Join Us to Celebrate ACCP's 50th Anniversary!

2019 Annual Meeting
American College of Clinical Pharmacology®

Reflecting on Our History & Shaping the Future of Clinical Pharmacology

September 15 – 17, 2019
Fairmont Chicago Millennium Park
Chicago, IL

Preliminary Program

#2019ACCP
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Join Us for the 2019 ACCP Annual Meeting!

Reflecting on Our History & Shaping the Future of Clinical Pharmacology

September 15th – 17th in Chicago!

In 2019, the American College of Clinical Pharmacology® (ACCP) will be celebrating its 50th Anniversary! We hope you can join us in Chicago as we look back at the milestones ACCP has reached over the past 50 years and where our future lies. To commemorate this milestone, there will be an Anniversary Gala on Saturday, September 14th, accompanied with lots of pomp and circumstance to celebrate this moment in ACCP history. Plan now to attend the 2019 ACCP Annual Meeting, September 15th – 17th, at the Fairmont Chicago Millennium Park.

This year’s meeting is focused on “Reflecting on Our History & Shaping the Future of Clinical Pharmacology” and will be a meeting you will not want to miss! Consistent with ACCP’s commitment to excellence in science and education, the 2019 Annual Meeting Program Committee, co-chaired by Drs. Joan Korth-Bradley, Lily Mulugeta and Michael J. Fossler, Jr, is working diligently to provide a diverse and exceptional educational program that meets the needs of healthcare professionals and scientists with an interest in one or more of the myriad of applications of clinical pharmacology ranging from research and drug development to patient care. Speakers spanning the breadth of academia, industry, regulatory agencies, consulting companies and clinical specialties will present educational and scientific programs organized into topic tracks that allow attendees to uniquely tailor content selection to their individual interests.

A series of special Student, Trainee & Early-stage Professional-focused programs is planned that provide exposure to innovative science and career development opportunities.

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

Enjoy the chance to socialize and network at the Anniversary Gala, during Evening Receptions and Poster Sessions, at twice-daily tea/coffee breaks, at the Lunch & Awards Sessions and the Annual Business Meeting.

We strongly encourage you and your colleagues to join us for this outstanding educational and scientific event. For those who have never had the opportunity to attend an ACCP Annual Meeting, join us in 2019 and see for yourself how ACCP makes a difference by providing healthcare professionals and scientists with a forum to exchange knowledge and ideas that promote and expand the value of clinical pharmacology in healthcare and drug development. Registration is now open! Remember to register early for the Anniversary Gala and Pre-meeting Workshops, as seating is limited.

The Fairmont Chicago Millennium Park offers scenic views of downtown Chicago, luxury accommodations and fine dining. We look forward to hosting you at this beautiful venue that is uniquely designed with 63,000 sq ft of unobstructed meeting space, promising a meeting experience unlike any other.

For your benefit, deluxe accommodations at the special rate of $229 have been negotiated. The cutoff date for reservations at this group rate is August 23, 2019.

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

We look forward to celebrating our 50th Anniversary with you in Chicago! Come learn, network and be part of an excellent and educational scientific event in the clinical pharmacology community!

Enjoy the chance to socialize and network at the Anniversary Gala, during Evening Receptions and Poster Sessions, at twice-daily tea/coffee breaks, at the Lunch & Awards Sessions and the Annual Business Meeting.

We strongly encourage you and your colleagues to join us for this outstanding educational and scientific event. For those who have never had the opportunity to attend an ACCP Annual Meeting, join us in 2019 and see for yourself how ACCP makes a difference by providing healthcare professionals and scientists with a forum to exchange knowledge and ideas that promote and expand the value of clinical pharmacology in healthcare and drug development. Registration is now open! Remember to register early for the Anniversary Gala and Pre-meeting Workshops, as seating is limited.

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Workshops & Symposia at the 2019 ACCP Annual Meeting are identified as being part of either the “Development Track” (DT) or the “Patient-centric Track” (P-CT) to make it easier for attendees to determine which courses they prefer to attend.

SATURDAY, SEPTEMBER 14, 2019

<table>
<thead>
<tr>
<th>Workshop</th>
<th>Time</th>
<th>Title</th>
<th>CO-CHAIRS</th>
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<tbody>
<tr>
<td>Pre-meeting Workshop 1</td>
<td>8:00 AM – 12:00 PM</td>
<td>R Basics for Every Clinical Pharmacologist: Easily Create Reproducible Figures, Tables &amp; Diagnostic Plots Using Tidyverse Libraries Such as Dplyr &amp; Ggplot2 (DT)</td>
<td>Jennifer E. Hibma, PharmD, Clinical Pharmacologist &amp; Pharmacometrician, Pfizer Inc, Global Product Development, Global Pharmacometrics and Gopichand Gottipati, PhD, Reviewer, US Food &amp; Drug Administration, OMPT/CDER/OTS/OCPP</td>
</tr>
<tr>
<td>Pre-meeting Workshop 2</td>
<td>8:00 AM – 12:00 PM</td>
<td>Clinical Pharmacology: Statistical Aspects &amp; Methods, an ACCP/ASA Jointly-sponsored Workshop (DT)</td>
<td>Alfred H. Balch, PhD, MA, Adjunct Associate Professor, Univ of Utah School of Medicine and Chief Executive Officer, Summit Statistics LLC</td>
</tr>
<tr>
<td>Pre-meeting Workshop 3</td>
<td>1:30 – 5:30 PM</td>
<td>Interprofessional Education in Pharmacogenomics, an ACCP/AACP Jointly-sponsored Workshop (DT &amp; P-CT)</td>
<td>David F. Kisor, PharmD, Professor &amp; Director of Pharmacogenomics Education, Manchester Univ, Pharmacy &amp; Pharmacogenomics Programs and Philip E. Empey, PharmD, PhD, Associate Director, Inst for Precision Medicine &amp; School of Pharmacy, Univ of Pittsburgh</td>
</tr>
<tr>
<td>Pre-meeting Workshop 4</td>
<td>1:30 – 5:30 PM</td>
<td>Decoding the Complexity of Transporter-mediated Drug-Drug Interactions &amp; Recent Advances in Endogenous Biomarkers &amp; Transporter Cocktail Studies (DT)</td>
<td>Ahmed Nader, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology &amp; Pharmacometrics and Mohamed Emeliegy, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology</td>
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SUNDAY, SEPTEMBER 15, 2019

<table>
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<th>Session</th>
<th>Time</th>
<th>Title</th>
<th>CO-PRESENTERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plenary Session</td>
<td>8:00 – 9:30 AM</td>
<td>To Infinity &amp; Beyond! The Expanding Roles of Data Sharing &amp; Collaboration (DT)</td>
<td>Jeffrey S. Barrett, PhD, Head, Bill &amp; Melinda Gates Medical Research Inst, Quantitative Sciences and John F. Crowley, JD, MBA, Chairman of the Board &amp; Chief Executive Officer, Amicus Therapeutics Inc</td>
</tr>
</tbody>
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Symposium 1 | 10:00 – 11:30 AM | Clinical Therapeutics in Obesity: A Tribute to the Work of Darrell R. Abernethy (DT & P-CT) | David J. Greenblatt, MD, Professor, Tufts Univ School of Medicine and Christina R. Chow, PhD, Head of Research, Emerald Lake Safety |

Symposium 2 | 10:00 – 11:30 AM | The Evolution of Pharmacokinetic Studies in Patients With Impaired Renal Function: Emerging Designs & Trends (DT) | Lorraine M. Rusch, PhD, President, High Point Clinical Trials Ctr |

Symposium 3 | 1:30 – 5:00 PM | Communicating Your Science: An Integrated Scientific Writing Symposium & Workshop for Early-stage Professionals & Trainees (DT & P-CT) | Matthew B. Dufek, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics and Oliver Grundmann, PhD, Clinical Associate Professor, Director, Univ of Florida Coll of Pharmacy, Medicinal Chemistry |

Symposium 4 | 1:30 – 3:00 PM | Pediatric Therapeutic Drug Monitoring & Drug Development in the Age of Pharmacometrics, an ISoP/ACCP Clinical Pharmacometrics Special Interest Group Jointly-sponsored Symposium (DT & P-CT) | Marc H. Scheetz, PharmD, Professor, Midwestern Univ, Chicago Coll of Pharmacy, Pharmacy Practice & Coll of Graduate Studies, Pharmacology and John Carl Panetta, PhD, Biomedical Modeler, St Jude Children’s Research Hosp, Pharmaceutical Sciences |

Symposium 5 | 3:30 – 5:00 PM | Real-world Data to Real-world Evidence: Opportunities & Challenges for Clinical Pharmacology & Precision Medicine (DT & P-CT) | Anuradha Ramamoorthy, PhD, Policy Lead, Guidance & Policy Team, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/CDER and Mark Rogge, PhD, Global Head, Takeda Pharmaceuticals Int’l, Quantitative Translational Sciences |
Program at a Glance

MONDAY, SEPTEMBER 16, 2019

Roger Jelliffe Individualized Therapy Award Presentation  8:00 – 9:30 AM
Ushering in the Age of Individualized Dosing: Where Do We Go From Here? (P-CT)
PRESENTER: Diane R. Mould, President, Projections Research Inc

Symposium 6  10:00 – 11:30 AM
Model-informed Drug Development for Long-acting Injectable Products (DT)
CO-CHAIRS: Lanyan (Lucy) Fang, PhD, Associate Director (Acting), US Food & Drug Administration, Quantitative Methods & Modeling, Office of Research & Standards, Office of Generic Drugs, CDER and Viera Lukacova, PhD, Director, Simulations Plus Inc, Simulation Sciences

