PBPK Modeling for the Development and Approval of Locally Acting Drug Products
MARCH 13, 2019 • 8:00 AM – 5:00 PM

Advancing QSP Toward Predictive Drug Development: From Targets to Treatments
MARCH 13, 2019 • 8:00 AM – 5:00 PM
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Dear Colleague,

I am eagerly awaiting the 2019 Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT) at the Marriott Wardman Park in Washington, DC, and so should you. The ASCPT Annual Meeting is the premier scientific event for scientists in clinical pharmacology and translational medicine, and 2019 promises to be the best meeting yet! The theme of the 2019 Annual Meeting is From Molecule to Patient.

The Scientific Program Committee, chaired by Piet H. van der Graaf, PhD, PharmD, has organized a cutting-edge program that addresses emerging clinical pharmacology and translational medicine issues that span the continuum of drug discovery, development, regulation, and utilization. The exciting line-up includes two outstanding Pre-Conference programs—PBPK Modeling for the Development and Approval of Locally Acting Drug Products and Advancing QSP Toward Predictive Drug Development: From Targets to Treatments. We are also pleased to bring back the very popular State of the Art lectures and the Innovation Forum, as well as a new session format, the Patient Forum, which bridges innovation in clinical pharmacology and therapeutics to the needs and perspectives of patients.

The program includes several sessions and special events that will focus on career development for students and trainees, as well as attendees at all levels of their careers, including Speed Mentoring, Clinical Pharmacology Workforce Skills and Networking: Postdoctoral Fellow/Trainee Career Path Exploration and Career Exploration and Transition Beyond Traditional Roles. 2019 will also feature the return of a live competition, Snake Pit: Grant Me the Money!, where teams will compete using approaches such as modeling and simulation to convince a panel of agency experts about the validity of their grant proposal.

ASCPT will continue its tradition of honoring those who have made remarkable contributions in the fields of clinical pharmacology and translational medicine. This year’s award recipients are Mary Relling, PharmD; Sara Van Driest, MD, PhD; J. Steven Leeder, PharmD, PhD; Joga Gobburu, PhD; Danjela Gnijdic, PhD, MPH; John Wagner, MD, PhD; Srim Krishnaswami, PhD; Christine Garnett, PharmD; and Deanna L. Kroetz, PhD. These outstanding individuals will be recognized during the Opening Session and throughout the Annual Meeting.

We will feature more than 300 Scientific Posters, Symposia, Workshops, Science at Sunrise, and Roundtable/Novel format sessions. Our Exhibit Hall includes companies featuring the latest products and solutions applicable to clinical pharmacology and translational medicine professionals.

I remind you to make your hotel reservation at the official headquarters hotel, the Marriott Wardman Park, before February 18, 2019. A special block of rooms has been reserved at the Marriott Wardman Park for our student/trainee attendees. If you are attending one of the Pre-Conferences, a special housing block at the Washington Hilton, which is less than a mile from the host hotel, Marriott Wardman Park, where the Pre-Conferences will take place, has been arranged for the night of March 12, 2019.

The ASCPT Annual Meeting is a premier location to experience and learn about emerging science and to network with colleagues from around the world. I look forward to you joining me in Washington, DC, this March!

Sincerely,

Dan Hartman, MD
PRESIDENT
THANK YOU!

ASCPT WOULD LIKE TO ACKNOWLEDGE AND THANK THE 2018–2019 SCIENTIFIC PROGRAM COMMITTEE FOR THEIR CONTRIBUTIONS TO THE 2019 ANNUAL MEETING.

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Ping Zhao, PhD

ASCPT WOULD LIKE TO ACKNOWLEDGE AND THANK THE 2018–2019 BOARD OF DIRECTORS FOR THEIR CONTRIBUTIONS, TIME, AND DEDICATION TO THE SOCIETY.

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Lei Zhang, PhD
Director

IMPORTANT DATES

THURSDAY, DECEMBER 13
Early Bird Registration Deadline

THURSDAY, JANUARY 17
Advanced Registration Deadline

MONDAY, FEBRUARY 18
Hotel Reservation Deadline
GENERAL INFORMATION

TARGET AUDIENCE
The intended audience for ASCPT 2019 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. 109 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. Booking information will be provided in registration confirmations.

For detailed information regarding Annual Meeting registration, securing housing, and travel information for Washington, DC, visit www.ascpt.org.

ASCPT CAREER CENTER
Looking for new job opportunities or recruiting for open positions? The ASCPT Career Center is designed to connect attendees with new employment opportunities, as well as assist companies with finding the qualified candidates they are searching for. Visit www.ascpt.org or email members@ascpt.org for details.

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 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 lisa@ascpt.org.
PBPK MODELING FOR THE DEVELOPMENT AND APPROVAL OF LOCALLY ACTING DRUG PRODUCTS

WEDNESDAY, MARCH 13, 2019 | 8:00 AM – 5:00 PM

Sponsor: ASCPT

This Pre-Conference will address challenges in developing physiologically-based pharmacokinetic (PBPK) models for locally acting drug products and using them during drug development and demonstration of bioequivalence (BE). The Pre-Conference will update the community with the latest progress in understanding drug distribution and delivery of locally acting drug products by PBPK modeling, stimulate discussion, and foster collaborations, especially with a focus on the following routes of delivery: inhalation, topical, ophthalmic, and other non-oral routes. The recent advancement of PBPK models offers a great opportunity to address the existing scientific challenges and regulatory needs across the product lifecycle.

Chairs: Liang Zhao, PhD, and Ping Zhao, PhD

8:00 AM – 8:05 AM
Introduction and Objectives
Liang Zhao, PhD
US Food and Drug Administration,
Silver Spring, MD
Ping Zhao, PhD
Bill & Melinda Gates Foundation,
Seattle, WA

8:05 AM – 8:20 AM
Opening Remarks: Challenges and Critical Role of PBPK for Locally Acting Drug Products in Regulatory Decisions
SPEAKER
Robert Lionberger, PhD
US Food and Drug Administration,
Silver Spring, MD

SESSION 1: ORALLY INHALED AND NASAL DRUG PRODUCTS

Moderators: Myong-Jin Kim, PharmD, and Robin O’Connor-Semmes, PhD

8:20 AM – 8:40 AM
Using PBPK to Link Systemic PK to Local Delivery in the Lung
SPEAKER
Guenther Hochhaus, PhD
University of Florida, Gainesville, FL

8:40 AM – 9:00 AM
CFD Lung Models for Drug Delivery
SPEAKER
Ching-Long Lin, PhD
University of Iowa, Iowa City, IA

9:00 AM – 9:20 AM
Application of PBPK Modeling for Inhalativa: Potential and Challenges
SPEAKER
Michael Block, PhD
Bayer, Leverkusen, Germany

