



ACCP

AMERICAN COLLEGE OF CLINICAL PHARMACOLOGY

Advancing Clinical Care through Pharmacology®

2016 Annual Meeting
American College of
Clinical Pharmacology

Clinical Pharmacology:

*Discovery and
Application
in the Era of
Precision Medicine*

September 25 – 27, 2016
Bethesda N Marriott Hotel &
Conference Ctr, Bethesda, MD

#2016ACCP

PRELIMINARY PROGRAM



ACCP

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Advancing Clinical Care through Pharmacology®

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American College of Clinical Pharmacology 2016 Program Committee

Co-chairs:

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

Members:

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

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Letter of Invitation from President & Program Co-chairs

Join Us for the 2016 ACCP Annual Meeting!

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

Dear Colleague:

It is our pleasure to invite you to attend the **2016 Annual Meeting** of the **American College of Clinical Pharmacology (ACCP)**, September 25th – 27th, at the Bethesda N Marriott Hotel & Conference Ctr in Bethesda, MD. This year's meeting is focused on **Clinical Pharmacology: Discovery and Application in the Era of Precision Medicine**. In accordance with ACCP's commitment to excellence in science and education, the 2016 Annual Meeting Program Committee, co-chaired by Drs. Vikram Arya, Honghui Zhou and Manish Gupta, has developed a diverse and exceptional educational program that meets the needs of a broad spectrum of healthcare professionals and scientists with an interest in clinical pharmacology applications from research and drug development to patient care. Speakers from academia, industry, regulatory and clinical entities will present programs organized into topic tracks that allow attendees to uniquely tailor content selection to their individual interests. Major clusters of topic areas include oncology drug development, including immuno-oncology, biologics and biosimilars, pediatric drug development, and precision medicine. The exciting mix of sessions includes the use of novel and innovative clinical pharmacology tools and principles to improve drug development and therapeutics for effective treatment of disease states such as HIV/AIDS, hepatitis C and cancer; orphan drug development; the application of the animal rule; the management of opioid dependence; the use of Big Data, physiologically-based PK/PD modeling and novel trial designs for pediatric drug development programs; improvements in clinical pharmacology labeling and streamlining of clinical pharmacology activities in early development.

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

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

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

We strongly encourage you and your colleagues to join us for this outstanding educational and scientific experience. If you have never attended an ACCP Annual Meeting, 2016 is the year to experience for yourself how ACCP makes a difference by providing healthcare professionals and scientists with a forum to exchange knowledge and ideas that promote and expand the value of clinical pharmacology in healthcare and drug development. Early Bird Registration rates end June 30th and don't forget to register early for the Pre-meeting Workshops, as seating is limited.

One of the premier hotels in Bethesda, MD, the Bethesda N Marriott Hotel & Conference Ctr has stylish, comfortable guest rooms and 50,000 square feet of high-tech event space designed to create a remarkable meeting experience. In addition to a room rate of \$179 for 2016 Annual Meeting attendees, ACCP has negotiated additional perks for those who book their hotel reservation using our designated room block. There will be complimentary Internet access provided to all Annual Meeting attendees in guest rooms for the duration of the meeting. All of the educational sessions, social events and networking will be held at the hotel, facilitating the ease with which meeting attendees can participate in events. Conveniently located near the White Flint Metro Station, there is easy access to downtown Bethesda, Rockville, Washington, DC and northern Virginia attractions. Come early or stay late and enjoy all that the Washington metro area has to offer.

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

We look forward to welcoming you to an outstanding 2016 ACCP Annual Meeting, where you will learn, network and be part of an excellent and educational scientific event in the clinical pharmacology community!



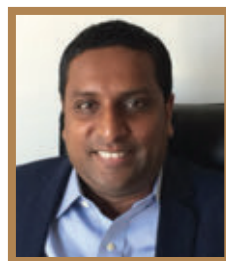
Bernd Meibohm, PhD
ACCP President



Vikram Arya, PhD
Program Co-chair



Honghui Zhou, PhD
Program Co-chair



Manish Gupta, PhD
Program Co-chair



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Program at a Glance

Workshops & Symposia at the 2016 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 would like to attend.

SATURDAY, SEPTEMBER 24, 2016

Pre-meeting Workshop 1 | 8:00 am – 12:00 pm

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

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

Pre-meeting Workshop 2 | 8:00 am – 12:00 pm

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

CO-CHAIRS: Sam Hariforoosh, PharmD, PhD, Associate Professor, Dept of Pharmaceutical Sciences, East Tennessee State Univ, Gatton Coll of Pharmacy and Ganesh Cherala, PhD, Senior Scientist, CONRAD

Pre-meeting Workshop 3 | 1:30 – 5:30 pm

Improving Therapeutics to Better Care for Older Adults & the Young (DT/AT)

CO-CHAIRS: S.W. Johnny Lau, PhD, Senior Clinical Pharmacologist, US Food & Drug Administration and Thomas Eissing, PhD, Head of Systems Pharmacology CV, Bayer Technology Services GmbH

Pre-meeting Workshop 4 | 1:30 – 5:00 pm

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

CO-CHAIRS: Justin C. Earp, PhD, Pharmacometrics Reviewer, US Food & Drug Administration and Anshu Marathe, PhD, Senior Staff Fellow, Div of Pharmacometrics, US Food & Drug Administration

SUNDAY, SEPTEMBER 25, 2016

Symposium 1 | 8:00 am – 12:00 pm

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

CO-CHAIRS: Nitin Mehrotra, PhD, Team Leader, Div of Pharmacometrics, US Food & Drug Administration and Kimberly L. Bergman, PharmD, Lead Pharmacologist, US Food & Drug Administration

Symposium 2 | 8:00 – 9:30 am

A 360° View of Immunogenicity: Qualitative & Quantitative Assessments to Understand its Implications on Pharmacokinetics, Safety & Efficacy (DT)

CO-CHAIRS: Chaitali Passey, PhD, Senior Research Investigator, Bristol-Myers Squibb Co and Sumit Rawal, PhD, Scientist, Regeneron Pharmaceuticals Inc

Symposium 3 | 10:00 am – 12:00 pm

Helping Advance the Immuno-Oncology Revolution: Trends in Translational Immuno-Oncology (DT/AT)

CO-CHAIRS: Sree Kasichayanula, PhD, Principal Scientist, Amgen Inc and Yu-Nien (Tom) Sun, PhD, Senior Director, Janssen Research & Development LLC

Symposium 4 | 1:30 – 5:30 pm

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

CO-CHAIRS: Gaurav Bajaj, PhD, Senior Research Investigator, Bristol-Myers Squibb Co and Ping Zhao, PhD, Lead, PBPK Program, Div of Pharmacometrics, US Food & Drug Administration

Symposium 5 | 1:30 – 3:00 pm

Addressing Opioid Dependence: Now is the Time (AT)

CO-CHAIRS: Lorraine M. Rusch, PhD, Vice President, Scientific Development, Altasciences Clinical Research and Michael J. Fossler, Jr, PharmD, PhD, Vice President, Qualitative Sciences, Trevena Inc

Symposium 6 | 3:30 – 5:30 pm

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

CO-CHAIRS: Vikram Arya, PhD, Senior Staff Fellow, Office of Clinical Pharmacology, US Food & Drug Administration and Shirley Seo, PhD, Team Leader, Office of Clinical Pharmacology, US Food & Drug Administration



Program at a Glance

Workshops & Symposia at the 2016 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 would like to attend.

