ACCP

American College of Clinical Pharmacology®

Advancing Clinical Care through Pharmacology®

Celebrating ACCP's 50th Anniversary!

2019 Annual Meeting
American College of Clinical Pharmacology®

Reflecting on Our History & Shaping the Future of Clinical Pharmacology

Chemotherapy

Pharmacology

Antibiotics

Personalized Medicine

Clinical Medicine

Synthesis of Drugs

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

FINAL PROGRAM

ACCP

American College of Clinical Pharmacology®

Advancing Clinical Care through Pharmacology®

Join Us for the 2020 ACCP Annual Meeting!

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!

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

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 facebook LinkedIn

ACCP Registration Desk Hours

Friday, September 13th	5:00 – 7:00 PM	B1 Foyer
Saturday, September 14th	7:00 AM – 5:30 PM	B1 Foyer
Sunday, September 15th	6:30 AM – 7:00 PM	Imperial Foyer
Monday, September 16th	7:00 AM – 7:00 PM	Imperial Foyer
Tuesday, September 17th	7:00 AM – 5:30 PM	Imperial Foyer

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.

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ACCP365 Mobile App

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:
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Table of Contents

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
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Gopichand Gottipati, PhD
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Dionna J. Green, MD
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Arun MM Ram, MBBS, MD
Lorraine M. Rusch, PhD
Catherine MT Sherwin, PhD, MSc

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Advancing Clinical Care through Pharmacology®

Letter of Welcome from President & Program Co-chairs

Welcome to the 2019 ACCP Annual Meeting!

Reflecting on Our History & Shaping the Future of Clinical Pharmacology

#2019ACCP

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!!

Vikram Arya, PhD
President, ACCP

Joan Korth-Bradley, PharmD, PhD
Program Co-chair

Lily (Yeruk) A. Mulugeta, PharmD
Program Co-chair

Michael J. Fossler Jr, PharmD, PhD
Program Co-chair

Program at a Glance

ACCP gratefully acknowledges the unrestricted educational grant received in support of this program from Pfizer Inc

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

ACCP Registration Desk Open
5:00 – 7:00 PM | *B1 Foyer*

ACCP Executive Committee Meeting & Dinner (invitation only)
6:00 – 10:00 PM | *Ambassador Room*

SATURDAY, SEPTEMBER 14, 2019

ACCP Registration Desk Open
7:00 AM – 5:30 PM | *B1 Foyer*

ACCP Board of Regents Meeting
8:00 AM – 1:00 PM | *Cuvee*

Pre-meeting Workshop 1 | **8:00 AM – 12:00 PM**
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/OCP
Rouge

Pre-meeting Workshop 2 | **8:00 AM – 12:00 PM**
Clinical Pharmacology: Statistical Aspects & Methods, an ACCP/ASA Jointly-sponsored Workshop (DT)
CHAIR: Alfred H. Balch, PhD, MA, Adjunct Associate Professor, Univ of Utah School of Medicine and Chief Executive Officer, Summit Statistics LLC
State Room

Pre-meeting Workshop 3 | **1:30 – 5:30 PM**
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
Rouge

Pre-meeting Workshop 4 | **1:30 – 5:30 PM**
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
State Room

ACCP Publications Committee Meeting
2:30 – 3:30 PM | *Embassy*

ACCP Finance Committee Meeting
3:00 – 5:00 PM | *37th Floor Board Room*

ACCP Honors & Awards Committee Meeting
3:30 – 4:30 PM | *Embassy*

ACCP 50th Anniversary Gala (advance registration required)
6:30 – 10:00 PM | *Rouge*

SUNDAY, SEPTEMBER 15, 2019

ACCP Registration Desk Open
6:30 AM – 7:00 PM | *Imperial Foyer*

Continental Breakfast
7:00 – 8:00 AM | *Imperial Ballroom - Front*

New Member & First-time Attendee Welcome
7:00 – 7:45 AM | *Royal*

Student, Trainee & Early-stage Professional Welcome
7:00 – 7:45 AM | *Imperial Ballroom - Back*

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

Welcome & Opening Remarks by ACCP President
7:45 – 8:00 AM | *Imperial Ballroom - Back*

Plenary Session | **8:00 – 9:30 AM**
To Infinity & Beyond! The Expanding Roles of Data Sharing & Collaboration (DT)
CO-PRESENTERS: Jeffrey S. Barrett, PhD, Head, Bill & Melinda Gates Medical Research Inst, Quantitative Sciences and John F. Crowley, JD, MBA, Chairman of the Board & Chief Executive Officer, Amicus Therapeutics Inc
Imperial Ballroom - Back

Symposium 1 | **10:00 – 11:30 AM**
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
Rouge

Symposium 2 | **10:00 – 11:30 AM**
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
Imperial Ballroom - Back

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

Program at a Glance

Continued

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
Rouge

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
Imperial Ballroom - Back

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 Ramamoorthy, 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
Imperial Ballroom - Back

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

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*

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**
Ushering in the Age of Individualized Dosing: Where Do We Go From Here? (P-CT)
PRESENTER: Diane R. Mould, PhD, President, Projections Research Inc
Imperial Ballroom - Back

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
Rouge

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
Imperial Ballroom - Back

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

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
- ACCP Member-Get-a-Member Awards
- 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/OCP
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

ACCP
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Invited Keynote

Monday, September 16, 2019 | Lunch & Awards Session | 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.

2019 ACCP Recognition Award Winners

ACCP Distinguished Investigator Award

Sunday, September 15, 2019 | Lunch & Awards Session | Imperial Ballroom - Back

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.

ACCP Honorary Fellowship Award

Sunday, September 15, 2019 | Lunch & Awards Session | Imperial Ballroom - Back

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.

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2019 ACCP Recognition Award Winners

Nathaniel T. Kwit Memorial Distinguished Service Award

Sunday, September 15, 2019 | Lunch & Awards Session | Imperial Ballroom - Back

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.

McKeen Cattell Memorial Award

Sunday, September 15, 2019 | Lunch & Awards Session | Imperial Ballroom - Back

James Truong, PharmD – Clinical Pharmacy Coordinator of Infectious Diseases, Brooklyn Hosp Ctr

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

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

2019 ACCP Recognition Award Winners

Roger Jelliffe Individualized Therapy Award

ACKNOWLEDGEMENT – Monday, September 16, 2019 | Lunch & Awards Session
Imperial Ballroom - Back

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

Monday, September 16, 2019 | Lunch & Awards Session | Imperial Ballroom - Back

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. Wilhems 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 Assocation 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.

ACCP
American College of Clinical Pharmacology®
Advancing Clinical Care through Pharmacology®

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

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

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)

IPCE CREDIT™

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.

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Faculty Disclosure Information

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 Pharmaceutics 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. Dufek: employee, ownership interest – AbbVie Inc

Andrea Edginton: ownership interest, receive other type of financial compensation – Design2Code Inc

Mohamed Elmeliegy: 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 Kottilil: 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 – Allecra Therapeutics; research grant – CARE Ftdn; research grant – Nevakar Inc; consultant/advisory board – SIGA Technologies Inc

Mohamad Shebley: 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; Boston Bio Medical Inc; Eleven Biotherapeutics Inc; EMD Serono; Formation Biologics Inc; Gilde Healthcare; Ignyta Inc; Immunome 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 Harirforoosh
Shiew-Mei Huang
David F. Kisor
Viera Lukacova
Mehul Mehta
Wayne T. Nicholson
John Carl Panetta
Alejandro Perez-Pitarch
Atiqur Rahman
Anuradha Ramamoorthy
Jane E. Ranshaw
Klaus Schaffler
Stephan Schmidt
Satish Sharan
April N. Smith
Kimberly A. Struble
Sara L. Van Driest
Yaning Wang
Lynne Yao

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 – CRIO

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*

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

SATURDAY, SEPTEMBER 14, 2019 | Pre-meeting Workshop 2 | 8:00 AM – 12:00 PM

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

GOALS & OBJECTIVES:

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

1. Explain the application of statistical principles to noncompartmental analysis of pharmacokinetic data in a variety of designs and endpoints based on an understanding of distributional assumptions behind common pharmacokinetic endpoints derived from concentration-time data (e.g., AUC, C_{max}) 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

SATURDAY, SEPTEMBER 14, 2019 | 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

SATURDAY, SEPTEMBER 14, 2019 | Pre-meeting Workshop 4 | 1:30 – 5:30 PM

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

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

Jeffrey S. Barrett, PhD

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

John F. Crowley, JD, MBA

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.

