ASCPT 2024 ANNUAL MEETING
THE BROADMOOR, COLORADO SPRINGS
MARCH 27 – 29, 2024

NEW HORIZONS
FOR GLOBAL OUTREACH

ASCPT
American Society for
Clinical Pharmacology
& Therapeutics

<u>Important Dates & General Information</u>

Wednesday, DECEMBER 20, 2023, 4:00 PM EDT
Early Bird Registration Deadline
Friday, JANUARY 25, 2024, 4:00 PM EDT
Advanced Registration Deadline
Wednesday, MARCH 6, 2024
Hotel Reservation Deadline

TARGET AUDIENCE
The intended audience for ASCPT 2024 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 Colorado Springs, 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.

PRE-CONFERENCE PROGRAMS

Empowering Clinical Pharmacologists and Translational Scientists Using Artificial Intelligence: Unlocking Potential with Cutting-Edge Use Cases

Tuesday, March 26, 2024, 8:30 AM – 5:30 PM

*Co-Sponsored by the IQ consortium AI/ML working group and Internal Society of Pharmacometrics (ISoP)

Chairs:
- Mohamed Shahin, PhD, Pfizer
- James Lu, PhD, Genentech
- C.J. Musante, PhD, Pfizer

For many years, clinical pharmacologists have been using mathematical models to represent physiological processes and explore the relationships between drugs and changes in PK/PD over time. The rapid advancements in imaging, diagnostics, computing, and communication technologies have created a vast data landscape that clinical pharmacologists now need to navigate.

While various Artificial Intelligence (AI) techniques have proven to be powerful computational approaches in other data-rich fields, their application in clinical pharmacology is still in its early stages. Implementing AI in clinical pharmacology and translational science holds the potential to develop more effective therapies and address patients' unmet clinical needs more efficiently and quickly. Demonstrating successful case studies and best practices of AI use by clinical pharmacologists and translational scientists is crucial for broader adoption in these fields, both regionally and globally.

This Pre-Conference will showcase different aspects of AI used in clinical pharmacology and translational science, including cutting-edge AI tools, commonly used data sources, and successful case studies and applications. We will feature interdisciplinary teams presenting how AI has improved prediction models in both clinical settings and drug development. Additionally, this Pre-Conference will explore the potential opportunities of using large language models like ChatGPT and other medical foundational models to establish a better paradigm for incorporating AI in clinical pharmacology and drug development.

Learning Objectives:

1. Upon completion, participants will gain insights into the various AI-driven applications in drug development, dosing optimization, translational science, biomarker discovery, and disease modeling.
2. Upon completion, participants will learn about potential applications of large language models in clinical pharmacology and translational sciences, including literature mining, hypothesis generation, and enhancing communications between stakeholders.
3. Upon completion, participants will understand the regional and international disparities that limit the wide adoption of AI in clinical pharmacology and translational science and potential solutions to promote global applications in these fields.

Tuesday, March 26, 2024, 8:30 AM – 5:30 PM

Clinical Trial Diversity & Inclusion: How Clinical Pharmacology Can Support the Implementation of Regulatory Guidance on Diversity Plans

Chairs:

- Aarti Sawant, PhD, AstraZeneca
- Rashmi Mehta, PhD, GlaxoSmithKline

In a recent FDA draft guidance (April 2022), the FDA recommends that sponsors developing investigational medical products enroll an adequate number of trial participants from under-represented populations and prepare a diversity plan. Generating a diversity plan in early clinical development can be a challenging task as safety and tolerability of investigational products across diverse populations is not fully established.

In this pre-conference, experts from industry, academia, IQ, and regulators will discuss how to utilize clinical pharmacology tools in drug development to implement the guidance and generate diversity plans. Case study presentations will demonstrate how clinical pharmacology concepts can be used to increase enrollment of under-represented populations in clinical trials by enhanced understanding of the disposition of molecules, performing risk assessments using M&S (determine restrictions on concomitant medications or in organ impairment), developing well-designed clinical trials (e.g. inclusion of Asian cohort in Phase 1 study), and applying technologies to enable DCT. An interactive workshop session will reinforce the key learning points of the presentations and case studies.

Learning Objectives:

1. Obtain an understanding of how to utilize clinical pharmacology tools to implement the guidance on diversity plans to increase the participation of under-represented populations in clinical trials.
2. Learn from case studies where clinical pharmacology practices have resulted in increased enrollment in subsequent trials.
3. Foster collaboration and advance the efforts towards increased diversity in clinical trials.

