ACCP

American College of Clinical Pharmacology

Advancing Clinical Care through Pharmacology®

2017 Annual Meeting
American College of Clinical Pharmacology

Emerging Technologies in Clinical Pharmacology

September 17 – 19, 2017

Hilton San Diego Resort & Spa, San Diego, CA

Co-chairs: ***Gilbert J. Burckart, PharmD & Catherine MT Sherwin, PhD, MS***

FINAL PROGRAM

ACCP
American College of Clinical Pharmacology
Advancing Clinical Care through Pharmacology®

Join Us for the 2018 ACCP Annual Meeting!

Discovery & Innovation in Clinical Pharmacology: *Application to Patient Care*

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

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

FUTURE MEETINGS:

2019 ACCP Annual Meeting
September 15 – 17, 2019
Fairmont Chicago Millennium Park, Chicago, IL

Did You Know?

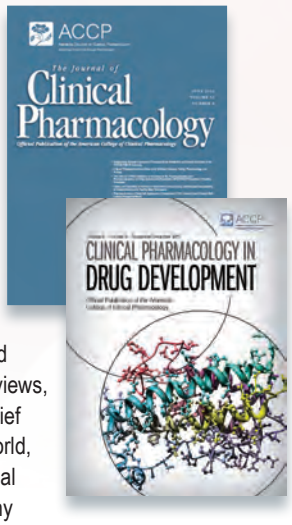
Use the expanded ACCP Mobile App to find all the meeting information you're looking for!

- Customize your profile on the App and make yourself available to establish contact and network with fellow attendees by chat/instant message
- View profiles of Faculty, Exhibitors & Sponsors, Award Winners and ACCP Staff with contact information
- Detailed schedule of events organized by each day and track, including times, locations and session description, with search functionality
- Presentations from all sessions available real time and archival viewing (.pdf format) during and after the event
- Access Session Evaluation Links and CE Post-event Test Links
- See a map of the Hilton San Diego Resort & Spa

ACCP continues to expand its Continuing Education Program!

An accredited provider of Continuing Medical Education (CME) and Continuing Pharmacy Education (CPE), ACCP has further expanded its Continuing Education Program. In 2017, ACCP enhanced its webinar offering, including live and On Demand events for the ACCP Virtual Journal Club, ACCP Fundamentals Tutorials webinars, ACCP Therapeutic Dilemmas and other webinars. See page 56 for more information.

Publish Your Manuscript in *The Journal of Clinical Pharmacology*



The Journal of Clinical Pharmacology (JCP) has seen a 23% increase over the previous year in full-article downloads. With its highly-skilled, dedicated Editorial Board, the JCP boasts some of the fastest turnaround times on first and final decisions, and manuscript submitters routinely comment on the rapid turnaround. Original research articles, reviews, commentaries, letters to the editor and brief reports are submitted from all over the world, making the JCP a truly international journal for scientists and clinicians spanning many disciplines. Themed supplements and themed virtual issues provide a unique focus that highlights articles of interest on current topics. The JCP also publishes ACCP Policy Statements as they are available, as well as the Core Entrustables: Pearls for Practice™ articles.

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

Clinical Pharmacology in Drug Development (CPDD) is becoming well known as an international, peer-reviewed journal focused on publishing high-quality clinical pharmacology studies in drug development. CPDD has seen a number of exciting changes in the last year, beginning with the addition of international colleagues to the Editorial Board, an expanding international reach resulting in one-third of manuscripts being submitted from colleagues outside the US and steadily-increasing submission rates. Of appeal to authors is the rapid processing time, providing prompt publication of study results. Plans are in place to increase the size of the journal in the coming years to accommodate this increase in demand.

Dr. David J. Greenblatt, Editor-in-Chief, spearheaded the application for MEDLINE® indexing of CPDD through the National Library of Medicine. The application was approved in early 2016 and CPDD content is now searchable via MEDLINE®/PubMed®.

Attending the Meeting as a Student or Trainee?

ACCP has planned a series of events specifically to benefit Students, Trainees & Young Professionals! See page 41 for details.

Interested in joining ACCP?

Stop by the ACCP Registration Desk for complete information or to complete a profile and pay 2018 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 the Pavilion 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. Please see pages 43 – 46 for more information.

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

ACCP Registration Desk Hours / Foyer

Friday, September 15th	4:00 – 7:00 pm	Foyer
Saturday, September 16th	7:00 am – 5:30 pm	Foyer
Sunday, September 17th	6:30 am – 7:00 pm	Foyer
Monday, September 18th	7:00 am – 7:00 pm	Foyer
Tuesday, September 19th	7:00 am – 5:30 pm	Foyer

Lost & Found

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

ACCP
American College of Clinical Pharmacology
Advancing Clinical Care through Pharmacology®

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American College of Clinical Pharmacology 2017 Program Committee

Co-chairs:

Gilbert J. Burckart, PharmD
Catherine MT Sherwin, PhD, MS

Members:

John N. van den Anker, MD, PhD
Lawrence J. Cohen, PharmD
Amelia N. Deitchman, PharmD
Lorraine M. Rusch, PhD
Laurent Vernillet, PharmD, PhD
Honghui Zhou, PhD

Letter of Welcome from President & Program Co-chairs

Welcome to the 2017 ACCP Annual Meeting!

Emerging Technologies in Clinical Pharmacology

#2017ACCP

Dear Colleague:

It is our pleasure to welcome you to the **2017 Annual Meeting** of the **American College of Clinical Pharmacology (#2017ACCP)**, ***Emerging Technologies in Clinical Pharmacology.*** The 2017 Annual Meeting Program Committee, co-chaired by Drs. Catherine MT Sherwin and Gilbert J. Burckart, has worked diligently to provide a diverse and exceptional educational program to meet the needs of healthcare professionals and scientists with an interest in one or more of the myriad of applications of clinical pharmacology ranging from research and drug development to patient care. Speakers spanning the breadth of academia, industry, regulatory agencies, consulting companies and clinical specialties will present educational and scientific programs organized into topic tracks, allowing attendees to uniquely tailor content selection to their individual interests.

The four Pre-meeting Workshops on Saturday, September 16th, cover topics such as the labeling of off-patent medications for pediatric use, perspectives on physiologically-based pharmacokinetic modeling for labeling initiatives, therapeutic drug monitoring in advancing patient care and strategies for dose selection of therapies used in different areas of oncology. The 3-Day meeting begins with a Plenary Session on *Predicting Pharmacokinetics/Pharmacodynamics in the Individual Patient*: *Separating Reality from Hype* by Leslie Z. Benet, PhD, Professor, Univ of California, San Francisco, and continues with a mixture of several shorter Symposia combined with our traditional four-hour educational format. Major clusters of topic areas include: **drug development** – innovative approaches to post-marketing surveillance, master protocols, the path forward after a failed primary endpoint assessment, early-phase study designs, modeling of adherence, challenges and opportunities of inhaled medicines and HIV/AIDS in the 21st century; **pediatrics** – clinical trial simulations, efficacy of antiepileptic drugs for specific indications, drug effect on pediatric bone health, therapeutic options for the treatment of obesity and the use of kinase inhibitors in pediatric patients; **pharmacometrics** – optimizing dosage and frequency; and **clinical** – the next wave of cancer therapies and the highly-anticipated Tuesday afternoon events on the evolving science of biosimilars and the opioid abuse & misuse epidemic.

The Invited Keynote, William E. Evans, PharmD, Faculty Member, Endowed Chair in Pharmacogenomics, St Jude Children's Research Hosp, will speak at the Lunch & Awards Session on Monday.

A series of special Student, Trainee & Young Professional-focused programs on Sunday, September 17th, will provide exposure to innovative science and career development opportunities.

Poster Sessions held on Sunday and Monday evening will focus on new findings and preliminary data presented by a wide spectrum of attendees.

Enjoy the chance to socialize and network at the Evening Receptions during the Poster Sessions, at twice-daily tea/coffee breaks and at the Lunch & Awards Sessions on Sunday and Monday.

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.

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 2017 ACCP Annual Meeting and look forward to your participation and feedback!

John N. van den Anker, MD, PhD
ACCP President

Gilbert J. Burckart, PharmD
Program Co-chair

Catherine MT Sherwin, PhD, MS
Program Co-chair

Program at a Glance

FRIDAY, SEPTEMBER 15, 2017

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

ACCP Executive Committee Meeting & Dinner
6:00 – 9:00 pm | *Private Dining Room*

SATURDAY, SEPTEMBER 16, 2017

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

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

Pre-meeting Workshop 1 | **8:00 am – 12:00 pm**
Should Off-patent Medications Be Labeled for Pediatric Use?: ACCP/PPAG Jointly-sponsored Symposium
CO-CHAIRS: Michael D. Reed, PharmD and Gilbert J. Burckart, PharmD
St Tropez

Pre-meeting Workshop 2 | **8:00 am – 12:00 pm**
Best Practice Approaches to Physiologically-based Pharmacokinetic Modeling for Labeling Initiatives: Industry & Regulatory Perspectives
CO-CHAIRS: Karthik Venkatakrishnan, PhD and Karen Rowland Yeo, PhD
Monte Carlo

Pre-meeting Workshop 3 | **1:30 – 5:30 pm**
Therapeutic Drug Monitoring in Advancing Patient Care: Is This Time Different?
CO-CHAIRS: Neeraj Gupta, PhD and Manish Gupta, PhD
St Tropez

Pre-meeting Workshop 4 | **1:30 – 5:30 pm**
Modeling & Simulation Strategies for Dose Selection of Targeted Anticancer Agents
CO-CHAIRS: Ahmed H. Salem, PhD and Murad Melhem, PhD
Monte Carlo

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

2017 – 2018 Annual Meeting Program Committee Meeting
3:00 – 4:30 pm | *Portofino*

Public Policy Committee Meeting
3:00 – 4:30 pm | *Boardroom*

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

Regents & Awards Dinner (invitation only)
6:30 – 8:30 pm | *Terrazza Ballroom*

SUNDAY, SEPTEMBER 17, 2017

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

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

Welcome & Opening Remarks by President of ACCP
7:45 – 8:00 am | *Monte Carlo*

Plenary | **8:00 – 9:30 am**
Predicting Pharmacokinetics/Pharmacodynamics in the Individual Patient: Separating Reality from Hype
Leslie Z. Benet, PhD
Monte Carlo

Symposium 1 | **10:00 am – 12:00 pm**
Innovative Scientific & Risk-based Quantitative Approaches to Post-marketing Surveillance of New & Generic Drug Products
CO-CHAIRS: Lawrence J. Lesko, PhD and Lanyan (Lucy) Fang, PhD
Monte Carlo

Symposium 2 | **10:00 am – 12:00 pm**
Optimizing Dose/Dosing Frequency for a Biologic: Clinical, Regulatory & Commercial Perspectives
CO-CHAIRS: Gaurav Bajaj, PhD and Sumit Rawal, PhD
San Marino

Lunch & Awards Session | **12:10 – 1:20 pm**
San Marino & Monte Carlo

- ACCP Distinguished Investigator Award
- ACCP Honorary Fellowship Award
- Nathaniel T. Kwit Memorial Distinguished Service Award
- McKeen Cattell Memorial Award

Symposium 3 | **1:30 – 3:30 pm**
Master Protocols in Drug Development
CO-CHAIRS: Dionna J. Green, MD and Kevin Watt, MD, PhD
Monte Carlo

Symposium 4 | **1:30 – 5:30 pm**
Next Wave in Cancer Medicine: Mechanisms & Progress for Emerging Therapeutics
CO-CHAIRS: Lucy Lee, PharmD and Luna Musib, PhD
San Marino

Student Panel Discussion & Career Guidance
1:30 – 3:00 pm | *Las Palmas & Marseilles*

Student Poster Presentations
3:00 – 4:00 pm | *Las Palmas & Marseilles*

Student Networking Reception
4:00 – 5:00 pm | *Fresco's Lounge*

Symposium 5 | **4:00 – 5:30 pm**
Clinical Trial Simulations in Pediatric Drug Development
CO-CHAIRS: Janelle Burnham, MD and Daniel Gonzalez, PharmD, PhD
Monte Carlo

Opening Reception & Poster Session 1 & Exhibits
5:30 – 7:30 pm | *Pavilion*

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

Program at a Glance

MONDAY, SEPTEMBER 18, 2017

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

Continental Breakfast
7:00 – 8:00 am | *Pavilion*

Exhibit Hall Open
7:00 – 10:00 am | *Pavilion*

Annual Business Meeting
7:15 – 8:00 am | *San Marino*

Symposium 6 | **8:00 – 9:30 am**
Therapeutic Options for Obesity Treatment in Children, Adolescents & Young Adults
CO-CHAIRS: Catherine MT Sherwin, PhD, MS and Janelle D. Vaughns, MD
San Marino

Symposium 7 | **8:00 am – 12:00 pm**
Modeling of Adherence: Applications in Drug Development & Clinical Practice
CO-CHAIRS: Ayyappa Chaturvedula, PhD and Mark Sale, MD
Monte Carlo

Symposium 8 | **10:00 am – 12:00 pm**
Kinase Inhibitors in Pediatric Patients: Experiences, Pharmacology & Future Applications
CO-CHAIRS: Jonathan Constance, PhD and Geert W. 't Jong, MD, PhD
San Marino

Lunch & Awards Session | **12:10 – 1:20 pm**
San Marino & Monte Carlo

- 2017 ACCP Student & Trainee Abstract Awards
- Wayne A. Colburn Memorial Award
- ACCP New Member Abstract Award
- ACCP Member-Get-a-Member Awards
- Special Acknowledgement
- Invited Keynote Address
- BMS Mentorship in Clinical Pharmacology Award

Symposium 9 | **1:30 – 3:30 pm**
What to Do After a Pivotal Trial Has Failed Primary Endpoint Assessment: Totality of Evidence-based Drug Development Challenges & Opportunities
CHAIR: Yan Xu, PhD
San Marino

Symposium 10 | **1:30 – 5:30 pm**
Challenges & Opportunities in the Development of Inhaled Medicines
CO-CHAIRS: Clive Page, BSc, PhD and Anne Lexmond, PharmD, PhD
Monte Carlo

Exhibit Hall Open | **3:00 – 8:00 pm** | *Pavilion*

Symposium 11 | **4:00 – 5:30 pm**
Pioneering NAFLD/NASH Early-phase Clinical Pharmacology Study Designs
CO-CHAIRS: Lorraine M. Rusch, PhD and Sabina Paglialunga, PhD
San Marino

Evening Reception & Poster Session 2 & Exhibits
5:30 – 7:30 pm | *Pavilion*

Editorial Board Dinner (invitation only)
7:30 – 9:30 pm | *Terrazza Ballroom*

TUESDAY, SEPTEMBER 19, 2017

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

Continental Breakfast
7:00 – 8:00 am | *Pavilion*

Exhibit Hall Open
7:00 – 10:00 am | *Pavilion*

Student Event: Special Access to the Experts
7:00 – 8:00 am | *Portofino*

Education Committee Meeting
7:00 – 8:00 am | *Las Palmas*

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

Symposium 12 | **8:00 – 9:30 am**
Assessment of Drug Effect on Pediatric Bone Health
CHAIR: Gilbert J. Burckart, PharmD
San Marino

Symposium 13 | **8:00 am – 12:00 pm**
21st Century HIV/AIDS: An Evolving Drug Development & Technology Paradigm
CO-CHAIRS: Jomy George, PharmD and Parag Kumar, PharmD
Monte Carlo

Symposium 14 | **10:00 am – 12:00 pm**
Full Extrapolation of Efficacy from Adults to Children of Antiepileptic Drugs Indicated for the Treatment of Partial-onset Seizures
CHAIR: Angela Men, PhD, MD
San Marino

Lunch
12:10 – 1:20 pm | *San Marino & Monte Carlo*
Lunch is provided, but there is no organized event; pick up lunch and you are welcome to sit outside or in the meeting rooms

Symposium 15 | **1:30 – 5:30 pm**
Biosimilars: An Evolving Science
CO-CHAIRS: Darrell R. Abernethy, MD, PhD and Bernd Meibohm, PhD
San Marino

Symposium 16 | **1:30 – 5:30 pm**
Opioid Abuse & Misuse: A Rising Epidemic in America
CO-CHAIRS: Sam Harirforoosh, PharmD, PhD and Arsham Alamian, PhD, MSc, MACE
Monte Carlo

Invited Keynote

Monday, September 18, 2017 | Lunch & Awards Session | San Marino & Monte Carlo Rooms

William E. Evans, PharmD

Faculty Member, Endowed Chair in Pharmacogenomics, St Jude Children's Research Hosp

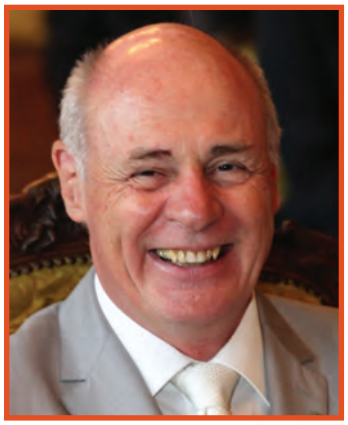
"How Emerging Technologies in Clinical Pharmacology are Driving Precision Medicine in Cancer: Acute Leukemia as a Paradigm"

Dr. Evans joined St Jude Children's Research Hosp (SJCRH) as a student in 1972, chaired the Pharmaceutical Sciences Dept from 1986–2002, served as Scientific Director & Executive Vice President from 2002–2004 and as Chief Executive Officer of SJCRH from 2004–2014. He currently holds the ALSAC Endowed Chair of Pharmacogenomics at SJCRH and is a Professor at the Univ of Tennessee Coll of Pharmacy and Medicine.

