



## **Important Dates & General Information**

**THURSDAY, DECEMBER 12, 2019, 4:00 PM EDT**

Early Bird Registration Deadline

**FRIDAY, JANUARY 17, 2020, 4:00 PM EDT**

Advanced Registration Deadline

**MONDAY, FEBRUARY 24, 2020**

Hotel Reservation Deadline

### **TARGET AUDIENCE**

The intended audience for ASCPT 2020 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. 108 or 109 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. Booking information will be provided in registration confirmations. For detailed information regarding Annual Meeting registration, securing housing, and travel information for Houston, TX, 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 EXHIBIT HALL AND PARTNERSHIP**

The Exhibit Hall offers innovative ways for attendees to experience the latest and greatest tools and services for the clinical pharmacology and translational medicine field. Interested in learning more about becoming an exhibitor or a sponsoring partner? Contact [dyanne@ascpt.org](mailto:dyanne@ascpt.org) for exhibitor opportunities or [lisa@ascpt.org](mailto:lisa@ascpt.org) for sponsor opportunities.

### **ASCPT REPLAY: ANNUAL MEETING ON-DEMAND**

Take ASCPT home with you! All attendees will receive complimentary access to our exclusive, online digital library featuring the best of the ASCPT 2020 Annual Meetings with ASCPT Replay! Enjoy sessions you may have missed with access to an online digital library of key sessions presented at the Meeting. Experience side-by-side video and slide presentations of sessions including State of the Art lectures, Featured Speakers, Patient Forum, and other select content.



## PRE-CONFERENCE PROGRAMS

### MID3 Rollercoaster Workshop

Wednesday, March 18, 2020

8:00 AM – 5:00 PM

Marriott Marquis in Houston, TX

#### Chairs

Sandra Visser, PhD, GlaxoSmithKine

Sriram Krishnaswami, PhD, Pfizer

#### Why You Should Attend!

Welcome and step aboard the Model-informed Drug Discovery and Development (MID<sup>3</sup>) Rollercoaster Workshop where you will experience the highs and lows of (hyper) accelerated drug development. Ten teams of ten participants each will take a small molecule from first in human through to Phase 3 (maybe) with real-time trial execution! This unique workshop will offer attendees an opportunity to submerge themselves in developing a drug and decision-making around this. Participants will gain learnings with respect to decision-making around trial design, dose and schedule selection, therapeutic benefit vision relative to standard of care, changing competitive landscape, and go/no go decisions.

#### Format:

- The format would be new, interactive, various scenarios, dynamic with real time simulations
- At each decision point, some key concepts around interpretation, extrapolation, and decision-making tools will be laid out and discussed in addition to each team rationalizing their decisions.
- Clinical pharmacology understanding is critical to the determination of the optimal dose.
- Emerging external data from competitors and backup compounds will be added to the mix.
- Semi-competitive element by keeping a score on decisions that have impact on costs and time.

#### High Level Summary of Workshop

Teams will start with the following:

- Simulated Phase 1 results for PK + Biomarker for single and repeated dose will be distributed
- Distribute Phase 2a (POC) results for PK + Biomarker + clinical endpoint + safety info
- Distribute Phase 2b (dose ranging) results for PK + Biomarker + clinical endpoint + safety info
- Distribute Phase 3 results for Efficacy and Safety

Attendance for the Pre-Conference is limited to 100 attendees. Register early to secure your seat!



## PRE-CONFERENCE PROGRAMS (continued)

### Translational and Clinical Pharmacology Advances in Anti-infective Development

Wednesday, March 18, 2020

8:00 AM – 5:00 PM

Marriott Marquis in Houston, TX

#### Chairs

Matthew Rizk, PhD, Merck

Melanie Nicol, PharmD, PhD, University of Minnesota

#### Why You should Attend!

This Pre-Conference will focus on the role of translational approaches in anti-infective development and clinical pharmacology considerations. The aim is to bring together individuals interested in anti-infective translational approaches, QSP models, and clinical characterization of special populations.

This Pre-Conference will also feature a poster session!

