Harmonized Safety Monitoring of Immunization in Pregnancy
International Consensus Conference
March 29-30, 2016
Lister Hill Center Auditorium
National Institutes of Health Campus
Bethesda, Maryland, USA

The conference will bring together regulators, scientists, academia and industry experts to help resolve existing challenges of safety monitoring of immunization in pregnancy and to reach conclusions that will be valuable to a globally concerted approach.

This conference is inspired by the work performed by GAIA project partners and volunteers worldwide.

Scientific Committee

Ajoke Sobanjo-TerMeulen	Bill & Melinda Gates Foundation
Karen Bok	National Vaccine Program Office
Jan Bonhoeffer	Brighton Collaboration Foundation (Chair)
Steven Hirschfeld	National Institutes of Health
Sonali Kochhar	Global Healthcare Consulting
Paul Heath	St. George's University of London
Flor Muñoz	Baylor College of Medicine
Pieter Neels	Vaccine-Advice
Mirjana Nesin	National Institutes of Health
Sharon Bergquist	Bill & Melinda Gates Foundation
Linda Eckert	University of Washington

Organizing Commitee

Abbie Charlet, IABS
Simone Casagrande, BCF
Rosalina Bray, NIH
Ángel Honrado, SYNAPSE

Day 1 – Tuesday, March 29, 2016

08:00 - 08:30 **Registration & Welcome Coffee**

08:40 – 08:45 Welcome and Introduction
Steven Hirschfeld, Associate Director for Clinical Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, Maryland, U.S.A.

08:45 – 08:55 Opening remarks
Peter Marks, Director, Center for Biologics Evaluation and Research, Food and Drug Administration, Silver Spring, Maryland, U.S.A.

08:55 – 09:20 BMGF maternal immunization strategy and platform
Ajoke Sobanjo-ter Meulen, Senior Program Manager, Bill & Melinda Gates Foundation, Seattle, Washington, U.S.A.

09:20 – 09:30 Meeting objectives and overview
Jan Bonhoeffer, President, Brighton Collaboration Foundation; Vice-Chair, Pediatric Infectious Diseases and Vaccines, University Children's Hospital, Basel, Switzerland

Session 1
Challenges and opportunities for harmonized safety monitoring of immunization in pregnancy
Chair: Ajoke Sobanjo-ter Meulen, Senior Program Manager, Bill & Melinda Gates Foundation, Seattle, Washington, U.S.A.

09:30 - 09:45 Immunization in Pregnancy Safety Monitoring- Challenges and Guidance
Sonali Kochhar, CEO and Medical Director, Global Healthcare Consulting, New Delhi, India

09:45 – 10:00 Challenges of safety monitoring of immunization in pregnancy clinical trials in LMIC
Clare Cutland, Senior Medical Officer, University of the Witwatersrand / Wits Health Consortium, Johannesburg, South Africa

10:00 – 10:15 Safety monitoring in immunization in pregnancy efforts at the National Vaccine Program Office
Karin Bok, Senior Vaccine Science Advisor, Vaccine Safety Lead, National Vaccine Program Office, Department of Health and Human Services, Washington, D.C.

10:15 – 10:30 Safety monitoring in immunization in pregnancy efforts in NIH
Mirjana Nesin, Senior Medical Officer, NIH / NIAID / DMID, Bethesda, Maryland, U.S.A.

10:30 – 10:45 GAIA Project Overview
Jan Bonhoeffer, President, Brighton Collaboration Foundation; Vice-Chair, Pediatric Infectious Diseases and Vaccines, University Children's Hospital, Basel, Switzerland

10:45 – 11:15 **Panel Discussion**

11:15 – 11:30 **Coffee Break**

Session 2
Challenges and opportunities for providing guidance
Addressing regulatory considerations in the clinical development of vaccines indicated for use in pregnancy
Chair: Marion Gruber, Director**,** Office of Vaccines Research and Review, CBER / FDA, Silver Spring, Maryland, U.S.A.