Dr. Evans received his BSc and PharmD degrees from the Univ of Tennessee Ctr for the Health Sciences (1973, 1974) and has received honorary doctoral degrees from Rhodes Coll, the Ohio State Univ, the Univ of Florida, the Medical Univ of South Carolina and Rosalind Franklin Univ of Medicine and Science.

For the past 40 years, his research has focused on the pharmacodynamics and pharmacogenomics of anticancer agents in children with acute lymphoblastic leukemia, for which he has received three consecutive National Inst of Health MERIT Awards from the National Cancer Inst. Dr. Evans has authored over 400 scientific publications. He has received several national awards for his research, including the 2009 Pediatric Oncology Award from the American Society of Clinical Oncology (shared with Mary V. Relling of SJCRH), the 2009 Team Science Prize from the American Association of Cancer Research (shared with leukemia colleagues at SJCRH), the 2012 Remington Medal from APhA and the 2013 Oscar B. Hunter Award from the American Society of Clinical Pharmacology and Therapeutics. He was elected to the Inst of Medicine of the National Academy of Sciences in 2002, the US National Academy of Medicine and the German National Academy of Sciences (2016).

2017 ACCP Recognition Award Winners



ACCP Distinguished Investigator Award

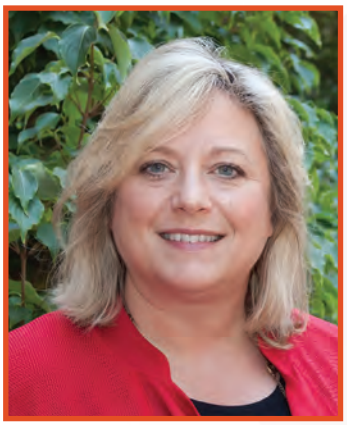
Sunday, September 17, 2017 | Lunch & Awards Session | San Marino & Monte Carlo Rooms

Nick Holford, MBChB, FRACP, FAAPS, FISoP – Professor of Clinical Pharmacology, Univ of Auckland, Auckland, New Zealand

"Nomogram to Next Dose"

The ACCP 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.

Dr. Holford has dedicated his career to advancing the science of clinical pharmacology. Some of his key contributions include the development of theory-based approaches such as allometric scaling, greatly aiding pediatric dosing and drug development, clinical trial simulation, disease progression modeling and the development of web-based dosing tools. He is viewed as a key thought leader in the field of clinical pharmacology and pharmacometrics and is a very worthy recipient of the 2017 ACCP Distinguished Investigator Award.



ACCP Honorary Fellowship Award

Sunday, September 17, 2017 | Lunch & Awards Session | San Marino & Monte Carlo Rooms

Angela DM Kashuba, BScPhm, PharmD, DABCP – John A. & Deborah S. McNeill Jr Distinguished Professor; Chair, Div of Pharmacotherapy & Experimental Therapeutics, Eshelman School of Pharmacy; Director, Clinical Pharmacology & Analytical Chemistry Core, UNC Ctr for AIDS Research; Adjunct Professor of Medicine, UNC School of Medicine, Div of Infectious Diseases

"The Power of Pharmacology to Influence a Field"

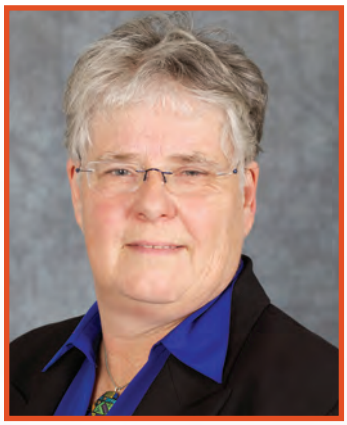
The ACCP Honorary Fellowship Award is given annually to a Non-member of ACCP and is meant to recognize primary activities within the immediate domain of clinical pharmacology. The award recognizes overall contributions to the field, rather than any particular scientific work, by a senior investigator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

Dr. Kashuba has authored over 200 manuscripts and has received over $25 million in research funding. She leads a research group focused on optimizing antiretroviral pharmacology in the treatment, prevention and eradication of HIV infection. She is currently a member of the Advisory Committee for the Office of Research on Women's Health at the National Inst of Health, making her an outstanding recipient of the 2017 ACCP Honorary Fellowship Award.

2017 Honors & Awards Committee

April M. Barbour, PhD • Vera S. Donnenberg, PhD • Jomy George, PharmD, BCPS (AQ-ID)
Daniel Gonzalez, PharmD, PhD • Navin S. Goyal, PhD
Howard E. Greenberg, MD, MSE, MBA • Manoj P. Jadhav, PhD
Lily A. Mulugeta, PhD • Martina D. Sahre, PhD • Laurent Vernillet, PharmD, PhD

2017 ACCP Recognition Award Winners



Nathaniel T. Kwit Memorial Distinguished Service Award

Sunday, September 17, 2017 | Lunch & Awards Session | San Marino & Monte Carlo Rooms

Susan K. McCune, MD – Director, Office of Pediatric Therapeutics, Office of the Commissioner, US Food & Drug Administration

"The Clinical Pharmacology of Caffeine & the Legacy of Dr. Nathaniel T. Kwit"

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 ACCP 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.

Dr. McCune has directed a diverse number of initiatives that have promoted innovation in clinical trial design and regulatory science, as well as cross-disciplinary and cross-sector collaboration. She led the CDER Critical Path Innovation Meetings, served as the Director of the Translational Medicine Team in the Office of Translational Sciences in CDER, was the Co-director of the CDER Biomarker Qualification Program and was instrumental in the launch of the International Neonatal Consortium. Currently, she is continuing to encourage innovative and collaborative strategies in the pediatric arena as the Director of the Office of Pediatric Therapeutics at the US FDA. Her commitment to fostering innovation and collaboration make her an outstanding recipient of the 2017 Nathaniel T. Kwit Distinguished Service Award.

McKeen Cattell Memorial Award

Sunday, September 17, 2017 | Lunch & Awards Session | San Marino & Monte Carlo Rooms

Huanian Zhang, BS – Licensed Pharmacist, Wuhan Children's Hosp, China

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: **"Pharmacokinetic Characteristics and Clinical Outcomes of Vancomycin in Young Children With Various Degrees of Renal Function"** Authors: Huanian Zhang, BS, Yang Wang, BS, Ping Gao, MS, Jiasheng Hu, MS, Yujun Chen, MS, Long Zhang, MD, Xiantao Shen, MS, Hua Xu, BS and Qiong Xu, MS. Published in *The Journal of Clinical Pharmacology*. Volume 56, Issue 6, pages 740–748, December, 2015.

2017 ACCP Recognition Award Winners

Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award

Monday, September 18, 2017 | Lunch & Awards Session | San Marino & Monte Carlo Rooms

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

"The Millennial Clinical Pharmacologist: How to Tackle the Brave New World"

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

Dr. Meibohm has served as a mentor for numerous postdoctoral fellows, graduate and undergraduate students and visiting scientists. Most importantly, the achievements of the mentees under his guidance are impressive, including not only scientific publications and presentations, but also active involvement and leadership in professional organizations. These contributions and more make Dr. Meibohm a very well-deserving recipient of the 2017 Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award.

ACCP Abstract Awards Program & Member-Get-a-Member Awards

Monday, September 18, 2017 | Lunch & Awards Session | San Marino & Monte Carlo Rooms

2017 ACCP Student & Trainee Abstract Awards

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.

ACCP 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.

2017 ACCP Student & Trainee Abstract Award Winners

- **Kristina M. Brooks, PharmD (Poster #047)** *National Inst of Health, Bethesda, MD*
- **Michael F. Hwang, PharmD (Poster #017)** *Univ of North Carolina, Rowland Heights, CA*
- **Satyawan B. Jadhav, PhD (Poster #071)** *Univ of Florida, Gainesville, FL*
- **Vipada Khaowroongrueng, MS (Poster #054)** *Univ of Florida, Coll of Pharmacy, Gainesville, FL*
- **Harisudhan Thanukrishnan, MPharm (Poster #072)** *Univ of Pittsburgh, Pittsburgh, PA*
- **Hechuan Wang, MS (Poster #094)** *Univ of Maryland, Baltimore, MD*
- **Elaine F. Williams, PhD, RN (Poster #073)** *Children's National Health System, Washington, DC*
- **Jincheng Yang, BS (Poster #090)** *Univ of California, San Diego, La Jolla, CA*

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 24.5 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 24.5 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Workshop 1: ***Should Off-patent Medications Be Labeled for Pediatric Use? ACCP/PPAG Jointly-sponsored Symposium*** 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 Pediatric Pharmacy Association. The American College of Clinical Pharmacology is accredited by the ACCME to provide Continuing Medical Education for physicians.

Continuing Education Process for 2017

Attendees interested in earning Continuing Education credit should have specifically requested that when registering for the 2017 Annual Meeting. Attendees who indicated they want to obtain Continuing Education credit will be provided with access to post-event tests for the sessions offering CE. Completion of the post-event tests and printing of Continuing Education credit certificates is required to earn CE credit. 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 (MMDD) 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.

Please note: All CE post-event tests must be completed by November 15, 2017. Anything completed later than this is not accepted by ACPE.

Faculty Disclosure Information

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

Farshad Ahadian*: principal investigator (research support) – Boston Scientific, SI-Bone, Mainstay Medical

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

Jeffrey S. Barrett: employee (salary) – Sanofi

Leslie Z. Benet*: member board of directors (ownership interest) – Impax Laboratories Inc; consultant (fees) – Takeda Pharmaceutical Co Ltd, Sandoz Inc (Oriel Therapeutics), Denali Therapeutics

N. Seth Berry*: employee (salary) – QuintilesIMS Holdings Inc

Samuel Blackman: employee (salary) – Silverback Therapeutics Inc; former employee/consultant (salary/consulting fees) – Juno Therapeutics Inc

Edmund Capparelli*: member Drug and Safety Monitoring Board (consulting fee) – Cempra Inc, The Medicines Co; PK Consultant Pediatric Antibiotic Study (consulting fee) – Rempex Pharmaceuticals Inc

Andrew Chang*: employee (salary/ownership interest) – Pfizer Inc

Ayyappa Chaturvedula: consulting (honorarium) – Maven Pharma Srl

Ene Ette: employee (salary) – Anoixis Corp

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

Kevin Freise: employee (salary/stock) – AbbVie Inc

Daniel Gonzalez*: contracted research (research support) – Cempra Inc and Jacobus Pharmaceutical Co Inc

Srijib Goswami: employee (salary) – Insight RX Inc

Jay Grobler*: employee (salary/stock/travel expenses) – Merck & Co

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

Neeraj Gupta: employee (salary) – Takeda Pharmaceuticals Co Ltd

Jessica Haberer: consulting (honorarium) – Merck & Co; (stock) – Natera Inc

Dina Halegoua-De Marzio: clinical investigator (received no monetary compensation) – Intercept Pharmaceuticals Inc, Gilead Sciences Inc, Genfit SA, Galectin Therapeutics Inc

Tae Han: employee (salary/stocks) – AbbVie Inc

Guenther Hochhaus*: consulting (fees) – Apotex Inc, Celon Laboratories Ltd, Cipla Inc, Aurobindo Pharma Ltd

Angela DM Kashuba*: principal investigator/investigator-initiated research (grant funding to UNC) – Gilead Sciences Inc, Merck & Co; consulting (fee) – Merck & Co

Holly Kimko: employee (salary) – Janssen: Pharmaceutical Co of Johnson & Johnson

Parag Kumar*: (stock) – Ionis Pharmaceuticals; study investigator (non-financial) – Matinas BioPharma Hldgs

Lucy Lee: employee (salary) – Infinity Pharmaceuticals Inc

Lawrence J. Lesko*: advisory board (honorarium) – Certara, Tabula Rasa Healthcare, Myriad Genetics Inc, Simcyp Ltd

Chi-Chung Li: employee (salary) – Genentech Inc; (stocks/stock options) – Roche

Linzhong Li: employee (salary) – Simcyp Ltd

Donald E. Mager: President/CEO (salary/ownership interest) – Enhanced Pharmacodynamics LLC

Kapil Mayawala: employee (salary/stock options) – Merck & Co

Bernd Meibohm*: consulting (fees) – Meibohm Consulting LLC

Murad Melhem: employee (salary) – Amgen Inc

Jeremiah Momper*: stockholder (stock/stock options) – Illumina Inc; consulting (fees) – Epocrates Inc

Diane R. Mould: consulting (salary) – Projections Research Inc

Luna Musib: employee (salary) – Genentech Inc; former employee (stocks/stock options) – Roche Holding AG

Douglas Nordli, Jr*: principal investigator/research (salary support) – National Inst of Health

Clive Page*: Co-founder (stock) – Verona Pharma plc; consulting (consultancy payments) – hVIVO plc, Recipharm AB, Eurodrug Ltd

Sabina Paglialunga: employee (salary) – Celerion

Parul Patel*: employee (salary) – ViiV Healthcare

Sofia Paul: employee (salary/stock) – Novartis Pharmaceuticals Corp

William Prucka*: employee (salary/stocks) – Eli Lilly & Co; spouse: employee (salary/stocks) – Eli Lilly & Co

Sumit Rawal: employee (salary) – Regeneron Pharmaceuticals Inc

Mark Rogge*: employee (salary/bonus) – Takeda Pharmaceuticals Co Ltd

Amit Roy: employee (salary/stock) – Bristol-Myers Squibb Co

Michelle A. Rudek: speaker (honorarium) – Otsuka America Pharmaceutical Inc; spouse: employee (salary/stock) – Novavax Inc

Lorraine M. Rusch: employee (salary) – High Point Clinical Trials Ctr; former employee (stock) – Cara Therapeutics, Acorda Therapeutics Inc

Ahmed H. Salem: employee (salary/stock) – AbbVie Inc

Stephan Schmidt: consulting (honorarium) – Bayer AG, INC Research

Gopi Shankar*: employee (salary/stock) – Johnson & Johnson; employee (salary) – Grandview Hosp

Jan Snoeys: employee (salary/stock) – Janssen R&D Belgium

Karthik Venkatakrishnan: employee (salary) – Takeda Pharmaceuticals Co Ltd

Lisa von Moltke: employee (salary/stock) – Alkermes Inc; employee (stock) – Sanofi-Genzyme

Yan Xu: employee (salary/stock) – Janssen Research & Development LLC

Karen Rowland Yeo: employee (salary) – Simcyp Ltd (part of Certara)

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Faculty Disclosure Information

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

Darrell R. Abernethy*
Arsham Alamian*
Sharyn Baker*
Robert L. Barkin*
Marc Baum*
Steven Belinsky*
John Bradley*
Gilbert J. Burckart*
Janelle Burnham*
Jonathan Constance*
Hartmut Derendorf*
Lanyan (Lucy) Fang*
Ben Forbes*
Jomy George*
Joga Gobburu
Dionna J. Green*
Bahru Habtemariam
Sam Harirforoosh*
R. Donald Harvey*
Shiew-Mei Huang
Geert W. 't Jong*
Catherijne Knibbe*
Kevin Krudys*
Beth Laube*
Jennifer Le*
J. Steven Leeder
Anne Lexmond*
Robert Lionberger*
Chao Liu
Jeannine McCune
Mehul Mehta*
Angela Men*
Gregory R. Polston*
Skorn Ponrartana*
Dionne Price*
Elizabeth Raetz*
Michael D. Reed*
Mark Sale
Bavna Saluja*
Sarah Schrieber*
Amar Sethi
Marjorie Shapiro*
Catherine MT Sherwin*
Kimberly Struble*
Mark Templeman*
Ekaterini Tsilou*
Janelle D. Vaughns*
Alexander A. Vinks
Yaning Wang
Kevin Watt*
Lynne Yao*

*This disclosure list includes all 2017 Annual Meeting Faculty. Continuing education credits are offered for 13 of the 17 available Workshops & Symposia. The Faculty participating in Workshops & Symposia offering CE credit are noted with an asterisk.

The following activity planners have indicated they have disclosures:

Lorraine M. Rusch: employee (salary) – High Point Clinical Trials Ctr; former employee (stock) – Cara Therapeutics, Acorda Therapeutics Inc

John N. van den Anker: consulting (fees) – Orphazyme ApS; board member (consulting fee) – J&J Pediatric Advisory Committee; member Drug and Safety Monitoring Board (consulting fee) – Mesoblast Ltd, Endo Pharmaceuticals Inc; Chair Drug and Safety Monitoring Board (consulting fee) – Nutrinia Ltd

Laurent Vernillet: employee (salary) – SK Life Science Inc

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

The following planners have indicated they have no disclosures:

Gilbert J. Burckart
Lawrence J. Cohen
Amelia N. Deitchman
Dionna J. Green
Catherine MT Sherwin

Pre-meeting Workshops

SATURDAY, SEPTEMBER 16, 2017 | Pre-meeting Workshop 1 | 8:00 am – 12:00 pm

ST TROPEZ ROOM

Should Off-patent Medications Be Labeled for Pediatric Use?: ACCP/ PPAG Jointly-sponsored Symposium

APPLICATION TRACK

Offers both CME and CPE Credit

UAN #0238-9999-17-007-L05-P

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

This Workshop 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 Pediatric Pharmacy Association. The American College of Clinical Pharmacology is accredited by the ACCME to provide Continuing Medical Education for physicians.

