E-BOOK

SCIENTIFIC WORKSHOP

Assessing Potential Consequences of Maternal Immunization on Neonatal Outcomes

8–9 June, 2026

Zurich, Switzerland

Europe

IABS

IABS

International Alliance for Biological Standardization

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ABOUT THE CONFERENCE

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 COMMITTEES

Scientific Committee

Pieter Neels – **IABS Co-Chair of the Human Vaccines Committee, Belgium**
Frank Vandendriessche – **IABS Co-Chair of the Human Vaccines Committee, Belgium**
Steve Black – **Global Vaccine Data Network, U.S.A.**
Marco Cavaleri – **European Medicines Agency, UK**
Kathryn Edwards – **Vanderbilt University, U.S.A.**
Janet Englund – **Seattle Children's Hospital, U.S.A.**
Stephen Evans – **London School of Hygiene & Tropical Medicine, UK**
Tessa Goetghebeur – **Saint-Pierre Hospital, Belgium**
Jennifer Griffin – **Global Vaccine Data Network, U.S.A.**
Isabel Leroux-Roels – **Gent University, Belgium**
Kirsten Maertens – **Antwerpen University, Belgium**
Arnaud Marchant – **Faculty of Medicine ULB, Belgium**
Pierrette Melin – **Liege University, Belgium**
Flor Muñoz – **Baylor College of Medicine, U.S.A.**
David Radley – **Pfizer, U.S.A.**
Anna Seale – **Gates Foundation, UK**
Peggy Webster – **GSK, U.S.A.**
Nina Wressnigg – **CEPI, Austria**

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**

SCIENTIFIC PROGRAM

Day 1: Monday 8 June, 2026

8:30 - 9:00 **Registration & Welcome Coffee**

9:00 - 9:10 **Opening of the Meeting – Welcome**
Pieter Neels and Frank Vandendriessche - Co-chairs of the Human Vaccine Committee, IABS

Session 1: Experience from RCT's with RSV maternal vaccines

Session Chair: Anna Seale, Gates Foundation

9:10 - 9:25 **Vaccination of pregnant women: scientific context and scope of discussion**
Flor Muñoz, Baylor College of Medicine, U.S.A.

9:25 - 9:50 **Data and analysis from the GSK GRACE trial**
Jens-Ulrich Stegmann, GSK, U.S.A.

9:50 - 10:15 **Data and analysis from the Pfizer MATISSE trial**
David Radley, Pfizer, U.S.A.

10:15 - 10:30 **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 - 11:00 **Morning Coffee Break**

11:00 - 11:25 **Summary of the RSV vaccine findings on prematurity and how it informed impact studies -** Shabir Madhi, University of Witwatersrand, South Africa (virtual)

11:25 - 11:45 **Could statistical methods matter?**
Stephen Evans, London School of Hygiene & Tropical Medicine, UK (virtual)

SCIENTIFIC PROGRAM

11:45 - 12:25

Panel Discussion: Considerations from regulatory authority and vaccine recommending bodies considerations
Moderator: Hanna Nohynek, Finnish Institute for Health Finland
Marco Cavaleri, EMA, UK
James Southern, SAHPRA, South Africa
Madhava Ram Balakrishnan, WHO, Switzerland
Victoria Prudence Nambasa, AMA, South Africa
Conall Watson, UKHSA, UK
Marion Gruber, IAVI, U.S.A. (virtual)

12:25 - 1:25 Lunch Break

Session 2: Break Out Sessions – What can be done differently in RCT's

Session Chair: Steve Black, Global Vaccine Data Network, U.S.A.

1:25 - 1:35

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 - 2:20

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 - 3:00

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 - 3:30 Afternoon Coffee Break

3:30 - 3:50

Feedback from breakout sessions & Q&A
- **Statistics:** Benjamin Atkins, Global Vacccine Data Network, Australia
- **Clinical:** Flor Muñoz, Baylor College of Medicine, U.S.A.

SCIENTIFIC PROGRAM

Session 3: Looking beyond RSV vaccines

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

3:50 - 4:10 **Immunogenicity and Safety assessment of GBS-NN/NN2 in Pregnant Women**
Lidia Oostvogels, Minervax, Denmark

4:10 - 4:30 **Planned safety assessment in Pfizer's Phase-3 GBS trial, BEATRIX**
David Radley, Pfizer, U.S.A.

4:30 - 4:50 **Safety and Immunogenicity of a two dose Ebola vaccine among pregnant women in Rwanda**
Julien Nyombayire, Center for Family Health Research, Rwanda

4:50 - 5:00 **Sanitary Break**

5:00 - 5:20 **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 - 5:40 **Pregnancy outcomes following maternal vaccination with recombinant pertussis vaccines: Evidence from three observational studies in Thailand**
Souad Mansouri, BioNet, Australia

5:40 - 5:50 **Conclusion & End of Day 1**

SCIENTIFIC PROGRAM

Day 2: Tuesday 9 June, 2026

8:00 - 8:25 **Registration & Welcome Coffee**

8:25 - 8:30 **Welcome back**
Pieter Neels and Frank Vandendriessche - Co-chairs of the Human Vaccine Committee, IABS

Session 4: Looking beyond registrational RCT data sets

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

8:30 - 8:40 **Contextualising prematurity**
Jezid Miranda, Universidad de Cartagena, Colombia

8:40 - 8:50 **Prematurity Across the Lifecourse: Consequences, Context, and Inequity**
Hannah Davies, London School of Hygiene & Tropical Medicine, UK

8:50 - 9:10 **Lessons Learned from Maternal Immunization**
Janet Englund, Seattle Children's Hospital, U.S.A.

9:10 - 9:20 **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 - 9:40 **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 - 10:00 **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 - 10:30 Morning Coffee Break

10:30 - 11:10 **Panel Discussion: methods for post approval assessment of safety of maternal vaccination – What was learned?**
Moderator: Nina Wressnigg, CEPI, Austria
Nick Andrews, UKHSA, UK
Marco Cavaleri, EMA, UK
Stephen Evans, London School of Hygiene & Tropical Medicine, UK (Virtual)
Deshayne Fell, Pfizer, U.S.A.
Kirsty Le Doare, City St George's, University of London, UK
Shabir Madhi, University of Witwatersrand, South Africa (Virtual)
Annette Regan, Kaiser Permanente, U.S.A.
Katerina Rok Song, IVI, South Korea

SCIENTIFIC PROGRAM

Session 5: Break Out Session - What can be done differently with observational & RWE data sets

11:10 - 12:00
Breakout discussion: Brainstorming on how future data sets best are generated?
Facilitator: Anette Regan, Kaiser Permanente, U.S.A.

12:00 - 12:15
Feedback from the breakout session
Annette Regan, Kaiser Permanente, U.S.A.

12:15 - 12:35
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 - 1:35
Lunch Break

Session 6: Wrapping up

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

1:35 - 1:55
Wrap-up: ways forward from a statistical/methodological perspective
Anette Regan, Kaiser Permanente, U.S.A.
Benjamin Atkins, Global Vaccine Data Network, Australia

1:55 - 2:15
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 - 2:35
Ways forward from a regulatory and NITAG perspective
Marco Cavaleri, EMA, UK

2:35 - 2:50
Actions to progress
Steve Black, Global Vaccine Data Network, U.S.A.

2:50 - 3:00
Conclusion & End of the Meeting
Pieter Neels and Frank Vandendriessche - Co-chairs of the Human Vaccine Committee, IABS

UPCOMING IABS
CONFERENCES & WORKSHOPS

IABS-EU Inno4VAC Final Stakeholder Meeting

September 28-29, 2026
Leiden, The Netherlands

VIRTUAL MEETING

Regulatory Science Conference Bovine Serum: Challenges and Opportunities in the Research and Development and Manufacture of Vaccines and Other Biological Products

September 29-30, 2026
VIRTUAL MEETING

12th Statistics Workshop: From Data to Patients – CMC Statisticians Contributions to Quality, Safety, and Efficacy of Pharmaceutical Products

October 20-22, 2026
Rockville, MD, U.S.A.

