Celebrating 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
Join Us for the
2020 ACCP Annual Meeting!

Translating Clinical Pharmacology Research into Patient-centered Care

September 20 – 22, 2020
Bethesda N Marriott Hotel & Conf Ctr
Bethesda, MD

FUTURE MEETINGS:

2021 ACCP Annual Meeting
September 12 – 14, 2021
Renaissance Phoenix Downtown Hotel
Phoenix, AZ

2022 ACCP Annual Meeting
September 25 – 27, 2022
Bethesda N Marriott Hotel & Conf Ctr
Bethesda, MD

2023 ACCP Annual Meeting
September 10 – 12, 2023
Hyatt Regency Bellevue
Bellevue, WA
Did You Know?

Have you downloaded the NEW ACCP365 Mobile App? It’s more than a meeting app!
The NEW ACCP365 Mobile App is ACCP’s year-round access mobile app. More than just a meeting app, it’s an all access pass to all things ACCP, any time, any place! Delete the old ACCP Meeting App and download the ACCP365 Mobile App now to get access to everything you need from ACCP!

Discover: How ACCP365 enhances your experience with ACCP at the Annual Meeting and beyond
Connect: With colleagues and peers throughout the year
Access: Annual Meeting information, On Demand CE webinars, ACCP Journals, ACCP Job Center and more while on the go 24/7/365

Use the Game Zone within ACCP365 while at the Annual Meeting and get points for entering QR codes for the sessions you attend, Tweeting using ACCP365 with the hashtag #2019ACCP, completing session Evaluations & Post-event Self-assessments and testing your memory in the Mindbender Quiz.

Links to Syllabi, Evaluations and Post-event Self-assessments can be found in ACCP365. Don’t forget to put your name on your Evaluations to be included in the daily drawing for gift cards! See page 4 for everything you need to know about the NEW ACCP365 Mobile App.

Attending the Meeting as a Student or Trainee?
ACCP has planned a series of events specifically to benefit Students & Trainees! See page 47 for details.

Attending the Meeting as an Early-stage Professional (1–10 years in first full-time position)?
Join other Early-stage Professionals Monday, 7:30 AM in Cuvee, and learn about programs ACCP is developing to support your professional growth!

Interested in joining ACCP?
Stop by the ACCP Registration Desk for more information and start getting ACCP Member Benefits today!

ACCP’s Continuing Education programs now offer CE credits for the healthcare team!
ACCP is jointly accredited by ACCME, ACPE and ANCC to provide continuing education credits for physicians, pharmacists/pharmacologists and nurses through its educational programs.

Register for the 2020 Annual Meeting at 2019 prices!
Register for the 2020 Annual Meeting before you leave the 2019 Annual Meeting and receive 2019 registration prices. Stop by the ACCP Registration Desk to process your payment for this promotion.

ACCP gratefully acknowledges Frontage Clinical Services for their sponsorship of the ACCP 50th Anniversary Lapel Pins!
In celebration of ACCP’s 50th Anniversary, we have created a Lapel Pin as a gift to all Annual Meeting attendees. Please accept this memento as a token of our appreciation for your support throughout the years.

Thank you to our Sponsors
ACCP is grateful for the support of all 2019 Annual Meeting Sponsors & Supporters, whose generous support permits ACCP to continue to provide an exceptional meeting experience. See pages 48 & 49 for a listing of all Sponsors & Supporters.

Evening Receptions, Exhibit Hall, Poster Sessions and More!
Exhibitor support is critical to the success of the ACCP Annual Meeting. We encourage you to visit our Exhibitors in the Imperial Ballroom-Front during the day and the Evening Receptions to learn about new technologies and service offerings. These exceptional Exhibitors are the leaders in their fields and are anxious to share with you the latest information on how they can help you meet your goals! Please take a moment to thank them for their support. We invite you to get your colleagues together and have some fun playing the Jeopardy Game during the Evening Receptions! Oh, and don’t forget to capture your moment in the photo booth in the Exhibit Hall, sponsored by DUCK FLATS Pharma!

Follow ACCP on

ACCP Registration Desk Hours

Lost & Found
Any found items should be given to ACCP Staff at the ACCP Registration Desk. Persons wishing to retrieve a lost item should also contact ACCP Staff at the ACCP Registration Desk.
The New ACCP365 Mobile App – it’s more than a meeting app!

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

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

ACCP365 also provides pertinent ACCP Annual Meeting information such as:

- Access a list of Attendees, Faculty, Exhibitors & Sponsors
- Use the Connect feature to network directly with Attendees
- Easily review a schedule of daily Sessions, Poster Presentations & Special Events
- Download Pre-meeting Workshop & Symposia Syllabi
- Use the Live Polling feature during certain Pre-meeting Workshops & Symposia
- Direct links to complete Session Evaluations and Post-event Self-assessments
- Take notes specific on Sessions & Attendees
- Ability to participate in ACCP’s NEW Game Zone where you can accumulate points by scanning QR codes associated with Sessions & Events you attend, completing a quiz, utilizing Twitter within ACCP365 to share your experience and pictures during the Annual Meeting, complete Session Evaluations and Post-event Self-assessments. The Attendee with the most points will win a $50 gift card which will be mailed after the ACCP Annual Meeting!
- Learn more about the 2019 ACCP Recognition & Student Award Winners
- Pertinent Hotel & Travel information

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

Connect:
With colleagues and peers throughout the year

Access:
On Demand webinars, ACCP Journals, ACCP Job Center and more while on the go 24/7/365
American College of Clinical Pharmacology®
2019 Annual Meeting
Program Committee

Co-chairs:
Joan Korth-Bradley, PharmD, PhD
Lily (Yeruk) A. Mulugeta, PharmD
Michael J. Fossler Jr, PharmD, PhD

Members:
Vikram Arya, PhD
April M. Barbour, PhD
John S. Bradley, MD
Richard C. Brundage, PharmD, PhD
Jonathan E. Constance, PhD
Gopichand Gottipati, PhD
Navin S. Goyal, PhD
Dionna J. Green, MD
Nitin Mehrotra, PhD
Ahmed Nader, PhD
Natella Y. Rakhmanina, MD, PhD
Arun MM Ram, MBBS, MD
Lorraine M. Rusch, PhD
Catherine MT Sherwin, PhD, MSc

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Astellas Ad – pg. 55, Thieme Ad – pg. 55.
Welcome to the 2019 ACCP Annual Meeting!

Reflecting on Our History & Shaping the Future of Clinical Pharmacology

Welcome to the 2019 Annual Meeting of the American College of Clinical Pharmacology® (ACCP) and thank you for joining us to celebrate our 50th Anniversary!

We look forward to a meeting focused on “Reflecting on Our History & Shaping the Future of Clinical Pharmacology!” 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 A. Mulugeta and Michael J. Fossler Jr, has worked diligently to provide a diverse and exceptional educational program that meets the needs of healthcare professionals and scientists with an interest in one or more of the myriad of applications of clinical pharmacology ranging from research and drug development to patient care. Sessions include four Pre-meeting Workshops, a Plenary Session, the Roger Jelliffe Individualized Therapy Award Presentation and 16 Symposia. A diverse group of international Faculty 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. Invited Keynote, Alex Zhavoronkov, PhD, will present on “Machine Learning: Will We Still Need Clinical Pharmacologists in the Next Decade?”

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

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

Enjoy the chance to socialize and network at the 50th Anniversary Gala, during Evening Receptions and Poster Sessions, at twice-daily tea/coffee breaks, at the Lunch & Awards Sessions and we invite all attendees to learn more about ACCP at the Annual Business Meeting.

For those who are attending the ACCP Annual Meeting for the first time, you will experience for yourself how ACCP makes a difference by providing healthcare professionals and scientists with a forum to exchange knowledge and ideas that promote and expand the value of clinical pharmacology in healthcare and drug development.

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

We welcome you to an outstanding meeting and the celebration of our 50th Anniversary and look forward to your participation and feedback!!
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.