11:30 – 11:45 Pre-licensure Safety assessments in the neonate and infant: Summary of the deliberations from the Vaccines and Related Biological products Advisory Committee on Maternal Immunization.
Marion Gruber, Director**,** Office of Vaccines Research and Review, CBER / FDA, Silver Spring, Maryland, U.S.A.

11:45 - 12:00 Post-marketing surveillance systems for Immunization in Pregnancy
Hector Izurieta, Office of Biostatistics and Epidemiology, CBER/FDA, Silver Spring, Maryland, U.S.A.

12:00 – 12:15 Addressing regulatory challenges for data and labelling in EMA
Pieter Neels, Member of the Board, IABS-EU; former CHMP member; former EMA Vaccine Working Party Vice-chair; Associate Professor University of Namur; Director, Vaccine-Advice BVBA, Zoersel, Belgium

12:15 – 12:30 Approach to licensing and labelling of vaccines for immunization in pregnancy – developing countries
James Southern, Advisor to the South Africa Medicines Control Council, Cape Town, South Africa

12:30 – 13:00 Panel Discussion

13:00 – 14:00 **Buffet Lunch**

Session 3
Defining neonatal and obstetric outcomes

Co-chairs:
Christopher Zahn, Vice President, Practice Activities, American College of Obstetricians and Gynecologists, Washington, D.C.
Sonali Kochhar, CEO and Medical Director, Global Healthcare Consulting

14:00 - 14:30 GAIA Clinical Trials Guidelines and Data Collection Matrix
Chrissie Jones, Clinical Lecturer, St. George's University of London, United Kingdom
Flor Muñoz, Associate Professor of Pediatrics, Baylor College of Medicine, Houston, Texas, U.S.A

14:30 – 15:00 Defining maternal outcomes
Linda Eckert, Professor of Obstetrics & Gynecology, University of Washington, Seattle, Washington, U.S.A.

15:00 – 15:30 Defining neonatal outcomes
Flor Muñoz, Associate Professor of Pediatrics, Baylor College of Medicine, Houston, Texas, U.S.A.

15:30 – 15:45 **Coffee break**

15:45 – 16:45 **Discussion** on applicability and usefulness of guidance, matrix and case definitions

Day 2 – Wednesday, March 30, 2016

08:00 – 08:30 **Registration**

08:30 – 08:45 Summary of Day 1
Jan Bonhoeffer, President, Brighton Collaboration Foundation; Vice-Chair, Pediatric Infectious Diseases and Vaccines, University Children's Hospital, Basel, Switzerland

Session 4
Observational studies

Chair: James Stark, Pfizer, New York, New York, U.S.A.

08:45 – 09:00 Review of observational research studies of neonatal and obstetric outcomes following immunization in LMIC
Daniel Weibel, Assistant Professor**,** Erasmus Medical Center, Rotterdam, The Netherlands

09:00-09:15 Methodological challenges in conducting observational research on pregnancy outcomes
Sonia Hernandez-Diaz, Professor of Epidemiology, Harvard T.H. Chan School of Public Health, U.S.A.

09:15 – 09:30 Implementation of a survey to assess feasibility of implementing neonatal and obstetric outcomes for observational research in LMIC
James Stark, Pfizer, New York, New York, U.S.A.

09:30 – 09:45 Surveillance of pre-and-post-natal care in LMIC: assessments from the field
Christentze Schmiegelow, Project Leader; Centre for Medical Parasitology, Department of Immunology and Microbiology University of Copenhagen, Copenhagen, Denmark

09:45 – 10:15 **Panel Discussion**

10:15 – 10:30 **Coffee Break**

Session 5

Elements of a clinical trial and post licensure monitoring platform

Chair: Miriam Sturkenboom, Erasmus University Medical Center, Rotterdam, The Netherlands; President of VACCINE.GRID Foundation

10:30 – 10:45 CDC maternal immunization safety monitoring activities
Pedro Moro, Medical Epidemiologist, Centers for Disease Control and Prevention, Atlanta, Georgia, U.S.A.

