



ACCP

AMERICAN COLLEGE OF CLINICAL PHARMACOLOGY®

Advancing Clinical Care through Pharmacology®

2018 Annual Meeting American College of Clinical Pharmacology®

*Discovery & Innovation in Clinical Pharmacology:
Application to Patient Care*



September 23 – 25, 2018
Bethesda N Marriott Hotel & Conf Ctr
Bethesda, MD

Co-chairs: *Dionna J. Green, MD & Amalia M. Issa, PhD, MPH*

FINAL PROGRAM

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Advancing Clinical Care through Pharmacology®

Join Us to Celebrate ACCP's 50th Anniversary **2019 ACCP Annual Meeting!**

Reflecting on Our History & Shaping the Future of Clinical Pharmacology

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

*Be sure to attend
the 50th Anniversary
Gala on Saturday,
Sept 14th!*

Chemotherapy

Pharmacology

Antibiotics

Personalized
Medicine

Clinical
Medicine

Synthesis
of Drugs



ACCP is a proud provider of Continuing Medical Education (CME) & Continuing Pharmacy Education (CPE)

FUTURE MEETINGS:

2020 ACCP Annual Meeting

September 20 – 22, 2020

Bethesda N Marriott Hotel & Conf Ctr

Bethesda, MD

Did You Know?

Use the expanded ACCP Mobile App to find all the meeting information you're looking for!

- Easily access a list of Attendees, Faculty, Exhibitors & Sponsors
- Easily access daily Sessions, Poster Presentations and Special Events via a flexible search engine
- Chat with colleagues weeks before arriving at the ACCP Annual Meeting to schedule get togethers and stay connected before, during and after the meeting
- Keep organized by creating your own individualized schedule, customizing it with educational and social events you would like to attend
- Share your experience on Facebook or LinkedIn
- Access new job listings in the Career Center
- Learn more about the 2018 ACCP Recognition & Student Award Winners
- Direct links to daily Session Evaluations and CE Post-event Tests
- Take notes specific to Sessions and people
- Easy access to hotel location map and hotel floor plans

Register for the 2019 Annual Meeting at 2018 prices!

In 2019, ACCP will celebrate its 50th anniversary! Register for the 2019 Annual Meeting before you leave the 2018 Annual Meeting and receive 2018 registration prices. Stop by the ACCP Registration Desk and ask Staff to process your payment for this promotion.

ACCP continues to expand its Continuing Education Program!

An accredited provider of Continuing Medical Education (CME) and Continuing Pharmacy Education (CPE), ACCP has further expanded its Continuing Education Program. See page 52 for a listing of categories of educational courses available from ACCP.

Publish Your Manuscript in *The Journal of Clinical Pharmacology* or *Clinical Pharmacology in Drug Development*

Submit your manuscript to *The Journal of Clinical Pharmacology* (JCP) or *Clinical Pharmacology in Drug Development* (CPDD). Both journals have highly-skilled international Editorial Boards and some of the fastest turnaround times on first and final decisions. JCP publishes original research articles, reviews, commentaries, letters to the editor and brief reports submitted from all over the world, making the JCP a truly international journal for scientists and clinicians spanning many disciplines. CPDD publishes high-quality clinical pharmacology studies in drug development. Both journals are MedLine® indexed.



Attending the Meeting as a Student, Trainee or Young Professional?

ACCP has planned a series of events specifically to benefit our young colleagues! See page 45 for details.

Interested in joining ACCP?

Stop by the ACCP Registration Desk for complete information or to complete a profile and pay 2019 Dues entitling you to ACCP Member Benefits.

Thank You to Our Sponsors

ACCP gratefully thanks High Point Clinical Trials Ctr for providing lanyards for attendees, Wiley Periodicals Inc for sponsoring the Student, Trainee & Young Professional events and DUCK FLATS Pharma LLC for sponsoring the photo booth in the Exhibit Hall. See page 46 for a listing of all Sponsors.

Take Time to Visit Our Exhibitors!

Exhibitor support is critical to the success of the ACCP Annual Meeting. We encourage you to visit our Exhibitors in the Grand Ballroom E-H during breakfast, breaks or 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.

Follow ACCP on



ACCP Registration Desk Hours / Foyer

Friday, September 21 st	5:00 – 7:00 PM	Grand Ballroom Foyer
Saturday, September 22 nd	7:00 AM – 5:30 PM	Grand Ballroom Foyer
Sunday, September 23 rd	6:30 AM – 7:00 PM	Grand Ballroom Foyer
Monday, September 24 th	7:00 AM – 7:00 PM	Grand Ballroom Foyer
Tuesday, September 25 th	7:00 AM – 5:30 PM	Grand Ballroom Foyer

Lost & Found

Any found items should be given to ACCP Staff at the ACCP Registration Desk in the Grand Ballroom Foyer. Persons wishing to retrieve a lost item should also contact ACCP Staff at the ACCP Registration Desk.



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Mobile App

Don't forget to download The ACCP Annual Meeting Mobile App!

App Store (iTunes)



or Google Play Stores



The ACCP Meeting
Mobile App will appear as:



The ACCP Mobile App is an easy and convenient way to navigate the 2018 ACCP Annual Meeting on your Apple (iOS) and Android smartphones and tablets. It contains all of the event information that you'll need to make the most of your experience.

- Easily access a list of Attendees, Faculty, Exhibitors & Sponsors
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- Take notes specific to Sessions and people
- Easy access to hotel location map and hotel floor plans
- Use the Mobile App for live polling during courses



How the ACCP Mobile App enhances your experience at the ACCP Annual Meeting

Connect:

With colleagues and peers before, during and after the meeting

Share:

Your experience with those who couldn't make it to the meeting by posting to your social media accounts

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American College of Clinical Pharmacology® 2018 Annual Meeting Program Committee

Co-chairs:

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Amalia M. Issa, PhD, MPH

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AMERICAN COLLEGE OF CLINICAL PHARMACOLOGY®
Advancing Clinical Care through Pharmacology®

Letter of Welcome from President & Program Co-chairs

Welcome to the 2018 ACCP Annual Meeting!

Discovery & Innovation in Clinical Pharmacology: Application to Patient Care

#2018ACCP

Welcome to the 2018 Annual Meeting of the American College of Clinical Pharmacology® (ACCP), “Discovery & Innovation in Clinical Pharmacology: Application to Patient Care”. Consistent with ACCP’s commitment to excellence in science and education, the 2018 Annual Meeting Program Committee, co-chaired by Drs. Dionna J. Green and Amalia M. Issa, 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. 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.

On Saturday, September 22nd, a series of **Pre-meeting Workshops** will cover topics such as:

- Organ-on-a-Chip: What Is It & How Can It Advance the Role of Clinical Pharmacology in Drug Discovery & Development?;
- Applications of Quantitative & Systems Pharmacology from Drug Development to Patient Care;
- Working Towards Becoming an Effective Communicator;
- Model-informed, Optimal Neonatal Clinical Trial Design.

On Sunday, the **Plenary** session will open the 3-day meeting with a presentation on “Will Digital Health Transform Drug Development?” and Monday morning will feature a lively **Debate** on “Do We Still Need Clinical Pharmacology?” Symposium topics during the 3-day meeting include:

- **Pharmacometrics** – using physiologically-based pharmacokinetic (PBPK) modeling during pregnancy & lactation studies and an ACCP/ISoP jointly-sponsored event on pharmacometrics at the bedside;
- **Pediatrics** – innovations in pediatric HIV drug development and the extrapolation of intrinsic and extrinsic factors from adult pharmacokinetics to pediatric patients;
- **Drug Development** – the missing piece in the puzzle in intestinal influx transporters, using clinical pharmacology to break down barriers to generic drug substitution, non-traditional approaches to bioequivalence, the opportunities and challenges of studying targeted anticancer drugs in healthy volunteers and the ACCP/CSRC jointly-sponsored event on various facets of assessing cardiac safety;

- **Patient Care** – perspectives of nonalcoholic steatohepatitis, 2nd generation immuno-oncology products and the evolving clinical & regulatory requirements of assessing physical dependence and drug withdrawal symptoms;
- **Biostatistics** – dose finding and methodological & statistical consideration in drug development for rare diseases;
- **Pharmacogenetics/Precision Medicine** – implementation of preemptive pharmacogenetics and the ACCP/AAPS jointly-sponsored event using PBPK and population pharmacokinetic strategies for precision medicine in pediatrics; and
- **Novel Technologies** – perspectives on the opportunities & challenges in oligonucleotide-based therapies.

The Invited Keynote, Bruce C. Carleton, PharmD, Professor & Chair, Div of Translational Therapeutics, Dept of Pediatrics, Faculty of Medicine, Univ of British Columbia; Director, Pharmaceutical Outcomes Program, BC Children’s Hosp and Senior Clinician Scientist, BC Children’s Hosp Research Inst, will present “Pharmacogenomics & Risk Decision Making: Putting Patients First” during the Lunch & Awards Session on Monday.

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

Poster Sessions held on Sunday and Monday evenings will focus on new findings and preliminary data presented by a wide spectrum of attendees. Enjoy the chance to socialize and network at the Evening Receptions during the Poster Sessions, at twice-daily tea/coffee breaks, at the Lunch & Awards Sessions and the Annual Business Meeting.

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

We welcome you to an outstanding 2018 ACCP Annual Meeting and look forward to your participation and feedback!



John N. van den Anker,
MD, PhD
ACCP President



Dionna J. Green,
MD
Program Co-chair



Amalia M. Issa,
PhD, MPH
Program Co-chair

Program at a Glance

Workshops & Symposia at the 2018 ACCP Annual Meeting are identified as being part of either the “Discovery Track” (DT) or the “Application Track” (AT) to make it easier for attendees to determine which courses they prefer to attend.

FRIDAY, SEPTEMBER 21, 2018

ACCP Registration Desk Open

5:00 – 7:00 PM | [Grand Ballroom Foyer](#)

ACCP Executive Committee Meeting & Dinner

6:00 – 10:00 PM | [Middlebrook](#)

SATURDAY, SEPTEMBER 22, 2018

ACCP Registration Desk Open

7:00 AM – 5:30 PM | [Grand Ballroom Foyer](#)

ACCP Board of Regents Meeting

8:00 AM – 1:00 PM | [Forest Glen](#)

Pre-meeting Workshop 1 | 8:00 – 11:30 AM

Organ-on-a-Chip: What Is It & How Can It Advance the Role of Clinical Pharmacology in Drug Discovery & Development? (DT)

CHAIR: Rajanikanth Madabushi, PhD, Team Lead, US Food & Drug Administration, Guidance & Policy Team, OCP/OTS/CDER

[Grand Ballroom H](#)

Pre-meeting Workshop 2 | 8:00 AM – 12:00 PM

Applications of Quantitative & Systems Pharmacology from Drug Development to Patient Care (DT)

CO-CHAIRS: Ayyappa Chaturvedula, PhD, Associate Professor, Univ of North Texas Health Science Ctr, Pharmacotherapy and Rukmini Kumar, PhD, Principal Scientist, Vantage Research

[Grand Ballroom G](#)

Pre-meeting Workshop 3 | 1:30 – 5:00 PM

Working Towards Becoming an Effective Communicator (AT)

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

[Grand Ballroom H](#)

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

Model-informed, Optimal Neonatal Clinical Trial Design (DT)

CO-CHAIRS: Catherine MT Sherwin, PhD, MSc, Associate Professor, Univ of Utah School of Medicine, Pediatrics and Jian Wang, PhD, Associate Director, US Food & Drug Administration, Office of Drug Evaluation IV, CDER

[Grand Ballroom G](#)

ACCP Finance Committee Meeting

3:00 – 5:00 PM | [Great Falls](#)

ACCP Publications Committee Meeting

3:30 – 4:30 PM | [Oakley](#)

ACCP Honors & Awards Committee Meeting

3:30 – 4:30 PM | [Middlebrook](#)

ACCP Regents & Awards Reception (invitation only)

5:30 – 6:30 PM | [Brookside Foyer](#)

ACCP Regents & Awards Dinner (invitation only)

6:30 – 8:30 PM | [Brookside A&B](#)

SUNDAY, SEPTEMBER 23, 2018

ACCP Registration Desk Open

6:30 AM – 7:00 PM | [Grand Ballroom Foyer](#)

Continental Breakfast

7:00 – 8:00 AM | [Grand Ballroom Foyer](#)

Students, Trainees & Young Professionals Welcome

7:00 – 7:45 AM | [Grand Ballroom A-C](#)

New Member & First-time Attendee Welcome

7:00 – 7:45 AM | [Grand Ballroom D](#)

Welcome & Opening Remarks by President

7:45 – 8:00 AM | [Grand Ballroom D](#)

Plenary Session | 8:00 – 9:30 AM

Will Digital Health Transform Drug Development? (DT & AT)

PRESENTERS: Timothy Peters-Strickland, MD, Vice President Global Clinical Development, Otsuka Pharmaceutical Development & Commercialization Inc, CNS & Digital Medicine and Jonathan Knights, PhD, Associate Director, Otsuka Pharmaceutical Development & Commercialization Inc, Data Sciences

[Grand Ballroom D](#)

Symposium 1 | 10:00 – 11:30 AM

Conducting Clinical Pharmacology & Bioavailability Studies of Targeted Anticancer Drugs in Healthy Subjects: Opportunities & Challenges (DT)

CO-CHAIRS: Mark Kirstein, PharmD, Associate Professor, Univ of Minnesota Coll of Pharmacy & Masonic Cancer Ctr, Experimental & Clinical Pharmacology and Ahmed H. Salem, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

[Grand Ballroom A-C](#)

Symposium 2 | 10:00 AM – 12:00 PM

Intestinal Influx Transporters: A Missing Piece in the Puzzle? (DT)

CO-CHAIRS: Lei Zhang, PhD, Deputy Director, US Food & Drug Administration, Office of Research & Standards, Office of Generic Drugs, Ctr for Drug Evaluation & Research and Zhu Zhou, PhD, Assistant Clinical Professor, Univ of the Pacific, Pharmaceuticals & Medicinal Chemistry

[Grand Ballroom D](#)

Lunch Buffet

11:30 AM – 1:15 PM | [Grand Ballroom Foyer](#)

Lunch & Awards Session

12:00 – 1:30 PM | [Grand Ballroom D](#)

- ACCP Distinguished Investigator Award
- ACCP Honorary Fellowship Award
- Nathaniel T. Kwit Memorial Distinguished Service Award
- Tanabe Young Investigator Award
- McKeen Cattell Memorial Award



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Program at a Glance

Continued

SUNDAY, SEPTEMBER 23, 2018

Symposium 3 | 1:30 – 3:00 PM

Can Intrinsic & Extrinsic Factors From Adult Pharmacokinetics Really Be Extrapolated to Pediatric Patients: What are We Missing? (AT)

CO-CHAIRS: Mariam Ahmed, PhD, MSc, BPharm, Clinical Pharmacology Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology and Mohamad Shebley, PhD, Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

[Grand Ballroom A-C](#)

Symposium 4 | 1:30 – 5:30 PM

Pharmacometrics at the Bedside, an ACCP/ISoP Clinical Pharmacometrics Special Interest Group Jointly-sponsored Symposium (AT)

CO-CHAIRS: Amelia N. Deitchman, PharmD, PhD, T32 Clinical Pharmacology Postdoctoral Fellow, Univ of California San Francisco, Bioengineering & Therapeutic Sciences and Michael N. Neely, MD, MSc, Associate Professor of Pediatrics, Univ of Southern California, Keck School of Medicine, Pediatrics

[Grand Ballroom D](#)

Symposium 5 | 3:30 – 5:00 PM

Nonalcoholic Steatohepatitis: Perspectives of a Patient, a Hepatologist & a Pharmacologist (AT)

CHAIR: Sabina Paglialunga, PhD, Associate Director, Scientific Affairs, Celerion

[Grand Ballroom A-C](#)

Opening Reception & Poster Session 1 & Exhibits

5:00 – 7:00 PM | [Grand Ballroom E-H](#)

MONDAY, SEPTEMBER 24, 2018

ACCP Registration Desk Open

7:00 AM – 7:00 PM | [Grand Ballroom Foyer](#)

Continental Breakfast

7:00 – 8:00 AM | [Grand Ballroom E-H](#)

Exhibit Hall Open

7:30 – 10:00 AM | [Grand Ballroom E-H](#)

Meet the ACCP/ISoP Special Interest Group

7:00 – 8:00 AM | [Grand Ballroom D](#)

ACCP Public Policy Committee Meeting

7:00 – 8:00 AM | [Great Falls](#)

ACCP Education Committee Meeting

7:00 – 8:00 AM | [Brookside B](#)

Debate | 8:00 – 9:30 AM

Do We Still Need Clinical Pharmacology? (AT)

SPEAKERS & MODERATOR: Lawrence J. Lesko, PhD, Emeritus Clinical Professor & Founding Director, Ctr for Pharmacometrics & Systems Pharmacology, Univ of Florida; Michael D. Reed, PharmD, Emeritus Professor of Pediatrics, School of Medicine, Case Western Reserve Univ and Michael J. Fossler Jr, PharmD, PhD, Vice President, Trevena Inc, Clinical Operations & Quantitative Sciences

[Grand Ballroom D](#)

Symposium 6 | 10:00 – 11:30 AM

Implementation of Preemptive Pharmacogenetics: Opportunities, Challenges & Successes (AT)

CHAIR: Javier G. Blanco, PhD, Professor, School of Pharmacy & Pharmaceutical Sciences, Univ at Buffalo, The State Univ of New York, Pharmaceutical Sciences

[Grand Ballroom D](#)

Symposium 7 | 10:00 – 11:30 AM

Utility of Physiologically-based Pharmacokinetic Modeling During Pregnancy & Lactation Drug Studies (DT)

CO-CHAIRS: Jian Wang, PhD, Associate Director, US Food & Drug Administration, Office of Drug Evaluation IV, CDER and Catherine MT Sherwin, PhD, MSc, Associate Professor, Univ of Utah School of Medicine, Pediatrics

[Grand Ballroom A-C](#)

Lunch Buffet

11:30 AM – 1:00 PM | [Grand Ballroom Foyer](#)

Lunch & Awards Session

11:45 AM – 1:15 PM | [Grand Ballroom D](#)

- ACCP Student Abstract Award Acknowledgements
- Wayne A. Colburn Memorial Award
- ACCP New Member Abstract Award
- ACCP/ISoP SIG Student Abstract Award
- ACCP Member-Get-a-Member Acknowledgements
- Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award
- Roger Jelliffe Individualized Therapy Award
- Invited Keynote

Symposium 8 | 1:30 – 5:00 PM

Can Clinical Pharmacology Break Down Barriers to Generic Substitution? (DT)

CO-CHAIRS: Robert Lionberger, PhD, Director, US Food & Drug Administration, Office of Research & Standards, Office of Generic Drugs and Stephan Schmidt, PhD, Certara Professor, Associate Professor & Associate Director, Ctr for Pharmacometrics & Systems Pharmacology, Univ of Florida

[Grand Ballroom A-C](#)

Program at a Glance

Continued

MONDAY, SEPTEMBER 24, 2018

Symposium 9 | 1:30 – 5:15 PM

Precision Medicine in Pediatrics: Reducing Variability in Exposure Across Age & Developmental Status with Physiologically-based Pharmacokinetic & Population Pharmacokinetic Strategies, an ACCP/AAPS Jointly-sponsored Symposium (AT)

