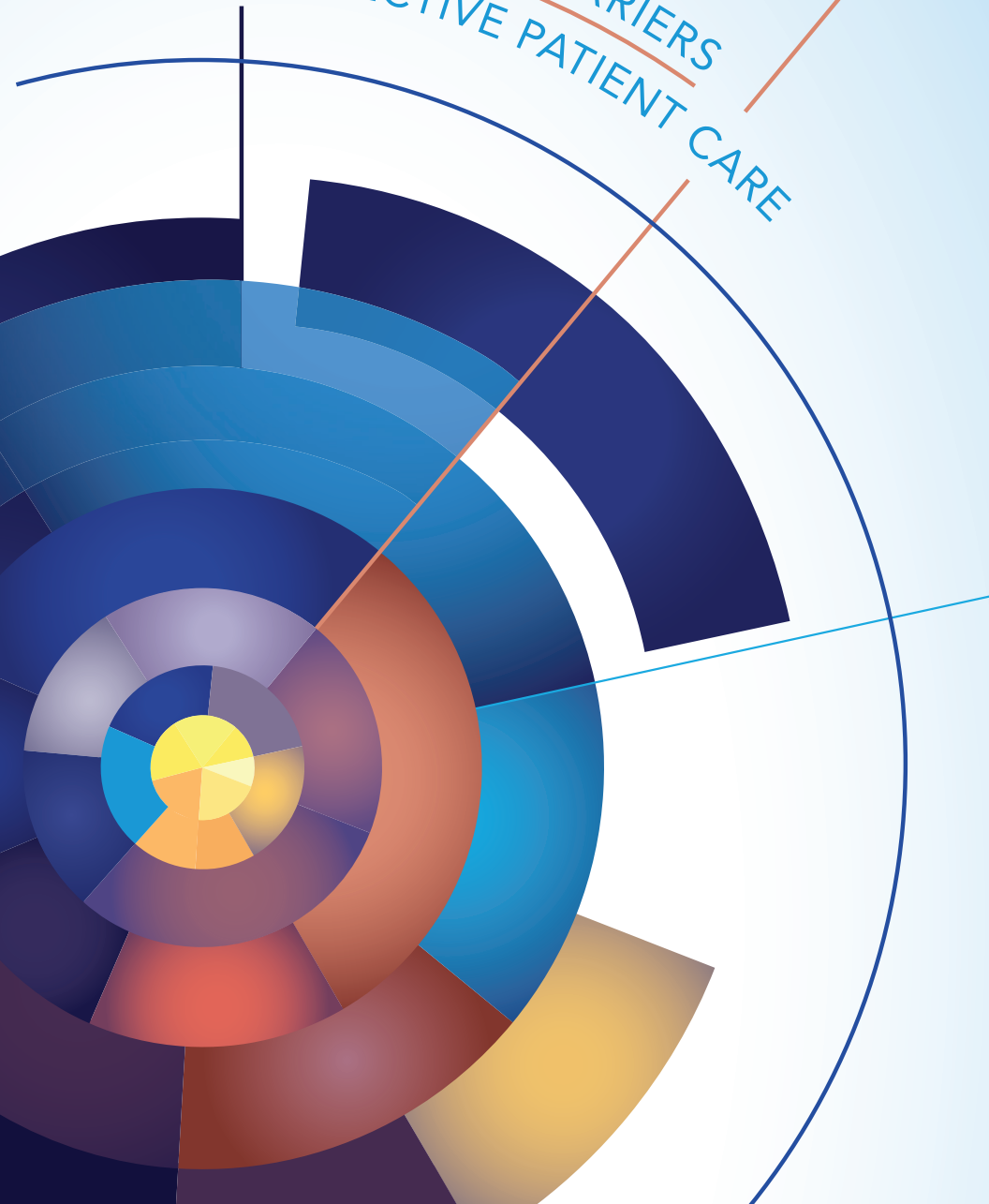


ASCPT 2018 ANNUAL MEETING
MARCH 21-24, 2018 • HILTON ORLANDO • ORLANDO, FL

PROGRAM & PRECONFERENCES

BREAKING DOWN BARRIERS TO EFFECTIVE PATIENT CARE





ASCPT 2019 ANNUAL MEETING

MARCH 13-16 • WASHINGTON MARRIOTT WARDMAN PARK • WASHINGTON, DC



120TH ANNUAL MEETING

CALL FOR PROPOSALS

PROPOSAL SUBMISSION DEADLINE

June 1, 2018, 4:00 PM ET



The theme for the 2019 Annual Meeting is
“From Molecule to Patient.”

This reflects the critical role of clinical pharmacology
in the translation of fundamental science to novel medicines
that can transform the lives of patients.

Dan Hartman, MD
President

Piet H. van der Graaf, PharmD, PhD
Scientific Program Committee Chair

CONNECT WITH US



For guidelines and to submit a proposal, visit www.ascpt.org

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WELCOME MESSAGE

2

ASCPT 2018 ANNUAL MEETING

Dear Colleague:

Welcome to Orlando and to the 119th Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), the premier scientific event for scientists in clinical pharmacology and translational medicine. We have an outstanding scientific program planned for you with the latest developments in our science, world renowned speakers, exhibits, posters, and the perfect networking opportunity to see your colleagues in one place.

With a theme of *Breaking Down Barriers to Effective Patient Care*, ASCPT 2018 features two tremendous Pre-conference programs, along with a few sessions that are sure to be highlights of our meeting, including the Innovation Forum showcasing the work of three innovators in the areas of translational science and medicine, clinical pharmacology, regulatory science and healthcare. We know you won't want to miss the *Pharmacometrics Skills Competition: MIDD Gran Prix*. From our final professional and student teams, to the panel of ASCPT celebrity judges, this session is sure to energize the audience with a uniquely novel learning experience.

ASCPT 2018 includes three excellent State of the Art lectures by Jack Gilbert, PhD, University of Chicago; Mara Aspinnall, MBA, Health Catalysts; and Sebastian Schneeweiss, MD, ScD, Harvard Medical School. Featured speakers include Deanna L. Kroetz, PhD, University of California, San Francisco and Angela Kashuba, PharmD, University of North Carolina at Chapel Hill.

ASCPT will honor those who have made remarkable contributions in the field of clinical pharmacology and translational medicine. This year's award recipients include Richard Pazdur, MD; Steven Ryder, MD; David Strauss, MD, PhD; Amita Joshi, PhD, Hartmut Derendorf, PhD; William J. Jusko, PhD; Gregory L. Kearns, PharmD, PhD; France Mentré, MD, PhD; and Kenneth Schmadler, MD.

We have a host of new and engaging opportunities for our student and trainee attendees, along with a Special Session, *Career Development for Everyone*. You will want to take advantage of all of these unique sessions.

Visit the Poster and Exhibit Hall where over 350 scientific poster presenters and 55 exhibitors will showcase their research, products, and services for you. We will be featuring Poster Walks as well as Exhibit Walks and multiple networking opportunities. Don't forget to have your professional headshot taken while in the Orange Ballroom Foyer.

Please join me in thanking the many people who have made this meeting possible, including the Scientific Program Committee under the leadership of Peter H. O'Donnell, MD, Network leaders, Karthik Venkatakrisnan, PhD, Lei Zhang, PhD, and Joan Korth-Bradley, PharmD, PhD, as well as the Community Chairs and Vice Chairs.

Finally, I encourage you to make the most of your time here in Orlando with the many learning and networking opportunities available and thank you for attending ASCPT 2018!

Sincerely,



Kellie Schoolar Reynolds, PharmD
President

ACKNOWLEDGMENTS

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

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Director

Paolo Vicini, PhD
Director

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

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THE INTEGRATED CLINICAL PHARMACOLOGY PLATFORM: Optimizing Drug Development

Science. Quality. Solutions.

Reaching your important early clinical milestones in today's complex environment requires scientific excellence, quality delivery and comprehensive solutions. At Covance, that's our focus.

Find out more about our unique integrated approach at:

Product Theater Lunch at ASCPT
Thursday, March 22, 2018 | Key West A | 12:30 PM

Join Oren Cohen, MD, Chief Medical Officer and Global Head of Clinical Pharmacology Services at Covance as he discusses an integrated approach to optimize your early clinical development program. Learn how our integrated solutions, which include Phase I GMP manufacturing, biomarker capabilities and special population studies can advance your development program in the critical early phases.



Oren Cohen, MD
*Chief Medical Officer and
Global Head of Clinical
Pharmacology Services
Covance*

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SCHEDULE-AT-A-GLANCE

SCHEDULE-AT-A-GLANCE

WEDNESDAY, MARCH 21, 2018

8:00 AM – 6:30 PM	ASCPT Info Desk and Registration Open	Orlando Ballroom Foyer
8:00 AM – 6:30 PM	Speaker Ready Room Open	Key West D
8:00 AM – 11:00 AM	ASCPT Board of Directors Meeting <i>(By Invitation Only)</i>	Ruby Lake
10:00 AM – 5:00 PM	PRE-CONFERENCE <i>Pediatric Drug Development: Challenges and Opportunities in Extrapolation</i>	Orlando I
11:00 AM – 7:00 PM	Headshot Lounge Open <i>(Sponsored by Certara)</i>	Orange Ballroom Foyer
11:30 AM – 1:30 PM	ASCPT & Wiley Meeting <i>(By Invitation Only)</i>	Ruby Lake
1:00 PM – 5:00 PM	PRE-CONFERENCE <i>Pharmacometrics Meets Health Economics: Quantitative Approaches in the Translation from Efficacy to Real World Effectiveness and to Cost-Effective Patient Care</i>	Orlando II
1:00 PM – 3:00 PM	TPM Network Meeting	Florida 5
3:30 PM – 4:30 PM	MHA & EC Joint Community Meeting	Florida 5
3:30 PM – 5:00 PM	CTS Editorial Team Meeting <i>(By Invitation Only)</i>	Key West A
4:30 PM – 6:30 PM	Exhibit and Poster Hall Open	Orange Ballroom
5:00 PM – 6:00 PM	DRO Network Meeting	Florida 5
5:00 PM – 6:30 PM	Opening Reception <i>(Sponsored by Certara)</i> <i>(Light food and beverages will be served)</i>	Orange Ballroom
5:00 PM – 6:30 PM	Poster Session: Presidential Trainee Showcase, Encore, Late-Breaking, and Oral Abstract Posters	Orange Ballroom
5:10 PM – 5:25 PM	Presidential Trainee Abstract Awards	Fountain Plaza on the Promenade
5:25 PM – 5:55 PM	Poster Walk I: <i>Pharmacometrics and Pharmacokinetics</i>	Orange Ballroom Foyer
6:00 PM – 6:30 PM	Poster Walk II: <i>Oncology</i>	Orange Ballroom Foyer
6:00 PM – 6:30 PM	Exhibit Walk	Orange Ballroom
6:00 PM – 7:30 PM	PhRMA Foundation Reception <i>(By Invitation Only)</i>	Pocket Lake

- PRE-CONFERENCE
- SYMPOSIA
- WORKSHOP
- SCIENCE AT SUNRISE
- ROUNDTABLE/NOVEL FORMAT

SCHEDULE-AT-A-GLANCE

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ASCP 2018 ANNUAL MEETING

THURSDAY, MARCH 22, 2018

6:30 AM – 5:00 PM	ASCP Info Desk and Registration Open	Orlando Ballroom Foyer
6:30 AM – 5:00 PM	Speaker Ready Room Open	Key West D
7:00 AM – 7:45 AM	Awards Breakfast <i>(By Invitation Only)</i>	Key West A
7:00 AM – 8:00 AM	Networking Breakfast	Florida Foyer
7:00 AM – 8:00 AM	Journal Club <i>(RSVP Required)</i>	Key West B
7:00 AM – 8:00 AM	PMK & RS Joint Community Meeting	Orlando II
8:00 AM – 9:00 AM	Opening Session	Orlando IV
9:00 AM – 10:00 AM	STATE OF THE ART LECTURE Jack Gilbert, PhD	Orlando IV
9:00 AM – 10:00 AM	Celerion Product Theater	Key West A
9:00 AM – 1:30 PM	Exhibit and Poster Hall Open	Orange Ballroom
10:00 AM – 10:30 AM	Morning Break	Orange Ballroom
10:00 AM – 10:30 AM	Learning Lounge <i>(Sponsored by Clinilabs)</i>	Orange Ballroom
10:15 AM – 11:15 AM	Rawls-Palmer Progress in Medicine Award Lecture Gregory L. Kearns, PharmD, PhD	Orlando I
10:30 AM – 11:30 AM	SPO & ITC Joint Community Meeting	Key West A
10:30 AM – 12:30 PM	SYMPOSIA <i>Integrating New Information Increasing Our Understanding of Placebo Response and Implications for Drug Development</i>	Orlando II
	<i>Considerations for Selection of Immuno- Oncology Based Drug Combinations</i>	Orlando IV
11:00 AM – 7:00 PM	Headshot Lounge Open <i>(Sponsored by Certara)</i>	Orange Ballroom Foyer
11:15 AM – 12:15 PM	FEATURED SPEAKER Angela Kashuba, PharmD	Florida 1/2
12:00 PM – 1:30 PM	PSP Editorial Team Meeting <i>(By Invitation Only)</i>	Sand Lake
12:00 PM – 1:30 PM	Speed Mentoring <i>(Pre-registration Required)</i>	Florida 5

- PRE-CONFERENCE
- SYMPOSIA
- WORKSHOP
- SCIENCE AT SUNRISE
- ROUNDTABLE/NOVEL FORMAT

SCHEDULE-AT-A-GLANCE

12:00 PM – 1:30 PM	Training Program Directors Meeting <i>(By Invitation Only)</i>	Key West C
12:00 PM – 1:30 PM	Finance Committee Meeting <i>(By Invitation Only)</i>	Ruby Lake
12:30 PM – 1:30 PM	Grab & Go Lunch in the Exhibit Hall	Orange Ballroom/Hotel Food Outlets
12:30 PM – 1:30 PM	Covance Hosted Event	Key West A
1:30 PM – 2:45 PM	Leon I. Goldberg Early Investigator Award Lectures Michael Pacanowski, PharmD <i>(2017 Awardee)</i> David Strauss, MD, PhD <i>(2018 Awardee)</i>	Orlando II
1:30 PM – 3:00 PM	ROUNDTABLE/NOVEL FORMAT <i>Quantitative Clinical Pharmacology of Antimicrobials: Is it Time to Move Past MIC?</i>	Orlando I
1:30 PM – 3:00 PM	WORKSHOP <i>Clinical and Translational Pharmacology of siRNA Therapies</i>	Orlando IV
2:00 PM – 3:00 PM	SP & ONC Joint Community Meeting	Florida 1/2
2:45 PM – 3:15 PM	Afternoon Break	Orlando/Orange Ballroom Foyer
3:15 PM – 4:45 PM	INNOVATION FORUM	Orlando IV
4:30 PM – 6:30 PM	Exhibit and Poster Hall Open	Orange Ballroom
5:00 PM – 6:30 PM	Poster Session I	Orange Ballroom
5:00 PM – 6:30 PM	President's Networking Reception	Orange Ballroom
5:15 PM – 5:45 PM	Poster Walk III: <i>Pharmacogenomics</i>	Orange Ballroom Foyer
5:45 PM – 6:15 PM	Exhibit Walk	Orange Ballroom
6:00 PM – 6:30 PM	Poster Walk IV: <i>Psychiatry, Maternal-Fetal Pharmacology, and Tuberculosis</i>	Orange Ballroom Foyer
6:15 PM – 7:15 PM	Donor Reception <i>(By Invitation Only)</i>	Championsgate
6:30 PM – 8:00 PM	UCSF/Stanford/Genentech Reception <i>(By Invitation Only)</i>	Key West A
8:30 PM – 10:00 PM	Gavel Club Dessert Reception <i>(By Invitation Only)</i>	President's Suite

- PRE-CONFERENCE
- SYMPOSIA
- WORKSHOP
- SCIENCE AT SUNRISE
- ROUNDTABLE/NOVEL FORMAT

SCHEDULE-AT-A-GLANCE

FRIDAY, MARCH 23, 2018

6:30 AM – 5:00 PM	ASCPT Info Desk and Registration Open	Orlando Ballroom Foyer
6:30 AM – 5:00 PM	Speaker Ready Room Open	Key West D
6:45 AM – 8:00 AM	Network & Community Leaders Orientation Meeting <i>(By Invitation Only)</i>	Key West A
7:00 AM – 8:00 AM	Networking Breakfast	Orange Ballroom
7:00 AM – 8:30 AM	Trainee Breakfast <i>(Pre-registration Required)</i>	David's Restaurant
7:00 AM – 8:30 AM	Poster Session II	Orange Ballroom
7:00 AM – 9:00 AM	IQ Consortium–CPLG Meeting <i>(By Invitation Only)</i>	Turkey Lake
7:00 AM – 9:00 AM	American Board of Clinical Pharmacology (ABCP) Board Meeting <i>(By Invitation Only)</i>	Ruby Lake
7:00 AM – 1:30 PM	Exhibit and Poster Hall Open	Orange Ballroom
7:30 AM – 9:00 AM	SCIENCE AT SUNRISE <i>Non-Traditional Pathway to Drug Approval</i>	Orlando II
	<i>Transforming Clinical Practice with Translational Informatics and Multi-Omics Data Science</i>	Orlando I
7:30 AM – 9:00 AM	Joint Journal Editorial Boards Meeting <i>(By Invitation Only)</i>	Florida 6/7
8:00 AM – 9:00 AM	Biologics & BTT Joint Community Meeting	Florida 1/2
9:00 AM – 10:00 AM	PRA Health Sciences Product Theater	Key West A
9:15 AM – 10:15 AM	STATE OF THE ART LECTURE Mara Aspinall, MBA	Orlando IV
10:00 AM – 10:30 AM	Morning Break	Orange Ballroom
10:00 AM – 10:30 AM	Learning Lounge <i>(Sponsored by Pharmaron)</i>	Orange Ballroom
10:00 AM – 11:00 AM	TI & PMG Joint Community Meeting	Florida 1/2
10:30 AM – 11:30 AM	Sheiner-Beal Pharmacometrics Award Lecture France Mentré, MD, PhD	Orlando II

- PRE-CONFERENCE
- SYMPOSIA
- WORKSHOP
- SCIENCE AT SUNRISE
- ROUNDTABLE/NOVEL FORMAT

SCHEDULE-AT-A-GLANCE

10:30 AM – 12:30 PM	SYMPOSIA	
	<i>Healthy Volunteer Studies in Oncology Drug Development: Pivotal Considerations Toward Optimal Deployment</i>	Orlando IV
	<i>Biomarkers and Translational Tools to Inform Development of New Therapeutics for Neurodegeneration</i>	Orlando I
11:00 AM – 12:00 PM	GH & INF Joint Community Meeting	Key West A
11:30 AM – 12:30 PM	Oral Abstract Session I: <i>Pharmacometrics and Pharmacokinetics</i>	Florida 1/2
12:00 PM – 1:30 PM	CPT Editorial Team Meeting <i>(By Invitation Only)</i>	Ruby Lake
12:30 PM – 1:15 PM	Grab & Go Lunch in the Exhibit Hall	Orange Ballroom/ Hotel Food Outlets
12:30 PM – 1:15 PM	Ask NIGMS: Conversations Over Lunch	Key West C
12:30 PM – 1:30 PM	PAREXEL Product Theater	Key West A
1:15 PM – 2:45 PM	WORKSHOP	
	<i>Translational Medicine & Clinical Pharmacology Strategies Supporting Acceleration of Development of Anti-Infective Drugs</i>	Orlando I
1:15 PM – 2:45 PM	FEATURED SPEAKER	
	Deanna L. Kroetz, PhD	Orlando IV
1:45 PM – 2:45 PM	Oral Abstract Session II: <i>Pharmacology Topics in the Popular Press—Opioids, Ketamine, Immune Checkpoint Inhibitors, and Digital Health</i>	Florida 1/2
1:45 PM – 3:45 PM	QP Network Meeting	Orlando II

- PRE-CONFERENCE
- SYMPOSIA
- WORKSHOP
- SCIENCE AT SUNRISE
- ROUNDTABLE/NOVEL FORMAT

SCHEDULE-AT-A-GLANCE

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ASCT 2018 ANNUAL MEETING

FRIDAY, MARCH 23, 2018 (CONTINUED)

2:30 PM – 3:00 PM	Afternoon Break	Orlando/Orange Ballroom Foyer
2:30 PM – 3:30 PM	IQVIA Product Theater	Key West A
3:00 PM – 4:00 PM	Oscar B. Hunter Career Award in Therapeutics Lecture William J. Jusko, PhD	Florida 1/2
3:00 PM – 4:30 PM	SPECIAL SESSION <i>#Science</i>	Orlando IV
3:00 PM – 4:30 PM	WORKSHOP <i>Unveiling the Genetic Architecture of Human Disease for Precision Medicine</i>	Orlando I
4:45 PM – 6:15 PM	SPECIAL SESSION <i>Career Development for Everyone</i>	Florida 1/2
4:45 PM – 6:15 PM	WORKSHOP <i>Mechanistic Joint Modeling for Longitudinal and Time-to-Event Data in Oncology Drug Development, Recent Advances, and Toward Personalized Medicine</i>	Orlando I
6:15 PM – 7:15 PM	Pharmacometrics Skills Competition Reception by Certara <i>(By Invitation Only)</i>	Key West A
6:30 PM – 7:30 PM	University of Florida, College of Pharmacy Gator Reception <i>(By Invitation Only)</i>	Lake Eola

- PRE-CONFERENCE
- SYMPOSIA
- WORKSHOP
- SCIENCE AT SUNRISE
- ROUNDTABLE/NOVEL FORMAT

SCHEDULE-AT-A-GLANCE

SATURDAY, MARCH 24, 2018

6:30 AM – 8:00 AM	Networking Breakfast	Orlando Ballroom Foyer
7:00 AM – 12:00 PM	ASCPT Info Desk and Registration Open	Orlando Ballroom Foyer
7:00 AM – 1:00 PM	Speaker Ready Room Open	Key West D
7:00 AM – 9:00 AM	SPECIAL SESSION <i>Pharmacometrics Skills Competition: MIDD Gran Prix</i>	Orlando IV
7:30 AM – 9:00 AM	ROUNDTABLE/NOVEL FORMAT <i>Delivery of Pharmacogenomics Test Results in Patient Care</i>	Orlando I
9:15 AM – 10:15 AM	STATE OF THE ART LECTURE Sebastian Schneeweiss, MD, ScD	Orlando IV
10:15 AM – 10:45 AM	Morning Break	Orlando Ballroom Foyer
10:30 AM – 12:30 PM	ASCPT Board of Directors Meeting <i>(By Invitation Only)</i>	Ruby Lake
10:30 AM – 12:30 PM	SYMPOSIA <i>Demonstrating Biosimilarity with Clinical PK and PD Data in Lieu of Comparative Efficacy</i>	Orlando I
	<i>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</i>	Orlando IV
11:30 AM – 12:30 PM	Oral Abstract Session III: <i>Drug Transporters and Pharmacogenomics</i>	Florida 1/2
12:30 PM – 1:15 PM	Networking Lunch	Hotel Food Outlets
1:15 PM – 2:45 PM	WORKSHOP <i>Substrate-Dependent Polymorphic Effects in CYP-Mediated Drug Metabolism and Challenges for Pharmacogenetics Implementation</i>	Orlando II
1:15 PM – 3:15 PM	SYMPOSIA <i>Pragmatic Approaches to Improvements in Pediatric Drug Therapy</i>	Florida 1/2
	<i>Innovation in Clinical Dose Selection and Trial Optimization Using Bayesian Approaches: Steps Toward Accelerated Patient Care</i>	Orlando I

- PRE-CONFERENCE
- SYMPOSIA
- WORKSHOP
- SCIENCE AT SUNRISE
- ROUNDTABLE/NOVEL FORMAT

SPECIAL EVENTS & 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/Novel Formats and Science at Sunrise sessions will span the DDRU continuum.

D DISCOVERY **D** DEVELOPMENT
R REGULATION **U** UTILIZATION

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.

D **D** **R** **U**

PRE-CONFERENCE PROGRAMS

On Wednesday, March 21, ASCPT offers 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, and students and fellows.

Pediatric Drug Development: Challenges and Opportunities in Extrapolation

Pharmacometrics Meets Health Economics: Quantitative Approaches in the Translation from Efficacy to Real World Effectiveness and to Cost-Effective Patient Care

Please refer to pages 33-38 for details on these Pre-conference sessions.

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, the Innovation Forum, and select Workshops, Symposia, and Special Sessions. Visit the ASCPT Info Desk for more details.

EXHIBIT WALKS

Learn first-hand about the many useful services in the ASCPT Exhibit Hall and meet some outstanding scientists along the way! Join members of the ASCPT Board of Directors on brief Exhibit Walks around the Hall. There’s a lot to learn in these short, guided sessions, and you’ll enjoy the collegueship of some wonderful people, and be rewarded for your efforts. Please refer to the Schedule-At-A-Glance or Scientific Agenda for Exhibit Walk dates and times.

PROGRAM HIGHLIGHTS

OPENING RECEPTION AND SHOWCASE OF PRESIDENTIAL 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 Presidential Trainee Abstracts. The first Poster Walk sessions of this year’s meeting will immediately follow the Presidential Trainee Awards Presentation.

Opening Reception Sponsored by:

CERTARA

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 prestigious ASCPT awards recognizing outstanding achievements in clinical pharmacology and translational science.

SPECIAL EVENTS & HIGHLIGHTS

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, and Sam Volchenbom, 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. A moderated Q&A session will follow these dynamic presentations.

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.

Be sure to stop by the Craft Beer Station sponsored by Nuventra!

ASK NIGMS:

CONVERSATIONS OVER LUNCH

12:30 PM – 1:15 PM

FRIDAY, MARCH 23, 2018

Interested in learning more about opportunities for funding from the National Institute of General Medical Sciences (NIGMS)? Join Rochelle Long, PhD, for an informal conversation over lunch and learn more about two exciting opportunities:

MIRA grants: of interest to both established investigators with current NIGMS support, as well as new early stage investigators; and, Tools and Technologies FOAs: of interest to those who want to develop practical, time-limited, non-hypothesis-driven tool/tech projects.

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 was simulated by Drs. Alan Forrest and Mark Lovren. The scenario and data were made available to teams—divided into professional and student categories—months prior to the meeting. The teams worked together and submitted their drug development decision to a panel of expert reviewers. During this session, the top two teams in each category will present their decision to a mock clinical development team, an ASCPT Judging Panel, as well as the audience, who will cast votes in real time via the ASCPT 2018 Annual Meeting mobile app. This session is sure to be educational and fun for all involved!

Organizers and contestants of the Competition are invited to a special reception hosted by Certara from 6:15 PM – 7:15 PM, Friday, March 23, 2018, in Key West A!

CERTARA

SPECIAL EVENTS & HIGHLIGHTS

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ASCPT 2018 ANNUAL MEETING

STATE OF THE ART LECTURES

ASCPT IS HONORED TO WELCOME JACK GILBERT, PHD, MARA ASPINALL, MBA, AND SEBASTIAN SCHNEEWEISS, MD, SCD, AS THE 2018 STATE OF THE ART LECTURERS.



THURSDAY, MARCH 22, 2018

9:00 AM – 10:00 AM
ORLANDO IV

Jack Gilbert, PhD, University of Chicago, Chicago, IL

Invisible Influence: The Microbiome in Precision Medicine

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.



FRIDAY, MARCH 23, 2018

9:15 AM – 10:15 AM
ORLANDO IV

Mara Aspinall, MBA, Health Catalysts, Tucson, AZ

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

Ms. Aspinall is the CEO of Health Catalysts, an investment and advisory firm dedicated to the growth of new healthcare companies, as well as 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.

SPECIAL EVENTS & HIGHLIGHTS

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MARCH 21-24, 2018 • HILTON ORLANDO



SATURDAY, MARCH 24, 2018

9:15 AM – 10:15 AM

ORLANDO IV

Sebastian Schneeweiss, MD, ScD, Harvard Medical School, Boston, MA
Using Complex Healthcare Databases to Evaluate the Safety and Effectiveness of Newly Marketed Medications

Dr. Schneeweiss is a Professor of Medicine at Harvard Medical School and Vice Chief of the Division of Pharmacoepidemiology, Brigham and Women's Hospital. In addition to his roles at Harvard, he is Science Lead of Aetion, a software enabled healthcare company that builds a global real-world data network with rapid cycle analytics capabilities. Dr. Schneeweiss is Director of the Harvard-Brigham Drug Safety Research Center funded by FDA/CDER and Co-Chair of the Methods Core of the FDA Sentinel Initiative. He was President of the International Society for Pharmacoepidemiology and an inaugural member of the PCORI Methodology Committee.

His research in Healthcare Data Science focuses on the comparative effectiveness and safety of newly marketed biopharmaceuticals. He has developed analytic methods to improve the scientific rigor of epidemiologic analyses of complex longitudinal healthcare databases. The overarching theme of his research is applying advanced real-world data analytics transparently and rapidly for regulatory decision making in the US, EU, and East Asia. His work is published in over 350 articles.

FEATURED SPEAKERS

JOIN US FOR THE TWO ASCPT 2018 ANNUAL MEETING FEATURED SPEAKER SESSIONS AND HEAR PRESENTATIONS FROM YOUR FELLOW ASCPT MEMBERS.



THURSDAY, MARCH 22, 2018

11:15 AM – 12:15 PM

FLORIDA 1/2

Angela Kashuba, PharmD
University of North Carolina at Chapel Hill, Chapel Hill, NC
The Impact of Clinical Pharmacology in HIV Cure Research



FRIDAY, MARCH 23, 2018

1:15 PM – 2:15 PM

ORLANDO IV

Deanna L. Kroetz, PhD
University of California, San Francisco, San Francisco, CA
Reverse Translational Studies to Understand Drug-Induced Toxicity

SPECIAL EVENTS & HIGHLIGHTS

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ASCP 2018 ANNUAL MEETING

STUDENT AND TRAINEE INFORMATION

The ASCPT 2018 Annual Meeting features several education sessions and networking events designed specifically for trainees and young scientists to guide them in their personal and professional development. For 2018, ASCPT has redesigned its offerings, including a Trainee Breakfast, a new and improved Speed Mentoring session, and a special session, *Career Development for Everyone*, all of which are designed to bring early career, mid-career, and senior scientists together for support, collaboration, and mentorship.

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

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Board Liaison

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Trainee Breakfast Subcommittee Chair

Anuradha Ramamoorthy, PhD
Career Development for Everyone Subcommittee Chair

Georgios Vlasakakis, PhD
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Craig W. Hendrix, MD

Myong-Jin Kim, PharmD

Mengyao Li, PhD

Konstantina M. Vanevski, MD

TRAINEE BREAKFAST

7:00 AM – 8:30 AM

FRIDAY, MARCH 23, 2018

Students and trainees can enjoy the opportunity to meet mid-career and senior scientists from academia, industry, regulatory, and consulting environments to discuss topics of their choice in a relaxed, small group atmosphere.

This is a ticketed event; you must have registered and received a ticket with your registration materials to attend this breakfast.