10:45 - 11:00 Maternal Immunization Pharmacovigilance in LMIC
Eve Lackritz, Deputy Director, Seattle Children's, Global Alliance to Prevent Prematurity and Stillbirth (GAPPS), Seattle, Washington, U.S.A.

11:00 – 11:15 Harmonising safety assessment in PAHO countries - focus on immunisation in pregnancy programs in LMIC
Alba Maria Ropero Alvarez, Unit Chief, Comprehensive Family Immunization at Pan American Health Organization (PAHO)

11:15 – 11:45 Harmonized case definition- code mapping of key terms, enabling terms
Steven Hirschfeld, Associate Director for Clinical Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, Maryland, U.S.A.
Theresa Quinn, National Cancer Institute, Bethesda, Maryland, U.S.A.; **George Chang**, National Cancer Institute, Bethesda, Maryland, U.S.A

11:45 – 12:00 Requirements for a data sharing infrastructure
Miriam Sturkenboom, Erasmus University Medical Center, Rotterdam, The Netherlands; President of VACCINE.GRID Foundation

12:00 – 12:30 **Panel Discussion** (including Saad Omer, Professor, Emory Vaccine Centre)

12:30 – 13:30 **Buffet Lunch**

Session 6

Stakeholder implementation of tools and standards

Chair: Alejandro Cravioto, Senior Scientist, Global Evaluative Sciences, Inc., Seattle, Washington, U.S.A.

13:30 – 13:40 Manufacturer perspective I
Linda Hanssens, Pediatric Vaccines, GlaxoSmithKline Biologicals, Rixensart, Belgium

13:40 – 13:50 Manufacturer perspective II
Tamala Mallet-Moore, Global Pharmacovigilance and Epidemiology, Sanofi Pasteur, Swiftwater, Pennsylvania, U.S.A.

13:50 – 14:00 Manufacturer perspective III
Allison August, Maternal Immunization Development, Novavax, Gaithersburg, Maryland, U.S.A.

14:00 – 14:30 **Panel Discussion**

14:30 – 14:45 Monitoring maternal and neonatal health outcomes in LMIC
Peter Waiswa, Lead, International Network of Health Demographic Surveillance Sites (INDEPTH Network)

14:45 – 15:00 Harmonising safety assessment in immunisation in pregnancy clinical trials in Nepal
Mark Steinhoff, Director, Global Health Center, Cincinnati Children's Hospital

15:00 --15:15 **Coffee Break**

15.15 - 15.30 Establishing safety monitoring for a maternal immunization clinical trial in a The Gambia and considerations for implementation
Ed Clarke, Medical Research Council UK, The Gambia Unit, Banjul, The Gambia

15.30 - 15.45 Harmonized safety monitoring of immunization in pregnancy implementation- Zika vaccine
Richard H. Beigi , Associate Professor, Magee-Womens Hospital , Pittsburgh, USA

15:45 – 16:00 Considerations for conducting a Zika vaccine trial for Immunization in Pregnancy in LIMC's
Anthony A Marfin, Medical Epidemiologist, Japanese Encephalitis Vaccine Introduction & Sustainability Project, PATH

16:00 – 16:30 Panel discussion (including **Bill Kapogiannis**, Program Director, NICHD; **Margarita Gomez Lorenzo**, Medical Officer, NIAID; **Saad Omer**, Professor, Emory Vaccine Centre)

Session 7

Conclusions and Next Steps

Chair: Steven Hirschfeld, Associate Director for Clinical Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, Maryland, U.S.A

16:30 – 17:15 Panel discussion: consensus during conference and proposed road map towards optimal safety data for immunization in pregnancy based on a globally harmonized approach (including the **Session Chairs and Jan**)

17:15 – 17:30 Summing up and the way forward
Steven Hirschfeld, Associate Director for Clinical Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, Maryland, U.S.A.

17:30 **Close of conference**