Public Meeting
Study Approaches & Methods to Evaluate the Safety of Drugs & Biological Products during Pregnancy in the Post-approval Setting

Docket Number FDA-2014-N-0157

May 28-29, 2014

Agenda

DAY 1

7:30 – 8:00 am Registration

8:00 – 8:05 am Welcome and Introduction
Vicki Moyer, MS
Senior Regulatory Project Manager, Pediatric and Maternal Health Staff (PMHS), Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER)

8:05 – 8:15 am Opening Remarks
Sandra Kweder, MD, FACP
Deputy Office Director, OND, CDER

8:15 – 8:25 am Meeting objectives and goals
Solomon Iyasu MD, MPH
Director, Office of Pharmacovigilance & Epidemiology (OPE), Office of Surveillance and Epidemiology (OSE), CDER

8:25 – 8:50 am Pregnancy Registries and other Post-approval Studies
Current status and FDA observations
Leyla Sahin, MD, FACOG
Medical Officer, PMHS, OND, CDER
Hoda T. Hammad, MS, MPH
ORISE fellow, OPE, OSE, CDER

8:50 – 9:00 am Clarifying questions for the presenters from the panel
**Topic 1: Pregnancy registries- Perspectives/challenges relating to data collection and analyses**

9:00 – 9:05 am  **Moderator Introduction to Topic 1:**  
Melissa Tassinari, PhD DABT  
Senior Clinical Advisor, PMHS, OND, CDER

9:05 – 9:25 am  **Study Design and Methodology**  
Sonia Hernández-Díaz, MD, DrPH  
Director of the Pharmacoepidemiology Program and Associate Professor of Epidemiology, Harvard School of Public Health

9:25 – 9:45 am  **Comparison Group**  
Lewis B. Holmes, MD  
Director, North American Anti- Epileptic Drug Pregnancy Registry, Professor of Pediatrics, Harvard Medical School

9:45 – 10:00 am  **BREAK**

10:00 – 10:20 am  **Multi-product registries**  
Jessica Albano, PhD, MPH  
Sr. Director, Epidemiology, Post Approval & Strategic Services, INC Research LLC

10:20 – 10:40 am  **Data collection/ experience with vaccines**  
Adel Abou-Ali, PharmD, ScD, MS,  
Deputy Director of Global Pharmacoepidemiology and Risk Management, Sanofi-Pasteur (Industry representative)

10:40 – 10:55 am  **Clarifying questions for the presenters from panel**

10:55 – 11:55 pm  **Topic 1 Panel discussion and Q&A**

11:55 – 12:00 pm  **Moderator Wrap-up morning session**

12:00 – 1:00 pm  **LUNCH (On your own)**

1:00 – 1:50 pm  **Open Public Comment**

**Topic 2: Enrollment, retention, communication**

1:50 – 1:55 pm  **Moderator Introduction to Topic 2**  
Pamela E. Scott, PhD, MA  
Director, Research and Development, Office of Women’s Health (OWH), Office of the Commissioner (OC)
1:55 – 2:15 pm  **Using digital outreach and innovative partnerships to raise awareness about pregnancy exposure registries**  Kimberly A. Thomas, MPH  Sr. Public Health Advisor, Health Communication and Outreach, OWH, OC

2:15 – 2:35 pm  **Perspective from Teratogen Information Service**  Christina Chambers, PhD, MPH  Professor of Pediatrics, University of California San Diego, Organization of Teratology Information Specialists Collaborative Research Group

2:35 – 2:55 pm  **An Obstetrician’s Perspective**  Michael F. Greene, MD  Professor of Obstetrics, Gynecology and Reproductive Biology Harvard Medical School, Director of Obstetrics, Vincent Department of Obstetrics and Gynecology, Massachusetts General Hospital

2:55 – 3:05 pm  **A Patient’s perspective**  Julia S. Beck, Founder of Forty Weeks

3:05 – 3:20 pm  **Topic 2 Clarifying questions for the presenters from panel**

3:20 – 3:35 pm  **BREAK**

3:35 – 4:35pm  **Topic 2 Panel Discussion and Q&A**

4:35 – 4:40 pm  **Wrap-up Day 1**  Leyla Sahin, MD, FACOG  PMHS, OND, CDER
DAY 2

8:00 – 8:05 am  Welcome  
Vicki Moyer, MS  
Senior Regulatory Project Manager, PMHS, OND, CDER

8:05 – 8:10 am  Yesterday and Today  
Michael D. Nguyen, MD  
CDR, U.S. Public Health Service  
Acting Director, Division of Epidemiology (DE), Office of Biostatistics and Epidemiology (OBE), Center for Biologics Evaluation and Research (CBER)

Topic 3: Alternative Approaches for Data Collection

8:10 – 8:15 am  Moderator Introduction to Topic 3  
Judy Staffa, PhD, RPh  
Director, Division of Epidemiology II, OPE, OSE, CDER

8:15 – 8:35 am  Combined registry and case control approach  
Allen A. Mitchell, MD  
Director, Slone Epidemiology Center, Professor of Epidemiology and Pediatrics, Boston University Schools of Public Health and Medicine

8:35 – 9:00 am  Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP)  
Susan Andrade, ScD  
Research Associate Professor/Senior Research Associate  
Meyers Primary Care Institute/University of Massachusetts Medical School  
Sulfonamide use during the first trimester of pregnancy and the risk of select congenital anomalies  
Craig Hansen, PhD  
Senior Research Fellow, Kaiser Permanente, Georgia; Sansom Institute for Health Research, University of South Australia

9:00 – 9:25 am  U.S. Department of Defense (DoD) Birth and Infant Health Registry  
Ava Marie S. Conlin, DO, MPH  
Medical Epidemiologist, Deployment Health Research Department, Naval Health Research Center
The DoD Mother-Child Database
COL Trinka Coster, MD, MS, Director
Rosenie Thelus, PhD, MPH, Epidemiologist
Office of Surgeon General of the Army, Pharmacovigilance Center

9:25 – 9:45 am Evaluating Vaccine Safety During Pregnancy: The Vaccine Safety Datalink Experience
Allison Naleway, PhD
Senior Investigator, Kaiser Permanente Northwest, The Center for Health Research

9:45 – 10:05 am Pharmacovigilance of Exposures to Medicines and Vaccines During Pregnancy
Adrian Dana, MD
Clinical Safety & Risk Management, Merck & Co. (Industry representative)

10:05 – 10:20 am Topic 3 Clarifying questions for the presenters from panel

10:20 – 10:35 am BREAK

10:35 – 11:05 am Open Public Comment

11:05 – 12:05 pm Topic 3 Panel Discussion and Q&A
Moderator Judy Staffa, PhD, RPh
Director, Division of Epidemiology II, OPE, OSE, CDER

Topic 4: How to move forward?

12:05 – 1:05 pm Panel Discussion and Q&A
Moderator: Melissa Tassinari, PhD DABT
Senior Clinical Advisor, PMHS, OND, CDER

1:05 – 1:15 pm Closing Remarks
CDER-OND, CDER-OSE, CBER-OBE, OWH