REGISTRATION FORM

2025 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop

September 24–26, 2025 • Bethesda North Marriott Hotel & Conference Center—Rockville, MD | ***ww2.amstat.org/meetings/biop/2025***

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 12, 2025, 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 12	After August 12	
Registrant	$435	$460	$_____
Academic (nonstudent)	$275	$300	$_____
Biopharm Section Member	$340	$365	$_____
Government Employee	$175	$200	$_____
Student	$25	$50	$_____

ROUNDTABLE LUNCHEON *(No added fee, please include a selection.)*

Thursday, September 25

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

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

SHORT COURSES

$120 each through August 12; $125 each after August 12

8:30 a.m.–12:00 p.m.

❑ **SC01:** A Practical Guide to Estimand Implementation $_____

❑ **SC02:** Bayesian Study Design and Analysis in Regulatory Science $_____

❑ **SC03:** Targeted Learning for Randomized Controlled Trials and Hybrid Studies in the Era of Artificial Intelligence and Machine Learning $_____

❑ **SC04:** AI-Generated R Code in Combination with Simulation Software for Clinical Trial Design – A Case Study Approach $_____

❑ **SC05:** Precision Medicine and Companion Diagnostics: Statistical and Design Considerations $_____

1:30 p.m.–5:00 p.m.

❑ **SC06:** Improving Power and Precision in Randomized Trials using Covariate Adjustment $_____

❑ **SC07:** Graphical Multiple Comparison Procedures: Combining Flexibility with Optimality $_____

❑ **SC8:** Quantitative Decision-Making for Staging up to Phase 3 Clinical Development $_____

❑ **SC9:** Statistical Considerations and Design Strategies for Dose Optimization in Simple and Complex Settings $_____

❑ **SC10:** Statistical Design and Analysis of Hybrid Controlled Trials with Real-World External Controls $_____

OTHER

❑ Workshop Mixer, Thursday, September 25, 5:45 p.m. – 6:30 p.m.

❑ Yes! I would like a printed conference program.

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

TOTAL $_____

CANCELATION POLICY: Cancellations received by 5:00 p.m. ET on August 12 will be refunded, less a $25 processing fee and $10 processing fee for each short course. Cancellations received from August 13 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 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 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 25

TL01 Statistical Considerations and Innovations in Seamless Designs to Accelerate Clinical Development
Ran Liao

TL02 Opportunities and Challenges in the Application of Modern Covariate Adjustment Methods
Christian Pipper, Klaus Holst

TL03 Application of Dynamic Borrowing Method in Clinical Trial Designs
Hao Sun, Jerry Li

TL04 Adaptive Platform Trials: Lessons Learned and the Road Ahead
Theis Lange, Mark Van Der Laan

TL05 Considerations of Dose Optimization in Oncology Drug Development
Zheng Li

TL06 Practical Considerations in Pivotal Trial Designs in Renal Diseases from Both Industry and Regulatory Perspectives
Cassie Dong, Lingling An

TL07 Advantages and Challenges of Platform Trials in Non-Oncology Fields
Ran Liu

TL08 Utilization of AI/ML Models for Borrowing Historical Data in Drug Development
Yibo Wang

TL09 Intricacies in the Design and Analysis of Ophthalmology Clinical Trials
Adeniyi Adewale

TL10 Tipping Point Analyses for Time-to-Event Endpoints in Regulatory Submissions
Haiming Zhou, Philip He

TL11 Causal Artificial Intelligence and Machine Learning for Generating Regulatory-Grade Real-World Evidence
Maya Petersen, Hana Lee

TL12 Modern Causal Inference in Non-Interventional Studies: Statistical & Methodologic Considerations
Mark Van Der Laan, Susan Gruber

TL13 The Role of Statisticians in Adapting to ICH E6(R3) Revision
Justine Rochon

TL14 Go/No-Go Decision-Making of Transitioning to Phase 3 Study in Clinical Development
Yusuke Yamaguchi, Annie Wang

TL15 Statistical Methods for Multi-Reader Multi-Case (MRMC) Data Analyses
Tinghui Yu

TL16 Digital Biomarkers: The Final Frontier of Clinical Trials—A Roundtable Exploration
Raul Torres

TL17 Is the Estimand Framework Useful for Safety Evaluation in Clinical Trials?
Steven Sun

TL18 Unlocking the Power of External Data and Data Fusion in Regulatory Decision-Making
Mark Van Der Laan, Lei Nie

TL19 Use of Real-World Data in Drug Approval for Hematological and Rare Disease Clinical Trials
Lola Luo

TL20 Adaptive Pooling Strategies for Surrogate Endpoint Validation in Cell Therapy: A Dynamic Information Borrowing Framework
Wengcong Chen, Jinjie Chen

TL21 Navigating Safety Reporting Requirements and Safety Assessment for IND: Insights and Discussions on FDA 2021 Guidance
Parul Bhargava, Viviana Rodriguez

TL22 Bridging the Gap: Navigating the Transition from Academia to the Pharmaceutical Industry
Yanhong Zhou, Yan Lin

TL23 Discussion on Changes to the US Federal Government and Its Effects on Statisticians Working on Drug Development Across Industry and Government
Disa Yu

TL24 Interpretable Deep Learning-Based Multi-Omics and Clinical Data Integration in Clinical Trial Development Opportunities and Challenges
Hong Wang, Wenting Wang

TL25 Am I a Data Scientist or a Statistician? Or Am I Cool Enough to Juggle Both Hats?
Ji Lin

TL26 Large Language Models in Regulatory Science and Real-World Evidence: Opportunities, Pitfalls, and Next Steps
Kajsa Kvist, Tala Fakhouri

TL27 Integration of AI and MIDD (Model-Informed Drug Development) with a Special Focus on the M15 Guidance Document - General Principles for MIDD
Yuying Jin, Zhiwei Zhang

TL28 Credibility Assessment of Artificial Intelligence Usage in Clinical Trials
Sudipta Saha

TL29 AI-Driven Innovation in Clinical Trial Acceleration
Ju Ji, Andy Dang

TL30 Empower Drug Development Through AI-based Digital Twins
Haiyan Wu

TL31 Enhancing Pharmacovigilance Through AI: A Novel Approach to Safety Signal Detection
Jagannath Ghosh, Eren Demirhan

TL32 Integrating AI/ML to Advance Drug Development: Innovative Methodologies and Regulatory Perspectives
Hiya Banerjee

TL33 Problematic Post-Hoc Graphics in HELIOS-B
Theodore Lystig

For additional information, please visit *ww2.amstat.org/meetings/biop/2025*.