

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

David J. Greenblatt, M.D.
Louis Lasagna Endowed Professor
Tufts University School of Medicine

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 Cardiomatabolic 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