FACILITATORS FOR THE 2018 TRAINEE BREAKFAST:

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Michael Bargfrede, BSc
Akintunde Bello, PhD
Lisa J. Benincosa, PhD
Galina Bernstein, PhD
Richard Bertz, PhD
Eric Burroughs, ME
Daniel Chan, PhD
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Daniel Gonzalez, PharmD, PhD
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Gina Patel, PhD
Dipti Pawaskar, PhD
Richard Peck, MD
Minoli Perera, PharmD, PhD
Mark C. Rogge, PhD
Aubrey Stoch, MD
Ashley Strougo, PhD

SPECIAL EVENTS & HIGHLIGHTS

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Jesse Swen, PhD, PharmD
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Howard Uderman, MD
Sandra A.G. Visser, PhD
Hua Lang, PhD
Kyunghye Yang, PhD
Xinning Yang, PhD
Theresa Yuraszeck, PhD
Julia Z. Zack, PharmD

SPEED MENTORING

12:00 PM – 1:30 PM
THURSDAY, MARCH 22, 2018

Speed Mentoring is back, and better than ever! This re-envisioned event allows for the opportunity for a rotation of 1:1 consultations with other members in your sector of interest.

This is a ticketed event; you must have registered and received a ticket with your registration materials to attend this luncheon.

2018 MENTORS:

Dan Hartman, MD

Academia

Matthew K. Breitenstein, PhD
Hartmut Derendorf, PhD
Kelly E. Dooley, MD, PhD
Julio Duarte, PharmD, PhD
Daniel Gonzalez, PharmD, PhD
Sean Hennessy, PharmD, PhD
Daniel L. Hertz, PharmD, PhD
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Radojka Savic, PhD
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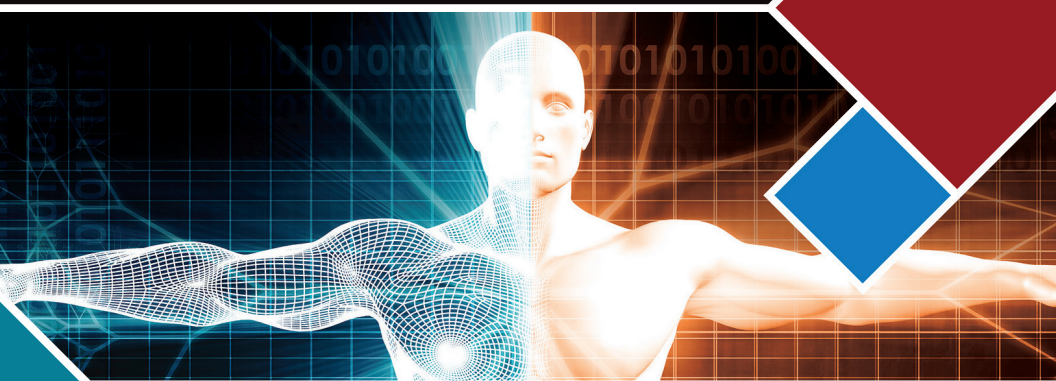
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Jill Fielder-Kelly, MS
Sirj Goswami, PhD
David Y. Mitchell, PhD
Robin O'Connor-Semmes, PhD
Virginia (Ginny) Schmith, PhD
Jeff Wald, PhD

Industry

Ghada F. Ahmed, PhD
Indranil (Neil) Bhattacharya, PhD
Sandeep Dutta, PhD
Puneet Gaitonde, PhD
Richard Graham, PhD
Neeraj Gupta, PhD
Donald Heald, PhD
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Angela James, PhD
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Val Kitchen, MBChB
Joan Korth-Bradley, PharmD, PhD
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Guy Meno-Tetang, PhD
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Daniele Ouellet, PhD
Dolly A. Parasrampur, PhD
Matthew L. Rizk, PhD
Ahmed H. Salem, PhD
Winnie Sohn, PhD
Michael Tortorici, PharmD, PhD
Ashit Trivedi, PhD
Karthik Venkatakrishnan, PhD
Paolo Vicini, PhD
Karthick Vishwanathan, PhD
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Jenna L. Voellinger, PhD
Joseph Ware, PhD
Larissa A. Wenning, PhD
Marc Yago, PhD
Songmao (Ben) Zheng, PhD

Regulatory

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Fax (703) 836-5223
Web www.ascpt.org

REGISTRATION HOURS ORLANDO BALLROOM FOYER

Please refer to the Schedule-At-A-Glance for registration hours.

SPEAKER READY ROOM KEY WEST D

ASCPT provides technical support through the services available in the Speaker Ready Room, located in Key West D. Speakers have the opportunity to review and revise their upcoming presentations. Speakers are strongly encouraged to check in to the Speaker Ready Room a minimum of 90 minutes in advance of their scheduled presentation. The A/V support staff will be available to make changes to presentations received in advance and assist with technical issues.

Please refer to the Schedule-At-A-Glance for the Speaker Ready Room hours.

BADGES

For security reasons, all attendees MUST wear their badge at all times for admission to sessions, the poster and exhibit hall, and social events.

Please have your picture ID ready to present when you pick up your badge materials. Once issued, badges are non-transferable.

If you need to have a badge reprinted, a photo ID is required.

ADA COMPLIANCE

ASCPT makes every effort to comply with the Americans with Disabilities Act. For additional information, please contact the ASCPT office at (703) 836-6981 ext. 108 or via email at meetings@ascpt.org.

ASCPT ETHICS STATEMENT

All scientific presentations at the ASCPT-sponsored events must adhere to the highest standards of scientific ethics, including acknowledgements or references to sources (both scientific and financial), and the absence of promotional content or endorsement of commercial products. Any relationship that could be perceived as a conflict of interest must be disclosed prior to the meeting.

ASCPT DISCLAIMER STATEMENT

Speakers are responsible for the content and ideas shared in their oral and written presentations. ASCPT is not responsible for, nor do we endorse, any oral statements or written information given by presenters at this meeting.

WI-FI ACCESS

ASCPT and Covance are pleased to provide complimentary Wi-Fi to our meeting attendees. Please see the access information below, which is also listed on the back of your badge.

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Password: COVANCE2018

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Download the ASCPT Annual Meeting mobile app to access the up-to-the-minute schedule, speaker information, exhibitor and sponsor details, floor plans, session evaluations, attendee list, and more! Search "ASCPT" in your app store to download the app.

The ASCPT 2018 mobile app is proudly sponsored by:

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BUSES TO POINTE ORLANDO

ASCPT is providing shuttle buses to take attendees to/from Pointe Orlando, a nearby entertainment/restaurant venue, on Thursday and Friday evening from 6:00 PM to 11:00 PM. Bus departures will be at the Group Arrival area between David's Restaurant and the Marketplace. Take the escalators to the lower level to board the bus.

GENERAL INFORMATION

MEETING EVALUATIONS

Please take the time to evaluate the Annual Meeting and its daily sessions through the Annual Meeting app. Your feedback is important to us and is used to improve future meetings. We encourage all who attend the Annual Meeting and the Pre-conferences to complete the evaluation. Attendees will be provided with a certificate of attendance upon completion of the evaluation. The online evaluation will be available from March 21, 2018 – April 20, 2018.

ASCPT INFO DESK

ORLANDO BALLROOM FOYER

At the ASCPT Info Desk, formerly known as “ASCPT Central,” you’ll have the opportunity to:

- Update your membership record and profile
- Speak with a member of the ASCPT Journal Family Editorial Staff
- Sign up to participate on various ASCPT Committees and Task Forces
- Volunteer as a *CPT*, *CTS*, or *PSP* manuscript or abstract reviewer
- Join ASCPT or refer a colleague for membership

And much more!

Please refer to the Schedule-At-A-Glance for ASCPT Info Desk hours.

CHARGING STATIONS

Look for charging stations throughout the Annual Meeting space to power up your mobile devices.

Charging station proudly sponsored by:



COMPLIMENTARY HEADSHOTS

ASCPT is proud to offer complimentary headshots for ASCPT Annual Meeting attendees. Take advantage of this opportunity to have a professional headshot taken by the official ASCPT photographer, International Center for Documentary Arts (ICDA). Conveniently located in the meeting foyer, no appointment is necessary and it will only take a few minutes of your time!

Please refer to the Schedule-At-A-Glance for Headshot Lounge hours.

Headshot Lounge proudly sponsored by:



POSTER AND EXHIBIT HALL HOURS

THE EXHIBIT HALL IS LOCATED IN THE ORANGE BALLROOM

Please refer to the Schedule-At-A-Glance for Poster Session and Exhibit Hall hours and additional information.

EXHIBITOR-HOSTED EVENTS

Select ASCPT exhibitors are offering special, sponsored presentations throughout the Annual Meeting. Product Theaters, Special Events, and Learning Lounges are opportunities for our attendees to learn more on specific areas of interest from speakers sourced by the sponsoring exhibitor. Space at these events is limited.

HOTEL SAFETY

Your safety while attending the Annual Meeting is important to ASCPT and the Hilton Orlando. In case of an emergency please dial 911 from the nearest house phone. Should there be a hotel emergency please follow the directions provided on the public address system and by hotel staff.

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.

POLICY ON CHILDREN, SPOUSES, AND GUESTS

The ASCPT Annual Meeting is strictly intended for adult attendance and participation. For their safety, and out of respect for the professional environment, children under the age of 16 are not permitted to attend any portion of the Annual Meeting, including but not limited to, educational sessions, networking and social events, and the Poster and Exhibit Hall.

If your child(ren) will accompany you to Orlando, and another adult will not be traveling with you, please make arrangements for care while you are attending Annual Meeting functions.

If your spouse or guest will accompany you to the Annual Meeting, please note that ASCPT does not offer spouse programs. However, the concierge at the Hilton

Orlando is adept at making arrangements for dining reservations, excursion reservations, providing shopping and transportation information, and answering general questions about local attractions.

ASCPT and your fellow colleagues appreciate your compliance with this policy.

BABYSITTING SERVICES

Neither ASCPT or the Hilton Orlando are affiliated with the babysitting agencies provided, and as such are not responsible for the services rendered.

The fees for babysitting services vary by vendor and holiday rates may also apply. Direct payment is required to the vendor. No room charges or master billing for babysitting services are permitted.

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Registrants of the ASCPT Annual Meeting agree to allow ASCPT and its official photographer and/or videographer to photograph or videotape them in the context of the meeting setting. Footage captured by the official ASCPT photographer/videographer may be used in future print educational, and electronic promotional and archival materials.

NO PHOTOGRAPHY

Use of camera or digital recording devices by attendees is not permitted. Attendees are not permitted to photograph or record session slides or posters during conference events.

MEAL VOUCHERS

Meal vouchers valued up to \$25 for Thursday, Friday, and Saturday will be provided to all registered attendees. Meal vouchers may be used between 11:30 AM and 1:30 PM for Grab & Go Lunch in the Exhibit Hall (Thursday & Friday) or at the following hotel food outlets: David's Restaurant, The Bistro, Tropics Pool Bar & Grill, Lobby Bar, and Marketplace.

GENERAL INFORMATION

ASCPT NETWORK AND COMMUNITY DESIGNATIONS

Communities are categorized into three main Networks: Quantitative Pharmacology (QP), Translational & Precision Medicine (TPM), and Development, Regulatory & Outcomes (DRO). Each educational session is correlated with or reflective of Communities to assist you with session selections that best represent your field(s) of interest.

EARLY CAREER COMMUNITY (EC)

(falls within all networks)

QP NETWORK

Biologics

Pharmacometrics &

Pharmacokinetics (PMK)

Systems Pharmacology (SP)

Translational Informatics (TI)

TPM NETWORK

Biomarkers & Translational Tools (BTT)

Infectious Diseases (INF)

International Transporter Consortium (ITC)

Mental Health & Addiction (MHA)

Oncology (ONC)

Pharmacogenomics (PMG)

Pharmacometabolomics (PM)

Special Populations (SPO)

DRO NETWORK

Drug Utilization & Outcomes (DUO)

Early Development & Drug Safety (EDDS)

Global Health (GH)

Regulatory Science (RS)

ACKNOWLEDGMENT OF NETWORKS & COMMUNITIES

ASCPT would like to give special thanks to the leadership of the Networks & Communities and recognize their dedication and contributions to important Society endeavors.

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Shruti Agrawal, PhD
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PM Community, Vice Chair

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SPO Community, Chair

Paulien Ravenstijn, PhD
SPO Community, Vice Chair

Erica L. Woodahl, PhD
SPO Community, Past Chair

Lei Zhang, PhD
DRO Network, Chair

Donald L. Heald, PhD
DRO Network, Vice Chair

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DUO Community, Chair

Joshua J. Gagne, PharmD, ScD
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Tobias Gerhard, PhD
DUO Community, Past Chair

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EDDS Community, Chair

Sandeep Dutta, PhD
EDDS Community, Vice Chair

John T. Sullivan, MD
EDDS Community, Past Chair

Radojka Savic, PhD
GHC Community, Chair

Terrence F. Blaschke, MD
GHC Community, Vice Chair

Robin O'Connor-Semmes, PhD
RS Community, Chair

Anuradha Ramamoorthy, PhD
RS Community, Vice Chair

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ASCPT wishes to thank and acknowledge the efforts of the 2017-2018 Scientific Awards Nomination Task Force and the 2017-2018 Scientific Awards Selection Task Force.

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ASCP 2018 ANNUAL MEETING

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Andre Terzic, MD, PhD
Mark J. Dresser, PhD
David Y. Mitchell, PhD
Joann Data, MD, PhD, and Herman Cantrell
Piet H. van der Graaf, PhD, PharmD
Dan Hartman, MD
Virginia (Ginny) Schmith, PhD
Kathleen M. Giacomini, PhD
Peter Honig, MD
John T. Sullivan, MD, ChB
Carl C. Peck, MD
Steven Ryder, MD
Morna Conway, PhD
Arnold G. Vulto, PhD
John F. Beary, III, MD
Sharon J. Swan, FASAE, CAE

CORPORATE & MATCHING DONORS

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GENERAL INFORMATION

NETWORK & COMMUNITY MEETINGS

NETWORK MEETINGS

Translational & Precision Medicine (TPM) Network Meeting

WEDNESDAY, MARCH 21, 2018

1:00 PM – 3:00 PM

FLORIDA 5

Join the TPM Network for a brief business meeting followed by two talks: “*Genome-Wide Association Study of Antipsychotic Pharmacokinetics*,” presented by Kirstin L. Bigos, PhD, and “*Precision Medicine with Indigenous People*,” presented by Erica Woodahl, PhD. The meeting will close with a discussion and programming strategy session and a presentation on “*What’s Next on the Horizon in Precision Medicine*,” presented by Kelly E. Dooley, MD, PhD, and Matthew L. Rizk, PhD.

Development, Regulatory & Outcomes (DRO) Network Meeting

WEDNESDAY, MARCH 21, 2018

5:00 PM – 6:00 PM

FLORIDA 5

DRO invites you to attend their Network meeting which will include a business meeting, DRO-based scientific presentation, RS Community showcase, and Community “pulse” discussions with ASCPT members.

Quantitative Pharmacology (QP) Network Meeting

FRIDAY, MARCH 23, 2018

1:45 PM – 3:45 PM

ORLANDO II

The Quantitative Pharmacology Network has over 1,000 members from across all sectors of ASCPT who are passionate about the application of quantitative pharmacology principles to drug/biologic/target discovery, development and clinical practice. Our Network meeting will feature:

- Flash presentations highlighting examples of the impact of QP within our discipline and illustrating opportunities for collaboration across traditional pharmacometrics/systems pharmacology and the emerging discipline of translational informatics to enable next-generation translational medicine.
- Highlighting initiatives from our volunteer leaders and Early Career members.
- Providing updates from across our Network and Communities.
- A panel discussion, “Breaking Down Barriers in Quantitative Translational Medicine: Opportunities for Scientific Collaborations.”

There will be an opportunity for you to share your programming ideas, to network with other members, and to learn how you can get more involved.

GENERAL INFORMATION

COMMUNITY MEETINGS

Early Career Community (EC) and Mental Health and Addiction (MHA)

Kick-Off Meeting

WEDNESDAY, MARCH 21, 2018

3:30 PM – 4:30 PM

FLORIDA 5

Join ASCPT's newest Communities for their inaugural in-person meeting. Learn more about their 2018/2019 goals and how you can contribute to their Community growth, programming and more!

Pharmacometrics & Pharmacokinetics (PMK) and Regulatory Science (RS) Joint Community Meeting

THURSDAY, MARCH 22, 2018

7:00 AM – 8:00 AM

ORLANDO II

This meeting will feature Community introductions, updates, and accomplishments, as well as sharing of ideas for the 2019 Annual Meeting programming and webinar series. Shiew-Mei Huang, PhD, will present a special talk, *"The Need for Collaborations and Real World Data - Clinical Pharmacology Perspective."*

Special Populations (SPO) and International Transporter Consortium (ITC) Joint Community Meeting

THURSDAY, MARCH 22, 2018

10:30 AM – 11:30 AM

KEY WEST A

The SPO and ITC Communities will give a brief update of their Community achievements and goals for 2018. Additionally, four flash presentations will be presented by several young scientists featuring topics applicable to SPO and ITC members.

Systems Pharmacology (SP) and Oncology (ONC) Joint Community Meeting

THURSDAY, MARCH 22, 2018

2:00 PM – 3:00 PM

FLORIDA 1/2

To fully realize the opportunities for mechanistic, model informed oncology drug development, the SP and ONC Communities will present a cross-disciplinary discussion. Learning objectives of this joint meeting include: review of 2017 accomplishments

and forecast of 2018 activities, identification of areas of shared interest, and solicitation of feedback regarding programming.

Biologics and Biomarkers & Translational Tools (BTT) Joint Community Meeting

FRIDAY, MARCH 23, 2018

8:00 AM – 9:00 AM

FLORIDA 1/2

This session will include a Community business discussion and programming ideas and feature two scientific presentations, *Intra Tumor Analysis of Trastuzumab Distribution by PID Staining*, *Breakthrough Method with High Visibility and Single Cell Quantification and Improved Prediction of Infliximab Clearance Using Erythrocyte Sedimentation Rate and Anti-Infliximab Antibody Levels in Pediatric Patients with Inflammatory Bowel Disease*.

Translational Informatics (TI) and Pharmacogenomics (PMG) Joint Community Meeting

FRIDAY, MARCH 23, 2018

10:00 AM – 11:00 AM

FLORIDA 1/2

M. Eileen Dolan, PhD, will deliver a scientific talk highlighting challenges and opportunities at the intersection of TI and PMG. Following, a panel discussion will focus on challenges and opportunities of the Community's members.

Global Health (GH) and Infectious Diseases (INF) Joint Community Meeting

FRIDAY, MARCH 23, 2018

11:00 AM – 12:00 PM

KEY WEST A

Join the GH and INF Communities as they come together to feature short, high-level presentations by internationally-recognized leaders from each Community, data-focused presentations by trainees, and a brainstorming discussion on future initiatives to bring skills, science, and energy on key global health problems and continuing infectious disease threats.



ASCPT 2019 ANNUAL MEETING

MARCH 13-16 • WASHINGTON MARRIOTT WARDMAN PARK • WASHINGTON, DC

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2019
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NOMINATIONS

NOMINATION
DEADLINE

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MAY 31
2018

AWARD NOMINATION SITE
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Help ASCPT recognize outstanding science and achievement in clinical pharmacology and translational medicine.

- Gary Neil Prize for Innovation in Drug Development
- Leon I. Goldberg Early Investigator Award
- Oscar B. Hunter Career Award in Therapeutics
- Rawls-Palmer Progress in Medicine Award
- Sheiner-Beal Pharmacometrics Award
- Henry W. Elliott Distinguished Service Award
- William B. Abrams Award in Geriatric Clinical Pharmacology
- Malle Jurima-Romet Mid-Career Leadership Award
- Darrell Abernethy Young Investigator Award
- ASCPT Mentor Award

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 American Society for
Clinical Pharmacology
& Therapeutics



PRE-CONFERENCES

PEDIATRIC DRUG DEVELOPMENT: CHALLENGES AND OPPORTUNITIES IN EXTRAPOLATION

WEDNESDAY, MARCH 21, 2018

10:00 AM – 5:00 PM

ORLANDO I

CO-SPONSORS

IQ Consortium, Pediatric Working Group, Clinical Pharmacology Leadership Group, and ASCPT Special Populations Community

OVERVIEW

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.

CHAIRS

Konstantina M. Vanevski, MD, Bayer Health Care, Foster City, CA; Dionna Green, MD, US Food and Drug Administration, Silver Spring, MD; Ashley Strougo, PhD, Sanofi, Frankfurt, Germany; Lily (Yurek) Mulugeta, PharmD, US Food and Drug Administration, Silver Spring, MD

HANDOUTS

Handouts for this session will be available in the ASCPT 2018 Annual Meeting app. Be sure to download the app in advance of your arrival in Orlando.

SYMPOSIUM: PEDIATRIC ONCOLOGY

10:00 AM – 10:30 AM

Implications of FDARA 2017 on Pediatric Cancer Drug Development

Gregory H. Reaman, MD, US Food and Drug Administration, Silver Spring, MD

10:30 AM – 11:00 AM

Innovative Pediatric Oncology Drug Development Approaches: The Pharma Perspective

Stephen Simko, MD, Genentech, South San Francisco, CA

11:00 AM – 12:00 PM

PANEL DISCUSSION

Gregory H. Reaman, MD, US Food and Drug Administration, Silver Spring, MD; Stephen Simko, MD, Genentech, South San Francisco, CA; Leslie Dickmann, PhD, Genentech, South San Francisco, CA; Stacy S. Shord, PharmD, U.S. Food and Drug Administration, Silver Spring, MD; Jaszianne Tolbert, MD, Children’s Mercy Hospital, Kansas City, MO

12:00 PM – 1:00 PM

LUNCH

PEDIATRIC DRUG DEVELOPMENT: CHALLENGES AND OPPORTUNITIES IN EXTRAPOLATION

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ASCP 2018 ANNUAL MEETING

WEDNESDAY, MARCH 21, 2018 (CONTINUED)

10:00 AM – 5:00 PM

ORLANDO I

1:00 PM – 5:00 PM

**MOCK-TEAM WORKSHOP:
EXTRAPOLATION IN TYPE 2 DIABETES**

FACILITATOR

Lawrence Lesko, PhD

Emeritus Professor, Department of
Pharmaceutics, University of Florida
Scientific Advisor, Certara, Lake Nona, 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 North Wales, PA

PHYSICIAN

Jan Marquard, MD

Medical Expert, Pediatrics & Endocrinology
(Clinical Project Lead, Pediatric Programs in
Diabetes), Boehringer-Ingelheim Pharma,
Ingelheim, Germany

STATISTICIAN

Margaret Gamalo-Siebers, PhD

Principal Research Scientist, Global Statistics
Sciences Statistics SME, Pediatric Steering
Committee, Eli Lilly, Indianapolis, IN

PEDIATRICS-ENDOCRINOLOGY

Phil Zeitler, MD, PhD

Professor and Section Head, Endocrinology;
Department of Pediatrics, University of
Colorado, Anschutz Medical Campus;
Medical Director, Children's Hospital,
Colorado Clinical & Translational Research
Center, Aurora, CO

REGULATORS

Lynne Yao, MD

Director, Division of Pediatrics, Office of New
Drugs; Chair, Pediatric Review Committee
(PeRC), US Food and Drug Administration,
Silver Spring, MD

Lisa Yanoff, MD

Team Leader, Division of Metabolic and
Endocrine Products, US Food and Drug
Administration, Silver Spring, MD

Cecile Ollivier, MS

(Virtual Attendance)

Scientific Officer, European Medicines
Agency, London, UK

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

WEDNESDAY, MARCH 21, 2018

1:00 PM – 5:00 PM

ORLANDO II

CO-SPONSORS

ASCPT Quantitative Pharmacology and Development, Regulatory & Outcomes Networks; and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)

OVERVIEW

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, Pfizer, Groton, CT; Richard Willke, PhD, ISPOR, Lawrenceville, NJ

1:00 PM – 1:05 PM

OPENING REMARKS

Jing Liu, PhD, Pfizer, Groton, CT

1:05 PM – 1:20 PM

Background/Introduction: Role of Pharmacometrics and Health Economics for Cost-effective Patient Care

Richard Willke, PhD, ISPOR, Lawrenceville, NJ

1:20 PM – 1:50 PM

Understanding the Comparative Efficacy and Effectiveness via Meta-Analysis: Health Economics Approach

Jeroen P. Jansen, PhD, Precision Health, Boston, MA

1:50 PM – 2:20 PM

Understanding the Comparative Efficacy and Effectiveness via Model-Based Meta-Analysis: Pharmacometrics Approach

Jaap Mandema, PhD, Certara Strategic Consulting, Princeton, NJ

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

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ASCP 2018 ANNUAL MEETING

WEDNESDAY, MARCH 21, 2018 (CONTINUED)

1:00 PM – 5:00 PM

ORLANDO II

2:20 PM – 2:50 PM

Linking Pharmacometrics and Health Economics: Quantitative Approaches to Cost-Effectiveness Evaluations of Health Care Decisions

Dyfrig Hughes, PhD, University of Bangor, North Wales, United Kingdom

2:50 PM – 3:10 PM

BREAK

3:10 PM – 3:40 PM

Leveraging Novel Simulation Techniques to Incorporate Pharmacometrics in Pharmacoeconomic Models

Jaime Caro, MDCM, Evidera, Waltham, MA

3:40 PM – 4:10 PM

Industry Perspectives: Examples on How to Assess Values in Drug Development

Neeta Tandon, MA, Janssen Pharmaceuticals, Titusville, NJ

4:10 PM – 4:50 PM

Panel Discussion: Can Linked Pharmacometric-Health Economic Evidence Improve Early Evaluation of New Medicines?

LEADER

Scott Marshall, PhD, Pfizer, Sandwich, Kent, United Kingdom

All speakers will participate as panelists.

4:50 PM – 5:00 PM

Closing Remarks

Jing Liu, PhD, Pfizer, Groton, CT



SCIENTIFIC AGENDA

SCIENTIFIC AGENDA

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MARCH 21-24, 2018 • HILTON ORLANDO

WEDNESDAY, MARCH 21, 2018

10:00 AM – 5:00 PM

PRE-CONFERENCE

Pediatric Drug Development: Challenges and Opportunities in Extrapolation

ORLANDO I

1:00 PM – 3:00 PM

TPM NETWORK MEETING

FLORIDA 5

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

ORLANDO II

3:30 PM – 4:30 PM

MHA & EC JOINT COMMUNITY MEETING

FLORIDA 5

5:00 PM – 6:00 PM

DRO NETWORK MEETING

FLORIDA 5

5:00 PM – 6:30 PM

Opening Reception

(Light food and beverages will be served)

ORANGE BALLROOM

Opening Reception Sponsored by:



5:00 PM – 6:30 PM

POSTER SESSION

Presidential Trainee Showcase, Encore Posters, Late-Breaking Posters, and Oral Abstract Posters

ORANGE BALLROOM

5:10 PM – 5:25 PM

Presidential Trainee Abstract Awards

FOUNTAIN PLAZA ON THE PROMENADE

ASCPT PRESIDENTIAL TRAINEE AWARD RECIPIENTS

Arjun P. Athreya, MS

University of Illinois at Urbana-Champaign

Kit Wun Kathy Cheung, PharmD

University of California, San Francisco

Rachel Dalton, PharmD

University of Montana

Jacqueline Gerhart, MS

UNC Eshelman School of Pharmacy

Sophie Gravel, BSc

University of Montreal – CRCHUM

Ming-Fen Ho, PhD

Mayo Clinic

Sarah Kim, PhD

University of Florida

Dea Kojovic, BSc

University of Toronto

Alix Leblanc, PhD

The Ohio State University

Stephanie Nicole Liu, PharmD

Indiana University School of Medicine

Michael Martin, PharmD, PhD

University of California, San Francisco

Rina Nishii, MS

St. Jude Children's Research Hospital

Jagdeep T. Podichetty, PhD

Indiana University School of Medicine

Sonal Singh, PhD

University of Florida

D. Max Smith, PharmD

University of Florida

Ming-Liang Tan, PhD

US Food and Drug Administration

Tanaya Vaidya, MS

University of Florida

Ye Xiong, PhD, Cincinnati Children's

Hospital Medical Center

Ling Zou, PhD, University of California,

San Francisco



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SCIENTIFIC AGENDA

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ASCP 2018 ANNUAL MEETING

WEDNESDAY, MARCH 21, 2018

5:25 PM – 5:55 PM

POSTER WALK I

Pharmacometrics and Pharmacokinetics

CO-CHAIRS

Piet H. van der Graaf, PhD, PharmD, and
Sandra A.G. Visser, PhD

ORANGE BALLROOM FOYER

PWI-001

*PHYSIOLOGICALLY-BASED
PHARMACOKINETIC MODELING OF
FLUCONAZOLE USING PLASMA AND
CEREBROSPINAL FLUID SAMPLES
COLLECTED FROM PRETERM AND
TERM INFANTS.*

Presenter: Jacqueline Gerhart, MS, UNC
Eshelman School of Pharmacy

PWI-002

*PHYSIOLOGICALLY-BASED
PHARMACOKINETIC MODEL
INCORPORATING EXTRAHEPATIC
GLUCURONIDATION PREDICTS
INTEGRASE INHIBITOR
PHARMACOKINETICS.*

Presenter: Stephanie Nicole Liu, PharmD,
Indiana University School of Medicine

PWI-003

*TRANSLATIONAL PHARMACOKINETIC/
PHARMACODYNAMIC MODEL PREDICTS
DEPATUXIZUMAB MAFODOTIN TUMOR
GROWTH INHIBITION IN PATIENTS.*

Presenter: Rajendar Mittapalli, PhD, AbbVie

PWI-004

*SIMULATING THE CLINICAL IMPACT
OF INCOMPLETE ADHERENCE
DURING TREATMENT WITH
TOFACITINIB: IMPLICATIONS OF
AN INDIRECT PHARMACOKINETIC/
PHARMACODYNAMIC RELATIONSHIP.*

Presenter: Manisha Lamba, PhD, Pfizer

6:00 PM – 6:30 PM

POSTER WALK II

Oncology

CO-CHAIRS

Neeraj Gupta, PhD, and
Stacy S. Shord, PharmD

ORANGE BALLROOM FOYER

PWII-001

*TARGETING OATP1B2 TO AMELIORATE
PACLITAXEL-INDUCED CHRONIC
PERIPHERAL NEUROPATHY.*

Presenter: Alix Leblanc, PhD,
The Ohio State University

PWII-002

*MECHANISTIC MODELING TO
UNDERSTAND INTRA-TUMOR SPATIAL
DISTRIBUTION OF ANTIBODY DRUG
CONJUGATES: INSIGHTS INTO DOSING
STRATEGY IN ONCOLOGY.*

Presenter: Manoj Chiney, PhD, AbbVie

PWII-003

*SYSTEMS PHARMACOLOGICAL
ANALYSIS OF A TUMOR PRIMING
COMBINATION THERAPY TO OVERCOME
HER2 AND MTOR THERAPIES
RESISTANCE IN BREAST CANCER.*

Presenter: Tanaya Vaidya, MS,
University of Florida

PWII-004

*DOSE SELECTION FOR THERAPEUTIC
PROTEINS IN ENTRY INTO HUMAN
STUDIES: ROCHE EXPERIENCE FROM
2004 TO 2016.*

Presenter: Sian Lennon-Chrimes, PhD,
Roche Innovation Center Welwyn

6:00 PM – 6:30 PM

EXHIBIT WALK

CHAIR

Walter Kraft, MD

ORANGE BALLROOM

Join us on a guided tour of select exhibitors in the Exhibit Hall. Led by Walter Kraft, MD, the Exhibit Walk provides new knowledge on offerings for clinical pharmacologists and translational scientists.