5th Controlled Human Infection Model Workshop

December, 2026
Southeast Asia

Analytics in Cell Therapy: Ensuring Quality in Flow Cytometry established guidelines for Flow Cytometry And QC needs in Cell Therapy

Spring 2027
Barcelona, Spain

3rd IABS Workshop on Real World Evidence: Pragmatic Randomized Controlled Vaccine Trials: towards global alignment and methodological standards

November 18-19, 2026
Leiden, The Netherlands

BIOSKETCH

Prof. Nick Andrews

UKHSA, UK

Prof Nick Andrews is Head of Vaccines Analysis within the Immunisation Department of the UK Health Security Agency. In this role he has worked extensively on post licensure vaccine safety, impact and effectiveness assessment, clinical trials and correlates of protection. He is a member of the World Health Organization Global Advisory Committee on Vaccine Safety and WHO SAGE Ebola and Malaria vaccine advisory groups. He is a project lead on a research collaboration on using electronic health records for vaccine assessment with the London School of Hygiene and Tropical Medicine (LSHTM). He regularly provides evidence vaccine effectiveness and safety to the Joint Committee on Vaccination and Immunisation. He lectures at the LSHTM, New York University in London and on vaccine courses internationally.

BIOSKETCH

Dr. Benjamin Atkins

GVDN, Australia

Ben is a Senior Statistician and Data Scientist for the Global Vaccine Data Network (GVDN), based at the Murdoch Children's Research Institute in Melbourne, Australia. In this role, he provides statistical and computational leadership for global vaccine safety studies, particularly Rapid Cycle Analyses (RCA), the estimation of background rates in LMICs, and maternal and neonatal safety following immunisation during pregnancy. Prior to his work in pharmacovigilance, Ben was a postdoctoral member of the COVID-19 response team at the University of Warwick, where he developed mathematical models to inform UK government decision-making during the pandemic. Ben holds a PhD in Mathematics for Real-World Systems from the University of Warwick, specialising in the mathematical modelling and management of infectious disease outbreaks. He is passionate about cross-disciplinary collaboration, novel computational solutions, and finding ways to communicate complex results to support data-driven public health decisions.

BIOSKETCH

Dr. Madhava Ram Balakrishnan

WHO, Switzerland

Dr Madhava Ram Balakrishnan is a medical epidemiologist and vaccine safety expert with extensive experience in immunization safety, pharmacovigilance, public health surveillance and health systems strengthening. He currently serves as Medical Officer in the Pharmacovigilance team at the World Health Organization (WHO) headquarters in Geneva, Switzerland, where his work focuses on global vaccine safety, adverse events following immunization (AEFI), adverse events following maternal immunization (AEFMI), causality assessment, digital tools, guidance development, training and country support. At WHO headquarters, Dr Balakrishnan has contributed to the development, refinement and implementation of WHO methodologies for AEFI causality assessment, including practical tools, training materials and electronic platforms that support consistent, transparent and evidence-based decision-making by national expert committees. He has played a central role in strengthening digital approaches for vaccine safety, including the WHO AEFI causality assessment software, VigiFlow- and VigiMobile-aligned reporting workflows, and electronic approaches that improve the quality, timeliness and use of safety data across immunization programmes and regulatory systems.
A major current area of his work is maternal immunization safety. He is leading the development of WHO guidance and tools for reporting, investigating and assessing the cause of AEFMI, including a structured methodology and software-assisted approach for evaluating events in pregnant women, foetuses and neonates. This work brings together case-based investigation, standardized data collection, expert causality assessment and risk communication, with technical inputs from international experts and country collaborators.

Dr Balakrishnan has contributed to WHO guidance, manuals and training resources on vaccine safety for priority public health contexts, including COVID-19, Ebola, mpox and maternal immunization. He also contributes to WHO vaccination policy guidance, including inputs to WHO vaccine position papers through the Immunization, Vaccines and Biologicals (IVB) steering processes. His technical support spans National

BIOSKETCH

Immunization Programmes, National Regulatory Authorities, WHO regional and country offices, and collaborating centres, with emphasis on practical implementation in diverse settings.

Before joining WHO headquarters, Dr Balakrishnan held technical roles with WHO in India and the WHO South-East Asia Region, where he supported and led surveillance and immunization-related work for vaccine-preventable diseases, including poliomyelitis, measles and Japanese encephalitis, as well as broader public health surveillance activities.

Selected areas of contribution:
• WHO AEFI causality assessment methodology, tools, training materials and software-assisted workflows.
• WHO AEFMI reporting, investigation and causality assessment framework for maternal, foetal and neonatal events.
• Vaccine safety guidance and training for COVID-19, Ebola, mpox and other priority immunization contexts.
• Support to Member States, National Immunization Programmes and National Regulatory Authorities on vaccine safety surveillance and pharmacovigilance systems.
• Technical inputs to WHO vaccination policy guidance and vaccine position paper processes.

ABSTRACT

Title: How to tackle causality assessment: work done in WHO context

Dr. Madhava Ram Balakrishnan, WHO, Switzerland
Prof. Kathryn Edwards, Vanderbilt University, U.S.A.

Maternal immunization strategies have been described as an approach to prevent serious disease in pregnant women and their infants. Maternal immunization with diphtheria toxoid was studied in the early 1950's. Tetanus toxoid vaccine was successfully implemented worldwide for prevention of maternal and neonatal tetanus based on early clinical trials initially conducted in New Guinea in the early 1960's. Although maternal immunization decreased during the later 20th century, the 2009 influenza A pandemic demonstrated increased risks of influenza infection during pregnancy and the benefits of maternal influenza immunization. Influenza maternal immunization has now been approved by many regulatory agencies. Increasing rates of neonatal pertussis resulted in the implementation of maternal immunization with acellular pertussis vaccines beginning in 2012 in many countries. Pregnancy was determined to be a risk factor for severe COVID-19 disease, although clinical trials in pregnancy were delayed. Benefits of COVID-19 vaccine to prevent both maternal and infant disease were subsequently demonstrated.

Studies of maternal immunization have demonstrated safety in pregnant women and infants. The active transfer of vaccine-specific antibodies and the potential decrease in antibody transmission with placental infections has been demonstrated. Good transmission of maternal vaccine-related antibody in high-risk pregnancies and even premature infants has also been described. Decreased antibody production in infants following active immunization has been seen following several maternal vaccines, but subsequent boosting with childhood vaccination appeared to ameliorate this finding. The benefits of maternal immunization today include benefits to maternal and neonatal health and cost-effectiveness when integrated into clinical arms of health care.

BIOSKETCH

Dr. Steve Black

Global Vaccine Data Network, U.S.A.

Dr. Steven Black is a pediatric infectious disease specialist who received degrees in Biology and Chemistry from the University of California Santa Barbara and an MD degree from the University of California San Diego.

He completed a fellowship in pediatric infectious diseases at the University of California San Francisco. He has spent more than 30 years conducting clinical trials and safety studies of vaccines including being the principal investigator in five pivotal licensure trials and six phase four post marketing trials. He has also conducted numerous phase 1-2 clinical trials. He is co-Director of the 25 country Global Vaccine Data network currently engaged in the safety evaluation of COVID-19 and other vaccines. He is work package lead for DSMB activities for the CEPI funded SPEAC project supporting the assessment of vaccine safety in CEPI funded clinical trials. He is currently Emeritus Professor of Pediatrics at the University of Cincinnati Children's Hospital in Ohio U.S.A. and Honorary Professor of Pediatrics at the University of Auckland in New Zealand. He is editor in chief of the Pediatric Infectious Disease Journal.

BIOSKETCH

Dr. Marco Cavaleri

EMA, UK

Marco Cavaleri is Head of Department, Public Health Threats. He is the Chair of EMA Emergency Task Force (ETF) and responsible for EMA activities for emergent pathogens, vaccines and AMR. He has been leading the EMA activities during the COVID-19 pandemic on vaccines and therapeutics.

He serves in different advisory groups at WHO, including PDVAC, R&D Blueprint TAG on prioritisation of therapeutics and clinical trials working group.
Marco Cavaleri is a Pharmacologist who spent several years in industry in R&D mainly in the area of anti-infectives covering different positions in preclinical and clinical development of new antibacterial, antitubercular and antifungal agents.

He has expertise in microbiology, animal models, vaccines, translational science and clinical trials.

He is co-author of several publications related to vaccines, infectious diseases and regulation of medicines.

BIOSKETCH

Dr. Hannah Davies

LSHTM, UK

Dr. Hannah G Davies is an Academic Clinical Lecturer in Public Health within the Institute for Global Health at University College London, with honorary appointments at the London School of Hygiene & Tropical Medicine, City St George's, University of London, and the UK Health Security Agency. She is a clinician and researcher specialising in maternal and infant infectious diseases, vaccinology, maternal immunisation, neonatal infections, and vaccine safety surveillance. Her work focuses on improving maternal and newborn outcomes through epidemiology, clinical research, and public health, with particular interests in Group B Streptococcus and global health. She completed her PhD at St George's, University of London, based on large maternal–infant cohort studies in Uganda, and has worked clinically and academically across the UK, Uganda, and Sierra Leone.