CO-CHAIRS:

Michael D. Reed, PharmD, Director, Rainbow Clinical Research Ctr, Rainbow Babies & Children's Hosp; Professor, Pediatrics, School of Medicine, Case Western Reserve Univ

Gilbert J. Burckart, PharmD, Associate Director, Pediatrics, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration

TARGET AUDIENCE:

This Workshop will be useful for patient care clinicians, clinician scientists, drug/device developers, clinical investigators, regulatory specialists, industry and government-based investigators and scientists.

GOALS AND OBJECTIVES:

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

1. Analyze the therapeutic and financial impacts of off-label drug use in pediatric practice;
2. Define a multi-tiered strategy to effectively address the challenges of precise data capture for support of revising the FDA-approved drug label;
3. Compare the advantages and disadvantages of contemporary clinical trial designs used to obtain labeling data for drug use in children.

8:00 – 8:30 am

Are Off-patent, Off-label Medications a Problem in Pediatric Therapeutics Today?

John Bradley, MD, Professor, Clinical Pediatrics, Univ of California, San Diego

8:30 – 9:00 am

The BPCA Program for Labeling Off-patent Medications

Ekaterini Tsilou, MD, Medical Officer, Eunice Kennedy Shriver National Inst of Child Health & Human Development, National Inst of Health

9:00 – 9:30 am

What is the Standard for Adding a Drug & Monograph to a Pediatric Formulary?: Institutions, Systems & Pharmacy Benefit Managers

Jennifer Le, PharmD, MAS, Professor, Clinical Pharmacy, Univ of California, San Diego, Skaggs School of Pharmacy & Pharmaceutical Sciences

9:30 – 10:00 am / **Break**

10:00 – 10:30 am

What Evidence is Required for Changing an FDA Label?

Lynne Yao, MD, Director, Div of Pediatric & Maternal Health, Office of New Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

10:30 – 11:00 am

Can Opportunistic Studies Be Expanded to Provide Sufficient Evidence for Labeling?: Proof of Concept

Kevin Watt, MD, PhD, Assistant Professor, Pediatrics, Duke Univ Medical Ctr, Duke Clinical Research Inst

11:00 – 11:30 am

The Value of the Drug Label to Point of Care Pediatrics

Jeremiah Momper, PharmD, PhD, Assistant Professor, Univ of California, San Diego, Skaggs School of Pharmacy & Pharmaceutical Sciences

11:30 am – 12:00 pm

Panel Discussion: Controversies & Challenges

MONTE CARLO ROOM

Best Practice Approaches to Physiologically-based Pharmacokinetic Modeling for Labeling Initiatives: Industry & Regulatory Perspectives

APPLICATION TRACK

CO-CHAIRS:

Karthik Venkatakrishnan, PhD, Senior Director, Quantitative Clinical Pharmacology (Oncology), Takeda Pharmaceuticals Co Ltd

Karen Rowland Yeo, PhD, Vice President, Simcyp Ltd (part of Certara)

TARGET AUDIENCE:

Clinical pharmacologists, pharmacists and clinicians would be interested in this Workshop and those in an industry setting are likely to derive the most benefit.

GOALS AND OBJECTIVES:

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

1. Describe the basic concepts of physiologically-based pharmacokinetic (PBPK) modeling and its value as an emerging technology in clinical pharmacology;
2. Identify clinical questions that warrant the application of PBPK modeling in drug development, particularly for informing the drug label to optimize therapeutic use across patient populations;
3. Implement best-practice approaches for PBPK model development, including data requirements, aligned with regulatory expert opinion, in order to increase confidence in model-informed applications in drug development and pharmacotherapy;
4. Appreciate the data required to support modeling initiatives in special populations, including pediatrics and organ impairment;
5. Reflect upon examples of successful translation of PBPK to labeling for small molecule drugs to inform next-generation applications to solve problems unique to emerging biotherapeutic modalities.

8:00 – 8:05 am

Introduction

Karthik Venkatakrishnan, PhD, Senior Director, Quantitative Clinical Pharmacology (Oncology), Takeda Pharmaceuticals Co Ltd

8:05 – 8:35 am

PBPK Modeling: Concepts & Best Practice Approaches

Karen Rowland Yeo, PhD, Vice President, Simcyp Ltd (part of Certara)

8:35 – 9:05 am

Application of PBPK Modeling to Support Labeling Initiatives: Case Studies

Jan Snoeys, PhD, Scientific Director & Fellow Pharmacokinetics, Dynamics & Metabolism, Janssen R&D Belgium

9:05 – 9:35 am

Strategic Application of PBPK Modeling in an Industry Setting to Support Labeling Initiatives: Case Studies

Lisa von Moltke, MD, Vice President, Clinical Research, Alkermes Inc

9:35 – 10:00 am / Break

10:00 – 10:30 am

Application of PBPK Modeling to Support Labeling Initiatives: A Regulatory Perspective

Shiew-Mei Huang, PhD, Deputy Office Director, Office of Clinical Pharmacology, Office of Translational Sciences, Ctr for Drug Evaluation & Research, US Food & Drug Administration

10:30 – 11:00 am

PBPK Modeling in Pediatrics: Current Status

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

11:00 – 11:30 am

PBPK Modeling of Biologics: Current Status

Donald E. Mager, PharmD, PhD, Professor, Pharmaceutical Sciences, Univ at Buffalo, SUNY

11:30 am – 12:00 pm

Panel Discussion

SATURDAY, SEPTEMBER 16, 2017 | Pre-meeting Workshop 3 | 1:30 – 5:30 pm

ST TROPEZ ROOM

Therapeutic Drug Monitoring in Advancing Patient Care: Is This Time Different?

APPLICATION TRACK

CO-CHAIRS:

Neeraj Gupta, PhD, Senior Scientific Director, Takeda Pharmaceuticals Co Ltd

Manish Gupta, PhD, Group Director, Bristol-Myers Squibb Co

TARGET AUDIENCE:

This Workshop will be useful for attendees from academia, industry and clinicians. It should also benefit an audience who is engaged in the clinical development of large molecules and oncology or pediatric drugs, as well as attendees that may be interested in the reimbursement landscape for biologics.

GOALS AND OBJECTIVES:

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

1. Apply therapeutic drug monitoring in various disease settings such as inflammatory and malignant diseases, including pediatrics;
2. Compare a newly-available, user-friendly decision support tool (currently being tested in clinical trials in adult and pediatric patients with inflammatory bowel disease) with the other available tools.

1:30 – 1:35 pm

Introduction

Neeraj Gupta, PhD, Senior Scientific Director, Takeda Pharmaceuticals Co Ltd

1:35 – 2:05 pm

Why Most Therapeutic Drug Monitoring is Not as Useful as It Should Be: Opportunities & Challenges

Lawrence J. Lesko, PhD, Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Dept of Pharmaceutics, Coll of Pharmacy, Univ of Florida

2:05 – 2:35 pm

Therapeutic Drug Management for Monoclonal Antibodies in Inflammatory & Malignant Diseases

Alexander A. Vinks, PharmD, PhD, Professor, Pediatrics & Pharmacology, Director, Div of Clinical Pharmacology, Cincinnati Children's Hosp Medical Ctr, Univ of Cincinnati, Coll of Medicine

2:35 – 3:00 pm

Application of Therapeutic Drug Monitoring in Pediatrics

Jeffrey S. Barrett, PhD, Vice President & Global Head of Translational Informatics, Global Head, Pediatric Clinical Pharmacology, Sanofi

3:00 – 3:30 pm

Therapeutic Drug Monitoring in Oncology

Jeannine McCune, PharmD, Professor, City of Hope Cancer Ctr & Affiliate Professor, Dept of Pharmacy, Univ of Washington

3:30 – 4:00 pm / **Break**

4:00 – 4:30 pm

Overcoming Adoption Barriers of Cloud-based Precision Dosing in Healthcare

Srijib Goswami, PhD, Founder & Chief Executive Officer, Insight RX Inc

4:30 – 5:00 pm

Clinical Decision Support Tools for Therapeutic Drug Monitoring for Monoclonal Antibodies

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

5:00 – 5:30 pm

Panel Discussion

MONTE CARLO ROOM

Modeling & Simulation Strategies for Dose Selection of Targeted Anticancer Agents

DISCOVERY TRACK

This Workshop is supported in part by an Educational Grant from AbbVie Inc

CO-CHAIRS:

Ahmed H. Salem, PhD, Associate Director, Clinical Pharmacology & Pharmacometrics, AbbVie Inc

Murad Melhem, PhD, Principal Scientist, Amgen Inc

TARGET AUDIENCE:

This Workshop will be useful for clinical pharmacologists and pharmacometricians from industry, academia and regulatory agencies who are involved in drug development.

GOALS AND OBJECTIVES:

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

1. Develop and apply more efficient dose selection approaches during oncology drug development;
2. Identify clinical design considerations for proper dose finding in oncology drug development;
3. Explain how a model-based approach can help in optimizing dosage regimens and compare the different modeling & simulation techniques that can be used;
4. List and address challenges specific to dose selection of combination therapies in oncology;
5. Explain regulatory perspectives on optimizing dosage regimens of oncology drugs.

1:30 – 1:35 pm

Introduction

Ahmed H. Salem, PhD, Associate Director, Clinical Pharmacology & Pharmacometrics, AbbVie Inc

1:35 – 2:00 pm

Quantitative Clinical Pharmacology in Oncology Drug Development: Enabling Rational Dose Selection from Translational to Global Drug Development

Karthik Venkatakrishnan, PhD, Senior Director, Quantitative Clinical Pharmacology (Oncology), Takeda Pharmaceuticals Co Ltd

2:00 – 2:30 pm

Exposure-Response Analysis of Venetoclax in Multiple Myeloma: Application of Frequentist & Bayesian Approaches for Combination Therapy Dose Selection

Kevin Freise, PhD, Assistant Director, Clinical Pharmacology & Pharmacometrics, AbbVie Inc

2:30 – 3:00 pm

Application of Markov Structure-based Logistic Regression Modeling to Adverse Reactions Characterization in Oncology

Ene Ette, PhD, President & Chief Executive Officer, Anoixis Corp

3:00 – 3:30 pm

Clinical Study Design to Enable Proper Dose Finding in Oncology

Kapil Mayawala, PhD, Director, Quantitative Pharmacology & Pharmacometrics, Oncology, Merck & Co

3:30 – 4:00 pm / Break

4:00 – 4:30 pm

Utility of Exposure-Response Analyses in Drug Development for Leukemia

Michelle A. Rudek, PharmD, PhD, Associate Professor, Johns Hopkins Univ

4:30 – 5:00 pm

Data-driven Dose Selection in Oncology Drug Development

Bahru Habtemariam, PharmD, Acting Team Leader, Office of Clinical Pharmacology, Div of Clinical Pharmacology V, US Food & Drug Administration

5:00 – 5:30 pm

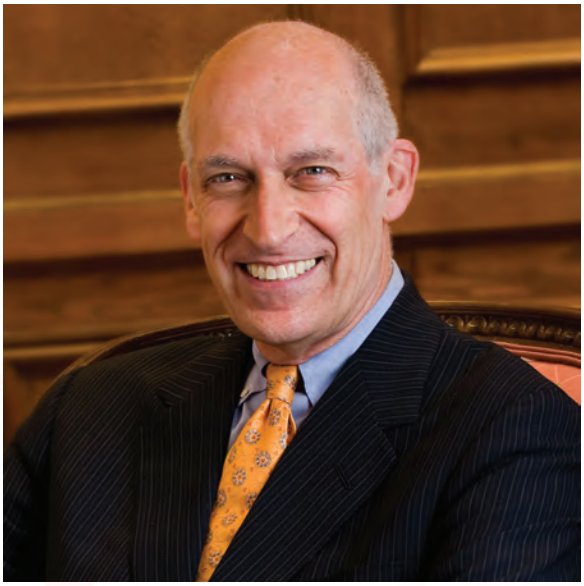
Panel Discussion and Q&A

Plenary Session

SUNDAY, SEPTEMBER 17, 2017 | Plenary Session | 8:00 – 9:30 am

MONTE CARLO ROOM

Predicting Pharmacokinetics/ Pharmacodynamics in the Individual Patient: Separating Reality from Hype



APPLICATION TRACK

Offers both CME and CPE Credit
UAN #0238-0000-17-008-L05-P
ACPE – 1.5 CONTACT HOURS/APPLICATION-BASED

Leslie Z. Benet, PhD, Professor & former Chairman (1978-1998), Dept of Bioengineering & Therapeutic Sciences, Schools of Pharmacy & Medicine, Univ of California, San Francisco

TARGET AUDIENCE:

This Plenary Session will be useful for attendees with PharmD, PhD and/ or MD degrees that are involved in the application of pharmacokinetic/ pharmacodynamic (PK/PD) data to patient care.

GOALS AND OBJECTIVES:

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

1. Describe the history of PK/PD prediction;
2. List examples of where PK/PD prediction has not been informative for drug use in individual patients;
3. Explain how PK/PD prediction fits into the current concept of “precision medicine” for patients;
4. Synthesize a process by which PK/PD prediction is appropriately applied to individual patient care.

MONTE CARLO ROOM

Innovative Scientific & Risk-based Quantitative Approaches to Post-marketing Surveillance of New & Generic Drug Products

APPLICATION TRACK

Offers both CME and CPE Credit

UAN #0238-0000-17-009-L05-P

ACPE – 2 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Lawrence J. Lesko, PhD, Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Dept of Pharmaceutics, Coll of Pharmacy, Univ of Florida

Lanyan (Lucy) Fang, PhD, Team Leader, US Food & Drug Administration

TARGET AUDIENCE:

This Symposium will be useful for clinical investigators in drug development, clinical pharmacologists and quantitative scientists in post-marketing surveillance.

GOALS AND OBJECTIVES:

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

1. Apply combined biosimulation and systems pharmacology approaches for post-marketing surveillance of innovator and generic medical products;
2. Demonstrate how modern biosimulation and systems pharmacology approaches can address the scientific and regulatory challenges underlying the surveillance of approved drugs.

10:00 – 10:05 am

Introduction

Lanyan (Lucy) Fang, PhD, Team Leader, US Food & Drug Administration

10:05 – 10:45 am

Industrial Perspective: Post-marketing Surveillance for Innovator Products

Mark Rogge, PhD, Global Head & Vice President, Quantitative Clinical Pharmacology, Takeda Pharmaceuticals Co Ltd

10:45 – 11:15 am

Monitoring & Evaluating the Success of Generic Drug Substitution

Robert Lionberger, PhD, Director, Office of Research & Standards, Office of Generic Drugs, US Food & Drug Administration

11:15 am – 12:00 pm

An Innovative Model- & Systems-based Approach to Post-marketing Surveillance of New & Generic Drug Products

Lawrence J. Lesko, PhD, Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Dept of Pharmaceutics, Coll of Pharmacy, Univ of Florida

SAN MARINO ROOM

Optimizing Dose/Dosing Frequency for a Biologic: Clinical, Regulatory & Commercial Perspectives

APPLICATION TRACK

CO-CHAIRS:

Gaurav Bajaj, PhD, Associate Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb Co

Sumit Rawal, PhD, Research Scientist, Regeneron Pharmaceuticals Inc

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists and pharmacometricians from the pharmaceutical and biotech industries, academia, clinicians, regulatory scientists and scientists working in the early/late development space.

GOALS AND OBJECTIVES:

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

1. Identify strategies for dose/dose regimen optimization during drug development;
2. List challenges specific to clinical pharmacology and the impact on changing dose/dose regimen during development of biologics;
3. Explain clinical design considerations for biologics;
4. Identify the advantages and disadvantages of changing dosing frequency for a biologic.

10:00 – 10:10 am

Introduction

Gaurav Bajaj, PhD, Associate Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb Co

10:10 – 10:30 am

Optimal Dosing for Targeted Therapies in Oncology: Drug Development Cases Leading by Example

Kapil Mayawala, PhD, Director, Quantitative Pharmacology & Pharmacometrics, Oncology, Merck & Co

10:30 – 10:50 am

Model-based Analyses to Optimize Dosing Regimen During Development & Post-approval

Amit Roy, PhD, Group Director, Bristol-Myers Squibb Co

10:50 – 11:10 am

Model-based Assessment of Dosing Strategies in Children for Monoclonal Antibodies Exhibiting Target-mediated Drug Disposition

Stephan Schmidt, PhD, Associate Professor & Associate Director, Dept of Pharmaceutics, Univ of Florida

11:10 – 11:30 am

Regulatory Perspectives on Optimizing Dose/Dosing Frequency in Combination Settings

Chao Liu, PhD, Pharmacometrics Reviewer, Div of Pharmacometrics, Office of Clinical Pharmacology, US Food & Drug Administration

11:30 am – 12:00 pm

Panel Discussion and Q&A

MONTE CARLO ROOM

Master Protocols in Drug Development

APPLICATION TRACK

Offers both CME and CPE Credit

UAN #0238-0000-17-010-L01-P
ACPE – 2 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Dionna J. Green, MD, Medical Officer & Policy Lead, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration

Kevin Watt, MD, PhD, Assistant Professor, Pediatrics, Duke Univ Medical Ctr, Duke Clinical Research Inst

TARGET AUDIENCE:

The primary audience includes clinicians and scientists from industry, regulatory and other government agencies, academia and non-profit organizations who are involved in the development of medical products.