For complete abstract content, download the ASCPT 2018 Annual Meeting mobile app.

THURSDAY, MARCH 22, 2018

7:00 AM – 7:45 AM

AWARDS BREAKFAST

(By Invitation Only)

KEY WEST A

7:00 AM – 8:00 AM

PMK & RS JOINT COMMUNITY MEETING

ORLANDO II

8:00 AM – 9:00 AM

OPENING SESSION

ORLANDO IV

State of the Society Address

Kellie Schoolar Reynolds, PharmD,
ASCPT President

Recognition of the Scientific Program Committee

Peter H. O'Donnell, MD,
University of Chicago, Chicago, IL

AWARDS PRESENTER

Kellie Schoolar Reynolds, PharmD,
ASCPT President

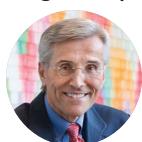
2018 Henry W. Elliott Distinguished Service Award



RECIPIENT

Steven Ryder, MD,
Alexion Pharmaceuticals,
New Haven, CT

2018 Gary Neil Prize for Innovation in Drug Development



RECIPIENT

Richard Pazdur, MD,
US Food and Drug
Administration,
Silver Spring, MD

2018 William B. Abrams Award in Geriatric Clinical Pharmacology



RECIPIENT

Kenneth Schmader, MD,
Duke University School of
Medicine, Durham, NC

2018 Malle Jurima-Romet Mid-Career Leadership Award



RECIPIENT

Amita Joshi, PhD,
Genentech, South
San Francisco, CA

2018 ASCPT Mentor Award



RECIPIENT

Hartmut Derendorf, PhD,
University of Florida,
Gainesville, FL

2018 David J. Goldstein Trainee Award



RECIPIENT

Sonal Singh, PhD, University
of Florida, Gainesville, FL

2018 Jason Morrow Trainee Award



RECIPIENTS

Kit Wun Kathy Cheung,
PharmD, University of
California, San Francisco,
San Francisco, CA



Rina Nishii, MS, St. Jude
Children's Research
Hospital, Memphis, TN



Ming-Fen Ho, PhD, Mayo
Clinic, Rochester, MN

Top Membership Recruiters

RECIPIENTS



Mohamed H. Shahin, PhD,
University of Florida,
Gainesville, FL



Alexander A. Vinks, PharmD,
PhD, Cincinnati Children's
Hospital Medical Center,
Cincinnati, OH

SCIENTIFIC AGENDA

THURSDAY, MARCH 22, 2018

CPT: Pharmacometrics & Systems Pharmacology Award

PRESENTER

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

RECIPIENT



Robert Bies, PharmD, PhD, University at Buffalo, SUNY, Buffalo, NY

Clinical and Translational Science Award

PRESENTER

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

RECIPIENT



Karthik Venkatakrisnan, PhD, Takeda, Cambridge, MA

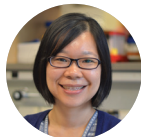
PhRMA FOUNDATION AWARDS

2017 Post Doctoral Fellowships in Translational Medicine

PRESENTER

Michael Liebman, PhD, IPQ Analytics; Chair, PhRMA Foundation, Advisory Committee on Translational Medicine and Therapeutics; Kennett Square, PA

RECIPIENTS



Isabel Lam, PhD, Brigham and Women's Hospital and Dana-Farber Cancer Institute, Boston, MA



Norelle Wildburger, PhD, Washington University School of Medicine, St. Louis, MO

2017 Faculty Development Award

PRESENTER

Michael Liebman, PhD, IPQ Analytics; Chair, PhRMA Foundation, Advisory Committee on Translational Medicine and Therapeutics; Kennett Square, PA

RECIPIENT



Mike Montana, MD, PhD, Washington University School of Medicine, St. Louis, MO

2017 Paul Calabresi Medical Student Fellowship

PRESENTER

Michael Liebman, PhD, IPQ Analytics; Chair, PhRMA Foundation, Advisory Committee on Translational Medicine and Therapeutics; Kennett Square, PA

RECIPIENTS



Nikhil Chavali, Vanderbilt University School of Medicine, Nashville, TN



Richard A. Morgan, MSc, Charles R. Drew University of Medicine and Science and David Geffen School of Medicine at UCLA, Los Angeles, CA

2018 Award in Excellence in Clinical Pharmacology

PRESENTER

Michael Liebman, PhD, IPQ Analytics; Chair, PhRMA Foundation, Advisory Committee on Translational Medicine and Therapeutics; Kennett Square, PA

RECIPIENT



Darrell R. Abernethy, MD, PhD

ACCEPTING: *Rollin Abernethy, PhD, Professor Emeritus, University of Wyoming*

CEO REMARKS

Sharon J. Swan, FASAE, CAE

TRANSITION TO THE FUTURE

Kellie Schoolar Reynolds, PharmD

ASCP President

Dan Hartman, MD

ASCP President-Elect

David Y. Mitchell, PhD

ASCP Incoming President-Elect

SCIENTIFIC AGENDA

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MARCH 21-24, 2018 • HILTON ORLANDO

THURSDAY, MARCH 22, 2018

9:00 AM – 1:30 PM

EXHIBIT AND POSTER HALL OPEN
ORANGE BALLROOM

9:00 AM – 10:00 AM

STATE OF THE ART LECTURE
ORLANDO IV

CHAIR

Peter H. O'Donnell, MD
University of Chicago, Chicago, IL



SPEAKER

*Invisible Influence:
The Microbiome in
Precision Medicine*
Jack Gilbert, PhD, University
of Chicago, Chicago, IL

9:00 AM – 10:00 AM

CELERION PRODUCT THEATER
KEY WEST A

SPEAKER

*Oncology Drug Development:
Phase I Trials in Healthy Volunteers*
Michael Di Spirito, MSc, Celerion

Product Theater Sponsored by:



10:00 AM – 10:30 AM

CLINILABS LEARNING LOUNGE
*Six Keys to Conducting Successful
Phase I Studies*
ORANGE BALLROOM

Learning Lounge Sponsored by:



10:15 AM – 11:15 AM

AWARD LECTURE
Rawls-Palmer Progress in Medicine
Award Lecture
ORLANDO I

AWARD PRESENTER

J. Steven Leeder, PharmD, PhD, Children's
Mercy Hospital, Kansas City, MO



SPEAKER

Gregory L. Kearns, PharmD,
PhD, Arkansas Children's
Research Institute,
Little Rock, AR

10:30 AM – 11:30 AM

SPO & ITC JOINT COMMUNITY MEETING
KEY WEST A

10:30 AM – 12:30 PM

SYMPOSIUM

*Integrating New Information Increasing Our
Understanding of Placebo Response and
Implications for Drug Development*
ORLANDO II

COMMUNITIES

Regulatory Science,
Pharmacometrics & Pharmacokinetics



CHAIR

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

SPEAKERS

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

*Genetics of the Placebo Response: What
Can We Learn from the Placebome?*
Kathryn T. Hall, PhD, Brigham and Women's
Hospital and Harvard Medical School,
Boston, MA

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

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

Select sessions from the ASCPT 2018 Annual Meeting will be professionally recorded and distributed for *ASCPT Replay: Annual Meeting On-Demand*.

SCIENTIFIC AGENDA

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ASCPT 2018 ANNUAL MEETING

THURSDAY, MARCH 22, 2018

Upon completion of this Symposium, the attendee should be able to:

- Understand the placebo (a group of genome-related mediators that affect an individual's response to placebo treatments) and of the neurological evidence that multiple neurotransmitter and molecular pathways mediate placebo effects.
- Understand of how placebo response influences phase III failures and describe traditional and novel clinical study design and pharmacometric strategies to optimize drug-placebo differences.

10:30 AM – 12:30 PM

SYMPOSIUM

Considerations for Selection of Immuno-Oncology Based Drug Combinations
ORLANDO IV

COMMUNITIES

Oncology, Biomarker & Translational Tools



CHAIRS

Apurvasena Parikh, PhD, AbbVie,
Redwood City, CA

Lokesh Jain, PhD, Merck & Co., Rahway, NJ

SPEAKERS

An Immunogenomic View of Personalized Cancer Medicine

Thomas Hudson, MD, AbbVie,
Redwood City, CA

Rationale for Immuno-Oncology Combinations: Strategies for Selection of Combination Treatments and Clinical Evaluation

Jianda Yuan, PhD, MD, Merck Research Laboratories, Rahway, NJ

Immuno-Oncology Combinations - Clinical Trial Design Consideration

Lillian L. Siu, MD, University of Toronto,
Toronto, ON, Canada

Quantitative Systems Pharmacology Models on Immuno-Oncology to Inform Combination Strategies

Gabriel Helmlinger, PhD, AstraZeneca,
Waltham, MA

Upon completion of this Symposium, the attendee should be able to:

- Illustrate the application of data from immune and genomic profiling of tumors, growing knowledge of biology pathways and bioinformatics data to inform rationale combination of oncology and immuno-oncology agents.
- Highlight various types of clinical trial designs being used to assess combinations as well as discuss their advantages and limitations. Illustrate the utility of modeling approaches using integrated data to enable efficient decision making.

11:15 AM – 12:15 PM

FEATURED SPEAKER

FLORIDA 1/2

CHAIR

Kellie Schoolar Reynolds, PharmD,
ASCPT President



SPEAKER

The Impact of Clinical Pharmacology in HIV Cure Research

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

12:30 PM – 1:30 PM

COVANCE HOSTED EVENT

KEY WEST A

SPEAKER

The Integrated Clinical Pharmacology Platform: Optimizing Drug Development
Oren Cohen, MD, Covance

Special Event Sponsored by:

COVANCE
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Select sessions from the ASCPT 2018 Annual Meeting will be professionally recorded and distributed for *ASCPT Replay: Annual Meeting On-Demand*.

THURSDAY, MARCH 22, 2018

1:30 PM – 2:45 PM

AWARD LECTURES

Leon I. Goldberg Early Investigator

Award Lectures

ORLANDO II

AWARD PRESENTER

Issam Zineh, PharmD, US Food and Drug Administration, Silver Spring, MD



SPEAKERS

2017 Award Recipient

Michael Pacanowski, PharmD, US Food and Drug Administration, Silver Spring, MD



2018 Award Recipient

David Strauss, MD, PhD, US Food and Drug Administration, Silver Spring, MD

1:30 PM – 3:00 PM

ROUNDTABLE/NOVEL FORMAT

Quantitative Clinical Pharmacology of

Antimicrobials: Is it Time to Move Past MIC?

ORLANDO I

COMMUNITIES

Infectious Diseases,
Pharmacometrics & Pharmacokinetics



CHAIRS

Matthew L. Rizk, PhD, Merck,
North Wales, PA

Coen van Hasselt, PhD, Leiden University,
Leiden, Netherlands

SPEAKERS

The Case for MIC and PK/PD

Indices—What We're Doing is Just Fine

David Andes, MD, University of Wisconsin,
Madison, WI

Why MIC is Poison for the Mind

Hartmut Derendorf, PhD,
University of Florida, Gainesville, FL

*Experiences with MIC-Based PK/
PD Indices in the Dose Selection of
Antimicrobial Drugs*

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

*The Case Against MIC—Better Decisions with
Pharmacometrics and Systems Approaches*

Elisabet Nielsen, PhD,
Uppsala University, Uppsala, Sweden

Upon completion of this Roundtable, the
attendee should be able to:

- Understand how MIC-based methods have been utilized to drive PK/PD understanding dose regimen selection and how pharmacometric approaches can be leveraged to a greater extent in antimicrobial development to further improve dose selection and optimization.
- Explain the advantages and disadvantages of MIC-based versus pharmacometric approaches to characterize antimicrobial PK/PD and the clinical challenges of treating patients with antibiotics in the era of AMR.

SCIENTIFIC AGENDA

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ASCPT 2018 ANNUAL MEETING

THURSDAY, MARCH 22, 2018

1:30 PM – 3:00 PM

WORKSHOP

Clinical and Translational Pharmacology of siRNA Therapies

ORLANDO IV

COMMUNITIES

Pharmacogenomics, Biomarker & Translational Tools



CHAIRS

Sharvari Bhagwat, PhD, Amgen, South San Francisco, CA

Jason H. Karnes, PharmD, PhD, University of Arizona, Tucson, AZ

SPEAKERS

A Progress Report on siRNA Therapeutics

Judy Lieberman, MD, PhD, Boston Children's Hospital and Harvard Medical School, Boston, MA

siRNA Therapeutics: Target Identification, Discovery and Early Development Considerations

Stacey Melquist, PhD, Arrowhead Pharmaceuticals, Madison, WI

Bioanalytical Assays to Support the Advancement of siRNA Drug Development from Pre-Clinical to Clinical Stages

Brooke Rock, PhD, Amgen, South San Francisco, CA

Upon completion of this Workshop, the attendee should be able to:

- Understand the mechanism and kinetics of siRNA-mediated gene silencing that is crucial for clinical applications of siRNA therapeutics.
- Appreciate the challenges of translational and clinical pharmacology of siRNA and contribute to the design of FIH and early clinical pharmacology studies of siRNA therapeutics.

2:00 PM – 3:00 PM

SP & ONC JOINT COMMUNITY MEETING
FLORIDA 1/2

3:15 PM – 4:45 PM

SPECIAL SESSION

Innovation Forum
ORLANDO IV

Join us at the 2018 Innovation Forum and listen to three compelling speakers who are leveraging technology and innovation to make breakthroughs in science. This session is sure to be idea-inspiring and thought-provoking for all who attend.

CHAIR

Peter H. O'Donnell, MD, University of Chicago, Chicago, IL

SPEAKERS

Virtually Better: How Virtual Reality is Easing Pain, Calming Nerves, and Improving Health the Drug-Free Way
Brennan Spiegel, MD, Cedars-Sinai Health System, Los Angeles, California

Technology meets Neuroscience: A Vision of the Future of Brain Optimization
Adam Gazzaley, MD, PhD, University of California, San Francisco, San Francisco, CA

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

4:30 PM – 6:30 PM

EXHIBIT AND POSTER HALL OPEN
ORANGE BALLROOM

5:00 PM – 6:30 PM

PRESIDENT'S NETWORKING
RECEPTION
ORANGE BALLROOM

5:00 PM – 6:30 PM

POSTER SESSION I
ORANGE BALLROOM

Select sessions from the ASCPT 2018 Annual Meeting will be professionally recorded and distributed for *ASCPT Replay: Annual Meeting On-Demand*.

THURSDAY, MARCH 22, 2018

5:15 PM – 5:45 PM

POSTER WALK III

Pharmacogenomics

ORANGE BALLROOM FOYER

CHAIRS

Larisa H. Cavallari, PharmD, and Sony Tuteja, PharmD

PWIII-001

*OUTPATIENT CYP2D6 GENOTYPE-SUPPORTED OPIOID THERAPY: A PROSPECTIVE TRIAL.***Presenter:** D. Max Smith, PharmD, University of Florida

PWIII-002

*A MULTIFACTORIAL CYTOCHROME P450 2D6 GENOTYPE-PHENOTYPE PREDICTION APPROACH TO IMPROVE PRECISION OF CLINICAL PHARMACOGENETIC TEST INTERPRETATION.***Presenter:** Rachel Dalton, PharmD, University of Montana

PWIII-003

*SLCO1B1 rs4149056 PHENOME-WIDE ASSOCIATION STUDY (PHEWAS) WITH SURVEY DATA FROM THE HARVARD PERSONAL GENOME PROJECT.***Presenter:** Caitrin McDonough, PhD, University of Florida

PWIII-004

*EFFECTS OF TYPE 2 DIABETES ON DUODENAL CYP450 ACTIVITIES.***Presenter:** Sophie Gravel, BSc, University of Montreal - CRCHUM

5:45 PM- 6:15 PM

EXHIBIT WALK

ORANGE BALLROOM

CHAIR

Aubrey Stoch, MD

Join us on a guided tour of select exhibitors in the Exhibit Hall. Led by Aubrey Stoch, MD, the Exhibit Walk provides new knowledge on offerings for clinical pharmacologists and translational scientists.

6:00 PM – 6:30 PM

POSTER WALK IV

Psychiatry, Maternal-Fetal Pharmacology, and Tuberculosis

ORANGE BALLROOM FOYER

CHAIRS

Dionna Green, MD, and Susan I. Vear, MD

PWIV-001

*IMPLEMENTING DATA MINING AND MACHINE LEARNING TECHNIQUES TO DRUG DEVELOPMENT IN SCHIZOPHRENIA.***Presenter:** Jagdeep T. Podichetty, PhD, Indiana University School of Medicine

PWIV-002

*FACTOR GRAPHS IDENTIFY SEX-SPECIFIC ANTIDEPRESSANT RESPONSE PROFILES: CITALOPRAM/ ESCITALOPRAM AS MOLECULAR PROBES FOR SUBGROUPS OF MAJOR DEPRESSIVE DISORDER PATIENTS.***Presenter:** Arjun P. Athreya, MS, University of Illinois at Urbana-Champaign

PWIV-003

*ELEVATED SFLT-1 IN PRE-ECLAMPSIA IS ASSOCIATED WITH A DOWNREGULATION OF TRANSPORTERS IN HUMAN PLACENTA.***Presenter:** Dea Kojovic, BSc, University of Toronto

PWIV-004

*TRANSLATIONAL MODEL OF PYRAZINAMIDE SITE-OF-ACTION PHARMACOKINETIC DISTRIBUTION IN A RABBIT MODEL OF TUBERCULOSIS AND IN TB PATIENTS.***Presenter:** Michael Martin, PharmD, PhD, University of California, San Francisco

SCIENTIFIC AGENDA

FRIDAY, MARCH 23, 2018

7:00 AM – 1:30 PM

EXHIBIT AND POSTER HALL OPEN
ORANGE BALLROOM

7:00 AM – 8:30 AM

POSTER SESSION II
ORANGE BALLROOM

7:30 AM – 9:00 AM

SCIENCE AT SUNRISE

*Transforming Clinical Practice with
Translational Informatics and Multi-Omics
Data Science*

ORLANDO I

COMMUNITIES

Translational Informatics, Oncology



CHAIRS

Matthew K. Breitenstein, PhD, University of
Pennsylvania, Philadelphia, PA

Nicholas Tatonetti, PhD, Columbia University,
New York, NY

SPEAKERS

*Algorithms, Rapid Analyses, and Data
Integrity in Clinical Practice*

Sam Volchenbom, MD, PhD,
University of Chicago, Chicago, IL

*Knowledge Representation Standards
as a Translational Pivot*

Robert Freimuth, PhD, Mayo Clinic,
Rochester, MN

*The Role of Informatics in
Off-Label Recommendations
and Biomarker-Guided Therapies*

Subha Madhavan, PhD, Georgetown
University, Washington, DC

Upon completion of this Science at Sunrise,
the attendee should be able to:

- Gain practical and clinical-focused perspectives of boundary spanning informatics approaches needed for implementation of clinical pharmacology knowledge into clinical practice.
- Understand critical differences between translational bioinformatics and clinical informatics, and where data science, knowledge representation, inference, interpretation, and implementation occur across these domains.

7:30 AM – 9:00 AM

SCIENCE AT SUNRISE

Non-Traditional Pathway to Drug Approval
ORLANDO II

COMMUNITIES

Regulatory Science,
Pharmacometrics & Pharmacokinetics



CHAIRS

Islam Younis, PhD, US Food and Drug
Administration, Silver Spring, MD

Hazem Hassan, PhD, University of Maryland
School of Pharmacy, Baltimore, MD

SPEAKERS

*Opportunities and Challenges for Drug
Development Utilizing the Animal Rule
Regulatory Paradigm*

Andrea Powell, PhD, US Food and Drug
Administration, Silver Spring, MD

*Approaches for Dose Translation under the
Animal Rule Paradigm: Regulatory Perspective*
Islam Younis, PhD, 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*
Sandeep Dutta, PhD, Amgen,
Thousand Oaks, CA

Upon completion of this Science at Sunrise,
the attendee should be able to:

- Understand the requirements for approval and the approval process of products under the animal rule.
- Understand the role of clinical pharmacology in translating the effective animal dose to an effective human dose for drugs developed under the animal rule.

8:00 AM – 9:00 AM

BIOLOGICS & BTT JOINT
COMMUNITY MEETING
FLORIDA 1/2

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SCIENTIFIC AGENDA

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MARCH 21-24, 2018 • HILTON ORLANDO

FRIDAY, MARCH 23, 2018

9:00 AM – 10:00 AM

PRA HEALTH SCIENCES
PRODUCT THEATER
KEY WEST A

SPEAKER

Q&A Driven Early Clinical Drug Development, with Case Examples on the Value of Early Learning
Ewoud-Jan van Hoogdalem, PhD
PRA Health Sciences

Product Theater Sponsored by:



PRAHEALTHSCIENCES

9:15 AM – 10:15 AM

STATE OF THE ART LECTURE
ORLANDO IV

CHAIR

Kellie Schoolar Reynolds, PharmD,
ASCPT President



SPEAKER

Data is the New Black: How the Fourth Industrial Revolution is Changing Healthcare
Mara Aspinall, MBA, Health Catalysts, Tucson, AZ

10:00 AM – 10:30 AM

PHARMARON LEARNING LOUNGE
Clinical Metabolism
ORANGE BALLROOM

Learning Lounge Sponsored by:



10:00 AM – 11:00 AM

TI & PMG JOINT COMMUNITY MEETING
FLORIDA 1/2

Select sessions from the ASCPT 2018 Annual Meeting will be professionally recorded and distributed for *ASCPT Replay: Annual Meeting On-Demand*.

10:30 AM – 11:30 AM

AWARD LECTURE
Sheiner-Beal Pharmacometrics
Award Lecture
ORLANDO II

AWARD PRESENTER

Mats Karlsson, PhD, Uppsala University,
Uppsala, Sweden



SPEAKER

France Mentré, MD, PhD,
University of Paris Diderot,
Paris, France

10:30 AM – 12:30 PM

SYMPOSIUM
Healthy Volunteer Studies in Oncology Drug Development: Pivotal Considerations Toward Optimal Deployment
ORLANDO IV

COMMUNITIES

Oncology, Early Development & Drug Safety



CHAIRS

Daria Stypinski, PhD, Pfizer,
South San Francisco, CA

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

SPEAKERS

Patient Care in Clinical Pharmacology Oncology Trials: Principal Investigator Perspective

Eric Roeland, MD, UC San Diego Moores Cancer Center, La Jolla, CA

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

Use of Healthy Volunteers in Clinical Oncology Drug Development

Weiwei Tan, PhD, Pfizer, San Diego, CA

Regulatory Challenges in the Use of Healthy Volunteers

Nicole Drezner, MD, US Food and Drug Administration, Silver Spring, MD

SCIENTIFIC AGENDA

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ASCP 2018 ANNUAL MEETING

FRIDAY, MARCH 23, 2018

Upon completion of this Symposium, the attendee should be able to:

- Describe practical and ethical considerations of using HV in oncology trials. The current FDA guidances related to conduct of oncology trials in HV. Lastly, the critical considerations for oncology trial design in HV.
- Synthesize a strategic ODD plan that utilizes HV. Define role of clinical pharmacology/pharmacometrics in integrating HV data with preclinical and patient data for decision-making across all ODD phases.

10:30 AM – 12:30 PM

SYMPOSIUM

Biomarkers and Translational Tools to Inform Development of New Therapeutics for Neurodegeneration

ORLANDO I

COMMUNITIES

Biomarker & Translational Tools,
Pharmacometrics & Pharmacokinetics



CHAIRS

Sreeraj Macha, PhD, Merck & Co.,
Kenilworth, NJ

Daniela J. Conrado, PhD, Critical Path
Institute, Cambridge, MA

SPEAKERS

*Can Application of Quantitative
Clinical Pharmacology Improve Early
Clinical Development Success in
Neurodegenerative Diseases?*

Gianluca Nucci, PhD, Pfizer, Cambridge, MA

*Translation from Bench to Bedside: PET Tracers
for Use in Neuroscience Drug Development*

Eric Hostetler, PhD, Merck & Co., West Point, PA

*Model-Informed Biomarker Qualification:
Alzheimer and Parkinson Disease*

Neuroimaging Biomarkers

Daniela J. Conrado, PhD, Critical Path
Institute, Tucson, AZ

*Item Response Models for Translation
in CNS Disorders*

Mats Karlsson, PhD, Uppsala University,
Uppsala, Sweden

Upon completion of this Symposium,
the attendee should be able to:

- Explain the challenges unique to neurodegenerative disorders including disease heterogeneity, slow disease progression, and large inter-patient variability.
- Describe the latest developments and quantitative strategies implemented in the neuroscience area utilizing biomarkers and translational approaches to inform early and late stages of development.

11:00 AM – 12:00 PM

GH & INF JOINT COMMUNITY MEETING
KEY WEST A

11:30 AM – 12:30 PM

ORAL ABSTRACT SESSION I

Pharmacometrics and Pharmacokinetics
FLORIDA 1/2

CHAIRS

Hazem Hassan, PhD, and Jin Yan Jin, PhD

OI-001

*ASSESSING THE ROLE OF HEART
TISSUE CONCENTRATION IN BOTTOM
UP MECHANISTIC PREDICTION OF QT
PROLONGATION BY MOXIFLOXACIN
USING PBPK-QST MODELING.*

Presenter: Nikunj Kumar Patel, MS,
Simcyp (a Certara Company)

OI-002

*WHEN POPULATION PK MODELING
HELPS DRIVE ONCOLOGY PHASE I
TRIAL: FIRST IMPLEMENTATION OF
EXPOSURE DRIVEN DOSE ESCALATION
WITH OVERDOSE CONTROL DESIGN.*

Presenter: Sandrine Micallef, PhD, Roche

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FRIDAY, MARCH 23, 2018

01-003

*PHYSIOLOGICALLY BASED
PHARMACOKINETIC MODELING OF THE
EFFECT OF CHRONIC KIDNEY DISEASE
ON THE PHARMACOKINETICS OF
NONRENALLY ELIMINATED DRUGS.*

Presenter: Ming-Liang Tan, PhD, US Food and Drug Administration

01-004

*IMPROVED PREDICTION OF INFLIXIMAB
CLEARANCE USING ERYTHROCYTE
SEDIMENTATION RATE AND ANTI-
INFLIXIMAB ANTIBODY LEVELS
IN PEDIATRIC PATIENTS WITH
INFLAMMATORY BOWEL DISEASE.*

Presenter: Ye Xiong, PhD, Cincinnati Children's Hospital Medical Center

12:30 PM – 1:30 PM

PAREXEL PRODUCT THEATER
KEY WEST A

SPEAKER

*EMA Safety Risk Identification/Mitigation
Guideline 2018 – Importance of Modeling
in Early Development*

Matthias Kruse, MD, PAREXEL

Product Theater Sponsored by:

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YOUR JOURNEY. OUR MISSION.[®]

1:15 PM – 2:45 PM

WORKSHOP

*Translational Medicine & Clinical
Pharmacology Strategies Supporting
Acceleration of Development of Anti-
Infective Drugs*

ORLANDO I

COMMUNITIES

Global Health,
Early Development & Drug Safety



CHAIRS

Stephan Chalon, MD, PhD, Medicines for Malaria Venture, Geneva, Switzerland

David Wesche, MD, PhD, Bill & Melinda Gates Foundation, Seattle, WA

SPEAKERS

*Human Malaria Challenge Model
in Early Development*

James S. McCarthy, MD, QIMR Berghofer Medical Research Institute and Royal Brisbane and Women's Hospital, Queensland, Australia

*Model-Informed Malaria Drug Development
from Animal Models to Phase II*

Nathalie Gobeau, PhD, Medicines for Malaria Venture, Geneva, Switzerland

*Clinical Pharmacology Aspects of Anti-
Infective Drugs – Regulatory Experiences*
Dakshina Chilukuri, PhD, US Food and Drug Administration, Silver Spring, MD

Upon completion of this Workshop, the attendee should be able to:

- Understand how the mouse-SCID (severe combined immunodeficient) model and controlled human malaria infection models have been optimized to support early proof of pharmacology, pharmacokinetics/pharmacodynamics in anti-malarial drugs development.
- Discuss model-informed drug development and how it relates to accelerated entry of new chemical entities into efficacy studies in endemic areas and regulatory decisions under PDUFA VI.

1:15 PM – 2:45 PM

FEATURED SPEAKER
ORLANDO IV

CHAIR

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



SPEAKER

*Reverse Translational
Studies to Understand
Drug-Induced Toxicity*
Deanna L. Kroetz, PhD,
University of California, San
Francisco, San Francisco, CA

SCIENTIFIC AGENDA

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ASCP 2018 ANNUAL MEETING

FRIDAY, MARCH 23, 2018

1:45 PM – 2:45 PM

ORAL ABSTRACT SESSION II

Pharmacology Topics in the Popular Press—Opioids, Ketamine, Immune Checkpoint Inhibitors, and Digital Health
FLORIDA 1/2

CHAIRS

Tamorah Rae Lewis, MD, PhD, and
Richard Peck, MD

OII-001

EVALUATION OF RBP-6000 EFFECTS ON QT INTERVAL DURING TREATMENT FOR OPIOID USE DISORDER.

Presenter: Virginia (Ginny) Schmith, PhD,
Nuventra Pharma Sciences

OII-002

KETAMINE AND KETAMINE METABOLITES AS NOVEL ESTROGEN RECEPTOR LIGANDS: INDUCTION OF CYP2A6, CYP2B6 AND AMPA RECEPTOR —GENOMIC LINKS TO SEX-DIFFERENCES IN KETAMINE RESPONSE.

Presenter: Ming-Fen Ho, PhD, Mayo Clinic

OII-003

APPLICATION OF A SYSTEMS PHARMACOLOGY APPROACH FOR A DETAILED INVESTIGATION OF AN ADVERSE DRUG REACTION DUE TO DISTINCT MECHANISMS OF IMMUNE CHECKPOINT INHIBITORS.

Presenter: Sarah Kim, PhD,
University of Florida

OII-004

SMART TRIALS: ASSESSMENT OF AT-HOME SAMPLING AND DIGITAL HEALTH TECHNOLOGIES IN A CLINICAL PILOT TRIAL.

Presenter: Marissa Dockendorf, PhD, Merck

1:45 PM – 3:45 PM

QP NETWORK MEETING

ORLANDO II

2:30 PM - 3:30 PM

IQVIA PRODUCT THEATER

KEY WEST A

SPEAKER

Transforming Early Clinical Development – Using Innovative Approaches to Enhance Efficiencies, Lower Costs and Improve Outcomes
Ashish Jain, Vice President and Global Head,
Early Clinical Development, IQVIA

Product Theater Sponsored by:



3:00 PM – 4:00 PM

AWARD LECTURE

**Oscar B. Hunter Career Award
in Therapeutics Lecture**

FLORIDA 1/2

AWARD PRESENTER

Carl C. Peck, MD, University of California,
San Francisco Center for Drug Development
Science, San Luis Obispo, CA



SPEAKER

William J. Jusko, PhD,
University at Buffalo, SUNY,
Buffalo, NY

3:00 PM – 4:30 PM

WORKSHOP

Unveiling the Genetic Architecture of Human Disease for Precision Medicine
ORLANDO I

Communities: Pharmacogenomics,
International Transporter Consortium



CHAIRS

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

Jason H. Karnes, PharmD, PhD,
University of Arizona, Tucson, AZ



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FRIDAY, MARCH 23, 2018

SPEAKERS

Human Genetic Studies to Inform Drug Discovery and Early Development

Robert M. Plenge, MD, PhD, Celgene, Cambridge, MA

Mutations in SLC Transporters are Causal for Rare Disease

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

Racial/Ethnic and Genetic Differences in the Response and Disposition of Newly Approved Drugs

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

Upon completion of this Workshop, the attendee should be able to:

- Describe how genetic studies of human diseases represent experiments of nature and can be mined to identify new drug targets in an emerging approach to drug discovery.
- Explain recent evidence for the incorporation of ethnic differences in drug response and the genetic architecture that underlies variation in drug response.