BIOSKETCH

Dr. Alemayehu Duga

Africa CDC, Ethiopia

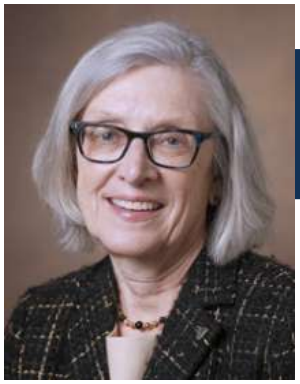
Alemayehu is a pharmacist and pharmacoepidemiologist with expertise in pharmaco vigilance and vaccine safety. He currently serves as a Senior Pharmaco vigilance Technical Officer at the Africa Centres for Disease Control and Prevention (Africa CDC), where he supports continental and national efforts to strengthen systems for monitoring the safety of vaccines and medicines, including during outbreak and emergency settings.

His work focuses on the design and implementation of safety surveillance systems, including both passive and active approaches such as cohort event monitoring (CEM), sentinel site surveillance, and signal detection. He has contributed to the establishment and operationalization of pharmacovigilance frameworks across multiple African Union Member States, including the development of policies, guidelines, and standard operating procedures aligned with regulatory and public health priorities.
Alemayehu has been involved in large-scale initiatives aimed at enhancing vaccine safety monitoring capacity in Africa, including activities under the Africa CDC–Mastercard Foundation "Saving Lives and Livelihoods" program. His role includes providing technical support to national authorities, facilitating coordination between pharmacovigilance centers, immunization programs, and regulatory bodies, and supporting data-driven decision-making.

His areas of interest include vaccine safety in special populations, safety surveillance during public health emergencies, and the epidemiology of adverse drug reactions. He has contributed to scientific publications, technical reports, and training programs in pharmacovigilance, with a focus on strengthening sustainable systems in resource-limited settings.

Alemayehu holds a Bachelor of Pharmacy (BPharm) and a Master of Science (MSc) in Pharmacoepidemiology and Pharmacovigilance.

BIOSKETCH



Prof. Kathryn Edwards

Vanderbilt University, U.S.A.

Kathryn M. Edwards, MD, Professor of Pediatrics Emerita at Vanderbilt University has led many of the pivotal clinical trials of vaccines licensed in the past several decades and has played a major role in their implementation.

She has had an extensive experience in leading NIH-funded multicenter initiatives; in designing, conducting, and analyzing pivotal Phase I, II, and III clinical studies on vaccines and therapeutics; in facilitating networking with basic and clinical investigators with a wide range of interests and expertise; and in mentoring many of the investigators who currently lead vaccine research programs globally. She has also been active in evaluating vaccine safety as the former leader of the CDC-funded Center for Immunization Safety Assessment site at Vanderbilt where she and her colleagues assess adverse events associated with vaccines in subjects of all ages.

Dr. Edwards has also conducted comprehensive pneumonia surveillance studies in adults and children and established the New Vaccine Surveillance Network at Vanderbilt. She is currently serving on several Data Safety and Monitoring Committees.

ABSTRACT

Title: How to tackle causality assessment: work done in WHO context

Dr. Madhava Ram Balakrishnan, WHO, Switzerland
Prof. Kathryn Edwards, Vanderbilt University, U.S.A.

Maternal immunization strategies have been described as an approach to prevent serious disease in pregnant women and their infants. Maternal immunization with diphtheria toxoid was studied in the early 1950's. Tetanus toxoid vaccine was successfully implemented worldwide for prevention of maternal and neonatal tetanus based on early clinical trials initially conducted in New Guinea in the early 1960's. Although maternal immunization decreased during the later 20th century, the 2009 influenza A pandemic demonstrated increased risks of influenza infection during pregnancy and the benefits of maternal influenza immunization. Influenza maternal immunization has now been approved by many regulatory agencies. Increasing rates of neonatal pertussis resulted in the implementation of maternal immunization with acellular pertussis vaccines beginning in 2012 in many countries. Pregnancy was determined to be a risk factor for severe COVID-19 disease, although clinical trials in pregnancy were delayed. Benefits of COVID-19 vaccine to prevent both maternal and infant disease were subsequently demonstrated.

Studies of maternal immunization have demonstrated safety in pregnant women and infants. The active transfer of vaccine-specific antibodies and the potential decrease in antibody transmission with placental infections has been demonstrated. Good transmission of maternal vaccine-related antibody in high-risk pregnancies and even premature infants has also been described. Decreased antibody production in infants following active immunization has been seen following several maternal vaccines, but subsequent boosting with childhood vaccination appeared to ameliorate this finding. The benefits of maternal immunization today include benefits to maternal and neonatal health and cost-effectiveness when integrated into clinical arms of health care.

BIOSKETCH

Prof. Janet Englund

Seattle Children's Hospital, U.S.A.

Janet Englund, MD, Professor of Pediatrics at the University of Washington/Seattle Children's Hospital, studies the diagnosis, prevention, and treatment of respiratory viruses. She has studied new vaccines and prevention measures against respiratory diseases in children, pregnant persons, and immunocompromised patients. She has worked collaboratively on large surveillance studies assessing community spread of respiratory viruses in households and vaccine effectiveness. Her research group has studied prevention of disease in infants using passive monoclonal antibody and maternal immunization. She is part of the New Vaccine Surveillance Network of the US CDC which assesses the effectiveness of vaccines and monoclonal antibodies in children.

ABSTRACT

Title: Lessons Learned from Maternal Immunization J. Englund

Prof. Janet Englund

Maternal immunization strategies have been described as an approach to prevent serious disease in pregnant women and their infants. Maternal immunization with diphtheria toxoid was studied in the early 1950's. Tetanus toxoid vaccine was successfully implemented worldwide for prevention of maternal and neonatal tetanus based on early clinical trials initially conducted in New Guinea in the early 1960's. Although maternal immunization decreased during the later 20th century, the 2009 influenza A pandemic demonstrated increased risks of influenza infection during pregnancy and the benefits of maternal influenza immunization. Influenza maternal immunization has now been approved by many regulatory agencies. Increasing rates of neonatal pertussis resulted in the implementation of maternal immunization with acellular pertussis vaccines beginning in 2012 in many countries. Pregnancy was determined to be a risk factor for severe COVID-19 disease, although clinical trials in pregnancy were delayed. Benefits of COVID-19 vaccine to prevent both maternal and infant disease were subsequently demonstrated.

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BIOSKETCH

Prof. Stephen Evans

London School Of Hygiene & Tropical Medicine, UK

Stephen Evans is Emeritus Professor of Pharmacoepidemiology at the London School of Hygiene and Tropical Medicine (LSHTM). He is the statistician to the the "Coalition for Epidemic Preparedness Innovations" (CEPI) meta-Data and Safety Monitoring Board.

After a BSc in Physics & Chemistry, he worked in the computer industry and at CERN, Geneva, then went to The London Hospital and Medical College (LHMC) in 1970. He did the MSc in Medical Statistics (1978) at The London School of Hygiene and Tropical Medicine (LSHTM), and was made Professor of Medical Statistics in 1990 at LHMC.

He left LHMC in 1995 for the UK Medicines Control Agency (MCA, now MHRA) and was there until 2002 with a brief period at Quintiles (now IQVIA). He became Professor of Pharmacoepidemiology at LSHTM (part-time) on retirement from the MCA in 2002.

From 2006 to 2018, he was on the EU committees on medicines safety, as a European Commission appointed independent Expert, and was a member of the WHO Global Advisory Committee on Vaccine Safety (2006-12). He gave written and Oral evidence on assessing safety of vaccines to the UK Covid Inquiry conducted by Baroness Hallett.

He has been on various editorial boards, including the British Journal of Clinical Pharmacology and was an Associate Editor of Pharmaco-epidemiology and Drug Safety. He was a statistical advisor to the British Medical Journal and a member of its editorial review committee for over 15 years. He is an Honorary Fellow of The Royal College of Physicians of London.

ABSTRACT

Stephen Evans, Emeritus Professor of Pharmacoepidemiology, Department of Medical Statistics, London School of Hygiene & Tropical Medicine

Title: Could Statistical methods matter?

The typical analysis of preterm birth following vaccination of a pregnant mother in a randomised trial involves treating the timing of delivery as a simple binary outcome; before 37 weeks of gestational age is preterm. This is not generally statistically efficient. It is also dependent on accurate estimation of gestational age at birth, which is not necessarily easy, particularly in resource-poor settings.

Taking into account the continuous time from date of vaccination has several advantages. The outcome itself is measurable very precisely in all settings; it allows for the possibility of studying effects that could occur at very low gestational ages; regression methods can take estimated gestational age at vaccination into account. The latter is important because the proportion of preterm births varies with the timing of vaccination which is the start of follow-up in a trial.