### FRIDAY, SEPTEMBER 13, 2019

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<th>Event</th>
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<tr>
<td>ACCP Registration Desk Open</td>
<td>5:00 – 7:00 PM</td>
<td>B1 Foyer</td>
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<tr>
<td>ACCP Executive Committee Meeting &amp; Dinner (invitation only)</td>
<td>6:00 – 10:00 PM</td>
<td>Ambassador Room</td>
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### SATURDAY, SEPTEMBER 14, 2019

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<tr>
<td>ACCP Registration Desk Open</td>
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<td>B1 Foyer</td>
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<tr>
<td>ACCP Board of Regents Meeting</td>
<td>8:00 AM – 1:00 PM</td>
<td>Cuvee</td>
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**Pre-meeting Workshop 1**

R Basics for Every Clinical Pharmacologist: Easily Create Reproducible Figures, Tables & Diagnostic Plots Using Tidyverse Libraries Such as Dplyr & Ggplot2 (DT)

**Co-Chairs:** Jennifer E. Hibma, PharmD, Clinical Pharmacologist & Pharmacometrician, Pfizer Inc, Global Product Development, Global Pharmacometrics and Gopichand Gottipati, PhD, Reviewer, US Food & Drug Administration, OMPT/CDER/OTS/CP

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<tr>
<td>Pre-meeting Workshop 1</td>
<td>8:00 AM – 12:00 PM</td>
<td>Embassy</td>
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**Pre-meeting Workshop 2**

Clinical Pharmacology: Statistical Aspects & Methods, an ACCP/ASA Jointly-sponsored Workshop (DT & P-CT)

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

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<th>Event</th>
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<tr>
<td>Pre-meeting Workshop 2</td>
<td>8:00 AM – 12:00 PM</td>
<td>State Room</td>
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**Pre-meeting Workshop 3**

Interprofessional Education in Pharmacogenomics, an ACCP/AACP Jointly-sponsored Workshop (DT & P-CT)

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

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<tr>
<td>Pre-meeting Workshop 3</td>
<td>1:30 – 5:30 PM</td>
<td>State Room</td>
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**Pre-meeting Workshop 4**

Decoding the Complexity of Transporter-mediated Drug-Drug Interactions & Recent Advances in Endogenous Biomarkers & Transporter Cocktail Studies (DT)

**Co-Chairs:** Ahmed Nader, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics and Mohamed Elmeliegy, PhD, Associate Director, Pfizer Inc, Clinical Pharmacology

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<td>Pre-meeting Workshop 4</td>
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### SUNDAY, SEPTEMBER 15, 2019

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<tr>
<td>ACCP Registration Desk Open</td>
<td>6:30 AM – 7:00 PM</td>
<td>Imperial Foyer</td>
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**Continental Breakfast**

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<tr>
<td>Continental Breakfast</td>
<td>7:00 – 8:00 AM</td>
<td>Imperial Ballroom - Front</td>
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**New Member & First-time Attendee Welcome**

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<td>New Member &amp; First-time Attendee Welcome</td>
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**Student, Trainee & Early-stage Professional Welcome**

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<td>Student, Trainee &amp; Early-stage Professional Welcome</td>
<td>7:00 – 7:45 AM</td>
<td>Imperial Ballroom - Back</td>
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**Exhibit Hall Open**

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<td>Exhibit Hall Open</td>
<td>7:00 AM – 7:00 PM</td>
<td>Imperial Ballroom - Front</td>
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**Welcome & Opening Remarks by ACCP President**

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<tr>
<td>Welcome &amp; Opening Remarks by ACCP President</td>
<td>7:45 – 8:00 AM</td>
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**Plenary Session**

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<tr>
<td>Plenary Session</td>
<td>8:00 – 9:30 AM</td>
<td>Imperial Ballroom - Back</td>
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**Symposium 1**

Clinical Therapeutics in Obesity: A Tribute to the Work of Darrell R. Abernethy (DT & P-CT)

**Co-Chairs:** David J. Greenblatt, MD, Professor, Tufts Univ School of Medicine and Christina R. Chow, PhD, Head of Research, Emerald Lake Safety

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<td>Symposium 1</td>
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**Symposium 2**

The Evolution of Pharmacokinetic Studies in Patients With Impaired Renal Function: Emerging Designs & Trends (DT)

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

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<td>Symposium 2</td>
<td>10:00 – 11:30 AM</td>
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**Lunch Buffet**

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<tr>
<td>Lunch Buffet</td>
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<td>Imperial Ballroom Foyer</td>
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Program at a Glance

SUNDAY, SEPTEMBER 15, 2019

Lunch & Awards Session
11:45 AM – 1:15 PM | Imperial Ballroom - Back
• ACCP Distinguished Investigator Award
• ACCP Honorary Fellowship Award
• Nathaniel T. Kwit Memorial Distinguished Service Award
• McKeen Cattell Memorial Award

Symposium 3 | 1:30 – 5:00 PM
Communicating Your Science: An Integrated Scientific Writing Symposium & Workshop for Early-stage Professionals & Trainees (DT & P-CT)
CO-CHAIRS: 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)
CO-CHAIRS: 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)
CO-CHAIRS: Anuradha Ramamorthy, PhD, Policy Lead, Guidance & Policy Team, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/CDER and Ivy Song, PhD, Senior Director, Takeda Pharmaceuticals Int’l Inc, Quantitative Clinical Pharmacology

Opening Reception, Exhibits & Poster Session 1
5:00 – 7:00 PM | Imperial Ballroom - Back

MONDAY, SEPTEMBER 16, 2019

ACCP Registration Desk Open
7:00 AM – 7:00 PM | Imperial Foyer

Continental Breakfast
7:30 – 8:30 AM | Imperial Ballroom - Front

Exhibit Hall Open
7:30 AM – 7:00 PM | Imperial Ballroom - Front

Early-stage Professionals Gathering
7:30 – 8:30 AM | Cuvee

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, 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

Lunch Buffet
11:30 AM – 1:15 PM | Imperial Ballroom Foyer

Meet the ISoP/ACCP Special Interest Group
7:30 – 8:30 AM | Rouge

ACCP Public Policy Committee Meeting
7:30 – 8:30 AM | Regal

ACCP Education Committee Meeting
7:30 – 8:30 AM | Royal

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

Lunch & Awards Session
11:45 AM – 1:15 PM | Imperial Ballroom - Back
• ACCP Student Abstract Award Acknowledgements
• Wayne A. Colburn Memorial Award
• ACCP New Member Abstract Award
• ACCP/ISoP SIG Student Abstract Award
• Elliot S. Vesell Student Abstract Award
• JCP & CPDD Top Reviewer Awards
• Roger Jelliffe Individualized Therapy Award Acknowledgement
• Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award

Invited Keynote Address – “Machine Learning: Will We Still Need Clinical Pharmacologists in the Next Decade?” Alex Zhavoronkov, PhD – Founder & Chief Executive Officer, Insilico Medicine Inc

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/OCPP

Rouge
Program at a Glance

Continued

MONDAY, SEPTEMBER 16, 2019

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

Student, Trainee & Early-stage Professional (STEP) Panel Discussion & Career Guidance
1:30 – 3:00 PM | Cuvee

STEP Networking Reception
3:00 – 4:00 PM | Cuvee

STEP Podium Presentations
4:00 – 5:00 PM | Cuvee

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, Director, Pfizer Inc, Clinical Pharmacology, Oncology & Global Product Development
Imperial Ballroom - Back

Evening Reception, Exhibits & Poster Session 2
5:00 – 7:00 PM | Imperial Ballroom - Front

JCP & CPDD Editorial Board Dinner (invitation only)
7:00 – 9:00 PM | Millennium Room

TUESDAY, SEPTEMBER 17, 2019

ACCP Registration Desk Open
7:00 AM – 5:30 PM | Imperial Foyer

Continental Breakfast
7:00 – 8:00 AM | Imperial Foyer

ACCP 2019 – 2020 Annual Meeting Program Committee Meeting
7:00 – 8:00 AM | Cuvee

ACCP Membership Committee Meeting
7:00 – 8:00 AM | Regal

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 & Pharmacometrics, Global Product Development and April M. Barbour, PhD, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics
Rouge

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, Senior Scientific Director, Takeda Pharmaceutical Co Ltd, Quantitative & Translational Sciences
Imperial Ballroom - Back

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
Imperial Ballroom - Back

Lunch Buffet
11:30 AM – 1:15 PM | Imperial Foyer

Lunch & ACCP Annual Business Meeting (open to all)
11:45 AM – 1:15 PM | Imperial Ballroom - Back

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 S. Goyal, PhD, Director, GlaxoSmithKline plc, Clinical Pharmacology
Rouge

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
Imperial Ballroom - Back

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, Quantitative Clinical Pharmacology, AstraZeneca plc, Early Clinical Development
Imperial Ballroom - Back
Alex Zhavoronkov, PhD – Founder & Chief Executive Officer, Insilico Medicine Inc

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

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 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.
Julie A. Johnson, PharmD – Dean & Distinguished Professor, Univ of Florida Coll of Pharmacy

“Precision Medicine: Improving Clinical Outcomes Through Pharmacogenomics”

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.

