# AGENDA

## Advances in Fetal Pharmacology & Therapeutics

## Workshop sponsored by US FDA and University of Maryland CERSI

**Thursday, October 21, 2021**

**10:00 – 10:05 AM: Welcome and Introduction**

Gilbert J. Burckart, Pharm.D. – **Moderator**
Associate Director for Pediatrics, Office of Clinical Pharmacology
Center for Drug Evaluation and Research (CDER)
US Food and Drug Administration (FDA)

**10:05 – 10:20 AM: General regulatory considerations**

Dionna Green, M.D., FCP
Deputy Director, Office of Pediatric Therapeutics
Office of the Commissioner (OC), FDA

**10:20 – 10:40 AM: Antenatal steroids to prevent respiratory distress syndrome in the preterm newborn – considerations for fetal safety and efficacy**

Alan Jobe, M.D., Ph.D.
Cincinnati Children's Hospital
Emeritus Professor of Pediatrics

**10:40 – 11:00 AM: Ethical and Regulatory considerations**

Kevin Prohaska, DO, MPH
Associate Director/Senior Medical Policy Advisor,
Office of Good Clinical Practice
OC, FDA

**Fetal Safety Studies – Moderator: Kyunghun Park, Pharm.D. (Reviewer, Division of Biotechnology Review & Research II, Office of Pharmaceutical Quality, CDER, FDA)**

**11:00 – 11:20 AM: Nonclinical assessment to inform maternal and fetal safety in clinical trials enrolling pregnant women**

Kim Hatfield, Ph.D.
Lead Toxicologist
Division of Pharmacology Toxicology for Rare Diseases, Pediatric Urology and Reproductive Medicine
CDER, FDA

**11:20 – 11:40 AM: Clinical assessment of fetal well-being and fetal safety indicators**

Anna David, Ph.D.
Professor of Obstetrics and Maternal Fetal Medicine
Maternal & Fetal Medicine
UCL EGA Institute for Womens Health
Faculty of Population Health Sciences
University College, London, UK

**11:40 – 12:00 PM: Model development and effects of opioids on neural tube defects**

Amy Inselman, Ph.D.
Research Biologist, Division of Systems Biology
National Center for Toxicological Research (NCTR), FDA

Grace Lee, Ph.D.
Pharmacologist, Division of Pharmacology Toxicology for Neuroscience
CDER, FDA

***12:00 – 12:30 PM: LUNCH BREAK***

**<u>Fetal Therapeutics</u> – Moderator: Gerri Baer, M.D. (Team Leader, Pharmacovigilance & Neonatology Team, Office of Pediatric Therapeutics, OC, FDA)**

**12:30 – 12:50 PM: Fetal diagnostics**

Louise Wilings-Haug, M.D., Ph.D.
Associate Obstetrician & Gynecologist, Brigham and Women's Hospital
Professor of Obstetrics, Gynecology and Reproductive Biology, Harvard Medical School

**12:50 – 1:10 PM: Fetal arrhythmias**

Janette Strasburger, M.D.
Pediatric Cardiology, Pediatrics
Children's Wisconsin
Researcher, Herma Heart Institute
Professor, the Medical College of Wisconsin

**1:10 – 1:30 PM: Fetal therapies to target inflammation**

Dr**.** Sarah Stock MD, Ph.D. ,
Reader and Honorary Consultant Maternal and Fetal Medicine
Usher Institute, University of Edinburgh
NINE Edinburgh BioQuarter, 9 Little France Road,
Edinburgh EH16 4UX

**1:30 – 1:50 PM: In utero stem cell transplantation for the treatment of prenatally diagnosed diseases**

Tippi Mackenzie, M.D
Professor, Surgery, UCSF Division of Pediatric Surgery and fetal treatment center
Pediatric Surgeon, UCSF Benioff Children's Hospital, San Francisco

***1:50 – 2:05 PM: BREAK***

**2:05 – 3:00 PM: Panel Discussion and Questions**

**3:00 – 3:15 PM: Wrap up and Adjourn Day 1**

Gilbert J. Burckart, Pharm. D.

**Friday, October 22, 2021**

**10:00 – 10:05 AM: Welcome and Introduction**

André Dallmann, Ph.D.
Scientist Systems Pharmacology
Research & Development, Pharmaceuticals,
Bayer AG, Germany

**General aspects of maternal-fetal modeling & simulation – Moderator: André Dallmann (Bayer AG)**

**10:05 – 10:25 AM: Pregnancy-induced anatomical and physiological changes relevant to physiologically-based pharmacokinetic (PBPK) modeling**

Anne Zajicek, M.D., Pharm.D., FAAP
Deputy Director, Office of Clinical Research
National Institutes of Health

**10:25 – 10:45 AM: Quantifying placental drug transfer with ex vivo cotyledon perfusion assays as PBPK input**

Rick Greupink, Pharm.D., Ph.D.
Assistant professor of Pharmacology, member of staff at
Department of Pharmacology & Toxicology
Radboud University Medical Center, Nijmegen, The Netherlands.

**10:45 – 11:05 AM: Selecting the Right Dose for Pregnant Women Using PBPK**

Ping Zhao, Ph.D.
Senior Program Officer
Bill & Melinda Gates Foundation
Seattle, Washington, United States

**<u>Modeling & simulation case studies</u> – Moderator: Varsha Mehta, Pharm.D. (MS Office of Clinical Pharmacology-Pediatrics, CDER, FDA)**

**11:05 – 11:25 PM: Successful prediction of fetal exposure to transported and non-transported drugs using *in vitro* studies and PBPK M&S**

Jashvant D. Unadkat, Ph.D.
Milo Gibaldi Endowed Professor, Department of Pharmaceutics
School of Pharmacy, University of Washington

**11:25 – 11:45 AM: Mechanistic modeling of placental drug transfer and fetal-neonatal drug exposure**

André Dallmann, Ph.D.
Scientist Systems Pharmacology
Research & Development, Pharmaceuticals,
Bayer AG, Germany

**11:45 – 12:05 AM: Maternal-fetal PBPK modeling of antipsychotic drugs as case study**

Miao Li, Ph.D.
Visiting Scientist
Division of Biochemical Toxicology
NCTR, FDA

**12:05 – 12:25 PM: Predicting drug exposure in fetus and genital tract during pregnancy**

Adeniyi Olagunju, Ph.D.
Tenure Track Fellow
Centre of Excellence for Long-acting Therapeutics
Department of Pharmacology & Therapeutics
University of Liverpool, Liverpool, UK

**<u>Regulatory perspective</u> – Moderator: Dionna Green, M.D. (Deputy Director, Office of Pediatric Therapeutics, OC, FDA)**

**12:25 – 12:45 PM: MHRA perspective on pregnancy PPBPK models**

Paola Coppola, MSc
Pharmacokinetics Assessor
Medicines and Healthcare Products, Regulatory Agency
London, UK

**12:45 – 1:05 PM: FDA perspective on pregnancy-fetal PBPK models**

Lynne Yao, M.D.
Director, Division of Pediatric and Maternal Health
CDER, FDA

**1:05 – 1:55 PM: Panel Discussion and Questions**

**1:55 – 2:00 PM: Wrap up and Adjourn Day 2**
André Dallmann, Ph.D.

*Note: all times are in ET*