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

SUNDAY, SEPTEMBER 15, 2019 | Symposium 2 | 10:00 – 11:30 AM

IMPERIAL BALLROOM - BACK

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

Introduction: The Evolution of Pharmacokinetic Studies in Patients With Impaired Renal Function – Emerging Designs & Trends

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

SUNDAY, SEPTEMBER 15, 2019 | Symposium 3 | 1:30 – 5:00 PM

ROUGE

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

This Symposium is supported in part by a Sponsorship from Wiley

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 – 3:00 PM

The Big Black Box: The Review & Revision Process of Your Manuscript Explained & How It Helps You in Writing Your Manuscript

Stephan Schmidt, BPharm, PhD, Associate Director, Univ of Florida, Ctr for Pharmacometrics & Systems Pharmacology

3:00 – 3:30 PM / **Break**

3:30 – 5:00 PM

Interactive Hands-on Scientific Writing Workshop for Graduate Students, Trainees or Early-stage Professionals in Clinical Pharmacology

Jane E. Ranshaw, MBA, President, Jane Ranshaw & Associates Inc and Oliver Grundmann, PhD, Clinical Associate Professor, Director, Univ of Florida Coll of Pharmacy, Medicinal Chemistry

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.

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

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

ACCP
American College of Clinical Pharmacology®
Advancing Clinical Care through Pharmacology®

Roger Jelliffe Individualized Therapy Award Presentation

MONDAY, SEPTEMBER 16, 2019 | Presentation | 8:30 – 9:30 AM

IMPERIAL BALLROOM - BACK

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.

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

MONDAY, SEPTEMBER 16, 2019 | Symposium 7 | 10:00 – 11:30 AM

IMPERIAL BALLROOM - BACK

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

MONDAY, SEPTEMBER 16, 2019 | Symposium 8 | 1:30 – 5:00 PM

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

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.

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

MONDAY, SEPTEMBER 16, 2019 | Symposium 10 | 3:30 – 5:00 PM

IMPERIAL BALLROOM - BACK

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/OCP

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/OCP

3:40 – 3:55 PM

HIV & Cancer Curative Approaches: Cross-disciplinary Research

Steven G. Deeks, MD, Professor of Medicine in Residence, Univ of California San Francisco

3:55 – 4:15 PM

Lessons Learned from HIV Drug Development That Can Be Utilized in Oncology

Islam R. Younis, PhD, Director, Astellas Pharma USA Inc, Clinical Pharmacology & Exploratory Development

4:15 – 4:30 PM

Clinical Pharmacology Challenges in the Development of Immuno-oncology Agents

Akintunde Bello, PhD, 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

TUESDAY, SEPTEMBER 17, 2019 | Symposium 11 | 8:00 – 11:30 AM

ROUGE

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

TUESDAY, SEPTEMBER 17, 2019 | Symposium 12 | 8:00 – 9:30 AM

IMPERIAL BALLROOM - BACK

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

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

Laser-evoked Potential Method in Healthy Volunteers: Its Predictive Validity of Therapeutic Efficacy in Neuropathic Pain & Its Value in Early Clinical Development Decision Making

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

TUESDAY, SEPTEMBER 17, 2019 | Symposium 14 | 1:30 – 5:00 PM

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.

1:30 – 1:40 PM

Emerging Technologies in Quantitative Pharmacology: An Introduction

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

1:40 – 2:00 PM

Applied & Emerging Technologies for Model-based Drug Development

April M. Barbour, PhD, Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics

2:00 – 2:25 PM

An Industry Perspective on Allocating Resources & Balancing Budgets in a Diversifying Field

Megan Gibbs, PhD, BScPharm, Vice President, AbbVie Inc, Clinical Pharmacology & Pharmacometrics Therapeutic Areas

2:25 – 3:00 PM

An Academic Perspective on Training the Future Quantitative Pharmacologist: Casting a Wide Net or Choosing an Area of Expertise

Richard C. Brundage, PhD, Professor, Univ of Minnesota, Experimental & Clinical Pharmacology

3:00 – 3:30 PM / **Break**

3:30 – 4:00 PM

A Regulatory Perspective on Conducting & Reviewing Analyses Which Utilize Emerging Technologies

Yaning Wang, PhD, Director, US Food & Drug Administration, Pharmacometrics, Office of Clinical Pharmacology, CDER

4:00 – 4:40 PM

Considerations & Future Directions for the Development of Open-source Pharmacometric Software

Marc R. Gastonguay, PhD, Chief Executive Officer & Founder, Metrum Research Group

4:40 – 5:00 PM

Faculty Panel Discussion, Questions & Answers, Learner Feedback & Evaluations

TUESDAY, SEPTEMBER 17, 2019 | Symposium 15 | 1:30 – 3:00 PM

IMPERIAL BALLROOM - BACK

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

TUESDAY, SEPTEMBER 17, 2019 | Symposium 16 | 3:30 – 5:00 PM

IMPERIAL BALLROOM - BACK

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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Faculty

Last Name	First Name	Course	Affiliation
AbuAsal	Bilal	Symposium 8	Clinical Pharmacologist, US Food & Drug Administration, OMPT/CDER/OTS/OCP
Ahmed	Mariam	Symposium 10	Staff Fellow, US Food & Drug Administration, OMPT/CDER/OTS/OCP
Al-Huniti	Nidal	Symposium 16	Executive Director & US Oncology Lead, AstraZeneca plc, Quantitative Clinical Pharmacology
Ayyoub	Amal	Symposium 16	Clinical Pharmacology Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology, Office of Translational Sciences, CDER
Balch	Alfred H.	Pre-meeting Workshop 2	Adjunct Associate Professor, Univ of Utah School of Medicine and Chief Executive Officer, Summit Statistics LLC
Barbour	April M.	Symposia 11 & 14	Director, Incyte Research Inst, Clinical Pharmacokinetics, Drug Metabolism & Biopharmaceutics
Barrett	Jeffrey S.	Plenary Session	Head, Bill & Melinda Gates Medical Research Inst, Quantitative Sciences
Beckman	Robert A.	Symposium 16	Professor, Oncology & Biostatistics, Bioinformatics & Biomathematics, Georgetown Univ Medical Ctr, Lombardi Comprehensive Cancer Ctr & Innovation Ctr for Biomedical Informatics
Bello	Akintunde	Symposium 10	Vice President, Bristol-Myers Squibb Co, Head, Clinical Pharmacology & Pharmacometrics
Bertino Jr	Joseph S.	Symposium 3	Editor-in-Chief, *The Journal of Clinical Pharmacology*
Bhatnagar	Vishal	Symposium 15	Medical Officer, US Food & Drug Administration, Hematology Products, CDER
Bhattacharya	Indranil	Symposium 12	Senior Scientific Director, Takeda Pharmaceutical Co Ltd, Quantitative & Translational Sciences
Bies	Robert	Pre-meeting Workshop 2	Associate Professor of Pharmaceutical Sciences, State Univ of New York at Buffalo School of Pharmacy and Member, Computational & Data Enabled Sciences & Engineering Program
Bonate	Peter	Pre-meeting Workshop 2	Executive Director, Astellas Pharma Inc, Pharmacokinetics, Modeling & Simulation
Brundage	Richard C.	Symposium 14	Professor, Univ of Minnesota, Experimental & Clinical Pharmacology
Burckart	Gilbert J.	Symposium 4	Associate Director for Pediatrics, US Food & Drug Administration, Office of Clinical Pharmacology
Chen	Yingxue	Symposium 16	Director, Quantitative Clinical Pharmacology, AstraZeneca plc, Early Clinical Development
Chow	Christina R.	Symposium 1	Head of Research, Emerald Lake Safety
Cohn	Susan E.	Symposium 9	Professor of Medicine, Northwestern Univ Feinberg School of Medicine
Coop	Andrew	Symposium 7	Professor, Univ of Maryland School of Pharmacy
Crowley	John F.	Plenary Session	Chairman of the Board & Chief Executive Officer, Amicus Therapeutics Inc
Deeks	Steven G.	Symposium 10	Professor of Medicine in Residence, Univ of California San Francisco
Dehn	Clayton A.	Symposium 2	Vice President, High Point Clinical Trials Ctr, Clinical Pharmacology Svcs
Dufek	Matthew B.	Symposium 3	Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics
Edginton	Andrea	Symposium 4	Associate Director, Graduate Studies & Research, Associate Professor, Univ of Waterloo, School of Pharmacy