Julie A. Johnson, PharmD is Dean of the Univ of Florida Coll of Pharmacy and Distinguished Professor of Pharmacy & Medicine. Dr. Johnson’s research focuses on cardiovascular pharmacogenomics and genomic medicine implementation, for which she has been named a Clarivate Analytics Highly Cited Scientist in 2015, 2016, 2017 and 2018 indicating she is in the top 1% of the most highly-cited scientists in her field globally. Dr. Johnson has served in numerous capacities with the National Inst of Health, the US Food & Drug Administration and leadership roles in multiple professional societies, including as President of the American Society of Clinical Pharmacology & Therapeutics. She has received numerous awards and honors and was elected to the National Academy of Medicine in 2014.

Amarnath Sharma, MPharm, PhD – Vice President, Global Head, Clinical Pharmacology & Pharmacometrics, Janssen R&D

“Pharmaceutical R&D: The Challenge & Opportunity”

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.

Amarnath Sharma is Vice President, Global Head of Clinical Pharmacology & Pharmacometrics at Janssen R&D. Dr. Sharma joined Janssen in 2013 from Pfizer Inc, where he held various positions since 2002. Most recently, he was Vice President, Head of Clinical Research & Precision Medicine Group. Before joining Pfizer, he worked at Pharmacia, SmithKline Beecham and Eli Lilly & Co in various therapeutic areas, including oncology, immunology, inflammation, infectious disease and neuroscience. Together he brings over 24 years of broad, cross-functional experience in translational medicine, clinical pharmacology, PK/PD modeling and clinical operations as scientific leader and manager. He has published over 70 manuscripts in peer-reviewed journals and 50 abstracts in diverse areas such as clinical pharmacology, PK/PD modeling and liposome formulation and he holds three patents.

Dr. Sharma earned a PhD in Pharmaceutics from SUNY at Buffalo in 1994. He also holds BPharm & MPharm degrees from the Inst of Technology, Banaras Hindu Univ, India.
Peter H. Wiernik, MD – President, Cancer Research Fdtn
“40 Years of Cancer Treatment Development”

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.

Peter H. Wiernik, MD began his career 48 years ago with the study of anthracyclines. He performed the first randomized clinical trial of daunorubicin compared with standard treatment for adults with acute myeloid leukemia and demonstrated the substantial advantage for anthracyclines, which are still essential for treatment of that neoplasm. Based on pharmacokinetic studies, he designed and conducted the first clinical trial of high-dose intermittent daunorubicin therapy, an approach that has regained favor today. Subsequently, he saved paclitaxel from being discarded by the National Cancer Inst due to highly toxic, even lethal infusion reactions by developing a pretreatment regimen that virtually eliminated those reactions and allowed the drug to become a major treatment for common solid tumors. Dr. Wiernik was instrumental in the Phase 1–3 study of dozens of new agents and the design of many new treatments for leukemia and lymphoma throughout his career. He demonstrated that early-stage Hodgkin lymphoma could be optimally treated with chemotherapy alone, which made staging laparotomy obsolete. He is currently involved in the study of familial hematologic malignancies.

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”
2019 ACCP Recognition Award Winners

Roger Jelliffe Individualized Therapy Award

Dr. Mould's presentation will be given Monday, September 16, 2019, 8:30 – 9:30 AM, Imperial Ballroom - Back

Diane R. Mould, PhD – 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.

Dr. Mould received her PhD in Pharmaceutics and Pharmaceutical Chemistry at The Ohio State Univ (OSU) in 1989. She spent 29 years as a pharmacokineticist in industry where she specialized in population pharmacokinetic/pharmacodynamic modeling. She has conducted population PK/PD analyses of hematopoietic agents, monoclonal antibodies, anti-cancer & anti-viral agents, antipsychotic, cardiovascular and sedative/hypnotic agents. Currently, Dr. Mould is President of Projections Research Inc, a consulting company offering pharmacokinetic and pharmacometric services. She has published 89 peer-reviewed articles, 18 book chapters, made 116 national and international presentations and presented six podium sessions on advanced modeling and simulation approaches. Dr. Mould has authored and presented 105 posters at both national and international meetings. She is an Adjunct Professor at the Univ of Rhode Island, OSU and the Univ of Florida and teaches an annual class on disease progression modeling at the National Inst of Health. She is a member of the editorial board for Journal of Pharmacokinetics & Pharmacodynamics, Clinical Pharmacology & Therapeutics and Clinical Pharmacology & Therapeutics Pharmacometrics & Systems Pharmacology. She is a Fellow of the American College of Clinical Pharmacology® and of the American Association of Pharmaceutical Sciences.

Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award

Guenther Hochhaus, PhD – Professor, Univ of Florida Coll of Pharmacy

“How Can We Further Improve Graduate Education in Clinical Pharmacology?”

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

Dr. Hochhaus received his PhD in 1984 at the Inst of Pharmaceutical Chemistry, Westf. Wihlems Univ (Münster, Germany). He completed a postdoctoral fellowship at the Univ of California San Francisco and subsequently joined the Univ of Florida’s Coll of Pharmacy as an Assistant Professor in 1987, where he continues to serve today as a Professor of Pharmaceutics. Dr. Hochhaus’ research interest is in evaluating inhalation drugs through in vitro and pharmacokinetic approaches. He collaborates with regulatory authorities to improve methodology for drug approval of generic inhalation drugs.

Dr. Hochhaus is a Fellow of the American Association of Pharmaceutical Scientists and the American College of Clinical Pharmacology® (ACCP). In 1998, he was recipient of the Young Investigator Award of the German Airway and Lung Research Society and also received ACCP’s Tanabe Young Investigator Award. He was awarded the Univ of Florida Foundation Research Professorship in 2006 and 2015. He has published more than 200 research papers.
2019 ACCP Recognition Award Winners

ACCP Abstract Awards Program & Member-Get-a-Member Awards
Monday, September 16, 2019 | Lunch & Awards Session | Imperial Ballroom - Back

2019 ACCP Student Abstract Award Acknowledgements
Given for the best abstracts submitted by Students & Trainees for presentation at each year’s Annual Meeting.

Wayne A. Colburn Memorial Award
Honors the memory of the late Wayne A. Colburn, former ACCP President, and will be given for the best paper among the Student & Trainee Award Winners, as judged by an onsite judging team during the Poster Sessions at the Annual Meeting. The winner will be announced during the Monday luncheon and the author will give a short talk outlining the findings of the study.

ACCP New Member Abstract Award
Given for the best abstract submitted by a New Member of ACCP for presentation at the Annual Meeting. Abstracts submitted by New Members will be judged during the Poster Sessions. The winner will be announced during the Monday luncheon and the author will give a short talk outlining the findings of the study.

ACCP/ISoP Special Interest Group (SIG) Student Abstract Award
Identifies areas of submission that are consistent with the SIG’s focus and Student & Trainee abstracts within those areas are reviewed and scored by SIG Leadership. The top scoring of these abstracts is the recipient of the ACCP/ISoP Student Abstract Award. At the time the award is presented, the author presents a short talk outlining the findings of the study.