MONDAY, SEPTEMBER 26, 2016

Symposium 7 | 8:00 am – 12:00 pm

Establishing Biosimilarity: The European Perception, Experience & Future Trends (DT/AT)

CO-CHAIRS: Hildegard Sourgens, MD, PhD, President Elect, European Federation for Exploratory Medicines Development and Hartmut Derendorf, PhD, Distinguished Professor & Chair, V. Ravi Chandran Professor in Pharmaceutical Sciences, Univ of Florida

Symposium 8 | 8:00 – 9:30 am

Informing Pediatric Development Programs: Leveraging Big Data (DT)

CO-CHAIRS: Jeffrey Barrett, PhD, Vice President, Translational Informatics, Sanofi and Lily (Yeruk) Mulugeta, PharmD, Scientific Lead for Pediatrics, Div of Pharmacometrics, US Food & Drug Administration

Symposium 9 | 10:00 am – 12:00 pm

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

CO-CHAIRS: Jian Wang, PhD, Senior Clinical Pharmacologist, US Food & Drug Administration and John van den Anker, MD, PhD, Chief, Div of Clinical Pharmacology, Children's National Health System

Symposium 10 | 1:30 – 5:30 pm

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

CO-CHAIRS: Suraj Bhansali, MS, PhD, Manager, Oncology Clinical Pharmacology, Novartis Pharmaceuticals Corp and Xiao Hu, PhD, Senior Pharmacometrician, Biogen Inc

Symposium 11 | 1:30 – 3:05 pm

Cutting-edge Abstract Presentations (DT/AT)

CO-CHAIRS: Lawrence J. Cohen, PharmD, Professor & Coordinator of Interprofessional Education, Univ of North Texas System, Coll of Pharmacy and Walter Kraft, MD, Professor, Thomas Jefferson Univ

Symposium 12 | 3:30 – 5:30 pm

Rethinking Clinical Pharmacology-related Labeling for Improved Utility & Comprehension (DT/AT)

CO-CHAIRS: Joseph A. Grillo, PharmD, Associate Director for Labeling & Health Communications, US Food & Drug Administration and Julie Bullock, PharmD, Director, d3 Medicine LLC

TUESDAY, SEPTEMBER 27, 2016

Symposium 13 | 8:00 am – 12:00 pm

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

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

Symposium 14 | 8:00 – 9:30 am

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

CO-CHAIRS: Jennifer Sheng, PhD, PharmD, Associate Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb Co and Diansong Zhou, PhD, Director, AstraZeneca plc

Symposium 15 | 10:00 – 11:45 am

Combination Therapy in Oncology: Challenges & Strategies in Clinical Pharmacology (AT)

CO-CHAIRS: Yilong Zhang, PhD, Principal Scientist, Amgen Inc and Satyendra Suryawanshi, PhD, Associate Director, Bristol-Myers Squibb Co

Symposium 16 | 1:30 – 5:30 pm

Clinical Pharmacology Strategies in Precision Medicine-based Drug Development & Preventive Medicine (DT/AT)

CO-CHAIRS: Priyanka Jadhav, PhD, Translational Clinical Pharmacologist, CRC Pharma LLC, Jinshan Shen, PhD, Director, Clinical Pharmacology, Vertex Pharmaceuticals Inc and Manoj Jadhav, PhD, Translational Clinical Pharmacologist, CRC Pharma LLC

Symposium 17 | 1:30 – 5:30 pm

Reproducible Visualization & Data Analysis With R (DT)

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



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2016 ACCP Recognition Award Winners



Distinguished Investigator Award

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

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

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



Honorary Fellowship Award

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

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



Nathaniel T. Kwit Memorial Distinguished Service Award

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

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

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

2016 ACCP Recognition Award Winners



Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award

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

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

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



Tanabe Young Investigator Award

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

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

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



McKeen Cattell Memorial Award

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

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

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



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Students & Trainees

Annual Meeting Events for Students & Trainees

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

- Substantially **discounted registration fees** for the Annual Meeting and free or discounted fees for other educational events on cutting-edge, relevant topics related to clinical pharmacology and the optimal use of therapeutics. These interactions provide Students & Trainees with access to a forum for new scientific ideas and healthcare professionals of various disciplines meeting to discuss areas of common interest.
- **ACCP Student Abstract Awards Program** is designed to recognize outstanding research abstracts submitted by Students & Trainees at the Annual Meeting. Each award consists of a certificate, a \$1,000 honorarium, a complimentary Annual Meeting registration and an invitation to the Board of Regents Dinner at the Annual Meeting.
- From the pool of Student Abstract Award winners, one is selected to receive the **Wayne A. Colburn Memorial Award**, as judged by the Program Committee during the Poster Sessions at the Annual Meeting. The winner of the Wayne A. Colburn Memorial Award will also receive a plaque and an additional honorarium of \$500. At the time the award is presented, the author will be asked to give a 5 – 10 minute presentation, using 2 – 3 slides, outlining the results.

ACCP Awards and Previous Winners

Student & Trainee-specific Events

In conjunction with the Student Outreach Committee, ACCP has planned a series of events to enhance the professional growth of Students & Trainees. These events are provided at no cost to Annual Meeting attendees, we simply ask that you RSVP when ACCP contacts you about participating so we hold a place for you!

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

- **Panel Discussion on Career Guidance** (2:00 – 3:30 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** (3:30 – 4:30 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.

- **Student Networking Reception** (4:30 – 5:30 pm) – After the Podium Presentations, join us for the Student Networking Reception where you can interact on a more personal level with Panel Discussion speakers and other ACCP Mentors to ask the burning questions that will help you make decisions about your future.
- **Poster Tours** (5:30 – 6:30 pm) – Small groups of Students & Trainees will be hosted by an ACCP Fellow or senior Member to tour the poster area and discuss preselected posters that provide exceptional educational content or presentation.

Special Access to the Experts – Schools represented by groups of six or more Students & Trainees will be provided with a higher level of access to ACCP leadership. Select ACCP leaders will have a sit-down roundtable session with those Students & Trainees to discuss opportunities for further involvement in ACCP during their training and how to subsequently grow in the organization throughout their careers.

Send Us Your CV for a Review!

Give your CV impact! Submit your CV to SOC@ACCP1.org by August 15th for a review and suggestions by ACCP Mentors. Students & Trainees attending the 2016 Annual Meeting and wishing to discuss their CV in person with a Mentor should note such when submitting the CV. Arrangements may be made through KLevy@ACCP1.org for anyone wishing to meet live with a Mentor during the Annual Meeting.

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

Visit us at [facebook](#) [Linked in](#).

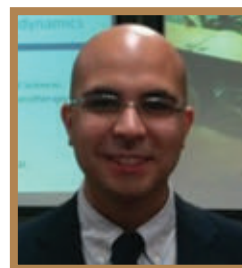
ACCP Member Benefits

Join ACCP

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



Amelia N. Deitchman, PharmD



Daniel Gonzalez, PharmD, PhD

Abstracts & Posters

Abstract Timeline

April 15, 2016	Abstract Submission Deadline
Mid-May 2016	Abstract notifications sent by email to first authors regarding decisions by the Program Committee on the status of acceptance
June 6, 2016	Deadline to submit Registration Form & Abstract Contract or to withdraw abstract

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

SUBMISSION OF ABSTRACTS IN THE FOLLOWING AREAS IS ENCOURAGED:

- Absorption, Distribution, Metabolism and Elimination
 - Applications of Modeling and Simulation
 - Big Data
 - Biosimilars
 - Chronic Pain 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 Liver Injury
 - Drug Interactions
 - Effectiveness and Impact on Quality of Life
 - Emerging Technologies
 - Experimental Pharmacology in *In Vitro* and *In Vivo* Studies
 - HIV/AIDS
 - Infectious Diseases (Antibiotics/Vaccines)
 - Mechanism of Action
 - Model-based Drug Development
 - New and Adaptive Clinical Trial Designs
 - Novel Use of Antidepressants
 - Oncology
 - Orphan Drugs
 - Pharmacoeconomics
 - Pharmacoepidemiology
 - Pharmacogenomics
 - Pharmacometrics
 - Precision Medicine as it Relates to Drug Development
 - Precision Medicine as it Relates to Patient Care
- continued on next column...*

- Regulatory Issues
- Risk Management/Legal Issues
- Safety and Efficacy
- Special Populations, Including Women, Children, the Elderly and Obese Patients
- 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

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.
- All compounds that are designated by code must be identified adequately.
- 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 and 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.
- Remember that your abstract will appear in print exactly as you submit it. Any misspellings, poor hyphenations and grammatical errors will be glaringly apparent in the published abstract.
- 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.