Symposium 7  10:00 – 11:30 AM
The Opioid Crisis: The Accompanying Increase in Infectious Diseases & How the Crisis Can Be Mitigated (P-CT)
CHAIR: Samer El-Kamary, MD, MS, MPH, Clinical Reviewer, US Food & Drug Administration, Antiviral Products, CDER and Adjunct Associate Professor, Univ of Maryland School of Medicine

Symposium 8  1:30 – 5:30 PM
Clinical Drug Development for Modified-release Drug Products: Regulatory Considerations & Application of Model-informed Exposure-Response Analysis to Waive Efficacy Studies (DT)
CHAIR: Bilal AbuAsal, PhD, Clinical Pharmacologist, US Food & Drug Administration, OMPT/CDER/OTS/OCP

Symposium 9  1:30 – 3:00 PM
Latest Advances in Treatment, Prophylaxis & Pharmacogenomics of HIV (P-CT)
CHAIR: Sam Harirforoosh, PharmD, PhD, Associate Professor, East Tennessee State Univ Coll of Pharmacy, Pharmaceutical Sciences

Symposium 10  3:30 – 5:00 PM
Convergence of Therapeutic Approaches in Oncology & HIV to Target Immune Evasion: Integrating Clinical Pharmacology Lessons Learned (DT & P-CT)
CO-CHAIRS: Mariam Ahmed, PhD, Staff Fellow, US Food & Drug Administration, OMPT/CDER/OTS/OCP and Daria Stypinski, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology, Oncology & Global Product Development

TUESDAY, SEPTEMBER 17, 2019

Symposium 11  8:00 – 11:30 AM
Considerations for Expanding Oncology Trial Eligibility Criteria to Include Patients With Organ Impairment (DT)
CO-CHAIRS: Joanna C. Masters, PharmD, Associate Director, Pfizer Inc, Clinical Pharmacology & Pharmaceutics, Global Product Development and April M. Barbour, PhD, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics

Symposium 12  8:00 – 9:30 AM
Anticipate, Formulate, Adapt & Operate: Innovative Approaches for Clinical Pharmacologists to Impact Drug Development Through Clinical Trial Design (DT)
CO-CHAIRS: Ravi Shankar Prasad Singh, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology, Early Clinical Development, Worldwide Research & Development and Indranil Bhattacharya, PhD, Director, Biogen, Clinical Pharmacology & Pharmacometrics

Symposium 13  10:00 – 11:30 AM
Human Pharmacodynamic Models Supporting Decision Making in Neuroscience Drug Development (DT)
CHAIR: Tong Zhu, PhD, Executive Director, Astellas Pharma Global Development, Clinical Pharmacology & Exploratory Development

Symposium 14  1:30 – 5:00 PM
Emerging Technologies in Quantitative Pharmacology: Balancing Resources, Gaining Efficiencies & Cutting Costs (DT)
CO-CHAIRS: April M. Barbour, PhD, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics and Navin Goyal, PhD, Director, GlaxoSmithKline plc, Clinical Pharmacology

Symposium 15  1:30 – 3:00 PM
Optimizing Therapy & Accelerating Drug Development in Oncology Using Surrogate Endpoints (DT & P-CT)
CO-CHAIRS: Neeraj Gupta, PhD, Senior Scientific Director, Takeda Pharmaceuticals USA Inc, Quantitative Clinical Pharmacology and Kevin J. Freise, PhD, Scientific Director, AbbVie Inc, Oncology Early Development

Symposium 16  3:30 – 5:00 PM
Complex Innovative Methodologies in Oncology Clinical Trials: Towards Accelerating Development of Anti-cancer Therapies (DT)
CO-CHAIRS: Amal Ayyoub, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology, Office of Translational Sciences, CDER and Yingxue Chen, PhD, Director of Quantitative Clinical Pharmacology, AstraZeneca plc, Early Clinical Development
Alex Zhavoronkov, PhD – Founder & Chief Executive Officer, Insilico Medicine Inc

**Machine Learning: Will We Still Need Clinical Pharmacologists in the Next Decade?**

Monday, September 16, 2019 | Lunch & Awards Session

Alex Zhavoronkov, PhD, is the Founder & Chief Executive Officer of Insilico Medicine Inc, a leader in next-generation artificial intelligence technologies for drug discovery, biomarker development and aging research. At Insilico, Dr. Zhavoronkov pioneered the applications of generative adversarial networks and reinforcement learning for generating novel molecular structures with the desired properties and generation of synthetic biological and patient data. He was the first to develop deep multi-modal predictors of age using multiple data types. He set up R&D centers in countries including the United Kingdom, Korea, Russia, Hong Kong and Taiwan and launched multiple digital biomarker initiatives including Young.AI.

Prior to founding Insilico Medicine Inc, Dr. Zhavoronkov worked in senior roles at ATI Technologies Inc (acquired by Advanced Micro Devices Inc in 2006), NeuroG Neuroinformatics and YLabs.AI and he established AgeNet.net competitions and the Diversity.AI initiative. He is the Co-founder & Chief Science Officer (CSO) of the Biogerontology Research Foundation, a registered UK charity focusing on age-related diseases.

Since 2012, Dr. Zhavoronkov has published over 130 peer-reviewed research papers and two books, including *The Ageless Generation: How Biomedical Advances Will Transform the Global Economy*. From 2014 to 2018, he presented at over 200 academic and industry conferences. He serves on the editorial boards of some of the highest-impact journals in the field including *Aging, Aging Research Reviews* and *Frontiers in Genetics of Aging*. He also chairs the Annual Aging Research for Drug Discovery Forum and the Artificial Intelligence for Healthcare Forum at Basel Life, one of Europe’s largest industry events in drug discovery.
2019 ACCP Recognition Award Winners

ACCP Distinguished Investigator Award
Julie A. Johnson, PharmD – Dean & Distinguished Professor, Univ of Florida Coll of Pharmacy
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 Johnson’s bio.

ACCP Honorary Fellowship Award
Amarnath Sharma, MPharm, PhD – Vice President, Global Head, Clinical Pharmacology & Pharmacometrics, Janssen R&D
The ACCP Honorary Fellowship Award is given annually to a Non-member of ACCP and is meant to recognize primary activities within the immediate domain of clinical pharmacology. The award recognizes overall contributions to the field, rather than any particular scientific work, by a senior investigator or authority having a national or international reputation in the scientific, public service, legislative, governmental or other area of endeavor impacting the field.
See Dr Sharma’s bio.

Nathaniel T. Kwit Memorial Distinguished Service Award
Peter Wiernik, MD – President, Cancer Research Fdtn
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 or long-term and wide-ranging scientific studies having practical importance and other service-related functions. It is differentiated from the ACCP Distinguished Investigator Award in that it is not intended to recognize any distinct area of scientific investigation, but rather an overall contribution to the field.
See Dr Wiernik’s bio.
McKeen Cattell Memorial Award
James Truong, PharmD – Clinical Pharmacy Coordinator of Infectious Diseases, Brooklyn Hosp 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.

This year’s award-winning journal article is: “Individualized Pharmacokinetic Dosing of Vancomycin Reduces Time to Therapeutic Trough Concentrations in Critically Ill Patients” Authors: James Truong, PharmD, Shawn R. Smith, PharmD, John J. Veillette, PharmD and Steven C. Forland, PharmD. Published in *The Journal of Clinical Pharmacology*. Volume 58, Issue 9, pages 1123 – 1130, June, 2018.

Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award
Guenther Hochhaus, PhD – Professor, Univ of Florida Coll of Pharmacy
The Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award is given to an awardee who demonstrates exemplary promotion of clinical pharmacology, with emphasis on training/guidance of junior scientists and/or colleagues.

See Dr Hochhaus’s bio.

Roger Jelliffe Individualized Therapy Award
Diane R. Mould, PhD, FCP, FAAPS – President, Projections Research Inc
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 Mould’s bio.
Students, Trainees & Early-stage Professionals

Student, Trainee & Early-stage Professional (STEP) membership and participation in ACCP’s Annual Meeting are strongly encouraged and are beneficial on several levels:

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

Student, Trainee & Early-stage Professional-specific Events

On Sunday, September 15th, 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 concern.

On Monday, September 16th, the following events will be hosted:

• **Panel Discussion on Career Guidance** – A select group of ACCP Mentors whose careers have spanned various settings and disciplines within the field of clinical pharmacology will share their experiences and answer your questions in a relaxed, intimate atmosphere. If you are considering a career that includes any combination of academia, industry, regulatory or clinical roles, don’t miss this opportunity to hear what the experts have to say about how their own career paths progressed and what guidance they can provide to ensure your personal success!

• **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 by contacting KLevy@ACCP1.org.

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

ACCP Member Benefits

Join ACCP

Visit us at Facebook, LinkedIn, Twitter, Instagram

Abstracts & Posters

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>
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<tr>
<th>Date</th>
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<tr>
<td>April 15, 2019</td>
<td>Abstract Submission Site Closes</td>
</tr>
<tr>
<td>Mid-May 2019</td>
<td>Abstract notifications sent by email to corresponding authors regarding decisions by the Annual Meeting Program Committee on the status of acceptance</td>
</tr>
<tr>
<td>June 15, 2019</td>
<td>Deadline to submit Registration Form &amp; Abstract Contract or to withdraw abstract(s)</td>
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Submit an Abstract

Areas of Abstract Submission

Instructions for Abstracts & Posters

Guidelines for Poster Presentations

2019 Poster Session Schedule

**PLEASE NOTE:** POSTERS WILL BE JUDGED THE ENTIRE TIME THE POSTER SESSION IS IN PROGRESS.

**POSTER SESSION 1**
Sunday, September 15, 2019
5:00 – 7:00 PM

**POSTER SESSION 2**
Monday, September 16, 2019
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 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, 2018 and July 31, 2019.