Some suggestions for better methods of analysis taking these points into account will be presented. These include survival analysis methods like the proportional hazards (Cox) model. Methods chosen should reflect clinical brelevance as well as being statistically efficient.

Title: Is a different methodology needed for RCT's and non RCT data sets ?

The basic principles of analysis of a non-randomised study of an intervention (NRSI) such as vaccination should be dependent on its design. For typical cohort studies of vaccination in pregnancy, there is a conceptual "target trial" that can be envisaged. Analysis should reflect the best methods of analysis of the equivalent RCT. This includes taking into account the time from vaccination to birth, allowing for the fact that "time at risk" varies with the timing of vaccination

The choice of a comparator group has several issues. If an alternative vaccination is used as control, then the period of follow-up for each group is clearly defined. If an unvaccinated group is the control, there is no defined time of vaccination. This can lead to major bias in the analysis if the "immortal time" is not allowed for correctly. Typically, this should use a time-updated Cox model. There will be other confounding variables and selection biases which should be accounted for and the inherent uncertainty in the results must be acknowledged.

BIOSKETCH

Dr. Deshayne Fell

Pfizer, U.S.A.

Deshayne Fell joined Pfizer 3 years ago and is the Team Lead for the Global Real-World Epidemiology team conducting post-licensure effectiveness studies for the Maternal RSV Vaccine. Prior to joining Pfizer, she was a Professor of Epidemiology and Public Health at the University of Ottawa in Canada. Over many years in academia and public health, Deshayne's research has focused on infection and immunization during pregnancy.

She has also been a member of two World Health Organization working groups related to immunization during pregnancy and was a liaison member of Canada's National Advisory Committee on Immunization from 2020 to 2023.

BIOSKETCH

Dr. Tessa Goetghebuer

Saint-Pierre Hospital, Belgium

Tessa Goetghebuer, MD PhD, is a pediatrician, clinical consultant at the CHU St Pierre, and primary care consultant at the Office de la Naissance et de l'Enfance, Belgium.

She has worked as a clinician and clinical epidemiologist at the Medical Research Council Laboratories, The Gambia, conducting birth cohorts and vaccine response studies. She studied Epidemiology and Statistics at the London School of Hygiene and Tropical Medicine and worked as research fellow in genetic epidemiology at the John Radcliffe Hospital, Oxford, UK.

Her main research interest is prevention of infectious diseases in children, vaccination and working with vulnerable populations.

BIOSKETCH

Dr. Jennifer Griffin

GVDN, U.S.A.

Jennifer Griffin, PhD, MPH, is an epidemiologist with over a decade of experience leading large multi-country studies in vaccine safety, maternal and neonatal outcomes, and infectious disease epidemiology.

As Lead Epidemiologist for the Global Vaccine Data Network (GVDN), she coordinates international collaborations across Africa, Asia, and the Americas focused on strengthening vaccine safety surveillance and generating background rates of adverse events of special interest. Her work emphasizes rigorous study design, high-quality data systems, and the interpretation of complex safety evidence for regulators, policymakers, and immunization programs, with particular focus on populations often underrepresented in pre-licensure research, including pregnant women and populations in low- and middle-income countries.

BIOSKETCH

Dr. Marion Gruber

IAVI, U.S.A.

Marion F. Gruber, Ph.D., M.S., is a global leader in vaccine regulation and development with more than 30 years of experience spanning regulatory science, clinical development, and public health policy. She currently serves as Vice President for Public Health and Regulatory Science at the International AIDS Vaccine Initiative, where she leads regulatory and public health strategies to advance vaccines and biologics addressing global health priorities.

Dr. Gruber previously spent nearly three decades at the U.S. Food and Drug Administration, including 10 years as Director of the Office of Vaccines Research and Review (OVRR) within CBER. In this role, she led multidisciplinary teams responsible for the evaluation and approval of numerous vaccines, including the first licensed COVID-19 vaccine in the United States, Ebola vaccine, and multiple vaccines targeting influenza, pneumococcal disease, HPV, hepatitis B, and other infectious diseases.

An internationally recognized expert, Dr. Gruber advises global health organizations and industry on vaccine development and regulatory strategy. She is a member of the International Alliance for Biological Standardization and serves as a steering committee member of the FEEVA (Framework for Evidence Evaluation in Vaccine Assessment) initiative. She is also a core regulatory expert on a Coalition for Epidemic Preparedness Innovations-funded effort to develop correlates of protection playbooks for emerging infectious diseases, and has served as an advisor to the World Health Organization, contributing to global vaccine policy and safety oversight.

Dr. Gruber holds a Ph.D. in Microbiology from the Christian Albrecht University of Kiel and a Master's degree in Biology from the University of Ulm, Germany.

BIOSKETCH

Mrs Delyth Jones

GSK, UK

Delyth is VP and Global Biostatistics Leader for Vaccines, Infectious Diseases and HIV at GSK, based in the UK.

Delyth gained her MSc in Statistics from Sheffield University, UK, and has worked as a Statistician in pharmaceutical development for over 30 years. For the majority of her career, she supported clinical development programs for medicines, predominantly associated with neuroscience, metabolic, cardiovascular, and renal diseases. In 2023, she took on leadership of the GSK Biostatistics group supporting Vaccines R&D.

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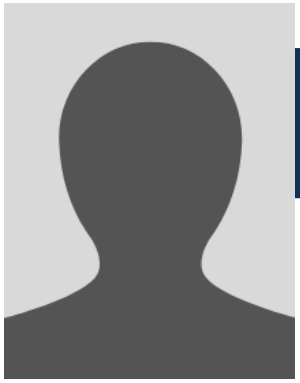

David Kaslow

FDA, U.S.A.

BIOSKETCH

Dr. Gwen Lemey

Antwerp University, Belgium

Gwen Lemey is a Postdoctoral Researcher at the Global Health Institute (GHI), University of Antwerp. Holding master's degrees in African Languages and Cultures (2005) and International Affairs and Diplomacy (2006), she joined GHI in 2013 as Project Coordinator, overseeing donor-funded research projects across Central and East Africa. She has contributed to an Ebola vaccine trial (2019-2022) with the Janssen vaccine, in partnership with the University of Kinshasa, DR Congo. Her PhD (2022–2025) explored research ethics and ancillary care in resource-constrained settings. Currently, in the PregInPoxVac Phase 3 trial-evaluating mpox vaccine immunogenicity and safety in maternal-infant cohorts-she builds further on this expertise. Gwen is passionate about ethical global health practices and equitable research in low-resource contexts.

ABSTRACT

Title: Strengthening quality assurance in clinical research in resource-constrained settings: The ethical imperative to develop, implement, and evaluate ancillary care policies

Dr. Gwen Lemey, University of Antwerp, Belgium

Background: PregInPoxVac is a Phase 3, open-label trial evaluating the safety and immunogenicity of subcutaneous MVA-BN vaccination in pregnant women in Boende, DR Congo. To assess maternal, foetal and neonatal outcomes (including miscarriage, stillbirth, and congenital infection), 362 pregnant women aged 16–35 years were enrolled and randomised 3:2 to receive two MVA-BN doses 28 days apart, either before 32 weeks' gestation or within 72 hours, postpartum. Given access to care constraints in the study setting, an ancillary care (AC) framework was developed and incorporated into trial design to address unmet healthcare needs beyond trial procedures, and to strengthen the study's quality assurance through enhanced adverse event collection and monitoring.

Methods: Between 27 June 2025 and 16 April 2026, 477 adverse events were reported during 430 unscheduled visits by 212 participants (58.6%). The most frequent events were influenza like illness (n=122), urogenital infections (n=109), mild preterm labour threat (n=73), malaria (n=44), and gastrointestinal illness (n=33). Most events were mild (n=439), six were severe, none leading to withdrawal. No event was assessed as vaccine related. AC interventions included direct medical care and provision of 917 concomitant medications.

Conclusion: These findings demonstrate a high burden of maternal morbidity and highlight the ethical and scientific value of integrating AC in settings with access to care constraints. AC provisions not only contribute to participant retention and wellbeing, but also improve adverse event reporting, timely clinical management, and data completeness, thereby strengthening the validity of safety assessments in maternal immunization trials in resource-constrained settings.