GOALS AND OBJECTIVES:

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

1. Describe the current drug development landscape and the inefficiencies that can be associated with clinical trials;
2. Demonstrate the utility of master protocols in increasing efficiency in drug development and speeding new therapies to patients;
3. Cite examples of master protocols employed in the areas of oncology, pediatrics and rare diseases and apply the practical, statistical, regulatory and scientific considerations when designing a master protocol.

1:30 – 2:00 pm

Pediatric Master Protocols: Lessons Learned

Kevin Watt, MD, PhD, Assistant Professor, Pediatrics, Duke Univ Medical Ctr, Duke Clinical Research Inst

2:00 – 2:30 pm

Utility & Challenges for Master Protocols in Oncology Clinical Trials: An Industry Perspective

Andrew Chang, PharmD, PhD, Clinical Pharmacology Lead, Pfizer Oncology Group, Pfizer Global Product Development

2:30 – 2:55 pm

Regulatory Considerations for Master Protocols

Lynne Yao, MD, Director, Div of Pediatric & Maternal Health, Office of New Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

2:55 – 3:15 pm

Statistical Considerations for Master Protocols

Dionne Price, PhD, Director, Div of Biometrics IV, Office of Biostatistics, Ctr for Drug Evaluation & Research, US Food & Drug Administration

3:15 – 3:30 pm

Panel Discussion

SUNDAY, SEPTEMBER 17, 2017 | Symposium 4 | 1:30 – 5:30 pm

SAN MARINO ROOM

Next Wave in Cancer Medicine: Mechanisms & Progress for Emerging Therapeutics

DISCOVERY TRACK

This Symposium is supported in part by an Educational Grant from AbbVie Inc

CO-CHAIRS:

Lucy Lee, PharmD, Director, Clinical Pharmacology, Infinity Pharmaceuticals Inc

Luna Musib, PhD, Senior Scientist, Clinical Pharmacology, Genentech Research & Early Development (gRED)

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists, physicians, scientists and other allied professionals.

GOALS AND OBJECTIVES:

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

1. Provide an overview of cancer medicine in the past, present and into the future;
2. Present four selected cases of next-wave cancer medicine that are emerging treatments or novel targets in the drug pipeline;
3. Discuss the current landscape, clinical pharmacology, pharmacokinetics/pharmacodynamics, progress, therapeutic implications and challenges for the selected cases of next-wave cancer medicine.

1:30 – 2:00 pm

Oncology Therapeutics: Snapshot of the Past, Present & Into the Future

Lucy Lee, PharmD, Director, Clinical Pharmacology, Infinity Pharmaceuticals Inc

2:00 – 2:45 pm

Antibody-Drug Conjugates Targeting Cancer Stem Cells

Tae Han, PhD, Director, Clinical Pharmacology & Pharmacometrics, AbbVie Stemcentrx LLC

2:45 – 3:30 pm

Personalized Cancer Vaccines Boosting Immunogenicity of Patient-specific Antigens

Chi-Chung Li, PhD, Senior Scientist, Clinical Pharmacology, Genentech Research & Early Development (gRED)

3:30 – 4:00 pm / **Break**

4:00 – 4:40 pm

Chimeric Antigen Receptor T-Cell Therapeutics for Cancer: Promise & Challenges

Samuel Blackman, MD, PhD, Senior Vice President, Head, Clinical Development, Silverback Therapeutics Inc

4:40 – 5:20 pm

Bispecific Antibodies Engaging Interaction of Both T-Cells & Tumor Cells

Linzhong Li, PhD, Principal Scientist/Head, Biologics, Simcyp Ltd

5:20 – 5:30 pm

Summary, Highlights and Q&A

Luna Musib, PhD, Senior Scientist, Clinical Pharmacology, Genentech Research & Early Development (gRED)

MONTE CARLO ROOM

Clinical Trial Simulations in Pediatric Drug Development

APPLICATION TRACK

Offers both CME and CPE Credit

UAN #0238-0000-17-011-L05-P

ACPE – 1.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Janelle Burnham, MD, Pediatrician & Commissioners Fellow, Office of Clinical Pharmacology, US Food & Drug Administration

Daniel Gonzalez, PharmD, PhD, Assistant Professor, Div of Pharmacotherapy & Experimental Therapeutics, UNC Eshelman School of Pharmacy, The Univ of North Carolina at Chapel Hill

TARGET AUDIENCE:

The application of clinical trial simulations in pediatric drug development would be relevant for clinical pharmacologists and clinicians working in academia, industry and regulatory agencies.

GOALS AND OBJECTIVES:

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

1. Inform the audience about the regulatory, industry and academic perspectives on the use of clinical trial simulations in pediatric drug development;
2. Present examples of how integration of clinical trial simulation can improve pediatric drug development;
3. Provide suggestions on the future direction of clinical trial simulation as an important tool in optimizing pediatric clinical trial design.

4:00 – 4:10 pm

Clinical Trial Simulations as a Tool to Guide Pediatric Drug Development

Daniel Gonzalez, PharmD, PhD, Assistant Professor, Div of Pharmacotherapy & Experimental Therapeutics, UNC Eshelman School of Pharmacy, The Univ of North Carolina at Chapel Hill

4:10 – 4:30 pm

The Use of Clinical Trial Simulations to Support the Validation of Mobile, Pharmacometric, Individualized Dosage Web Applications in Pediatric Drug Development

N. Seth Berry, PharmD, Senior Scientific Advisor, Clinical PK/PD Modeling & Simulation, QuintilesIMS Holdings Inc

4:30 – 4:50 pm

Clinical Trial Simulation for Pediatric Efficacy Trials: Case Studies

William Prucka, PhD, Director, Innovation Computational Statistics, Biometrics & Advanced Analytics, Eli Lilly & Co

4:50 – 5:10 pm

Regulatory Perspective on the Use of Clinical Trial Simulation in Pediatric Drug Development

Kevin Krudys, PhD, Pharmacometrics Team Leader, Office of Clinical Pharmacology, US Food & Drug Administration

5:10 – 5:30 pm

Panel Discussion

Moderator – Janelle Burnham, MD, Pediatrician & Commissioners Fellow, Office of Clinical Pharmacology, US Food & Drug Administration

MONDAY, SEPTEMBER 18, 2017 | Symposium 6 | 8:00 – 9:30 am

SAN MARINO ROOM

Therapeutic Options for Obesity Treatment in Children, Adolescents & Young Adults

APPLICATION TRACK

Offers both CME and CPE Credit

UAN #0238-0000-17-012-L05-P

ACPE – 1.5 CONTACT HOURS/APPLICATION-BASED

This Symposium is supported in part by the British Journal of Clinical Pharmacology

CO-CHAIRS:

Catherine MT Sherwin, PhD, MS, Chief, Div of Clinical Pharmacology, Univ of Utah

Janelle D. Vaughns, MD, Assistant Professor of Anesthesiology & Pediatrics, Children's National Health System

TARGET AUDIENCE:

The primary audience is clinical and research faculty from schools and colleges of medicine, pharmacy and nursing. It would also include pharmacologists, pharmacists, clinicians or graduate/postgraduate trainees wishing to better understand the implications of consensus guidelines on prescribing practices for obese patients.

GOALS AND OBJECTIVES:

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

1. Update participants on the therapeutic options for obesity treatment in children, adolescents and young adults;
2. Review the evidence-based dosing guidelines for commonly-used drugs in these special patient groups and describe what effective treatment options are available;
3. Explain concerns related to the scientific and regulatory challenges underlying the prescribing of drugs to obese patients;
4. Provide an overview on the clinical application of population pharmacokinetic/pharmacodynamic modeling and the use of mechanism-based analysis to individualized dosing schemes in morbidly obese children, adolescents and young adults.

8:00 – 8:20 am

Role of Pharmacologic Dosing Strategies in General Anesthesia During the Perioperative Period in Obese Children & Adolescents

Janelle D. Vaughns, MD, Assistant Professor of Anesthesiology & Pediatrics, Children's National Health System

8:20 – 8:40 am

How Do We Get Effective Therapeutic Options for Families With Children Dealing With Obesity?

Mark Templeman, MD, Pediatrician, Intermountain Hillcrest Pediatrics

8:40 – 9:00 am

Implications to Regulations & Labeling of Drugs for Therapeutics Used in Children, Adolescents & Young Adults

Dionna J. Green, MD, Medical Officer & Policy Lead, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration

9:00 – 9:20 am

The Influence of Morbid Obesity on the Pharmacokinetics & Pharmacodynamics of Drugs: Implications for Individualized Dosing

Catherijne Knibbe, PhD, PharmD, Professor, Individualized Drug Treatment, St Antonius Hosp, Dept of Clinical Pharmacy

9:20 – 9:30 am

Panel Discussion

MONTE CARLO ROOM

Modeling of Adherence: Applications in Drug Development & Clinical Practice

DISCOVERY TRACK

CO-CHAIRS:

Ayyappa Chaturvedula, PhD, Associate Professor, Univ of North Texas System Coll of Pharmacy

Mark Sale, MD, Senior Vice President, Nuventra Pharma Sciences

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists from academia and the pharmaceutical industry, public health researchers, physicians, pharmacists, pharmacometricians, pharmacokinetic/pharmacodynamic scientists and drug development scientists.

GOALS AND OBJECTIVES:

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

1. Compare various objective and subjective measures of adherence in clinical research;
2. Analyze various pharmacometric models for quantifying adherence;
3. Apply quantitative adherence models in clinical trial simulation and patient care.

8:00 – 8:05 am

Introduction

Ayyappa Chaturvedula, PhD, Associate Professor, Univ of North Texas System Coll of Pharmacy and Mark Sale, MD, Senior Vice President, Nuventra Pharma Sciences

8:05 – 8:45 am

Impact of Adherence on the Development of Medications for HIV Pre-exposure Prophylaxis

Mark Sale, MD, Senior Vice President, Nuventra Pharma Sciences

8:45 – 9:30 am

Collection & Interpretation of Adherence Data for Clinical Care & Intervention

Jessica Haberer, MD, MS, Associate Professor, Massachusetts General Hosp & Harvard Medical School

9:30 – 10:00 am / **Break**

10:00 – 10:40 am

Quantifying Adherence: Pharmacometrician's Perspective

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

10:40 – 11:30 am

Application of Quantitative Adherence Models

Ene Ette, PhD, President & Chief Executive Officer, Anoixis Corp

11:30 am – 12:00 pm

Panel Discussion and Q&A

MONDAY, SEPTEMBER 18, 2017 | Symposium 8 | 10:00 am – 12:00 pm

SAN MARINO ROOM

Kinase Inhibitors in Pediatric Patients: Experiences, Pharmacology & Future Applications

DISCOVERY TRACK

Offers both CME and CPE Credit

UAN #0238-0000-17-013-L01-P

ACPE – 2 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Jonathan Constance, PhD, Assistant Professor, Univ of Utah

Geert W. 't Jong, MD, PhD, Academic Pediatrician & Clinical Pharmacologist, Assistant Professor of Pediatrics, Internal Medicine & Pharmacology, Univ of Manitoba

TARGET AUDIENCE:

This Symposium will be useful for pharmacologists, pharmacists, clinicians or graduate/postgraduate trainees wishing to better understand the implications of kinase inhibitor (KI) use among pediatric patient populations, with an emphasis on pediatric malignancies.

GOALS AND OBJECTIVES:

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

1. Describe the current and prospective scope of kinase inhibitor therapy among children with cancer, while highlighting unique challenges in a developmental context;
2. Identify advances in the utilization of precision medicine (eg, genetic characteristics) to tailor KI therapeutic regimens in pediatric cancer patients. Moreover, participants will be able to relate how lessons learned in the last decade from KI use in the adult population will influence pediatric KI use. A special emphasis on being able to describe the benefits and risks associated with combination therapy (KI and conventional chemotherapy or other molecularly-targeted agent) in pediatric cancer;
3. Recognize that the confluence between normal growth and developmental processes in children and the introduction of KI therapy may reveal pediatric-specific adverse events, such as the disruption of normal bone growth.

10:00 – 10:10 am

Introduction

Jonathan Constance, PhD, Assistant Professor, Univ of Utah

10:10 – 10:30 am

The History, Current Practice & Prospects of Tyrosine Kinase Inhibitor Therapy in Pediatric Acute Lymphoblastic Leukemia Patients: The Expanding Role for Kinase Inhibitor Therapy

Elizabeth Raetz, MD, Professor, Pediatrics, Univ of Utah

10:30 – 10:50 am

Pharmacokinetics of Kinase Inhibitors in Children: Factors Influencing Variability

Sharyn Baker, PharmD, PhD, Chair & Professor, Div of Pharmaceutics & Pharmaceutical Chemistry, Ohio State Univ

10:50 – 11:10 am

Pharmacodynamics of Kinase Inhibitors in Children: Markers of Effect & Mechanisms of Resistance

R. Donald Harvey, PharmD, Associate Professor & Director, Phase I Section, Winship Cancer Inst of Emory Univ

11:10 – 11:30 am

Going Forward: Kinase Inhibitor Therapy for Pediatric Diseases

Geert W. 't Jong, MD, PhD, Academic Pediatrician & Clinical Pharmacologist, Assistant Professor of Pediatrics, Internal Medicine & Pharmacology, Univ of Manitoba

11:30 am – 12:00 pm

Panel Discussion and Q&A

SAN MARINO ROOM

What to Do After a Pivotal Trial Has Failed Primary Endpoint Assessment: Totality of Evidence-based Drug Development Challenges & Opportunities

APPLICATION TRACK

CHAIR:

Yan Xu, PhD, Associate Scientific Director, Global Clinical Pharmacology, Janssen: Pharmaceutical Co of Johnson & Johnson

TARGET AUDIENCE:

This Symposium will be useful for scientists from regulatory agencies, the pharmaceutical industry and academia to exchange their experience and views in totality of evidence for go/no-go decision and engage in active discussions, in particular what to do after a pivotal trial has failed primary endpoint assessment.

GOALS AND OBJECTIVES:

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

1. Apply totality of evidence to guide drug development decisions, eg considering the overall status of the pivotal trial, not just the primary endpoint;
2. Demonstrate a better understanding of evidence of effectiveness, which ought to be sought by establishing a body of evidence via multiple sources. A positive/negative *p* value by itself does not establish effectiveness or lack of evidence. No single index should substitute for scientific reasoning based on integrated knowledge;
3. List benefits and risks of sub-group analysis in drug development and personalized medicine.

1:30 – 1:35 pm

Introduction

Yan Xu, PhD, Associate Scientific Director, Global Clinical Pharmacology, Janssen: Pharmaceutical Co of Johnson & Johnson

1:35 – 2:05 pm

Beyond a Failed Pivotal Trial: Scientific & Strategic Thinking

Joga Gobburu, PhD, MBA, Professor of Pharmacy Practice & Science, Director, Ctr for Translational Medicine, Univ of Maryland School of Pharmacy

2:05 – 2:30 pm

Drug Development Challenges & Opportunities Based on Totality of Evidence: An Industry Perspective

Holly Kimko, PhD, Scientific Director/Fellow, Global Clinical Pharmacology, Janssen: Pharmaceutical Co of Johnson & Johnson

2:30 – 3:00 pm

Challenges in Drug Approval Based on Total Evidence of Safety & Efficacy from a Positive Oncology Trial

Sofia Paul, PhD, Senior Director, Biostatistics, Oncology, Novartis Pharmaceuticals Corp

3:00 – 3:30 pm

Totality of Evidence in Regulatory Decision Making: Learning from Confirmative Trials

Yaning Wang, PhD, Acting Director, Div of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Sciences, Ctr for Drug Evaluation & Research, US Food & Drug Administration

MONDAY, SEPTEMBER 18, 2017 | Symposium 10 | 1:30 – 5:30 pm

MONTE CARLO ROOM

Challenges & Opportunities in the Development of Inhaled Medicines

DISCOVERY TRACK

Offers both CME and CPE Credit

UAN #0238-0000-17-014-L05-P

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Clive Page, BSc, PhD, Professor, Pharmacology, Sackler Inst of Pulmonary Pharmacology, King's Coll London

Anne Lexmond, PharmD, PhD, Dept of Pharmaceutical Technology & Biopharmacy, Univ of Groningen

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists specializing in respiratory medicine, respiratory drug developers and researchers, both academic and industrial, regulators and respiratory physicians.

