ACCP

American College of Clinical Pharmacology

Advancing Clinical Care through Pharmacology®

2016 Annual Meeting
American College of
Clinical Pharmacology

Clinical Pharmacology:

Discovery and Application in the Era of Precision Medicine

September 25 – 27, 2016

Bethesda N Marriott Hotel & Conference Ctr, Bethesda, MD

Co-chairs: Vikram Arya, PhD, Honghui Zhou, PhD and Manish Gupta, PhD

FINAL PROGRAM

ACCP

American College of Clinical Pharmacology

Advancing Clinical Care through Pharmacology®

Join Us for the 2017 ACCP Annual Meeting!

ACCP is a proud provider of Continuing Medical Education (CME) & Continuing Pharmacy Education (CPE)

FUTURE MEETINGS:

2018 Annual Meeting
September 23 – 25, 2018
Bethesda N Marriott Hotel & Conference Ctr
Bethesda, MD

Did You Know?

Use the ACCP Mobile App to find all the meeting information you're looking for!

- Session schedules organized by each day and track, with search functionality
- Session details including times, locations, session description, Faculty profiles and presentations
- Presentations from all sessions available real time and archival viewing (.pdf format) during and after the event
- Access attendee and Faculty lists, with search functionality
- Establish contact and network with fellow attendees
- Chat/instant message with fellow attendees
- View profiles of Faculty, ACCP Staff, Exhibitors & Sponsors with contact information
- Customize profile and business card on mobile device and/or import LinkedIn profile

ACCP continues to expand its Continuing Education Program!

An accredited provider of Continuing Medical Education (CME) and Continuing Pharmacy Education (CPE), ACCP continues to expand its Continuing Education Program. In 2016, ACCP provided Journal CE articles each month and continued the ACCP Virtual Journal Club and Fundamentals Tutorials webinars, in addition to launching the Therapeutic Dilemmas webinars. Each of the live webinars is then made available On Demand. See page 13 for more information.

Virtual Journal Club

Publish Your Manuscript in *The Journal of Clinical Pharmacology*

- The average time from submission to first decision is 14 days
- For manuscripts that are revised, the average time from the first submission to final decision is 25 days
- Downloads from JCP have increased by approximately 150% since 2013
- With the JCP App you can read the Journal anytime on your smart phone or tablet. Download this from the Apple App store.

Clinical Pharmacology in Drug Development is now indexed by MEDLINE® and SCIE

Why publish with CPDD?

- Well respected: Official Journal of the ACCP
- A renowned international Editorial Board
- Growing international readership: full text article downloads increased by >38% in 2015!
- Quick and easy online submission and review process
- Rapid publication: articles are available online weeks ahead of issue publication
- Open access options available for authors who wish to make their article free for all to access online
- Immediate international exposure with PubMed/MEDLINE®, Web of Science: Science Citation Index Expanded (SCIE), Scopus, Chemical Abstracts, Embase and Google Scholar indexation

Attending the Meeting as a Student or Trainee?

ACCP has planned a series of events specifically to benefit Students & Trainees! See page 43 for details.

Interested in joining ACCP?

Stop by the ACCP Registration Desk for complete information or to complete a profile and pay 2017 Dues entitling you to ACCP Member Benefits.

Take Time to Visit Our Exhibitors!

Exhibitor support is critical to the success of the ACCP Annual Meeting. We encourage you to visit our Exhibitors in Ballroom Salon E-H during breakfast, breaks or the evening receptions to learn about new technologies and service offerings. These exceptional Exhibitors are the leaders in their fields and are anxious to share with you the latest information on how they can help you meet your goals! Please take a moment to thank them for their support. All attendees are invited to participate in the Exhibit Hall Contest to win one of two $50 gift cards by getting your game card stamped by all the Exhibitors. Game cards are provided in attendee tote bags.

"Like" ACCP and add to "My Page's Favorites" on Facebook or join ACCP's LinkedIn Group for regular updates.

ACCP Registration Desk Hours / Grand Foyer

Friday, September 23rd	4:00 – 7:00 pm	Grand Foyer
Saturday, September 24th	7:00 am – 5:30 pm	Grand Foyer
Sunday, September 25th	6:30 am – 7:00 pm	Grand Foyer
Monday, September 26th	7:00 am – 7:00 pm	Grand Foyer
Tuesday, September 27th	7:00 am – 5:30 pm	Grand Foyer

Lost & Found

Any found items should be given to ACCP Staff at the Registration Desk in the Grand Foyer. Persons wishing to retrieve a lost item should also contact ACCP Staff at the ACCP Registration Desk.

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Table of Contents

American College of Clinical Pharmacology 2016 Program Committee

Co-chairs:

Vikram Arya, PhD
Manish Gupta, PhD
Honghui Zhou, PhD

Members:

Nageshwar R. Budha, PhD
Lawrence J. Cohen, PharmD
Amelia N. Deitchman, PharmD
Nilima A. Kshirsagar, MBBS, MD, PhD
Nitin Mehrotra, PhD
Robert J. Noveck, MD, PhD, CPI
Stephan Schmidt, PhD
Jayabharathi Vaidyanathan, PhD
John van den Anker, MD, PhD

Letter of Welcome from President & Program Co-chairs

Welcome to the 2016 ACCP Annual Meeting!

Clinical Pharmacology: Discovery and Application in the Era of Precision Medicine

Dear Colleague:

It is our pleasure to welcome you to the **2016 Annual Meeting** of the **American College of Clinical Pharmacology (#2016ACCP)**, ***Clinical Pharmacology: Discovery and Application in the Era of Precision Medicine.*** The 2016 Annual Meeting Program Committee, co-chaired by Drs. Vikram Arya, Honghui Zhou and Manish Gupta, has developed a diverse and exceptional educational program to meet the needs of a broad spectrum of healthcare professionals and scientists with an interest in clinical pharmacology applications from research and drug development to patient care. ACCP is pleased to host a global panel of speakers from academia, industry, regulatory and clinical entities that will present programs organized into topic tracks, allowing each attendee to uniquely tailor content selection based on individual interests. Major clusters of topic areas include oncology drug development, including immuno-oncology, biologics and biosimilars, pediatric drug development and precision medicine. The exciting mix of sessions includes the use of novel and innovative clinical pharmacology tools and principles to improve drug development and therapeutics for effective treatment of disease states such as HIV/AIDS, Hepatitis C and cancer; orphan drug development; the application of the animal rule; the management of opioid dependence; the use of Big Data, physiologically-based PK/PD modeling and novel trial designs for pediatric drug development programs; improvements in clinical pharmacology labeling and streamlining of clinical pharmacology activities in early development.

New this year is a mixture of several shorter Symposia combined with our traditional four-hour format. For the first time, a select group of cutting-edge poster presentations will be hosted in an intimate setting that encourages discussion in a relaxed atmosphere. Of special note are Student & Trainee-focused programs that provide exposure to cutting-edge science and career development.

Poster Sessions held on Sunday and Monday evening will focus on new findings and preliminary data presented by a wide spectrum of attendees. Socialize and network at the catered receptions during the Poster Sessions, at twice-daily tea/coffee breaks and at the Lunch & Awards Sessions on Monday and Tuesday. At the lunch session on Tuesday, Kathy Hudson, PhD, Deputy Director for Science, Outreach and Policy at the National Inst of Health, will present the Keynote address.

Experience for yourself how ACCP makes a difference by providing healthcare professionals and scientists with a forum to exchange knowledge and ideas that promote and expand the value of clinical pharmacology in healthcare and drug development.

Please note that there is complimentary Internet access provided to all Annual Meeting attendees in guest rooms for the duration of the meeting. All of the educational sessions, social events and networking will be held at the hotel, facilitating the ease with which meeting attendees can participate in events. With the hotel's convenient location to the White Flint Metro Station, there is easy access to downtown Bethesda, Rockville, Washington, DC and northern Virginia attractions, making it easy to enjoy all that the Washington metro area has to offer.

ACCP remains an accredited provider of Continuing Medical Education (CME) and Continuing Pharmacy Education (CPE) credits for our educational events, provided to meeting attendees at no additional cost.

We welcome you to an outstanding 2016 ACCP Annual Meeting and look forward to feedback about your participation!

Bernd Meibohm, PhD
ACCP President

Vikram Arya, PhD
Program Co-chair

Honghui Zhou, PhD
Program Co-chair

Manish Gupta, PhD
Program Co-chair

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Program at a Glance

The 2016 ACCP Annual Meeting is supported in part by an Educational Grant from Pfizer Inc

FRIDAY, SEPTEMBER 23, 2016

ACCP Registration Desk Open | **4:00 – 7:00 pm**
Grand Foyer

ACCP Executive Committee Meeting | **6:00 – 9:00 pm**
Middlebrook

SATURDAY, SEPTEMBER 24, 2016

ACCP Registration Desk Open | **7:00 am – 5:30 pm**
Grand Foyer

Continental Breakfast | **7:30 – 8:30 am**
Glen Echo Foyer

ACCP Board of Regents Meeting | **8:00 am – 1:00 pm**
Glen Echo

Pre-meeting Workshop 1 | **8:00 am – 12:00 pm**
Translational Pharmacokinetics/Pharmacodynamics in Biotherapeutic Minimum Anticipated Biological Effect Level Dose Selection & Novel Protein Scaffolds
CO-CHAIRS: Honghui Zhou, PhD and Rong Shi, PhD
Ballroom Salon H

Pre-meeting Workshop 2 | **8:00 am – 12:00 pm**
Combating HIV/AIDS: Treatment, Pharmacogenetics & Pre-exposure Prophylaxis
CO-CHAIRS: Sam Harirforoosh, PharmD, PhD and Ganesh Cherala, PhD
Ballroom Salon G

Pre-meeting Workshop 3 | **1:30 – 5:30 pm**
Improving Therapeutics to Better Care for Older Adults & the Young
CO-CHAIRS: S.W. Johnny Lau, PhD and Thomas Eissing, PhD
Ballroom Salon H

Pre-meeting Workshop 4 | **1:30 – 5:00 pm**
The Other Bound of the Therapeutic Window: Exposure-Safety Analysis to Inform Dosing Decisions in Oncology
CO-CHAIRS: Justin C. Earp, PhD and Anshu Marathe, PhD
Ballroom Salon G

ACCP Finance Committee Meeting | **3:00 – 5:00 pm**
Middlebrook

Regents & Awards Reception (invitation only)
5:30 – 6:30 pm | *Brookside Foyer*

Regents & Awards Dinner (invitation only)
6:30 – 8:30 pm | *Brookside A&B*

SUNDAY, SEPTEMBER 25, 2016

ACCP Registration Desk Open | **6:30 am – 7:00 pm**
Grand Foyer

Continental Breakfast | **7:00 – 8:00 am**
Grand Foyer

Welcome and Opening Remarks by President
7:45 – 8:00 am | *Ballroom Salon A-C*

Symposium 1 | **8:00 am – 12:00 pm**
Clinical Pharmacology as a Cornerstone for Development of Products Under the Animal Rule: Determining an Effective Dose in Humans
CO-CHAIRS: Nitin Mehrotra, PhD and Kimberly L. Bergman, PharmD
Ballroom Salon A-C

Symposium 2 | **8:00 – 9:30 am**
A 360° View of Immunogenicity: Qualitative & Quantitative Assessments to Understand Its Implications on Pharmacokinetics, Safety & Efficacy
CO-CHAIRS: Chaitali Passey, PhD and Sumit Rawal, PhD
Ballroom Salon D

Symposium 3 | **10:00 am – 12:00 pm**
Helping Advance the Immuno-Oncology Revolution: Trends in Translational Immuno-Oncology
CO-CHAIRS: Sree Kasichayanula, PhD and Yu-Nien (Tom) Sun, PhD
Ballroom Salon D

Honors & Awards Committee Meeting | **12:00 – 1:30 pm**
Forest Glen

2016 – 2017 Program Committee Meeting
12:00 – 1:30 pm | *Glen Echo*

Membership Committee Meeting | **12:00 – 1:30 pm**
Middlebrook

Public Policy Committee Meeting | **12:00 – 1:30 pm**
Timberlawn

Symposium 4 | **1:30 – 5:30 pm**
Clinical Development of Biologics: Current Strategy, Challenges & Future Considerations
CO-CHAIRS: Gaurav Bajaj, PhD and Ping Zhao, PhD
Ballroom Salon A-C

Symposium 5 | **1:30 – 3:00 pm**
Addressing Opioid Dependence: Now is the Time
CO-CHAIRS: Lorraine M. Rusch, PhD and Michael J. Fossler, Jr, PharmD, PhD
Ballroom Salon D

Student Panel Discussion & Career Guidance
2:00 – 3:30 pm | *White Flint Amphitheater*

Student Podium Presentations | **3:30 – 4:30 pm**
White Flint Amphitheater

Symposium 6 | **3:30 – 5:30 pm**
Treatment of Hepatitis C with Direct-acting Antiviral Drugs: Opportunities & Challenges
CO-CHAIRS: Vikram Arya, PhD and Shirley Seo, PhD
Ballroom Salon D

Student Networking Reception | **4:30 – 5:30 pm**
Brookside Foyer

Opening Reception & Poster Session 1 & Exhibits
5:30 – 7:30 pm | *Ballroom Salon E-H*

Student Poster Tour | **5:45 – 6:30 pm**
Meet at ACCP Registration Desk at 5:30 pm

Program at a Glance

MONDAY, SEPTEMBER 26, 2016

ACCP Registration Desk Open | **7:00 am – 7:00 pm**
Grand Foyer

Continental Breakfast | **7:00 – 8:00 am**
Ballroom Salon E-H

Exhibit Hall Open | **7:00 – 10:00 am**
Ballroom Salon E-H

Annual Business Meeting | **7:15 – 8:00 am**
Ballroom Salon A-C

Symposium 7 | **8:00 am – 12:00 pm**
Establishing Biosimilarity: The European Perception, Experience & Future Trends
CO-CHAIRS: Hildegard Sourgens, MD, PhD and Hartmut Derendorf, PhD
Ballroom Salon A-C

Symposium 8 | **8:00 – 9:30 am**
Informing Pediatric Development Programs: Leveraging Big Data
CO-CHAIRS: Jeffrey Barrett, PhD and Lily (Yeruk) Mulugeta, PharmD
Ballroom Salon D

Symposium 9 | **10:00 am – 12:00 pm**
Little Children, Big Challenges: The Problems for Neonatal Drug Trials & the Way Forward
CO-CHAIRS: Jian Wang, PhD and John van den Anker, MD, PhD
Ballroom Salon D

Lunch Buffet | **11:45 am – 1:45 pm** | *Grand Foyer A-D*

Lunch & Awards Session | **12:10 – 1:20 pm**
Ballroom Salon A-D

- Distinguished Investigator Award
- Honorary Fellowship Award
- Nathaniel T. Kwit Memorial Distinguished Service Award
- McKeen Cattell Memorial Award
- Abstract Awards
- Member-Get-a-Member Awards

Symposium 10 | **1:30 – 5:30 pm**
Streamlining Clinical Pharmacology Strategies During Early Development: Assessment of Drug-Drug Interactions, Food Effect & QTc
CO-CHAIRS: Suraj G. Bhansali, MS, PhD and Xiao Hu, PhD
Ballroom Salon A-C

Symposium 11 | **1:30 – 3:00 pm**
Cutting-edge Abstract Presentations
CO-CHAIRS: Lawrence J. Cohen, PharmD, Walter K. Kraft, MD and Amalia M. Issa, PhD
Ballroom Salon D

Exhibit Hall Open | **3:00 – 7:30 pm** | *Ballroom Salon E-H*

Symposium 12 | **3:30 – 5:30 pm**
Rethinking Clinical Pharmacology-related Labeling for Improved Utility & Comprehension
CO-CHAIRS: Joseph A. Grillo, PharmD and Julie Bullock, PharmD
Ballroom Salon D

Evening Reception & Poster Session 2 & Exhibits
5:30 – 7:30 pm | *Ballroom Salon E-H*

Editorial Board Dinner (invitation only) | **7:30 – 9:30 pm**
Brookside A&B

TUESDAY, SEPTEMBER 27, 2016

ACCP Registration Desk Open | **7:00 am – 5:30 pm**
Grand Foyer

Continental Breakfast | **7:00 – 8:00 am**
Ballroom Salon E-H

Student Event: Special Access to the Experts
7:00 – 8:00 am | *Ballroom Salon E-H*

Exhibit Hall Open | **7:00 – 10:00 am**
Ballroom Salon E-H

Education Committee Meeting | **7:00 – 8:00 am**
Great Falls

Publications Committee Meeting | **7:00 – 8:00 am**
Middlebrook

Symposium 13 | **8:00 am – 12:00 pm**
Orphan Drug Development in Adults & Pediatrics: Industry, Academia & Regulatory Perspectives
CO-CHAIRS: Vijay Ivaturi, PhD and Venkatesh Atul Bhattaram, PhD
Ballroom Salon A-C

Symposium 14 | **8:00 – 9:30 am**
Clinical Applications of Physiologically-based Pharmacokinetics/ Pharmacodynamics for Pediatrics: Academic, Industry & Regulatory Perspectives
CO-CHAIRS: Jennifer Sheng, PhD, PharmD and Diansong Zhou, PhD
Ballroom Salon D

Symposium 15 | **10:00 – 11:45 am**
Combination Therapy in Oncology: Challenges & Strategies in Clinical Pharmacology
CO-CHAIRS: Yilong Zhang, PhD and Satyendra Suryawanshi, PhD
Ballroom Salon D

Lunch Buffet | **11:45 am – 1:45 pm** | *Grand Foyer A-D*

Lunch & Awards Session | **12:10 – 1:20 pm**
Ballroom Salon A-D

- Tanabe Young Investigator Award
- Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award
- Keynote Presentation: "The Precision Medicine Initiative" Kathy L. Hudson, PhD, Deputy Director for Science, Outreach and Policy at the National Inst of Health

Symposium 16 | **1:30 – 5:30 pm**
Clinical Pharmacology Strategies in Precision Medicine-based Drug Development & Preventive Medicine
CO-CHAIRS: Priyanka Jadhav, PhD, Jinshan Shen, PhD and Manoj P. Jadhav, PhD
Ballroom Salon A-C

Symposium 17 | **1:30 – 5:30 pm**
Reproducible Visualization & Data Analysis With R
CHAIR: Devin Pastoor, MTOX
Ballroom Salon D

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Keynote Speaker

Tuesday, September 27, 2016 | 12:50 – 1:20 pm | Ballroom Salon A – D

Kathy L. Hudson, PhD
Deputy Director for Science, Outreach and Policy at the National Inst of Health

"The Precision Medicine Initiative"

Kathy L. Hudson, PhD, is the Deputy Director for Science, Outreach and Policy at the National Inst of Health (NIH). Dr. Hudson leads the science policy, legislation, communication and outreach efforts of the NIH and serves as a senior advisor to the NIH Director. She is responsible for creating major new strategic and scientific initiatives for NIH and is currently leading the planning and creation of the President's Precision Medicine Initiative Cohort Program. Dr. Hudson was a key architect of the National Ctr for Advancing Translational Sciences and the NIH BRAIN Initiative. She directs the agency's efforts to advance biomedical research through policy development, public and stakeholder communication & education and innovative projects & partnerships.