ASCPT Annual Meeting
PRELIMINARY SCHEDULE AT A GLANCE

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

TUESDAY, MARCH 26, 2024
7:30 AM – 5:00 PM
ASCPT INFO DESK AND REGISTRATION OPEN

8:30 AM – 5:30 PM
PRE-CONFERENCE
Empowering Clinical Pharmacologists and Translational Scientists Using Artificial Intelligence: Unlocking Potential with Cutting-Edge Use Cases

PRE-CONFERENCE
Clinical Pharmacology Concepts to Address the FDA Recommendation for a Clinical Trial Diversity Plan

WEDNESDAY, MARCH 27, 2024

11:00 AM – 6:30 PM
ASCPT INFO DESK AND REGISTRATION 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
Attaining Equity of Access to Research

SPEAKER
Catriona Waitt, PhD, University of Liverpool

THURSDAY, MARCH 28, 2024

7:00 AM – 6:30 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

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SPEAKER
Kelly Chibale, PhD, H3D Research Centre
Drug Discovery Out of Africa

9:30 AM – 10:30 AM
Deep Science Session
Meet the Expert: Real World Data in Drug Development and Utilization (Part 1)

CHAIRS
Naomi Gronich, MD, Technion
Mohamed Elmeliegy, PhD, Pfizer

SPEAKERS
Linda Kalilani, MSc, PhD, GlaxoSmithKline
Emily Bratton, MPH, PhD, IQVIA
Elisabetta Patorno, MD, PhD, Harvard Medical School

9:30 AM – 10:30 AM
SCIENTIFIC SESSION
Is Pharmacogenetic Testing a Vital Tool for Enhancing Therapeutic Management of Patients Worldwide?

CHAIRS
Piet van der Graaf, PhD, PharmD, Certara
Kathleen Giacomini, PhD, University of California, San Francisco

SPEAKERS
Henk-Jan Guchelaar, PharmD, PhD, Professor, Leiden University
David Greenblatt, MD, Professor, Tufts University
Karen Brown, PharmD, Research Scientist, University of Montana
Neil Hanchard, PhD, Clinician Investigator, National Institute of Health

9:30 AM – 10:30 AM
SCIENTIFIC SESSION
Transporter Research for Global Outreach: Unleashing the Power of Everything, Everywhere, All at Once

CHAIRS
Sook Wah Yee, PhD, University of California, San Francisco
Kit Wun Kathy Cheung, PharmD, Genentech

SPEAKERS
Vikram Arya, PhD, US Food and Drug Administration
Jashvant D. Unadkat, PhD, University of Washington
Sibylle Neuhoff, PhD, Certara

10:30 AM – 11:00 AM
NETWORKING BREAK

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11:00 AM – 11:45 AM
AWARD LECTURE
Leon Goldberg Early Investigator Award Lecture
Moving From Point-Based Analysis to Systems-Based Modeling: Integration of Knowledge to Address Antimicrobial Resistance

SPEAKER
Gauri Rao, PharmD, University of North Carolina

11:00 AM – 11:45 AM
FEATURED SPEAKER

SPEAKER
TBD

11:00 AM – 12:00 PM
SCIENTIFIC SESSION
Novel Advancements in the Treatment of Mood and Anxiety Disorders in Children and Perspectives on Implementation and Outreach in Underserved Communities

CHAIRS
Nithya Srinivas, PhD
Stephani Stancil, PhD, University of Missouri

SPEAKERS
Jeffrey Strawn, MD, University of Cincinnati
Stephani Stancil, PhD, University of Missouri
Arjun Athreya, PhD, Mayo Clinic
Erica L. Woodahl, PhD, University of Montana

11:00 AM – 12:00 PM
SCIENTIFIC SESSION
Equity, Data, and Representation in Real-World Clinical Trials and Virtual Populations

CHAIRS
Kyunghee Yang, PhD, Simulations Plus
Daniel Gonzalez, PharmD, PhD, Duke University

SPEAKERS
Jeffrey Woodhead, PhD, Simulations Plus
Murali Ramanathan, PhD, University at Buffalo

12:00 PM – 1:30 PM
LUNCH BREAK

1:30 PM – 3:00 PM
PATIENT FORUM

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MODERATOR
John Wagner, MD, PhD, Koneksa Health

