



Important Dates & General Information

Thursday, January 23, 2025, 4:00 PM EDT

Early Bird Registration Deadline

Monday, May 19, 2025, 4:00 PM EDT

Advanced Registration Deadline

Tuesday, May 6, 2025

Hotel Reservation Deadline

TARGET AUDIENCE

The intended audience for ASCPT 2025 is clinical pharmacologists, translational scientists, and other scientists in the early phase drug discovery, development, regulatory, and utilization space.

ADA COMPLIANCE

ASCPT makes every effort to comply with the Americans with Disabilities Act. For additional information, please contact ASCPT at (703) 836-6981, ext. 105 or 108, or email at meetings@ascpt.org.

REGISTRATION, HOTEL, AND TRAVEL INFORMATION

Annual Meeting attendees are required to register for the Annual Meeting before booking their hotel accommodations for the in-person conference. Booking information will be provided with your registration confirmation. For more information about Annual Meeting registration, securing housing, and travel information for Washington, DC, visit www.ascpt.org.

ASCPT NETWORKS AND COMMUNITIES

As the primary forum for member exchange and networking, ASCPT's Networks and Communities promote interaction among members who share a common field of interest. All education sessions are associated with Networks/Communities to help plan your Annual Meeting experience. Network and Community year-round webinars and meetings are announced as confirmed on www.ascpt.org.

ASCPT PARTNERSHIP OPPORTUNITIES

ASCPT offers unique and innovative opportunities to reach your target audience and maximize your ROI. Interested in learning more about becoming a partner? Contact lisa@ascpt.org for partner opportunities.

SESSIONS-AT-A-GLANCE BY COMMUNITY

BIOLOGICS (BIO)	
THURSDAY, MAY 29	
9:30-10:30	Transformative Advancements in the Treatment of Immune-Mediated Diseases: Integrating Patient-Centric Clinical Pharmacology with Translational MID3 for Biologics
FRIDAY, MAY 30	
11:00-12:00	Optimizing Dose Selection For Bispecifics: Lessons Learned
BIOMARKERS & TRANSLATIONAL TOOLS (BTT)	
THURSDAY, MAY 29	
9:30-10:15	Leon I. Goldberg Early Investigator Award Lecture
11:00-12:00	From Data to Recovery: Integrating EHR, Omics, and Pragmatic Clinical Trials for Faster Drug Development
FRIDAY, MAY 30	
11:00-11:45	Oscar B. Hunter Career Award in Therapeutics Lecture
CELL, GENE, REGENERATIVE & NUCLEI ACID (CGRN)	
THURSDAY, MAY 29	
9:30-10:30	Challenges and Opportunities of RNA Therapeutics, A Roller Coaster from Discovery to Recovery I: Pioneering Patient-Centric RNA Therapeutics for Rare Diseases
DRUG UTILIZATION & OUTCOMES (DUO)	
FRIDAY, MAY 30	
11:00-12:00	Informed Treatment Decisions; Model-Based Meta-Analysis + Machine Learning = Accurately Ranking Treatment Effectiveness + Predicting New Trials
1:30-2:30	Pediatric Extrapolation: Unlocking the Clinical Pharmacology Toolbox to Accelerate Drug Access for Our Little Patients
EARLY CAREER (EC)	
FRIDAY, MAY 30	
8:15-9:15	ASCPT Community Face-Off: Perspectives on Patient Centricity Across the ASCPT Community Spectrum
INFECTIOUS DISEASES (INF)	
THURSDAY, MAY 29	
3:30-4:15	2024 Darrell Abernethy Early Stage Investigator Award Lecture
MEMBRANE TRANSPORTER (MT)	
THURSDAY, MAY 29	
9:30-10:15	Leon I. Goldberg Early Investigator Award Lecture
MENTAL HEALTH & ADDICTION (MHA)	
FRIDAY, MAY 30	
8:15-9:15	Global Strategies for Clinical Pharmacology and Labelling in the Treatment of Mental Disorders in Pregnant and Lactating People
11:00-12:00	GLP-1 Agonists for Addiction: A Novel Therapeutic Approach toward Recovery for an Undertreated Disorder
3:00-4:00	How Can Clinician Researchers Leverage Their Clinical Service to Contribute Real-World Patient Outcomes to Advance Precision Medicine Utilization and Generate Discovery?
ONCOLOGY (ONC)	
THURSDAY, MAY 29	
9:30-10:30	Exploring Expanded Access: Balancing Patient Needs and Regulatory Considerations