CO-CHAIRS: Robert Bies, PharmD, PhD, Associate Professor, State Univ of New York at Buffalo, Pharmaceutical Sciences and Catherine MT Sherwin, PhD, MSc, Associate Professor, Univ of Utah School of Medicine, Pediatrics

[Grand Ballroom D](#)

Student, Trainee & Young Professional (STYP) Panel Discussion & Career Guidance

1:30 – 3:00 PM | [Brookside A](#)

STYP Networking Reception

3:00 – 4:00 PM | [Brookside A](#)

STYP Podium Presentations

4:00 – 5:00 PM | [Brookside A](#)

Exhibit Hall Open

3:00 – 7:00 PM | [Grand Ballroom E-H](#)

Evening Reception & Poster Session 2 & Exhibits

5:00 – 7:00 PM | [Grand Ballroom E-H](#)

JCP & CPDD Editorial Board Dinner (invitation only)

7:00 – 9:00 PM | [Brookside A&B](#)

TUESDAY, SEPTEMBER 25, 2018

ACCP Registration Desk Open

7:00 AM – 5:30 PM | [Grand Ballroom Foyer](#)

Continental Breakfast

7:00 – 8:00 AM | [Grand Ballroom E-H](#)

Exhibit Hall Open

7:30 – 10:00 AM | [Grand Ballroom E-H](#)

ACCP 2018 – 2019 Annual Meeting Program Committee Meeting

7:00 – 8:00 AM | [Middlebrook](#)

ACCP Membership Committee Meeting

7:00 – 8:00 AM | [Great Falls](#)

Symposium 10 | 8:00 – 9:30 AM

Assessing Physical Dependence & Drug Withdrawal Symptoms: Understanding the Evolving Clinical & Regulatory Requirements (AT)

CO-CHAIRS: Jack Henningfield, PhD, Vice President, Research, Health Policy & Abuse Liability, Pinney Associates Inc and Professor, Behavioral Biology, Johns Hopkins Univ School of Medicine, Psychiatry & Behavioral Sciences and Beatrice Setnik, PhD, Vice President, Scientific & Clinical Strategy, Syneos Health and Adjunct Professor, Univ of Toronto, Toxicology & Pharmacology

[Grand Ballroom D](#)

Symposium 11 | 8:00 AM – 12:00 PM

The Challenging World of Cardiac Safety Evaluation & Utilization of Concentration-QT Analyses of Phase 1 Data to Waive the Thorough QT Study Requirement, an ACCP/CSRC Jointly-sponsored Symposium (DT)

CO-CHAIRS: Apurvasena Parikh, PhD, Associate Principal Pharmacokineticist, AbbVie Inc, Clinical Pharmacology & Pharmacometrics; Andrew Chang, PharmD, PhD, Clinical Pharmacology Lead, Pfizer Inc, Global Product Development, Oncology and Norman Stockbridge, MD, PhD, Division Director, US Food & Drug Administration, Cardiovascular & Renal Products, CDER

[Grand Ballroom A-C](#)

Symposium 12 | 10:00 AM – 12:00 PM

Pediatric HIV Drug Development: Big Challenges Call for Innovation in Little People (DT)

CO-CHAIRS: Kristina M. Brooks, PharmD, Postdoctoral Fellow, Univ of Colorado, Pharmaceutical Sciences and Jomy George, PharmD, Pharmacokineticist, National Inst of Health, Clinical Pharmacokinetics Research Unit

[Grand Ballroom D](#)

Lunch Buffet

12:00 – 1:15 PM | [Grand Ballroom Foyer](#)

Lunch & ACCP Annual Business Meeting (open to all)

12:00 – 1:30 PM | [Grand Ballroom D](#)

Symposium 13 | 1:30 – 3:00 PM

Oligonucleotide-based Therapies: A Multistakeholder Perspective of the Opportunities & Challenges (DT)

CHAIR: Anuradha Ramamoorthy, PhD, Policy Lead, US Food & Drug Administration, Office of Clinical Pharmacology, CDER

[Grand Ballroom D](#)

Symposium 14 | 1:30 – 3:00 PM

Bioequivalence: Non-traditional Approaches (DT)

CO-CHAIRS: Laszlo Endrenyi, PhD, Professor Emeritus, Univ of Toronto, Pharmacology & Toxicology and Alfred H. Balch, PhD, MA, Associate Professor, Univ of Utah, Pediatrics

[Grand Ballroom A-C](#)

Symposium 15 | 3:30 – 5:00 PM

Methodological & Statistical Considerations in Pediatric & Rare Disease Drug Development: External Control Groups & Dose Selection (DT)

CO-CHAIRS: Gopichand Gottipati, PhD, Pharmacometrics Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology and Marc R. Gastonguay, PhD, Chief Executive Officer, Metrum Research Group LLC

[Grand Ballroom A-C](#)

Symposium 16 | 3:30 – 5:00 PM

2nd Generation Immuno-oncology Products: Beyond Monoclonal Antibodies (AT)

CO-CHAIRS: Vijay V. Upreti, PhD, Director, Amgen Inc, Clinical Pharmacology & Modeling Simulation, Medical Sciences and Chaitali Passey, PhD, Associate Director, Genmab A/S

[Grand Ballroom D](#)



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AMERICAN COLLEGE OF CLINICAL PHARMACOLOGY®
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Invited Keynote



Monday, September 24, 2018 | Lunch & Awards Session | Grand Ballroom D

Bruce C. Carleton, PharmD

Professor & Chair, Div of Translational Therapeutics, Dept of Pediatrics, Faculty of Medicine, Univ of British Columbia; Director, Pharmaceutical Outcomes Program, BC Children's Hosp and Senior Clinician Scientist, BC Children's Hosp Research Inst

“Pharmacogenomics & Risk Decision Making: Putting Patients First”

Dr. Carleton's lifelong goal is to make medication use more effective and safer for all patients, particularly children. His research focus is on the impact of drug therapy on human health and quality of life. He is particularly interested in developing better ways to evaluate the effectiveness of drugs and medication-use models designed to improve patient health, as well as practical surveillance systems to improve the safe use of medication.

A key element of Dr. Carleton's research is the communication of results to clinicians, patients, healthcare administrators and government officials who hold the responsibility of improving patient care and systems of healthcare delivery.

In addition to his appointment as Professor of Pediatrics and Chair of the Div of Translational Therapeutics, Dept of Pediatric Medicine at the Univ of British Columbia (UBC), Dr. Carleton is a Senior Clinician Scientist at BC Children's Hosp Research Inst. He directs the Pharmaceutical Outcomes Program at BC Children's Hosp and has served in that capacity since 1994. He holds appointments at UBC in the Ctr for Health Services & Policy Research, the School of Population & Public Health and the Faculty of Pharmaceutical Sciences and the School of Health Information Science, Univ of Victoria. Dr. Carleton's public service is expansive and includes serving as a charter member on the national Canadian Expert Drug Advisory Committee. Dr. Carleton was recently asked to serve the US Government as a Special Government Employee to advise the Advisory Committee for Pharmaceuticals & Clinical Pharmacology of the US Food & Drug Administration.

2018 ACCP Recognition Award Winners



ACCP Distinguished Investigator Award

Sunday, September 23, 2018 | Lunch & Awards Session | Grand Ballroom D

Craig W. Hendrix, MD – Wellcome Professor & Director, Div of Clinical Pharmacology, Johns Hopkins Univ

“Clinical Pharmacology Impact in HIV Pre-exposure Prophylaxis”

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

Dr. Hendrix is the Wellcome Professor & Director, Div of Clinical Pharmacology, at Johns Hopkins Univ. He is internationally known for his work in HIV/AIDS with over 200 original articles. As the Principal Investigator (PI) of clinical studies on antiretroviral pharmacology, he and his research

team have made significant contributions to HIV pre-exposure prophylaxis by developing novel methods to study drug delivery and local distribution of various investigational agents, as well as their pharmacokinetic/pharmacodynamic relationships to inform drug development and improve patient care. The research support for Dr. Hendrix over the past decade includes NIH funding as PI or Project Leader for seven NIH program project grants, PI of an R01 grant and Principal Pharmacologist in two HIV prevention networks, as well as support from the Gates Foundation and the pharmaceutical industry. He is an active member on several scientific advisory boards in academia, industry and government, served on several FDA Advisory Committees and serves as an Editor or Reviewer for over 15 different scientific journals. In 2017, Dr. Hendrix received the PhRMA Foundation Award for Excellence.



ACCP Honorary Fellowship Award

Sunday, September 23, 2018 | Lunch & Awards Session | Grand Ballroom D

Markus Müller, MD – Professor & President, Medical Univ of Vienna

“Transforming a University Hospital by Clinical Pharmacology”

The 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.

Dr. Müller currently serves as the President of the Medical Univ of Vienna, Austria, an institution with an excellent reputation that also includes the largest hospital in Europe, AKH Vienna, with

over 2,200 beds. Before his appointment as President of the university, Dr. Müller served for many years as Chair of the Dept of Clinical Pharmacology at the Medical Univ of Vienna, one of the largest clinical pharmacology units in Europe. He has developed the method of clinical microdialysis, which he used for many studies to determine the target site concentrations in healthy volunteers, as well as patients. He was also Principal Investigator on trials on ABC-transporter PET imaging tracers, on Alzheimer's plaque PET imaging tracers, on Alzheimer's vaccines and on cell-based H5N1 and H1N1 influenza vaccines. He has over 250 articles in peer-reviewed journals.



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2018 ACCP Recognition Award Winners



Nathaniel T. Kwit Memorial Distinguished Service Award

Sunday, September 23, 2018 | Lunch & Awards Session | Grand Ballroom D

Nilima Arun Kshirsagar, MD, PhD, FACC (USA), FRCP (UK) FNAMS FNAS (India)
– National Chair in Clinical Pharmacology, Indian Council for Medical Research, Government of India, New Delhi Chairperson Subcommittee of DTAB Government of India to Review FDC, former Dean, Director, Acting Vice Chancellor, State Health Univ of Maharashtra

“Clinical Pharmacology – Team Science from Drug Discovery, Development to Disaster Management”

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 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.

An MD, PhD by training, Fellow of ACCP and Royal College of Physicians (UK), member of WHO and Government of India Committees, Dr. Kshirsagar has held several key positions, including National Chair Clinical Pharmacology, Indian Council of Medical Research, Government of India, and has worked tirelessly to further the discipline in the South Asia region. She started the Dept of Clinical Pharmacology in two premier medical colleges & hospitals in Mumbai and trained several MD, PhD and MSc students. A recipient of several awards, including the Dr. BC Roy National Award, the VASVIK Industrial Research Award, ICRI Lifetime Achievement Award and Mumbai Mayor's Award, she has 250+ publications in high-impact national and international journals. Dr. Kshirsagar has been a committed member of ACCP. She established the South Asian College, an Affiliate of ACCP in 2006 – 2007, which hosts an annual international conference and several workshops in collaboration with national and international partners from industry, academia and government.



Tanabe Young Investigator Award

Sunday, September 23, 2018 | Lunch & Awards Session | Grand Ballroom D

Neeraj Gupta, PhD, FCP – Senior Scientific Director, Quantitative Clinical Pharmacology, Takeda Pharmaceuticals Int'l Co

“Model-informed Drug Development: Ixazomib, as a Case Study”

The Tanabe Young Investigator Award is given on a biannual basis (on even numbered years) and is funded by a grant from Tanabe Research Labs USA. The award recognizes the significant contributions of an investigator who has made unusual strides in research related to clinical pharmacology and whose career shows promise of outstanding achievements at a relatively early stage, typically 10–12 years post-research degree. The candidate need not be a Member or Fellow of ACCP.

Dr. Gupta is Senior Scientific Director, Quantitative Clinical Pharmacology at Takeda Pharmaceuticals USA Inc. He holds a PhD in Pharmacokinetics from the Univ of Iowa. His career in industry has resulted in outstanding contributions to the development of several anticancer therapeutics including ixazomib & brigatinib. Dr. Gupta's innovative leadership of the model-informed and patient-centric development of ixazomib for multiple myeloma has received much external recognition in the scientific community, resulting in a total of 24 publications on the molecule. He has authored 40 manuscripts & over 90 abstracts and has given numerous invited presentations. He has played a pivotal role in mentoring the next generation of scientists & drug developers through his direct line managerial responsibilities at Takeda, mentorship of interns & external teaching responsibilities. An active Fellow in ACCP, he serves on the Membership Committee.

2018 ACCP Recognition Award Winners



McKeen Cattell Memorial Award

Sunday, September 23, 2018 | Lunch & Awards Session | Grand Ballroom D

Isabel Reinecke, Dr. rer. Nat. – Senior Modeling & Simulation Expert, Clinical Pharmacometrics, Bayer AB (on behalf of Bayer AG)

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

This year's award-winning journal article is: "**Model-Based Dose Selection for Intravaginal Ring Formulations Releasing Anastrozole and Levonorgestrel Intended for the Treatment of Endometriosis Symptoms**" Authors: Isabel Reinecke, PhD, Marcus-Hillert Schultze-Mosgau, PhD, Rüdiger Nave, PhD, Heinz Schmitz, MD, Bart A. Ploeger, PhD. Published in *The Journal of Clinical*

Pharmacology. Volume 57, Issue 5, pages 640 – 651, May, 2017.



Bristol-Myers Squibb Mentorship in Clinical Pharmacology Award

Monday, September 24, 2018 | Lunch & Awards Session | Grand Ballroom D

Marc R. Gastonguay, PhD, FISoP – Chief Executive Officer, Metrum Research Group LLC

"Open Science: A Key to the Future Growth of 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. Gastonguay is an internationally-renowned quantitative clinical pharmacologist with two decades of contributions towards clinical pharmacology at large. As part of his mission at Metrum Research Group LLC and as a member of the adjunct faculty at various universities, Dr. Gastonguay regularly mentors industry scientists, graduate students and post-doctoral fellows. His 100+ publications, including posters, manuscripts & conference presentations, are a clear testament to his achievements. He is a strong proponent of the idea that the growth of science is a community responsibility with Open Science at its roots. Under his vision & leadership, Metrum develops & provides freely-available open content, including extensive formal training resources in pharmacometrics (six semester's worth of open courseware), multiple open-source tools & open disease models.



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2018 ACCP Recognition Award Winners



Roger Jelliffe Individualized Therapy Award

Monday, September 24, 2018 | Lunch & Awards Session | Grand Ballroom D

Roger W. Jelliffe, MD, FCP – Professor of Medicine Emeritus, Dept of Medicine, Univ of Southern California Keck School of Medicine, Founder & Director Emeritus, Laboratory of Applied Pharmacokinetics & Bioinformatics

“Individualizing Drug Therapy”

Long-time ACCP Fellow, Roger W. Jelliffe, MD, FCP, will be honored with an award named after him, acknowledging his pioneering use of clinical pharmacology & pharmacometrics to optimize therapeutic medication dosing in individual patients. Starting in 2019, the Roger W. Jelliffe Individualized Therapy Award will be given annually to a Member or Non-member of ACCP & is intended to recognize an individual who significantly advances the field of personalized medicine by improving the use of drugs or biologics in patients.

ACCP Abstract Awards Program & Member-Get-a-Member Awards

Monday, September 24, 2018 | Lunch & Awards Session | Grand Ballroom D

2018 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 the Program Committee 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/ISO P Special Interest Group (SIG) Student Abstract Award: identifies areas of submission that are consistent with its focus and Student & Trainee abstracts within those areas are reviewed and scored by SIG Leadership. The top scoring Student abstract is the recipient of the ACCP/ISO P Student Abstract Award.

At the time the award is presented, the author presents a short talk outlining the findings of the study.

2018 ACCP Student & Trainee Abstract Award Winners

- **Justine Badée, PhD (Poster #055) Univ of Florida**
- **Sonoko Kawakatsu, BS (Poster #083) Univ of California San Diego**
- **Xiaomei I. Liu, MS, PharmD (Poster #009) Children’s National Health System**
- **Surulivelrajan Mallayasamy, PhD (Poster #070) Univ of North Texas Health Science Ctr**
- **Nguyen Thi Thu Phuong, MD, PhD (Poster #098) Inje Univ Coll of Medicine**
- **Alexander J. Prokopienko, PharmD (Poster #058) Univ of Pittsburgh School of Pharmacy**
- **Yichao Yu, PhD (Poster #100) Univ of Florida Coll of Pharmacy**
- **Hongfei Zhang, MS (Poster #086) Univ of Pittsburgh**

2018 Honors & Awards Committee

April M. Barbour, PhD • Noam Epstein, MD, MS • Jomy George, PharmD, BCPS (AQ-ID)
Daniel Gonzalez, PharmD, PhD • Navin S. Goyal, PhD • Howard E. Greenberg, MD, MSE, MBA
Manoj P. Jadhav, PhD • Lily A. Mulugeta, PharmD • Martina D. Sahre, PhD • Laurent Vernillet, PharmD, PhD

Educational Accreditation

Target Audience

The 2018 ACCP Annual Meeting will be of educational benefit to clinical pharmacologists, pharmacists, physicians and clinical researchers 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, development & application that are relevant to patient-centered outcomes;
2. Define *in silico* pharmacology and describe the utility & types of quantitative approaches in drug discovery & development;
3. Describe emerging trends in the study of pharmacology in special populations, including generalizability & limitations of applying general population data to these clinical groups;
4. Explore ways in which cutting-edge clinical pharmacology science contributes to patient care decisions at the bedside.

Accreditation Statements



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

The ACPE Universal Activity Numbers (UAN), amount of contact hours available and CPE target audience designations, are noted within each course of the program for a maximum of 48.25 Contact Hours. Pharmacists should claim only the contact hours commensurate with the extent of their participation in the activity. All CPE activities of this live event are knowledge-based.



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

Designation Statement

The American College of Clinical Pharmacology designates this live educational activity for a maximum of 48.25 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Disclosure: Joint Providership

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) and the Accreditation Council for Pharmacy Education (ACPE), including courses developed in joint providership between the American College of Clinical Pharmacology and the following organizations: the American Association of

Pharmaceutical Scientists, the Cardiac Safety Research Consortium and the International Society of Pharmacometrics. The American College of Clinical Pharmacology is accredited by the ACCME and ACPE to provide continuing medical education for physicians and continuing pharmacy education for pharmacists.

Disclosure: Commercial Support

The American College of Clinical Pharmacology accepts and discloses any and all commercial support for the 2018 ACCP Annual Meeting, including any grants, sponsorships, exhibit fees and other support in accordance with the ACCME and ACPE Standards for Commercial Support.

Disclosure: Planning Committee and Faculty Disclosure of Commercial Interests

Members of the 2018 ACCP Annual Meeting Program Committee report nothing to disclose related to the educational content. Faculty disclosures are provided on pages 16–17 of this Final Program and in the Syllabus for each educational course.

