the Next Generation: Effective Strategies for Mentoring Young Statisticians in the Pharmaceutical Industry
Xiaoling Wu

TL25 Biostatisticians Should Actively Engage in Benefit-Risk Assessment for 510(k) Medical Devices
Terry Liao, US Food and Drug Administration

TL26 Statistical Innovation in Drug and Device Development and Regulation: How Can We Maximize Its Impact?
Marc Vandemeulebroecke, UCB Farchim SA

For additional information, please visit *ww2.amstat.org/meetings/biop/2024*.