



Important Dates & General Information

THURSDAY, DECEMBER 15, 2022, 4:00 PM EDT

Early Bird Registration Deadline

Friday, MARCH 10, 2023, 4:00 PM EDT

Advanced Registration Deadline

Thursday, FEBRUARY 23, 2023

Hotel Reservation Deadline

TARGET AUDIENCE

The intended audience for ASCPT 2023 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 via email at meetings@ascpt.org.

REGISTRATION, HOTEL, AND TRAVEL INFORMATION

Annual Meeting attendees are required to register for the Annual Meeting prior to booking their hotel accommodations for the in-person conference. Booking information will be provided in registration confirmations. For detailed information regarding Annual Meeting registration, securing housing, and travel information for Atlanta, GA, 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 will correlate to Networks/Communities to help assist in planning 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.

ANNUAL MEETING ON-DEMAND ACCESS

All in-person and online-only attendees will receive complimentary access to all of the professionally recorded scientific sessions the ASCPT 2023 Annual Meeting. Enjoy sessions you may have missed or those you want to revisit with access to the on-demand content in the Cadmium site. Access will be available for six months after the close of the Annual Meeting.

ASCPT Annual Meeting COVID-19 Policies

To safeguard the health and safety of all who attend ASCPT 2023 in-person, ASCPT will comply with federal, state, and



local-issued health and safety precautions, including the CDC's Guidance for Events, as an integral part of the execution of the onsite Annual Meeting.

These guidelines are constantly evolving, and ASCPT will make reasonable efforts to ensure all registered attendees are informed of the final health and safety requirements and precautions that will be implemented onsite closer to the first day of the event. Please view our full COVID-19 Policies [here](#).

PRE-CONFERENCE PROGRAM

Advancing the Utilization of Real-World Data (RWD) and Real-World Evidence (RWE) in Clinical Pharmacology and Translational Research

Tuesday, March 21, 2023, 9:00 AM – 5:30 PM

Co-Sponsored by the IQ Consortium

Chairs:

- Paulien Ravenstijn, PhD, Affimed GmbH
- Karen Rowland Yeo, PhD, Certara
- Jing Liu, PhD, Pfizer

Additional Organizing Committee Members:

- Mariam Ahmed, PhD
- Pooja Manchandani, PhD
- Anuradha Ramamoorthy, PhD
- IQ RWE Workgroup: Rui Zhu, PhD, and Cyrus Ghobadi, MD, PhD

RWD and RWE have been routinely used in epidemiology, clinical practice, and post approval regulatory decisions. Despite the fact that there have been published examples and new regulatory guidelines in recent years, there remains a lack of general understanding on RWD and RWE and how this approach can be applied in clinical pharmacology and translational research.

This Pre-Conference experience will include state of the art presentations from a diverse panel of experts from academia, industry, and regulatory, access to presentations on selected case studies reflective of current practices for RWE/RWD in drug development, an interactive workshop to reinforce learnings of applications of RWE/RWE in drug development, poster presentations submitted by participants, and forward-looking panel discussion from global representatives.

Who Should Attend?

This Pre-Conference will be of significant interest to clinical pharmacologists and modeling communities in industry, regulatory, and academia as it has widespread application throughout.

Learning objectives:

- To introduce the essentials of RWD and RWE



- To provide education on the data source, quality and analytics involved in generation of RWE from RWD
- To discuss the necessary framework for application of RWD and RWE application in the scope of clinical pharmacology, translational research, drug development and approval

Attendance for the in-person Pre-Conference is limited to 150 attendees. Register early to secure your seat! Online-only registration is available for those who are unable to participate in-person.