ONCOLOGY (ONC) cont.	
FRIDAY, MAY 30	
11:00-12:00	Optimizing Dose Selection For Bispecifics: Lessons Learned
1:30-2:30	Dose-Optimization in Oncology: Identifying Gaps and Opportunities
PHARMACOGENOMICS (PGX)	
WEDNESDAY, MAY 28	
3:00-4:45	Dolores Shockley Diversity and Inclusion in Clinical Research Award Lecture
THURSDAY, MAY 29	
11:00-12:00	From Data to Recovery: Integrating EHR, Omics, and Pragmatic Clinical Trials for Faster Drug Development
FRIDAY, MAY 30	
11:00-11:45	Oscar B. Hunter Career Award in Therapeutics Lecture
3:00-4:00	How Can Clinician Researchers Leverage Their Clinical Service to Contribute Real-World Patient Outcomes to Advance Precision Medicine Utilization and Generate Discovery?
PHARMACOMETRICS & PHARMACOKINETICS (PMK)	
THURSDAY, MAY 29	
11:00-11:45	Sheiner-Beal Pharmacometrics Award Lecture
3:30-4:30	Balancing Patient-Centric and Model-Informed Drug Development (MIDD) Approaches to Optimize Dose Selection in Rare Diseases: Are We There Yet?
FRIDAY, MAY 30	
1:30-2:30	Unleashing the Power of Large Language Models in Drug Development: Transformative Insights and Innovative Applications
SATURDAY, MAY 31	
8:30-3:00	Revolutionizing End-to-End Drug Discovery, Development, and Clinical Utilization Through Quantitative Medicine Post-Conference [§]
PHYSIOLOGICAL BASED PHARMACOKINETIC MODELING AND SIMULATION (PBPK)	
THURSDAY, MAY 29	
11:00-12:00	Challenges and Opportunities of RNA Therapeutics, A Roller Coaster from Discovery to Recovery II: Translational Science with an Emphasis on Special Populations
RARE DISEASES (RD)	
THURSDAY, MAY 29	
9:30-10:30	Challenges and Opportunities of RNA Therapeutics, A Roller Coaster from Discovery to Recovery I: Pioneering Patient-Centric RNA Therapeutics for Rare Diseases
9:30-10:30	Exploring Expanded Access: Balancing Patient Needs and Regulatory
3:30-4:30	Balancing Patient-Centric and Model-Informed Drug Development (MIDD) Approaches to Optimize Dose Selection in Rare Diseases: Are We There Yet?
FRIDAY, MAY 30	
3:00-4:00	Advancing Decentralized Clinical Trials for Rare Diseases and Special Populations: Perspectives and Opportunities
SPECIAL POPULATIONS (SPO)	
WEDNESDAY, MAY 28	
3:00-4:45	Dolores Shockley Diversity and Inclusion in Clinical Research Award Lecture
THURSDAY, MAY 29	
11:00-12:00	Challenges and Opportunities of RNA Therapeutics, A Roller Coaster from Discovery to Recovery II: Translational Science with an Emphasis on Special Populations

[§] The post-conference requires an additional fee.

SPECIAL POPULATIONS (SPO) cont.	
FRIDAY, MAY 30	
8:15-9:15	Global Strategies for Clinical Pharmacology and Labelling in the Treatment of Mental Disorders in Pregnant and Lactating People
11:00-12:00	GLP-1 Agonists for Addiction: A Novel Therapeutic Approach toward Recovery for an Undertreated Disorder
3:00-4:00	Advancing Decentralized Clinical Trials for Rare Diseases and Special Populations: Perspectives and Opportunities
TRANSLATIONAL INFORMATICS (TI)	
THURSDAY, MAY 29	
9:30-10:30	Transformative Advancements in the Treatment of Immune-Mediated Diseases: Integrating Patient-Centric Clinical Pharmacology with Translational MID3 for Biologics
FRIDAY, MAY 30	
1:30-2:30	Unleashing the Power of Large Language Models in Drug Development: Transformative Insights and Innovative Applications

POST-CONFERENCE PROGRAM

Revolutionizing End-to-End Drug Discovery, Development, and Clinical Utilization Through Quantitative Medicine

Saturday, May 31, 2025, 8:30 AM – 3:00 PM ET

Chairs:

Chunze Li, PhD, Genentech

Qi Liu, PhD, US Food and Drug Administration

C.J. Musante, PhD, Pfizer

Bringing a new therapeutic agent to patients entails significant expenses, time, and risks, compounded by scientific, regulatory, and clinical utilization challenges. In response to these challenges, innovative quantitative approaches and technologies, collectively known as quantitative medicine (QM), are being incorporated into drug discovery and development to improve efficiencies and patient outcome. QM involves the development and application of exposure-based, biological, and quantitative modeling and simulation approaches using nonclinical, clinical, and real-world data to optimize end-to-end drug development efficiency. By enabling informed decision-making and treatment optimization, QM aims to bring transformative medicines to clinical utilization in a timely manner. In March 2024, the FDA announced the establishment of a CDER Quantitative Medicine (QM) Center of Excellence (CoE) to catalyze the integration and consistent application of QM methodologies across drug development lifecycles.