9:20 AM – 9:40 AM
Impact of Orally Inhaled and Nasal Drug Product PBPK Models on Product Development and Regulatory Decision Making
SPEAKER
Ross Walenga, PhD
US Food and Drug Administration,
Silver Spring, MD

9:40 AM – 10:05 AM
Session Discussion

10:05 AM – 10:20 AM
Break

SESSION 2: DERMAL DRUG DELIVERY

Moderators: Min Li, PhD, and Lakshmi Vasist, PharmD

10:20 AM – 10:40 AM
Skin Physiology and Clinical Considerations for PBPK Models of the Skin
SPEAKER
Howard Maibach, MD
University of California, San Francisco, San Francisco, CA

10:40 AM – 11:00 AM
PBPK Models of the Skin (Considering Dosage Form Properties)
SPEAKER
Michael Roberts, PhD, DSc
University of South Australia and The University of Queensland Australia, Queensland, Australia

11:00 AM – 11:20 AM
PBPK Modeling of Dermally Applied Drug Products to Support Clinical Development and Regulatory Assessment
SPEAKER
Nikunjkumar Patel, PhD
Simcyp (A Certara Company), Sheffield, United Kingdom

11:20 AM – 11:40 AM
PBPK Modeling for the Development of Dermatological Drug Products and its Regulatory Impact
SPEAKER
Eleftheria Tsakalozou, PhD
US Food and Drug Administration, Silver Spring, MD

11:40 AM – 12:05 PM
Session Discussion

12:05 PM – 1:30 PM
Networking Lunch, and Poster Session
Poster Presentations
PRE-CONFERENCE PROGRAMS

SESSION 3: OPHTHALMIC DRUG PRODUCTS
Moderators: Xinyuan Zhang, PhD, and David Wesche, MD, PhD

1:30 PM – 1:50 PM
An Integrated Multiscale-Multiphysics Modeling of Ocular Drug Delivery and Pharmacokinetics
SPEAKER
Andrzej Przekwas, PhD
CFD Research Corporation, Huntsville, AL

1:50 PM – 2:10 PM
Developing PBPK for Ocular Delivery
SPEAKER
Michael B. Bolger, PhD
Simulations Plus, Lancaster, CA

2:10 PM – 2:30 PM
Use of PBPK Model to Evaluate Impact of Ophthalmic Drug Product’s Critical Quality Attributes on BA/BE Assessment
SPEAKER
Andrew Babiskin, PhD
US Food and Drug Administration, Silver Spring, MD

2:30 PM – 2:55 PM
PANEL DISCUSSION

2:55 PM – 3:15 PM
BREAK AND POSTER SESSION

SESSION 4: METHODS AND IMPLEMENTATION CHALLENGES
Moderators: Ping Zhao, PhD, and Lei Zhang, PhD

3:15 PM – 3:30 PM
European Experience of Biopharmaceutical Applications of PBPK Models
SPEAKER
Susan Cole, PhD
Medicines & Healthcare Products Regulatory Agency, London, United Kingdom

3:30 PM – 3:50 PM
Challenges in Using PBPK Models for Locally Acting Drug Products to Inform Regulatory Decision Makings
SPEAKER
Liang Zhao, PhD
US Food and Drug Administration, Silver Spring, MD

3:50 PM – 4:50 PM
PANEL DISCUSSION

4:50 PM – 5:00 PM
CONCLUDING REMARKS
ADVANCING QSP TOWARD PREDICTIVE DRUG DEVELOPMENT:
FROM TARGETS TO TREATMENTS

WEDNESDAY, MARCH 13, 2019 | 8:00 AM – 5:00 PM

Co-Sponsors: ASCPT, Innovation & Quality Consortium, and the International Society of Pharmacometrics (ISoP)
Chairs: Cynthia J. Musante, PhD, Jane Bai, PhD, and Suzana Petanceska, PhD

OVERVIEW:
Quantitative Systems Pharmacology (QSP) is an emerging field with increasing utilization in recent years. This full-day Pre-Conference will focus on applications of QSP in drug discovery, development, and regulatory reviews. Through presentations and panel discussions, this session aims to raise awareness amongst scientists and decision-makers in academia, the pharmaceutical and biotech industries, and regulatory/funding agencies on:

• The potential value of QSP in drug discovery, development, and review, as illustrated by recent case study examples;
• Real and perceived technical and operational challenges to implementing a QSP approach; and
• Roadblocks and opportunities for greater adoption and acceptance.

This session is aimed for a broad audience; if you are a clinician, executive, scientist, or part of a drug discovery or development team, please join us to find out how QSP can improve decision-making from targets to treatments.

8:00 AM – 8:15 AM
OPENING REMARKS
Jane Bai, PhD
US Food and Drug Administration, Silver Spring, MD
Cynthia J. Musante, PhD
Pfizer, Cambridge, MA
Suzana Petanceska, PhD
National Institutes of Aging/National Institutes of Health, Bethesda, MD

8:15 AM – 10:15 AM
SESSION 1: INTRODUCTION AND CURRENT STATUS OF QSP
Introduction to QSP in Drug Discovery and Development: a Historical, Current and Future Perspective
SPEAKER
Piet H. van der Graaf, PhD, PharmD
Certara, Canterbury, United Kingdom

Developing a Knowledge Base and Infrastructure to Enable QSP for Alzheimer's Disease Research and Drug Development
SPEAKER
Suzana Petanceska, PhD
National Institutes of Aging/National Institutes of Health, Bethesda, MD

Trends Towards the Industrialization of Quantitative Systems Pharmacology in Drug Research & Development
SPEAKER
Vikram P. Sinha, PhD
Merck Research Laboratories, Merck & Co., Upper Gwynedd, PA

Quantitative Systems Pharmacology at the US Food and Drug Administration: From Aspiration to Translation
SPEAKER
Issam Zineh, PharmD
US Food and Drug Administration, Silver Spring, MD

10:15 AM – 10:45 AM
BREAK

10:45 AM – 12:00 PM
SESSION 2: RECENT QSP APPLICATIONS IN DRUG DISCOVERY AND DEVELOPMENT & DECISION-MAKING
Talk Title TBA
SPEAKER
Joel Dudley, PhD
Mount Sinai, New York, NY

Recent Applications of Quantitative Systems Pharmacology in IQ Consortium: From Data to Decisions
SPEAKER
Mindy Magee, PharmD
GlaxoSmithKline, Collegeville, PA

Regulatory Perspectives on QSP
SPEAKER
Yaning Wang, PhD
US Food and Drug Administration, Silver Spring, MD

12:00 PM – 12:45 PM
NETWORKING LUNCH

12:45 PM – 2:00 PM
POSTER SESSION
2:00 PM – 3:00 PM
SESSION 3: QSP MODEL ASSESSMENT IN DRUG DISCOVERY, DEVELOPMENT & DECISION-MAKING

Needs and Approaches for Model Assessment & Qualification: A Pharma Perspective
SPEAKER
Saroja Ramanujan, PhD
Genentech, South San Francisco, CA

Development and Validation of a Quantitative Systems Pharmacology Model for In Silico Cardiac Safety Assessment under the CiPA Initiative
SPEAKER
Zhihua Li, PhD
US Food and Drug Administration, Silver Spring, MD

3:00 PM – 4:30 PM
POINT-COUNTERPOINT AND PANEL DISCUSSION: THE PATH FORWARD
Point-Counterpoint and panel discussion with audience participation to discuss topics of interest, which may include: the potential value of QSP in drug discovery, development, and review; real and perceived technical and operational challenges to implementing a QSP approach; and roadblocks and opportunities for greater adoption and acceptance.

