

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 – 4:30 PM (ET)

**Welcome & Introduction**

- 9:00 AM – 9:10 AM **Welcome and Overview**  
*Tamara Johnson, FDA*
- 9:10 AM – 9:15 AM **Introductory Remarks**  
*Robert M. Califf, Commissioner of the FDA*
- 9:15 AM – 9:35 AM **In Utero Exposure to Drug and Biologic Products: Regulatory Considerations**  
*Katie Kratz, FDA*  
*Sonaly McClymont, FDA*

**Background Session: Background and Current Landscape**

- 9:35 AM – 9:50 AM **Mechanisms of Placental Transfer for Small Molecules and Biologics**  
*Leslie Myatt, Oregon Health & Science University*
- 9:50 AM – 10:10 AM **Fetal Transfer of Small Molecules**  
*Raman Venkataramanan, University of Pittsburgh*
- 10:10 AM – 10:30 AM **Placental Transfer of Immunosuppressive Biologics: Current Clinical Pharmacology Landscape**  
*Edwin Lam, Johnson & Johnson*
- 10:30 AM – 10:50 AM **Current Clinical Landscape**  
*Uma Mahadevan, University of California San Francisco*
- 10:50 AM – 11:05 AM **Benefit-Risk Conceptual Framework for In Utero Exposure to Immunosuppressive Medications**  
*Laura Bozzi, Johnson & Johnson*

11:05 AM – 11:25 AM **BREAK**

**Session 1: Current Clinical and Safety Considerations**

11:25 AM – 12:10 PM **Panel Discussion**

**Moderator:** Leyla Sahin, FDA

**Panelists:**

- Kevin Ault, Western Michigan University
- L. Latéy Bradford, University of Maryland
- Maria Fernanda Scantamburlo Fernandes, Eli Lilly and Company
- Natalie Hayden, Patient Representative
- Uma Mahadevan, University of California San Francisco
- Vani Vannappagari, ViiV Healthcare

12:10 PM – 1:10 PM

LUNCH

## Session 2: Nonclinical Evaluation of Placental Transfer and Immunotoxic Potential

1:10 PM – 1:25 PM

**Relevant In Vitro and Ex Vivo Assessments for Small Molecules and Biologics**

*Nick Illsley, Placental Research Group LLC, Rutgers University*

1:25 PM – 1:40 PM

**In Silico Assessments for Small Molecules and Biologics**

*Rohan Lewis, University of Southampton*

1:40 PM – 2:00 PM

**In Vivo Animal Assessments**

*John M. DeSesso, Exponent*

2:00 PM – 2:15 PM

**Nonclinical Guidances Pertinent to Developmental Immunotoxicity**

*David McMillan, FDA*

2:15 PM – 2:55 PM

**Panel Discussion**

**Moderator:** *Jashvant Unadkat, University of Washington*

**Panelists:**

- John M. DeSesso, Exponent
- Nick Illsley, Placental Research Group LLC, Rutgers University
- Rohan Lewis, University of Southampton
- David McMillan, FDA
- Dinesh Stanislaus, GSK

2:55 PM – 3:15 PM

BREAK

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

3:15 PM – 4:00 PM

**Panel Discussion**

**Moderator:** *Kelly Stone, FDA*

**Panelists:**

- Michael Keller, Children's National/George Washington University
- Ofer Levy, Boston Children's/Harvard University
- Jeff Roberts, Merck Research Laboratories

4:00 PM – 4:15 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 Clinical Investigations in Children to Assess the Impact of Placental Transfer of Drugs and Biologics with Immunosuppressive Properties**  
*Melanie E. Bhatnagar, FDA*

9:20 AM – 9:40 AM      **How Can We Predict Fetal Drug Exposure Throughout Pregnancy To Inform Fetal Safety?**  
*Jashvant Unadkat, University of Washington*

9:40 AM – 10:00 AM      **Clinical Pharmacology and Modelling of Drug Transfer Across the Placenta and Fetal Exposures: Biologics**  
*Ruth Oliver, Takeda*

10:00 AM – 11:05 AM      **Panel Discussion**  
**Moderators:** *Lily Mulugeta, FDA & Sonaly McClymont, FDA*  
**Panelists:**  
– *Joseph Cafone, Johnson & Johnson*  
– *Mona Khurana, FDA*  
– *Elisa Ochfeld, Children’s Hospital of Philadelphia*  
– *Ruth Oliver, Takeda*  
– *Jashvant Unadkat, University of Washington*

11:05 AM – 11:25 AM      **BREAK**

## Session 5: Synthesis, Future Directions, and Next Steps

11:25 AM – 12:50 PM      **Panel Discussion**  
**Moderator:** *Lynne Yao, FDA*  
**Panelists:**  
– *Kevin Ault, Western Michigan University*  
– *Giorgia Berardi, EU Network – Italian Medicines Agency*  
– *Natalie Hayden, Patient Representative*  
– *Ofer Levy, Boston Children’s/Harvard University*  
– *Robert “Skip” Nelson, Johnson & Johnson*  
– *Aaron C. Pawlyk, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)*  
– *Marie Teil, UCB*

12:50 PM – 1:00 PM      **Closing Remarks**  
*Tamara Johnson, FDA*