FDA & UNIVERSITY OF MARYLAND CERSI

PHARMACOKINETIC EVALUATION IN PREGNANCY VIRTUAL PUBLIC WORKSHOP

Monday, May 16, 2022 & Tuesday, May 17, 2022

Engaging stakeholders in dialogue to assess available science and data gaps to advance the conduct of PK studies in pregnant individuals for CDER-regulated products.

May 16 10:00am – 3:00pm (ET)

Day 1 - Welcome & Introduction

10:00 – 10:10	Welcome & Introductory remarks *Leyla Sahin, FDA*
	Keynote Address *Robert Califf, Commissioner of Food and Drugs*

Session 1: Considerations for Conduct of PK Studies in Pregnant Individuals

Introduction of Speakers – *Daphne Guinn*

10:10 – 10:25	General landscape of existing regulatory guidance and drug labeling in pregnancy *Leyla Sahin, FDA*
10:25 – 10:40	Ethical considerations for enrolling pregnant individuals in clinical studies *Anne Lyerly, University of North Carolina*
10:40 – 11:00	Physiologic changes during pregnancy and impact on drug disposition and response *Ahizechukwu Eke, John Hopkins University*
11:00 – 11:15	PK studies in pregnancy – Regulatory experience *Su-Young Choi, FDA*
11:15 – 11:30	Public health perspective on PK studies in pregnancy *Martina Penazzato, WHO-IMPAACT*
11:30 – 11:45	The conundrum of clinical studies in pregnancy: Industry view *Michael Fossler, Cytel*
11:45 – 11:55	Q&A – *Morning speakers*

11:55 – 12:15	BREAK
12:15 – 12:35	Design considerations for pharmacokinetic studies in pregnant individuals *Mary Hebert, University of Washington*
12:35 – 12:55	Designing PK Studies in Pregnancy – Part II *Catherine Stika, Northwestern University*
12:55 – 1:10	Importance of achieving racial and ethnic equity in pregnancy clinical research *Adetola Louis-Jacques, University of Florida*
1:10 –1:20	Q&A – *Afternoon speakers*
1:20 – 2:50	Panel Discussion ***Moderators*** – *Lynne Yao, FDA & Solange Corriol-Rohou, AstraZeneca* Panelists – ▪ *Yodit Belew, FDA* ▪ *Christina Bucci-Rechtweg, Novartis* ▪ *Maged Costantine, Ohio State University* ▪ *Melanie Kerr, Patient Representative* ▪ *Aaron Pawlyk, NIH/NICHD* ▪ *Raman Venkataramanan, University of Pittsburgh*
2:50 – 3:00	Closing Remarks *Elimika Pfuma Fletcher, FDA*

May 17 10:00am – 2:00pm (ET)

Introduction of Speakers – CAPT *Anissa Davis-Williams*

Day 2 - Welcome & Introduction

10:00 – 10:10	Welcome & Introductory remarks *Elimika Pfuma Fletcher, FDA*

Session 2: Modeling Pregnancy Pharmacokinetics

10:10 – 10:25	Overview of current modeling approaches to support studies in pregnancy *Jeff Barrett, Critical Path*
10:25 – 10:40	The role of modelling and trial design considerations – regulatory perspective *Susan Cole, MHRA*
10:40 – 10:55	Industry perspective on role of PBPK modeling in pregnancy *Amy Cheung, Certara*
10:55 – 11:10	Predicting maternal-fetal exposure to drugs using a mechanistic PBPK model *Jashvant Unadkat, University of Washington*

11:10 – 11:20 Q&A – *Session 2 Speakers*

11:20 – 12:10 Panel Discussion

Moderator – Elimika Pfuma Fletcher, FDA

Panelists –

- *Karim Azer, Axcella*
- *Gil Burckart, FDA*
- *Andre Dallmann, Bayer*
- *Manuela Grimstein, FDA*
- *Sara Quinney, Indiana University*

12:10 – 12:25 BREAK

Session 3: Data Interpretation & Translation into Dosing Recommendations in Pregnancy

12:25 – 12:40 Innovative data analytics to inform pharmacokinetics and dosing of drugs in pregnancy
Mathangi Gopalakrishnan, University of Maryland

12:40 – 12:55 Translating data into dosing recommendations in pregnancy
Brookie Best, University of California San Diego

12:55 – 1:05 Q&A – *Session 3 Speakers*

1:05 – 1:50 Panel Discussion

Moderators – Elimika Pfuma Fletcher, FDA & Sara Quinney, Indiana University

Panelists –

- *Edmund Capparelli, University of California San Diego*
- *Steve Caritis, University of Pittsburgh*
- *Kellie Reynolds, FDA*
- *Ashley Strougo, Sanofi*
- *Kimberly Struble, FDA*

1:50 – 2:00 Closing Remarks & Future Directions
Lynne Yao
Director, Division of Pediatrics and Maternal Health, Office of New Drugs, CDER

Additional information

This workshop is open to the public; however, registration is required at: https://bioeumd.wufoo.com/forms/modi0au1wjs8as/.

More information about this event can be found at: https://go.usa.gov/xu2MX