3:00 PM – 4:30 PM

SPECIAL SESSION

#Science

ORLANDO IV

COMMUNITIES

Special Populations,
Drug Utilization & Outcomes



CHAIRS

Violette Gijzen, MD, PhD, VieCuri Medical Centre, Venlo, Netherlands

Valentina Shakhnovich, MD, Children's Mercy, Kansas City, MO

SPEAKERS

Opportunities for Using Internet Search to Learn About Drug Response

Russ B. Altman, MD, PhD, Stanford University, Stanford, CA

Will You Follow Me? The Future of Social Media in Healthcare

Michele Maddux, PhD, Children's Mercy, Kansas City, MO

Social Media Mining for Pharmacovigilance: Challenges and Opportunities for Case-Control Studies

Graciela Gonzalez-Hernandez, PhD, University of Pennsylvania, Philadelphia, PA

Upon completion of this Special Session, the attendee should be able to:

- Provide guidance on the current legal framework of communicating through social media and discuss the opportunity to use social media for interaction with patients as well as academia, industry, and agencies.
- Understand patient engagement, study recruitment, and patient group empowerment in healthcare and science.

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

ORLANDO I

COMMUNITIES

Translational Informatics, Pharmacometrics & Pharmacokinetics



CHAIRS

Diansong Zhou, PhD, AstraZeneca, Waltham, MA, and Jennifer Sheng, PhD, Bristol-Myers Squibb, Lawrenceville, NJ

SPEAKERS

Mechanistic Joint Models Characterizing the Relationship Between Nonlinear Prostate Specific Antigen Kinetics and Survival in Prostate Cancer Patients

France Mentré, MD, PhD, University of Paris Diderot, Paris, France

Joint Modeling Tumor Burden and Time to Event Data in Oncology Trials, Theoretical Consideration and Application in Non-Small Cell Lung Cancer Study

Ye Shen, PhD, University of Georgia, Athens, GA

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SCIENTIFIC AGENDA

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ASCP 2018 ANNUAL MEETING

FRIDAY, MARCH 23, 2018

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

Nidal Al-Huniti, PhD, AstraZeneca, Waltham, MA

Upon completion of this Workshop, the attendee should be able to:

- Review the methodology, utilities and limitations of joint models for longitudinal and time-to-event data, including sample size considerations and dynamic prediction.
- Provide a comprehensive clinical and scientific understanding of joint modeling and its applications in clinical development, and demonstrate with clinical examples in oncology therapeutic area.

4:45 PM – 6:15 PM

SPECIAL SESSION

Career Development for Everyone
FLORIDA 1/2

CHAIRS

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

Virginia (Ginny) Schmith, PhD,

Nuventra Pharma Sciences, Durham, NC

SPEAKER

Evidence-Based Mentorship

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

PANELISTS

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

Hartmut Derendorf, PhD, University of Florida, Gainesville, FL

Amita Joshi, PhD, Genentech, South San Francisco, CA

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

SATURDAY, MARCH 24, 2018

7:00 AM – 9:00 AM

SPECIAL SESSION

Pharmacometrics Skills Competition:

MIDD Gran Prix

ORLANDO IV

COMMUNITIES

Pharmacometrics & Pharmacokinetics, Systems Pharmacology



CHAIRS

Julie Dumond, PharmD, University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC

Mark R. Lovern, PhD, Certara, Raleigh, NC

Nathan S. Teuscher, PhD, Certara, Raleigh, NC

Alan Forrest, PharmD, University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC

PANEL OF JUDGES

Anne C. Heatherington, PhD, Summit Therapeutics, Cambridge, MA

Richard L. Lalonde, PharmD, Bradenton, FL

France Mentré, MD, PhD, University of Paris Diderot, Paris, France

Carl C. Peck, MD, University of California, San Francisco Center for Drug Development Science, San Luis Obispo, CA

Issam Zineh, PharmD, US Food and Drug Administration, Silver Spring, MD

Upon completion of this Special Session, the attendee should be able to:

- Demonstrate several approaches to resolving modeling complexities in drug development decisions, and how best to communicate these findings to a clinical team in order to influence decisions and impact patient care.
- Highlight potential differences in software packages used in population analyses that may lead to varied decision-making in the drug development process.

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SCIENTIFIC AGENDA

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MARCH 21-24, 2018 • HILTON ORLANDO

SATURDAY, MARCH 24, 2018

7:30 AM – 9:00 AM

ROUNDTABLE/NOVEL FORMAT

Delivery of Pharmacogenomics Test Results in Patient Care

ORLANDO I

COMMUNITY

Pharmacogenomics



CHAIRS

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

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

SPEAKERS

Delivery of Pharmacogenetics Results to Patients in an Era of Global Travel

Jesse Swen, PharmD, PhD, Leiden University Medical Center, Leiden, Netherlands

The Patient-Clinician Encounter in a Pharmacogenomics Clinic in a Community Health System

Henry (Mark) Dunnenberger, PharmD, NorthShore University Health System, Evanston, IL

Communicating Pharmacogenetic Test Results to Patients—What do They Want to Know?

Theresa Strong, PhD, Foundation for Prader-Willi Research, Walnut, CA

Upon completion of this Roundtable, the attendee should be able to:

- Understand patient perspectives on pharmacogenomics and need for patient education.
- Describe how pharmacogenomics can be integrated into the clinical patient visit.

9:15 AM – 10:15 AM

STATE OF THE ART LECTURE

ORLANDO IV

CHAIR

Sean Hennessy, PharmD, PhD, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA



SPEAKER

Using Complex Healthcare Databases to Evaluate the Safety and Effectiveness of Newly Marketed Medications
Sebastian Schneeweiss, MD, ScD, Harvard Medical School and Brigham and Women's Hospital, Boston, MA

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SCIENTIFIC AGENDA

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ASCP 2018 ANNUAL MEETING

SATURDAY, MARCH 24, 2018

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

ORLANDO IV

COMMUNITIES

Pharmacometrics & Pharmacokinetics, Regulatory Science



CHAIRS

Neeraj Gupta, PhD, Takeda, Cambridge, MA

Anne C. Heatherington, PhD, Summit Therapeutics, Cambridge, MA

SPEAKERS

Bridging Patient Needs with Regulatory Flexibility in Rare Disease Drug Development

Bilal AbuAsal, PhD, US Food and Drug Administration, Silver Springs, MD

Approval of Eteplirsen: Patient Advocate Perspective

Katherine Lambertson, BS, BA, Genetic Alliance, Washington, DC

Industry Perspective on Rare Disease Drug Development

Keith M. Gottesdiener, MD, Rhythm Pharmaceuticals, New York, NY

Drug Development in Rare Diseases (Amyloidosis): Consortium Perspective

Kristen Hsu, BS, Amyloidosis Research Consortium, Newton, MA

Upon completion of this Symposium, the attendee should be able to:

- Understand the unprecedented level of flexibility used by FDA to support accelerated approval of a drug for a rare disease (DMD)
- Explore the role of patient advocacy and research consortia in drug development and approval

10:30 AM – 12:30 PM

SYMPOSIUM

Demonstrating Biosimilarity with Clinical PK and PD Data in Lieu of Comparative Efficacy

ORLANDO I

COMMUNITIES

Biologics, Regulatory Science



CHAIRS

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

John Davis, PhD, Regeneron, Tarrytown, NY

SPEAKERS

The Role of PK and PD in the Regulatory Framework for Biosimilars Approval

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

PD Markers and Biosimilars Development

Gary Fanjiang, MD, MBA, Amgen, Thousand Oaks, CA

The Role of Mechanistic PKPD Modeling in Explaining Variability in Efficacy

Outcomes for Biosimilars

Wojciech Krzyzanski, PhD, University at Buffalo, SUNY, Buffalo, NY

Innovative Approaches to Maximize the Value of PK/PD Program in Developing Biosimilars

Peijuan Zhu, PhD, Sandoz, Basking Ridge, NJ

Upon completion of this Symposium, the attendee should be able to:

- Describe the regulatory framework of using PK and PD data to evaluate clinically meaningful differences between a biosimilar and its reference product, and potential concerns about relying on PK/PD similarity without comparative efficacy data.
- Describe current challenges and guiding principles for exploring opportunities for innovative approaches to improve efficiency of biosimilar development; learn to navigate the complexity of biological processes and seek potential PD markers.

SATURDAY, MARCH 24, 2018

11:30 AM – 12:30 PM

ORAL ABSTRACT SESSION III

Drug Transporters and Pharmacogenomics
FLORIDA 1/2

CHAIRS

Mohamed H. Shahin, PhD, and
Alexander G. Vandell, PharmD, PhD

OIII-001

INTERACTIONS OF AZO DYES COMMONLY USED IN ORAL DRUG PRODUCTS WITH THE ORGANIC ANION TRANSPORTING PEPTIDE 2B1 AND HUMAN GUT BACTERIA.

Presenter: Ling Zou, PhD,
University of California, San Francisco

OIII-002

CHARACTERIZING THE ONTOGENY OF TEN RENAL TRANSPORTERS IN AFRICAN AMERICANS USING QUANTITATIVE PROTEOMICS, GENE EXPRESSION ANALYSIS AND CLINICAL DATA.

Presenter: Kit Wun Kathy Cheung, PharmD,
University of California, San Francisco

OIII-003

PRECLINICAL EVALUATION OF NUDT15 GENOTYPE-GUIDED THIOPURINE DOSE INDIVIDUALIZATION USING CRISPR-CAS9 MOUSE MODEL.

Presenter: Rina Nishii, MS,
St. Jude Children's Research Hospital

OIII-004

TARGETED SEQUENCING IDENTIFIES MISSENSE VARIANT IN THE BEST3 GENE ASSOCIATED WITH ANTIHYPERTENSIVE RESPONSE TO THIAZIDE DIURETICS.

Presenter: Sonal Singh, PhD,
University of Florida

1:15 PM – 2:45 PM

WORKSHOP

Substrate-Dependent Polymorphic Effects in CYP-Mediated Drug Metabolism and Challenges for Pharmacogenetics Implementation

ORLANDO II

COMMUNITIES

Pharmacogenomics



CHAIRS

Daniel L. Hertz, PharmD, PhD, University of Michigan, Ann Arbor, MI

Emily Scott, PhD, University of Michigan, Ann Arbor, MI

SPEAKERS

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

Substrate-Specific Metabolism of CYP2D6: How can CYP2D6 Phenotype Prediction be Improved?

Andrea Gaedigk, PhD, Children's Mercy, Kansas City, MO

Accommodating Substrate-Dependence in CYP Genotype to Activity Phenotype Translation for Pharmacogenetic Implementation

Kelly Caudle, PharmD, PhD, St. Jude Children's Research Hospital, Memphis, TN

Upon completion of this Workshop, the attendee should be able to:

- Describe substrate-dependent effects of CYP2B6 and CYP2D6 polymorphism that have been discovered *in vitro* and the challenges and progress of assessing substrate-dependent metabolism in clinical pharmacokinetic analyses.
- Recognize the limitations of the current system to account for substrate-specific metabolism when predicting CYP phenotype from genotype information.



SCIENTIFIC AGENDA

60

ASCP 2018 ANNUAL MEETING

SATURDAY, MARCH 24, 2018

1:15 PM – 3:15 PM

SYMPOSIUM

Pragmatic Approaches to Improvements in Pediatric Drug Therapy

FLORIDA 1/2

Communities: Drug Utilization & Outcomes, Special Populations



CHAIRS

Geert W. 't Jong, MD, PhD, University of Manitoba, Winnipeg, MB, Canada

Catherine Sherwin, PhD, University of Utah School of Medicine, Salt Lake City, UT

SPEAKERS

Building Expertise in Pediatric Formulations: How to Improve Expertise of and Access to Pediatric Formulations
Catherine Litalien, MD, CHU Ste-Justine, Montreal, QC, Canada

Drug Safety in Pediatrics: Shifting from Catching up to Moving Forward
Michael Rieder, MD, PhD, University of Western Ontario, London, ON, Canada

Novel Approaches to Clinical Trials: How Smart Design Can Improve Yield
Saskia N. de Wildt, MD, PhD, Radboud University, Nijmegen, The Netherlands

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

Upon completion of this Symposium, the attendee should be able to:

- Discuss pragmatic solutions to drug studies in infants including dose estimation based on pre-clinical and adult data and how to effectively communicate this knowledge to researchers, health care providers and patients and their families.
- Discuss novel clinical trial design to facilitate the pragmatic conduct of drug studies in children with chronic and rare disease in terms of feasibility, recruitment, timely conduct of the study and patient and family acceptability and buy-in.

1:15 PM – 3:15 PM

SYMPOSIUM

Innovation in Clinical Dose Selection and Trial Optimization using Bayesian Approaches: Steps Toward Accelerated Patient Care

ORLANDO I

COMMUNITIES

Pharmacometrics & Pharmacokinetics, Regulatory Science



CHAIRS

Indrajeet Singh, PhD, Janssen Pharmaceuticals, Spring House, PA

Ying Ou, PhD, Amgen, South San Francisco, CA

SPEAKERS

Bayesian Statistics and its Implications for Drug Development
Stephen Ruberg, PhD, Eli Lilly, Indianapolis, IN

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

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

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

Upon completion of this Symposium, the attendee should be able to:

- Discuss the limitations of traditional clinical trial designs for developing drugs for patients in need and how novel approaches are being implemented to overcome these limitations.
- Understand the basic concept of Bayesian statistics and its impact on drug development. The application of Bayesian methodology in innovative trial design in early to late stage development including biosimilars.



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Booth: 222

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Booth: 100

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As a division of BioTelemetry, Inc. (NASDAQ: BEAT), BioTelemetry Research provides expert Cardiac and Imaging core lab solutions for the advancement of clinical drug development. We offer global operational support for cardiovascular monitoring in all therapeutic areas, and advanced imaging analyses in cardiovascular, oncology, neurology, metabolic, musculoskeletal and medical device studies. For more information please visit www.gobio.com/research.

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Booth: 301

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Booth: 228

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Duke Early Phase Clinical Research partners with the pharmaceutical industry, technology companies, government agencies, foundations, and academic centers to bring clinical validation to innovation. Our academic thought leadership, research unit, specialized patient databases, and clinical and operational expertise accelerates the development of therapies, diagnostics, and medical devices to humans.

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Booth: 223

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High Point Clinical Trials Center has provided comprehensive clinical site services since 2008. Our 42,000 foot facility consists of three unique units for the execution of outpatient and inpatient clinical studies. In addition to healthy normal Phase I studies, we focus on specialty populations such as Diabetes, NASH, Renal Impairment, Respiratory, CNS, Cardiovascular and Nicotine.

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ICON plc is a global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device industries. The company specializes in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. With headquarters in Dublin, Ireland, ICON currently, operates from 97 locations in 38 countries and has approximately 13,100 employees.

Booth: 202

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InSysBio will be presenting quantitative systems pharmacology (QSP) modeling services and QSP modeling platforms including Immune Response Template, tau and amyloid bet AD platform.

Booth: 106

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IQVIA (NYSE:IQV) is a leading global provider of information, innovative technology solutions and contract research services dedicated to using analytics and science to help healthcare stakeholders find better solutions for their patients. Solutions are powered by the IQVIA CORE™, which combines big data, advanced technology, analytics and extensive industry knowledge. Formed through the merger of IMS Health and Quintiles, IQVIA has approximately 55,000 employees worldwide. Learn more at iqvia.com.

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Booth: 108

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Booth: 515

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Booth: 224

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Booth 205

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Booth: 231

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Booth: 321

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Booth: 102

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Booth: 209

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MARCH 21-24, 2018 • HILTON ORLANDO

PRODUCT THEATERS AND EXHIBITOR HOSTED EVENTS

THURSDAY, MARCH 22, 2018

CELERION PRODUCT THEATER

9:00 AM – 10:00 AM

KEY WEST A



Oncology Drug Development: Phase I Trials in Healthy Volunteers

Through a series of case studies, Michael Di Spirito, MSc, Director, Clinical Pharmacology & Pharmacometrics, will present creative Phase I oncology study designs and explore the results that were achieved. Berry Delicious refreshments will be provided, and space is limited to 50 attendees.

CLINILABS LEARNING LOUNGE

10:00 AM – 10:30 AM

ORANGE BALLROOM



Six Keys to Conducting Successful Phase I Studies

Clinilabs will discuss six simple yet essential elements of Phase I success that can be employed on any Phase I unit. Each key will be presented in practical terms with examples to highlight each key. Attendees will learn how protocol development, subject pre-screening, subject authentication, subject diversity, standard operating procedures, and laboratory and pharmacy oversight provide meaningful and impactful advantages to Phase I studies, enabling each study to be a success.

COVANCE HOSTED EVENT

12:30 PM – 1:30 PM

KEY WEST A



The Integrated Clinical Pharmacology Platform: Optimizing Drug Development
Join Oren Cohen, MD, Chief Medical Officer and Global Head of Clinical Pharmacology Services at Covance, as he discusses an integrated approach to optimize your early clinical development program. Learn integrated solutions like Phase I GMP manufacturing, biomarker capabilities and special population studies can advance your development program in the early phases. A full lunch will be provided, and space is limited to 50 attendees.

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ASCP 2018 ANNUAL MEETING

FRIDAY, MARCH 23, 2018

PRA HEALTH SCIENCES PRODUCT THEATER

9:00 AM – 10:00 AM

KEY WEST A



PRAHEALTHSCIENCES

Q&A Driven Early Clinical Drug Development, with Case Examples on the Value of Early Learning

Join PRA Health Sciences for their special session presented by Ewoud-Jan van Hoogdalem, PhD, RPh, ClinPharm, Vice-President Scientific Affairs - Clinical Pharmacology. Sunshine State refreshments will be provided, and space is limited to 50 attendees.

PHARMARON LEARNING LOUNGE

10:00 AM – 10:30 AM

ORANGE BALLROOM



Clinical Metabolism

Pharmaron will present research on their integrated services from drug metabolism including Radiosynthesis (3H/14C), in vitro/in vivo metabolism, Phase I Clinical Pharmacology Center (CPC) for human 14C studies, and Advanced Bioanalytical Sciences (ABS) including AMS technology.

PAREXEL PRODUCT THEATER

12:30 PM – 1:30 PM

KEY WEST A

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EMA Safety Risk Identification/Mitigation Guideline 2018 – Importance of Modeling in Early Development

Matthias Kruse, MD, will discuss the systematic approach to evaluating nonclinical data, protocol design and other key aspects to mitigate risk in First in Human (FIH) studies. The new EMA guidance, introduced February 2018, for identifying and mitigating the safety risks will be reviewed for early clinical studies. Laura Iavarone will review the role of modeling and simulation including the PK and PKPD translational aspect of preclinical data to humans, selection of starting doses and definition of exposure-limit criteria within protocols. Boxed lunches (redeemable with your lunch voucher) and Grandma's Pantry dessert will be provided, and space is limited to 50 attendees.

IQVIA PRODUCT THEATER

2:30 PM – 3:30 PM

KEY WEST A

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IQVIA[™]

Transforming Early Clinical Development – Using Innovative Approaches to Enhance Efficiencies, Lower Costs and Improve Outcomes

Join Ashish Jain, Vice President and Global Head, Early Clinical Development for IQVIA as he will provide an overview of the early phase delivery challenges, and how innovative approaches are proving to revolutionize the ECD space. With more early phase development using hybrid models, additional challenges are being realized. Hear how you can overcome these challenges and move to the next generation of early clinical development. Cupcakes will be served, and space is limited to 50 attendees.

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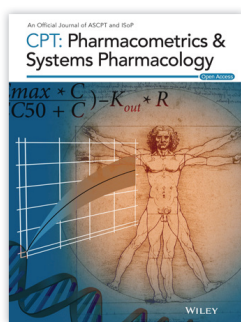
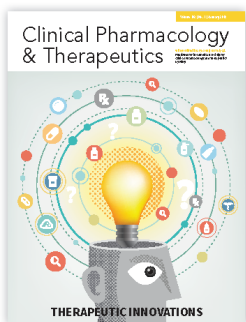


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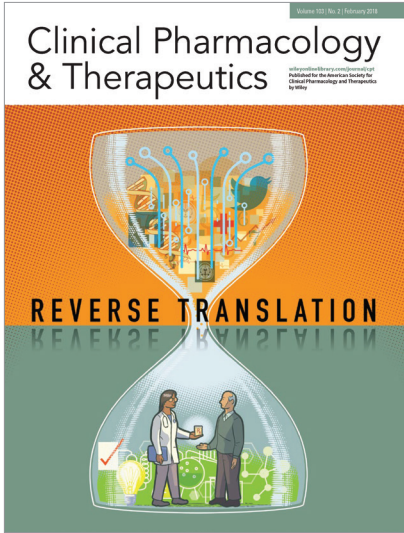


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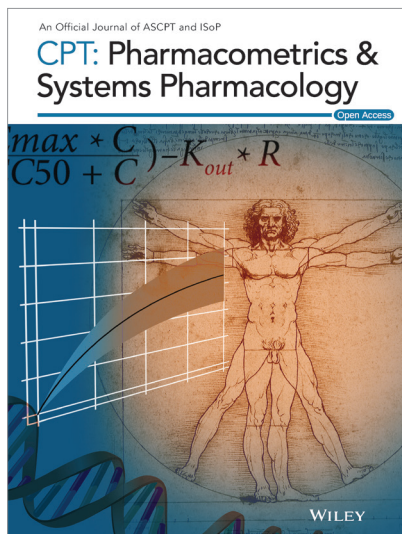
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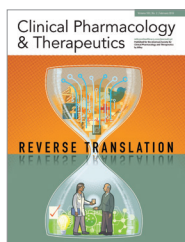
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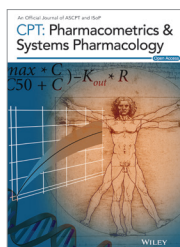
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CTS welcomes high quality, scientifically sound, original manuscripts focused on clinical pharmacology and translational science, including animal, *in vitro*, *in silico*, and clinical studies supporting the breadth of drug discovery, development, regulation and clinical use of both traditional drugs and innovative modalities. Topics of interest include:

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 - Clinical pharmacology studies with a focus on translational research in discovery, development, regulation and use of pharmacologic agents to improve clinical outcome, and inform optimal use of therapeutics in patients
 - Evaluation of all categories of biomarkers, including analytical validation, clinical validation, and qualification across modalities (e.g. molecular, histology, imaging, physiology)
 - Studies of response to a therapeutic intervention in a particular disease that may translate to a response in another disease, as well as translation of safety signals across species and/or patient populations
- The science and practice of translational medicine, including topics such as models of human disease and their therapeutic implications as well as practical aspects like improvements to study design or conduct and translational medicine methods.
 - Studies that guide phase II dose selection
 - Studies that demonstrate effective translation between basic and clinical science
 - Precision medicine
 - Genomic medicine, including pharmacogenomics, next generation sequencing, pharmacometabolomics, and functional genomics
 - Big data, real world data, electronic and mobile health applications, as well as wearables
 - Informatics, bioinformatics, pharmacoepidemiology, and pharmaco-economic modeling
 - Regulatory and public health policy implications of translational studies
 - Quantitative and systems pharmacology, PK/PD model-based and mechanistic understanding of disease biology and pharmacology, as these relate to translational medicine
 - Negative results of an important scientific question executed with high quality experimental design and rigorous data analysis, which disproves a hypothesis or produces negative results

JOURNALS & POSTERS

ACKNOWLEDGMENTS

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ASCPT WISHES TO THANK THE ABSTRACT REVIEWERS FOR THEIR TIME AND EFFORT REVIEWING ABSTRACTS SUBMITTED FOR THE ASCPT 2018 ANNUAL MEETING

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PT: Presidential Trainee Posters

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5:00 PM – 6:30 PM

WEDNESDAY, MARCH 21

ORANGE BALLROOM

PT-001

TARGETED SEQUENCING IDENTIFIES MISSENSE VARIANT IN THE *BEST3* GENE ASSOCIATED WITH ANTIHYPERTENSIVE RESPONSE TO THIAZIDE DIURETICS.

S. Singh¹, Z. Wang², M.H. Shahin¹, T.Y. Langaee¹, Y. Gong¹, C.W. McDonough¹, K.R. Bailey³, S.T. Turner⁴, A. Chapman⁵, J.G. Gums¹, A.L. Beitelshes⁶, R.M. Cooper-DeHoff¹, S. Scherer⁷, E. Boerwinkle², J.A. Johnson¹;

¹Department of Pharmacotherapy and Translational Research and Center for Pharmacogenomics, University of Florida, Gainesville, FL, USA, ²Human Genetics and Institute of Molecular Medicine, University of Texas Health Science Center, Houston, TX, USA, ³Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic, Rochester, MN, USA, ⁴Division of Nephrology and Hypertension, Mayo Clinic, Rochester, MN, USA, ⁵Section of Nephrology University of Chicago, Chicago, IL, USA, ⁶College of Medicine, University of Maryland, Baltimore, MD, USA, ⁷Human Genome Sequencing Center, Baylor College of Medicine, Houston, TX, USA.

PT-002

KETAMINE AND KETAMINE METABOLITES AS NOVEL ESTROGEN RECEPTOR LIGANDS: INDUCTION OF CYP2A6, CYP2B6 AND AMPA RECEPTOR—GENOMIC LINKS TO SEX-DIFFERENCES IN KETAMINE RESPONSE.

M.-F. Ho, M. Miranda de Araujo Correia, J.N. Ingle, L. Wang, S.H. Kaufmann, R.M. Weinshilboun; Mayo Clinic, Rochester, MN, USA.

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ASCP 2018 ANNUAL MEETING

PT-003

CHARACTERIZING THE ONTOGENY OF TEN RENAL TRANSPORTERS IN AFRICAN AMERICANS USING QUANTITATIVE PROTEOMICS, GENE EXPRESSION ANALYSIS AND CLINICAL DATA.

K. Cheung¹, L. Zhang², S.M. Huang², K.M. Giacomini¹; ¹University of California, San Francisco, San Francisco, CA, USA, ²Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation & Research, US Food and Drug Administration, Silver Spring, MD, USA.

PT-004

PRECLINICAL EVALUATION OF *NUDT15* GENOTYPE-GUIDED THIOPURINE DOSE INDIVIDUALIZATION USING CRISPR-CAS9 MOUSE MODEL.

R. Nishii¹, T. Moriyama¹, L. Janke¹, C. Suiter¹, L. Li¹, T.-N. Lin¹, K. Kihira², H. Toyoda², M. Kato³, A. Manabe⁴, S. Kham⁵, N. Jiang⁵, K. Koh⁶, T. Masatoshi⁷, A.E. Yeoh⁵, H. Hori², J.J. Yang¹; ¹St. Jude Children's Research Hospital, Memphis, TN, USA, ²Mie University Graduate School of Medicine, Mie, Japan, ³National Center for Child Health and Development, Tokyo, Japan, ⁴St. Luke's International Hospital, Tokyo, Japan, ⁵National University of Singapore, Singapore, Singapore, ⁶Saitama Children's Medical Center, Saitama, Japan, ⁷Tokyo Medical and Dental University Graduate School of Medicine, Tokyo, Japan.

PT-005

APPLICATION OF A SYSTEMS PHARMACOLOGY APPROACH FOR A DETAILED INVESTIGATION OF AN ADVERSE DRUG REACTION DUE TO DISTINCT MECHANISMS OF IMMUNE CHECKPOINT INHIBITORS.

S. Kim¹, G. Lahu², M. Vakilynejad³, L.J. Lesko¹, M.N. Trame¹; ¹Center for Pharmacometrics and Systems Pharmacology, Department of Pharmaceutics, University of Florida, Orlando, FL, USA, ²thinkQ2, Baar, Switzerland, ³Takeda Oncology, Cambridge, MA, USA.

PT-006

IMPROVED PREDICTION OF INFLIXIMAB CLEARANCE USING ERYTHROCYTE SEDIMENTATION RATE AND ANTI-INFLIXIMAB ANTIBODY LEVELS IN PEDIATRIC PATIENTS WITH INFLAMMATORY BOWEL DISEASE.

Y. Xiong, L. Bauman, T. Mizuno, T. Fukuda, M. Dong, M. Rosen, A.A. Vinks; Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA.

PT-007

PHYSIOLOGICALLY BASED PHARMACOKINETIC MODELING OF THE EFFECT OF CHRONIC KIDNEY DISEASE ON THE PHARMACOKINETICS OF NONRENALLY ELIMINATED DRUGS.

M.-L. Tan¹, P. Zhao², L. Zhang¹, Y.-F. Ho³, T.D. Nolin⁴, A. Galetin⁵, S.-M. Huang¹; ¹US Food and Drug Administration, Silver Spring, MD, USA, ²Gates Foundation, Seattle, WA, USA, ³National Taiwan University, Taipei, Taiwan, ⁴University of Pittsburgh, Pittsburgh, PA, USA, ⁵University of Manchester, Manchester, UK.

PT-008

INTERACTIONS OF AZO DYES COMMONLY USED IN ORAL DRUG PRODUCTS WITH THE ORGANIC ANION TRANSPORTING PEPTIDE 2B1 AND HUMAN GUT BACTERIA.

L. Zou¹, P. Spanogiannopoulos², Z. Ni³, E. Tsakalozou³, L. Zhang³, P. Turnbaugh², K. Giacomini¹; ¹Department of Bioengineering and Therapeutic Sciences, Schools of Pharmacy and Medicine, University of California, San Francisco, San Francisco, CA, USA, ²Department of Microbiology and Immunology, G.W. Hooper Research Foundation, University of California, San Francisco, San Francisco, CA, USA, ³Office of Research and Standards, Office of Generic Drugs, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD, USA.

PT-009

PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODELING OF FLUCONAZOLE USING PLASMA AND CEREBROSPINAL FLUID SAMPLES COLLECTED FROM PRETERM AND TERM INFANTS.

J.G. Gerhart¹, K.M. Watt², A. Edginton³, K.C. Wade⁴, D.K. Benjamin, Jr.², P.B. Smith², C.P. Hornik², M. Cohen-Wolkowicz², S. Duara⁵, A.S. Ross⁶, K. Shattuck⁷, D.L. Stewart⁸, N. Neu⁹, D. Gonzalez¹;
¹University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC, USA, ²Duke Clinical Research Institute, Durham, NC, USA, ³University of Waterloo, Kitchener, ON, Canada, ⁴Children's Hospital of Philadelphia, Philadelphia, PA, USA, ⁵University of Miami, Miami, FL, USA, ⁶Arkansas Children's Hospital, Little Rock, AR, USA, ⁷University of Texas Medical Branch, Galveston, TX, USA, ⁸University of Louisville, Louisville, KY, USA, ⁹Columbia University Medical Center, New York, NY, USA.