Faculty

Last Name	First Name	Course	Affiliation
El-Kamary	Samer	Symposium 7	Clinical Reviewer, US Food & Drug Administration, Antiviral Products, CDER and Adjunct Associate Professor, Univ of Maryland School of Medicine
Elmeliegy	Mohamed	Pre-meeting Workshop 4	Associate Director, Pfizer Inc, Clinical Pharmacology
Empey	Philip E.	Pre-meeting Workshop 3	Associate Director, Inst for Precision Medicine & School of Pharmacy, Univ of Pittsburgh
Fang	Lanyan (Lucy)	Symposium 6	Associate Director, US Food & Drug Administration, Quantitative Methods & Modeling, Office of Research & Standards, Office of Generic Drugs, CDER
Figg	William Douglas	Symposium 15	Senior Investigator, National Cancer Inst, Molecular & Clinical Pharmacology Program
Freise	Kevin J.	Symposium 15	Scientific Director, AbbVie Inc, Oncology Early Development
Gammal	Roseann S.	Pre-meeting Workshop 3	Assistant Professor, MCPHS Univ School of Pharmacy, Pharmacy Practice
Gastonguay	Marc R.	Symposium 14	Chief Executive Officer & Founder, Metrum Research Group
Giacomini	Kathleen M.	Pre-meeting Workshop 4	Professor, Univ of California San Francisco, Bioengineering & Therapeutic Sciences
Gibbs	Megan	Symposium 14	Vice President, AbbVie Inc, Clinical Pharmacology & Pharmacometrics Therapeutic Areas
Gottipati	Gopichand	Pre-meeting Workshop 1	Reviewer, US Food & Drug Administration, OMPT/CDER/OTS/OCP
Goyal	Navin S.	Symposium 14	Director, GlaxoSmithKline plc, Clinical Pharmacology
Greenblatt	David J.	Symposia 1 & 3	Professor, Tufts Univ School of Medicine
Grundmann	Oliver	Symposium 3	Clinical Associate Professor, Director, Univ of Florida Coll of Pharmacy, Medicinal Chemistry
Guglieri-Lopez	Beatriz	Pre-meeting Workshop 1	Postdoctoral Fellow in Pharmacometrics & Clinical Pharmacology, Univ of Maryland Baltimore
Gupta	Neeraj	Symposium 15	Senior Scientific Director, Takeda Pharmaceuticals USA Inc, Quantitative Clinical Pharmacology
Gwise	Thomas	Symposium 11	Deputy Division Director, US Food & Drug Administration, DBV/CDER/OTS/OB
Harirforoosh	Sam	Symposium 9	Professor, East Tennessee State Univ Coll of Pharmacy, Pharmaceutical Sciences
Hendrix	Craig W.	Symposium 9	Wellcome Professor & Director, Johns Hopkins Univ School of Medicine, Clinical Pharmacology
Hibma	Jennifer E.	Pre-meeting Workshop 1	Clinical Pharmacologist & Pharmacometrician, Pfizer Inc, Global Product Development, Global Pharmacometrics
Huang	Shiew-Mei	Pre-meeting Workshop 4 & Symposium 5	Deputy Director, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/CDER
Jain	Lokesh	Symposium 12	Director, Merck & Co, Quantitative Pharmacology & Pharmacometrics
Karlsson	Mats	Symposium 6	Professor of Pharmacometrics, Uppsala Univ, Pharmaceutical Biosciences
Kisor	David F.	Pre-meeting Workshop 3	Professor & Director of Pharmacogenomics Education, Manchester Univ, Pharmacy & Pharmacogenomics Programs

Faculty

Last Name	First Name	Course	Affiliation
Kottilil	Shyam	Symposium 7	Professor, Univ of Maryland, Inst of Human Virology
Krishnaswami	Sriram	Symposium 8	Medicine Team Lead, Pfizer Inc, Global Product Development
Lamba	Manisha	Symposium 8	Director, Celgene Corp, Clinical Pharmacokinetics and Modeling & Simulation
Light	Gregory A.	Symposium 13	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
Lukacova	Viera	Symposia 6 & 8	Director, Simulations Plus Inc, Simulation Sciences
Masters	Joanna C.	Symposium 11	Associate Director, Pfizer Inc, Clinical Pharmacology & Pharmacometrics, Global Product Development
Mehta	Mehul	Symposium 8	Director, US Food & Drug Administration, Clinical Pharmacology I, OCP/CDER
Menon	Rajeev M.	Symposium 8	Senior Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics
Morimoto	Bruce	Symposium 2	Vice President, Alkahest Inc, Drug Development Operations
Mould	Diane R.	Roger Jelliffe Individualized Therapy Award Presentation & Symposium 12	President, Projections Research Inc
Nader	Ahmed	Pre-meeting Workshop 4	Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics
Nicholson	Wayne T.	Pre-meeting Workshop 3	Consultant, Anesthesiology & Perioperative Medicine, Assistant Professor of Anesthesiology & Pharmacology, Mayo Clinic Coll of Medicine & Science
Noveck	Robert J.	Symposium 2	Principal, Noveck Consultancy
Ouellet	Daniele	Symposium 11	Vice President & Global Head of Pharmacometrics, Pfizer Inc, Clinical Pharmacology
Panetta	John Carl	Symposium 4	Biomedical Modeler, St Jude Children's Research Hosp, Pharmaceutical Sciences
Patterson	Scott	Pre-meeting Workshop 2	Senior Director & Head, Sanofi Pasteur, Statistical Innovation
Perez-Pitarch	Alejandro	Pre-meeting Workshop 1	ORISE Fellow, US Food & Drug Administration
Rahman	Atiqur	Symposium 11	Director, US Food & Drug Administration, Clinical Pharmacology V, Office of Clinical Pharmacology, OTS/CDER
Ramamoorthy	Anuradha	Symposium 5	Policy Lead, Guidance & Policy Team, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/CDER
Ranshaw	Jane E.	Symposium 3	President, Jane Ranshaw & Associates Inc
Ruiz-Garcia	Ana	Pre-meeting Workshop 1	Senior Director, Pfizer Inc, Global Pharmacometrics
Rusch	Lorraine M.	Symposium 2	President, High Point Clinical Trials Ctr

