ASCPT American Society for Clinical Pharmacology & Therapeutics

ASCPT 2018 ANNUAL MEETING | MARCH 21-24, 2018 • HILTON ORLANDO • ORLANDO, FL

PRELIMINARY PROGRAM

BREAKING DOWN BARRIERS TO EFFECTIVE PATIENT CARE

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WELCOME

Dear Colleague,

It is with great excitement that I invite you to join me at the premier scientific event for scientists in clinical pharmacology and translational medicine, the 2018 Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), at the Hilton Orlando Hotel in Orlando, Florida.

The Scientific Program Committee, chaired by Peter H. O'Donnell, MD, has organized a world-class meeting that addresses cutting-edge clinical pharmacology and translational medicine issues which span the continuum of drug discovery, development, regulation, and utilization. The theme of our 2018 meeting is Breaking Down Barriers to Effective Patient Care.

The 2018 scientific program includes two outstanding Pre-conference programs—*Pharmacometrics Meets Health Economics: Quantitative Approaches in the Translation from Efficacy to Real World Effectiveness and Cost-Effective Patient Care* and *Pediatric Drug Development: Challenges and Opportunities in Extrapolation*. In addition, we have several innovative formats and offerings, including the *Pharmacometrics Skills Competition: MIDD Gran Prix* and *Career Development for Everyone*.

The program includes two of our esteemed members as Featured speakers—Deanna Kroetz, PhD, University of California, San Francisco and Angela Kashuba, PharmD, University of North Carolina, Chapel Hill. ASCPT will honor those who have made remarkable contributions in the fields of clinical pharmacology and translational medicine during the Opening Session and throughout the Annual Meeting. This year's award recipients are Steve Ryder, MD; Richard Pazdur, MD; David Strauss, MD, PhD; Amita Joshi, PhD; Hartmut Derendorf, PhD; William Jusko, PhD; Gregory Kearns, PharmD, PhD; France Mentré, MD, PhD; and Kenneth Schmader, MD.

Special events are planned specifically for our student and trainee attendees, including the new and enhanced Trainee Breakfast, Speed Mentoring, and a Career Development Session, among others.

We will feature more than 350 Scientific Posters, Symposia, Workshops, Science at Sunrise, and an Innovation Forum. Our Exhibit Hall will showcase a wide range of products and services for our ASCPT meeting attendees.

I encourage you to make your hotel reservation at the official headquarters hotel, the Hilton Orlando, before February 23, 2018. Staying at the Hilton not only makes the meeting more accessible to you, but also allows ASCPT the financial flexibility to host and fund the highest quality scientific program. A special block of rooms has been reserved at the Hilton for our student/trainee and government attendees.

The ASCPT Annual Meeting is a premier opportunity to learn about the emerging science and to network with colleagues from around the globe. I look forward to seeing you in Orlando!

Sincerely,

Kellie Schoolar Reynolds, PharmD
President

THANK YOU

ASCPT WOULD LIKE TO ACKNOWLEDGE AND THANK THE 2017–2018 SCIENTIFIC PROGRAM COMMITTEE FOR THEIR CONTRIBUTIONS TO THIS YEAR'S ANNUAL MEETING.

Peter H. O'Donnell, MD
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Vice Chair

Susan M. Abdel-Rahman, PharmD
Immediate Past Chair

Kellie Schoolar Reynolds, PharmD
President

Julie A. Johnson, PharmD
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Neeraj Gupta, PhD
Dionna Jeter Green, MD
Hazem Hassan, MS, PhD
Jin Yan Jin, PhD
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Tamorah Rae Lewis, MD, PhD
Kari Morrissey, PhD
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Rada Savic, PhD
Mohamed H. Shahin, BPharm, PhD
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Vikram P. Sinha, PhD
Sony Tuteja-Stevens, PharmD, MS
Alexander G. Vandell, PharmD, PhD
Susan I. Vear, MD, MSCI
Sandra A.G. Visser, PhD
Liewei Wang, MD, PhD
Larissa A. Wenning, PhD

ASCPT WOULD LIKE TO ACKNOWLEDGE AND THANK THE 2017–2018 BOARD OF DIRECTORS FOR THEIR CONTRIBUTIONS, TIME, AND DEDICATION TO THE SOCIETY.

Kellie Schoolar Reynolds, PharmD
President

Dan Hartman, MD
President-Elect

Julie A. Johnson, PharmD
Immediate Past President

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Director

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Director

IMPORTANT DATES

THURSDAY, DECEMBER 14
Early Bird Registration Deadline

THURSDAY, JANUARY 18
Advanced Registration Deadline

FRIDAY, FEBRUARY 23
Hotel Reservation Deadline

GENERAL INFORMATION

TARGET AUDIENCE

The intended audience for ASCPT 2018 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 via email at meetings@ascpt.org.

REGISTRATION, HOTEL, AND TRAVEL INFORMATION

Annual Meeting attendees will be 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 Orlando, FL, visit www.ascpt.org.

ASCPT CAREER CENTER

Looking for new job opportunities or recruiting for open positions? The ASCPT Job Board 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. Communities are categorized into three main Networks: Quantitative Pharmacology (QP), Translational & Precision Medicine (TPM), and Development, Regulatory & Outcomes (DRO). All education sessions will correlate to Networks/Communities to help assist you in planning your Annual Meeting experience.

ASCPT EXHIBIT HALL AND PARTNERSHIP

The Exhibit Hall continues to expand and offer 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.

PRE-CONFERENCE PROGRAMS

ASCPT will offer two scientific Pre-conference programs designed for scientists and health professionals engaged in all aspects of clinical pharmacology and translational science, including educators, regulatory officials, consultants, industry professionals, students, and trainees. These Pre-conferences will take place immediately preceding the ASCPT 2018 Annual Meeting and will sell out, so we encourage you to register early.

PEDIATRIC DRUG DEVELOPMENT: CHALLENGES AND OPPORTUNITIES IN EXTRAPOLATION

10:00 AM – 5:00 PM
WEDNESDAY, MARCH 21, 2018
Half-day symposium and mock-team workshop
Co-Sponsors: *IQ Consortium, Pediatric Working Group, Clinical Pharmacology Leadership Group, and ASCPT Special Populations Community*

A recent paradigm change in pediatric drug development has centered on earlier and more innovative approaches to clinical research in children, with the goal of generating data that can support regulatory approval and/or provide useful information for practitioners in labeling, thereby minimizing the potential risk associated with "off-label" use. This pre-conference session will explore these issues through the lenses of both oncology and Type 2 Diabetes for the pediatric patient.