4:30 PM – 4:35 PM
QSP POSTER PRESENTATION AWARD
PRESENTER
Piet H. van der Graaf, PhD, PharmD
Editor-in-Chief, PSP

4:35 PM – 4:50 PM
CONCLUDING REMARKS
Jane Bai, PhD
US Food and Drug Administration, Silver Spring, MD
Cynthia J. Musante, PhD
Pfizer, Cambridge, MA
Suzana Petanceska, PhD
National Institutes of Aging/National Institutes of Health, Bethesda, MD
**2019 THEME AND CONTENT CATEGORIZATION**

To achieve the goal of attaining a diverse, well-rounded education program, the Scientific Program Committee (SPC) has developed an overall Annual Meeting theme of “From Molecule to Patient.” This theme is incorporated in Symposia, Workshops, Roundtables/Novel Formats, and Science at Sunrise sessions, and throughout the entire program. The SPC has identified and branded Symposia, Workshops, Roundtables/Novel Formats, and Science at Sunrise sessions according to the drug discovery, development, regulation, and utilization (DDRU) continuum. Component(s) of the DDRU continuum that apply to the particular Symposium, Workshop, Roundtable/Novel Format, and Science at Sunrise sessions have been identified and branded accordingly.

For example, this image indicates that the corresponding session includes the Discovery and Development components of the DDRU continuum.

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

Take ASCPT home with you! As a special offering this year, all attendees will receive access to our exclusive, online digital library featuring the best of the ASCPT 2019 Annual Meeting 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, the Innovation Forum, and new in 2019, the Patient Forum.

**OPENING SESSION**

8:00 AM – 10:00 AM

THURSDAY, MARCH 14, 2019

ASCPT President, Dan Hartman, MD, kicks off the ASCPT 2019 Annual Meeting and presents several prestigious awards recognizing outstanding achievements in clinical pharmacology and translational science. The first State of the Art Lecture of the meeting will begin immediately following the award presentations.

**OPENING RECEPTION AND SHOWCASE OF TOP TRAINEE ABSTRACTS**

5:00 PM – 6:30 PM

WEDNESDAY, MARCH 13, 2019

ASCPT invites you to join your colleagues on Wednesday evening for the first networking event of the Meeting. Interact with fellow scientists from all over the globe, and view a showcase of 2019’s Top Trainee Abstracts. The first Poster Walk sessions of this year’s meeting will immediately follow the Presidential Trainee Abstract Awards Presentation.
STATE OF THE ART LECTURES

Penny Heaton, MD
BILL & MELINDA GATES MEDICAL RESEARCH INSTITUTE, CAMBRIDGE, MA
From Molecule to Patient: A Global Health Perspective

9:00 AM – 10:00 AM
THURSDAY, MARCH 14, 2019
ASCPT welcomes Penny Heaton, MD, as a State of the Art speaker. Dr. Heaton has been a tireless advocate for combating inequities in health for over twenty years, with a passion for finding new and effective interventions against diseases affecting the world’s poorest people. Dr. Heaton’s career journey as a pediatric infectious disease physician spans from the Centers for Disease Control and Prevention to the pharmaceutical industry before joining the Bill & Melinda Gates Foundation in 2013 to lead the vaccine development team. Dr. Heaton recognized the need to disrupt global health by applying cutting-edge science and technology to combat age-old diseases in the world’s poorest populations. Now, she is charged with leading the Bill & Melinda Gates Medical Research Institute (Gates MRI)—a nonprofit biotech organization focused on thinking big, exploring novel ideas, collaborating across disciplines, and being fearless in its approach to scientific inquiry in ways that aren’t always possible in the private sector or in academic research labs. The institute’s focus is translational medicine, with the ambitious goals of eradicating malaria, accelerating the end of the tuberculosis epidemic, and ending diarrheal deaths in children.

James (Jay) Bradner, MD
NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, CAMBRIDGE, MA
A New Science of Therapeutics for Undruggable Targets

9:00 AM – 10:00 AM
FRIDAY, MARCH 15, 2019
James (Jay) Bradner, MD, President of the Novartis Institutes for BioMedical Research (NIBR), is welcomed as a State of the Art speaker. He is a member of the Executive Committee of Novartis. Prior to joining Novartis, Dr. Bradner was on the faculty of Harvard Medical School in the Department of Medical Oncology at the Dana-Farber Cancer Institute in the United States. Dr. Bradner is a co-founder of five biotechnology companies and has authored more than 200 scientific publications and 30 US patent applications. Dr. Bradner is a graduate of Harvard University and the University of Chicago Medical School. He completed his residency in medicine at Brigham and Women’s Hospital and his fellowship in medical oncology and hematology at the Dana-Farber Cancer Institute. He has been honored with many awards and was elected into the American Society for Clinical Investigation in 2011 and the Alpha Omega Alpha Honor Medical Society in 2013.

Robert S. Langer, Jr., ScD
MASSACHUSETTS INSTITUTE OF TECHNOLOGY, CAMBRIDGE, MA
From Molecule to Patient: A Biotech Perspective

1:00 PM – 2:00 PM
FRIDAY, MARCH 15, 2019
ASCPT welcomes Robert S. Langer, Jr., ScD, as a State of Art speaker. Dr. Langer is one of 13 Institute Professors at MIT (an Institute Professor is the highest honor awarded to a faculty member). His h-index of 259 is the highest of any engineer in history. He has over 1,300 issued and pending patents that have been licensed or sublicensed to over 350 companies. He served as Chairman of the US Food and Drug Administration’s Science Board (highest advisory board) from 1999-2002. Dr. Langer is one of a very few individuals elected to the National Academy of Medicine, the National Academy of Engineering, the National Academy of Sciences, and the National Academy of Inventors. He is one of four living individuals to receive both the US National Medal of Science and the US National Medal of Technology and Innovation. In 2015, Dr. Langer received the Queen Elizabeth Prize for Engineering. He has also received the Draper Prize (considered the engineering Nobel Prize), Albany Medical Center Prize, Wolf Prize for Chemistry, Millennium Technology Prize, Priestley Medal (highest award of the American Chemical Society), Gairdner Prize, Kyoto Prize, Breakthrough Prize and the Lemelson-MIT prize, for being “one of history’s most prolific inventors in medicine.” He holds 33 honorary doctorates, including honorary degrees from Harvard and Yale.
INNOVATION FORUM

10:30 AM – 12:00 PM
FRIDAY, MARCH 15, 2019
The 2019 Innovation Forum will be a thought-provoking and idea-inspiring interactive session on cutting-edge methods and technology in drug discovery and development, including artificial intelligence and machine learning, the intersection between engineering, imaging and medicine, therapeutic targeting of RNA splicing, and mobile and digital health.