Disclosure: Requirements for Successful Completion

Attendees requesting Continuing Education (CME/CPE) credits must indicate their credit request during registration for the 2018 ACCP Annual Meeting. Attendees wishing to obtain credits must attend one or more Continuing Education courses and must pass each requested course's learning assessment. The learners must also complete the requisite course evaluation(s) and PRINT the certificate(s) no later than October 31, 2018. **Beyond that point, requests to complete CE post-event processes for credit will incur an administrative late fee of \$200 and must be completed by December 31, 2018.**

Disclosure: Additional CPE Requirements

In addition to the above, attendees seeking CPE credit must provide ACCP with their NABP Profile Number and the month and day of their birth during registration. The NABP Profile Number and birthday information is required for ACCP to transmit CPE credit information to the National Association of Boards of Pharmacy (NABP) via the CPE Monitor. ACCP cannot report CPE credits for individuals who fail to provide their NABP Profile Number and correct MMDD of birth to ACCP during registration.

Other Information

The 2018 ACCP Annual Meeting Program at a Glance can be found on pages 7–9.



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Faculty Disclosure Information

The Accreditation Council for Continuing Medical Education (ACCME) and the Accreditation Council for Pharmacy Education (ACPE) govern the Standards of Independence for accredited continuing education (CE) for physicians and pharmacists. The ACCME and ACPE provide 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/ACPE-defined commercial interest which may be related to the content of their presentation. (See the individual course Syllabus for details.) 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. Please contact CE@ACCP1.org with any questions.

Khaled Abduljalil, PhD
Annie Buchanan, MD
Elise Burmeister Getz, PhD
Ruthanna Davi, PhD
Richard Geary, PhD
Srijib Goswami, PhD

Jack Henningfield, PhD
Howard L. Kaufman, MD
Mark Kirstein, PharmD
Jonathan Knights, PhD
Elizabeth A. Lakota, PharmD, MS
Mohamed-Eslam Mohamed, PhD

Chaitali Passey, PhD
Dragos Roman, MD
Mohamad Shebley, PhD
Alexander A. Vinks, PharmD, PhD
Hao Xiong, PhD

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

Mariam Ahmed, PhD, MSc, BPharm
Barbara Ameer, PharmD, MBA
Karim Azer, PhD
Justin Bader, PharmD, MBA
Alfred H. Balch, PhD, MA
Jeffrey S. Barrett, PhD
Helen M. Berman, PhD
Robert Bies, PharmD, PhD
Javier G. Blanco, PhD
Kristina M. Brooks, PharmD
Bram Brouwers, MSc, PhD
Gilbert J. Burckart, PharmD
Edmund Capparelli, PharmD
Kelly E. Caudle, PharmD, PhD
Andrew Chang, PharmD, PhD

Ayyappa Chaturvedula, PhD
Murat Cirit, PhD
Amelia N. Deitchman, PharmD, PhD
Matthew Dufek, PhD
Mark Dunnenberger, PharmD
Justin Earp, PhD
Laszlo Endrenyi, PhD
Michael J. Fossler Jr, PharmD, PhD
Margaret Gamalo-Siebers, PhD
Marc R. Gastonguay, PhD
Jomy George, PharmD
Kathleen M. Giacomini, PhD
Gopichand Gottipati, PhD
Dionna J. Green, MD
Chyi-Hung Hsu, PhD

Chuanpu Hu, PhD
Shiew-Mei Huang, PhD
Terry Hyslop, PhD
Amalia M. Issa, PhD, MPH
Lars Johannesen, PhD
Julie A. Johnson, PharmD
James Kalabus, PhD
Evan Kharasch, MD, PhD
Jennifer J. Kiser, PharmD
Catherijne AJ Knibbe, PharmD, PhD
Kattayoun Kordy, MD
Rukmini Kumar, PhD
J. Steven Leeder, PharmD, PhD
Alicja Lerner, MD, PhD
Lawrence J. Lesko, PhD

Faculty Disclosure Information

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

Robert Lionberger, PhD

Rajanikanth Madabushi, PhD

Susan McCune, MD

Michael McDonnell, MD

France Mentre, PhD, MD

Amilcar L. Morales-Cardona, MD

Javid Moslehi, MD

Andrew E. Mulberg, MD

Yeruk A. Mulugeta, PharmD

Michael N. Neely, MD, MSc

Sabina Paglialunga, PhD

Apurvasena Parikh, PhD

Neil J. Parrott, MSc

Timothy Peters-Strickland, MD

David S. Pisetsky, MD, PhD

Bhagwat Prasad, PhD

Isabelle Ragueneau-Majlessi, MD, MS

Atiqur Rahman, PhD

Anuradha Ramamoorthy, PhD

Michael D. Reed, PharmD

Alexandre Ribeiro, PhD

Hobart Rogers, PharmD, PhD

Ahmed H. Salem, PhD

Ameet Sarpatwari, JD, PhD

Stephan Schmidt, PhD

Sarah Schrieber, PharmD

Shirley K. Seo, PhD

Beatrice Setnik, PhD

Catherine MT Sherwin, PhD, MSc

Vikram Sinha, PhD

Eric A. Sobie, PhD

Norman Stockbridge, MD, PhD

Judith A. Swan, PhD

Danilo A. Tagle, PhD

Robert Temple, MD

J. Rick Turner, PhD, DSc

Mark Turner, MD

Vijay V. Upreti, PhD

Manthena Varma, PhD

Matthew Wagoner, PhD

Jian Wang, PhD

Yaning Wang, PhD, MS

Yow-Ming Wang, PhD

Robert M. Ward, MD

John P. Wikswow, PhD

Lynne Yao, MD

Islam R. Younis, PhD

Anne Zajicek, MD, PharmD

Lei Zhang, PhD

Liang Zhao, PhD

Zhu Zhou, PhD

The following Annual Meeting Program Committee Members disclose no financial relationship(s) with ACCME/ACPE-defined commercial interests related to their participation on the Annual Meeting Program Committee.

Barbara Ameer, PharmD, MBA

Satjit S. Brar, PharmD, PhD

Kristina M. Brooks, PharmD

Gilbert J. Burckart, PharmD

Steven J. Crosby, MA, BSP, RPh

Dionna J. Green, MD

Amalia M. Issa, PhD, MPH

Parag Kumar, PharmD

Pooja Manchandani, PhD

Diane R. Mould, PhD

Anne J. Paccaly, PharmD, PhD

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John N. van den Anker, MD, PhD

Islam R. Younis, PhD



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Pre-meeting Workshops

SATURDAY, SEPTEMBER 22, 2018 | Pre-meeting Workshop 1 | 8:00 – 11:30 AM

GRAND BALLROOM H

Organ-on-a-Chip: What Is It & How Can It Advance the Role of Clinical Pharmacology in Drug Discovery & Development?

DISCOVERY TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-026-L01-P

ACPE – 3.0 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:

Rajanikanth Madabushi, PhD, Team Lead, US Food & Drug Administration, Guidance & Policy Team, OCP/OTS/CDER

TARGET AUDIENCE:

This Workshop will be useful for academic, industry and regulatory scientists who are interested in drug discovery and development.

GOALS & OBJECTIVES:

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

1. Describe organ-on-a-chip microphysiological systems;
2. Illustrate how organ-on-a-chip systems are currently used in drug discovery and development;
3. Discuss the application of organ-on-a-chip systems in understanding ADME characteristics;
4. Discuss the application of organ-on-a-chip systems for mechanistic safety assessment.

8:00 – 8:05 AM

Organ-on-a-Chip: What Is It & How Can It Advance the Role of Clinical Pharmacology in Drug Discovery & Development?

Rajanikanth Madabushi, PhD, Team Lead, US Food & Drug Administration, Guidance & Policy Team, OCP/OTS/CDER

8:05 – 8:30 AM

Organ-on-a-Chip 101

John P. Wikswa, PhD, Gordon A. Cain Univ Professor, Vanderbilt Univ, Vanderbilt Inst for Integrative Biosystems Research & Education

8:30 – 8:55 AM

What's on the Horizon for Organs-on-Chips: NIH Perspective

Danilo A. Tagle, PhD, Associate Director for Special Initiatives, National Ctr for Advancing Translational Sciences, National Inst of Health, Office of the Director

8:55 – 9:20 AM

Role for Organ-on-a-Chip in Drug Development: A Clinical Pharmacology Perspective

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

9:20 – 9:50 AM / Break

9:50 – 10:10 AM

Application of Organ-on-a-Chip for Drug Metabolism & Pharmacokinetic Assessment: Industry Perspective

Neil J. Parrott, MSc, Distinguished Scientist, F. Hoffman-La Roche AG, Pharmaceutical Sciences

10:10 – 10:30 AM

Application of Organ-on-a-Chip for Drug Metabolism & Pharmacokinetic Assessment: Academia Perspective

Murat Cirit, PhD, Principal Investigator, Massachusetts Inst of Technology, Biological Engineering

10:30 – 10:50 AM

Application of Organ-on-a-Chip for Mechanistic Assessment

Alexandre Ribeiro, PhD, Staff Fellow (Biological Scientist), US Food & Drug Administration, Ctr for Drug Evaluation & Research

10:50 – 11:10 AM

Application of Organ-on-a-Chip for Mechanistic Assessment: Industry Perspective

Matthew Wagoner, PhD, Associate Director of Investigative Toxicology, Takeda Pharmaceuticals Co Ltd, Drug Safety Research Evaluation

11:10 – 11:30 AM

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

Pre-meeting Workshops

SATURDAY, SEPTEMBER 22, 2018 | Pre-meeting Workshop 2 | 8:00 AM – 12:00 PM

GRAND BALLROOM G

Applications of Quantitative & Systems Pharmacology from Drug Development to Patient Care

DISCOVERY TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-027-L01-P

ACPE – 3.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Ayyappa Chaturvedula, PhD, Associate Professor, Univ of North Texas Health Science Ctr, Pharmacotherapy

Rukmini Kumar, PhD, Principal Scientist, Vantage Research

TARGET AUDIENCE:

This Workshop will be useful for drug development scientists, clinical pharmacologists, pharmacometricians, physician scientists, systems pharmacology scientists, mathematical biologists and regulatory scientists.

GOALS & OBJECTIVES:

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

1. Explain the current scope of quantitative & systems pharmacology (QSP) and future directions;
2. Identify the applications of QSP in drug development and patient care;
3. Describe the workflow of implementation involved in the QSP approach.

8:00 – 8:10 AM

Applications of Quantitative & Systems Pharmacology (QSP) from Drug Development to Patient Care

Rukmini Kumar, PhD, Principal Scientist, Vantage Research

8:10 – 8:50 AM

Current Vision & Future Directions of QSP in Drug Development

Eric A. Sobie, PhD, Associate Professor, Pharmacological Sciences, The Icahn School of Medicine at Mount Sinai

8:50 – 9:30 AM

Optimal Delivery of QSP in the Pharmaceutical R&D Environment: Science & Administration

Karim Azer, PhD, Head of Quantitative Systems Pharmacology & Drug Metabolism Pharmacokinetics Modeling, Quantitative Sciences, Bill & Melinda Gates Medical Research Inst

9:30 – 10:00 AM / Break

10:00 – 10:40 AM

Regulatory Perspectives of QSP in Drug Development

Justin Earp, PhD, Scientific Lead for Biologic & Biosimilar Products, Div of Pharmacometrics, Office of Clinical Pharmacology, US Food & Drug Administration

10:40 – 11:40 AM

Patient Care Applications of QSP in a Post-genomic Era

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

11:40 AM – 12:00 PM

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



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Pre-meeting Workshops

SATURDAY, SEPTEMBER 22, 2018 | Pre-meeting Workshop 3 | 1:30 – 5:00 PM

GRAND BALLROOM H

Working Towards Becoming an Effective Communicator

APPLICATION TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-028-L01-P

ACPE – 3.0 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:

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

TARGET AUDIENCE:

This Workshop will be useful for graduate students, trainees and pharmacy/pharmacology professionals in academia, clinical practice and research.

GOALS & OBJECTIVES:

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

1. Explain the process of researching journal options that match your works' messages to strategically target journal submissions;
2. Critically evaluate the language and structure that help make writing compelling to the reader;
3. Explore the value of effectively telling the clinical pharmacologist's story to non-scientist policymakers;
4. Identify engaging approaches to effectively and accurately communicate with patients and consumers.

1:30 – 1:40 PM

Working Towards Becoming an Effective Communicator

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

1:40 – 2:10 PM

Optimizing Scholarly Written Communications: Finding Niche Manuscript Opportunities to Reach Your Target Audience

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

2:10 – 3:30 PM

Optimizing Scholarly Written Communications: Writing Workshop – Effective Writing from the Readers' Perspective

Judith A. Swan, PhD, Associate Director for Writing in Science & Engineering, Princeton Univ, Princeton Writing Program

3:30 – 4:00 PM / Break

4:00 – 4:25 PM

Interacting with Audiences Outside the Sciences: Communicating with Decision & Policy Makers – From 'Lost in Translation' to Next Gen Interactions

Amalia M. Issa, PhD, MPH, Professor, Univ of the Sciences Philadelphia, Pharmaceutical Sciences and Founding Director, Personalized Medicine & Targeted Therapeutics Ctr

4:25 – 4:55 PM

Interacting with Audiences Outside the Sciences: Communicating with Consumers & Patients

Barbara Ameer, RPh, PharmD, MBA, Adjunct Associate Professor, Rutgers Robert Wood Johnson Medical School, Medicine and Helen M. Berman, PhD, Professor Emerita of Chemistry & Chemical Biology, Rutgers, The State Univ of New Jersey

4:55 – 5:00 PM

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

Pre-meeting Workshops

SATURDAY, SEPTEMBER 22, 2018 | Pre-meeting Workshop 4 | 1:30 – 5:30 PM

GRAND BALLROOM G

Model-informed, Optimal Neonatal Clinical Trial Design

DISCOVERY TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-029-L01-P

ACPE – 3.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Catherine MT Sherwin, PhD, MSc, Associate Professor, Univ of Utah School of Medicine, Pediatrics

Jian Wang, PhD, Associate Director, US Food & Drug Administration, Office of Drug Evaluation IV, CDER

TARGET AUDIENCE:

This Workshop will be useful for clinical pharmacologists and neonatologists from pharmaceutical/biotechnology companies and regulatory agencies, pharmacometricians, clinical researchers and drug development scientists who have an interest in applying and/or currently apply principles of pediatric clinical pharmacology to innovate and accelerate drug development for neonatal patients. 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 model-informed, optimal neonatal clinical trial design.

GOALS & OBJECTIVES:

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

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

1:30 – 1:50 PM

Challenges & Opportunities in Model-informed, Optimal Neonatal Clinical Trial Design

Robert M. Ward, MD, Professor Emeritus, Univ of Utah, Pediatrics

1:50 – 2:20 PM

Ontogeny of Drug Disposition: Implications for the Dose-Exposure-Response Relationship in Neonates

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

2:20 – 2:50 PM

Clinical Outcome Measures, Surrogate Endpoints & Biomarkers

Mark Turner, MD, Senior Lecturer, Univ of Liverpool & Consultant Neonatologist, Liverpool Women's NHS Fdn Trust

2:50 – 3:10 PM

Utilization of Adult Data & Bayesian Methodology in Designing Pediatric Pharmacokinetic Studies: How Much is Historical Adult Data Worth?

Chyi-Hung Hsu, PhD, Director, Janssen Research & Development LLC, Global Clinical Pharmacology

3:10 – 3:30 PM

Pharmacokinetic Sampling: Sample Size Considerations/Oppportunistic Methods, Blood Volume & Bioanalytical Assays

Catherine MT Sherwin, PhD, MSc, Associate Professor, Univ of Utah School of Medicine, Pediatrics

3:30 – 4:00 PM / Break

4:00 – 4:20 PM

Adaptive Borrowing of Adult Information in Analyzing Pediatric Data

Chuanpu Hu, PhD, Scientific Director, Janssen Research & Development LLC, Global Clinical Pharmacology

4:20 – 4:40 PM

Innovative Trial Design & Extrapolation in Drug Development for Neonates

Kattayoun Kordy, MD, Global Pediatric Medical Director, Development, Science & Innovation, Novartis, Pediatric Ctr of Excellence

4:40 – 5:10 PM

Considerations for Conducting Neonatal Clinical Trials

Susan McCune, MD, Director, Office of Pediatric Therapeutics, Office of the Commissioner, US Food & Drug Administration

5:10 – 5:25 PM

Regulatory Perspective of the Challenges & Opportunities Associated with Model-informed, Optimal Neonatal Clinical Trial Design

Dionna J. Green, MD, Deputy Director, Office of Pediatric Therapeutics, Office of the Commissioner, US Food & Drug Administration

5:25 – 5:30 PM

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



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Plenary Session

SUNDAY, SEPTEMBER 23, 2018 | Plenary Session | 8:00 – 9:30 AM

GRAND BALLROOM D

Will Digital Health Transform Drug Development?

DISCOVERY & APPLICATION TRACKS

Offers both CME & CPE Credit

UAN #0238-0000-18-009-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

PRESENTERS:

Timothy Peters-Strickland, MD, Vice President Global Clinical Development, Otsuka Pharmaceutical Development & Commercialization Inc, CNS & Digital Medicine

Jonathan Knights, PhD, Associate Director, Otsuka Pharmaceutical Development & Commercialization Inc, Data Sciences

TARGET AUDIENCE:

This Plenary Session will be useful for students and professionals from industry and academia working in the field of drug development, clinical pharmacology, devices and digital medicine/health.

GOALS & OBJECTIVES:

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

1. Define the terms and concepts of digital health and digital medicine, where they intersect and how they are different;
2. Analyze the change brought about by the introduction of digital tools/technology in the healthcare ecosystem, including the drug development process, as well as the impact on patients, caregivers and healthcare professionals in research and clinical practice settings;
3. Identify and discuss current and future trends regarding the role of digital health in drug development.



Timothy Peters-Strickland, MD



Jonathan Knights, PhD

SUNDAY, SEPTEMBER 23, 2018 | Symposium 1 | 10:00 – 11:30 AM

GRAND BALLROOM A–C

Conducting Clinical Pharmacology & Bioavailability Studies of Targeted Anticancer Drugs in Healthy Subjects: Opportunities & Challenges

DISCOVERY TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-010-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Mark Kirstein, PharmD, Associate Professor, Univ of Minnesota Coll of Pharmacy & Masonic Cancer Ctr, Experimental & Clinical Pharmacology

Ahmed H. Salem, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists from industry, academia and regulatory agencies who are involved in the development of targeted anticancer agents.

GOALS & OBJECTIVES:

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

1. Describe the rationale for conducting clinical pharmacology studies of targeted anticancer agents in healthy subjects and decide when it would be appropriate to pursue this population;
2. Explain the process to initiate and conduct a clinical pharmacology study of a targeted anticancer agent in healthy subjects, including study design considerations;
3. Discuss the challenges/limitations, advantages and future prospects for conducting clinical pharmacology studies of targeted anticancer agents in healthy subjects.

10:00 – 10:05 AM

Conducting Clinical Pharmacology & Bioavailability Studies of Targeted Anticancer Drugs in Healthy Subjects: Opportunities & Challenges – Setting the Stage

Ahmed H. Salem, PhD, Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

10:05 – 10:30 AM

Healthy Subjects Studies of Anticancer Agents: Past & Present

Mark Kirstein, PharmD, Associate Professor, Univ of Minnesota Coll of Pharmacy & Masonic Cancer Ctr, Experimental & Clinical Pharmacology

10:30 – 10:55 AM

Studying Navitoclax, a Bcl-2 Family Inhibitor, in Healthy Subjects: Ethical Considerations, Risk/Benefit Assessments & Management

Hao Xiong, PhD, Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

10:55 – 11:20 AM

Regulatory Perspective on Conducting Studies of Targeted Anticancer Drugs in Healthy Subjects

Atiqur Rahman, PhD, Division Director, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/OMPT/CDER

11:20 – 11:30 AM

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



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Symposia

SUNDAY, SEPTEMBER 23, 2018 | Symposium 2 | 10:00 AM – 12:00 PM

GRAND BALLROOM D

Intestinal Influx Transporters: A Missing Piece in the Puzzle?

