



## **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](mailto: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](http://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](http://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](mailto: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

Samira Jamalain, 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

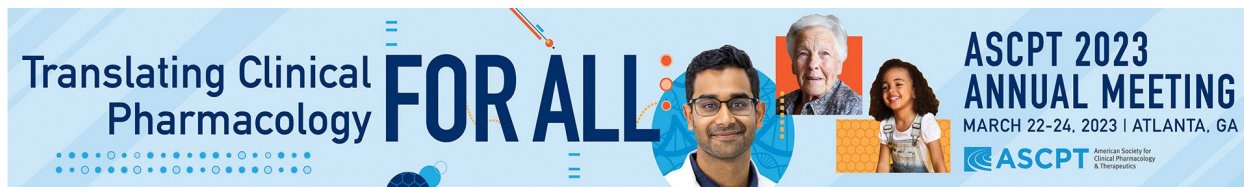
Wrap Up

## SPEAKER

Jing Liu, PhD, Pfizer



4:35 PM – 5:30 PM  
POSTERS AND REFRESHMENTS



## PRELIMINARY SCHEDULE AT A GLANCE

6:30 AM – 5:00 PM

ASCPT INFO DESK AND REGISTRATION OPEN

### 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

*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

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

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

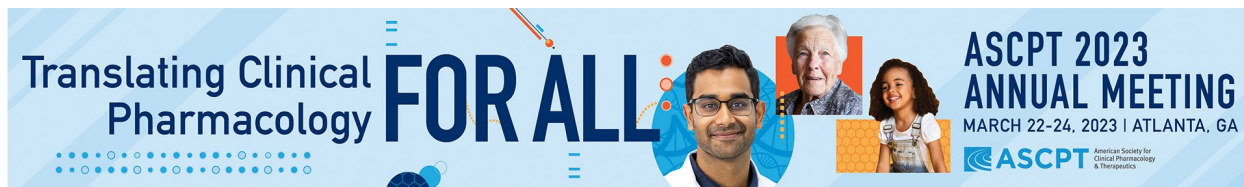
Michelle Campbell, PhD, US Food and Drug Administration

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

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**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

10:30 AM – 11:00 AM

Celerion Product Theater

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, 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

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  
*\*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

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

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

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

10:30 AM – 11:00 AM

Parexel Theater



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 - 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

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