This post-conference session will delve into various aspects of QM employed in drug development across lifecycles, showcasing cutting-edge quantitative modeling tools such as population PK, exposure-response, mechanistic PK/PD modeling, quantitative pharmacology modeling, and artificial intelligence/machine learning (AI/ML), alongside their practical applications. Interdisciplinary teams will present how QM has bolstered decision-making confidence, streamlined drug development, and optimized clinical utilization from industry, global regulatory, and medical practice perspectives. Case studies elucidating model-informed dose optimization and novel modality development will be featured. An interactive workshop session will further reinforce key learning points.

Learning Objectives:

1. Gain insight into a spectrum of innovative quantitative tools, including population PK, exposure-response, mechanistic PK/PD modeling, quantitative pharmacology modeling (QSP), PBPK, and Artificial Intelligence/Machine learning (AI/ML).
2. Understand optimal utilization of QM tools across drug discovery, development and clinical utilization, including target selection, lead optimization, translation, dose optimization, combination strategy, generic drug development, patient treatment.
3. Identify the challenges hindering the wide adoption of QM in end-to-end drug development and explore potential solutions to promote global regulatory acceptance and medical application.

ASCPT 2025 ANNUAL MEETING PRELIMINARY SCHEDULE

Times/events are subject to change. All times are Eastern Time.

Wednesday, May 28, 2025

11:00 AM - 6:30 PM

Registration and ASCPT Info Desk Open

3:00 PM - 4:00 PM

Opening Session

4:00 PM - 4:45 PM

Dolores Shockley Diversity and Inclusion in Clinical Research Award Lecture

Representing the Under-Represented in Pharmacogenomic Discovery & Implementation

SPEAKER

Nita Limdi, MPH, PharmD, PhD, University of Alabama at Birmingham

5:00 PM - 6:30 PM

Opening Reception & Poster Session I

Thursday, May 29, 2025

7:00 AM - 6:30 PM

Registration and ASCPT Info Desk Open

7:00 AM - 8:00 AM

Network/Community Networking Breakfast

8:15 AM - 9:15 AM

State of the Art Lecture

SPEAKER

TBD

9:30 AM - 10:30 AM

Award Lecture

Leon I. Goldberg Early Investigator Award Lecture

Translational Stories: Biomarkers and Drug Transporters in Chemotherapy-Induced Peripheral Neuropathy

SPEAKER

Tore Stage, PhD, University of Southern Denmark

Thursday, May 29, 2025 cont.

9:30 AM - 10:30 AM

Scientific Session

Challenges and Opportunities of RNA Therapeutics, A Roller Coaster from Discovery to Recovery I: Pioneering Patient-Centric RNA Therapeutics for Rare Diseases

CHAIRS

Hazem Hassan, PhD, RPh, Regeneron

Islam Younis, PhD, Merck

SPEAKERS

Hobart Rogers, PharmD, PhD, US Food and Drug Administration

Alexandre Sostelly, PhD, Alnylam

9:30 AM - 10:30 AM

Scientific Session

Exploring Expanded Access: Balancing Patient Needs and Regulatory Considerations

CHAIRS

Mariam Ahmed, PhD, Takeda

Daria Stypinski, PhD, DS Clinical Pharmacology Consulting

SPEAKERS

Indranil Bhattacharya, PhD, Takeda

Mira (Mitze) Klingenberg, RN, Voices for ALS

9:30 AM - 10:30 AM

Scientific Session

Transformative Advancements in the Treatment of Immune-Mediated Diseases: Integrating Patient-Centric Clinical Pharmacology with Translational MID3 for Biologics

CHAIRS

Sihem Bihorel, PharmD, PhD, Merck

Li Zhang, PhD, Daiichi Sankyo

SPEAKERS

Brian Cicali, PhD, Translational Informatics Community

Sihem Bihorel, PharmD, PhD, Merck

Dipak Pisal, PhD, US Food and Drug Administration

Li Zhang, PhD, Daiichi Sankyo

10:30 AM - 11:00 AM

Networking Break

Thursday, May 29, 2025 cont.