Dr. Hudson's professional experience includes serving as the NIH Chief of Staff; Acting Deputy Director of the National Ctr for Advancing Translational Sciences, NIH; the Assistant Director of the National Human Genome Research Inst, NIH; and the founder and Director of the Genetics and Public Policy Ctr at Johns Hopkins Univ. Also at Hopkins, Dr. Hudson was an Associate Professor in the Berman Inst of Bioethics, Inst of Genetic Medicine and Dept of Pediatrics.

Dr. Hudson holds a PhD in Molecular Biology from the Univ of California at Berkeley, an MS in Microbiology from the Univ of Chicago and a BA in Biology from Carleton Coll.

Abstract Awards Program

Student & Trainee Abstract Award Winners

Student & Trainee Abstract Awards are given for the best abstracts submitted by Students & Trainees for presentation at each year's Annual Meeting.

Wayne A. Colburn Memorial Award

The Wayne A. Colburn Memorial Award honors the memory of the late Wayne A. Colburn, former ACCP President, and will be given for the best paper among the Student & Trainee Award Winners, as judged by the Program Committee during the Poster Sessions at the Annual Meeting. The winner will be announced during the Monday luncheon and the author will give a short talk outlining the findings of the study in Symposium 11.

New Member Abstract Award

The New Member Abstract Award is given for the best abstract submitted by a New Member of ACCP for presentation at the Annual Meeting. Abstracts submitted by New Members will be judged during the Poster Sessions. The winner will be announced during the Monday luncheon and the author will give a short talk outlining the findings of the study in Symposium 11.

2016 Student & Trainee Abstract Award Winners

Student Abstract Award Winners will present their posters at both Poster Sessions

- **Sumit Basu, PhD (Poster #089)** *Univ of Florida, Orlando, FL*
- **Kristina M. Brooks, PharmD (Poster #041)** *National Inst of Health, Bethesda, MD*
- **Amelia N. Deitchman, PharmD (Poster #013)** *Univ of Florida, Orlando, FL*
- **Asma El-Zailik, BS (Poster #014)** *Univ of Houston, Houston, TX*
- **Edwin Lam, PharmD (Poster #061)** *Long Island Univ, Brooklyn, NY*
- **Naveen Mangal, BS, MS (Poster #088)** *Univ of Florida, Orlando, FL*
- **Mahua Sarkar, MS (Poster #001)** *Univ of Houston, Houston, TX*
- **Tanaya Vaidya, MS (Poster #040)** *Univ of Florida, Orlando, FL*
- **Jessica Wojciechowski (Poster #076)** *Univ of South Australia, Adalaide, AU*

2016 ACCP Recognition Award Winners

Distinguished Investigator Award

Monday, September 26, 2016 | 12:15 – 12:35 pm | Ballroom Salon A – D

"From Methotrexate to Targeted Therapies for Cancer: Individualizing the Approach"

Bruce A. Chabner, MD – Professor of Medicine, Harvard Medical School; Emeritus Director of Clinical Research, Massachusetts General Hosp Cancer Ctr; Co-leader, Translational Pharmacology & Early Therapeutic Trials Program at the Dana Farber/ Harvard Cancer Ctr

The Distinguished Investigator Award is given annually and is intended to recognize superior scientific expertise and accomplishments by a senior investigator, usually involving a distinct area of research in basic or clinical pharmacology, for which the individual is internationally known. The candidate need not be a Member or Fellow of ACCP.

Dr. Chabner has performed seminal and extensive work in the field of cancer drug discovery and development. His lifelong contributions to the field of clinical pharmacology and oncology make him a worthy recipient of the 2016 ACCP Distinguished Investigator Award.

Honorary Fellowship Award

Monday, September 26, 2016 | 12:35 – 12:55 pm | Ballroom Salon A – D

"Optimal Design in Pharmacometrics and Dose of Favipiravir for Ebola"

France Mentré, PhD, MD – Director of Research, Vice Director, Graduate School of Public Health, Univ of Paris & Head, Biostatistics Dept, Bichat Hosp

The Honorary Fellowship Award is given annually to a Non-member of ACCP and is meant to recognize primary activities within the immediate domain of clinical pharmacology. The award recognizes overall contributions to the field, rather than any particular scientific work, by a senior investigator or authority having a national or international reputation in the scientific, public service, legislative, governmental or other area of endeavor impacting the field.

Dr. Mentré holds leadership positions in several scientific organizations which support clinical pharmacology research and is the current Chair of the Executive Committee of the World Conference on Pharmacometrics and an Associate Editor of the *Journal of Pharmacometrics and Systems Pharmacology*. She has made substantial contributions to the field of clinical pharmacology through research and training of basic and clinical pharmacologists, as well as through the development of tools to facilitate research in clinical pharmacology, making her a fitting recipient of the 2016 ACCP Honorary Fellowship Award.

2016 Honors & Awards Committee

Vera Donnenberg, PhD • Claude Abdallah, MD, MSc Pharm • April Barbour, PhD
Steven J. Crosby, MA, BSP, RPh • Navin Goyal, PhD • Howard Greenberg, MD, MSE, MBA
Manoj P. Jadhav, PhD • Jatinder Mukker, PhD • Eric Olson, PhD
Laurent Vernillet, PharmD, PhD • Peter Wiernik, MD

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2016 ACCP Recognition Award Winners

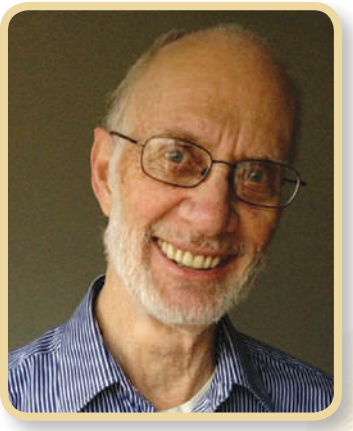
Nathaniel T. Kwit Memorial Distinguished Service Award

Monday, September 26, 2016 | 12:55 – 1:15 pm | Ballroom Salon A – D

Margaret Hamburg, MD – Foreign Secretary for the National Academy of Medicine; previously Commissioner, US Food & Drug Administration

The Nathaniel T. Kwit Memorial Distinguished Service Award is given in memory of the late Nathaniel T. Kwit, MD, FCP, a founding Fellow of ACCP, who served as a Regent for 5 years and as Treasurer for 20 years. The primary intent of this award is to recognize accomplishments of a general nature which benefit the field of clinical pharmacology. These may be in the area of teaching, administration, service with ACCP or long-term and wide-ranging scientific studies having practical importance and other service-related functions. It is differentiated from the Distinguished Investigator Award in that it is not intended to recognize any distinct area of scientific investigation, but rather an overall contribution to the field. The candidate need not be an ACCP Member or Fellow.

While Commissioner of the US Food & Drug Administration, Dr. Hamburg supported regulatory initiatives for personalized drug therapy. Her extensive contributions, directly and indirectly relevant to clinical pharmacology, make her an outstanding recipient of the 2016 Nathaniel T. Kwit Memorial Distinguished Service Award.



McKeen Cattell Memorial Award

Monday, September 26, 2016 | 1:15 – 1:20 pm | Ballroom Salon A – D

Daniel A. Spyker, PhD, MD – Consulting Senior Director, Drug Safety & Pharmacovigilance, Alexza Pharmaceuticals Inc; Adjunct Professor, Dept of Internal Medicine, Uniformed Services Univ of Health Sciences; Adjunct Assistant Professor of Emergency Medicine, Oregon Health & Science Univ

The McKeen Cattell Memorial Award is made in memory of the late McKeen Cattell, MD, PhD, FCP, the first editor of *The Journal of Clinical Pharmacology* (JCP) and co-founder of ACCP. This award is made annually, recognizing an outstanding research paper published in the JCP during the preceding year. The award is typically presented to the first author of the paper.

This year's award-winning journal article is: **"Multiple-dose Pharmacokinetics of Inhaled Loxapine in Subjects on Chronic, Stable Antipsychotic Regimens"** Authors: Daniel A. Spyker, PhD, MD, Robert A. Riesenberg, MD and James V. Cassella, PhD. Published in *The Journal of Clinical Pharmacology* Volume 55, Issue 9, pages 985–994, September 2015.

2016 ACCP Recognition Award Winners

Tanabe Young Investigator Award

Tuesday, September 27, 2016 | 12:15 – 12:30 pm | Ballroom Salon A – D

"How Quantitative & Systems Pharmacology Can Bring Value to R&D and, Ultimately, to the Patient"

Stephan Schmidt, PhD – Assistant Professor, Univ of Florida, Ctr for Pharmacometrics & Systems Pharmacology; Chair of the Int'l Pharmaceutical Federation's Special Interest Group on Pharmacometrics & Systems Pharmacology; Incoming Chair of the ASCPT's Special Interest Group on Systems Pharmacology

The Tanabe Young Investigator Award recognizes the significant contributions of an investigator who has made unusual strides in research related to clinical pharmacology and whose career shows promise of outstanding achievements at a relatively early stage, typically 10 – 12 years post-research degree. The candidate need not be a Member or Fellow of ACCP.

Dr. Schmidt's research focuses on the application of quantitative systems pharmacology to address clinically-relevant questions in the areas of antimicrobial chemotherapy, pediatrics, diabetes, cardiovascular safety and post-menopausal osteoporosis. He is a bright young investigator in drug modeling and clinical pharmacology and has an extraordinary track record of achievement since joining the faculty at the Univ of Florida in 2012, making him a deserving recipient of the 2016 Tanabe Young Investigator Award.

Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award

Tuesday, September 27, 2016 | 12:30 – 12:50 pm | Ballroom Salon A – D

"From Books to Grooks"

Richard Brundage, PharmD, PhD – Professor of Experimental & Clinical Pharmacology, Univ of Minnesota, Coll of Pharmacy

The Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award is given annually to an awardee who demonstrates exemplary promotion of clinical pharmacology, with emphasis on training/guidance of junior scientists and/or colleagues.

Dr. Brundage is widely recognized for exceptional mentoring abilities and unfailing dedication to students and trainees. He is an extraordinary teacher and an enthusiastic mentor who is passionate about his work. His academic accomplishments and mentorship of the current and future generation of clinical pharmacologists and pharmacists make Dr. Brundage a well-deserving recipient of the 2016 Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award.

Educational Accreditation

Accreditation Statements

The American College of Clinical Pharmacology is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

The ACPE universal program numbers assigned and hours of credit are noted within each segment of the program for a maximum of 28 Contact Hours. All CPE activities are application-based.

The American College of Clinical Pharmacology is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Designation Statement

The American College of Clinical Pharmacology designates this live educational activity for a maximum of 28 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Symposium 7: Establishing Biosimilarity: The European Perception, Experience & Future Trends has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the American College of Clinical Pharmacology and the European Federation for Exploratory Medicines Development. The American College of Clinical Pharmacology is accredited by the ACCME to provide continuing medical education for physicians.

Continuing Education Process for 2016

Attendees interested in earning continuing education credit should specifically request that when they register for the 2016 Annual Meeting. Attendees who indicated they want to obtain continuing education credit will be provided with access to post-event tests related to the courses they attend. Completion of the post-event tests is required to earn the credit and to print continuing education credit certificates. Post-event tests require a 75% passing score.

Attendees seeking CPE credit should, if they have not already done so, provide ACCP with their NABP Profile Number and the month and date of their birthday via email at CE@ACCP1.org. The profile number and birthday information is used when ACCP sends CPE credit information to the National Association of Boards of Pharmacy (NABP) using CPE Monitor. Pharmacists/pharmacy technicians are asked to obtain their NABP e-Profile ID by contacting the National Association of Boards of Pharmacy or by contacting NABP Customer Service at 847-391-4406.

Please note: If pharmacists/pharmacy technicians fail to set up their NABP e-Profile Identification Number, ACCP will not be able to provide the ACPE/NABP with the information which will allow pharmacists/pharmacy technicians to track completed continuing pharmacy education credit(s). ACCP cannot be responsible for individuals who have not taken the necessary steps to obtain their NABP e-Profile Identification Number and who have not provided this to ACCP prior to CPE post-event testing. For more information, or for answers to Frequently Asked Questions regarding CPE Monitor, please visit Accreditation Council for Pharmacy Education.

What is CPE Monitor?

CPE Monitor is a national, collaborative effort by ACPE and the National Association of Boards of Pharmacy (NABP) to provide an electronic system for pharmacists/pharmacy technicians to track their completed Continuing Pharmacy Education (CPE) credits. It also offers state boards of pharmacy the opportunity to electronically authenticate the CPE units completed by their licensees, rather than requiring pharmacists/pharmacy technicians to submit proof of completion statements upon request or for random audits.

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- **ACCP Fundamentals Tutorials:** Designed to provide a "not too technical" overview of clinical pharmacology, this series is available On Demand;
- **Therapeutic Dilemmas:** This webinar series will continue in the fall of 2016 and is available as a live webinar, then On Demand;
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Virtual Journal Club

Couldn't attend all the sessions or have a colleague that couldn't attend?

Coming in October – the following sessions from the 2016 ACCP Annual Meeting will be available On Demand:

Attendees of the 2016 Annual Meeting can access these events at no charge.

- **Symposium 1:** *Clinical Pharmacology as a Cornerstone for Development of Products Under the Animal Rule: Determining an Effective Dose in Humans*
- **Symposium 2:** A 360° View of Immunogenicity: Qualitative & Quantitative Assessments to Understand Its Implications on Pharmacokinetics, Safety & Efficacy
- **Symposium 3:** Helping Advance the Immuno-Oncology Revolution: Trends in Translational Immuno-Oncology
- **Symposium 4:** Clinical Development of Biologics: Current Strategy, Challenges & Future Considerations
- **Symposium 5:** Addressing Opioid Dependence: Now is the Time
- **Symposium 6:** Treatment of Hepatitis C with Direct-acting Antiviral Drugs: Opportunities & Challenges

To view the entire ACCP CE Catalog, visit **https://ce.accp1.org/**

Faculty Disclosure Information

The following Faculty participants have indicated they have a disclosure related to the content of their presentation.

Gaurav Bajaj: employee (salary) – Bristol-Myers Squibb Co

Jeffrey Barrett: employee (salary) – Sanofi

Jonathan Benjamin: employee (salary/stock) – Amgen Inc

Suraj G. Bhansali: employee (salary/stock) – Novartis Pharmaceuticals Corp

Indranil Bhattacharya: employee (salary/ownership interest) – Pfizer Inc; former employee (ownership interest) – GlaxoSmithKline plc

****Satjit Brar:*** employee (salary/stock options) – Pfizer Inc

Julie Bullock: employee (salary) – d3 Medicine LLC

****Ganesh Cherala:*** employee (salary) – Novo Nordisk Inc

****Andrew T. Chow:*** employee (salary/stock) – Amgen Inc

****James Cloyd III:*** licensing agreement (royalties) – Univ of Minnesota, Ligand Pharmaceuticals Inc; licensing agreement (future royalties) – Univ of Minnesota, Allaysis LLC; advisory board and licensing agreement (honorarium/royalty agreement) – Lundbeck; consulting (fees) – Upsher-Smith Laboratories Inc, Xeris Pharmaceuticals Inc, Neurelis Inc, UCB Inc, Eisai Co Ltd

Dora W. Cohen: employee (salary) – Amgen Inc

****Lawrence J. Cohen:*** consultant and committee member (consulting fee) – PharMerica

****Alfred Corey:*** former employee (salary) – PAREXEL Intl; former employee (stock) – GlaxoSmithKline plc

****Gabriele Dallmann:*** consulting (fees) – various pharma companies

John D. Davis: employee (salary/stock options) – Regeneron Pharmaceuticals Inc

****Paul Declerck:*** speaking and teaching, non-product related (honoraria) – Celltrion Inc, Hospira, Novo Nordisk Inc, Pfizer Inc, Roche

****Hartmut Derendorf:*** consulting (honorarium) – PK PDyne Inc

Thomas Eissing: employee (salary/stock) – Bayer Technology Svcs Co/ Bayer AG

Raffaella Faggioni: employee (salary/stock) – MedImmune LLC/ AstraZeneca plc

Michael J. Fossler, Jr: employee (salary/stock) – Trevena Inc

Leonid Gibiansky: consulting (fees) – multiple pharmaceutical companies; published papers in collaboration with Genentech Inc, Bristol-Myers Squibb Co and Roche during 2015

****Varun Goel:*** employee (salary/stock) – Novartis Inst for Biomedical Research; spouse: employee (salary/stock) – Alnylam Pharmaceuticals, Vertex Pharmaceuticals Inc

Adam Golden: consulting (fees) – Magellan Health Inc

George R. Gunn, III: employee (salary/stock/stock options) – Janssen Research & Development LLC; patent licensing (payment) – Advaxis Inc

Manish Gupta: employee (salary/stock) – Bristol-Myers Squibb Co

R. Donald Harvey: clinical trial conduct (research funding to Emory) – Amgen Inc, ArQule Inc, AstraZeneca plc, Aveo Pharmaceuticals Inc, Bristol-Myers Squibb Co, Celgene Corp, Cleave Biosciences, Calithera Biosciences Inc, Eli Lilly & Co, Merck & Co, Novartis, Pfizer Inc, Sanofi, Takeda Pharmaceuticals USA Inc; advisory board (honorarium) – Bristol-Myers Squibb Co, Takeda Pharmaceuticals USA Inc

