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American College of Clinical Pharmacology 2017 Program Committee

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

Members:
John van den Anker, MD, PhD
Lawrence J. Cohen, PharmD
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Join Us for the 2017 ACCP Annual Meeting!

Emerging Technologies in Clinical Pharmacology

Dear Colleague:

It is our pleasure to invite you to attend the 2017 Annual Meeting of the American College of Clinical Pharmacology (ACCP), September 17th – 19th, at the Hilton San Diego Resort & Spa in San Diego, CA. This year’s meeting is focused on Emerging Technologies in Clinical Pharmacology. Consistent with ACCP’s commitment to excellence in science and education, 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 that meets 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 that allow attendees to uniquely tailor content selection to their individual interests.

On Saturday, September 16th, four Pre-meeting Workshops will 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 will begin 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 continue 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; pharmacoanalytics – 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 is William E. Evans, PharmD, Faculty Member, Endowed Chair in Pharmacogenomics, St Jude Children’s Research Hosp.

A series of special Student, Trainee & Young Professional-focused programs are planned that 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.

We strongly encourage you and your colleagues to join us for this outstanding educational and scientific experience. If you have never had the opportunity to attend an ACCP Annual Meeting, make 2017 the year to participate and see 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. Early Bird Registration rates end June 30th and don’t forget to register early for the Pre-meeting Workshops, as seating is limited.

The Hilton San Diego Resort & Spa is an easy ride from the airport and is close to area attractions in a thriving district that is home to excellent restaurants, theaters, art galleries, sports venues and shopping. Deluxe accommodations on the waterfront welcome the sun and breeze. For your benefit, a special room rate of $199 has been established. Please note: these rates include the resort fee, which is charged separately for any reservations outside of our room block. In addition, the special rate has been extended to three days before and after the meeting. The cutoff date for this group rate is August 31, 2017.

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 look forward to welcoming you to an outstanding 2017 ACCP Annual Meeting. Come learn, network and be part of an excellent and educational scientific event in the clinical pharmacology community!
Workshops & Symposia at the 2017 ACCP Annual Meeting are identified as being part of either the “Discovery Track” (DT) or the “Application Track” (AT) to make it easier for attendees to determine which courses they prefer to attend.

SATURDAY, SEPTEMBER 16, 2017

**Pre-meeting Workshop 1 | 8:00 am – 12:00 pm**
Should Off-patent Medications Be Labeled for Pediatric Use? ACCP/PPAG Jointly-sponsored Symposium (AT)

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, RPh, PharmD, Director, Rainbow Clinical Research Ctr, Rainbow Babies & Children’s Hosp, Case Western Reserve Univ School of Medicine and Gilbert J. Burckart, PharmD, Associate Director of Pediatrics, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration

**Pre-meeting Workshop 2 | 8:00 am – 12:00 pm**
Best Practice Approaches to Physiologically-based Pharmacokinetic Modeling for Labeling Initiatives: Industry & Regulatory Perspectives (AT)

CO-CHAIRS: Karthik Venkatakrishnan, PhD, Senior Director, Quantitative Clinical Pharmacology, Takeda Pharmaceuticals Co Ltd and Karen Rowland Yeo, PhD, Vice President, Simcyp (part of Certara)

**Pre-meeting Workshop 3 | 1:30 – 5:30 pm**
Therapeutic Drug Monitoring in Advancing Patient Care: Is This Time Different? (AT)

CO-CHAIRS: Neeraj Gupta, PhD, Senior Scientific Director, Takeda Pharmaceuticals Co Ltd and Manish Gupta, PhD, Group Director, Bristol-Myers Squibb Co

**Pre-meeting Workshop 4 | 1:30 – 5:30 pm**
Modeling & Simulation Strategies for Dose Selection of Targeted Anticancer Agents (DT)

CO-CHAIRS: Ahmed H. Salem, PhD, Associate Director, Clinical Pharmacology & Pharmacometrics, AbbVie Inc and Murad Melhem, PhD, Principal Scientist, Amgen Inc

SUNDAY, SEPTEMBER 17, 2017

**Plenary Session | 8:00 – 9:30 am**
Predicting Pharmacokinetics/Pharmacodynamics in the Individual Patient: Separating Reality from Hype (AT)

Leslie Z. Benet, PhD, Professor & former Chairman (1976–1998), Dept of Bioengineering & Therapeutic Sciences, Schools of Pharmacy & Medicine, Univ of California, San Francisco

**Symposium 1 | 10:00 am – 12:00 pm**
Innovative Scientific & Risk-based Quantitative Approaches to Post-marketing Surveillance of New & Generic Drug Products (AT)

CO-CHAIRS: Lawrence J. Lesko, PhD, Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Dept of Pharmaceutics, Coll of Pharmacy, Univ of Florida and Lanyan (Lucy) Fang, PhD, Team Leader, US Food & Drug Administration

**Symposium 2 | 10:00 am – 12:00 pm**
Optimizing Dose/Dosing Frequency for a Biologic: Clinical, Regulatory & Commercial Perspectives (AT)

CO-CHAIRS: Gaurav Bajaj, PhD, Associate Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb Co and Sumit Rawal, PhD, Research Scientist, Regeneron Pharmaceuticals Inc

**Symposium 3 | 1:30 – 3:30 pm**
Master Protocols in Drug Development (AT)

CO-CHAIRS: Diona J. Green, MD, Medical Officer & Policy Lead, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration and Kevin Watt, MD, PhD, Assistant Professor of Pediatrics, Duke Univ Medical Ctr, Duke Clinical Research Inst

**Symposium 4 | 1:30 – 5:30 pm**
Next Wave in Cancer Medicine: Mechanisms & Progress for Emerging Therapeutics (DT)

CO-CHAIRS: Lucy Lee, PharmD, Director, Clinical Pharmacology, Infinity Pharmaceuticals Inc and Luna Musib, PhD, Senior Scientist, Clinical Pharmacology, Genentech Research and Early Development (gRed)

**Symposium 5 | 4:00 – 5:30 pm**
Clinical Trial Simulations in Pediatric Drug Development (AT)

CO-CHAIRS: Janelle Baker, MD, Pediatrician & Commissioners Fellow, Office of Clinical Pharmacology, US Food & Drug Administration and Daniel Gonzalez, PharmD, PhD, Assistant Professor, Div of Pharmacotherapy & Experimental Therapeutics, UNC Eshelman School of Pharmacy, The Univ of North Carolina at Chapel Hill
Program at a Glance

Workshops & Symposia at the 2017 ACCP Annual Meeting are identified as being part of either the “Discovery Track” (DT) or the “Application Track” (AT) to make it easier for attendees to determine which courses they prefer to attend.

