The ACCP365 Mobile App – it’s more than a meeting app!

The ACCP365 Mobile App is ACCP’s year-round access mobile app. More than just a meeting app, it’s an all access pass to everything about ACCP, any time, any place! Download the ACCP365 Mobile App now to get access to:

- Use the Connect feature to network directly with Members
- Visit ACCP1.org
- Renew your membership
- Register for the ACCP Annual Meeting or other educational events
- Watch ACCP On Demand educational webinars
- Access JCP & CPDD journals
- Have on-the-go access to the ACCP Membership Directory
- Review new job listings in the ACCP Job Center
- Use ACCP Alerts to stay up-to-date on the latest in clinical pharmacology and ACCP News
- Access your Facebook, Twitter, LinkedIn and Instagram accounts

When the 2020 Annual Meeting arrives, ACCP365 also provides pertinent information such as:

- Access a list of Attendees, Faculty, Exhibitors & Sponsors
- Use the Connect feature to network directly with Attendees
- Easily review a schedule of daily Sessions, Poster Presentations & Special Events
- Download Pre-meeting Workshop & Symposia Syllabi
- Use the Live Polling feature during certain Pre-meeting Workshops & Symposia
- Direct links to complete Session Evaluations and Post-event Self-assessments
- Take notes specific to Sessions & Attendees
- Ability to participate in ACCP’s Game Zone where you can accumulate points by scanning QR codes associated with Sessions & Events you attend, completing a quiz, utilizing Twitter within ACCP365 to share your experience and pictures during the Annual Meeting or completing Session Evaluations and Post-event Self-assessments. The Attendee with the most points will win a $50 gift card which will be mailed after the ACCP Annual Meeting!
- Learn more about the 2020 ACCP Recognition & Student Award Winners
- Pertinent Hotel & Travel information

Discover:
How ACCP365 enhances your experience with ACCP at the Annual Meeting and beyond

Connect:
With colleagues and peers throughout the year

Access:
On Demand webinars, ACCP Journals, ACCP Job Center and more while on the go 24/7/365
American College of Clinical Pharmacology®
2020 Annual Meeting
Program Committee

Co-chairs:
Ayyappa Chaturvedula, PhD
Honghui Zhou, PhD

Members:
Claude Abdallah, MD, MSc
Barbara Ameer, PharmD, MBA
Vikram Arya, PhD
Michael J. Fossler Jr, PharmD, PhD
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Xiling Jiang, PhD
Joseph Ma, PharmD
Bernd Meibohm, PhD
Diane R. Mould, PhD
Arun Ram, MD
Stephan Schmidt, PhD
Catherine MT Sherwin, PhD, MSc
Amit Somani, PhD

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Join Us for the 2020 ACCP Annual Meeting!
Translating Clinical Pharmacology Research into Patient-centered Care

We invite you to join us for the 2020 Annual Meeting of the American College of Clinical Pharmacology®, Translating Clinical Pharmacology Research into Patient-centered Care, September 20 – 22, 2020 at the Bethesda N Marriott Hotel & Conf Ctr. Consistent with ACCP’s commitment to excellence in science and education, the 2020 Annual Meeting Program Committee, co-chaired by Drs. Ayyappa Chaturvedula and Honghui Zhou, has worked diligently to provide a diverse and exceptional educational program that meets the needs of healthcare professionals and scientists with an interest in one or more of the myriad of applications of clinical pharmacology ranging from research and drug development to patient care. Sessions include five Pre-meeting Workshops and twenty-one Symposia that include a diverse, global group of Faculty Speakers that span the breadth of academia, industry, regulatory agencies, consulting companies and clinical specialties. The educational programming is designed to encompass presentations on high-impact topics and is organized into tracks that allow Attendees to uniquely tailor content selection to their individual interests. Invited Keynote, Steven D. Gore, MD, will present on “20 Years of ‘Epigenetic’ Cancer Therapy – Who Are We Fooling?”

A series of special Student, Trainee & Early-stage Professional-focused programs will provide exposure to innovative science and career development opportunities. Of particular note is a panel discussion on generational differences in communication to help you achieve success at all stages of your career, plus a Pre-meeting Workshop on beginner level principles of population pharmacokinetics & fundamentals of NONMEM® software.

Poster Sessions, held during Sunday and Monday Evening Receptions, will focus on new findings and preliminary data presented by a wide spectrum of Attendees.

New in 2020, join us Sunday evening for PharmaFete, including a DJ, photo booth, Vegas-style game tables, light dinner fare & beer/wine. Enjoy the chance to socialize and network during Evening Receptions and Poster Sessions, including new Faculty in Focus events providing up close access to select Faculty, at twice-daily tea/coffee breaks, at the

Lunch & Awards Sessions and the Annual Business Meeting, open to anyone interested in learning about ACCP.

Also new in 2020 is our community outreach program, providing an opportunity for ACCP Members & meeting Attendees to make an impact in a uniquely personal way in the community where the meeting is held. This year, the recipient program is The Children’s Inn at the National Inst of Health (NIH), a residential facility that allows families with seriously ill children under care at the NIH to stay free of charge. We hope you will join us in the effort to support this worthwhile cause!

For those who have never had the opportunity to attend an ACCP Annual Meeting, join us in 2020 and see for yourself how ACCP hosts an outstanding educational and scientific event that provides 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. Registration is now open! Remember to register early for the Pre-meeting Workshops, as seating is limited.

The Bethesda N Marriott Hotel & Conf Ctr, an exceptional property, is perfect for comfortable accommodations and beautiful, high-tech meeting space. It is easily accessible from the White Flint Metrorail Station on the Red Line or is an easy ride from any of the three airports in the Washington/Baltimore area. For your benefit, accommodations at the special rate of $179 have been negotiated. The cutoff date for reservations at this group rate is August 28, 2020.

ACCP is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE) and the American Nurses Credentialing Center (ANCC) to provide credits for our educational courses. Credits are provided to meeting Attendees at no additional cost.

Come learn, network and be part of an excellent educational event in the clinical pharmacology community! We look forward to seeing you in September!

Vikram Arya, PhD
President, ACCP

Ayyappa Chaturvedula, PhD
Program Co-chair

Honghui Zhou, PhD
Program Co-chair
Workshops & Symposia at the 2020 ACCP Annual Meeting are identified as being part of either the “Drug Development Track” (DDT), the “Therapeutic Areas of Applied Clinical Pharmacology Track” (TCP), the “Applied Clinical Pharmacology Techniques Track” (ATT), the “Innovations Track” (IT), the “Quantitative Track” (QT) or the “Basic Science of Clinical Pharmacology Track” (BT) to make it easier for Attendees to determine which courses they prefer to attend.

**SATURDAY, SEPTEMBER 19, 2020**

**Pre-meeting Workshop 1 | 8:00 – 11:30 AM | DDT**
**Analysis & Reporting of QTc Prolongation Potential of New Drugs Using R Tools, Expectations & General Guidance for Regulatory Submissions**
CO-CHAIRS: Ana Ruiz-Garcia, PharmD, PhD, Senior Principal Scientist I, Metrum Research Group LLC and Dhananjay D. Marathe, PhD, Principal Scientist, Quantitative Pharmacology & Pharmacometrics, Merck & Co Inc

**Pre-meeting Workshop 2 | 8:00 – 11:30 AM | DDT**
**Individualized Drug Therapy: Maximally-precise Drug Therapy for Each Individual Patient, at the Bedside, in a Community Hospital Setting**
CHAIR: Michael N. Neely, MD, Chief, Infectious Diseases, Director, Laboratory of Applied Pharmacokinetics & Bioinformatics, Children’s Hosp Los Angeles, Professor of Pediatrics & Clinical Scholar, Keck School of Medicine, Univ of Southern California

**Pre-meeting Workshop 3 | 9:00 AM – 5:00 PM | ATT**
**A Beginner Level Workshop on the Principles of Population Pharmacokinetics & Fundamentals of NONMEM® Software for Students, Trainees & Early-stage Professionals**
CO-CHAIRS: Oliver Grundmann, PhD, Clinical Associate Professor & Director, Medicinal Chemistry, Coll of Pharmacy, Univ of Florida and Robert Bies, PharmD, PhD, Associate Professor, Pharmaceutical Sciences, Univ at Buffalo, School of Pharmacy & Pharmaceutical Sciences

**Pre-meeting Workshop 4 | 1:30 – 5:30 PM | TCP**
**Drug Development for Pregnant Women & Their Infants: Lessons Learned from HIV**
CHAIR: Jeremiah D. Momper, PharmD, PhD, Associate Professor, Univ of California San Diego

**Pre-meeting Workshop 5 | 1:30 – 5:30 PM | DDT**
**Innovative Drug Development in Asia: Challenges & Opportunities**
CO-CHAIRS: Haiyan Li, MD, Peking Univ Third Hosp, China and Gailing Li, PhD, Janssen Research & Development LLC

**SUNDAY, SEPTEMBER 20, 2020**

**Symposium 1 | 8:00 – 9:30 AM | DDT**
**Strategies & Considerations for the Assessment of Relative Dose Intensity in Oncology Drug Development**
CHAIR: Divya Samineni, PhD, Scientist, Genentech Inc

**Symposium 2 | 8:00 – 11:30 AM | TCP**
**What is the Right Dose in Cancer Patients With Hepatic Dysfunction? Considerations in the Translation of Pharmacokinetic Studies from Clinical Trial to Clinic**
CO-CHAIRS: Nithya Srinivas, PhD, Research Investigator, Incyte Corp and Islam R. Younis, PhD, Director, Astellas Pharma US Inc

**Symposium 3 | 10:00 – 11:30 AM | TCP**
**The Race to Develop New Targeted Therapies for Children With Brain Tumors: Where Do We Go?**
CO-CHAIRS: Gilbert J. Burckart, PharmD, Associate Director, Pediatrics, US Food & Drug Administration and Clinton F. Stewart, PharmD, Member & Interim Director, Pharmaceutical Sciences, St Jude Children’s Research Hosp

**Symposium 4 | 1:30 – 3:00 PM | TCP**
**Pediatric Renal Function: Why We Still Need to Explore Renal Maturation & Its Impact on Drug Therapies**
CO-CHAIRS: Jian Wang, PhD, Associate Director, Drug Evaluation IV, CDER, US Food & Drug Administration and Catherine MT Sherwin, PhD, Professor & Vice Chair for Research, Director, Pediatric Clinical Pharmacology, Pediatrics, Wright State Univ Boonshoft School of Medicine, Dayton Children’s Hosp

**Symposium 5 | 1:30 – 3:00 PM | DDT**
**Clinical Pharmacology in Anti-infective Drug Development**
CHAIR: Amit Somani, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration

**Symposium 6 | 3:30 – 5:30 PM | IT**
**Innovative Technologies in Patient-centric Drug Development: Promises & Challenges**
CO-CHAIRS: Anuradha Ramamoorthy, PhD, Policy Lead, Clinical Pharmacology, CDER, US Food & Drug Administration and Leslie Dickmann, PhD, MPH, Program Director, School of Pharmacy, Univ of Wisconsin Madison

**Symposium 7 | 3:30 – 5:30 PM | DDT**
**Conducting First-in-Human Studies in the Context of the Concomitant Use of Drug-Drug Interaction Victims & Perpetrators**
CO-CHAIRS: Olanrewaju Okusanya, PharmD, MS, Team Leader, US Food & Drug Administration and Vadryn Pierre, PharmD, Senior Clinical Pharmacokineticist, AstraZeneca plc
MONDAY, SEPTEMBER 21, 2020

Symposium 8  |  8:00 – 9:30 AM  |  ATT
Learning Health Systems: Leveraging Synergies Between Pharmacometrics & Pharmacoepidemiology for Efficient Healthcare Delivery  
CO-CHAIRS: Ayyappa Chaturvedula, PhD, Associate Professor, Pharmacotherapy, Univ of North Texas Health Science Ctr and Navin S. Goyal, PhD, Director, Clinical Pharmacology Modeling & Simulation, GlaxoSmithKline plc