GOALS AND OBJECTIVES:

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

1. Assess technical specifications of inhalation devices in relation to the purpose of the drug and the patient for whom the drug is intended;
2. Apply the principles of how to provide tailored inhaled drug therapy to the individual patient;
3. Identify emerging therapeutic opportunities for inhaled drug delivery;
4. Review the major issues facing the development of inhaled medicines.

1:30 – 1:35 pm

Introduction

Clive Page, BSc, PhD, Professor, Pharmacology, Sackler Inst of Pulmonary Pharmacology, King's Coll London

1:35 – 1:55 pm

Pharmacokinetics & Bioequivalence Testing of Orally-inhaled Steroids

Hartmut Derendorf, PhD, Distinguished Professor & Chair, Dept of Pharmaceutics, Univ of Florida

1:55 – 2:15 pm

Pulmonary Absorption & Bioavailability of Inhaled Products

Guenther Hochhaus, PhD, Professor, Dept of Pharmaceutics, Univ of Florida

2:15 – 2:50 pm

Target Populations & Inhalation Device Choices

Beth Laube, PhD, Professor, Pediatrics, Johns Hopkins Univ

2:50 – 3:25 pm

Beyond Asthma & COPD: Aerosol Delivery of Drugs for Cancer Treatment & Prevention

Steven Belinsky, PhD, Vice President, Academic Research & Senior Scientist, Lovelace Respiratory Research Inst

3:25 – 3:55 pm / **Break**

3:55 – 4:30 pm

Foamy Macrophages: What Do They Really Mean for the Safety of Inhaled Medicines?

Ben Forbes, PhD, Professor, King's Coll London

4:30 – 5:05 pm

Opportunities & Challenges Facing the Development of Inhaled Medicines

Bavna Saluja, PhD, Reviewer, Office of Clinical Pharmacology, Div of Clinical Pharmacology 2, US Food & Drug Administration

5:05 – 5:30 pm

Panel Discussion

SAN MARINO ROOM

Pioneering NAFLD/NASH Early-phase Clinical Pharmacology Study Designs

DISCOVERY TRACK

CO-CHAIRS:

Lorraine M. Rusch, PhD, President, High Point Clinical Trials Ctr

Sabina Paglialunga, PhD, Metabolic & Pharmacodynamic Specialist, Celerion

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists, physicians, metabolic scientists, hepatologists, research scientists, medical directors and bioanalytical scientists.

GOALS AND OBJECTIVES:

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

1. Implement study design considerations and discuss safety concerns for clinical NAFLD/NASH studies;
2. Compare invasive and non-invasive NAFLD/NASH measurements for diagnosis and treatment response assessments;
3. Explore strategic NAFLD/NASH biomarkers and implementation of these measurements in clinical studies and medical practice.

4:00 – 4:10 pm

Introduction

Lorraine M. Rusch, PhD, President, High Point Clinical Trials Ctr

4:10 – 4:30 pm

Non-invasive Approaches to Diagnosing & Evaluating Treatment Response in NAFLD & NASH

Dina Halegoua-De Marzio, MD, Assistant Professor, Medicine & Jefferson Fatty Liver Ctr Director, Thomas Jefferson Univ Hosp

4:30 – 4:50 pm

Leveraging Soluble Biomarkers for NAFLD/NASH Studies

Amar Sethi, MD, PhD, President & Chief Scientific Officer, Pacific Biomarkers Inc

4:50 – 5:10 pm

Optimizing NAFLD/NASH Study Design in Early Clinical Trials

Sabina Paglialunga, PhD, Metabolic & Pharmacodynamic Specialist, Celerion

5:10 – 5:30 pm

Panel Discussion and Q&A

TUESDAY, SEPTEMBER 19, 2017 | Symposium 12 | 8:00 – 9:30 am

SAN MARINO ROOM

Assessment of Drug Effect on Pediatric Bone Health

DISCOVERY TRACK

Offers both CME and CPE Credit

UAN #0238-0000-17-015-L01-P

ACPE – 1.5 CONTACT HOURS/APPLICATION-BASED

CHAIR:

Gilbert J. Burckart, PharmD, Associate Director, Pediatrics, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration

TARGET AUDIENCE:

This Symposium will be useful for pediatric drug developers (industry, regulators) and pediatric clinical pharmacologists.

GOALS AND OBJECTIVES:

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

1. Describe (a) normal patterns of growth and development in children, (b) pathophysiology of drug-induced changes in bone development in pediatric patients, (c) current FDA guidances relating to assessment of pediatric growth studies and (d) an example of a long-term assessment of bone growth in pediatric patients on inhaled and oral corticosteroids;
2. List the currently-established biomarkers for bone health assessment;
3. Describe the current understanding of using bone mineral density in assessing drug effect;
4. Synthesize a plan for data analysis of bone biomarkers from a pediatric drug development study.

8:00 – 8:25 am

The Importance of Pediatric Bone Health in the Safety Evaluation of a New Drug

Lynne Yao, MD, Director, Div of Pediatric & Maternal Health, Office of New Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

8:25 – 8:50 am

Bone Biomarkers in the Assessment of Pediatric Bone Health

Skorn Ponrartana, MD, MPH, Assistant Professor, Radiology, Children's Hosp Los Angeles, Keck School of Medicine, Univ of Southern California

8:50 – 9:15 am

Critical Clinical Pharmacology Factors in Measuring Bone Effects of Drugs in Pediatric Patients

Gilbert J. Burckart, PharmD, Associate Director, Pediatrics, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration

9:15 – 9:30 am

Panel Discussion

MONTE CARLO ROOM

21st Century HIV/AIDS: An Evolving Drug Development & Technology Paradigm

DISCOVERY TRACK

Offers both CME and CPE Credit

UAN #0238-0000-17-016-L02-P

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

This Symposium is supported in part by an Educational Grant from Gilead Sciences Inc

CO-CHAIRS:

Jomy George, PharmD, Pharmacokineticist, National Inst of Health

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

TARGET AUDIENCE:

The target audience would be healthcare professionals including pharmacists, physicians and nurses, plus research scientists in academia, industry and regulatory agencies with an interest in clinical pharmacology applications specific to HIV/AIDS treatment and prevention, HIV cure and HIV-associated co-infections.

GOALS AND OBJECTIVES:

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

1. Describe novel bioanalytical approaches and target reservoirs in the search for an HIV cure;
2. Explain the recent advances in drug formulations for both HIV treatment and prevention;
3. Identify challenges in the current regulatory process of the development and approval of biologics for HIV;
4. Appraise the evolving body of evidence on HIV therapeutics and the potential role of novel biologic agents;
5. Describe advancements and challenges in the treatment of HIV-associated opportunistic infections.

8:00 – 8:25 am

Advances in Formulations for HIV PrEP & Treatment: Injectable Nano Formulations

Parul Patel, PharmD, Clinical Pharmacology Program Leader for Cabotegravir, ViiV Healthcare

8:25 – 8:50 am

Advances in Formulations for HIV PrEP & Treatment: Solid Implantable Formulations

Jay Grobler, PhD, Director, Infectious Disease Biology, Merck & Co

8:50 – 9:20 am

Advances in Formulations for HIV PrEP: Topicals & Implantables

Marc Baum, PhD, Senior Faculty & President, Oak Crest Inst of Science

9:20 – 9:30 am

Q&A

9:30 – 10:00 am / **Break**

10:00 – 10:30 am

Broadly-neutralizing Monoclonal Antibodies: Next Generation of HIV/AIDS Therapeutics

Edmund Capparelli, PharmD, Professor, Clinical Pediatrics & Pharmacy, Univ of California, San Diego School of Medicine & Skaggs School of Pharmacy & Pharmaceutical Sciences

10:30 – 10:55 am

Regulatory Perspectives on the Development of New HIV Treatment & Prevention Modalities

Kimberly Struble, PharmD, Senior Clinical Analyst Team Leader, US Food & Drug Administration

10:55 – 11:20 am

Clinical Pharmacology of Novel Regimens & Formulations for HIV/AIDS-associated Co-infections

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

11:20 – 11:50 am

Novel Clinical Pharmacology Approaches in the Search for an HIV Cure

Angela DM Kashuba, BScPhm, PharmD, DABCP – John A. & Deborah S. McNeill Jr Distinguished Professor; Chair, Div of Pharmacotherapy & Experimental Therapeutics, Eshelman School of Pharmacy; Director, Clinical Pharmacology & Analytical Chemistry Core, UNC Ctr for AIDS Research; Adjunct Professor of Medicine, UNC School of Medicine, Div of Infectious Diseases

11:50 am – 12:00 pm

Q&A

TUESDAY, SEPTEMBER 19, 2017 | Symposium 14 | 10:00 am – 12:00 pm

SAN MARINO ROOM

Full Extrapolation of Efficacy from Adults to Children of Antiepileptic Drugs Indicated for the Treatment of Partial-onset Seizures

APPLICATION TRACK

Offers both CME and CPE Credit

UAN #0238-0000-17-017-L05-P

ACPE – 2 CONTACT HOURS/APPLICATION-BASED

CHAIR:

Angela Men, PhD, MD, Pharmacology Lead, US Food & Drug Administration

TARGET AUDIENCE:

This Symposium will be useful for primary care physicians, specialty physicians (in pediatrics), pharmacists, clinical pharmacologists, physician assistants, nurses, nurse practitioners, clinical research associates and basic scientists.

GOALS AND OBJECTIVES:

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

1. Obtain the agency perspectives on the full extrapolation of efficacy from adults to children of antiepileptic drugs (AEDs) indicated for the treatment of partial-onset seizures (POS) and required information to get approval of AEDs use in pediatric patients ≥4 years old of POS;
2. Differentiate POS similarity between adults and pediatrics;
3. Explain how quantitative pharmacokinetic/pharmacodynamic analysis supports the decision making on the new guideline.

10:00 – 10:20 am

Full Extrapolation of Efficacy in Children for Partial-onset Seizures: An FDA-UMD-PEACE Collaborative Project

Angela Men, PhD, MD, Pharmacology Lead, US Food & Drug Administration

10:20 – 10:40 am

Disease Similarity of Partial-onset Seizures Between Adults & Children: PEACE White Paper

Douglas Nordli, Jr, MD, Chief, Div of Pediatric Neurology & Co-director, Neurosciences Inst, Children's Hosp Los Angeles

10:40 – 11:00 am

Quantitative Analysis to Support Full Extrapolation of Efficacy in Pediatrics for Partial-onset Seizures

Joga Gobburu, PhD, MBA, Professor of Pharmacy Practice & Science, Director, Ctr for Translational Medicine, Univ of Maryland School of Pharmacy

11:00 – 11:30 am

Regulatory Impact of Efficacy Extrapolation on Pediatric Antiepileptic Drug Development

Mehul Mehta, PhD, Director, Div of Clinical Pharmacology I, US Food & Drug Administration

11:30 am – 12:00 pm

Q&A

SAN MARINO ROOM

Biosimilars: An Evolving Science

DISCOVERY TRACK

Offers both CME and CPE Credit

UAN #0238-0000-17-018-L01-P

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

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

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

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists in drug development and regulatory sciences, physicians and pharmacists exposed to biologics biosimilars in clinical practice and students, trainees and fellows in clinical pharmacology and related disciplines.

GOALS AND OBJECTIVES:

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

1. Provide detailed insights into the definition and assessment of critical quality attributes for biosimilars, determination of clinically-meaningful pharmacokinetic and pharmacodynamic differences between biosimilars and reference products, or the lack thereof, and the challenges and limitations to assess immunogenic potential during the clinical section of the comparability exercise;
2. Outline the requirements, interpretation and clinical application of results from comparability exercises for biosimilars relative to reference products;
3. Identify how a biosimilar becomes interchangeable.

1:30 – 1:35 pm

Introduction

Darrell R. Abernethy, MD, PhD, Associate Director, Drug Safety, Office of Clinical Pharmacology, US Food & Drug Administration and Bernd Meibohm, PhD, Professor & Associate Dean, Univ of Tennessee Health Science Ctr, Coll of Pharmacy

1:35 – 2:15 pm

The Determination of Critical Quality Attributes in the Assessment of Biosimilarity

Marjorie Shapiro, PhD, Chief, Laboratory of Molecular & Developmental Immunology, Office of Biological Products, Office of Pharmaceutical Quality, Ctr for Drug Evaluation & Research, US Food & Drug Administration

2:15 – 2:55 pm

Determination of "No Clinically-meaningful Difference": The Role of Pharmacokinetic/ Pharmacodynamic Evaluations

Sarah Schrieber, PharmD, Clinical Pharmacologist, US Food & Drug Administration

2:55 – 3:30 pm

Immunogenicity Assessment of Biosimilar Products

Gopi Shankar, PhD, Senior Director & Head, Bioanalytical Sciences & Immunogenicity, Janssen Research & Development LLC

3:30 – 4:00 pm / **Break**

4:00 – 4:40 pm

When Does a Biosimilar Become an Interchangeable?

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

4:40 – 5:30 pm

Panel Discussion

TUESDAY, SEPTEMBER 19, 2017 | Symposium 16 | 1:30 – 5:30 pm

MONTE CARLO ROOM

Opioid Abuse & Misuse: A Rising Epidemic in America

APPLICATION TRACK

Offers both CME and CPE Credit

UAN #0238-0000-17-019-L05-P

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Sam Harirforoosh, PharmD, PhD, Associate Professor, Gatton Coll of Pharmacy

Arsham Alamian, PhD, MSc, MACE, Associate Professor, Coll of Public Health, East Tennessee State Univ

TARGET AUDIENCE:

This Symposium will be useful for scientists, physicians, pharmacists and other healthcare providers who have an interest in the rising opioid epidemic and/or currently conduct research on opioid abuse, prescribe or dispense opioids or develop strategies for the management of opioid misuse, abuse, dependence or addiction.

GOALS AND OBJECTIVES:

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

1. Appraise the current and rising epidemic of opioid abuse and misuse;
2. Analyze the pharmacologic effects of opioids and their side effects;
3. Demonstrate knowledge of the new CDC guideline for prescribing opioids and its use as a clinical pharmacologic approach and alternative for treatment with a focus on buprenorphine and ketamine;
4. Consider pitfalls and strategies in opioid management in medical settings;
5. Illustrate the importance of medical policy and regulations in opioid therapy including risk assessments, urine drug tests and Prescription Drug Monitoring Programs.

1:30 – 1:35 pm

Introduction

Sam Harirforoosh, PharmD, PhD, Associate Professor, Gatton Coll of Pharmacy and Arsham Alamian, PhD, MSc, MACE, Associate Professor, Coll of Public Health, East Tennessee State Univ

1:35 – 2:10 pm

Epidemiology of Opioid Abuse & Misuse in America

Arsham Alamian, PhD, MSc, MACE, Associate Professor, Coll of Public Health, East Tennessee State Univ

2:10 – 2:45 pm

Clinical Pharmacology of Opioids & Their Adverse Effects

Sam Harirforoosh, PharmD, PhD, Associate Professor, Gatton Coll of Pharmacy

2:45 – 3:30 pm

CDC Guidelines Annotated as a Clinical Pharmacologic Approach & Alternatives for Treatment With a Presentation of Buprenorphine & Ketamine

Robert L. Barkin, MBA, PharmD, Clinical Pharmacologist for the Pain Ctrs of Evanston Hosp & Skokie Hosp of NorthShore Univ Health System, Dept of Anesthesiology, Professor, Rush Medical Coll, Faculty of Anesthesiology, Family Medicine & Pharmacology

3:30 – 4:00 pm / **Break**

4:00 – 4:35 pm

Difficult Patients, Difficult Doctors, Difficult Drugs: Pitfalls & Strategies in Opioid Management

Farshad Ahadian, MD, Clinical Professor, Dept of Anesthesiology, Medical Director, Ctr for Pain Medicine, Univ of California, San Diego

4:35 – 5:10 pm

Medical Policy & Regulations When Prescribing Opioid Therapy for Chronic Non-cancer Pain

Gregory R. Polston, MD, Clinical Professor, Anesthesia, Dept of Anesthesiology, Associate Medical Director, Ctr for Pain Medicine, Univ of California, San Diego