PATIENT FORUM

9:30 AM – 11:30 AM
SATURDAY, MARCH 16, 2019
The Patient Forum is a new session format aligned with the theme of the 2019 Annual Meeting, “From Molecule to Patient,” aimed to bridge innovation in clinical pharmacology and therapeutics to the needs and perspectives of patients. The Patient Forum will feature a small panel of presenters who will give informative talks followed by a moderated Q&A session with the audience. Topics include patient advocacy in rare diseases, patient-driven precision medicine, innovative approaches in drug development for minority communities, and the new patient-focused drug development regulatory framework.

PRESIDENT’S NETWORKING RECEPTION

5:00 PM – 6:30 PM
THURSDAY, MARCH 14, 2019
Join us for the President’s Networking Reception in the Exhibit and Poster Hall, offering further opportunities to network and interact with colleagues and exhibitors, and experience two more Poster Walk sessions, while we honor and recognize the contributions of ASCPT President, Dan Hartman, MD.
PROGRAM HIGHLIGHTS

SPECIAL SESSION
CLINICAL PHARMACOLOGY WORKFORCE SKILLS AND NETWORKING: POSTDOCTORAL FELLOW/TRAINEE CAREER PATH EXPLORATION
6:30 PM – 8:00 PM
WEDNESDAY, MARCH 13, 2019
This dynamic and motivating evening session designed for young investigators/fellows will provide information about the applications of clinical pharmacology in diverse fields, and career paths in the pharmaceutical industry and governmental regulatory agencies. Important skills and attributes for career success in the various sectors will be discussed. National Institutes of Health funding opportunities for trainees considering academic careers will also be highlighted. Breakout sessions will allow time for trainees to network with junior and senior scientists employed in the various sectors (academics, industry, government), and with each other. Pre-registration for this session is required.

NIH CONVERSATIONS
10:00 AM - 10:30 AM
THURSDAY, MARCH 14
and
3:15 PM – 3:45 PM
FRIDAY, MARCH 15
This is your opportunity to speak with NIGMS staff and ask your burning questions about NIH funding, new opportunities, and other funding issues. Don’t miss these exclusive sessions designed for you!

SPEED MENTORING
11:30 AM - 1:00 PM
THURSDAY, MARCH 14, 2019
Plan to attend the very popular and often sold-out Speed Mentoring event. ASCPT recognizes that all members, regardless of career stage, have a unique perspective to share, and all members can benefit from peer-to-peer learning opportunities. Sign up for this session with your Meeting registration if you’d like to be a mentee, or notify staff at meetings@ascpt.org if you’d like to serve in the mentor role. This event is a one-time opportunity for 1:1 consultation with other members. There are no conditions to serving in either role and both experiences are sure to be rewarding!

SPECIAL SESSION
CAREER EXPLORATION AND TRANSITION BEYOND TRADITIONAL ROLES
7:45 AM – 8:45 AM
FRIDAY, MARCH 15, 2019
Attendees will learn about underexplored, non-traditional career paths/roles and discover how to prepare for such non-traditional roles and career transitions. In addition to career transitions within sectors, there is a myriad of interesting opportunities for scientists with intensive research backgrounds that are not typically pursued. While non-traditional roles are exciting, rewarding, and accelerate growth, they are highly competitive and require meticulous planning, systematic preparation, focused skill building, and networking. This session will explore opportunities in such non-traditional roles and illuminate ways in which clinical pharmacologists and translational scientists can plan for career transitions by building relevant soft and technical skills as well as creating a network that will help with the transition. Attendees across all career stages are invited to participate.

SPECIAL SESSION
SNAKE PIT: GRANT ME THE MONEY!
3:45 PM – 5:45 PM
FRIDAY, MARCH 15, 2019
Effective communication skills are imperative to the implementation of innovative solutions to drug development challenges, and ultimately, to patient care. Participants will develop skills necessary for writing a compelling grant proposal to communicate their solution to a real-life problem that will influence drug utilization decisions that impact patient care. Teams will select from a diverse range of real-life scenarios proposed by the participating funding agencies for a range of drug molecules and diverse patient populations. Participants will form multi-disciplinary teams and use necessary approaches like modeling and simulation to convince the agency about the validity of their grant proposal.

EDUCATION SESSION
PRIMER ON IMMUNOLOGY AND CANCER IMMUNOTHERAPY
2:15 PM – 5:30 PM
FRIDAY, MARCH 15, 2019
Our understanding of cancer immune-biology has increased dramatically in recent years, leading to the successful development of novel immune-based treatment options to improve cancer patient outcomes. This primer on immunology and cancer immunotherapy is designed to provide a foundation for understanding core immunology principles as they relate to basic and clinical research in immunotherapy of cancer. In addition, the primer will also provide an overview of current advances in application of this knowledge in clinical pharmacology, systems medicine and quantitative methods for decision making.
**WEDNESDAY, MARCH 13, 2019**

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

8:00 AM – 11:00 AM
ASCPT BOARD OF DIRECTORS MEETING
By Invitation Only

8:00 AM – 5:00 PM
PRE-CONFERENCE
PBPK Modeling for the Development and Approval of Locally Acting Drug Products

8:00 AM – 5:00 PM
PRE-CONFERENCE
Advancing QSP Toward Predictive Drug Development: From Targets to Treatments

3:00 PM – 5:00 PM
SPECIAL POSTER SESSION: PHARMACOGENOMICS
Co-Sponsored by the Pharmacogenomics Community and the PGRN

4:30 PM – 6:30 PM
EXHIBIT AND POSTER HALL OPEN

5:00 PM – 5:15 PM
PRESIDENTIAL TRAINEE ABSTRACT AWARDS PRESENTATION

5:00 PM – 6:30 PM
OPENING RECEPTION
POSTER SESSION I: LATE-BREAKING, ENCORE, PRESIDENTIAL TRAINEE, AND ORAL ABSTRACT POSTERS