Symposium 9  |  8:00 – 9:30 AM  |  DDT
Building Bridges: Combination of Product Drug/Device Development With Biologics  
CO-CHAIRS: Jocelyn H. Leu, PharmD, PhD, Scientific Director, Janssen Research & Development LLC and Yow-Ming Wang, PhD, Associate Director, Biosimilars & Therapeutic Biologics, Clinical Pharmacology, CDER, US Food & Drug Administration

Symposium 10  |  10:00 – 11:30 AM  |  QT
What’s Next in Model-informed Drug Development? Joined Pharmacometrics & Epidemiological (Real-world Data) Approaches  
CHAIR: Yan Xu, MD, PhD, Director, Clinical Pharmacology & Pharmacometrics, Janssen Research & Development LLC

Symposium 11  |  10:00 – 11:30 AM  |  ATT
Assessing the Feasibility of Model-informed Precision Dosing: A Point-Counterpoint Debate, an ACCP/ISoP Jointly-sponsored Symposium  
CO-CHAIRS: Diane R. Mould, PhD, President, Projections Research Inc and Nikolas Onufrak, PharmD, Associate Director, Pharmacometrics, Boehringer Ingelheim

Symposium 12  |  1:30 – 3:00 PM  |  TCP
The Opioid Overdose Epidemic: Trends, Harms & Treatment  
CHAIR: Sam Harirforoosh, PharmD, PhD, Professor, Gatton Coll of Pharmacy, East Tennessee State Univ

Symposium 13  |  1:30 – 5:00 PM  |  ATT
Patient-reported Outcomes in Drug Development & Clinical Practice  
CHAIR: Barbara Amner, PharmD, MBA, Adjunct Associate Professor, Medicine, Rutgers Robert Wood Johnson Medical School

Symposium 14  |  3:30 – 5:30 PM  |  QT
Applying Pharmacometrics to Precision Dosing in the Lifecycle of Long-acting Injectable Products: Drug Development, Regulatory Approval & Clinical Practice  
CO-CHAIRS: Hong Lu, PhD, Scientific Director, Takeda Pharmaceuticals USA Inc and Lanyan (Lucy) Fang, PhD, Associate Director, Quantitative Methods & Modeling, US Food & Drug Administration

TUESDAY, SEPTEMBER 22, 2020

Symposium 15  |  8:00 – 9:30 AM  |  DDT
Applying Quantitative Clinical Pharmacology to Support the Drug Development of T cell-directing Bispecific Antibodies  
CO-CHAIRS: Weirong Wang, MD, PhD, Scientific Director, Janssen Research & Development LLC and Xiling Jiang, PhD, Staff Fellow, US Food & Drug Administration

Symposium 16  |  8:00 – 9:30 AM  |  DDT
Pharmacometrics & Formulations in Clinical Development: Unglamorous, but Highly Impactful  
CO-CHAIRS: Navin S. Goyal, PhD, Director, Clinical Pharmacology Modeling & Simulation, GlaxoSmithKline plc and Roberto Gomeni, PhD, President, Pharmacometria & Adjunct Professor, Pharmacotherapy & Experimental Therapeutics, Univ of North Carolina Eshelman School of Pharmacy

Symposium 17  |  10:00 – 11:30 AM  |  TCP
Innovative Approaches in the Use of Exposure-Response in Therapeutic Proteins to Support Pediatric Extrapolation  
CO-CHAIRS: Robert M. Nelson, MD, PhD, Senior Director, Pediatric Drug Development, Johnson & Johnson and Jocelyn H. Leu, PharmD, PhD, Scientific Director, Janssen Research & Development LLC

Symposium 18  |  10:00 – 11:30 AM  |  BT
Partial Area Under the Curve Analysis in Generic & New Drug Development  
CO-CHAIRS: Liang Zhao, PhD, Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration and Keith Gallicano, PhD, Chief Scientific Officer, Novum Pharmaceutical Research Svcs

Symposium 19  |  1:30 – 3:00 PM  |  DDT
Bacteriophage as a New Weapon to Fight Drug-resistant Bacteria  
CO-CHAIRS: Stephan Schmidt, PhD, Certara Professor, Associate Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Pharmacetics Lake Nona, Univ of Florida and Christopher Duplessis, MD, Associate Professor, Naval Medical Research Ctr

Symposium 20  |  1:30 – 5:30 PM  |  BT
Transporter-mediated Drug-Drug Interactions, Current Status & Future Perspectives: An ACCP/ISSX Jointly-sponsored Symposium  
CHAIR: Yanke Yu, PhD, Director, Clinical Pharmacology, Pfizer Inc

Symposium 21  |  3:30 – 5:00 PM  |  DDT
Beyond Pharmacokinetic Equivalence: Assessment of Pharmacodynamic Similarity in Biologic & Small Molecule Drug Development  
CO-CHAIRS: Peijuan Penny Zhu, PhD, Associate Director, Pharmacometrics, Janssen Research & Development LLC and Ping Ji, PhD, Biologics Lead, US Food & Drug Administration
Steven D. Gore, MD – Professor, Medicine (Hematology) & Director, Hematologic Malignancies, Yale Cancer Ctr

20 Years of ‘Epigenetic’ Cancer Therapy – Who Are We Fooling?

Monday, September 21, 2020  |  Lunch & Awards Session

Dr. Steven Gore joined the Yale Cancer Ctr as Professor of Medicine (Hematology) & Director of Hematologic Malignancies in 2013 following 23 years on the faculty of the Sidney Kimmel Comprehensive Cancer Ctr at Johns Hopkins in the Div of Hematologic Malignancies. He has been recognized as a leader in clinical and translational research in myeloid malignancies, especially myelodysplastic syndrome and clinical applications of epigenetics in cancer therapeutics. Dr. Gore is co-chair of the Leukemia Steering Committee for the National Clinical Trials Network and a member of the Leukemia Core Committee and Leukemia Laboratory Committee of the Eastern Cooperative Oncology Group. He has developed several National Cancer Inst and pharma-sponsored early-phase trials with translational endpoints, as well as multicenter and cooperative group protocols in myelodysplastic syndrome, including the first randomized trial comparing the impact of the addition of a histone deacetylase inhibitor to a DNA methyltransferase inhibitor in myelodysplastic syndrome. Dr. Gore has chaired eight biannual international workshops on the Clinical Translation of Epigenetic Therapy in Cancer Therapeutics. He also serves on the External Advisory Board of the Univ of Chicago Comprehensive Cancer Ctr and has served on advisory boards and response adjudicating committees for a variety of pharma companies.

See Dr. Gore's CV
ACCP Distinguished Investigator Award
Michael D. Reed, PharmD – Professor Emeritus, Pediatrics, Case Western Reserve Univ
School of Medicine
The ACCP Distinguished Investigator Award is given annually and is intended to recognize superior scientific expertise and accomplishments by a senior investigator, usually involving a distinct area of research in basic or clinical pharmacology for which the individual is internationally known.
See Dr. Reed’s bio

ACCP Honorary Fellowship Award
Michael Cohen-Wolkowiez, MD, PhD – Professor, Pediatrics, Duke Univ
The ACCP Honorary Fellowship Award is given annually to a Non-member of ACCP and is meant to recognize primary activities within the immediate domain of clinical pharmacology. The award recognizes overall contributions to the field, rather than for 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.
See Dr. Cohen-Wolkowiez’s bio

Nathaniel T. Kwit Memorial Distinguished Service Award
Vera S. Donnenberg, PhD – Associate Professor, Cardiothoracic Surgery, School of Medicine and Pharmaceutical Sciences, School of Pharmacy, Univ of Pittsburgh
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 five 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, long-term and wide-ranging scientific studies having practical importance, and other service-related functions. It is differentiated from the ACCP Distinguished Investigator Award in that it is not intended to recognize any distinct area of scientific investigation, but rather an overall contribution to the field.
See Dr. Donnenberg’s bio
McKeen Cattell Memorial Award
Michael Ganetsky, MD – Assistant Professor, Emergency Medicine, Harvard Medical School and Director, Medical Toxicology, Emergency Medicine, Beth Israel Deaconess Medical Ctr
The McKeen Cattell Memorial Award is given 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 given 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.

See Dr. Ganetsky's bio

Tanabe Young Investigator Award
Ayyappa Chaturvedula, PhD – Associate Professor, Univ of North Texas System Coll of Pharmacy
The Tanabe Young Investigator Award is given on a biannual basis (on even numbered years), and is funded by a grant from Tanabe Research Labs USA. The 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.

See Dr. Chaturvedula's bio

Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award
Deanna Kroetz, PhD, BSc – Director, Pharmaceutical Sciences & Pharmacogenomics Graduate Program, Univ of California San Francisco
The Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award is given annually to an awardee who demonstrates exemplary promotion of clinical pharmacology, with emphasis on training/guidance of junior scientists and/or colleagues.

See Dr. Kroetz's bio

Roger Jelliffe Individualized Therapy Award
Michael N. Neely, MD – Chief, Infectious Diseases, Director, Laboratory of Applied Pharmacokinetics & Bioinformatics, Children’s Hosp Los Angeles, Professor of Pediatrics & Clinical Scholar, Keck School of Medicine, Univ of Southern California
The Roger Jelliffe Individualized Therapy Award is given annually to a Member or Non-member of ACCP and is intended to recognize an individual who significantly advances the field of personalized medicine by improving the use of drugs or biologics in patients.

See Dr. Neely's bio
Target Audience
The 2020 ACCP Annual Meeting will be of educational benefit to clinical pharmacologists, pharmacists, physicians, clinical researchers, nurse practitioners and physician assistants from academia, regulatory, industry and healthcare involved in the discovery, development and/or application of drug therapies in patient care.

Learning Objectives
As a result of attending this meeting, the learner will be able to:
1. Identify new innovations in drug discovery, clinical development & regulatory science that are relevant to streamlining clinical development;
2. Define model-informed drug development and describe the utility of quantitative approaches in drug discovery & development;
3. Describe emerging trends in the study of clinical pharmacology in special populations, including generalizability & limitations of applying general population data to these clinical groups;
4. Explore ways in which cutting-edge clinical pharmacology science contributes to patient care decisions at the bedside.

Joint Accreditation Statement
In support of improving patient care, the American College of Clinical Pharmacology® is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE) and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Interprofessional Continuing Education Credit (IPCE)
This activity was planned by and for the healthcare team and learners will receive a maximum of 26 Interprofessional Continuing Education (IPCE) credits for learning and change.

CME Credit Designation Statement
The American College of Clinical Pharmacology designates this Live educational activity for a maximum of 26 AMA PRA Category 1 Credits™. Physicians should claim only the credits commensurate with the extent of their participation in the activity.

CPE Credit Designation Statement
The ACPE Universal Activity Numbers (UAN), amount of Contact Hours available and CPE target audience designations, are noted within each course of the program for a maximum of 57.5 Contact Hours. Pharmacists should claim only the Contact Hours commensurate with the extent of their participation in the activity.

Reporting CPE Credits:
Attendees seeking CPE credits must also provide ACCP with their National Association of Boards of Pharmacy (NABP) Profile Number and the month and day of their birth via email to CE@ACCP1.org. The NABP Profile Number and birthday information is required for ACCP to transmit CPE credit information via the CPE Monitor. ACCP cannot report CPE credits for individuals who fail to provide their NABP Profile Number and correct MMDD of birth upon request.

Earning Credits:
Attendees wishing to obtain credits must attend one or more CME/CPE courses and complete each requested course’s Post-event Self-assessment, Evaluation, claim the credits and PRINT the Certificate(s) no later than November 19, 2020. Beyond that point, requests will incur an administrative late fee of $200. All credit requests must be submitted by no later than December 31, 2020.

Other Information
The 2020 ACCP Annual Meeting Program at a Glance can be found on pages 5 – 6.
Student, Trainee & Early-stage Professional membership and participation in ACCP's Annual Meeting are strongly encouraged and are beneficial on several levels:

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

Student, Trainee & Early-stage Professional-specific Events

On Saturday, September 19th, join us for an exceptional hands-on tutorial in Pre-meeting Workshop 3: A Beginner Level Workshop on the Principles of Population Pharmacokinetics & Fundamentals of NONMEM® Software for Students, Trainees & Early-stage Professionals (please note that there is a separate fee for this event).