PT-010

TARGETING OATP1B2 TO AMELIORATE PACLITAXEL-INDUCED CHRONIC PERIPHERAL NEUROPATHY.

A.F. Leblanc¹, J.A. Sprowl², P. Alberti³, A. Chiorazzi³, G. Cavaletti³, A. Sparreboom¹, S. Hu¹; ¹The Ohio State University, Columbus, OH, USA, ²D'Youville College, Buffalo, NY, USA, ³University of Milano-Bicocca, Monza, Italy.

PT-011

EFFECTS OF TYPE 2 DIABETES ON DUODENAL CYP450 ACTIVITIES.

S. Gravel¹, B. Panzini², F. Bélanger³, A. Grangeon³, F. Gaudette³, J.-L. Chiasson², J. Turgeon³, V. Michaud³; ¹Faculty of Pharmacy, University of Montreal - CRCHUM, Montreal, QC, Canada, ²Faculty of Medicine, University of Montreal - CHUM, Montreal, QC, Canada, ³CRCHUM, Montreal, QC, Canada.

PT-012

OUTPATIENT *CYP2D6* GENOTYPE-SUPPORTED OPIOID THERAPY: A PROSPECTIVE TRIAL.

D.M. Smith¹, K.W. Weitzel¹, A.R. Elsey², D.T. Wake³, Y. Gong¹, B.Q. Duong¹, K. Newsom⁴, S.M. Smith¹, P. Starostik⁴, M.J. Clare-Salzler⁴, S.O. Schmidt⁵, J.A. Johnson¹, R. Fillingim⁶, L.H. Cavallari¹; ¹Department of Pharmacotherapy and Translational Research, College of Pharmacy, University of Florida, Gainesville, FL, USA, ²Clinical and Translational Science Institute, University of Florida, Gainesville, FL, USA, ³NorthShore University HealthSystem, Evanston, IL, USA, ⁴Department of Pathology, Immunology & Laboratory Medicine, College of Medicine, University of Florida, Gainesville, FL, USA, ⁵Department of Community Health and Family Medicine, College of Medicine, University of Florida, Gainesville, FL, USA, ⁶University of Florida Pain Research and Intervention Center of Excellence, Gainesville, FL, USA.

PT-013

PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODEL INCORPORATING EXTRAHEPATIC GLUCURONIDATION PREDICTS INTEGRASE INHIBITOR PHARMACOKINETICS.

S.N. Liu, J.B. Lu, Z. Desta, B.T. Gufford; Division of Clinical Pharmacology, Department of Medicine, Indiana University School of Medicine, Indianapolis, IN, USA.

PT-014

IMPLEMENTING DATA MINING AND MACHINE LEARNING TECHNIQUES TO DRUG DEVELOPMENT IN SCHIZOPHRENIA.

J.T. Podichetty¹, O.R. Schantz¹, R.F. Begstrom¹, R.R. Beis², M. Vakilynejad³; ¹Indiana University School of Medicine, Indianapolis, IN, USA, ²University at Buffalo, Buffalo, NY, USA, ³Takeda Pharmaceuticals, Cambridge, MA, USA.

PT-015

ELEVATED SFLT-1 IN PRE-ECLAMPSIA IS ASSOCIATED WITH A DOWNREGULATION OF TRANSPORTERS IN HUMAN PLACENTA.

D. Kojovic, M. Piquette-Miller; University of Toronto, Toronto, ON, Canada.

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ASCP 2018 ANNUAL MEETING

PT-016

A MULTIFACTORIAL CYTOCHROME P450 2D6 GENOTYPE-PHENOTYPE PREDICTION APPROACH TO IMPROVE PRECISION OF CLINICAL PHARMACOGENETIC TEST INTERPRETATION.

R. Dalton¹, S.-B. Lee², K. Claw³, B. Prasad³, B. Phillips³, D.D. Shen³, A. Gaedigk⁴, T.A. Thornton⁵, D. Nickerson², K.E. Thummel³, E.L. Woodahl¹; ¹Department of Biomedical and Pharmaceutical Sciences, University of Montana, Missoula, MT, USA, ²Department of Genome Sciences, University of Washington, Seattle, WA, USA, ³Department of Pharmaceutics, University of Washington, Seattle, WA, USA, ⁴Division of Clinical Pharmacology, Toxicology & Therapeutic Innovation, Children's Mercy Kansas City and School of Medicine, University of Missouri-Kansas City, Kansas City, MO, USA, ⁵Department of Biostatistics, University of Washington, Seattle, WA, USA.

PT-017

FACTOR GRAPHS IDENTIFY SEX-SPECIFIC ANTIDEPRESSANT RESPONSE PROFILES: CITALOPRAM/ESCITALOPRAM AS MOLECULAR PROBES FOR SUBGROUPS OF MAJOR DEPRESSIVE DISORDER PATIENTS.

A.P. Athreya¹, D. Neavin², M. Frye², M. Skime², R. Kaddurah-Daouk³, A. Rush³, W. Matson⁴, R.K. Iyer¹, W. Bobo², L. Wang², R.M. Weinsilboum²; ¹University of Illinois at Urbana-Champaign, Urbana, IL, USA, ²Mayo Clinic, Rochester, MN, USA, ³Duke University, Durham, NC, USA, ⁴Counterpoint Health Solutions Inc, Bedford, MA, USA.

PT-018

SYSTEMS PHARMACOLOGICAL ANALYSIS OF A TUMOR PRIMING COMBINATION THERAPY TO OVERCOME HER2 AND MTOR THERAPIES RESISTANCE IN BREAST CANCER.

T. Vaidya¹, A. Ande¹, B. Nguyen Tran¹, A. Brown², S. Ait-Oudhia¹; ¹Center for Pharmacometrics and Systems Pharmacology at Lake Nona, Department of Pharmaceutics, University of Florida, College of Pharmacy, Orlando, FL, USA, ²Institute for Therapeutic Innovation at Lake Nona, Department of Medicine, University of Florida, College of Medicine, Orlando, FL, USA.

PT-019

TRANSLATIONAL MODEL OF PYRAZINAMIDE SITE-OF-ACTION PHARMACOKINETIC DISTRIBUTION IN A RABBIT MODEL OF TUBERCULOSIS AND IN TB PATIENTS.

M. Martin¹, M. Zimmerman², V. Dartois², R. Savic¹; ¹University of California, San Francisco, San Francisco, CA, USA, ²Rutgers University, New Brunswick, NJ, USA.

E-001

A MACHINE LEARNING ALGORITHM TO CLASSIFY FDA CATEGORY C DRUGS.

M. Boland¹, F. Polubriaginof², N.P. Tatonetti²; ¹University of Pennsylvania, Philadelphia, PA, USA, ²Columbia University, New York, NY, USA.

E-002

CLINICAL TRIAL SIMULATIONS AND PHARMACOMETRICS ANALYSIS IN PEDIATRICS: APPLICATION TO INHALED LOXAPINE IN CHILDREN AND ADOLESCENTS.

M. Dong¹, T. Fukuda¹, S. Selim², M. Smith², L. Rabinovich-Guilatt², J.V. Cassella³, A.A. Vinks¹; ¹Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA, ²Teva Pharmaceuticals, Frazer, PA, USA, ³Alexza Pharmaceuticals, Inc., Mountain View, CA, USA.

E-003

A DECONVOLUTION INFORMED PHARMACODYNAMIC MODEL FOR THE QUANTIFICATION OF DRUG EFFECTS ON HIGHLY PULSATILE ENDOGENOUS PROFILES.

M.J. van Esdonk¹, J. Stevens², P.H. van der Graaf¹, J. Burggraaf³; ¹Division of Systems Biomedicine and Pharmacology, Leiden Academic Centre for Drug Research, Leiden University, Leiden, Netherlands, ²Department of Clinical Pharmacy and Pharmacology, University Medical Center Groningen, Groningen, Netherlands, ³Centre for Human Drug Research, Leiden, Netherlands.

E-004

IMPACT OF FEDERAL REGULATORY CHANGES ON CLINICAL PHARMACOLOGY AND DRUG DEVELOPMENT: THE COMMON RULE AND THE 21ST CENTURY CURES ACT.

J.F. Burris¹, T. Puglisi²; ¹Georgetown University, Washington, DC, USA, ²Consultant, Cambridge, MD, USA.

E-005

PBPK MODELING FOR THERAPEUTIC NANOPARTICLES LOADED WITH DRUG: DISTRIBUTION AND RELEASE.

E. Metelkin, **O. Demin**; InSysBio, Moscow, Russian Federation.

E-006

TRANSLATIONAL QSP MODEL OF AMYLOID BETA ALLOWS TO PREDICT BOTH SHORT AND LONG TERM RESPONSE OF AD PATIENTS TO DIFFERENT THERAPIES.

T. Karelina¹, O. Demin¹, O. Demin Jr¹, T. Nicholas²; ¹InSysBio, Moscow, Russian Federation, ²Pfizer global R&D, Groton, CT, USA.

LB-001

TRANSLATIONAL PKPD MODEL-INFORMED DOSE SELECTION FOR JNJ54175446 P2X7 RECEPTOR ANTAGONIST POSITION EMISSION TOMOGRAPHY IMAGING STUDY.

X. Miao¹, A. Hijzen², M. Schmidt², M. Ceusters², P. de Boer², P. Ravenstijn², P. Nandy³, H. Zhou¹, Y. Xu¹; ¹Janssen Research & Development, Spring House, PA, USA, ²Janssen Research & Development, Beerse, Belgium, ³Janssen Research & Development, Raritan, NJ, USA.

LB-002

POPULATION PHARMACOKINETICS OF AG-348 IN HEALTHY VOLUNTEERS AND ADULT PATIENTS WITH PYRUVATE KINASE DEFICIENCY.

H. Jia, V. Iyer, A.J. Barbier, L. Hua, H. Mangus, H. Yang, M. Liang, K. Le; Agios Pharmaceuticals, Inc., Cambridge, MA, USA.

LB-003

NOVEL IMPLEMENTATION OF GENOTYPE-GUIDED PROTON PUMP INHIBITOR THERAPY IN CHILDREN: A PILOT, RANDOMIZED, MULTI-SITE PRAGMATIC TRIAL.

E.J. Schwartz¹, E.B. Mougey², N.A. Chambers³, J.M. Denham³, H. Al-Atrash³, R.A. Gomez³, P.J. Palomo³, S. Taufiq², D.E. George², J. Evans², Y. Gong¹, K.V. Blake², J.A. Johnson¹, J.J. Lima², J.P. Franciosi³; ¹University of Florida, Gainesville, FL, USA, ²Nemours Children's Specialty Care, Jacksonville, FL, USA, ³Nemours Children's Hospital, Orlando, FL, USA.

LB-004

INHALATION PROFILE MODELING FOR FLUTICASONE PROPIONATE DRY POWDER INHALERS IN HEALTHY VOLUNTEERS DURING A FOUR WAY CROSSOVER BIOEQUIVALENCE STUDY.

A. Kurumaddali¹, U. Schilling¹, M.-J. Chen¹, Y. Jiao¹, B. Seay², S.M. Baumstein³, M.N. Abu-Hasan², D.S. Conti⁴, M. Oguntimein⁴, R. Delvadia⁴, L. Winner⁵, C. Tabulov¹, B. Saluja⁴, J. Bullitta¹, G. Hochhaus¹; ¹Department of Pharmaceutics, College of Pharmacy, University of Florida, Gainesville, FL, USA, ²Division of Pediatric Pulmonary and Sleep Medicine, Department of Pediatrics, College of Medicine, University of Florida, Gainesville, FL, USA, ³Department of Pharmacotherapy and Translational Research, College of Pharmacy, University of Florida, Gainesville, FL, USA, ⁴US Food and Drug Administration, Silver Spring, MD, USA, ⁵Department of Statistics, College of Liberal Arts and Sciences, University of Florida, Gainesville, FL, USA.

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LB-005

IMPLEMENTING PRE-EMPTIVE PHARMACOGENOMIC TESTING FOR A PANEL OF PHARMACOGENES IN THE PREPARE STUDY (U-PGX CONSORTIUM): RESULTS FROM THE FIRST 1,000 PATIENTS.

C.H. van der Wouden¹, C. Dávila-Fajardo², V. Dolžan³, G.P. Patrinos⁴, M. Pirmohamed⁵, G. Sunder-Plassmann⁶, G. Toffoli⁷, **J.J. Swen¹**, H.-J. Guchelaar¹; ¹Leiden University Medical Center, Leiden, Netherlands, ²Granada University Hospital, Granada, Spain, ³University of Ljubljana, Ljubljana, Slovenia, ⁴University of Patras, Patras, Greece, ⁵Royal Liverpool University Hospital and University of Liverpool, Liverpool, UK, ⁶Medical University of Vienna, Vienna, Austria, ⁷National Cancer Institute, Aviano, Netherlands.

LB-006

UNEXPLORED OCT1 VARIANTS: THE CHARACTERIZATION OF GENETIC POLYMORPHISMS IN NON-EUROPEAN POPULATIONS.

E.A. Ennis, B. Vora, S. Yee, K.M. Giacomini; University of California, San Francisco, San Francisco, CA, USA.

LB-007

EXPECTED POPULATION IMPACT OF MALNUTRITION ON TB OUTCOMES IN CHILDREN IN INDIA, BANGLADESH, AND CAMBODIA.

K.K. Radtke, R.M. Savic; University of California, San Francisco, San Francisco, CA, USA.

LB-008

A CASE OF SEVERE CARDIOTOXICITY IN A PEDIATRIC PATIENT FOLLOWING FLUOROURACIL ADMINISTRATION.

J. Belsky, N.D. Yeager, J.A. Fitch, D. Nandi, A. Kuhn, S. Vear; Nationwide Children's Hospital, Columbus, OH, USA.

LB-009

CLOPIDOGREL MARKEDLY INCREASES THE PLASMA CONCENTRATIONS OF DASABUVIR.

M.K. Itkonen, **A. Tornio**, O. Lapatto-Reiniluoto, M. Neuvonen, P.J. Neuvonen, M. Niemi, J.T. Backman; University of Helsinki and Helsinki University Hospital, Helsinki, Finland.

LB-010

PREDICTING THE IMPACT OF CYP2D6/UGT2B7 GENE-DRUG AND CYP MEDIATED DRUG-DRUG INTERACTIONS ON OXYCODONE AND OXYMORPHONE PHARMACOKINETICS.

C. De Miranda Silva¹, N. Mangal¹, V. Michaud², J. Turgeon², L.J. Lesko¹, S. Schmidt¹; ¹University of Florida, Orlando, FL, USA, ²Université de Montréal, Montréal, QC, Canada.

POSTER SESSION I

5:00 PM – 6:30 PM

THURSDAY, MARCH 22
ORANGE BALLROOM

PI-001

GENOME-WIDE META-ANALYSES REVEAL NOVEL PREDICTORS OF HEART RATE RESPONSE TO β -BLOCKERS IN THE PHARMACOGENOMIC EVALUATION OF ANTIHYPERTENSIVE RESPONSES (PEAR) STUDIES.

M.H. Shahin¹, D.J. Conrado², D. Gonzalez³, Y. Gong¹, M.T. Lobmeyer¹, A.L. Beitelshes⁴, E. Boerwinkle⁵, J.G. Gums¹, A. Chapman⁶, S.T. Turner⁷, R.M. Cooper-DeHoff¹, J.A. Johnson¹; ¹Department of Pharmacotherapy and Translational Research and Center for Pharmacogenomics, College of Pharmacy, University of Florida, Gainesville, FL, USA, ²Department of Pharmaceutics, College of Pharmacy, University of Florida, Gainesville, FL, USA, ³Division of Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC, USA, ⁴Department of Medicine, University of Maryland, Baltimore, MD, USA, ⁵Human Genetics Center and Institute of Molecular Medicine, University of Texas Health Science Center, Houston, TX, USA, ⁶Department of Medicine, The University of Chicago, Chicago, IL, USA, ⁷Division of Nephrology and Hypertension, Department of Internal Medicine, Mayo Clinic, Rochester, MN, USA.

PI-002

β 2-ADRENERGIC RECEPTOR GENE AFFECTS THE NEGATIVE CHRONOTROPIC EFFECTS OF β -BLOCKERS IN THE PEAR AND PEAR2 STUDIES.

M.H. Shahin¹, D.J. Conrado², D. Gonzalez³, Y. Gong¹, M.T. Lobmeyer¹, A.L. Beitelshes⁴, E. Boerwinkle⁵, J.G. Gums¹, A. Chapman⁶, S.T. Turner⁷, R.M. Cooper-DeHoff¹, J.A. Johnson¹; ¹Department of Pharmacotherapy and Translational Research and Center for Pharmacogenomics, College of Pharmacy, University of Florida, Gainesville, FL, USA, ²Department of Pharmaceutics, College of Pharmacy, University of Florida, Gainesville, FL, USA, ³Division of Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC, USA, ⁴Department of Medicine, University of Maryland, Baltimore, MD, USA, ⁵Human Genetics Center and Institute of Molecular Medicine, University of Texas Health Science Center, Houston, TX, USA, ⁶Department of Medicine, The University of Chicago, Chicago, IL, USA, ⁷Division of Nephrology and Hypertension, Department of Internal Medicine, Mayo Clinic, Rochester, MN, USA.

PI-003

MINING ELECTRONIC HEALTH RECORDS DATA UNLOCKS NOVEL INSIGHTS ABOUT ANTIHYPERTENSIVE MEDICATION USE AND THE RISK OF INCIDENT GOUT.

M.H. Shahin¹, D.K. Balasubramanian², E.T. Lima³, H. Mansoor⁴, E. Schmidt⁵, J.A. Johnson³, F. Modave²; ¹University of Florida, Gainesville, FL, USA, ²Biomedical Informatics Program, Department of Health Outcomes and Policy, University of Florida, Gainesville, FL, USA, ³Department of Pharmacotherapy and Translational Research and Center for Pharmacogenomics, College of Pharmacy, University of Florida, Gainesville, FL, USA, ⁴Department of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida, Gainesville, FL, USA, ⁵Biomedical Informatics Team, Department of Health Outcomes and Policy, College of Medicine, University of Florida, Gainesville, FL, USA.

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PI-004

SURVIVAL ANALYSIS BASED ON MACHINE LEARNING METHODS: A SIMULATIONS STUDY FOR PERFORMANCE EVALUATION.

X.J. Gong, M. Hu, J. Zhao; US Food and Drug Administration, Silver Spring, MD, USA.

PI-005

KINASE RELATED ADVERSE EVENT ANALYSIS FOR SMALL-MOLECULE KINASE INHIBITORS USING MACHINE LEARNING APPROACH.

X. Gong, M. Hu, J. Liu, L. Zhao; US Food and Drug Administration, Silver Spring, MD, USA.

PI-006

EVALUATING THE POTENTIAL RELEVANCE OF PHARMACOGENOMIC INFORMATION FOR MEDICATIONS ADMINISTERED TO SURGICAL PATIENTS.

E.H. Jhun, K. Danahey, D.M. Dickerson, S. Shahul, R. Knoebel, M.J. Ratain, P.H. O'Donnell; University of Chicago, Chicago, IL, USA.

PI-007

PHARMACOGENOMIC EVIDENCE IN PERIOPERATIVE DRUGS FOR CLINICAL IMPLEMENTATION.

E. Jhun, K. Danahey, B. Borden, M. Stalker, D.M. Dickerson, S. Shahul, R. Knoebel, M.J. Ratain, P.H. O'Donnell; University of Chicago, Chicago, IL, USA.

PI-008

PHARMACOKINETIC, TOLERABILITY AND SAFETY PROFILE OF SA001 TABLET, A NOVEL ORAL TREATMENT FOR DRY EYE SYNDROME, AFTER SINGLE ADMINISTRATIONS IN HEALTHY SUBJECTS.

Y. Kim¹, J. Oh¹, A. Kim², E. Kim¹, H. Yoo¹, S. Yoon³, S. Lee¹, K.-S. Yu¹; ¹Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea, ²Clinical Trial Center, Ajou University Medical Center, Suwon, Republic of Korea, ³Clinical Trials Center, Seoul National University Bundang Hospital, Seongnam, Republic of Korea.

PI-009

PHARMACOKINETIC, TOLERABILITY AND SAFETY PROFILES OF SA001 TABLET, A NOVEL ORAL TREATMENT FOR DRY EYE SYNDROME, AFTER MULTIPLE ADMINISTRATIONS IN HEALTHY SUBJECTS.

Y. Kim¹, J. Oh¹, A. Kim², E. Kim¹, H. Yoo¹, S. Yoon³, S. Lee¹, K.-S. Yu¹; ¹Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea, ²Clinical Trial Center, Ajou University Medical Center, Suwon, Republic of Korea, ³Clinical Trials Center, Seoul National University Bundang Hospital, Seongnam, Republic of Korea.

PI-010

WHAT FACTORS MAY IMPACT THE PHARMACOKINETIC CHANGES OF DRUGS IN SUBJECTS WITH HEPATIC IMPAIRMENT?

J. Li¹, Z. Dong¹, S.-C. Lee², **L. Zhang²**; ¹Office of Clinical Pharmacology, Office of Translational Sciences, CDER, US Food and Drug Administration, Silver Spring, MD, USA, ²Office of Research and Standards, Office of Generic Drugs, CDER, US Food and Drug Administration, Silver Spring, MD, USA.

PI-011

EVALUATION OF PH-DEPENDENT DRUG-DRUG INTERACTIONS FOR WEAK BASE DRUGS: AN UPDATE FOR NEW MOLECULAR ENTITIES APPROVED IN 2013-2017.

J. Li¹, Z. Dong¹, F. Wu², L. Zhang³, S.-C. Lee⁴, **L. Zhang⁴**; ¹Office of Clinical Pharmacology, Office of Translational Sciences, CDER, US Food and Drug Administration, Silver Spring, MD, USA, ²Office of New Drug Products, Office of Pharmaceutical Quality, CDER, US Food and Drug Administration, Silver Spring, MD, USA, ³Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality, CDER, US Food and Drug Administration, Silver Spring, MD, USA, ⁴Office of Research and Standards, Office of Generic Drugs, CDER, US Food and Drug Administration, Silver Spring, MD, USA.

PI-012

PERFORMANCE OF SEQUENTIAL AND SIMULTANEOUS PK/PD MODELING OF QT INTERVALS WITH PHASE I STUDIES TO PREDICT THOROUGH QT STUDY OUTCOMES.

J. Lu, N. Al-Huniti, G. Helmlinger, J. Li; AstraZeneca, Waltham, MA, USA.

PI-013

EXPOSURE- QT PROLONGATION ASSESSMENT USING LINEAR MIXED-EFFECTS VS. LINEAR QUANTILE MIXED-EFFECTS MODELING OF PHASE I STUDY DATA.

J. Lu, N. Al-Huniti, E. Masson, G. Helmlinger, J. Li; AstraZeneca, Waltham, MA, USA.

PI-014

PHARMACOKINETIC COMPARISON OF NEW LENALIDOMIDE 25 MG CAPSULES AFTER A SINGLE ORAL ADMINISTRATION IN HEALTHY KOREAN SUBJECTS.

S. Moon¹, K. Jang¹, S. Park², M.-G. Kim¹; ¹Chonbuk National University Hospital, Jeonju, Republic of Korea, ²Chong Kun Dang Pharm., Gyeonggi-do, Republic of Korea.

PI-015

COMPARATIVE PHARMACOKINETICS OF TENOFOVIR DISOPROXIL PHOSPHATE AND TENOFOVIR DISOPROXIL FUMARATE AFTER A SINGLE ORAL ADMINISTRATION IN HEALTHY KOREAN SUBJECTS.

S. Moon¹, S. Lee², I.-J. Jang², K.-S. Yu²; ¹Center for Clinical Pharmacology, Biomedical Research Institute, Chonbuk National University Hospital, Jeonju-si, Jeollabuk-do, Republic of Korea, ²Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea.

PI-016

THE NATIONWIDE IMPACT OF IMPLEMENTING A PREEMPTIVE PHARMACOGENETIC PANEL APPROACH TO GUIDE DRUG PRESCRIBING IN PRIMARY CARE IN THE NETHERLANDS.

P.C. Bank, **J.J. Swen**, H.J. Guchelaar; Leiden University Medical Center, Leiden, Netherlands.

PI-017

A NATIONWIDE CROSS-SECTIONAL SURVEY ON KNOWLEDGE, EXPERIENCE, AND ATTITUDES OF PHARMACY STUDENTS TOWARDS PHARMACOGENETICS.

P.C. Bank, **J.J. Swen**, H.J. Guchelaar; Leiden University Medical Center, Leiden, Netherlands.

PI-018

POPULATION PHARMACOKINETICS MODEL WITH ENTEROHEPATIC CIRCULATION FOR AZD3241 IN SUBJECTS WITH MULTIPLE SYSTEM ATROPHY.

X. Tong, D. Zhou, A. Savage, J.A. Mullen, Y. Li, J. Li, N. Al-Huniti, H. Xu; AstraZeneca, Waltham, MA, USA.

PI-019

A PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODEL TO PREDICT CEFTAZIDIME EXPOSURE IN HEALTHY AND RENAL IMPAIRMENT SUBJECTS.

X. Tong, H. Xu, J. Li, N. Al-Huniti, D. Zhou; AstraZeneca, Waltham, MA, USA.

PI-020

CYP2C19 GENETIC VARIANTS INFLUENCE STEADY-STATE VORICONAZOLE METABOLISM AND PHARMACOKINETICS.

M. Torres, I.F. Metzger, C. Moon, J.B. Lu, T.C. Skaar, D. Zeruesenay; Indiana University, Indianapolis, IN, USA.

PI-021

GENETIC PREDICTORS OF VORICONAZOLE ADVERSE EFFECTS IN HEALTHY VOLUNTEERS.

M. Torres¹, A. Gelal², I.F. Metzger¹, D. Zeruesenay¹; ¹Indiana University, Indianapolis, IN, USA, ²Dokuz Eylul University, Izmir, Turkey.

PI-022

UTILITY OF PBPK TO PREDICT EXPOSURE IN RENAL AND HEPATIC IMPAIRMENT POPULATION.

T. Pearl, D. Zhou, G. Moorthy, E. Masson, **K. Vishwanathan**; AstraZeneca, Waltham, MA, USA.

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PI-023

COMPARISON OF CHILD-PUGH CLASSIFICATION AND NCI CLASSIFICATION OF HEPATIC IMPAIRMENT.

T. Pearl, D. Zhou, G. Moorthy, E. Masson, **K. Vishwanathan**; AstraZeneca, Waltham, MA, USA.

PI-024

STAGGERING VENETOCLAX AND DIGOXIN ADMINISTRATION TO MINIMIZE GASTROINTESTINAL P-GLYCOPROTEIN INHIBITION: A MODEL-BASED ANALYSIS.

A.A. Alhadab¹, A.H. Salem², K.J. Freise²;
¹University of Minnesota College of Pharmacy, Minneapolis, MN, USA,
²AbbVie Inc., North Chicago, IL, USA.

PI-025

A SEMI-MECHANISTIC MODEL OF RITONAVIR CYP3A INHIBITION AND PHARMACOKINETIC INTERACTION WITH CYP3A SUBSTRATE VENETOCLAX.

A.A. Alhadab¹, A.H. Salem², K.J. Freise²;
¹University of Minnesota College of Pharmacy, Minneapolis, MN, USA,
²AbbVie Inc., North Chicago, IL, USA.

PI-026

THE DEVELOPMENT OF A LIQUID CHROMATOGRAPHY-TANDEM MASS SPECTROMETRY METHOD FOR THE QUANTIFICATION OF OXFENDAZOLE IN HUMAN PLASMA.

T. Bach¹, S. Bae², R. D'Cunha¹, P.L. Winokur³, G. An¹; ¹Division of Pharmaceuticals and Translational Therapeutics, College of Pharmacy, University of Iowa, Iowa City, IA, USA, ²College of Pharmacy, University of Iowa, Iowa City, IA, USA, ³Department of Internal Medicine, College of Medicine, University of Iowa, Iowa City, IA, USA.

PI-027

TUMOR PROTEIN D54 AFFECTS BREAST CANCER SENSITIVITY TO METFORMIN TREATMENT THROUGH ITS NOVEL FUNCTION OF REGULATING PYRUVATE DEHYDROGENASE.

Y. Zhuang¹, C.V. Frazier², J. Yu¹, S. Qin¹, R.C. Ly¹, R. Weinshilboum¹, L. Wang¹;
¹Mayo Clinic, Rochester, MN, USA,
²Fisk University, Nashville, TN, USA.

PI-028

RECRUITMENT FOR PHARMACOGENOMIC TESTING AS STRATIFIED BY HEALTH SYSTEM: INSIGHTS FROM THE INGENIOUS TRIAL.

C.R. Fulton, K.D. Levy, B.T. Gufford, Z. Desta, P.R. Dexter, T.C. Skaar, M.T. Eadon; Indiana University, Indianapolis, IN, USA.

PI-029

DRUG-GENE AND DRUG-DRUG INTERACTIONS ASSOCIATED WITH TRAMADOL AND CODEINE THERAPY IN THE INGENIOUS TRIAL.

C.R. Fulton, M.T. Eadon, K.D. Levy, B.T. Gufford, B.S. Decker, M. Swart, K.S. Collins, M. Torres, S. Kanuri, S. Liu, P.R. Dexter, T. De Luca, Z. Desta, T.C. Skaar; Indiana University Purdue University Indianapolis, Indianapolis, IN, USA.

PI-030

INVOLVEMENT OF STAT3 AND PREGNANE X RECEPTOR ON THE REGULATION OF HEPATIC TRANSPORTERS DURING INFLAMMATION.

W.A. Abualsunun, M. Piquette-Miller; University of Toronto, Toronto, ON, Canada.

PI-031

NON-ALCOHOLIC STEATOHEPATITIS PATIENTS HAVE INCREASED SYSTEMIC AND HEPATIC ⁹⁹Tc-MEBROFENIN EXPOSURE DUE TO REDUCED HEPATIC UPTAKE AND IMPAIRED BILIARY CLEARANCE.

I. Aili¹, M. Ivanovic¹, A. Barritt¹, M. Niemi², K.L. Brouwer¹; ¹University of North Carolina-CH Hospitals, Chapel Hill, NC, USA, ²University of Helsinki, Helsinki, Finland.

PI-032

OCTN1-MEDIATED TRANSPORT OF CYTARABINE IN ACUTE MYELOID LEUKEMIA.

J.T. Anderson, D.R. Buelow, S. Hu, A.A. Gibson, A. Sparreboom, S.D. Baker; The Ohio State University, Columbus, OH, USA.

PI-033

RESPONSE TO ACUTE DOSES OF D-AMPHETAMINE IN YOUNG ADULTS WITH BIPOLAR PHENOTYPE.

D. Arndt, H. de Wit; The University of Chicago, Chicago, IL, USA.

PI-034

MIR-362-3P INHIBITS HERG CURRENT AND REDUCES PROLIFERATION IN BREAST CANCER CULTURED CELLS.

A. Assiri¹, M. Shao¹, N. Mourad¹, P. Kiel², T. Skaar², B. Overholser¹; ¹Purdue University, College of Pharmacy, Indianapolis, IN, USA, ²Indiana University, School of Medicine, Indianapolis, IN, USA.