SPEAKERS
Diane Stephenson, PhD, Critical Path Institute
Sarah Dolan, Patient
Qi Liu, PhD, US Food and Drug Administration

1:30 PM – 2:30 PM
Deep Science Session
Meet the Expert: Real World Data in Drug Development and Utilization (Part 2)

CHAIRS:
Naomi Gronich, MD, Technion
Mohamed Elmeliegy, PhD, Pfizer

SPEAKERS:
Linda Kalilani, MSc, PhD, GlaxoSmithKline
Emily Bratton, MPH, PhD, IQVIA
Elisabetta Patorno, MD, PhD, Harvard Medical School

3:00 PM – 3:00 PM
NETWORKING BREAK

3:30 PM – 4:30 PM
Oral Abstract I: Assessing Drug Safety in Special Populations

CHAIRS
Daniel Gonzalez, PharmD, PhD, Duke University
Elimika P. Pfuma Fletcher, PharmD, PhD, US Food and Drug Administration

3:30 PM – 4:30 PM
SCIENTIFIC SESSION
Harnessing the Power of Image-Based Biomarkers: Advancing Model-Informed Precision Medicine

CHAIRS:
Jagdeep Podichetty, PhD, Critical Path Institute
Nadia Terranova, PhD, Ares Trading S. A.

SPEAKERS:
Laurent Dercle, MD, PhD, Columbia University Irving Medical Center
Nadia Terranova, PhD, Director, Head of Advanced Data Analytics in Quantitative Pharmacology, Ares Trading S.A, an affiliate of Merck KGaA
Sarah Kim, PhD, University of Florida

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3:30 PM – 4:15 PM
AWARD LECTURE
Sheiner-Beal Pharmacometrics Award Lecture
Revolutionizing PK/PD Analysis through the Development of Modeling Software and Training

SPEAKER
Amy Racine-Poon, PhD, Novartis

3:30 PM – 4:15 PM
AWARD LECTURE
2023 Darrell Abernethy Early Stage Investigator Award Lecture
Quantifying the Effects of Age on Cannabidiol Dispositions

SPEAKER
Zhu Zhou, PhD, City University of New York

5:00 PM – 6:30 PM
President's Networking Reception

5:20 PM – 5:50 PM
POSTER WALK I

5:55 PM – 6:25 PM
POSTER WALK II

FRIDAY, MARCH 29, 2024

6:30 AM – 12:00 PM
ASCPT INFO DESK AND REGISTRATION OPEN

7:00 AM – 8:00 AM
Network/Community Networking Breakfast

8:15 AM – 9:00 AM
FEATURED SPEAKER

SPEAKER
Karthik Venkatakrishnan, PhD, EMD Serono Research & Development Institute, Inc
Opportunities for Quantitative Clinical Pharmacology from Translational to Global Drug Development

8:15 AM – 9:15 AM
SPECIAL SESSION
Unleashing Your Leadership Potential via Volunteering and Networking within ASCPT: A Journey of Growth

CHAIRS:

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Charul Avachat, MS, University of Minnesota
Mohamed Shahin, PhD, Pfizer

SPEAKERS:
Karen Rowland Yeo, PhD, Certara UK
Anuradha Ramamoorthy, PhD, US Food and Drug Administration
Shravani Etrouth, PharmD, Clinical pharmacist intern, AIG Hospitals
Sharon Swan, MS, CAE, CEO Emeritus, ASCPT

8:15 AM – 9:15 AM
SCIENTIFIC SESSION
Wheel of (Mis)Fortune: Global Partnerships to Tackle Pediatric Infectious Diseases

CHAIRS
Amy Cheung, PhD, Certara
Lionel Tan, MD, PhD, ViiV

SPEAKERS
TBD

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

SPEAKER
Delali Attiogbe Attipoe, DNDi
Living Lessons from Lab to Executive Leadership

10:30 AM – 11:00 AM
NETWORKING BREAK

11:00 AM – 11:45 AM
AWARD LECTURE
Oscar B. Hunter Career Award in Therapeutics
Transporters in Precision Medicine: From Orphans to Drug Targets

SPEAKER
Kathleen Giacomini, PhD, University of California, San Francisco

11:00 AM – 12:00 PM
SCIENTIFIC SESSION
ChatGPT

CHAIRS:
Suraj Bhansali, PhD, Excelra
Brian Cicali, PhD, University of Florida

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SPEAKERS:
Hao Zhu, PhD, US Food and Drug Administration
Paul Liang, MS, Carnegie Mellon University
Wesley Anderson, PhD, Critical Path Institute