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Manoj P. Jadhav: employee (salary) – CRC Pharma LLC

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Xiling Jiang: employee (salary/stock) – Johnson & Johnson

Trevor N. Johnson: employee (salary) – Simcyp Ltd (part of Certara)

****Mats O. Karlsson:*** consulting (fees) – Boehringer Ingelheim GmbH, Pfizer Inc; (stock) – Pharmetheus AB, Wellhagen & Karlsson AB

Sree Kasichayanula: employee (salary/stock) – Amgen Inc

****Parag Kumar:*** collaboration (product) – Matinas BioPharma Holdings Inc

****J. Steven Leeder:*** consulting (fees go to employer – US Food & Drug Administration) – Neurocrine Biosciences Inc

Lawrence J. Lesko: consulting (fees) – Amgen Inc, Biogen Inc, Relypsa Inc, Merrimack Pharmaceuticals Inc

Chunze Li: employee (salary/stock) – Genentech Inc

Donald E. Mager: Principal Investigator (potential research grant for systems modeling in immuno-oncology) – Bristol-Myers Squibb Co

Christina L. Mayer: employee (salary/stock) – Janssen Research & Development LLC

Bernd Meibohm: consulting (fees) – Alexion Pharmaceuticals Inc, AstraZeneca plc, Boehringer Ingelheim GmbH, Biogen Inc, F Hoffmann-La Roche AG, Merck KGaA, Novartis, Sanofi, Teva Pharmaceutical Industries Ltd, Tonix Pharmaceuticals Holding Corp

Prasun Mishra: employee (salary/stock) – Genentech Inc – a subsidy of Roche group; former employee (salary/stock) – Gilead Sciences Inc

Faculty Disclosure Information

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Chaitali Passey: employee (salary) – Bristol-Myers Squibb Co; former employee (salary) – Merck & Co

****Ronald J. Portman:*** employee (salary/stock) – Novartis Pharmaceuticals Corp

Sumit Rawal: employee (salary) – Regeneron Pharmaceuticals Inc

****Zachary Rome:*** employee (salary) – Patagonia Pharmaceuticals LLC

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****Huub Schellekens:*** member ad board (honorarium) – Merck Serono & Merck & Co; consulting (fees) – Eagle Pharmaceuticals Inc

Jan-Frederik Schlender: employee (salary) – Bayer Technology Svcs GmbH

Edward M. Sellers: consulting (fees) – DL Global Partners Inc

Jinshan Shen: employee (salary/stock options) – Radius Health Inc; former employee (salary/stock options/restricted stock) – Vertex Pharmaceuticals Inc

Jennifer Sheng: employee (salary) – Bristol-Myers Squibb Co

Rong Shi: employee (salary/stock) – Bristol-Myers Squibb Co

Vikram Sinha: employee (salary) – Merck & Co

****Konstantine W. Skordos:*** employee (salary/stock) – Novartis Inst for Biomedical Research; former employee (salary/stock) – Biogen Inc

****P. Brian Smith:*** consulting (fees) – Abbvie Inc

****Hildegard Sourgens:*** consulting, medical writing (honoraria) – Bayer AG, Formycon AG, mibe GmbH Arzneimittel, Max Zeller Söhne AG

Sven Stegemann: employee part-time (salary) – Capsugel

****Mark Sulkowski:*** consultant/advisory board (honorarium) – AbbVie Inc, Bristol-Myers Squibb Co, Cocrystal Pharma Inc, Gilead Sciences Inc, Merck & Co, Janssen Pharmaceuticals Inc, Trek Therapeutics PBC

Yu-Nien (Tom) Sun: employee (salary/stock) – Johnson & Johnson

Satyendra Suryawanshi: employee (salary/stock) – Bristol-Myers Squibb Co

Zheng Yang: employee (salary/stock/stock options) – Bristol-Myers Squibb Co

Yilong Zhang: employee (salary/stock) – Amgen Inc

Diansong Zhou: employee (salary) – AstraZeneca plc

Honghui Zhou: employee (salary/stock/stock options) – Johnson & Johnson

The following Faculty have indicated they have no disclosures related to their presentation:

Darrell R. Abernethy
****Bilal S. AbuAsal***
****Hae-Young Ahn***
****Shashi Amur***
****Vikram Arya***
****Gerri Baer***
****Kimberly L. Bergman***
****Venkatesh Atul Bhattaram***
Eric Brodsky
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Leonard Campanello
Ruth S. Day
****Gustavo F. Doncel***
Sir Gordon W. Duff
****Justin C. Earp***
Jeffry Florian
Christine Garnett
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****Sam Harirforoosh***
****Amalia M. Issa***
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Brian Jacobs
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Patricia W. Slattum
****John van den Anker***
****Jian Wang***
Yow-Ming C. Wang
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Anne Zajicek
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Ping Zhao

*This disclosure list includes all 2016 Annual Meeting Faculty. Continuing education credit is offered for ten of the 17 available Workshops and Symposia. The Faculty participating in Workshops and Symposia offering CE credit are noted with an asterisk.

The following activity planners have indicated they have disclosures:

Nageshwar Budha: employee (salary) – Genentech Inc; former employee (stock) – Hoffmann-La Roche

Lawrence J. Cohen: consultant and committee member (consulting fee) – PharMerica

Manish Gupta: employee (salary/stock) – Bristol-Myers Squibb Co

Honghui Zhou: employee (salary/stock/stock options) – Johnson & Johnson

The following planners have indicated they have no disclosures:

Vikram Arya
Amelia N. Deitchman
Nilima A. Kshirsagar
Nitin Mehrotra
Robert Noveck
Stephan Schmidt
Jayabharathi Vaidyanathan
John van den Anker

SATURDAY, SEPTEMBER 24, 2016 | Pre-meeting Workshop 1 | 8:00 am – 12:00 pm

BALLROOM SALON H

Translational Pharmacokinetics/ Pharmacodynamics in Biotherapeutic Minimum Anticipated Biological Effect Level Dose Selection & Novel Protein Scaffolds

DISCOVERY TRACK

CO-CHAIRS:

Honghui Zhou, PhD, Senior Director & Janssen Fellow, Janssen Research & Development LLC

Rong Shi, PhD, Clinical Pharmacology Lead, Bristol-Myers Squibb Co

TARGET AUDIENCE:

The target audience includes preclinical and translational pharmacokinetic and pharmacodynamic (PK/PD) scientists, drug development scientists, clinical pharmacologists and those working in clinical and regulatory settings.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Discuss the advantages of novel scaffolds (eg, modified ADCC/CDC response, tissue penetration, specific targeting) & potential challenges (eg, PK, immunogenicity) relative to traditional monoclonal antibodies;
2. Discuss approaches to address these challenges and to maximize the advantages of using translational and PK/PD tools;
3. Have a holistic understanding of the available translational and PK/PD tools to face the challenges of drug development with novel scaffolds;
4. Provide an overview and share knowledge on lessons learned about the TeGenero anti-CD28 antagonist TNG1412 cytokine storm incidence;
5. Provide a comprehensive understanding of the concept of the Minimum Anticipated Biological Effect Level (MABEL) by Sir Gordon Duff;
6. Demonstrate examples of MABEL calculations in biologics programs;
7. Discuss the challenges and methodologies in calculating MABEL for First-in-Human starting dose;
8. Discuss under what circumstances the MABEL approach for First-in-Human starting dose should be used.

8:00 – 8:10 am

Introduction

Honghui Zhou, PhD, Senior Director & Janssen Fellow, Janssen Research & Development LLC and Rong Shi, PhD, Clinical Pharmacology Lead, Bristol-Myers Squibb Co

8:10 – 8:40 am

Translational Considerations in Developing Bispecific Antibodies: What Can We Learn from Mechanistic PK/PD Modeling?

Bernd Meibohm, PhD, Professor & Associate Dean, Univ of Tennessee Health Science Ctr, Coll of Pharmacy

8:40 – 9:10 am

Experience in Oncology Clinical Pharmacology & Oversight on ADC: Challenges & Opportunities for Translational PK/PD in ADC Development

Chunze Li, PhD, Senior Scientist, Genentech Inc

9:10 – 9:40 am

Perspectives on Clinical Development of Abbreviated Antibody Constructs

Indranil Bhattacharya, PhD, Director, Pfizer Inc

9:40 – 10:00 am / **Break**

10:00 – 10:30 am

Intensive Review of "Expert Group on Phase 1 Clinical Trials: Final Report"

Sir Gordon W. Duff, Professor & Chair of the Biotechnology & Biological Sciences Research Council, St Hilda's Coll, Univ of Oxford

10:30 – 10:50 am

To MABEL or Not to MABEL: A Biomarker & Model-based Approach to Dose Selection for First-in-Human Studies of Biologics

Raffaella Faggioni, PhD, Senior Director, Clinical Pharmacology & DMPK, MedImmune LLC/AstraZeneca plc

10:50 – 11:10 am

PK/PD Integration of Nonclinical Data for the Determination of MABEL & First-in-Human Starting Dose: Case Studies with Biologics in Immunoscience

Zheng Yang, PhD, Director, Bristol-Myers Squibb Co

11:10 – 11:30 am

Regulatory Perspectives in Developing Biotherapeutics with Novel Protein Scaffolds

Yow-Ming C. Wang, PhD, Clinical Pharmacology (Biologics) Team Leader, US Food & Drug Administration

11:30 am – 12:00 pm

Panel Discussion

Pre-meeting Workshops

SATURDAY, SEPTEMBER 24, 2016 | Pre-meeting Workshop 2 | 8:00 am – 12:00 pm

BALLROOM SALON G

Combating HIV/AIDS: Treatment, Pharmacogenetics & Pre-exposure Prophylaxis

APPLICATION TRACK

Offers both CME and CPE Credit

UAN #0238-0000-16-002-L02-P

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Sam Harirforoosh, PharmD, PhD, Associate Professor, Dept of Pharmaceutical Sciences, East Tennessee State Univ, Gatton Coll of Pharmacy

Ganesh Cherala, PhD, Research Scientist, Research Technologies, Novo Nordisk Inc

TARGET AUDIENCE:

A better understanding of critical contributors of successful pharmacotherapy is an important step in delivering optimal healthcare. This Workshop will distill information, both evidence-based and theoretical, to the target audience of clinicians, pharmacists and scientists in practice, as well as in clinical research and drug development environments.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Describe HIV pharmacotherapy and analyze the potential of pre-exposure prophylaxis (PrEP) in combating the HIV epidemic globally;
2. Describe the influence of pharmacogenetics herein and the utility of pharmacogenetic biomarkers;
3. Demonstrate the utility of multi-purpose technologies to improve reproductive and sexual health;
4. Provide an update on drug-drug, drug-food and drug-herb interactions in HIV pharmacotherapy.

8:00 – 8:05 am

Introduction

Ganesh Cherala, PhD, Research Scientist, Research Technologies, Novo Nordisk Inc

8:05 – 8:35 am

Challenges of HIV Infection in 2016

Jonathan P. Moorman, MD, PhD, Professor, East Tennessee State Univ, Quillen Coll of Medicine

8:35 – 9:00 am

Pharmacogenetics of HIV Drugs

Sam Harirforoosh, PharmD, PhD, Associate Professor, Dept of Pharmaceutical Sciences, East Tennessee State Univ, Gatton Coll of Pharmacy

9:00 – 9:30 am

Biomarkers in HIV & HCV Drug Development

Shashi Amur, PhD, Scientific Lead, Biomarker Qualification Program, US Food & Drug Administration

9:30 – 10:00 am / **Break**

10:00 – 10:30 am

HIV Pre-exposure Prophylaxis Drug Development: A Clinical Pharmacologist's Inside View

Craig W. Hendrix, MD, Wellcome Professor & Director, Johns Hopkins Univ School of Medicine

10:30 – 11:00 am

Development of Multipurpose Technologies for the Prevention of HIV & Unintended Pregnancies: Can We Kill Two Birds with One Stone?

Gustavo F. Doncel, MD, PhD, Scientific Director, CONRAD & Professor of Obstetrics & Gynecology, Eastern Virginia Medical School

11:00 – 11:30 am

Update on Drug Interactions in HIV

Parag Kumar, PharmD, Director, Clinical Pharmacokinetics Research Lab, National Inst of Health

11:30 am – 12:00 pm

Panel Discussion

SATURDAY, SEPTEMBER 24, 2016 | Pre-meeting Workshop 3 | 1:30 – 5:30 pm

BALLROOM SALON H

Improving Therapeutics to Better Care for Older Adults & the Young

DISCOVERY & APPLICATION TRACKS

CO-CHAIRS:

S.W. Johnny Lau, PhD, Senior Clinical Pharmacologist, US Food & Drug Administration

Thomas Eissing, PhD, Head of Systems Pharmacology CV, Bayer Technology Svcs GmbH

TARGET AUDIENCE:

The target audience includes clinical pharmacologists, pharmacometricians, systems pharmacologists, pharmaceutical scientists and clinicians, as well as fellows and students from industry, academia and regulatory institutions.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Understand the issues of developing pharmacotherapy for older adults and the young;
2. Understand the regulatory aspects of developing pharmacotherapy for older adults and the young;
3. Learn from the regulatory aspect of developing drug products for the young and apply that to the older adult population;
4. Develop patient-centric or age-appropriate pharmaceutical products;
5. Apply pharmacokinetics and pharmacodynamics, as well as pharmacometrics and systems pharmacology, to better care for older adults and the young.

1:30 – 1:40 pm

Introduction

S.W. Johnny Lau, PhD, Senior Clinical Pharmacologist, US Food & Drug Administration

1:40 – 2:10 pm

Medication Issues & Potential Solutions for Frail Older Adults

Adam Golden, MD, MBA, Professor, Internal Medicine, Univ of Central Florida, Coll of Medicine, Associate Chief of Staff, Geriatrics & Extended Care, Orlando Veterans Affairs Medical Ctr

2:10 – 2:35 pm

Are There Unique Issues for the Development of Drug Products for the Older Adult?

Darrell R. Abernethy, MD, PhD, Associate Director for Drug Safety, Office of Clinical Pharmacology, US Food & Drug Administration

2:35 – 3:00 pm

Regulatory & Clinical Pharmacology Considerations for Developing Drug Products for Pediatric Patients

Gilbert J. Burckart, PharmD, Associate Director for Pediatrics, US Food & Drug Administration

3:00 – 3:30 pm / **Break**

3:30 – 4:00 pm

Pharmaceutical Drug Product Design in the Context of Effectiveness & Safety & Their Importance in Achieving Therapeutic Outcomes

Sven Stegemann, PhD, Professor, Graz Univ of Technology

4:00 – 4:30 pm

Applying Pharmacokinetic & Pharmacodynamic Principles to Improve Care for Older Adults

Patricia W. Slattum, PharmD, PhD, Professor of Pharmacotherapy & Outcomes Science, Virginia Commonwealth Univ

4:30 – 5:00 pm

Pharmacometric Approaches to Better Care for Older Adults & the Young

Thomas Eissing, PhD, Head of Systems Pharmacology CV, Bayer Technology Svcs GmbH and Jan-Frederik Schlender, MSc, Pharmacist, Scientist Systems Pharmacology, Bayer Technology Svcs GmbH

5:00 – 5:30 pm

Panel Discussion

Pre-meeting Workshops

SATURDAY, SEPTEMBER 24, 2016 | Pre-meeting Workshop 4 | 1:30 – 5:00 pm

BALLROOM SALON G

The Other Bound of the Therapeutic Window: Exposure-Safety Analysis to Inform Dosing Decisions in Oncology

DISCOVERY TRACK

Offers both CME and CPE Credit

UAN #0238-0000-16-003-L05-P

ACPE – 3 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Justin C. Earp, PhD, Pharmacometrics Reviewer, US Food & Drug Administration

Anshu Marathe, PhD, Team Leader, Div of Clinical Pharmacology II, US Food & Drug Administration

TARGET AUDIENCE:

The target audience includes drug development scientists from the pharmaceutical industry working in the area of oncology, academic organizations, scientists from cancer hospitals involved in drug development of oncology agents and regulatory scientists working in the area of oncology. Although the focus of the activity is in the oncology therapeutic area, the principles discussed in this topic can be applied to other therapeutic areas as well.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Understand the uniqueness of characterizing exposure-response for safety in oncology drug development programs;
2. Review current practices and identify the methodological challenges involved in conducting exposure-safety analyses for oncology agents;
3. Highlight case studies demonstrating the common methodologies/ challenges in conducting oncology exposure-safety analyses;
4. Analyze and compare possible approaches for adequate exposure-safety analyses that can contribute to informed dosing decisions.

1:30 – 1:40 pm

Introduction

Justin C. Earp, PhD, Pharmacometrics Reviewer, US Food & Drug Administration

1:40 – 2:10 pm

Exposure-Safety Analyses to Drive Decision Making in Oncology

Anshu Marathe, PhD, Team Leader, Div of Clinical Pharmacology II, US Food & Drug Administration

2:10 – 2:40 pm

Strategies for Exposure-Safety Modeling & Simulation in Oncology with a Focus on Trial Execution Aspects

Mats O. Karlsson, PhD, Professor, Dept of Pharmaceutical Biosciences, Uppsala Univ

2:40 – 3:00 pm

Q&A

3:00 – 3:30 pm / **Break**

3:30 – 4:00 pm

Exposure-Safety Analysis for Oncology Drugs: An Industry Perspective

Varun Goel, PhD, Fellow, Clinical Pharmacology, Novartis Inst for Biomedical Research

4:00 – 4:30 pm

Balancing Exposure-Safety & Efficacy Analysis for Deriving Dosing in Oncology: Case Examples

Satjit Brar, PharmD, PhD, Associate Director, Clinical Pharmacology, Pfizer Inc

4:30 – 5:00 pm

Panel Discussion

(including Konstantine W. Skordos, PhD [Novartis Inst for Biomedical Research] and Atiqur Rahman, PhD [US Food & Drug Administration])

SUNDAY, SEPTEMBER 25, 2016 | Symposium 1 | 8:00 am – 12:00 pm

BALLROOM SALON A–C

Clinical Pharmacology as a Cornerstone for Development of Products Under the Animal Rule: Determining an Effective Dose in Humans

DISCOVERY TRACK

Offers both CME and CPE Credit

UAN #0238-0000-16-004-L01-P

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Nitin Mehrotra, PhD, Team Leader, Div of Pharmacometrics, US Food & Drug Administration

Kimberly L. Bergman, PharmD, Lead Pharmacologist, US Food & Drug Administration

TARGET AUDIENCE:

The target audience includes clinical pharmacologists, pharmacometricians and translational medicine scientists from the pharmaceutical industry, academia and regulatory agencies who have an interest in applying and/or currently apply the principles of clinical pharmacology modeling and simulation in drug development of products under the Animal Rule.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Understand the drug development and approval process of products under the Animal Rule;
2. Analyze and understand the role of clinical pharmacology modeling and simulation in dose selection in humans for development of products under the Animal Rule;
3. Highlight the case studies where clinical pharmacology modeling and simulation played a significant role in drug development or regulatory decisions.