#### Tentative Agenda:

- 8:00 AM – 8:30 AM – Opening remarks and introductions
- 8:30 AM – 9:15 AM – Keynote #1: the pivotal role of translation in anti-infective development
- 9:15 AM – 9:40 AM – Speaker #1: current practices in the design and interpretation of *in vitro* and animal models for anti-infective PK/PD
- 9:40 AM – 10:05 AM – Novel approaches in mechanistic and QSP models in anti-infective development
- 10:05 AM – 10:20 AM – Break
- 10:20 AM – 10:45 AM – Assessing combination drug products
- 10:45 AM – 11:30 AM – Panel discussion on translational approaches and the growing role of systems models
- 11:30 AM – 12:00 PM – Trainee and/or early career presentations
- 12:00 PM – 1:30 PM – Networking lunch and Poster Session
- 1:30 PM – 2:15 PM – Special populations and novel clinical methodologies for anti-infectives
- 2:15 PM – 2:40 PM – Use of innovative trial designs in anti-infective development
- 2:40 PM – 3:05 PM – Regulatory considerations and streamlined pathways for anti-infectives
- 3:05 PM – 3:20 PM – Break
- 3:20 PM – 3:45 PM – Understanding patient characteristics and impact on PK/PD
- 3:45 PM – 4:10 PM – The role of therapeutic drug monitoring and personalized dosing in anti-infectives
- 4:10 PM – 5:00 PM – Panel discussion on clinical development of anti-infectives and ensuring a robust data package



## PRELIMINARY SCHEDULE AT A GLANCE

### WEDNESDAY, MARCH 18, 2020

8:00 AM – 5:00 PM

PRE-CONFERENCE

*MID3 Rollercoaster Workshop*

8:00 AM – 5:00 PM

PRE-CONFERENCE

*Translational and Clinical Pharmacology Advances in Anti-infective Development*

4:30 PM – 6:30 PM

EXHIBIT AND POSTER HALL OPEN

5:00 PM – 6:30 PM

OPENING RECEPTION

POSTER SESSION: LATE-BREAKING, ENCORE, AND PRESIDENTIAL TRAINEE POSTERS

7:00 PM – 9:00 PM

DESIGN YOUR OWN SESSION

*Trainee Career Path Exploration and Networking Session*

#### **Chairs**

Kim L.R. Brouwer, PharmD, PhD, University of North Carolina

Scott A. Waldman, MD, PhD, Thomas Jefferson University

David Y. Mitchell, PhD, Nuventra, Inc.

#### **SPEAKERS**

Sandra Visser, PhD, GlaxoSmithKline

Kellie Schoolar Reynolds, PharmD, PhD

### THURSDAY, MARCH 19, 2020

6:30 AM – 5:00 PM

ASCPT INFO DESK AND REGISTRATION OPEN

7:00 AM – 8:00 AM

BREAKFAST

8:00 AM – 10:00 AM

OPENING SESSION - STATE OF THE ART LECTURE



9:00 AM – 1:30 PM  
EXHIBIT AND POSTER HALL OPEN

10:00 AM – 10:30 AM  
MORNING BREAK

10:00 AM – 10:30 AM  
FEATURED SPEAKER  
Steven Ryder, MD, Rallybio

10:00 AM – 10:30 AM  
AWARD LECTURE  
Rawls-Palmer Progress in Medicine Award Lecture

10:00 AM – 10:30 AM  
NOVEL FORMAT  
*Challenges and Opportunities in Implementation of Joint Adolescent-Adult Early Phase Oncology Trials: Integrating Progress Made and Lessons Learned so Far*

**Chairs**

Rajendar K. Mittapalli, PhD, Pfizer Inc.  
Suresh Agarwal, PhD, RPh, Amgen Inc.

**SPEAKERS**

Lia Gore, MD, University of Colorado  
Qi Liu, PhD, US Food and Drug Administration  
Su young Kim, MD, PhD, AbbVie Inc.

12:00 PM – 1:00 PM  
LUNCH

1:00 PM – 2:30 PM  
PATIENT FORUM

1:00 PM – 2:30 PM  
NOVEL FORMAT  
*Moving Pharmacogenomics into Practice: It's All About the Evidence!*

**Chairs**

Larisa H. Cavallari, PharmD, University of Florida  
Natasha J. Petry, PharmD, BCACP, North Dakota State University



#### SPEAKERS

Jasmine Luzum, PharmD, PhD, University of Michigan

Michael Pacanowski, PharmD, MPH

Joe Walker, PharmD, Celgene

Annette Taylor, PhD, LabCorp

1:00 PM – 2:00 PM

#### AWARD LECTURE

Sheiner-Beal Pharmacometrics Award Lecture

1:30 PM – 2:30 PM

#### ORAL ABSTRACT

2:30 PM – 2:45 PM

#### AFTERNOON BREAK

2:45 PM – 3:45 PM

#### AWARD LECTURE

Leon I. Goldberg Early Investigator Award Lecture

2:45 PM – 4:45 PM

#### SYMPOSIUM

*Overcoming Tumor Resistance in Cancer Therapy: Applying Evolutionary Principles from Bench to Bedside*