FOR QUESTIONS, PLEASE CONTACT: TBossert@ACCP1.org or 571-291-3493 ext 3.
Target Audience
The 2019 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.

Accreditation Statements
The American College of Clinical Pharmacology® is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of Continuing Pharmacy Education (CPE).

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 47 Contact Hours. Pharmacists should claim only the Contact Hours commensurate with the extent of their participation in the activity.

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

Designation Statement
The American College of Clinical Pharmacology designates this Live educational activity for a maximum of 47 AMA PRA Category 1 Credits™. Physicians should claim only the credits commensurate with the extent of their participation in the activity.

Disclosure: Joint Providership
This activity has been planned and implemented in accordance with the accreditation requirements and policies of the ACCME and the ACPE, including courses developed in joint providership between the American College of Clinical Pharmacology and the following organizations: the American Association of Colleges of Pharmacy, the American Statistical Association and the International Society of Pharmacometrics. The American College of Clinical Pharmacology is accredited by the ACCME and ACPE to provide continuing medical education for physicians and continuing pharmacy education for pharmacists.

Disclosure: Commercial Support
The American College of Clinical Pharmacology accepts and discloses any and all commercial support for the 2019 ACCP Annual Meeting, including any grants, Sponsorships, Exhibit fees and other support in accordance with the ACCME and ACPE Standards for Commercial Support.

Disclosure: Planning Committee & Faculty Disclosure of Commercial Interests
Members of the 2019 ACCP Annual Meeting Program Committee report nothing to disclose related to the educational content. Faculty disclosures will be provided in the Final Program and in the Syllabus for each educational course.

Disclosure: Requirements for Successful Completion
Attendees requesting CME/CPE credits must indicate their credit request during registration for the 2019 ACCP Annual Meeting. Attendees wishing to obtain credits must attend one or more CME/CPE courses and must pass each requested course’s learning assessment. The learners must also complete the requisite course’s Self-assessment Post-test, Evaluation, claim the credits and PRINT the Certificate(s) no later than October 31, 2019. Beyond that point, requests to complete CME/CPE post-event processes will incur an administrative late fee of $200 and must be finalized no later than December 31, 2019.

Disclosure: Additional CPE Requirements
Attendees seeking CPE credit 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 to ACCP during registration.

Other Information
The 2019 ACCP Annual Meeting Program at a Glance can be found on pages 4 & 5.
R Basics for Every Clinical Pharmacologist: Easily Create Reproducible Figures, Tables & Diagnostic Plots Using Tidyverse Libraries Such as Dplyr & Ggplot2

DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #0238-0000-19-017-L01-P
ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:
Jennifer E. Hibma, PharmD, Clinical Pharmacologist & Pharmacometrician, Pfizer Inc, Global Product Development, Global Pharmacometrics
Gopichand Gottipati, PhD, Reviewer, US Food & Drug Administration, OMPT/CDER/OTS/OCP

TARGET AUDIENCE:
This Workshop will be useful for clinical pharmacologists from all business sectors, including academia, industry, regulatory and clinical who utilize principles of data science in research. In addition, interprofessional learners from healthcare-related universities and trainee programs will develop techniques to maximize the value of their data through effective communication of results and diagnostics, including reproducible R scripts.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Apply R basics, i.e., reading data into R, accessing R packages, organizing and commenting R code, have a working knowledge of essential commands for a clinical pharmacologist;
2. Demonstrate the use of dplyr verbs to solve the most common data manipulation challenges;
3. Display pharmacokinetic and pharmacodynamic data in figures and tables for presentations, reports and manuscripts;
4. Design diagnostic plots for population pharmacokinetic/pharmacodynamic analyses.

8:00 – 8:30 AM
Introduction to RStudio & Quick Overview of R Markdown
Jennifer E. Hibma, PharmD, Clinical Pharmacologist & Pharmacometrician, Pfizer Inc, Global Product Development, Global Pharmacometrics

8:30 – 9:00 AM
Data Manipulation Using Dplyr & Tidyr With Hands-on Session
Gopichand Gottipati, PhD, Reviewer, US Food & Drug Administration, OMPT/CDER/OTS/OCP

9:00 – 9:30 AM
Ggplot2 for Data Visualization With Hands-on Session
Ana Ruiz-Garcia, PharmD, PhD, Senior Director, Pfizer Inc, Global Pharmacometrics

9:30 – 10:00 AM / Break

10:00 – 10:50 AM
Noncompartmental Analysis Using R With Hands-on Session
Beatriz Guglieri-Lopez, PharmD, PhD, Postdoctoral Fellow in Pharmacometrics & Clinical Pharmacology, Univ of Maryland Baltimore

10:50 – 11:40 AM
Diagnostic Plots Using NONMEM Output File & R With Hands-on Session
Alejandro Perez-Pitarch, PharmD, PhD, ORISE Fellow, US Food & Drug Administration

11:40 AM – 12:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Clinical Pharmacology: Statistical Aspects & Methods, an ACCP/ASA Jointly-sponsored Workshop

DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #0238-9999-19-018-L04-P
ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

CHAIR:
Alfred H. Balch, PhD, MA, Adjunct Associate Professor, Univ of Utah School of Medicine and Chief Executive Officer, Summit Statistics LLC

TARGET AUDIENCE:
This Workshop will be useful for clinical pharmacologists from pharmaceutical/biotechnology companies and regulatory agencies, pharmacometricians, clinical researchers and drug development scientists who have an interest in applying and/or who currently apply principles of data science in clinical pharmacology. The target audience would include clinical and research faculty from schools and colleges of medicine, pharmacy and nursing, pharmacologists, pharmacists, clinicians or graduate/postgraduate trainees wishing to better understand their data and maximize the value of their data through effective communication of results and diagnostics.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Explain the application of statistical principles to noncompartmental analysis of pharmacokinetic data in a variety of designs and endpoints based on an understanding of distributional assumptions behind common pharmacokinetic endpoints derived from concentration-time data (e.g., AUC, Cmax) and understand principles of hypothesis testing for bioequivalence;
2. Distinguish between modeling and simulation;
3. Describe the impact of prospective vs retrospective design and appropriate analysis in drug development/population inference, as well as in individual patient care settings, including the principles of Bayesian and Frequentist inference in these settings;
4. Identify when to use decision support tools vs population analysis;
5. List the different types of models (parametric, semiparametric, nonparametric) and how these relate to pharmacokinetics/pharmacodynamics, drug development and patient/individualized-patient care models;
6. Differentiate between deterministic and Monte Carlo Simulation and how simulation can be used to improve decision making;
7. List ways to analyze, compare and combine multiple retrospective studies from institutional and public databases with clinical pharmacology and safety endpoints.

8:00 – 8:15 AM
Overview: Clinical Pharmacology – Statistical Aspects & Methods
Alfred H. Balch, PhD, MA, Adjunct Associate Professor, Univ of Utah School of Medicine and Chief Executive Officer, Summit Statistics LLC

8:15 – 9:00 AM
Classical Clinical Pharmacology: Bioequivalence, Bioavailability, Dose Proportionality & Noncompartmental Analysis
Robert Bies, PharmD, PhD, Associate Professor of Pharmaceutical Sciences, State Univ of New York at Buffalo School of Pharmacy and Member, Computational & Data Enabled Sciences & Engineering Program and Scott Patterson, PhD, PStat, Sanofi Pasteur, Statistical Innovation

9:00 – 9:30 AM
Modeling & Simulation for Drug Development
Peter Bonate, PhD, Executive Director, Astellas Pharma Inc, Pharmacokinetics, Modeling & Simulation

9:30 – 10:00 AM / Break

10:00 – 10:45 AM
Modeling & Simulation for Patient Care/Individualized Medicine
Robert Bies, PharmD, PhD, Associate Professor of Pharmaceutical Sciences, State Univ of New York at Buffalo School of Pharmacy and Member, Computational & Data Enabled Sciences & Engineering Program

10:45 – 11:30 AM
Data Science & Retrospective Data in Public Databases
Alfred H. Balch, PhD, MA, Adjunct Associate Professor, Univ of Utah School of Medicine and Chief Executive Officer, Summit Statistics LLC

11:30 AM – 12:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Pre-meeting Workshops

SATURDAY, SEPTEMBER 14, 2019 | Pre-meeting Workshop 3 | 1:30 – 5:30 PM

Interprofessional Education in Pharmacogenomics, an ACCP/AACP Jointly-sponsored Workshop

DEVELOPMENT & PATIENT-CENTRIC TRACKS
Offers both CME & CPE Credit
UAN #0238-9999-19-019-L01-P
ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

As part of this Workshop, registrants are strongly encouraged, but not required, to submit a sample to receive their blinded, personal genetic testing report free of charge for use in the Workshop. Any results will be used strictly for this Workshop and not for other research purposes. To participate in the genetic testing, participants will be required to remit the genetic testing Consent Form by July 1st and return the provided genetic testing kit to Genemarkers LLC by July 15th. Supply is limited. Contact CE@ACCP1.org for more details. Please note those registering after the July 1st deadline may still participate in the Workshop, but will not be able to submit a sample.

