Program at a Glance

Workshops & Symposia at the 2017 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.

SATURDAY, SEPTEMBER 16, 2017

Pre-meeting Workshop 1 | 8:00 am – 12:00 pm

Should Off-patent Medications Be Labeled for Pediatric Use? ACCP/PPAG Jointly-sponsored Symposium (AT)

This Workshop has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the American College of Clinical Pharmacology and the Pediatric Pharmacy Association. The American College of Clinical Pharmacology is accredited by the ACCME to provide Continuing Medical Education for physicians.

CO-CHAIRS: Michael D. Reed, RPh, PharmD, Director, Rainbow Clinical Research Ctr, Rainbow Babies & Children's Hosp, Case Western Reserve Univ School of Medicine and Gilbert J. Burckart, PharmD, Associate Director of Pediatrics, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration

Pre-meeting Workshop 2 | 8:00 am – 12:00 pm

Best Practice Approaches to Physiologically-based Pharmacokinetic Modeling for Labeling Initiatives: Industry & Regulatory Perspectives (AT)

CO-CHAIRS: Karthik Venkatakrishnan, PhD, Senior Director, Quantitative Clinical Pharmacology, Takeda Pharmaceuticals Co Ltd and Karen Rowland Yeo, PhD, Vice President, Simcyp (part of Certara)

Pre-meeting Workshop 3 | 1:30 – 5:30 pm

Therapeutic Drug Monitoring in Advancing Patient Care: Is This Time Different? (AT)

CO-CHAIRS: Neeraj Gupta, PhD, Senior Scientific Director, Takeda Pharmaceuticals Co Ltd and Manish Gupta, PhD, Group Director, Bristol-Myers Squibb Co

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

Modeling & Simulation Strategies for Dose Selection of Targeted Anticancer Agents (DT)

CO-CHAIRS: Ahmed H. Salem, PhD, Associate Director, Clinical Pharmacology & Pharmacometrics, AbbVie Inc and Murad Melhem, PhD, Principal Scientist, Amgen Inc

SUNDAY, SEPTEMBER 17, 2017

Plenary Session | 8:00 – 9:30 am

Predicting Pharmacokinetics/Pharmacodynamics in the Individual Patient: Separating Reality from Hype (AT)

Leslie Z. Benet, PhD, Professor & former Chairman (1978–1998), Dept of Bioengineering & Therapeutic Sciences, Schools of Pharmacy & Medicine, Univ of California, San Francisco

Symposium 1 | 10:00 am – 12:00 pm

Innovative Scientific & Risk-based Quantitative Approaches to Post-marketing Surveillance of New & Generic Drug Products (AT)

CO-CHAIRS: Lawrence J. Lesko, PhD, Professor & Director, Ctr for Pharmacometrics & Systems Pharmacology, Dept of Pharmaceutics, Coll of Pharmacy, Univ of Florida and Lanyan (Lucy) Fang, PhD, Team Leader, US Food & Drug Administration

Symposium 2 | 10:00 am – 12:00 pm

Optimizing Dose/Dosing Frequency for a Biologic: Clinical, Regulatory & Commercial Perspectives (AT)

CO-CHAIRS: Gaurav Bajaj, PhD, Associate Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb Co and Sumit Rawal, PhD, Research Scientist, Regeneron Pharmaceuticals Inc

Symposium 3 | 1:30 – 3:30 pm

Master Protocols in Drug Development (AT)

CO-CHAIRS: Dionna J. Green, MD, Medical Officer & Policy Lead, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration and Kevin Watt, MD, PhD, Assistant Professor of Pediatrics, Duke Univ Medical Ctr, Duke Clinical Research Inst

Symposium 4 | 1:30 – 5:30 pm

Next Wave in Cancer Medicine: Mechanisms & Progress for Emerging Therapeutics (DT)

CO-CHAIRS: Lucy Lee, PharmD, Director, Clinical Pharmacology, Infinity Pharmaceuticals Inc and Luna Musib, PhD, Senior Scientist, Clinical Pharmacology, Genentech Research and Early Development (gRed)

Symposium 5 | 4:00 – 5:30 pm

Clinical Trial Simulations in Pediatric Drug Development (AT)

CO-CHAIRS: Janelle Baker, MD, Pediatrician & Commissioners Fellow, Office of Clinical Pharmacology, US Food & Drug Administration and Daniel Gonzalez, PharmD, PhD, Assistant Professor, Div of Pharmacotherapy & Experimental Therapeutics, UNC Eshelman School of Pharmacy, The Univ of North Carolina at Chapel Hill

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MONDAY, SEPTEMBER 18, 2017

Symposium 6 | 8:00 – 9:30 am

Therapeutic Options for Obesity Treatment in Children, Adolescents & Young Adults (AT)

This Symposium is supported in part by the *British Journal of Clinical Pharmacology*.