8:00 – 8:15 am

Introduction: Setting the Stage

Nitin Mehrotra, PhD, Team Leader, Div of Pharmacometrics, US Food & Drug Administration

8:15 – 8:40 am

The Animal Rule: Approval of New Drugs & Biological Products When Human Efficacy Studies Are Not Ethical or Feasible

Andrea M. Powell, PhD, Pharmacologist, Counter-terrorism & Emergency Coordination, US Food & Drug Administration

8:40 – 9:05 am

The Animal Rule: The Role of Clinical Pharmacology in Determining an Effective Dose in Humans

Kimberly L. Bergman, PharmD, Lead Pharmacologist, US Food & Drug Administration

9:05 – 9:30 am

Perspective on the Clinical Pharmacology Approach for Rational Choice of Drug & Dose in Product Development Under the Animal Rule: Example for Treating Patients Acutely Exposed to Myelosuppressive Doses of Radiation

Andrew T. Chow, PhD, Executive Director, Amgen Inc

9:30 – 10:00 am / **Break**

10:00 – 10:25 am

The Use of Modeling & Simulation in the Raxibacumab Development Program

Alfred Corey, BS, Consultant, AC Pharmaco LLC

10:25 – 10:50 am

Application of Quantitative Clinical Pharmacology in Dose Selection for Products Developed Under the Animal Rule: Case Studies

Lian Ma, PhD, Pharmacometrics Reviewer, US Food & Drug Administration

10:50 am – 12:00 pm

Panel Discussion

SUNDAY, SEPTEMBER 25, 2016 | Symposium 2 | 8:00 – 9:30 am

BALLROOM SALON D

A 360º View of Immunogenicity: Qualitative & Quantitative Assessments to Understand Its Implications on Pharmacokinetics, Safety & Efficacy

DISCOVERY TRACK

CO-CHAIRS:

Chaitali Passey, PhD, Senior Research Investigator, Bristol-Myers Squibb Co

Sumit Rawal, PhD, Scientist, Regeneron Pharmaceuticals Inc

TARGET AUDIENCE:

The target audience includes clinical pharmacologists, clinicians, pharmacometricians, regulators and bioanalytical scientists.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Understand the best practices for reporting and visualization of immunogenicity data;
2. Demonstrate and compare quantitative approaches to assess the impact of immunogenicity on pharmacokinetics;
3. Understand the implications of immunogenicity on safety and efficacy of therapeutic protein products in a clinical setting.

8:00 – 8:05 am

Session Overview

Chaitali Passey, PhD, Senior Research Investigator, Bristol-Myers Squibb Co

8:05 – 8:30 am

A Qualitative Look at Immunogenicity Data During Drug Development

George R. Gunn III, PhD, Associate Scientific Director, Janssen Research & Development LLC

8:30 – 8:55 am

Quantitative Approaches to Assess Immunogenicity During Drug Development of Biologics

Leonid Gibiansky, PhD, President, QuantPharm LLC

8:55 – 9:20 am

Risk Assessment & Mitigation Strategies for Immunogenicity of Therapeutic Proteins

Amy Rosenberg, MD, Supervisory Medical Officer, Div of Therapeutic Proteins, US Food & Drug Administration

9:20 – 9:30 am

Q&A

SUNDAY, SEPTEMBER 25, 2016 | Symposium 3 | 10:00 am – 12:00 pm

BALLROOM SALON D

Helping Advance the Immuno-Oncology Revolution: Trends in Translational Immuno-Oncology

DISCOVERY & APPLICATION TRACKS

CO-CHAIRS:

Sree Kasichayanula, PhD, Principal Scientist, Amgen Inc

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

TARGET AUDIENCE:

The target audience includes physicians, pharmacists, researchers and regulators who are seeking to understand translational research in oncology immunotherapy, along with pharmacokinetics/pharmacodynamics (PK/PD) and systems modeling and the future of drug development to treat patients with cancer. The Symposium attendees will be able to learn and appreciate the utility of novel technologies, such as imaging, and their roles, along with PK/PD, in targeted therapy in oncology. Recent translational advances that helped accelerate combination immunotherapy development, along with future outlook in this disease area, will also be covered.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Understand recent advances in translational drug development in cancer immunotherapy;
2. Appreciate the utility of imaging in oncology translational models;
3. Conceptualize the differences in combination immunotherapy and the utility of translational models in acceleration of combination oncology development;
4. Compare the role of traditional PK/PD models and recent advances in systems modeling.

10:00 – 10:10 am

Introduction

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

10:10 – 10:30 am

Bench to Bedside: Recent Examples in Translating Medicine in Cancer Drug Development

Jonathan Benjamin, MD, Medical Director, Amgen Inc

10:30 – 10:50 am

Understanding the Utility of Imaging in Targeted Drug Delivery: Opportunities & Challenges in Immuno-Oncology

Bart Hendriks, PhD, Senior Director of Nanoimaging, Merrimack Pharmaceuticals Inc

10:50 – 11:10 am

Preclinical Models for Defining Efficacy of Immunotherapy Combinations: Mapping the Road for Acceleration to Clinic

Christina L. Mayer, PharmD, Senior Scientist, Biologics Clinical Pharmacology, Janssen Research & Development LLC

11:10 – 11:30 am

Advances & the Future Role of Immuno-Oncology Systems Models

Donald E. Mager, PharmD, PhD, Associate Professor, Univ at Buffalo, State Univ of New York

11:30 am – 12:00 pm

Panel Discussion

SUNDAY, SEPTEMBER 25, 2016 | Symposium 4 | 1:30 – 5:30 pm

BALLROOM SALON A–C

Clinical Development of Biologics: Current Strategy, Challenges & Future Considerations

DISCOVERY TRACK

CO-CHAIRS:

Gaurav Bajaj, PhD, Senior Research Investigator, Bristol-Myers Squibb Co

Ping Zhao, PhD, Lead, PBPK Program, Div of Pharmacometrics, US Food & Drug Administration

TARGET AUDIENCE:

The session will cover the challenges in clinical pharmacology associated with development of early clinical candidates during Phase 1/2 stages. The target audience includes clinical pharmacologists and pharmacometricians from the pharmaceutical and biotech industries and academia, clinicians and regulatory scientists, scientists working on early drug development and graduate students/trainees in pharmaceutical sciences and clinical pharmacology.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Understand challenges in clinical development of monoclonal antibodies (mAbs);
2. Discuss dose-optimization strategies of mAbs for pivotal trials and the possible strategies for mAbs that are approved and are being used in combination with another biologic;
3. Discuss challenges related to characterization of non-linear pharmacokinetics of mAbs and the implication on clinical development;
4. Analyze and predict immunogenicity of mAbs and the impact on clinical efficacy and safety;
5. Understand the current status, limitation, challenges and future directions of using physiologically-based pharmacokinetic and pharmacodynamic (PBPK/PD) models in drug development for biologics;
6. Apply PBPK models to predict drug interaction potential for antibody-drug conjugates.

1:30 – 1:40 pm

Introduction

Gaurav Bajaj, PhD, Senior Research Investigator, Bristol-Myers Squibb Co

1:40 – 2:10 pm

Clinical Pharmacology Considerations for Biologics: Important Concepts

Diane R. Mould, PhD, President, Projections Research Inc

2:10 – 2:35 pm

Communicating Concepts Correctly

John D. Davis, BPharm, PhD, Senior Director, Regeneron Pharmaceuticals Inc

2:35 – 3:00 pm

How the Development of Combination Therapy in Biologics Can Be Different Than Monotherapy

Manish Gupta, PhD, Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb Co

3:00 – 3:30 pm / **Break**

3:30 – 4:00 pm

Application of Physiologically-based Pharmacokinetics in Biologics in Drug Development With a Case Example to Predict Disease-mediated Therapeutic Protein Interaction

Xiling Jiang, PhD, Senior Scientist, Janssen Research & Development LLC

4:00 – 4:30 pm

Application of Physiologically-based Pharmacokinetic Models to Predict Drug Interactions for Antibody-Drug Conjugates

Chunze Li, PhD, Senior Scientist, Genentech Inc

4:30 – 5:00 pm

Regulatory Considerations in Biologics Development

Hong Zhao, PhD, Master Reviewer of Clinical Pharmacology/ Team Leader, US Food & Drug Administration

5:00 – 5:30 pm

Panel Discussion

SUNDAY, SEPTEMBER 25, 2016 | Symposium 5 | 1:30 – 3:00 pm

BALLROOM SALON D

Addressing Opioid Dependence: Now is the Time

APPLICATION TRACK

CO-CHAIRS:

Lorraine M. Rusch, PhD, Vice President, Commercial Development, Celerion Inc

Michael J. Fossler, Jr, PharmD, PhD, Vice President, Quantitative Sciences, Trevena Inc

TARGET AUDIENCE:

The target audience includes clinical pharmacologists involved in basic and applied clinical research focused on analgesia management, pharmacists involved in filling and reporting opioid prescriptions, medical directors, chief medical officers of organizations developing new chemical entities for pain management, physicians (both those practicing in the pain management area and those not as familiar) and health economics professionals.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Understand and delineate common challenges that persons suffering with substance use disorder face while attempting to secure treatment options such as suboxone and/or methadone and counseling programs;
2. Demonstrate a basic understanding of the principles of the neurobiology involved in addictions, treatment options available and basic medical practice towards the management of addiction;
3. Consider the alternative of decriminalizing those who voluntarily commit to substance treatment through novel community policing programs that secure immediate aid for addicts in need;
4. Understand and utilize new programs (training, grants, increased buprenorphine prescribing) proposed by the US Health & Human Services (HHS) and budgeted for 2016 ($133M in new funding).

1:30 – 1:35 pm

Introduction

Michael J. Fossler, Jr, PharmD, PhD, Vice President, Quantitative Sciences, Trevena Inc

1:35 – 1:55 pm

Addiction: An Imprecise Problem in a World of Precision Medicine

Edward M. Sellers, MD, PhD, Professor Emeritus, Pharmaceuticals, Medicine & Psychiatry, Univ of Toronto

1:55 – 2:20 pm

HHS: Policies to Address Opioid-drug Related Overdose, Death & Dependence

Jinhee Lee, PharmD, Senior Pharmacy Advisor, Substance Abuse & Mental Health Svcs Administration

2:20 – 2:40 pm

Gloucester Police Department Angel Initiative & the Police Assisted Addiction Recovery Initiative (PAARI)

Leonard Campanello, MS, Chief of Police, City of Gloucester, MA Police Dept MAFE

2:40 – 3:00 pm

Panel Discussion

SUNDAY, SEPTEMBER 25, 2016 | Symposium 6 | 3:30 – 5:30 pm

BALLROOM SALON D

Treatment of Hepatitis C with Direct-acting Antiviral Drugs: Opportunities & Challenges

APPLICATION TRACK

Offers both CME and CPE Credit

UAN #0238-0000-16-005-L01-P

ACPE – 2 CONTACT HOURS/APPLICATION-BASED

This Symposium is supported in part by an Educational Grant from Merck Sharp & Dohme Corp (A subsidiary of Merck & Co Inc)

CO-CHAIRS:

Vikram Arya, PhD, Silver Spring, MD

Shirley Seo, PhD, Team Leader, Office of Clinical Pharmacology, US Food & Drug Administration

TARGET AUDIENCE:

The target audience includes physicians, clinical pharmacologists, pharmacists and academic research scientists.

GOALS AND OBJECTIVES:

The goal of this course is to provide participants with an insight into the various strategies for treatment of Hepatitis C and to discuss the various challenges of treating HCV-infected patients in the era of all oral direct-acting antiviral (DAA) therapies.

Following completion of this activity, the learner will be able to:

1. Understand recent advances in the treatment of Hepatitis C with DAA drugs and identify the various knowledge gaps;
2. Demonstrate knowledge of the role of clinical pharmacology in optimizing the dose and treatment duration of DAAs for various genotypes;
3. Understand the various dosing recommendations of DAAs in some specific populations (for example HIV/HCV co-infected and transplant patients).

3:30 – 3:35 pm

Introduction

Vikram Arya, PhD, Silver Spring, MD

3:35 – 4:00 pm

Challenges Associated with the Use of Direct-acting Antiviral Drugs in Specific Populations

Mark Sulkowski, MD, Professor of Medicine, Johns Hopkins Univ School of Medicine

4:00 – 4:25 pm

Ultra-short Duration Therapy: Reality or Myth?

Shyam Kottilil, MD, PhD, Professor of Medicine, Inst of Human Virology, Univ of Maryland

4:25 – 4:50 pm

Knowledge Gaps in the Development of Direct-acting Antiviral Drugs: How Clinical Pharmacology Has Contributed to Closing Them

Shirley Seo, PhD, Team Leader, Office of Clinical Pharmacology, US Food & Drug Administration

4:50 – 5:30 pm

Panel Discussion

MONDAY, SEPTEMBER 26, 2016 | Symposium 7 | 8:00 am – 12:00 pm

BALLROOM SALON A–C

Establishing Biosimilarity: The European Perception, Experience & Future Trends

DISCOVERY & APPLICATION TRACKS

Offers both CME and CPE Credit

UAN #0238-9999-16-006-L01-P

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the American College of Clinical Pharmacology and the European Federation for Exploratory Medicines Development. The American College of Clinical Pharmacology is accredited by the ACCME to provide continuing medical education for physicians.

CO-CHAIRS:

Hildegard Sourgens, MD, PhD, President Elect, European Federation for Exploratory Medicines Development

Hartmut Derendorf, PhD, Distinguished Professor & Chair, V. Ravi Chandran Professor in Pharmaceutical Sciences, Univ of Florida

TARGET AUDIENCE:

The target audience includes healthcare professionals who are involved in the research and development of biopharmaceuticals/biosimilars, regulatory affairs (competent authorities; pharmaceutical industry), pharmacovigilance and/or biotech start-ups.

GOALS AND OBJECTIVES:

The goal is for participants to learn from the European Medicines Agency's (EMA) 15-year experience in biosimilars and assess if similar concepts can be adopted in the US.

Following completion of this activity, the learner will be able to:

1. Demonstrate the primary contribution of analytical comparability and its meaning for clinical development;
2. Analyze the European experience with respect to clinical and nonclinical development programs, approval success, post-marketing performance and the failures of European biosimilar programs (as far as these can be made public);
3. Develop the impact of pharmacokinetics/pharmacodynamics to detect differences between a reference medicinal product and a biosimilar;
4. Demonstrate the safety of biologicals and biosimilars based on the European experience;
5. Demonstrate the discriminative power of analytics and pharmacokinetic and/or pharmacodynamic profiles vs Phase 3 trials.

8:00 – 8:20 am

Introduction/EMA & FDA Guidance Review

Hildegard Sourgens, MD, PhD, President Elect, European Federation for Exploratory Medicines Development

8:20 – 9:00 am

How Similar is Similar? The European Biosimilar Quality Experience

Paul Declerck, PhD, Professor, Dean of the Faculty of Pharmaceutical Sciences, Univ of Leuven

9:00 – 9:40 am

Clinical Strategies for Biosimilar Development: A European Perspective

Gabriele Dallmann, PhD, Co-founder, Biopharma Excellence GbR

9:40 – 10:10 am / **Break**

10:10 – 10:50 am

The European Experience With Safety Testing of Biologicals and Biosimilars

Huub Schellekens, MD, PhD, Chair, Professor in Pharmaceutical Biotechnology, Utrecht Univ

10:50 – 11:30 am

Current Status & Future Trends in Biologics & Biosimilar Development & Approval in the US

Hae-Young Ahn, PhD, RAC, Deputy Director, Div of Clinical Pharmacology III, US Food & Drug Administration

11:30 am – 12:00 pm

Panel Discussion

BALLROOM SALON D

Informing Pediatric Development Programs: Leveraging Big Data

DISCOVERY TRACK

CO-CHAIRS:

Jeffrey Barrett, PhD, Vice President, Translational Informatics, Sanofi

Lily (Yeruk) Mulugeta, PharmD, Scientific Lead for Pediatrics, Div of Pharmacometrics, US Food & Drug Administration

TARGET AUDIENCE:

The target audience includes drug development scientists in both academia and industry, regulators, clinicians, clinical pharmacologists and statisticians.

GOALS AND OBJECTIVES:

One of the more compelling challenges in pediatric drug development, as well as the consideration on expanded indications in children for existing approved agents, is understanding the pediatric disease progression. Data sources that include large and unstructured formats, ie, Big Data, are available, but their role in pediatric drug development is only at the genesis stage. Sources of Big Data include the electronic medical record (EMR) and large multi-institution administrative databases which consist of information on demographics, laboratory findings, microbiology data, medical order, procedures, surgery and clinical outcomes. The session will explore potential frameworks for how existing data can be used in pediatric drug development to optimize protocol design and enhance patient recruitment. The session will highlight case studies and discuss unique data sources that can be leveraged.

Following completion of this activity, the learner will be able to:

1. Review varying types of data that can be leveraged to support pediatric trial design;
2. Present examples on how efficiency of pediatric trials can be improved using existing data;
3. Discuss the limitations and generalizability of data from EMR as it applies to pediatric drug development.