CO-CHAIRS:
David F. Kisor, PharmD, Professor & Director of Pharmacogenomics Education, Manchester Univ, Pharmacy & Pharmacogenomics Programs
Philip E. Empey, PharmD, PhD, Associate Director, Inst for Precision Medicine & School of Pharmacy, Univ of Pittsburgh

TARGET AUDIENCE:
This Workshop will be useful for physicians, nurse practitioners, physician assistants and pharmacists across therapeutic areas and therapeutic drug monitoring services.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Identify resources related to healthcare provider competencies in pharmacogenomics;
2. Identify the pharmacogene(s) of interest to be evaluated for specific patient cases;
3. Interpret pharmacogene genotyping results relative to drug/drug dose selection for specific patient cases;
4. Describe a decision-making process integrating current pharmacogenomic guidelines and information.
Decoding the Complexity of Transporter-mediated Drug-Drug Interactions & Recent Advances in Endogenous Biomarkers & Transporter Cocktail Studies

DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #0238-0000-19-020-L01-P
ACPE – 3.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Ahmed Nader, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics
Mohamed Elmeliegy, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology

TARGET AUDIENCE:
This Workshop will be useful for clinical pharmacologists working in academia, the pharmaceutical industry or regulatory settings.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Explain recent advances using in vitro, clinical and in silico approaches to define transport-mediated drug-drug interaction (DDI) potential for new drugs in development;
2. Discuss novel approaches to developing and validating cocktails for transporter substrates to be used in clinical DDI evaluations and evaluations of potential endogenous biomarkers of transporter activity;
3. Describe the implications of transporter-mediated DDI clinical study results in terms of extrapolation to other compounds and informing labeling language.

1:30 – 2:00 PM
Current Challenges & Future State of Transporter-mediated DDIs in Drug Development
Ahmed Nader, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

2:00 – 2:30 PM
Practical Approaches to Evaluate Transporter-mediated DDI Potential & the Interplay With Drug Metabolizing Enzymes
Mohamad Shebley, PhD, Director & Volwiler Research Fellow, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

2:30 – 3:00 PM
Clinical Relevance of Transporter Induction as a Mechanism for Clinical DDIs
Mohamed Elmeliegy, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology

3:00 – 3:30 PM
Perspectives on the Use of Endogenous Metabolites as Biomarkers for Transporter-mediated DDI Evaluation
Kathleen M. Giacomini, PhD, Professor, Univ of California San Francisco, Bioengineering & Therapeutic Sciences

3:30 – 4:00 PM / Break

4:00 – 4:30 PM
Recent Advances in the Development of Transporter Substrate Cocktails for Use in Clinical DDI Studies
Peter Stopfer, PhD, Global Head Clinical PK/PD, Boehringer Ingelheim Pharma GmbH & Co KG, Translational Medicine & Clinical Pharmacology

4:30 – 5:00 PM
Regulatory Perspective on Approaches to Predict Transporter-mediated DDIs, Interpretation of DDI Study Results & Implications for Labeling
Shiew-Mei Huang, PhD, Deputy Director, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/CDER

5:00 – 5:30 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
To Infinity & Beyond! The Expanding Roles of Data Sharing & Collaboration

DEVELOPMENT TRACK

Offers both CME & CPE Credit
UAN #0238-0000-19-021-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-PRESENTERS:
Jeffrey S. Barrett, PhD, Head, Bill & Melinda Gates Medical Research Inst, Quantitative Sciences
John F. Crowley, JD, MBA, Chairman of the Board & Chief Executive Officer, Amicus Therapeutics Inc

TARGET AUDIENCE:
This Plenary Session will be useful for clinical pharmacologists working in academic, pharmaceutical industry or regulatory settings.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. State how both drug development and clinical therapeutics may change over the next 50 years and how the pharmaceutical industry, regulators, private foundations and the healthcare system will contribute to that change;
2. Recall several ways in which the discipline of clinical pharmacology will need to adapt to meet the changing drug development and therapeutic landscape over the next five decades;
3. Articulate the main barriers to the development of effective and safe therapies for rare diseases;
4. Give several examples of how developers, regulators, payers and funding can contribute toward a viable and sustainable model for the development of therapies for rare diseases.

See Dr Barrett’s bio.

See Mr Crowley’s bio.
Clinical Therapeutics in Obesity: A Tribute to the Work of Darrell R. Abernethy

DEVELOPMENT & PATIENT-CENTRIC TRACKS
Offers both CME & CPE Credit
UAN #0238-0000-19-001-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
David J. Greenblatt, MD, Professor, Tufts Univ School of Medicine
Christina R. Chow, PhD, Head of Research, Emerald Lake Safety

TARGET AUDIENCE:
This Symposium will be useful for physicians, pharmacists, nurse practitioners, physician assistants and clinical investigators.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Distinguish among clinically-available metrics of obesity and apply the appropriate method of assessment to the specific patient;
2. Design dosage regimen modifications appropriate for an obese patient based on objective clinical and physicochemical parameters;
3. Anticipate and act on therapeutic adjustments needed in the bariatric surgical patient in the post-operative period.

10:00 – 10:25 AM
Drug Distribution & Clearance in Obesity: The Contributions of Dr. Abernethy
David J. Greenblatt, MD, Professor, Tufts Univ School of Medicine

10:25 – 10:50 AM
Drug Persistence in Obesity: Implications for Patient Safety
Christina R. Chow, PhD, Head of Research, Emerald Lake Safety

10:50 – 11:20 AM
Pharmacotherapy in Bariatric Surgical Patients: A Clinical & Research Challenge
April N. Smith, PharmD, Associate Professor of Pharmacy Practice, Creighton Univ & Clinical Pharmacist, CHI Immanuel Medical Ctr, Acute Care & Bariatric Surgery

11:20 – 11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
The Evolution of Pharmacokinetic Studies in Patients With Impaired Renal Function: Emerging Designs & Trends

DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #0238-0000-19-002-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

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

TARGET AUDIENCE:
This Symposium will be useful for pharmacologists, drug development professionals, ADME scientists, regulatory specialists, physicians, nephrologists and gerontologists.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Explain the physiological and medical aspects of chronic kidney disease as it relates to drug development;
2. Differentiate between the US and EU guidelines for conducting renal impairment studies;
3. Describe the various strategies which can be employed to address the requirements of conducting a renal impairment study based on the actual ADME characteristics of the drug in development;
4. Demonstrate renal impairment studies to meet the regulatory guidelines which are executable and medically manageable.

10:00 – 10:10 AM
Lorraine M. Rusch, PhD, President, High Point Clinical Trials Ctr

10:10 – 10:30 AM
Medical Management of Renally-impaired Patients
Robert J. Noveck, MD, PhD, Principal, Noveck Consultancy

10:30 – 10:55 AM
The Drug Developer’s Approach to Evaluating Renally-impaired Patients as Part of an NDA Submission
Bruce Morimoto, PhD, Vice President, Alkahest Inc, Drug Development Operations

10:55 – 11:15 AM
The Challenge of Patient Identification, Enrollment & Medical Management of Renally-impaired Patients
Clayton A. Dehn, MS, Vice President, High Point Clinical Trials Ctr, Clinical Pharmacology Svcs

11:15 – 11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Communicating Your Science: An Integrated Scientific Writing Symposium & Workshop for Early-stage Professionals & Trainees

DEVELOPMENT & PATIENT-CENTRIC TRACKS
Offers both CME & CPE Credit
UAN #0238-0000-19-003-L04-P
ACPE – 3 CONTACT HOURS/APPLICATION-BASED

CO-CHAIRS:
Matthew B. Dufek, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics
Oliver Grundmann, PhD, Clinical Associate Professor, Director, Univ of Florida Coll of Pharmacy, Medicinal Chemistry

TARGET AUDIENCE:
This Symposium will be useful for graduate students, postdoctoral fellows/trainees and early-stage professionals in academia, government and industry.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Identify writing skills which are essential for the communication of scientific research and work;
2. List the key steps of outlining, drafting, editing and submitting a manuscript to communicate research to the scientific community or within current careers in clinical pharmacology;
3. Demonstrate the process of writing, reviewing, editing and revising draft scientific manuscripts to improve the likelihood of acceptance and provide a high-quality revised manuscript;
4. Describe different manuscript formats (brief reports, short communications, expert opinions, full-length articles and review articles), journal differences and appropriate supporting documents/supplemental material that are necessary for communication of scientific research.