11:00 AM - 12:00 PM

Featured Speaker

SPEAKER

TBD

11:00 AM - 12:00 PM

Award Lecture

Sheiner-Beal Pharmacometrics Award Lecture

Systems Thinking, Complexity and Pharmacometrics in Drug Development and Evaluation

SPEAKER

Ene Ette, MBA, PhD, Anoxis Corporation

11:00 AM - 12:00 PM

Scientific Session

Challenges and Opportunities of RNA Therapeutics, A Roller Coaster from Discovery to Recovery II: Translational Science with an Emphasis on Special Populations

CHAIRS

Kunal Taskar, PhD, GlaxoSmithKline

Bianca van Groen, PharmD, PhD, Hoffmann-La Roche

SPEAKERS

Nina Isoherranen, PhD, University of Washington

Farzaneh Salem, PharmD, PhD, GlaxoSmithKline

Patricia Sanwald-Ducray, PharmD, PhD, Roche

11:00 AM - 12:00 PM

Scientific Session

From Data to Recovery: Integrating EHR, Omics, and Pragmatic Clinical Trials for Faster Drug Development

CHAIRS

Nihal El Rouby, PharmD, PhD, University of Cincinnati

Mai Mehanna, PhD, US Food and Drug Administration

SPEAKERS

Julie Johnson, PharmD, The Ohio State University

Michael Pacanowski, MPH, PharmD, US Food and Drug Administration

Alan Shuldiner, MD, Regeneron Genetics Center

Thursday, May 29, 2025 cont.

12:00 PM - 1:30 PM

Networking Lunch

1:30 PM - 3:00 PM

Patient Forum

3:00 PM - 3:30 PM

Networking Break

3:30 PM - 4:30 PM

Award Lecture

2024 Darrell Abernethy Early Stage Investigator Award Lecture

SPEAKER

Amelia Deitchman, PharmD, PhD, University of California, San Francisco

3:30 PM - 4:30 PM

Scientific Session

Balancing Patient-Centric and Model-Informed Drug Development (MIDD) Approaches to Optimize Dose Selection in Rare Diseases: Are We There Yet?

CHAIRS

Sathej Gopalakrishnan, PhD, Merck KGaA

Noha Rayad, PhD, Alexion

SPEAKERS

Rajesh Krishna, MBA, PhD, Certara

Ruojing Li, PhD, US Food and Drug Administration

Roberta Smith, Alagille Syndrome Alliance

3:30 PM - 4:30 PM

Oral Abstracts

5:00 PM - 6:30 PM

President's Networking Reception & Poster Session II

Friday, May 30, 2025

7:00 AM - 12:00 PM

Registration and ASCPT Info Desk Open

7:00 AM - 8:00 AM

Network/Community Networking Breakfast

Friday, May 30, 2025 cont.

8:15 AM - 9:15 AM

Featured Speaker

SPEAKER

TBD

8:15 AM - 9:15 AM

Scientific Session

ASCPT Community Face-Off: Perspectives on Patient Centricity Across the ASCPT Community Spectrum

CHAIRS

Jacqueline Gerhart, PhD, Pfizer

Patrick Hanafin, PhD, GlaxoSmithKline

SPEAKERS

TBD

8:15 AM - 9:15 AM

Scientific Session

Global Strategies for Clinical Pharmacology and Labelling in the Treatment of Mental Disorders in Pregnant and Lactating People

CHAIRS

Kristin Bigos, PhD, BullFrog AI

Farzaneh Salem, PharmD, PhD, GlaxoSmithKline

SPEAKERS

Venkateswaran Chithambaram Pillai, PhD, US Food and Drug Administration

Xian Pan, PhD, Certara

Lindsay Standeven, MD, Johns Hopkins

9:30 AM - 10:30 AM

State of the Art Lecture

SPEAKER

TBD

10:30 AM - 11:00 AM

Networking Break

Friday, May 30, 2025 cont.