5:20 PM – 5:50 PM
POSTER WALK I

5:55 PM – 6:25 PM
POSTER WALK II

6:00 PM – 7:30 PM
PhRMA FOUNDATION RECEPTION
By Invitation Only

**6:30 PM – 8:00 PM**
SPECIAL SESSION
Clinical Pharmacology Workforce Skills and Networking: Postdoctoral Fellow/Trainee Career Path Exploration
Pre-Registration Required

**Chair:** Kim L.R. Brouwer, PharmD, PhD
University of North Carolina at Chapel Hill, Chapel Hill, NC

**Chair:** Eileen Dolan, PhD
University of Chicago Medical Center, Chicago, IL

**Chair:** Scott A. Waldman, MD, PhD
Thomas Jefferson University, Philadelphia, PA

**Chair:** Nicole R. Zane, PharmD, PhD
Children’s Hospital of Philadelphia, Philadelphia, PA

**THURSDAY, MARCH 14, 2019**

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

7:00 AM – 7:45 AM
AWARDS BREAKFAST
By Invitation Only

7:00 AM – 8:00 AM
BREAKFAST VOUCHERS FOR HOTEL RESTAURANTS

8:00 AM – 10:00 AM
OPENING SESSION
STATE OF THE ART LECTURE
From Molecule to Patient: A Global Health Perspective
Penny Heaton, MD
Bill & Melinda Gates Medical Research Institute, Cambridge, MA

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
NIH CONVERSATIONS

10:30 AM – 11:30 AM
FEATURED SPEAKER
Nancy J. Brown, MD
Vanderbilt University, Nashville, TN
THURSDAY, MARCH 14, 2019

10:30 AM – 11:30 AM
Rawls-Palmer Progress in Medicine Award Lecture
J. Steven Leeder, PharmD, PhD
Children’s Mercy Hospital, Kansas City, MO

10:30 AM – 12:00 PM
WORKSHOP
Applications of Immunopharmacogenomics: Predicting, Preventing, and Understanding Immune-Mediated Adverse Drug Reactions

Pharmacogenomics and Biologics
Chair: Jason Karnes, PharmD, PhD
University of Arizona, Tucson, AZ
Chair: Ryan Funk, PharmD, PhD
University of Kansas Medical Center, Kansas City, KS

Understanding Immune-Mediated Drug Toxicities: A Roadmap for Translation and Discovery with Emerging Treatments
SPEAKER
Elizabeth Phillips, MD
Vanderbilt University, Nashville, TN

Predicting Immune-Mediated Adverse Drug Reactions and Emerging Immunogenetic Discoveries
SPEAKER
Jason Karnes, PharmD, PhD
University of Arizona, Tucson, AZ

Preventing Immune-Mediated Adverse Drug Reactions: Large-Scale Translation of Immunopharmacogenomics
SPEAKER
Munir Pirmohamed, PhD
University of Liverpool, Liverpool, United Kingdom

10:30 AM – 12:00 PM
WORKSHOP
CAR-T Cells as Game Changers in Cancer Treatment: How Innovative Clinical and Translational Pharmacology Concepts Evolved Along with the Regulatory Framework to Expedite Treatments for Life-Threatening Diseases

Pharmacometrics & Pharmacokinetics and Early Career
Chair: Ashit Trivedi, PhD
Amgen, Thousand Oaks, CA
Chair: Aline Barth, PhD
GlaxoSmithKline, Collegeville, PA

The Pharmacology of T-cell Therapies
SPEAKER
Michael Milone, PhD
University of Pennsylvania, Philadelphia, PA

Summary of Clinical Pharmacology and Biopharmaceutics for CAR-T: A Tisagenlecleucel Case Study
SPEAKER
Karen Thudium, PharmD
Novartis, East Hanover, NJ

The FDA’s Regulatory Framework for CAR-T Cell Therapies
SPEAKER
Peter Marks, MD, PhD
US Food and Drug Administration, Silver Spring, MD

11:30 AM – 1:00 PM
SPEED MENTORING
Pre-Registration Required

12:00 PM – 1:00 PM
GRAB & GO LUNCH IN THE EXHIBIT HALL AND VOUCHERS FOR HOTEL RESTAURANTS

2:00 PM – 2:30 PM
AFTERNOON BREAK

2:30 PM – 4:30 PM
SYMPOSIUM
Physiologically Based Pharmacokinetic (PBPK) Modeling in Vulnerable Populations: Pregnant Women, Breastfeeding Infants, Neonates, and Young Children

Special Populations and Pharmacometrics & Pharmacokinetics
Chair: Tamorah Rae Lewis, MD, PhD
Children’s Mercy Hospital, Kansas City, MO
Chair: Sara Quinney, PhD
Indiana University School of Medicine, Indianapolis, IN

PBPK in Pregnant Women and Fetal Drug Exposure
SPEAKER
Jashvant Unadkat, PhD
University of Washington School of Pharmacy, Seattle, WA

PBPK Modeling to Inform Drug Exposure in Breastfeeding Infants
SPEAKER
Shinya Ito, MD
Hospital for Sick Children, Toronto, ON, Canada
THURSDAY, MARCH 14, 2019

Comparison of Various PBPK Models in Neonates: Research from the FDA Division of Pharmacometrics
SPEAKER
Yaning Wang, PhD
US Food and Drug Administration, Silver Spring, MD

PBPK In Young Children: The Importance of Ontogeny Functions
SPEAKER
Jean Dinh, PharmD, PhD
Children’s Mercy Hospital, Kansas City, MO

2:30 PM – 4:30 PM
Ready for Prime Time: Implementing Adherence Programs in Drug Development and Post Approval Settings

Global Health
Chair: Terrence Blaschke, MD
Stanford University, Stanford, CA
Chair: Rada Savic, PhD
University of California, San Francisco, San Francisco, CA

Versatility and Scalability of Solutions to Monitor and Improve Medication Adherence
SPEAKER
Bruce V. Thomas, JD
The Arcady Group, Richmond, VA

Insights From Monitoring Adherence in Clinical Trials and in Clinical Care: Understanding the Key Question of Drug Forgiveness
SPEAKER
Bernard Vrijens, PhD
AARDEX Group, Visé, Belgium

Controlling Tuberculosis: The Impact of Interventions to Improve Adherence in High-Burden, Low-Income Settings
SPEAKER
Rada Savic, PhD
University of California, San Francisco, San Francisco, CA

Optimizing Adherence Monitoring to Support Differentiated Care, Better Efficiency and Improved Outcomes
SPEAKER
Jessica Haberer, MD
Massachusetts General Hospital, Boston, MA

2:30 PM – 4:30 PM
SYMPOSIUM
How Artificial Intelligence and Machine Learning Techniques Are Revolutionizing Drug Discovery and Development

Regulatory Science and Pharmacometrics & Pharmacokinetics
Chair: Islam Younis, PhD
US Food and Drug Administration, Silver Spring, MD
Chair: Ahmed Othman, PhD
AbbVie, North Chicago, IL

