**Bridging Drug Efficacy and Safety to the Obese: Considerations and Scientific Approaches**

**November 9, 2022**

**8:15 am - 4:15 pm**

**Agenda**

**Overarching Principle:** Obese patients are a large segment of the U.S. population and should be included in drug development studies.

**Workshop Objectives:**

1. Review the implications of obesity on drug safety, efficacy, dosing and disposition in adult and pediatric patients.
2. Discuss:
   a. If adult and pediatric patients should be identified and studied as a special population in new drug development programs
   b. When it may be appropriate to include obese patients in drug development studies to develop specific dosing guidelines for obese patients

**SESSION 1  Obesity and Drug Development in Adults**

**8:15 am - 8:25 am  Welcome and introduction**

Varsha Mehta, Pharm.D., MS
Senior Staff Fellow for Pediatrics
Office of Clinical Pharmacology, CDER, FDA

**8:25 am - 8:40 am  Opening remarks**

Robert M. Califf, M.D.
Commissioner of Food and Drugs
Office of the Commissioner, FDA

**8:40 am - 9:10 am  Epidemiology of Adult and Pediatric Obesity**

Frank B. Hu, M.D., MPH, Ph.D.
Professor and Chair
Department of Nutrition
Harvard T.H. Chan School of Public Health

**9:10 am - 9:40 am  Special Populations and Regulatory Considerations in Drug Development-Obese Patients**

Rajanikanth Madabushi, Ph.D.
Associate Director for Guidance and Scientific Policy
Office of Clinical Pharmacology, CDER, FDA

**9:40 am - 10:10 am  Impact of Obesity on Drug Disposition and Response**
10:10 am - 10:40 am  
Role of Modeling and Simulation in Obesity - Evaluating the Effects on Drug Disposition and Efficacy in adult patients  
Hao Zhu, Ph.D., Mstat  
Division Director, Pharmacometrics  
Office of Clinical Pharmacology, CDER, FDA

10:40 am - 11:10 am  
How a systems approach may help drug development cater for better dose adjustment in obese patients  
Amin Rostami-Hodjegan, Ph.D., FCP, FAAPS, FJSSX, FBPS  
Professor of Systems Pharmacology  
Director of Centre for Applied Pharmacokinetics Research/University of Manchester UK  
Senior Vice President of R&D and Chief Scientific Officer, Certara, Princeton, USA

11:10 am - 11:20 am  
Coffee break

11:20 am - 12:00 pm  
Case examples in Obesity and drug use in adult patients  
Dosing contraceptives in Obese patients  
Alison Edelman, M.D., MPH  
Professor, Obstetrics and Gynecology  
Department of Obstetrics & Gynecology  
Complex Family Planning Fellowship Director at Oregon Health & Science University

Dosing Anesthetics and analgesics in the Obese patient  
Michel M.R.F. Struys, M.D., Ph.D., FRCA  
Professor and Chair, Department of Anesthesiology  
University of Groningen-University Medical Center Groningen, The Netherlands  
Professor, Department of Basic and Applied Medical Sciences  
Ghent University, Gent, Belgium

12:00 pm - 1:00 pm  
Lunch Break

SESSION 2  Obesity and Drug Development in Pediatric Patients

1:00 pm - 1:10 pm  
Review session objectives

Varsha Mehta, Pharm.D., MS  
Senior Staff Fellow - Pediatrics  
Office of Clinical Pharmacology, CDER, FDA
1:10 pm - 1:40 pm  
*Obesity Considerations in Pediatric Drug Development Program*

Applications submitted to the FDA

Varsha Mehta, Pharm.D., MS  
Senior Staff Fellow for Pediatrics  
Office of Clinical Pharmacology, CDER, FDA

1:40 pm - 2:10 pm  
*Current Methods to Characterize Drug Disposition and Optimize Dosing in Children with Obesity*

Daniel Gonzalez, Pharm.D., Ph.D.  
Associate Professor  
Division of Pharmacotherapy and Experimental Therapeutics  
UNC Eshelman School of Pharmacy, The University of North Carolina at Chapel Hill

2:10 pm - 2:40 pm  
*Dosing Anti-infectives in the Obese Pediatric Patient*

Michael Neely, M.D., MSc, FCP  
Chief, Division of Infectious Diseases  
Director, Laboratory of Applied Pharmacokinetics and Bioinformatics,  
The Saban Research Institute,  
Children’s Hospital Los Angeles  
Professor and Clinical Scholar, Department of Pediatrics,  
Keck School of Medicine, University of Southern California

2:40 pm - 3:10 pm  
*Pharmacokinetics and Dose Optimization of Anticoagulants in Children with Obesity*

Jackie Gerhart, Ph.D., MBA, MS  
Associate Director  
Clinical Pharmacology Lead  
GPD Pfizer  
Collegeville, PA

3:10 pm - 4:00 pm  
*Panel Discussion*

**Moderator** - Varsha Mehta, Pharm.D., MS  
Senior Staff Fellow - Pediatrics  
Office of Clinical Pharmacology, CDER, FDA

Alexander (Sander) Vinks Ph.D., Pharm.D., FCP  
Professor of Pediatrics & Pharmacology  
University of Cincinnati, College of Medicine  
Cincinnati Children’s Research Foundation Endowed Chair  
Director, Division of Clinical Pharmacology
Cincinnati Children’s Hospital Medical Center

**Joga Gobburu, Ph.D.**
Professor of Pharmacy Practice and Science and School of Medicine Director, Center for Translational Medicine University of Maryland

**Gilbert Burckart, Pharm.D.**
Associate Director-Pediatrics Office of Clinical Pharmacology, CDER, FDA

**Jaya Vaidyanathan, Ph.D.**
Associate Director-Therapeutic Review Division of Cardiometabolic and Endocrine Pharmacology Office of Clinical Pharmacology, OTS, CDER, FDA

**Laura Higginbotham, M.D., MPH**
Lead Physician, Division of Diabetes, Lipid Disorders, and Obesity CDER, OND, FDA

**Kenneth T. Moore, MA, MS, FAHA**
Scientific Director Cardiovascular and Metabolism Medical Affairs Janssen Pharmaceuticals Inc. Titusville, USA

4:00 pm - 4:15 pm  **Closing remarks**

**Issam Zineh, Pharm.D., MPH, FCP, FCCP**
Director Office of Clinical Pharmacology, CDER, FDA