11:00 AM – 12:00 PM
SCIENTIFIC SESSION
Fountain of Youth: Fighting Aging to Prevent Age-Related Diseases

CHAIRS:
Aline Barth, PhD, Pfizer
Lei Zhang, PhD, US Food and Drug Administration

SPEAKERS:
Aline Barth, PhD, Pfizer
Janice Schwartz, MD, Professor, University of California, San Francisco
James Kirkland, MD, PhD, Mayo Clinic

11:00 AM – 12:00 PM
SCIENTIFIC SESSION
Expanding Regulatory Science: Regulatory Complementarity & Reliance

CHAIRS:
Ted Grasela, PharmD, PhD, Azimuth Global Health Consulting
David Wesche, MD, PhD, Certara

SPEAKERS:
Jackson Mukonzo, PhD, Makerere University
Helen Ndagije, PhD, National Drug Authority
Yow-Ming Wang, PhD, US Food and Drug Administration
Ian Hudson, MD, Bill & Melinda Gates Foundation

12:00 PM – 1:30 PM
LUNCH

1:30 PM – 2:15 PM
AWARD LECTURE
Rawls-Palmer Progress in Medicine Award Lecture
Advancing Clinical Pharmacology with the Science of Hepatic Transporters: Impact on Drug Development and Patient Care

SPEAKER
Kim Brouwer, PharmD, PhD, University of North Carolina

1:30 PM – 2:30 PM
SCIENTIFIC SESSION

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Leveraging Artificial Intelligence and Machine Learning to Facilitate Individualized Precision Dosing

CHAIRS
Tomoyuki Mizuno, PhD, Cincinnati Children's Hospital Medical Center
Iris Minichmayr, PhD, Uppsala University

SPEAKERS
Jean-Baptiste Woillard, PharmD, PhD, Limoges University Hospital
Jasmin Hughes, PhD, InsightRX
Ethan Poweleit, BS, University of Cincinnati

1:30 PM – 2:30 PM
SCIENTIFIC SESSION
Expanding Horizons of Quantitative Clinical Pharmacology Globally- What to Expect and Get Ready for Next Decade?

CHAIRS:
Ravi Singh, PHD, Pfizer
Neeraj Gupta, PhD, Takeda

SPEAKERS:
Akintunde Bello, PhD, Bristol Myers Squibb
Amita Joshi, PhD, Genentech
Adeniyi Olagunju, PhD, University of Liverpool

1:30 PM – 2:30 PM
SCIENTIFIC SESSION
Psychedelics: New Horizons for the Treatment of Psychiatric Disorders that Deteriorate Global Human Health

CHAIRS:
Robert Stratford, Jr., PhD, Otsuka-US
Gina Pastino, PhD, Cerevel Therapeutics

SPEAKERS:
John McCorvy, PhD, Medical College of Wisconsin
Matthew Johnson, PhD, Johns Hopkins University

2:30 PM – 3:00 PM
NETWORKING BREAK

3:00 PM – 4:00 PM
Scientific Session
When AI Meets Drug Development

CHAIRS
Zhu Zhou, PhD, City University of New York
Liang Zhao, PhD, US Food and Drug Administration

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SPEAKERS
Zhu Zhou, PhD, City University of New York
Anshul Kanakia, PhD, AstraZeneca
Mark Sale, MD, Certara
Liang Zhao, PhD, US Food and Drug Administration

3:00 PM – 4:00 PM
SCIENTIFIC SESSION
Revolutionizing the Clinical Research for Long-Acting Injectables: What to Expect Globally?

CHAIRS
Navin Goyal, PhD, Janssen

SPEAKERS
Yuqing Gong, PhD, US Food and Drug Administration
Navin Goyal, PhD, Janssen
Susan Ford, PhD, GlaxoSmithKline

3:00 PM – 4:00 PM
Oral Abstract II: Impact of Pharmacogenetics in Real-Life Settings

CHAIRS
Virginia (Ginny) D. Schmith, PhD, Schmith PK/PD Consulting LLC
Akinyemi O. Oni-Orisan, PharmD, PhD, University of California, San Francisco

3:00 PM – 4:00 PM
PUBLIC POLICY AND INNOVATION IN DRUG DEVELOPMENT