The Rise of Deep Learning in Drug Discovery
SPEAKER
Russ Altman, MD, PhD
Stanford University, Stanford, CA

The Most Promising Areas of Machine Learning in Drug Development
SPEAKER
Nidal Al-Huniti, PhD
AstraZeneca, Boston, MA

Application of Machine Learning to Predict Clinical Activity of Drug Combinations
SPEAKER
Yunfang Guan, PhD
The University of Michigan, Ann Arbor, MI

Potential Application of Machine Learning in Regulatory Setting
SPEAKER
Qi Liu, PhD
US Food and Drug Administration, Silver Spring, MD

3:30 PM – 4:30 PM
Oscar B. Hunter Career Award in Therapeutics Lecture
Mary Relling, PharmD
St. Jude Children’s Research Hospital, Memphis, TN

4:30 PM – 6:30 PM
EXHIBIT AND POSTER HALL OPEN

5:00 PM – 6:30 PM
PRESIDENT’S NETWORKING RECEPTION
POSTER SESSION II
## THURSDAY, MARCH 14, 2019

**5:20 PM – 5:50 PM**  
POSTER WALK III

**5:55 PM – 6:25 PM**  
POSTER WALK IV

**6:30 PM – 8:00 PM**  
DONOR AND GAVEL CLUB RECEPTION  
*By Invitation Only*

**6:30 PM – 8:00 PM**  
UCSF/STANFORD/GENENTECH RECEPTION  
*By Invitation Only*

## FRIDAY, MARCH 15, 2019

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

**7:00 AM – 8:00 AM**  
BREAKFAST VOUCHERS FOR HOTEL RESTAURANTS

**7:00 AM – 9:00 AM**  
AMERICAN BOARD OF CLINICAL PHARMACOLOGY (ABCP) BOARD MEETING  
*By Invitation Only*

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

**7:15 AM – 8:45 AM**  
SCIENCE AT SUNRISE  
*Opportunities in Evaluating Abuse Deterrence of Opioid Drug Products*

**7:30 AM – 9:00 AM**  
JOINT JOURNAL EDITORIAL BOARDS MEETING  
*By Invitation Only*

**7:45 AM – 8:45 AM**  
SPECIAL SESSION  
*Career Exploration and Transition Beyond Traditional Roles*

**8:00 AM – 9:00 AM**  
POSTER SESSION III  
*PART 1*

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**Quantitative Analysis of Opioid ADF PK/PD**  
*SPEAKER*  
**Bradly Vince, DO**  
*Altasciences Clinical Research / Vince & Associates, Overland Park, KS*

**Nasal PK Study of Abuse-Deterrent Opioid Products Following Insufflation of Physically Manipulated Products**  
*SPEAKER*  
**Liang Zhao, PhD**  
*US Food and Drug Administration, Silver Spring, MD*

**7:30 AM – 9:00 AM**  
JOINT JOURNAL EDITORIAL BOARDS MEETING  
*By Invitation Only*

**7:45 AM – 8:45 AM**  
SPECIAL SESSION  
*Career Exploration and Transition Beyond Traditional Roles*

**8:00 AM – 9:00 AM**  
POSTER SESSION III  
*PART 1*

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**Transitioning from Big Pharma to a Start-Up: Challenges and Opportunities**  
*SPEAKER*  
**Mark Dresser, PhD**  
*Denali Therapeutics, South San Francisco, CA*

**Hyper-Accelerating Career Transitions into Management Consulting and Venture Capital**  
*SPEAKER*  
**Rosemarie Truman, BA**  
*Gazelle Futures, Bethesda, MD*

**Transitioning into Patent Law as a Scientist**  
*SPEAKER*  
**Erin Heenan, PhD, JD**  
*Sterne, Kessler, Goldstein and Fox, Washington, DC*
## FRIDAY, MARCH 15, 2019

### 10:30 AM – 12:00 PM

**WORKSHOP**

*Geriatric Clinical Pharmacology: State of the Art in a Neglected Majority*

**Chair:** Robin O’Connor-Semmes, PhD  
PAREXEL International, Research Triangle Park, NC  

**Co-Chair:** Donald L. Heald, PhD  
Johnson & Johnson, Spring House, PA

#### Regulatory Science and Pharmacometrics & Pharmacokinetics

**Applying Clinical Pharmacology Principles to Improve Care for the Older Adult**

**SPEAKER**  
Patricia Slattum, PharmD, PhD  
Virginia Commonwealth University, Richmond, VA

**Regulatory Perspectives in Developing Drug Products for Older Adults in the United States**

**SPEAKER**  
S.W. Johnny Lau, PhD  
US Food and Drug Administration, Silver Spring, MD

#### Pharmacometric Approaches to Streamline Pharmacotherapy in Older Adults

**SPEAKER**  
Jan Schlender, PhD  
Bayer AG, Leverkusen, Germany

### 10:30 AM – 12:00 PM

**NOVEL FORMAT**

*All of Us and More!*

**Pharmacogenomics and Global Health**

**Chair:** Kathleen M. Giacomini, PhD  
University of California, San Francisco, San Francisco, CA  

**Co-Chair:** Minoli Perera, PharmD, PhD  
Northwestern University, Chicago, IL

#### All of Us Research Program

**SPEAKER**  
Joni L. Rutter, PhD  
National Institutes of Health, Bethesda, MD

#### Overview of National Human Genome Institute’s Programs and Projects in Genome Medicine

**SPEAKER**  
Simona Volpi, PharmD, PhD  
National Human Genome Research Institute, Bethesda, MD

### 12:00 PM – 1:00 PM

**TRAINING PROGRAM DIRECTORS MEETING**

**POSTER SESSION III PART 2**

**FINANCE COMMITTEE MEETING**  
*By Invitation Only*

**GRAB & GO LUNCH IN THE EXHIBIT HALL AND VOUCHERS FOR HOTEL RESTAURANTS**
FRIDAY, MARCH 15, 2019

1:00 PM – 2:00 PM
STATE OF THE ART LECTURE
From Molecule to Patient: A Biotech Perspective
Robert S. Langer, Jr., ScD
Massachusetts Institute of Technology, Cambridge, MA

2:15 PM – 3:15 PM
Leon I. Goldberg Early Investigator Award Lecture
Sara Van Driest, MD, PhD
Vanderbilt University, Nashville, TN

2:15 PM – 3:15 PM
Sheiner-Beal Pharmacometrics Award Lecture
Joga Gobburu, PhD
University of Maryland, Baltimore, MD

2:15 PM – 3:15 PM
FEATURED SPEAKER
Neal L. Benowitz, MD
University of California San Francisco, San Francisco, CA