The Elliot S. Vesell Student Abstract Award
In 2019, in celebration of ACCP’s 50th anniversary and in memory of Dr. Elliot S. Vesell, long-time Fellow, former President & Honorary Regent of ACCP, an award will be given to the top Student Abstract in the area of pharmacogenomics.

2019 ACCP Student & Trainee Abstract Award Winners

• Yaa Y. Anane, BSc (Poster #113)
  East Tennessee State Univ Gatton Coll of Pharmacy

• Mary Gockenbach, BS (Poster #076)
  US Food & Drug Administration

• Abhinav Kurumaddali, BS Pharm, MPharm (Poster #077)
  Univ of Florida

• Sun Kwon, PhD (Poster #095)
  Stanford Univ School of Medicine

• Xiaomei Liu, PharmD (Poster #128)
  Children’s National Medical Ctr

• Pradeep B. Lukka, PhD (Poster #052)
  Univ of Tennessee Health Science Ctr

• Glauco HB Nardotto, PhD (Poster #020)
  School of Pharmaceutical Sciences of Ribeirão Preto

• Sumeet Singla, MS (Poster #078)
  Univ of Iowa

• ACCP/ISoP SIG Student Abstract Award – Mary Gockenbach, BS (Poster #076)
  US Food & Drug Administration

• The Elliot S. Vesell Student Abstract Award – Yaa Y. Anane, BSc (Poster #113)
  East Tennessee State Univ Gatton Coll of Pharmacy

2019 Honors & Awards Committee
Amelia N. Deitchman, PharmD, PhD • Daniel Gonzalez, PharmD, PhD
Mathangi Gopalakrishnan, PhD • Navin S. Goyal, PhD • Matthew Hruska, PharmD, PhD
Naveen Mangal, PhD • Jatinder K. Mukker, PhD • Jian Wang, PhD, MSRS • Peter H. Wiernik, MD
Theodoros Xanthos, MD, MSc Med, PhD • Honghui Zhou, PhD
Educational Accreditation

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.

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

In support of improving patient care, this activity has been planned and implemented by the American Association of College of Pharmacy, the American Statistical Association and the International Society of Pharmacometrics. The American College of Clinical Pharmacology is jointly accredited by the ACCME, the ACPE and the ANCC to provide continuing education for the healthcare team.

Interprofessional Continuing Education Credit (IPCE)
This activity was planned by and for the healthcare team and learners will receive 47.5 Interprofessional Continuing Education (IPCE) credits for learning and change.

Requesting Credits
Attendees wishing to obtain credits must attend one or more CE courses and complete each requested course’s Post-event Self-assessment, Evaluation, claim the credits and PRINT the Certificate(s) no later than October 31, 2019. Beyond that point, requests will incur an administrative late fee of $200. All credit requests must be submitted by no later than December 31, 2019.

CPE Credit 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 upon request.

Other Information
The 2019 ACCP Annual Meeting Program at a Glance can be found on pages 7 – 9.
The ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities™ provides the following definition: A commercial interest is any entity producing, marketing, reselling or distributing healthcare goods or services consumed by, or used on, patients.

The following Faculty participants have indicated a financial relationship with an ACCME-defined commercial interest which may be related to the content of their presentation. These presentations have been peer reviewed by ACCP’s CE Compliance Committee and have been found to be evidence-based, unbiased and non-promotional in nature. Continuing education credits have therefore been awarded. This list is effective as of August 20, 2019. Please contact CE@ACCP1.org with any questions.

Nidal Al-Huniti: employee – AstraZeneca plc
April M. Barbour: employee, ownership interest – Incyte Corp
Robert A. Beckman: ownership interest – Johnson & Johnson; consultant/advisory board – Vertex Pharmaceuticals Inc; consultant/advisory board – Zymeworks, Inc
Akintunde Bello: employee, ownership interest – Bristol-Myers Squibb Co
Indranil Bhattacharya: employee, ownership interest – Biogen; ownership interest – Pfizer Inc; employee – Takeda Pharmaceuticals Int’l Inc
Robert Bies: other research support, research grant – US Food & Drug Administration; speaker/honoraria – Janssen through Belmore Neidrauer LLP; research grant – National Inst of Health; research grant – Takeda Pharmaceuticals Int’l Inc; research grant – US Department of Defense
Peter Bonate: employee – Astellas US Pharma Inc
Yingxue Chen: employee – AstraZeneca plc
Christina R. Chow: employee, ownership interest – Emerald Lake Safety
Susan E. Cohn: consultant/advisory board, received financial material support – Merck & Co Inc
Andrew Coop: employee/co-founder – ALT Pharmaceuticals LLC
John F. Crowley: employee/board chair – Amicus Therapeutics Inc
Steven G. Deeks: consultant/advisory board – AbbVie Inc; consultant/advisory board – Bryologyx Inc; consultant/advisory board – Enochian Biosciences Inc; research grant – Gilead Sciences Inc; research grant – Merck & Co Inc; research grant – ViIV Healthcare
Clayton A. Dehn: employee – High Point Clinical Trials Ctr
Matthew B. Ducfek: employee, ownership interest – AbbVie Inc
Andrea Edginton: ownership interest, receive other type of financial compensation – Design2Code Inc
Mohamed Eimeliegy: employee – Pfizer Inc
Kevin J. Freise: employee, ownership interest – AbbVie Inc
Marc R. Gastonguay: employee – Metrum Research Group
Megan Gibbs: employee, ownership interest – AbbVie Inc
Navin S. Goyal: employee – GlaxoSmithKline plc
Neeraj Gupta: employee – Takeda Pharmaceuticals Int’l Inc
Craig W. Hendrix: research grant – Gilead Sciences Inc; research grant – ViIV Healthcare/GlaxoSmithKline plc
Jennifer E. Hibma: employee – Pfizer Inc
Lokesh Jain: employee – Merck & Co Inc
Mats Karlsson: consultant/advisory board, ownership interest – Pharmetheus AB
Shyam Kottiiil: consultant/advisory board – American Gene Technologies Int’l; research grant – Arbutus Biopharma Corp; consultant/advisory board, research grant – Gilead Sciences Inc; consultant/advisory board – GlaxoSmithKline; consultant/advisory board, research grant – Merck & Co Inc
Sriram Krishnaswami: employee, ownership interest – Pfizer Inc
Manisha Lamba: employee – Celgene Corp
Gregory A. Light: consultant/advisory board – Astellas Pharma US Inc; consultant/advisory board – Heptares Therapeutics; consultant/advisory board – NASA; consultant/advisory board – NeuroSig Inc; consultant/advisory board – US Navy
Joanna C. Masters: employee, ownership interest – Pfizer Inc
Rajeev M. Menon: employee, ownership interest – AbbVie Inc
Bruce Morimoto: employee – Alkahest Inc
Diane R. Mould: consultant/advisory board – Projections Research Inc
Ahmed Nader: employee – AbbVie Inc
Robert J. Noveck: employee – Noveck Consultancy
Daniele Ouellet: employee, ownership interest – Pfizer Inc
Scott Patterson: employee – Sanofi Pasteur
Ana Ruiz-Garcia: employee – Pfizer Inc
Lorraine M. Rusch: employee – High Point Clinical Trials Ctr
Marc H. Scheetz: consultant/advisory board – Achaogen Inc; research grant – Allegra Therapeutics; research grant – CARE Fdn; research grant – Nevakar Inc; consultant/advisory board – SIGA Technologies Inc
Mohamad Shibley: employee – AbbVie Inc
Ravi Shankar Prasad Singh: employee – Bioverativ Inc; employee – Boehringer Ingelheim Pharmaceuticals Inc; employee – Pfizer Inc
Ivy Song: employee – Takeda Pharmaceuticals Int’l Inc