11:00 AM - 12:00 PM

Award Lecture

Oscar B. Hunter Career Award in Therapeutics Lecture
Improving Clinical Outcomes through Pharmacogenetics

SPEAKER

Julie Johnson, PharmD, The Ohio State University

11:00 AM - 12:00 PM

Scientific Session

GLP-1 Agonists for Addiction: A Novel Therapeutic Approach toward Recovery for an Undertreated Disorder

CHAIRS

Susan Learned, MD, PharmD, PhD, Learned Consulting Group
Vijay Ramchandani, PhD, National Institute on Alcohol Abuse and Alcoholism

SPEAKERS

Patricia Sue Grigson, PhD, Penn State University
Christian Hendershot, PhD, University of Southern California
Lorenzo Leggio, MD, PhD, National Institute on Drug Abuse

11:00 AM - 12:00 PM

Scientific Session

Informed Treatment Decisions; Model-Based Meta-Analysis + Machine Learning = Accurately Ranking Treatment Effectiveness + Predicting New Trials

CHAIRS

Ghada Ahmed, PhD, UCB
William Denney, PhD, Human Predictions

SPEAKERS

Ghada Ahmed, PhD, UCB
Christina Crater, MD, UCB
William Denney, PhD, Human Predictions
Pinky Dua, PhD, UCB
Alan Maloney, PhD, Equation AB

Friday, May 30, 2025 cont.

11:00 AM - 12:00 PM

Scientific Session

Optimizing Dose Selection for Bispecifics: Lessons Learned

CHAIRS

Mohamed-Eslam Mohamed, PhD, RPh, AbbVie

Ahmed Othman, PhD, Exelixis, Inc.

SPEAKERS

Brian Christmas, PhD, US Food and Drug Administration

Tommy Li, PhD, Genmab

Priyanka Madia, PhD, Gilead Sciences

12:00 PM - 1:30 PM

Networking Lunch

1:30 PM - 2:30 PM

Award Lecture

Rawls-Palmer Progress in Medicine Award Lecture

SPEAKER

Janice Schwartz, MD, University of California, San Francisco

1:30 PM - 2:30 PM

Scientific Session

Dose-Optimization in Oncology: Identifying Gaps and Opportunities

CHAIRS

Ya-Feng Wen, PharmD, PhD, Gilead Sciences

SPEAKERS

Brian Booth, PhD, US Food and Drug Administration

Naveen Mangal, PhD

Jeffrey Moscow, MD, National Cancer Institute

Karthik Venkatakrisnan, PhD, EMD Serono

Friday, May 30, 2025 cont.

1:30 PM - 2:30 PM

Scientific Session*Pediatric Extrapolation: Unlocking the Clinical Pharmacology Toolbox to Accelerate Drug Access for Our Little Patients*

CHAIRS

Yuli Qian, PhD, AbbVie

Aarti Sawant, PhD, AstraZeneca

SPEAKERS

Gilbert Buckart, PharmD, US Food and Drug Administration

Lindsay Clegg, PhD, AstraZeneca

Mohamed-Eslam Mohamed, PhD, RPh, AbbVie

1:30 PM - 2:30 PM

Scientific Session*Unleashing the Power of Large Language Models in Drug Development: Transformative Insights and Innovative Applications*

CHAIRS

Jamie Connarn, PhD, Amgen

Jagdeep Podichetty, PhD, Critical Path Institute

SPEAKERS

Joga Gobburu, MBA, PhD, University of Maryland

Emily Nieves, Massachusetts Institute of Technology

Murali Ramanathan, PhD, University at Buffalo

2:30 PM - 3:00 PM

Networking Break

3:00 PM - 4:00 PM

Scientific Session*Advancing Decentralized Clinical Trials for Rare Diseases and Special Populations: Perspectives and Opportunities*

CHAIRS

Jackson Burton, PhD, Biogen

Katty Wan, PhD, Pfizer

SPEAKERS

Elimika Fletcher, PharmD, PhD, US Food and Drug Administration

Michelle Lorenz, Voices for ALS

Laura Shaughnessy, PhD, UCB

Friday, May 30, 2025 cont.

3:00 PM - 4:00 PM

Scientific Session

How Can Clinician Researchers Leverage Their Clinical Service to Contribute Real-World Patient Outcomes to Advance Precision Medicine Utilization and Generate Discovery?

CHAIRS

Emily Cicali, PharmD, University of Florida

Madeline Norris, PharmD, University of Florida

SPEAKERS

Mari Cayabyab, PharmD, Hospital of the University of Pennsylvania

Kristen Jacobsen, PharmD, Sanford Imagenetics

Vijay Ramchandani, PhD, National Institute on Alcohol Abuse and Alcoholism

3:00 PM - 4:00 PM

Oral Abstracts

Saturday, May 31, 2025

8:30 AM – 3:00 PM

Post-Conference[®]

Revolutionizing End-to-End Drug Discovery, Development, and Clinical Utilization Through Quantitative Medicine

⑤ *The post-conference requires an additional fee.*