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Abstracts & Posters

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 decision letter by mid-May, please contact the ACCP Executive Office at 571-291-3493 ext 3 or by email at JLeeper@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 scheduled, as per the schedule noted in the next column. Student Award Winners display their posters during both sessions.
- The posters will remain on the boards during the poster session for viewing. The poster 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.
- Authors must be present at their assigned board location during the first hour of the scheduled poster session. Assistants may be used, as necessary, during the session.
- Bring only items which can be mounted on poster boards. There will be no electrical or projection capabilities provided.
- All items for posting should be prepared in advance, with posting alone remaining. Graphic supplies will not be available.
- Poster board location numbers and author names will be mounted in the upper left hand corner of 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.

2016 Poster Session & Judging Schedule

Please note: Posters will be judged the entire time the Poster Session is in progress.

POSTER SESSION 1

Sunday, September 25, 2016

5:30 – 7:30 pm

All posters must be posted between 1:00 – 3:00 pm on September 25th. Posters other than Student Award Winners must be taken down between 11:00 am and 12:00 pm on September 26th.

POSTER SESSION 2

Monday, September 26, 2016

5:30 – 7:30 pm

Posters must be posted between 1:00 – 3:00 pm on September 26th and must be taken down between 11:00 am and 12:00 pm on September 27th.

Abstract Awards

To be considered for the Student Abstract or New Member Abstract Awards, participants must submit abstracts by the April 15th deadline.

Candidates for the New Member Abstract Award are New Members who have joined ACCP and paid dues between August 1, 2015 and July 31, 2016.

FOR QUESTIONS, PLEASE CONTACT:

JLeeper@ACCP1.org or 571-291-3493 ext 3.

Educational Accreditation

Accreditation Statements



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

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



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

Designation Statement

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

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

Continuing Education Process for 2016

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

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

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

What is CPE Monitor?



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

As we approach the 2016 ACCP Annual Meeting, more detailed instructions will be provided via email to all meeting attendees.



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Pre-meeting Workshops

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

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

DISCOVERY TRACK

CO-CHAIRS:

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

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

8:00 – 8:10 am

Introduction

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

8:10 – 8:40 am

Translational Considerations in Developing

Bispecific Antibodies: What Can We Learn from Mechanistic PK/PD Modeling?

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

8:40 – 9:10 am

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

Sandhya Girish, PhD, Director, Genentech Inc

9:10 – 9:40 am

Perspectives on Clinical Development of Abbreviated Antibody Constructs

Indranil Bhattacharya, PhD, Director, Pfizer Inc

9:40 – 10:00 am / Break

10:00 – 10:30 am

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

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

10:30 – 10:50 am

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

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

10:50 – 11:10 am

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

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


11:10 – 11:30 am

Regulatory Perspectives in Developing Biotherapeutics with Novel Protein Scaffolds

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

11:30 am – 12:00 pm

Panel Discussion



Pre-meeting Workshops

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

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

APPLICATION TRACK

Offers both CME and CPE Credit

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

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

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

Ganesh Cherala, PhD, Senior Scientist, CONRAD

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

8:00 – 8:05 am

Introduction

Ganesh Cherala, PhD, Senior Scientist, CONRAD

8:05 – 8:35 am

Challenges of HIV Infection in 2016

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

8:35 – 9:00 am

Pharmacogenetics of HIV Drugs

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

9:00 – 9:30 am

Biomarkers in HIV & HCV Drug Development

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

9:30 – 10:00 am / Break

10:00 – 10:30 am

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

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

10:30 – 11:00 am

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

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

11:00 – 11:30 am

Update on Drug Interactions in HIV

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

11:30 am – 12:00 pm

Panel Discussion



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Pre-meeting Workshops

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

Improving Therapeutics to Better Care for Older Adults & the Young

DISCOVERY & APPLICATION TRACKS

CO-CHAIRS:

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

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

1:30 – 1:40 pm

Introduction

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

1:40 – 2:10 pm

Medication Issues & Potential Solutions for Frail Older Adults

Adam Golden, MD, MBA, Associate Program Director of Internal Medicine Residency, Associate Professor of Internal Medicine, Univ of Central Florida, Coll of Medicine

2:10 – 2:35 pm

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

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

2:35 – 3:00 pm

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

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

3:00 – 3:30 pm / Break

3:30 – 4:00 pm

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

Sven Stegemann, PhD, Professor, Graz Univ of Technology

4:00 – 4:30 pm

Applying Pharmacokinetic & Pharmacodynamic Principles to Improve Care for Older Adults

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


4:30 – 5:00 pm

Pharmacometric Approaches to Better Care for Older Adults & the Young

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

5:00 – 5:30 pm

Panel Discussion



Pre-meeting Workshops

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

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

DISCOVERY TRACK

Offers both CME and CPE Credit

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

ACPE – 3 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

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

Anshu Marathe, PhD, Senior Staff Fellow, Div of Pharmacometrics, US Food & Drug Administration

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

1:30 – 1:40 pm

Introduction

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

1:40 – 2:10 pm

Exposure-Safety Analyses to Drive Decision Making in Oncology

Anshu Marathe, PhD, Senior Staff Fellow, Div of Pharmacometrics, US Food & Drug Administration

2:10 – 2:40 pm

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

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

2:40 – 3:00 pm

Q&A

3:00 – 3:30 pm / Break

3:30 – 4:00 pm

Exposure-Safety Analysis for Oncology Drugs: An Industry Perspective

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

4:00 – 4:30 pm

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

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

4:30 – 5:00 pm

Panel Discussion

(including Konstantine W. Skordos, PhD [Novartis Pharmaceuticals Corp], Kourosh Parivar, MPharm [Pfizer Inc] and Atiqur Rahman, PhD [US Food & Drug Administration])



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Symposia

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

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

DISCOVERY TRACK

Offers both CME and CPE Credit

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

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

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

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

8:00 – 8:15 am

Introduction: Setting the Stage

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

8:15 – 8:40 am

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

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

8:40 – 9:05 am

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

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

9:05 – 9:30 am

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

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

9:30 – 10:00 am / Break

10:00 – 10:25 am

The Use of Modeling & Simulation in the Raxibacumab Development Program

Alfred Corey, BS, Director, Quantitative Clinical Development, Parexel Int'l

10:25 – 10:50 am

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

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

10:50 am – 12:00 pm

Panel Discussion

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

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

DISCOVERY TRACK

CO-CHAIRS:

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

Sumit Rawal, PhD, Scientist, Regeneron Pharmaceuticals Inc

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

8:00 – 8:05 am

Session Overview

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

8:05 – 8:30 am

A Qualitative Look at Immunogenicity Data During Drug Development

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

8:30 – 8:55 am

Quantitative Approaches to Assess Immunogenicity During Drug Development of Biologics

Leonid Gibiansky, PhD, President, QuantPharm LLC

8:55 – 9:20 am

What Does Immunogenicity Mean in a Clinical Setting?