**MONDAY, SEPTEMBER 18, 2017**

**Symposium 6 | 8:00 – 9:30 am**
Therapeutic Options for Obesity Treatment in Children, Adolescents & Young Adults (AT)
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 and Janelle D. Vaughns, MD, Assistant Professor of Anesthesiology & Pediatrics, Children’s National Health System

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**Symposium 7 | 8:00 am – 12:00 pm**
Modeling of Adherence: Applications in Drug Development & Clinical Practice (DT)
CO-CHAIRS: Ayyappa Chaturvedula, PhD, Associate Professor, Univ of North Texas System Coll of Pharmacy and Mark Sale, MD, Senior Vice President, Nuventra Pharma Sciences

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**Symposium 8 | 10:00 am – 12:00 pm**
Kinase Inhibitors in Pediatric Patients: Experiences, Pharmacology & Future Applications (DT)
CO-CHAIRS: Jonathan Constance, PhD, Assistant Professor, Univ of Utah and G. W. ’t Jong, MD, PhD, Academic Pediatrician & Clinical Pharmacologist, Assistant Professor of Pediatrics, Internal Medicine & Pharmacology, Univ of Manitoba

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**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 (AT)
CHAIR: Yan Xu, PhD, Associate Scientific Director, Global Clinical Pharmacology, Janssen. Pharmaceutical Co of Johnson & Johnson

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**Symposium 10 | 1:30 – 5:30 pm**
Challenges & Opportunities in the Development of Inhaled Medicines (DT)
CO-CHAIRS: Clive Page, BSc, PhD, Professor of Pharmacology, Sackler Inst of Pulmonary Pharmacology, King’s Coll and Anne Lemarkson, PharmD, PhD, Dept of Pharmaceutical Technology & Biopharmacy, Univ of Groningen

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**Symposium 11 | 4:00 – 5:30 pm**
Pioneering NAFLD/NASH Early-phase Clinical Pharmacology Study Designs (DT)
CO-CHAIRS: Lorraine Rusch, PhD, President, High Point Clinical Trials Ctr and Sabina Paglialunga, PhD, Metabolic & Pharmacodynamic Specialist, Celerion

**TUESDAY, SEPTEMBER 19, 2017**

**Symposium 12 | 8:00 – 9:30 am**
Assessment of Drug Effect on Pediatric Bone Health (DT)
CHAIR: Gilbert J. Burckart, PharmD, Associate Director of Pediatrics, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration

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**Symposium 13 | 8:00 am – 12:00 pm**
21st Century HIV/AIDS: An Evolving Drug Development & Technology Paradigm (DT)
CO-CHAIRS: Jomy George, PharmD, Pharmacokineticist, National Inst of Health and Parag Kumar, PharmD, Director, Clinical Pharmacokinetics Research Unit, National Inst of Health

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**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 (AT)
CHAIR: Angela Men, PhD, MD, Pharmacology Lead, US Food & Drug Administration

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**Symposium 15 | 1:30 – 5:30 pm**
Biosimilars: An Evolving Science (DT)
CO-CHAIRS: Darrell R. Abernethy, MD, PhD, Associate Director for 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

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**Symposium 16 | 1:30 – 5:30 pm**
Opioid Abuse & Misuse: A Rising Epidemic in America (AT)
CO-CHAIRS: Sam Harifooroosh, PharmD, PhD, Associate Professor, Gatton Coll of Pharmacy and Arsham Alamian, PhD, MSc, MACE, Assistant Professor, Coll of Public Health, East Tennessee State Univ
William E. Evans, PharmD – Faculty Member, Endowed Chair in Pharmacogenomics, St Jude Children’s Research Hosp

Pharmacogenomics: Technology Accelerating Discovery and Translation to Precision Medicine

Monday, September 18, 2017 at the Lunch & Awards Session | 12:10 – 1:20 pm

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).
ACCP Distinguished Investigator Award
Nick Holford, MBChB, FRACP, FAAPS, FISoP – Professor of Clinical Pharmacology, Univ of Auckland, Auckland, New Zealand

The Distinguished Investigator Award is given annually and is intended to recognize superior scientific expertise and accomplishments by a senior investigator, usually involving a distinct area of research in basic or clinical pharmacology, for which the individual is internationally known.

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
Angela DM Kashuba, BScPhm, PharmD, DABCP – John A. and Deborah S. McNeill Jr Distinguished Professor of Pharmacy; Chair, Div of Pharmacotherapy & Experimental Therapeutics, Eshelman School of Pharmacy; Adjunct Professor of Medicine, Dept of Infectious Diseases, Univ of North Carolina at Chapel Hill

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

Dr. 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.
Nathaniel T. Kwit Memorial Distinguished Service Award
Susan K. McCune, MD – Director, Office of Pediatric Therapeutics, Office of the Commissioner, US Food & Drug Administration

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

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
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.

Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award
Bernd Meibohm, PhD, FCP, FAAPS – Professor & Associate Dean, Univ of Tennessee Health Science Ctr, Coll of Pharmacy

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.
Student, Trainee & Young Professional 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, the following events will be hosted:

- **Panel Discussion on Career Guidance** (1:30 – 3:00 pm) – 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) – 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) – 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.

- **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, ACCP will provide Access to the Experts in two groups, one for Students & Trainees and another for Young Professionals. 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, how to subsequently grow in the organization throughout their careers or any number of other topics of concern.

**CV Reviews!**

All Students, Trainees & Young Professionals are encouraged to provide their CV for review and suggestions by ACCP Mentors. You may make arrangements for a face-to-face meeting with the Mentor to discuss the review by contacting KLevy@ACCP1.org.

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

Visit us at [facebook](#)  [LinkedIn](#).