PI-035

DEVELOPMENT OF A PHARMACOKINETIC-PHARMACODYNAMIC MODEL OF ALN-GO1, AN INVESTIGATIONAL RNAI THERAPEUTIC FOR PRIMARY HYPEROXALURIA.

H. Attarwala, V. Goel, T. McGregor, D. Erbe, P. Haslett, G. Robbie; Alnylam Pharmaceuticals, Cambridge, MA, USA.

PI-036

SAFETY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF MULTIPLE DOSES OF INTRANASAL GLN-1062, A PRODRUG OF GALANTAMINE, IN HEALTHY ELDERLY SUBJECTS.

C. Bakker¹, J. van der Aart¹, E. 't Hart¹, D. Kay², G. Groeneveld¹, A. Maelicke²; ¹Centre for Human Drug Research, Leiden, Netherlands, ²Neurodyn Inc., Charlottetown, PE, Canada.

PI-037

PHARMACOKINETIC COMPARISON OF AMLODIPINE/LOSARTAN/ROSUVASTATIN FIXED-DOSE COMBINATION AND AMLODIPINE/LOSARTAN FIXED-DOSE COMBINATION WITH ROUSUVASTATIN TABLET.

M. Ban¹, S. Lee¹, J.-H. Ryou¹, E. Kim¹, H. Son², J. Jung², K.-S. Yu¹, J.-Y. Chung³; ¹Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea, ²Hanmi Pharmaceutical Co., Ltd., Seoul, Republic of Korea, ³Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Bundang Hospital, Seongnam, Republic of Korea.

PI-038

THE EPIGENETIC MARKER 5-HYDROXYMETHYLCYTOSINE DIFFERENTIATES NEUROBLASTOMA RISK GROUP AND OUTCOMES.

E.K. Barr¹, M.A. Applebaum¹, J. Nie¹, W. Zhang², C. He¹, S.L. Cohn¹; ¹University of Chicago, Chicago, IL, USA, ²Northwestern, Chicago, IL, USA.

PI-039

DRUG INTERACTION STUDY OF APIXABAN WITH CYCLOSPORINE AND TACROLIMUS: RESULTS FROM A PHASE I, OPEN-LABEL, Crossover TRIAL IN HEALTHY VOLUNTEERS.

B. Bashir, B.D. Tran, S. Mantravadi, D.F. Stickle, I. Chervoneva, W.K. Kraft; Thomas Jefferson University, Philadelphia, PA, USA.

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PI-040

DISCOVERY OF SNPS ASSOCIATED WITH CHEMOTHERAPY-INDUCED PERIPHERAL NEUROPATHY USING MODEL ESTIMATED PARAMETERS AS PHENOTYPES.

J. Bhongsatiern¹, P. Carbonetto², K.C. Chua³, S. Mehrotra⁴, P.D. Evans⁵, E.R. Gamazon⁶, H. Rugo⁶, D.L. Kroetz³, J.V. Gobburu⁴, M.J. Ratain¹, N.J. Cox⁵, M.R. Sharma¹; ¹Department of Medicine, University of Chicago, Chicago, IL, USA, ²Research Computing Center, University of Chicago, Chicago, IL, USA, ³Department of Bioengineering and Therapeutic Sciences, University of California, San Francisco, CA, USA, ⁴Center for Translational Medicine, University of Maryland, Baltimore, MD, USA, ⁵Division of Genetic Medicine, Vanderbilt University, Nashville, TN, USA, ⁶Department of Medicine, University of California, San Francisco, CA, USA.

PI-041

PREDICTORS OF LIVER TOXICITY ASSOCIATED WITH VORICONAZOLE EXPOSURE AMONG PEDIATRIC AND YOUNG ADULT PATIENTS.

E. Biltaji, E.K. Korgenski, C. Sherwin, J.E. Constance; University of Utah, Salt Lake City, UT, USA.

PI-042

IMPACT OF PREEMPTIVE *CYP2D6* GENOTYPING: RESULTS FROM AN INSTITUTIONAL PHARMACOGENOMICS PROGRAM.

A.C. Boeke¹, K. Danahey², B.A. Borden², Y.M. Lee³, X. Pei², E.K. Leung⁴, K.-T.J. Yeo⁴, M.J. Ratain⁵, P.H. O'Donnell⁵; ¹Pritzker School of Medicine, The University of Chicago, Chicago, IL, USA, ²Center for Personalized Therapeutics, The University of Chicago, Chicago, IL, USA, ³Department of Clinical Pharmacology, University of Colorado, Skaggs School of Pharmacy and Pharmaceutical Sciences, Aurora, CO, USA, ⁴Department of Pathology, The University of Chicago, Chicago, IL, USA, ⁵Department of Medicine, The University of Chicago, Chicago, IL, USA.

PI-043

IMPACT OF THE DUAL OREXIN RECEPTOR ANTAGONIST ACT-541468 ON THE PHARMACOKINETICS OF THE CYP3A4 PROBE DRUG MIDAZOLAM AND ASSESSMENT OF THE EFFECT OF FOOD ON ACT-541468.

M.-L. Boof¹, M. Ufer¹, A. Halabi², J. Dingemans¹; ¹Idorsia Pharmaceuticals Ltd, Allschwil, Switzerland, ²CRS Clinical Research Services Kiel GmbH, Kiel, Germany.

PI-044

GENOME-WIDE PATHWAY ANALYSIS OF ALLOPURINOL RESPONSE ASSOCIATES NON-RESPONSE WITH IL-1.

D. Brackman¹, E. Jorgenson², M. Kubo³, K.M. Giacomini¹; ¹University of California, San Francisco, San Francisco, CA, USA, ²Kaiser Permanente Northern California, Oakland, CA, USA, ³RIKEN IMS, Yokohama City, Japan.

PI-045

PEDIATRIC CLINICAL TRIAL SIMULATION IN DRUG DEVELOPMENT: ARGATROBAN.

J. Burnham¹, D. Gonzalez², M.F. Hwang², D. Green¹, J. Ye¹, R. Madabushi¹, M. Zahurak³, G. Rosner³, G.J. Burckart¹; ¹US Food and Drug Administration, Silver Spring, MD, USA, ²University of North Carolina, Chapel Hill, NC, USA, ³Johns Hopkins University, Baltimore, MD, USA.

PI-046

POPULATION PHARMACOKINETICS OF PREGABALIN IN PEDIATRIC AND ADULT SUBJECTS WITH PARTIAL ONSET SEIZURES AND HEALTHY VOLUNTEERS TO SUPPORT DOSING IN PEDIATRIC SUBJECTS.

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PI-047

ABEMACICLIB INHIBITS RENAL TRANSPORTERS BUT DOES NOT AFFECT GLOMERULAR FILTRATION RATE.

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PI-048

CONTRIBUTION OF TUMORAL AND HOST OCT1 TO SORAFENIB ACTIVITY.

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PI-049

PREDICTION OF A LACK OF EFFECT OF ELIGLUSTAT ON A SENSITIVE CYP3A SUBSTRATE USING PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODELING.

J. Chen, S. Turpault, V. Kalamaluru; Sanofi US, Bridgewater, NJ, USA.

PI-050

MECHANISTIC MODELING TO UNDERSTAND INTRA-TUMOR SPATIAL DISTRIBUTION OF ANTIBODY DRUG CONJUGATES: INSIGHTS INTO DOSING STRATEGY IN ONCOLOGY.

M. Chiney¹, S. Bhatnagar², J. Weddell¹, J.P. Gibbs¹, M. Shebley¹; ¹Abbvie, North Chicago, IL, USA, ²University of Michigan, Ann Arbor, MI, USA.

PI-051

META-ANALYSIS IDENTIFIES VARIANTS IN *S1PR1* ASSOCIATED WITH MICROTUBULE TARGETING AGENT-INDUCED SENSORY PERIPHERAL NEUROPATHY IN CALGB 40101 AND 40502 (ALLIANCE).

K.C. Chua¹, C. Ho², T. Mushiroda³, C. Jiang⁴, F. Mulkey⁴, M. Kubo³, L.N. Shulman⁵, H.S. Rugo⁶, K. Owzar⁴, D.L. Kroetz⁷; ¹Pharmaceutical Sciences and Pharmacogenomics Graduate Program, University of California, San Francisco, San Francisco, CA, USA, ²School of Pharmacy, University of California, San Francisco, San Francisco, CA, USA, ³Laboratory for Genotyping Development, Riken Center for Integrative Medical Sciences, Kanagawa, Japan, ⁴Alliance Statistics and Data Center, Duke University, Durham, NC, USA, ⁵Abramson Cancer Center, University of Pennsylvania, Philadelphia, PA, USA, ⁶Department of Medicine, University of California, San Francisco, San Francisco, CA, USA, ⁷Department of Bioengineering and Therapeutic Sciences, University of California, San Francisco, San Francisco, CA, USA.

PI-052

POPULATION PHARMACOKINETICS OF CEFAZOLIN IN NON-OBESE, OBESE, AND MORBIDLY OBESE PATIENTS WITH INFECTIOUS DISEASES.

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PI-053

HIGH-THROUGHPUT BIOASSAY TO FUNCTIONALLY TEST GENETIC VARIANTS IN MICRORNA TARGET SITES OF DRUG DISPOSITION GENES.

K.S. Collins¹, J. Ipe¹, H. Gao¹, Y. Liu¹, A. Gaedigk², T.C. Skaar¹; ¹Indiana University School of Medicine, Indianapolis, IN, USA, ²Children's Mercy Hospital, Kansas City, MO, USA.

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CYTOMEGALOVIRUS INFECTION AND ALZHEIMER'S DISEASE: OPPORTUNITIES FOR NOVEL THERAPEUTIC TARGETS.

A. Costa Sa, J.R. Brown; Computational Biology and Statistics, Target Sciences, R&D, GlaxoSmithKline, Collegeville, PA, USA.

PI-055

IMPROVING PATENCY OF JUGULAR VEIN CATHETERS IN RATS WITH A NITROCELLULOSE COATING.

T. De Luca, K.A. Hargreaves, K.S. Collins, E.A. Benson; Indiana University School of Medicine, Indianapolis, IN, USA.

PI-056

CLINICAL EFFICACY OF TIGECYCLINE-TETRACYCLINE COMBINATIONS AGAINST *P. AERUGINOSA* INFECTIONS.

A.N. Deitchman¹, R.S. Singh², H. Derendorf¹; ¹University of Florida, Gainesville, FL, USA, ²Pfizer, Inc., Cambridge, MA, USA.

PI-057

EARLY LIFE EXPOSURE TO ANTIBIOTICS AND ONSET OF INFLAMMATORY BOWEL DISEASE IN CHILDREN: A SYSTEMATIC REVIEW AND META ANALYSIS.

M. Delara, B.F. Chauhan, W. El-Matary, G.W. 't Jong; University of Manitoba, Winnipeg, MB, Canada.

PI-058

PROSPECTIVE VALIDATION OF A POPULATION PHARMACOKINETIC MODEL DERIVED DOSING ALGORITHM OF ATOMOXETINE, A *CYP2D6* MODEL SUBSTRATE.

J.C. Dinh¹, B.T. Black¹, B.J. Matzuka², K.T. Gibson¹, L. Van Haandel¹, A. Gaedigk¹, S.E. Soden¹, S.M. Abdel-Rahman¹, J.S. Leeder¹; ¹Children's Mercy Hospital, Kansas City, MO, USA, ²qPharmetra, Cary, NC, USA.

PI-059

TARGET ATTAINMENT ANALYSIS OF VANCOMYCIN IN PATIENTS WITH HEART FAILURE.

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PI-060

THE PREVALENCE OF ATYPICAL ANTIPSYCHOTIC MEDICATION CHANGES BASED ON CYP2D6 GENOTYPING IN PATIENTS WITH PSYCHIATRIC DISORDERS.

O.M. Dong¹, L. Young², T. Wiltshire¹, N. Guenzel³; ¹UNC Chapel Hill, Chapel Hill, NC, USA, ²Augusta University, Augusta, GA, USA, ³University of Nebraska Medical Center, Lincoln, NE, USA.

PI-061

THE EFFECT OF PROTEIN BINDING ON THE BREAKPOINT FOR ANTIBIOTICS.

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PI-062

EXTRAPOLATION OF THE PHARMACOKINETICS AND EFFICACY OF LEUPROLIDE ACETATE FOR CENTRAL PRECOCIOUS PUBERTY TO A NEW 6 MONTH DEPOT FORMULATION.

M. Dufek, S. Mensing, N.M. Mostafa; AbbVie, North Chicago, IL, USA.

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BETA-1 ADRENERGIC RECEPTOR GENOTYPE AND SUSCEPTIBILITY TO JUNCTIONAL ECTOPIC TACHYCARDIA AFTER CONGENITAL HEART SURGERY.

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PI-064

PREVALENCE OF ACTIONABLE GENOTYPES AND DRUG EXPOSURE AMONG PATIENTS UNDERGOING CARDIAC CATHETERIZATION IN THE UNIVERSITY OF FLORIDA PERSONALIZED MEDICINE PROGRAM.

N. El Rouby¹, S. Mosley¹, D. Wake², X. Liu¹, K.W. Weitzel¹, A.R. Eley¹, A. Riva¹, T. Langaee¹, A.G. Winterstein¹, J.A. Johnson¹, L.H. Cavallari¹; ¹University of Florida, Gainesville, FL, USA, ²NorthShore University HealthSystem, Evanston, IL, USA.

PI-065

TACROLIMUS PBPB MODELING USING REALISTIC PHYSIOLOGICAL FACTORS IN RENAL TRANSPLANT PATIENTS.

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PI-066

MULTI-SITE INVESTIGATION OF STRATEGIES FOR THE IMPLEMENTATION OF *CYP2C19* GENOTYPE-GUIDED ANTIPLATELET THERAPY.

P.E. Empey¹, J.M. Stevenson¹, S. Tuteja², K.W. Weitzel³, D.J. Angiolillo⁴, A.L. Beitelshes⁵, J.C. Coons¹, J.D. Duarte⁶, F. Franchi⁴, L.J. Jeng⁵, J.A. Johnson³, R.P. Kreuz⁷, N.A. Limdi⁸, K.A. Maloney⁵, A. Owusu Obeng⁹, J.F. Peterson¹⁰, N. Petry¹¹, V.M. Pratt⁷, F. Rollini⁴, S.A. Scott⁹, T.C. Skaar⁷, M.R. Vesely⁵, G.A. Stouffer¹², R.A. Wilke¹³, L.H. Cavallari³, C.R. Lee¹²; ¹University of Pittsburgh, Pittsburgh, PA, USA, ²University of Pennsylvania, Philadelphia, PA, USA, ³University of Florida, Gainesville, FL, USA, ⁴University of Florida College of Medicine, Jacksonville, FL, USA, ⁵University of Maryland, Baltimore, MD, USA, ⁶University of Illinois at Chicago, Chicago, IL, USA, ⁷Indiana University School of Medicine, Indianapolis, IN, USA, ⁸University of Alabama at Birmingham, Birmingham, AL, USA, ⁹The Mount Sinai Hospital, New York, NY, USA, ¹⁰Vanderbilt University Medical Center, Nashville, TN, USA, ¹¹North Dakota State University, Fargo, ND, USA, ¹²University of North Carolina, Chapel Hill, NC, USA, ¹³University of South Dakota Sanford School of Medicine, Sioux Falls, SD, USA.

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FUNCTIONAL CHARACTERIZATION OF LOW FREQUENCY *SLC2A2* MUTATIONS REVEALS THEIR IMPACT ON GLUT2 TRANSPORT AND DISEASE EXPRESSION.

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IDENTIFYING FACTORS ASSOCIATED WITH VARIABILITY IN RESPONSE TO CLOPIDOGREL THERAPY IN EGYPTIAN PATIENTS WITH ACUTE CORONARY SYNDROME.

S. Fathy¹, M.H. Shahin², T. Langae², B.M. Khalil¹, A. Saleh³, N.A. Sabry⁴, L.L. El-Wakeel⁴, L.H. Cavallari², M.F. Schaal¹; ¹Department of Clinical Pharmacy, Faculty of Pharmacy, Misr International University, Cairo, Egypt, ²Department of Pharmacotherapy and Translational Research and Center for Pharmacogenomics, College of Pharmacy, University of Florida, Gainesville, FL, USA, ³Department of Cardiology, Faculty of Medicine, Ain Shams University, Cairo, Egypt, ⁴Department of Clinical Pharmacy and Pharmacy Practice, Faculty of Pharmacy, Ain Shams University, Cairo, Egypt.

PI-069

THE PROTEIN KINASE INHIBITORS MIDOSTAURIN AND NINTEDANIB ARE TIME-DEPENDENT INHIBITORS OF CYP3A4.

A.M. Filppula¹, T.M. Mustonen¹, J.T. Backman²; ¹University of Helsinki, Helsinki, Finland, ²University of Helsinki and Helsinki University Hospital, Helsinki, Finland.

PI-070

RETROSPECTIVE EXAMINATION OF CLINICAL PHARMACOLOGY REVIEWS FROM FDA ON ONCOLOGY BIOLOGICS FOR POTENTIAL BENEFIT OF THERAPEUTIC DRUG MONITORING.

B.A. Fleisher, S. Ait-Oudhia; University of Florida, Orlando, FL, USA.

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DART: AN INTEGRATED PLATFORM FOR CLINICAL PHARMACOLOGY DATA ANALYSIS, REPORTING, AND KNOWLEDGE TRANSFER.

B. Wang¹, B. Corrigan², **P. Gaitonde**²; ¹Brown University, Providence, RI, USA, ²Pfizer Inc., Groton, CT, USA.

PI-072

BENZNIDAZOLE METABOLITES IN URINE FROM PATIENTS TREATED FOR CHAGAS DISEASE.

D. Rocco¹, C.A. Perez Montilla¹, S. Moroni¹, J. Altcheh¹, **F. Garcia-Bournissen**²;

¹Children's Hospital of Buenos Aires, Buenos Aires, Argentina, ²Children's Hospital of Buenos Aires "Dr Ricardo Gutierrez", National Research Council (CONICET), Buenos Aires, Argentina.

PI-073

GENETIC POLYMORPHISMS IN *SLCO1B1* ARE NOT ASSOCIATED WITH ALTERED VOXILAPREVIR EXPOSURE.

K. Garrison, Q. Song, L. Stamm, J. Ling, A. Mathias; Gilead Sciences, Foster City, CA, USA.

PI-074

EXPERIENTIAL LEARNING FOR PHARMACOGENOMIC EDUCATION OF PHARMACISTS: A PILOT STUDY.

J. Giri, W.T. Nicholson, C.R. Vitek, C.M. Formea, E.T. Matey, A.K. Ragab, T.B. Curry; Mayo Clinic, Rochester, MN, USA.

PI-075

A PROSPECTIVE STUDY OF THE OPTIMAL "THERAPEUTIC WINDOW" ON ANTIPLATELET THERAPY IN CHINESE PATIENTS WITH ACS OR UNDERGOING PCI.

L. Gong, G. Yang, Q. Pei, C. Guo, J. Li; The Third Xiangya Hospital of Central South University, Changsha, China.

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A NOVEL APPROACH TO ASSESS DRUG PALATABILITY IN CHILDREN.

G.L. Kearns¹, S. Bai², **G. Goode**¹; ¹Arkansas Children's Research Institute, Little Rock, AR, USA, ²University of Arkansas for Medical Sciences, Little Rock, AR, USA.

PI-077

MODEL-BASED EVALUATION OF COPROPORPHYRIN I AS A BIOMARKER FOR ORGANIC ANION TRANSPORTING POLYPEPTIDES TO PREDICT CLINICAL DRUG-DRUG INTERACTIONS.

C. Guo¹, R. Sane², L. Liu², Y. Chen², K. Yoshida²; ¹University of North Carolina at Chapel Hill, Chapel Hill, NC, USA, ²Genentech Inc, South San Francisco, CA, USA.

PI-078

GENETIC POLYMORPHISMS AT THE PREGNANE X RECEPTOR AND CYP3A5 LOCI INFLUENCE THE PHARMACOKINETICS OF TACROLIMUS IN RENAL TRANSPLANT PATIENTS.

D.R. Hahn¹, C. Emoto¹, U. Christians², R.R. Alloway³, A.A. Vinks¹, T. Fukuda¹; ¹Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA, ²IC42 Integrated Solutions in Clinical Research and Development, Denver, CO, USA, ³University of Cincinnati College of Medicine, Cincinnati, OH, USA.

PI-079

SEMI-PBPK MODEL TO PREDICT PLASMA AND SPUTUM EXPOSURES AFTER INHALED TOBRAMYCIN IN HEALTHY VOLUNTEERS AND CYSTIC FIBROSIS PATIENTS.

B. Hanna, J. Venitz; Virginia Commonwealth University, Richmond, VA, USA.

PI-080

GREEN TEA DECREASES RALOXIFENE SYSTEMIC EXPOSURE TO BELOW THE PRE-DEFINED NO EFFECT RANGE IN HEALTHY VOLUNTEERS.

J.S. McCune¹, D. Tian², P.A. Hardy², N.B. Cech³, D.D. Shen⁴, M.E. Layton², J.R. White², M.F. Paine²; ¹City of Hope, Duarte, CA, USA, ²Washington State University, Spokane, WA, USA, ³University of North Carolina at Greensboro, Greensboro, NC, USA, ⁴University of Washington, Seattle, WA, USA.

PI-081

DEVELOPMENT OF A HIGH-THROUGHPUT BIOASSAY TO FUNCTIONALLY TEST INTRONIC GENETIC VARIANTS PREDICTED TO ALTER PRE-MRNA SPLICING.

K. Hargreaves¹, J. Ipe¹, R. Li², Y. Liu², T. Skaar¹; ¹Indiana University School of Medicine, Indianapolis, IN, USA, ²Indiana University - Purdue University Indianapolis, Indianapolis, IN, USA.

PI-082

VARIABILITY IN THE GROWTH OF TYPE 2 DIABETIC CHILDREN COMPARED TO CENTER FOR DISEASE CONTROL AND PREVENTION REFERENCES.

C.M. Hosey-Cojocari, C. Bi, Y. Yan, J. Leeder; Children's Mercy Hospital, Kansas City, KS, USA.

PI-083

SIMULTANEOUS DETERMINATION METHOD FOR TOLVAPTAN AND ITS FIVE MAJOR METABOLITES IN HUMAN PLASMA USING AN LC-MS/MS AND ITS CLINICAL APPLICATION.

K. Hoshikawa, T. Naito, J. Kawakami; Hamamatsu University School of Medicine, Hamamatsu, Japan.

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INTEGRATED USE OF *IN VITRO* AND *IN VIVO* DATA FOR SYSTEMATIC PREDICTION OF DRUG-DRUG INTERACTIONS CAUSED BY INHIBITIONS OF MULTIPLE CYP SPECIES BY MARKOV CHAIN MONTE CARLO METHOD.

S. Hozuki, H. Yoshioka, H. Sato, A. Hisaka; Laboratory of Clinical Pharmacology and Pharmacometrics, Graduate School of Pharmaceutical Sciences, Chiba University, Chiba, Japan.

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A STATISTICAL BIOEQUIVALENCE METHOD TO REDUCE SAMPLE SIZE FOR PARALLEL BE STUDY DESIGN: A CASE EXAMPLE FOR LONG-ACTING INJECTABLE DRUGS.

Y. Lien, M. Hu, L. Fang, M.-J. Kim, L. Zhao; US Food and Drug Administration, Silver Spring, MD, USA.

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CARRIER-MEDIATED TRANSPORT OF DOXORUBICIN IN CARDIOMYOCYTES.

K.M. Huang¹, T. Magdy², S. Hu¹, A.A. Gibson¹, A. Sparreboom¹, P. Burridge²; ¹The Ohio State University, Columbus, OH, USA, ²Northwestern University, Chicago, IL, USA.

PI-087

A COMPARISON OF PHARMACOKINETICS AND SAFETY OF HCP1401, A FIXED DOSE COMBINATION OF AMLODIPINE, LOSARTAN, AND CHLORTHALIDONE, WITH A LOOSE COMBINATION IN HEALTHY SUBJECTS.

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A PARTIAL REPLICATED CROSSOVER STUDY TO COMPARE THE PHARMACOKINETICS OF HIGHLY VARIABLE DRUGS: FIXED-DOSE COMBINATION OF FIMASARTAN/ATORVASTATIN VS. SEPARATE TABLETS.

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TESTING OF INTRA-SUBJECT VARIABILITY IN HEALTHY VOLUNTEERS FOLLOWING THE 2012 FDA BIOEQUIVALENCE CRITERIA FOR NARROW THERAPEUTIC INDEX DRUGS.

P. Jayachandran, H. Okochi, L.A. Frassetto, L.Z. Benet; University of California, San Francisco, San Francisco, CA, USA.

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PHARMACOKINETIC AND PHARMACODYNAMIC INTERACTIONS BETWEEN EVOGLIPTIN AND PIOGLITAZONE AFTER ORAL ADMINISTRATION IN HEALTHY SUBJECTS.

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EXPLORATION OF BIOMARKERS INCLUDING SERUM MIR-122 TO EVALUATE LIVER TOXICITY POTENTIAL OF DWP14012, A NOVEL POTASSIUM-COMPETITIVE ACID BLOCKER.

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EVALUATION OF THE EFFECT OF SORBITOL ON ABSORPTION OF RUXOLITINIB USING PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODELING AND SIMULATION.

T. Ji, X. Chen, S. Yeleswaram; Incyte, Wilmington, DE, USA.

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QUANTITATIVE SYSTEMS PHARMACOLOGY MODELING OF T CELL ACTIVATION AND CD28/CTLA4 CO-SIGNALING INTERACTION.

D. Holland¹, **Y. Ji**², B. Gomes³; ¹Johns Hopkins School of Medicine, Baltimore, MD, USA, ²Novartis, East Hanover, NJ, USA, ³Novartis, Cambridge, MA, USA.

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PHARMACOKINETIC DRUG INTERACTION AND SAFETY AMONG CLARITHROMYCIN, AMOXICILLIN, AND ILAPRAZOLE.

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PI-095

PHARMACOKINETIC INTERACTION BETWEEN RALOXIFENE AND CHOLECALCIFEROL IN HEALTHY KOREAN MALE SUBJECTS.

W. Kang, S. Seong, B. Ohk, H.-J. Kim, Y.-R. Yoon; Kyungpook National University Hospital, Daegu, Republic of Korea.

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DYSREGULATION OF RENAL TRANSPORTERS IN A RODENT MODEL OF VIRAL INFECTION.

N. Karimian Pour, M. Piquette Miller; Leslie Dan Faculty of Pharmacy, Toronto, ON, Canada.

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EVALUATION OF APPROACHES TO MITIGATE DECREASED EXPOSURE OF LEVONORGESTREL BY ORAL EFAVIRENZ WHEN LEVONORGESTREL IS ADMINISTERED AS A SUBDERMAL IMPLANT: A SIMULATION TRIAL.

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COMPARATIVE PHARMACOKINETICS/ PHARMACODYNAMICS AND SAFETY PROFILES AFTER SUBCUTANEOUS ADMINISTRATION OF DA3030 AND FILGRASTIM IN HEALTHY SUBJECTS.

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PI-099

A PHARMACOKINETIC COMPARISON BETWEEN FIXED-DOSE COMBINATION AND SEPARATE TABLETS OF ROSUVASTATIN AND METFORMIN IN FED STATE AND FOOD EFFECT OF FIXED-DOSE COMBINATION IN HEALTHY SUBJECTS.

E. Kim¹, S.-J. Rhee¹, Y. Kim¹, J. Oh¹, H. Suh², Y. Lee², Y. Lee², J.-Y. Cho¹, K.-S. Yu¹, H. Lee³; ¹Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea, ²Global Research Institute, BCWORLD Pharm. Co., LTD., Gyeonggi-do, Republic of Korea, ³Department of Transdisciplinary Studies, Graduate School of Convergence Science and Technology, Seoul National University, Suwon, Republic of Korea.

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EVALUATION OF CHANGES IN CYP3A ACTIVITY IN PREGNANT WOMEN DURING TRIMESTER USING ENDOGENOUS MARKERS.

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CAN LIVER RELATED LABORATORY PARAMETERS PREDICT THE SYSTEMIC EXPOSURE CHANGE OF DRUGS?

E. Kim¹, S. Chung², **I. Kim**²; ¹University of Michigan, Ann Arbor, MI, USA, ²US Food and Drug Administration, Silver Spring, MD, USA.

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PHARMACOKINETIC COMPARISON OF TELMISARTAN, AMLODIPINE, AND HYDROCHLOROTHIAZIDE IN HEALTHY MALE VOLUNTEERS.

M.-G. Kim, Y. Kim, S. Lee, S.-Y. Kim; Chonbuk National University Hospital, Jeonju, Republic of Korea.

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EXPOSURE-RESPONSE RELATIONSHIPS FOR SAFETY AND EFFICACY OF SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR IN HCV-INFECTED PATIENTS IN PHASE III STUDIES.

B.J. Kirby, L.M. Stamm, L. Ni, A. Mathias; Gilead Sciences, Foster City, CA, USA.

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A 14C ORAL BIOAVAILABILITY MICROTRACER STUDY SHOWS THAT ORAL ACETAMINOPHEN EXPOSURE IS LOW AND ERRATIC IN CRITICALLY ILL CHILDREN: A CASE FOR I.V. ACETAMINOPHEN.

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J. Li, Y. He; US Food and Drug Administration, Silver Spring, MD, USA.

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X. Liu¹, J. Swen¹, M. Diekstra², E. Boven³, D. Castellano⁴, H. Gelderblom¹, R. Mathijssen⁵, S. Vermeulen⁶, E. Oosterwijk⁶, K. Junker⁷, M. Roessler⁸, T. Rafnar⁹, M. Radu¹⁰, T. Eisen¹¹, C. Rodríguez-Antona¹², J. García-Donas¹³, S. Böhringer¹, L. Kiemeny⁶, B. Rini¹⁴, H.-J. Guchelaar¹; ¹Leiden University Medical Center, Leiden, Netherlands, ²Maastricht University Medical Center, Maastricht, Netherlands, ³VU University Medical Center, Amsterdam, Netherlands, ⁴Hospital Universitario 12 de Octubre, Madrid, Spain, ⁵Erasmus MC Cancer Institute, Rotterdam, Netherlands, ⁶Radboud University Medical Center, Nijmegen, Netherlands, ⁷Saarland University, Homburg, Germany, ⁸CESAR Central European Society for Anticancer Drug Research-EWIV, Vienna, Austria, ⁹deCODE Genetics/Amgen, Reykjavik, Iceland, ¹⁰University of Medicine and Pharmacy Carol Davila, Bucuresti, Romania, ¹¹Cambridge Biomedical Campus, Cambridge, UK, ¹²Spanish National Cancer Research Centre, Madrid, Spain, ¹³Centro Integral Oncológico HM Clara Campal, Madrid, Spain, ¹⁴Cleveland Clinic Taussig Cancer Institute, Cleveland, OH, USA.

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C. Maass, N. Sorensen, E. Geishecker, M. Cirit; Massachusetts Institute of Technology, Cambridge, MA, USA.

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P.R. Malik, A.N. Edginton; University of Waterloo, Waterloo, ON, Canada.

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L.A. Marcath, J. Xi, E. Hoylman, K. Kidwell, S. Kraft, D.L. Hertz; University of Michigan, Ann Arbor, MI, USA.