Amy Rosenberg, MD, Director, Div of Therapeutic Proteins, US Food & Drug Administration

9:20 – 9:30 am

Q&A



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Symposia

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

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

DISCOVERY & APPLICATION TRACKS

CO-CHAIRS:

Sree Kasichayanula, PhD, Principal Scientist, Amgen Inc

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

10:00 – 10:10 am

Introduction

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

10:10 – 10:30 am

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

Richard Williams, MBBS, PhD, Medical Director, Amgen Inc

10:30 – 10:50 am

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

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

10:50 – 11:10 am

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

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

11:10 – 11:30 am

Advances & the Future Role of Immuno-Oncology Systems Models

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

11:30 am – 12:00 pm

Panel Discussion

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

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

DISCOVERY TRACK

CO-CHAIRS:

Gaurav Bajaj, PhD, Senior Research Investigator, Bristol-Myers Squibb Co
Ping Zhao, PhD, Lead, PBPK Program, Div of Pharmacometrics, US Food & Drug Administration

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

1:30 – 1:40 pm

Introduction

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

1:40 – 2:10 pm

Clinical Pharmacology Considerations for Biologics: Important Concepts

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

2:10 – 2:35 pm

Communicating Concepts Correctly

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

2:35 – 3:00 pm

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

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

3:00 – 3:30 pm / Break

3:30 – 4:00 pm

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

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

4:00 – 4:30 pm

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

Chunze Li, PhD, Senior Scientist, Genentech Inc

4:30 – 5:00 pm

Regulatory Considerations in Biologics Development

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

5:00 – 5:30 pm

Panel Discussion



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Symposia

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

Addressing Opioid Dependence: Now is the Time

APPLICATION TRACK

CO-CHAIRS:

Lorraine M. Rusch, PhD, Vice President, Scientific Development, Altasciences Clinical Research

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

1:30 – 1:35 pm

Introduction

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

1:35 – 1:55 pm

Addiction: An Imprecise Problem in a World of Precision Medicine

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

1:55 – 2:20 pm

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

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

2:20 – 2:40 pm

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

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

2:40 – 3:00 pm

Panel Discussion

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

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

APPLICATION TRACK

Offers both CME and CPE Credit

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

ACPE – 2 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

Vikram Arya, PhD, Senior Staff Fellow, Office of Clinical Pharmacology, US Food & Drug Administration

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

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

3:30 – 3:35 pm

Introduction

Vikram Arya, PhD, Senior Staff Fellow, Office of Clinical Pharmacology, US Food & Drug Administration

3:35 – 4:00 pm

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

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

4:00 – 4:25 pm

Ultra-short Duration Therapy: Reality or Myth?

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

4:25 – 4:50 pm

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

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

4:50 – 5:30 pm

Panel Discussion



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Symposia

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

Establishing Biosimilarity: The European Perception, Experience & Future Trends

DISCOVERY & APPLICATION TRACKS

Offers both CME and CPE Credit

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

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

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

CO-CHAIRS:

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

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

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

8:00 – 8:20 am

Introduction/EMA & FDA Guidance Review

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

8:20 – 9:00 am

How Similar is Similar? The European Biosimilar Quality Experience

Paul DeClerck, PhD, Professor, Univ of Leuven

9:00 – 9:40 am

Clinical Strategies for Biosimilar Development: A European Perspective

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

9:40 – 10:10 am / **Break**

10:10 – 10:50 am

The European Experience With Safety Testing of Biologicals and Biosimilars

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

10:50 – 11:30 am

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

Hae-Young Ahn, PhD, RAC, Deputy Director, Div of Clinical Pharmacology 3, US Food & Drug Administration

11:30 am – 12:00 pm

Panel Discussion

MONDAY, SEPTEMBER 26, 2016 | Symposium 8 | 8:00 – 9:30 am

Informing Pediatric Development Programs: Leveraging Big Data

DISCOVERY TRACK

CO-CHAIRS:

Jeffrey Barrett, PhD, Vice President, Translational Informatics, Sanofi
Lily (Yeruk) Mulugeta, PharmD, Scientific Lead for Pediatrics, Div of Pharmacometrics, US Food & Drug Administration

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

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

8:00 – 8:15 am

Introduction to Big Data and its Relevance for Pediatric Drug Development

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

8:15 – 8:30 am

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

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

8:30 – 8:45 am

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

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

8:45 – 9:00 am

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

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

9:00 – 9:15 am

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

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

9:15 – 9:30 am

Panel Discussion

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



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Symposia

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

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

APPLICATION TRACK

Offers both CME and CPE Credit

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

ACPE – 2 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

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

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

10:00 – 10:05 am

Overview: Challenges & Opportunities

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

10:05 – 10:20 am

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

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

10:20 – 10:35 am

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

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

10:35 – 10:50 am

Innovative Trial Designs for Neonatal Studies

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

10:50 – 11:05 am

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

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

11:05 – 11:20 am

Regulatory Considerations

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

11:20 – 11:30 am

International Neonatal Consortium Update

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

11:30 am – 12:00 pm

Panel Discussion

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

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

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

DISCOVERY TRACK

CO-CHAIRS:

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

Xiao Hu, PhD, Senior Pharmacometrician, Biogen Inc

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

1:30 – 1:40 pm

Introduction

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

1:40 – 2:10 pm

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

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

2:10 – 2:35 pm

Early Assessment of DDI Potential in Combination Clinical Trials

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

2:35 – 3:00 pm

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

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

3:00 – 3:30 pm / **Break**

3:30 – 4:00 pm

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

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

4:00 – 4:30 pm

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

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

4:30 – 5:00 pm

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

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

5:00 – 5:30 pm

Panel Discussion



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Symposia

MONDAY, SEPTEMBER 26, 2016 | Symposium 11 | 1:30 – 3:05 pm

Cutting-edge Abstract Presentations

DISCOVERY & APPLICATION TRACKS

Offers both CME and CPE Credit

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

ACPE – 1.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

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

Walter Kraft, MD, Professor, Thomas Jefferson Univ

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

1:30 – 1:40 pm

Introduction & Abstract Award Winner Announcement

Lawrence J. Cohen, PharmD, Professor & Coordinator of Interprofessional Education, Univ of North Texas System, Coll of Pharmacy and Walter Kraft, MD, Professor, Thomas Jefferson Univ

1:40 – 1:49 pm

Abstract #1

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

1:50 – 1:59 pm

Abstract #2

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

2:00 – 2:09 pm

Abstract #3

(5 minute presentation; 3 minutes of questions)

2:10 – 2:19 pm

Abstract #4

(5 minute presentation; 3 minutes of questions)

2:20 – 2:29 pm

Abstract #5

(5 minute presentation; 3 minutes of questions)

2:30 – 2:39 pm

Abstract #6

(5 minute presentation; 3 minutes of questions)

2:40 – 2:49 pm

Abstract #7

(5 minute presentation; 3 minutes of questions)

2:50 – 2:59 pm

Abstract #8

(5 minute presentation; 3 minutes of questions)

2:59 – 3:05 pm

Wrap Up

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

Rethinking Clinical Pharmacology-related Labeling for Improved Utility & Comprehension

DISCOVERY & APPLICATION TRACKS

Offers both CME and CPE Credit

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

ACPE – 2 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

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

Julie Bullock, PharmD, Director, d3 Medicine LLC

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

3:30 – 3:40 pm

Introduction

Julie Bullock, PharmD, Director, d3 Medicine LLC

3:40 – 4:00 pm

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

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

4:00 – 4:20 pm

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

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

4:20 – 4:40 pm

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

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

4:40 – 5:00 pm

Strategies for Enhancing Quality, Utility & Clarity in Clinical Pharmacology Labeling

Ruth Day, PhD, Associate Professor, Psychology & Neuroscience, Duke Univ

5:00 – 5:30 pm

Panel Discussion

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



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Symposia

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

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

DISCOVERY TRACK

Offers both CME and CPE Credit

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

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:

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

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

8:00 – 8:15 am

Introduction

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

8:15 – 8:40 am

FDA Flexibility in Facilitating Drug Development in Rare Diseases

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

8:40 – 9:10 am

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

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

9:10 – 9:35 am

Drug Development in Rare Neurological Diseases: Clinical Pharmacology Perspective

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

9:35 – 10:00 am / Break

10:00 – 10:30 am

Bootstrapping Orphan Drug Development

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

10:30 – 11:00 am

Some Statistical Issues in Rare Disease Clinical Trial Design

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

11:00 am – 12:00 pm

Panel Discussion

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

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

DISCOVERY TRACK

CO-CHAIRS:

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

Diansong Zhou, PhD, Director, AstraZeneca plc

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

8:00 – 8:10 am

Introduction

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

8:10 – 8:30 am

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

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

8:30 – 8:50 am

Pediatric PBPK Strategies & Tools During Drug Development

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

8:50 – 9:10 am

Pediatric PBPK Modeling: Regulatory Experience & Perspective

Ping Zhao, PhD, Lead, Physiologically-based Pharmacokinetic Program, Div of Pharmacometrics, US Food & Drug Administration