**ACCP Member Benefits**

**Join ACCP**

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
Abstract Submission Timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tr>
<td>January 23, 2017</td>
<td>Abstract Submission site opens</td>
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<tr>
<td>April 17, 2017</td>
<td>Abstract Submission site closes</td>
</tr>
<tr>
<td>Mid-May 2017</td>
<td>Abstract notifications sent by email to first authors regarding decisions by the Annual Meeting Program Committee on the status of acceptance</td>
</tr>
<tr>
<td>June 9, 2017</td>
<td>Deadline to submit Registration Form &amp; Abstract Contract or to withdraw abstract(s)</td>
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Please note: Poster presenters have the sole obligation of ensuring that the information and spelling on all authors and content is accurate at the time of submission. ACCP holds no responsibility for corrections after publication of any materials related to the meeting.

Areas of Abstract Submission

- Absorption, Distribution, Metabolism and Elimination
- Applications of Modeling and Simulation
- Big Data
- Biosimilars
- Chronic Pain and Opioid Management
- Clinical Pharmacokinetics and Pharmacodynamics
- Clinical Pharmacology Education
- Clinical Trials and Human Pharmacology
- Counterfeit Drugs
- Decision Making in Research and Development
- Disease Management
- Drug-induced Organ Injury
- Drug Interactions
- Effectiveness and Impact on Quality of Life
- Emerging Technologies in Clinical Pharmacology
- Experimental Pharmacology in In Vitro and In Vivo Studies
- HIV/AIDS
- Immunology/Immunotherapy
- Infectious Diseases (Antibiotics/Vaccines)
- Mechanism of Action
- Model-based Drug Development
- New and Adaptive Clinical Trial Designs
- Novel Use of Antidepressants
- Oncology
- Orphan Drugs
- Pediatrics
- Pharmacoeconomics
- Pharmacoepidemiology
- Pharmacogenomics
- Pharmacometrics
- Precision Medicine as it Relates to Drug Development
- Precision Medicine as it Relates to Patient Care
- Regulatory Issues
- Risk Management/Legal Issues
- Safety and Efficacy
- Special Populations
- Therapeutic Drug Monitoring
- Translational Medicine, Including Biomarkers and/or Imaging

PRIMARY CRITERIA FOR ACCEPTANCE OF ABSTRACTS ARE:

- Applicability to clinical pharmacology and translational medicine
- Innovation and scientific merit
- Relevance to ACCP’s mission

ACCP accepts encore poster presentations; however, encores must be documented as such when the abstract is submitted.

EACH ABSTRACT MUST CONTAIN:

- A statement of purpose, innovation or hypothesis
- Description of methods and materials
- Data and results
- Interpretation, conclusion and significance

Instructions for Abstracts & Posters

WHEN PREPARING YOUR POSTER FOR PRESENTATION AT THE ACCP ANNUAL MEETING, WE KINDLY ASK THAT YOU ADHERE TO THE FOLLOWING GUIDELINES:

- All material should be legible from distances of at least three feet.
- Presenter’s name must be underlined throughout the entire document.
- For all authors, initial or first name must precede last name.
- Institutional affiliation and city are required.
- Ensure that the street address, zip code, degrees and grant support are NOT listed within the abstract.
- Use only standard abbreviations.
- Do not indent the title.
- Capitalize the first letter of trade names.
- Nonproprietary (generic) names are required the first time a drug is mentioned, written in lower case letters.
- Abstract is limited to approximately 350 words (2,780 characters, including spaces) which includes titles. One table is permitted; it will not be counted or applied to word limitations.
- When using abbreviations for compounds, spell out in full the first mention, followed by the abbreviation in parentheses. Do not abbreviate compounds within the title of the abstract.
- Special characters are permitted.
- Important Size Limitations: No larger than the usable size of the poster board which is 45 inches tall and 67 inches wide. All posters will be mounted horizontally.
NOTICES REGARDING DECISION BY PROGRAM COMMITTEE:
Corresponding authors will be notified by email in mid-May regarding the status of their abstracts for the ACCP Annual Meeting. If you have not received a notification of decision via email by mid-May, please contact the ACCP Executive Office at 571-291-3493 ext 3 or by email at TBossert@ACCP1.org.

BOARD SIZE:
Posters will be displayed on poster boards with a usable space 45 inches tall x 67 inches wide. Posters should be mounted on poster boards using pushpins.

BOARD MATERIAL:
Fabric that will accommodate pushpins.

GENERAL INFORMATION:
• Posters must be placed on poster boards prior to the Poster Session on the day(s) your poster is to be presented as per the schedule noted in the next column. Please note: Student Abstract Award winners display their posters during both sessions.
• Posters must be displayed during the entire Poster Session and authors should be present at their assigned board location during the Poster Session.
• Posters will be judged the entire time the Poster Session is in progress.
• Posters must be removed as per the schedule noted in the next column. Please contact Staff at the ACCP Registration Desk if your poster has been removed. Posters unclaimed at the end of the meeting will be discarded.
• Bring only items which can be mounted on poster boards. There will be no electrical or projection capabilities provided.
• Poster board location numbers and author names will be mounted on each board. This number corresponds with the number assigned to you in the acceptance letter and will be so identified in the Final Program. Please note, the board location is NOT the abstract number.
• New Member abstracts will be identified with “New Member” ribbons placed on the board next to the board number.
• Student Abstract Award winners will be identified with “Award Winner” ribbons placed on the board next to the board number.

2017 Poster Session & Judging Schedule

POSTER SESSION 1
Sunday, September 17, 2017
5:30 – 7:30 pm
All posters must be posted between 1:00 – 3:00 pm on September 17th. Posters other than Student Award Winners must be taken down between 11:00 am and 12:00 pm on September 18th.

POSTER SESSION 2
Monday, September 18, 2017
5:30 – 7:30 pm
Posters must be posted between 1:00 – 3:00 pm on September 18th and must be taken down between 11:00 am and 12:00 pm on September 19th.

Abstract Awards
To be considered for the Student Abstract or New Member Abstract Awards, participants must have submitted abstracts by the April deadline.

Candidates for the New Member Abstract Award are New Members who have joined ACCP and paid dues between August 1, 2016 and July 31, 2017.

FOR QUESTIONS, PLEASE CONTACT:
TBossert@ACCP1.org or 571-291-3493 ext 3.
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 specifically request that when they register for the 2017 Annual Meeting. Attendees who indicated they want to obtain Continuing Education credit will be provided with access to pre- and post-event tests for the sessions offering CE. Completion of the post-event tests is required to earn the credit and to print Continuing Education credit certificates. Post-event tests require a 75% passing score.