Continued on next page…
Faculty Disclosure Information

Daniel R. Stevens: employee – Veloxis Pharmaceuticals A/S
Peter Stopfer: employee – Boehringer Ingelheim Pharma GmbH & Co KG
Daria Stypinski: employee – Pfizer Inc
Anthony W. Tolcher: consultant/advisory board – Abbvie Inc; Adagene Inc; ADC Therapeutics SA; Agenus Inc; advisory committee/board member, consultant/advisory board – Ascentage Pharma; consultant/advisory board – Bayer Healthcare Pharmaceuticals; Bioinvent Int’l; Birdie Pharmaceuticals USA Inc Inc; Boston Bio Medical Inc; Eleven Biotherapeutics Inc; EMD Serono; Formation Biologics Inc; Gilde Healthcare; Ignyta Inc; Immuneone Inc; ImmunoMet Therapeutics Inc; Jazz Pharmaceuticals plc; Mekanistic Therapeutics LLC; Nanobiotix; NBE-Therapeutics AG; Nuvalent Inc; Pelican Therapeutics Inc; Pierre Fabre Pharmaceuticals Inc; Ridgeway Pharmacy Ltd; Scitemex; Seattle Genetics; advisory committee, board member – Symphogen A/S; speaker/honoraria – Univ of Alabama Birmingham
Mark Walzer: employee – Astellas Pharma US Inc
Islam R. Younis: employee – Astellas Pharma Inc
Tong Zhu: ownership interest – Abbott/AbbVie Inc; employee – Astellas Pharma US Inc

The following Faculty participants have indicated no financial relationships with an ACCME/ACPE-defined commercial interest related to their presentation:

Bilal AbuAsal
Mariam Ahmed
Amal Ayyoub
Alfred H. Balch
Jeffrey S. Barrett
Joseph S. Bertino Jr
Vishal Bhatnagar
Richard C. Brundage
Gilbert J. Burckart
William Douglas Figg
Samer El-Kamary
Philip E. Empey
Lanyan (Lucy) Fang
Roseann S. Gammal
Kathleen M. Giacomini
Gopichand Gottipati
David J. Greenblatt
Oliver Grundmann
Beatriz Guglieri-Lopez
Thomas Gwise
Sam Hariforoosh
Shiew-Mei Huang
David F. Kisor
Viera Lukacova
Mehul Mehta
Wayne T. Nicholson
John Carl Panetta
Alejandro Perez-Pitarch
Atiqur Rahman
Anuradha Ramamoorthy

The following members of the 2019 Annual Meeting Program Committee have indicated a financial relationship with an ACCME-defined commercial interest.

April M. Barbour: employee, ownership interest – Incyte Corp
Ayyappa Chaturvedula: consultant – Global Pharmaceutical Advisors LLC
Michael J. Fossler Jr: employee – Travena Inc
Navin S. Goyal: employee, stock owner – GlaxoSmithKline plc; stock owner – Merck & Co Inc; Gilead Sciences Inc, Incyte Corp, Bausch Healthcare Companies Inc, Celgene Corp, Bristol-Myers Squibb Co, Roche, Teva Pharmaceutical Industries Ltd
Joan Korth-Bradley: employee, stock owner – Pfizer Inc
Nitin Mehrotra: employee, stock owner – Merck & Co Inc
Ahmed Nader: employee – AbbVie Inc
Lorraine M. Rusch: employee – High Point Clinical Trials Ctr; spouse stock owner – Acorda Therapeutics Inc, Cara Therapeutics Inc; advisory; board/stock owner – CROI
Honghui Zhou: employee, stock owner – Johnson & Johnson

The following Annual Meeting Program Committee Members have indicated no financial relationships with an ACCME-defined commercial interest.

Vikram Arya
Karim Azer
John S. Bradley
Richard C. Brundage
Jonathan E. Constance
Gopichand Gottipati
Dionna J. Green
Lily (Yeruk) A. Mulugeta
Natella Y. Rakhmanina
Arun MM Ram
Catherine MT Sherwin
ACCP Staff:
Krista L. Levy – Nothing to disclose
Haydee Barno – Nothing to disclose
Pre-meeting Workshops

SATURDAY, SEPTEMBER 14, 2019 | Pre-meeting Workshop 1 | 8:00 AM – 12:00 PM

ROUGE

R Basics for Every Clinical Pharmacologist: Easily Create Reproducible Figures, Tables & Diagnostic Plots Using Tidyverse Libraries Such as Dplyr & Ggplot2

DEVELOPMENT TRACK
Offers Interprofessional Continuing Education (IPCE) Credits
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 Rscripts.

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
Pre-meeting Workshops

STATE ROOM

Clinical Pharmacology: Statistical Aspects & Methods, an ACCP/ASA Jointly-sponsored Workshop

DEVELOPMENT TRACK

Offers Interprofessional Continuing Education (IPCE) Credits

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, pharmacometrists, 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

Scott Patterson, PhD, PStat, Senior Director & Head, 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 Workshop 3
1:30 – 5:30 PM

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

DEVELOPMENT & PATIENT-CENTRIC TRACKS
Offers Interprofessional Continuing Education (IPCE) Credits
UAN #0238-9999-19-019-L01-P
ACPE – 3.5 CONTACT HOURS/APPLICATION-BASED

This Pre-meeting Workshop is partially supported in-kind by Genemarkers LLC

Sample data for analysis will be provided during the Workshop.

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.

1:30 – 2:00 PM
Pharmacogenomics: Current Landscape & Interprofessional Competencies
David F. Kisor, PharmD, Professor & Director of Pharmacogenomics Education, Manchester Univ, Pharmacy & Pharmacogenomics Programs

2:00 – 2:40 PM
Pharmacogenomics Decision Making: Science to Practice
Philip E. Empey, PharmD, PhD, Associate Director, Inst for Precision Medicine & School of Pharmacy, Univ of Pittsburgh

2:40 – 3:30 PM
Considerations for Applying Pharmacogenomics in Clinical Practice
Wayne T. Nicholson, MD, PharmD, Consultant, Anesthesiology & Perioperative Medicine, Assistant Professor of Anesthesiology & Pharmacology, Mayo Clinic Coll of Medicine & Science

3:30 – 4:00 PM / Break

4:00 – 5:00 PM
Case Presentations/Interactive Session
Roseann S. Gammal, PharmD, Assistant Professor, MCPHS Univ School of Pharmacy, Pharmacy Practice

5:00 – 5:30 PM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Pre-meeting Workshops

STATE ROOM

Decoding the Complexity of Transporter-mediated Drug-Drug Interactions & Recent Advances in Endogenous Biomarkers & Transporter Cocktail Studies

DEVELOPMENT TRACK

Offers Interprofessional Continuing Education (IPCE) Credits
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
Plenary Session

SUNDAY, SEPTEMBER 15, 2019 | Plenary Session | 8:00 – 9:30 AM

IMPERIAL BALLROOM - BACK

To Infinity & Beyond! The Expanding Roles of Data Sharing & Collaboration

DEVELOPMENT TRACK

Offers Interprofessional Continuing Education (IPCE) Credits
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.
Symposia

SUNDAY, SEPTEMBER 15, 2019 | Symposium 1 | 10:00 – 11:30 AM

ROUGE

Clinical Therapeutics in Obesity: A Tribute to the Work of Darrell R. Abernethy

DEVELOPMENT & PATIENT-CENTRIC TRACKS

Offers Interprofessional Continuing Education (IPCE) Credits

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 and 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 Interprofessional Continuing Education (IPCE) Credits
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 Interprofessional Continuing Education (IPCE) Credits
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 Jr, 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 – 2:40 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
Symposia

SUNDAY, SEPTEMBER 15, 2019 | Symposium 4 | 1:30 – 3:00 PM

**IMPERIAL BALLROOM - BACK**

**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 Interprofessional Continuing Education (IPCE) Credits
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.