DISCOVERY TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-011-L05-P

ACPE – 2.0 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Lei Zhang, PhD, Deputy Director, US Food & Drug Administration, Office of Research & Standards, Office of Generic Drugs, Ctr for Drug Evaluation & Research

Zhu Zhou, PhD, Assistant Clinical Professor, Univ of the Pacific, Pharmaceutics & Medicinal Chemistry

TARGET AUDIENCE:

This Symposium will be useful for regulators, industry, academia, clinicians and others who are interested in drug development.

GOALS & OBJECTIVES:

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

1. Describe main mechanistic findings and the clinical relevance of intestinal OATP2B1/1A2 transporters;
2. Explain the methodologies and mechanistic modeling strategy to evaluate these influx transporters during drug development;
3. Explore knowledge gaps and the regulatory perspective on the topic.

10:00 – 10:10 AM

Intestinal Influx Transporters: A Missing Piece in the Puzzle?

Lei Zhang, PhD, Deputy Director, US Food & Drug Administration, Office of Research & Standards, Office of Generic Drugs, Ctr for Drug Evaluation & Research

10:10 – 10:30 AM

Intestinal Drug Interactions Mediated by OATPs: A Systematic Review of Preclinical & Clinical Findings

Isabelle Ragueneau-Majlessi, MD, MS, Clinical Professor, Director, Drug Interaction Database Program, Univ of Washington, Pharmaceutics

10:30 – 10:50 AM

The Effects of Excipients on Intestinal Drug Transporters

Kathleen M. Giacomini, PhD, Professor, Univ of California San Francisco, Bioengineering & Therapeutic Sciences

10:50 – 11:10 AM

Decoding the Contribution of Intestinal Influx Transporters to Clinical Drug-Drug Interactions: Application in Drug Development – *In Vitro*, Preclinical & Physiologically-based Pharmacokinetic Mechanistic Modeling

Manthana Varma, PhD, Associate Research Fellow, Pfizer Inc, Medicine Design

11:10 – 11:30 AM

Regulatory Science Perspective on Intestinal Influx Transporters & Their Role in Drug-Drug Interactions

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

11:30 AM – 12:00 PM

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

SUNDAY, SEPTEMBER 23, 2018 | Symposium 3 | 1:30 – 3:00 PM

GRAND BALLROOM A–C

Can Intrinsic & Extrinsic Factors From Adult Pharmacokinetics Really Be Extrapolated to Pediatric Patients: What are We Missing?

APPLICATION TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-012-L05-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Mariam Ahmed, PhD, MSc, BPharm, Clinical Pharmacology Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology

Mohamad Shebley, PhD, Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

TARGET AUDIENCE:

This Symposium will be useful for regulatory and drug development professionals.

GOALS & OBJECTIVES:

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

1. Identify the current gap in knowledge related to dosing in pediatrics, including the invalidity of the adult extrapolation for presented cases;
2. Describe the practical and ethical considerations for conducting Phase 1 (P1) studies in the target pediatric patients;
3. List critical aspects for P1 trial design in pediatric patients;
4. Define the role of clinical pharmacology/pharmacometrics in integrating data from preclinical, adult studies and pediatric patients for better informing labeling decisions in pediatric patients.

1:30 – 1:35 PM

Dosing Recommendations in Pediatrics: Background

Mariam Ahmed, PhD, MSc, BPharm, Clinical Pharmacology Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology

1:35 – 1:45 PM

Dosing Recommendations in Pediatrics: The Current State

Islam R. Younis, PhD, Team Leader, US Food & Drug Administration, Office of Clinical Pharmacology

1:45 – 2:00 PM

Ethical Challenges In Pediatric Studies

Gilbert J. Burckart, PharmD, Associate Director for Pediatrics, US Food & Drug Administration, Office of Clinical Pharmacology

2:00 – 2:20 PM

Clinical Pharmacology Strategies to Bridge the Gap: The Role of Modeling & Simulation

Jeffrey S. Barrett, PhD, Head, Quantitative Sciences, Bill & Melinda Gates Medical Research Inst

2:20 – 2:30 PM

The Use of Pharmacokinetic/Pharmacodynamic Modeling for the Extrapolation of Dosing From Adults to Pediatric Patients: Case Study

Matthew Dufek, PhD, Associate Director, AbbVie Inc, Clinical Pharmacokinetics & Pharmacodynamics

2:30 – 3:00 PM

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



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Symposia

SUNDAY, SEPTEMBER 23, 2018 | Symposium 4 | 1:30 – 5:30 PM

GRAND BALLROOM D

Pharmacometrics at the Bedside, an ACCP/ISoP Clinical Pharmacometrics Special Interest Group Jointly-sponsored Symposium

APPLICATION TRACK

Offers both CME & CPE Credit

UAN #0238-9999-18-013-L01-P

ACPE – 3.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Amelia N. Deitchman, PharmD, PhD, T32 Clinical Pharmacology Postdoctoral Fellow, Univ of California San Francisco, Bioengineering & Therapeutic Sciences

Michael N. Neely, MD, MSc, Associate Professor of Pediatrics, Univ of Southern California, Keck School of Medicine, Pediatrics

TARGET AUDIENCE:

This Symposium will be useful for all parties interested in the implementation of pharmacometric tools in patient care, including clinicians (physicians, pharmacists, nurses), clinical pharmacologists, pharmacometricians, academic and government researchers, regulators and healthcare profession educators.

GOALS & OBJECTIVES:

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

1. Demonstrate the clinical utility of pharmacometrics;
2. Compare multiple pharmacometric tools currently available to clinicians;
3. Discuss current limitations and the steps needed to implement and better utilize these technologies.

1:30 – 1:40 PM

Clinical Pharmacometrics in Patient Care: An Overview

Amelia N. Deitchman, PharmD, PhD, T32 Clinical Pharmacology Postdoctoral Fellow, Univ of California San Francisco, Bioengineering & Therapeutic Sciences

1:40 – 2:35 PM

Pharmacometrics Software for Non-pharmacometricians: The Children's Hosp Los Angeles Busulfan Experience

Michael N. Neely, MD MSc, Associate Professor of Pediatrics, Univ of Southern California, Keck School of Medicine, Pediatrics

2:35 – 3:30 PM

Integrating Decision Support into Clinical Workflow: Lessons Learned

Srijib Goswami, PhD, Co-founder & CEO, InsightRX Inc

3:30 – 4:00 PM / Break

4:00 – 4:55 PM

Pharmacokinetic/Pharmacodynamic Compass: Bringing Infectious Diseases Pharmacometrics to the Patient's Bedside

Justin Bader, PharmD, MBA, Assistant Director, Inst for Clinical Pharmacodynamics Inc, Outcomes Research and Elizabeth A. Lakota, PharmD, MS, Assistant Director, Inst for Clinical Pharmacodynamics Inc, Pharmacometrics

4:55 – 5:30 PM

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

SUNDAY, SEPTEMBER 23, 2018 | Symposium 5 | 3:30 – 5:00 PM

GRAND BALLROOM A–C

*Nonalcoholic Steatohepatitis:
Perspectives of a Patient, a
Hepatologist & a Pharmacologist*

APPLICATION TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-014-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:

Sabina Paglialunga, PhD, Associate Director, Scientific Affairs, Celerion

TARGET AUDIENCE:

This Symposium will be useful for physicians, clinical pharmacologists, metabolic scientists, hepatologists, research scientists, medical/scientific directors and medical/scientific advisors.

GOALS & OBJECTIVES:

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

1. List current pharmacological, dietary and exercise approaches to treating nonalcoholic steatohepatitis (NASH);
2. Describe novel, noninvasive diagnostic tools to identify patients at risk of severe disease and monitor treatment response;
3. Define the current pharmacological and regulatory landscape of NASH.

3:30 – 3:40 PM

**Nonalcoholic Steatohepatitis (NASH):
Perspectives of a Patient, a Hepatologist & a
Pharmacologist**

*Sabina Paglialunga, PhD, Associate Director, Scientific Affairs,
Celerion*

3:40 – 4:00 PM

**A Patient's Perspective: Current NASH
Management Strategies**

*Bram Brouwers, MSc, PhD, Clinical Research Scientist, Eli Lilly &
Co, Diabetes Design Hub*

4:00 – 4:20 PM

**A Hepatologist's Perspective: Novel, Noninvasive
Approaches to Diagnosing NASH**

*Amilcar L. Morales-Cardona, MD, Associate Program Director,
Brooke Army Medical Ctr, Internal Medicine*

4:20 – 4:40 PM

**A Pharmacologist's Perspective: Opportunities &
Challenges in NASH Drug Development**

*Sabina Paglialunga, PhD, Associate Director, Scientific Affairs,
Celerion*

4:40 – 5:00 PM

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



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Debate

MONDAY, SEPTEMBER 24, 2018 | Debate | 8:00 – 9:30 AM

GRAND BALLROOM D

Do We Still Need Clinical Pharmacology?

APPLICATION TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-007-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

SPEAKERS & MODERATOR:

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

Michael D. Reed, PharmD, Emeritus Professor of Pediatrics, School of Medicine, Case Western Reserve Univ

Michael J. Fossler Jr, PharmD, PhD, Vice President, Trevena Inc, Clinical Operations & Quantitative Sciences

TARGET AUDIENCE:

This Debate will be useful for physicians, pharmacists or other scientists either involved in or interested in early drug development.

GOALS & OBJECTIVES:

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

1. State the major issues currently facing clinical pharmacology as a discipline;
2. Give at least three perceived strengths and three perceived deficiencies of clinical pharmacology as currently practiced in contemporary drug development;
3. State four ways in which a pharmacometrics-based approach toward drug development offers significant advantages over a clinical pharmacology-based approach;
4. State four ways in which a clinical pharmacology-based approach toward drug development offers significant advantages over a pharmacometrics-based approach;
5. Articulate the future of drug development with and without clinical pharmacology.

8:00 – 8:05 AM

Framing the Issue

Michael J. Fossler Jr, PharmD, PhD, Vice President, Trevena Inc, Clinical Operations & Quantitative Sciences

8:05 – 8:45 AM

Presentation of Points of View

8:45 – 9:05 AM

Rebuttals

Lawrence J. Lesko, PhD, Emeritus Clinical Professor & Founding Director, Ctr for Pharmacometrics & Systems Pharmacology, Univ of Florida and Michael D. Reed, PharmD, Emeritus Professor of Pediatrics, School of Medicine, Case Western Reserve Univ

9:05 – 9:30 AM

Questions/Comments from Audience



Lawrence J. Lesko, PhD



Michael D. Reed, PharmD



Michael J. Fossler Jr, PharmD, PhD

MONDAY, SEPTEMBER 24, 2018 | Symposium 6 | 10:00 – 11:30 AM

GRAND BALLROOM D

Implementation of Preemptive Pharmacogenetics: Opportunities, Challenges & Successes

APPLICATION TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-015-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:

Javier G. Blanco, PhD, Professor, School of Pharmacy & Pharmaceutical Sciences, Univ at Buffalo, The State Univ of New York, Pharmaceutical Sciences

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacists, pharmaceutical scientists, clinical and basic pharmacologists and members of the healthcare team.

GOALS & OBJECTIVES:

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

1. Identify current efforts directed towards the implementation of preemptive pharmacogenetics;
2. Describe the major challenges, opportunities and successes related to the implementation of preemptive pharmacogenetics;
3. Discuss whether preemptive pharmacogenetic testing is adding value to contemporary pharmacotherapeutic strategies.

10:00 – 10:10 AM

Implementation of Preemptive Pharmacogenetics: Opportunities, Challenges & Successes – A Snapshot of Pharmacogenetic Testing in the State of New York

Javier G. Blanco, PhD, Professor, School of Pharmacy & Pharmaceutical Sciences, Univ at Buffalo, The State Univ of New York, Pharmaceutical Sciences

10:10 – 10:30 AM

Facilitating Pharmacogenetics into Clinical Practice: The Clinical Pharmacogenetics Implementation Consortium

Kelly E. Caudle, PharmD, PhD, Director, Clinical Pharmacogenetics Implementation Consortium, St Jude Children's Research Hosp, Pharmaceutical Sciences

10:30 – 10:50 AM

Implementing Pharmacogenomics in a Community Health System: Lessons Learned

Mark Dunnenberger, PharmD, Director, Pharmacogenomics, NorthShore Univ HealthSystem, Ctr for Personalized Medicine

10:50 – 11:10 AM

Improving Clinical Outcomes Through Pharmacogenetics

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

11:10 – 11:30 AM

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



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Symposia

MONDAY, SEPTEMBER 24, 2018 | Symposium 7 | 10:00 – 11:30 AM

GRAND BALLROOM A–C

Utility of Physiologically-based Pharmacokinetic Modeling During Pregnancy & Lactation Drug Studies

DISCOVERY TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-016-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Jian Wang, PhD, Associate Director, US Food & Drug Administration, Office of Drug Evaluation IV, CDER

Catherine MT Sherwin, PhD, MSc, Associate Professor, Univ of Utah School of Medicine, Pediatrics

TARGET AUDIENCE:

This Symposium 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 currently apply pharmacometric principles to improve the quality and quantity of data available to assess the safety of medications used during pregnancy and lactation. 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 the utility of physiologically-based pharmacokinetic (PBPK) modeling during pregnancy and lactation.

GOALS & OBJECTIVES:

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

1. Identify gaps in knowledge and research on safe and effective therapies for pregnant and lactating women;
2. Describe how to use applications of PopPK and PBPK to improve the quality and quantity of data available to assess the safety of medications used during pregnancy and lactation;
3. Evaluate current approaches to the collection of data when drugs are used or expected to be used during pregnancy and lactation.

10:00 – 10:05 AM

Utility of Physiologically-based Pharmacokinetic (PBPK) Modeling During Pregnancy & Lactation Drug Studies

Jian Wang, PhD, Associate Director, US Food & Drug Administration, Office of Drug Evaluation IV, CDER

10:05 – 10:15 AM

PBPK Modeling During Pregnancy & Lactation Drug Studies: Overview, Challenges & Opportunities

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

10:15 – 10:35 AM

PBPK Modeling to Predict Drug Exposure in Pregnant Women

Alexander A. Vinks, PharmD, PhD, Professor & Division Director, Cincinnati Children's Hosp Medical Ctr, Clinical Pharmacology

10:35 – 10:55 AM

A Pregnancy-PBPK Model for Disposition of Drugs Metabolized by CYP1A2, CYP2D6 & CYP3A4

Khaled Abduljalil, PhD, Principal Scientist, Certara UK Ltd, Simcyp Div, Systems Pharmacology

10:55 – 11:15 AM

Regulatory Perspective for the Application of PBPK Modeling During Pregnancy & Lactation

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

11:15 – 11:30 AM

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

MONDAY, SEPTEMBER 24, 2018 | Symposium 8 | 1:30 – 5:00 PM

GRAND BALLROOM A–C

Can Clinical Pharmacology Break Down Barriers to Generic Substitution?

DISCOVERY TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-017-L01-P

ACPE – 3.0 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Robert Lionberger, PhD, Director, US Food & Drug Administration, Office of Research & Standards, Office of Generic Drugs

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

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists, healthcare professionals and regulatory scientists.

GOALS & OBJECTIVES:

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

1. Describe how access to generic drugs can break down barriers to effective patient care;
2. Explain the historical context for generic drug substitution in the US;
3. List ways in which generic drug substitution interacts with the evolving science of product equivalence;
4. Synthesize ways in which clinical pharmacology can aid the equivalence evaluation of complex generic products.

1:30 – 1:40 PM

Can Clinical Pharmacology Break Down Barriers to Generic Substitution?

Robert Lionberger, PhD, Director, US Food & Drug Administration, Office of Research & Standards, Office of Generic Drugs

1:40 – 2:20 PM

Impact of Variation in the Physical Characteristics of Generic Drugs on Adherence & Patient Experiences

Ameet Sarpatwari, JD, PhD, Instructor in Medicine, Brigham & Women's Hosp/Harvard Medical School, Pharmacoepidemiology & Pharmacoeconomics

2:20 – 3:00 PM

Batch-to-Batch Variability & Implications for the Generic BE Standard

Elise Burmeister Getz, PhD, Director, Oriol Therapeutics Inc, a Novartis Co, Clinical Pharmacology

3:00 – 3:30 PM / Break

3:30 – 4:10 PM

Bioequivalence & Clinical Implications of Generic Bupropion

Evan Kharasch, MD, PhD, Professor of Anesthesiology, Director of Research Innovation, Duke Univ School of Medicine, Anesthesiology

4:10 – 4:50 PM

A Model- & Systems-based Approach to Assess & Ensure Generic Substitution

Liang Zhao, PhD, Director, US Food & Drug Administration, CDER/OGD/DQMM

4:50 – 5:00 PM

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



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Symposia

MONDAY, SEPTEMBER 24, 2018 | Symposium 9 | 1:30 – 5:15 PM

GRAND BALLROOM D

Precision Medicine in Pediatrics: Reducing Variability in Exposure Across Age & Developmental Status with Physiologically-based Pharmacokinetic & Population Pharmacokinetic Strategies, an ACCP/AAPS Jointly-sponsored Symposium

APPLICATION TRACK

Offers both CME & CPE Credit

UAN #0238-9999-18-018-L01-P

ACPE – 3.25 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Robert Bies, PharmD, PhD, Associate Professor, State Univ of New York at Buffalo, Pharmaceutical Sciences

Catherine MT Sherwin, PhD, MSc, Associate Professor, Univ of Utah School of Medicine, Pediatrics

TARGET AUDIENCE:

This Symposium will be useful for pharmaceutical/biotechnology companies and regulatory agencies, pharmacometricians, clinical researchers and drug development scientists. 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 the development of precision medicine in pediatric patients.

GOALS & OBJECTIVES:

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

1. Apply therapeutic optimization in the assessment of individualized exposure;
2. Demonstrate several examples related to optimization of those individual predictions using population pharmacokinetic and physiologically-based pharmacokinetic models developed in the laboratory.