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

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

What is CPE Monitor?

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

As we approach the 2017 ACCP Annual Meeting, more detailed instructions will be provided via email to all meeting attendees.
Pre-meeting Workshops

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

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, RPh, PharmD, Director, Rainbow Clinical Research Ctr, Rainbow Babies & Children’s Hosp, Case Western Reserve Univ School of Medicine
Gilbert J. Burckart, PharmD, Associate Director of 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
Anne Zajicek, MD, PharmD, Chief, Obstetric & Pediatric Pharmacology & Therapeutics Branch, 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 of 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 of 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
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, Takeda Pharmaceuticals Co Ltd
- Karen Rowland Yeo, PhD, Vice President, Simcyp (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, Takeda Pharmaceuticals Co Ltd

8:05 – 8:35 am
PBPK Modeling: Concepts & Best Practice Approaches
Karen Rowland Yeo, PhD, Vice President, Simcyp (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 plc

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 of Pharmaceutical Sciences, Univ at Buffalo, SUNY

11:30 am – 12:00 pm
Panel Discussion
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 of 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
Pricing & Reimbursement Challenges Facing Payers Regarding Tumor Necrosis Factor Inhibitors
TBD

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
Modeling & Simulation Strategies for Dose Selection of Targeted Anticancer Agents

DISCOVERY TRACK

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**

**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.

**LEARNING OBJECTIVES:**

At the end of the presentation, the attendee 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.
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 of the 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
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, 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, Assistant Professor & Associate Director, Univ of Florida

11:10 – 11:30 am
Regulatory Perspectives on Optimizing Dose/Dosing Frequency in Combination Settings
Jeffrey Florian, PhD, Team Leader, US Food & Drug Administration

11:30 am – 12:00 pm
Panel Discussion and Q&A
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 of 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

The Evolution of the Master Protocol & Current Experience in the Pre-competitive Space
Kevin Watt, MD, PhD, Assistant Professor of 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
Next Wave in Cancer Medicine: Mechanisms & Progress for Emerging Therapeutics

DISCOVERY TRACK

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 of 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)
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 Baker, 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
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 Baker, MD, Pediatrician & Commissioners Fellow, Office of Clinical Pharmacology, US Food & Drug Administration
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
Catherine Knibbe, PhD, PharmD, Professor, Individualized Drug Treatment, St Antonius Hosp, Dept of Clinical Pharmacy

9:20 – 9:30 am
Panel Discussion
Modeling of Adherence: Applications in Drug Development & Clinical Practice

DISCOVERY TRACK

CO-CHAIRS:
Ayappa 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
Ayappa 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
Craig Hendrix, MD, Wellcome Professor & Director, Div of Clinical Pharmacology, Johns Hopkins Univ School of Medicine

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, Travena 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
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
G. 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 of 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 KIs 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: KI Therapy for Pediatric Diseases
G. 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
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, e.g., 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
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 of Pharmacology, Sackler Inst of Pulmonary Pharmacology, King’s Coll
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 of Pharmacology, Sackler Inst of Pulmonary Pharmacology, King’s Coll

1:35 – 1:55 pm
Pharmacokinetics & Bioequivalence Testing of Orally-inhaled Steroids
Hartmut Derendorf, PhD, Distinguished Professor & Chair, Univ of Florida

1:55 – 2:15 pm
Pulmonary Absorption & Bioavailability of Inhaled Products
Günther Hochhaus, PhD, Professor, 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
Symposium 11 | 4:00 – 5:30 pm

Pioneering NAFLD/NASH Early-phase Clinical Pharmacology Study Designs

**DISCOVERY TRACK**

**CO-CHAIRS:**
Lorraine 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.

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**4:00 – 4:10 pm**

*Introduction*

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

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**4:10 – 4:30 pm**

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

Dina Halegoua-De Marzio, MD, Assistant Professor of 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*
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 of 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, 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 of 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 of Pediatrics, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration

9:15 – 9:30 am
Panel Discussion

DISCOVERY TRACK
Offers both CME and CPE Credit
UAN #0238-0000-17-016-L02-P
ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

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;

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 of Infectious Disease Biology, Merck & Co

8:50 – 9:20 am
Advances in Formulations for HIV PrEP: Topicals & Implantables
Craig Hendrix, MD, Wellcome Professor & Director, Div of Clinical Pharmacology, Johns Hopkins Univ School of Medicine

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 of 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, Antiviral Medical 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 Bioanalytical & Pharmacometric Approaches to Targeting Viral Reservoirs in the Search for an HIV Cure
Angela Kashuba, PharmD, John & Deborah McNeill, Jr Distinguished Professor, Director, CFAR Clinical Pharmacology & Analytical Chemistry Core Adjunct Professor, Infectious Diseases, UNC Eshelman School of Pharmacy

11:50 am – 12:00 pm
Q&A
# 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.

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<tr>
<th>Time</th>
<th>Session Title</th>
<th>Speaker</th>
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<tr>
<td>10:00 – 10:20 am</td>
<td><strong>Full Extrapolation of Efficacy in Children for Partial Onset Seizures:</strong> An FDA-UMD-PEACE Collaborative Project</td>
<td>Angela Men, PhD, MD, Pharmacology Lead, US Food &amp; Drug Administration</td>
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<tr>
<td>10:20 – 10:40 am</td>
<td><strong>Disease Similarity of Partial Onset Seizures Between Adults &amp; Children:</strong> PEACE White Paper</td>
<td>Douglas Nordli, Jr, MD, Chief, Div of Pediatric Neurology &amp; Co-director, Neurosciences Inst, Children’s Hosp Los Angeles</td>
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<tr>
<td>10:40 – 11:00 am</td>
<td><strong>Quantitative Analysis to Support Full Extrapolation of Efficacy in Pediatrics for Partial Onset Seizures</strong></td>
<td>Shailly Mehrotra, BPharm, PhD Candidate, Univ of Maryland</td>
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<tr>
<td>11:00 – 11:30 am</td>
<td><strong>Regulatory Impact of Drug Development of AEDs for Pediatrics</strong></td>
<td>TBD</td>
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<tr>
<td>11:30 am – 12:00 pm</td>
<td><strong>Q&amp;A</strong></td>
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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 for 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 for 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

(Invited) 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

TBD

2:55 – 3:30 pm

Immunogenicity Assessment of Biosimilar Products

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

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 for Drug Safety, Office of Clinical Pharmacology, US Food & Drug Administration

4:40 – 5:30 pm

Panel Discussion
**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, Assistant Professor, Coll of Public Health, East Tennessee State Univ

**TARGET AUDIENCE:**

This Symposium will be useful for scientists, physicians, pharmacists and other health care 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.