Faculty

Last Name	First Name	Course	Affiliation
Schaffler	Klaus	Symposium 13	Managing & Medical Director, Human Pharmacodynamic Research
Scheetz	Marc H.	Symposium 4	Professor, Midwestern Univ, Chicago Coll of Pharmacy, Pharmacy Practice & Coll of Graduate Studies, Pharmacology
Schmidt	Stephan	Symposium 3	Associate Director, Univ of Florida, Ctr for Pharmacometrics & Systems Pharmacology
Sharan	Satish	Symposium 6	Visiting Associate, US Food & Drug Administration, Quantitative Methods & Modeling, Office of Research & Standards, Office of Generic Drugs, CDER
Shebley	Mohamad	Pre-meeting Workshop 4	Director & Volwiler Research Fellow, AbbVie Inc, Clinical Pharmacology & Pharmacometrics
Singh	Ravi Shankar Prasad	Symposium 12	Associate Director, Pfizer Inc, Clinical Pharmacology, Early Clinical Development, Worldwide Research & Development
Smith	April N.	Symposium 1	Associate Professor of Pharmacy Practice, Creighton Univ and Clinical Pharmacist, CHI Immanuel Medical Ctr, Acute Care & Bariatric Surgery
Song	Ivy	Symposium 5	Senior Director, Takeda Pharmaceuticals Int'l Inc, Quantitative Clinical Pharmacology
Stevens	Daniel R.	Symposium 8	Director of Medical Affairs, Veloxis Pharmaceuticals Inc
Stopfer	Peter	Pre-meeting Workshop 4	Global Head Clinical PK/PD, Boehringer Ingelheim Pharma GmbH & Co KG, Translational Medicine & Clinical Pharmacology
Struble	Kimberly A.	Symposium 9	Medical Team Leader, US Food & Drug Administration, CDER, Antiviral Products
Stypinski	Daria	Symposium 10	Director, Pfizer Inc, Clinical Pharmacology, Oncology & Global Product Development
Tolcher	Anthony W.	Symposium 11	Director of Clinical Research & Co-Founder, Next Oncology
Van Driest	Sara L.	Symposium 5	Assistant Professor, Vanderbilt Univ Medical Ctr, Pediatrics & Medicine
Walzer	Mark	Symposium 13	Director, Astellas Pharma Global Development, Clinical Pharmacology & Exploratory Development
Wang	Yaning	Symposium 14	Director, US Food & Drug Administration, Pharmacometrics, Office of Clinical Pharmacology, CDER
Yao	Lynne	Symposium 12	Director, US Food & Drug Administration, Pediatric & Maternal Health
Younis	Islam R.	Symposia 7 & 10	Director, Astellas Pharma USA Inc, Clinical Pharmacology & Exploratory Development
Zhu	Tong	Symposium 13	Executive Director, Astellas Pharma Global Development, Clinical Pharmacology & Exploratory Development

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ACCP Honor Wall

We are deeply grateful for your support of ACCP over the past 50 years and for your donation to the Honor Wall in celebration of ACCP's 50th Anniversary!

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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;
- Presented a poster at an ACCP Annual Meeting;
- Participated as Faculty at an ACCP Annual Meeting.

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

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

- 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.

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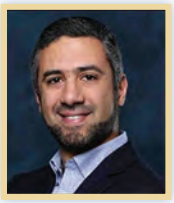
How to Enhance Your Career Through Engagement with ACCP

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 Constance. 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

Annual Meeting Events for Students, Trainees & Early-stage Professionals

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

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

Student, Trainee & Early-stage Professional-specific Events

On **Sunday, September 15th**, the following event will be hosted:

- **STEP Welcome Breakfast** (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.

ACCP gratefully acknowledges the support of Takeda Pharmaceuticals Co Ltd for the Student, Trainee & Early-stage Professional Events

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!

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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**.

Kacey Anderson, PhD

Oliver Grundmann, PhD, MS, MEd

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2019 ACCP Annual Meeting Exhibitors

ACCP is grateful for the support of its Exhibitors. Visit the Exhibit Hall to learn more about the latest offerings from these outstanding companies!

Altasciences is a forward-thinking, mid-size contract research organization offering pharmaceutical and biotechnology companies of all sizes a proven, flexible approach to preclinical and early-phase clinical studies, from lead candidate selection to proof of concept. For over 25 years, Altasciences has been integrating into clients' projects to help support educated, faster and more complete early drug development decisions. Altasciences' full-service solutions include preclinical safety testing, clinical pharmacology, bioanalysis, program management, medical writing, biostatistics, data management and more, all of which can be tailored to specific sponsor requirements. Altasciences… helping sponsors get better drugs to the people who need them, faster.

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**

Exhibitors

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**

Exhibitors

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**

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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.

www.fda.gov/about-fda/center-drug-evaluation-and-research/office-clinical-pharmacology **Exhibit #: 15**

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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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Poster Session 1

Sunday, Sept 15th / 5:00 – 7:00 PM
IMPERIAL BALLROOM - FRONT

Clinical Pharmacokinetics (ADME)

Poster	Type	Title	Authors
001	NM	Pharmacokinetics and Absolute Bioavailability of Ribociclib Following Oral Administration in Healthy Volunteers	A. M. Abdelhady, H. Yin, K. Rodriguez Lorenc, Y. Ji
002		Pharmacokinetics and Pharmacodynamic Response of Cenicriviroc in Healthy Subjects of Japanese and Caucasian Ethnicity	S. Ayalasomayajula, L. Yao, E. Kaczynski, D. McGeeney, E. Martins, T. Carrothers, S. Seyedkazemi, R. Boinpally, A. Periclou
003	NM	Single- and Multiple-dose Tolerability and Pharmacokinetics of ACT-519276: A Novel Iminosugar	M. Géhin, M. Melchior, P. N. Sidharta, A. Crucitti, J. Dingemanse
004		Consistently Low Exposure to Diazepam Following Diazepam Rectal Gel in Subjects With Typical Exposure Following Diazepam Buccal Film	A. H. Heller, S. Wargacki, D. J. Wyatt, G. Slatko
005		Clinical Pharmacokinetics of Mivebresib (ABBV-075), a Bromodomain and Extra Terminal Inhibitor, Given as Monotherapy in Patients With Advanced Solid Tumors and Acute Myeloid Leukemia	B. A. Jonas, G. Borthakur, P. N. Lara, I. Aldoss, D. Rizzieri, T. Prebet, B. H. O'Neil, R. Szmulewitz, P. LoRusso, M. Barve, J. C. Sachdev, J. Wolff, B. Hu, J. Schmidt, R. M. Menon, K. J. Freise, R. Joshi, S. A. Piha-Paul
006		Population Pharmacokinetic and Concentration-QTc Analysis of Quizartinib in Patients With *FLT3*-ITD-positive Relapsed/Refractory Acute Myeloid Leukemia	D. Kang, E. Ludwig, D. Jaworowicz, H. Huang, J. Fiedler-Kelly, M. Abutarif, Y. Choi, K. Kobayashi, J. Mendell, O. Yin
007		Pharmacokinetics of Risankizumab in Healthy Caucasian, Japanese and Chinese Subjects	A. Khatri, Y. Pang, L. Cheng, A. A. Othman
008		Population Pharmacokinetics of the Chimeric Anti-GD2 Antibody, ch14.18, in Children With High-risk and Recurrent Neuroblastoma: Results From a Phase 1/2a Multicenter Trial	T. Kimura, Y. Fukaya, C. Nitani, K. Yoshimura, T. Taguchi, J. Hara
009		Effect of Gastric Acid-reducing Agents on the Pharmacokinetics and Efficacy of Lemborexant	I. Landry, J. Aluri, N. Hall, G. Filippov, B. Lalovic, Y. Miyajima, T. Ueno, M. Moline, L. Reyderman
010		Effect of Severe Renal Impairment on Pharmacokinetics, Safety and Tolerability of Lemborexant	I. Landry, J. Aluri, N. Hall, G. Filippov, S. Dayal, M. Moline, L. Reyderman
011	E	A Phase 1 Study of Opicapone Pharmacokinetics and Its Effects on Catechol-O-Methyltransferase Activity and Levodopa Pharmacokinetics in Patients With Stable Parkinson's Disease	G. Loewen, P. LeWitt, C. Olanow, K. Kieburtz, G. S. Liang, R. Jimenez, K. Olson, E. Roberts

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Poster Session 1

Sunday, Sept 15th / 5:00 – 7:00 PM
IMPERIAL BALLROOM - FRONT

Clinical Pharmacokinetics (ADME) (continued)