On Sunday, September 20th, the following event will be hosted:

- **STEP Welcome Breakfast** – ACCP will welcome Students, Trainees & Early-stage Professionals and provide them with an opportunity to meet ACCP Leadership in a casual setting to discuss career guidance, educational options, opportunities for further involvement in ACCP, how to subsequently grow in the organization throughout their careers and any number of other topics of interest.

On Monday, September 21st, the following events will be hosted:

- **Panel Discussion on Career Guidance** – Effective communication is essential at all stages of your career. As you prepare for future positions, it is critical to understand generational differences in communication styles. This panel discussion will address topics such as how junior and senior colleagues tackle problem solving differently due to technological advances and how clinical pharmacology colleagues at different career levels teach each other to ensure success.

- **STEP Networking Reception** – Join us for the STEP Networking Reception where you can interact on a more personal level with Panel Discussion speakers and other ACCP Mentors to chat in a casual setting about questions that will help you make decisions about your future.

- **Podium Presentations** – A select number of Student & Trainee Abstract Award winners will present their research in a Podium Presentation to an audience of Annual Meeting Attendees. Support your colleagues by being a part of this important event.

CV Reviews!

All Students, Trainees & Early-stage Professionals are encouraged to provide their CV for review and suggestions by ACCP Mentors. You may submit your CV for review to KLevy@ACCP1.org by August 1, 2020.

ACCP encourages all colleagues, from Students & Trainees to established professionals, to [Submit an Abstract](#). Don’t miss this opportunity to showcase your research to a global, interprofessional clinical pharmacology audience!

**Abstract Submission Timeline**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tr>
<td>January 15, 2020</td>
<td>Abstract Submission Site Opened</td>
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<tr>
<td>April 15, 2020</td>
<td>Abstract Submission Site Closes</td>
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<td>Mid-May 2020</td>
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<td>June 15, 2020</td>
<td>Deadline to submit Registration Form &amp;</td>
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<td>Poster Presentation Acceptance Form or to</td>
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<td>withdraw abstract(s)</td>
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**Submit an Abstract**

**Areas of Abstract Submission**

**Instructions for Abstracts**

**Student & Trainee Abstract Awards Program**

**Guidelines for Poster Presentations**

**2020 Poster Session Schedule**

**POSTER SESSION 1**

Sunday, September 20, 2020

5:00 – 7:00 PM

**POSTER SESSION 2**

Monday, September 21, 2020

5:00 – 7:00 PM

To be considered for the Student & Trainee Abstract, New Member Abstract, ACCP/ISoP SIG Student Abstract or Elliot S. Vesell Student 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, 2019 and July 31, 2020.

**FOR QUESTIONS, PLEASE CONTACT:**

TBossert@ACCP1.org or 571-291-3493 ext 3.
Analysis & Reporting of QTc Prolongation Potential of New Drugs Using R Tools, Expectations & General Guidance for Regulatory Submissions

DRUG DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-008-L05-P
ACPE – 3 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Ana Ruiz-Garcia, PharmD, PhD, Senior Principal Scientist I, Metrum Research Group LLC
Dhananjay D. Marathe, PhD, Principal Scientist, Quantitative Pharmacology & Pharmacometrics, Merck & Co Inc

TARGET AUDIENCE:
This Workshop will be useful for clinical pharmacologists and drug developers.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Become familiar with the ECG-pharmacokinetic analysis using R;
2. Create a report using R Markdown;
3. Gain understanding about the sample size and exposure margin requirements for TQT substitution request based on studies without a positive control;
4. Have a deeper understanding of some of the common challenges and potential solutions for design/analysis issues.

8:00 – 9:30 AM
ECG-Pharmacokinetic Analysis Using R: Theory & Hands On
Steve Riley, PharmD, PhD, Senior Director, Clinical Pharmacology, Pfizer Inc

9:30 – 9:40 AM / Break

9:40 – 10:40 AM
Goodness-of-Fit Diagnostics Using R & R Markdown Reporting Tool
Ana Ruiz-Garcia, PharmD, PhD, Senior Principal Scientist I, Metrum Research Group LLC

10:40 – 11:15 AM
Experience Regarding Expectations & General Guidance for Regulatory Submissions Under ICH E14 Q&A (R3) for TQT Study Substitution Requests Based on Concentration-QTc Analysis
Dhananjay D. Marathe, PhD, Principal Scientist, Quantitative Pharmacology & Pharmacometrics, Merck & Co Inc

11:15 – 11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Individualized Drug Therapy: Maximally-precise Drug Therapy for Each Individual Patient, at the Bedside, in a Community Hospital Setting

DRUG DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-009-L05-P
ACPE – 3 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:
Michael N. Neely, MD, Chief, Infectious Diseases, Director, Laboratory of Applied Pharmacokinetics & Bioinformatics, Children’s Hosp Los Angeles, Professor of Pediatrics & Clinical Scholar, Keck School of Medicine, Univ of Southern California

TARGET AUDIENCE:
This Workshop will be useful for professionals interested in individualizing drug therapy for patients in a community hospital setting.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Have a working idea of the foundations of parametric and nonparametric population pharmacokinetic/dynamic modeling;
2. Know the principles of setting a specific point target goal for each patient according to the need for the drug and a risk of toxicity which is appropriate to accept in order to get the hoped-for benefit from the drug;
3. Understand the foundations of multiple-model, maximally-precise dosing;
4. Understand the process of monitoring the patient and making an individual drug model for each patient;
5. Understand the estimation of creatinine clearance when serum creatinine is changing;
6. Understand the management of drug dosage in dialysis patients;
7. Understand the interacting multiple-model approach to tracking drug behavior in highly-unstable patients;
8. Be acquainted with the management of patients with ventilator-assisted pneumonia, HIV, aminoglycoside and digoxin therapy.

8:00 – 8:45 AM
Why Consider Nonparametric Pharmacokinetic/Pharmacodynamic Modeling?
Michael N. Neely, MD, Chief, Infectious Diseases, Director, Laboratory of Applied Pharmacokinetics & Bioinformatics, Children’s Hosp Los Angeles, Professor of Pediatrics & Clinical Scholar, Keck School of Medicine, Univ of Southern California

8:45 – 9:30 AM
Applied Pharmacokinetic/Pharmacodynamic Modeling of Single-drug & Combination Therapy for Infectious Diseases
George Drusano, MD, Professor of Medicine, Director, Inst for Therapeutic Innovation, Coll of Medicine, Univ of Florida

9:30 – 10:00 AM / Break

10:00 – 11:15 AM
Model-guided Precision Dosing to Control Individual Therapy
Michael N. Neely, MD, Chief, Infectious Diseases, Director, Laboratory of Applied Pharmacokinetics & Bioinformatics, Children’s Hosp Los Angeles, Professor of Pediatrics & Clinical Scholar, Keck School of Medicine, Univ of Southern California

11:15 –11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
A Beginner Level Workshop on the Principles of Population Pharmacokinetics & Fundamentals of NONMEM® Software for Students, Trainees & Early-stage Professionals

APPLIED CLINICAL PHARMACOLOGY TECHNIQUES TRACK

Offers both CME & CPE Credit
UAN #JA4008220-0000-20-010-L04-P
ACPE – 6.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Oliver Grundmann, PhD, Clinical Associate Professor & Director, Medicinal Chemistry, Coll of Pharmacy, Univ of Florida
Robert Bies, PharmD, PhD, Associate Professor, Pharmaceutical Sciences, Univ at Buffalo, School of Pharmacy & Pharmaceutical Sciences

TARGET AUDIENCE:
This Workshop will be useful for graduate students, postdoctoral fellows/trainees and early-stage professionals in the field of pharmacy, pharmacometrics, clinical pharmacology and clinical pharmacy practice with limited working knowledge in population pharmacokinetics and NONMEM® software. This Workshop is applicable to participants across academia, the pharmaceutical industry and regulatory agencies. Prerequisite for this Workshop: Participants should have a basic understanding of pharmacokinetic principles such as absorption, distribution, metabolism and excretion. Some familiarity with open-source R-software for statistical analysis, data plotting and pharmacokinetic/pharmacodynamic quantitative packages such as mrugsolve and nlmixr is encouraged.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Define pharmacometrics-based approaches and population pharmacokinetics and explore the applications to drug development paradigms;
2. Compare various techniques for exploratory data analysis and gain theoretical and practical knowledge with clinically-relevant examples;
3. Analyze clinical population pharmacokinetic and pharmacodynamic datasets and apply foundational knowledge to describe variability in real-world data;
4. Apply regulatory perspective to population pharmacokinetics and demonstrate the importance of population pharmacokinetics for regulatory submission and interpretation.

9:00 – 9:10 AM
Introduction to Workshop, Speakers & Pharmacometrics
Oliver Grundmann, PhD, Clinical Associate Professor & Director, Medicinal Chemistry, Coll of Pharmacy, Univ of Florida

9:10 – 9:30 AM
Importance of Pharmacometrics in Drug Development & Historical Perspective
Sumit Basu, PhD, Senior Scientist, Quantitative Pharmacology & Pharmacometrics, Merck & Co Inc

9:30 – 9:45 AM / Break

9:45 – 10:45 AM
Introduction to Population Pharmacokinetic Analyses
Robert Bies, PharmD, PhD, Associate Professor, Pharmaceutical Sciences, Univ at Buffalo, School of Pharmacy & Pharmaceutical Sciences

10:45 AM – 12:00 PM
Exploratory Data Analysis Theory + Hands-on Exercise
Pooja Manchandani, PhD, Senior Clinical Pharmacokineticist, Clinical Pharmacology & Pharmacometrics, AbbVie Inc and Aksana Jones, MS, Associate Director, Pharmacometrics, Cognigen Corp, a Simulations Plus Co

12:00 – 1:00 PM / Lunch Break

1:00 – 1:45 PM
NONMEM® Architecture
Aksana Jones, MS, Associate Director, Pharmacometrics, Cognigen Corp, a Simulations Plus Co

1:45 – 3:15 PM
Hands-on Exercise in NONMEM®
Sumit Basu, PhD, Senior Scientist, Quantitative Pharmacology & Pharmacometrics, Merck & Co Inc and Robert Bies, PharmD, PhD, Associate Professor, Pharmaceutical Sciences, Univ at Buffalo, School of Pharmacy & Pharmaceutical Sciences

3:15 – 3:30 PM / Break

3:30 – 4:30 PM
Regulatory Perspectives on Population Pharmacokinetic Analyses
Dhananjay D. Marathe, PhD, Principal Scientist, Quantitative Pharmacology & Pharmacometrics, Merck & Co Inc

4:30 – 5:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Drug Development for Pregnant Women & Their Infants: Lessons Learned from HIV

THERAPEUTIC AREAS OF APPLIED CLINICAL PHARMACOLOGY TRACK

Offers both CME & CPE Credit
UAN #JA4008220-0000-20-011-L01-P
ACPE – 3.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:
Jeremiah D. Momper, PharmD, PhD, Associate Professor, Univ of California San Diego

TARGET AUDIENCE:
This Workshop will be useful for clinical pharmacologists in academic, industry and regulatory settings (MD, PharmD, PhD) and clinicians involved in the treatment of pregnant women (MD or PharmD).

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Describe changes in drug disposition during pregnancy and postpartum that impact dosing requirements;
2. Identify issues with the use of pharmacoenhancers during pregnancy;
3. Explain how physiologically-based pharmacokinetic modeling can be used to scale the pharmacokinetics of a drug from well-investigated populations to pregnant women and their fetuses;
4. Describe the regulatory environment for the conduct of clinical trials in pregnant women living with HIV.