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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| 1:30 – 1:35 pm| **Introduction**  
*Sam Harirforoosh, PharmD, PhD, Associate Professor, Gatton Coll of Pharmacy and Arsham Alamian, PhD, MSc, MACE, Assistant 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, Assistant 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| **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* |
| 4:00 – 4:35 pm| **Medical Policy & Regulations When Prescribing Opioid Therapy for Chronic Non-cancer Pain**  
*Gregory R. Polston, MD, Clinical Professor of Anesthesia, Dept of Anesthesiology, Associate Medical Director, Ctr for Pain Medicine, Univ of California, San Diego* |
| 4:35 – 5:10 pm| **Panel Discussion** |
| 5:10 – 5:30 pm| **Panel Discussion** |
The American College of Clinical Pharmacology (ACCP) is a non-profit membership association with a 45+ year history of providing exceptional interprofessional, accredited Continuing Education programs, publications, networking and other career-enhancing opportunities to a wide spectrum of healthcare professionals using clinical pharmacology in disciplines from research to patient care. Membership includes MDs, PharmDs, PhDs, post-doctoral candidates, students and others from academia, industry, regulatory and clinical entities who are seeking to advance their career through the Member Benefits offered by ACCP.

Why Should You Join the American College of Clinical Pharmacology?
Your membership in ACCP now gets you more and is your way to stay at the top of your professional game!

- Confidently achieve a high level of professional performance by staying on the cutting edge of clinical pharmacology developments;
- Build professional relationships that last a lifetime;
- Be part of a vibrant professional community with similar goals and objectives;
- Shape the future of clinical pharmacology.

ACCP Member Benefits get you there!

- Free access to the latest scientific research. Members have free online access to ACCP’s high-quality publications, The Journal of Clinical Pharmacology, published for over 50 years, and Clinical Pharmacology in Drug Development, introduced in 2012. eTOC notifications are sent for both journals, and the JCP eTOC highlights journal articles eligible for Continuing Education credit and Editor’s Choice articles. Archives of The Journal of Clinical Pharmacology dating back to 1961 and Clinical Pharmacology in Drug Development since 2012 are available to Members.

- Free CME and CPE credits on selected articles in The Journal of Clinical Pharmacology.

- Free online educational activities. Our program of online educational events provides you with 24/7 access and includes the ACCP Fundamentals Tutorials series, the ACCP Virtual Journal Club and the ACCP Therapeutic Dilemmas series, all available live, then On Demand.

- Discounted registration for the ACCP Annual Meeting, your source for current, interprofessional ACCME & ACPE-accredited Continuing Education programs in a live format.

- Free access to Annual Meeting recorded events for Annual Meeting attendees and discounted access for other Members.

- Networking opportunities and, for Students, Trainees & Young Professionals, access to Mentors.

- 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.

- Receipt of information from the clinical pharmacology community for Members who opt in to receive the daily news format, routine recall/drug safety notices from FDA Medwatch, FDA Bursts or AAMC notifications.

- Receipt of routine updates from ACCP about developments in the field of clinical pharmacology and future ACCP events.

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

Before you apply for membership, please note if any of the following pertain to you and contact KLevy@ACCP1.org for existing login credentials:

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

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

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

- May 7, 2017
- September 16, 2017

To Join ACCP as a Member: Complete/Update a Profile, including the information on the Demographics tab, and upload your CV.

To Join ACCP as a Student Member: Complete/Update a Profile, including the information on the Demographics tab, and upload your CV and some form of Student Verification.

Persons interested in becoming a Fellow should join as a Member and notify KLevy@ACCP1.org about their interest in becoming a Fellow.
JOIN TODAY AND SAVE
Save up to $400 on your registration by joining ACCP today and enjoy Member Benefits all year!
ACCP Members receive access to the latest scientific research via ACCP publications (The Journal of Clinical Pharmacology and Clinical Pharmacology in Drug Development), online Job Center, networking opportunities and complimentary monthly Continuing Education activities and events. Join ACCP now and receive the discounted ACCP Member registration rate.

2017 ACCP ANNUAL MEETING  September 17 – 19, 2017 • Hilton San Diego Resort & Spa, San Diego, CA

ACCP continues to offer exciting tools for your professional growth and remains committed to offering Continuing Medical Education (CME) and Continuing Pharmacy Education (CPE) credits for educational events. The 2017 ACCP Annual Meeting offers Continuing Education credit, at no additional cost to attendees. Whether you need CE credits or not, this meeting provides you with valuable information to achieve your professional goals. Join a global audience of healthcare professionals in a focused, educational atmosphere that also provides time to network with colleagues, new and old.

Annual Meeting registration fees vary based on registration categories and options. All Members must be in good standing at the time of registration to receive Member rates. ACCP is pleased to offer special registration rates to members of Sister Organizations (AAPS, ASCPT, ASPET, BPS, CSPT, EUFEMED, ISAP, ISoP and PPAG), as well as to our colleagues from US government entities. When registering, please select the appropriate pricing category from the options noted below. Membership in Sister Organizations, Student status and employment at a government entity will be verified.

Save up to $400 on your registration by joining ACCP today and enjoy Member Benefits all year! To receive the discounted ACCP Member registration rate, please join ACCP, allow the system to send a receipt acknowledging your dues payment and proceed to register for the meeting.

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<th>ADVANCE 7/1/2017 – 8/31/2017</th>
<th>ONSITE 9/1/2017 – 9/19/2017</th>
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<td>Pre-meeting Workshops (each) – Student Member or Non-member</td>
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CANCELLATION/REFUND POLICY:
Meeting registration cancellations must be submitted via email to Reg@ACCP1.org no later than August 15th and are subject to a $250 nonrefundable processing fee. After August 15th, no cancellations will be permitted and only substitutions will be considered. The transfer of your registration to another person will be considered by contacting Reg@ACCP1.org or 571-291-3493 ext 3.
Visitors to the US must have a valid passport. The American College of Clinical Pharmacology encourages attendees to familiarize themselves with US Visa requirements and to apply for necessary visas as early as possible, at least 3 to 4 months prior to the meeting.