8:00 – 8:15 am

Introduction to Big Data & Its Relevance for Pediatric Drug Development

Jeffrey Barrett, PhD, Vice President, Translational Informatics, Sanofi

8:15 – 8:30 am

The Value of Historical Electronic Health Records Data to Guide Relevant Clinical Questions Around Pediatric Standard of Care: A Perspective from Cerner

Brian Jacobs, MD, Vice President, Chief Medical Information Officer & Chief Information Officer, Children's National Health System

8:30 – 8:45 am

Combining Bedside & Clinical Research Data to Inform Disease Progression and Outcomes/ Biomarker Selection

Diane R. Mould, PhD, President, Projections Research Inc

8:45 – 9:00 am

Deriving Insight & Value from Electronic Health Records: Opportunities and Challenges of Neonatal Clinical Research in the Big Data Era

P. Brian Smith, MD, MHS, MPH, Professor of Pediatrics, Duke Univ Medical Ctr

9:00 – 9:15 am

Using Existing Data Sources for Advancing Clinical Trials: A Regulatory Perspective

Jeffry Florian, PhD, Team Leader, Div of Pharmacometrics, US Food & Drug Administration

9:15 – 9:30 am

Panel Discussion

(including Brian Jacobs, MD [Children's National Health System], P. Brian Smith, MD, MHS, MPH [Duke Univ Medical Ctr], Anne Zajicek, MD, PharmD [National Inst of Health], Lynne Yao, MD [US Food & Drug Administration], Vikram Sinha, PhD [Merck Research Laboratories] and Diane R. Mould, PhD [Projections Research Inc])

MONDAY, SEPTEMBER 26, 2016 | Symposium 9 | 10:00 am – 12:00 pm

BALLROOM SALON D

Little Children, Big Challenges: The Problems for Neonatal Drug Trials & the Way Forward

APPLICATION TRACK

Offers both CME and CPE Credit

UAN #0238-0000-16-007-L01-P

ACPE – 2 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Jian Wang, PhD, Senior Clinical Pharmacologist, US Food & Drug Administration

John van den Anker, MD, PhD, Chief, Div of Clinical Pharmacology, Children's National Health System

TARGET AUDIENCE:

The target audience includes clinical pharmacologists from both pharmaceutical & biotechnology companies and regulatory agencies, pharmacometricians, clinical researchers and drug development scientists who have an interest in applying and/or currently apply principles of pediatric clinical pharmacology to innovate and accelerate drug development for neonatal patients.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Review the challenges and opportunities in neonatal drug development from a preclinical and clinical pharmacology perspective;
2. Demonstrate how understanding ontogeny and clinical data together inform neonatal dose selection;
3. Discuss approaches that can be used to improve efficiency and feasibility of neonatal trials;
4. Evaluate the use of optimal clinical trial design in neonatal patients;
5. Discuss safety evaluation in neonates;
6. Update participants about the FDA pediatric guidances and the international neonatal consortium.

10:00 – 10:05 am

Overview: Challenges & Opportunities

John van den Anker, MD, PhD, Chief, Div of Clinical Pharmacology, Children's National Health System

10:05 – 10:20 am

Ontogeny of Drug-metabolizing Enzymes & Drug Transporters: What is Known & Unknown

J. Steven Leeder, PharmD, PhD, Director, Div of Clinical Pharmacology, Toxicology & Therapeutic Innovation, Children's Mercy Hosp

10:20 – 10:35 am

Considerations on Clinical Outcome Measures & Biomarkers: Pediatric Trials Network Experience

P. Brian Smith, MD, MHS, MPH, Professor of Pediatrics, Duke Univ Medical Ctr

10:35 – 10:50 am

Innovative Trial Designs for Neonatal Studies

Lynne Yao, MD, Director, Div of Pediatric & Maternal Health, US Food & Drug Administration

10:50 – 11:05 am

Extrapolation in Neonates: What is the Role of Clinical Pharmacology?

Ronald J. Portman, MD, Executive Director, Pediatric Therapeutic Area, Novartis Pharmaceuticals Corp

11:05 – 11:15 am

Neonatal Safety Studies

Gilbert J. Burckart, PharmD, Associate Director for Pediatrics, US Food & Drug Administration

11:15 – 11:30 am

International Neonatal Consortium Update

Susan McCune, MD, Deputy Director, Office of Translational Sciences, US Food & Drug Administration

11:30 am – 12:00 pm

Panel Discussion

(including Gerri Baer, MD, Medical Officer/Neonatologist, US Food & Drug Administration)

MONDAY, SEPTEMBER 26, 2016 | Symposium 10 | 1:30 – 5:30 pm

BALLROOM SALON A–C

Streamlining Clinical Pharmacology Strategies During Early Development: Assessment of Drug-Drug Interactions, Food Effect & QTc

DISCOVERY TRACK

CO-CHAIRS:

Suraj G. Bhansali, MS, PhD, Manager, Oncology Clinical Pharmacology, Novartis Pharmaceuticals Corp

Xiao Hu, PhD, Senior Pharmacometrician, Biogen Inc

TARGET AUDIENCE:

The target audience includes clinical pharmacologists, pharmacokineticists and clinicians. The international scientific community in academia, the pharmaceutical & biotechnology industries or regulatory authorities associated with clinical drug development will also be particularly interested in this topic based on the common challenges faced during development of oncology compounds.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Understand challenges specific to oncology clinical drug development;
2. Evaluate the timing of clinical pharmacology studies for oncology compounds in reference to the normal clinical development plan and discuss benefits of doing studies at an early stage;
3. Discuss strategies for early assessment of food effect, QTc and drug-drug interactions (DDI);
4. Discuss considerations to streamline proarrhythmic risk assessment during early clinical development.

1:30 – 1:40 pm

Introduction

Suraj G. Bhansali, MS, PhD, Manager, Oncology Clinical Pharmacology, Novartis Pharmaceuticals Corp and Xiao Hu, PhD, Senior Pharmacometrician, Biogen Inc

1:40 – 2:10 pm

An Overview of Early Clinical Pharmacology Studies: Assessment of Drug-Drug Interactions, Food Effect & QTc in an Oncology Setting

Suraj G. Bhansali, MS, PhD, Manager, Oncology Clinical Pharmacology, Novartis Pharmaceuticals Corp

2:10 – 2:35 pm

Early Assessment of Drug-Drug Interaction Potential in Combination Clinical Trials

Konstantine W. Skordos, PhD, Director, Clinical Pharmacology, Translational Clinical Oncology, Novartis Pharmaceuticals Corp

2:35 – 3:00 pm

Food Effects in Early Cancer Drug Development: More Than Meets the Eye

Lawrence J. Lesko, PhD, Clinical Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Univ of Florida

3:00 – 3:30 pm / **Break**

3:30 – 4:00 pm

It's Time to Revise ICH E14 Guidance: The History, Opportunities, Challenges & Directions of QTc Analysis

Christine Garnett, PharmD, Clinical Analyst, US Food & Drug Administration

4:00 – 4:30 pm

Key Considerations in Study Design & Analysis Methods of New Drugs' QT Assessment Using a Phase 1 Study

Jiang Liu, PhD, Scientific Lead for QT, US Food & Drug Administration

4:30 – 5:00 pm

Using Concentration-QTc Analysis to Obtain a Waiver for TQT Study

Cara Nelson, PhD, Clinical Pharmacologist II, Gilead Sciences Inc

5:00 – 5:30 pm

Panel Discussion

MONDAY, SEPTEMBER 26, 2016 | Symposium 11 | 1:30 – 3:00 pm

BALLROOM SALON D

Cutting-edge Abstract Presentations

DISCOVERY & APPLICATION TRACKS

Offers both CME and CPE Credit

UAN #0238-0000-16-008-L01-P

ACPE – 1.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Lawrence J. Cohen, PharmD, Professor & Coordinator of Interprofessional Education, Univ of North Texas System Coll of Pharmacy

Walter K. Kraft, MD, Professor, Thomas Jefferson Univ

Amalia M. Issa, PhD, Professor & Chair, Personalized Medicine & Targeted Therapeutics, Univ of the Sciences

TARGET AUDIENCE:

The target audience includes physicians, pharmacists and clinical pharmacologists involved in basic and applied clinical research who are interested in state-of-the-art investigations.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Describe at least two of the abstracts from a curated list of the top abstracts submitted for the 2016 ACCP Annual Meeting;
2. Identify a novel area or focus of clinical pharmacology research;
3. Interact with the authors of multiple cutting-edge abstracts from a variety of disciplines.

1:30 – 1:40 pm

Introduction & Abstract Award Winner Announcement

Lawrence J. Cohen, PharmD, Professor & Coordinator of Interprofessional Education, Univ of North Texas System Coll of Pharmacy, Walter K. Kraft, MD, Professor, Thomas Jefferson Univ and Amalia M. Issa, PhD, Professor & Chair, Personalized Medicine & Targeted Therapeutics, Univ of the Sciences

1:40 – 1:49 pm

Abstract #1

Wayne A. Colburn Memorial Award (5 minute presentation; 3 minutes of questions)

1:50 – 1:59 pm

Abstract #2

New Member Abstract Award (5 minute presentation; 3 minutes of questions)

2:00 – 2:09 pm

Abstract #3

(5 minute presentation; 3 minutes of questions)

2:10 – 2:19 pm

Abstract #4

(5 minute presentation; 3 minutes of questions)

2:20 – 2:29 pm

Abstract #5

(5 minute presentation; 3 minutes of questions)

2:30 – 2:39 pm

Abstract #6

(5 minute presentation; 3 minutes of questions)

2:40 – 2:49 pm

Abstract #7

(5 minute presentation; 3 minutes of questions)

2:50 – 2:59 pm

Abstract #8

(5 minute presentation; 3 minutes of questions)

3:00 pm

Wrap Up

MONDAY, SEPTEMBER 26, 2016 | Symposium 12 | 3:30 – 5:30 pm

BALLROOM SALON D

Rethinking Clinical Pharmacology-related Labeling for Improved Utility & Comprehension

DISCOVERY & APPLICATION TRACKS

Offers both CME and CPE Credit

UAN #0238-0000-16-009-L03-P

ACPE – 2 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Joseph A. Grillo, PharmD, Associate Director for Labeling & Health Communications, US Food & Drug Administration

Julie Bullock, PharmD, Senior Director, d3 Medicine LLC

TARGET AUDIENCE:

The target audience includes scientists in the pharmaceutical industry, healthcare providers and regulatory professionals.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Present stakeholder experiences (eg, industry, academia/clinical practice, FDA, cognitive scientist) regarding clinical pharmacology-related information in labeling;
2. Explore different labeling formats (eg, tables, figures, structured text) to further enhance the presentation of clinical pharmacology information in labeling;
3. Provide an overview of key principles included in the FDA Clinical Pharmacology Section Labeling guidance (under revision).

3:30 – 3:40 pm

Introduction

Julie Bullock, PharmD, Senior Director, d3 Medicine LLC

3:40 – 4:00 pm

Developing Clinical Pharmacology Labeling for Improved Utility & Comprehension: Industry Perspective

Dora W. Cohen, BA, MA, Executive Director, Global Labeling, Amgen Inc

4:00 – 4:20 pm

Strategies for Enhancing Quality, Utility & Clarity in Clinical Pharmacology Labeling: A Regulatory Perspective

Joseph A. Grillo, PharmD, Associate Director for Labeling & Health Communications, US Food & Drug Administration

4:20 – 4:40 pm

Utility & Comprehension of Clinical Pharmacology Labeling: A Healthcare Provider Perspective

Patricia W. Slattum, PharmD, PhD, Professor of Pharmacotherapy & Outcomes Science, Virginia Commonwealth Univ

4:40 – 5:00 pm

Enhanced Displays of Clinical Pharmacology Information: Effects on Attention, Comprehension & Memory

Ruth S. Day, PhD, Director, Medical Cognition Laboratory, Psychology & Neuroscience, Duke Univ

5:00 – 5:30 pm

Panel Discussion

(including Eric Brodsky, MD [US Food & Drug Administration])

TUESDAY, SEPTEMBER 27, 2016 | Symposium 13 | 8:00 am – 12:00 pm

BALLROOM SALON A–C

Orphan Drug Development in Adults & Pediatrics: Industry, Academia & Regulatory Perspectives

DISCOVERY TRACK

Offers both CME and CPE Credit

UAN #0238-0000-16-010-L01-P

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

This Symposium is supported in part by an Educational Grant from Amicus Therapeutics

CO-CHAIRS:

Vijay Ivaturi, PhD, Assistant Professor, Univ of Maryland Baltimore

Venkatesh Atul Bhattaram, PhD, Senior Staff Fellow, Office of Clinical Pharmacology, US Food & Drug Administration

TARGET AUDIENCE:

The target audience includes researchers, clinicians, entrepreneurs and academic technology transfer staff interested in orphan drug development.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Describe state-of-the-art research on orphan drug development;
2. Understand the regulatory pathways available for orphan drug development;
3. Facilitate greater research collaboration and creation of learning communities across disciplines, sectors and initiatives;
4. Discuss entrepreneurial opportunities and mechanisms to innovate and excel in orphan drug development.

8:00 – 8:15 am

Introduction

Vijay Ivaturi, PhD, Assistant Professor, Univ of Maryland Baltimore and Venkatesh Atul Bhattaram, PhD, Senior Staff Fellow, Office of Clinical Pharmacology, US Food & Drug Administration

8:15 – 8:40 am

FDA Flexibility in Facilitating Drug Development in Rare Diseases

Devanand Jillapalli, MD, Medical Officer, Office of Orphan Drug Products Development, US Food & Drug Administration

8:40 – 9:10 am

Can Universities Make a Difference in the Development of Orphan Drugs?

James Cloyd III, PharmD, Professor, Neurology & Experimental & Clinical Pharmacology, Univ of Minnesota, Coll of Pharmacy

9:10 – 9:35 am

Drug Development in Rare Neurological Diseases: Clinical Pharmacology Perspective

Bilal S. AbuAsal, PhD, Clinical Pharmacologist, US Food & Drug Administration

9:35 – 10:00 am / **Break**

10:00 – 10:30 am

Bootstrapping Orphan Drug Development

Zachary Rome, BS, MST, Co-founder & Executive Vice President, Patagonia Pharmaceuticals LLC

10:30 – 11:00 am

Statistical Issues In Rare Disease Clinical Trial Design

Anindya Roy, PhD, Professor, Univ of Maryland Baltimore County

11:00 am – 12:00 pm

Panel Discussion

TUESDAY, SEPTEMBER 27, 2016 | Symposium 14 | 8:00 – 9:30 am

BALLROOM SALON D

Clinical Applications of Physiologically-based Pharmacokinetics/ Pharmacodynamics for Pediatrics: Academic, Industry & Regulatory Perspectives

DISCOVERY TRACK

CO-CHAIRS:

Jennifer Sheng, PhD, PharmD, Associate Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb Co

Diansong Zhou, PhD, Director, Quantitative Clinical Pharmacology, AstraZeneca plc

TARGET AUDIENCE:

The target audience includes clinical pharmacologists in the pharmaceutical industry and reviewers at the US Food & Drug Administration.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Describe the opportunities and challenges in pediatric physiologically-based pharmacokinetic and pharmacodynamic (PBPK/PD) modeling;
2. Illustrate how pediatric PBPK modeling can be used to answer clinical development questions with case examples.

8:00 – 8:10 am

Introduction

Jennifer Sheng, PhD, PharmD, Associate Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb Co

8:10 – 8:30 am

Overview of Development of Integrated Pediatric Physiologically-based Pharmacokinetic/ Pharmacodynamic Models

Trevor N. Johnson, PhD, Principal Scientist, Simcyp Ltd

8:30 – 8:50 am

Pediatric PBPK Strategies & Tools During Drug Development

Tycho Heimbach, PhD, Director, Drug Metabolism & Pharmacokinetics, Novartis Pharmaceuticals Corp

8:50 – 9:10 am

Pediatric PBPK Modeling: Regulatory Experience & Perspective

Ping Zhao, PhD, Lead, PBPK Program, Div of Pharmacometrics, US Food & Drug Administration

9:10 – 9:30 am

Panel Discussion

TUESDAY, SEPTEMBER 27, 2016 | Symposium 15 | 10:00 – 11:45 am

BALLROOM SALON D

Combination Therapy in Oncology: Challenges & Strategies in Clinical Pharmacology

APPLICATION TRACK

CO-CHAIRS:

Yilong Zhang, PhD, Principal Scientist, Amgen Inc

Satyendra Suryawanshi, PhD, Associate Director, Bristol-Myers Squibb Co

TARGET AUDIENCE:

The target audience includes clinical pharmacologists, physicians and healthcare professionals, oncology researchers in both industry and academics and graduate students in pharmaceutical sciences and clinical pharmacology.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Understand the combination requirements and challenges in small- and large-molecule oncology drug development;
2. Utilize clinical pharmacology strategies to optimize dose selection in oncology combination trials;
3. Apply mechanistic models including physiologically-based pharmacokinetics (PBPK) to address complex clinical pharmacology issues;
4. Gain regulatory insight on current status of supporting regulatory decisions using PBPK results, including the use of PBPK data in product labels.