Oncology symposium (2 hours)

Chairs: *Konstantina M. Vanevski, MD and Dionna Jeter Green, MD*

Speakers: *Gregory H. Reaman, MD*
Associate Director, Office of Hematology and Oncology Products; Office of New Drugs/CDER/US Food and Drug Administration
Hubert Caron, MD, PhD
Senior Medical Director Pediatric Oncology at Roche and Global Development Team Leader; Pediatrics (iPODD) Genentech, a member of the Roche Group; Research Professor at AMC, Amsterdam

The pediatric oncology symposium and panel discussion will focus on the limited scope of pediatric extrapolation, including challenges and opportunities for this specific therapeutic area. Two didactic sessions will:

1. Discuss challenges and opportunities in pediatric oncology drug development and provide an overview of the attributes of on-going and planned trials and strategies for enhancing pediatric drug development
2. Discuss innovative clinical trial approaches, assess the feasibility and potential design of mechanism-of-action based Phase I/II master trial platforms for concurrently studying multiple molecules across a range of relevant pediatric tumor types, and prioritized criteria that may help identify the most promising molecules to take forward from a master trial into pivotal studies. These may include discussions on the joint FDA/EMA master trial protocol proposal, named iMATRIX, that has been evaluated.

A follow up panel discussion will be dedicated to considerations for a pediatric master protocol. Within this context, panelists may discuss trial design and molecular prioritization criteria; the role of a multi-stakeholder decision-making body and governance; logistical and operational considerations and challenges; and fulfilling regional pediatric regulations and addressing globalization challenges.

Type 2 diabetes extrapolation workshop (3 hours)

The Extrapolation in Type 2 Diabetes Workshop is designed to mimic the multidisciplinary project team discussion environment that every pharmaceutical industry needs to undergo in order to propose an extrapolation plan. Hence, participants of this mock-project team will involve members from the academia and industry with the various expertise required for this exercise. The expertise identified to be of relevance is: clinical pharmacology, medical, statistics and translational science. A facilitator will be included to ensure that the discussions are focused to achieve the objectives of this proposal. Finally, regulators will be available on the call to provide input and participate as needed.

The extrapolation exercise will be for a hypothetical drug indicated for the treatment of diabetes type 2. The exact mechanism of action is still to be decided. The level of detail on this hypothetical drug will be adjusted to allow discussion of difference scenarios. The workshop will allow participants to gain insight on evidence synthesis and team member contributions and will provide an opportunity for participants to observe the pediatric planning process from inception to submission.

Chairs: *Ashley Strougo, PhD, and Lily (Yeruk) Mulugeta, PharmD*

Speakers: *Lawrence Lesko, PhD, FCP; Jeffrey Barrett, PhD; Jan Marquard, MD; Margaret Gamalo-Siebers, PhD; Phil Zeitler, MD, PhD; Lynne Yao, MD; and Cecile Olliver*

MOCK-TEAM PARTICIPANTS

Facilitator: *Lawrence Lesko, PhD, FCP*
Clinical Professor and Director of the Center for Pharmacometrics and Systems Pharmacology in the University of Florida, College of Pharmacy at Lake Nona in Orlando, FL

Clinical pharmacology: *Jeffrey Barrett, PhD*
Vice President and Global Head of the Interdisciplinary Program in Pharmacometrics and Global Head of Pediatric Clinical Pharmacology at Sanofi Pharmaceuticals

(CONTINUED ON NEXT PAGE)

PRE-CONFERENCE PROGRAMS

Physician: *Jan Marquard, MD*
Medical Expert Pediatrics & Endocrinology; Team Member Medicine (Medical project lead TA metabolism/pediatric programs in diabetes) at Boehringer-Ingelheim Pharma, Ingelheim, Germany

Statistician: *Margaret Gamalo-Siebers, PhD*
Principal Research Scientist, Eli Lily and Company, member of the Pediatric & Small Population Drug Development Team, DIA Bayesian Working Group

Pediatrics-Endocrinology: *Phil Zeitler, MD, PhD*
Professor and Section Head, Endocrinology; Medical Director, Children's Hospital Colorado Clinical & Translational Research Center

Regulators: *Lynne Yao, MD*
Director, Division of Pediatrics, Office of New Drugs; Chair, Pediatric Review Committee (PeRC); US Food and Drug Administration (FDA)
Cecile Ollivier
European Medicines Agency

PHARMACOMETRICS MEETS HEALTH ECONOMICS: QUANTITATIVE APPROACHES IN THE TRANSLATION FROM EFFICACY TO REAL WORLD EFFECTIVENESS AND TO COST-EFFECTIVE PATIENT CARE

1:00 PM – 5:00 PM
WEDNESDAY, MARCH 21, 2018
Half day pre-conference with multiple engaging lectures and opportunities for discussion
Co-Sponsors: *ASCPT Quantitative Pharmacology and Development, Regulatory & Outcomes Networks; and International Society for Pharmacoeconomics and Outcomes Research*
Translation from efficacy in randomized controlled trials (RCT) to real world effectiveness and to cost-effective patient care is an emerging interest and the ultimate goal for clinical pharmacology and therapeutics. Featuring prominent leaders in the fields of clinical pharmacology, outcome research, and pharmacoeconomics, this pre-conference will promote inter-disciplinary collaboration and present state-of-the-art science and application of quantitative approaches at these junctures.

Chairs: *Jing Liu, PhD,* and *Richard Willke, PhD*

TOPICS AND SPEAKERS

Opening remarks
Jing Liu, PhD
Pfizer

Background/introduction: Role of Pharmacometrics and Health Economics for Cost-Effective Patient Care
Richard Willke, PhD
Chief Scientific Officer, ISPOR

Understanding the Comparative Efficacy and Effectiveness Via Meta-Analysis: Health Economics Approach
Jeroen P. Jansen, PhD, MSc
Chief Scientist, Precision Health Economics

Understanding the Comparative Efficacy and Effectiveness Via Model-Based Meta-Analysis: Pharmacometrics Approach
Jaap Mandema, PhD
President, Certara Strategic Consulting

Linking Pharmacometrics and Health Economics: Quantitative Approaches to Cost-Effectiveness Evaluations of Health Care Decisions
Dyfrig Hughes, PhD
Professor, Centre for Health Economics and Medicines Evaluation, University of Bangor, UK

Leveraging Novel Simulation Techniques to Incorporate Pharmacometrics in Pharmacoeconomic Models
Jaime Caro, MDCM, FRCPC, FACP
Chief Scientist, Evidera

Industry Perspectives: Examples on How to Assess Values in Drug Development
Myoung Kim, PhD
Vice President, Health Economics & Outcomes Research, Janssen Pharmaceuticals, Inc.