1:30 – 1:40 PM
Communicating Your Science
Matthew B. Dufek, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

1:40 – 2:10 PM
From Blank Screen to Published Article: How to Get Started Communicating & Publishing Your Research as a Graduate Student, Trainee or Early-stage Professional in Clinical Pharmacology
Joseph S. Bertino, PharmD, Editor-in-Chief, The Journal of Clinical Pharmacology

2:10 – 2:40 PM
Putting the Pieces Together: The Elements of a Good Scientific Manuscript
David J. Greenblatt, MD, Professor, Tufts Univ School of Medicine

2:40 – 3:00 PM
The Big Black Box: The Review & Revision Process of Your Manuscript Explained & How It Helps You in Writing Your Manuscript
Stephan Schmidt, BPharm, PhD, Associate Director, Univ of Florida, Ctr for Pharmacometrics & Systems Pharmacology

3:00 – 3:30 PM / Break

3:30 – 5:00 PM
Interactive Hands-on Scientific Writing Workshop for Graduate Students, Trainees or Early-stage Professionals in Clinical Pharmacology
Jane E. Ranshaw, MBA, President, Jane Ranshaw & Associates Inc and Oliver Grundmann, PhD, Clinical Associate Professor, Director, Univ of Florida Coll of Pharmacy, Medicinal Chemistry
Pediatric Therapeutic Drug Monitoring & Drug Development in the Age of Pharmacometrics, an ISoP/ACCP Clinical Pharmacometrics Special Interest Group Jointly-sponsored Symposium

DEVELOPMENT & PATIENT-CENTRIC TRACKS
Offers both CME & CPE Credit
UAN #0238-9999-19-004-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Marc H. Scheetz, PharmD, Professor, Midwestern Univ, Chicago Coll of Pharmacy, Pharmacy Practice & Coll of Graduate Studies, Pharmacology
John Carl Panetta, PhD, Biomedical Modeler, St Jude Children’s Research Hosp, Pharmaceutical Sciences

TARGET AUDIENCE:
This Symposium will be useful for all parties interested in new therapeutic drug monitoring (TDM) methods in the setting of pediatrics, including physicians, pharmacists, nurse practitioners, physician assistants, clinical pharmacologists, pharmacometricians, academic and government researchers, regulators and health profession educators.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Summarize the advancements in pediatric TDM research and implementation in the age of pharmacometrics;
2. Evaluate different applications of pharmacometric TDM tools in the clinical care of pediatric patients;
3. Identify how collaborative efforts between researchers, clinicians and regulatory agencies can facilitate optimal treatment and improved outcomes in patients.

1:30 – 1:40 PM
Introduction: Pediatric Therapeutic Drug Monitoring & Drug Development in the Age of Pharmacometrics
Marc H. Scheetz, PharmD, Professor, Midwestern Univ, Chicago Coll of Pharmacy, Pharmacy Practice & Coll of Graduate Studies, Pharmacology

1:40 – 2:00 PM
Applications of Model-informed Drug Development in Pediatric Patients
Gilbert J. Burckart, PharmD, Associate Director for Pediatrics, US Food & Drug Administration, Office of Clinical Pharmacology

2:00 – 2:25 PM
WAPPS-Hemo: A Global Effort to Improve Hemophilia Prophylaxis Using Pharmacometrics
Andrea Edginton, PhD, Associate Director, Graduate Studies & Research, Associate Professor, Univ of Waterloo, School of Pharmacy

2:25 – 2:45 PM
Therapeutic Drug Monitoring in Pediatric Acute Lymphoblastic Leukemia
John Carl Panetta, PhD, Biomedical Modeler, St Jude Children’s Research Hosp, Pharmaceutical Sciences

2:45 – 3:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Symposia

SUNDAY, SEPTEMBER 15, 2019 | Symposium 5 | 3:30 – 5:00 PM

Real-world Data to Real-world Evidence: Opportunities & Challenges for Clinical Pharmacology & Precision Medicine

DEVELOPMENT & PATIENT-CENTRIC TRACKS

Offers both CME & CPE Credit

UAN #0238-0000-19-005-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Anuradha Ramamoorthy, PhD, Policy Lead, Guidance & Policy Team, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/CDER
Mark Rogge, PhD, Global Head, Takeda Pharmaceuticals Int’l, Quantitative Translational Sciences

TARGET AUDIENCE:

This Symposium will be useful for regulators, industry scientists, clinicians, pharmacists, scientists from academia and others interested in drug development.

GOALS & OBJECTIVES:

Following the completion of this activity, the learner will be able to:
1. Describe the regulatory policy framework in the US that is supporting the broad scope of real-world data (RWD) and real-world evidence (RWE) in drug development, approval and patient care;
2. Identify potential roles for RWD and RWE to improve drug development and patient care;
3. Discuss potential roles, opportunities and challenges for clinical pharmacology and precision medicine in generating RWE.

3:30 – 3:45 PM

Real-world Evidence: What is It? What Can It Do for Us?

Anuradha Ramamoorthy, PhD, Policy Lead, Guidance & Policy Team, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/CDER

3:45 – 4:05 PM

Integrating Clinical & Genomic Data to Improve Patient Care

Sara L. Van Driest, MD, PhD, Assistant Professor, Vanderbilt Univ Medical Ctr, Pediatrics & Medicine

4:05 – 4:25 PM

RWD, RWE & the Need for Collaboration

Shiew-Mei Huang, PhD, Deputy Director, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/CDER

4:25 – 4:45 PM

Real-world Data Will Transform Translational Research & Development

Mark Rogge, PhD, Global Head, Takeda Pharmaceuticals Int’l, Quantitative Translational Sciences

4:45 – 5:00 PM

Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Ushering in the Age of Individualized Dosing: Where Do We Go From Here?

PATIENT-CENTRIC TRACK

Offers both CME & CPE Credit
UAN #0238-0000-19-022-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

PRESENTER:
Diane R. Mould, President, Projections Research Inc

TARGET AUDIENCE:
This Presentation will be useful for an interprofessional audience of physicians, pharmacists, pharmacologists and other prescribers.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Explain the need for individualized dosing;
2. List the regulatory and medical concerns for individualized dosing;
3. Identify the reasons for therapeutic failures of biologics;
4. Describe the application of Bayesian approaches to dose selection;
5. Explore the impact on current standard medical practice.

Diane R. Mould is the recipient of the 2019 Roger Jelliffe Individualized Therapy Award.

See Dr Mould's bio.
Model-informed Drug Development for Long-acting Injectable Products

DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #0238-0000-19-006-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Lanyan (Lucy) Fang, PhD, Associate Director (Acting), US Food & Drug Administration, Quantitative Methods & Modeling, Office of Research & Standards, Office of Generic Drugs, CDER
Viera Lukacova, PhD, Director, Simulations Plus Inc, Simulation Sciences

TARGET AUDIENCE:
This Symposium will be useful for clinical pharmacology and modeling & simulation scientists.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Describe opportunities and challenges in the development of long-acting injectable products;
2. Identify opportunities for model-informed drug development for new and generic long-acting injectable products;
3. Discuss challenges and opportunities from a regulatory perspective.

10:00 – 11:30 AM
Model-informed Drug Development for Long-acting Injectable Products
Lanyan (Lucy) Fang, PhD, Associate Director (Acting), US Food & Drug Administration, Quantitative Methods & Modeling, Office of Research & Standards, Office of Generic Drugs, CDER

10:00 – 10:10 AM
Model-informed Drug Development for Long-acting Injectable Products
Lanyan (Lucy) Fang, PhD, Associate Director (Acting), US Food & Drug Administration, Quantitative Methods & Modeling, Office of Research & Standards, Office of Generic Drugs, CDER

10:10 – 10:30 AM
Opportunities & Challenges for Modeling & Simulation in Development of Long-acting Injectable Products
Satish Sharan, PhD, Visiting Associate, US Food & Drug Administration, Quantitative Methods & Modeling, Office of Research & Standards, Office of Generic Drugs, CDER

10:30 – 11:00 AM
Application of a Physiologically-based Pharmacokinetic Modeling Approach in the Development of Long-acting Injectable Products
Viera Lukacova, PhD, Director, Simulations Plus Inc, Simulation Sciences

11:00 – 11:20 AM
Development of Model-informed Strategies for Long-acting Injectable Products
Mats Karlsson, PhD, Professor of Pharmacometrics, Uppsala Univ, Pharmaceutical Biosciences

11:20 – 11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
**The Opioid Crisis: The Accompanying Increase in Infectious Diseases & How the Crisis Can Be Mitigated**

**PATIENT-CENTRIC TRACK**

Offers both CME & CPE Credit  
UAN #0238-0000-19-007-L01-P  
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

**CHAIR:**  
Samer El-Kamary, MD, MS, MPH, Clinical Reviewer, US Food & Drug Administration, Antiviral Products, CDER and Adjunct Associate Professor, Univ of Maryland School of Medicine

**TARGET AUDIENCE:**  
This Symposium will be useful for physicians, pharmacists, researchers, clinical pharmacologists and healthcare professionals from regulatory agencies, academia, industry and clinical settings.

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

1. Define the magnitude of the opioid crisis and the recent changes to prescription guidelines;
2. Identify the increase in infectious disease incidence due to the opioid crisis;
3. Describe state-of-the-art knowledge regarding current therapies and innovative molecules for opioid use disorder;
4. Identify challenges conducting clinical trials in patients with opioid use disorder.

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10:00 – 10:10 AM  
**The Intersection of the Opioid Crisis & Infectious Diseases**  
Shyam Kottilil, MD, PhD, Professor, Univ of Maryland, Inst of Human Virology

10:10 – 10:30 AM  
**Interactions Between Anti-infectives & Opioids: What Do We Know?**  
Hazem E. Hassan, PhD, MS, RPh, Clinical Pharmacologist, US Food & Drug Administration, Office of Clinical Pharmacology, CDER

10:30 – 10:55 AM  
**Challenges Conducting Clinical Trials of New Anti-infective Drugs in Individuals With Opioid Use Disorder**  
Samer El-Kamary, MD, MS, MPH, Clinical Reviewer, US Food & Drug Administration, Antiviral Products, CDER and Adjunct Associate Professor, Univ of Maryland School of Medicine

10:55 – 11:20 AM  
**Current Therapies for Opioid Use Disorder & New, Safer Analgesics Under Development**  
Andrew Coop, PhD, Professor, Univ of Maryland School of Pharmacy

11:20 – 11:30 AM  
**Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations**
Clinical Drug Development for Modified-release Drug Products: Regulatory Considerations & Application of Model-informed Exposure-Response Analysis to Waive Efficacy Studies

DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #0238-0000-19-008-L01-P
ACPE – 3 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:
Bilal AbuAsal, PhD, Clinical Pharmacologist, US Food & Drug Administration, OMPT/CDER/OTS/OCP

TARGET AUDIENCE:
This Symposium will be useful for scientists working in clinical drug development and regulatory agencies and scientists/academics working in the field of biopharmaceutics and clinical pharmacology.