#### Chairs

Yan Ji, PhD, Novartis Institutes for Bio-Medical Research

Yanguang Cao, PhD, University of North Carolina

#### SPEAKERS

Thomas McDonald, PhD, Dana-Farber Cancer Institute

Robert Gatenby, MD, Moffitt Cancer Center

Jeffrey A. Engelman, MD, PhD, Novartis Oncology

2:45 PM – 4:45 PM

#### SYMPOSIUM

*Promise and Challenge of Real-World Data for Inferences on Drug Safety and Efficacy*

#### Chairs

Almut Winterstein, RPh, PhD, University of Florida

Anne Heatherington, PhD, Takeda Pharmaceuticals

#### SPEAKERS

Emily Brouwer, MPH, PharmD, PhD, Takeda Pharmaceuticals

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

Pascal Chanu, PharmD, Genentech, Roche



2:45 PM – 4:45 PM

SYMPOSIUM

*Vaccine R&D Gets a Shot from Pharmacometrics*

**Chairs**

Nitin Mehrotra, PhD, Merck & Co.

Sophie Rhodes, PhD, London School of Hygiene and Tropical Medicine

**SPEAKERS**

Jeff Sachs, PhD, Merck & Co.

Xiaoying Chen, PhD, Pfizer Inc.

Michael White, PhD, Institut Pasteur

4:30 PM–6:30 PM

EXHIBIT AND POSTER HALL OPEN

5:00 PM – 6:30 PM

PRESIDENT'S NETWORKING RECEPTION

POSTER SESSION

**FRIDAY, MARCH 20, 2020**

7:00 AM – 8:00 AM

BREAKFAST

7:15 AM – 8:45 AM

SCIENCE AT SUNRISE

*Big Drug Data: A Guide to Utilizing Electronic Health Records for Clinical Pharmacology Research*

**Chairs**

Caitrin W. McDonough, PhD, University of Florida

Jason Karnes, PharmD, PhD, The University of Arizona

**SPEAKERS**

Leena Choi, PhD, Vanderbilt University Medical Center

Dana Crawford, PhD, Case Western Reserve University

7:15 AM – 8:45 AM

SCIENCE AT SUNRISE

*Recent Advances in the Use of Liquid Biopsies in Personalized Medicine Towards Cancer Detection, Genotyping and PK-PD Analysis*

**Chairs**

Karthick Vishwanathan, PhD, AstraZeneca

Elimika Pfuma Fletcher, PhD, US Food and Drug Administration



**SPEAKERS**

Micheal Cheng, MD, Dana Farber Cancer Institute  
Minetta Liu, MD, Mayo Clinic  
Ganesh Mugundu, MPharm, PhD, AstraZeneca

7:00 AM – 1:30 PM  
EXHIBIT AND POSTER HALL OPEN

9:00 AM – 10:00 AM  
STATE OF THE ART LECTURE

10:00 AM – 10:30 AM  
MORNING BREAK

10:30 PM – 12:30 PM  
SYMPOSIUM  
*Clinical Pharmacology Worldwide: A Global Health Perspective*

**Chairs**

Larissa Wenning, PhD, Merck  
Jennifer Hibma, PharmD, Pfizer

**SPEAKERS**

Colin Pillai, PhD, CP+ Associates  
Katarina Ilic, MD, PhD, Takeda  
Howard McLeod, PharmD, DeBartolo Family Personalized Medicine Institute  
Pierre Theodore, MD, Johnson & Johnson

10:30 PM – 12:30 PM  
SYMPOSIUM  
*Challenging the Status Quo: Innovating the Landscape for Drug Development for Neurodegenerative Diseases*

**Chairs**

Nitin Mehrotra, PhD, Merck  
Kevin Krudys, PhD, Division of Neurology Products, FDA

**SPEAKERS**

Aubrey Stoch, MD, Merck  
Josh Cosman, PhD, Biogen  
Viji Chelliah, PhD, Certara

10:30 PM – 12:30 PM  
SYMPOSIUM  
*Artificial Intelligence: From Buzzword to Useful Tool in Clinical Pharmacology - What a Clinical Pharmacologist Needs to Know*





### **Chairs**

Aline Barth, PhD, GlaxoSmithKline

Daniele Ouellet, PhD, Pfizer

### **SPEAKERS**

Navin Goyal, PhD, GlaxoSmithKline

Jagdeep Podichetty, PhD, Critical Path Institute

Jin Jin, PhD, Genentech

Mohamed Shahin, PhD, Pfizer Inc.