The purpose of the visit determines what type of visa will be needed. Visitors planning to visit or attend a meeting most likely will apply for a B-1 Visa. For comprehensive B-1 Visa information, please visit the US State Department’s Visitor Visa Website.

To request a Letter of Invitation to attend the ACCP Annual Meeting, please submit a written request by following the instructions on the ACCP website.

VISA WAIVER PROGRAM
Foreign citizens traveling from certain eligible countries may be able to visit the US without a visa, through the Visa Waiver Program (VWP) if they meet requirements, including having a valid Electronic System for Travel Authorization (ESTA) approval.

The VWP allows citizens of participating countries to travel to the US without a visa for stays of 90 days or less when they meet all requirements as per the VWP website. Travelers must be eligible to use the VWP and have a valid ESTA approval prior to travel.

These sites provide helpful information on visas and travel to the US:
• http://travel.state.gov
• http://usembassy.state.gov
• http://www.dhs.gov/us-visit

DISCLAIMER
Please note that this information is given in good faith, but that the regulations may change and the only authoritative sources of information are the US Government websites.
The ACCP 2017 Annual Meeting will take place at the Hilton San Diego Resort & Spa in San Diego, CA – a charming city in a thriving academic, pharmaceutical and biotech community.

**Traveling from outside the United States?** Make sure you are familiar with US Visa requirements and, if necessary, request a Letter of Invitation from ACCP.

**Hilton San Diego Resort & Spa**
1775 East Mission Bay Dr
San Diego, CA 92109
Tel: (619) 276-4010

Located in beautiful, sunny San Diego, the Hilton San Diego Resort & Spa is an easy ride to area attractions in a thriving district that is home to excellent restaurants, theaters, art galleries, sports venues and shopping.

Deluxe accommodations at the Hilton San Diego Resort & Spa are decorated to match the bright and festive hues of this waterfront oasis. Each room has luxury bedding and linens, designer furnishings and an open and airy feel that welcomes in the sun and breeze. For a true treat, opt for an extended patio guest room complete with a captivating fire pit. See more about hotel amenities.

For your benefit, a special room rate of $199 has been established. **Please note: these rates include the resort fee, which is charged separately for any reservations outside of our room block.** In addition, the special rate has been extended to three days before and after the conference. A limited number of upgrades are available for the following room types. Optional upgrades are not guaranteed and are based on availability at time of reservation. The cutoff date for this group rate is August 31, 2017.

A limited number of rooms at a government rate are available on a first-come, first-served basis.

<table>
<thead>
<tr>
<th>Room Type</th>
<th>Rate</th>
<th>Includes Resort Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Room</td>
<td>$199</td>
<td>Yes</td>
</tr>
<tr>
<td>Garden View Villa</td>
<td>$219</td>
<td>Yes</td>
</tr>
<tr>
<td>Bay View Villa</td>
<td>$239</td>
<td>Yes</td>
</tr>
<tr>
<td>Garden View Studio</td>
<td>$259</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Reservations can also be made by calling the Hilton San Diego Resort & Spa directly at (619) 276-4010 and providing the group name 2017 ACCP Annual Meeting and group code ACC97.

We anticipate that rooms will sell quickly and advise you to make reservations early. After the cutoff date of August 31st, reservations will be accepted at prevailing rates on a room available basis and must be booked directly with the hotel.

By booking through the ACCP room block and helping us meet our hotel contract obligations, you ensure the security of your reservation and you help ACCP maintain reasonable meeting registration costs for the future. Please note that ACCP is not working with outside entities to make hotel room reservations for the Annual Meeting! Reservations should be made only by using the online link provided or by calling the Hilton San Diego Resort & Spa directly and using the reservation code provided. Solicitations by outside organizations could imperil your personal information and result in problems with your reservation. If you receive communications from anyone other than ACCP Staff or the hotel related to your hotel reservation, please contact ACCP immediately by phone 571-291-3493 ext 3 or via email at TBossert@ACCP1.org.
Air & Ground Transportation

Nearest Airport: San Diego Int’l - Lindbergh Field
Distance from hotel: 6 miles
Drive time: 10 minutes
Directions: Take I-5 north to Sea World Dr, turn left at the top of the exit. Turn right on East Mission Bay Dr. The resort is 3/4 mile on the left.

Taxi: Many companies provide taxicab service at San Diego Int’l Airport. If you need a taxi, simply follow the signs leading to the Transportation Plazas. A Transportation Coordinator will place you with the first available taxi, unless you specify a particular taxicab company.

Shuttles: Shuttle service is available at the Transportation Plazas across from Terminals 1 and 2. From Terminal 1, cross the skybridge and take the escalators or the elevators to street level. From Terminal 2, use the pedestrian crosswalk conveniently located outside the Terminal 2 Baggage Claim Area to access the Transportation Plaza. A Customer Service Representative will place you with the first available shuttle, unless you specify a particular shuttle company.

Hotel Parking: Limited parking is available on-site.

Area Attractions

Located on the coast of the Pacific Ocean, San Diego is widely known as “America’s Finest City.” Famous for its miles and miles of white-sand beaches and amazing weather, the city offers an abundance of fun attractions for visitors of all ages. Make sure to plan a little extra time during your visit and check out some of these top things to do in the area.

THEME AND AMUSEMENT PARKS

SeaWorld San Diego – (4 miles from hotel)

Come celebrate the wonders of the sea at SeaWorld® San Diego. Experience the Shamu® show, One Ocean® and thrilling rides like Journey to Atlantis®, Shipwreck Rapids® and Wild Arctic®. Feed and touch dolphins and bat rays and get up-close to beluga whales, polar bears, sharks and penguins. Enjoy fascinating aquariums and exotic birds from around the world.