Tentative Schedule

Tuesday, March 21, 2023

9:00 AM – 9:10 AM

Opening & Welcome

SPEAKER

Karen Rowland Yeo, PhD, Certara

9:10 AM – 9:35 AM

Lecture 1: Introduction of RWD and RWE and advancing utilization of RWD and RWE in clinical pharmacology and translational research – academia perspective

SPEAKER

Almut Winterstein, PhD, University of Florida

9:35 AM – 10:00 AM

Lecture 2: Advancing utilization of RWD and RWE in clinical pharmacology and model-informed drug development – industry perspectives

SPEAKER

Brian Corrigan, PhD, Pfizer

10:00 AM – 10:25 AM

Lecture 3: Advancing their utilization in clinical pharmacology – regulatory perspectives

SPEAKER

Qi Liu, PhD, US Food and Drug Administration

10:25 AM – 10:50 AM

Lecture 4: Real world data sources, quality, and analytics considerations for generating RWE

SPEAKER

Jeff Barrett, PhD, Critical Path Institute

10:50 AM – 11:00 AM

BREAK

11:00 Am – 12:30 PM



Real case studies demonstrating the application of RWD/RWE in drug development for various scenarios.

- Special populations
- DDI
- Disease progression modeling
- Translational research/ Reverse translation
- Totality of evidence for drug approvals

SPEAKERS

Rui Zhu, PhD, Genentech

Cyrus Ghobadi, MD, PhD, Eli Lilly

Samira Jamalian, PhD, Genentech

12:30 PM – 1 :30 PM

LUNCH and POSTERS

1 :30 PM – 2 :45 PM

Hands-on Workshop – Drug X: Breakout groups

2:45 PM – 3:30 PM

Cross-group learnings from breakout groups

MODERATOR

Paulien Ravenstijn, PhD, Affimed GmbH

3:30 PM – 3:45 PM

COFFEE BREAK

3:45 PM – 4:30 PM

Panel discussion with presenters and panelists from academia, industry, EMA, FDA, WHO on the vision/future of RWE/RWD in clinical pharmacology, translational research and drug development and approval; data quality & data standards

MODERATOR

Jing Liu, PhD, Pfizer

4:30 PM – 4:35 PM

Wrap Up

SPEAKER

Jing Liu, PhD, Pfizer

4:35 PM – 5:30 PM

POSTERS AND REFRESHMENTS



PRELIMINARY SCHEDULE AT A GLANCE

TUESDAY, MARCH 21, 2023

9:00 AM – 5:30 PM

PRE-CONFERENCE

Advancing the Utilization of Real-World Data (RWD) and Real-World Evidence (RWE) in Clinical Pharmacology and Translational Research

WEDNESDAY, MARCH 22, 2023

8:00 AM – 11:30 AM

BOARD OF DIRECTORS MEETING

By Invitation Only

12:00 PM – 1:30 PM

ACCESS+ Leadership Accelerator

1:00 PM – 5:00 PM

ASCPT INFO DESK AND REGISTRATION OPEN

3:00 PM – 4:00 PM

OPENING SESSION

4:00 PM – 5:00 PM

Dolores Shockley Diversity and Inclusion in Clinical Research Award Lecture

SPEAKER

Toluwalase Ajayi, MD, Scripps Research Institute

5:00 PM – 6:30 PM

OPENING RECEPTION

POSTER SESSION: PRESIDENTIAL TRAINEE SHOWCASE & POSTERS and POSTER SESSION I

5:20 PM – 5:50 PM

POSTER WALK I: Leveraging PBPK Modeling to Support Drug Utilization

5:55 PM – 6:25 PM

POSTER WALK II: Translational Approaches for Optimal Dosing In Patients

THURSDAY, MARCH 23, 2023

6:30 AM – 5:00 PM

ASCPT INFO DESK AND REGISTRATION OPEN



7:00 AM – 8:00 AM

BREAKFAST

8:15 AM – 9:15 AM

STATE OF THE ART LECTURE

SPEAKER

Priti Hegde, PhD, Foundation Medicine

9:30 AM – 10:30 AM

SCIENTIFIC SESSION

How Could Debunking Biases in R&D Decisions Lead to More Equitable Healthcare?