1:30 – 2:15 PM
Improving Outcomes Through Prospective Studies in Pregnant & Breastfeeding Women Living With HIV
Jeremiah D. Momper, PharmD, PhD, Associate Professor, Univ of California San Diego

2:15 – 3:00 PM
Pharmacoenhancers During Pregnancy & Postpartum: Progress to Date & Future Directions
Mark Mirochnick, MD, Professor of Pediatrics & Chief, Neonatology, Boston Univ of Medicine

3:00 – 3:30 PM / Break

3:30 – 4:15 PM
Physiologically-based Pharmacokinetic Modeling of Hepatic Metabolism & Renal Elimination During Pregnancy: Current State of the Art
André Dallmann, PhD, Scientist, Systems Pharmacology, Bayer Healthcare Pharmaceuticals

4:15 – 5:00 PM
Regulatory Perspective on Evaluating Antiretroviral Drugs During Pregnancy
Kimberly A. Struble, PharmD, Senior Clinical Analyst Team Leader, US Food & Drug Administration

5:00 – 5:30 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Innovative Drug Development in Asia: Challenges & Opportunities

DRUG DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-012-L04-P
ACPE – 3.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Haiyan Li, MD, Peking Univ Third Hosp, China
Gailing Li, PhD, Janssen Research & Development LLC

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

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Be aware of drug development in Asia and potential opportunities for future collaborations;
2. Be aware of the growing role and responsibility of clinical pharmacology and pharmacometrics in transforming the pharmaceutical industry in Asia;
3. Apply clinical pharmacology & pharmacometrics knowledge and skills to facilitate the implementation of ICH E5 & E17;
4. Explore the opportunities for collaboration in education and training to facilitate the development of Asian capabilities and capacity in clinical pharmacology for a truly global effort in bringing innovative medicine to patients in need worldwide.

1:30 – 1:35 PM
Introduction
Haiyan Li, MD, Peking Univ Third Hosp, China and Gailing Li, PhD, Janssen Research & Development LLC

1:35 – 2:00 PM
Innovative Drug Development in China: Challenges & Opportunities
Haiyan Li, MD, Peking Univ Third Hosp, China

2:00 – 2:30 PM
Expanding Role of Clinical Pharmacology in India
Nilima A. Kshirsagar, MBBS, MD, National Chair, Clinical Pharmacology, ICMR Gov't of India

2:30 – 3:00 PM
Capability Building Through Collaboration
Junko Sato, PhD, Director, Int’l Cooperation, Pharmaceuticals & Medical Devices Agency

3:00 – 3:30 PM / Break

3:30 – 4:00 PM
Journey of Zanubrutinib Development in BeiGene
Yan Ren, PhD, Director, Clinical Pharmacology, BeiGene Ltd

4:00 – 4:30 PM
Convergence Approaches in Drug Development in Korea
Howard Lee, MD, PhD, Clinical Pharmacology & Therapeutics, Seoul National Univ Hosp & Coll of Medicine

4:30 – 5:30 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Strategies & Considerations for the Assessment of Relative Dose Intensity in Oncology Drug Development

DRUG DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-013-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:
Divya Samineni, PhD, Scientist, Genentech Inc

TARGET AUDIENCE:
This Symposium will be useful for clinical pharmacologists, biostatisticians, oncologists and drug safety scientists.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Describe the relevance of relative dose intensity (RDI) and the clinical/regulatory implications for an inadequate evaluation of RDI on treatment outcomes and regulatory approvals;
2. List the strategic/practical constraints, heterogeneity and inherent biases associated with the current clinical assessment techniques for estimation of RDI during the course of treatment;
3. Adopt novel methodologies and strategic recommendations to evaluate patient-specific RDI values and the impact of individual delays and/or dose reductions reported throughout treatment on treatment outcomes and dosing recommendations;
4. Verbalize the regulatory perspectives on the assessment of drug tolerability and the impact on aligning with regulatory needs to guide review decisions.

8:00 – 8:15 AM
Relative Dose Intensity: The Neglected Variable in Clinical Trials
Divya Samineni, PhD, Scientist, Genentech Inc

8:15 – 8:35 AM
Practical Considerations for the Assessment of Relative Dose Intensity and the Impact on Treatment Outcomes in Oncology Clinical Trials: A Literature Review
Whitney Kirschbrown, PharmD, PhD, Scientist, Genentech Inc

8:35 – 8:55 AM
A Novel Methodology to Address the Association Between Relative Dose Intensity & Survival Outcomes
Carlo Lancia, PhD, Data Scientist, ASML Holding NV

8:55 – 9:15 AM
Regulatory Considerations to Determine Drug Tolerability & Lessons Learned from Past Examples
Yaning Wang, PhD, Director, US Food & Drug Administration

9:15 – 9:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
What is the Right Dose in Cancer Patients With Hepatic Dysfunction? Considerations in the Translation of Pharmacokinetic Studies from Clinical Trial to Clinic

THERAPEUTIC AREAS OF APPLIED CLINICAL PHARMACOLOGY TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-014-L04-P
ACPE – 3 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Nithya Srinivas, PhD, Research Investigator, Incyte Corp
Islam R. Younis, PhD, Director, Astellas Pharma US Inc

TARGET AUDIENCE:
This Symposium will be useful for clinical oncology providers treating patients with hepatic impairment in the setting of clinical trials and in general practice, and for clinical pharmacologists in academia, industry or regulatory fields.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Describe the different approaches for grading hepatic impairment and the sensitivities of these approaches for detecting changes in drug exposure;
2. Discuss the interplay between Child-Pugh criteria and National Cancer Inst criteria in informing dosing recommendations in cancer patients;
3. Evaluate the current paradigm and recent trends for deriving dosing recommendations in cancer patients with hepatic impairment;
4. Describe how dosing recommendation for drugs indicated to treat cancer patients with hepatic impairment are utilized in the clinic.

8:00 – 8:20 AM
Introduction: What is the Right Dose in Cancer Patients With Hepatic Dysfunction?
Nithya Srinivas, PhD, Research Investigator, Incyte Corp

8:20 – 8:50 AM
Methods to Assess Hepatic Impairment & Implications for Pharmacokinetics in Oncology
Islam R. Younis, PhD, Director, Astellas Pharma US Inc

8:50 – 9:30 AM
An Industry Perspective on Recent Trends in Supporting Dosing Recommendations for Oncology Drugs for Patients With Hepatic Impairment
Mohamed Elmeliegy, PhD, Associate Director, Pfizer Inc

9:30 – 10:00 AM / Break

10:00 – 10:20 AM
Regulatory Expectations on Data Collection & Analysis Approaches to Inform Dosing Recommendations for Oncology Drugs in Cancer Patients With Hepatic Impairment
Hisham Qosa, PhD, Research Fellow, US Food & Drug Administration

10:20 – 10:55 AM
Proceed With Caution: An Oncologist’s Perspective on Dosing of Oncology Drugs in Patients With Hepatic Dysfunction
Peter H. Wiernik, MD, President, Cancer Research Fdtn

10:55 – 11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
The Race to Develop New Targeted Therapies for Children With Brain Tumors: Where Do We Go?

THERAPEUTIC AREAS OF APPLIED CLINICAL PHARMACOLOGY TRACK

Offers both CME & CPE Credit
UAN #JA4008220-0000-20-015-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Gilbert J. Burckart, PharmD, Associate Director, Pediatrics, US Food & Drug Administration
Clinton F. Stewart, PharmD, Member & Interim Director, Pharmaceutical Sciences, St Jude Children’s Research Hosp

TARGET AUDIENCE:
This Symposium will be useful for clinicians, regulatory scientists, industry scientists and academic researchers.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Understand the impact of pediatric legislative initiatives on the development of drugs for rare and/or molecularly-diverse tumor types;
2. Understand clinical trial considerations for evaluating targeted therapies for rare and/or molecularly-diverse tumor types;
3. Understand types of pediatric brain tumors and the relevant molecular targets;
4. Describe drug properties and determinants of drug penetration across the blood brain barrier.

10:00 – 10:15 AM
Impact of Pediatric Legislative Initiatives: Where We Are & Where We Are Going
Gilbert J. Burckart, PharmD, Associate Director, Pediatrics, US Food & Drug Administration

10:15 – 10:35 AM
Pediatric Brain Tumors & Relevant Molecular Markers
Clinton F. Stewart, PharmD, Member & Interim Director, Pharmaceutical Sciences, St Jude Children’s Research Hosp

10:35 – 10:55 AM
Evaluating Targeted Therapies in Rare and/or Diverse Tumor Types: Current Status & Promise of Pediatric Master Protocols
Elimika Pfuma Fletcher, PharmD, PhD, Policy Lead/Senior Clinical Pharmacologist, US Food & Drug Administration

10:55 – 11:15 AM
Developing a Drug for Brain Tumors: Considerations for Crossing the Blood Brain Barrier
Timothy Heffron, PhD, Associate Director, Genentech Inc

11:15 – 11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Pediatric Renal Function: Why We Still Need to Explore Renal Maturation & Its Impact on Drug Therapies

THERAPEUTIC AREAS OF APPLIED CLINICAL PHARMACOLOGY TRACK

Offers both CME & CPE Credit
UAN #JA4008220-0000-2016-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Jian Wang, PhD, Associate Director, Drug Evaluation IV, CDER, US Food & Drug Administration
Catherine MT Sherwin, PhD, Professor & Vice Chair for Research, Director, Pediatric Clinical Pharmacology, Pediatrics, Wright State Univ Boonshoft School of Medicine, Dayton Children’s Hosp

TARGET AUDIENCE:
This Symposium will be helpful for clinical pharmacologists from pharmaceutical/biotechnology companies and regulatory agencies, pharmacometrists, clinical researchers and drug development scientists. The target audience would include clinical and research faculty from schools and colleges of medicine, pharmacy and nursing, plus pharmacologists, pharmacists, clinicians or graduate/postgraduate trainees wishing to better understand the development of precision medicine in pediatric patients.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Explore the utilization of equations used to define pediatric renal function and how this relates to individualized drug exposure;
2. Demonstrate several examples related to optimization of those models that incorporate renal function and utility of individual predictions using population pharmacokinetic models;
3. Provide an understanding of the complexity of dealing with varying renal function that is impacted by disease processes, such as Cystic Fibrosis;
4. Explore the impact of specific physiological factors such as age (e.g. neonatal) and weight (e.g. obesity) when estimating varying renal function and the impact on pharmacokinetic parameters such as clearance.

1:30 – 1:45 PM
Introduction: Why We Still Need to Explore Renal Maturation & Its Impact on Drug Therapies
Jian Wang, PhD, Associate Director, Drug Evaluation IV, CDER, US Food & Drug Administration

1:45 – 2:00 PM
Commonly-used Equations to Define Renal Function & Estimate Pharmacokinetic Parameters
Yifei Zhang, PhD, ORISE Fellow, US Food & Drug Administration

2:00 – 2:15 PM
The Influence of Cystic Fibrosis on the Maturation of Renal Function
Hesham Al-Sallami, PharmD, PhD, Senior Lecturer, Univ of Otago

2:15 – 2:30 PM
What Do We Know About Renal Maturation in Patients With Childhood Obesity?
Catherijne AJ Knibbe, PharmD, PhD, Professor, Individualized Drug Treatment, St Antonius Hosp/Leiden Univ

2:30 – 2:45 PM
Are We Close to Consensus on Renal Maturation, Neonates & Determining Pharmacokinetics?
Catherine MT Sherwin, PhD, Professor & Vice Chair for Research, Director, Pediatric Clinical Pharmacology, Pediatrics, Wright State Univ Boonshoft School of Medicine, Dayton Children’s Hosp

2:45 – 3:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Clinical Pharmacology in Anti-infective Drug Development

DRUG DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-017-L04-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:
Amit Somani, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration

TARGET AUDIENCE:
This Symposium will be useful for clinical pharmacologists from academia and the pharmaceutical industry, industry leaders/decision makers, graduate students, postdoctoral fellows, pharmacists, pharmacometricians, pharmacokinetic/pharmacodynamic scientists and drug development scientists.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Apply the knowledge of clinical pharmacology’s role in anti-infective development programs to enhance ongoing and future drug development programs in this therapeutic area;
2. Compare and assess the value of various preclinical or clinical pharmacology approaches used among the discussed anti-infective drug development programs;
3. Help stakeholders make informed decisions during drug development and facilitate judicious use of available resources (e.g., cross-disciplinary scientific talent, knowledge repository, available guidances unique to the anti-infective area, money or other);
4. Create excellent value for all stakeholders and provide patients with access to the newer anti-infective treatments in a more affordable and timely manner.