Poster	Type	Title	Authors
012		Mass Balance and Pharmacokinetics of a Single Oral Dose of ^{14}C-Centanafadine in Healthy Adult Subjects	S. Mehrotra, O. Alabi, S. Roth, P. Bricmont, J. Gordon, S. Shoaf
013	NM	Pharmacokinetics of Vancomycin in Children Admitted to the Intensive Care Unit of a Tertiary Care Hospital	K. Sridharan, A. Al-Daylami, S. Veeramuthu, R. P. Sequeira, K. A. Al-Khaja
014		Trends in the Design and Conduct of Pharmacokinetic Studies in Patients With Impaired Renal Function	M. Tanguay, I. Freije, F. Achkar
015	NM	Pharmacokinetics, Pharmacodynamics and Immunogenicity of JNJ-55920839, an Antibody Targeting Interferon α/ω in Healthy Subjects and Subjects With Mild to Moderate Systemic Lupus Erythematosus	Z. Yao, M. Chevrier, S. Marciniak, B. Srivastava, A. Sharma, Z. Xu
016		A Phase 1, Open-label, Two-period, Fixed-sequence Study of the Effect of a Proton Pump Inhibitor On the Relative Bioavailability of the Proposed Commercial Tablet Formulation of Palbociclib in Healthy Volunteers	Y. Yu, A. Plotka, M. O'Gorman, H. Shi, D. Wang
017	S	Implementation of a Pediatric Medical Cannabis Research Program	S. Barr, M. Diliberto, G. Moorthy, C. Vedar, A. Adam, J. Irizarry, E. Ward, B. Yerys, A. Bennett, A. Zuppa
*019	S	Effect of Pregnancy on the Renal Elimination of Raltegravir and Its Glucuronide Metabolite in HIV-infected Women	F. L. Moreira, G. Duarte, M. Marques, C. M. Coutinho, P. P. Melli, V. L. Lanchote
020	P, S, SA	HIV Coinfection Does Not Alter the Pharmacokinetics of Rifampicin, Pyrazinamide and Ethambutol in Patients With Tuberculosis	G. B. Nardotto, V. R. Bollela, A. Rocha, O. Della Pasqua, V. L. Lanchote
021		Absorption, Distribution, Metabolism and Excretion of Aprocitentan, a Dual Endothelin Receptor Antagonist, in Humans	P. N. Sidharta, H. Fischer, S. Delahaye, J. Dingemanse

Drug Interactions

Poster	Type	Title	Authors
022		Results from Two Drug-Drug Interaction Studies: Effect of Aprocitentan on the Pharmacokinetics of Midazolam or Rosuvastatin in Healthy Male Subjects	P. N. Sidharta, J. Dingemanse
023		Current Trends in Clinical Combined Oral Contraceptive Drug Interaction Studies	A. Choi, C. Yu
024		Opioids Inhibit the Activity of Molecularly-targeted Chemotherapy in Bcr-Abl-Positive Leukemic Cells	J. E. Constance, T. Satterlee
025		Ibrutinib Does Not Have Clinically-relevant Interactions With Oral Contraceptives or Substrates of CYP3A and CYP2B6	J. de Jong, A. Mitselos, W. Jurczak, R. Cordoba, C. Panizo, T. Wrobel, J. Jiao, J. Sukbuntherng, D. Ouellet, P. Hellemans
026		Lack of Clinically-relevant Effect of Upadacitinib on Plasma Exposures of Rosuvastatin and Atorvastatin	M. F. Mohamed, S. Coppola, T. Feng, H. Camp, A. A. Othman
027		Drug-Drug Interaction Studies of Elagolix With Oral and Transdermal Low-dose Hormonal Add-back Therapy	A. Nader, N. Mostafa, F. Ali, M. Shebley
028		CYP3A4 Interaction Potential of the T-type Calcium Channel Blocker ACT-709478, a Potential New Antiepileptic Drug	M. Ort, M. Richard, P. Kaufmann, R. Kornberger, J. Dingemanse

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*Numbers out of sequence indicate Posters that were withdrawn.

Please visit **ACCP1.org** for updates on the Abstract Submission process and deadlines for the 2020 Annual Meeting

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Poster Session 1

Sunday, Sept 15th / 5:00 – 7:00 PM
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Drug Interactions (continued)

Poster	Type	Title	Authors
029	NM	Evaluation of Ipatasertib Interaction With a Strong CYP3A4 Inhibitor, Itraconazole, and Endogenous Substrate of OATP1B1/1B3 Substrate, Coproporphyrin I and III in One Drug-Drug Interaction Study	R. S. Sane, E. Plise, V. Malhi, B. Chen, L. Musib
030		Effect of Rifampin-mediated Inhibition of the Hepatic Uptake Transporters OATP1B1 and OATP1B3 on the Pharmacokinetics of the $P2Y_{12}$ Receptor Antagonist Selatogrel (ACT-246475)	U. Schilling, M. Ufer, J. Dingemanse
031		Combination of Olanzapine and Samidorphan Does Not Have a Clinically-significant Effect on the Pharmacokinetics of Lithium or Valproate	L. Sun, S. Yagoda, B. Yao, L. von Moltke
032		Application of Dissolution Profile Comparison for Gastric pH-dependent Drug-Drug Interaction Prediction	L. Miao, F. Wu, X. Yang, A. Ramamoorthy, S. Lee, K. Raines, L. Zhang, P. Seo
*034	NM, S	Pharmacokinetics of Novel Experimental Combination Therapy of Paclitaxel and Calcipotriol for the Treatment of Pancreatic Ductal Adenocarcinoma	V. R. Lincha, C. Hsiao, J. Zhao, C. Li, D. Chow
035	S	Prevalence of Drug-Drug Interactions in Oncology Patients Enrolled in Two Completed SWOG Clinical Trials	L. A. Marcath, C. M. Finley, S. Wong, D. L. Hertz
*037	S	Inhibitory Effects of P-cresol Toward Mycophenolic Acid Glucuronidation in Pooled Human Liver Microsomes: Mechanisms of Interaction and *In Vitro-In Vivo* Prediction	Y. Rong, T. K. Kiang

Emerging Technologies

Poster	Type	Title	Authors
038		Optimizing I/E Criteria for Early Nonalcoholic Steatohepatitis Clinical Studies With FibroScan®	S. Paglialunga

Pediatrics

Poster	Type	Title	Authors
039	NM	A Pediatric Covariate Function for CYP3A-mediated Midazolam Clearance Can Scale Clearance of Selected CYP3A Substrates in Children	J. M. Brussee, E. H. Krekels, E. Calvier, S. Palic, A. Rostami-Hodjegan, M. Danhof, J. S. Barrett, S. N. de Wildt, C. A. Knibbe
040		Extrapolation of Pharmacokinetics and Pharmacodynamics of Sunitinib for Pediatric Patients With Gastrointestinal Stromal Tumors	R. Khosravan, E. Wang, S. G. DuBois, K. Janeway
041		Body Surface Area-based Dosing of Intravenous Golimumab in Pediatric Subjects With Polyarticular Juvenile Idiopathic Arthritis Demonstrates Similar Pharmacokinetic Exposures as Adult Subjects With Rheumatoid Arthritis: Week 52 Results from GO-VIVA	J. H. Leu, C. Hsu, M. Clark, K. Bensley, X. Li, K. Lo, A. Sharma, H. Zhou, Z. Xu
042	NM, S	A Two-pronged Modeling Approach to Quantify Midazolam Pharmacodynamics in Critically-ill Mechanically-ventilated Children	P. J. Upadhyay, N. J. Vet, S. C. Goulooze, E. H. Krekels, S. N. de Wildt, C. A. Knibbe
043		Empiric Treatment of Neonatal Early-onset Sepsis: A Retrospective Analysis of the University of Utah Hospital Cases	J. S. Wagstaff, M. G. Newman, E. Y. Enioutina

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Poster Session 1

Sunday, Sept 15th / 5:00 – 7:00 PM
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Pediatrics (continued)