CO-CHAIRS: Catherine MT Sherwin, PhD, MS, Chief, Div of Clinical Pharmacology, Univ of Utah and Janelle D. Vaughns, MD, Assistant Professor of Anesthesiology & Pediatrics, Children's National Health System

Symposium 7 | 8:00 am – 12:00 pm

Modeling of Adherence: Applications in Drug Development & Clinical Practice (DT)

CO-CHAIRS: Ayyappa Chaturvedula, PhD, Associate Professor, Univ of North Texas System Coll of Pharmacy and Mark Sale, MD, Senior Vice President, Nuventra Pharma Sciences

Symposium 8 | 10:00 am – 12:00 pm

Kinase Inhibitors in Pediatric Patients: Experiences, Pharmacology & Future Applications (DT)

CO-CHAIRS: Jonathan Constance, PhD, Assistant Professor, Univ of Utah and G. W. 't Jong, MD, PhD, Academic Pediatrician & Clinical Pharmacologist, Assistant Professor of Pediatrics, Internal Medicine & Pharmacology, Univ of Manitoba

Symposium 9 | 1:30 – 3:30 pm

What to Do After a Pivotal Trial Has Failed Primary Endpoint Assessment: Totality of Evidence-based Drug Development Challenges & Opportunities (AT)

CHAIR: Yan Xu, PhD, Associate Scientific Director, Global Clinical Pharmacology, Janssen: Pharmaceutical Co of Johnson & Johnson

Symposium 10 | 1:30 – 5:30 pm

Challenges & Opportunities in the Development of Inhaled Medicines (DT)

CO-CHAIRS: Clive Page, BSc, PhD, Professor of Pharmacology, Sackler Inst of Pulmonary Pharmacology, King's Coll and Anne Lexmond, PharmD, PhD, Dept of Pharmaceutical Technology & Biopharmacy, Univ of Groningen

Symposium 11 | 4:00 – 5:30 pm

Pioneering NAFLD/NASH Early-phase Clinical Pharmacology Study Designs (DT)

CO-CHAIRS: Lorraine Rusch, PhD, President, High Point Clinical Trials Ctr and Sabina Paglialunga, PhD, Metabolic & Pharmacodynamic Specialist, Celerion

TUESDAY, SEPTEMBER 19, 2017

Symposium 12 | 8:00 – 9:30 am

Assessment of Drug Effect on Pediatric Bone Health (DT)

CHAIR: Gilbert J. Burckart, PharmD, Associate Director of Pediatrics, Office of Clinical Pharmacology, Ctr for Drug Evaluation & Research, US Food & Drug Administration

Symposium 13 | 8:00 am – 12:00 pm

21st Century HIV/AIDS: An Evolving Drug Development & Technology Paradigm (DT)

CO-CHAIRS: Jomy George, PharmD, Pharmacokineticist, National Inst of Health and Parag Kumar, PharmD, Director, Clinical Pharmacokinetics Research Unit, National Inst of Health

Symposium 14 | 10:00 am – 12:00 pm

Full Extrapolation of Efficacy from Adults to Children of Antiepileptic Drugs Indicated for the Treatment of Partial Onset Seizures (AT)

CHAIR: Angela Men, PhD, MD, Pharmacology Lead, US Food & Drug Administration

Symposium 15 | 1:30 – 5:30 pm

Biosimilars: An Evolving Science (DT)

CO-CHAIRS: Darrell R. Abernethy, MD, PhD, Associate Director for Drug Safety, Office of Clinical Pharmacology, US Food & Drug Administration and Bernd Meibohm, PhD, Professor & Associate Dean, Univ of Tennessee Health Science Ctr, Coll of Pharmacy

Symposium 16 | 1:30 – 5:30 pm

Opioid Abuse & Misuse: A Rising Epidemic in America (AT)

CO-CHAIRS: Sam Harirforoosh, PharmD, PhD, Associate Professor, Gatton Coll of Pharmacy and Arsham Alamian, PhD, MSc, MACE, Assistant Professor, Coll of Public Health, East Tennessee State Univ