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

1. Describe regulatory considerations for modified-release drug development from a clinical pharmacology perspective and gain insight into US Food & Drug Administration review experience with modified-release drug development;
2. Analyze case examples where model-based exposure-response analysis was used to waive efficacy studies by establishing a bridge between the modified-release product and a reference immediate-release product;
3. Evaluate the application of a mechanistic physiologically-based pharmacokinetic in vitro/in vivo correlation approach to develop a modified-release product by targeting a desired pharmacokinetic profile.

1:30 – 1:45 PM
Regulatory & Clinical Pharmacology Considerations for Clinical Drug Development of Modified-release Drug Products
Mehul Mehta, PhD, Director, US Food & Drug Administration, Clinical Pharmacology I, OCP/CDER

1:45 – 2:10 PM
Regulatory Experience With Modified-release Drug Development
Bilal AbuAsal, PhD, Clinical Pharmacologist, US Food & Drug Administration, OMPT/CDER/OTS/OCP

2:10 – 2:35 PM
Application of Exposure-Response Analyses to Establish the Pharmacodynamic Similarity of a Once-daily Regimen to an Approved Twice-daily Dosing Regimen for the Treatment of HCV Infection
Rajeev M. Menon, PhD, Senior Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

2:35 – 3:00 PM
Application of Model-informed Development to Support the Registration of a Once-daily Regimen of an Extended-release Formulation
Sriram Krishnaswami, PhD, Medicine Team Lead, Pfizer Inc, Global Product Development and Manisha Lamba, PhD, Director, Celgene Corp, Clinical Pharmacokinetics and Modeling & Simulation

3:00 – 3:30 PM / Break

3:30 – 4:00 PM
Case Study of the Evaluation of a Flexible Drug Concentration Monitoring Approach in Patients Receiving Extended-release Tablets of a Narrow Therapeutic Index Drug
Daniel R. Stevens, PharmD, Director of Medical Affairs, Veloxis Pharmaceuticals Inc

4:00 – 4:30 PM
Utility of Mechanistic In Vitro/In Vivo Correlation & Mechanistic In Vitro Dissolution Modeling in the Development of Modified-release Formulations
Viera Lukacova, PhD, Director, Simulations Plus Inc, Simulation Sciences

4:30 – 5:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Latest Advances in Treatment, Prophylaxis & Pharmacogenomics of HIV

PATIENT-CENTRIC TRACK
Offers both CME & CPE Credit
UAN #0238-0000-19-009-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

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

TARGET AUDIENCE:
This Symposium will be useful for distilling information, both evidence-based and theoretical, to the target audience of clinicians, pharmacists and scientists in practice, as well as in clinical research and drug development environments.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Discuss current treatments of HIV infection;
2. Demonstrate the role of genetics in HIV infection treatment;
3. Explain strategies for the prevention of HIV infection;
4. Discuss the regulatory issues for developing new therapies for the treatment and prevention of HIV-1 infection.

1:30 – 1:50 PM
Challenges of HIV Infection Treatment
Susan E. Cohn, MD, MPH, Professor of Medicine, Northwestern Univ Feinberg School of Medicine

1:50 – 2:10 PM
Pharmacogenetics of HIV Drugs: A Focus on Integrase Inhibitors
Sam Harirforoosh, PharmD, PhD, Associate Professor, East Tennessee State Univ Coll of Pharmacy, Pharmaceutical Sciences

2:10 – 2:30 PM
Development of HIV Pre-exposure Prophylaxis that Provides Essential CHOICE for Populations at Risk
Craig W. Hendrix, MD, Wellcome Professor & Director, Johns Hopkins Univ School of Medicine, Clinical Pharmacology

2:30 – 2:50 PM
Regulatory Perspectives on the Development of Products for the Treatment & Prevention of HIV-1 Infection
Kimberly A. Struble, PharmD, US Food & Drug Administration, CDER, Antiviral Products

2:50 – 3:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Convergence of Therapeutic Approaches in Oncology & HIV to Target Immune Evasion: Integrating Clinical Pharmacology Lessons Learned

DEVELOPMENT & PATIENT-CENTRIC TRACKS

Offers both CME & CPE Credit

UAN #0238-0000-19-010-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Mariam Ahmed, PhD, Staff Fellow, US Food & Drug Administration, OMPT/CDER/OTS/OCP
Daria Stypinski, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology, Oncology & Global Product Development

TARGET AUDIENCE:
This Symposium will be useful for oncology and infectious disease practitioners and researchers.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Compare the overlapping mechanisms in HIV and cancer that have made similar treatment strategies possible;
2. Identify approaches from HIV research that are being utilized in oncology and apply clinical pharmacology lessons learned;
3. Identify approaches from oncology that are being evaluated in HIV research and apply clinical pharmacology lessons learned;
4. Explain how the role and skill set required of clinical pharmacologists are being transformed by the emergence of combination therapy approaches and the transition to immune targeting.

3:30 – 3:40 PM
Convergence of Therapeutic Approaches in Oncology & HIV to Target Immune Evasion: Integrating Clinical Pharmacology Lessons Learned from Combination Drug Regimens, Checkpoint Inhibitors, CAR-Ts & Other Approaches
Mariam Ahmed, PhD, Staff Fellow, US Food & Drug Administration, OMPT/CDER/OTS/OCP

3:40 – 3:55 PM
HIV & Cancer Curative Approaches: Cross-disciplinary Research
Steven G. Deeks, MD, Professor of Medicine in Residence, Univ of California San Francisco

3:55 – 4:15 PM
Lessons Learned from HIV Drug Development That Can Be Utilized in Oncology
Islam R. Younis, PhD, Director, Astellas Pharma USA Inc, Clinical Pharmacology & Exploratory Development

4:15 – 4:30 PM
Clinical Pharmacology Challenges in the Development of Immuno-oncology Agents
Akintunde Bello, PhD, Head, Bristol-Myers Squibb Co, Clinical Pharmacology & Pharmacometrics

4:30 – 4:50 PM
From Antivirals to Immuno-oncology: Changing Expectations in the Era of Combination Therapies & Immune Target Modalities
Daria Stypinski, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology, Oncology & Global Product Development

4:50 – 5:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Considerations for Expanding Oncology Trial Eligibility Criteria to Include Patients With Organ Impairment

DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #0238-0000-19-011-L01-P
ACPE – 3 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Joanna C. Masters, PharmD, Associate Director, Pfizer Inc, Clinical Pharmacology & Pharmacometrics, Global Product Development
April M. Barbour, PhD, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics

TARGET AUDIENCE:
This Symposium will be useful for clinical oncology providers treating patients with renal or hepatic impairment within or outside of clinical trials and for clinical pharmacologists in academia, industry or regulatory designing or reviewing oncology clinical trials and/or informing dose regimen selection for special populations within or outside of a clinical trial.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Highlight the role of clinical pharmacologists in determining trial inclusion/exclusion criteria, including generation and interpretation of nonclinical and early clinical data, physiologically-based pharmacokinetic, population pharmacokinetic or pharmacokinetic/pharmacodynamic models and human ADME data;
2. Evaluate the risks and benefits of expanding trial eligibility criteria to include organ-impaired patients in oncology trials based on the amount of total data available at that time in development;
3. Formulate a robust clinical pharmacology strategy for a drug in development, including incorporation of data generated from trials with expanded eligibility criteria to include organ-impaired patients;
4. Explain how to treat special population patients within a larger clinical trial using expanded eligibility criteria.

8:00 – 8:10 AM
Introduction & Overview of Oncology Trial Eligibility Criteria Initiatives & the Role of Clinical Pharmacology
Joanna C. Masters, PharmD, Associate Director, Pfizer Inc, Clinical Pharmacology & Pharmacometrics, Global Product Development

8:10 – 8:40 AM
Clinical Pharmacology Data Supporting Inclusion of Organ-impaired Patients in Oncology Trials: A Regulatory Perspective
Atiqur Rahman, PhD, Director, US Food & Drug Administration, Clinical Pharmacology V, Office of Clinical Pharmacology, OTS/CDER

8:40 – 9:05 AM
Considerations for Study Design & Primary Analysis When Including Populations of Organ-impaired Patients in Oncology Clinical Trials
Thomas Gwise, PhD, Deputy Division Director, US Food & Drug Administration, DBV/CDER/OTS/OB

9:05 – 9:30 AM
How to Expand Oncology Clinical Development Plans to Promote Inclusion of Organ-impaired Patients: Cross-functional Considerations in Industry
Kourosh Parivar, MPharm, Vice President & Head, Pfizer Inc, Oncology Clinical Pharmacology

9:30 – 10:00 AM / Break

10:00 – 10:30 AM
Challenges & Opportunities When Treating Organ-impaired Patients in Early- & Late-phase Oncology Trials
Anthony W. Tolcher, MD, Director of Clinical Research & Co-Founder, Next Oncology

10:30 – 10:55 AM
Quantitative Clinical Pharmacology to Support Dosing in Special Populations
April M. Barbour, PhD, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics

10:55 – 11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Anticipate, Formulate, Adapt & Operate: Innovative Approaches for Clinical Pharmacologists to Impact Drug Development Through Clinical Trial Design

DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #0238-0000-19-012-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Ravi Shankar Prasad Singh, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology, Early Clinical Development, Worldwide Research & Development
Indranil Bhattacharya, PhD, Director, Biogen, Clinical Pharmacology & Pharmacometrics

TARGET AUDIENCE:
This Symposium will be useful for students and professionals from industry and academia working in drug development and actively involved in clinical trial design.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Identify current and future trends in clinical trial designs in oncology and non-oncology therapeutic areas;
2. List the challenges and opportunities of innovation in pediatric study designs;
3. Analyze the differences in approaches of trial design for different therapeutic areas;
4. Describe innovative strategies in clinical trial design.