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R. Matsukane¹, M. Hayashi¹, M. Takahashi², H. Aikawa¹, M. Ohuchi¹, H. Okada², S. Masuda³, A. Hamada¹; ¹Division of Molecular Pharmacology, National Cancer Center Research Institute, Tokyo, Japan, ²Product Development Division, Bio-Healthcare Business Unit, Healthcare Business Headquarters, Konica Minolta, Inc., Tokyo, Japan, ³Department of Clinical Pharmacology and Biopharmaceutics, Graduate School of Pharmaceutical Sciences, Kyushu University, Fukuoka, Japan.

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B. McPhail¹, C. Emoto¹, T. Fukuda¹, D. Butler¹, J. Wiles², A.A. Vinks¹; ¹Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA, ²St. Mary's Medical Center, Evansville, IN, USA.

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K. Mizuno¹, T. Fukuda¹, S. Chandra², J. Zhao³, A. Teusink-Cross⁴, R.A. Marsh², K. Setchell³, P.A. Mehta², A.A. Vinks¹; ¹Division of Clinical Pharmacology, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA, ²Division of Bone Marrow Transplantation and Immune Deficiency, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA, ³Division of Pathology and Laboratory Medicine, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA, ⁴Division of Pharmacy, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA.

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J.C. Euteneuer, **T. Mizuno**, T. Fukuda, J. Zhao, K.D. Setchell, A.A. Vinks; Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA.

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G. Moorthy, E. Masson, K. Vishwanathan; AstraZeneca, Waltham, MA, USA.

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P. Pollak, N. Dehar, M. Peng; University of Calgary, Calgary, AB, Canada.

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S. Qin, F. Xie, P. Yin, J. Yu, Y. Zhuang, M. Koli, L. Wang, P.T. Vedell, D. Hillman, R.M. Weinsilboum, L. Wang; Mayo Clinic, Rochester, MN, USA.

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S.-J. Rhee, S. Lee, E. Kim, H. Lee, K.-S. Yu; Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea.

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K. Rogers¹, S. Nayak¹, S.W. Martin¹, I. Bhattacharya², R. Singh¹; ¹Pfizer Inc., Cambridge, MA, USA, ²Summit Therapeutics PLC, Cambridge, MA, USA.

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J.-H. Ryou, S. Lee, J. Hwang, H. Lee, K.-S. Yu, I.-J. Jang, S. Lee; Seoul National University College of Medicine and Hospital, Seoul, Republic of Korea.

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E. Schuck¹, Y. Yu², G. Lai³, J. Aluri¹, L. Reyderman¹, R. Shumaker¹, J. Ferry¹, Z. Hussein⁴; ¹Eisai Inc., Woodcliff Lake, NJ, USA, ²Pfizer Inc., San Diego, CA, USA, ³Eisai Inc., Andover, MA, USA, ⁴Eisai Ltd., Hatfield, UK.

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S. Seong, W. Kang, B. Ohk, B. Kim, M.-R. Gwon, H.-J. Kim, S. Cho, H. Lee, Y.-R. Yoon; Kyungpook National University Hospital Clinical Trial Center, Daegu, Republic of Korea.

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S. Singh¹, Y. Gong¹, C.W. McDonough¹, K.R. Bailey², A.L. Beitelshes³, E. Boerwinkle⁴, A.B. Chapman⁵, J.G. Gums¹, S.T. Turner⁶, R.M. Cooper-DeHoff¹, J.A. Johnson¹; ¹Department of Pharmacotherapy and Translational Research and Center for Pharmacogenomics, University of Florida, Gainesville, FL, USA, ²Division of Biostatistics, Department of Health Sciences Research, Mayo Clinic, Rochester, MN, USA, ³College of Medicine, University of Maryland, Baltimore, MD, USA, ⁴Human Genetics and Institute of Molecular Medicine, University of Texas Health Science Center, Houston, TX, USA, ⁵Section of Nephrology, University of Chicago, Chicago, IL, USA, ⁶Division of Nephrology and Hypertension, Mayo Clinic, Rochester, MN, USA.

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R. Sleightholm, S. Kanvinde, Y. Chhonker, D. Oupicky, D.J. Murry; University of Nebraska Medical Center, Omaha, NE, USA.

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E. Sokol¹, R. Engelmann¹, N. Pinto², A. Starkey¹, M. Nall¹, H. Lai³, H. Nadel⁴, B. Shulkin⁵, Y. Pu¹, D. Appelbaum¹, G. Yanik⁶, S. Cohn¹, S. Armato¹, S. Volchenboum¹; ¹University of Chicago, Chicago, IL, USA, ²University of Washington, School of Medicine, Seattle, WA, USA, ³Children's Hospital of Orange County, Orange, CA, USA, ⁴University of British Columbia, Vancouver, BC, Canada, ⁵St. Jude Children's Research Hospital, Memphis, TN, USA, ⁶University of Michigan, School of Medicine, Ann Arbor, MI, USA.

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N. Srinivas, M. Cottrell, N. White, C. Sykes, H. Prince, D. Gonzalez, A.D. Kashuba; University of North Carolina at Chapel Hill, Chapel Hill, NC, USA.

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S.L. Stancil¹, S. Rahman², R.F. Tyndale³, J.S. Leeder², R.E. Pearce²; ¹Division of Pharmacology, Toxicology and Therapeutic Innovation, Children's Mercy Kansas City; Division of Pharmacology and Toxicology, University of Missouri-Kansas City School of Pharmacy, Kansas City, MO, USA, ²Division of Pharmacology, Toxicology and Therapeutic Innovation, Children's Mercy Kansas City, Kansas City, MO, USA, ³Department of Pharmacology and Toxicology, University of Toronto, Toronto, ON, Canada.

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M. Takeuchi¹, T. Kobayashi², T. Biss³, F. Kamali⁴, S. Vear⁵, R. Ho⁶, F. Bajolle⁷, M.-A. Lorient⁷, K. Shaw⁸, B. Carleton⁹, A.-K. Hamberg¹⁰, M. Wadelius¹⁰, K. Hirono¹¹, M. Taguchi¹², T. Wakamiya¹³, M. Yanagimachi¹⁴, K. Hirai¹⁵, K. Itoh¹⁵, L. Brandão¹⁶, S. Ito¹⁷; ¹Division of Clinical Pharmacology and Toxicology, The Hospital for Sick Children, Toronto, Canada and Division of Pediatrics, Yokohama City University Hospital, Yokohama, Japan, ²Division of Clinical Research Planning, Department of Development Strategy, Center for Clinical Research and Development, National Center for Child Health and Development, Tokyo, Japan, ³Institute of Cellular Medicine, Newcastle University, Newcastle, UK, ⁴Institute of Cellular Medicine Newcastle University, Newcastle, UK, ⁵Division of Pediatric Hematology/Oncology/BMT, Nationwide Children's Hospital, Columbus, OH, USA, ⁶Department of Pediatrics, Monroe Carell Jr Children's Hospital, Nashville, TN, USA, ⁷Université Paris Descartes, Inserm Unité Mixte de Recherche (UMR)-S, Paris, France, ⁸DNA Genotek Inc., Ottawa, ON, Canada, ⁹Pharmaceutical Outcomes Programme, BC Children's Hospital, Vancouver, BC, Canada, ¹⁰Department of Medical Sciences, Clinical Pharmacology, Uppsala University, Uppsala, Sweden, ¹¹Department of Pediatrics, University of Toyama, Toyama, Japan, ¹²Graduate School of Medicine and Pharmaceutical Sciences, University of Toyama, Toyama, Japan, ¹³Department of

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IDENTIFICATION OF MATE1 AS A HIGH-AFFINITY CARRIER OF DOFETILIDE.

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A.G. Vandell¹, K.L. Duchin¹, M. Desai¹, K. Bupathi¹, R. Gajee¹, C.A. Zamora², L. Biernat³, Q. Wang¹, F. Kobayashi¹, H. Zhang¹, L. Zhang¹, **H. Zahir**¹; ¹Daiichi Sankyo Inc., Basking Ridge, NJ, USA, ²Worldwide Clinical Trials, San Antonio, TX, USA, ³Medpace, Inc., Cincinnati, OH, USA.

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T. Long, V. Arya, T.D. Nolin, **K. Wu**; US Food and Drug Administration, Silver Spring, MD, USA.

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H. Xu, D. Zhou, Khanh Bui, Maria Learoyd, Alienor Berges, Helen Tomkinson, Nidal Al-Huniti, Jianguo Li; AstraZeneca, Waltham, MA, USA.

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EVALUATION OF THE RELATIONSHIPS BETWEEN DAPTOMYCIN SERUM CONCENTRATION AND MUSCULOSKELETAL TOXICITY.

T. Yamada¹, K. Suetsugu¹, R. Nishida², N. Miyake², N. Shimono², M. Soda³, K. Kitaichi³, S. Masuda¹; ¹Department of Pharmacy, Kyushu University Hospital, Fukuoka, Japan, ²Center for the Study of Global Infection, Kyushu University Hospital, Fukuoka, Japan, ³Laboratory of Pharmaceutics, Gifu Pharmaceutical University, Gifu, Japan.

PI-157

PHARMACOKINETIC/PHARMACODYNAMIC INTERACTIONS BETWEEN EVOGLIPTIN AND GLIMEPIRIDE IN HEALTHY MALE VOLUNTEERS.

H. Yoo, Y. Kim, J. Sunwoo, Y. Kim, H. Lee, I.-J. Jang, K.-S. Yu; SNUH, Seoul, Republic of Korea.

PI-158

A POPULATION PHARMACOKINETIC ANALYSIS OF CEFAZOLIN PLASMA AND SKELETAL MUSCLE CONCENTRATIONS IN INFANTS UNDERGOING CARDIAC SURGERY.

N.R. Zane¹, M.R. Gastonguay², A.S. Himebauch¹, A.F. Zuppa¹; ¹Children's Hospital of Philadelphia, Philadelphia, PA, USA, ²Metrum Research Group, Tariffville, CT, USA.

POSTER SESSION II

7:00 AM – 8:30 AM

FRIDAY, MARCH 23

ORANGE BALLROOM

PII-001

POPULATION PHARMACOKINETIC MODEL OF AZD8186, A POTENT AND SELECTIVE INHIBITOR OF PI3KB δ , IN PATIENTS WITH ADVANCED SOLID TUMORS.

G. Moorthy¹, M. Sunnåker², H. Schmidt², S. Colebrook³, W. Brugger³, T. Klinowska³, G. Mugundu¹; ¹AstraZeneca, Waltham, MA, USA, ²IntiQuan GmbH, Basel, Switzerland, ³AstraZeneca, Cambridge, UK.

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PII-002

DEVELOPMENT AND VALIDATION OF A VOLUMETRIC ABSORPTIVE MICROSAMPLING ASSAY FOR ANALYSIS OF VORICONAZOLE AND VORICONAZOLE N-OXIDE IN HUMAN WHOLE BLOOD.

G.S. Moorthy, H. Jogiraju, C. Vedar, N. Zane, A.F. Zuppa; The Children's Hospital of Philadelphia, Philadelphia, PA, USA.

PII-003

SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF REPEAT DOSES OF THE NAV1.7-SELECTIVE SODIUM CHANNEL BLOCKER BIIB074 IN HEALTHY SUBJECTS.

H. Naik¹, D. Steiner¹, M. Versavel², J. Palmer², R. Fong³; ¹Biogen, Cambridge, MA, USA, ²Convergence Pharmaceuticals, Ltd, Cambridge, UK, ³GlaxoSmithKline, King of Prussia, PA, USA.

PII-004

SAFETY, TOLERABILITY AND PHARMACOKINETICS OF SINGLE DOSES OF THE NAV1.7-SELECTIVE SODIUM CHANNEL BLOCKER BIIB074 IN HEALTHY SUBJECTS.

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PII-005

DIFFERENTIAL INHIBITION OF SGLT1 BY CANAGLIFLOZIN VS. DAPAGLIFLOZIN AND EMPAGLIFLOZIN: A DRUG-DISEASE MODELING STUDY.

T. Yakovleva¹, **V. Sokolov**¹, L. Chu², R.C. Penland², W. Tang³, P.J. Greasley⁴, S. Johansson⁴, K. Peskov¹, G. Helmlinger², D.W. Boulton³; ¹M&S Decisions, Moscow, Russian Federation, ²Early Clinical Development, IMED Biotech Unit, AstraZeneca, Boston, MA, USA, ³Early Clinical Development, IMED Biotech Unit, AstraZeneca, Gaithersburg, MD, USA, ⁴Early Clinical Development, IMED Biotech Unit, AstraZeneca, Gothenburg, Sweden.

PII-006

DIFFERENTIATION OF ANTI-PCSK9 ANTIBODIES AND SYNTHESIS INHIBITORS: A DRUG-DISEASE MODELING STUDY.

V. Sokolov¹, E. Hurt-Camejo², C. Nilsson³, K. Zhudonkov¹, S. Skrtic³, B. Hamrén³, K. Peskov¹, G. Helmlinger⁴, R. Jansson-Löfmark²; ¹M&S Decisions, Moscow, Russian Federation, ²CVMD IMED, AstraZeneca, Gothenburg, Sweden, ³Early Clinical Development, AstraZeneca, Gothenburg, Sweden, ⁴Early Clinical Development, AstraZeneca, Boston, MA, USA.

PII-007

DESCRIPTIVE REVIEW OF EXTENDED-RELEASE DRUG PRODUCTS APPROVED IN FDA BETWEEN 2013 AND 2017.

B. AbuAsal, L. Almansour, M. Ahmed, S. Hamed, R. Uppoor, M. Mehta; Office of Clinical Pharmacology, Office of Translational Science, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, MD, USA.

PII-008

ROMIPLOSTIM, A THROMBOPOIETIN RECEPTOR AGONIST, AS AN EFFECTIVE COUNTERMEASURE FOR ACUTE RADIATION SYNDROME IN MICE.

L. Abuqayyas¹, D.I. Bunin², P.Y. Chang², C.E. Green², L. Yan¹, G. Balasubramanian¹; ¹Amgen Inc., Thousand Oaks, CA, USA, ²SRI International, Menlo Park, CA, USA.

PII-009

PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODEL OF SAVOLITINIB AND METABOLITE, M2, UTILIZED IN DECISION NOT TO GENOTYPE PATIENTS FOR CYP450 POLYMORPHISMS.

P. Sharma, C. Howes, R. Markandu, T. Sahota, **G.F. Ahmed**; AstraZeneca, Cambridge, UK.

PII-010

COMPARISON OF PHARMACOKINETICS OF BMS-986165, A TYK2 INHIBITOR, IN JAPANESE AND NON-JAPANESE HEALTHY SUBJECTS.

U. Aras, D. Bei, B. He, Y. Ishida, L. Hansen, B. Murthy, Y. Liu, I.G. Girgis; Bristol-Myers Squibb, Princeton, NJ, USA.

PII-011

DEVELOPMENT OF A PHARMACOKINETIC-PHARMACODYNAMIC MODEL OF ALN-TTRSC02, AN INVESTIGATIONAL RNAI THERAPEUTIC FOR THE TREATMENT OF HEREDITARY TTR AMYLOIDOSIS.

H. Attarwala, V. Goel, J. Vest, V. Karsten, E. Green, G. Robbie; Alnylam Pharmaceuticals, Cambridge, MA, USA.

PII-012

CLINICALLY NEGLIGIBLE PHARMACOKINETIC AND PHARMACODYNAMIC INTERACTIONS BETWEEN LANABECESTAT AND WARFARIN.

M.A. Ayan-Oshodi¹, A.R. Kugler², S.W. Andersen¹, D.E. James¹, S.A. Monk¹, J. Mullen³, J.A. Zimmer¹, B.A. Willis¹; ¹Eli Lilly, Indianapolis, IN, USA, ²Coastal Pharma Group, Concord, MA, USA, ³AstraZeneca Pharmaceuticals, Waltham, MA, USA.

PII-013

CLOPIDOGREL BUT NOT PRSUGREL ELEVATES THE CONCENTRATIONS OF MONTELUKAST BY INHIBITING ITS CYP2C8 MEDIATED METABOLISM.

M.K. Itkonen, A. Tornio, A.M. Filppula, M. Neuvonen, P.J. Neuvonen, M. Niemi, **J.T. Backman**; University of Helsinki, Department of Clinical Pharmacology, Helsinki, Finland.

PII-014

PHYSIOLOGICALLY BASED PHARMACOKINETIC MODELING TO SUPPORT DOSING OF ORAL PARICALCITOL IN PEDIATRIC POPULATIONS FOR THE TREATMENT OF CHRONIC KIDNEY DISEASE.

S. Basu, M.B. Dufek, N.M. Mostafa, M. Shebley; AbbVie, North Chicago, IL, USA.

PII-015

PHARMACOKINETICS, FOOD EFFECT, AND SAFETY OF GS-9131, A NOVEL N(T)RTI FOR USE IN TREATMENT EXPERIENCED HIV-INFECTED SUBJECTS.

R. Begley, S.R. Majeed, H. Cao, S. West, A. Vu, J. Ling, J.M. Custodio, A. Mathias; Gilead Sciences, Foster City, CA, USA.

PII-016

ARTIFICIAL PANCREAS: RESULTS OF THE FIRST CLINICAL TRIAL IN LATIN AMERICA WITH AN ARGENTINEAN ALGORITHM.

W.H. Belloso; Hospital Italiano de Buenos Aires, Buenos Aires, Argentina.

PII-017

EFFECT OF RECREATIONAL DRUG EXPERIENCE ON THE PHARMACOKINETICS AND THE DRUG LIKING OF INSUFFLATED TAMPERED OPIOIDS.

G. Bernstein¹, J. Oldenhof¹, C. Mills¹, B. Setnik², S. Schmidt³, N. Hakim⁴, C. Dick⁴; ¹INC Research, Toronto, ON, Canada, ²INC Research, Raleigh, NC, USA, ³University of Florida, Gainesville, FL, USA, ⁴Elite Laboratories, Inc., Northvale, NJ, USA.

PII-018

AN EVIDENCE BASED STRATEGY TO IMPROVE EXPOSURE OF EZUTROMID.

I. Bhattacharya¹, A. Bye², J. Tinsley³, N. Robinson³, G. Horne³, K. Davies⁴, S. Harriman¹, A. Heatherington¹; ¹Summit Therapeutics PLC, Cambridge, MA, USA, ²Summit Therapeutics PLC, Redhill, UK, ³Summit Therapeutics PLC, Abingdon, UK, ⁴University of Oxford, Oxford, UK.

PII-019

ASSESSMENT OF MIDAZOLAM PHARMACOKINETICS IN HEPATICALLY IMPAIRED POPULATIONS BY PBPK.

M. Block¹, A. Schneider², K. Coboecken¹, J. Schlender¹; ¹Bayer AG, Leverkusen, Germany, ²Ruprecht-Karls-Universität Heidelberg, Heidelberg, Germany.

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PII-020

IMPACT OF THE MODERATE CYP3A4 INHIBITOR DILTIAZEM ON THE SINGLE-DOSE PHARMACOKINETICS OF THE DUAL OREXIN RECEPTOR ANTAGONIST ACT-541468.

M.-L. Boof¹, M. Ufer¹, A. Halabi², J. Dingemans¹, ¹Idorsia Pharmaceuticals Ltd, Allschwil, Switzerland, ²CRS Clinical Research Services Kiel GmbH, Kiel, Germany.

PII-021

CHANGES IN PROVIDER KNOWLEDGE AND PERCEPTIONS OF PHARMACOGENOMICS AFTER PARTICIPATION IN AN INSTITUTIONAL IMPLEMENTATION STUDY.

B.A. Borden, K. Danahey, P. Galecki, L. Patrick-Miller, R. Wellmann, S. Lee, M. Siegler, M.J. Sorrentino, W.M. Stadler, D.O. Meltzer, M.J. Ratain, P.H. O'Donnell; The University of Chicago, Chicago, IL, USA.

PII-022

CORRECTING FOR THE INDIVIDUAL PATIENT REGRESSION TO THE MEAN EFFECT.

S. Branders, G. Bernard, A. Pereira; Tools4Patient, Gosselies, Belgium.

PII-023

TAILORED SIMULATION TRAINING AS AN INNOVATIVE TRAINING CONCEPT TO FACILITATE SUCCESSFUL STUDY CONDUCT AND RECRUITMENT.

B.B. Burckhardt¹, A.M. Ciplea¹, A. Laven¹, K. Kleine², L. Ablonczy³, J.M. Breur⁴, M. Dalinghaus⁵, M. van der Meulen⁵, I. Klingmann⁶, L. Spatenkova⁶, V. Swoboda⁷, M. Bajcetic⁸, A. Keatley-Clark⁹, S. Laeer¹, F.B. Lagler¹⁰; ¹Institut of Clinical Pharmacy and Pharmacotherapy, Heinrich-Heine-University, Duesseldorf, Germany, ²Simply Quality, Weilheim, Germany, ³Gottsegen György Hungarian Institute of Cardiology, Budapest, Hungary, ⁴Wilhelmina Children's Hospital/University Medical Center Utrecht, Pediatric Heart Center, Utrecht, Netherlands, ⁵Erasmus Universitair Medisch Centrum Rotterdam, Rotterdam, Netherlands, ⁶Pharmaplex, Wezembeek-Oppem, Belgium, ⁷Medical University of Vienna, Vienna, Austria, ⁸Univerzitetna Dečja Klinika, Belgrade, Serbia, ⁹Children's Heart Federation, London, UK, ¹⁰Institute for Hereditary Metabolic Diseases, Paracelsus Medical University, Salzburg, Austria.

PII-024

EXPOSURE-RESPONSE ANALYSIS OF PREGABALIN FOR PARTIAL ONSET SEIZURES IN PEDIATRIC AND ADULT SUBJECTS.

P.L. Chan¹, J. Liu², L. McFadyen¹, S.F. Marshall¹; ¹Pfizer Limited, Sandwich, UK, ²Pfizer Inc., Groton, CT, USA.

PII-025

EXPOSURE-RESPONSE RELATIONSHIP OF ABEMACICLIB AND QTCF IN HEALTHY SUBJECTS.

J.C. Chappell¹, J. Royalty², P. Turner¹, P. Kulanthaivel¹, M. Fein³, K. Whitehurst⁴, H. Coleman⁴, A.Y. Chiang¹; ¹Eli Lilly & Company, Indianapolis, IN, USA, ²Covance Early Clinical Development, Madison, WI, USA, ³Covance Clinical Research Unit, Daytona Beach, FL, USA, ⁴Covance Clinical Research Unit, Evansville, IN, USA.

PII-026

THE EFFECTS OF THE CYP3A INHIBITOR, ITRACONAZOLE, AND THE CYP3A INDUCER, RIFAMPIN, ON THE PHARMACOKINETICS OF THE MAO-B INHIBITOR, HT-3951, IN HEALTHY SUBJECTS.

C.M. Charriez¹, D.J. Carpenter¹, P.K. Vuppala², M.A. Graham², C. Curtis³, I. Hoffmann¹, J.M. Parsons¹, J. Ruckle⁴, P. Perera¹; ¹Dart NeuroScience, LLC, San Diego, CA, USA, ²KinderPharm, LLC, Exton, PA, USA, ³Compass Research, LLC, Orlando, FL, USA, ⁴Pacific Pharma Group, LLC, Tacoma, WA, USA.

PII-027

PHYSIOLOGICALLY BASED PHARMACOKINETIC MODELING FOR ASSESSMENT OF ELIGLUSTAT INTERACTION POTENTIAL WITH CYP2D6 AND CYP3A INHIBITORS.

J. Chen, S. Turpault, V. Kalamaluru; Sanofi US, Bridgewater, NJ, USA.

PII-028

ADAPTIVE ONCOLOGY PHASE I STUDY OF FIRST-IN-CLASS INHIBITOR OF ATAXIA TELANGIECTASIA MUTATED PROTEIN KINASE, IN COMBINATION WITH OLAPARIB.

Y. Chen¹, M. Pass², N. Buil Bruna², C. Stephens², A. Pierce², H. Gabra², H. Tomkinson², E. Masson¹; ¹AstraZeneca, Waltham, MA, USA, ²AstraZeneca, Cambridge, UK.

PII-029

EXPLORING THE IMPACT OF SMOKING ON THE RESPONSE TO CLOPIDOGREL: A PBPK-PD STUDY.

M. Chetty, K. Abduljalil, K. Rowland-Yeo; Simcyp, Sheffield, UK.

PII-030

DEVELOPMENT OF PHYSIOLOGICALLY BASED PHARMACOKINETIC MODEL OF UPADACITINIB.

M. Chiney, M.-E.F. Mohamed, A.A. Othman, M. Shebley; AbbVie, North Chicago, IL, USA.

PII-031

LATE-STAGE DEVELOPMENT AND PATIENT POPULATION APPLICATIONS OF A QUANTITATIVE SYSTEMS PHARMACOLOGY MODEL OF POTASSIUM HOMEOSTASIS FOR SODIUM ZIRCONIUM CYCLOSILICATE.

L. Chu¹, L. Clegg², R.C. Penland¹, M. Någård², G. Helmlinger¹, D.W. Boulton²; ¹Quantitative Clinical Pharmacology, AstraZeneca, Waltham, MA, USA, ²Quantitative Clinical Pharmacology, AstraZeneca, Gaithersburg, MD, USA.

PII-032

INCREASED RISK OF MEDICATION-RELATED PROBLEMS DUE TO CONCOMITANT ADMINISTRATION OF CYP2D6-DEPENDENT OPIOIDS AND CYP2D6 INTERACTING DRUGS.

B. Cicali, J. Turgeon, J. Verzicco, C.H. Knowlton, V. Michaud; Tabula Rasa HealthCare, Philadelphia, NJ, USA.

PII-033

EVALUATION OF RENAL FUNCTION FOLLOWING ADMINISTRATION OF BICTEGRAVIR IN HIV-1 UNINFECTED SUBJECTS AS ASSESSED BY MARKERS OF GLOMERULAR FILTRATION RATE.

J.M. Custodio, H. Wang, A. Vu, D. Xiao, H. Martin, B.P. Kearney, A. Mathias; Gilead Sciences, Foster City, CA, USA.

PII-034

INTEGRATED POPULATION PHARMACOKINETIC ANALYSIS OF ERYTHROPOIETIN IN HUMAN ADULTS AND PREMATURE INFANTS.

R. D'Cunha¹, X. Yan², R. Schmidt¹, J.A. Widness¹, P. Veng-Pedersen¹, G. An¹; ¹University of Iowa, Iowa City, IA, USA, ²Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA.

PII-035

QUANTITATIVE SYSTEMS PHARMACOLOGY MODELING OF BISPECIFIC ANTIBODIES AND CAR-T IN ACUTE LYMPHOBLASTIC LEUKEMIA.

O. Demin Jr., A. Nikitich, O. Demin; InSysBio, Moscow, Russian Federation.

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PII-036

A STUDY TO EVALUATE THE PHARMACOKINETICS AND TASTE PROFILE OF A PROTOTYPE ORALLY DISINTEGRATING TABLET FORMULATION OF MK-0663.

P. Dogterom¹, K. Abd Elaziz¹, R. de Jong¹, P. Fackler²; ¹QPS Netherlands, Groningen, Netherlands, ²Merck, Sharp & Dohme, Kenilworth, NJ, USA.

PII-037

PROTEIN ABUNDANCE OF CLINICALLY RELEVANT DRUG METABOLIZING ENZYMES IN THE HUMAN LIVER AND ALONG THE INTESTINE: A COMPARATIVE ANALYSIS IN PAIRED TISSUE SPECIMENS.

M. Drożdżik¹, D. Busch², J. Lapczuk¹, J. Müller², M. Kurzawski¹, S. Oswald²; ¹Department of Pharmacology, Szczecin, Poland, ²Department of Clinical Pharmacology, Greifswald, Germany.

PII-038

CLINICAL TRAIL SIMULATIONS OF THE EXTRAPOLATED PHARMACOKINETICS, SAFETY, AND EFFICACY OF PARICALCITOL IN CHILDREN 2 - 9 YEARS OF AGE WITH CHRONIC KIDNEY DISEASE.

S. Stodtmann, N.M. Mostafa, **M.B. Dufek**; AbbVie, North Chicago, IL, USA.

PII-039

A GENERALIZED QUANTITATIVE SYSTEMS PHARMACOLOGY PLATFORM AND EXAMPLE APPLICATION IN METABOLIC SYNDROME.

G. Dwivedi¹, Q. Chen², J.H. Chen², S.P. Burns³; ¹PricewaterhouseCoopers, Boston, MA, USA, ²PricewaterhouseCoopers, New York City, NY, USA, ³PricewaterhouseCoopers, Philadelphia, PA, USA.

PII-040

PBPK MODELING OF THE DISSOLUTION AND FOOD EFFECT OF A NON-MODEL COMPOUND: THE VENETOCLAX STORY.

A. Emami Riedmaier, D.J. Lindley, J.A. Hall, S. Castleberry, R.T. Slade, P. Stuart, R.A. Carr, T.B. Borchardt, D.A. Bow, M. Nijssen; AbbVie, Chicago, IL, USA.

PII-041

IMPACT OF HEPATIC OCT1 ONTOGENY ON MORPHINE CLEARANCES IN NEONATES AND SMALL INFANTS: COMPARISON OF BOTTOM-UP AND TOP-DOWN MODELING AND SIMULATION.

C. Emoto¹, T.N. Johnson², S. Neuhoff², D. Hahn¹, A.A. Vinks¹, T. Fukuda¹; ¹Division of Clinical Pharmacology, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA, ²Simcyp Limited (a Certara company), Sheffield, UK.

PII-042

ENABLING PARTICIPATORY PHARMACOGENOMICS EDUCATION THROUGH THE TEST2LEARN PLATFORM.

S.M. Adams, J.M. Stevenson, J.C. Coons, L.A. Berenbrok, **P.E. Empey**; University of Pittsburgh, Pittsburgh, PA, USA.

PII-043

PREDICTING RAPID AND DELAYED PROPOFOL AWAKENING USING CYP2B6 GENE VARIANTS, UGT1A9, AGE, AND GENDER WITH MACHINE LEARNING.

A.R. Eugene¹, B. Eugene², R. DiCenzo¹, A.F. Harrlason¹; ¹Shenandoah University, Bernard J. Dunn School of Pharmacy, Inova Center for Personalized Health, Fairfax, VA, USA, ²Maria Curie-Skłodowska University, Lublin, Poland.

PII-044

APPLICATION OF PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODELING FOR PREDICTION OF CYP-MEDIATED DRUG-DRUG INTERACTIONS INVOLVING ETHINYLESTRADIOL.

U. Ezuruike, H. Humphries, M. Dickens, S. Neuhoff, I. Gardner, K. Rowland-Yeo; Simcyp Limited, Sheffield, UK.

PII-045

INHIBITION OF INTESTINAL OATP1A2 AS A POTENTIAL MECHANISM FOR DECREASED AXELOPRAN ABSORPTION IN HEALTHY VOLUNTEERS.

B.C. Ferslew, A. Amrite, R. Vickery, D.L. Bourdet; Theravance Biopharma, South San Francisco, CA, USA.

PII-046

POPULATION PHARMACOKINETIC AND PHARMACODYNAMIC MODELING OF DS-9001A, ANTI-PCSK9 ANTICALIN-ABD, TO OPTIMIZE DESIGN OF PHASE II STUDIES.