1:30 – 1:42 PM
Clinical Pharmacology Considerations in Drug Development of Pretomanid
Amit Somani, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration

1:42 – 1:54 PM
Clinical Pharmacology Considerations in Drug Development of Omadacycline
Sonia Pahwa, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration

1:54 – 2:07 PM
Future Opportunities for Application of Quantitative Systems Pharmacology or Other Quantitative Pharmacology Approaches to Enhance the Efficiency of Anti-infective Drug Development Programs
Scott Van Wart, PhD, Vice President & Chief Scientific Officer, Enhanced Pharmacodynamics LLC

2:07 – 2:24 PM
Clinical Pharmacology Considerations for Anti-infective Products Developed Under the Animal Rule
Kunyi Wu, PharmD, Clinical Pharmacology Reviewer, US Food & Drug Administration

2:24 – 2:36 PM
The Current State & Future Prospects for Anti-infective Drugs in Pediatrics
TBD

2:36 – 3:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Innovative Technologies in Patient-centric Drug Development: Promises & Challenges

INNOVATIONS TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-018-L05-P
ACPE – 2 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Anuradha Ramamoorthy, PhD, Policy Lead, Clinical Pharmacology, CDER, US Food & Drug Administration
Leslie Dickmann, PhD, MPH, Program Director, School of Pharmacy, Univ of Wisconsin Madison

TARGET AUDIENCE:
This Symposium will be useful for regulators, industry, academia, clinicians and others who are interested in patient-centered drug development and healthcare delivery.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Learn how innovative digital technologies and outpatient sampling techniques are currently used;
2. Discuss opportunities for leveraging digital health technologies in clinical trials;
3. Discuss opportunities for leveraging outpatient sampling strategies in clinical trials;
4. Learn about challenges and potential mitigation strategies that can help realize patient-centric drug development and healthcare delivery.

3:30 – 3:45 PM
Emerging Innovative Technologies: Introduction to the Landscape
Anuradha Ramamoorthy, PhD, Policy Lead, Clinical Pharmacology, CDER, US Food & Drug Administration

3:45 – 4:05 PM
Lessons Learned from Leveraging Digital Health Technologies & Outpatient Sampling in Clinical Drug Development
Marissa Dockendorf, PhD, Principal Scientist, Merck & Co Inc

4:05 – 4:25 PM
Wearable Devices in Clinical Trials: Hype & Hypothesis
John Wagner, MD, PhD, Partner, Foresite Capital

4:25 – 4:45 PM
Regulatory Perspective on Digital Health Technologies
Elizabeth Kunkoski, PhD, Health Scientist Policy Analyst, Medical Policy, CDER, US Food & Drug Administration

4:45 – 5:05 PM
Real & Perceived Challenges & Solutions in Leveraging Innovative Technologies
Leslie Dickmann, PhD, MPH, Program Director, School of Pharmacy, Univ of Wisconsin Madison

5:05 – 5:30 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation

DRUG DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-019-L05-P
ACPE – 2 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Olanrewaju Okusanya, PharmD, MS, Team Leader, US Food & Drug Administration
Vadryn Pierre, PharmD, Senior Clinical Pharmacokineticist, AstraZeneca plc

TARGET AUDIENCE:
This Symposium will be useful for drug discovery and development scientists, clinical pharmacologists, preclinical pharmacologists and toxicologists, clinician scientists, systems pharmacology scientists, mathematical biologists and regulatory scientists.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Explain the challenges in evaluating novel therapies in patients that require therapies known to be either drug-drug interaction victims or perpetrators;
2. Review the challenges in selecting initial doses for First-in-Human evaluation in patients that are on therapies known to be perpetrators of drug-drug interactions;
3. Discuss approaches that allow for the initiation of doses in the presence of interacting concomitant medications;
4. Evaluate the use of quantitative clinical pharmacology and in vivo/in vitro data to support initial dose selection without compromising safety.

3:30 – 4:00 PM
Challenges in Conducting First-in-Human Studies in Patients on Drugs Known to Be a Victim or Perpetrator of Drug-Drug Interactions
Kelly Norsworthy, MD, Medical Officer, US Food & Drug Administration

4:00 – 4:30 PM
Applying Clinical Pharmacology Principles to Support Early Dose Selection of Doses in First-in-Human Studies in Patients on Concomitant Interacting Medications
Brian Furmanski, PhD, Senior Director, Clinical Pharmacology & Regulatory Affairs, Nuventra Pharma Sciences

4:30 – 5:00 PM
Model-based Approach for Selecting Doses for First-in-Human Studies in Patients on Drugs Known to Be a Victim or Perpetrator of Drug-Drug Interactions
Vadryn Pierre, PharmD, Senior Clinical Pharmacokineticist, AstraZeneca plc

5:00 – 5:25 PM
Novel Study Design Approaches to Assess the Impact of Potential Drug-Drug Interactions in First-in-Human Studies
Olanrewaju Okusanya, PharmD, MS, Team Leader, US Food & Drug Administration

5:25 – 5:30 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Learning Health Systems: Leveraging Synergies Between Pharmacometrics & Pharmacoepidemiology for Efficient Healthcare Delivery

APPLIED CLINICAL PHARMACOLOGY TECHNIQUES TRACK

Offers both CME & CPE Credit
UAN #JA4008220-0000-20-020-L04-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Ayyappa Chaturvedula, PhD, Associate Professor, Pharmacotherapy, Univ of North Texas Health Science Ctr
Navin S. Goyal, PhD, Director, Clinical Pharmacology Modeling & Simulation, GlaxoSmithKline plc

TARGET AUDIENCE:
This Symposium will be helpful for clinicians (MD, PharmD) working in patient care settings, as well as clinical pharmacologists and pharmacometricians working in drug development.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Discuss the Inst of Medicine’s proposal on learning health systems and their role in healthcare delivery;
2. Understand the changing regulatory environment for drug effectiveness demonstration;
3. Understand the role of pharmacoepidemiology to bridge between efficacy and effectiveness of the integrated analysis in drug development via case studies;
4. Evaluate the role of pharmacometrics in supporting real-world evidence and synergies with pharmacoepidemiology.

8:00 – 8:15 AM
Learning Health Systems: Introduction to an Emerging Paradigm
Ayyappa Chaturvedula, PhD, Associate Professor, Pharmacotherapy, Univ of North Texas Health Science Ctr

8:15 – 8:35 AM
Models of Healthcare Delivery: Future of Medicine
Alexander A. Vinks, PharmD, PhD, Professor & Division Director, Clinical Pharmacology, Cincinnati Children’s Hosp Medical Ctr

8:35 – 8:55 AM
How Should a Pharmacometric Model Look for a Practicing Clinician to Bring Better Outcomes?
Michael N. Neely, MD, Chief, Infectious Diseases, Director, Laboratory of Applied Pharmacokinetics & Bioinformatics, Children’s Hosp Los Angeles, Professor of Pediatrics & Clinical Scholar, Keck School of Medicine, Univ of Southern California

8:55 – 9:15 AM
Efficacy & Effectiveness in the Continuum of Drug Development
Annesha White, PharmD, MS, PhD, Associate Dean for Assessment & Associate Professor, Univ of North Texas System Coll of Pharmacy

9:15 – 9:25 AM
Path Forward to Expanding Learning Health Systems
Alexander A. Vinks, PharmD, PhD, Professor & Division Director, Clinical Pharmacology, Cincinnati Children’s Hosp Medical Ctr

9:25 – 9:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Building Bridges: Combination of Product Drug/Device Development With Biologics

**DRUG DEVELOPMENT TRACK**

*Offers both CME & CPE Credit*

UAN #JA4008220-0000-20-021-L04-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

**CO-CHAIRS:**

Jocelyn H. Leu, PharmD, PhD, Scientific Director, Janssen Research & Development LLC

Yow-Ming Wang, PhD, Associate Director, Biosimilars & Therapeutic Biologics, Clinical Pharmacology, CDER, US Food & Drug Administration

**TARGET AUDIENCE:**
This Symposium will be useful for primary care and specialty physicians, pharmacists, clinical pharmacologists, clinical research associates, basic scientists and other healthcare professionals with an interest in learning about the development of combination products for biologics.

**GOALS & OBJECTIVES:**
Following the completion of this activity, the learner will be able to:

1. Recognize the industry and agency perspectives on clinical pharmacology strategies for the development of combination products;
2. Discuss considerations in designing the bridging approach and assessing the bridging data for combination products;
3. Identify the opportunities for pharmacokinetic/pharmacodynamic analyses to demonstrate clinical relevance for the development of combination products;
4. Identify the opportunities for clinical pharmacologists and pharmacometricians in the development of combination products.

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8:00 – 8:20 AM

**Combination Product Bridging: Using the Right Tools**

Suzette Roan, JD, Senior Director, Regulatory Affairs, Devices & Combination Products, Sanofi

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8:20 – 8:40 AM

**Relevance of Bioequivalence Studies for Bridging from Prefilled Syringe to Autoinjector for Monoclonal Antibodies**

Kenneth Kulmatycki, BSc Pharm, PhD, Director, Novartis Inst for Biomedical Research

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8:40 – 9:00 AM

**Challenges & Opportunities in Building the Scientific Bridge: Case Studies**

Jocelyn H. Leu, PharmD, PhD, Scientific Director, Janssen Research & Development LLC

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9:00 – 9:20 AM

**Building the Bridge for Biologic Drug/Device Combination Products: Regulatory Perspectives**

Yow-Ming Wang, PhD, Associate Director, Biosimilars & Therapeutic Biologics, Clinical Pharmacology, CDER, US Food & Drug Administration

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9:20 – 9:30 AM

**Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation**
What’s Next in Model-informed Drug Development? Joined Pharmacometrics & Epidemiological (Real-world Data) Approaches

QUANTITATIVE TRACK
 Offers both CME & CPE Credit
 UAN #JA4008220-0000-20-022-L04-P
 ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:
Yan Xu, MD, PhD. Director, Clinical Pharmacology & Pharmacometrics, Janssen Research & Development LLC

TARGET AUDIENCE:
This Symposium will be helpful for scientists from the pharmaceutical industry and academia with responsibilities or involvement in model-based drug development/pharmacometrics, clinical pharmacology and pharmacoepidemiology, plus medical, PhD and pharmacy students who are interested in those same areas.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Understand the history and current state of modeling & simulation in drug development and clinical practice;
2. Understand challenges in modeling & simulation and how the knowledge gap can be addressed by an integrated pharmacometric and epidemiologic (real-world data [RWD]) approach;
3. Understand the benefits and risks of the integrated analysis in drug development via case studies (value and lessons learned);
4. Understand the regulatory perspective on how the proposed strategy may facilitate regulatory decision making by adding to ‘totality of evidence’.

10:00 – 10:05 AM
Yan Xu, MD, PhD, Director, Clinical Pharmacology & Pharmacometrics, Janssen Research & Development LLC

10:05 – 10:30 AM
Integrating Pharmacometrics & Epidemiological Approaches: Why, What and How?
Stephan Schmidt, PhD, Certara Professor, Associate Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Pharmaceutics Lake Nona, Univ of Florida

10:30 – 10:55 AM
Interdisciplinary Pharmacometrics Linking Oseltamivir Pharmacology, Influenza Epidemiology & Health Economics to Inform Antiviral Use in Pandemics: A Case Study
Patrick Smith, PharmD, Senior Vice President, Certara

10:55 – 11:20 AM
Time to Join Pharmacometrics & Epidemiological Analyses for Real-world Validation of Model-based Projection: A Regulatory Perspective
Yaning Wang, PhD, Director, Pharmacometrics, Clinical Pharmacology, US Food & Drug Administration

11:20 – 11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Assessing the Feasibility of Model-informed Precision Dosing: A Point-Counterpoint Debate, an ACCP/ISoP Jointly-sponsored Symposium

APPLIED CLINICAL PHARMACOLOGY TECHNIQUES TRACK

**Offers both CME & CPE Credit**

UAN #JA4008220-9999-20-023-L04-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

**CO-CHAIRS:**

Diane R. Mould, PhD, President, Projections Research Inc  
Nikolas Onufrak, PharmD, Associate Director, Pharmacometrics, Boehringer Ingelheim

**TARGET AUDIENCE:**

This Symposium will be useful for professionals who prescribe, develop, evaluate or optimize evidence-based drug therapy for patients, including physicians, pharmacists, nurses, academics, regulators and members of the pharmaceutical industry.