5:10 – 5:30 pm

Panel Discussion

Faculty

Last Name	First Name	Activity	Affiliation
Abernethy	Darrell R.	Symposium 15	Associate Director, Drug Safety, Office of Clinical Pharmacology, US Food & Drug Administration
Ahadian	Farshad	Symposium 16	Clinical Professor, Dept of Anesthesiology, Medical Director, Ctr for Pain Medicine, Univ of California, San Diego
Alamian	Arsham	Symposium 16	Associate Professor, Coll of Public Health, East Tennessee State Univ
Bajaj	Gaurav	Symposium 2	Associate Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb Co
Baker	Sharyn	Symposium 8	Chair & Professor, Div of Pharmaceutics & Pharmaceutical Chemistry, Ohio State Univ
Barkin	Robert L.	Symposium 16	Clinical Pharmacologist for the Pain Ctrs of Evanston Hosp & Skokie Hosp of NorthShore Univ Health System, Dept of Anesthesiology, Professor, Rush Medical Coll, Faculty of Anesthesiology, Family Medicine & Pharmacology
Barrett	Jeffrey S.	Pre-meeting Workshop 3	Vice President & Global Head of Translational Informatics, Global Head, Pediatric Clinical Pharmacology, Sanofi
Baum	Marc	Symposium 13	Senior Faculty & President, Oak Crest Inst of Science
Belinsky	Steven	Symposium 10	Vice President, Academic Research & Senior Scientist, Lovelace Respiratory Research Inst
Benet	Leslie Z.	Plenary	Professor & former Chairman (1978 – 1998), Dept of Bioengineering & Therapeutic Sciences, Schools of Pharmacy & Medicine, Univ of California, San Francisco
Berry	N. Seth	Symposium 5	Senior Scientific Advisor, Clinical PK/PD Modeling & Simulation, QuintilesIMS Holdings Inc
Blackman	Samuel	Symposium 4	Senior Vice President, Head, Clinical Development, Silverback Therapeutics Inc
Bradley	John	Pre-meeting Workshop 1	Professor, Clinical Pediatrics, Univ of California, San Diego
Burckart	Gilbert J.	Pre-meeting Workshop 1 & Symposium 12	Associate Director, Pediatrics, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration
Burnham	Janelle	Symposium 5	Pediatrician & Commissioners Fellow, Office of Clinical Pharmacology, US Food & Drug Administration
Capparelli	Edmund	Symposium 13	Professor, Clinical Pediatrics & Pharmacy, Univ of California, San Diego School of Medicine & Skaggs School of Pharmacy & Pharmaceutical Sciences
Chang	Andrew	Symposium 3	Clinical Pharmacology Lead, Pfizer Oncology Group, Pfizer Global Product Development
Chaturvedula	Ayyappa	Symposium 7	Associate Professor, Univ of North Texas System Coll of Pharmacy
Constance	Jonathan	Symposium 8	Assistant Professor, Univ of Utah
Derendorf	Hartmut	Symposium 10	Distinguished Professor & Chair, Dept of Pharmaceutics, Univ of Florida
Ette	Ene	Pre-meeting Workshop 4 & Symposium 7	President & Chief Executive Officer, Anoixis Corp
Fang	Lanyan (Lucy)	Symposium 1	Team Leader, US Food & Drug Administration
Forbes	Ben	Symposium 10	Professor, King's Coll London
Fossler, Jr	Michael J.	Symposium 7	Vice President, Quantitative Sciences, Trevena Inc
Freise	Kevin	Pre-meeting Workshop 4	Assistant Director, Clinical Pharmacology & Pharmacometrics, AbbVie Inc
George	Jomy	Symposium 13	Pharmacokineticist, National Inst of Health

Faculty

Last Name	First Name	Activity	Affiliation
Gobburu	Joga	Symposia 9 & 14	Professor of Pharmacy Practice & Science, Director, Ctr for Translational Medicine, Univ of Maryland School of Pharmacy
Gonzalez	Daniel	Symposium 5	Assistant Professor, Div of Pharmacotherapy & Experimental Therapeutics, UNC Eshelman School of Pharmacy, The Univ of North Carolina at Chapel Hill
Goswami	Srijib	Pre-meeting Workshop 3	Founder & Chief Executive Officer, Insight RX Inc
Green	Dionna J.	Symposia 3 & 6	Medical Officer & Policy Lead, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration
Grobler	Jay	Symposium 13	Director, Infectious Disease Biology, Merck & Co
Gupta	Manish	Pre-meeting Workshop 3	Group Director, Bristol-Myers Squibb Co
Gupta	Neeraj	Pre-meeting Workshop 3	Senior Scientific Director, Takeda Pharmaceuticals Co Ltd
Haberer	Jessica	Symposium 7	Associate Professor, Massachusetts General Hosp & Harvard Medical School
Habtemariam	Bahru	Pre-meeting Workshop 4	Acting Team Leader, Office of Clinical Pharmacology, Div of Clinical Pharmacology V, US Food & Drug Administration
Halegoua-De Marzio	Dina	Symposium 11	Assistant Professor, Medicine & Jefferson Fatty Liver Ctr Director, Thomas Jefferson Univ Hosp
Han	Tae	Symposium 4	Director, Clinical Pharmacology & Pharmacometrics, AbbVie Stemcentrx LLC
Harirforoosh	Sam	Symposium 16	Associate Professor, Gatton Coll of Pharmacy
Harvey	R. Donald	Symposium 8	Associate Professor & Director, Phase I Section, Winship Cancer Inst of Emory Univ
Hochhaus	Guenther	Symposium 10	Professor, Dept of Pharmaceutics, Univ of Florida
Huang	Shiew-Mei	Pre-meeting Workshop 2	Deputy Office Director, Office of Clinical Pharmacology, Office of Translational Sciences, Ctr for Drug Evaluation & Research, US Food & Drug Administration
Jong	Geert W. 't	Symposium 8	Academic Pediatrician & Clinical Pharmacologist, Assistant Professor of Pediatrics, Internal Medicine & Pharmacology, Univ of Manitoba
Kashuba	Angela DM	Symposium 13	John A. & Deborah S. McNeill Jr Distinguished Professor; Chair, Div of Pharmacotherapy & Experimental Therapeutics, Eshelman School of Pharmacy; Director, Clinical Pharmacology & Analytical Chemistry Core, UNC Ctr for AIDS Research; Adjunct Professor of Medicine, UNC School of Medicine, Div of Infectious Diseases
Kimko	Holly	Symposium 9	Scientific Director/Fellow, Global Clinical Pharmacology, Janssen: Pharmaceutical Co of Johnson & Johnson
Knibbe	Catherijne	Symposium 6	Professor, Individualized Drug Treatment, St Antonius Hosp, Dept of Clinical Pharmacy
Krudys	Kevin	Symposium 5	Pharmacometrics Team Leader, Office of Clinical Pharmacology, US Food & Drug Administration
Kumar	Parag	Symposium 13	Director, Clinical Pharmacokinetics Research Unit, National Inst of Health
Laube	Beth	Symposium 10	Professor, Pediatrics, Johns Hopkins Univ
Le	Jennifer	Pre-meeting Workshop 1	Professor, Clinical Pharmacy, Univ of California, San Diego, Skaggs School of Pharmacy & Pharmaceutical Sciences
Lee	Lucy	Symposium 4	Director, Clinical Pharmacology, Infinity Pharmaceuticals Inc
Leeder	J. Steven	Pre-meeting Workshop 2	Director, Div of Clinical Pharmacology, Toxicology & Therapeutic Innovation, Children's Mercy Hosp

Last Name	First Name	Activity	Affiliation
Lesko	Lawrence J.	Pre-meeting Workshop 3 & Symposium 1	Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Dept of Pharmaceutics, Coll of Pharmacy, Univ of Florida
Lexmond	Anne	Symposium 10	Dept of Pharmaceutical Technology & Biopharmacy, Univ of Groningen
Li	Chi-Chung	Symposium 4	Senior Scientist, Clinical Pharmacology, Genentech Research & Early Development (gRED)
Li	Linzhong	Symposium 4	Principal Scientist/Head, Biologics, Simcyp Ltd
Lionberger	Robert	Symposium 1	Director, Office of Research & Standards, Office of Generic Drugs, US Food & Drug Administration
Liu	Chao	Symposium 2	Pharmacometrics Reviewer, Div of Pharmacometrics, Office of Clinical Pharmacology, US Food & Drug Administration
Mager	Donald E.	Pre-meeting Workshop 2	Professor, Pharmaceutical Sciences, Univ at Buffalo, SUNY
Mayawala	Kapil	Pre-meeting Workshop 4 & Symposium 2	Director, Quantitative Pharmacology & Pharmacometrics, Oncology, Merck & Co
McCune	Jeannine	Pre-meeting Workshop 3	Professor, City of Hope Cancer Ctr & Affiliate Professor, Dept of Pharmacy, Univ of Washington
Mehta	Mehul	Symposium 14	Director, Div of Clinical Pharmacology I, US Food & Drug Administration
Meibohm	Bernd	Symposium 15	Professor & Associate Dean, Univ of Tennessee Health Science Ctr, Coll of Pharmacy
Melhem	Murad	Pre-meeting Workshop 4	Principal Scientist, Amgen Inc
Men	Angela	Symposium 14	Pharmacology Lead, US Food & Drug Administration
Momper	Jeremiah	Pre-meeting Workshop 1	Assistant Professor, Univ of California, San Diego, Skaggs School of Pharmacy & Pharmaceutical Sciences
Mould	Diane R.	Pre-meeting Workshop 3	President, Projections Research Inc
Musib	Luna	Symposium 4	Senior Scientist, Clinical Pharmacology, Genentech Research & Early Development (gRED)
Nordli, Jr	Douglas	Symposium 14	Chief, Div of Pediatric Neurology & Co-director, Neurosciences Inst, Children's Hosp Los Angeles
Page	Clive	Symposium 10	Professor, Pharmacology, Sackler Inst of Pulmonary Pharmacology, King's Coll London
Paglialunga	Sabina	Symposium 11	Metabolic & Pharmacodynamic Specialist, Celerion
Patel	Parul	Symposium 13	Clinical Pharmacology Program Leader for Cabotegravir, ViiV Healthcare
Paul	Sofia	Symposium 9	Senior Director, Biostatistics, Oncology, Novartis Pharmaceuticals Corp
Polston	Gregory R.	Symposium 16	Clinical Professor, Anesthesia, Dept of Anesthesiology, Associate Medical Director, Ctr for Pain Medicine, Univ of California, San Diego
Ponrartana	Skorn	Symposium 12	Assistant Professor, Radiology, Children's Hosp Los Angeles, Keck School of Medicine, Univ of Southern California
Price	Dionne	Symposium 3	Director, Div of Biometrics IV, Office of Biostatistics, Ctr for Drug Evaluation & Research, US Food & Drug Administration
Prucka	William	Symposium 5	Director, Innovation Computational Statistics, Biometrics & Advanced Analytics, Eli Lilly & Co
Raetz	Elizabeth	Symposium 8	Professor, Pediatrics, Univ of Utah
Rawal	Sumit	Symposium 2	Research Scientist, Regeneron Pharmaceuticals Inc
Reed	Michael D.	Pre-meeting Workshop 1	Director, Rainbow Clinical Research Ctr, Rainbow Babies & Children's Hosp; Professor, Pediatrics, School of Medicine, Case Western Reserve Univ

Faculty

Last Name	First Name	Activity	Affiliation
Rogge	Mark	Symposium 1	Global Head & Vice President, Quantitative Clinical Pharmacology, Takeda Pharmaceuticals Co Ltd
Roy	Amit	Symposium 2	Group Director, Bristol-Myers Squibb Co
Rudek	Michelle A.	Pre-meeting Workshop 4	Associate Professor, Johns Hopkins Univ
Rusch	Lorraine M.	Symposium 11	President, High Point Clinical Trials Ctr
Sale	Mark	Symposium 7	Senior Vice President, Nuventra Pharma Sciences
Salem	Ahmed H.	Pre-meeting Workshop 4	Associate Director, Clinical Pharmacology & Pharmacometrics, AbbVie Inc
Saluja	Bavna	Symposium 10	Reviewer, Office of Clinical Pharmacology, Div of Clinical Pharmacology 2, US Food & Drug Administration
Schmidt	Stephan	Symposium 2	Associate Professor & Associate Director, Dept of Pharmaceutics, Univ of Florida
Schrieber	Sarah	Symposium 15	Clinical Pharmacologist, US Food & Drug Administration
Sethi	Amar	Symposium 11	President & Chief Scientific Officer, Pacific Biomarkers Inc
Shankar	Gopi	Symposium 15	Senior Director & Head, Bioanalytical Sciences & Immunogenicity, Janssen Research & Development LLC
Shapiro	Marjorie	Symposium 15	Chief, Laboratory of Molecular & Developmental Immunology, Office of Biological Products, Office of Pharmaceutical Quality, Ctr for Drug Evaluation & Research, US Food & Drug Administration
Sherwin	Catherine MT	Symposium 6	Chief, Div of Clinical Pharmacology, Univ of Utah
Snoeys	Jan	Pre-meeting Workshop 2	Scientific Director & Fellow Pharmacokinetics, Dynamics & Metabolism, Janssen R&D Belgium
Struble	Kimberly	Symposium 13	Senior Clinical Analyst Team Leader, US Food & Drug Administration
Templeman	Mark	Symposium 6	Pediatrician, Intermountain Hillcrest Pediatrics
Tsilou	Ekaterini	Pre-meeting Workshop 1	Medical Officer, Eunice Kennedy Shriver National Inst of Child Health & Human Development, National Inst of Health
Vaughns	Janelle D.	Symposium 6	Assistant Professor of Anesthesiology & Pediatrics, Children's National Health System
Venkatakrishnan	Karthik	Pre-meeting Workshops 2 & 4	Senior Director, Quantitative Clinical Pharmacology (Oncology), Takeda Pharmaceuticals Co Ltd
Vinks	Alexander A.	Pre-meeting Workshop 3	Professor, Pediatrics & Pharmacology, Director, Div of Clinical Pharmacology, Cincinnati Children's Hosp Medical Ctr, Univ of Cincinnati, Coll of Medicine
von Moltke	Lisa	Pre-meeting Workshop 2	Vice President, Clinical Research, Alkermes Inc
Wang	Yaning	Symposium 9	Acting Director, Div of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Sciences, Ctr for Drug Evaluation & Research, US Food & Drug Administration
Watt	Kevin	Pre-meeting Workshop 1 & Symposium 3	Assistant Professor, Pediatrics, Duke Univ Medical Ctr, Duke Clinical Research Inst
Xu	Yan	Symposium 9	Associate Scientific Director, Global Clinical Pharmacology, Janssen: Pharmaceutical Co of Johnson & Johnson
Yao	Lynne	Pre-meeting Workshop 1 & Symposia 3 & 12	Director, Div of Pediatric & Maternal Health, Office of New Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration
Yeo	Karen Rowland	Pre-meeting Workshop 2	Vice President, Simcyp Ltd (part of Certara)

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- **Opportunity to enhance your leadership skills** by volunteering for one of ACCP's many committees or by Mentoring Students, Trainees & Young Professionals.
- **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.
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- **Receipt of routine updates from ACCP** about developments in the field of clinical pharmacology and future ACCP events.

How to Join ACCP

ACCP has several categories of membership, please join using the membership category that is most appropriate for you. To join, go to **ACCP1.org**, then select Join and the Member or Student Member profile, as appropriate, complete the profile and make payment.

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.

ACCP membership runs on a calendar year, January to December. Dues renewal notifications are sent in September for the coming year.

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 11, 2018
- May 6, 2018
- September 22, 2018

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 & Young Professionals

Annual Meeting Events for Students, Trainees & Young Professionals

Student, Trainee & Young Professional (STYP) membership and participation in ACCP's Annual Meeting are strongly encouraged and are beneficial on several levels:

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

Student, Trainee & Young Professional-specific Events

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

On **Sunday, September 17th**, please plan to attend:

- **Panel Discussion on Career Guidance** (1:30 – 3:00 pm | Las Palmas & Marseilles Rooms) – 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** (3:00 – 4:00 pm | Las Palmas & Marseilles Rooms) – 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.
- **STYP Networking Reception** (4:00 – 5:00 pm | Fresco's Lounge) – After the Podium Presentations, join us for the STYP 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.

STYP Networking Reception sponsored by DUCK FLATS Pharma LLC

- **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 & Young Professionals will be hosted by an ACCP Mentor to tour the poster area and discuss preselected posters that provide exceptional educational content or presentation.

Special Access to the Experts

On **Tuesday, September 19th**, from 7:00 – 8:00 am, please plan to attend Access to the Experts! This higher level of access to ACCP leadership over breakfast and a sit-down roundtable session provides an Intimate opportunity to discuss career guidance, educational options, opportunities for further involvement in ACCP and how to subsequently grow in the organization throughout your career or any number of other topics of concern. There will be two groups, one for Students & Trainees and another for Young Professionals.

CV Reviews!

Students, Trainees & Young Professionals who submitted their CV for review and have not yet made arrangements for a face-to-face meeting with the Mentor to discuss the review may still do so by contacting KLevy@ACCP1.org or stopping by the ACCP Registration Desk.

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

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The **Student, Trainee & Young Professional (STYP) Committee**, co-chaired by Amelia N. Deitchman, PharmD and Kacey Anderson, PhD, 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 STYP@ACCP1.org.