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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

IMPERIAL BALLROOM - BACK

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

DEVELOPMENT & PATIENT-CENTRIC TRACKS

Offers Interprofessional Continuing Education (IPCE) Credits
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
Ivy Song, PhD, Senior Director, Takeda Pharmaceuticals Int’l Inc, Quantitative Clinical Pharmacology

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
Ivy Song, PhD, Senior Director, Takeda Pharmaceuticals Int’l Inc, Quantitative Clinical Pharmacology

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 Interprofessional Continuing Education (IPCE) Credits
UAN #0238-0000-19-022-L01-P
ACPE – 1.0 CONTACT HOURS/KNOWLEDGE-BASED

PRESENTER:
Diane R. Mould, PhD, 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, PhD, is the recipient of the 2019 Roger Jelliffe Individualized Therapy Award.
Symposia

MONDAY, SEPTEMBER 16, 2019 | Symposium 6 | 10:00 – 11:30 AM

ROUGE

Model-informed Drug Development for Long-acting Injectable Products

DEVELOPMENT TRACK

Offers Interprofessional Continuing Education (IPCE) Credits
UAN #0238-0000-19-006-L01-P
ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:
Lanyan (Lucy) Fang, PhD, Associate Director, 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 – 10:10 AM
Model-informed Drug Development for Long-acting Injectable Products
Lanyan (Lucy) Fang, PhD, Associate Director, 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 Interprofessional Continuing Education (IPCE) Credits
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.

10:00 – 10:20 AM
The Intersection of the Opioid Crisis & Infectious Diseases
Shyam Kottilil, MD, PhD, Professor, Univ of Maryland, Inst of Human Virology

10:20 – 10:40 AM
Interactions Between Anti-infectives & Opioids: What Do We Know?
Islam R. Younis, PhD, Director, Astellas Pharma USA Inc, Clinical Pharmacology & Exploratory Development

10:40 – 11:00 AM
Challenges In 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

11:00 – 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
ROUGE

Clinical Drug Development for Modified-release Drug Products: Regulatory Considerations & Application of Model-informed Exposure-Response Analysis to Waive Efficacy Studies

DEVELOPMENT TRACK
Offers Interprofessional Continuing Education (IPCE) Credits
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
Bilal AbuAsal, PhD, Clinical Pharmacologist, US Food & Drug Administration, OMPT/CDER/OTS/OCP and 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
**Symposia**

**MONDAY, SEPTEMBER 16, 2019 | Symposium 9 | 1:30 – 3:00 PM**

**IMPERIAL BALLROOM - BACK**

**Latest Advances in Treatment, Prophylaxis & Pharmacogenomics of HIV**

**PATIENT-CENTRIC TRACK**

*Offers Interprofessional Continuing Education (IPCE) Credits*

UAN #0238-0000-19-009-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

**CHAIR:**

Sam Harirforoosh, PharmD, PhD, 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.

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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, 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, Medical Team Leader, 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 Interprofessional Continuing Education (IPCE) Credits
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/OCPP
Daria Stypinski, PhD, 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/OCPP

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, Vice President, Bristol-Myers Squibb Co, Head, 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, 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 Interprofessional Continuing Education (IPCE) Credits
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 Patients With Organ Impairment 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 Tailor Oncology Clinical Development Plans to Promote Inclusion of Organ-impaired Patients: Cross-functional Considerations in Industry
Daniele Ouellet, PhD, Vice President & Global Head of Pharmacometrics, Pfizer Inc, Clinical Pharmacology

9:30 – 10:00 AM / Break

10:00 – 10:30 AM
A Pragmatic Approach to Eligibility for Phase 1 Clinical Trials in Oncology
Anthony W. Tolcher, MD, Director of Clinical Research & Co-Founder, Next Oncology

10:30 – 11:00 AM
Quantitative Clinical Pharmacology to Support Dosing in Special Populations
April M. Barbour, PhD, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics

11:00 – 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 Interprofessional Continuing Education (IPCE) Credits
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, Senior Scientific Director, Takeda Pharmaceutical Co Ltd, Quantitative & Translational Sciences

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, Senior Scientific Director, Takeda Pharmaceutical Co Ltd, Quantitative & Translational Sciences

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

9:20 – 9:30 AM
Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations
Symposia

TUESDAY, SEPTEMBER 17, 2019 | Symposium 13 | 10:00 – 11:30 AM

IMPERIAL BALLROOM - BACK

Human Pharmacodynamic Models Supporting Decision Making in Neuroscience Drug Development

DEVELOPMENT TRACK
Offers Interprofessional Continuing Education (IPCE) Credits
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
Neurophysiological Biomarkers to Predict & Monitor Response to CNS Therapeutics
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
### Symposium 14

**ROUGE**

**Emerging Technologies in Quantitative Pharmacology: Balancing Resources, Gaining Efficiencies & Cutting Costs**

**DEVELOPMENT TRACK**

Offers Interprofessional Continuing Education (IPCE) Credits  
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 S. 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.

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<th>Time</th>
<th>Session</th>
<th>Speaker</th>
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<tr>
<td>1:30 – 1:40 PM</td>
<td>Emerging Technologies in Quantitative Pharmacology: An Introduction</td>
<td>Navin S. Goyal, PhD, Director, GlaxoSmithKline plc, Clinical Pharmacology</td>
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<tr>
<td>1:40 – 2:00 PM</td>
<td>Applied &amp; Emerging Technologies for Model-based Drug Development</td>
<td>April M. Barbour, PhD, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism &amp; Biopharmaceutics</td>
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<td>2:00 – 2:25 PM</td>
<td>An Industry Perspective on Allocating Resources &amp; Balancing Budgets in a Diversifying Field</td>
<td>Megan Gibbs, PhD, BScPharm, Vice President, AbbVie Inc, Clinical Pharmacology &amp; Pharmacometrics Therapeutic Areas</td>
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<td>2:25 – 3:00 PM</td>
<td>An Academic Perspective on Training the Future Quantitative Pharmacologist: Casting a Wide Net or Choosing an Area of Expertise</td>
<td>Richard C. Brundage, PhD, Professor, Univ of Minnesota, Experimental &amp; Clinical Pharmacology</td>
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<td>3:00 – 3:30 PM</td>
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<td>3:30 – 4:00 PM</td>
<td>A Regulatory Perspective on Conducting &amp; Reviewing Analyses Which Utilize Emerging Technologies</td>
<td>Yaning Wang, PhD, Director, US Food &amp; Drug Administration, Pharmacometrics, Office of Clinical Pharmacology, CDER</td>
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<td>4:00 – 4:40 PM</td>
<td>Considerations &amp; Future Directions for the Development of Open-source Pharmacometric Software</td>
<td>Marc R. Gastonguay, PhD, Chief Executive Officer &amp; Founder, Metrum Research Group</td>
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<td>4:40 – 5:00 PM</td>
<td>Faculty Panel Discussion, Questions &amp; Answers, Learner Feedback &amp; Evaluations</td>
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Optimizing Therapy & Accelerating Drug Development in Oncology Using Surrogate Endpoints

DEVELOPMENT & PATIENT-CENTRIC TRACKS
Offers Interprofessional Continuing Education (IPCE) Credits
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 Interprofessional Continuing Education (IPCE) Credits
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, 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, 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, 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
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<td>Symposium 6</td>
<td>Associate Director, US Food &amp; Drug Administration, Quantitative Methods &amp; Modeling, Office of Research &amp; Standards, Office of Generic Drugs, CDER</td>
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<td>Figg</td>
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<td>Professor, East Tennessee State Univ Coll of Pharmacy, Pharmaceutical Sciences</td>
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<td>Craig W.</td>
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<td>Wellcome Professor &amp; Director, Johns Hopkins Univ School of Medicine, Clinical Pharmacology</td>
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<td>Professor of Pharmacometrics, Uppsala Univ, Pharmaceutical Biosciences</td>
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<td>Professor &amp; Director of Pharmacogenomics Education, Manchester Univ, Pharmacy &amp; Pharmacogenomics Programs</td>
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<td>Professor, Univ of Maryland, Inst of Human Virology</td>
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<td>Krishnaswami</td>
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<td>Symposium 8</td>
<td>Medicine Team Lead, Pfizer Inc, Global Product Development</td>
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<td>Lambo</td>
<td>Manisha</td>
<td>Symposium 8</td>
<td>Professor &amp; Deputy Vice Chair, Univ of California San Diego, Psychiatry Education &amp; Training and Director, Veterans Administration San Diego Healthcare System, Mental Health Research &amp; Mental Illness Research, Education &amp; Clinical Ctr</td>
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Why Join ACCP?

Looking for a society that provides the right benefits to enhance your career?