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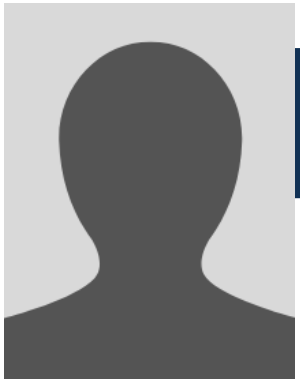

Prof. Isabel Leroux-Roels

Gent University, Belgium

Prof. Isabel Leroux-Roels (MD, PhD) is Head of the Center for Vaccinology (CEVAC) at Ghent University Hospital and Associate Professor at Ghent University, Belgium. Her research focuses on the clinical development and evaluation of vaccines, with particular expertise in early-phase clinical trials, vaccine safety, immunogenicity, and immune monitoring. She has extensive experience as principal investigator in international vaccine studies involving novel vaccine technologies and vaccines targeting respiratory infectious diseases. In addition to her research activities, she contributes to national immunization policy discussions as a member of the Belgian NITAG. She is committed to advancing evidence-based vaccination strategies across different populations and throughout the life course.

BIOSKETCH

Prof. Kirsty Le Doare

City St George's, University of London, UK

Kirsty Le Doare is a Professor of Vaccinology and Immunology at City St George's University of London. She lives in Uganda where she is a Principal Scientist at Makerere University – Johns Hopkins University (MU-JHU) Research Collaboration. She is a clinician researcher in Paediatric Infectious Diseases and has established a large urban cohort in Uganda as a vaccine platform with her main interest being age-related immune responses to infectious diseases in pregnant women and their babies. She is currently a consultant working with the WHO on maternal immunisations, focussing on Group B Streptococcal vaccines.

BIOSKETCH

Prof. Shabir Madhi

University of Witwatersrand, South Africa

Shabir A. Madhi, M.B.B.C.H. (Wits), FCPaeds (SA), Ph.D.

Shabir Madhi is the Dean of the Faculty of Health Sciences and Professor of Vaccinology at the University of the Witwatersrand, Johannesburg, South Africa. He also holds the position of Director of the South African Medical Research Council Vaccines and Infectious Diseases Analytics Research Unit (VIDA) and is co-Director of the African Leadership Initiative for Vaccinology Expertise (ALIVE).

He is an internationally recognised for his research on vaccines against life threatening disease in childhood, including against respiratory pathogens, as well as vaccines in pregnant women and people living with HIV. His research includes contributing to clinical development of vaccines against pneumococcus, rotavirus, and SARS-CoV-2; as well as maternal vaccines against Group B streptococcus, influenza virus, pertussis and respiratory syncytial virus

ABSTRACT

Title: Summary of the RSV vaccine findings on prematurity and how it informed impact studies

Prof. Shabir Madhi, University of Witwatersrand, South Africa

Maternal vaccination with the Respiratory Syncytial Virus (RSV) pre-fusion F- protein vaccine have been demonstrated to be efficacious and effective in protecting against severe RSV lower respiratory tract infections. Nevertheless, a signal suggestive of an increased risk of preterm birth in vaccine recipients, almost exclusively in upper-middle income countries, led to caution in the prescribed gestational age when vaccination has been recommended for use. The lower gestational age at which RSV maternal vaccine is recommended varies between countries, ranging from 24 weeks up to 32 weeks of gestational age. The vaccine efficacy trials in which a possible association with preterm birth were undertaken during the COVID-19 pandemic, with the excess of cases among vaccine recipients temporally associated with resurgent waves of COVID-19. Observational studies post-implementation of maternal RSV vaccine have not observed any association to preterm birth. As the causes of preterm birth are multi-factorial, observational studies could be heavily influenced due to confounders Consequently, to provide a definitive answer as to whether or not maternal RSV vaccination is associated with preterm birth, a randomised controlled trial is underway, which has been powered to evaluate as a co-primary endpoint the safety of maternal RSV vaccine in relation to preterm birth.

BIOSKETCH

Prof. Kirsten Maertens

Antwerp University, Belgium

Prof. Kirsten Maertens is affiliated with the Centre for the Evaluation of Vaccination located at the University of Antwerp. Prof. Maertens is conducting research on different aspects of vaccination in pregnancy. Her comprehensive research portfolio includes a wide spectrum of research within the maternal immunization field going from clinical trials looking at safety and immunogenicity of this vaccination strategy to research focusing on vaccine confidence.

The first pathogen she focused her research on was pertussis. But over the last years, her research also broadened up to other vaccine preventable diseases which are a target for maternal immunization like RSV, GBS, Mpox and COVID-19.

Prof. Maertens is also a member of the National Immunization Advisory Board in Belgium where she is currently responsible for the revision of the guideline on maternal immunization.

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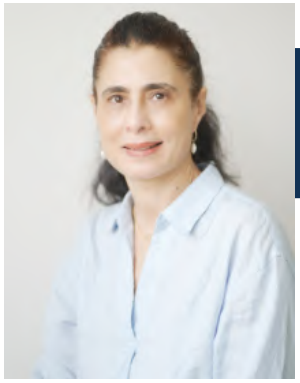

Mrs. Souad Masouri

BioNet

Souad Mansouri is a clinical development leader with over 28 years of global experience across vaccines, infectious diseases, CNS, and biologics. She has extensive expertise in maternal immunisation, pertussis vaccine development, and global regulatory strategy.

She is a former senior leader at a top-three global CRO, with broad experience in multinational clinical programs and regulatory interactions. In her current work, she contributes to the development and registration of vaccines including Boostagen® and Pertagen®, and supports BioNet's clinical development activities.

ABSTRACT

Title: Pregnancy outcomes following maternal vaccination with recombinant pertussis vaccines: evidence from three observational studies in Thailand

Chenchit Pichailuck[1], Surasith Chaithongwongwatthana[2], Librada Fortuna[3], Chawanee Kerdsomboon[3], Vilasinee Yuwaree[3], Souad Mansouri[3]
[1] Unit of Sexual Medicine, Department of Obstetrics and Gynaecology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand
[2] Department of Obstetrics and Gynecology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand
[3] BioNet-Asia Co-Ltd, Bangkok, Thailand

Background: Maternal immunisation against pertussis is an established strategy to protect young infants. While tetanus-diphtheria-acellular pertussis (Tdap) vaccines are widely used, data on recombinant pertussis vaccines administered during pregnancy remain limited.

Methods: Pregnancy outcomes following maternal vaccination with recombinant pertussis vaccines, either monovalent aP or combined TdaP, were evaluated across three observational studies conducted in Thailand. Adverse events, pregnancy complications, and birth outcomes were assessed.

Results: 3062 pregnant women were included into the analysis. The safety profile was consistent with that expected in the general pregnant population. Rates of preterm birth, low birth weight, and congenital anomalies were within background ranges. No vaccine-related safety signals were identified. Maternal vaccination elicited robust immune responses at one-month post vaccination and at delivery, supporting transplacental antibody transfer to infants.

Conclusion: These findings provide evidence supporting the safety and immunogenicity of maternal immunisation with recombinant pertussis vaccines. The results contribute to the evidence base informing greater maternal vaccination strategies for the prevention of pertussis in early infancy.

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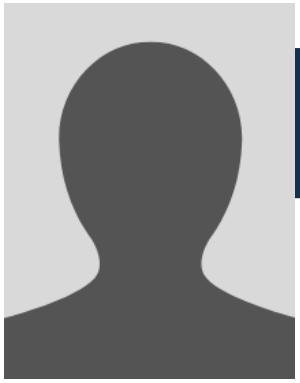

Prof. Arnaud Marchant

Université Libre de Bruxelles, Belgium

BIOSKETCH

Prof. Pierrette Melin

Liège University, Belgium

Her background, education & position, she is:

- Pharmacist, post-graduated specialist in clinical biology, PhD in Biomedical and Experimental Sciences from University of Liege, Belgium, for research in "Epidemiology of group B streptococci among pregnant women and infants".
- Emeritus professor (since October 2020) at the faculty of medicine, University of Liege.
- Past head of the clinical microbiology department at University hospital of Liege.
- Past founder and director of the National Reference Centre Streptococcus agalactiae.
- Past member of the CIRM (Centre Intégré de Recherche sur le Médicament).
- Since 2002, expert of the Belgian Superior Health Council.
- Since 2013, member of the College of the Belgian Superior Health Council.
- Since 2024, member of the bureau of the same College of the Belgian Superior Health Council.
- Since 2018, expert of the QCMD (Quality Control Molecular Diagnostic, Glasgow, UK) for Streptococcus agalactiae.

Research interest and skill:

- She has a 4-decade experience and research in group B streptococcal infections, diseases, diagnostic methods and prevention strategies.
- She is involved in national and international working groups for the prevention and management of GBS neonatal infections and chairs the group of clinical and public health representatives who re-evaluates the prevention strategies and updates the guidelines.
- Furthermore, she is a committed supporter of the development, validation and implementation of new technologies and products always aiming to improve the management of infectious diseases.