Amelia N. Deitchman, PharmD

Kacey Anderson, PhD

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www.altasciences.com Booth #: 203

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www.celerion.com Booth #: 106

Exhibitors

Clinical Pharmacology of Miami LLC (CPMI), an Evolution Research Group Portfolio Co, is a private early-development CRU. CPMI's management team includes Kenneth Lasseter, MD, Stacy Dilzer, RN, BSN and Cooper Shamblen. Equipped with 120 beds, CPMI recruits healthy volunteers and specialized populations: hepatic/renal impairment, sexual dysfunction, diabetes, NASH and others. CPMI has completed over 1900 trials from First-in-Man through Phase IIa.
www.evolutionresearchgroup.com **Booth #: 302**

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Medpace is a full-service CRO dedicated to accelerating the global development of safe and effective therapeutics. Our early-phase teams provide innovations in translational medicine techniques – bench to bedside strategies – supporting success early on. Our unique philosophy emphasizes an uncompromising commitment to clinical research and the highest level of performance.
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Exhibitors

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NOCCR and VRG are privately-owned multispecialty clinical research centers which are members of the Alliance for Multispecialty Research. NOCCR-Knoxville is a fully-equipped Phase I Unit with 50 beds and 24,500+ sq ft of space located within the Univ of Tennessee Medical Ctr. This unit excels at First-in-Human, procedurally complex trials and special populations. VRG and NOCCR-New Orleans primarily conduct later phase studies in a broad array of therapeutic areas.
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Exhibitors

Quotient Clinical is a drug development services provider focused on helping clients reduce the time and cost of bringing a drug to market. We deliver integrated capabilities including formulation development, GMP drug product manufacturing and clinical pharmacology services to biotech and pharmaceutical clients globally.
www.quotientclinical.com **Booth #: 303**

Rudraya is a Scientific Platform and Information Technology Service provider to pharmaceutical, biotechnology and healthcare organizations with core focus on High Performance Computing, Cloud Computing, Mobile Medical Applications and Clinical Data Management. Our Customers range from 7 out of the top 10 pharma companies to emerging biotechs. Rudraya's team supports and maintains 8 to 1,600+ cores NONMEM/R compute clusters running 24x7. Rudraya's product range includes: SONIC – Computing Platform and KEEP – Clinical Databases Platform.
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Jeff Wald PhD | Executive Director, Clinical Pharmacology | jeff.wald@qpharmetra.com

Kevin Dykstra PhD, FCP | Chief Executive Officer | kevin.dykstra@qpharmetra.com

Dave Dlesk | VP Business Development | dave.dlesk@qpharmetra.com

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Poster Session 1

Sunday, September 17, 2017 / 5:30 – 7:30 pm / PAVILION

Clinical Pharmacokinetics & Pharmacodynamics

Poster	Type	Title	Authors
001	NM	Pharmacokinetic Simulation of a 150 mg QOD Dose Regimen for the Pharmacological Chaperone Migalastat HCl in Fabry Disease	F. K. Johnson, K. J. Valenzano, J. P. Castelli, N. Skuban, J. A. Barth
002		Impact of Glucose Regimen on the Pharmacokinetics of Canagliflozin in Comparative Bioavailability Studies in Healthy Volunteers	L. Bessiere, C. Dussault, C. Gauvin, J. Wang, M. Lefebvre
003		Effects of CYP3A4 and P-glycoprotein Inhibition by Itraconazole and Cyclosporine, Individually, on the Pharmacokinetics of Sparsentan (RE-021), a First-in-Class, Potent, Orally-active, Dual-acting Angiotensin II (Type 1) Receptor Blocker and Endothelin Type A Receptor Antagonist	M. Karol, X. Pan-Zhou, K. Leach, A. Martinez, R. Komers
004	E	A Study to Evaluate the Effect of JNJ-63623872 (Pimodivir) on Cardiac Repolarization Interval in Healthy Subjects	T. Kosoglou, I. Seghers, W. van Duijnhoven, S. Deleu, H. Fennema, L. Leopold
005		A Phase 1, Randomized, Crossover, Open-label, Study of the Pharmacokinetics, Safety and Tolerability of JZP-110 in Healthy Adults With and Without Food	K. Zomorodi, M. Kankam, J. Li
006	E	An Open-label, Single-dose, Phase 1 Study of the Pharmacokinetics and Safety of JZP-110 in Subjects With Normal or Impaired Renal Function and With End-stage Renal Disease Requiring Hemodialysis	K. Zomorodi, D. Chen, L. Lee, K. Lasseter, T. Marbury
007		Clinical Evaluation of the Effect of Food on the Pharmacokinetics of ALKS 3831, a New Treatment in Development for Schizophrenia	L. Sun, D. McDonnell, L. von Moltke
008		Assessment of the Relative Bioavailability of Dabigatran Etexilate as Pellets on Food and as Granules Resolved in Reconstitution Solution, Compared With Dabigatran Etexilate as Hard Capsules	F. Huang, S. Wiebe, A. Jungnik, S. Gropper, M. Brueckmann, K. Hohl, R. Sennewald, I. Tartakovsky, S. Haertter
009		Effects of Ethnicity on Pharmacokinetics and Safety of DS-1040 in Healthy Males	F. Pizzagalli, C. Rambaran, F. Kobayashi, J. Pav, A. Vandell, V. Warren, V. Dishy, J. Zhou, T. Limsakun
010	S, NM	Pharmacokinetics of Free Mycophenolic Acid in Patients with Childhood-onset Systemic Lupus Erythematosus	L. Agu, D. Zhang, A. P. Sagcal-Gironella, D. S. Chow
011	S, NM	Compartmental Pharmacokinetic Model Analysis for Mycophenolic Acid and its Glucuronide Metabolite in Patients With Childhood-onset Systemic Lupus Erythematosus	L. Agu, L. Wu, A. P. Sagcal-Gironella, D. S. Chow
012	S, NM	Hepatic Metabolic Functions in Living-donor Liver Transplant Patients	M. Miah, M. Li, X. Wu, A. Humar, A. Tevar, C. Hughes, R. Venkataramanan
013	S, NM	Clinical Management of Antidepressants During Pregnancy	S. M. Illamola, V. Young, K. Job, A. H. Balch, M. W. Varner, C. MT Sherwin
014	S	Characterization of the Relationship Between PF-06463922 Steady-state Trough Concentrations With Plasma Exposures and Optimization of Pharmacokinetic Sampling	S. Kawakatsu, Y. K. Pithavala, J. Chen
015	S	Modeling the Time Course of Thrombocytes in Patients with Relapsed and Refractory Acute Lymphoblastic Leukemia Treated with Inotuzumab Ozogamicin	S. Kawakatsu, M. Garrett, A. Ruiz-Garcia, J. Boni, E. Vandendries, A. Advani, H. M. Kantarjian, J. C. Masters
016		Population Pharmacokinetics of Polymyxin B: A Tool for Guiding Optimal Clinical Dosing	P. Manchandani, V. Thamlikitkul, L. S. Lee, Y. Dubrovskaya, J. T. Babic, V. H. Tam

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Poster Session 1

Sunday, September 17, 2017 / 5:30 – 7:30 pm / PAVILION

Clinical Pharmacokinetics & Pharmacodynamics (continued)

Poster	Type	Title	Authors
017	P, S, SA, NM	External Validation of Two Fluconazole Infant Population Pharmacokinetic Models	M. F. Hwang, R. J. Beechinor, K. C. Wade, D. K. Benjamin, C. P. Hornik, S. Duara, K. A. Kennedy, M. Cohen-Wolkowiez, D. Gonzalez
018	S	Population Pharmacokinetic Modeling of Metformin in Patients Undergoing Gastric Bypass Surgery	A. El-Zailik, L. K. Cheung, V. Sherman, D. S. Chow
019		Confirmation of the Cardiac Safety of OBE022 in a Phase 1 Study in Healthy Subjects Using Intensive ECG Assessments and the Effect of a Meal on QTc to Show Assay Sensitivity	J. Taubel, U. Lorch, G. Ferber, O. Pohl

Clinical Trials & Human Pharmacology

Poster	Type	Title	Authors
020		The 24-hour Profile of Moxifloxacin Effect on QTc: A Reflection of Diurnal Variations	J. Taubel, S. Fernandes, G. Ferber
021		Rosuvastatin 5 mg Demonstrates Equivalent Improvements in Serum Lipid Parameters Compared to Atorvastatin 20 mg in Hypercholesterolaemic Patients: An Observational, Naturalistic Study	P. K. Sharma, V. Singh, A. Gupta
022		Review of Phase 1 Dose Escalation Strategy for Antibody-Drug Conjugates in Early Clinical Drug Development in Oncology	M. Chiney, H. Xiong, M. Gibbs, R. M. Menon
023		The Utility of Chest X-ray Screening for First-in-Human Studies	S. Uppal, K. Macci, S. Tarabar, D. Potter, N. Epstein
024		Pharmacokinetics, Safety and Tolerability of PBI-4050, a Novel Anti-fibrotic Drug, in Healthy Human Subjects and in Patients With Stable Renal Impairment	J. Lanthier, M. Tanguay, R. Larouche, V. Pichette, J. Moran, L. Gagnon, P. Laurin, J. Barabé, F. Cesari
025		Assessment of Peripheral Serotonin Synthesis in Man Using Stable Isotope-labeled Tryptophan	M. Gehin, R. W. Welford, M. Garzotti, P. Groenen, O. Nayler, P. Sidharta, J. Dingemanse
026		Pharmacokinetics of DSTP3086S, Anti-STEAP1 Antibody-Drug Conjugate, in Patients with Metastatic Castration-resistant Prostate Cancer: Results from a First-in-Human Phase 1 Study	B. Wang
027		A Phase 1 Study of Fluorapacin Injection in Combination With Pemetrexed in Advanced Non-small Cell Lung Cancer Patients	L. Wu, J. Liu, J. Shentu, Y. Zheng, Y. Zhai, X. Hu, G. Wu, J. Zhou, Q. Zhao
028	S	Clinical Evaluation of the Safety and Preliminary Efficacy of Continuous Infusion of Treprostinil in Preventing Ischemia and Reperfusion Injury in Adult Orthotopic Liver Transplant Recipients	O. Almazroo, M. Miah, V. C. Pillai, A. Humar, A. Tevar, C. Hughes, A. AlKhafaji, A. Demetris, S. Dermont, S. Fedorek, H. Johnson, R. Lopez, R. Planinsic, B. Sengupta, I. Sethu, R. Venkataramanan

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Poster Session 1

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Experimental Pharmacology in In Vitro & In Vivo Studies

Poster	Type	Title	Authors
029		Model-based Validation of C-peptide as the Primary Biomarker in Type 1 Diabetic Patients: An Example of Experimental Medicine	G. Vlasakakis, M. A. Young
031	E	Comparison in Tissue Distribution and Selectivity Among the Three Sodium-glucose Cotransporter Inhibitors Empagliflozin, Dapagliflozin and Canagliflozin	E. Mayoux, S. Liebig, H. Martin, M. Mark
032		Plasma Endothelin-1 Levels and Oxidative Stress Markers in Neonates of Different Gestational Ages	S. Briyal, G. Pais, G. Stefanov, B. Puppala, L. Schweig, A. Gulati
033		A Decrease in Apoptosis Due to IRL-1620 is Mediated via the PI3K/Akt Pathway in a Rodent Model of Alzheimer's Disease	S. Briyal, D. Banerjee, H. Sharthiya, M. Fornaro, A. Gulati
034		Brain Vascular Endothelial Growth Factor and Nerve Growth Factor and Endothelin B Receptor Expression Increases Following Minocycline Treatment in Neonatal Rats With Hypoxic Ischemia	M. G. Hornick, A. Valladolid, S. Sharma, L. Schweig, P. Prazad, A. Gulati
035		Prenatal Oxycodone Exposure Alters Endothelin B Receptor Expression in the Developing Rat Brain	M. G. Hornick, S. Thakadiyil, L. Schweig, P. Prazad, G. Stefanov, A. Gulati
036		BQ-123, an ET_A Receptor Antagonist, Reversed Morphine Tolerance in Mice When Administered Intravenously	S. Bhalla, S. Briyal, S. Andurkar, A. Gulati
039	S	Endothelin B Receptor Agonist, IRL-1620, Significantly Improves Motor Functions in a Rat Model of Spinal Cord Injury	J. Ridgeway, M. G. Hornick, S. Briyal, M. Fornaro, A. Gulati

Immunology/Immunotherapy

Poster	Type	Title	Authors
040		IVIG Patterns Among Pediatric Patients With Neoplasms Admitted to US Pediatric Hospitals	E. Enioutina, J. Wilkes, J. Olson, E. Thorell, A. Pavia, C. MT Sherwin, A. H. Balch

Oncology

Poster	Type	Title	Authors
041		Thyroid Medication Utilization and Its Relationship to Breast Cancer Characteristics	G. H. Sokol, L. S. Loftus, S. McIntyre, T. Oliver, L. Cantilena
042		To Take or Not to Take with Meals? Unravelling Issues Related to Food Effects Labeling for Oral Antineoplastic Drugs	J. Deng, S. Brar, L. J. Lesko
043		A Phase 1 Study to Evaluate the Pharmacokinetics of a Single Dose of YN968D1 Mesylate Tablets in Healthy Male Caucasian, Japanese and Chinese Subjects	L. Pesco Koplowitz, B. Koplowitz, C. H. Park, A. N. McGinn
044	S, NM	Pharmacokinetics of Pulse-high-dose Erlotinib in Advanced Pancreatic Cancer Patients	S. Lin, M. Nikanjam, E. V. Capparelli, T. Reid
045	S	A Proof-of-Concept *In Vitro* Study to Overcome Resistance to HER2-targeted Therapy in Breast Cancer	Y. Franco, L. A. Perez, S. Bihorel

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Poster Session 1 & 2

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Pharmacoeconomics

Poster	Type	Title	Authors
046	NM	Evaluation of Chronic Care Model in Primary Care Clinics: The Economic Outcomes of Utilization of Medication Therapy Management for Chronic Diseases	T. Chung, P. Quan, R. Hernandez, E. Wei, A. Libaud-Moal, M. Bollich, Y. Le, L. Nguyen, L. Lal, J. M. Swint, C. Begley

Pharmacogenomics

Poster	Type	Title	Authors
047	S, SA	Influence of ABCB1 Single Nucleotide Polymorphisms on Dabigatran Exposure Alone and in Combination with Ritonavir and Cobicistat	K. M. Brooks, J. M. George, F. Pangilinan, P. Wakim, V. Natarajan, L. A. Gordon, S. R. Penzak, R. Alfaro, A. Kellogg, M. McManus, C. Hadigan, P. Kumar

Pharmacometrics

Poster	Type	Title	Authors
048	NM	An Integrated Population Pharmacokinetic Model of Depatuxizumab Mafodotin, an Anti-epidermal Growth Factor Receptor Antibody-Drug Conjugate, in Patients with Glioblastoma Multiforme or Advanced Solid Tumors Likely to Overexpress Epidermal Growth Factor Receptor	R. K. Mittapalli, S. Stodtmann, S. Mensing, R. M. Menon, H. Xiong
049		Data Listing and the Analysis for Immunogenicity of Biologic Agents: Correlation With Efficacy and Pharmacokinetics	G. Bernstein, J. Steyn, H. Mehta, J. He, A. Andrion, J. Oldenhof
050		Population Pharmacokinetic Analysis for Guadecitabine (SG-110) and Decitabine after Subcutaneous Dosing with SGI-110 in Patients with Relapsed/ Refractory Acute Myeloid Leukemia and Myelodysplastic Syndromes	A. Oganesian, E. Gibiansky, H. M. Kantarjian, G. J. Roboz, K. W. Yee, P. L. Kropf, M. Azab, J. Issa, L. Gibiansky
051		Predicting Future Calcineurin Inhibitor Concentrations in Pediatric Transplant Recipients to Reduce Drug Monitoring Burden	J. E. Rower, C. Stockmann, K. M. Molina, C. MT Sherwin
052	S, E, NM	Evaluation of Effect of Adherence Patterns on the Sample Size and Power: A Simulation Study	S. Mallayasamy, M. J. Fossler, Jr, A. Chaturvedula

Regulatory Issues

Poster	Type	Title	Authors
053		Impact of Federal Regulatory Changes on Drug Development: The Common Rule and the 21st Century Cures Act	J. T. Puglisi, J. F. Burris

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Absorption, Distribution, Metabolism & Elimination

Poster	Type	Title	Authors
054	P, S, SA	Application of Large-pore Microdialysis in Interstitial Sampling of Therapeutic Monoclonal Antibody	V. Khaowroongrueng, S. B. Jadhav, M. Fueth, M. B. Otteneder, W. Richter, H. Derendorf
056		A Study to Characterize the Absorption, Metabolism and Excretion of ^{14}C-JNJ-63623872 (Pimodivir) in Humans	T. Kosoglou, I. Wynant, T. Kakuda, H. Fennema, L. Leopold

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Poster Session 2

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Absorption, Distribution, Metabolism & Elimination (continued)

Poster	Type	Title	Authors
057		Metabolism of Veledimex, an Activator Ligand for the RheoSwitch Therapeutic System®, for Controlled Delivery of Immunotherapy	H. Cai, K. Kassahun, G. Luo, A. Mutlib, J. Miao, F. Lebel, J. Barrett
058		Relative Bioavailability, Dose Proportionality, Food Effect and Palatability of a New Sorafenib Tablet for Oral Suspension	J. Lettieri, A. Ajavon-Hartmann, M. Berse, F. Huang
059	S, NM	Differential Impact of Minocycline Dose and Route of Administration on Brain and Spinal Cord Exposures of Riluzole	M. Sarkar, R. Grill, R. Grossman, D. S. Chow