HTA Perspectives: Can Linked Pharmacometric-Health Economic Evidence Improve Early Evaluation of New Medicines?
Speaker TBA

Panel discussion and closing remarks
Leader: *Scott Marshall, PhD*
Pfizer, UK

PROGRAM HIGHLIGHTS

2018 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 "Breaking Down Barriers to Effective Patient Care." This theme is incorporated in Symposia, Workshops, Roundtables/Novel Formats, and Science at Sunrise sessions, and throughout the entire program.

The SPC has resumed the identification and branding of sessions according to the drug discovery, development, regulation, and utilization (DDRU) continuum to be consistent with ASCPT's Strategic Plan and the ongoing work of its members. At the 2018 Annual Meeting, Symposia, Workshops, Roundtables, and Science at Sunrise sessions will span the DDRU continuum.

Component(s) of the DDRU continuum that apply to the particular Symposium, Workshop, Roundtable, and Science at Sunrise session have been identified and branded accordingly.

D DISCOVERY
D DEVELOPMENT
R REGULATION
U UTILIZATION

D D R U

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! Revisit the best of the ASCPT 2018 Annual Meeting and 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, and the Innovation Forum.

Purchase with registration to receive a discounted rate!

OPENING RECEPTION AND SHOWCASE OF TOP TRAINEE ABSTRACTS

5:00 PM – 6:30 PM

WEDNESDAY, MARCH 21, 2018

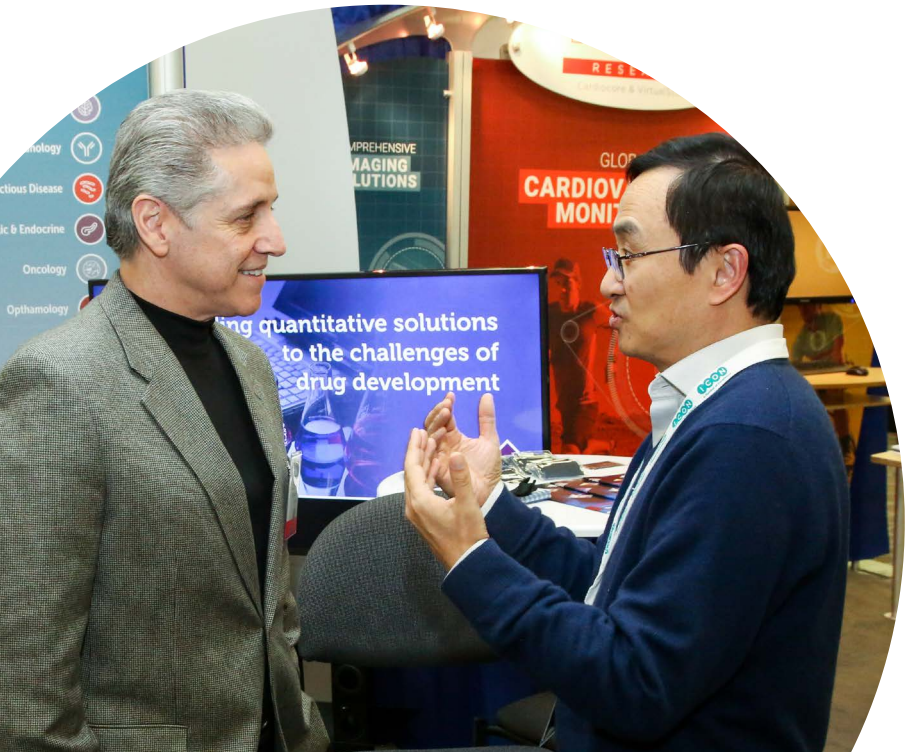
ASCPT invites you to join your colleagues on Wednesday evening for the first networking event of the meeting. Interact with fellow scientists from all over the globe, and view a showcase of 2018's Top Trainee Abstracts. The first Poster Walk sessions of this year's meeting will immediately follow the Showcase.

OPENING SESSION

8:00 AM – 9:00 AM

THURSDAY, MARCH 22, 2018

ASCPT President, Kellie Schoolar Reynolds, PharmD, kicks off the ASCPT 2018 Annual Meeting and presents several prestigious awards recognizing outstanding members.



PROGRAM HIGHLIGHTS

STATE OF THE ART LECTURES

Jack Gilbert, PhD

UNIVERSITY OF CHICAGO, CHICAGO, IL

Invisible Influence: The Microbiome in Precision Medicine

9:00 AM – 10:00 AM

THURSDAY, MARCH 22, 2018

ASCPT is honored to welcome Jack Gilbert, PhD, of the University of Chicago, as a State of the Art Lecturer. Dr. Gilbert is the Director of the Microbiome Center and a Professor of Surgery at the University of Chicago. He is also Group Leader for Microbial Ecology at Argonne National Laboratory, Research Associate at the Field Museum of Natural History, Scientific Fellow at the Marine Biological Laboratory, and the Yeoh Ghim Seng Visiting Professorship in Surgery at the National University of Singapore. Dr. Gilbert uses molecular analysis to test fundamental hypotheses in microbial ecology. He has authored more than 250 peer reviewed publications and book chapters on metagenomics and approaches to ecosystem ecology. He is the founding Editor-in-Chief of mSystems journal. In 2014 he was recognized on Crain's Business Chicago's 40 Under 40 List, and in 2015 he was listed as one of the 50 most influential scientists by Business Insider, and in the Brilliant Ten by Popular Scientist. In 2016 he won the Altemeier Prize from the Surgical Infection Society, and the WH Pierce Prize from the Society for Applied Microbiology for research excellence. He also co-authored "Dirt is Good" published in 2017, a popular science guide to the microbiome and children's health.

