
**FDA-University of Maryland CERSI
Public Workshop
Optimizing Pregnancy Registries**

May 7-8, 2026

DAY 1: Thursday, May 7, 2026

Welcome and Opening Remarks

- 9:00 – 9:10 am Leyla Sahin, M.D.
Division of Pediatrics and Maternal Health (DPMH)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine
(ORPURM)
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
- 9:10 – 9:20 am Kaveeta Vasisht, M.D. Pharm D.
Associate Commissioner for Women’s Health
Director, Office of Women’s Health
Office of the Commissioner, FDA

Session 1: Current State of Pregnancy Registries

- 9:20 – 9:40 am **Pregnancy Registries - Current Status and FDA observations**
Wenjie Sun, M.D.
DPMH, ORPURM, OND, CDER
- 9:40 – 10:00 am **Update on FDA PDUFA VII activities**
Youjin Wang, Ph.D. (FDA)
Regulatory Science Staff
Office of Surveillance and Epidemiology (OSE), CDER, FDA
- 10:00 – 10:20 am **Healthcare Provider Perspective**
Megan E. B. Clowse, M.D., MPH
Duke University School of Medicine
- 10:20 – 10:40 am **Academic Perspective**
Lee S. Cohen, M.D.
Harvard Medical School

10:40 – 11:00 am **BREAK**

11:00 – 11:20 am **Industry Perspective**
Keele Wurst, Ph.D., M.S., RPh
GlaxoSmithKline

11:20 – 11:40 am **Introduction to Multi-product Pregnancy Registries: Antiretroviral pregnancy registry**
Jessica Albano, Ph.D., MPH
EPIphany Real-World Research

11:40 am – 12:40 pm **Session 1 Panel discussion and Q&A**

Panelists:

- Jessica Albano, Ph.D., MPH
- Keele Wurst, Ph.D., M.S., RPh
- Megan Clowse, M.D., MPH
- Kayla Stomack
- ACOG Representative

12:40 – 1:40 pm **LUNCH BREAK** (On your own)

Session 2: Optimizing Design of Pregnancy Registries in Context of Totality of Evidence

1:40 – 2:40 pm **Pregnancy Registry Patient Perspectives**

- Kayla Stomack
- Lisa Feret

Database and pregnancy registries

Sonia Hernandez-Diaz, M.D., DrPH
Harvard T. Chan School of Public Health

Industry perspectives on integration of evidence from non-registry sources

Marie Teil, M.D.
UCB Biopharma SRL

2:40 – 3:00 pm **BREAK**

3:00 – 4:00 pm **Session 2 Panel Discussion and Q&A**

Panelists:

- Sonia Hernandez-Diaz, M.D., DrPH
- Marie Teil, M.D.
- Lee Cohen, M.D.
- Lisa Feret

4:00 – 4:15 pm

Closing Remarks

Lynne Yao, M.D. (FDA)
DPMH, ORPUM, OND, CDER

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DAY 2: Friday, May 8, 2026

9:00 – 9:05 am **Welcome**
Leyla Sahin, M.D.
DPMH, ORPURM, OND, CDER, FDA

Session 3: Partnerships and Future Directions

9:05 – 9:25 am **Introduction to Strategically Coordinated Registry Networks**
Danica Marinac-Dabic, M.D., Ph.D., MMSc, FISPE (FDA)
Office of Clinical Evidence and Analysis
Office of Product Evaluation and Quality
Center for Devices and Radiological Health (CDRH)

9:25 – 9:45 am **Lessons Learned from Coordinated Registry Networks via Public-Private Partnerships**
Gregory Pappas, M.D., Ph.D.
Office of Biostatistics and Pharmacovigilance (OBPV)
Center for Biologics Evaluation and Research (CBER)
FDA

9:45 – 10:05 am **Lessons learned from Public-Private Partnerships**
Kourtney Davis, Ph.D., MSPH
Johnson & Johnson

10:05 – 10:25 am **FNIH Partnership Models for Accelerating Pregnancy Health**
Tania Navak Kamphaus, Ph.D.
Foundation for NIH, Bethesda, MD

10:25 – 10:40 am **BREAK**

10:40 – 11:00 am **Experience with Multi-Sponsored Consortia and Public-Private Partnerships to Develop Coordinated Population Cohorts and Registries: Lessons Learned**
Carla Rodriguez, Ph.D., MPH
Reagan-Udall Foundation for the FDA

11:00 – 11:20 am **Beyond Multi-Product Registries and Registry Networks: Can a single, national pregnancy registry fill knowledge gaps more efficiently and quickly?**
Christina Chambers, Ph.D., MPH
University of California San Diego

11:20 am – 12:20 pm **Session 3: Future Directions Panel Discussion and Q&A**

Panelists:

- Christina Chambers, Ph.D., MPH
- Kourtney Davis, Ph.D., MSPH
- Aaron Pawlyk, Ph.D. (NIH/NICHD)
- Gregory Pappas, M.D., Ph.D.

12:20 – 12:40 pm Closing Remarks
Leyla Sahin, M.D.
DPMH, ORPURM, OND, CDER, FDA

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