1:30 – 1:45 PM

Introduction to Precision Medicine in Pediatrics

Robert Bies, PharmD, PhD, Associate Professor, State Univ of New York at Buffalo, Pharmaceutical Sciences

1:45 – 2:25 PM

Population Approaches to Minimizing Variability in Exposure in Pediatric Patients

Catherine MT Sherwin, PhD, MSc, Associate Professor, Univ of Utah School of Medicine, Pediatrics

2:25 – 3:05 PM

Physiologically-based Pharmacokinetics (PBPK) Models & Precision Medicine in Pediatric Populations: Capturing Growth & Maturation in Neonates & Infants

Bhagwat Prasad, PhD, Assistant Professor, Univ of Washington, Pharmaceutics

3:05 – 3:35 PM / **Break**

3:35 – 4:20 PM

Predictive Performance of PBPK Models in Special Populations

Catherijne AJ Knibbe, PharmD, PhD, Professor of Individualized Drug Treatment, Leiden Academic Ctr for Drug Research, Leiden Univ & St Antonius Hosp Nieuwegein, Systems Biomedicine & Pharmacology and Clinical Pharmacy

4:20 – 4:55 PM

The Application of Precision Medicine in Clinical Studies for Pediatrics to Reduce Variability

Anne Zajicek, MD, PharmD, Deputy Director, Office of Clinical Research, Immediate Office of the Director, National Inst of Health

4:55 – 5:15 PM

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

TUESDAY, SEPTEMBER 25, 2018 | Symposium 10 | 8:00 – 9:30 AM

GRAND BALLROOM D

Assessing Physical Dependence & Drug Withdrawal Symptoms: Understanding the Evolving Clinical & Regulatory Requirements

APPLICATION TRACK**Offers both CME & CPE Credit****UAN #0238-0000-18-019-L05-P****ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED****CO-CHAIRS:**

Jack Henningfield, PhD, Vice President, Research, Health Policy & Abuse Liability, Pinney Associates Inc and Professor, Behavioral Biology, Johns Hopkins Univ School of Medicine, Psychiatry & Behavioral Sciences

Beatrice Setnik, PhD, Vice President, Scientific & Clinical Strategy, Syneos Health and Adjunct Professor, Univ of Toronto, Toxicology & Pharmacology

TARGET AUDIENCE:

This Symposium will be useful for attendees who are involved in the clinical development and regulatory submission of drugs. This would include clinical pharmacologists, regulatory and medical affairs. Attendees who are practicing medicine (physicians, nurses) would find this information very useful in their clinical practice, as the Symposium will cover common withdrawal symptoms and methods to identify and mitigate these symptoms in clinical practice.

GOALS & OBJECTIVES:

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

1. Identify the new regulatory requirements and clinical methods to evaluate the physical dependency of drugs;
2. List the clinical methodological approaches to evaluate drug withdrawal, rebound effects and physical dependence;
3. Apply clinical trial data from physical dependency studies into the clinical setting to mitigate safety risks when administering drugs with dependency potential;
4. Describe the signs and symptoms of physical dependency and understand the relevance of rebound effect when abruptly discontinuing CNS-active drugs in patients.

8:00 – 8:10 AM

Assessing Physical Dependence & Drug Withdrawal Symptoms: Understanding the Evolving Clinical & Regulatory Requirements – Assessment of Physical Dependence & Withdrawal in Clinical Trials

Jack Henningfield, PhD, Vice President, Research, Health Policy & Abuse Liability, Pinney Associates Inc and Professor, Behavioral Biology, Johns Hopkins Univ School of Medicine, Psychiatry & Behavioral Sciences

8:10 – 8:30 AM

Evaluating Drug Dependence: Regulatory, Methodological & Clinical Challenges

Alicja Lerner, MD, PhD, Medical Officer, US Food & Drug Administration, Controlled Substance Staff, CDER

8:30 – 8:50 AM

Evaluating Drug Dependency in Healthy & Patient Populations: Additional Clinical Considerations

Beatrice Setnik, PhD, Vice President, Scientific & Clinical Strategy, Syneos Health and Adjunct Professor, Univ of Toronto, Toxicology & Pharmacology

8:50 – 9:10 AM

Mitigating Drug Withdrawal in Clinical Practice: Addressing Data Gaps & Patient Needs

Michael McDonnell, MD, Associate Medical Director, Syneos Health, Early Phase Toronto

9:10 – 9:30 AM

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



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TUESDAY, SEPTEMBER 25, 2018 | Symposium 11 | 8:00 AM – 12:00 PM

GRAND BALLROOM A–C

The Challenging World of Cardiac Safety Evaluation & Utilization of Concentration-QT Analyses of Phase 1 Data to Waive the Thorough QT Study Requirement, an ACCP/CSRC Jointly-sponsored Symposium

DISCOVERY TRACK

Offers both CME & CPE Credit

UAN #0238-9999-18-020-L01-P

ACPE – 3.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Apurvasena Parikh, PhD, Associate Principal Pharmacokineticist, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

Andrew Chang, PharmD, PhD, Clinical Pharmacology Lead, Pfizer Inc, Global Product Development, Oncology

Norman Stockbridge, MD, PhD, Division Director, US Food & Drug Administration, Cardiovascular & Renal Products, CDER

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists working in the pharmaceutical industry or regulatory settings, plus clinical researchers and physicians, pharmacists and nurses involved in prescribing, dispensing and administering drugs to patients.

GOALS & OBJECTIVES:

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

1. Describe the relevance of cardiac safety considerations to drug development and therapeutic use;
2. Apply the use of exposure-response analysis of data from early-stage clinical trials to evaluate QT prolongation of small molecules and biologics;
3. Analyze regulatory, academic and industry perspectives on opportunities and challenges associated with pro-arrhythmia risk monitoring and use of early-stage clinical studies, instead of dedicated thorough QT studies.

8:00 – 8:05 AM

Approaches to Assess Pro-arrhythmia & Cardiovascular Risk in Novel Drug Development: The Yin & the Yang

Apurvasena Parikh, PhD, Associate Principal Pharmacokineticist, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

8:05 – 8:40 AM

The Challenging World of Cardiac Safety Evaluation

Norman Stockbridge, MD, PhD, Division Director, US Food & Drug Administration, Cardiovascular & Renal Products, CDER

8:40 – 9:15 AM

Regulatory Perspective for Using C-QTc as the Primary Analysis in TQT & Phase 1 Studies: Trial Design, ECG Quality Evaluation, Evaluation of Modeling/Simulation Results & Decision Making

Lars Johannesen, PhD, Staff Fellow, US Food & Drug Administration, Cardiovascular & Renal Products, CDER

9:15 – 9:50 AM

Use of Data from Early Clinical Trials to Support Thorough QT Study Waiver for Upadacitinib & Utility of Food Effect to Demonstrate ECG Assay Sensitivity

Mohamed-Eslam Mohamed, PhD, Assistant Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics

9:50 – 10:20 AM / Break

10:20 – 10:55 AM

Cardiac Safety Considerations in Drug Therapeutic Use

J. Rick Turner, PhD, DSc, Expert Consultant, DRT Strategies Inc

10:55 – 11:30 AM

Identifying Cardiac Safety Signals in the Era of Personalized Medicine

Javid Moslehi, MD, Director, Cardio-Oncology Program, Assistant Professor of Medicine, Vanderbilt School of Medicine, Cardiology

11:30 AM – 12:00 PM

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

TUESDAY, SEPTEMBER 25, 2018 | Symposium 12 | 10:00 AM – 12:00 PM

GRAND BALLROOM D***Pediatric HIV Drug Development: Big Challenges Call for Innovation in Little People*****DISCOVERY TRACK****Offers both CME & CPE Credit****UAN #0238-0000-18-021-L02-P****ACPE – 2.0 CONTACT HOURS/KNOWLEDGE-BASED****CO-CHAIRS:****Kristina M. Brooks, PharmD**, Postdoctoral Fellow, Univ of Colorado, Pharmaceutical Sciences**Jomy George, PharmD**, Pharmacokineticist, National Inst of Health, Clinical Pharmacokinetics Research Unit**TARGET AUDIENCE:**

This Symposium will be useful for healthcare professionals including pharmacists, physicians and nurses, plus research scientists in academia, industry and regulatory agencies with an interest in clinical pharmacology applications specific to pediatrics and pediatric HIV/AIDS treatment.

GOALS & OBJECTIVES:

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

1. Review current approaches in antiretroviral pharmacokinetic trial design in pediatric patients;
2. Identify challenges with the development of age-appropriate antiretroviral formulations in pediatric patients;
3. Discuss the practical considerations for dose selection in pediatric patients to ensure target exposure attainments;
4. Describe the innovative application of modeling and simulation in pediatric HIV trial design.

10:00 – 10:05 AM

Pediatric HIV Drug Development: Big Challenges Call for Innovation in Little People*Jomy George, PharmD, Pharmacokineticist, National Inst of Health, Clinical Pharmacokinetics Research Unit*

10:05 – 10:30 AM

Challenges & Innovations in Pediatric HIV Pharmacokinetic Trial Design*Jennifer J. Kiser, PharmD, Associate Professor, Univ of Colorado, Pharmaceutical Sciences*

10:30 – 10:55 AM

Applications of Modeling & Simulation in Pediatric HIV Trial Design & Dose Determination*Edmund Capparelli, PharmD, Professor of Clinical Pediatrics & Pharmacy, Univ of California San Diego, Host-Microbe Systems & Therapeutics*

10:55 – 11:20 AM

Pediatric HIV Drug Development: Industry Perspective*Annie Buchanan, MD, Physician Project Lead, ViiV Healthcare, Dolutegravir Pediatric Program*

11:20 – 11:45 AM

Pediatric HIV Drug Development: Regulatory Experiences*Shirley K. Seo, PhD, Division Director, US Food & Drug Administration, Div of Clinical Pharmacology 3, OCP/OTS/CDER*

11:45 – 11:50 AM

Pediatric HIV Drug Development: Session Wrap Up*Kristina M. Brooks, PharmD, Postdoctoral Fellow, Univ of Colorado, Pharmaceutical Sciences*

11:50 AM – 12:00 PM

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



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TUESDAY, SEPTEMBER 25, 2018 | Symposium 13 | 1:30 – 3:00 PM

GRAND BALLROOM D

Oligonucleotide-based Therapies: A Multistakeholder Perspective of the Opportunities & Challenges

DISCOVERY TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-022-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CHAIR:

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

TARGET AUDIENCE:

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

GOALS & OBJECTIVES:

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

1. Describe the recent progress and latest developments in oligonucleotide-based therapies;
2. List how oligonucleotide-based therapies are targeting a wide range of disease indications and can address unmet medical needs;
3. Discuss major scientific, clinical and clinical pharmacology challenges in the development of oligonucleotide-based therapies.

1:30 – 1:40 PM

Oligonucleotide-based Therapies: An Overview

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

1:40 – 2:00 PM

Oligonucleotide-based Therapies for the Treatment of Diseases With Unmet Medical Needs

David S. Pisetsky, MD, PhD, Professor of Medicine & Immunology, Duke Univ Medical Ctr

2:00 – 2:20 PM

Designing & Developing Oligonucleotide-based Therapies for the Treatment of Neurodegenerative Diseases

Richard Geary, PhD, Senior Vice President, Development, Ionis Pharmaceuticals Inc

2:20 – 2:40 PM

Regulatory Considerations of Oligonucleotide-based Therapies: A Clinical Pharmacology Perspective

Hobart Rogers, PharmD, PhD, Clinical Pharmacologist, US Food & Drug Administration, Office of Clinical Pharmacology, CDER

2:40 – 3:00 PM

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

TUESDAY, SEPTEMBER 25, 2018 | Symposium 14 | 1:30 – 3:00 PM

GRAND BALLROOM A–C

Bioequivalence: Non-traditional Approaches

DISCOVERY TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-023-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Laszlo Endrenyi, PhD, Professor Emeritus, Univ of Toronto,
Pharmacology & Toxicology

Alfred H. Balch, PhD, MA, Associate Professor, Univ of Utah, Pediatrics

Faculty travel is supported in part by a donation from Summit Statistics LLC

TARGET AUDIENCE:

This Symposium will be useful for regulators and those in industry, but also to anyone who wants to develop their thinking about what it means for pharmacological interventions to be exchangeable. As an example, the original Two One-Sided Test developed by Schuirmann in 1977 became used whenever equivalence was considered and was generalized to consider non-inferiority in Phase III trials for new drug approval. The topic is also useful to those who are interested in reducing healthcare costs while maintaining good patient care.

GOALS & OBJECTIVES:

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

1. Identify strategies of evaluating therapeutic equivalence in non-standard settings;
2. Given knowledge of pharmacokinetic (PK)/pharmacodynamic (PD) properties of a drug, identify correctly a situation that calls for a standard of equivalence that is not based on a non-compartmental PK model or *in vitro* dissolution;
3. Given a situation that requires a PD endpoint, propose a sensible trial design that will employ a PD endpoint and an equivalence criterion for evaluation of that endpoint;
4. Given a trial design with a highly-variable drug or narrow therapeutic window drug, propose a sensible trial design and appropriate analysis that will successfully address this issue.

1:30 – 1:35 PM

Bioequivalence: Non-traditional Approaches*Alfred H. Balch, PhD, MA, Associate Professor, Univ of Utah, Pediatrics*

1:35 – 1:55 PM

Bioequivalence, Biosimilarity & Interchangeability*Laszlo Endrenyi, PhD, Professor Emeritus, Univ of Toronto, Pharmacology & Toxicology*

1:55 – 2:15 PM

Individual Bioequivalence, Population Bioequivalence, Metered Dose Inhalers & Biosimilars*Terry Hyslop, PhD, Professor, Director of Duke Cancer Inst Biostatistics, Duke Univ, Biostatistics & Bioinformatics*

2:15 – 2:35 PM

Evaluation of Model-based Bioequivalence Statistical Approaches for Sparse Designs Pharmacokinetic Studies*France Mentre, PhD, MD, Professor of Biostatistics, Univ Paris Diderot – INSERM, Team Biostatistical Modeling, Clinical Investigation & Pharmacometrics in Infectious Diseases*

2:35 – 2:55 PM

Biosimilars: What is Different & What is Similar to Bioequivalence?*Sarah Schrieber, PharmD, Co-Director, US Food & Drug Administration, Therapeutic Biologics Program, CDER/OTS/OCP/IO*

2:55 – 3:00 PM

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



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TUESDAY, SEPTEMBER 25, 2018 | Symposium 15 | 3:30 – 5:00 PM

GRAND BALLROOM A–C

Methodological & Statistical Considerations in Pediatric & Rare Disease Drug Development: External Control Groups & Dose Selection

DISCOVERY TRACK

Offers both CME & CPE Credit

UAN #0238-0000-18-024-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Gopichand Gottipati, PhD, Pharmacometrics Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology

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

TARGET AUDIENCE:

This Symposium will be useful for clinical pharmacologists, statisticians, clinicians and pharmacometricians.

GOALS & OBJECTIVES:

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

1. Identify how alternative data can be properly used through prospective design and analysis to provide a potential external control group in clinical trials as an alternative to single-arm, uncontrolled trials;
2. Review how alternative data, which often includes many more patients than could have been studied prospectively, can facilitate understanding of the disease and the treatments in subgroups and relationships among endpoints;
3. Discuss methodological and statistical considerations when using an external control including the types and sources of external data;
4. Present specific examples to illustrate challenges and opportunities for integration of external control in pediatric and rare disease drug development;
5. Describe some of the challenges and dose-finding approaches in pediatric and rare-disease drug development.

3:30 – 3:45 PM

Integrating Real World Data in Pediatric Clinical Trials

Margaret Gamalo-Siebers, PhD, Principal Research Scientist, Eli Lilly & Co, Global Statistical Sciences

3:45 – 4:00 PM

Creating a Synthetic Control Arm from Previous Clinical Trials

Ruthanna Davi, PhD, Senior Director & Biostatistician, Medidata Solutions Inc, Data Science

4:00 – 4:10 PM

Prospective & Retrospective Registry for Meeting the Needs of Rare Diseases & Pediatric Drug Development

Andrew E. Mulberg, MD, Vice President, Amicus Therapeutics Inc, Global Regulatory Affairs

4:10 – 4:25 PM

Challenges with Dose Selection for Lysosomal Storage Diseases: Case Examples – Regulatory & Industry Perspectives

Yow-Ming Wang, PhD, Co-Director, Therapeutic Biologics Program, Office of Clinical Pharmacology, Office of Translational Sciences, Ctr for Drug Evaluation & Research, US Food & Drug Administration and Marc R. Gastonguay, PhD, Chief Executive Officer, Metrum Research Group LLC

4:25 – 5:00 PM

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

Robert Temple, MD [US Food & Drug Administration], Gopichand Gottipati, PhD [US Food & Drug Administration], Marc R. Gastonguay, PhD [Metrum Research Group LLC], Jeffrey S. Barrett, PhD [Bill & Melinda Gates Medical Research Inst], Lynne Yao, MD [US Food & Drug Administration], Dragos Roman, MD [US Food & Drug Administration], Vikram Sinha, PhD [Merck & Co Inc], Yeruk A. Mulugeta, PharmD [US Food & Drug Administration] and Margaret Gamalo-Siebers, PhD [Eli Lilly & Co]

TUESDAY, SEPTEMBER 25, 2018 | Symposium 16 | 3:30 – 5:00 PM

GRAND BALLROOM D**2nd Generation Immuno-oncology Products: Beyond Monoclonal Antibodies****APPLICATION TRACK***Offers both CME & CPE Credit*

UAN #0238-0000-18-025-L01-P

ACPE – 1.5 CONTACT HOURS/KNOWLEDGE-BASED

CO-CHAIRS:

Vijay V. Upreti, PhD, Director, Amgen Inc, Clinical Pharmacology & Modeling Simulation, Medical Sciences

Chaitali Passey, PhD, Associate Director, Genmab A/S

TARGET AUDIENCE:

This Symposium will be useful for clinicians, clinical pharmacologists, pharmacometricians and regulators.

GOALS & OBJECTIVES:

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

1. List key immuno-oncology monoclonal antibodies under development or in market that target various immune-related pathways;
2. Describe different immune mechanisms targeted for cancer treatment, especially the emerging targets;
3. List the key pharmacokinetic and pharmacodynamic considerations for developing 2nd generation immuno-oncology products.