Mara Aspinall, MBA

HEALTH CATALYSTS, TUCSON, AZ

Data is the New Black: How the Fourth Industrial Revolution is Changing Healthcare

9:15 AM – 10:15 AM

FRIDAY, MARCH 23, 2018

ASCPT is honored to welcome Mara G. Aspinall, MBA, President and CEO of Health Catalysts, as a State of the Art Lecturer. In addition to her roles at Health Catalysts, an investment and advisory firm dedicated to the growth of new healthcare companies, Aspinall is also Executive Chairman of GenePeeks, a genomic based informatics company with a differentiated variant interpretation technology platform. Throughout her career, Aspinall has spearheaded initiatives to educate payers and policymakers on genomics and personalized medicine. She served as an active member of the Health and Human Services Secretary's Advisory Council on Genetics, Health & Society, in both the Obama and Bush administrations. Aspinall co-founded the International School of Biomedical Diagnostics at Arizona State University and Dublin City University, the first and only School dedicated entirely to Diagnostics as an independent discipline. Aspinall was named Arizona Biosciences Leader of the Year in 2016 by the Arizona Biotechnology Association and one of the "100 Most Inspiring People in Life Sciences" by PharmaVOICE magazine. Mara started her business career at the strategic consulting firm Bain & Company. She holds an MBA from Harvard Business School and a BA in International Relations from Tufts University.

9:15 AM – 10:15 AM

SATURDAY, MARCH 24, 2018

Speaker TBA

PROGRAM HIGHLIGHTS

SPEED MENTORING

12:00 PM – 1:30 PM

THURSDAY, MARCH 22, 2018

Plan to attend the new and improved Speed Mentoring event, which has been reformatted for 2018. The 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 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-off 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!

INNOVATION FORUM

3:15 PM – 4:45 PM

THURSDAY, MARCH 22, 2018

This session highlights the work of Brennan Spiegel, MD, of Cedars-Sinai Health Services Research; Adam Gazzaley, MD, PhD, of Neuroscape; Sam Volchenboum, MD, PhD, of the University of Chicago, all of whom have made outstanding innovative contributions in the areas of translational science and medicine, clinical pharmacology, regulatory science, and healthcare. The presentations are "TED-style" talks of 10-15 minutes each and the session will conclude with a moderated Q&A session.

PRESIDENT'S NETWORKING RECEPTION

5:00 PM – 6:30 PM

THURSDAY, MARCH 22, 2018

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, Kellie Schoolar Reynolds, PharmD.

TRAINEE BREAKFAST

7:00 AM – 8:30 AM

FRIDAY, MARCH 23, 2018

Students and trainees, come meet mid-career and senior scientists in academia, industry, regulatory, and consulting environments and discuss topics of your choice related to your current or future field of study. Have questions about what a day-in-the-life is like? Career possibilities? Skill sets you should focus on? Advantages and disadvantages of working in a specific area? Come get these and other questions answered in a relaxed, small group atmosphere.

SPECIAL EDUCATION SESSIONS

CAREER DEVELOPMENT FOR EVERYONE

4:45 PM – 6:15 PM

FRIDAY, MARCH 23, 2018

In 2018, ASCPT will launch a brand new Career Development Webinar Series for members of all career stages, focused on a variety of issues that are important to clinical pharmacologists, translational scientists, and other scientists in the early phase drug discovery, development, regulatory, and utilization space. The Career Development for Everyone session at the Annual Meeting will kick off this new program. Enjoy a dynamic presentation on the importance of mentorship from all perspectives, followed by a panel discussion of ASCPT members from various sectors and career stages. Finally, make your voice heard by participating in a discussion to generate ideas for the new webinar series.

PHARMACOMETRICS SKILLS COMPETITION: MIDD GRAN PRIX

7:00 AM – 9:00 AM

SATURDAY, MARCH 24, 2018

This longitudinal team-based activity will demonstrate approaches to complex data analysis, and underscore the importance of communication skills for pharmacometricians. To arrive at a defined drug development decision, a complex pharmacokinetic/pharmacodynamic data set will be simulated by Drs. Alan Forrest and Mark Lovern. The scenario and data will be available to teams—divided into professional and student categories—months prior to the meeting. The teams will work together and submit their drug development decision, supported by their data analysis to the session organizers, who will judge the submissions. The top two teams in each category will present their decision to a mock clinical development team at this Annual Meeting session, and cash prizes will be awarded to the winners of the competition.

SCHEDULE

WEDNESDAY, MARCH 21, 2018

8:00 AM – 6:30 PM
ASCPT CENTRAL AND REGISTRATION OPEN

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

10:00 AM – 5:00 PM
PRE-CONFERENCE
Pediatric Drug Development: Challenges and Opportunities in Extrapolation

1:00 PM – 5:00 PM
PRE-CONFERENCE
Pharmacometrics Meets Health Economics: Quantitative Approaches in the Translation from Efficacy to Real World Effectiveness and to Cost-Effective Patient Care

3:30 PM – 5:00 PM
CTS EDITORIAL TEAM MEETING
By Invitation Only

5:00 PM – 6:30 PM
OPENING RECEPTION
EXHIBIT HALL OPEN
LATE-BREAKING, ENCORE, AND
PRESIDENTIAL TRAINEE POSTERS

5:10 PM – 5:25 PM
SHOWCASE OF TOP TRAINEE ABSTRACTS

5:25 PM – 5:55 PM
POSTER WALK I:
Pharmacometrics and Pharmacokinetics

6:00 PM – 6:30 PM
POSTER WALK II:
Oncology

6:30 PM – 8:00 PM
PhRMA FOUNDATION RECEPTION
By Invitation Only

THURSDAY, MARCH 22, 2018

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

7:00 AM – 7:45 AM
AWARDS BREAKFAST

7:00 AM – 8:00 AM
NETWORKING BREAKFAST

7:00 AM – 8:00 AM
JOURNAL CLUB
By Invitation Only

8:00 AM – 9:00 AM
OPENING SESSION

9:00 AM – 10:00 AM
STATE OF THE ART LECTURE
Invisible Influence: The Microbiome in Precision Medicine

Jack Gilbert, PhD
University of Chicago, Chicago, IL

9:00 AM – 1:30 PM
EXHIBITS & POSTERS

10:15 AM – 11:15 AM
Rawls-Palmer Progress in Medicine Award Lecture
Gregory L. Kearns, PharmD, PhD
Arkansas Children's Hospital, Little Rock, AR

10:30 AM – 12:30 PM
SYMPOSIUM
Considerations for Selection of Immuno-Oncology Based Drug Combinations

D D R U

Oncology (ONC), Biomarker & Translational Tools (BTT)

Chair: *Apurvasena Parikh, PhD*
AbbVie, Redwood City, CA

Chair: *Lokesh Jain, PhD*
Merck, Rahway, NJ

(CONTINUED ON NEXT PAGE)