Poster	Type	Title	Authors
044		Population Pharmacokinetics of Sunitinib in Pediatric Patients With Gastrointestinal Stromal Tumors and Other Solid Tumors	E. Wang, S. G. DuBois, C. Wetmore, A. Verschuur, R. Khosravan
045		Population Pharmacokinetics/Pharmacodynamics of Sunitinib in Pediatric Patients With Solid Tumors	E. Wang, S. G. DuBois, C. Wetmore, R. Khosravan
046		Physiologically-based Pharmacokinetic Modeling and Simulation of Sunitinib in Pediatrics	Y. Yu, S. G. DuBois, C. Wetmore, R. Khosravan
047		A Population Pharmacokinetic Analysis of Plasma and Skeletal Muscle Concentrations of Cefazolin in Children Undergoing Cardiac Surgery	N. R. Zane, A. S. Himebauch, M. R. Gastonguay, A. Zuppa
048	S	Quantifying the Morphine Concentration-Effect Relationship for Postoperative Pain in Children Using Item Response Theory Modeling	S. C. Goulooze, T. de Kluis, M. van Dijk, E. H. Krekels, I. Ceelie, S. N. de Wildt, D. Tibboel, C. A. Knibbe
049	NM, S	Population Pharmacokinetic Model of Eribulin Mesylate in Children With Refractory or Recurrent Solid Tumors	T. R. Larson, E. S. Schafer, R. E. Rau, C. G. Minard, E. Fox, B. J. Weigel, J. M. Reid
050	NM, S	Prophylactic Voriconazole in Pediatric Hematopoietic Stem Cell Transplant Patients: A Pharmacokinetic Study and Therapeutic Drug Monitoring	T. Takahashi, A. R. Smith, P. A. Jacobson, J. Fisher, N. Rubin, M. Kirstein
051	S	Patterns of Medication Exposures in Children Supported by Extracorporeal Membrane Oxygenation	C. Thibault, H. Collier, J. Heichel, E. Schwartz, A. Zuppa
052	NM, S, SA	Pediatric Exposure of Lacosamide Adjunctive Antiepileptic Therapy in Children Under Four Years of Age	P. B. Lukka, M. Woods, R. Chhim, J. Wheless, B. Meibohm

Rare Diseases

Poster	Type	Title	Authors
053		Exposure-Response of Migalastat in Support of Extrapolation of Efficacy from Adults to Children With Fabry Disease, a Rare Lysosomal Disorder	F. Johnson, J. Marier, A. Mulberg
054	NM, S	Novel Universal Screening Method to Characterize the *In Vitro* Hemoglobin Binding Kinetics of Synthetic Allosteric Effectors of Hemoglobin as Potential Sickle Cell Disease Therapeutics	X. Xu, M. Ghatke, O. Abdulmalik, M. Safo, J. Venitz

Special Populations

Poster	Type	Title	Authors
055		Use of Intravenous Immunoglobulin to Treat Encephalitis in a Pediatric Hospital Network	A. H. Balch, J. Wilkes, E. Y. Enioutina
056		Evaluation of the Pharmacokinetics and Safety of Ivosidenib in Subjects With Mild or Moderate Hepatic Impairment or Normal Hepatic Function	B. Fan, D. Dai, M. Cohen, H. Xu, F. Yin, R. Nagaraja, M. Mobilia, C. Almon, F. Basile, H. Yang
057		Renal Impairment Study Designs: Trends, Optimization and Adaptive Approach, A Review	J. Michaud, V. Pichette, É. Sicard, T. C. Marbury, W. B. Smith, J. Huguet
058		Dosage Adjustment of Itacitinib, a JAK-1 Inhibitor, is Not Recommended in Subjects With Renal Impairment	N. Srinivas, A. M. Barbour, N. Epstein, Z. Xun, J. Harris, B. Yuska, X. Chen, S. Yeleswaram, N. Punwani

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Poster Sessions 1 & 2

Sunday, Sept 15th / 5:00 – 7:00 PM
IMPERIAL BALLROOM - FRONT

Special Populations (continued)

Poster	Type	Title	Authors
059	S	Clinical Impacts of Roux-en-Y Gastric Bypass Surgery on the Metabolism of Atorvastatin and Simvastatin and Pharmacokinetic/Pharmacodynamic Correlation Incorporating Weight Loss Outcomes	A. El-Zailik, L. Cheung, Y. Wang, V. Sherman, D. Chow
060	S	Pharmacokinetics of Intraperitoneal Vancomycin in Patients on Automated Peritoneal Dialysis	E. Lam, Y. Lien, V. Vozmediano, S. Schmidt, W. Kraft, J. Zhang
061	S	Ketamine Population Pharmacokinetics in Critically-ill Patients on Extracorporeal Membrane Oxygenation Therapy	Y. Lien, E. Lam, V. Vozmediano, A. Rochani, G. Kaushal, J. Tanjuakio, B. Thoma, H. Hirose, W. Kraft, S. Schmidt
062	S	Off-label Drug Use in Geriatric Population: Do We Have Enough Evidence?	S. A. Pai, A. R. Juvekar

Transporters

Poster	Type	Title	Authors
063		Mechanistic Models as Framework for Understanding Biomarker Disposition: Predictions of Creatinine-Drug Interactions	D. Scotcher, V. Arya, X. Yang, P. Zhao, L. Zhang, S. M. Huang, A. Rostami-Hodjegan, A. Galetin
064	S	Calibrating An *In Vitro* System With Rosuvastatin and Estradiol 17-β-D-glucuronide/cholecystokinin-8 as Substrates to Predict Transporter-mediated Clinical Drug-Drug Interaction With Rosuvastatin Using Static and Physiologically-based Pharmacokinetic Models	K. Cheung, Z. Gáborik, T. Farasyn, R. Li, E. Plise, P. Kovács, R. Sane

Women's Health

Poster	Type	Title	Authors
065		Sex Hormones and the QT Interval: J-Tpeak and Tpeak-Tend Assessment and Further Insights Into the Physiological Effects	J. Täubel, S. Coates, K. Prasad, G. Rosano, G. Ferber, L. Van Langenhoven, S. Fernandes, D. Djumanov, A. Sugiyama

Monday, Sept 16th / 5:00 – 7:00 PM
IMPERIAL BALLROOM - FRONT

Adverse Drug Effects

Poster	Type	Title	Authors
066		Photosensitivity-induced Drug Use and Skin Cancer	G. H. Sokol, L. S. Loftus, T. Oliver, J. Ayub, G. Wright, D. Wenk
067	NM	The Effect of Hypertension & Antihypertensives on Female Sexual Dysfunction	Q. Zhong
068	S	Data Sources Supporting US Food & Drug Administration Drug Safety Communications	D. Shepshelovich, T. Schochat, A. Gafter-Gvili, A. Tibau, E. Amir, N. Tau

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Poster Session 2

Monday, Sept 16th / 5:00 – 7:00 PM

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Applications of Modeling & Simulation

Poster	Type	Title	Authors
069		Quantification of Critical Mechanisms for Statin Drug Interactions Using Physiologically-based Pharmacokinetic Modeling	K. D. Alam, S. Chung, N. Isoherranen, S. Huang
070	NM	Risk Factor Analysis of Coronary Artery Diseases Using Artificial Intelligence	J. Patel, B. Naik, M. Vyas, S. Singh, N. Patel, J. Pandya, K. Panchal, J. Vanparia, H. Shah, C. Mojidra
071		Patient- and Disease-characteristic Predictors of Systemic Exposure to Crisaborole	V. Purohit, S. Riley, H. Tan, W. Ports
072		Application of Translational Modeling to Inform Clinical Development of JNJ-67864238 (PTG-200), An Orally-administered, Locally-acting Peptide Antagonist of IL-23 Receptor for the Treatment of Inflammatory Bowel Disease	Y. Xu, T. Kosoglou, R. Strauss, B. Kanwar, X. Cheng, H. Zhou
073		A Concentration-QTc Analysis to Determine the Effect of Pexidartinib on the QTc Interval	H. Zahir, B. Darpo, X. Gu, R. Brown, O. Yin, G. Atiee, J. Greenberg, T. Kakkar, F. LaCreta
074	NM, S	A Mathematical Model of the High-dose Hook Effect	A. Chind
075	E, S	Subcutaneous Sarilumab and Subcutaneous and Intravenous Tocilizumab: Interleukin-6, Receptor Occupancy and Effects on C-Reactive Protein Levels in Patients With Rheumatoid Arthritis	C. Xu, P. Nolain, Q. Lu, A. Paccaly, M. Iglesias-Rodriguez, G. St John, R. Maldonado, T. Ishii, E. Choy, V. Kanamaluru
076	P, S, SA	Development of a Virtual HIV Pregnant Population for Use in Physiologically-based Pharmacokinetic Modeling	M. Gockenbach, J. Momper, M. Grimstein, M. Mirochnick, E. V. Capparelli, K. Struble, T. Johnson, H. Sachs
077	P, S, SA	A Semiphysiological Approach for Evaluating the Sensitivity of Pharmacokinetics to Detect Differences in Regional Lung Deposition of Orally-inhaled Drug Products	A. Kurumaddali, E. Amini, S. K. Drescher, M. Chen, J. Bulitta, G. Hochhaus
078	NM, S, SA	Pharmacodynamic Modeling of the Relationship Between Tetrahydrocannabinol Concentrations and Corresponding Changes in Heart Rate	S. K. Singla, G. An, M. Donovan, L. Ponto