BIOSKETCH

- She has a long-standing experience with the development and implementation of both conventional and advanced diagnostic tests in the clinical microbiology laboratory.
- She has also developed cooperation in Group B Streptococcal epidemiology with the University of Leon in Nicaragua, with the University of Montevideo in Uruguay and Bach Mai Hospital, Hanoi Vietnam.
- She is involved in research on antimicrobial resistance.

Other:

She was work package leader:

- In the EC-funded FP7 project, DEVANI 2008-2011 (Design of a vaccine to immunize neonates against GBS infections through a durable maternal immune response),
- In the EC-funded FP7 project, C4L 2011-2014 (« Chips for Life", the overall objective was to develop a panel of dedicated rapid diagnostic tests to allow the medical staff to link antibiotic prescription on evidence-based diagnosis)
- In several national or regional funded projects as
- In the Federation Wallonie-Bruxelles Pole Biowin funded project 2016-2020 FRISBY: Fast and Reliable ultra-sensitive identification of Streptococcus B at delivery.

For more than 2 decades, she was also technical auditor (ISO15189) for BELAC, the Belgian Accreditation Organization.

BIOSKETCH

Dr. Solange Milolo

Kinshasa University, Congo

Dr. Milolo is an Assistant Lecturer in the Department of Tropical Medicine at the University of Kinshasa, Democratic Republic of the Congo. Her work focuses on emerging infectious diseases, epidemiological dynamics in African settings, and the implementation of clinical research in resource-limited environments. She has developed expertise at the interface of clinical investigation, public health, and research-capacity strengthening in underserved regions.

Dr. Milolo currently serves as Study Site Coordinator in Boende, Tshuapa Province, for the PregInPoxVac clinical trial, an international study evaluating mpox vaccination in pregnant women and infants. In this role, she coordinates scientific and operational activities at the study site, oversees participant follow-up and data quality, and ensures compliance with ethical, regulatory, and Good Clinical Practice standards. She also contributes to adapting study procedures to local realities, including sociocultural and healthcare-system challenges affecting maternal and child health.

Her research interests include the interactions between biological, behavioural, environmental, and social determinants involved in the emergence and transmission of infectious diseases. She is particularly interested in integrating clinical, epidemiological, and community-level data to improve prevention strategies, outbreak preparedness, and vaccine implementation in vulnerable populations.

Dr. Milolo actively collaborates with national and international research institutions and contributes to scientific publications and multidisciplinary research networks dedicated to strengthening infectious disease research and maternal immunization efforts in Africa.

ABSTRACT

Title: Mpox (MVA-BN) vaccination in pregnancy. Perspectives and challenges in data collection in remote resource-constrained settings (PregInPoxVac)

Dr. Paulina Morales Ruiz, Global Health Institute, University of Antwerp, Antwerp, Belgium.
Paulina.moralesruiz@uantwerpen.be
Dr. Solange Milolo, Tropical Medicine Department, University of Kinshasa, Kinshasa, Democratic Republic of the Congo.
solangemilolo43@gmail.com
+243 815726184

Background: Mpox is endemic in the Democratic Republic of the Congo (DRC), where pregnant women face an elevated risk of severe disease, foetal loss, stillbirth, and congenital infection. Despite evidence of Modified Vaccinia Ankara–Bavarian Nordic (MVA-BN) safety in adults and MVA-BN-Filo safety in pregnancy, mpox vaccination for pregnant women remains off-label and clinical data are lacking. To address this gap, PregInPoxVac is conducting a Phase 3, open-label trial to evaluate the safety and immunogenicity of MVA-BN in pregnant women in Boende, DRC.

Methods: PregInPoxVac enrolled 362 pregnant women aged 16–35 years in their second or third trimester, randomised (3:2) to receive a homologous two-dose MVA-BN regimen during gestation or within 72 hours postpartum. Immunogenicity is assessed by the neutralising antibody response at day 42. Safety and reactogenicity are evaluated using local and systemic adverse events, following the Brighton SPEAC and FDA guidelines, and maternal, foetal, and neonatal outcomes are assessed per WHO GAIA guidelines. Given the remote, resource-limited setting, we implemented practical strategies to address expected challenges; including limited literacy, incomplete adverse-event capture, and participant retention, alongside operational, logistical, and socio-cultural barriers. These included tailored material development, an ancillary care policy, community engagement and health system strengthening.

Conclusion: PregInPoxVac demonstrates that rigorous maternal vaccine research can be conducted in remote, resource-limited settings through context-adapted strategies. Beyond operational insights, it will provide the first prospective safety and immunogenicity data on MVABN vaccination during pregnancy, informing mpox vaccination policies for pregnant women and future vaccine trials in similar settings.

BIOSKETCH

Dr. Jezid Miranda

Cartagena University, Colombia

Dr. Jezid Miranda is a Subspecialist in Maternal Fetal Medicine, holding a PhD in Fetal Medicine from the esteemed Fetal I&D Medicine Research Center and FetalMed PhD—a unique global consortium established across three centers of excellence in fetal and perinatal medicine in Europe, located in Barcelona (Spain), Leuven (Belgium), and Lund (Sweden). He serves as an Associate Professor of Maternal Fetal Medicine/ Gynecology & Obstetrics at the Faculty of Medicine, Universidad de Cartagena, in Cartagena, Colombia.

His extensive experience in translational research focuses on biomarkers for various pregnancy complications, including preterm labor and placental pathology, with the overarching goal of preventing maternal and perinatal morbidity and mortality. This research has led to over 40 publications in international journals with significant impact factors. Dedicated to my academic career, he actively participates in research project evaluation committees in the fields of maternal and perinatal health and serve as an associate reviewer for international journals in Gynecology and Obstetrics. He is deeply committed to advancing scientific knowledge in developing countries, enhancing regional capabilities in fetal surgery, and addressing maternal mortality as a priority.

ABSTRACT

Title: Contextualizing Prematurity

Dr. Jezid Miranda, University of Cartagena, Colombia

Preterm birth remains a major determinant of adverse fetal and neonatal outcomes, requiring a nuanced obstetric perspective that integrates pathophysiology, risk assessment, and prevention. Understanding the multifactorial drivers of prematurity—particularly infection, inflammation, and placental dysfunction—is essential to guide targeted interventions. In this context, maternal immunization plays a critical role not only in reducing infectious triggers of preterm birth but also in improving fetal resilience through passive immunity. Optimizing pregnancy outcomes, therefore, depends on combining early risk stratification, timely obstetric management, and vaccine strategies, placing the fetus at the center of care to reduce both the incidence and impact of prematurity.

BIOSKETCH

Dr. Paulina Morales Ruiz

Antwerpen University, Belgium

Paulina Morales-Ruiz is a GP and PhD researcher at the Global Health Institute (GHI), University of Antwerp, where she oversees the maternal vaccination component of the PregInPoxVac project, investigating the safety and immunogenicity of the MVA-BN vaccine in pregnant women in the Democratic Republic of the Congo.

She holds an international Master's in Infectious Diseases and One Health, with clinical and field experience spanning Mexico, the UK, and Kenya.

Her research encompasses COVID-19 and HIV vaccine allocation modelling, vaccination strategies, and the co-design of One Health education programs. Beyond research, she co-chairs the WOMXN in One Health (WOH) working group, advocating for gender equity in global health and amplifying women's lived experiences in One Health policy and practice.

ABSTRACT

Title: Mpox (MVA-BN) vaccination in pregnancy. Perspectives and challenges in data collection in remote resource-constrained settings (PregInPoxVac)

Dr. Paulina Morales Ruiz, Global Health Institute, University of Antwerp, Antwerp, Belgium.
Paulina.moralesruiz@uantwerpen.be
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Conclusion: PregInPoxVac demonstrates that rigorous maternal vaccine research can be conducted in remote, resource-limited settings through context-adapted strategies. Beyond operational insights, it will provide the first prospective safety and immunogenicity data on MVABN vaccination during pregnancy, informing mpox vaccination policies for pregnant women and, future vaccine trials in similar settings.

BIOSKETCH

Prof. Flor Muñoz

Baylor College of Medicine, U.S.A.

Flor M. Muñoz, MD, MSc, is an associate professor of pediatrics, infectious diseases, molecular virology and microbiology at Baylor College of Medicine and Texas Children's Hospital in Houston, TX. She is a physician-scientist with research activities focusing on the evaluation of vaccine safety and efficacy in special populations including pregnant women, children, and people with compromised immune systems, as well as the epidemiology and treatment of respiratory pathogens such as RSV, influenza, SARS-CoV2, and pertussis.