9:10 – 9:30 am

Panel Discussion



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Symposia

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

Combination Therapy in Oncology: Challenges & Strategies in Clinical Pharmacology

APPLICATION TRACK

CO-CHAIRS:

Yilong Zhang, PhD, Principal Scientist, Amgen Inc

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

10:00 – 10:10 am

Introduction

Yilong Zhang, PhD, Principal Scientist, Amgen Inc

10:10 – 10:30 am

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

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

10:30 – 10:50 am

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

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

10:50 – 11:10 am

Clinical Pharmacology Considerations in Oncology Combination Studies

Sree Kasichayanula, PhD, Principal Scientist, Amgen Inc

11:10 – 11:30 am

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

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

11:30 – 11:45 am

Panel Discussion

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

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

DISCOVERY & APPLICATION TRACKS

CO-CHAIRS:

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

Jinshan Shen, PhD, Director, Clinical Pharmacology, Vertex Pharmaceuticals Inc

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

1:30 – 1:40 pm

Introduction

Jinshan Shen, PhD, Director, Clinical Pharmacology, Vertex Pharmaceuticals Inc

1:40 – 2:05 pm

Why Clinical Pharmacology is Positioned Well to Excel in Precision Medicine

Joga Gobburu, PhD, MBA, Professor, Univ of Maryland

2:05 – 2:30 pm

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

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

2:30 – 3:00 pm

Genetics & Precision Medicine: The Way Forward!

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

3:00 – 3:30 pm / **Break**

3:30 – 3:55 pm

Multi-domain Inference in Healthcare

Mattia Proserpi, PhD, Associate Professor, Univ of Florida

3:55 – 4:20 pm

Clinical Pharmacology in Precision Medicine: Drug Development Strategy for Cardiovascular Indications

Gangadhar Sunkara, PhD, Executive Director, Novartis Inst for Biomedical Research

4:20 – 4:45 pm

Pharmacogenomics in Drug Development of Precision Medicine – An FDA Perspective

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

4:45 – 5:30 pm

Panel Discussion



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Symposia

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

Reproducible Visualization & Data Analysis With R

DISCOVERY TRACK

Offers both CME and CPE Credit

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

ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CHAIR:

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

TARGET AUDIENCE:

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

GOALS AND OBJECTIVES:

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

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

1:30 – 1:45 pm

Introduction

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

1:45 – 2:00 pm

Introduction to a Reproducible R Workflow with Rstudio, Rmarkdown

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

2:00 – 2:15 pm

Introduction to ggplot2 for Data Visualization

Kaori Ito, PhD, Director, Pfizer Inc

2:15 – 2:45 pm

Hands-on Activity

Kaori Ito, PhD, Director, Pfizer Inc

2:45 – 3:00 pm

Solutions Demonstration

Kaori Ito, PhD, Director, Pfizer Inc

3:00 – 3:30 pm / **Break**

3:30 – 4:00 pm

Introduction to Data Management with dplyr

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

4:00 – 4:15 pm

Additional dplyr & Introduction to tidyr

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

4:15 – 5:15 pm

Hands-on Activity Using dplyr, tidyr & ggplot2

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

5:15 – 5:30 pm

Wrap Up, Q&A, Additional Resources

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



Why Join ACCP?

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

Why Should You Join the American College of Clinical Pharmacology?

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- **Networking opportunities** and, for Students & Trainees, access to Mentors.
- **Opportunity to enhance your leadership skills** by volunteering for one of ACCP's many committees or by Mentoring Students & Trainees.
- **Opportunity to develop educational activities** that make a difference by submitting proposals for ACCP educational events and getting involved in the clinical pharmacology community.

- **Access to the ACCP Job Center** to view jobs and post your resume.
- **Receipt of information from the clinical pharmacology community** for Members who opt in to receive the daily news format, routine recall/drug safety notices from FDA Medwatch, FDA Bursts or AAMC notifications.
- **Receipt of routine updates from ACCP** about developments in the field of clinical pharmacology and 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. All applications must be submitted in full 30 days before the Board of Regents Meetings, the dates of which are noted below:

- May 1, 2016
- September 24, 2016

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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.



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Registration Information



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offering Continuing Medical Education (CME) and Continuing Pharmacy Education (CPE) credits for educational events. The 2016 ACCP Annual Meeting offers 28 hours of Continuing Education credit, **at no additional cost to attendees.**

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to members of Sister Organizations (AAPS, AGAH, ASCPT, ASPET, BPS, CSPT, ISAP and ISO), as well as to our colleagues from the FDA, NIH, CDC and other 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.

Discounts are available during the Early Bird registration period for groups of six or more persons from the same organization. Please contact JLeeper@ACCP1.org or 571-291-3493 ext 3.

REGISTRATION DEADLINE for Pre-meeting Workshops is August 15, 2016. ACCP reserves the right to cancel Pre-meeting Workshops due to low attendance. Should cancellation be required, registrants will receive a full refund for the cost of the Pre-meeting Workshop only.

REGISTRATION INFORMATION	EARLY BIRD	ADVANCE	ONSITE
	4/1/2016 – 6/30/2016	7/1/2016 – 8/31/2016	9/1/2016 – 9/27/2016
Member – Three Days	\$800	\$1,120	\$1,225
Member – One Day	\$385	\$455	\$505
Non-member – Three Days	\$1,220	\$1,515	\$1,650
Non-member – One Day	\$485	\$530	\$585
Sister Org/US Government Colleague – Three Days	\$960	\$1,275	\$1,380
Sister Org/US Government Colleague – One Day	\$440	\$510	\$560
Student Member – Three Days	\$315	\$360	\$400
Student Member – One Day	\$155	\$175	\$200
Student Non-member – Three Days	\$425	\$480	\$515
Student Non-member – One Day	\$195	\$215	\$235
Pre-meeting Workshops (each) – Member	\$280	\$310	\$325
Pre-meeting Workshops (each) – Non-member	\$305	\$330	\$355
Pre-meeting Workshops (each) – Member Sister Org/US Government Colleague	\$305	\$330	\$355
Pre-meeting Workshops – Student Member or Non-member	\$115	\$115	\$115

CANCELLATION/REFUND POLICY:

Meeting registration cancellations must be submitted via email to Reg@ACCP1.org no later than Monday, 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.

International Attendees

International Attendees

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 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 2016 ACCP Annual Meeting, please submit an email request at JLeeper@ACCP1.org.

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.