An Immunogenomic View of Personalized Cancer Medicine
SPEAKER
Thomas Hudson, MD
AbbVie, Redwood City, CA

Quantitative Systems Pharmacology (QSP) Models on Immune-Oncology to Inform Combination Strategies
SPEAKER
Gabriel Helmlinger, PhD
AstraZeneca, Waltham, MA

Rationale for Immuno-Oncology Combinations: Strategies for Selection of Combination Treatments and Clinical Evaluation
SPEAKER
David Kaufman, MD
Merck Research Laboratories, North Wales, PA

Immuno-Oncology Combinations–Clinical Trial Design Consideration
SPEAKER
Lillian L. Siu, MD
University of Toronto, Toronto, ON, Canada

10:30 AM – 12:30 PM
SYMPOSIUM
Integrating New Information Increasing Our Understanding of Placebo Response and Implications for Drug Development

D D R U

Regulatory Science (RS), Pharmacometrics & Pharmacokinetics (PMK)

Chair: *Teodora (Dora) Pene Dumitrescu, PhD*
GlaxoSmithKline, King of Prussia, PA

Case Study in Placebo Modeling and its Effect on Drug Development
SPEAKER
Julie Passarell, MA
Cognigen Corporation, Buffalo, NY

Application of Placebo Model in Drug Development–A Regulatory Perspective
SPEAKER
Yaning Wang, PhD
US Food and Drug Administration, Silver Spring, MD

Genetics of the Placebo Response: What Can We Learn From the Placebome?
SPEAKER
Kathryn Hall, PhD
Harvard Medical School, Boston, MA

Collaboration Across Fields to Minimize Placebo Response and Maximize the Potential for Positive Phase III Outcomes
SPEAKER
Virginia (Ginny) Schmith, PhD
Nuventra Pharma Sciences, Durham, NC

11:15 AM – 12:15 PM
FEATURED SPEAKER
The Impact of Clinical Pharmacology in HIV Cure Research

Angela Kashuba, PharmD
University of North Carolina at Chapel Hill, Chapel Hill, NC

12:00 PM – 1:30 PM
SPEED MENTORING
Registration Required

12:00 PM – 1:30 PM
CLINICAL PHARMACOLOGY PROGRAM DIRECTORS MEETING
By Invitation Only

12:00 PM – 1:30 PM
FINANCE COMMITEE MEETING
By Invitation Only

12:00 PM – 1:30 PM
PSP EDITORIAL TEAM MEETING
By Invitation Only

12:30 PM – 1:30 PM
LUNCH IN THE EXHIBIT HALL

1:30 PM – 2:30 PM
Leon I. Goldberg Early Investigator Award Lectures
Michael Pacanowski, PharmD, MPH, US Food and Drug Administration, Silver Spring, MD: 2017 Award Recipient
David Strauss, MD, PhD, US Food and Drug Administration, Silver Spring, MD: 2018 Award Recipient

(CONTINUED ON NEXT PAGE)

1:30 PM – 3:00 PM
ROUNDTABLE/NOVEL FORMAT
Quantitative Clinical Pharmacology of Antimicrobials: Is it Time to Move Past MIC?

D D R U

Pharmacometrics & Pharmacokinetics (PMK), Infectious Diseases (INF)

Chair: *Coen van Hasselt, PhD*
Leiden University, Leiden, Netherlands

Chair: *Matthew Rizk, PhD*
Merck, North Wales, PA

A Clinician's Perspective: What is Best for the Patient?
SPEAKER
Markus Zeitlinger, MD
Medical University of Vienna, Vienna, Austria

A Regulator's Perspective–Experiences with MIC-Based PK-PD Indices in the Dose Selection of Antimicrobial Drugs
SPEAKER
Yang He, PhD
US Food and Drug Administration, Washington, DC

The Case for MIC and PK-PD Indices–What We're Doing is Just Fine
SPEAKER
David Andes, MD
University of Wisconsin, Madison, WI

The Case Against MIC–Better Decisions with Pharmacometrics and Systems Approaches
SPEAKER
Lena Friberg, PhD
Uppsala University, Uppsala, Sweden

1:30 PM – 3:00 PM
WORKSHOP
Clinical and Translational Pharmacology of siRNA Therapies

D D R U

Pharmacogenomics (PMG), Biomarker & Translational Tools (BTT)

Chair: *Jason Karnes, PharmD, PhD*
University of Arizona, Tucson, AZ

Chair: *Sharvari Bhagwat, PhD*
Amgen, South San Francisco, CA

Bioanalytical Assays to Support the Advancement of siRNA Drug Development from Pre-clinical to Clinical Stages
SPEAKER
Brooke Rock, PhD
Amgen, South San Francisco, CA

siRNA Therapeutics: Target Identification, Discovery and Early Development Considerations
SPEAKER
Stacey Melquist, PhD, PMP
Arrowhead Pharmaceuticals, Madison, WI

A Progress Report on siRNA Therapeutics
SPEAKER
Judy Lieberman, MD, PhD
Boston Children's Hospital and Harvard Medical School, Boston, MA

3:15 PM – 4:45 PM
INNOVATION FORUM
Chair: *Peter H. O'Donnell, MD*
University of Chicago, Chicago, IL

Digital Health Technologies, Including Virtual Reality and Social Media, as Means to Improve Health Outcomes
Brennan Spiegel, MD, MSHS
Cedars-Sinai Health Services Research, Los Angeles, CA

Leveraging Video Games and Other Consumer Friendly Technologies to Improve Brain Health
Adam Gazzaley, MD, PhD
University of California, San Francisco, San Francisco, CA

Patient-Reported Digital Health Data for Clinical Trial Reporting
Sam Volchenboum, MD, PhD
University of Chicago, Chicago, IL

5:00 PM – 6:30 PM
PRESIDENT'S NETWORKING RECEPTION
EXHIBIT HALL OPEN
POSTER SESSION I

5:15 PM – 5:45 PM
POSTER WALK III:
Pharmacogenomics

6:00 PM – 6:30 PM
POSTER WALK IV:
Psychiatry, Maternal-Fetal Pharmacology, and Tuberculosis

6:15 PM – 7:15 PM
DONOR RECEPTION
By Invitation Only

8:30 PM – 10:00 PM
GAVEL CLUB DESSERT RECEPTION
By Invitation Only

(CONTINUED ON NEXT PAGE)