Clinical Trials

Poster	Type	Title	Authors
079		Results of a Randomized Clinical Trial Related to the Effectiveness of Flakozid, An Antiviral Drug of Herbal Origin	V. V. Bortnikova, L. V. Krepkova, V. V. Karabaeva, G. F. Sidel'nikova, P. G. Mizina, K. M. Job, C. M. Sherwin, E. Y. Enioutina
080	NM, E	Phase 1 Study on the Safety, Tolerability and Pharmacodynamic Effects of ASP4345 for the Treatment of Cognitive Impairment in Patients With Schizophrenia	A. Desai, L. Benner, R. Wu, L. Gertsik, P. Maruff, G. Light, T. Uz, G. Marek, T. Zhu
081		Effects of a Cytochrome P450 3A4 Inducer (Rifampicin) on the Pharmacokinetics of BI 425809, a Novel Glycine Transporter 1 Inhibitor	M. Desch, G. Wunderlich, K. Liesenfeld, T. Chan, H. Rosenbrock, S. Keller, J. Link, S. Wind
082		Concerns and Considerations Regarding the Prevalence of Supplement Use in the Context of Clinical Trials	M. A. Fein, C. A. Dehn, L. A. Rusch

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Monday, Sept 16th / 5:00 – 7:00 PM
IMPERIAL BALLROOM - FRONT

Clinical Trials (continued)

Poster	Type	Title	Authors
083		Safety and Pharmacokinetics of High-dose TAS-303 in Healthy Volunteers: A Single-center, Single-blind, Randomized, Placebo-controlled, Parallel-group, Multiple-ascending Dose Study	R. Hanada, T. Takenaka, A. Suzuki, S. Toda
084		Single- and Multiple-dose Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Profiles of ASP0367/MA-0211: Results from Phase 1 Study	M. Ito, S. Tauscher-Wisniewski, R. Smulders, T. Wojtkowski, A. Yamada, A. Koibuchi, R. Goldwater
085		Characterization of Exposure to Cigarette Smoke Constituents in Adult Smokers Switching to E-vapor Products	D. Oliveri, J. Wang, S. Miller, J. Edmiston, M. Sarkar
086		The Effect of C-peptide and Glucose on QTcF, J-Tpeak and Tpeak-Tend	S. Coates, L. Van Langenhoven, S. Fernandes, D. Djumanov, G. Ferber, J. Täubel
087		Influence of Calcium Blockade on the QT Effects of a Meal	J. Täubel, S. Coates, K. Prasad, G. Rosano, L. Van Langenhoven, S. Fernandes, A. Sugiyama
088		The Effect of Glucose and Moxifloxacin on Cardiac Repolarization in Patients With Type 1 Diabetes	J. Täubel, S. Cole, H. Wibberley, L. Van Langenhoven, S. Fernandes, J. A. Camm
089	S	Combined Pediatric and Adult Trials Submitted to the US Food & Drug Administration	S. J. Miyagi, D. J. Green, J. M. Burnham, J. van den Anker, G. J. Burckart

Drug Development

Poster	Type	Title	Authors
*091		Multiple-ascending Dose Study in Healthy Subjects to Assess the Pharmacokinetics and Tolerability of the T-type Calcium Channel Blocker ACT-709478, a Potential New Antiepileptic Drug	M. Richard, P. Kaufmann, M. Ort, R. Kornberger, J. Dingemanse
092		Pharmacokinetic Considerations in the Development and Selection of Itacitinib Phase 3 Formulation for the Treatment of Graft-vs-Host Disease	N. Srinivas, A. M. Barbour, D. Modi, J. Shi, R. Landman, Z. Xun, T. Sheth, B. Parikh, S. Yeleswaram, N. Punwani
093	NM, S	Identifying Drug Target for Prenatal Cannabinoid Exposure-mediated Learning and Memory Deficits	P. D. Pinky, J. Bloemer, S. E. Setti, R. T. Heslin, Y. Du, A. Dityatev, M. N. Reed, V. Suppiramaniam

Experimental Pharmacology in In Vitro/In Vivo Studies

Poster	Type	Title	Authors
094	S	Urinary Biomarker and Histopathological Evaluation of Vancomycin and Piperacillin-tazobactam Nephrotoxicity in Comparison With Vancomycin in a Rat Model and a Confirmatory Cellular Model	G. M. Pais, J. Liu, S. Avedissian, A. Gilchrist, N. J. Rhodes, T. Lodise, J. Fitzgerald, K. Downes, M. H. Scheetz, VANCO TOX Group
095	S, SA	Topical Focal Adhesion Kinase Inhibitor Promotes Skin Regeneration and Scar Prevention in a Preclinical Porcine Model	S. H. Kwon, B. Kuehlmann, A. Trotsyuk, T. Dohi, M. Hu, M. Longaker, G. Gurtner

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Poster Session 2

Monday, Sept 16th / 5:00 – 7:00 PM
IMPERIAL BALLROOM - FRONT

Human Pharmacology

Poster	Type	Title	Authors
096		Genome-wide H3K9 Acetylation Changes Associated With 5-azacytidine Treatment in Primary Acute Myeloid Leukemia Cells	H. Carraway, S. Malkaram, A. Shatnawi, A. Siddig, J. Fan, J. Denvir, D. Primerano, T. Fandy
097	S	Emerging Therapies for Hyperglycemia in Acute Ischemic Stroke: Glucagon-like Peptide 1 Receptor Agonists and Dipeptidyl Peptidase IV Inhibitors	F. Ferrari, A. Moretti, R. F. Villa

Infectious Diseases

Poster	Type	Title	Authors
098	NM, E	Dose Optimization of Ivermectin in Children: A Model-based Approach to Achieve Equivalent Exposure Coverage in Children and Adults	J. M. Brussee, J. D. Schulz, J. T. Coulibaly, J. Keiser, M. Pfister
099	S	Traditional Piperacillin/Tazobactam Dosing Regimen Fails to Achieve β-Lactamase Inhibitor Targets	S. N. Kalaria, M. Gopalakrishnan, E. Heil
100	NM, S	An *In Vitro* Toxicodynamic Model to Assess Renal Cell Viability With Polymyxin B	J. Liu, G. M. Pais, A. Gilchrist, A. Lee, N. J. Rhodes, A. R. Hauser, M. H. Scheetz

Model-informed Drug Development

Poster	Type	Title	Authors
101		One Size Does Not Fit All: Justification for Different Venetoclax Doses Across Indications	A. H. Salem, S. Gopalakrishnan, K. Freise, D. Samineni, S. Mensing, R. Menon
102		Population Pharmacokinetic/Pharmacodynamic Modeling of Loncastuximab Tesirine and Blood Gamma-glutamyltransferase in a Phase 1 Study of Patients With Non-Hodgkin Lymphoma	X. Zhang, D. Ungar, Y. Qin, J. Boni

Novel Use of Therapeutics/Drug Repurposing

Poster	Type	Title	Authors
103	S	Pharmacokinetics and Locomotor Efficacy of Riluzole and Minocycline Combination in Spinal Cord Injured Rats	M. Sarkar, C. Seward, R. Grill, R. Grossman, D. Chow

Oncology/Immuno-oncology

Poster	Type	Title	Authors
104	NM	Plasma Hyaluronan as a Predictive Pharmacodynamic Biomarker for Efficacy in Subjects With Pancreatic Cancer Following PEGylated rHuman Hyaluronidase Plus Gemcitabine and Nab-paclitaxel Treatment	J. Rashid, Y. Liu, Y. Huang, R. Sekulovich

Other Therapeutic Areas

Poster	Type	Title	Authors
105	NM	Relationship Between Acne Vulgaris and Insulin Resistance Markers and Effect of Isotretinoin on Insulin Resistance Markers in Patients With Acne Vulgaris: A Systematic Review and Meta-analysis	H. Singh, A. Raizada, H. Soni, A. K. Kakkar, J. Singh, C. S. Gautam