Applications of Modeling & Simulation

Poster	Type	Title	Authors
060	NM	Quantitative Systems Pharmacology Modeling in Diabetes-Cardiovascular Drug Research and Development	K. Azer, B. Goebel
061		Evaluation of the Influence of Renal Impairment on the Pharmacokinetics of Gepotidacin Using a Physiologically-based Pharmacokinetic Model	D. Nguyen, G. Tai, C. Perry, E. Dumont, D. Gardiner, M. Hossain
062	S, NM	Omeprazole Limited-sampling Strategies to Predict Clearance: Implications for Cytochrome P450 2C19 Phenotyping	S. Lin, M. Nikanjam, E. V. Capparelli, A. Allegrini, D. Pavone, D. Yim, M. Hammami, J. Bertino, Y. Park, J. Kang, O. Yin, J. Ma
064	S	Population Pharmacokinetic Modeling of Ceftriaxone in Healthy Adults and Optimization of the Blood Sampling Scheme for Pediatric Population	D. V. Neves, V. L. Lanchote, S. Oosterholt, O. Pasqua
065	S	The Application of Physiologically-based Pharmacokinetic Modeling to Predict BI 44370 Pharmacokinetics in Human and Drug-Drug Interaction with Midazolam	Y. Yu, R. S. Sane, J. Zhou, H. Q. Nguyen, H. Derendorf, S. Haertter

Big Data

Poster	Type	Title	Authors
066	S, NM	Depression and Framingham CHD Risk in a Korean Community-based Cohort Study	H. Jang, Y. Song, J. Kim, M. Kim, H. Lee, Y. Kim, Y. Kim, J. Oh, I. Kim
067	S	Association Between Selective Serotonin Reuptake Inhibitors and Major Adverse Cardiovascular Events: A Meta-analysis of Randomized Controlled Trials	Y. Kim, Y. Lee, M. Kim, Y. Song, Y. Kim, H. Jang, J. Oh, I. Kim

Clinical Pharmacology Education

Poster	Type	Title	Authors
068		Entrustable Professional Activity in Clinical Pharmacology	V. S. Donnenberg, J. F. Burris, J. M. Korth-Bradley, P. H. Wiernik, L. J. Cohen

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Drug Interactions

Poster	Type	Title	Authors
071	P, S, SA	*In Silico* Evaluation of a Pharmacokinetic Interaction between Fusidic Acid and Statins Using a Physiologically-based Pharmacokinetics Modeling Approach	S. B. Jadhav, H. Derendorf
072	NM, S, SA	Effect of Voriconazole Coadministration on Tacrolimus Levels and Its Association With Clinical Covariates in Lung Transplant Recipients: A Single-center Retrospective Evaluation	H. Thanukrishnan, C. R. Ensor, R. Venkataramanan
073	S, SA	Perioperative Drug Interactions in Adolescent Patients Presenting for Sleeve Gastrectomy	E. F. Williams, J. Vaughns, J. C. Muret, J. N. van den Anker, E. P. Nadler
074		Pharmacokinetic Drug-Drug Interactions Between Letermovir and Immunosuppressants	S. Macha, A. Adedoyin, W. Marshall, S. Fox-Bosetti, D. Kropeit, C. Cho, O. von Richter, F. Liu, T. Zhao, V. Levine, D. Panebianco, J. McCrea, P. Auger, J. Brejda, K. M. Dunnington, A. Mirzac, A. Hohnstein, C. Brandquist, W. Heber, T-J. Faihst, H. Rübsamen-Schaeff, D. de Alwis, M. Iwamoto
075	E, NM	No Clinically-significant Interaction of MK-3682 With the HIV Medications Dolutegravir, Raltegravir, Rilpivirine and Tenofovir Disoproxil Fumarate	H. Manthos, C. Brandquist, J. Brejda, T. E. O'Reilly, W. Gao, L. Arrington, X. Glasgow, J. A. Luk, E. G. Rhee, W. L. Marshall, M. Iwamoto, N. D. Kim
076		Drug-Drug Interaction of Midazolam with Elagolix, a Novel Oral GnRH Antagonist: Analyses of Data from Two Studies	A. R. Polepally, M. B. Dufek, S. P. Dharia, K. Kamradt, J. Lin, P. M. Peloso, C. E. Klein, N. Mostafa, J. Ng
078	E	Ethanol PK/PD Interactions with Dexmethylphenidate and dl-Methylphenidate Spheroidal Oral Drug Absorption Systems in Healthy Volunteers	K. S. Patrick, A. B. Straughn, H. Zhu, O. T. Reeves III, H. Bernstein, J. Shi, H. J. Johnson, J. M. Knight, A. T. Smith, R. J. Malcolm, J. S. Markowitz
079		Effect of Rifampin on the Pharmacokinetics of ALKS 3831, a New Treatment in Development for Schizophrenia, in Healthy Human Subjects	L. Sun, D. McDonnell, M. Yu, L. von Moltke
080		Effect of Carbamazepine on the Pharmacokinetics of the Nav1.7-selective Sodium Channel Blocker BIIB074 in Healthy Subjects	H. Naik, M. Versavel, Y. Zhao, G. Layton, J. Dunbar
081		Effect of Itraconazole on the Pharmacokinetics of the Nav1.7-specific Sodium Channel Blocker BIIB074 in Healthy Subjects	H. Naik, M. Versavel, Y. Zhao, X. Miao, J. Dunbar
082		A Clinical Study Assessing Potential Induction of CYP3A4 and CYP2B6 by Steady-state Sparsentan (RE-021), a First-in-Class, Potent, Dual Angiotensin II Blocker and Endothelin Type A Receptor Antagonist, Using Midazolam and Bupropion as *In Vivo* Probes	M. Karol, X. Pan-Zhou, K. Leach, A. Martinez, S. Korb, K. Lyons, R. Komers
083		Prevalence of Potential Drug-Drug Interactions With Direct Oral Anticoagulants in Elderly Inpatients	T. Polasek, H. Forbes
084		Evaluation of the Effects of a pH-elevating Agent and Strong CYP3A4 Inducer on the Repeat Dose Pharmacokinetics of Dabrafenib	N. Nebot, H. Arkenau, J. Nemunaitis, J. Chaves, J. D. Lickliter, G. J. Weiss, D. Lee, Y. Huang, E. Bouillaud, A. St-Pierre
085	S	Effect of 5,7-Dimethoxyflavone on Sorafenib Pharmacokinetics in Mice	S. Bae, R. D'Cunha, J. Shao, G. An
086	S	Characterization of CITCO and Implications for Lymphoma Treatment	W. D. Hedrich, L. Li, D. Li, Y. Lu, H. Hassan, H. Wang
087		Effects of the Coadministration of Multiple Doses of Elagolix on the Pharmacokinetics and Safety of Digoxin in Healthy Women	J. Ng, A. Salem, D. Carter, C. E. Klein

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Poster Session 2

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Drug-induced Organ Injury

Poster	Type	Title	Authors
088	S	Effect of Diclofenac Nanoparticle Formulation on Rat Cardiac Tissue	C. L. Carter, A. S. Cofer, D. E. Murrell, J. W. Denham, S. Harirforoosh
089	S	Cardiac Outcomes Following Administration of a Celecoxib Nanoparticle Formulation in Rats	A. S. Cofer, C. L. Carter, D. E. Murrell, J. W. Denham, S. Harirforoosh

HIV/AIDS

Poster	Type	Title	Authors
090	P, S, SA	Population Pharmacokinetics of Lopinavir/Ritonavir: Changes Across Formulations and Human Development from Infancy through Adulthood	J. Yang, M. Nikanjam, B. M. Best, J. Pinto, E. G. Chadwick, E. Daar, P. L. Havens, N. Rakhmanina, E. V. Capparelli
091	NM	Optimization of Antiretroviral Therapy by Pharmacist Intervention in Hospitalized Patients	E. Dowers, F. Zamora
092	S	Comparison of Side-effect Profiles Among Integrase Strand Transfer Inhibitor Regimens	D. E. Murrell, D. B. Cluck, J. P. Moorman, S. C. Karpen, S. Harirforoosh

Model-based Drug Development

Poster	Type	Title	Authors
093		Optimizing Venetoclax Dose in Combination With Low-dose Cytarabine in Elderly Patients with Newly-diagnosed Acute Myeloid Leukemia: An Exposure-Response Analysis	S. Agarwal, S. Gopalakrishnan, S. Mensing, J. Hayslip, R. M. Menon, A. Salem
094	S, SA	AEOL10150 Improves 180-day Survival of Lethally-irradiated Rhesus Macaques	H. Wang, J. McManus, J. V. Gobburu, V. Ivaturi
095	S	Dose and Regimen Determination Study of AEOL10150 as a Mitigator of Radiation-induced Lung Injury in C57L/J Mice	H. Wang, J. McManus, I. L. Jackson, Z. Vujaskovic, J. V. Gobburu, V. Ivaturi
096	E	Model-informed Drug Development for Ixazomib, an Oral Proteasome Inhibitor	N. Gupta, M. Hanley, P. Diderichsen, H. Yang, Y. Huh, A. Ke, Z. Teng, R. Labotka, D. Berg, C. Patel, G. Liu, H. van de Velde, K. Venkatakrishnan
097	S, NM	A Novel, Interactive Quantitative Clinical Pharmacology Approach Applied to Biomarker Identification in Oncology	Y. Lien, V. Sharma, S. Basu, H. Yang, W. Wang, H. Zhou, S. Bihorel, S. Schmidt
098	S, E	Relationship Between Short-term Response Rates and Long-term Survival in Acute Myeloid Leukemia and Relapsed or Refractory Multiple Myeloma	N. Mangal, A. Salem, R. M. Menon, S. Agarwal, K. Freise

Pediatrics

Poster	Type	Title	Authors
099	NM	Association of Meropenem Clearance, Covariates and Estimated Glomerular Filtration Rate in Neonates	E. Muhari-Stark, X. Chen, C. MT Sherwin, Y. Wang, J. Wang, L. Yao
100		Use of Enrichment Strategies in Pediatric Drug Development	D. Green, X. Liu, T. Hua, J. Burnham, G. Burckart, I. Zineh
101		Population Pharmacokinetics of Defibrotide in Japanese Pediatric and Adult Patients for the Prevention of Veno-occlusive Disease	T. Kimura, C. Ogawa, T. Fukuda, S. Taniguchi, K. Horibe, K. Yoshimura, Y. Mori, K. Ohashi, C. Nitani, H. Gotoh, A. Kikuta

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Pediatrics (continued)

Poster	Type	Title	Authors
102		Characterization of Dasatinib Pharmacokinetics in Support of Dose Recommendation in Pediatric Patients with Philadelphia Chromosome Positive Chronic Myeloid Leukemia In Chronic Phase	X. Wang, A. Bello, A. Roy
103	S	Prescription Drug Shortages: Impact on Neonatal Intensive Care	V. Ziesenitz, E. Fox, M. Zocchi, J. N. van den Anker, M. Mazer-Amirshahi
104	S, E	The Pharmacokinetics of Fentanyl and its Derivatives in Children: A Comprehensive Review	V. Ziesenitz, J. Vaughns, G. Koch, A. Atkinson, G. Mikus, J. N. van den Anker

Precision Medicine as it Relates to Patient Care

Poster	Type	Title	Authors
105		Prospective AUC-guided Vancomycin Dosing Trial	M. Neely, L. Kato, G. Youn, L. Kraler, B. Jones, E. Minejima
106		Comparative Cost-effectiveness and Outcomes Assessment of Two Gene-expression Classifiers for Colorectal Cancer	A. M. Issa, V. Chaudhuri
107	S	Individualized Dosing Adjustments for Patients Undergoing Continuous Renal Replacement Therapy	S. N. Kalaria, M. Armahizer, P. McCarthy, J. V. Gobburu, M. Gopalakrishnan

Safety & Efficacy

Poster	Type	Title	Authors
108	E, NM	MK-3682 (HCV NS5B Inhibitor) and MK-8408 (HCV NS5A Inhibitor) Do Not Cause a Clinically-meaningful QTc Prolongation in Healthy Subjects	T. Marenco, H. Manthos, W. Gao, L. Arrington, J. Brejda, X. S. Glasgow, N. Cardillo Marricco, Z. Machnes, J. A. Luk, G. Garrett, T. E. O'Reilly, D. Armas, A. Jain, M. Iwamoto, N. D. Kim
109		Establishment and Evaluation of Simple and Remote Supervision System for Anticancer Drug Preparation	H. Tanaka, K. Takahashi, K. Yamaguchi, K. Atagi, K. Aoki, T. Motoki, T. Inoue, K. Higuchi, N. Shinohara, T. Nozaki, K. Okamura, M. Asakura, S. Kosaka, H. Houchi
110		Patient-level Data Analysis Revealed the Real Incidence and Impact of Celecoxib on Edema	W. Wang, S. Qazi, L. Murphy, A. Mehta, M. Munsif, Z. Yim, V. Trieu
111		Safety and Tolerability of a New Clinical Lot of Reference Endotoxin (LPS [CCRE Lot 94332B10]) in Healthy Subjects	R. Noveck, J. Guptill, C. Foss, B. Hauser, A. F. Suffredini
112	E	Medication Errors Among Health Professionals in Nigeria: A National Survey	O. O. Ogunleye

Special Populations

Poster	Type	Title	Authors
114	E	Single-dose Pharmacokinetics of ALP2011 in Subjects With Various Degrees of Hepatic Impairment	J. Michaud, C. Fazio, S. Boily, E. Sicard, M. Lefebvre

Therapeutic Drug Monitoring

Poster	Type	Title	Authors
115	S, NM	Voriconazole Therapeutic Target Attainment Among Pediatric Patients	E. Biltaji, E. K. Korgenski, C. MT Sherwin, J. E. Constance

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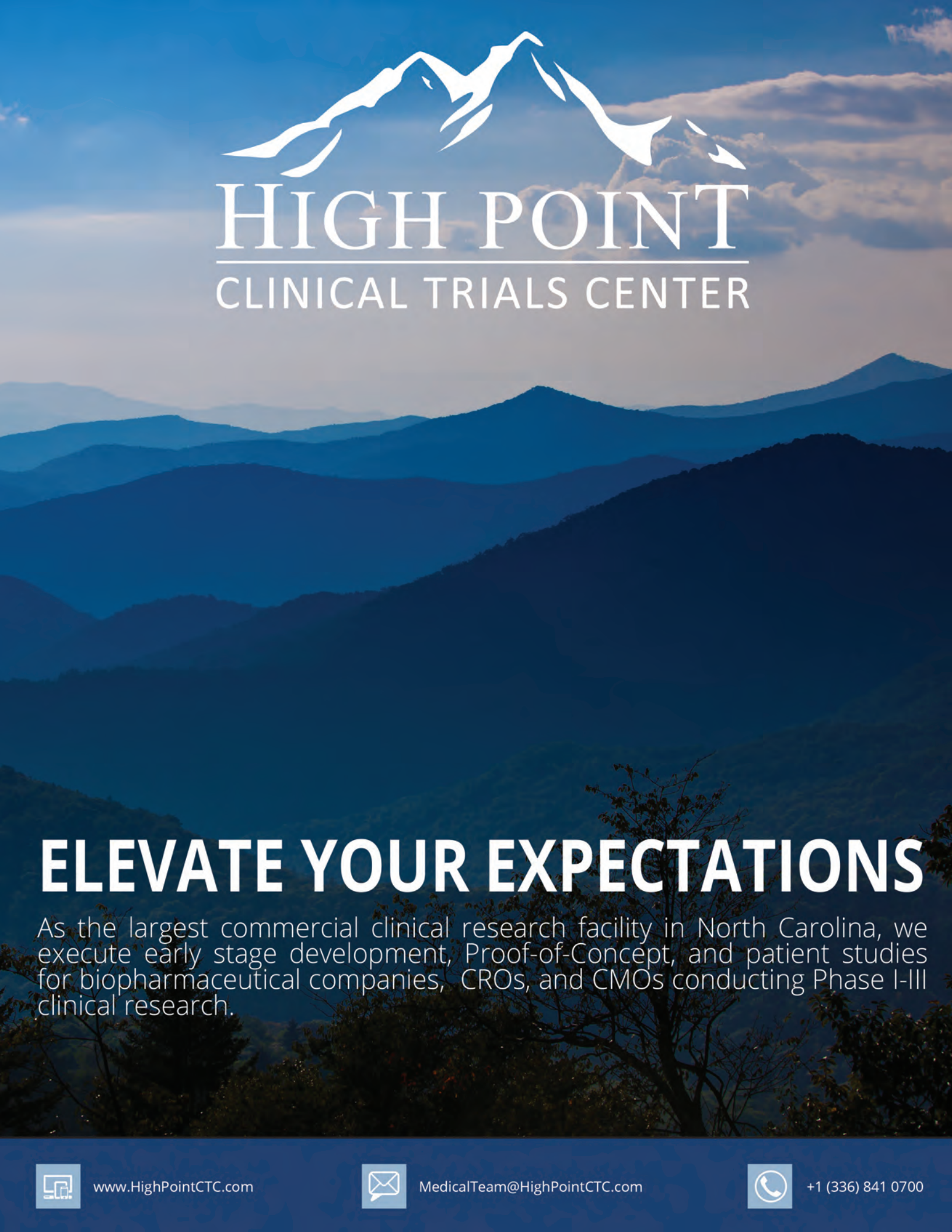
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