

HYBRID WORKSHOP



# SCIENTIFIC WORKSHOP ASSESSING POTENTIAL CONSEQUENCES OF MATERNAL IMMUNIZATION ON NEONATAL OUTCOMES

June 8-9 2026 - Zurich, Switzerland



**Website**

[events.iabs.org/Maternal-Immunization](https://events.iabs.org/Maternal-Immunization)

*Europe*



International Alliance for  
Biological Standardization

# OBJECTIVES OF THE WORKSHOP

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 hybrid Workshop in Zurich (CH) 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 COMMITTEE

- Frank VANDENDRIESSCHE – IABS Co-Chair of the Human Vaccines Committee, Belgium
- Pieter NEELS – IABS Co-Chair of the Human Vaccines Committee, Belgium
- Steve BLACK – Global Data Network, U.S.A.
- Marco CAVALERI – European Medicines Agency, UK
- Rebecca CHANDLER – CEPI, Sweden
- Kathryn EDWARDS – Vanderbilt University, Medical Center, U.S.A.
- Janet ENGLUND – Seattle Children’s Hospital, U.S.A.
- Stephen EVANS – London School of Hygiene & Tropical Medicine, UK
- Tessa GOETGHEBUER – Saint-Pierre Hospital, Belgium
- Jennifer GRIFFIN – Global Data Network, U.S.A.
- David KASLOW – CBER FDA, U.S.A.
- Isabel LEROUX-ROELS – Gent University, Belgium
- Arnaud MARCHANT – Faculty of Medicine ULB, Belgium
- Kirsten MAERTENS – Antwerpen University, Belgium
- Pierrette MELIN – Liege University, Belgium
- Flor MUÑOZ – Baylor College of Medicine, U.S.A.
- Lidia OOSTVOGELS – Minervax, Denmark
- David RADLEY – Pfizer, U.S.A.
- Anna SEALE – Gates Foundation, UK
- Peggy WEBSTER – GSK, U.S.A.

# ORGANIZING COMMITTEE

- Frank VANDENDRIESSCHE – IABS Co-Chair of the Human Vaccines Committee, Belgium
- Pieter NEELS – IABS Co-Chair of the Human Vaccines Committee, Belgium
- Steve BLACK – Global Vaccine Data Network, U.S.A.
- Kathryn EDWARDS – Vanderbilt University – Medical Center, U.S.A.
- Lidia OOSTVOGELS – Minervax, Denmark
- Flor MUÑOZ – Baylor College of Medicine, U.S.A.
- Marlène MARTINS – IABS Secretariat

# 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

# AGENDA

TIMES ARE INDICATED CET TIME

## DAY 1 - Monday 8 of June, 2026

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8.30-9.00am *Registrations*

9.00-9.10am Opening of the meeting – Welcome  
Pieter Neels and Frank Vandendriessche – Co-chairs of the Human Vaccine Committee, IABS

### Session I – Experience from RCT's with RSV maternal vaccines

Session Chair: Anna Seale, Gates Foundation, U.S.A.

9.10-9.25am **Vaccination of pregnant women: scientific context and scope of discussion**  
Flor Muñoz – Baylor College of Medicine, U.S.A.

9.25-9.50am **Data and analysis from the GSK GRACE trial**  
Jens-Ulrich Stegmann – GSK, U.S.A.

9.50-10.15am **Data and analysis from the Pfizer MATISSE trial**  
David Radley – Pfizer, U.S.A.

10.15-10.30am **General Perspective of DSMB Chairs**  
Flor Muñoz – Baylor College of Medicine, U.S.A.  
Kathryn Edwards – Vanderbilt University, U.S.A.  
Steve Black – Global Vaccine Data Network, U.S.A.

10.30-11.00am *Morning Coffee Break*

11.00-11.25am **Summary of the RSV vaccine findings on prematurity and how it informed impact studies**  
Shabir Madhi – University of Witwatersrand, South Africa (**Virtual**)

11.25-11.45am **Could statistical methods matter?**  
Stephen Evans – London School of Hygiene & Tropical Medicine, UK  
**(Virtual)**

11.45am-12.25pm **Panel Discussion: Considerations from regulatory authority and vaccine recommending bodies considerations**  
*Moderator: Hanna Nohynek – Finnish Institute for Health and Welfare, Finland*

Marco Cavaleri – EMA, UK  
James Southern – SAHPRA, South Africa  
Madhava Ram Balakrishnan – WHO, Switzerland  
Victoria Prudence Nambasa – AMA, South Africa **(Virtual)**  
Conall Watson – UKHSA, UK  
Marion Gruber – IAVI, U.S.A. **(Virtual)**

12.25-1.25pm *Lunch Break*

**Session II - Break Out Sessions – What can be done differently in RCT's**  
Session Chair: Steve Black, Global Vaccine Data Network, U.S.A.

1.25-1.35pm **Introduction Breakouts: How to assess safety in RCT's: possible endpoints/outcomes and methodologies**  
Steve Black – Global Vaccine Data Network, U.S.A.

1.35-2.20pm **Breakout (1): what outcomes related to prematurity to look at in RCT's**  
Facilitators:  
Alex Duga – CDC, Ethiopia  
Flor Muñoz – Baylor College of Medicine, U.S.A.