12:30 PM - 1:30 PM

LUNCH

1:30 AM – 2:30 PM

STATE OF THE ART LECTURE

2:45 PM – 3:45 PM

AWARD LECTURE

Oscar B. Hunter Career Award Lecture

2:45 PM – 3:45 PM

FEATURED SPEAKER

CJ Musante, PhD, Pfizer

2:45 PM – 3:45 PM

ORAL ABSTRACT

3:45 PM – 4:00 PM

AFTERNOON BREAK

4:00 PM – 5:00 PM

ORAL ABSTRACT

4:00 PM – 5:00 PM

WORKSHOP/ ROUNDTABLE

*Marijuana for Medical Use: Scientific and Regulatory Challenges*

### **Chairs**

Lei Zhang, PhD, US Food and Drug Administration

Zhu Zhou, PhD, University of the Pacific

### **SPEAKERS**

Tory Spindle, PhD, Johns Hopkins University School of Medicine

Mary Paine, PhD, Washington State University

Shiew-Mei Huang, PhD



4:00 PM – 5:00 PM

SYMPOSIUM

*Novel Modalities - The New Frontier for Innovative Clinical Pharmacology Strategies*

**Chairs**

Yow-Ming C. Wang, PhD, US Food and Drug Administration

Chunze Li, PhD, Genentech

SPEAKERS

Weirong Wang, PhD, Janssen BioTherapeutics

Kai-Hsin (Ken) Liao, PhD, Pfizer Inc.

Matt Hsu, PhD, Amgen

Xiaofei Wang, PhD, US Food and Drug Administration

**SATURDAY, MARCH 21, 2020**

7:30 AM – 9:00 AM

SCIENCE AT SUNRISE

*Epigenetic Effects in Interindividual Variability in Drug Response: From Discovery to Clinical Implementation*

**Chairs**

Gabriele Stocco, PhD, University of Trieste

Paulien Ravenstijn, PhD, Janssen Research & Development

SPEAKERS

William Evans, PharmD, St. Jude Children's Research Hospital

Todd Skaar, PhD, Indiana University

Hannah C. Ainsworth, PhD, Wake Forest University Health Sciences

7:30 AM – 9:00 AM

SCIENCE AT SUNRISE

*2020 Vision: It's Time to Challenge the Conventional Organ Impairment Studies?*

**Chairs**

Ying Ou, PhD, Beigene

Jitendra Kanodia, Theravance Biopharma Inc.

SPEAKERS

Richard Graham, PhD, Theravance Biopharma

Raj Madabushi, PhD, US Food and Drug Administration

9:15 AM – 11:15 AM

SYMPOSIUM

*Translational PK/PD and Clinical Pharmacology Considerations for the Development of T-Cell Dependent Bispecific (TDB) Therapeutic Antibodies in Immuno-oncology*



### **Chairs**

Yow-Ming C. Wang, PhD, FDA

Yu-Nien (Tom) Sun, PhD, Janssen Research & Development LLC.

### **SPEAKERS**

Saileta Prabhu, PhD, Genentech

Songmao Zheng, PhD, Janssen Research & Development, LLC.

Dhaval K. Shah, PhD, University at Buffalo

Olanrewaju Okusanya, PharmD, US Food and Drug Administration

9:15 AM – 11:15 AM

### **SYMPOSIUM**

*Contemporary Issues in Drug Safety, Presented by the Sternfels Prize*

### **Chairs**

Christina R. Chow, PhD, Emerald Lake Safety

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

### **SPEAKERS**

Thomas Roth, PhD, Wayne State University

Robert Plenge, MD, PhD, Celgene

9:15 AM – 11:15 AM

### **SYMPOSIUM**

*Innovations in Clinical Pharmacology and Therapeutics for Mental Health and Addiction Disorders: Applying Artificial Intelligence and Model-based Approaches*

### **Chairs**

Vijay A. Ramchandani, PhD, NIH

Joga Gobburu, PhD, MBA, University of Maryland

### **SPEAKERS**

Arjun Athreya, PhD, Mayo Clinic

Mathangi Gopalakrishnan, MPharm, PhD, University of Maryland

Albert Burgess-Hull, PhD, National Institute on Drug Abuse Intramural Research Program

11:30 AM – 12:30 PM

### **ORAL ABSTRACT**

11:30 AM – 12:30 PM

### **ORAL ABSTRACT**

11:30 AM – 1:00 PM

### **NOVEL FORMAT**

*Current Landscape of Precision Medicine Clinics: Approaches from Various Practitioners to Improve the Fit of those Genes!*



**Chairs**

Meghan J. Arwood, PharmD, University of Florida  
Peter H. O'Donnell, MD, The University of Chicago

**SPEAKERS**

Russ B. Altman, MD, PhD, Stanford University  
Gillian C. Bell, PharmD, Mission Health  
Marci L. Schwartz, MS, Geisinger Genomic Medicine Institute