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 – 10:20am	**Multi-product registries** Jessica Albano, PhD, MPH Sr. Director, Epidemiology, Post Approval & Strategic Services, INC Research LLC
10:20 – 10:40am	**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

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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