3:30 – 3:40 PM

2nd Generation Immuno-oncology Products: Beyond Monoclonal Antibodies

Chaitali Passey, PhD, Associate Director, Genmab A/S

3:40 – 4:00 PM

Bi-specific T-Cell Engagers: Clinical Pharmacology & Modeling Simulation Aspects of Development

Vijay V. Upreti, PhD, Director, Amgen Inc, Clinical Pharmacology & Modeling Simulation, Medical Sciences

4:00 – 4:20 PM

The Clinical Development Perspective on Oncolytic Viruses

Howard L. Kaufman, MD, Chief Medical Officer, Replimune Group

4:20 – 4:40 PM

Pharmacokinetic/Pharmacodynamic Aspects of Developing CAR-T Therapies

James Kalabus, PhD, Senior Scientist, Medical Sciences, Amgen Inc, Clinical Pharmacology, Modeling & Simulation

4:40 – 5:00 PM

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



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Last Name	First Name	Course	Affiliation
Abduljalil	Khaled	Symposium 7	Principal Scientist, Certara UK Ltd, Simcyp Div, Systems Pharmacology
Ahmed	Mariam	Symposium 3	Clinical Pharmacology Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology
Ameer	Barbara	Pre-meeting Workshop 3	Adjunct Associate Professor, Rutgers Robert Wood Johnson Medical School, Medicine
Azer	Karim	Pre-meeting Workshop 2	Head of Quantitative Systems Pharmacology & Drug Metabolism Pharmacokinetics Modeling, Quantitative Sciences, Bill & Melinda Gates Medical Research Inst
Bader	Justin	Symposium 4	Assistant Director, Inst for Clinical Pharmacodynamics Inc, Outcomes Research
Balch	Alfred H.	Symposium 14	Associate Professor, Univ of Utah, Pediatrics
Barrett	Jeffrey S.	Symposia 3 & 15	Head, Quantitative Sciences, Bill & Melinda Gates Medical Research Inst
Berman	Helen M.	Pre-meeting Workshop 3	Professor Emerita of Chemistry & Chemical Biology, Rutgers, The State Univ of New Jersey
Bies	Robert	Symposium 9	Associate Professor, State Univ of New York at Buffalo, Pharmaceutical Sciences
Blanco	Javier G.	Symposium 6	Professor, School of Pharmacy & Pharmaceutical Sciences, Univ at Buffalo, The State Univ of New York, Pharmaceutical Sciences
Brooks	Kristina M.	Symposium 12	Postdoctoral Fellow, Univ of Colorado, Pharmaceutical Sciences
Brouwers	Bram	Symposium 5	Clinical Research Scientist, Eli Lilly & Co, Diabetes Design Hub
Buchanan	Annie	Symposium 12	Physician Project Lead, ViiV Healthcare, Dolutegravir Pediatric Program
Burckart	Gilbert J.	Symposium 3	Associate Director for Pediatrics, US Food & Drug Administration, Office of Clinical Pharmacology
Burmeister Getz	Elise	Symposium 8	Director, Oriel Therapeutics Inc, a Novartis Co, Clinical Pharmacology
Capparelli	Edmund	Symposium 12	Professor of Clinical Pediatrics & Pharmacy, Univ of California San Diego, Host-Microbe Systems & Therapeutics
Caudle	Kelly E.	Symposium 6	Director, Clinical Pharmacogenetics Implementation Consortium, St Jude Children's Research Hosp, Pharmaceutical Sciences
Chang	Andrew	Symposium 11	Clinical Pharmacology Lead, Pfizer Inc, Global Product Development, Oncology
Chaturvedula	Ayyappa	Pre-meeting Workshop 2	Associate Professor, Univ of North Texas Health Science Ctr, Pharmacotherapy
Cirit	Murat	Pre-meeting Workshop 1	Principal Investigator, Massachusetts Inst of Technology, Biological Engineering
Davi	Ruthanna	Symposium 15	Senior Director & Biostatistician, Medidata Solutions Inc, Data Science
Deitchman	Amelia N.	Symposium 4	T32 Clinical Pharmacology Postdoctoral Fellow, Univ of California San Francisco, Bioengineering & Therapeutic Sciences
Dufek	Matthew	Symposium 3	Associate Director, AbbVie Inc, Clinical Pharmacokinetics & Pharmacodynamics
Dunnenberger	Mark	Symposium 6	Director, Pharmacogenomics, NorthShore Univ HealthSystem, Ctr for Personalized Medicine
Earp	Justin	Pre-meeting Workshop 2	Scientific Lead for Biologic & Biosimilar Products, Div of Pharmacometrics, Office of Clinical Pharmacology, US Food & Drug Administration
Endrenyi	Laszlo	Symposium 14	Professor Emeritus, Univ of Toronto, Pharmacology & Toxicology
Fossler Jr	Michael J.	Debate	Vice President, Trevena Inc, Clinical Operations & Quantitative Sciences
Gamalo-Siebers	Margaret	Symposium 15	Principal Research Scientist, Eli Lilly & Co, Global Statistical Sciences
Gastonguay	Marc R.	Symposium 15	Chief Executive Officer, Metrum Research Group LLC

Last Name	First Name	Course	Affiliation
Geary	Richard	Symposium 13	Senior Vice President, Development, Ionis Pharmaceuticals Inc
George	Jomy	Symposium 12	Pharmacokineticist, National Inst of Health, Clinical Pharmacokinetics Research Unit
Giacomini	Kathleen M.	Symposium 2	Professor, Univ of California San Francisco, Bioengineering & Therapeutic Sciences
Goswami	Srijib	Symposium 4	Co-founder & CEO, InsightRX Inc
Gottipati	Gopichand	Symposium 15	Pharmacometrics Reviewer, US Food & Drug Administration, Office of Clinical Pharmacology
Green	Dionna J.	Pre-meeting Workshop 4	Deputy Director, Office of Pediatric Therapeutics, Office of the Commissioner, US Food & Drug Administration
Henningfield	Jack	Symposium 10	Vice President, Research, Health Policy & Abuse Liability, Pinney Associates Inc and Professor, Behavioral Biology, Johns Hopkins Univ School of Medicine, Psychiatry & Behavioral Sciences
Hsu	Chyi-Hung	Pre-meeting Workshop 4	Director, Janssen Research & Development LLC, Global Clinical Pharmacology
Hu	Chuanpu	Pre-meeting Workshop 4	Scientific Director, Janssen Research & Development LLC, Global Clinical Pharmacology
Huang	Shiew-Mei	Pre-meeting Workshop 1 & Symposium 2	Deputy Director, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, US Food & Drug Administration
Hyslop	Terry	Symposium 14	Professor, Director of Duke Cancer Inst Biostatistics, Duke Univ, Biostatistics & Bioinformatics
Issa	Amalia M.	Pre-meeting Workshop 3	Professor, Univ of the Sciences Philadelphia, Pharmaceutical Sciences and Founding Director, Personalized Medicine & Targeted Therapeutics Ctr
Johannesen	Lars	Symposium 11	Staff Fellow, US Food & Drug Administration, Cardiovascular & Renal Products, CDER
Johnson	Julie A.	Symposium 6	Dean & Distinguished Professor, Univ of Florida, Coll of Pharmacy
Kalabus	James	Symposium 16	Senior Scientist, Medical Sciences, Amgen Inc, Clinical Pharmacology, Modeling & Simulation
Kaufman	Howard L.	Symposium 16	Chief Medical Officer, Replimune Group
Kharasch	Evan	Symposium 8	Professor of Anesthesiology, Director of Research Innovation, Duke Univ School of Medicine, Anesthesiology
Kirstein	Mark	Symposium 1	Associate Professor, Univ of Minnesota Coll of Pharmacy & Masonic Cancer Ctr, Experimental & Clinical Pharmacology
Kiser	Jennifer J.	Symposium 12	Associate Professor, Univ of Colorado, Pharmaceutical Sciences
Knibbe	Catherijne AJ	Symposium 9	Professor of Individualized Drug Treatment, Leiden Academic Ctr for Drug Research, Leiden Univ & St Antonius Hosp Nieuwegein, Systems Biomedicine & Pharmacology and Clinical Pharmacy
Knights	Jonathan	Plenary Session	Associate Director, Otsuka Pharmaceutical Development & Commercialization Inc, Data Sciences
Kordy	Kattayoun	Pre-meeting Workshop 4	Global Pediatric Medical Director, Development, Science & Innovation, Novartis, Pediatric Ctr of Excellence
Kumar	Rukmini	Pre-meeting Workshop 2	Principal Scientist, Vantage Research
Lakota	Elizabeth A.	Symposium 4	Assistant Director, Inst for Clinical Pharmacodynamics Inc, Pharmacometrics
Leeder	J. Steven	Pre-meeting Workshop 4	Director, Clinical Pharmacology, Toxicology & Therapeutic Innovation, Children's Mercy Hosp, Pediatrics
Lerner	Alicja	Symposium 10	Medical Officer, US Food & Drug Administration, Controlled Substance Staff, CDER
Lesko	Lawrence J.	Debate	Emeritus Clinical Professor & Founding Director, Ctr for Pharmacometrics & Systems Pharmacology, Univ of Florida
Lionberger	Robert	Symposium 8	Director, US Food & Drug Administration, Office of Research & Standards, Office of Generic Drugs



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Last Name	First Name	Course	Affiliation
Madabushi	Rajanikanth	Pre-meeting Workshop 1	Team Lead, US Food & Drug Administration, Guidance & Policy Team, OCP/OTS/CDER
McCune	Susan	Pre-meeting Workshop 4	Director, Office of Pediatric Therapeutics, Office of the Commissioner, US Food & Drug Administration
McDonnell	Michael	Symposium 10	Associate Medical Director, Syneos Health, Early Phase Toronto
Mentre	France	Symposium 14	Professor of Biostatistics, Univ Paris Diderot – INSERM, Team Biostatistical Modeling, Clinical Investigation & Pharmacometrics in Infectious Diseases
Mohamed	Mohamed-Eslam	Symposium 11	Assistant Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics
Morales-Cardona	Amilcar L.	Symposium 5	Associate Program Director, Brooke Army Medical Ctr, Internal Medicine
Moslehi	Javid	Symposium 11	Director, Cardio-Oncology Program, Assistant Professor of Medicine, Vanderbilt School of Medicine, Cardiology
Mulberg	Andrew E.	Symposium 15	Vice President, Amicus Therapeutics Inc, Global Regulatory Affairs
Mulugeta	Yeruk A.	Symposium 15	Clinical Reviewer, US Food & Drug Administration, Office of New Drugs/Div of Pediatrics
Neely	Michael N.	Symposium 4	Associate Professor of Pediatrics, Univ of Southern California, Keck School of Medicine, Pediatrics
Paglalunga	Sabina	Symposium 5	Associate Director, Scientific Affairs, Celerion
Parikh	Apurvasena	Symposium 11	Associate Principal Pharmacokineticist, AbbVie Inc, Clinical Pharmacology & Pharmacometrics
Parrott	Neil J.	Pre-meeting Workshop 1	Distinguished Scientist, F. Hoffman-La Roche AG, Pharmaceutical Sciences
Passey	Chaitali	Symposium 16	Associate Director, Genmab A/S
Peters-Strickland	Timothy	Plenary Session	Vice President Global Clinical Development, Otsuka Pharmaceutical Development & Commercialization Inc, CNS & Digital Medicine
Pisetsky	David S.	Symposium 13	Professor of Medicine & Immunology, Duke Univ Medical Ctr
Prasad	Bhagwat	Symposium 9	Assistant Professor, Univ of Washington, Pharmaceutics
Ragueneau-Majlessi	Isabelle	Symposium 2	Clinical Professor, Director, Drug Interaction Database Program, Univ of Washington, Pharmaceutics
Rahman	Atiqur	Symposium 1	Division Director, US Food & Drug Administration, Office of Clinical Pharmacology, OTS/OMPT/CDER
Ramamoorthy	Anuradha	Symposium 13	Policy Lead, US Food & Drug Administration, Office of Clinical Pharmacology, CDER
Reed	Michael D.	Debate	Emeritus Professor of Pediatrics, School of Medicine, Case Western Reserve Univ
Ribeiro	Alexandre	Pre-meeting Workshop 1	Staff Fellow (Biological Scientist), US Food & Drug Administration, Ctr for Drug Evaluation & Research
Rogers	Hobart	Symposium 13	Clinical Pharmacologist, US Food & Drug Administration, Office of Clinical Pharmacology, CDER
Roman	Dragos	Symposium 15	Deputy Director, US Food & Drug Administration, Div of Gastroenterology & Inborn Errors Products
Salem	Ahmed H.	Symposium 1	Associate Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics
Sarpawari	Ameet	Symposium 8	Instructor in Medicine, Brigham & Women's Hosp/Harvard Medical School, Pharmacoepidemiology & Pharmacoeconomics
Schmidt	Stephan	Pre-meeting Workshop 2 & Symposium 8	Certara Professor, Associate Professor & Associate Director, Ctr for Pharmacometrics & Systems Pharmacology, Univ of Florida
Schrieber	Sarah	Symposium 14	Co-Director, US Food & Drug Administration, Therapeutic Biologics Program, CDER/OTS/OCP/IO

Last Name	First Name	Course	Affiliation
Seo	Shirley K.	Symposium 12	Division Director, US Food & Drug Administration, Div of Clinical Pharmacology 3, OCP/OTS/CDER
Setnik	Beatrice	Symposium 10	Vice President, Scientific & Clinical Strategy, Syneos Health and Adjunct Professor, Univ of Toronto, Toxicology & Pharmacology
Shebley	Mohamad	Symposium 3	Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics
Sherwin	Catherine MT	Pre-meeting Workshop 4 & Symposia 7 & 9	Associate Professor, Univ of Utah School of Medicine, Pediatrics
Sinha	Vikram	Symposium 15	Associate Vice President & Head, Merck & Co Inc, Quantitative Pharmacology & Pharmacometrics
Sobie	Eric A.	Pre-meeting Workshop 2	Associate Professor, Pharmacological Sciences, The Icahn School of Medicine at Mount Sinai
Stockbridge	Norman	Symposium 11	Division Director, US Food & Drug Administration, Cardiovascular & Renal Products, CDER
Swan	Judith A.	Pre-meeting Workshop 3	Associate Director for Writing in Science & Engineering, Princeton Univ, Princeton Writing Program
Tagle	Danilo A.	Pre-meeting Workshop 1	Associate Director for Special Initiatives, National Ctr for Advancing Translational Sciences, National Inst of Health, Office of the Director
Temple	Robert	Symposium 15	Deputy Director for Clinical Sciences, US Food & Drug Administration, Ctr for Drug Evaluation & Research
Turner	J. Rick	Symposium 11	Expert Consultant, DRT Strategies Inc
Turner	Mark	Pre-meeting Workshop 4	Senior Lecturer, Univ of Liverpool & Consultant Neonatologist, Liverpool Women's NHS Fdtn Trust
Upreti	Vijay V.	Symposium 16	Director, Amgen Inc, Clinical Pharmacology & Modeling Simulation, Medical Sciences
Varma	Manthena	Symposium 2	Associate Research Fellow, Pfizer Inc, Medicine Design
Vinks	Alexander A.	Symposium 7	Professor & Division Director, Cincinnati Children's Hosp Medical Ctr, Clinical Pharmacology
Wagoner	Matthew	Pre-meeting Workshop 1	Associate Director of Investigative Toxicology, Takeda Pharmaceuticals Co Ltd, Drug Safety Research Evaluation
Wang	Jian	Pre-meeting Workshop 4 & Symposium 7	Associate Director, US Food & Drug Administration, Office of Drug Evaluation IV, CDER
Wang	Yaning	Symposium 7	Director, US Food & Drug Administration, Div of Pharmacometrics, Office of Clinical Pharmacology
Wang	Yow-Ming	Symposium 15	Co-Director, Therapeutic Biologics Program, Office of Clinical Pharmacology, Office of Translational Sciences, Ctr for Drug Evaluation & Research, US Food & Drug Administration
Ward	Robert M.	Pre-meeting Workshop 4	Professor Emeritus, Univ of Utah, Pediatrics
Wikswa	John P.	Pre-meeting Workshop 1	Gordon A. Cain Univ Professor, Vanderbilt Univ, Vanderbilt Inst for Integrative Biosystems Research & Education
Xiong	Hao	Symposium 1	Director, AbbVie Inc, Clinical Pharmacology & Pharmacometrics
Yao	Lynne	Symposia 7 & 15	Director, US Food & Drug Administration, Pediatric & Maternal Health
Younis	Islam R.	Symposium 3	Team Leader, US Food & Drug Administration, Office of Clinical Pharmacology
Zajicek	Anne	Symposium 9	Deputy Director, Office of Clinical Research, Immediate Office of the Director, National Inst of Health
Zhang	Lei	Symposium 2	Deputy Director, US Food & Drug Administration, Office of Research & Standards, Office of Generic Drugs, Ctr for Drug Evaluation & Research
Zhao	Liang	Symposium 8	Director, US Food & Drug Administration, CDER/OGD/DQMM
Zhou	Zhu	Symposium 2	Assistant Clinical Professor, Univ of the Pacific, Pharmaceuticals & Medicinal Chemistry



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- **Receipt of routine updates from ACCP** about developments in the field of clinical pharmacology and future ACCP events.

ACCP Member Testimonial

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



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

How to Join ACCP

ACCP has several categories of membership, please join using the membership category that is most appropriate for you. To join, go to ACCP1.org, then select Join and the Member or Student Member profile, 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 10, 2019
- May 5, 2019
- September 14, 2019

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

Students, Trainees & Young Professionals

Annual Meeting Events for Students, Trainees & Young Professionals

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

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

Student, Trainee & Young Professional-specific Events

On **Sunday, September 23rd**, the following event will be hosted:

- **STYP Welcome Breakfast** (7:00 – 7:45 AM, Grand Ballroom A-C) – Grab breakfast in the Grand Ballroom Foyer and join 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 or any number of other topics of concern.

On **Monday, September 24th**, the following events will be hosted:

- **Panel Discussion on Career Guidance** (1:30 – 3:00 PM, Brookside A) – 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!
- **STYP Networking Reception** (3:00 – 4:00 PM, Brookside A) – After the Panel Discussion, join us for the STYP Networking Reception where you can interact on a more personal level with Panel Discussion speakers and other ACCP Mentors to ask the burning questions that will help you make decisions about your future.
- **Podium Presentations** (4:00 – 5:00 PM, Brookside A) – A select number of Student Abstract Award winners will present their research in a Podium Presentation to an audience of Annual Meeting attendees. Support your colleagues by being part of this important event.

All STYP events are sponsored by:

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CV Reviews!

All Students, Trainees & Young 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 and Enjoy the Benefits of ACCP Membership!

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The **Student, Trainee & Young Professional (STYP) Committee**, co-chaired by Amelia N. Deitchman, PharmD, PhD and Kacey Anderson, PhD, is critical in providing guidance regarding Student, Trainee & Young 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 & Young Professionals. Have a great idea? Please share it with us at STYP@ACCP1.org.



Amelia N. Deitchman, PharmD, PhD



Kacey Anderson, PhD



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www.altasciences.com Booth #: 201



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www.biopharmaservices.ca Booth #: 404



Clinical Pharmacology of Miami Inc (CPMI), an ERG Portfolio Company, has completed over 1,900 studies in their newly-renovated Phase 1 facility. Equipped with 120 beds, CPMI specializes in NHV and specialized populations including hepatic impairment, renal insufficiency, hypertension, sexual dysfunction, obesity, diabetes and NASH. Trial expertise includes FIH, SAD/MAD, PK/PD, BE/BA, QTc/ TQT, DDI and Food Interaction. Four successful FDA inspections.

Evolution Research Group is the largest, independent site network in the US with a focus on neuroscience, early phase and special populations.

www.joinaresearchstudy.com Booth #: 203





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High Point Clinical Trials Center has provided comprehensive (Phase I-III) clinical site services since 2008. Our 42,000 ft² facility consists of three unique units for the execution of outpatient and inpatient clinical studies. In addition to healthy normal Phase I studies, we focus on specialty populations such as Metabolic Diseases, NASH, Renal Respiratory, CNS, Cardiovascular and Nicotine.

www.highpointctc.com Booth #: 305



ALPHADAS® is a compelling end-to-end software solution that expedites key drug development decision making and provides operational savings throughout the business. Stop by and learn why ALPHADAS has become the standard by which organizations around the world accelerate and streamline early-phase clinical trial operations and services.

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Lixoft was founded in 2011 and is based on a seven-year research program on biostatistics and modeling led by the Inria Institute. Lixoft sells advanced software applications for the modeling and simulation of drug development and clinical trials.

www.lixoft.com Booth #: 302



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Metrum Research Group LLC 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 450 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, METWORX (our cloud-based platform) and mrgsolve (our R package for simulations from ODE-based models).

www.metrumrg.com Booth #: 101



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 University of Tennessee Medical Center. 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.