Dr. Muñoz actively participates in various national and international committees and research networks including the American Academy of Pediatricians Section of Infectious Diseases (SOID) (Chair elect),the American College of Obstetrics and Gynecology (ACOG) Immunization Expert Group, the Infectious Diseases Society of America, the Committee for Research of the European Society of Infectious Diseases (ESPID), the Latin American Society of Pediatric Infectious Diseases (SLIPE), the CDC National Vaccine Surveillance Network (NVSN), the Global Vaccine Data Network (GVDN) project, and the Coalition for Epidemic Preparedness Innovations (CEPI)-Safety Platform for Emergency vACcines (SPEAC)-Brighton Collaboration project where she leads the Special Populations work group. Dr. Munoz is Chair of the institutional review board at Baylor College of Medicine. She is a member of the Board of Directors of the National Foundation of Infectious Diseases (NFID) and of the FDA VRBPAC. She contributes to projects supported by private and public organizations, including the World Health Organization to address infectious disease prevention to improve the health of women and children worldwide.

ABSTRACT

Prof. Flor Muñoz, Baylor College of Medicine, U.S.A.

This presentation will provide an overview of the current landscape of maternal immunization. We will discuss the rationale for the recommendations of vaccines for use in pregnancy and review specific indications and contraindications. Vaccines under evaluation and future vaccines will be discussed, as well as the pathway for research abd regulatory approval. The topic will emphasize the importance if safety assessment and existing as well as developing tools for evaluation, to contextualize preterm birth as a safety outcome.

BIOSKETCH

Mrs. Victoria Prudence Nambasa

AMA, South Africa

Victoria is the Senior Programme Officer- Safety Surveillance, supporting the operationalisation of the African Medicines Agency (AMA). She transitioned into this role from the African Union Development Agency (AUDA-NEPAD), where she supported the African Union Smart Safety Surveillance Programme. In this capacity, she led the signal management activities for cross-country safety data and broader product safety monitoring activities for participating member states.

Prior to joining AUDA-NEPAD and AMA, Victoria served as Manager of Pharmacovigilance at the National Drug Authority (NDA) in Uganda. She has 15 years of experience in medicines regulation, with specialist expertise in pharmacovigilance and medicines quality assurance.

She is a pharmacist and holds a master's degree in Pharmacovigilance and Pharmacoepidemiology, as well as an MSc in Pharmaceuticals and Health Supplies Management. She is currently pursuing a doctorate focused on strengthening systems for the safety surveillance of maternal vaccines.

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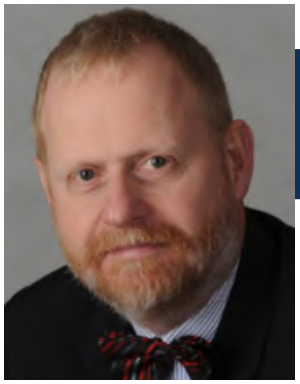


Dr. Pieter Neels

IABS, Belgium

Dr. Pieter Neels is a native of Belgium where he trained as an MD (University of Antwerp, 1985) and was boarded as a general practitioner. In 1994, his interest for medical research led him to work for a pharmaceutical company. In 1997, he joined the Belgian Ministry of Public Health as a senior evaluator of the clinical part of registration files in the field of cardiology, nephrology,
endocrinology (diabetes), ...

In 2001 he was appointed CPMP member. In 2002 he was asked to take over all Belgian central vaccine rapporteurships. During this year he became infected by the world of vaccines and until June 2013 he was the rapporteur of more than 15 vaccines.

After being an observer for more than 5 years at the Vaccine Working Party, he was elected vice-chair of this CHMP Working Party for discussion on development and evaluation of registration files for vaccines until June 2013.

The Belgian agency started a spearhead policy in 2007 and Dr. Neels was appointed co-ordinator for the spearhead domain vaccines.

EMA/CHMP has asked Dr. Neels has be an observer at the SAGE/WHO meetings and to attend several scientific meetings on vaccines until June 2013. WHO has asked Dr. Neels to attend many meetings on vaccine development all over the world in order to share the EU regulatory requirements/competence in
vaccinology.

Dr. Neels is also a member of the worldwide network on vaccine promotion ashe is asked to attend the ADVAC course (Foundation Mérieux) and the IABS conferences.

BIOSKETCH

Prof. Hanna Nohynek

Finnish Institute for Health and Welfare, Finland

Hanna Nohynek is Professor and Chief Physician, former Deputy Head of the Infectious Diseases Control and Vaccines Unit of the Department of Health Security at the Finnish Institute for Health and Welfare (THL). She has served as secretary, and still being a member of the Finnish National Immunization Technical Advisory Group (NITAG; KRAR), leads the subgroup on Strategic development of the influenza vaccination programme and is a member of the subgroup on the SARS-CoV-2 vaccination strategy. She was instrumental in designing the first THL (KTL) health advisory for refugees and asylum seekers in Finland, studying the narcolepsy signal post pandemic vaccination, designing the introduction of the HPV vaccine to the national immunization programme, the introduction of the live attenuated influenza vaccine for children, and strategy and introduction of the covid-19 vaccines in Finland. She practices travel health in Aava.

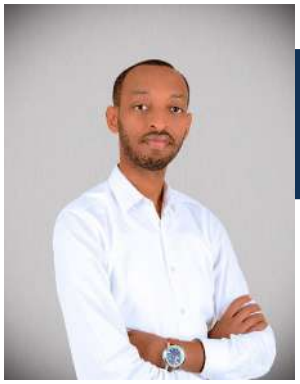
Her present research interests are register-based vaccine impact studies, evidence based policy/decision making, vaccine safety, hesitancy, SARS-CoV-2, RSV, influenza and pneumococcus. She coordinated the IMI funded consortia work packages on Preparation for future RSV product assessment of PROMISE (www.imi-promise.eu), and Field studies and Communication for DRIVE on brand specific influenza vaccine effectiveness (www.drive-eu.org; ended June 2022). She co-led the EU DG Sante funded Joint Action Vaccines (https://eu-jav.com/) work package on Vaccine Hesitancy which ended in March 2022.

She has authored more than 220 original articles. She teaches, giving over 30 invited lectures annually and guiding elective, graduate and PhD students. She belongs to the external faculty of the University of Tampere MSc course on Global Health.

BIOSKETCH

She has served on expert committees evaluating several vaccines in Finland, and as an advisor to the EU, EMA, IMI/IHI, IVI, WHO, GAVI, SIDA/SRC, and the Finnish MOFA. She chaired the WHO SAGE external evaluation (EAGSE), was WHO SAGE Chair 2023-2025, Chair of the WHO SAGE working group on COVID-19 vaccines, and WHO SAGE subgroup on Influenza Vaccines. She chaired EPIET in 1998-2001 and EDCTP in 2002-3. She was a member of the WHO GACVS (2006-2012). Presently she is member of the ECDC NITAG coordinating committee, and is Trustee Emeritus Member of the Board of the International Vaccine Institute. She belongs to the Faculty of ADVAC since 2000, initiated the EPIET vaccine module in 1997 and the Finnish Diploma Course on Global Health in 2000. She also initiated the Finnish Vaccinators Manual and Finnish Travel Health Advisory.

BIOSKETCH



Dr. Julien Nyombayire

Center for Family Health Research, Rwanda

Dr. Nyombayire is a research clinician at the Center for Family Health Research (CFHR) in Rwanda, a long-standing clinical research institution established in Rwanda since 1986 and formerly known as Projet San Francisco. With more than 16 years' experience in clinical research, Dr Nyombayire has served as an investigator in several observational cohort studies as well as multicenter clinical trials of preventive vaccine and therapeutics in various infectious diseases area including HIV, Ebola, Covid-19 and Malaria. He has recently served as the Principal Investigator for the first ever Phase 1 clinical trial of an mRNA HIV vaccine candidate conducted in Africa and a co-investigator of the first large Phase 3 Ebola vaccine trial among pregnant women in Rwanda. Dr Nyombayire has extensive experience in the management of large infection diseases prevention programs (e.g. HIV, Ebola) involving most at risk populations and in collaboration with large external funding agencies. He is currently the principal investigator of a large national HIV prevention program for Key and Priority Populations in Rwanda serving >100,000 at risk individuals every year. In addition to safety follow-up of participants enrolled in clinical trials, Dr Nyombayire is involved in the care and treatment of patients living with HIV and patients with symptoms of sexually transmitted infections (STIs) as part of his daily clinical duties.

Dr Nyombayire currently serves as the Executive Director of CFHR. He holds a degree of General Medicine and Surgery from the National University of Rwanda and a Master's of Sciences degree in Clinical Trials from the London School of Hygiene and Tropical Medicine as well as several professional certifications in the management of clinical trials. He serves as a board member of the Rwanda National Research Ethics Committee and the University of Global

Health Equity Institutional Review Board. He has also been a member of the Scientific Advisory Group for Marburg Disease Response during the 2024 MVD outbreak in Rwanda.

