FDA-University of Maryland CERSI Public Workshop:
Evaluating Immunosuppressive Effects of In Utero Exposure to Drug and Biologic Products

Thursday, July 11, 2024 & Friday, July 12, 2024

Workshop Goal

Engage stakeholders in dialogue to assess the value and design of studies to evaluate placental transfer and potential clinical impact of drug and biologics with immunosuppressive properties on infants

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Day 1 9:00 AM – 4:00 PM (ET)

Welcome & Introduction

9:00 AM – 9:10 AM	**Welcome and Overview** *Tamara Johnson, FDA*
9:10 AM – 9:15 AM	**Introductory remarks** *Keynote Speaker TBD*
9:15 AM – 9:35 AM	**Current Regulatory Landscape** *Katherine Kratz, FDA* *Sonaly McClymont, FDA*

Background Session: Background and Current Landscape

9:35 AM – 9:50 AM	**Biological Background of Placental Transfer** *Les Myatt, Oregon Health & Science University*
9:50 AM – 10:10 AM	**Current Clinical Pharmacology Landscape of Small Molecules** *Raman Venkataramanan, University of Pittsburgh*
10:10 AM – 10:30 AM	**Current Clinical Pharmacology Landscape of Biologics** *Edwin Lam, J&J Innovative Medicine*
10:30 AM – 10:50 AM	**Current Clinical Landscape** *Uma Mahadevan, UCSF*
10:50 AM – 11:05AM	**Clinical Risk-Benefit Conceptual Framework** *Laura Bozzi, J&J Innovative Medicine*
11:05 AM – 11:20AM	**BREAK**

Session 1: Value – Current Clinical and Safety Considerations

11:20 AM – 12:05 PM	**Panel Discussion** ***Moderator:*** *Leyla Sahin, FDA* **Panelists:**

- *Uma Mahadevan, UCSF*
- *Kevin Ault, Western Michigan University*
- *Latéy Bradford, University of Maryland*
- *Natalie Hayden, Patient Representative*
- *Vani Vannappagari, ViiV Healthcare*
- *Maria Fernanda Scantamburlo Fernandes, Eli Lilly*

12:05 AM – 1:05 PM **LUNCH**

Session 2: Nonclinical Evaluation of Placental Transfer and Immunotoxic Potential

1:05 PM – 1:20 PM **Relevant In Vitro and Ex Vivo Assessments**
Nick Illsley, NJ Medical School, Rutgers Univ, Placental Research Group LLC

1:20 PM – 1:35 PM **Relevant In Silico Assessments**
Rohan Lewis, University of Southampton

1:35 PM – 1:55 PM **In Vivo Animal Assessments**
John DeSesso, Exponent Consulting Company

1:55 PM – 2:05 PM **Regulatory Nonclinical Perspective**
David McMillan, FDA

2:05 PM – 2:35 PM **Panel Discussion**
Moderator: *Jashvant Unadkat, University of Washington*
Panelists:
- *Nick Illsley, NJ Medical School, Rutgers Univ, Placental Research Group LLC*
- *Rohan Lewis, University of Southampton*
- *John DeSesso, Exponent Consulting Company*
- *David McMillan, FDA*
- *Dinesh Stanislaus, GSK*

2:35 PM – 2:50 PM **BREAK**

Session 3: Framing Concerns for In Utero Exposed Infants Based on Available Data

2:50 PM – 3:50 PM **Panel Discussion**
Moderator: *Kelly Stone, FDA*
Panelists:
- *Mike Keller, Children's National/George Washington University*
- *Ofer Levy, Boston Children's/Harvard University*
- *Jeff Roberts, Merck*
- *Marie Teil, UCB*
- *TBD*

3:50 PM – 4:00 PM **Day 1 Closing Remarks**
Tamara Johnson, FDA

Day 2 9:00 AM – 1:00 PM (ET)

Welcome & Introduction

9:00 AM – 09:10 AM **Welcome & Introductory remarks**
Tamara Johnson, FDA

Session 4: Clinical Study Design Considerations

9:10 AM – 9:20 AM **Ethical Considerations for Inclusion of Infants in Clinical Trials**
Melanie Bhatnagar, FDA

9:20 AM – 9:35 AM **Pharmacology and Modeling of Small Molecule Transfer across the Placenta**
Jashvant Unadkat, University of Washington

9:35 AM – 9:50 AM **Pharmacology and Modeling of Biologic Transfer across the Placenta**
Ruth Oliver, Takeda

9:50 AM – 11:00AM **Panel Discussion**
Moderators: *Lily Mulugeta, FDA & Sonaly McClymont, FDA*
Panelists:
- *Jashvant Unadkat, University of Washington*
- *Ruth Oliver, Takeda*
- *Joseph Cafone, J&J Innovative Medicine*
- *Mona Khurana, FDA*
- *TBD*

11:00 AM – 11:15 AM **BREAK**

Session 5: Logistical Considerations, Future Directions, and Next Steps

11:15 AM – 12:30 PM **Panel Discussion**
Moderator: *Lynne Yao, FDA*
Panelists:
- *Skip Nelson, J&J Innovative Medicine*
- *Marie Teil, UCB*
- *Kevin Ault, Western Michigan University*
- *Ofer Levy, Boston Children's/Harvard University*
- *Aaron Pawlyk, NICHD*
- *TBD*

12:30 PM – 12:40 PM **Closing Remarks**
Tamara Johnson, FDA