**GOALS & OBJECTIVES:**

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

1. Understand the industrial impact, regulatory requirements and clinical potential of model-informed precision dosing (MIPD);
2. Recognize the unique challenges facing widespread adoption of MIPD within each domain;
3. Stimulate discussion and formation of collaborative networks across domains for the strategic advancement of MIPD.

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**10:00 – 10:05 AM**

**Introduction: The Feasibility of Model-informed Precision Dosing**

Nikolas Onufrak, PharmD, Associate Director, Pharmacometrics, Boehringer Ingelheim

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**10:05 – 10:25 AM**

**An Industry Perspective**

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

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**10:25 – 10:45 AM**

**A Regulatory Perspective**

Yow-Ming Wang, PhD, Associate Director, Biosimilars & Therapeutic Biologics, Clinical Pharmacology, CDER, US Food & Drug Administration

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**10:45 – 11:05 AM**

**A Clinical Perspective**

Adam Frymoyer, MD, Clinical Associate Professor, Pediatrics, Stanford Univ School of Medicine

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**11:05 – 11:25 AM**

**Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation**

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**11:25 – 11:30 AM**

**Closing Remarks**

Diane R. Mould, PhD, President, Projections Research Inc and Nikolas Onufrak, PharmD, Associate Director, Pharmacometrics, Boehringer Ingelheim
The Opioid Overdose Epidemic: Trends, Harms & Treatment

THERAPEUTIC AREAS OF APPLIED CLINICAL PHARMACOLOGY TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-024-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:
Sam Harirforoosh, PharmD, PhD, Professor, Gatton Coll of Pharmacy, East Tennessee State Univ

TARGET AUDIENCE:
This Symposium will be useful for physicians, pharmacists, scientists, clinical pharmacologists and other healthcare providers who interact with patients with opioid use disorder or conduct research in the field of substance abuse prevention and treatment.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Describe recent trends in the prescription opioid epidemic, including interactions with and transitions to overdose of heroin and fentanyl;
2. Analyze pharmacologic effects of prescription opioids, heroin and fentanyl;
3. Identify novel therapeutic options for treating opioid use disorder;
4. Illustrate current federal response in the management of the opioid crisis.

1:30 – 1:50 PM
Prescription Opioids, Heroin & Fentanyl: A Rising Crisis
Arsham Alamian, PhD, MSc, MACE, Associate Professor, Director, Master of Public Health Program, Coll of Public Health, East Tennessee State Univ

1:50 – 2:10 PM
Clinical Pharmacology of Prescription Opioids, Heroin & Fentanyl & Their Adverse Effects
Sam Harirforoosh, PharmD, PhD, Professor, Gatton Coll of Pharmacy, East Tennessee State Univ

2:10 – 2:30 PM
Treatment Options for Opioid Use Disorder
Luana Colloca, MD, PhD, MS, Associate Professor, Director, CTSA TL1 Pre- and Postdoctoral Training Program, Univ of Maryland School of Nursing

2:30 – 2:50 PM
TBD: FDA speaker

2:50 – 3:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Symposia

MONDAY, SEPTEMBER 21, 2020  |  Symposium 13  |  1:30 – 5:00 PM

Patient-reported Outcomes in Drug Development & Clinical Practice

APPLIED CLINICAL PHARMACOLOGY TECHNIQUES TRACK

Offers both CME & CPE Credit
UAN #JA4008220-0000-20-025-L05-P
ACPE – 3 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:
Barbara Ameer, PharmD, MBA, Adjunct Associate Professor, Medicine, Rutgers Robert Wood Johnson Medical School

TARGET AUDIENCE:
This Symposium will be useful for individuals with professional degrees (MD, PharmD or PhD) who are involved in drug and device development. The Symposium will inform clinicians who follow evidence-based clinical practice guidelines when making therapeutic decisions on individual patients.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Understand the challenges of using patient-reported outcomes (PRO) data to assess treatment benefit and/or risk during a clinical trial;
2. Outline the process used by the US Food & Drug Administration in assessing the tools that collect PRO data during a clinical trial for adding a claim to a product label;
3. Explain a lesson learned from incorporation of PRO instruments in the care of patients with a rare disease;
4. Delineate the role of patients in defining values and preferences about treatment for inclusion in practice guidelines.

1:30 – 1:40 PM
Introduction to Patient-reported Outcomes (PROs): Capturing & Communicating the Patient Experience for Medical Product Development & Clinical Practice
Barbara Ameer, PharmD, MBA, Adjunct Associate Professor, Medicine, Rutgers Robert Wood Johnson Medical School

1:40 – 2:35 PM
Patient-reported Outcomes in Chronic Heart Failure: Clinical & Regulatory Challenges & Achievements
John A. Spertus, MD, MPH, Adjunct Professor, Medicine, Washington Univ School of Medicine St Louis

2:35 – 3:15 PM
Regulatory Perspective on PRO Measures in Product Development for Oncology Drug Labeling
Bellinda King-Kallimanis, PhD, Senior Staff Fellow, US Food & Drug Administration

3:15 – 3:30 PM / Break

3:30 – 4:15 PM
Patient-reported Outcomes in Pediatric Oncology
Allison Barz Leahy, MD, Attending Physician, Oncology, Cellular Therapy & Transplant Section, Children’s Hosp of Philadelphia

4:15 – 4:45 PM
Patient-important Input: What’s the Impact on Medical Product Labeling & Clinical Practice Guidelines in 2020?
Barbara Ameer, PharmD, MBA, Adjunct Associate Professor, Medicine, Rutgers Robert Wood Johnson Medical School

4:45 – 5:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Applying Pharmacometrics to Precision Dosing in the Lifecycle of Long-acting Injectable Products: Drug Development, Regulatory Approval & Clinical Practice

QUANTITATIVE TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-026-L03-P
ACPE – 2 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Hong Lu, PhD, Scientific Director, Takeda Pharmaceuticals USA Inc
Lanyan (Lucy) Fang, PhD, Associate Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

TARGET AUDIENCE:
This Symposium will be useful for drug developers, regulators, physicians and pharmacists.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Describe the complex pharmacokinetic characteristics of long-acting injectible products that lead to both challenges and opportunities in applying model-informed approaches in development, regulatory approval and clinical dosing practice;
2. Learn a novel quantitative framework for identifying the dose and formulation that maximize the benefit-risk ratio using in vitro/in vivo correlation. Apply the modeling strategy to other sustained-release products;
3. Describe the need and approaches for individualized dosing of antipsychotics and discuss the challenges of translating them to a product or tool adopted by healthcare providers in clinical practice;
4. Describe how receptor pharmacology, pharmacokinetics and pharmacodynamics of antipsychotics are combined to optimize clinical outcomes of antipsychotics and apply the proposed thought flow to other disease areas with target-mediated therapy.

3:30 – 3:35 PM
Introduction
Lanyan (Lucy) Fang, PhD, Associate Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

3:35 – 3:55 PM
Clinical Application of Pharmacometrics in Dosing Management of Long-acting Injectable (LAI) Antipsychotics
Hong Lu, PhD, Scientific Director, Takeda Pharmaceuticals USA Inc

3:55 – 4:15 PM
Convolution-based Approach for Modeling, Establishing In Vitro/in Vivo Correlation & Optimizing the In Vivo Drug Release Properties of LAI Products
Roberto Gomeni, PhD, President, PharmacoMetrica & Adjunct Professor, Pharmacotherapy & Experimental Therapeutics, Univ of North Carolina Eshelman School of Pharmacy

4:15 – 4:35 PM
Generating Model-integrated Evidence for Developing & Approving Complex Generic LAI Products
Liang Zhao, PhD, Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

4:35 – 4:55 PM
Role of Pharmacometrics in Guiding Clinical Practice Dosing of LAI Products
Yaning Wang, PhD, Director, Pharmacometrics, Clinical Pharmacology, US Food & Drug Administration

4:55 – 5:15 PM
Receptor Occupancy & Clinical Effects: A Review
Ariel Graff, MD, PhD, Head, Multimodal Imaging Group, Campbell Family Mental Health Research Inst

5:15 – 5:30 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Applying Quantitative Clinical Pharmacology to Support the Drug Development of T cell-redirecting Bispecific Antibodies

DRUG DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #JA4008220-0000-20-027-L04-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Weirong Wang, MD, PhD, Scientific Director, Janssen Research & Development LLC
Xiling Jiang, PhD, Staff Fellow, US Food & Drug Administration

TARGET AUDIENCE:

This Symposium will be useful for drug discovery and development scientists, clinical pharmacologists, pharmacometricians, clinician scientists, systems pharmacology scientists, mathematical biologists and regulatory scientists.

GOALS & OBJECTIVES:

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

1. Review the challenges and opportunities in T cell-redirecting bispecific antibody drug development from a clinical and clinical pharmacology perspective;
2. Explain the mechanism of action of T cell-redirecting bispecific antibodies and the associated toxicity;
3. Discuss quantitative approaches that characterize T cell-redirecting bispecific antibody-induced cytotoxicity and cytokine release;
4. Evaluate the use of quantitative clinical pharmacology in supporting the drug development of T cell-redirecting bispecific antibodies with regard to both efficacy and safety.
Pharmacometrics & Formulations in Clinical Development: Unglamorous, but Highly Impactful

DRUG DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #JA4008220-0000-20-028-L04-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Navin S. Goyal, PhD, Director, Clinical Pharmacology Modeling & Simulation, GlaxoSmithKline plc

Roberto Gomeni, PhD, President, PharmacoMetrica & Adjunct Professor Pharmacotherapy & Experimental Therapeutics, Univ of North Carolina Eshelman School of Pharmacy

TARGET AUDIENCE:

This Symposium will be helpful for clinical pharmacologists, pharmacometricians and drug developers.

GOALS & OBJECTIVES:

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

1. Identify opportunities for using a pharmacometrics approach to characterize and optimize formulation properties during clinical drug development;

2. Understand considerations in employing population pharmacokinetics to characterize drug exposure across changes in formulations: a. Do’s and Don’ts, b. Technical aspects and c. Regulatory considerations;

3. Understand the limitations of this approach;

4. Provide a methodological framework for developing pharmacological treatments with drug delivery and dosing strategy suitable to optimize clinical benefit of the treatment.

8:00 – 8:25 AM

Bridging Formulations Across Pivotal Studies in Late-stage Development via Model-based Approach

Navin S. Goyal, PhD, Director, Clinical Pharmacology Modeling & Simulation, GlaxoSmithKline plc

8:25 – 8:50 AM

In Vitro/In Vivo Correlation: Population Pharmacokinetics & Formulation Development

Roberto Gomeni, PhD, President, PharmacoMetrica & Adjunct Professor Pharmacotherapy & Experimental Therapeutics, Univ of North Carolina Eshelman School of Pharmacy

8:50 – 9:15 AM

Model-based Approach or Phase 3 Efficacy Study?

