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
*Support Provided by Metrum

Chairs:

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

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

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

6:30 AM – 5:00 PM
ASCPT INFO DESK AND REGISTRATION OPEN

TUESDAY, MARCH 21, 2023

7:00 AM – 5:00 PM
Speaker Ready Room Open

8:00 AM – 5:00 PM
Registration Open

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
By Invitation Only

11:00 AM – 6:30 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
Disparities in Medication Consumption During Pregnancy: Lessons Learned from PowerMom

SPEAKER
Toluwalase Ajayi, MD, Scripps Research Translational 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

7:00 AM – 6:30 PM
ASCPT INFO DESK AND REGISTRATION OPEN

7:00 AM – 8:00 AM
BREAKFAST
**Coffee Sponsored by Certara*

8:15 AM – 9:15 AM
STATE OF THE ART LECTURE

Cynthia Whitney, MD, MPH, CHAMPS
Title TBD

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
XXX
SPEAKERS
Lorna Warwick, BA, Lymphoma Coalition
Chunze Li, PhD, Genentech
Salaheldin Hamed, PhD, US Food and Drug Administration

10:30 AM – 10:45 AM
Nuvisan Learning Lounge

10:30 AM – 11:00 AM
NETWORKING BREAK
*Brought To You By Merck

10:30 AM – 11:00 AM
Celerion Product Theater

11:00 AM – 11:45 AM
FEATURED SPEAKER
Richard Peck, MD, University of Liverpool
Precision Dosing For All: The Future of Clinical Pharmacology

11:00 AM – 11:45 AM
AWARD LECTURE
Leon I. Goldberg Early Investigator Award Lecture

SPEAKER
Jasmine Luzum, PharmD, PhD, University of Michigan
Race-Based Medicine: What It Is and What Is the Danger?

11:00 AM – 12:00 PM
SCIENTIFIC SESSION
Drug Transporter Pharmacogenomics – When It Matters and When It Doesn't

CHAIRS
Sook Wah Yee, PhD, 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

1:00 PM – 1:30 PM
Labcorp Product Theater

1:15 PM – 1:30 PM
Nova Learning Lounge

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, Journalist, Founder of BodyPolitic
Lisa McCorkell, Patient-Led Research Collaboration

STATE OF THE ART LECTURE

2:15 PM – 3:15 PM
SPEAKER
Priti Hegde, PhD, Foundation Medicine

3:15 PM – 3:45 PM
NETWORKING BREAK
**Brought to You by Takeda*

3:15 PM – 3:45 PM
Certara Learning Lounge

3:15 PM – 3:45 PM
Worldwide Clinical Trials Product Theater

3:45 PM – 4:30 PM
AWARD LECTURE
Sheiner-Beal Pharmacometrics Award Lecture
The Rising Role of Modeling in Oncology: A Journey from Learning to Confirming

SPEAKER
René Bruno, PhD, Genentech

3:45 PM – 4:30 PM

AWARD LECTURE
Darrell Abernethy Award Lecture
The Blood-Brain Barrier: The Last Frontier in Pharmacokinetics

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
President's 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 – 12:00 PM
ASCPT INFO DESK AND REGISTRATION OPEN

7:00 AM – 8:00 AM
Poster Session III
Late-Breaking, Encore, Trials-in-Progress
**Poster Hall Closes at 12:30 PM*

7:00 AM – 8:00 AM

Network/Community Networking Breakfast

8:15 AM – 9:00 AM
FEATURED SPEAKER
Embracing the Data and Digital Revolution of R&D

SPEAKER
Anne Heatherington, PhD, Takeda

8:15 AM – 9:00 AM
AWARD LECTURE
Rawls Palmer Progress in Medicine Award Lecture
Mixing Natural Products with Medicine: Is It Safe?

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 Venkatakrishnan, 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
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

10:30 AM – 10:45 AM

InsightRX Micro-Learning Lounge

10:30 AM – 11:00 AM
NETWORKING BREAK
*Brought To You By esqLABS

10:30 AM – 11:00 AM
Parexel Theater

11:00 AM – 11:45 AM
AWARD LECTURE
Oscar B. Hunter Career Award in Therapeutics
Drug Development: Yesterday, Today, Tomorrow

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
Application of Quantitative Pharmacology Approaches to Characterize the Influence of Age, Obesity, and Drug-Drug Interactions on Pharmacokinetics in the Pediatric Population

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 - Embracing Their Application to Advocate and Advance Personalized Treatment of CNS Disorders

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
Katarina Ilic, MD, MPH, PhD, Takeda
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

CHAIR:
Charul Avachat, MS, University of Minnesota