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qPharmetra LLC, a global leader in pharmacometric modeling and clinical pharmacology consulting, uses quantitative methods to help drug development organizations choose the best dose, design efficient trials and develop analyses supporting positive regulatory reviews. Our clinical pharmacology services help drug development organizations develop their clinical pharmacology plans, analyze preclinical PK/PD data to support candidate selection and to design Phase 1 trials effectively advancing your development programs. We work with companies of all sizes at all development stages to model better medicines.

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www.simulations-plus.com Booth #: 301



TNO will exhibit the latest developments on the use of microtracer-labeled drugs in clinical pharmacology. Besides the use of microtracers to establish absolute bioavailability, the application of the automated AMS analysis, combined with simultaneous direct hrMS/MS for metabolite profiling, will be shown.

www.tno.nl Booth #: 104



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Other ACCP Webinars – a series of specialty events offered as live webinars featuring a presentation followed by questions and discussion; also available On Demand.

* All live sessions are recorded and available On Demand for up to 3 years.

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Poster Session 1

Sunday, Sept 23rd / 5:00 – 7:00 PM & Monday, Sept 24th / 8:00 – 10:00 AM
GRAND BALLROOM E-H

Applications of Modeling & Simulation

Poster	Type	Title	Authors
001		Trough vs AUC-guided Dosing of Vancomycin in Infant Patients in Saudi Arabia	A. Alsultan, M. Abouelkheir, A. A. Albassam, E. Alharbi, A. Assiri, S. Alqahtani
002	S	Prediction of the Pharmacokinetics of Drugs in Pediatric Populations Using Physiologically-based Pharmacokinetic Models Integrating Newly-determined Ontogenies of Hepatic UDP-glucuronyltransferase Enzymes	J. Badée, N. J. Parrott, S. Fowler, S. Schmidt
003	S, NM	Evaluation of the Sensitivity of Concluding Bioequivalence Using Population Pharmacokinetic Model-based Simulations	K. Fairman, M. Srinivasan, A. Chaturvedula
004	NM	Exposure-Response Modeling and Simulation in Assessing QTc Prolongation Risk of Itacitinib in Healthy Volunteers	X. Gong, B. Darpo, H. Xue, K. He, A. M. Barbour, N. Epstein, X. Chen, S. Yeleswaram
005		Population Pharmacokinetic Modeling of Enzyme Replacement Therapy ATB200 and Pharmacological Chaperone AT2221 in Adult Patients With Pompe Disease and Simulation to Predict Adolescent Exposures	J. L. Hajjar, J. T. Mondick, M. R. Gastonguay, A. E. Mulberg, F. K. Johnson
006	S	Population Parent-Metabolite Pharmacokinetic Modeling of Acetaminophen Protein Adducts, a Biomarker of Acetaminophen-induced Hepatotoxicity	S. Jiang, V. Vozmediano, L. James, S. Rahman, S. Schmidt
007	S	Pharmacokinetic/Pharmacodynamic Modeling of Intravenous Ferric Carboxymaltose in Pediatric Subjects With Iron Deficiency Anemia	J. Jones, A. Butcher, T. Rodgers, C. Farrell, N. Blackman
008	S	Using a Physiologically-based Pharmacokinetic Modeling Approach to Identify the Drug-Drug Interaction Mechanism of Nifedipine and a Proton Pump Inhibitor, Omeprazole	M. Le Merdy, D. Sun, Z. Ni, A. Babiskin, S. Lee, L. Zhao, J. Fan
009	S, SA, P	Physiologically-based Pharmacokinetic Modeling of Emtricitabine in Pregnant Women	X. I. Liu, J. Momper, J. N. van den Anker, K. Watt, D. Green, G. J. Burckart, A. Dallmann
010		Quantitative Prediction of Buprenorphine and Samidorphan Pharmacokinetics in Humans When Sublingually Administered in Combination as ALKS 5461 and of Metabolically-based Drug-Drug Interactions With ALKS 5461 as Perpetrator	H. Lu, K. Rowland Yeo, M. Hard, V. Kumar, L. von Moltke
011	S	Physiologically-based Pharmacokinetic Modeling Approach to Predict Steady-state Plasma Exposure of Trepstinil Following Oral Administration in Liver Transplant Recipients	M. Miah, R. Venkataraman, A. Humar
012		An IQ Working Group on Physiologically-based Pharmacokinetic Model Predictions of Food Effect: Definition of Best Practices for Application in Clinical Drug Development	N. J. Parrott, A. E. Riedmaier

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Sunday, Sept 23rd / 5:00 – 7:00 PM & Monday, Sept 24th / 8:00 – 10:00 AM
GRAND BALLROOM E-H

Clinical Pharmacokinetics & Pharmacodynamics

Poster	Type	Title	Authors
013		Pharmacokinetics of Venetoclax in Combination With Rituximab in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia: Phase 3 MURANO Study	P. Agarwal, R. Deng, L. Gibiansky, T. Lu, H. Ding, X. Li, S. Kshirsagar, D. Lu, C. Li, S. Girish, Y. Li, M. Boyer, K. Humphrey, K. J. Freise, A. H. Salem, J. F. Seymour, A. P. Kater, M. Mobasher, D. R. Miles
014	NM	Single- and Multiple-dose Pharmacokinetics of YPL-001, a Novel Botanical Drug Product in Development for the Treatment of Respiratory Inflammatory Diseases	J. Batonga, C. Engel, M. Abu-Rashid, P. Ruhn, F. Vickers, Y. Lee, J. Yoo, S. Lew, G. Criner, M. Dransfield, S. Arora, C. Tomek, F. Fakh, J. Pritchard
015		Exposure-Response Analysis of Venetoclax in Combination With Rituximab in Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia: Phase 3 MURANO Study	R. Deng, L. Gibiansky, T. Lu, X. Li, D. Lu, C. Li, S. Girish, Y. Li, M. Boyer, N. Shankar, K. Humphrey, K. J. Freise, A. H. Salem, J. F. Seymour, A. P. Kater, M. Mobasher, D. R. Miles
016	NM	Pharmacokinetic/Pharmacodynamic Modeling of Onset of Relief With a Fast-release Aspirin Formulation in Sore Throat Pain and Dental Pain Models	J. D. Kearbey, M. Voelker, H. Derendorf
017	S	Impacts of Gastric Bypass Surgery on the Pharmacokinetics of Simvastatin, Atorvastatin, Rosuvastatin and Their Active Metabolites	A. El-Zailik, L. K. Cheung, Y. Wang, V. Sherman, D. S-L. Chow
018	S, NM	Population Pharmacokinetics of Metoclopramide in Infants, Children and Adolescents	S. Ge, S. Mendley, J. Gerhart, C. Melloni, C. Hornik, J. Sullivan, A. Atz, P. Delmore, A. Tremoulet, B. Poindexter, B. Harper, E. Payne, S. Lin, M. Cohen-Wolkowicz, D. Gonzalez
019		Impact of Formulation Characteristics and Food on GSK2798745 Pharmacokinetics	N. Goyal, A. Oughton, R. Schroyer, P. Skrdla, D. Sprecher
020		Pharmacokinetics of a Novel TRPV4 Channel Blocker, GSK2798745, in Healthy Volunteers and Heart Failure Subjects	N. Goyal, A. Oughton, R. Schroyer, P. Skrdla, S. Kumar, D. Fernando, J. Cheriyan, D. Sprecher
021		Quantitative Biomarkers for Psychostimulant Response: Results from a Double-blind, Placebo-controlled Study of Armodafinil on Neurocognitive Function, Driving Performance and Electroencephalogram in Healthy Volunteers	J. Kast, F. Weinelt, A. N. Deitchman, A. Danos, H. Chandasana, S. Eisenschenk, C. N. Seubert, H. Derendorf
022	S, NM, E	Impact of High-titer Immune Plasma on the Pharmacokinetics of Haemagglutination Inhibition Titers in Hospitalized Adults With Severe Influenza	L. W. Kibathi, Y. Wu, J. George, P. Kumar, R. T. Davey, J. Beigel
023	S	Pharmacokinetic Assessment of Voriconazole and N-oxide Metabolite in Pediatric Hematopoietic Stem Cell Transplant Recipients	A. Alharbi, A. Smith, P. Jacobson, J. Fisher, N. Rubin, W. Chan, M. Kirstein
024		Single, Ascending-dose Pharmacokinetics of the E-Selectin/CXCR4 Dual Antagonist GMI-1359 After Intravenous Infusions of 0.1, 0.2, 0.5, 1, 2 and 3.5 mg/kg to Healthy Volunteers	H. Flanner, W. Kramer, A. Sarkar, C. D. Wolfgang, J. Peterson, H. Thackray, J. L. Magnani
025		Sublingual vs Oral Bioavailability of Samidorphan and Food Effect Evaluation in Healthy Volunteers	V. Kumar, H. Lu, L. von Moltke, M. Hard
026	S	Effect of Disease Activity on Pharmacokinetics and Pharmacodynamics of Atorvastatin in Patients With Systemic Lupus Erythematosus	R. Cestari, R. de Oliveira, E. Donadi, G. Nardotto, A. Rocha, M. Marques, J. Caris, V. L. Lanchote
027	NM	Population Pharmacokinetic/Pharmacodynamic Modeling of IMGN779, a Next-generation Anti-CD33 Selective Antibody-Drug Conjugate	B. Matin, K. Petersson, N. McBrine, K. Watkins, C. M. Sloss, K. Dykstra, K. Culm-Merdek
028		An Improved Liquid Chromatography-Tandem Mass Spectrometric Method for the Quantitation of Dexmedetomidine in Small Volume of Pediatric Plasma	G. S. Moorthy, C. Vedar, A. Moorthy, J. L. Prodell, A. F. Zuppa
029		Pharmacokinetics, Safety and Tolerability of SEP-363856 in Healthy Adult Male Subjects and in Adult Patients With Schizophrenia Following Oral Administration	N. Poola, S. Sunkaraneni, G. Galluppi, S. Hopkins, Y. Chen, K. Thompson, K. Koblan

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Poster Session 1

Sunday, Sept 23rd / 5:00 – 7:00 PM & Monday, Sept 24th / 8:00 – 10:00 AM
GRAND BALLROOM E-H

Clinical Pharmacokinetics & Pharmacodynamics (continued)

Poster	Type	Title	Authors
030	NM	A Phase 1 Study in Healthy Subjects to Assess the Safety, Pharmacokinetics and Pharmacodynamics of Multiple Oral Doses of XQ-1H, a Novel Ginkgolide B Derivative	F. Shao, S. Zhou, L. Wang, L. Xie, N. Ou
031		A Success Story for the First Fixed-dose Combination Treatment for Gout Based on Drug Exposure and Serum Uric Acid Relationship	R. Singh, X. Wang, A. Marathe, B. Saluja, J. Liu, Y. Wang, C. Sahajwalla
032	E	Does Hepatic Impairment Affect the Exposure of Monoclonal Antibodies?	Q. Sun, S. Seo, C. Liu, K. Reynolds
033	S, E, NM	Use of Physiologically-based Pharmacokinetic Modeling to Evaluate the Effect of Chronic Kidney Disease on the Disposition of Hepatic CYP2C8 and OATP1B Drug Substrates	M. Tan, P. Zhao, L. Zhang, Y. Ho, M. Varma, S. Neuhoff, T. D. Nolin, A. Galetin, S. Huang
034		Assay for Bergamottin and 6,7-Dihydroxybergamottin in Grapefruit Juice and a Microsampling Assay for Analysis of Voriconazole and Voriconazole N-oxide in Human Whole Blood	C. Vedar, G. S. Moorthy, N. Zane, J. L. Prodel, A. F. Zuppa
035	NM	The Relative Bioavailability Study of DS-1040 Tablet to Powder-in-bottle and Effect of Food on DS-1040 Tablet in Healthy Subjects	L. Xie, F. Kobayashi, J. Pav, C. Zamora, V. Vashi, J. Zhou, T. Limsakun
036	E	Pharmacodynamic Effect and Safety of Single-dose Sarilumab SC or Tocilizumab Intravenous or Subcutaneous in Patients With Rheumatoid Arthritis	T. Ishii, Y. Sato, Y. Munakata, M. Kajiwara, Y. Takahashi, F. Anwar, A. Paccaly, P. Kovalenko, J. Parrino, A. Boyapati, C. Xu
037		A Phase 1, Open-label, Randomized, Six-sequence, Three-period, Three-treatment Crossover Study to Assess the Relative Bioavailability of Palbociclib Solution vs Free-base Capsule and the Food Effect of Oral Solution in Healthy Volunteers	Y. Yu, A. Plotka, M. O'Gorman, Y. Liang, H. Shi, A. Jain, X. Zhang, D. Wang
038	S	Simultaneous Retrodialysis by Calibrator for Rapid <i>In Vivo</i> Recovery Determination in Clinical Target Site Microdialysis	Y. Yu, H. Chandasana, T. Sangari, C. N. Seubert, H. Derendorf

Clinical Trials & Human Pharmacology

Poster	Type	Title	Authors
039		Compstatin Cp40 (AMY-101): A C3-targeted Complement Inhibitor Reaching Its Prime for Bedside Intervention	J. Lambris, D. Yancopoulou, L. Rusch, E. Sayias
040	NM	A Study to Determine the Relative Bioavailability and Dose Proportionality of the FMS-like Tyrosine Kinase 3 Inhibitor, Quizartinib, and Its Active Metabolite, AC886	J. Li, D. Trone, J. Mendell, G. Gammon
041		A First-in-Human Trial Comparing Pharmacokinetics, Pharmacodynamics and Safety of Cannabis Following Multiple, Ascending Doses of Dried Tablets Delivered by Smoking Inhalation	J. Michaud, M. Lefebvre, S. Mathieu, A. Papageorgiou, G. Wood, I. Holmes, E. Sicard, G. Chamberland
042		Changes in Biomarkers of Potential Harm Due to Reduced Exposure to Cigarette Smoke in Adult Smokers: Results of Combined Analysis of Two Clinical Studies (Part 1)	C. Sakaguchi, H. Ohara, Y. Nagata
043		Changes in Biomarkers of Potential Harm Due to Reduced Exposure to Cigarette Smoke in Adult Smokers: Results of Combined Analysis of Two Clinical Studies (Part 2)	H. Ohara, C. Sakaguchi, Y. Nagata

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Poster Session 1 & 2

Sunday, Sept 23rd / 5:00 – 7:00 PM & Monday, Sept 24th / 8:00 – 10:00 AM
GRAND BALLROOM E-H

Drug Interactions

Poster	Type	Title	Authors
044		Effect of Itraconazole or Rifampin on the Pharmacokinetics of Itacitinib, a JAK-1 Inhibitor, in Healthy Volunteers	A. M. Barbour, N. Punwani, N. Epstein, X. Chen, S. Yeleswaram
045	E	Sustained Impairment of Lurasidone Clearance After Discontinuation of Posaconazole: Impact of Obesity and Implications for Patient Safety	D. J. Greenblatt, J. S. Harmatz, M. Ryan, C. R. Chow
046	E	Pomalidomide Pharmacokinetics in Patients With HIV on Antiretroviral Therapy	J. George, C. Peer, R. Ramaswami, K. Lurain, P. Goncalves, A. Widell, M. Polizzotto, T. Uldrick, R. Yarchoan, W. Figg
047	NM	A Drug-Drug Interaction Study of Epacadostat With UGT1A9 Inhibitor Mefenamic Acid: Results from a Phase 1, Open-label, Crossover Trial in Healthy Volunteers	T. Ji, X. Gong, X. Yang, N. Punwani, X. Chen, S. Yeleswaram
048	NM	A Drug-Drug Interaction Study of Epacadostat with Augmentin® (Amoxicillin/Clavulanate): Results From a Phase 1, Open-label, Crossover Trial in Healthy Volunteers	T. Ji, X. Chen, N. Punwani, X. Gong, S. Yeleswaram
049		Effects of Itraconazole or Rifampin on the Pharmacokinetics of Buprenorphine and Samidorphan When Sublingually Administered in Combination as ALKS 5461 in Healthy Subjects	H. Lu, M. Hard, L. von Moltke
050		The Effects of Single-dose Kuvan® (Sapropterin Dihydrochloride) on the Pharmacokinetics of Digoxin, a Sensitive P-glycoprotein Substrate, in Healthy Subjects	G. Patel, K. Hammon, J. Lilienstein, L. Kankipati, R. Rowell, J. Henshaw
051		Criteria-based Assessment of Protein Kinase Inhibitors as Perpetrators of Pharmacokinetic Drug-Drug Interactions	T. M. Polasek, A. Rowland, G. E. Glass
052		A Clinical Drug-Drug Interaction Study With Midazolam to Assess the Effect of DUR-928 on CYP3A4	J. Shah, G. Mille, A. Miksztal, W. Lin
053	E	Optimization of a Drug Transporter Probe Cocktail (Digoxin, Furosemide, Metformin and Rosuvastatin): Potential Screening Tool for Transporter-mediated Drug-Drug Interactions	P. Stopfer, T. Giessmann, K. Hohl, S. Hutzel, S. Schmidt, D. Gansser, N. Ishiguro, M. E. Taub, A. Sharma, T. Ebner, F. Mueller
054	NM	Evaluation of the Effect of Uridine Diphosphate-Glucuronosyltransferase Inhibition by Valproic Acid on Vixotrigine Pharmacokinetics in Healthy Volunteers	Y. Zhao, M. Versavel, R. Christmann, H. Naik

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Absorption, Distribution, Metabolism & Elimination

Poster	Type	Title	Authors
055	S, SA	Characterization of the Ontogeny of Hepatic UDP-glucuronyltransferase Enzymes Based on Glucuronidation Activity Measured in Human Liver Microsomes	J. Badée, N. Qiu, S. N. de Wildt, A. C. Collier, N. J. Parrott, S. Schmidt, S. Fowler
056		Human Absorption, Metabolism and Elimination of Itacitinib in Healthy Male Adult Volunteers	J. Boer, A. M. Barbour, K. Kennedy, N. Punwani, N. Epstein, X. Chen, S. Diamond, S. Yeleswaram
057	NM	Human Absorption, Metabolism and Elimination of Epacadostat in Healthy Male Adult Volunteers	X. Gong, X. Yang, J. Boer, S. Diamond, X. Chen, N. Punwani, S. Yeleswaram
058	S, SA, P	Activation of Flavin-containing Monooxygenase Formation of a Gut-derived Cardiovascular Disease Risk Factor in Kidney Disease	A. J. Prokopenko, R. E. West, J. R. Stubbs, T. D. Nolin

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Biosimilars

Poster	Type	Title	Authors
060		The Role of Clinical Pharmacology Studies in Biosimilars Approval: United States and European Focus	M. Shehayeb, R. Abbas

Clinical Pharmacology Education

Poster	Type	Title	Authors
061	S, NM	Cultural Competence Assessment Prior to Advanced Pharmacy Practice Experiences in Second-year Pharmacy Students	B. Dang, S. Doroudgar, H. Nguyen, R. Matsumoto

Decision Making in Research & Development

Poster	Type	Title	Authors
062		Inflammation: Undefined, Unrestrained, Promiscuous Use in Medicine and Implications for Clinical Pharmacology	G. Sokol, L. S. Loftus, T. Oliver, J. Livezey, L. Cantilena