Benjamin Weber, PhD, Director, Boehringer Ingelheim

9:15 – 9:30 AM

Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Innovative Approaches in the Use of Exposure-Response in Therapeutic Proteins to Support Pediatric Extrapolation

THERAPEUTIC AREAS OF APPLIED CLINICAL PHARMACOLOGY TRACK
Offers both CME & CPE Credit
UAN #JA4008220-0000-20-029-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Robert M. Nelson, MD, PhD, Senior Director, Pediatric Drug Development, Johnson & Johnson
Jocelyn H. Leu, PharmD, PhD, Scientific Director, Janssen Research & Development LLC

TARGET AUDIENCE:
This Symposium will be useful for primary care and specialty physicians, pharmacists, clinical pharmacologists, clinical research associates, basic scientists and other healthcare professionals with an interest in learning about the use of extrapolation and Bayesian approaches for pediatric drug development.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Discuss challenges in the use of extrapolation in drug development for pediatrics;
2. Identify the opportunities for exposure-response analyses in pediatric studies to extrapolate to adult pivotal studies;
3. Identify the utility of the Bayesian Approach to designing pediatric studies;
4. Discuss case studies using extrapolation for pediatric studies.

10:00 – 10:15 AM
Introduction to the Use of Extrapolation in Pediatric Drug Development
Robert M. Nelson, MD, PhD, Senior Director, Pediatric Drug Development, Johnson & Johnson

10:15 – 10:30 AM
The Pharmacology of Therapeutic Proteins (ADME) in Pediatrics
Bernd Meibohm, PhD, Associate Dean for Research & Graduate Programs, Univ of Tennessee Health Science Ctr

10:30 – 10:45 AM
The Use of Exposure-Response With Therapeutic Proteins in Pediatric Drug Development
Marc Gastonguay, PhD, Chief Executive Officer, Metrum Research Group LLC

10:45 – 11:00 AM
Bayesian Approaches to Pediatric Pharmacokinetic Studies
Chyi-Hung Hsu, PhD, Scientific Director, Janssen Research & Development LLC and Jian Wang, PhD, Associate Director, Drug Evaluation IV, CDER, US Food & Drug Administration

11:00 – 11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Partial Area Under the Curve Analysis in Generic & New Drug Development

BASIC SCIENCE OF CLINICAL PHARMACOLOGY TRACK

Offers both CME & CPE Credit
UAN #JA4008220-0000-20-030-L04-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Liang Zhao, PhD, Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration
Keith Gallicano, PhD, Chief Scientific Officer, Novum Pharmaceutical Research Svcs

TARGET AUDIENCE:
This Symposium will be helpful for members of industry, academic institutes and government officials who are involved in the development and review of generic and new drugs.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Understand the approach in deciding when and how to use an appropriate partial area under the curve (pAUC) metric for assessment of bioequivalence and comparative bioavailability;
2. Understand the applicability of pAUC metrics in both generic and new drug development;
3. Understand the regulatory point of view on pAUC and its impact on different therapeutic areas such as hyperactivity disorder, insomnia and pain;
4. Understand an industry perspective on the challenges in study design involving pAUC for bioequivalence purposes.

10:00 – 10:05 AM
Introduction to Partial Area Under the Curve (pAUC) Recommendations: A Regulatory Perspective
Liang Zhao, PhD, Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

10:05 – 10:15 AM
Appropriateness of pAUCs to Evaluate Shape Difference in Pharmacokinetic Profiles
Keith Gallicano, PhD, Chief Scientific Officer, Novum Pharmaceutical Research Svcs

10:15 – 10:35 AM
Current Status for pAUC Recommendations in Product-specific Guidance & Case Examples
Lanyan (Lucy) Fang, PhD, Associate Director, Quantitative Methods & Modeling, Research & Standards, Generic Drugs, Ctr for Drug Evaluation & Research, US Food & Drug Administration

10:35 – 10:55 AM
Partial AUC Improved Metrics for Assessing Bioequivalence: An Industry Perspective
Charles DiLiberti, MS, President, Montclair Bioequivalence Svcs LLC

10:55 – 11:15 AM
Usage of pAUC for Evaluation of New Drug Applications for the Treatment of Migraine
Sabarinath Nair Sreedharan, PhD, Team Leader, Cancer Pharmacology I, Clinical Pharmacology, Translational Sciences, Ctr for Drug Evaluation & Research, US Food & Drug Administration

11:15 – 11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Bacteriophage as a New Weapon to Fight Drug-resistant Bacteria

DRUG DEVELOPMENT TRACK

Offers both CME & CPE Credit

UAN #JA4008220-0000-20-031-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Stephan Schmidt, PhD, Certara Professor, Associate Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Pharmaceutics Lake Nona, Univ of Florida

Christopher Duplessis, MD, Associate Professor, Naval Medical Research Ctr

TARGET AUDIENCE:

This Symposium will be useful for drug discovery and development scientists, clinical pharmacologists, clinician scientists and regulatory scientists.

GOALS & OBJECTIVES:

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

1. Review the current challenges in treating multidrug-resistant (MDR) bacterial infections using antibiotics and the need for developing efficacious non-antibiotic antimicrobial therapies;
2. Explain the mechanism of bacteriophage therapy;
3. Discuss the recent progress of bacteriophage therapy in treating MDR bacterial infections;
4. Evaluate the future potential of bacteriophage therapy in treating MDR bacterial infections.

1:30 – 1:55 PM

The Current Challenges in Treating Multidrug-resistant (MDR) Bacterial Infection

Stephan Schmidt, PhD, Certara Professor, Associate Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Pharmaceutics Lake Nona, Univ of Florida

1:55 – 2:20 PM

The History of Bacteriophage Therapy & Mechanism of Action

Biswajit Biswas, PhD, Chief, Phage Science, Genomics, Naval Medical Research Ctr

2:20 – 2:45 PM

The Recent Progress of Bacteriophage Therapy in Treating MDR Bacterial Infections & Future Potential

Christopher Duplessis, MD, Associate Professor, Naval Medical Research Ctr

2:45 – 3:00 PM

Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Transporter-mediated Drug-Drug Interactions, Current Status & Future Perspectives: An ACCP/ISSX Jointly-sponsored Symposium

BASIC SCIENCE OF CLINICAL PHARMACOLOGY TRACK
Offers both CME & CPE Credit
UAN #JA4008220-9999-20-032-L04-P
ACPE – 3.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:
Yanke Yu, PhD, Director, Clinical Pharmacology, Pfizer Inc

TARGET AUDIENCE:
This Symposium will be useful for graduate students, postdoctoral fellows/trainees and professionals in the field of pharmacy, pharmacometrics, clinical pharmacology and clinical pharmacy practice seeking a more in-depth understanding of transporter-mediated drug-drug interactions. This Symposium is applicable to participants across academia, the pharmaceutical industry and regulatory agencies.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Compare different regulatory bodies’ (US Food & Drug Administration, European Medicines Agency) requirements for transporter-mediated drug-drug interactions (DDI);
2. Understand current industrial and regulatory perspective on the role of the animal model, mechanistic static model and physiologically-based pharmacokinetic modeling approaches in prediction and assessment of transporter-mediated DDI;
3. Understand the current status of endogenous transporter biomarkers;
4. Understand the current status of pharmacogenomics of drug transporters.

1:30 – 1:40 PM
Overview of Transporter-mediated Drug-Drug Interaction (DDI)
Yanke Yu, PhD, Director, Clinical Pharmacology, Pfizer Inc

1:40 – 2:05 PM
Evolution of Regulatory Guidance (US Food & Drug Administration) on Transporter-mediated DDI
Xinning Yang, PhD, Policy Lead, CDER/OTS/OCP, US Food & Drug Administration

2:05 – 2:30 PM
European Medicines Agency’s Perspectives on Transporter-mediated DDI
Carolien Versantvoort, PhD, Clinical Pharmacology Assessor, Medicines Evaluation Board, European Medicines Agency

2:30 – 2:55 PM
Pharmacogenomics of Drug Transporters & Its Clinical Implication
Kathleen M. Giacomini, PhD, Professor, Univ of California San Francisco

2:55 – 3:20 PM
Break

3:20 – 3:45 PM
Preclinical Tools to Quantitatively Predict Transporter DDIs: Mechanistic Static Models & In Vivo Animal Models
Manthena Varma, PhD, Associate Research Fellow, Pharmacokinetics, Dynamics & Metabolism, Pfizer Inc

3:45 – 4:10 PM
Endogenous Biomarkers for Assessing Transporter-mediated DDI
Manoli Vourvahis, PhD, Senior Director, Clinical Pharmacology, Pfizer Inc

4:10 – 4:35 PM
Modeling & Simulation of Transporter-mediated DDI: A View from an Industry/Consortium Transporter Focus Group
Venkatesh Pillai Reddy, PhD, Associate Principal Scientist, AstraZeneca plc

4:35 – 5:00 PM
The Application of Physiologically-based Pharmacokinetic Modeling in Evaluating Transporter-mediated DDI: A Regulatory Science Perspective
Xinyuan Zhang, PhD, PBPK Lead, Pharmacometrics/OCP/OTS/CDER, US Food & Drug Administration

5:00 – 5:30 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Beyond Pharmacokinetic Equivalence: Assessment of Pharmacodynamic Similarity in Biologic & Small Molecule Drug Development

DRUG DEVELOPMENT TRACK

Offers both CME & CPE Credit
UAN #JA4008220-0000-20-033-L04-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Peijuan Penny Zhu, PhD, Associate Director, Pharmacometrics, Janssen Research & Development LLC
Ping Ji, PhD, Biologics Lead, US Food & Drug Administration

TARGET AUDIENCE:
This Symposium will be useful for clinical pharmacologists, regulatory scientists and clinical researchers who work in or are interested in biologic, biosimilar and small molecule drug development, including those with MD, PharmD or PhD backgrounds.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Know representative case studies of using pharmacodynamic (PD) similarity to support registration of a biosimilar or to demonstrate similarity of biologics which have undergone major manufacturing changes;
2. Be informed on representative case studies using PD similarity in place of pharmacokinetic equivalence to support the development of locally-administered drugs (e.g., for locally GI-directed treatment);
3. Understand the selection of dose and evaluation of dose-response relationship in study design and be informed on methods for justifying the margins for PD similarity assessment;
4. Be informed about how to properly correct for baselines in PD similarity evaluation and understand the statistical considerations of PD similarity evaluation when assessing baseline-normalized PD endpoint.

3:30 – 3:35 PM
Introduction to the Topic of Pharmacodynamic Similarity Assessment in Drug Development
Ping Ji, PhD, Biologics Lead, US Food & Drug Administration and Peijuan Penny Zhu, PhD, Associate Director, Pharmacometrics, Janssen Research & Development LLC

3:35 – 4:00 PM
Pharmacodynamic Similarity Assessment in Biosimilar Development: Reducing the Burden of Comparative Clinical Efficacy Studies
Oliver von Richter, PhD, Director, Sandoz Biopharmaceuticals

4:00 – 4:25 PM
Trial Design & Statistical Considerations on the Assessment of Pharmacodynamic Similarity
Peijuan Penny Zhu, PhD, Associate Director, Pharmacometrics, Janssen Research & Development LLC

4:25 – 4:50 PM
Pharmacodynamic Similarity in Biologic & Small Molecule Drug Development: A Regulatory Perspective
Yaning Wang, PhD, Director, Pharmacometrics, Clinical Pharmacology, US Food & Drug Administration

4:50 – 5:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluation
Looking for a society that provides the right benefits to enhance your career?

Membership in ACCP offers support and professional development at every level of your career. An inclusive, Member-focused/Member-driven organization, ACCP consistently strives to exceed the expectations of its Members by providing ways to stay at the top of your professional game!

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

How do ACCP Member Benefits enhance your career?