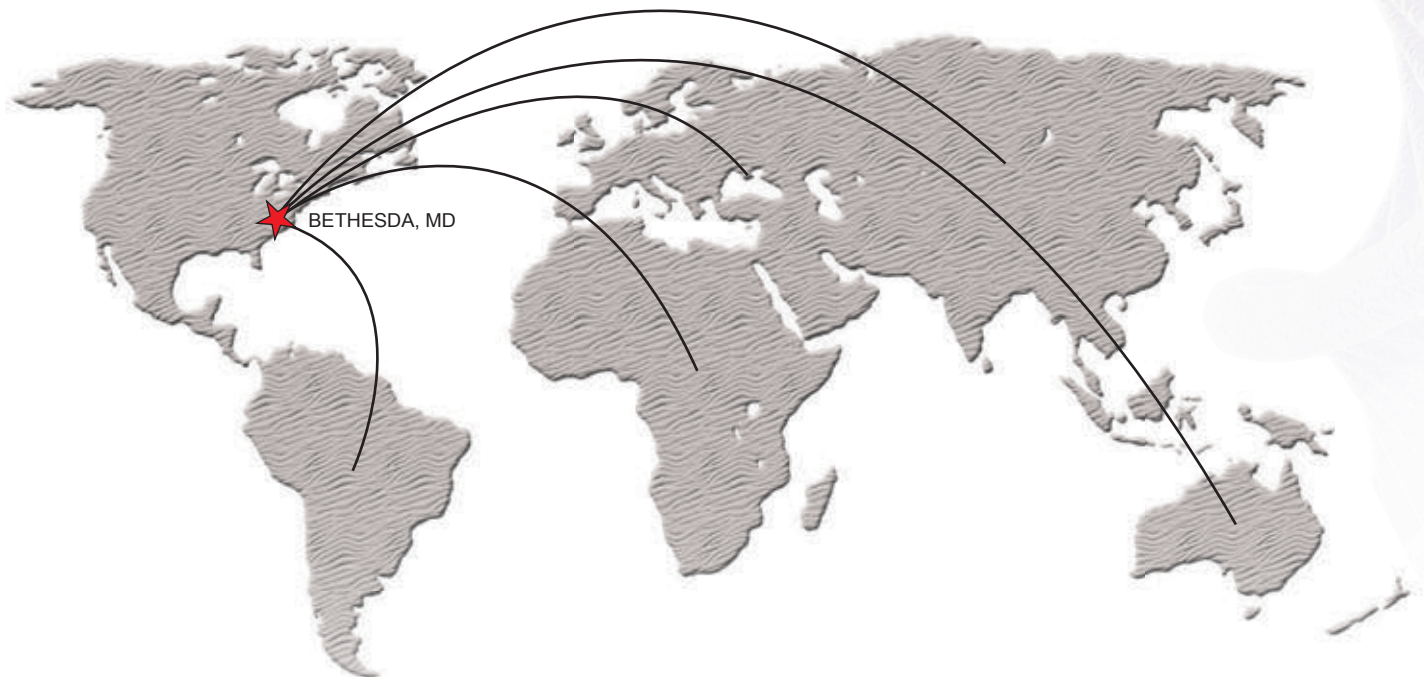
The VWP allows citizens of participating countries to travel to the US without a visa for stays of 90 days or less when they meet all requirements as per the VWP website. Travelers must be eligible to use the VWP and have a valid [ESTA](#) approval prior to travel.

These sites provide helpful information on visas and travel to the United States:

- <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 the regulations may change and the only authoritative sources of information are the US Government websites noted above.





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Travel & Hotel

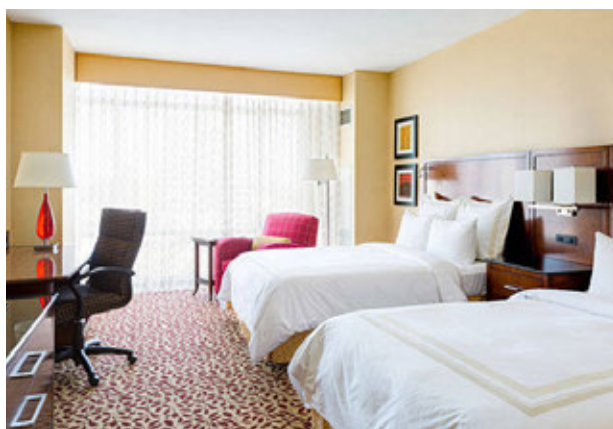
Travel



The 2016 ACCP Annual Meeting will take place at the **Bethesda N Marriott Hotel & Conference Ctr**, Bethesda, Maryland – a dynamic city just outside Washington, DC, a leading center for biomedical research and home to the National Inst of Health (NIH) and Bethesda Naval Hosp (Bethesda Naval Medical Ctr).

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

Hotel



Bethesda N Marriott Hotel & Conference Ctr
5701 Marinelli Rd
North Bethesda, Maryland 20852
Tel: (301) 822-9200

Located in Montgomery County, outside Washington, DC, the Bethesda N Marriott Hotel & Conference Ctr is perfect for comfortable accommodations, quick access to the meeting and a short distance to

public transportation. Just across the street from the White Flint Metro Station, it is an easy ride to area attractions in a thriving district that is home to more than 200 restaurants, two live theatres, over 20 art galleries and some of the best shopping in the Washington, DC metro area!

A wide range of stylish guest rooms and suites await you at the Bethesda N Marriott Hotel & Conference Ctr, which also includes a Concierge level to welcome both business and leisure travelers with everything needed for a remarkable hotel experience. Well-furnished rooms, high-speed Internet access, on-site dining and 24-hour privileges at the hotel fitness center and heated indoor pool will create a relaxing and productive stay. Specifically designed with 50,000 sq ft of high-tech conference space, this hotel promises a meeting experience unlike any other.

For your benefit, a special room rate of **\$179** has been established. In addition, the special rate has been extended to three days before and after the conference.

Online Reservations: <https://resweb.passkey.com/go/b7fda76e>

Phone Reservations: Call 877-212-5752 and give the group name ACCP Annual Meeting.

The cutoff date for this group rate is **Thursday, September 1, 2016**.

We anticipate that rooms will sell quickly and advise you to make reservations early. After the cutoff date of September 1st, 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 noted above or by calling the Bethesda N Marriott Hotel & Conference Ctr directly and using the reservation code provided above. 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 JLeeper@ACCP1.org.

Nearest Airports: DCA (23 miles), IAD (25 miles), BWI (36 miles)

Nearest Bus & Metro Station: White Flint Metro Station 0.3 miles

Nearest Train Station: Union Station 20 miles

Parking:

Parking is available onsite, with in and out privileges.

Rates: \$5 per hour or \$15 daily, per car.

Air Transportation

Ronald Reagan Washington National Airport (DCA)

This airport may be the best choice for attendees traveling within the continental US. It does have more limited flight schedules than the two other airports and, as a result, fares can be higher. However, it is convenient due to the accessibility of the Metrorail system located inside Ronald Reagan National Airport, which can deliver travelers safely and cost-effectively to the White Flint Metro Stop located directly across the street from the Bethesda N Marriott Hotel & Conference Ctr.

Distance to conference venue: 23 miles

Estimated Metrorail service fee: \$6.90 USD (one way)

Estimated SuperShuttle: \$33 USD (one way)

Estimated taxi fare: \$55 USD (one way)

This hotel does not provide shuttle service.

Washington Dulles International Airport (IAD)

International attendees traveling from outside of the continental US may find that using Washington Dulles Int'l Airport is a better fit for their air travel needs as it provides for customs facilities and caters more to the international traveler. Travelers can take a bus from the airport to the Wiehle Metrostop on the Silver Line for travel by Metrorail.

Distance to conference venue: 25 miles

Estimated bus/Metrorail service fee: \$8.60 USD (one way)

Estimated SuperShuttle: \$30 USD (one way)

Estimated taxi fare: \$60 USD (one way)

This hotel does not provide shuttle service.

Baltimore/Washington International Thurgood Marshall Airport (BWI)

While Baltimore/Washington Int'l is an international airport, its location is the furthest from the Bethesda N Marriott Hotel & Conference Ctr, which may make travel time consuming and more expensive.

Distance to conference venue: 36 miles

Estimated bus/Metrorail service fee: \$10 USD (one way)

Estimated SuperShuttle: \$42 USD (one way)

Estimated taxi fare: \$70 USD (one way)

This hotel does not provide shuttle service.

Ground Transportation

For attendees arriving to the area by air, the Bethesda N Marriott Hotel & Conference Ctr is located 20 – 40 miles from the three metropolitan area airports. There are several ground transportation options from each airport: public transportation (Washington Metrobus or Metrorail), private taxi/Uber service or shared ride service (SuperShuttle).

Public Transportation: Public Transportation options (bus and/or Metrorail service) vary from each airport. Attendees flying into DCA, IAD or BWI may take advantage of Washington Metropolitan Area Transit Authority (WMATA) services. Information on specific routes, times, and fares, which vary according to time and date of travel, can be obtained on the WMATA website (<http://wmata.com>). The hotel is across the street from the **White Flint (Red Line) Metro Station**.

Transportation from DCA: *Estimated Travel Time: Metrorail – 50 minutes*

An elevated Metrorail Station is connected to the concourse level of Terminals B and C at Reagan National Airport. Use either of two pedestrian bridges on the concourse level which connect directly to the station. From the station, take the Blue Line Metro towards Largo Station, exit at the Metro Center Station. Transfer to the Red Line Metro towards Shady Grove. Exit at the White Flint Metro Station.