10:00 – 10:10 am

Introduction

Yilong Zhang, PhD, Principal Scientist, Amgen Inc

10:10 – 10:30 am

Clinical Perspectives in Combination Requirements & Challenges in Small- & Large-molecule Oncology Drug Development

R. Donald Harvey, PharmD, Associate Professor & Director, Phase I Clinical Trials Program, Winship Cancer Inst, Emory Univ

10:30 – 10:50 am

Application of Physiologically-based Pharmacokinetic Modeling to Facilitate Dose Optimization in Combination Therapy

Karen Rowland Yeo, PhD, Senior Scientific Advisor, Simcyp Ltd

10:50 – 11:10 am

Clinical Pharmacology Considerations in Oncology Combination Studies

Sree Kasichayanula, PhD, Principal Scientist, Amgen Inc

11:10 – 11:30 am

Utility of PBPK in the Oncology Drug Development Experience of Using Quantitative Data Generated from Clinical Pharmacology Programs in Regulatory Decision Making & Product Labels

Ping Zhao, PhD, Lead, PBPK Program, Div of Pharmacometrics, US Food & Drug Administration

11:30 – 11:45 am

Panel Discussion

TUESDAY, SEPTEMBER 27, 2016 | Symposium 16 | 1:30 – 5:30 pm

BALLROOM SALON A–C

Clinical Pharmacology Strategies in Precision Medicine-based Drug Development & Preventive Medicine

DISCOVERY & APPLICATION TRACKS

CO-CHAIRS:

Priyanka Jadhav, PhD, Translational Clinical Pharmacologist, CRC Pharma LLC

Jinshan Shen, PhD, Senior Director, Drug Metabolism & Pharmacokinetics, Radius Health Inc

Manoj P. Jadhav, PhD, Translational Clinical Pharmacologist, CRC Pharma LLC

TARGET AUDIENCE:

The target audience includes healthcare professionals, including physicians, clinical pharmacologists and basic scientists who are involved in drug development and research in industry and academics. The course is also applicable to students pursuing their MD, PhD or PharmD.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Understand recent advances in research and development in the area of precision medicine;
2. Implement recent advances related to research and treatment using a personalized medicine approach, as appropriate;
3. Understand and discuss the role of genetics, pharmacogenomics, Big Data and regulations in the implementation of this concept of precision medicine.

1:30 – 1:40 pm

Introduction

Jinshan Shen, PhD, Senior Director, Drug Metabolism & Pharmacokinetics, Radius Health Inc

1:40 – 2:05 pm

Why Clinical Pharmacology is Positioned Well to Excel in Precision Medicine

Jogarao V. Gobburu, PhD, MBA, Professor, Univ of Maryland

2:05 – 2:30 pm

Clinical Pharmacology of Precision Medicine Treating Cancer Patients

Qi Liu, PhD, Clinical Pharmacology Team Leader, US Food & Drug Administration

2:30 – 3:00 pm

Genetics & Precision Medicine: The Way Forward!

Prasun Mishra, MSc, PhD, Scientist/Principal Investigator, Genentech Inc

3:00 – 3:30 pm / **Break**

3:30 – 3:55 pm

Multi-domain Inference in Healthcare

Mattia Prosperi, PhD, Associate Professor, Univ of Florida

3:55 – 4:20 pm

Clinical Pharmacology in Cardiovascular Precision Medicine

Manoj P. Jadhav, PhD, Translational Clinical Pharmacologist, CRC Pharma LLC

4:20 – 4:45 pm

Pharmacogenomics in Drug Development of Precision Medicine – An FDA Perspective

Michael Pacanowski, PharmD, MPH, Associate Director for Genomics & Targeted Therapy, US Food & Drug Administration

4:45 – 5:30 pm

Panel Discussion

TUESDAY, SEPTEMBER 27, 2016 | Symposium 17 | 1:30 – 5:30 pm

BALLROOM SALON D

Reproducible Visualization & Data Analysis With R

DISCOVERY TRACK

Offers both CME and CPE Credit

UAN #0238-0000-16-018-L-01-P

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CHAIR:

Devin Pastoor, MTOX, Software Engineer & PhD Candidate, Ctr for Translational Medicine, Schools of Pharmacy & Medicine, Univ of Maryland Baltimore

TARGET AUDIENCE:

The target audience includes persons that use R for data management, statistical analysis or visualization. Attendees should have basic R exposure (read in a dataset, basic data management), with varied examples, material and solutions catered to beginner, intermediate and advanced users.

GOALS AND OBJECTIVES:

Following completion of this activity, the learner will be able to:

1. Use best practices in quickly managing, analyzing and visualizing data in a reproducible fashion;
2. Use hands-on examples to introduce and explore a data management pipeline that leverages best-in-class R packages for easy-to-use, powerful workflows.

1:30 – 1:45 pm

Introduction

Devin Pastoor, MTOX, Software Engineer & PhD Candidate, Ctr for Translational Medicine, Schools of Pharmacy & Medicine, Univ of Maryland Baltimore

1:45 – 2:00 pm

Introduction to a Reproducible R Workflow with Rstudio, Rmarkdown

Devin Pastoor, MTOX, Software Engineer & PhD Candidate, Ctr for Translational Medicine, Schools of Pharmacy & Medicine, Univ of Maryland Baltimore

2:00 – 2:20 pm

Introduction to ggplot2 for Data Visualization

Kaori Ito, PhD, Director, Pfizer Inc

2:20 – 2:45 pm

Hands-on Activity

Kaori Ito, PhD, Director, Pfizer Inc

2:45 – 3:00 pm

Solutions Demonstration

Kaori Ito, PhD, Director, Pfizer Inc

3:00 – 3:30 pm / **Break**

3:30 – 4:00 pm

Introduction to Data Management with dplyr

Devin Pastoor, MTOX, Software Engineer & PhD Candidate, Ctr for Translational Medicine, Schools of Pharmacy & Medicine, Univ of Maryland Baltimore

4:00 – 4:15 pm

Additional dplyr & Introduction to tidyr

Vijay Ivaturi, PhD, Assistant Professor, Univ of Maryland Baltimore

4:15 – 5:00 pm

Hands-on Activity Using dplyr, tidyr & ggplot2

Vijay Ivaturi, PhD, Assistant Professor, Univ of Maryland Baltimore

5:00 – 5:30 pm

Wrap Up, Q&A, Additional Resources

Devin Pastoor, MTOX, Software Engineer & PhD Candidate, Ctr for Translational Medicine, Schools of Pharmacy & Medicine, Univ of Maryland Baltimore

Faculty

Last Name	First Name	Activity	Affiliation
Abernethy	Darrell R.	Pre-meeting Workshop 3	Associate Director for Drug Safety, Office of Clinical Pharmacology, US Food & Drug Administration
AbuAsal	Bilal S.	Symposium 13	Clinical Pharmacologist, US Food & Drug Administration
Ahn	Hae-Young	Symposium 7	Deputy Director, Div of Clinical Pharmacology III, US Food & Drug Administration
Amur	Shashi	Pre-meeting Workshop 2	Scientific Lead, Biomarker Qualification Program, US Food & Drug Administration
Arya	Vikram	Symposium 6	Silver Spring, MD
Baer	Gerri	Symposium 9	Medical Officer/Neonatologist, US Food & Drug Administration
Bajaj	Gaurav	Symposium 4	Senior Research Investigator, Bristol-Myers Squibb Co
Barrett	Jeffrey	Symposium 8	Vice President, Translational Informatics, Sanofi
Benjamin	Jonathan	Symposium 3	Medical Director, Amgen Inc
Bergman	Kimberly L.	Symposium 1	Lead Pharmacologist, US Food & Drug Administration
Bhansali	Suraj G.	Symposium 10	Manager, Oncology Clinical Pharmacology, Novartis Pharmaceuticals Corp
Bhattacharya	Indranil	Pre-meeting Workshop 1	Director, Pfizer Inc
Bhattaram	Venkatesh Atul	Symposium 13	Senior Staff Fellow, Office of Clinical Pharmacology, US Food & Drug Administration
Brar	Satjit	Pre-meeting Workshop 4	Associate Director, Clinical Pharmacology, Pfizer Inc
Brodsky	Eric	Symposium 12	Associate Director, Labeling Development Team, Office of New Drugs, US Food & Drug Administration
Bullock	Julie	Symposium 12	Senior Director, d3 Medicine LLC
Burckart	Gilbert J.	Pre-meeting Workshop 3 & Symposium 9	Associate Director for Pediatrics, US Food & Drug Administration
Campanello	Leonard	Symposium 5	Chief of Police, City of Gloucester, MA Police Dept MAFE
Cherala	Ganesh	Pre-meeting Workshop 2	Research Scientist, Research Technologies, Novo Nordisk Inc
Chow	Andrew T.	Symposium 1	Executive Director, Amgen Inc
Cloyd III	James	Symposium 13	Professor, Neurology & Experimental & Clinical Pharmacology, Univ of Minnesota, Coll of Pharmacy
Cohen	Dora W.	Symposium 12	Executive Director, Global Labeling, Amgen Inc
Cohen	Lawrence J.	Symposium 11	Professor & Coordinator of Interprofessional Education, Univ of North Texas System Coll of Pharmacy
Corey	Alfred	Symposium 1	Consultant, AC Pharmaco LLC
Dallmann	Gabriele	Symposium 7	Co-founder, Biopharma Excellence GbR
Davis	John D.	Symposium 4	Senior Director, Regeneron Pharmaceuticals Inc
Day	Ruth S.	Symposium 12	Director, Medical Cognition Laboratory, Psychology & Neuroscience, Duke Univ

Faculty

Last Name	First Name	Activity	Affiliation
Declerck	Paul	Symposium 7	Professor, Dean of the Faculty of Pharmaceutical Sciences, Univ of Leuven
Derendorf	Hartmut	Symposium 7	Distinguished Professor & Chair, V. Ravi Chandran Professor in Pharmaceutical Sciences, Univ of Florida
Doncel	Gustavo F.	Pre-meeting Workshop 2	Scientific Director, CONRAD & Professor of Obstetrics & Gynecology, Eastern Virginia Medical School
Duff	Sir Gordon W.	Pre-meeting Workshop 1	Professor & Chair of the Biotechnology & Biological Sciences Research Council, St Hilda's Coll, Univ of Oxford
Earp	Justin C.	Pre-meeting Workshop 4	Pharmacometrics Reviewer, US Food & Drug Administration
Eissing	Thomas	Pre-meeting Workshop 3	Head of Systems Pharmacology CV, Bayer Technology Svcs GmbH
Faggioni	Raffaella	Pre-meeting Workshop 1	Senior Director, Clinical Pharmacology & DMPK, MedImmune LLC/AstraZeneca plc
Florian	Jeffry	Symposium 8	Team Leader, Div of Pharmacometrics, US Food & Drug Administration
Fossler, Jr	Michael J.	Symposium 5	Vice President, Quantitative Sciences, Trevena Inc
Garnett	Christine	Symposium 10	Clinical Analyst, US Food & Drug Administration
Gibiansky	Leonid	Symposium 2	President, QuantPharm LLC
Gobburu	Jogarao V.	Symposium 16	Professor, Univ of Maryland
Goel	Varun	Pre-meeting Workshop 4	Fellow, Clinical Pharmacology, Novartis Inst for Biomedical Research
Golden	Adam	Pre-meeting Workshop 3	Professor, Internal Medicine, Univ of Central Florida, Coll of Medicine, Associate Chief of Staff, Geriatrics and Extended Care, Orlando Veterans Affairs Medical Ctr
Grillo	Joseph A.	Symposium 12	Associate Director for Labeling & Health Communications, US Food & Drug Administration
Gunn, III	George R.	Symposium 2	Associate Scientific Director, Janssen Research & Development LLC
Gupta	Manish	Symposium 4	Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb Co
Harirforoosh	Sam	Pre-meeting Workshop 2	Associate Professor, Dept of Pharmaceutical Sciences, East Tennessee State Univ, Gatton Coll of Pharmacy
Harvey	R. Donald	Symposium 15	Associate Professor & Director, Phase I Clinical Trials Program, Winship Cancer Inst, Emory Univ
Heimbach	Tycho	Symposium 14	Director, Drug Metabolism & Pharmacokinetics, Novartis Pharmaceuticals Corp
Hendriks	Bart	Symposium 3	Senior Director of Nanoimaging, Merrimack Pharmaceuticals Inc
Hendrix	Craig W.	Pre-meeting Workshop 2	Wellcome Professor & Director, Johns Hopkins Univ School of Medicine
Hu	Xiao	Symposium 10	Senior Pharmacometrician, Biogen Inc
Issa	Amalia M.	Symposium 11	Professor & Chair, Personalized Medicine & Targeted Therapeutics, Univ of the Sciences
Ito	Kaori	Symposium 17	Director, Pfizer Inc

Faculty

Last Name	First Name	Activity	Affiliation
Ivaturi	Vijay	Symposia 13 & 17	Assistant Professor, Univ of Maryland Baltimore
Jacobs	Brian	Symposium 8	Vice President, Chief Medical Information Officer & Chief Information Officer, Children's National Health System
Jadhav	Manoj P.	Symposium 16	Translational Clinical Pharmacologist, CRC Pharma LLC
Jadhav	Priyanka	Symposium 16	Translational Clinical Pharmacologist, CRC Pharma LLC
Jiang	Xiling	Symposium 4	Senior Scientist, Janssen Research & Development LLC
Jillapalli	Devanand	Symposium 13	Medical Officer, Office of Orphan Drug Products Development, US Food & Drug Administration
Johnson	Trevor N.	Symposium 14	Principal Scientist, Simcyp Ltd
Karlsson	Mats O.	Pre-meeting Workshop 4	Professor, Dept of Pharmaceutical Biosciences, Uppsala Univ
Kasichayanula	Sree	Symposia 3 & 15	Principal Scientist, Amgen Inc
Kottilil	Shyam	Symposium 6	Professor of Medicine, Inst of Human Virology, Univ of Maryland
Kraft	Walter K.	Symposium 11	Professor, Thomas Jefferson Univ
Kumar	Parag	Pre-meeting Workshop 2	Director, Clinical Pharmacokinetics Research Lab, National Inst of Health
Lau	S.W. Johnny	Pre-meeting Workshop 3	Senior Clinical Pharmacologist, US Food & Drug Administration
Lee	Jinhee	Symposium 5	Senior Pharmacy Advisor, Substance Abuse & Mental Health Svcs Administration
Leeder	J. Steven	Symposium 9	Director, Div of Clinical Pharmacology, Toxicology & Therapeutic Innovation, Children's Mercy Hosp
Lesko	Lawrence J.	Symposium 10	Clinical Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Univ of Florida
Li	Chunze	Pre-meeting Workshop 1 & Symposium 4	Senior Scientist, Genentech Inc
Liu	Jiang	Symposium 10	Scientific Lead for QT, US Food & Drug Administration
Liu	Qi	Symposium 16	Clinical Pharmacology Team Leader, US Food & Drug Administration
Ma	Lian	Symposium 1	Pharmacometrics Reviewer; US Food & Drug Administration
Mager	Donald E.	Symposium 3	Associate Professor, Univ at Buffalo, State Univ of New York
Marathe	Anshu	Pre-meeting Workshop 4	Team Leader, Div of Clinical Pharmacology II, US Food & Drug Administration
Mayer	Christina L.	Symposium 3	Senior Scientist, Biologics Clinical Pharmacology, Janssen Research & Development LLC
McCune	Susan	Symposium 9	Deputy Director, Office of Translational Sciences, US Food & Drug Administration
Mehrotra	Nitin	Symposium 1	Team Leader, Div of Pharmacometrics, US Food & Drug Administration
Meibohm	Bernd	Pre-meeting Workshop 1	Professor & Associate Dean, Univ of Tennessee Health Science Ctr, Coll of Pharmacy

Faculty

Last Name	First Name	Activity	Affiliation
Mishra	Prasun	Symposium 16	Scientist/Principal Investigator, Genentech Inc
Moorman	Jonathan P.	Pre-meeting Workshop 2	Professor, East Tennessee State Univ, Quillen Coll of Medicine
Mould	Diane R.	Symposia 4 & 8	President, Projections Research Inc
Mulugeta	Lily (Yeruk)	Symposium 8	Scientific Lead for Pediatrics, Div of Pharmacometrics, US Food & Drug Administration
Nelson	Cara	Symposium 10	Clinical Pharmacologist II, Gilead Sciences Inc
Pacanowski	Michael	Symposium 16	Associate Director for Genomics & Targeted Therapy, US Food & Drug Administration
Passey	Chaitali	Symposium 2	Senior Research Investigator, Bristol-Myers Squibb Co
Pastoor	Devin	Symposium 17	Software Engineer & PhD Candidate, Ctr for Translational Medicine, Schools of Pharmacy & Medicine, Univ of Maryland Baltimore
Portman	Ronald J.	Symposium 9	Executive Director, Pediatric Therapeutic Area, Novartis Pharmaceuticals Corp
Powell	Andrea M.	Symposium 1	Pharmacologist, Counter-terrorism & Emergency Coordination, US Food & Drug Administration
Prosperi	Mattia	Symposium 16	Associate Professor, Univ of Florida
Rahman	Atiqur	Pre-meeting Workshop 4	Director, Div of Clinical Pharmacology V, US Food & Drug Administration
Rawal	Sumit	Symposium 2	Scientist, Regeneron Pharmaceuticals Inc
Rome	Zachary	Symposium 13	Co-founder & Executive Vice President, Patagonia Pharmaceuticals LLC
Rosenberg	Amy	Symposium 2	Supervisory Medical Officer, Div of Therapeutic Proteins, US Food & Drug Administration
Rowland Yeo	Karen	Symposium 15	Senior Scientific Advisor, Simcyp Ltd
Roy	Anindya	Symposium 13	Professor, Univ of Maryland Baltimore County
Rusch	Lorraine M.	Symposium 5	Vice President, Commercial Development, Celerion Inc
Schellekens	Huub	Symposium 7	Chair, Professor in Pharmaceutical Biotechnology, Utrecht Univ
Schlender	Jan-Frederik	Pre-meeting Workshop 3	Pharmacist, Scientist Systems Pharmacology, Bayer Technology Svcs GmbH
Sellers	Edward M.	Symposium 5	Professor Emeritus, Pharmaceuticals, Medicine & Psychiatry, Univ of Toronto
Seo	Shirley	Symposium 6	Team Leader, Office of Clinical Pharmacology, US Food & Drug Administration
Shen	Jinshan	Symposium 16	Senior Director, Drug Metabolism & Pharmacokinetics, Radius Health Inc
Sheng	Jennifer	Symposium 14	Associate Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb Co

Faculty

Last Name	First Name	Activity	Affiliation
Shi	Rong	Pre-meeting Workshop 1	Clinical Pharmacology Lead, Bristol-Myers Squibb Co
Sinha	Vikram	Symposium 8	Associate Vice President, Head Quantitative Pharmacology, Merck Research Laboratories
Skordos	Konstantine W.	Pre-meeting Workshop 4 & Symposium 10	Director, Clinical Pharmacology, Translational Clinical Oncology, Novartis Pharmaceuticals Corp
Slattum	Patricia W.	Pre-meeting Workshop 3 & Symposium 12	Professor of Pharmacotherapy & Outcomes Science, Virginia Commonwealth Univ
Smith	P. Brian	Symposia 8 & 9	Professor of Pediatrics, Duke Univ Medical Ctr
Sourgens	Hildegard	Symposium 7	President Elect, European Federation for Exploratory Medicines Development
Stegemann	Sven	Pre-meeting Workshop 3	Professor, Graz Univ of Technology
Sulkowski	Mark	Symposium 6	Professor of Medicine, Johns Hopkins Univ School of Medicine
Sun	Yu-Nien (Tom)	Symposium 3	Senior Director, Janssen Research & Development LLC
Suryawanshi	Satyendra	Symposium 15	Associate Director, Bristol-Myers Squibb Co
van den Anker	John	Symposium 9	Chief, Div of Clinical Pharmacology, Children's National Health System
Wang	Jian	Symposium 9	Senior Clinical Pharmacologist, US Food & Drug Administration
Wang	Yow-Ming C.	Pre-meeting Workshop 1	Clinical Pharmacology (Biologics) Team Leader, US Food & Drug Administration
Yang	Zheng	Pre-meeting Workshop 1	Director, Bristol-Myers Squibb Co
Yao	Lynne	Symposia 8 & 9	Director, Div of Pediatric & Maternal Health, US Food & Drug Administration
Zajicek	Anne	Symposium 8	Branch Chief, National Inst of Health
Zhang	Yilong	Symposium 15	Principal Scientist, Amgen Inc
Zhao	Hong	Symposium 4	Master Reviewer of Clinical Pharmacology/Team Leader, US Food & Drug Administration
Zhao	Ping	Symposia 4, 14 & 15	Lead, PBPK Program, Div of Pharmacometrics, US Food & Drug Administration
Zhou	Diansong	Symposium 14	Director, Quantitative Clinical Pharmacology, AstraZeneca plc
Zhou	Honghui	Pre-meeting Workshop 1	Senior Director & Janssen Fellow, Janssen Research & Development LLC

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Why Join ACCP?