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Monday, Sept 16th / 5:00 – 7:00 PM
IMPERIAL BALLROOM - FRONT

Pharmacodynamics

Poster	Type	Title	Authors
106	S	Efficacy of Morphine Maintenance and Rescue Analgesia After Cardiac Surgery in Children Using Repeated Time-to-Event Analysis	S. de Hoogd, A. J. Valkenburg, S. C. Goulooze, E. H. Krekels, M. van Dijk, D. Tibboel, C. A. Knibbe

Pharmacoepidemiology

Poster	Type	Title	Authors
*108		Impact of Kratom Use on Chronic Health Conditions in US Users	C. A. Veltri, O. Grundmann
109	NM, S	Novel Application of Pharmacoepidemiology for the Examination of Possible Pharmacokinetic/Pharmacodynamic Mechanisms of Macrolide Antibiotic Resistance	B. Cicali, S. Schmidt, J. D. Brown

Pharmacogenomics

Poster	Type	Title	Authors
110	S	The Role of CYP2C19 Genetic Variants on Voriconazole Pharmacokinetics in Pediatric Hematopoietic Stem Cell Transplant Recipients	M. Mohamud, A. Alharbi, T. Takahashi, A. R. Smith, P. A. Jacobson, J. Fisher, N. Rubin, M. Kirstein
111	NM, S	Thresholds of Evidence Required for Robust Pharmacogenomic Biomarkers	R. Tanoshima, G. Wright, B. Drögemöller, P. Khayat, S. Dean, C. Ross, B. Carleton
112	NM, S	The ImPreSS Trial: Implementation of Point-of-care Pharmacogenomic Decision Support in Perioperative Care	T. M. Truong, J. Apfelbaum, S. Shahul, M. Anitescu, D. Leibovitz, R. Knoebel, X. van Wijk, K. Yeo, M. J. Ratain, P. H. O'Donnell
113	NM, S, SA	Examination of Asymmetric Dimethylarginine Levels in the Presence and Absence of Type 2 Diabetes With Exploratory Genetic Association Analysis	Y. Y. Anane, R. W. Fankhouser, D. E. Murrell, K. Abakah, H. H. Quach, A. N. Seay, A. V. Hanley, K. W. Bullins, D. L. Hurley, S. Harirforoosh

Pharmacometrics & Systems Pharmacology

Poster	Type	Title	Authors
114	NM	Population Pharmacokinetic Analysis of Plerixafor in Pediatric Cancer Patients	P. Bhagunde, Y. Chen, Y. Gao, Z. Qian, G. Emmons, V. Kanamaluru, Q. Lu
115		Retrospective Evaluation of Phase 2 and 3 Clinical Trials for the Selection of Sampling Times and Its Implications	N. Heo, P. Bonate
116		Quantitative Systems Pharmacology Model of Amyloid Beta and Plaque Dynamics in Alzheimer's Disease Upon Treatment With Anti-amyloid Beta and β Secretase Inhibitor Drugs	K. Madrasi, L. Lin, H. Abdul, J. Burke, J. Apgar, L. Wille, L. Gruenbaum, F. Hua
117		A Quantitative Modeling Analysis of Antibody-Drug Conjugate and Payload Tumor Penetration: Role of Payload Tumoral Distribution in Efficacy	B. Matin, L. Lanieri, R. Laleau, J. Ponte, K. Culm-Merdek
118	E	Population Pharmacokinetic and Pharmacodynamic Analysis of GLPG1690, an Autotaxin Inhibitor, in Healthy Volunteers and Patients With Idiopathic Pulmonary Fibrosis	A. Taneja, J. Desrivot, P. Diderichsen, R. Blanque, L. Allamassey, L. Fagard, A. Fieuw, E. van der Aar, F. Namour

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Poster Session 2

Monday, Sept 16th / 5:00 – 7:00 PM
IMPERIAL BALLROOM - FRONT

Pharmacometrics & Systems Pharmacology (continued)

Poster	Type	Title	Authors
119		A Physiologically-based Pharmacokinetic Model for Intravenous Voriconazole in Pediatric Patients With and Without Cancer	V. K. Yellepeddi, J. S. Wagstaff, J. E. Constance
120		Population Pharmacokinetic and Exposure-Response of Neutropenia Analyses in First-line Patients With Advanced Breast Cancer With Palbociclib Treatment	Y. Yu, D. Wang
121		Population Pharmacokinetic and Exposure-Response of Neutropenia Analyses in Patients With Advanced Breast Cancer that Has Progressed After Prior Endocrine Therapy With Palbociclib Treatment	Y. Yu, D. Wang
122		Pharmacodynamic Modeling of Longitudinal Hemoglobin Change and Logistic Regression Analyses of Anemia in Cancer Patients Treated With Talazoparib	Y. Yu, L. DeAnnuntis, A. Czibere, D. Wang
123		Population Pharmacodynamic Modeling of Longitudinal Tumor Size Change After Talazoparib Treatment	Y. Yu, A. Czibere, D. Wang
124		Phase 2 to Phase 3 Prediction of Progression-free Survival Using Early Tumor Response in Advanced Breast Cancer With Germline BRCA Mutations	Y. Yu, D. Wang
125		Assessment of Early Tumor-size Change to Predict Overall Survival in Patients With Advanced Breast Cancer that Has Progressed After Prior Endocrine Therapy	Y. Yu, D. Wang
126	S	Lung Retention and Bronchodilation of Inhaled Beta-agonist Fenoterol Described by a Pharmacodynamic-driven Pharmacokinetic/Pharmacodynamic Model Incorporating Cardiac Effects in Asthmatic Patients	S. K. Drescher, M. Chen, Y. Jiao, J. Bulitta, G. Hochhaus
127	NM, S	Quantitative Benefit-Risk Assessment of P-gp-mediated Drug-Drug Interactions of Dabigatran Coadministered With Pharmacokinetic Enhancers in Patients With Renal Impairment	K. Lingineni, N. Farhan, S. Kim, L. Gordon, S. Penzak, C. Hadigan, J. George, S. Schmidt
128	P, S, SA	Analysis of Emtricitabine and Acyclovir Exposure Throughout the Complete Course of Pregnancy	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

Regulatory Issues

Poster	Type	Title	Authors
129		The Implementation of Human Maximal Usage Trial Paradigm to Topical Antiseptic Active Ingredients to Determine their Safety	S. Yi, L. Oh, S. Shin, D. Zhang, D. Bashaw

Safety & Efficacy

Poster	Type	Title	Authors
130		The Use of Early Clinical Data With Mirvetuximab Soravtansine to Evaluate QT/QTc Prolongation Potential	V. Chamberlain Santos, J. Wang, P. Slatcher, K. Dykstra, K. Culm-Merdek
131		Pharmacodynamics, Pharmacokinetics, Safety and Tolerability of ASP6981 in Subjects With Schizophrenia	J. Huang, J. Young, P. Maruff, G. Light, D. Brown, L. Gertsik, L. Benner, P. Bonate, G. Marek, T. Uz

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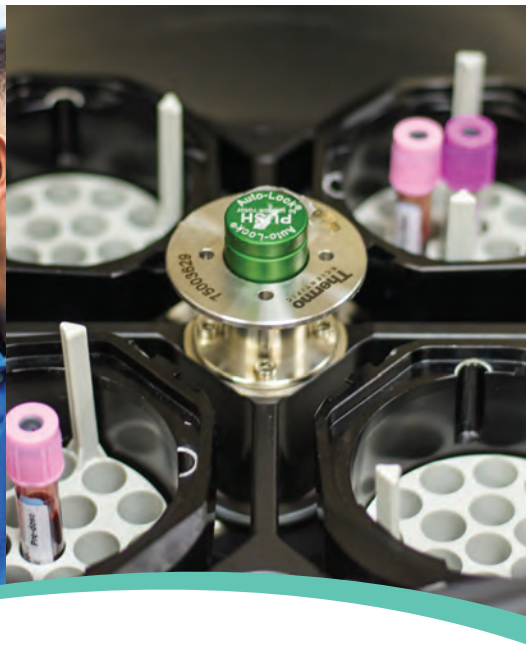

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