

**2016 International Conference on Pharmacoepidemiology (Dublin, Ireland)
Vaccines and Medicines in Pregnancy Special Interest Groups (SIG) Symposium**

90 minute session

Topic: Maternal Immunization

Title: Implementing the GAIA Definitions of Obstetric and Neonatal Outcomes for Observational Research in Resource-Limited Settings

Panelists/Presenters:

- Julijana Dukanovic, Erasmus Medical Center, Rotterdam, Netherlands
- Andrea Margulis, RTI Health Solutions, Barcelona, Spain
- Christentze Schmiegelow, University of Copenhagen, Denmark
- James Stark, Pfizer Inc., New York, USA
- Miriam Sturkenboom, Erasmus Medical Center, Rotterdam, Netherlands
- Corinne de Vries, European Medicines Agency, London, United Kingdom

Background: The increasing portfolio of maternal vaccines in development is an important strategy for the reduction of maternal and neonatal mortality and morbidity. Monitoring the safety of these potentially transformative vaccines presents new challenges, one of which is the harmonization of research processes across sites, data sources and populations. The recently established multi-partner Global Alignment for Immunization Safety Assessment in Pregnancy initiative (GAIA) has been designed to develop guidance for the collection, analysis, and presentation of safety outcome data on immunization in pregnancy, to create standardized case definitions for key obstetric and neonatal events, and to assess their applicability in high and low and middle income countries (LMIC). To date, the application of the standardized case definitions for key obstetric and neonatal events has focused on implementation in clinical trials with less emphasis on observational research specifically in LMIC.

Objectives: 1) To understand the practicality of implementing the GAIA obstetric and neonatal outcomes case definitions in high and LMIC; 2) To review observational studies investigating obstetric and neonatal outcomes following immunization in high and LMIC.

This symposium would benefit researchers who implement vaccine clinical trials or conduct post-marketing surveillance and studies among pregnant women in developed and LMIC.

Description: The ISPE SIGs for Medicines in Pregnancy and for Vaccines jointly evaluated the feasibility of implementing the GAIA pregnancy and neonatal case definitions for observational research in LMIC. This symposium will be devoted to exploring how well the GAIA definitions can be translated from researchers, regulators, and field operators will be shared and the impact on observational research will be discussed. Results and experiences from high and LMIC will be shared and the impact on observational research will be discussed. Lessons learned will inform future modifications of case definitions and propose guidance for subsequent research.

Symposium format:

1. Introduction of symposium and description of maternal vaccines

Symposium Abstract

2. Review of observational studies of neonatal and obstetric outcomes following immunization in LMIC
3. Methodological challenges in conducting observational research on pregnancy outcomes
4. Implementation of a survey to assess feasibility of implementing definitions of neonatal and obstetric outcomes for observational research in LMIC
5. Surveillance or pre- and post-natal care in LMIC: Assessments from the field
6. Applicability of case definitions for observational research: A regulatory perspective
7. Panel discussion