FRIDAY, MARCH 23, 2018

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

6:45 AM – 8:00 AM
NETWORK & COMMUNITY LEADER BREAKFAST MEETING
By Invitation Only

7:00 AM – 1:30 PM
EXHIBIT HALL OPEN

7:00 AM – 8:00 AM
NETWORKING BREAKFAST

7:00 AM – 8:30 AM
TRAINEE BREAKFAST
Registration Required

7:00 AM – 8:30 AM
POSTER SESSION II

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

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

7:30 AM – 9:00 AM
SCIENCE AT SUNRISE
Transforming Clinical Practice with Translational Informatics and Multi-Omics Data Science

D D R U

Translational Informatics (TI), Oncology (ONC)

Chair: *Matthew Breitenstein, PhD*
University of Pennsylvania, Philadelphia, PA

Chair: *Nicholas Tatonetti, PhD*
Columbia University, New York, NY

The Role of Informatics in Off-Label Recommendations and Biomarker-Guided Therapies
SPEAKER
Subha Madhavan, PhD
Georgetown University, Washington, DC

Knowledge Representation Standards as a Translational Pivot
SPEAKER
Robert Freimuth, PhD
Mayo Clinic, Rochester, MN

Algorithms, Rapid Analyses, and Data Integrity in Clinical Practice
SPEAKER
Samuel Volchenboum, MD, PhD
University of Chicago, Chicago, IL

7:30 AM – 9:00 AM
SCIENCE AT SUNRISE
Non-Traditional Pathway to Drug Approval

D D R U

Regulatory Science (RS), Pharmacometrics & Pharmacokinetics (PMK)

Chair: *Hazem Hassan, PhD, MS, RPh, RCDS*
University of Maryland School of Pharmacy, Baltimore, MD

Chair: *Islam Younis, PhD, MS, BPharm*
US Food and Drug Administration, Silver Spring, MD

How Quantitative Pharmacology Can be Used to Facilitate Drug Approval Under the Animal Rule Paradigm: A Case Study in Acute Radiation Syndrome
SPEAKER
Murad Melhem, PhD, BPharm
Amgen, Thousand Oaks, CA

Approaches for Dose Translation Under the Animal Rule Paradigm: FDA Experience
SPEAKER
Islam Younis, PhD, MS, BPharm
US Food and Drug Administration, Silver Spring, MD

Opportunities and Challenges for Drug Development Utilizing the Animal Rule Regulatory Paradigm
SPEAKER
Andrea Powell, PhD
US Food and Drug Administration, Silver Spring, MD

(CONTINUED ON NEXT PAGE)

9:15 AM –10:15 AM
STATE OF THE ART LECTURE
Data is the New Black: How the Fourth Industrial Revolution is Changing Healthcare

Mara Aspinall, MBA
Health Catalysts, Tuscon, AZ

10:30 AM –11:30 AM
Sheiner-Beal Pharmacometrics Award Lecture
France Mentré, MD, PhD
University of Paris Diderot, Paris, France

10:30 AM – 12:30 PM
SYMPOSIUM
Biomarkers and Translational Tools to Inform Development of New Therapeutics for Neurodegeneration

D D R U

Biomarker & Translational Tools (BTT), Pharmacometrics & Pharmacokinetics (PMK)

Chair: *Klaus Romero, PhD*
Critical Path Institute, Tucson,AZ

Chair: *Sreeraj Macha, PhD*
Merck, Kenilworth, NJ

Model-Informed Biomarker Qualification: Alzheimer and Parkinson Disease Neuroimaging Biomarkers
SPEAKER
Daniela Conrado, PhD
Critical Path Institute, Tucson, AZ

Translation from Bench to Bedside: PET Tracers for Use in Neuroscience Drug Development
SPEAKER
Eric Hostetler, PhD
Merck, Kenilworth, NJ

Can Application of Quantitative Clinical Pharmacology Improve Early Clinical Development Success in Neurodegenerative Diseases?
SPEAKER
Gianluca Nucci, PhD
Pfizer, Cambridge, MA

Item Response Models for Translation in CNS Disorders
SPEAKER
Mats Karlsson, PhD
Uppsala University, Uppsala, Sweden

10:30 AM – 12:30 PM
SYMPOSIUM
Healthy Volunteer Studies in Oncology Drug Development: Pivotal Considerations Toward Optimal Deployment

D D R U

Oncology (ONC), Early Development & Drug Safety (EDDS)

Chair: *Mariam Ahmed, PhD*
US Food and Drug Administration, Silver Spring, MD

Chair: *Daria Stypinski, BPharm, PhD*
Pfizer, South San Francisco, CA

Regulatory Challenges in the Use of Healthy Volunteers
SPEAKER
Nicole Drezner, MD
US Food and Drug Administration, Silver Spring, MD

Use of Healthy Volunteers in Clinical Oncology Drug Development
SPEAKER
Weiwei Tan, PhD
Pfizer, San Diego, CA

Opportunities for Healthy Volunteer Clinical Pharmacology Studies in Oncology Drug Development: Targeted Agents, Immunomodulatory Agents, and Beyond Development
SPEAKER
Chirag Patel, PhD
Takeda, Cambridge, MA

Patient Care in Clinical Pharmacology Oncology Trials: Principal Investigator Perspective
SPEAKER
Eric Roeland, MD
UC San Diego Moores Cancer Center, La Jolla, CA

11:30 AM –12:30 PM
ORAL ABSTRACT SESSION I:
Pharmacometrics and Pharmacokinetics

12:00 PM – 1:30 PM
CPT EDITORIAL TEAM MEETING
By Invitation Only

12:30 PM – 1:15 PM
NETWORKING LUNCH

(CONTINUED ON NEXT PAGE)

1:15 PM – 2:45 PM
FEATURED SPEAKER
Reverse Translational Studies to Understand Drug-Induced Toxicity

Deanna Kroetz, PhD
University of California, San Francisco, San Francisco, CA

1:15 PM – 2:45 PM
WORKSHOP
Translational Medicine & Clinical Pharmacology Strategies Supporting Acceleration of Development of Anti-Infective Drugs

D D R U

Global Health (GH), Early Development & Drug Safety (EDDS)

Chair: *David Wesche, MD, PhD*
Clinical Pharmacology, Bill and Melinda Gates Foundation, Seattle, WA

Chair: *Stephan Chalon, MD, PhD*
Medicines for Malaria Venture, Geneva, Switzerland