8:00 – 8:15 AM
Applying the Best of Oncology Drug Development Paradigms to the Non-malignant Space
Indranil Bhattacharya, PhD, Director, Biogen, Clinical Pharmacology & Pharmacometrics

8:15 – 8:35 AM
Innovation in Late-phase Oncology Drug Development
Lokesh Jain, PhD, Director, Merck & Co, Quantitative Pharmacology & Pharmacometrics

8:35 – 8:50 AM
Approaches to Improve Oncology Clinical Trials: Adapt, Modify & Overcome
Diane R. Mould, PhD, President, Projections Research Inc

8:50 – 9:05 AM
Novel Clinical Trial Designs: Opportunities & Challenges in Early Development
Ravi Shankar Prasad Singh, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology, Early Clinical Development, Worldwide Research & Development

9:05 – 9:20 AM
Innovative Approaches in Pediatric Study Design: A Regulatory Perspective
Lily (Yeruk) Mulugeta, PharmD, Associate Director, US Food & Drug Administration, Pediatric & Maternal Health

9:20 – 9:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Human Pharmacodynamic Models Supporting Decision Making in Neuroscience Drug Development

DEVELOPMENT TRACK

Offers both CME & CPE Credit
UAN #0238-0000-19-013-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:
Tong Zhu, PhD, Executive Director, Astellas Pharma Global Development, Clinical Pharmacology & Exploratory Development

TARGET AUDIENCE:
This Symposium will be useful for academic, industrial and regulatory scientists who are interested in translational medicine, drug discovery and development.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Define the required clinical evaluation to establish a human pharmacology model for decision making;
2. Describe when/how pharmaceutical companies conduct human pharmacology studies during clinical development for early decision making;
3. List different decisions that can be made using human pharmacology results such as go/no-go for a compound, dose selection and personalized treatment.

10:00 – 10:10 AM
Challenges of Neuroscience Drug Development & the Role of Human Pharmacology Models in Early Development
Tong Zhu, PhD, Executive Director, Astellas Pharma Global Development, Clinical Pharmacology & Exploratory Development

10:10 – 10:30 AM
Klaus Schaffler, MD, Managing & Medical Director, Human Pharmacodynamic Research

10:30 – 10:50 AM
A Polysomnography Study in Healthy Volunteers to Evaluate the Central Nervous System Pharmacodynamic Effects of ASP8062, a GABAb Receptor Positive Allosteric Modulator
Mark Walzer, PhD, Director, Astellas Pharma Global Development, Clinical Pharmacology & Exploratory Development

10:50 – 11:10 AM
Electroencephalography & Event-related Potentials: Future Clinical Use of Neurophysiological Biomarkers to Predict & Monitor Treatment Response for Schizophrenia
Gregory A. Light, PhD, Professor & Deputy Vice Chair, Univ of California San Diego, Psychiatry Education & Training and Director, Veterans Administration San Diego Healthcare System, Mental Health Research & Mental Illness Research, Education & Clinical Ctr

11:10 – 11:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Emerging Technologies in Quantitative Pharmacology: Balancing Resources, Gaining Efficiencies & Cutting Costs

DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #0238-0000-19-014-L01-P
ACPE – 3 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
April M. Barbour, PhD, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics
Navin Goyal, PhD, Director, GlaxoSmithKline plc, Clinical Pharmacology

TARGET AUDIENCE:
This Symposium will be useful for quantitative pharmacologists who wish to gain an understanding of emerging technologies for pharmacokinetic analyses.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Highlight the breadth of model-based drug development by examining historical and emerging technologies;
2. Examine the efficiencies of novel or emerging technologies and also the challenges that accompany implementation of new software;
3. Discuss the current application of novel tools and whether there is any risk, regulatory or other, of using novel tools compared to those which are considered the gold standard;
4. Describe where the field of quantitative pharmacology is going over the next 5–10 years with regard to which tools may become more or less applied.

1:30 – 1:40 PM
Emerging Technologies in Quantitative Pharmacology: An Introduction
Navin Goyal, PhD, Director, GlaxoSmithKline plc, Clinical Pharmacology

1:40 – 2:00 PM
Applied & Emerging Technologies for Model-based Drug Development
April M. Barbour, PhD, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics

2:00 – 2:25 PM
An Industry Perspective on Allocating Resources & Balancing Budgets in a Diversifying Field
Megan Gibbs, PhD, BScPharm, Vice President, AbbVie Inc, Clinical Pharmacology & Pharmacometrics Therapeutic Areas

2:25 – 3:00 PM
An Academic Perspective on Training the Future Quantitative Pharmacologist: Casting a Wide Net or Choosing an Area of Expertise
Richard C. Brundage, PhD, Professor, Univ of Minnesota, Experimental & Clinical Pharmacology

3:00 – 3:30 PM / Break

3:30 – 4:00 PM
A Regulatory Perspective on Conducting & Reviewing Analyses Which Utilize Emerging Technologies
Yaning Wang, PhD, Director, US Food & Drug Administration, Pharmacometrics, Office of Clinical Pharmacology, CDER

4:00 – 4:40 PM
Considerations & Future Directions for the Development of Open-source Pharmacometric Software
Marc R. Gastonguay, PhD, Chief Executive Officer & Founder, Metrum Research Group

4:40 – 5:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Optimizing Therapy & Accelerating Drug Development in Oncology Using Surrogate Endpoints

DEVELOPMENT & PATIENT-CENTRIC TRACKS

Offers both CME & CPE Credit
UAN #0238-0000-19-015-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Neeraj Gupta, PhD, Senior Scientific Director, Takeda Pharmaceuticals USA Inc, Quantitative Clinical Pharmacology
Kevin J. Freise, PhD, Scientific Director, AbbVie Inc, Oncology Early Development

TARGET AUDIENCE:
This Symposium will be useful for attendees from academia, industry and clinicians. It will also benefit an audience which is interested in oncology drug development and developing drugs for rare diseases.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Define surrogate endpoints and explain why surrogate endpoints are needed in many types of cancer;
2. Explain the regulatory requirements to establish surrogacy of endpoints;
3. List the benefits and risks of the use of surrogate endpoints in place of established clinical endpoints;
4. Describe surrogate endpoints to clinical decision making and acceleration of drug development.

1:30 – 1:40 PM
Introduction: Optimizing Therapy & Accelerating Drug Development in Oncology Using Surrogate Endpoints
Neeraj Gupta, PhD, Senior Scientific Director, Takeda Pharmaceuticals USA Inc, Quantitative Clinical Pharmacology

1:40 – 2:05 PM
Clinical Relevance of Patient-specific Biomarkers Used to Optimize Cancer Treatment
William Douglas Figg, PharmD, Senior Investigator, National Cancer Inst, Molecular & Clinical Pharmacology Program

2:05 – 2:30 PM
Surrogate Endpoints in Regulatory Decision Making
Vishal Bhatnagar, MD, Medical Officer, US Food & Drug Administration, Hematology Products, CDER

2:30 – 2:50 PM
Optimizing Therapy Based on Surrogate Endpoints: An Integrated Semi-mechanistic Model of Minimal Residual Disease Response to Venetoclax Treatment in Chronic Lymphocytic Leukemia
Kevin J. Freise, PhD, Scientific Director, AbbVie Inc, Oncology Early Development

2:50 – 3:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Complex Innovative Methodologies in Oncology Clinical Trials: Towards Accelerating Development of Anti-cancer Therapies

DEVELOPMENT TRACK
Offers both CME & CPE Credit
UAN #0238-0000-19-016-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Amal Ayyoub, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology, Office of Translational Sciences, CDER
Yingxue Chen, PhD, Director of Quantitative Clinical Pharmacology, AstraZeneca plc, Early Clinical Development

TARGET AUDIENCE:
This Symposium will be useful for clinical drug development professionals, including clinical pharmacologists, biostatisticians and medical professionals involved in the planning and design of clinical trials.

GOALS & OBJECTIVES:
Following the completion of this activity, the learner will be able to:
1. Explore innovative methodologies implemented in oncology clinical trials (master protocols [umbrella, basket, platform trials]), expansion cohorts and adaptive designs that span drug development from First-in-Human to Phase 3 trials;
2. Describe the benefits of complex innovative methodologies and the challenges associated with implementation;
3. Explain the regulatory perspective on best practices to inform oncology drug development and approval of therapies.