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

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

How do ACCP Member Benefits enhance your career?

• Opportunities to engage with the society and enhance your own career start with membership and attending the ACCP Annual Meeting at discounted Member rates. ACCP maintains high financial standards and strives to maintain a reasonable cost of membership and Annual Meeting registration year-over-year to effectively serve the clinical pharmacology community by making it economical to become a Member and attend the meeting.
• Use the ACCP365 Mobile App for 24/7/365 access to all things ACCP any time, any place.
• Build your professional network, either connecting at Live events such as the Annual Meeting, by working collaboratively with colleagues on a committee or virtually through the ACCP365 app via direct connections with colleagues.
• A vibrant Mentoring Program allows Students, Trainees & Early-stage Professionals to receive guidance to further their career and also permits senior Members to provide guidance to colleagues transitioning into full-time professionals or in need of career advice.
• Discounted registration for educational events, including the Live Annual Meeting, Live and On Demand webinars and text-based events on articles from The Journal of Clinical Pharmacology. As a jointly-accredited provider, ACCP offers ICPE credits for most events at no additional cost.
• Opportunity to enhance your leadership skills and get involved in the clinical pharmacology community by developing and proposing continuing education activities for the ACCP Annual Meeting or one of the webinars in the series ACCP hosts year-round.

• Free access to the latest scientific research. Members have free online access to ACCP’s high-quality publications, The Journal of Clinical Pharmacology, published for over 50 years, and Clinical Pharmacology in Drug Development, introduced in 2012, including eTOC notifications and online archives.
• The Pharmacometrics web-based learning resource brought to ACCP by the Univ of Maryland Ctr for Translational Medicine. The content offers a beginner’s guide to pharmacometric theory, modeling and application.
• 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.

How to Join ACCP

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

BEFORE YOU APPLY FOR MEMBERSHIP, PLEASE NOTE IF ANY OF THE FOLLOWING PERTAIN TO YOU AND CONTACT KLevy@ACCP1.org FOR EXISTING LOGIN CREDENTIALS:
• Been a Member of ACCP in the past;
• Have attended an ACCP Annual Meeting;
• Participated as Faculty at an ACCP Annual Meeting.

ACCP membership runs on a calendar year, January to December. Dues renewal notifications are sent in September for the coming year. Please note: A membership application is not considered complete until all required documents have been submitted and acknowledged by the ACCP Executive Office and dues have been paid. All applications must be submitted in full 30 days before the Board of Regents Meetings, the dates of which are noted below:
• February 9, 2020
• May 3, 2020
• September 19, 2020

Persons interested in becoming a Fellow should join as a Member and notify KLevy@ACCP1.org about their interest in becoming a Fellow.
ACCP Member Benefits support you through all the stages of your career. Learn how these Members have used ACCP Member Benefits to change the trajectory of their careers!

Michael J. Fossler Jr, PharmD, PhD, FCP, Vice President, Quantitative Sciences, Trevena Inc
“Membership in the American College of Clinical Pharmacology® is in large part responsible for any success that I have had in my clinical pharmacology career. The access to cutting-edge research in the journals, as well as the opportunity to publish in them, has been a crucial part of my career development. The ACCP Annual Meeting is not only an opportunity to learn about new science, it is a great networking opportunity. I have been privileged to have served ACCP in various capacities over my 21 years as a Member and look forward to future opportunities.”

Ahmed Nader, BCPS, PhD, Associate Director, Clinical Pharmacology & Pharmacometrics, AbbVie Inc
“Being a Member of ACCP has always given me the feeling of “this is where I belong”. The diversity of experiences, backgrounds and research interests among ACCP Members is incredibly unique and enriching to anyone who is part of this family. ACCP was there for me during my early career years, providing guidance and mentorship opportunities at times of critical decision making. Now as I progress in my professional career, ACCP remains the right place for me to give back and provide mentorship to Students and Early-stage Professionals. ACCP continues to be a great resource to me for professional development, networking and collaborations, continuing education and community engagement. ACCP’s Annual Meetings and journal publications have always provided the right environment for updates on cutting-edge clinical pharmacology research advances, as well as powerful scientific exchange. Serving as a reviewer for The Journal of Clinical Pharmacology and ACCP Annual Meeting and volunteering for various ACCP committees provides a wonderful opportunity for me to give back to the clinical pharmacology community and help shape and direct the field into the right path that fulfills our vision and hopes as clinical pharmacologists towards patients everywhere.”

Eman Biltaji, RPh, MSc, PhD, former Post Doctoral Research Associate, Div of Clinical Pharmacology, Dept of Pediatrics, School of Medicine, Univ of Utah
“Joining ACCP shifted my professional career in the right direction on many perspectives. From a research perspective, ACCP provides an excellent platform to learn about the latest research ideas in the field, whether it is through reviewing newsletters and updates or attending educational webinars and the ACCP Annual Meetings. I had the chance to present my research project and receive valuable feedback given by leaders in the field. From a professional perspective, ACCP offers endless opportunities to advance my career through the ACCP Mentoring Program, various committee activities, postings at the ACCP Job Center or networking at the ACCP Annual Meetings. On a personal perspective, I learned a lot from my professional interactions with ACCP Members and Staff, a very supportive community which is always willing to help. I am very grateful I have been introduced to ACCP by my mentors, Dr. Catherine Sherwin and Dr. Jonathan Con stance. I consider ACCP an integral part of my professional identity and would encourage other Members to become more involved with the society to get the maximal benefits from their membership.”

ACCP offers numerous opportunities, for any and all stages, to advance your career through involvement in the society:

**Year-round ACCP Activities**
- Publish an article in the JCP or CPDD
- Join the Editorial Board or become a Peer Reviewer for ACCP journals
- Volunteer for a Committee or become part of a Working Group/Advisory Group/Collaboration
- Register for a Live or On Demand Continuing Education webinar
- Serve as a Moderator or Faculty Speaker for a Live or On Demand webinar
- Complete the Continuing Education materials after a Live or On Demand webinar
- Participate as a Mentor or Mentee in ACCP’s Mentoring Program
- Encourage a colleague to join ACCP through the Member-Get-a-Member Program
- Submit a Letter of Support for an ACCP Fellow Application

**Annual Meeting-related Activities**
- Submit a nomination for an ACCP Recognition Award
- Submit a Proposal for a Pre-meeting Workshop or Symposium
- Serve as a First Author on a Poster at the Annual Meeting
- Serve as a Faculty Speaker for a Pre-meeting Workshop or Symposium
- Attend the ACCP Annual Meeting Pre-meeting Workshops and/or Symposia
- Volunteer to be an Abstract Reviewer or On-site Abstract Judge
- Participate in Student, Trainee & Early-stage Professional Events
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** (7:00 – 7:45 AM, Imperial Ballroom - Back) – Students, Trainees & Early-stage Professionals should grab breakfast in the Imperial Ballroom and join us for providing 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:

• **Early-stage Professionals Gathering** (1–10 years in first full-time position) (7:30 – 8:30 AM, Cuvee) – Join other Early-stage Professionals and learn about programs ACCP is developing to support your professional growth!

• **Panel Discussion on Career Guidance** (1:30 – 3:00 PM, Cuvee) – 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** (3:00 – 4:00 PM, Cuvee) – 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.

• **STEP Podium Presentations** (4:00 – 5:00 PM, Cuvee) – 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!

Students, Trainees & Early-stage Professionals who submitted their CV for review in advance of the meeting may stop by the ACCP Registration Desk on Sunday, if you wish to set up a face-to-face meeting to discuss the critique with a Mentor.

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

**ACCP Member Benefits**

**Join ACCP**

Visit us at [facebook](#), [Linkedin](#), [Twitter](#), [instagram](#)

The Student, Trainee & Early-stage Professional (STEP) Committee, co-chaired by Oliver Grundmann, PhD, MS, MEd and Kacey Anderson, PhD, is critical in providing guidance regarding Student, Trainee & Early-stage Professional needs and ensuring that those needs are consistently met by ACCP. The committee is comprised of Student Members, Members and Fellows and it focuses on activities at the Annual Meeting and provides guidance on programs, new and old, required to effectively support Students, Trainees & Early-stage Professionals. Have a great idea? Please share it with us at [STEP@ACCP1.org](mailto:STEP@ACCP1.org).