Model-informed Malaria Drug Development from Animal Models to Phase II
SPEAKER
Nathalie Gobeau, PhD
Medicines for Malaria Venture, Geneva, Switzerland

Human Malaria Challenge Model in Early Development
SPEAKER
James McCarthy, MD, PhD
Senior Scientist, QIMR Berghofer Medical Research Institute, Brisbane, Australia

Clinical Pharmacology Aspects of Malaria Drug Development–An FDA Perspective
SPEAKER
Dakshina Chilukuri, PhD
US Food and Drug Administration, Silver Spring, MD

1:45 PM – 2:45 PM
ORAL ABSTRACT SESSION II
Pharmacology Topics in the Popular Press: Opioids, Ketamine, Immune Checkpoint Inhibitors, and Digital Health

3:00 PM – 4:00 PM
Oscar B. Hunter Career Award Lecture
William J. Jusko, PhD
University at Buffalo, SUNY, Buffalo, NY

3:00 PM – 4:30 PM
SPECIAL SESSION
#Science

D D R U

Special Populations (SPO), Drug Utilization & Outcomes (DUO)

Chair: *Violette Gijsen, MD, PhD*
Erasmus Medical Center, Rotterdam, Netherlands

Chair: *Valentina Shakhnovich, MD*
Children's Mercy, Kansas City, MO

Will You Follow Me? The Future of Social Media in Healthcare
SPEAKER
Michele Maddux, PhD
Children's Mercy, Kansas City, MO

Opportunities for Using Internet Search to Learn About Drug Response
SPEAKER
Russ Altman, MD, PhD
Stanford University, Stanford, CA

Social Media Mining for Pharmacovigilance: Challenges and Opportunities for Case-Control Studies
SPEAKER
Graciela Gonzalez-Hernandez, PhD
University of Pennsylvania, Philadelphia, PA

(CONTINUED ON NEXT PAGE)

3:00 PM – 4:30 PM
WORKSHOP
Unveiling the Genetic Architecture of Human Disease for Precision Medicine

D D R U

Pharmacogenomics (PMG), International Transporter Consortium (ITC)

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

Chair: *Jason Karnes, PharmD*
University of Florida, Gainesville, FL

Human Genetic Studies to Inform Drug Discovery and Early Development
SPEAKER
Robert M. Plenge, MD, PhD
Celgene Summit, NJ

Racial/Ethnic and Genetic Differences in the Response and Disposition of Newly Approved Drugs
SPEAKER
Anuradha Ramamoorthy, PhD
US Food and Drug Administration, Silver Spring, MD

Mutations in SLC Transporters are Causal for Rare Disease
SPEAKER
Kathy Giacomini, PhD
University of California, San Francisco, San Francisco, CA

4:45 PM – 6:15 PM
SPECIAL SESSION
Career Development for Everyone

Chair: *Anuradha Ramamoorthy, PhD*
US Food and Drug Administration, Silver Spring, MD

SPEAKER
Sharon Straus, MD
University of Toronto, Toronto, ON, Canada

Panelist: *Piet H. van der Graaf, PharmD, PhD*
Certara, Canterbury, United Kingdom

Panelist: *Hartmut Derendorf, PhD*
University of Florida, Gainesville, FL

Panelist: *Amita S. Joshi, PhD*
Genentech, San Francisco, CA

Panelist: *Shiew-Mei Huang, PhD*
US Food and Drug Administration, Silver Spring, MD

4:45 PM – 6:15 PM
WORKSHOP
Mechanistic Joint Modeling for Longitudinal and Time-to-Event Data in Oncology Drug Development, Recent Advances, and Toward Personalized Medicine

D D R U

Translational Informatics (TI), Pharmacometrics & Pharmacokinetics (PMK)

Chair: *Diansong Zhou, PhD*
AstraZeneca, Waltham, MA

Chair: *Jennifer Sheng, PhD*
Bristol-Myers Squibb, Lawrenceville, NJ

Dynamic Predictions of Progression Free Survival and Overall Survival in Non-Small Cell Lung Cancer Using Tumor Sizes: A Longitudinal Joint Modeling Approach for Gefitinib
SPEAKER
Nidal Al-Huniti, PhD
AstraZeneca, Waltham, MA

Joint Modeling Approach to Characterize Longitudinal M-Protein and Progression-Free Survival in Elotuzumab-Treated Patients with Relapsed/Refractory Multiple Myeloma
SPEAKER
Jennifer Sheng, PhD
Bristol-Myers Squibb, Lawrenceville, NJ

Mechanistic Joint Models Characterizing the Relationship Between Nonlinear Prostate Specific Antigen Kinetics and Survival in Prostate Cancer Patients
SPEAKER
France Mentré, MD, PhD
University of Paris Diderot, Paris, France

(CONTINUED ON NEXT PAGE)

SATURDAY, MARCH 24, 2018

7:00 AM – 12:00 PM
ASCPT CENTRAL AND REGISTRATION OPEN

7:00 AM – 8:00 AM
NETWORKING BREAKFAST

7:00 AM – 9:00 AM
SPECIAL SESSION
Pharmacometrics Skills Competition: MIDD Gran Prix

Pharmacometrics & Pharmacokinetics (PMK), Systems Pharmacology (SP)

Chair: *Julie Dumond, PharmD, MS*
UNC Eshelman School of Pharmacy, Chapel Hill, NC

Chair: *Mark Lovern, PhD*
Certara, Raleigh, NC

Chair: *Alan Forrest, PharmD*
UNC Eshelman School of Pharmacy, Chapel Hill, NC

Chair: *Nathan S. Teuscher, PhD*
Certara, Raleigh, NC

7:30 AM – 9:00 AM
ROUNDTABLE/NOVEL FORMAT
Delivery of Pharmacogenomics Test Results in Patient Care

D D R U

Pharmacogenomics (PMG)

Chair: Andria Del Tredici, PhD
CogenDx, San Diego, CA

Chair: Sony Tuteja, PharmD
University of Pennsylvania, Philadelphia, PA

Communicating Pharmacogenetic Test Results to Patients–What do They Want to Know?
SPEAKER
Theresa Strong, PhD
Foundation for Prader-Willi Research, Walnut, CA

Delivery of Pharmacogenetics Results to Patients in an Era of Global Travel
SPEAKER
Jesse Swen, PharmD
Leiden University Medical Center, Leiden, Netherlands