The American College of Clinical Pharmacology (ACCP) is a non-profit membership association with a 45+ year history of providing exceptional interprofessional, accredited Continuing Education programs, publications, networking and other career-enhancing opportunities to a wide spectrum of healthcare professionals using clinical pharmacology in disciplines from research to patient care. Membership includes MDs, PharmDs, PhDs, post-doctoral candidates, students and others from academia, industry, regulatory and clinical entities who are seeking to advance their career through the Member Benefits offered by ACCP.

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- **Free CME and CPE credits on selected articles** in *The Journal of Clinical Pharmacology*.
- **Free online educational activities** Our program of online educational events provides you with 24/7 access and includes the ACCP Fundamentals Tutorials series, the ACCP Virtual Journal Club and the ACCP Therapeutic Dilemmas series (New in 2016!), all available live, then on demand.
- **Discounted registration for the ACCP Annual Meeting**, your source for current, interprofessional ACCME & ACPE-accredited Continuing Education programs in a live format.
- **Free access to Annual Meeting recorded events** for Annual Meeting attendees and discounted access for other Members.
- **Networking opportunities** and, for Students & Trainees, access to Mentors.
- **Opportunity to enhance your leadership skills** by volunteering for one of ACCP's many committees or by Mentoring Students & Trainees.
- **Opportunity to develop educational activities** that make a difference by submitting proposals for ACCP educational events and getting involved in the clinical pharmacology community.
- **Access to the ACCP Job Center** to view jobs and post your resume.
- **Receipt of information from the clinical pharmacology community** for Members who opt in to receive the daily news format, routine recall/drug safety notices from FDA Medwatch, FDA Bursts or AAMC notifications.
- **Receipt of routine updates from ACCP** about developments in the field of clinical pharmacology and future ACCP events.

ACCP membership runs on a calendar year, January to December. Dues renewal notifications are sent in September for the coming year. Persons joining between May 1st and July 31st pay a reduced half-year fee for the current calendar year. Please note that the half-year option is only available the first year of ACCP membership. All future payments must be full-year payments. Persons joining for the first time as of August 1st pay for the coming full calendar year dues and receive August – December of the current year at no cost.

BEFORE YOU APPLY FOR MEMBERSHIP, PLEASE NOTE IF ANY OF THE FOLLOWING PERTAIN TO YOU AND CONTACT KLevy@ACCP1.org FOR EXISTING LOGIN CREDENTIALS:

- Been a Member of ACCP in the past;
- Have attended an ACCP Annual Meeting;
- Presented a poster at an ACCP Annual Meeting;
- Participated as Faculty at an ACCP Annual Meeting.

How to Join ACCP

ACCP has several categories of membership, please join using the membership category that is most appropriate for you.

Please note: A membership application is not considered complete until all required documents have been submitted and acknowledged by the ACCP Executive Office and dues have been paid. All applications must be submitted in full 30 days before the Board of Regents Meetings, the dates of which are noted below:

- February 12, 2017
- May 7, 2017
- September 16, 2017

Persons interested in becoming a Fellow should join as a Member and notify KLevy@ACCP1.org about their interest in becoming a Fellow.

Students & Trainees

Annual Meeting Events for Students & Trainees

Student & Trainee membership and participation in ACCP's Annual Meeting are strongly encouraged and are beneficial on several levels:

- **Mentoring and expert guidance**
- **Student & Trainee-specific events at the Annual Meeting**
- **Substantially discounted registration fees for educational programs**
- **ACCP Student Abstract Awards Program**

Student & Trainee-specific Events

Panel Discussion, Podium Presentations, Student Networking Reception and Poster Tours

On **Sunday, September 25th**, the following events will be hosted:

- **Panel Discussion on Career Guidance** (2:00 – 3:30 pm, White Flint Amphitheater) – A select group of ACCP Mentors whose careers have spanned various settings and disciplines within the field of clinical pharmacology will share their experiences and answer your questions in a relaxed, intimate atmosphere. If you are considering a career that includes any combination of academia, industry, regulatory or clinical roles, don't miss this opportunity to hear what the experts have to say about how their own career paths progressed and what guidance they can provide to ensure your personal success!
- **Podium Presentations** (3:30 – 4:30 pm, White Flint Amphitheater) – Immediately following the Panel Discussion, a select number of Student Abstract Award winners will present their research in a Podium Presentation to an audience of Annual Meeting attendees. Support your colleagues by being part of this important event.
- **Student Networking Reception** (4:30 – 5:30 pm, Brookside Foyer) – After the Podium Presentations, join us for the Student Networking Reception where you can interact on a more personal level with Panel Discussion speakers and other ACCP Mentors to ask the burning questions that will help you make decisions about your future.
- **Poster Tours** (Meet at ACCP Registration Desk at 5:30 pm for a tour from 5:45 – 6:30 pm) – Small groups of Students & Trainees will be hosted by an ACCP Fellow or senior Member to tour the poster area and discuss preselected posters that provide exceptional educational content or presentation.

Special Access to the Experts

On Tuesday, September 27th, from 7:00 – 8:00 am in Ballroom Salon E – H, schools represented by groups of six or more Students & Trainees will be provided with a higher level of access to ACCP leadership. Select ACCP leaders will have a sit-down roundtable session with those Students & Trainees to discuss opportunities for further involvement in ACCP during their training and how to subsequently grow in the organization throughout their careers.

CV Reviews!

All Students & Trainees were encouraged to provide their CV for review and suggestions by ACCP Mentors. If you submitted a resume and did not make arrangements in advance, but wish to meet with the Mentor who reviewed your CV, please stop by the ACCP Registration Desk by the end of the day on Sunday, September 25th, to set up an appointment.

Join, Get Involved and Enjoy the Benefits of ACCP Membership!

Visit us at facebook LinkedIn

The **Student, Trainee & Young Professional Committee**, co-chaired by Daniel Gonzalez, PharmD, PhD and Amelia N. Deitchman, PharmD, is critical in providing guidance regarding Student, Trainee & Young Professional needs and ensuring that those needs are consistently met by ACCP. The committee is comprised of Student Members, Members and Fellows and it focuses on activities at the Annual Meeting and provides guidance on programs, new and old, required to effectively support Students, Trainees & Young Professionals. Have a great idea? Please share it with us at **SOC@ACCP1.org**.

Amelia N. Deitchman, PharmD

Daniel Gonzalez, PharmD, PhD

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Altasciences Clinical Research encompasses Algorithme Pharma in Montreal, QC and Vince & Associates Clinical Research in Overland Park, KS, as well as Algorithme Pharma USA in Fargo, ND, thereby making it one of the largest early-phase clinical CROs in North America. With over 25 years of industry experience, Altasciences provides early-phase clinical development services to an international customer base of biopharmaceutical and generic companies. Altasciences' full-service solutions offering in this critical stage of drug development includes medical writing, biostatistics, data management and bioanalysis.
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Clinical Pharmacology of Miami Inc is a private pharmaceutical research organization dedicated to the conduct of clinical trials (Phase I-IV) in the South Florida area. Kenneth C. Lasseter, MD, Stacy C. Dilzer, RN, BSN and E. Cooper Shamblen are the principals who make up our experienced management team. We have the experience, expertise and facility to conduct safe, well-controlled clinical research with new and existing drugs. Our research facility is state-of-the-art and fully equipped with 120 beds. Our local subject population includes healthy males and females, Hepatically impaired, Renal insufficiency, Hypertensive, Geriatric, Diabetic and Obese volunteers.
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Exhibitors

ERT is a leading provider of high-quality patient safety & efficacy endpoint data collection solutions for use in clinical trial development. ERT delivers a combination of technology, services and consulting that increase the accuracy and reliability of the patient data and improve the efficiency of the clinical development process throughout the product lifecycle.
www.ert.com

The **Medpace Clinical Pharmacology Unit (MCPU)** is an early-phase clinical pharmacology unit, conducting studies in normal healthy volunteers, special populations and patient populations over a spectrum of diseases. Medpace CPU is owned by Medpace Inc. MCPU features a 96-bed, state-of-the-art facility housed on the Medpace clinical research campus, which is centrally located in Cincinnati, Ohio.
www.medpace.com

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www.merck.com

Exhibitors

NOCCR and VRG are privately-owned, multispecialty clinical research groups which have conducted over 2,000 clinical trials in the last 30 years. With combined space exceeding 24,500 sq ft, full-time MDs, Nurse Practitioners, Nurse/Coordinators, EMTs, nursing assistants and separate regulatory, data and recruiting departments, we have earned a reputation for excellence and consistently exceeding enrollment goals. NOCCR-Knoxville is primarily a Phase I Unit with up to 50 beds. It is particularly well suited for conducting First-in-Human trials as it is situated within the Univ of Tennessee Medical Ctr, with a code team and 24-hour critical care coverage. This Unit is widely known for its ability to conduct procedurally-difficult trials and to recruit special populations, including volunteers with renal and hepatic insufficiency, elderly, postmenopausal, heart failure, hypertension and normal healthy volunteers. VRG and NOCCR-New Orleans are primarily focused on conducting later phase studies in a broad array of therapeutic areas.
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Poster Session 1

Sunday, September 25, 2016 / 5:30 – 7:30 pm, Ballroom Salon E – H

Absorption, Distribution, Metabolism & Elimination

Poster	Type	Title	Authors
001	S, SA, P	Impact of Coadministered Minocycline on Plasma Pharmacokinetics and Central Nervous System Distribution of Riluzole	Mahua Sarkar, Raymond Grill, Robert Grossman, Diana Chow
002		Effect of BI 187004, a Selective 11β-HSD1 Inhibitor, on Cytochrome P450 and P-glycoprotein Substrates in Healthy Subjects	John P. Sabo, Fabian Mueller, Arvid Jungnik, Habib Esmaeili, Ralf Thiedmann, Jing Wu, Lois Rowland, Susanna Freude, Laurent Vernillet
003	S, NM	Biliary Excretions of CZ48 and Its Active Moiety, Camptothecin, After Intravenous Administration of CZ48 in Rats	Yu Jin Kim, Yifan Tu, Daping Zhang, Diana Chow
004		Absolute Oral Bioavailability of Selexipag, a Novel Oral Prostacyclin IP Receptor Agonist, in Healthy Subjects	Noémie Hurst, Priska Kaufmann, Muriel Richard, Béatrice Astruc, Jasper Dingemanse
005		A Change in Posture Significantly Affects Plasma Concentrations of Immunoglobulin G, Such as Monoclonal Antibodies	Mattheus (Thijs) P. van Iersel, Maria Velinova, Ruud Lutgerink
008	S, NM	Does Gastric Bypass Surgery Affect Bioavailability of Orally-administered Darunavir? A Physiologically-based Pharmacokinetic Modeling Approach	Jihye Ahn, Bilal AbuAsal, Neha Pandit, Mathangi Gopalakrishnan

Clinical Pharmacokinetics & Pharmacodynamics (cont on next page)

Poster	Type	Title	Authors
009	S, NM	Stabilization of Pitavastatin and Its Lactone Metabolite in Clinical Pharmacokinetic Study Samples	Kristina M. Brooks, Raul Alfaro, David Ng, Jomy George, Tara Kuhn, Leslie G. Biesecker, Parag Kumar
010		Population Pharmacokinetics of Lopinavir/Ritonavir in Mexican Patients Infected with HIV	Miriam D. Carrasco-Portugal, Maria G. Lozoya-Moreno, Gustavo Reyes-Terán, Lina M. Barranco-Garduño, Francisco J. Flores-Murrieta
011		Pharmacokinetics and Safety of NSI-189 in Healthy Subjects: First-in-Human Single, Ascending Dose and Food Effect Study	Ronald Christopher, Lev Gertsik, Molly Sherman, Karl Johe, Larry Ereshefsky
012	NM	The Relative Bioavailability of Rilpivirine Following Administration of the New Tenofovir Alafenamide Single-tablet Regimen Rilpivirine/Emtricitabine/Tenofovir Alafenamide vs Rilpivirine/Emtricitabine/Tenofovir Disoproxil Fumarate	Joseph M. Custodio, Steve West, Heena Patel, Kah Hiing J. Ling, Huyen Cao, Erin Quirk, Brian P. Kearney

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Poster Session 1

Sunday, September 25, 2016 / 5:30 – 7:30 pm, Ballroom Salon E – H

Clinical Pharmacokinetics & Pharmacodynamics (cont on next page)

Poster	Type	Title	Authors
013	S, SA	Potential Implications of Atypical, Nonlinear Plasma Protein Binding on Tigecycline Clinical Pharmacokinetics	Amelia N. Deitchman, Ravi S. Singh, Johannes Kast, Uwe Liebchen, Hartmut Derendorf
014	S, SA, P	Impact of Gastric Bypass Surgery on the Pharmacokinetics and Pharmacodynamics of Simvastatin, Atorvastatin and Rosuvastatin	Asma El-Zailik, Lily K. Cheung, Vadim Sherman, Diana Chow
015		Pharmacokinetics of Oral Tizanidine, a CYP1A2 Substrate, in Mexicans: Evidence for Interethnic Variability	Francisco J. Flores-Murrieta, Miriam D. Carrasco-Portugal
016	S	Population Pharmacokinetic Analysis of Mycophenolate Mofetil in Pre-transplant and Post-transplant Pediatric Patients	Rodrigo Gonzalez, Alan Quiroz-Moguel, Pilar Garcia, Mara Medeiros, Gilberto Castaneda, Hartmut Derendorf
017		Effect of Intrinsic Factors on the Exposure of Faldaprevir in HCV-infected Patients: Pooled Analysis of Data from Three Faldaprevir Phase 3 Studies	Fenglei Huang, Sebastian Haertter, Anne-Marie Quinson
018		Assessment of the Effect of Faldaprevir on the QT Interval in Healthy Subjects	John P. Sabo, Michael Koenen-Bergmann, Anna Unseld, Armin Schultz, Fenglei Huang, Anne-Marie Quinson
019		Effect of Food on the Pharmacokinetics of a 150 mg Oral Dose of BI 1060469, a Novel Oral CRTH2 Antagonist, in Healthy Male Volunteers	Klaus Peter Kammerer, Peter Ruus, Simone Graeber, David Joseph, Verena Endriss, Alison Mackie, Chester Wood
020		The Pharmacokinetics, Pharmacodynamics, Safety, Tolerability and Food Effect of Duvelisib, an Oral, Dual PI3K-δ and PI3K-γ Inhibitor, in Healthy Human Subjects	Jahnavi Kharidia, Mattheus (Thijs) P. van Iersel, Jan Hartstra, Kerstin Allen, Charlotte McKee, Joi Dunbar
021		Safety and Pharmacokinetics of BI 1060469, a Novel Oral CRTH2 Antagonist, in Fed Healthy Females	Peter Ruus, Irene Vroegrijk, David Joseph, Verena Endriss, Alison Mackie, Chester Wood
022	S, NM	Comparative Pharmacokinetic Profiling of Various Polymyxin B Components	Pooja Manchandani, Yanina Dubrovskaya, Song Gao, Vincent H. Tam
023		Pharmacokinetics and Safety of TAK-648 Following Single and Repeat Dosing in Healthy and Type 2 Diabetes Mellitus Subjects	Michael D. Mayer, Juliana Oliveira, Stephanie Moran, Sai Nudurupati, Rui Sun
024	S, NM	Population Pharmacokinetics of Veliparib With and Without Topotecan Plus Carboplatin in Patients With Hematological Malignancies	Shailly Mehrotra, Mathangi Gopalakrishnan, Jogarao V. Gobburu, Jacqueline M. Greer, Ivana Gojo, Judy Karp, Keith Pratz, Michelle A. Rudek
026		Effect of Albiglutide on Cholecystokinin-induced Gallbladder Emptying in Healthy Subjects	Bonnie Shaddinger, Malcolm Young, Julia Billiard, David A. Collins, Nandana Prabhu, Azra Hussaini, Antonio Nino
027	NM	Pharmacokinetic and Pharmacodynamic Modeling of Peptide YY_{3-36} in Mice	Jie Shao, Mong-jen Chen, Philip J. Kuehl, David Vodak, Guenther Hochhaus
028		Bioequivalence Evaluation of Three Olanzapine-containing Tablet Formulations in Healthy Volunteers	Lei Sun, David McDonnell, Wenlei Liu, Denise Carter, Adam Simmons, Lisa L. von Moltke
029		Plasma Pharmacokinetic Profile of Trabedersen – TGF-β2-specific Antisense Oligonucleotide in Cancer Patients	Wen Wang, Larn Hwang
030		Safety and Pharmacokinetics of Multiple Rising, Oral Doses of BI 1060469, a Novel CRTH2 Antagonist, in Fasted Healthy Males and Males with Mild Asthma	Peter Ruus, Irene Vroegrijk, David Joseph, Verena Endriss, Alison Mackie, Chester Wood