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Kacey Anderson, PhD
Oliver Grundmann, PhD, MS, MEd
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www.altasciences.com  Exhibit #: 1

BioPharma Services Inc is a client-focused, regulatory-inspected contract research organization specializing in Bioequivalence studies and Phase I/IIa (including Abuse Liability, Alcohol and DD Interaction, FIM, SAD/MAD) Clinical Trials, with a total of 300 beds split between our clinical sites in Canada and the USA. We are a physician-owned, full-service provider with support services in Regulatory and Scientific Affairs, PK Design and Support, Medical Writing, Data Management/ Biostatistics and Bioanalytical services.

www.biopharmaservices.com  Exhibit #: 17

dMed, founded in Shanghai in 2016, has grown to nearly 500 professionals covering 12 China cities and three US offices. As a global, full-service clinical CRO, dMed is committed to delivering regulatory, clinical research - including biometrics, pharmacovigilance and clinical pharmacology services at global standard from both China and US.

www.dmedglobal.com  Exhibit #: 2
Frontage is a CRO providing integrated, scientifically-driven research, analytical and product development services throughout the drug discovery and development process to enable biopharmaceutical companies to achieve their drug development goals. We offer our clients comprehensive services in analytical testing and formulation development, drug metabolism and pharmacokinetics (DMPK), bioanalysis, preclinical safety and toxicology and early-phase clinical studies.

www.frontagelab.com  Exhibit #: 19

High Point Clinical Trials Ctr has provided comprehensive (Phase I-III) clinical site services since 2008. Our 42,000 sq ft facility consists of three units for the execution of outpatient and inpatient studies. In addition to Healthy Normal, HPCTC focuses on specialty populations such as Metabolic Diseases, NASH, Renal Impairment, Respiratory and Nicotine.

www.highpointctc.com  Exhibit #: 10

HUGHES & Associates LLC is your comprehensive executive search firm servicing the pharmaceutical and biotechnology industries. Whether your needs are finding a highly-specialized candidate or enhancing your career, we are prepared to accept and complete your most challenging assignments.

www.haallc.com  Exhibit #: 13

Metrum Research Group is the leading innovator in biomedical modeling and simulation. We have provided strategic decision making with the highest quality of scientific expertise for 150+ companies on over 550 projects. Visit our exhibit booth to learn about how we aim to defeat disease by taking a quantitative approach to drug development. Ask about job openings including Modeling & Simulation Scientist and Clinical Pharmacologist positions.

www.metrumrg.com  Exhibit #: 16
**Exhibitors**

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

www.noccr.com  Exhibit #: 5

**Nuventra** is a drug development consulting firm specializing in pharmacokinetics, pharmacodynamics and pharmacometrics. Our 30+ consultants, most with over 15 years of experience, serve as a virtual extension of your team. More than just providing results from an analysis, our group helps make those results actionable and provides strategic guidance throughout your development program.

www.nuventra.com  Exhibit #: 11

**qPharmetra**, a global leader in pharmacometric modeling, clinical pharmacology consulting and custom software tools, helps drug companies make better development decisions resulting in better medicines. qPharmetra’s core values of creativity, consistency and collaboration ensure that clients receive appropriate and repeatable analysis on time to support decision making and regulatory filings. We look forward to talking with you and learning how our team can help you bring your important medicines to patients more quickly.

www.qPharmetra.com  Exhibit #: 20
Rudraya Corp is a leading provider of Cloud Computing, Data Management and Visualizations Platforms (SONIC) supporting Drug Discovery at Pharmaceutical, Biotechnology and Healthcare organizations. Eight out of the top ten pharma companies are our customers, using SONIC to perform cutting-edge genomics, machine learning, modeling, clinical trial simulation, bioinformatics and other computation workflows.

www.rudraya.com  Exhibit #: 3

Simulations Plus is the premier developer of modeling & simulation solutions supporting drug discovery and development. With subsidiary companies Cognigen & DILIsym, we provide easy-to-use software (including GastroPlus™, ADMET Predictor™, KIWI™ and DILIsym®) and PBPK modeling, pharmacometrics and systems toxicology/pharmacology consulting to assist with safety risk assessment and preclinical/clinical development.

www.simulations-plus.com  Exhibit #: 9

TNO will exhibit the latest developments on the use of microtracer-labeled drugs in clinical pharmacology. Microtracers to establish absolute bioavailability and the application of the automated AMS analysis, combined with simultaneous direct hrMS/MS for metabolite profiling (MIST/mass balance), will be shown. Besides we will showcase in vitro and ex vivo platforms to investigate intestinal permeability, microbiome-induced metabolism and biliary excretion/DDIs/hepatic clearance.

www.tno.nl/en/focus-areas/healthy-living/roadmaps/biomedical-health/  Exhibit #: 18
**US Food & Drug Administration** - The Office of Clinical Pharmacology (OCP) in the FDA’s Office of Translational Sciences is a multidisciplinary organization of over 200 clinical pharmacologists, pharmacists, researchers, project managers and administrative staff. OCP’s goals are to enhance drug development, promote regulatory science and innovation and inform the optimal use of medications.


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Join us during the **Evening Receptions in the Exhibit Hall** and play the **Jeopardy Game**! Show us how much you know about everything from clinical pharmacology-related topics to popular culture. Get your colleagues together and have some fun!

Don’t forget to capture your moment by visiting the **photo booth in the Exhibit Hall** and create some memories!

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### Clinical Pharmacokinetics (ADME)

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<td>Identifying Drug Target for Prenatal Cannabinoid Exposure-mediated Learning and Memory Deficits</td>
<td>P. D. Pinky, J. Bloemer, S. E. Setti, R. T. Heslin, Y. Du, A. Dityatev, M. N. Reed, V. Suppiramaniam</td>
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### Experimental Pharmacology in In Vitro/In Vivo Studies

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### Human Pharmacology

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<td>Treatment in Primary Acute Myeloid Leukemia Cells</td>
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<td>F. Ferrari, A. Moretti, R. F. Villa</td>
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<td>Dose Optimization of Ivermectin in Children: A Model-based Approach to Achieve Equivalent Exposure Coverage in Children and Adults</td>
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### Model-informed Drug Development

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<td>J. Rashid, Y. Liu, Y. Huang, R. Sekulovich</td>
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### Other Therapeutic Areas

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# Pharmacodynamics

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# Pharmacoepidemiology

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# Pharmacometrics & Systems Pharmacology

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<td>N. Heo, P. Bonate</td>
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<td>A. Taneja, J. Desrivot, P. Diderichsen, R. Blanque, L. Allamassey, L. Fagard, A. Fieuw, E. van der Aar, F. Namour</td>
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<td>V. K. Yellepeddi, J. S. Wagstaff, J. E. Constance</td>
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<td>Y. Yu, L. DeAnnuntis, A. Czibere, D. Wang</td>
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<td>S. K. Drescher, M. Chen, Y. Jiao, J. Bulitta, G. Hochhaus</td>
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<td>Quantitative Benefit-Risk Assessment of P-gp-mediated Drug-Drug Interactions of Dabigatran Coadministered With Pharmacokinetic Enhancers in Patients With Renal Impairment</td>
<td>K. Lingineni, N. Farhan, S. Kim, L. Gordon, S. Penzak, C. Hadigan, J. George, S. Schmidt</td>
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<td>Analysis of Emtricitabine and Acyclovir Exposure Throughout the Complete Course of Pregnancy</td>
<td>X. Liu, J. D. Momper, N. Rakhmanina, J. van den Anker, D. J. Green, G. J. Burckart, B. M. Best, M. Mirochnick, E. V. Capparelli, A. Dallmann</td>
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<td>S. Yi, L. Oh, S. Shin, D. Zhang, D. Bashaw</td>
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<td>V. Chamberlain Santos, J. Wang, P. Slatcher, K. Dykstra, K. Culm-Merdek</td>
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