Transportation from IAD: *Estimated Travel Time: Bus – 15 minutes, Metrorail – 75 minutes*

Catch the Silver Line Express (Bus Timetable: <http://www.flydulles.com/iad/silver-line-express-bus-metrorail-station>) from IAD Airport to the Wiehle-Reston East Metro Station. Purchase a ticket at the Washington Flyer Coach ticket counter located at Arrivals Door #4 in the Main Terminal. Travelers will also board the Coach from this location. The buses depart approximately every 30 minutes. Take the bus to the Wiehle-Reston East Metro Station (Silver Line). Board the Silver Line Metro, heading towards Largo Station and exit at Metro Center Station. Transfer to the Red Line Metro towards Shady Grove. Get off at White Flint Metro Station.

Transportation from BWI: *Estimated Travel Time: Bus – 35 minutes, Metrorail – 1 hour*

Catch the BWI Express Bus (Bus Timetable: <https://www.wmata.com/bus/timetables/md/b30.pdf?n>) from BWI to the Greenbelt Metro Station. There are two WMATA Bus Stops; one located on the lower level of the International Concourse and the other located on the lower level of Concourse A/B. Bus number B30 will pick you up outside at the bus shelter. Bus fare is \$7. Follow the signs to "Public Transit." The buses depart approximately every 40 minutes. Take the Bus to the Greenbelt Metro Station (Green Line). Board the Green Line Metro, towards Branch Avenue, and get off at Fort Totten Station. Transfer to the Red Line Metro, towards Shady Grove, and get off at the White Flint Station.

Taxi: Taxi or Uber services are available from area airports. Time of day, route taken, day of week and traffic can dramatically influence the fare.

SuperShuttle: Tickets may be purchased as you board, but advance reservations are recommended. To book your shuttle service, please contact SuperShuttle by visiting their website (www.supershuttle.com).

Meeting attendees wishing to travel by train can access the Metrorail Red Line from Washington's Union Station to the White Flint Metro Stop located directly across from the Bethesda N Marriott Hotel & Conference Ctr.

Attendees arriving to the area by car should plan for significant traffic congestion on the Beltway (either direction) during morning and evening commutes.



ACCP

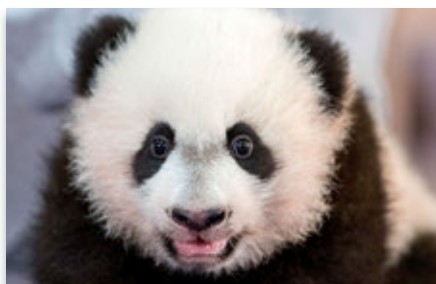
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Travel & Hotel

Area Attractions

We invite you to enjoy the lovely fall weather as you stroll outside to shop or dine at [Bethesda Row](#) or [Rockville Town Center](#). For an indoor shopping and dining experience, try [Mazza Gallerie](#) or [Montgomery Mall](#).

Make sure to plan a little extra time during your visit and check out some of these top things to do in the area. Nearby Metrorail access leads to Washington, DC's monuments, museums, wonderful restaurants, vibrant cultural activities and historic attractions. Popular attractions include:



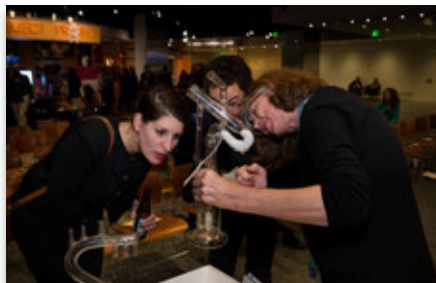
National Zoo: Covering more than 160 acres, the zoo is easily accessible by Metrorail. Bei Bei, the zoo's newest panda, is a very popular stop!



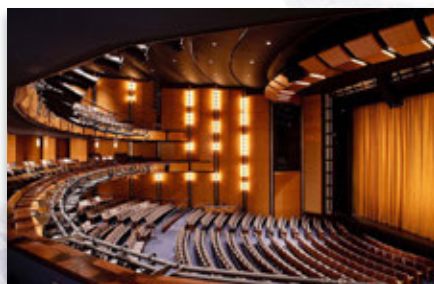
The Mall: Visited by more than 25 million people annually, this National Park contains the World War II Memorial, the Washington Monument, the Lincoln Memorial, Vietnam Veterans Memorial, Korean War Veterans Memorial, Franklin D. Roosevelt Memorial and Thomas Jefferson Memorial, plus more than 65 lesser known monuments and memorials.



National Air and Space Museum: This popular tourist attraction has something for everyone with a wide array of permanent and rotating exhibits. Don't miss the rock from the Moon on display for visitors to touch!



American History Museum: Beginning September 15, 2016, a new exhibit, "[Science Under the Glass](#)," is scheduled to open. The unique properties of glass – impermeability, durability, transparency and malleability – make it an essential material in the laboratory. An examination of the collection of scientific glassware, from the 1770s to the 1970s, reveals the underlying story of the growth of laboratory science in America, from an individual and isolated pursuit to a familiar and fundamental activity in educational, medical and research institutions throughout the country.



Kennedy Center: Home to the National Symphony Orchestra, National Opera & Ballet and many touring artists, we encourage you to check [Kennedy-Center.org](#) to see what performances are available during your stay.



White House: If you want a tour of the grounds and state rooms, you'll need to call your Congressional representative months in advance to help you secure a tour reservation. Advanced security and background checks are required.

Seen and done all the monuments and museums? Try venturing off the beaten path and discover these hidden gems:

- [Phillips Collection](#) • [George Washington Masonic National Memorial \(Alexandria\)](#) • [Marian Koshland Science Museum](#) • [Library of Congress](#)
- [National Geographic](#) • [National Arboretum](#) • [Frederick Douglass National Historic Site](#) • [Renwick Chapel \(Oak Hill Cemetery\)](#)
- [Roosevelt Island \(Rosslyn\)](#) • [Society of Cincinnati Mansion](#)

Why Exhibit at ACCP?

Who We Are

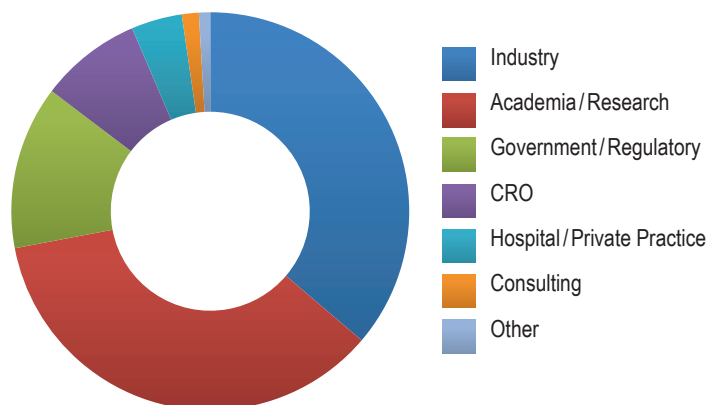
ACCP's diverse global membership is dedicated to improving the quality of patient care by optimizing the use of therapeutics. ACCP achieves this by providing Continuing Education to a broad range of clinicians and healthcare professionals spanning the scope of research and drug development to patient-related 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.

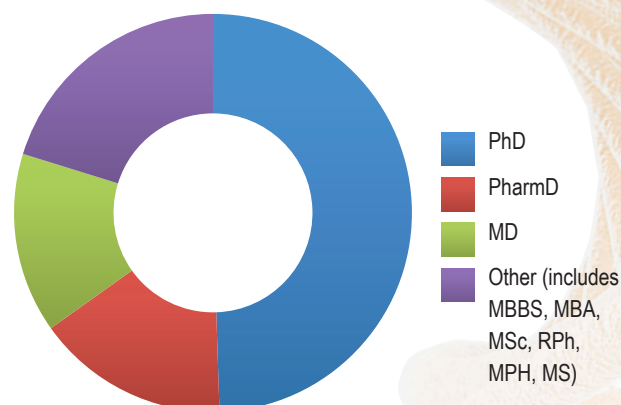
Vision & Mission

- 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.