2:15 PM – 5:30 PM
EDUCATION SESSION
Primer on Immunology and Cancer Immunotherapy
Pharmacometrics & Pharmacokinetics and Biomarkers & Translational Tools
Chair: Sree Kasichayanula, PhD
AbbVie Biotherapeutics, Redwood City, CA
Chair: Sandhya Girish, PhD
Genentech, South San Francisco, CA

Basic Immunology for Clinical Pharmacologists
SPEAKER
Timothy Bullock, PhD
University of Virginia, Charlottesville, VA

Developing Biomarkers for Optimizing Immuno-Therapeutics: Partnering with Clinical Pharmacologists
SPEAKER
Speaker TBD

Translational and Clinical Pharmacology Perspectives in Cancer Immunotherapy
SPEAKER
Amit Roy, PhD
Bristol-Myers Squibb, Princeton, NJ

3:15 PM – 3:45 PM
NIH CONVERSATIONS

3:45 PM – 5:15 PM
WORKSHOP
Evolution of Next Generation Therapeutics: Past, Present, and Future of Precision Medicines
Regulatory Science and Pharmacogenomics
Chair: Anuradha Ramamoorthy, PhD
US Food and Drug Administration, Silver Spring, MD
Chair: Rebecca Blanchard, PhD
CRISPR Therapeutics, West Point, PA

Evolution of Precision Medicines from a Regulatory Perspective
SPEAKER
Michael Pacanowski, PharmD, MPH
US Food and Drug Administration, Silver Spring, MD

Realizing the Potential for CRISPR to Transform Drug Development
SPEAKER
Rebecca Blanchard, PhD
CRISPR Therapeutics, West Point, PA

Nusinersen for Spinal Muscular Atrophy: The Translational Evolution of Antisense Oligonucleotides
SPEAKER
Richard Finkel, MD
Nemours Children’s Hospital, Orlando, FL
FRIDAY, MARCH 15, 2019

3:45 PM – 5:45 PM
SPECIAL SESSION
Snake Pit: Grant Me the Money!

Pharmacometrics & Pharmacokinetics and Early Career

Chair: Gauri Rao, PharmD
University of North Carolina, Chapel Hill, NC

Chair: Mark Lovern, PhD
Certara Strategic Consulting, Raleigh, NC

FACILITATORS
Julie Dumond, PharmD
University of North Carolina, Chapel Hill, NC

Nathan Teuscher, PhD
Certara Strategic Consulting, Raleigh, NC

Gauri Rao, PharmD
University of North Carolina, Chapel Hill, NC

3:45 PM – 5:45 PM
SYMPOSIUM
Connecting Cell Biology to Patient Populations—Clinical Applications of Multi-Scale Systems Pharmacology

Systems Pharmacology and Pharmacometrics & Pharmacokinetics

Chair: Daniel Kirouac, PhD
Applied BioMath, Oakland, CA

Chair: Michael Block, PhD
Bayer, Leverkusen, Germany

Bridging Mechanistic Models and Patient Data in Virtual Clinical Trials

SPEAKER
Feilim Mac Gabhann, PhD
Johns Hopkins University, Baltimore, MD

Personal Response to Pembrolizumab in Advanced Melanoma Patients Predicted by a Combined Mechanistic Model of Cellular Immunity, Cancer and Drug

SPEAKER
Zvia Agur, PhD
Institute for Medical BioMathematics, Bene-Atarot, Israel

Applications of QSP Towards New Patient Populations, Packaging Safety and Manufacturing Specifications in Hyperkalemia

SPEAKER
Lulu Chu, PhD
AstraZeneca, Waltham, MA

Strategies to Effectively Deploy Quantitative Systems Pharmacology Approaches in Clinical Development

SPEAKER
Paolo Vicini, PhD, MBA
MedImmune, Cambridge, United Kingdom

SATURDAY, MARCH 16, 2019

7:00 AM – 12:00 PM
ASCPT INFO DESK AND REGISTRATION OPEN

7:00 AM – 8:00 AM
BREAKFAST VOUCHERS FOR HOTEL RESTAURANTS

7:45 AM – 9:15 AM
SCIENCE AT SUNRISE
Catching a Glimpse of Gut Microbiome-Drug Interactions: What Clinical Pharmacologists Need to Know

Membrane Transporter and Regulatory Science

Chair: Sook Wah Yee, PhD
University of California, San Francisco, San Francisco, CA

Chair: Eugene Chen, PhD
Genentech, South San Francisco, CA

Gut Microbiome 101: You Are What You Eat

SPEAKER
Libusha Kelly, PhD
Albert Einstein College of Medicine, New York, NY

The Interaction of Gut Bacteria with Excipients: Effects on Transporter-Mediated Drug Absorption

SPEAKER
Kathleen M. Giacomini, PhD
University of California, San Francisco, San Francisco, CA

Regulatory Science Issues in the Effect of Microbiomes on Bioequivalence Determination for Generic Drug Products

SPEAKER
Lei Zhang, PhD
US Food and Drug Administration, Silver Spring, MD
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<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:15 AM – 9:15 AM</td>
<td>ORAL ABSTRACT SESSION I</td>
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<tr>
<td>9:30 AM – 11:30 AM</td>
<td>PATIENT FORUM</td>
<td>Chair: Piet H. van der Graaf, PhD, PharmD, Certara, Canterbury, United Kingdom</td>
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<td><strong>The Algorithm for Precision Medicine</strong></td>
<td>SPEAKER: Matthew Might, PhD, University of Alabama at Birmingham, Birmingham, AL</td>
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<td><strong>Patient-Focused Drug Development</strong></td>
<td>SPEAKER: Pujita Vaidya, MPH, US Food and Drug Administration, Silver Spring, MD</td>
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<td>9:30 AM – 11:30 AM</td>
<td>SYMPOSIUM</td>
<td><strong>Immunogenicity in Clinical Practice and Drug Development: When is it Significant?</strong></td>
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<td><strong>Biologics and Biomarkers &amp; Translational Tools</strong></td>
<td>Chair: Yow-Ming Wang, PhD, US Food and Drug Administration, Silver Spring, MD</td>
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<td><strong>Chair: Lora Hamuro, PharmD, PhD</strong></td>
<td>Bristol-Myers Squibb, Princeton, NJ</td>
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<td><strong>Immunogenicity Monitoring in Clinical Practice: From the Perspective of a Practicing Pediatric Gastroenterologist</strong></td>
<td>SPEAKER: Valentina Shakhnovich, MD, Children’s Mercy Kansas City, Kansas City, MO</td>
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<td><strong>Technical and Logistic Challenges in the Detection of Immunogenicity</strong></td>
<td>SPEAKER: Bernd Meibohm, PhD, University of Tennessee Health Science Center, Memphis, TN</td>
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<td><strong>Risk Assessment and Mitigation Strategies of Immunogenicity in Clinical Development: A Regulatory Perspective</strong></td>
<td>SPEAKER: Amy Rosenberg, MD, US Food and Drug Administration, Silver Spring, MD</td>
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<td>9:30 AM – 11:30 AM</td>
<td>SYMPOSIUM</td>
<td><strong>Open Data Revolution in Clinical Research: Current Challenges and Future Promises</strong></td>
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<td><strong>Translational Informatics, Biomarkers &amp; Translational Tools</strong></td>
<td>Chair: Daniela J. Conrado, PhD, Critical Path Institute, Cambridge, MA</td>
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<td><strong>Chair: Mohamed H. Shahin, PhD</strong></td>
<td>University of Florida, Gainesville, FL</td>
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<td><strong>Data Sharing: Where We’ve Been and Where We’re Going</strong></td>
<td>SPEAKER: Claudia Emerson, PhD, McMaster University, Hamilton, ON, Canada</td>
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<td><strong>Imposing Risk: Ethical Challenges in Data Sharing</strong></td>
<td>SPEAKER: Diego Silva, PhD, Simon Fraser University, Burnaby, BC, Canada</td>
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<td><strong>Toward Leveraging Publicly Accessible Clinical Trials</strong></td>
<td>SPEAKER: Sanchita Bhattacharya, MS, University of California, San Francisco, San Francisco, CA</td>
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<td>10:30 AM – 11:30 AM</td>
<td>ORAL ABSTRACT SESSION II</td>
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<td>11:30 AM – 1:30 PM</td>
<td>ASCPT BOARD OF DIRECTORS MEETING</td>
<td>By Invitation Only</td>
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<td>11:30 AM – 1:30 PM</td>
<td>LUNCH VOUCHERS FOR HOTEL RESTAURANTS</td>
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<td>12:30 PM – 1:30 PM</td>
<td>ORAL ABSTRACT SESSION III</td>
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**SATURDAY, MARCH 16, 2019**