CHAIRS

Sandra Visser, PhD, GlaxoSmithKine

Benjamin Weber, PhD, Novo Nordisk

SPEAKERS

Richard Lalonde, PharmD, University of Florida

Katarzyna Smietana, PhD, McKinsey & Company

Issam Zineh, MPH, PharmD, US Food and Drug Administration

9:30 AM – 10:30 AM

SCIENTIFIC SESSION

Diversity and Inclusion in Clinical Trials for Rare Diseases: Together We Can Achieve the Unachievable

CHAIRS

Mariam Ahmed, PhD, Takeda

Noha Rayad, PhD, Parexel

SPEAKERS

Michelle Campbell, PhD, US Food and Drug Administration

Clare Grace, PhD, Parexel

Youssef M. Roman, PharmD, PhD, Virginia Commonwealth University

9:30 AM – 10:30 AM

SCIENTIFIC SESSION

Hi Cancer, We Come with Bearing Gifts, Antibody-Drug Conjugate

CHAIRS

Zhu Zhou, PhD, York College/City University of New York

Mike Liao, PhD, Genentech

SPEAKERS

Lorna Warwick, BA, Lymphoma Coalition

Chunze Li, PhD, Genentech

Salaheldin Hamed, PhD, US Food and Drug Administration



10:30 AM – 11:00 AM

NETWORKING BREAK

11:00 AM – 11:45 AM

FEATURED SPEAKER

Richard Peck, MD, University of Liverpool

TITLE TBD

11:00 AM – 11:45 AM

AWARD LECTURE

Leon I. Goldberg Early Investigator Award Lecture

SPEAKER

Jasmine Luzum, PharmD, PhD, University of Michigan

TITLE TBD

11:00 AM – 12:00 PM

SCIENTIFIC SESSION

Drug Transporter Pharmacogenomics – When It Matters and When It Doesn't

CHAIRS

Sook Wah Yee, University of California, San Francisco

Kit Wun Kathy Cheung, PharmD, Genentech

SPEAKERS

Katarzyna Drozda, PharmD, US Food and Drug Administration

Peter M. Shaw, PhD, Merck & Co.

Mladen V. Tzvetkov, MD, University of Greifswald

12:00 PM – 1:30 PM

LUNCH BREAK

1:30 PM – 3:00 PM

PATIENT FORUM

MODERATOR

Sue Abdel-Rahman, PharmD, KCMO

SPEAKERS

Rasika Karnik, MD, University of Chicago

Elizabeth Rutkowski, MD, Augusta University

Fiona Lowenstein

Lisa McCorkell, Patient-Led Research Collaboration



2:15 PM – 3:15 PM

SCIENTIFIC SESSION

Developing Therapy for Every Kid with Cancer

CHAIRS

Jason Moore, PharmD, US Food and Drug Administration

Clinton F. Stewart, PharmD, St. Jude Children's Research Hospital

SPEAKERS

Olivia Campagne, PharmD, PhD, Takeda

Deepa Bhojwani, MD, Children's Hospital Los Angeles

Danielle Leach, MPA, National Brain Tumor Society

3:15 PM – 3:45 PM

NETWORKING BREAK

3:45 PM – 4:30 PM

AWARD LECTURE

Sheiner-Beal Pharmacometrics Award Lecture

SPEAKER

René Bruno, PhD, Genentech

3:45 PM – 4:30 PM

AWARD LECTURE

Darrell Abernethy Award Lecture

SPEAKER

Matthew McLaughlin, MD, Children's Mercy Hospital

3:45 PM – 4:45 PM

SCIENTIFIC SESSION

Jabbing Clinical Pharmacology with Vaccines Boosted by Modeling and Simulation

CHAIRS

Jeffrey R. Sachs, PhD, Merck

Amy Cheung, PhD, Certara

SPEAKERS

Jérémie Guedj, PhD – Research Director, French Institute of Health and Medical Research

Stephen Greene, PharmD, Moderna

Jeffrey P. Perley, PhD, Merck

5:00 PM – 6:30 PM

Networking Reception

POSTER SESSION II



5:20 PM – 5:50 PM

POSTER WALK III: *Impact of Pharmacogenomics in Real World Setting*

5:55 PM – 6:25 PM

POSTER WALK IV: *Clinical Pharmacology Study Design and Data Analysis to Optimize Drug Utilization in Diverse Patient Populations*