3:30 – 3:50 PM
Complex Innovative Designs in Oncology Drug Development: An Overview
Amal Ayyoub, PhD, Clinical Pharmacology Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology, Office of Translational Sciences, CDER

3:50 – 4:10 PM
Advanced Trial Designs in Oncology Drug Development
Yingxue Chen, PhD, Director of Quantitative Clinical Pharmacology, AstraZeneca plc, Early Clinical Development

4:10 – 4:30 PM
A Generalized Design for Confirmatory Basket Trials
Robert A. Beckman, MD, Professor of Oncology & Biostatistics, Bioinformatics & Biomathematics, Georgetown Univ Medical Ctr, Lombardi Comprehensive Cancer Ctr & Innovation Ctr for Biomedical Informatics

4:30 – 4:50 PM
Use of Historical Data in the Design & Analysis of Oncology Clinical Trials
Nidal Al-Huniti, PhD, Executive Director & US Oncology Lead, AstraZeneca plc, Quantitative Clinical Pharmacology

4:50 – 5:00 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Why Join ACCP?

Your membership in ACCP now gets you more and is your way to stay at the top of your professional game!

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

ACCP Member Benefits get you there!

- **Coming in 2019 – ACCP365 Mobile App** providing ease of access to all things ACCP any place, anytime and **Engagement Scoring** that reflects your participation in ACCP activities.
- **Discounted registration for the ACCP Annual Meeting**, your source for current, interprofessional ACCME- & ACPE-accredited Continuing Education programs in a Live format.
- **Networking opportunities** and, for Students, Trainees & Early-stage Professionals, access to Mentors.
- **Opportunity to enhance your leadership skills** by volunteering for one of ACCP’s many committees or by Mentoring Students, Trainees & Early-stage Professionals.
- **Opportunity to develop educational activities** that make a difference by submitting proposals for ACCP educational events and getting involved in the clinical pharmacology community.
- **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.
- **Free CME and CPE credits on selected articles** in *The Journal of Clinical Pharmacology*.
- **Free online educational activities.** Our program of online educational courses provides 24/7 access to Live and On Demand events.
- **Free access to Annual Meeting recorded events** for Annual Meeting attendees and discounted access for other Members.
- **Access to the ACCP Job Center** to view jobs and post your resume.
- **Receipt of information from the clinical pharmacology community** for Members who opt in to receive the daily news format, routine recall/drug safety notices from FDA Medwatch, FDA Bursts or AAMC notifications.
- **Receipt of routine updates from ACCP** about developments in the field of clinical pharmacology and future ACCP events.

**ACCP Member Testimonial**

“Certainly there were times when I was asking myself if I needed yet another professional membership, there are so many to choose from and one may think they offer similar benefits. But yet ACCP membership has provided me with more than just the obvious benefits of the Annual Meeting registration discount, The Journal of Clinical Pharmacology subscription, the email notifications (which are very applicable to clinical practice) and various other discounts. It is the Members that I have connected with, the collaborations that have grown into friendships over the years and the colleagues I can turn to when I need constructive criticism. It is not a sworn club that is closed to newbies, quite the opposite, just as I have been welcomed a decade ago so does the ACCP tradition continue today. So come on over and say hi!”

— Oliver Grundmann, PhD, MS, MEd, Director of Online Graduate Education Programs, Pharmaceutical Chemistry & Clinical Toxicology, Univ of Florida

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](http://www.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 KYoung@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 5, 2019
- September 14, 2019

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

JOIN TODAY AND SAVE

Save $575 or more on your registration by joining ACCP today and enjoy Member Benefits all year! ACCP Members receive access to the latest scientific research via ACCP publications (The Journal of Clinical Pharmacology and Clinical Pharmacology in Drug Development), 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.

2019 ACCP ANNUAL MEETING Sept 15 – 17, 2019 • Fairmont Chicago Millennium Park, Chicago, IL

We hope you can join us in Chicago as we celebrate 50 years of ACCP supporting the clinical pharmacology community. Join your colleagues at the 50th Anniversary Gala for a festive evening of music and merriment on Saturday, September 14th, as we reminisce about the past 50 years and set our sights on the future. You don’t want to miss this celebration which will include music, raffles, a video montage, a professional photographer and more to commemorate this historic event in ACCP’s history.

ACCP continues to offer exciting tools for your professional growth and remains committed to offering Continuing Medical Education (CME) and Continuing Pharmacy Education (CPE) credits for educational courses. 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. Registration is now open and we encourage you to join a global audience of healthcare professionals in a focused, educational atmosphere that also provides time to network with colleagues, new and old.

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

Save $575 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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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.
The 2019 ACCP Annual Meeting will take place at the Fairmont Chicago Millennium Park, Chicago, IL – an exceptional downtown hotel, located near 400+ acres of protected park space where you’ll enjoy beautiful views of Lake Michigan, Millennium and Grant Parks and the famous Chicago Skyline.

**Hotel**
Fairmont Chicago Millennium Park
200 N Columbus Dr
Chicago, IL 60601
Tel: (800) 526-2008
Group name: American College of Clinical Pharmacology

Located in the heart of downtown Chicago, the Fairmont Chicago Millennium Park is centrally located to many of the Windy City’s most popular attractions, such as the Chicago River Walk, Millennium Park and the Navy Pier, not to mention the shopping and restaurants available on the Magnificent Mile. This beautiful venue is uniquely designed with 63,000 sq ft of unobstructed meeting space and promises a meeting experience unlike any other.

For your benefit, a special room rate of $229 has been established. In addition, the special rate has been extended to three days before and after the meeting.

**Phone Reservations:** Call 800-526-2008 and use the group name American College of Clinical Pharmacology.

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 Fairmont Chicago Millennium Park directly and using the phone reservation code. Solicitations by outside organizations could imperil your personal information and result in problems with your reservation. If you receive communications from anyone other than ACCP Staff or the hotel related to your hotel reservation, please contact ACCP immediately by phone 571-291-3493 ext 3 or via email at Reg@ACCP1.org.

The cutoff date for reservations at this group rate is **Friday, August 23, 2019**. We anticipate that rooms will sell quickly and advise you to make reservations early. After the cutoff date of August 23rd, reservations will be accepted at prevailing rates on a room-available basis and must be booked directly with the hotel.

Please visit our [website](https://book.passkey.com/go/pharmacology2019) for Air & Ground Transportation and Area Attractions information.

**Traveling from outside the United States?** Visitors to the US must have a valid passport. The American College of Clinical Pharmacology® encourages attendees to familiarize themselves with [US Visa requirements](https://travel.state.gov/content/travel/en/us-visas/入境签证/visitor.html) 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](https://travel.state.gov/content/travel/en/us-visas/入境签证/visitor.html).

To request a Letter of Invitation to attend the ACCP Annual Meeting, please complete the form and submit the request via email to Reg@ACCP1.org.
In 2019, ACCP will celebrate its 50th Anniversary, don’t miss the opportunity to be part of this special celebration of 50 years serving the clinical pharmacology community! We are also excited to share the changes we have implemented after conducting interviews with Exhibitor Focus Groups to better meet the needs of our Exhibitors & Sponsors and to enhance the Exhibitor-attendee experience at the ACCP Annual Meeting. Our goal is to provide Exhibitors & attendees with an interactive networking platform that encourages meeting new people face-to-face and fostering long-term relationships with colleagues. These changes include enhancements to the Exhibit Hall layout, the Sponsorship opportunities and Exhibitor concessions. The newly-configured Exhibit Hall layout is designed for a better flow of traffic and much-improved networking space, including during receptions, designated breakfasts and breaks.

Even though we have implemented these changes, our 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.

Commit now to become a Sponsor or Exhibitor at the 2019 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:
• One (1) ticket to the 50th Anniversary Gala per Exhibiting company;
• 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 2019 ACCP Annual Meeting.

The Sponsorship opportunities were expanded to include more variety, flexibility and creativity to fit any budget in an a-la-carte style.
• New Sponsorship Levels;
• New Sponsorship Opportunities which include our recently-released ACCP365 Mobile App, social media wall and photo booth;
• Custom Sponsorships are available upon request.

Check out the 2019 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.
Sponsorship & Exhibit Space Application  
2019 ACCP Annual Meeting

COMPANY NAME _____________________________________________

ADDRESS ________________________________________________

CITY ______________________ STATE ______ ZIP _____________ COUNTRY ____________

CONTACT PERSON NAME____________________________________

PHONE _______ CELL PHONE ___________ EMAIL _____________________________

EXHIBIT SPACE

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

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

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

NO EXHIBIT SPACE - SPONSORSHIP ONLY  Check Here  q

METHOD OF PAYMENT (check one):

q Check** (Payable to ACCP in US Dollars drawn on a US Bank)

q VISA   q American Express   q MasterCard   q 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 2019 ACCP ANNUAL MEETING EXHIBIT FEE

PLEASE PROVIDE THE FOLLOWING WITH YOUR PAYMENT & SUBMISSION OF THIS FORM

1) DESCRIPTION OF COMPANY (50 words or less) - Email to Exhibit@ACCP1.org

2) YOUR COMPANY URL - Email to Exhibit@ACCP1.org

3) A HIGH-RESOLUTION LOGO (300 dpi) EPS, TIF OR JPEG format - Email to Exhibit@ACCP1.org

Closer to the date of the Annual Meeting, we will request information regarding your exhibitor registrations.
Why submit a Proposal for the 2020 ACCP Annual Meeting?

For 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 2020 ACCP Annual Meeting, September 20 – 22, 2020 in Bethesda, MD. 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 2020 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 participants highly recommend involvement in an ACCP Annual Meeting. Come and experience the difference!

All Proposals will be reviewed and scored by the ACCP 2020 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.

ACCP is an Accredited Provider of Continuing Medical Education (CME) by the Accreditation Council for Continuing Medical Education and Continuing Pharmacy Education (CPE) by the Accreditation Council for Pharmacy Education.