

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 pregnant individuals: 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 <i>Mary Hebert, University of Washington</i>
12:35 – 12:55	Designing PK Studies in Pregnancy – Part II <i>Catherine Stika, Northwestern University</i>
12:55 – 1:10	Importance of achieving racial and ethnic equity in pregnancy clinical research <i>Adetola Louis-Jacques, University of Florida</i>
1:10 – 1:20	Q&A – <i>Afternoon speakers</i>
1:20 – 2:50	Panel Discussion <i>Moderators – Lynne Yao, FDA & Solange Corriol-Rohou, AstraZeneca</i> Panelists – <ul style="list-style-type: none"> ▪ <i>Yodit Belew, FDA</i> ▪ <i>Christina Bucci-Rechtweg, Novartis</i> ▪ <i>Maged Costantine, Ohio State University</i> ▪ <i>Melanie Kerr, Patient Representative</i> ▪ <i>Aaron Pawlyk, NIH</i> ▪ <i>Raman Venkataramanan, University of Pittsburgh</i>
2:50 – 3:00	Closing Remarks <i>Elimika Pfuma Fletcher, FDA</i>

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 <i>Elimika Pfuma Fletcher, FDA</i>
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Session 2: Modeling Pregnancy Pharmacokinetics

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

- 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 Data interpretation & considerations for optimizing the dosing regimen
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>