Belmont Park – (4.5 miles from hotel)

Belmont Park is a historic oceanfront amusement park located in the Mission Bay area of San Diego. Here is a snapshot of the fun awaiting you at Belmont Park:
• Amusement park rides
• Zip line and sky climb
• Laser tag & maze
• Surfing in the only FlowBarrel wave machine in the US
• Escapology – a real life escape game experience where up to 6 players will be challenged to work together to find clues and solve puzzles to free themselves from the game room
• 4 dynamic oceanfront dining options
• Sunset over the Pacific Ocean from WaveHouse Beach Club

San Diego Zoo – (7 miles from hotel)

An urban paradise for all ages, the San Diego Zoo is a must-see with more than 4,000 rare and fascinating animals. See giant pandas, Komodo dragons, gorillas, tigers, flamingos, polar bears and many more.
ARTS & CULTURE

USS Midway Museum – (6 miles from hotel)

Create a once-in-a-lifetime memory exploring the USS Midway, the longest-serving US Navy aircraft carrier of the 20th century! Imagine living aboard a floating city at sea with 4,500 shipmates by exploring galleys, officer’s country, sleeping quarters and the 4-acre flight deck.

Reuben H. Fleet Science Ctr – (7 miles from hotel)

With 100+ exhibits to touch, films on the world’s first IMAX Dome Theater and hours of fun to be had, the Reuben H. Fleet Science Ctr in Balboa Park is an entertaining experience for all ages. Create colored shadows, touch a tornado, examine the vibration of guitar strings and get your hands on a variety of intriguing scientific phenomena.

PARKS & GARDENS

Balboa Park – (7 miles from hotel)

Rated in the top 10 parks in the US, Balboa Park features 16 unique gardens, including the Japanese Friendship Garden, the Inez Grant Parker Memorial Rose Garden featuring over 2,400 rose bushes and the Botanical Building with adjacent Koi and Lily Pond. The Botanical Building houses more than 2,100 plants, including a fascinating collection of cycads, ferns, orchids and palms. Balboa Park is also home to 15 museums and theaters, as well as the world-famous San Diego Zoo.

San Diego Botanic Garden – (20 miles from hotel)

A don’t miss for plant lovers, the San Diego Botanic Garden in Encinitas encompasses four miles of garden trails, including a wide collection of native and endangered plants, a whimsical children’s garden and the nation’s largest collection of bamboo species. The garden offers a full lineup of engaging events including workshops, plant sales and bird-watching tours.

For more options please visit https://www.sandiego.org/
Who We Are

ACCP’s diverse global membership is dedicated to improving the quality of patient care by optimizing the use of therapeutics. ACCP achieves this by providing Continuing Education to a broad range of clinicians and healthcare professionals spanning the scope of research and drug development to patient-related activities. Individuals can participate in live meetings, Journal CE activities, webinars or in other online educational activities that provide a forum for new scientific ideas and bring together healthcare professionals of various disciplines to discuss areas of common interest. ACCP maintains its commitment to offering Continuing Medical Education (CME) and Continuing Pharmacy Education (CPE) credit for qualified professionals. ACCP publishes The Journal of Clinical Pharmacology and Clinical Pharmacology in Drug Development, both of which are provided to Members at no additional cost.

ACCP continues to be an organization focused on meeting the needs of its Members and Annual Meeting attendees. With a vision of the value that clinical pharmacology brings to the future of drug development and healthcare, ACCP strives to provide healthcare professionals and scientists with a forum for the exchange of knowledge on topics ranging from research and drug development to clinical care.

Vision & Mission

- To improve health by optimizing therapeutics;
- Provide innovative leadership and interdisciplinary education that will enable the generation, integration and translation of scientific knowledge to optimize research, development and utilization of medication for the benefit of all.

Why Sponsor & Exhibit at the 2017 ACCP Annual Meeting?

The ACCP Annual Meeting provides an ideal opportunity to interact with your target audience. Attendees are from a cross section of organizational affiliations and roles uniquely positioned to take advantage of your product and service offerings. Get direct access to decision makers who are seeking face-to-face interactions about new, cutting-edge tools to enhance efficient drug development and quality patient care.

We invite you to commit now to Sponsor & Exhibit at the 2017 ACCP Annual Meeting!

Reserve your space by contacting us at Exhibit@ACCP1.org or 571-291-3493 ext 3. Deadline for final Sponsor & Exhibitor commitments is June 30, 2017.

Cancellation Policy

Cancellations in writing will be accepted until June 30, 2017 and are subject to a $500 administrative fee.

Compliance with PhRMA Code

ACCP respectfully requests that Sponsors & Exhibitors comply with the PhRMA Code on Interactions with Healthcare Professionals (http://www.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008-1.pdf) and other applicable codes and guidances related to Sponsor/Exhibitor and attendee interactions.
**Levels of Sponsorship**

All ACCP Annual Meeting Sponsors will be recognized for their support in the Final Program and with appropriate signage and acknowledgement during the course of the meeting. Items are available for Sponsorship on a first-come, first-served basis.

### PLATINUM: $10,000

Sponsor the ACCP Annual Meeting at the $10,000 Platinum Level and receive two full registrations to the 3-Day ACCP Annual Meeting (please note that Continuing Education credits cannot be obtained through this registration). The Platinum Sponsorship options include your choice of one of the following:

1. Exclusive Sponsorship of WiFi or Mobile App access provided to all attendees for one device of their choice + one Exhibit space. Business cards with your company logo and WiFi access code will be provided to all attendees; or
2. One Exhibit space + one option each from the Gold and Bronze Sponsorship menus; or
3. One option each from the Gold, Silver and Bronze Sponsorship menus.

### GOLD: $5,000

Sponsor the ACCP Annual Meeting at the $5,000 Gold Level and receive one full registration to the 3-Day ACCP Annual Meeting (please note that Continuing Education credits cannot be obtained through this registration). Please choose from one of the Gold Sponsorship options noted below:

- **TOTE BAGS** – Sponsor tote bags that will be provided to Annual Meeting attendees. Tote bags are used long after the meeting ends, ensuring ongoing visibility for your company name and logo.
- **STUDENT & TRAINEE RECEPTION / EVENT** – Student & Trainee Annual Meeting attendees participate in an event to network and learn from experts in the field of clinical pharmacology. Acknowledgement of sponsorship includes signage at the event and inclusion of company name and logo on Student & Trainee materials and in the Annual Meeting Final Program.

