IABS & IABS-EU Workshop on Assessing Consequences of Maternal Immunization on Foetal Outcomes

June 8-9, 2026 | Dorint Airport Hotel, Zurich, Switzerland

- HYBRID EVENT -

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, USA
Marco **Cavaleri** – European Medicines Agency, UK
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
Pierrette **Melin** – Liege University, Belgium
Pieter **Neels** – IABS Co-Chair of the Human Vaccines Committee, 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, USA
Nina **Wressnigg** – CEPI, Austria

Editorial Committee

Norman **Baylor** – Editor-in-Chief, Biologicals
Frank **Vandendriessche** – IABS Co-Chair of the Human Vaccines Committee, Belgium
Pieter **Neels** – IABS Co-Chair of the Human Vaccines Committee, Belgium

Day 1 – Monday 8th of June

8.30-9.00am **Registration & Welcome Coffee**

9.00-9.10am **Opening of the meeting – Welcome**
Pieter **Neels** and Frank **Vandendriessche** - IABS

Session I - Experience from RCT's with RSV maternal vaccines
Session Chair(s): TBC

9.10-9.25am **Vaccination of pregnant women: scientific context and scope of discussion**
Flor **Muñoz** – Texas Children's Hospital, USA

9.25-9.45am **Data and analysis from the GSK GRACE trial**
Jens-Ulrich **Stegmann**, GSK, USA

9.45-10.05am **Data and analysis from the Pfizer MATISSE trial**
David **Radley** - Pfizer, USA

10.05-10.20am **Role/perspective of DSMB's Chairs**
Geeta **Swamy -** Duke University School of Medicine, USA (Virtual)
Flor **Muñoz** – Texas Children's Hospital, USA

10.20-10.50am ***Morning Coffee Break***

10.50-11.10am **Summary of the RSV vaccine findings and how it informed impact studies**
Shabir **Madhi** – University of Witwatersrand, South Africa (Virtual)

11.10-11.30am	**Could statistical methods matter?** Stephen **Evans** – London School of Hygiene & Tropical Medicine, UK (Virtual)
11.30am-12.10pm	**Panel Discussion: Considerations from regulatory authority and vaccine recommending bodies considerations** Marco **Cavaleri –** EMA, UK Hanna **Nohynek** - Finnish Institute for Health and Welfare, Finland James **Southern -** SAHPRA Kirsty **Le Doare –** University of London, UK TBC AMA, WHO-AFRO
12.10-1.10pm	***Lunch***

Session II - Break Out Session Sessions – What can be done differently in RCT's
Session Chair(s): TBC

1.10-1.25pm	**Introduction Breakouts: How to assess safety in RCT's: possible endpoints/outcomes and methodologies** Steve **Black** – Global Vaccine Data Network, USA
1.25-2.05pm	**Breakout (1): what outcomes related to prematurity to look at in RCT's** Facilitator: Alex **Duga** – CDC, Ethiopia
2.05-2.55pm	**Breakout (2): what statistical methodologies can be used** Facilitator: David **Radley** – Pfizer, USA
2.55-3.25pm	***Afternoon Coffee Break***
3.40-4.00pm	**Feedback from breakout sessions** - Statistics: Delyth **Jones** – GSK, UK - Clinical: Flor **Muñoz** – Texas Children's Hospital, USA

Session III - Looking beyond RSV vaccines
Session Chair(s): TBC

3.15pm-4.05pm	**Immunogenicity and Safety assessment of GBS-NN/NN2 in Pregnant Women** Lidia **Oostvogels** – Minervax, Denmark
4.05-4.25pm	**Planned safety assessment in Pfizer's Phase-3 GBS trial, BEATRIX** David **Radley** – Pfizer, USA
4.25-4.45pm	**Safety and Immunogenicity of a two dose Ebola vaccine among pregnant women in Rwanda**

Julien **Nyombayire** - Center for Family Health Research, Rwanda

4.45-4.55pm *Sanitary Break*

4.55-5.15pm **Mpox (MVA-BN) vaccination in pregnancy. Perspectives and challenges in data collection in remote resource-constrained settings (PregInPoxVac)**
Paulina **Morales-Ruiz** - Global Health Institute, University of Antwerp, Belgium
Solange **Milolo** – University of Kinshasa, Congo

5.15-5.35pm **Pregnancy outcomes following maternal vaccination with a Pertussis-Only Vaccine: evidence from three observational studies**
Souad **Mansouri** – BioNet, Thailand

5.35-5.45pm *Conclusion & End of Day 1*

Day 2 – Tuesday 9th of June

8.00-8.25am **Registration & Welcome Coffee**

8.25-8.30am **Welcome back**
Pieter **Neels** and Frank **Vandendriessche - IABS**

Session IV - Looking beyond registrational RCT data sets
Session Chair(s): TBC

8.30-8.50am **Contextualising prematurity**
Jezid **Miranda -** Universidad de Cartagena, Colombia
Hannah **Davies** - London School of Hygiene & Tropical Medicine, UK

8.50-9.10am **What can be learned from vaccines already implemented?**
Janet **Englund** – Seattle Children's Hospital, USA

9.10-9.30am **Assessing the Safety of Maternal Immunization in Observational and Real World Data: Lessons learned from a global study**
Benjamin **Atkins** – Global Vaccine Data Network, Australia

9.30-9.40am **Is a different methodology needed for RCT's and non RCT data sets?**
Stephen **Evans** – London School of Hygiene & Tropical Medicine, UK (Virtual)

9.40-9.50am **How to tackle causality assessment: work done in WHO context**
Kathryn **Edwards -** Vanderbilt University, USA

9.50am-10.10am ***Morning Coffee Break***

10.20-11.00am	**Panel Discussion: Regulatory perspectives on post-approval approaches for assessment of safety of RSV vaccination – What was learned** Marco **Cavaleri** - EMA, UK James **Southern –** SAHPRA TBC FDA, WHO, AMA

Session V - Break Out Session - What can be done differently with observational & RWE data sets
Session Chair(s): TBC

11.00-11.50pm	**Breakout discussion: Brainstorming on how future data sets best are generated?** Facilitator: Anette **Regan** – Kaiser Permanente, USA
11.50-12.05pm	**Feedback from the breakout session** Jennifer **Griffin** – Global Vaccine Data Network, USA
12.05-12.25pm	**Strengthening quality assurance in clinical research in resource-constrained settings: The ethical imperative to develop, implement, and evaluate ancillary care policies"** Gwen **Lemey** - University of Antwerp, Belgium
12.25-1.25pm	***Lunch***

Session VI – Wrapping up
Session Chair(s): TBC

1.25-1.45pm	**Wrap-up: ways forward from a statistical/methodological perspective** **TBC**
1.45pm-2.05pm	**Wrap-up: ways forward from a clinical/medical perspective** Flor **Muñoz** – Texas Children's Hospital, USA Kristy **Le Doare –** University of London, UK
2.05-2.25pm	**Ways forward from a regulatory and NITAG perspective** Marco **Cavaleri** – EMA, UK
2.25pm-2.40pm	**Actions to progress** Steve **Black** – Global Vaccine Data Network, USA
2.40-2.50pm	*Conclusion & End of the meeting* Pieter **Neels** and Frank **Vandendriessche** – IABS, Belgium