6:30 PM – 7:30 PM

Donor Reception

By Invitation only

FRIDAY, MARCH 24, 2023

6:30 AM – 2:00 PM

ASCPT INFO DESK AND REGISTRATION OPEN

7:00 AM – 8:00 AM

Poster Session III

7:00 Am – 8:00 AM

Breakfast Available in the Poster Hall

8:15 AM – 9:00 AM

FEATURED SPEAKER

SPEAKER

Anne Heatherington, PhD, Takeda

8:15 AM – 9:00 AM

AWARD LECTURE

Rawls Palmer Progress in Medicine Award Lecture

SPEAKER

Mary Paine, PhD, RPh, Washington State University

8:15 AM – 9:15 AM

SCIENTIFIC SESSION

Moving the Needle for Enhancing Oncology Dose Optimization: A Fireside Chat with ASCPT's Scientific Thought Leadership

CHAIRS

Neeraj Gupta, PhD, Takeda

Karthik Venkatakrisnan, PhD, EMD Serono



SPEAKERS

Priya Jayachandran, PharmD, Pfizer
Piet Van der Graaf, PharmD, PhD, Certara
John Wagner, MD, PhD, Koneksa Health
Shirley Seo, PhD, US Food and Drug Administration

9:30 AM – 10:30 AM
STATE OF THE ART LECTURE
TBD

10:30 AM – 11:00 AM
NETWORKING BREAK

11:00 AM – 11:45 AM
AWARD LECTURE
Oscar B. Hunter Career Award in Therapeutics

SPEAKER
Janet Woodcock, MD, US Food and Drug Administration

11:00 AM – 12:00 PM
SCIENTIFIC SESSION
Diversity and Inclusion of Patient-Centric Clinical Evidence: Opportunities for Clinical Pharmacologists
CHAIRS
Sreeneeranj Kasichayanula, PhD, Gilead Sciences
Antari Khot, PhD, Takada

SPEAKERS
Donald Harvey, PharmD, Emory University
Melaina Boyce, EMD Serono
Anuradha Ramamoorthy, PhD, US Food and Drug Administration

12:00 PM – 1:30 PM
LUNCH

1:30 PM – 2:15 PM
AWARD LECTURE
Leon I. Goldberg Early Investigator Award Lecture

SPEAKER
Daniel Gonzalez, PharmD, PhD, University of North Carolina

1:30 PM – 2:30 PM
SCIENTIFIC SESSION
Translating QSP Modeling for All: Challenges in Communicating QSP



CHAIRS

Lulu Chu, PhD, Takeda
Eric Sobie, PhD, Mount Sinai

SPEAKERS

Dean Bottino, PhD, Takeda
Jingqi Gong, PhD, AbbVie
K. Melissa Hallow, PhD, University of Georgia

1:30 PM – 2:30 PM

SCIENTIFIC SESSION

Digital Biomarkers in Clinical Pharmacology: Advancing the Development of Precision Therapeutics

CHAIRS

Mathangi Gopalakrishnan, PhD, University of Maryland
Wei Yin, PhD, Takeda

SPEAKERS

Jasmin Imsirovic, PhD, Takeda
Gina Pastino, PhD, Cerevel Therapeutics
Andrew Potter, PhD, US Food and Drug Administration

2:30 PM – 3:00 PM

NETWORKING BREAK

3:00 PM – 4:00 PM

SCIENTIFIC SESSION

Regulatory, Operational, and Clinical Pharmacology Challenges of Conducting Clinical Trials in Low- and Middle-Income Countries

CHAIRS

Georgios Vlasakakis, PhD, GlaxoSmithKline
Katarina Ilic, MD, MPH, PhD, Takeda

SPEAKERS

Murray Lumpkin, MD, Bill & Melinda Gates Foundation
Jackson Mukonzo, PhD, Makerere University, Uganda

3:00 PM – 4:00 PM

SCIENTIFIC SESSION

Real-World Data Enabled by Advanced Data Analytics Towards More Accessible, Targeted, and Personalized Medicine

CHAIRS

Nadia Terranova, PhD, Merck Serono
Jackson Burton, PhD, Biogen

SPEAKERS



Jin Jin, PhD, Genentech
Olivier Michielin, MD, PhD, Lausanne University Hospital
Qi Liu, PhD, US Food and Drug Administration

3:00 PM – 4:00 PM
SPECIAL SESSION
Translating Your Story for All: Mastering Effective Communication Skills

CHAIRS:
Charul Avachat, MS, University of Minnesota