Distribution by Attendee Affiliation



Distribution by Attendee Degree



Why Sponsor and Exhibit at the 2016 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 and Exhibit at the 2016 ACCP Annual Meeting!

Reserve your space by contacting us at Exhibit@ACCP1.org or 571-291-3493 ext 3. **Deadline for final Sponsor and Exhibitor commitments is June 30, 2016.**

Educational Grants

Educational grants are used to support ACCP Annual Meeting live educational events, as well as online materials. For more information, please contact CE@ACCP1.org or the ACCP Executive Office at 571-291-3493 ext 2.

Cancellation Policy

Cancellations in writing will be accepted until June 30, 2016 and are subject to a \$500 administrative fee.



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Sponsorship Opportunities

Levels of Sponsorship

All ACCP Annual Meeting Sponsors will be recognized for their support in the Final Program, on ACCP's website 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) One Exhibit space + exclusive Sponsorship of WiFi access provided to all attendees for one device of their choice. 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:

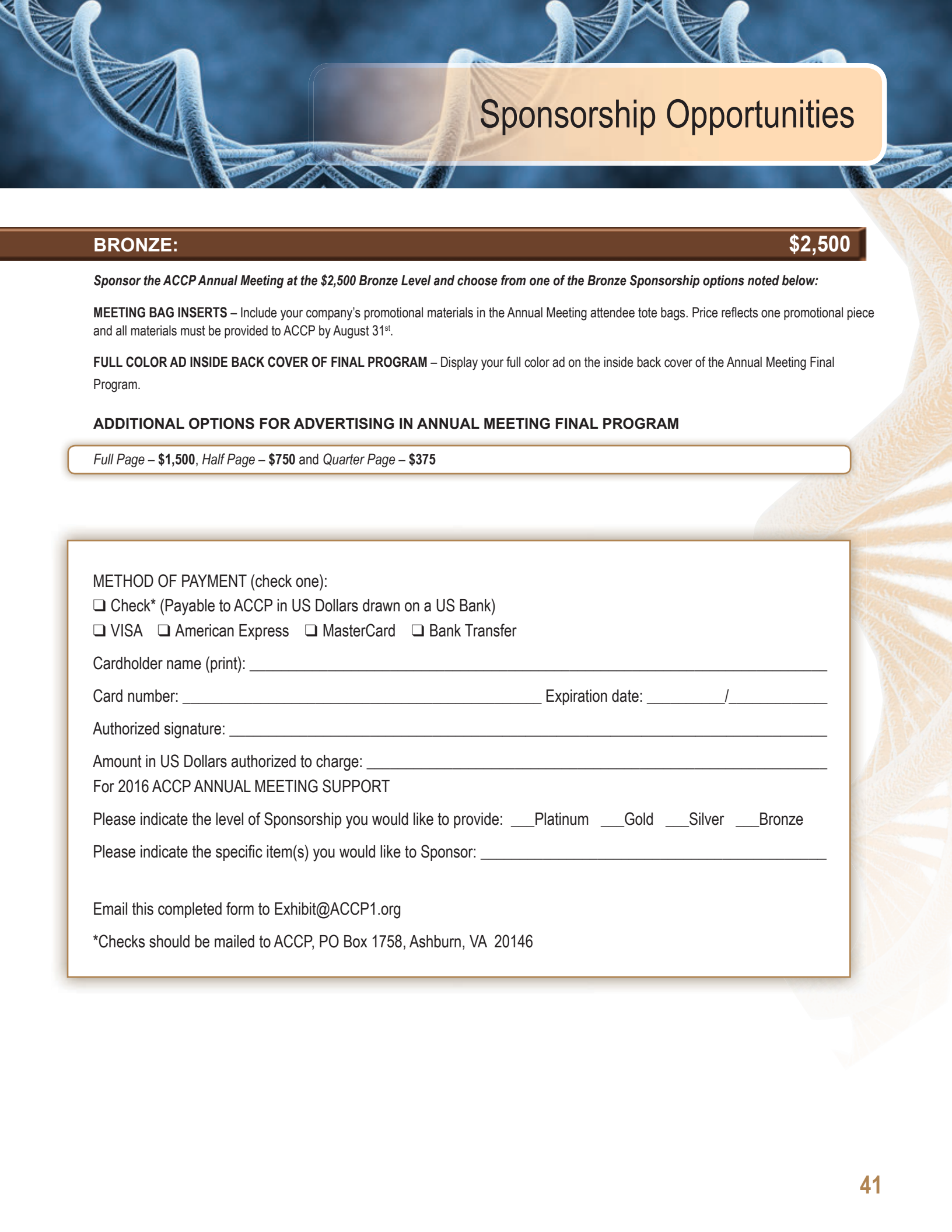
\$3,500

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

Full Page – \$1,500, Half Page – \$750 and Quarter Page – \$375

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 2016 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



ACCP

AMERICAN COLLEGE OF CLINICAL PHARMACOLOGY
Advancing Clinical Care through Pharmacology®

Exhibit Hall

Exhibit Hall

EXHIBIT HOURS:

Sunday, Sept 25th 5:00 – 8:00 pm

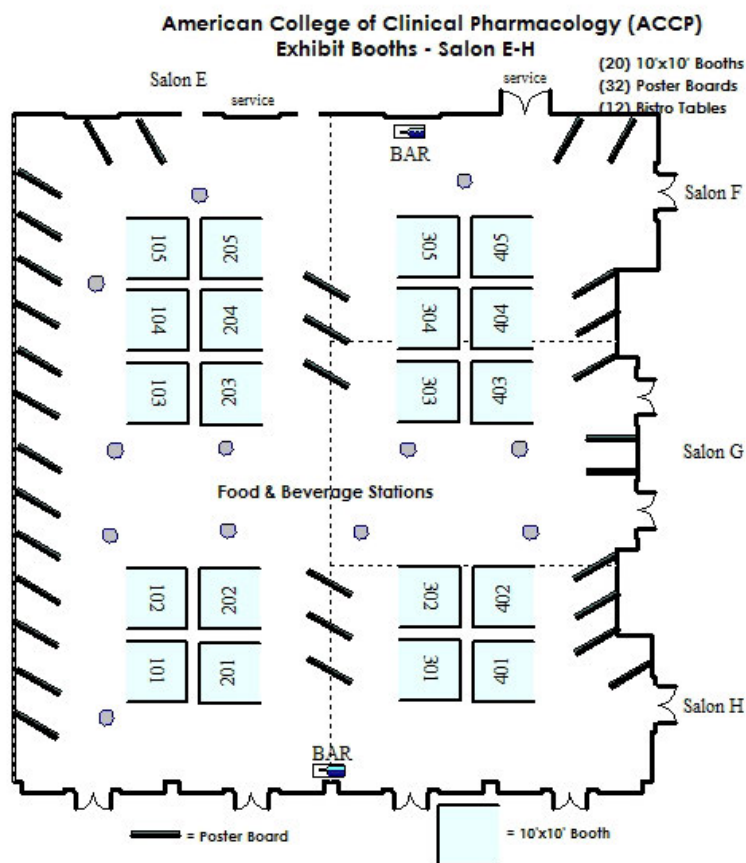
Monday, Sept 26th 7:00 – 11:00 am and 3:00 – 8:00 pm

Tuesday, Sept 27th 7:00 – 11:00 am

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 2016 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 – 2015 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.





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Exhibitor Registration Form

2016 ACCP Annual Meeting

Exhibit fee includes 10' booth space, one 6' table, two chairs and a wastebasket.

EXHIBIT COMPANY _____

ADDRESS _____

CITY _____ STATE _____ COUNTRY _____ ZIP _____

CONTACT PERSON* _____

*Person responsible for disseminating Exhibit information from ACCP.

PHONE _____ CELL PHONE _____ FAX _____ EMAIL _____

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

EXHIBIT FEE (Includes Two Exhibit Personnel PLUS 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 2016 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

ACCP's Tax ID number is 22-1950891