Disease Management

Poster	Type	Title	Authors
063		Use of Phosphate Binders In End-stage Renal Disease: An Experience from a Secondary-care Hospital In United Arab Emirates	S. A. Rabbani, S. Sridhar, P. GM Rao, M. T. Kurian, B. El Essawy

Drug-induced Adverse Outcomes

Poster	Type	Title	Authors
064	S	Metamizole-induced Agranulocytosis in an Adolescent With Atopic Dermatitis	V. Ziesenitz, D. Trachsel, A. A. Elzagallaai, M. J. Rieder, J. N. van den Anker

Experimental Pharmacology in In Vitro & In Vivo Studies

Poster	Type	Title	Authors
066		Reversal of Morphine Tolerance in Mice With Intravenous Administration of BQ123, an ET _A Receptor Antagonist	S. Bhalla, J. Lyne, S. Andurkar, A. Gulati
067		Synergistic Neuroprotective Potential of Trimetazidine and Progesterone in Cerebral Reperfusion Injury	V. V. Dhote, A. Mandloi, M. Kawadkar, A. Ganeshpurkar, M. Jadhav
069	E	The Development of an <i>In Vitro</i> Assay for the Prospective Determination of Aspirin Sensitivity and Its Validation in Patients Resistant to Low-dose Aspirin: A Proof of Concept Study	E. Westphal, C. Wisniewski, R. Michelle, M. Amsler, T. Aladeen, V. Bates, N. Smith, F. Gengo

HIV/AIDS

Poster	Type	Title	Authors
070	S, SA	Interpretation on the Coverage of HIV Pre-exposure Prophylaxis of Once-daily Tenofovir Regimen in the Partners Demonstration Project Using Population Pharmacokinetic Modeling and Simulation	S. Mallayasamy, A. Chaturvedula, M. J. Fossler, M. Sale, V. Goti, C. Hendrix, J. Haberer

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Infectious Diseases (Antibiotics/Vaccines)

Poster	Type	Title	Authors
071	E	An Integrated Efficacy and Safety Analysis of Single-dose Secnidazole 2 g Granules in the Treatment of Bacterial Vaginosis from Pivotal Phase 2 and Phase 3 Trials	H. Pentikis, N. Adetoro
072	S, E, NM	A Novel Dosing Algorithm for Gentamicin Dosing in (Morbidly) Obese Patients	C. Smit, R. E. Wasmann, S. C. Goulooze, E. J. Hazebroek, E. PA van Dongen, D. MT Burgers, J. W. Mouton, R. JM Brüggemann, C. AJ Knibbe
073	S, E, NM	Tobramycin Dosing in Morbidly-obese Individuals: The Influence of Body Weight on Aminoglycoside Pharmacokinetics	C. Smit, R. E. Wasmann, R. J. Wier, E. PA van Dongen, J. W. Mouton, R. JM Brüggemann, C. AJ Knibbe
074	S, NM	Investigation of Novel Pharmacokinetic/Pharmacodynamic Indices for Development of Antimicrobial Drugs With a Combination of Time- and Exposure-dependent Killing Features	C. Tang, H. Xia, M. Liao, Y. He

Mechanism of Action

Poster	Type	Title	Authors
075		Assessment of C-peptide Effects on Cardiac Ion Channel Currents	J. Taubel, S. Fernandes, D. Djumanov, G. Ferber

Model-based Drug Development

Poster	Type	Title	Authors
076		Population Pharmacokinetic Analysis of the Anaplastic Lymphoma Kinase Inhibitor Brigatinib: Model-informed Posology Decisions and Global Drug Development	N. Gupta, X. Wang, M. Prohn, E. Offman, N. Narasimhan, D. Kerstein, K. Venkatakrishnan
077	NM	Applying a Population Pharmacokinetic Approach to Bridge Formulations in Late-phase Drug Development	N. Thakkar, J. Green, G. Koh, S. Duparc, D. Tenero, N. Goyal
078	NM	Population Pharmacokinetics of Tafenoquine	N. Thakkar, J. Green, G. Koh, S. Duparc, D. Tenero, N. Goyal

New & Adaptive Clinical Trial Designs

Poster	Type	Title	Authors
079	NM	Implementation of a Pediatric Medical Cannabis Research Program	M. DiLiberto, J. L. Prodell, G. S. Moorthy, C. Vedar, J. Irizarry, A. F. Zuppa

Oncology

Poster	Type	Title	Authors
080		Evaluation of Bioequivalence of Apalutamide Formulations Using Clinical Trial Simulations: Comparison of Repeat- and Single-dose Studies	C. Chien, F. Saad, J. Jiao, D. Ouellet
081		Effect of Venetoclax on B-lymphocytes in Healthy Subjects	N. Dave, S. Gopalakrishnan, S. Mensing, A. H. Salem
082		The Impact of DNA Hypomethylating Agents on the Activity of Nuclear Sirtuins	Y. Cen, Z. Abd Elmageed, T. Fandy

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Oncology (continued)

Poster	Type	Title	Authors
083	S, SA, P	Population Pharmacokinetic Analysis of High-dose Methotrexate in Pediatric and Adult Oncology Patients	S. Kawakatsu, M. Nikanjam, D. Kuo, L. Alejandro, J. Momper, I. Saunders, S. Martinez, E. Capparelli
084		Non-inferiority of OT-101 (TGF- β 2 Specific Inhibitor) vs Standard Chemotherapy in Glioma	V. Trieu, D. Nam, L. Hwang
085	S	Population Pharmacokinetics of Paclitaxel in Breast Cancer Patients	H. Wang, D. Hertz, N. Henry, J. Gobburu, V. D. Ivaturi

Opioid & Other Substance Misuse Management

Poster	Type	Title	Authors
086	S, SA, P	Altered Buprenorphine Pharmacokinetics During Pregnancy: A Population Pharmacokinetic Analysis	H. Zhang, S. Cook, J. Bastian, H. Chen, S. Caritis, R. Venkataramanan

Pediatrics

Poster	Type	Title	Authors
087		Knowledge Gaps About Common Drugs in Obese Pediatric Patients	B. Ameer, M. Weintraub
088	S, NM	Physiologically-based Pharmacokinetic Model Incorporating Protein Binding Saturation to Predict Cefazolin Pharmacokinetics in Pediatric Populations	H. Chandasana, Y. Yu, T. Sangari, C. N. Seubert, H. Derendorf
089		The Utilization of Population Pharmacokinetic and Exposure-Response Modeling for Extrapolation from Adult to Pediatric Patients	M. B. Dufek, A. H. Salem, N. Kwatra, B. Klünder, S. Stodtmann, S. Mensing, N. M. Mostafa, P. Noertersheuser
090		A Phase 1 Study to Evaluate the Pharmacokinetic Properties of Tamibarotene in Relapse or Refractory Pediatric Solid Tumors	T. Kimura, T. Ushijima, J. Hara, H. Kawamoto, Y. Hamada, Y. Fukaya, A. Sato, A. Hamada, C. Nitani, T. Taguchi, K. Yoshimura, S. Nomura
091	S	Monoclonal Antibody Drug Development in the Pediatric Population	X. I. Liu, J. N. van den Anker, D. Green, G. J. Burckart, Y. Wang
092	E	Impact of Rewarming After Therapeutic Hypothermia on Gentamicin Pharmacokinetics in Neonates With Hypoxic Ischemic Encephalopathy	S. J. Miyagi, A. N. Massaro, A. Frymoyer

Pharmacoepidemiology

Poster	Type	Title	Authors
093	S	Kratom Use Patterns in the United States: State and National Trends	J. Nicewonder, C. Veltri, O. Grundmann

Pharmacometrics

Poster	Type	Title	Authors
094	S	Assessment of Covariates on Adherence to Tenofovir-based HIV Pre-exposure Prophylaxis Regimen Using Markov Modeling Approach	S. Mallayasamy, A. Chaturvedula, M. J. Fossler, M. Sale, C. Hendrix, J. Haberer
095		Development of a Population Pharmacokinetic Model for Lorlatinib Using Pooled Data from Non-Small Cell Lung Cancer Patients and Healthy Volunteers	J. Chen, B. Houk, Y. K. Pithavala, J. Clancy, A. Ruiz

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096		Population Pharmacokinetic Analysis of Plerixafor in Healthy Adults and Cancer Patients	Y. Gao, Y. Cheng, E. Doyle, V. Kanamaluru, Q. Lu
097		A Web-based, Interactive Population Pharmacokinetic Simulation Tool for Aripiprazole Lauroxil	H. Lu, B. Rege
098	S, SA, E, P	Development of a Physiologically-based Pharmacokinetic Model of Ethionamide in the Pediatric Population by Integrating Flavin-containing Monooxygenase 3 Maturational Changes Over Time	P. TT Nguyen, M. M. Parvez, M. J. Kim, J. Ho Lee, S. Ahn, J. L. Ghim, and J. G. Shin
099		Model-based Analysis to Predict Lirilumab Exposure With Flat Dosing in Subjects With Advanced Refractory Solid Tumors and Hematological Malignancies	K. Sanghavi, P. Andre, C. Paturel, A. Bello, M. Gupta, C. Passey
100	S, SA, P	Dosage Recommendations for Meropenem-Vaborbactam in End-stage Renal Disease Patients Receiving Hemodialysis: Application of Pharmacokinetic/ Pharmacodynamic Modeling and Simulation	Y. Yu, L. Zhuang, X. Wei, J. Florian, S. Jang, K. Reynolds, Y. Wang

Precision Medicine

Poster	Type	Title	Authors
101	S, NM	Trends in Pharmacometabolomics Research	I. V. Cohen, E. T. Cirulli, A. Telenti

Regulatory Issues

Poster	Type	Title	Authors
102	S	Renal Impairment Alters Clinical Pharmacokinetic Profile of Hepatic Reductase Substrates: A Study Utilizing the Univ of Washington Drug Interaction Database	B. Garzel, J. Yu, S. Argon, I. Ragueneau-Majlessi, T. D. Nolin, S. Huang
103	S	Best Practice Standards for Documentation of Exposure-Response Analysis	D. C. Jean, K. Maxfield, R. Madabushi, I. Zineh
104		Potential Systemic Exposure to Chlorhexidine Gluconate Following Topical Antiseptic Use in Neonates	S. Yi, L. Oh, D. Zhang, D. Bashaw

Risk Management/Legal Issues

Poster	Type	Title	Authors
105		Confirmation of the Cardiac Safety of P218, a New Investigational Medicinal Product for Prevention of Malaria Using Intensive Electrocardiogram Assessments and the Effect of a Meal on QTc to Show Assay Sensitivity	J. Taubel, U. Lorch, G. Ferber, S. Coates, S. Fernandes, M. ElGaaloul, C. Donini, S. Chalou

Safety & Efficacy

Poster	Type	Title	Authors
106		Clinical Implications of the Preclinical Studies of the Medicinal Herbs Affecting Thyroid Function: Are They Safe for Pregnant Women?	L. Krepkova, V. Bortnikova, C. MT Sherwin, E. Y. Enioutina
107		A Randomized, Double-blind, Placebo- and Positive-controlled, Four-period Crossover Study of the Effects of Solriamfetol (JZP-110) on QTcF Intervals in Healthy Participants	K. Zomorodi, D. Chen, L. Lee, D. Swearingen

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Special Populations

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108		The Effect of Hepatic Impairment on the Single-dose Pharmacokinetics of Oliceridine, a G Protein-biased Ligand at the μ -receptor	K. Arscott, K. Cochrane, F. Skobieranda, D. Burt, M. J. Fossler
109		Oliceridine, a G Protein-biased Ligand at the μ -receptor, Does Not Require Dose Adjustment in End-stage Renal Disease	K. Arscott, K. Cochrane, F. Skobieranda, D. Burt, M. J. Fossler
110		Changing Trends in Intravenous Immunoglobulin Use for Neurological Indications in Pediatric Patients: A Retrospective Review of Practices in a Network of Major US Pediatric Hospitals	A. Balch, J. Wilkes, C. MT Sherwin, E. Y. Enioutina
111	E	Impaired Rivaroxaban Clearance in Mild Renal Insufficiency With Verapamil Coadministration: Potential Implications for Bleeding Risk and Dose Selection	D. J. Greenblatt, M. Ismail, M. Patel, J. S. Harmatz, V. Lee, W. Nicholson, C. M. Rubino, C. R. Chow
112	E	Vortioxetine Disposition in Obesity: Potential Implications for Patient Safety	D. J. Greenblatt, J. S. Harmatz, C. R. Chow
113		Hyperuricemia May be a Suitable Cost-containing Screening Gateway for Determining Nonalcoholic Fatty Liver Disease/Nonalcoholic Steatohepatitis Clinical Trial Eligibility Requiring Hepatic Steatosis and/or Fibrosis	C. A. Dehn, N. McDonald, M. Fein, M. Pearson, L. Galitz, L. Rusch
114	NM	Characterization and Treatments of Neonatal Late-onset Sepsis: A Retrospective Analysis of the Univ of Utah Hosp Cases	J. Wagstaff, R. Eason, M. Newman, C. MT Sherwin, E. Y. Enioutina
115	S	A Quantitative Approach to Optimize Levetiracetam Dosing in Critically-ill Patients Undergoing Continuous Venovenous Hemofiltration: Results from an Open-label, Observational Pharmacokinetic Study	S. N. Kalaria, M. Armahizer, P. McCarthy, M. Gopalakrishnan
116	E	Effect of Renal Impairment on Upadacitinib Pharmacokinetics Results from a Phase 1 Study	M. F. Mohamed, S. Coppola, T. Feng, J. Anderson, A. Othman
117	E	Lack of Clinically-relevant Impact of Mild and Moderate Hepatic Impairment on Upadacitinib Pharmacokinetics: Results from a Phase 1 Study	M. F. Mohamed, S. Coppola, T. Feng, A. Lacerda, A. Othman
118		Comparing FibroScan [®] Results Between African-American and Caucasian Populations When Pre-screening for Nonalcoholic Liver Disease/Nonalcoholic Steatohepatitis Research Studies	M. Pearson, L. Galitz, M. Fein, L. Rusch, C. A. Dehn, N. McDonald
119		Pharmacokinetics and Safety of ALKS 3831, a Fixed-dose Combination of Olanzapine and Samidorphan, in Subjects With Hepatic Impairment Compared to Healthy Control Subjects	L. Sun, S. Yagoda, L. von Moltke
120	S	Management of Anaphylaxis and Allergic Reactions in Pediatric Patients With Long QT Syndrome	T. Welzel, V. Ziesenitz, S. Seitz, B. Donner, J. N. van den Anker

Translational Medicine, Including Biomarkers and/or Imaging

Poster	Type	Title	Authors
121	S	Utilization and Impact of Biomarker Investigations in the Early Identification of Cardiovascular Safety Issues	S. W. Todd, A. Ramamoorthy, J. Sun, A. Oluseyi, R. Schuck, S. Riazi, M. Pacanowski

Transporters

Poster	Type	Title	Authors
122	S, NM	Distinguishing the Hepatic Transport and Metabolism Pathways by Modeling ¹⁴ CO ₂ Production Rate Data: Application of Physiologically-based Pharmacokinetic Modeling to Erythromycin Breath Test in Healthy Subjects	Y. Franchetti, T. D. Nolin
123	NM	A Study to Explore the Effects of CXA-10 on the Pharmacokinetics of a Cocktail of Transport Protein Substrates via the Pharmacological Action of CXA-10 on Nrf2	R. M. Garner, C. Chieffo, T. J. Taylor, D. R. Mould, D. K. Jorkasky

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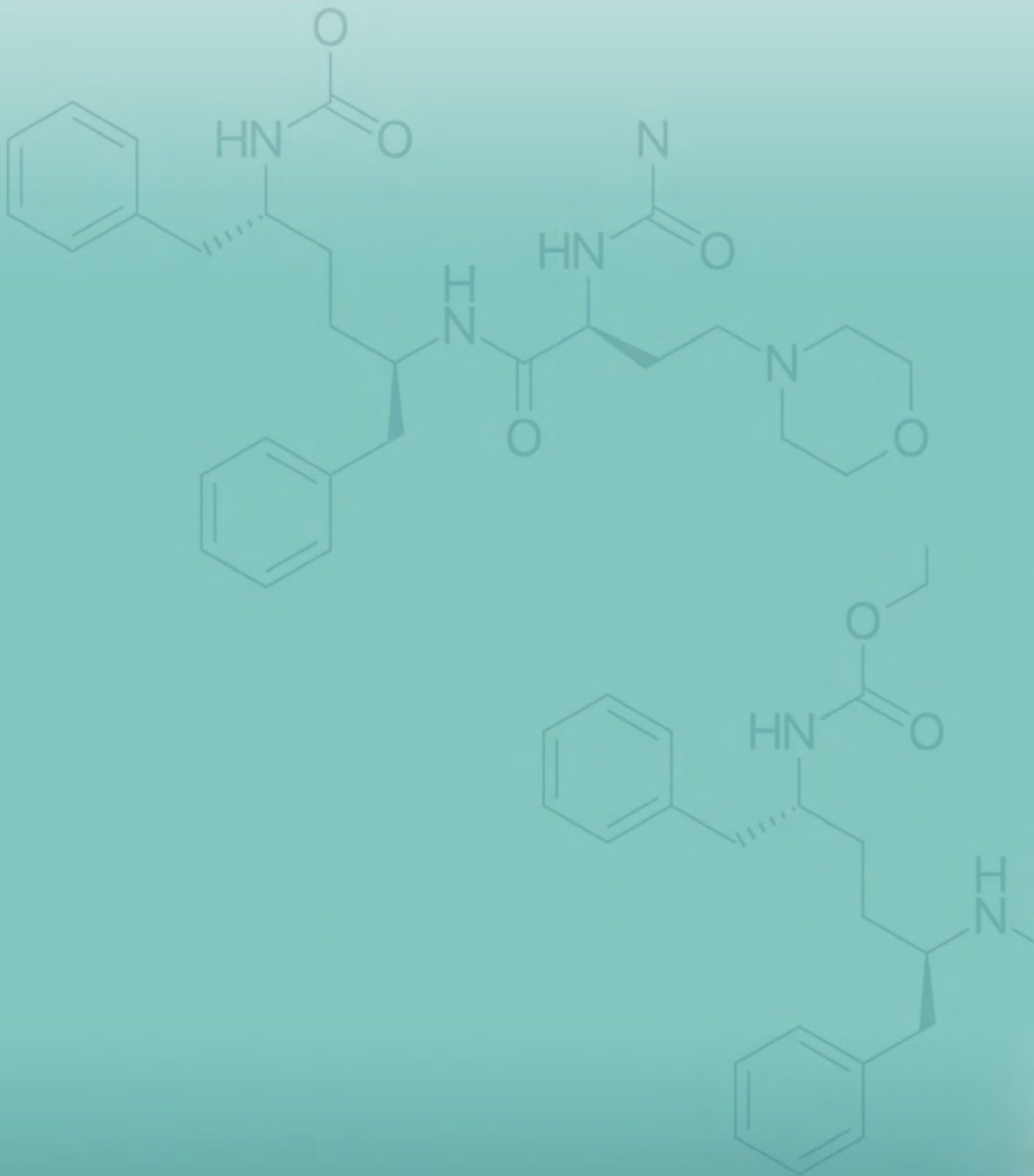
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