- Use the ACCP365 Mobile App for 24/7/365 access to all things ACCP, any time, any place.
- In 2019, ACCP received approval for the coveted Joint Accreditation by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE) and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team in the form of high-quality Live and On Demand educational courses. Most courses are free to ACCP Members.
- Opportunities to engage with the society and enhance your own career start with membership and attending the ACCP Annual Meeting at discounted Member rates. ACCP maintains high financial standards and strives to maintain a reasonable cost of membership and Annual Meeting registration year-over-year to effectively serve the clinical pharmacology community by making it economical to become a Member and attend the meeting.
- Build your professional network, either connecting at Live events such as the Annual Meeting, by working collaboratively with colleagues on a committee or virtually through the ACCP365 App via direct connections with colleagues.
- A vibrant Mentoring Program allows Students, Trainees & Early-stage Professionals to receive guidance to further their career and also permits senior Members to provide guidance to colleagues transitioning into full-time professionals or in need of career advice.
- Discounted registration for educational events, including the Live Annual Meeting, Live and On Demand webinars and text-based events on articles from The Journal of Clinical Pharmacology. As a jointly-accredited provider, ACCP offers Interprofessional Continuing Education Credits for most events at no additional cost.
- Opportunity to enhance your leadership skills and get involved in the clinical pharmacology community by developing and proposing continuing education activities for the ACCP Annual Meeting or one of the webinars in the series ACCP hosts year-round.
- Free access to the latest scientific research. Members have free online access to ACCP’s high-quality publications, The Journal of Clinical Pharmacology, published for over 50 years, and Clinical Pharmacology in Drug Development, introduced in 2012, including eTOC notifications and online archives.
- The Pharmacometrics web-based learning resource brought to ACCP by the Univ of Maryland Ctr for Translational Medicine offers a beginner’s guide to pharmacometric theory, modeling and application.
- Access to the ACCP Job Center to view jobs and post your resume. New in 2020, Job Ctr postings can be filtered to opportunities appropriate for your career level.
- Receipt of information from the clinical pharmacology community for Members who opt in to receive routine recall/drug safety notices from FDA MedWatch, FDA Bursts or AAMC notifications.
- Receipt of routine updates from ACCP about developments in the field of clinical pharmacology and future ACCP events.

How to Join ACCP

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

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

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

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

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

- May 3, 2020
- September 19, 2020
**CANCELLATION/REFUND POLICY:**
Meeting registration cancellations must be submitted via email to Reg@ACCP1.org no later than August 15th and are subject to a $250 nonrefundable processing fee. After August 15th, no cancellations will be permitted and only substitutions will be considered. The transfer of your registration to another person will be considered by contacting Reg@ACCP1.org or 571-291-3493 ext 3. Please see our policy in the event of meeting cancellation.

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### Registration Information

**JOIN TODAY & SAVE**
Save $600 or more on your registration by joining ACCP today and enjoy Member Benefits all year! ACCP Members receive access to current information through the ACCP365 App and to the latest scientific research via ACCP publications (*The Journal of Clinical Pharmacology* and *Clinical Pharmacology in Drug Development*), peer networking, opportunities to develop educational activities and complimentary Continuing Education activities and courses. Join ACCP now and receive the discounted ACCP Member registration rate.

2020 ACCP ANNUAL MEETING  Sept 20 – 22, 2020 • Bethesda N Marriott Hotel & Conf Ctr, Bethesda, MD

Registration is now open! Join a global audience of healthcare professionals in a focused, educational atmosphere that also provides time to network with colleagues, new and old. NEW at the 2020 ACCP Annual Meeting and included in the cost of registration, we invite you to join us at the Sunday PharmaFete social following the Opening Reception.

Annual Meeting registration fees vary based on membership type and options. All Members must be in good standing at the time of registration to receive Member registration rates. CME & CPE Credits are offered at no additional cost to Attendees. Whether you need CE credits or not, this meeting provides you with valuable information to achieve your professional goals.

ACCP is pleased to offer special registration rates to members of Sister Organizations (AAPS, ASCPT, ASPET, BPS, CSPT, EUFEMED, IATDMCT, ISAP, ISoP, ISSX and PPAG), as well as to our colleagues from US Government entities. When registering, please select the appropriate pricing category from the options noted below. Membership in Sister Organizations, Student status and employment at a government entity will be verified.

Save $600 or more on your registration by joining ACCP today and enjoy Member Benefits all year! To receive the discounted ACCP Member registration rate, please join ACCP, allow the system to send a receipt acknowledging your dues payment and proceed to register for the meeting.

Group discounts are available during the Early Bird registration period for groups of six or more persons from the same entity. regulations apply. Registrants are strongly encouraged to register online. A paper Reg Form is available for those who require it, please contact Reg@ACCP1.org.

**REGISTRATION INFORMATION**

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<tbody>
<tr>
<td>Member – 3 Days</td>
<td>$900</td>
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<td>$315 / $390*</td>
<td>$350 / $425*</td>
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<td>Pre-meeting Workshops (each) – Student Member/Non-member</td>
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<td>$145 / $160*</td>
<td>$150 / $165*</td>
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* Full Day Pre-meeting Workshop fee applies to Pre-meeting Workshop 3

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JOIN NOW!
Hotel
Bethesda N Marriott Hotel & Conf Ctr
5701 Marinelli Rd
North Bethesda, MD 20852
Tel: (877) 212-5752 (Group Name: ACCP Annual Meeting)

Bethesda, MD is a dynamic city just outside Washington, DC, a leading center for biomedical research and home to the National Inst of Health and Bethesda Naval Medical Ctr. The Bethesda N Marriott Hotel & Conf 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!

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 meeting.

The cutoff date for this group rate is Friday, August 28, 2020. We anticipate that rooms will sell quickly and advise you to make reservations early. After the cutoff date of August 28th, reservations will be accepted at prevailing rates on a room available basis and must be booked directly with the hotel.

Online Reservations: https://book.passkey.com/e/50000898

Reservations can also be made by calling the Bethesda N Marriott Hotel & Conf Ctr at 877-212-5752 and providing the group name ACCP Annual Meeting.

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 ACCP Annual Meeting! Reservations should only be made by using the online reservation link or by calling the Bethesda N Marriott Hotel & Conf Ctr directly and using the phone 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.

Please visit our website for Air & Ground Transportation and Area Attractions information.

Traveling from outside the United States? Make sure you are familiar with US Visa requirements. Visitors to the US must have a valid passport. The American College of Clinical Pharmacology® encourages Attendees to familiarize themselves with US Visa requirements and to apply for necessary visas as early as possible, at least 3 to 4 months prior to the meeting.

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

To request a Letter of Invitation to attend the ACCP Annual Meeting, please complete the form and submit an email request to Reg@ACCP1.org.
In 2019, ACCP conducted interviews with Exhibitor Focus Groups to understand how to better meet the needs of our valued Exhibitors & Sponsors and to enhance the Exhibitor-Attendee experience. The changes that ACCP implemented as a result of the interviews were well received and our goal is to continue to provide Exhibitors & Attendees with an interactive networking platform that encourages meeting new people face-to-face and fostering long-term professional relationships.

The open floor plan of the Exhibit Hall layout is designed for an ideal flow of traffic and networking space, especially during receptions, designated breakfasts and breaks.

Exhibit spaces remain reasonably priced at $2,250 per space, including two free Exhibitor Attendee registrations, or $2,750 per space, including two free Exhibitor Attendee registrations plus one Attendee at full registration who is permitted to attend the educational courses. (The Exhibitor full meeting registration does not confer Continuing Education credit).

Have a unique idea for a Sponsorship? Contact the ACCP Executive Office at 571-291-3493 ext 3 to see how we can collaborate to implement new and exciting Sponsorship opportunities.

Check out the 2020 Exhibitor & Sponsor Prospectus for Sponsorship Opportunities, select an Exhibit space or a Sponsorship opportunity and print out and complete your Sponsorship & Exhibit Space Application Form. Please contact the ACCP Executive Office at 571-291-3493 ext 3 regarding available Sponsorship opportunities or Exhibit spaces.

Commit now to become a Sponsor or Exhibitor at the 2020 ACCP Annual Meeting! The ACCP Annual Meeting provides an ideal opportunity to interact with your target audience. Attendees include a cross section of organizational affiliations uniquely positioned to take advantage of your product and service offering. 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.

ACCP Annual Meeting Exhibitors can expect the following concessions:
- Premium Exhibit space, including one (1) 6’ draped table, two (2) chairs and one (1) wastebasket;
- ACCP offers to include Exhibitor prize drawings in official meeting promotional materials;
- Lead Retrieval utilizing the ACCP365 Mobile App;
- One (1) lunch ticket per Exhibitor for all Lunch & Awards sessions;
- Pre-meeting and post-meeting Attendee list for the purposes of marketing your participation at the 2020 ACCP Annual Meeting;
- Premium listing and company description in Final Program, website and ACCP365 Mobile App.

Annual Meeting Attendees by Degree & Organizational Affiliation

ORGANIZATIONAL AFFILIATION

Academia
Clinical
Gov’t
Industry
Consulting
Other

DEGREE(S)

PhDMD
PharmD
MD
Other
Academia
Industry
Gov’t
Consulting
Other

Why Exhibit/Sponsor at ACCP?
Sponsorship & Exhibit Space Application
2020 ACCP Annual Meeting

COMPANY NAME _____________________________________________________________________

ADDRESS ___________________________________________________________________________________

CITY _______________________________ STATE __________ ZIP __________ COUNTRY ______________________

CONTACT PERSON NAME _____________________________________________________________________

PHONE _____________________ CELL PHONE _____________________ EMAIL _________________________________

EXHIBIT SPACE SELECTION

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

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

PLEASE PROVIDE 3 EXHIBIT SPACE CHOICES    #1 _______________ #2 _______________ #3 _______________

Exhibit Personnel Passes and Full Meeting Registration Passes associated with your Exhibit package may not be used for any Faculty/Speakers. As a Jointly Accredited provider of CME, CPE and ANCC credits, ACCP must ensure that education is separated from promotion and as such, Exhibitor registrations are considered promotional registrations. If Exhibitors wish to participate as Faculty/Speakers in the educational program, they must register and attend the CE program as learners and pay the appropriate fees.

SPONSORSHIP ONLY Check Here  

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: _____________________________________________________________________________

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

Amount in US Dollars authorized to charge: _______________________ For 2020 ACCP ANNUAL MEETING EXHIBIT FEE

PLEASE EMAIL THE FOLLOWING WITH YOUR PAYMENT & SUBMISSION OF THIS FORM TO TBOSSERT@ACCP1.ORG

1) DESCRIPTION OF COMPANY (50 words or less) – Applicable to Exhibitors Only!

2) YOUR COMPANY URL – Applicable to both Exhibitors & Sponsors!

3) A HIGH-RESOLUTION LOGO (300 dpi) EPS, TIF OR JPEG format – Applicable to both Exhibitors & Sponsors!

Closer to the date of the ACCP Annual Meeting, we will request information regarding your Exhibitor registrations.

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Call for 2021 Proposals is Now Open!

2021 Annual Meeting of the American College of Clinical Pharmacology®

*Spearheading Innovations in Clinical Pharmacology*

September 12 – 14, 2021
Renaissance Phoenix Downtown Hotel, Phoenix, AZ
Co-chairs: Richard C. Brundage, PharmD, PhD & Navin S. Goyal, PhD

Why submit a Proposal for the 2021 ACCP Annual Meeting?

For over 50 years, ACCP has provided exceptional educational programming to the clinical pharmacology community. Consistent with its focus on excellence in educational programming, planning is already underway for the 2021 ACCP Annual Meeting, September 12 – 14, 2021 in Phoenix, AZ. We invite you to Submit a Proposal for a Pre-meeting Workshop or a Symposium! Join the select cohort of Event Chairs and Faculty for the 2021 ACCP Annual Meeting Program. Attended by clinical pharmacology professionals from academia, industry, government and clinical settings who span the scope from research and drug development to patient-centered care, the ACCP Annual Meeting presents a unique opportunity to develop an educational event for a diverse, interprofessional audience focused on advancing the field of clinical pharmacology and enhancing the safe and effective use of medications in patients.

ACCP Annual Meeting Faculty highly recommend involvement in an ACCP Annual Meeting. Come and experience the difference!

All Proposals will be reviewed and scored by the ACCP 2021 Annual Meeting Program Committee. Submitters whose Proposals are selected will be asked to provide additional information, such as disclosure information, expected course outcomes, etc. at a later date. Please contact CE@ACCP1.org with questions.

In support of improving patient care, the American College of Clinical Pharmacology® is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE) and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.