### SILVER: $3,500

Sponsor the ACCP Annual Meeting at the $3,500 Silver Level and choose from one of the Silver Sponsorship options noted below:

- **LANYARDS** – Prominently display your company name and logo on lanyards worn by Annual Meeting attendees.
- **POSTER BOARDS** – Sponsor poster boards for the two Poster Sessions held on Sunday and Monday evenings, providing a unique opportunity for your logo to be displayed at the evening receptions attended by Annual Meeting attendees.
- **FULL COLOR AD ON BACK OF PROGRAM** – Display your full color ad on the back cover of the Annual Meeting Final Program.
Sponsorship Opportunities

BRONZE: $2,500

Sponsor the ACCP Annual Meeting at the $2,500 Bronze Level and choose from one of the Bronze Sponsorship options noted below:

MEETING BAG INSERTS – Include your company’s promotional materials in the Annual Meeting attendee tote bags. Price reflects one promotional piece and all materials must be provided to ACCP by August 31st.

FULL COLOR AD INSIDE BACK COVER OF FINAL PROGRAM – Display your full color ad on the inside back cover of the Annual Meeting Final Program.

ADDITIONAL OPTIONS FOR ADVERTISING IN ANNUAL MEETING FINAL PROGRAM

<table>
<thead>
<tr>
<th>Description</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Page – $1,500</td>
<td></td>
</tr>
<tr>
<td>Half Page – $750</td>
<td></td>
</tr>
<tr>
<td>Quarter Page – $375</td>
<td></td>
</tr>
</tbody>
</table>

METHOD OF PAYMENT (check one):

- Check* (Payable to ACCP in US Dollars drawn on a US Bank)
- VISA
- American Express
- MasterCard
- Bank Transfer

Cardholder name (print): ____________________________________________
Card number: _______________________________ Expiration date: ________/_______

Authorized signature: ____________________________________________

Amount in US Dollars authorized to charge: ____________________________

For 2017 ACCP ANNUAL MEETING SUPPORT

Please indicate the level of Sponsorship you would like to provide:  ___Platinum  ___Gold  ___Silver  ___Bronze

Please indicate the specific item(s) you would like to Sponsor: ____________________________

Email this completed form to Exhibit@ACCP1.org

*Checks should be mailed to ACCP, PO Box 1758, Ashburn, VA 20146-1758
Exhibit Hall

**EXHIBITOR SET UP:**
Sunday, Sept 17th  9:00 am – 4:00 pm

**EXHIBITOR HOURS:**
Sunday, Sept 17th  5:00 – 8:00 pm
Monday, Sept 18th  7:00 – 11:00 am and 3:00 – 8:00 pm
Tuesday, Sept 19th  7:00 – 11:00 am

**EXHIBITOR MOVE OUT:**
Tuesday, Sept 19th  11:00 am – 3:00 pm

ACCP utilizes creative, fresh ideas to get attendees interacting with Exhibitors. From Poster Sessions, evening receptions, breakfasts and coffee breaks to games that encourage interaction, we understand the importance of Exhibitors engaging with attendees.

For the 2017 ACCP Annual Meeting, booth space will be determined based on a point system. Historical participation in the ACCP Annual Meeting and reserving hotel rooms at the ACCP headquarters hotel from 2010 – 2016 are included in this point system. Other Exhibitors will be permitted booth selection on a first-come, first-served basis.

Exhibitors interested in more than one booth space should contact ACCP about options.
EXHIBITOR COMPANY ___________________________________________________________________________

ADDRESS ________________________________________________________________________________

CITY _______________________________ STATE __________ COUNTRY _______________________ ZIP ______________

CONTACT PERSON* ___________________________________________________________________________

*Person responsible for disseminating Exhibit information from ACCP.

PHONE _______________ CELL PHONE _______________ EMAIL _________________________________

EXHIBIT FEE (Includes Two Exhibit Personnel): $2,250 ____________ ADDITIONAL EXHIBITOR FEE: $250 each ____________

EXHIBIT FEE (Includes Two Exhibit Personnel PLUS Limit of One Full Registration to the Annual Meeting**): $2,750 _____________

BOOTH SPACE CHOICES    #1 _______________ #2 _______________ #3 _______________

A/V Requirements? (Please specify) Costs incurred to provide this equipment will be billed to the Exhibitor.

______________________________________________________________________________________________________

METHOD OF PAYMENT (check one):

❑ Check*** (Payable to ACCP in US Dollars drawn on a US Bank)  
❑ VISA  ❑ American Express  ❑ MasterCard  ❑ Bank Transfer

Cardholder name (print): ________________________________________________________________________

Card number: ___________________________________________________ Expiration date: __________/________________

Authorized signature: _______________________________________________________________________________

Amount in US Dollars authorized to charge: _______________________ For 2017 ACCP ANNUAL MEETING EXHIBIT FEE

Complimentary Exhibit Staff Person #1: Name ____________________________ Cell Phone ______________________

Email _______________________________________________________________________________________

Degree(s) to be displayed on attendee badge __________________________________________________________

Complimentary Exhibit Staff Person #2: Name ____________________________ Cell Phone ______________________

Email _______________________________________________________________________________________

Degree(s) to be displayed on attendee badge __________________________________________________________

Full Registrant designated to attend 3-Day Annual Meeting** (if applicable and purchased above)

Name ____________________________________________ Cell Phone _________________________

Email _______________________________________________________________________________________

Degree(s) to be displayed on attendee badge __________________________________________________________

**Please note that Continuing Education credit cannot be earned through this mode of registration; payment is required to earn credit, as enforced by the accreditation guidelines.

Additional ($250 Fee) Exhibit Staff Person #3: Name ______________________________ Cell Phone ______________

Email _______________________________________________________________________________________

Degree(s) to be displayed on attendee badge __________________________________________________________

Additional ($250 Fee) Exhibit Staff Person #4: Name ______________________________ Cell Phone ______________

Email _______________________________________________________________________________________

Degree(s) to be displayed on attendee badge __________________________________________________________

COPY THIS PAGE AS REQUIRED FOR ADDITIONAL EXHIBITOR PERSONNEL.

DESCRIPTION OF COMPANY (50 words or less) must be included with payment. Additionally, please send your company URL and high-resolution logo in EPS, JPEG, PNG, or GIF format to Exhibit@ACCP1.org at the time of Exhibitor registration.

***Checks should be mailed to ACCP, PO Box 1758, Ashburn, VA 20146-1758