The Patient-Clinician Encounter in a Pharmacogenomics Clinic in a Community Health System
SPEAKER
Henry Dunnenberger, PharmD
St. Jude Children's Research Hospital, Memphis, TN

9:15 AM – 10:15 AM
STATE OF THE ART LECTURE
Speaker TBA

10:30 AM – 12:30 PM
BOARD OF DIRECTORS MEETING
By Invitation Only

10:30 AM – 12:30 PM
SYMPOSIUM
Breaking Down Barriers for Quicker Access to Drugs for Rare Diseases: Perspectives from a Regulator, a Patient Advocate, a Drug Developer, and a Research Consortium

D D R U

Biologics, Regulatory Science (RS)

Chair: *Anne Heatherington, PhD*
Summit Therapeutics, Cambridge, MA

Chair: *Neeraj Gupta, PhD*
Takeda, Cambridge, MA

Drug Development in Rare Diseases (Amyloidosis): Consortium Perspective
SPEAKER
Isabella Lousada, MS
Amyloidosis Research Consortium, Newton, MA

Approval of Eteplirsen: Patient Advocate Perspective
SPEAKER
Sharon Terry, MS
Genetic Alliance, Washington, DC

Bridging Patient Needs with Regulatory Flexibility for DMD Patients: FDA Perspective
SPEAKER
Bilal AbuAsal, PhD
US Food and Drug Administration, Silver Spring, MD

Industry Perspective on Rare Disease Drug Development
SPEAKER
Keith Gottesdiener, MD, FACP
Rhythm Pharmaceuticals, New York, NY

(CONTINUED ON NEXT PAGE)

10:30 AM – 12:30 PM
SYMPOSIUM
Demonstrating Biosimilarity with Clinical PK and PD Data in Lieu of Comparative Efficacy

D D R U

Biologics, Regulatory Science (RS)

Chair: *John Davis, PhD*
Regeneron, Tarrytown, NY

Chair: *Yow-Ming Wang, PhD*
US Food and Drug Administration, Silver Spring, MD

Choosing Between PD Similarity Study and Comparative Efficacy Study
SPEAKER
Richard Markus, MD
Amgen, Thousand Oaks, CA

Innovative Approaches to Maximize the Value of PK-PD Program in Developing Biosimilars
SPEAKER
Shefali Kakar, PhD
Novartis, East Hanover, NJ

The Role of PK and PD in the Regulatory Framework for Biosimilars Approval
SPEAKER
Yow-Ming Wang, PhD
US Food and Drug Administration, Silver Spring, MD

The Role of Mechanistic PK-PD Modeling in Explaining Variability in Efficacy Outcomes for Biosimilars Development
SPEAKER
Wojciech Krzyzanski, PhD
University at Buffalo, SUNY, Buffalo, NY

11:30 AM – 12:30 PM
ORAL ABSTRACT SESSION III:
Drug Transporters and Pharmacogenomics

12:30 PM – 1:15 PM
NETWORKING LUNCH

1:15 PM – 2:45 PM
WORKSHOP
Substrate-Dependent Polymorphic Effects in CYP-Mediated Drug Metabolism and Challenges for Pharmacogenetics Implementation

D D R U

Pharmacogenomics (PMG)

Chair: *Emily Scott, PhD*
University of Michigan, Ann Arbor, MI

Chair: *Daniel Hertz, PharmD, PhD*
University of Michigan, Ann Arbor, MI

Substrate-Specific Metabolism of CYP2D6: How can CYP2D6 Phenotype Prediction be Improved?
SPEAKER
Andrea Gaedigk, MS, PhD
Children's Mercy Kansas City, Kansas City, MO

Accommodating Substrate-Dependence in CYP Genotype to Activity Phenotype Translation for Pharmacogenetic Implementation
SPEAKER
Kelly Caudle, PharmD, PhD
St. Jude Children's Research Hospital, Memphis, TN

Substrate-Dependent Polymorphic Metabolism and Disposition of CYP2B6 Substrates
SPEAKER
Evan Kharasch, MD, PhD
Washington University in St. Louis, St. Louis, MO

(CONTINUED ON NEXT PAGE)

1:15 PM – 3:15 PM
SYMPOSIUM
Innovation in Clinical Dose Selection and Trial Optimization Using Bayesian Approaches: Steps Toward Accelerated Patient Care

D D R U

Pharmacometrics & Pharmacokinetics (PMK), Regulatory Science (RS)

Chair: *Indrajeet Singh, PhD*
Janssen Pharmaceuticals, Spring House, PA

Chair: *Ying Ou, PhD*
Amgen, South San Francisco, CA

Bayesian Statistics and Its implications for Drug Development
SPEAKER
Stephen Ruberg, PhD
Eli Lilly, Indianapolis, IN

Bayesian Adaptive Trials in Oncology Drug Development–Maximizing the Synergy Between Statisticians and Clinical Pharmacologists
SPEAKER
Stuart Bailey, PhD
Novartis, Cambridge, MA

Challenges and Opportunities of Bayesian Adaptive Trials: Regulatory and Pharmacometrics Perspectives
SPEAKER
Yaning Wang, PhD
US Food and Drug Administration, Silver Spring, MD

Challenges and Opportunities of Bayesian Adaptive Trials: Where Do We Go From Here?
SPEAKER
Carl C. Peck, MD
UCSF Center for Drug Development Science, San Luis Obispo, CA

1:15 PM – 3:15 PM
SYMPOSIUM
Pragmatic Approaches to Improvements in Pediatric Drug Therapy

D D R U

Drug Utilization & Outcomes (DUO), Special Populations (SPO)

Chair: *Geert 't Jong, MD, PhD*
University of Manitoba, Winnipeg, MB, Canada

Chair: *Catherine Sherwin, PhD*
University of Utah, Salt Lake City, UT

Pragmatic Approaches to Drug Studies in Infants' Development
SPEAKER
John van den Anker, MD, PhD
Children's National Medical Center, Washington, DC

Building Expertise in Pediatric Formulations
SPEAKER
Catherine Litalien, MD, PhD
St. Justine Children's Hospital, Montreal, QC, Canada

Moving Forward in Pediatric Therapeutics: the Roles of Academia, Industry, and Government
SPEAKER
Catherine Sherwin, PhD
University of Utah School of Medicine, Salt Lake City, UT

Novel Clinical Trial Design for Children with Chronic and Rare Disorders
SPEAKER
Michael Rieder, MD, PhD
University of Western Ontario, London, ON, Canada

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