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Poster Session 1

Sunday, September 25, 2016 / 5:30 – 7:30 pm, Ballroom Salon E – H

Clinical Pharmacokinetics & Pharmacodynamics

Poster	Type	Title	Authors
031		Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single and Multiple, Oral Doses of BI 187004, a Selective 11β-hydroxysteroid Dehydrogenase1 Inhibitor, in Healthy Subjects and Patients With Type 2 Diabetes Mellitus	Jing Wu, Valerie Nock, Arvid Jungnik, Corinna Schoelch, Michael Wolff, Susanna Freude, Cornelia Schepers, John Yu, Tim Heise, Leona Plum-Moerschel, Fenglei Huang, Laurent Vernillent
032		Population Pharmacokinetics of Canakinumab in Children Younger Than Two Years Old With Cryopyrin-associated Periodic Syndrome	Lucy Xu, Bruno Bieth, Martin Fink, James Kalabus, Haiying Sun

Clinical Pharmacology Education

Poster	Type	Title	Authors
033		Some Thoughts About the Mean Concentration vs Time Plot	Michael J. Fossler, Jr

Clinical Trials & Human Pharmacology

Poster	Type	Title	Authors
034	S	*FPGS* rs1544105 and rs4451422 are Involved With High Levels of Plasmatic Concentration of Methotrexate in Mexican Children With Acute Lymphoblastic Leukemia	Fausto Zaruma-Torres, Ismael Lares-Asseff, Juan L. Chávez-Pacheco, Aarón Reyes-Espinoza, Ossyneidee Gutiérrez-Alvarez, Verónica Loera-Castañeda, María C. Arias-Peláez
035		Cardiac Safety and Pharmacokinetics of Pacritinib: A Phase 1, Randomized, Active- and Placebo-controlled, Three-way Crossover Study	Suliman Al-Fayoumi, Sherri Amberg, Huafeng Zhou, Lindsey Millard, Jack W. Singer, James P. Dean
036		Pharmacokinetics, Pharmacodynamics and Tolerability of Multiple-dose Administration of Cenerimod, a Selective Sphingosine-1-phosphate Subtype 1 Receptor Modulator	Pierre-Eric Juif, Jasper Dingemanse
037		Pharmacokinetics, Pharmacodynamics, Tolerability and Food Effect of Single-dose Administration of Cenerimod, a Selective Sphingosine-1-phosphate Subtype 1 Receptor Modulator, in the First-in-Human Study	Pierre-Eric Juif, Jasper Dingemanse
038		Profiling Adverse Events and Laboratory Measurements in Healthy Volunteers Who Received Placebo in AbbVie Phase 1 Trials	Hong Li, Jack Clifton II, Mukul Minocha, David Carter, Ahmed A. Othman, Yi-Lin Chiu
039		A Phase 1 Dose-escalation Study of the Safety and Pharmacokinetics of Felbinac Trometamol in Healthy Chinese Volunteers	Lihua Wu, Jian Liu, Jianzhong Shentu, You Zhai, Guolan Wu, Xingjiang Hu, Yunliang Zheng, Meihua Lin, Duo Lv, Juan Xu, Huili Zhou, Meixiang Zhu, Minglan Wu

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Poster Session 1

Sunday, September 25, 2016 / 5:30 – 7:30 pm, Ballroom Salon E – H

Oncology

Poster	Type	Title	Authors
040	S, SA	Development and Evaluation of Tri-functional Lipid Nanoparticles for Treatment of HER2-positive Breast Cancer Refractory to HER2 Therapy	Tanaya R. Vaidya, Sihem Bihorel
041	S, SA, NM, P	Failure of Intravenous Busulfan Test Dose Pharmacokinetics to Predict Once-daily Dosing in Pediatric Transplant Recipients	Kristina M. Brooks, Paul Jarosinski, Elizabeth Kang, Jomy George, Nirali N. Shah, John B. Le Gall, Suk See De Ravin, Thomas Hughes, Parag Kumar
042		Echocardiographic Evaluation of Cardiotoxic Drugs: Is Ejection Fraction Adequate?	Gerald H. Sokol, Loretta S. Loftus, Jorge Ayub, Louis Cantilena
043	S	Preclinical Evaluations of Two Vascular Endothelial Growth Factor Inhibitors in Combination With Rapamycin for the Treatment of Hepatocellular Carcinoma	Maher Chaar, Ferraro Mattew, Erica Johnson, Maxime Le Merdy, Ashley Brown, Sihem Bihorel
044	NM	Model-based Evaluations of the Exposure, Efficacy and Safety of a Nivolumab Flat-dosing Regimen in Patients With Melanoma or Non-small Cell Lung Cancer	Xiaochen Zhao, Satyendra Suryawanshi, Yan Feng, Xiaoning Wang, Brent McHenry, Ian M. Waxman, Anand Achanta, Akintunde Bello, Amit Roy, Shruti Agrawal

Translational Medicine, Including Biomarkers and/or Imaging

Poster	Type	Title	Authors
045	NM	Intra-target Microdosing, A Novel Drug Development Approach: Proof-of-Concept in Humans	Tal Burt, David MacLeod, Kihak Lee, Thomas Hawk, Timothy Turkington, Antoinette Santoro, Daniel K. DeMasi, Mark Feinglos, Robert Noveck, Malcolm Rowland

Chronic Pain Management

Poster	Type	Title	Authors
057		Randomized, Double-blind, Placebo- and Comparator-controlled Human Abuse Liability Study of an Experimental, Triple Monoamine Reuptake Inhibitor in Recreational Drug Abusers	Lynn R. Webster, Michael Smith

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Poster Session 2

Monday, September 26, 2016 / 5:30 – 7:30 pm, Ballroom Salon E – H

Applications of Modeling & Simulation

Poster	Type	Title	Authors
046		Application of a Physiologically-based Pharmacokinetic Model for the Evaluation of Single-point Plasma Phenotyping Method of CYP2D6	Rui Chen, Amin Rostami-Hodjegan, Haotian Wang, David Berk, Jun Shi, Pei Hu
047		Comparative Application of Published Top-down and Bottom-up Pharmacokinetic Models of Efavirenz With Respect to Observed Ethiopian Clinical Data	Abiy Habtewold, Andrew Castleman, Joel S. Owen
048		Development of a Physiologically-based Pharmacokinetic Model for Description of Valganciclovir and Ganciclovir Pharmacokinetics	Viera Lukacova, Petra Goelzer, Micaela Reddy, Gerard Greig, Bruno Reigner, Neil Parrott
050		Simulating Altered Omeprazole Kinetics in Elderly Individuals Using Physiologically-based Pharmacokinetic Population Modeling	Jan-Frederik Schlender, Niels Lautenbach, Tobias Kanacher, Michael Block, Thomas Eissing
051		Physiologically-based Pharmacokinetic Modeling to Predict the Human Pharmacokinetics of Olanzapine and Samidorphan When Administered in Combination as ALKS 3831	Lei Sun, Karen Rowland Yeo
052		Nonlinear Mixed-effects Pharmacokinetic-Pharmacogenetic Model of Intravenously-administered Delta-9-tetrahydrocannibinol in Healthy Volunteers	William R. Wolowich, Leah Bensimon, Robert Greif, Maren Kleine-Bruggeney, Hans Sachs, Werner Bernhard, Lorenz Theiler
053	S	Population Pharmacokinetics of Unbound Mycophenolic Acid in Pediatric and Adolescent Patients Post-hematopoietic Stem Cell Transplantation	Daping Zhang, Diana Chow, Jamie L. Renbarger

Biosimilars

Poster	Type	Title	Authors
054	E	Comparison of Metabolic and Mitogenic Response *In Vitro* of the Rapid-acting Insulin Lispro Product SAR342434 and US- and EU-approved Humalog®	Juergen Dedio, Birgit Niederhaus, Marcus Korn, Surya Prakash, Norbert Tennagels
055	E	Use of an *In Vitro* Model of Human Immunity to Evaluate the Innate Immune Profile of Originator and Biological Copies of Insulin Glargine	Ernesto Luna, Pankaj Agrawal, Riyaz Mehta, Maria E. Boone, Charlotte Vernhes, Colombe Denys, Bhaswati Mukherjee, Norbert Tennagels, Donald Drake

Decision Making in Research & Development

Poster	Type	Title	Authors
058		Use of an Obese Population in Phase 1 to Evaluate the Pharmacology of Oral CXA-10, an Endogenous, Nitro-fatty Acid Signaling Agent	Carla Chieffo, Jeff Botbyl, Kim Perry, Thomas M. Blok, Diane K. Jorkasky
059		Placebo as Gold Standard in Randomized, Controlled Trials Based on Literature Search: Potential Confounders and Ethical Concerns	Charles Oo

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Poster Session 2

Monday, September 26, 2016 / 5:30 – 7:30 pm, Ballroom Salon E – H

Drug Interactions

Poster	Type	Title	Authors
060	E	Effects of Multiple-dose Administration of Itraconazole on the Single-dose Pharmacokinetics of Conjugated Estrogens/Bazedoxifene in Postmenopausal Women	Carol Cronenberger, Anna Plotka, Kelly Ryan, Joanne Salageanu, William McKeand
061	S, SA	Communication of Drug Interactions with Gastric Acid-reducing Agents: A Survey of Clinical Practice Guidelines	Edwin Lam, Sue Chih Lee
062	NM	The Effect of Milk Thistle (*Silybum marianum*) and its Main Flavonolignans on CYP2C8 Enzyme Activity in Human Liver Microsomes	Ahmed A. Albassam, John S. Markowitz, Reginald F. Frye
063	S	Levo-tetrahydropalmatine Does Not Affect the Pharmacokinetics of Concomitantly-administered Cocaine in Rats	Shamia Faison, William D. Hedrich, Robert Gharavi, Hongbing Wang, Hazem Hassan
064	E	Effect of Steady-state Esuberaprost on the Safety, Pharmacokinetics and Pharmacodynamics of Warfarin in Healthy Adult Subjects	Gina Patel, Hugh Coleman, Xin Chen, Marni Peterson, Kirby von Kessler, Jordan Shin, Prakash Sista

Experimental Pharmacology in In Vitro & In Vivo Studies

Poster	Type	Title	Authors
065		Defining Endothelin-B Receptor-mediated Neurogenesis in Mice Tolerant to Opioids	Shruti Gulati, Shantel Jones, Seema Briyal, Anil Gulati, Shaifali Bhalla
066		Prenatal Exposure to Ethanol and Oxycodone Affects Neurogenesis and Impairs Development of the Neonatal Rat Brain	Shruti Gulati, Seema Briyal, Mary Leonard, Muhammad Ansari, Muralidhara Devarapalli, Lorene Schweig, Bhagya Puppala, Anil Gulati
067		Extended Therapeutic Window for Neuroprotection by IRL-1620 in the Treatment of Cerebral Ischemia	Ahmed Maki, Seema Briyal, Anil Gulati
068		Effect of Maternal Cannabinoid Abuse on CB1, ETB, VEGF and NGF Expression in the Postnatal Rat Brain	Kevin Cooper, Mary Leonard, Seema Briyal, Aarti Amlani, Preetha Prazad, Ramona Donovan, Anil Gulati
069	NM	Effect of Tidal Volume on Cardiovascular and Blood Gas Parameters in a Lipopolysaccharide Infusion Model of Septic Shock in the Rat	Gwendolyn Pais, Zhong Zhang, Suresh Havalad, Anil Gulati
070		*In Vitro* Pharmacologic Characteristics of Valbenazine and its Metabolites	Dimitri Grigoriadis, Evan Smith, Ajay Madan, Bill Aurora, Haig Bozigian

Mechanism of Action

Poster	Type	Title	Authors
071	S, NM	Development of Dependence After Exposure to Cannabis Smoke in Rats	Abhigyan Ravula, Adriaan Bruijnzeel, Barry Setlow, Marcelo Febo, Darin Jagnarine, Hartmut Derendorf

Model-based Drug Development

Poster	Type	Title	Authors
072	NM	Population Pharmacokinetics and Exposure-Response Modeling Analyses of Golimumab in Pediatric Patients With Moderate-to-Severe Ulcerative Colitis	Yan Xu, Omoniyi Adedokun, Daphne Chan, Chuanpu Hu, Zhenhua Xu, Richard Strauss, Honghui Zhou

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Poster Session 2

Monday, September 26, 2016 / 5:30 – 7:30 pm, Ballroom Salon E – H

Pharmacogenomics

Poster	Type	Title	Authors
074		Analysis of the CYP2D6*10 Allele in Relation to Dextromethorphan O-demethylation Capacity in a Chinese Population	Rui Chen, Xin Zheng, Jun Shi, Pei Hu

Pharmacometrics

Poster	Type	Title	Authors
076	S, SA, P	To Antidote or Not? Web-based Antidote Recommendation Tool for Acute Acetaminophen Overdose	Jessica Wojciechowski, Julie Desrochers, Wendy Klein-Schwartz, Suzanne Doyon, Jogarao V. Gobburu, Mathangi Gopalakrishnan
077		Population Pharmacokinetic and Pharmacodynamic Modeling of Glucalpidase and High-dose Methotrexate Using Modified Michaelis-Menten Elimination Model	Toshimi Kimura, Hiroshi Kawamoto, Yutaka Fukaya, Shinobu Kashiwase, Mariko Takahashi
078		Voriconazole Dosing in Children Under Two Years	Michael Neely, Xiaowei Fu, Ashley Margol, Teresa Rushing, Siyu Liu, Stan Louie
079	E	Disease-Drug Interaction of Sarilumab and Simvastatin in Patients With Rheumatoid Arthritis	Eun B. Lee, Nikki Daskalakis, Christine Xu, Anne Paccaly, Barry Miller, Roy Fleischmann, Inga Bodrug, Alan Kivitz
080		Model-based Meta-analysis of Progression-free Survival Time in Non-Hodgkin's Lymphoma Patients	Mengyao Li, Ahmed Hamed Salem, Shekman Wong, Kevin Freise

Regulatory Issues

Poster	Type	Title	Authors
081		Is Generic Tacrolimus Bioequivalent In Patients?	Alfred H. Balch, Tian Yu, Joseph E. Rower, Joseph R. Sherbotie, E.K. Korgenski, Catherine M.T. Sherwin
082	NM	Impact of Variability on Therapeutic Success for Drugs with Narrow Therapeutic Index	Elyes Dahmane, Mathangi Gopalakrishnan, Liang Zhao, Lanyan Fang, Jogarao V. Gobburu, Vijay Ivaturi
083	NM	A Signal-to-Noise Ratio Classification System of Drugs to Investigate Generic Drug Ineffectiveness Claims	Eliford N. Kitabi, Vijay Ivaturi, Lanyan Fang, Liang Zhao, Jogarao V. Gobburu, Mathangi Gopalakrishnan
084		Evaluation of QT Variation Over 24 h: Correlation With Food Intake	Jörg Täubel, Dilshat Djumanov, Sara Fernandes, Georg Ferber
085		Stability of the Effect of a Standardized Meal on QTc	Jörg Täubel, Sara Fernandes, Georg Ferber

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Monday, September 26, 2016 / 5:30 – 7:30 pm, Ballroom Salon E – H

Risk Management, Legal Issues

Poster	Type	Title	Authors
086		Risk-based Monitoring: A Global Study Focusing on Perception and Merits Among Clinical Investigational Sites	Prajna Kumar, Manoj P. Jadhav

Safety & Efficacy

Poster	Type	Title	Authors
087		QT Correction For Heart Rate: Use of the Absolute Correction Factor	Charles Oo, Thomas Chou, Michael J. Fossler, Jr

Special Populations, Including Women, Children, the Elderly & Obese Patients

Poster	Type	Title	Authors
088	S, SA, P, NM	Dose Optimization of Dichloroacetate Using a Semi-mechanistic Population Pharmacokinetic Model	Naveen Mangal, Albert Shroads, Taimour Langaee, Peter Stacpoole, Stephan Schmidt
089	S, SA	Development and Qualification of a Pediatric Population-based Pharmacokinetic Model for Biologics in PK-Sim®	Sumit Basu, Christoph Niederalt, Haitao Yang, Yi Ting Lien, Thomas Eissing, Stephan Schmidt
090	S	Vancomycin-associated Nephrotoxicity Among Pediatric Patients With Hematologic Malignancy	Rose Caston, Jonathan E. Constance, Alfred H. Balch, E.K. Korgenski, Catherine M.T. Sherwin
091	S	Pharmacokinetics of Clofarabine in Pediatric Subjects Prior to Allogenic Hematopoietic Cell Transplantation	Aksana K. Jones, Vijay Ivaturi, Janel Long-Boyle
092		Prediction of Valganciclovir and Ganciclovir Pharmacokinetics in Different Pediatric Groups Using a Physiologically-based Pharmacokinetic Model	Viera Lukacova, Petra Goelzer, Micaela Reddy, Gerard Greig, Bruno Reigner, Neil Parrott
093		Further Validation of a Novel Descriptor of Renal Drug Elimination in Neonates Using Teicoplanin	Virginia Ramos-Martín, Walter Yamada, Michael Neely
094	E	A Comparison of Safety and Pharmacokinetics of Esuberaprost (BPS-314*d*-MR) in Subjects with Normal, Mild and Moderate Hepatic Impairment	Gina Patel, Thomas Marbury, Kenneth Lasseter, Jolene K. Berg, Xin Chen, Stephanie Peychal, Kirby von Kessler, Jordan Shin, Prakash Sista
095		Venetoclax Pharmacokinetics in Hematological Malignancies Subjects with Renal and Hepatic Impairment	Aksana Jones, Kevin Freise, Suresh Agarwal, Maria Verdugo, Rod Humerickhouse, Shekman Wong, Ahmed Hamed Salem

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