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