M. Fukae, M. Kato, K. Yoshihara, H. Ishizuka, Daiichi Sankyo Co, Ltd., Tokyo, Japan.

PII-047

THE PHARMACOGENE VARIATION CONSORTIUM: INCORPORATION OF THE HUMAN CYTOCHROME P450 ALLELE NOMENCLATURE DATABASE.

A. Gaedigk¹, T.E. Klein², G.P. Twist¹, M. Whirl-Carrillo², N.A. Miller¹; ¹Children's Mercy Kansas City, Kansas City, MO, USA, ²Stanford University, Stanford, CA, USA.

PII-048

EFFECT OF ACID-REDUCING AGENTS ON THE PHARMACOKINETICS OF SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR FIXED-DOSE COMBINATION TABLET.

K. Garrison, L. Stamm, G. Ma, Y. Li, J. Ling, A. Mathias; Gilead Sciences, Foster City, CA, USA.

PII-049

IMPLEMENTATION OF A VANCOMYCIN MODEL-BASED DOSING TOOL INTEGRATED WITHIN THE ELECTRONIC HEALTH RECORD.

S. Goswami¹, R. Keizer¹, S. Ghaskari², L. Schneider¹, J.H. Faulkenberry², B. Chasmawala², H.T. Schwenk², A. Frymoyer²; ¹InsightRX, San Francisco, CA, USA, ²Stanford Children's Health, Palo Alto, CA, USA.

PII-050

MECHANISTIC RECEPTOR OCCUPANCY MODEL BASED ON COVALENT BINDING OF IBRUTINIB AND BTK: RECEPTOR OCCUPANCY OF BTK IS NOT DRIVEN BY THE MAXIMUM CONCENTRATION OF IBRUTINIB.

N. Haddish-Berhane¹, J. de Jong², M. Gonzalez¹, B. Chang³, J. Sukbuntherng³, D. Ouellet¹; ¹Janssen Research & Development, Spring House, PA, USA, ²Janssen Research & Development, San Diego, CA, USA, ³Pharmacyclics, Sunnyvale, CA, USA.

PII-051

NIVOLUMAB CLEARANCE IS TIME-VARYING IN ADVANCED MELANOMA AND STATIONARY IN ADJUVANT MELANOMA.

L.L. Hamuro, P. Statkevich, A. Bello, A. Roy, G. Bajaj; Bristol-Myers Squibb, Princeton, NJ, USA.

PII-052

TRANSLATIONAL PBPK MODELING OF IDH305, AN INHIBITOR AND INDUCER OF CYP3A4.

T. Heimbach¹, Y. Ji¹, F. Wu¹, W. Lin¹, H. Gu¹, G. Liang², Y. Cho², J. Zhang¹, W. Zhou¹, S. Kumar¹, S. Dodd², A. Brown², V. Schuck³, H. He¹; ¹Novartis, East Hanover, NJ, USA, ²Novartis, Cambridge, MA, USA, ³Certara, Parsippany, NJ, USA.

PII-053

CYP2C19-GUIDED VORICONAZOLE PROPHYLAXIS TO PREVENT BREAKTHROUGH FUNGAL INFECTIONS IN NEUTROPENIC CANCER PATIENTS.

J.K. Hicks, R.E. Quilitz, W. So, A.P. Velez, R.S. Komrokji, T.E. Kubal, J.E. Lancet, N.T. Mason, Y. Pasikhova, D. Qin, H.L. McLeod, J.N. Greene; Moffitt Cancer Center and Research Institute, Tampa, FL, USA.

PII-054

INDUCTION OF INTESTINAL CYP3A BY INTAKE OF CALCITRIOL, AN ACTIVE FORM OF VITAMIN D, IN RATS BREED WITH VITAMIN D FREE DIET.

A. Hisaka, M. Ochiai, T. Takatsu, H. Sato; Chiba University, Chiba, Japan.

PII-055

PHARMACOKINETICS AND SAFETY OF SAGE-217 CAPSULES IN HEALTHY SUBJECTS.

E. Hoffmann¹, J. Wald², H. Li¹, I. Kaul³, P.S. Watson¹, B. Berner¹, G.G. Nomikos¹; ¹Sage Therapeutics, Inc., Cambridge, MA, USA, ²qPharmetra, LLC, Cary, NC, USA, ³Kaul Consulting, LLC, Concord, MA, USA.

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PII-056

POPULATION PHARMACOKINETICS AND EXPOSURE-RESPONSE ANALYSES CONFIRM THE ALECTINIB 600 MG BID DOSE IN THE GLOBAL ALK INHIBITOR-NAÏVE POPULATION.

J.C. Hsu¹, F. Jaminion², E. Guerini², E. Nueesch³, B. Balas³, A. Zeaiter³, P.N. Morcos¹, N. Frey²; ¹Roche Innovation Center, New York, NY, USA, ²Roche Innovation Center, Basel, Switzerland, ³F. Hoffmann-La Roche Ltd., Basel, Switzerland.

PII-057

A FIRST-IN-HUMAN CANNABIS TRIAL: OVERVIEW OF THE COMPLEXITY TO CONDUCT A CLINICAL TRIAL TO ASSESS PHARMACOKINETIC AND PHARMACODYNAMICS FROM SINGLE-ASCENDING DOSES OF DRIED CANNABIS DELIVERED BY SMOKING - INHALATION.

J. Huguet¹, M. Lefebvre¹, J. Michaud¹, G. Wood¹, I. Holmes¹, G. Chamberland²; ¹Altasciences, Montreal, QC, Canada, ²Tetra Bio-Pharma Inc., Ottawa, ON, Canada.

PII-058

EVALUATION OF THE PHARMACOKINETICS OF A NEW PEDIATRIC FORMULATION OF IDELALISIB.

R. Humeniuk, S. Markova, A. Silva, J. Shen, C. Roudet, J. Silverman; Gilead Sciences, Foster City, CA, USA.

PII-059

POPULATION PHARMACOKINETICS OF VOLANESORSEN, AN ANTISENSE OLIGONUCLEOTIDE TARGETING HUMAN APOLIPOPROTEIN C-III, IN HEALTHY SUBJECTS AND PATIENTS WITH FAMILIAL CHYLOMICRONEMIA SYNDROME OR HYPERTRIGLYCERIDEMIA.

E. Hurh¹, R. Gunawan², J.W. Collins³, E.G. Burroughs³, Y. Wang²; ¹Akcea Therapeutics, Cambridge, MA, USA, ²Ionis Pharmaceuticals, Carlsbad, CA, USA, ³PAREXEL International, RTP, NC, USA.

PII-060

CIRCULATING PLASMA-MIRNAS AS BIOMARKERS FOR CYP2B6 ACTIVITY *IN VIVO*.

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DEVELOPMENT OF A MINIMAL PBPK MODEL TO ASSESS HEPATIC DISPOSITION OF ^{99m}TECHNETIUM-METBROFENIN IN NON-ALCOHOLIC STEATOHEPATITIS PATIENTS.

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PII-062

MODELING AND SIMULATION AS GATING FOR CLINICAL PHARMACOLOGY STUDIES OF INCB054828.

T. Ji, X. Chen, C. Lihou, E. Asatiani, S. Yeleswaram; Incyte, Wilmington, DE, USA.

PII-063

CLINICAL SAFETY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF ACT-246475: A SELECTIVE REVERSIBLE P2Y12 RECEPTOR ANTAGONIST.

P.-E. Juif, M. Boehler, M. Ufer, J. Dingemans; Idorsia Pharmaceuticals Ltd, Allschwil, Switzerland.

PII-064

TRANSLATIONAL MODELING OF MINIPIG AND DOG GLUCOSE AND INSULIN DATA ACCURATELY PREDICTS HUMAN INSULIN ACTION FOR MK-2640 BUT NOT ITS GLUCOSE-RESPONSIVE PHARMACOKINETICS.

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DIFFERENT TAU PATHOLOGY VARIANTS CAN BE DESCRIBED BY UNIQUE QSP MODEL STRUCTURE FOR THERAPY OUTCOME PREDICTION.

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PII-066

POPULATION DOSE-RESPONSE MODELING OF INCLISIRAN, A NOVEL SIRNA INHIBITOR TO PCSK9, IN PATIENTS AT HIGH CARDIOVASCULAR RISK WITH ELEVATED LDL CHOLESTEROL.

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A RANDOMIZED, PLACEBO CONTROLLED, SINGLE ASCENDING DOSE STUDY TO ASSESS THE SAFETY, PK, AND PD OF DS-9001A, A NOVEL SMALL BIOLOGIC PCSK9 INHIBITORS, IN HEALTHY SUBJECTS.

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PHARMACOKINETICS, PHARMACODYNAMICS, SAFETY, AND TOLERABILITY OF ACT-539313, A NOVEL SELECTIVE OREXIN-1 RECEPTOR ANTAGONIST, IN A FIRST-IN-HUMAN STUDY.

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EVALUATION OF CLINICAL DDI POTENTIAL OF METHOTREXATE USING PBPK MODELING.

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PII-070

AN OPEN-LABEL, 2-PERIOD, FIXED-SEQUENCE STUDY TO EVALUATE THE EFFECT OF LOPERAMIDE ON THE PHARMACOKINETICS OF NERATINIB IN HEALTHY SUBJECTS.

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QUANTITATIVE ASSESSMENT OF ADDITIONAL METRICS IN THE BIOEQUIVALENCE EVALUATION OF OXCARBAZEPINE EXTENDED-RELEASE TABLET.

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PII-072

PHARMACOKINETIC DRUG INTERACTION BETWEEN TELMISARTAN/AMLODIPINE AND HYDROCHLOROTHIAZIDE IN HEALTHY MALE VOLUNTEERS.

M.-G. Kim, S. Lee, Y. Kim, S.-Y. Kim; Chonbuk National University Hospital, Jeonju, Republic of Korea.

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THE IMPACT OF FOOD AND MEAL TYPE ON A DRUG-DRUG INTERACTION BETWEEN VOXILAPREVIR AND SOFOSBUVIR/VELPATASVIR.

B.J. Kirby, K.L. Garrison, L.M. Stamm, Q. Song, G. Shen, Y. Li, K.-H. Ling, A. Mathias; Gilead Sciences, Foster City, CA, USA.

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PHARMACOKINETIC AND EXPLORATORY EXPOSURE-RESPONSE ANALYSIS OF PERTUZUMAB IN PATIENTS WITH OPERABLE HER2-POSITIVE EARLY BREAST CANCER.

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SURVEYING EARLY-PHASE CLINICAL STUDY DESIGN AND LABEL-DOSE IN ONCOLOGY AREA: REVIEW OF RECENT TREND IN JAPAN.

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A PHASE I STUDY TO EVALUATE SAFETY, TOLERABILITY, PHARMACOKINETICS, FOOD EFFECT, AND DRUG INTERACTION OF AN ANTI-INFLAMMATORY PDE4 INHIBITOR CC11050.

J. Nissel, Y. Liu, L. Liu, Y. Xue, V. Khetani, K. Arakawa, P. Schafer, M. Palmisano, **G. Krishna**; Celgene, Summit, NJ, USA.

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BIOEQUIVALENCE OF METFORMIN IN ERTUGLIFLOZIN/METFORMIN FIXED DOSE COMBINATION TABLETS TO CANADIAN-SOURCED METFORMIN CO-ADMINISTERED WITH ERTUGLIFLOZIN UNDER FASTED AND FED STATES.

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SIMULATING THE CLINICAL IMPACT OF INCOMPLETE ADHERENCE DURING TREATMENT WITH TOFACITINIB: IMPLICATIONS OF AN INDIRECT PHARMACOKINETIC/PHARMACODYNAMIC RELATIONSHIP.

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IN SILICO PREDICTION OF THE CONCENTRATION-QTC RELATIONSHIPS FOR THE IQ/CSRC STUDY - IMPORTANT LESSONS.

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DOSE SELECTION FOR THERAPEUTIC PROTEINS IN ENTRY INTO HUMAN STUDIES: ROCHE EXPERIENCE FROM 2004 TO 2016.

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RESPIRATORY PHENOTYPIC RESPONSE TO SYSTEMIC CORTICOSTEROIDS IN INTUBATED PREMATURE INFANTS.

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MECHANISM BASED LONGITUDINAL COVARIATE MODELING OF PEMBROLIZUMAB TIME DEPENDENT CLEARANCE AND ITS CORRELATION WITH OVERALL SURVIVAL IN PATIENTS WITH NSCLC.

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PREDICTION OF HUMAN PHARMACOKINETICS OF ANTIBODY-DRUG CONJUGATES FROM NONCLINICAL DATA.

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ABATACEPT POPULATION PHARMACOKINETICS AND EXPOSURE-RESPONSE ANALYSES FOR DOSE RECOMMENDATION OF SC AND IV ABATACEPT IN PATIENTS WITH PSORIATIC ARTHRITIS.

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POPULATION PHARMACOKINETICS OF GLASDEGIB IN PATIENTS WITH ADVANCED HEMATOLOGIC AND SOLID TUMORS.

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A PAN-CANADIAN STUDY ON THE COMPOUNDED MEDICINES MOST IN NEED OF COMMERCIALIZED ORAL PEDIATRIC FORMULATIONS.

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EVALUATING THE PERFORMANCE OF CLASSICAL PK MODELS, 2ND-GEN MPBPK MODELS AND MPBPK MODELS WITH TMDD IN PREDICTING THERAPEUTIC MONOCLONAL ANTIBODY PK IN HUMAN.

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POPULATION PHARMACOKINETIC ANALYSIS OF ABBV-8E12 IN PATIENTS WITH PROGRESSIVE SUPRANUCLEAR PALSY.

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EVALUATION OF A TOCILIZUMAB AUTOINJECTOR: RESULTS OF HEALTHY VOLUNTEER BIOEQUIVALENCE AND RHEUMATOID PATIENT HUMAN FACTORS STUDIES.

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ENTOSPLETINIB CONCENTRATION-QT ANALYSIS.

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SLC01B1 rs4149056 PHENOME-WIDE ASSOCIATION STUDY WITH SURVEY DATA FROM THE HARVARD PERSONAL GENOME PROJECT.

C.W. McDonough, P.B. Chase, A. Loiacono, S. Waugh, F. Modave; University of Florida, Gainesville, FL, USA.

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A JOINT MODEL ANALYSIS TO CHARACTERIZE THE RELATIONSHIP BETWEEN PSA KINETICS AND RPFS IN PATIENTS WITH METASTATIC CASTRATE RESISTANT PROSTATE CANCER.

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NIFEDIPINE PHARMACOKINETICS IN PRETERM LABOR TOCOLYSIS.

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YEARLY MEDICAL EXPENDITURE IN PATIENTS TREATED WITH CYP2D6-DEPENDENT OPIOIDS AND IMPACT OF CONCOMITANT TREATMENT WITH CYP2D6 SUBSTRATE OR INHIBITOR DRUGS.

V. Michaud, B. Cicali, J. Verzicco, C.H. Knowlton, J. Turgeon; Tabula Rasa HealthCenter, Philadelphia, PA, USA.

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TRANSLATIONAL PHARMACOKINETIC/PHARMACODYNAMIC MODEL PREDICTS DEPATUXIZUMAB MAFODOTIN TUMOR GROWTH INHIBITION IN PATIENTS.

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PHARMACOKINETICS OF UPADACITINIB IN HEALTHY JAPANESE AND CHINESE SUBJECTS AND COMPARABILITY TO WESTERN SUBJECTS.

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PHARMACOKINETIC AND PHARMACODYNAMIC RELATIONSHIPS OF COPANLISIB IN PATIENTS WITH NON-HODGKIN LYMPHOMA AND ADVANCED SOLID TUMORS.

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PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODELING OF GLECAPREVIR AND PIBENTASVIR AS A COMBINATION: MECHANISTIC MODELING OF NON-LINEAR PHARMACOKINETICS.

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CONCENTRATION-RESPONSE OF OXYCODONE DRUG LIKING WITH DIFFERENT ROUTES OF ABUSE.

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PEGYLATED RECOMBINANT HUMAN PH20 DID NOT CHANGE THE PHARMACOKINETICS OR SAFETY OF DOCETAXEL IN METASTATIC NON-SMALL CELL LUNG CANCER SUBJECTS.

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EVALUATION OF THE EFFECTS OF REPEAT DOSE DABRAFENIB ON THE SINGLE DOSE PK OF AN OATP1B1/1B3 AND CYP3A4 SUBSTRATE.

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NO DIFFERENCES BETWEEN JAPANESE AND CAUCASIANS IN THE PHARMACOKINETICS OF SELONSERTIB, AN APOPTOSIS SIGNAL-REGULATING KINASE 1 INHIBITOR.

C.H. Nelson, B.J. Kirby, L. Wang, S. Djedjos, U. Patel, T. Tarnowski, A. Worth, A. Mathias; Gilead Sciences, Foster City, CA, USA.

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A PHARMACOKINETIC/ PHARMACODYNAMIC DRUG-DRUG INTERACTION OF AVATROMBOPAG WHEN COADMINISTERED WITH DUAL OR NON-DUAL CYP2C9 AND CYP3A PERPETRATORS TO HEALTHY VOLUNTEERS.

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DOSE-RELATED INFLAMMATORY EFFECTS OF INTRAVENOUS ENDOTOXIN IN HUMANS: EVALUATION OF A NEW CLINICAL LOT (CCRE LOT 94332B1) OF ESCHERICHIA COLI O:113 ENDOTOXIN.

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SINGLE- AND MULTIPLE-DOSE PHARMACOKINETICS AND PHARMACODYNAMICS OF ERTUGLIFLOZIN, AN ORAL SELECTIVE INHIBITOR OF SGLT2, IN HEALTHY SUBJECTS.

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PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODEL FOR SIMVASTATIN LACTONE AND ACID IN OBESE CHILDREN/ADOLESCENTS WITH DYSLIPIDAEMIA.

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***IN VITRO* PERMEATION METHOD FOR TOPICAL DERMATOLOGICAL DRUG.**

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PHARMACOKINETIC INTERACTION BETWEEN THE P-GLYCOPROTEIN SUBSTRATE DABIGATRAN ETEXILATE AND HCV DIRECT-ACTING ANTIVIRAL AGENTS, ODALASVIR AND SIMEPREVIR.

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PREDICTING NASH RELATED SCREEN FAILURE RATES IN PATIENTS WITH RENAL IMPAIRMENT.

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POPULATION PHARMACOKINETICS OF TAK264, A GUANYL CYCLASE C TARGETED ANTIBODY DRUG CONJUGATE, IN PATIENTS WITH ADVANCED GASTROINTESTINAL AND PANCREATIC MALIGNANCIES.

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DIFFERENCES IN 24-H AMBULATORY BLOOD PRESSURE MONITORING WITH ALTERNATE NIFEDIPINE EXTENDED-RELEASE TECHNOLOGIES RETAINED WHEN DOSE SCALED FROM 60 DOWN TO 30 MG.

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INTERACTIONS BETWEEN THREE CYP2D6 SUBSTRATES IN HUMAN LIVER MICROSOMES.

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PHARMACOKINETICS AND TOLERABILITY OF THE T-TYPE CALCIUM CHANNEL BLOCKER ACT-709478, A POTENTIAL NEW ANTIEPILEPTIC DRUG, IN A SINGLE-ASCENDING DOSE STUDY IN HEALTHY SUBJECTS.

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MULTIPLE MYELOMA QUANTITATIVE SYSTEMS PHARMACOLOGY MODEL: DEVELOPMENT AND USAGE FOR POMALIDOMIDE INFLUENCE EVALUATION.

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PHARMACOKINETICS OF FRUQUINTINIB IN HUMANS.

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EFFECTS OF ITRACONAZOLE ON THE PHARMACOKINETICS OF COPANLISIB, A NOVEL PAN-CLASS I PHOSPHATIDYLINOSITOL-3-KINASE INHIBITOR IN CANCER SUBJECTS.

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POPULATION PHARMACOKINETIC AND PHARMACODYNAMIC MODELING OF THE WEIGHT LOSS EFFECT OF LORCASERIN AND PHENTERMINE COMBINATION.

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A MECHANISTIC MODEL OF CREATININE RENAL DISPOSITION ACCOUNTING FOR ROLE OF MULTIPLE TRANSPORTERS AND PASSIVE PERMEABILITY.

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QUANTITATIVE DIFFERENCES IN VILLOUS LENGTH IN INFLAMED VS NON-INFLAMED HUMAN SMALL INTESTINE: IMPLICATIONS FOR ORAL DRUG ABSORPTION.

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SINGLE-AND MULTIPLE-DOSE SAFETY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF THE DUAL ENDOTHELIN RECEPTOR ANTAGONIST APROCITENTAN IN HEALTHY ADULT AND ELDERLY SUBJECTS.

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S. Pilote, C. Thibault, E. Jubinville, J. Routhier, M.C. Morissette, B. Drolet, **C. Simard**; Institut Universitaire de Cardiologie et de Pneumologie de Quebec, Quebec, QC, Canada.

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S.L. Stocker¹, J.E. Carland¹, M.A. Moran¹, S. Tang², C.Y. Li¹, J. Själin¹, T. Gilbey¹, G.G. Graham¹, K.M. Williams¹, D.J. Marriott¹, R.O. Day¹; ¹St Vincent's Hospital, Sydney, Australia, ²Singapore General Hospital, Singapore, Singapore.

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L. Sun, D. McDonnell, J. Liu, L. von Moltke; Alkermes, Inc., Waltham, MA, USA.

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Y. Suzuki, T. Naito, J. Kawakami; Department of Hospital Pharmacy, Hamamatsu University School of Medicine, Hamamatsu, Japan.

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P.K. Turner¹, J.C. Chappell¹, A.Y. Chiang¹, J. Royalty², M. Fein³, K. Whitehurst⁴, H. Coleman⁴, P. Kulanthaivel¹; ¹Eli Lilly & Company, Indianapolis, IN, USA, ²Covance Early Clinical Development, Madison, WI, USA, ³Covance Clinical Research Unit, Daytona Beach, FL, USA, ⁴Covance Clinical Research Unit, Evansville, WI, USA.

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G. Vlasakakis¹, B. Shaddinger², M.A. Young³; ¹GlaxoSmithKline, London, UK, ²GlaxoSmithKline, Upper Providence, PA, USA, ³Indivior, Richmond, VA, USA.

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M. Walzer¹, G. Marek¹, R. Wu¹, D. Han²; ¹Astellas Pharma Global Development, Northbrook, IL, USA, ²Parexel, Glendale, CA, USA.

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H. Xu¹, M.T. O'Gorman², S. Nepal², K. Ginman², M.J. Bergeron², K.C. Lee², L. Fumagalli³, L. Mendes da Costa⁴, Y.K. Pithavala¹; ¹Pfizer Inc, San Diego, CA, USA, ²Pfizer Inc, Groton, CT, USA, ³Pfizer Inc, Milan, Italy, ⁴Pfizer Inc, Brussels, Belgium.

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K. Yee¹, H. Kleijn², M. Dorr¹, R. Wrishko¹; ¹Merck & Co, Inc, Kenilworth, NJ, USA, ²Certara Strategic Consulting, Oss, Netherlands.

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K. Yoneyama¹, C. Schmitt², T. Chang³, G.G. Levy³; ¹Chugai Pharmaceutical Co., Ltd., Tokyo, Japan, ²F. Hoffmann-La Roche AG, Basel, Switzerland, ³Genentech, Inc., South San Francisco, CA, USA.

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J. Mendell¹, N. Cooperman², E. Sellers³, B. Vince⁴, D. Kelsh⁴, J. Lee⁵, V. Warren¹, **H. Zahir**¹; ¹Daiichi Sankyo, Inc., Basking Ridge, NJ, USA, ²Altreos Research Partners, Inc., Toronto, ON, Canada, ³DL Global Partners Inc., Toronto, ON, Canada, ⁴Vince and Associates Clinical Research, Overland Park, KS, USA, ⁵Daiichi Sankyo Pharma Development, Basking Ridge, NJ, USA.

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Y. Zhang¹, G. Baheti¹, M. Rojavin¹, M. Praus², M. Tortorici¹, J. Jochems¹, J. Sidhu³; ¹CSL Behring, King of Prussia, PA, USA, ²CSL Behring, Marburg, Germany, ³CSL Limited, Parkville, Australia.

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S. Zheng, J. Wang, W. Wang; Biologics Development Sciences, Janssen BioTherapeutics, Janssen R&D, Spring House, PA, USA.



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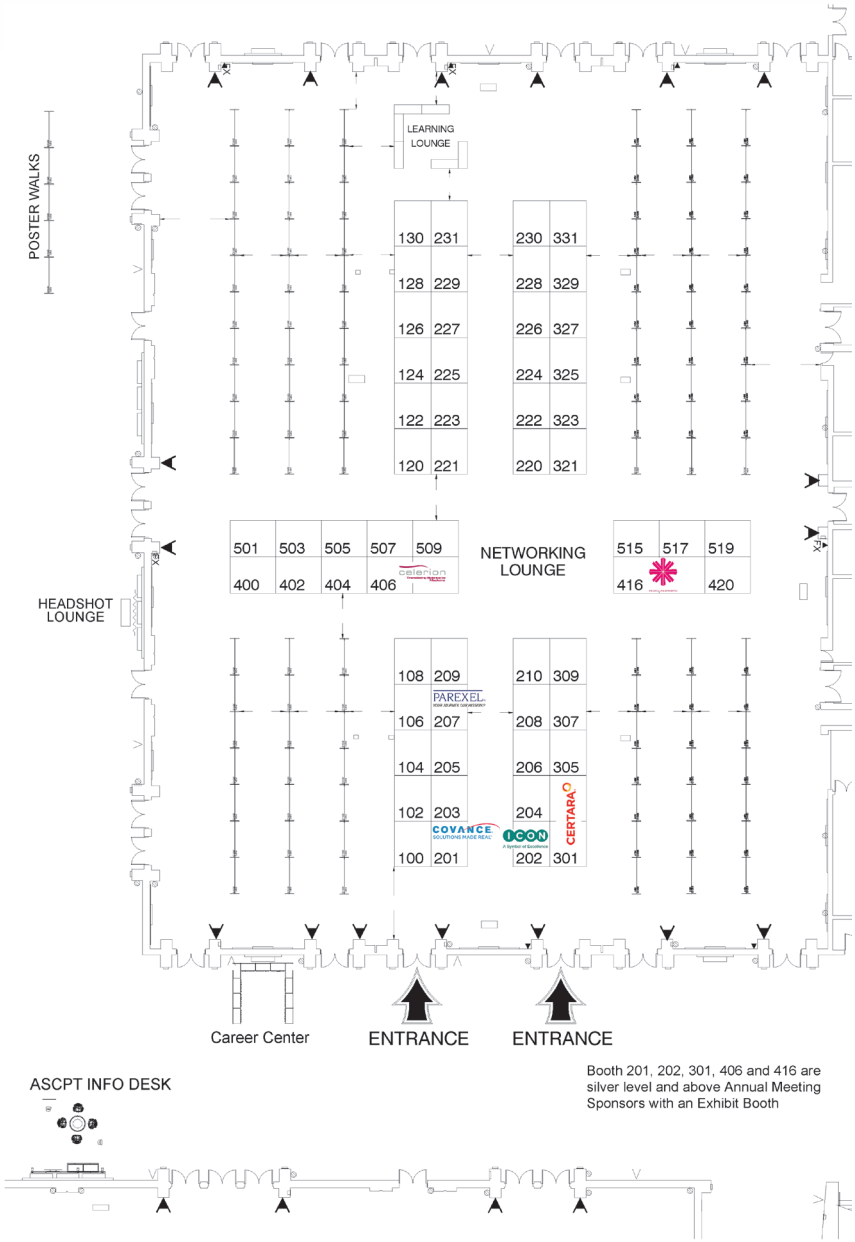
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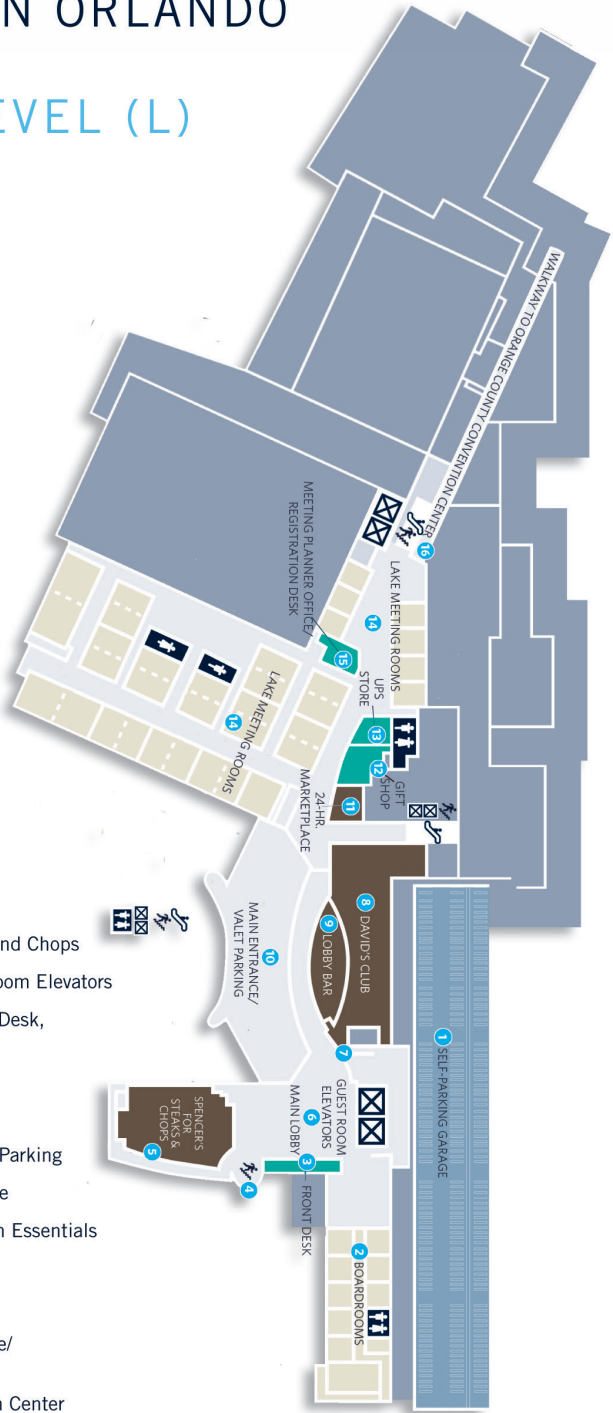
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-  Elevators
-  Restrooms





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- 2 Boardrooms
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- 4 Grand Staircase
- 5 Spencer's for Steaks and Chops
- 6 Main Lobby / Guest Room Elevators
- 7 Bell stand, Concierge Desk, Boarding Pass Station
- 8 David's Club
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- 13 UPS Store
- 14 Lake Meeting Rooms
- 15 Meeting Planner Office/ Registration Desk
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HOTEL LAYOUT HILTON ORLANDO

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-  Elevators
-  Restrooms

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- 2 eforea spa
- 3 24-hr. Fitness Center
- 4 Grand Staircase
- 5 The Bistro
- 6 Group Pick-up/Drop-off
- 7 Orlando Ballroom
- 8 Orange Ballroom
- 9 Florida Ballroom
- 10 The Promenade
- 11 Meeting Planner Office/Registration Desk
- 12 Key West
- 13 Key Largo

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