



Assessing Consequences of Maternal Immunization on Foetal Outcomes

June 9-10, 2026 in Zurich, Switzerland

For many years, vaccination during pregnancy was avoided due to concerns of adverse events to the baby. In recent years the data on benefit to protect both the pregnant woman and her child against several infectious diseases (e.g. tetanus, pertussis, influenza and COVID-19) have been convincing, leading to routine recommendations. Respiratory Syncytial Virus (RSV) is a major pathogen with substantial morbidity and mortality. Early attempts at vaccination of young infants with an inactivated vaccine resulted in enhanced disease following natural infection. Two companies independently initiated Phase-3 randomized clinical trials (RCT) of candidate RSV preF vaccines in pregnant women. One of the trials was halted because of a higher risk of preterm birth in the vaccine group. The RCT of the other vaccine in pregnant women led to approval with restrictions on use in early pregnancy in some jurisdictions. Following use of this vaccine, there is convincing evidence that infant RSV disease has been reduced, and the WHO and other vaccine advisory bodies have recommended its use during pregnancy. An alternative approach has been the use of monoclonal antibody against the prefusion protein.

Other candidate vaccines for use in pregnancy are under development e.g. candidate mRNA RSV, Group B Streptococcus and Zika virus vaccines. Safety of novel vaccines administered during pregnancy must be carefully assessed including possible impact on preterm birth. Some of these pathogens can cause preterm birth, so maternal vaccination might reduce preterm births.

The methods to study safety in future interventional and observational clinical studies require robust clinical data and strong statistical methods that use optimal approaches. The clinical relevance of a possible increased risk of preterm birth must be considered in a benefit-risk assessment.

In 2026, IABS will hold a Workshop aiming to contribute to methodology for safety assessment of maternal vaccines. The objective is to allow clinical, medical and statistical scientists including regulatory authorities to suggest standardized assessment of the impact of maternal immunization on preterm birth. The forum will engage multiple specialists in obstetrics, pediatrics, biostatistics, vaccine developers and regulators to discuss multiple perspectives around vaccination during pregnancy. These include methods to assess gestational age, the preferred time window for vaccination, collection of clinical/medical data concerning the preterm birth (potential causes, clinical assessment of the infant...) and the consequences of premature birth in different locales.

Scientific/Organizing Committee

Frank **Vandendriessche** – IABS Co-Chair of the Human Vaccines Committee, Belgium
Steve **Black** – Global Vaccine Data Network
Marco **Cavaleri** – European Medicines Agency, UK
Rebecca **Chandler** – CEPI, Sweden
Janet **Englund** – Seattle Children’s Hospital, USA
Stephen **Evans** – London School of Hygiene & Tropical Medicine, UK
Tessa **Goetghebuer** – Saint-Pierre Hospital, Belgium
David **Kaslow** – CBER FDA, USA
Isabel **Leroux-Roels** – Gent University, Belgium
Arnaud **Marchant** – Faculty of Medicine ULB, Belgium

Pieter **Neels** – IABS Co-Chair of the Human Vaccines Committee, Belgium
Pierrette **Melin** – Liege University, Belgium
Flor **Muñoz** – Texas Children’s Hospital, USA
Lidia **Oostvogels** – Minervax, Denmark
David **Radley** – Pfizer, USA
Anna **Seale** – Gates Foundation, UK
Kathryn **Edwards** – Vanderbilt University, USA
Kirsten **Maertens** – Antwerpen University, Belgium
Peggy **Webster** – GSK, USA
Jennifer **Griffin** – Global Vaccine Data Network

Workshop Preliminary Program

Day 1

Registration & Welcome Coffee

Opening of the meeting – Welcome

Pieter **Neels** and Frank **Vandendriessche** - IABS

Session I

Session Chair(s): TBC

Vaccination of pregnant women: the past, the present and the future

Flor **Muñoz** – Texas Children’s Hospital, USA

Data and analysis from the GSK GRACE trial

TBC, GSK, USA

Data and analysis from the Pfizer MATISSE trial

David **Radley** - Pfizer, USA

Role/perspective of DSMB's Chairs

Flor **Muñoz** – Texas Children’s Hospital, USA

Morning Coffee Break

Summary of findings and how it informed the impact study

TBC

Panel Discussion: Regulatory authority and vaccine recommending bodies considerations

EMA, FDA, AMA, WHO-AFRO, SAPHRA, UK

Could statistical methods matter?

Stephen Evans – London School of Hygiene & Tropical Medicine, UK

Lunch

Session II: Break Out Session

Session Chair(s): TBC

Introduction Breakouts: How to assess safety in RCT's: possible endpoints/outcomes and methodologies

Pieter Neels - IABS

Breakout (1): what outcomes related to prematurity to look at in RCT's

Breakout (2): what statistical methodologies can be used

Stephen Evans – London School of Hygiene & Tropical Medicine, UK

Afternoon Coffee Break

Feedback from breakout sessions

The results of Phase-2 study Immunogenicity and Safety of GBS-NN/NN2 in Pregnant Women

Lidia Oostvogels – Minervax, Denmark

Study of mRNA-1345 Vaccine Targeting Respiratory Syncytial Virus in Pregnant Women and in Infants Born to Vaccinated Mothers

TBC, Moderna

Safety database for VacPertagen for use for maternal immunization

TBC

Planned safety assessment in Pfizer's Phase-3 GBS trial, BEATRIX

David Radley – Pfizer, USA

Conclusion & End of Day 1

Day 2

Registration & Welcome Coffee

Welcome back

Pieter Neels and Frank Vandendriessche - IABS

Session III

Session Chair(s): TBC

Contextualising prematurity

TBC

What can be learned from vaccines already implemented?

Janet **Englund** – Seattle Children’s Hospital, USA

Options to assess safety in the future using observational datasets and RWD?

Jennifer **Griffin** – Global Vaccine Data Network

& Ben **Atkins** – Global Vaccine Data Network

Is a different methodology needed for RCT’s and non RCT data sets?

TBC

Morning Coffee Break

How to tackle causality assessment: work done in WHO context

Kathryn **Edwards** - Vanderbilt University, USA

How to tackle causality assessment: statistical aspects

TBC

Panel Discussion: Regulatory perspectives on post-approval approaches for assessment of safety of RSV vaccination – What was learned

EMA, FDA, WHO, AMA, SAFRA

Lunch

Session IV: Break Out Session

Session Chair(s): TBC

Introduction Break Out: Breakout: Brainstorming on how future data sets best are generated?

TBC

Breakout Groups

Feedback from the breakout session

Reporters

Wrap-up: ways forward from a statistical/methodological perspective

Stephen **Evans** - London School of Hygiene & Tropical Medicine, UK

Afternoon Coffee Break

Wrap-up: ways forward from a clinical/medical perspective

TBC

Ways forward from a regulatory and NITAG perspective

TBC

Conclusion & End of the meeting