**12:30 PM – 2:00 PM**

**NOVEL FORMAT**

*Will Antibody-Based Anti-Infective Therapies Save Conventional Treatment Failures? Opportunities and Challenges of Development of Antibody-based Anti-Infective Therapies*

**Infectious Diseases and Biologics**

**Chair:** Rong Deng, PhD  
Genentech, South San Francisco, CA

**Chair:** Yang He, PhD  
US Food and Drug Administration, Silver Spring, MD

**PK/PD Challenges of Developing Antibody-Based Anti-Infective Treatment**

**SPEAKER**

Joseph Balthasar, PhD  
University at Buffalo, SUNY, Buffalo, NY

*A Clinician's Perspective—The Opportunity and Challenges of Development of Antibody-Based Anti-Infective Treatment*

**SPEAKER**

Jorge Tavel, MD  
Genentech, South San Francisco, CA

**Experiences with Development of Antibody-Based Anti-Viral Drugs**

**SPEAKER**

Qin Sun, PhD  
US Food and Drug Administration, Silver Spring, MD

**12:30 PM – 2:30 PM**

**SYMPOSIUM**

**Drug Repositioning**

**Regulatory Science and Translational Informatics**

**Chair:** Katarina Ilic, MD, PhD, MPH  
Shire, Lexington, MA

**Chair:** Val Kitchen, MD  
GlaxoSmithKline, King of Prussia, PA

**Drug Repositioning**

**SPEAKER**

Weida Tong, PhD  
Division of Bioinformatics and Biostatistics, Little Rock, AR

**Discovering New Therapeutic Uses for Existing Molecules**

**SPEAKER**

Bobbie Ann Mount, PhD  
National Institutes of Health / National Center for Advancing Translational Sciences, Bethesda, MD

**Using Human Genetic Variation to Repurpose Existing Medications for New Diseases**

**SPEAKER**

Jill Pulley, MBA  
Vanderbilt University Medical Center, Nashville, TN

**The OPRC Pravastatin for Preeclampsia Prevention Study: Results & Learnings**

**SPEAKER**

Speaker TBA
SATURDAY, MARCH 16, 2019

12:30 PM – 2:30 PM
NOVEL FORMAT
MID3: Mission Impossible or Model-Informed, Drug Discovery and Development? Point / Counterpoint Discussions on Key Challenges

Pharmacometrics & Pharmacokinetics, Regulatory Science

Chair: Sriram Krishnaswami, PhD
Pfizer, Groton, CT
Chair: Sandra A.G. Visser, PhD
GlaxoSmithKline, Collegeville, PA

The Future Role of Pharmacometrics
SPEAKERS
Scott Marshall, PhD
Pfizer, Groton, CT
Marc Gastonguay, PhD
Metrum Research Group, Boston, MA

MID3: Primary Limitations to Success
SPEAKERS
Stacey Tannenbaum, PhD
Astellas Pharma, Northbrook, IL
Oscar Della Pasqua, PhD
University College London, London, United Kingdom

Model Innovations That Will be Disruptive
SPEAKERS
Joga Gobburu, PhD
University of Maryland, Baltimore, MD
Marc Gastonguay, PhD
Metrum Research Group, Boston, MA

Transforming Clinical Trial Designs
SPEAKERS
Oscar Della Pasqua, PhD
University College London, London, United Kingdom
Stacey Tannenbaum, PhD
Astellas Pharma, Northbrook, IL

Organizational Positioning and Opportunities
SPEAKERS
Joga Gobburu, PhD
University of Maryland, Baltimore, MD
Marc Gastonguay, PhD
Metrum Research Group, Boston, MA

Customer-Centricity
SPEAKERS
Daren Austin, PhD
GlaxoSmithKline, London, United Kingdom
Stacey Tannenbaum, PhD
Astellas Pharma, Northbrook, IL

The Ideal MID3 Scientist for the Future
SPEAKERS
Daren Austin, PhD
GlaxoSmithKline, London, United Kingdom
Piet H. van der Graaf, PhD, PharmD
Certara, Canterbury, United Kingdom
ASCPT is Giving You More with Your 2019 Registration!

Register for the ASCPT 2019 Annual Meeting and experience cutting-edge scientific presentations, State of the Art lectures, the Innovation Forum, the new Patient Forum, Exhibit Hall access, 3 scientific poster sessions, outstanding networking opportunities, career development sessions and events, and student/trainee programming.

Registration for the 2019 Annual Meeting Also Includes:

- Meal vouchers provided by ASCPT for breakfast on Thursday, Friday, and Saturday!
- Admission to two special receptions.
- Admission to Snake Pit: Grant Me the Money, an exciting, live competition!

DEADLINES

EARLY BIRD REGISTRATION
Thursday, December 13, 4:00 PM ET

ADVANCE REGISTRATION
Thursday, January 17, 4:00 PM ET

HOUSING DEADLINE
Monday, February 18