2.20-3.00pm **Breakout (2): what statistical methodologies can be used**  
Facilitator: Benjamin Atkins – Global Vaccine Data Network, Australia

- **Additional analysis on the MATISSE trial**  
David Radley – Pfizer, U.S.A.
- **Additional analysis on the GRACE trial**  
Delyth Jones – GSK, UK

3.00–3.30pm *Afternoon Coffee Break*

3.30–3.50pm **Feedback from breakout sessions & Q&A**

- Statistics: Benjamin Atkins – Global Vaccine Data Network, Australia
- Clinical: Flor Muñoz – Baylor College of Medicine, U.S.A.

### **Session III - Looking beyond RSV vaccines**

Session Chair: Janet Englund, Seattle Children's Hospital, U.S.A.

3.50–4.10pm **Immunogenicity and Safety assessment of GBS-NN/NN2 in Pregnant Women**  
Lidia Oostvogels – Minervax, Denmark

4.10–4.30pm **Planned safety assessment in Pfizer's Phase-3 GBS trial, BEATRIX**  
David Radley – Pfizer, U.S.A.

4.30–4.50pm **Safety and Immunogenicity of a two dose Ebola vaccine among pregnant women in Rwanda**  
Julien Nyombayire – Center for Family Health Research, Rwanda

4.50–5.00pm *Sanitary Break*

5.00–5.20pm **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

5.20–5.40pm **Pregnancy outcomes following maternal vaccination with recombinant pertussis vaccines: Evidence from three observational studies in Thailand**  
Souad Mansouri – BioNet, Thailand

5.40–5.50pm Conclusion & End of Day 1

## DAY 2 - Tuesday 9 of June, 2026

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8.00–8.25am *Registrations*

8.25–8.30am Welcome back  
Pieter Neels and Frank Vandendriessche – Co-chairs of the Human Vaccine Committee, IABS

### **Session IV – Looking beyond registrational RCT data sets**

Session Chair: Flor Muñoz – Baylor College of Medicine, U.S.A.

8.30–8.40am **Contextualising prematurity**  
Jezid Miranda – Universidad de Cartagena, Colombia

8.40–8.50am **Prematurity Across the Lifecourse: Consequences, Context, and Inequity**  
Hannah Davies – London School of Hygiene & Tropical Medicine, UK

8.50–9.10am **Lessons Learned from Maternal Immunization**  
Janet Englund – Seattle Children’s Hospital, U.S.A.

9.10–9.20am **Is a different methodology needed for RCT’s and non RCT data sets?**  
Stephen Evans – London School of Hygiene & Tropical Medicine, UK  
**(Virtual)**

9.20–9.40am **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

9.40–10.00am **How to tackle causality assessment of adverse events following immunization (AEFI) and maternal immunization (AEFMI)**  
Kathryn Edwards – Vanderbilt University, U.S.A.  
Madhava Ram Balakrishnan – WHO, Switzerland

10.00–10.30am *Morning Coffee Break*

10.30-11.10am **Panel Discussion: methods for post approval assessment of safety of maternal vaccination – What was learned?**

*Moderator: Nina Wressnigg, CEPI, Austria*

Nick Andrews – UKHSA, UK **(Virtual)**

Marco Cavaleri – EMA, UK

Deshayne Fell – Pfizer, U.S.A.

Annette Regan – Kaiser Permanente, U.S.A.

Stephen Evans – London School of Hygiene & Tropical Medicine, UK **(Virtual)**

Kirsty Le Doare – City St George's, University of London, UK

Katerina Rok Song – IVI, South Korea

Shabir Madhi – University of Witwatersrand, South Africa **(Virtual)**

**Session V – Break Out Session – What can be done differently with observational & RWE data sets**

11.10am-12.00pm **Breakout discussion: Brainstorming on how future data sets best are generated?**

Facilitator: Annette Regan – Kaiser Permanente, U.S.A.

12.00-12.15pm **Feedback from the breakout session**

Annette Regan – Kaiser Permanente, U.S.A.

12.15-12.35pm **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

12.35-1.35pm *Lunch*

**Session VI – Wrapping up**

Session Chair: Kathryn Edwards – Vanderbilt University, U.S.A.

1.35-1.55pm **Wrap-up: ways forward from a statistical/methodological perspective**

Annette Regan – Kaiser Permanente, U.S.A.

Benjamin Atkins – Global Vaccine Data Network, Australia

- 1.55-2.15pm **Wrap-up: ways forward from a clinical/medical perspective**  
Kirsty Le Doare – City St George’s, University of London, UK  
Flor Muñoz – Baylor College of Medicine, U.S.A.
- 2.15-2.35pm **Ways forward from a regulatory and NITAG perspective**  
Marco Cavaleri – EMA, UK
- 2.35-2.50pm **Actions to progress**  
Steve Black – Global Vaccine Data Network, U.S.A.
- 2.50-3.00pm *Conclusion & End of the meeting*  
Pieter Neels and Frank Vandendriessche – Co-chairs of the Human Vaccine Committee, IABS