ABSTRACT

Title: Safety and Immunogenicity of a two dose Ebola vaccine among pregnant women in Rwanda

Dr. Julien Nyombayire, Center for Family Health Research, Rwanda

Risk of death for both mother and fetus following Ebola virus infection is extremely high. In this study, healthy women in Rwanda aged ≥18 years were randomized to two-dose Ebola vaccination (Ad26.ZEBOV, MVA-BN-Filo) during pregnancy (group A) or postpartum (group B). Unvaccinated pregnant group B women served as control. This was a parallel, randomized, controlled, open-label, single-center trial to evaluate the safety (primary endpoint-outcomes of interest and serious adverse events (SAEs)) and immunogenicity (secondary endpoint) of the two-dose Ebola vaccination. Among 3,484 women screened, 2,013 were randomized, and 2,012 women and 1,945 infants born alive were descriptively analyzed. Adverse outcomes of interest occurred in women (5.2% in group A and 7.3% in group B) and infants (26.0% in group A and 25.6% in group B). The most common maternal outcome of interest was pathways to preterm birth (3.2% in group A and 3.4% in group B), and the most common infant outcome of interest was small for gestational age (14.3% in group A and 11.8% in group B). Maternal/fetal and neonatal/infant SAE frequencies were comparable between groups (9.8% in group A, 9.0% in group B and 21.9% in group A, 15.9% in group B, respectively). Anti-Ebola virus glycoprotein-specific binding antibody response (secondary endpoint) was sustained in ≥90% of women at 1 year postdose 1. In group A, binding antibodies were detected in cord blood (99%) and infant serum (95%) samples 14 weeks postbirth. The trial met all primary and secondary objectives. Ad26.ZEBOV, MVA-BN-Filo did not raise concerns regarding adverse maternal/fetal or neonatal/infant outcomes, had no unexpected safety issues, and induced binding antibody responses in women and offspring through passive transfer.

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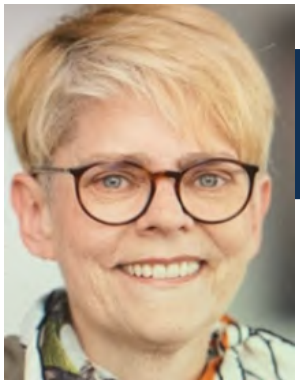

Mrs. Lidia Oostvogels

MinervaX, Denmark

Lidia Oostvogels qualified as a medical doctor at Ghent University in Belgium in 1991 and then spent nine years in a clinical development role with Boehringer Ingelheim. She has been working in vaccine development for more than 20 years, first with GSK, where she became Senior Director, Clinical and Epidemiology Project Lead, and was involved in clinical development of rotavirus, meningococcal, influenza and zoster vaccines.

She went on to become Senior Vice President, Area Head for Infectious Diseases and Senior Vice President for Clinical Development for prophylactic vaccines with CureVac (mRNA vaccines). Since 2022, Lidia has been with MinervaX as Chief Medical Officer – developing a maternal GBS vaccine. In addition to her professional commitments, Lidia is passionate about public health advocacy. She enjoys art, reading, and traveling, which she believes enriches her perspective on global health challenges.

ABSTRACT

Title: Immunogenicity and Safety assessment of GBS-NN/NN2 in Pregnant Women

Mrs. Lidia Oostvogels, MinervaX, Denmark

MinervaX' AlpN GBS vaccine is developed to address the important medical need for a novel prophylactic vaccine against Group B Streptococcus (GBS). AlpN GBS, is an Alum adjuvanted, protein-only vaccine based on fusions of highly immunogenic and protective protein domains from selected surface proteins of GBS - the Alpha-like protein family (AlpN). It is being tested in the clinic for use in pregnancy and in older people.

Vaccination during pregnancy will protect infants against devastating invasive GBS disease in the first months of life. When given early enough during pregnancy, the vaccine could potentially also protect against Adverse Pregnancy Outcomes such as Stillbirth and Preterm Delivery, which can be caused by GBS. AlpN GBS vaccine was shown to have an acceptable safety profile in both vaccinated mothers as their infants, after administration as a two-dose schedule to pregnant women in two completed Phase 2 trials. Antibodies induced in the mother were successfully transferred to the infant. The pivotal trial to support licensure of this vaccine, the MOTIVATION Trial (MOther To Infant protection by VAccinaTION), is under preparation.

BIOSKETCH

Mr. David Radley

Pfizer, U.S.A.

David Radley is Executive Director, Vaccines Clinical Research at Pfizer in Pearl River, NY, US..A. He holds an MSc.

in Biometry from Reading University, UK. He has worked in pharmaceutical development for 35 years, first in the UK and then since 1997 in the United States, when Rhone-Poulenc Rorer moved him to their headquarters in Pennsylvania. Since 2000, he has focused on vaccine research including HPV, meningococcal, staph aureus, RSV and GBS vaccines; first at Merck and (since 2014) at Pfizer.

He has regularly presented his research at scientific meetings on subjects as diverse as multicenter trials, combination of endpoints, noninferiority studies, data monitoring committees and long-term vaccine effectiveness monitoring.

ABSTRACT

Title: Data and Analysis from the Pfizer MATISSE Trial

Mr. David Radley, Pfizer, U.S.A.

MATISSE was the phase 3 efficacy trial of Pfizer's RSVpreF vaccine, conducted from 2020 - 2023. Data relating to infant safety outcomes will be presented, with a focus on preterm birth and its sequelae (Madhi et al, Obstet Gynecol. 2025). A numerical imbalance in the incidence of preterm birth in the vaccine group compared to placebo was observed. Multivariable analysis will be presented to explore regional variations and the subject characteristics (demographics, obstetrical history) associated with preterm birth. Potential confounding issues will be discussed such as receipt of other vaccinations during pregnancy and the SARS-CoV-2 pandemic. The critical role of vaccination timing during the pregnancy, and the need for careful interpretation of this factor, will be described. The challenges inherent in the assessment of gestational age and the approaches that were taken to address them will be covered. There will be a general review of the interpretation of modest treatment effects and the sample sizes required for confirm/refute them.

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

Mr. David Radley, Pfizer, U.S.A.

Pfizer has started enrollment into BEATRIX (group B strEptococcus mATeRnal and Infant vaX study), a Phase 3 study of its GBS vaccine, which is expected to continue until 2028. Enrollment is planned to occur in 18 countries globally, with significant LMIC representation. The study design will be reviewed, with particular focus on the elements intended to generate robust findings with respect to infant safety outcomes. These include: rigorous inclusion/exclusion criteria for the assessment of gestational age; staged enrollment by gestational age at vaccination; frequent DMC monitoring; and standardized classification of pathways to preterm delivery.

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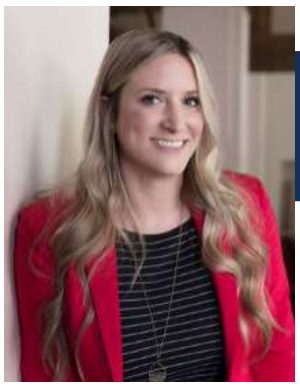

Dr. Annette Regan

Kaiser, U.S.A.

Dr. Annette Regan is a pediatric and perinatal infectious disease epidemiologist whose work centers on maternal, infant, and child health, with a particular focus on monitoring vaccine safety, effectiveness, and uptake. She is a Research Investigator and epidemiologist in the Division of Epidemiologic Research at Kaiser Permanente Southern California and an adjunct Associate Professor in the UCLA Fielding School of Public Health.

Dr. Regan has previously served in key public health roles at the U.S. Centers for Disease Control and Prevention and the Department of Health in Western Australia, where she developed novel vaccine safety surveillance systems for pregnant women. Her research has informed global immunization policy, including major studies on influenza, pertussis, and COVID-19 vaccination during pregnancy, and she continues to collaborate with agencies such as the CDC, WHO, and PAHO.

Dr. Regan holds a Masters of Public Health in Epidemiology from Emory University and a Masters and PhD in Infectious Diseases from the University of Western Australia. She is a current member of the Vaccine Safety Datalink team at Kaiser Permanente Southern California and a member of the Maternal Immunisation Working Group of the Global Vaccine Data Network. She receives research funding from the National Institutes of Health to evaluate the health effects of COVID-19 and RSV vaccination during pregnancy and the epidemiology of SARS-CoV-2 and other respiratory virus infections among young children.

BIOSKETCH

Dr. Katerina Rok Song

IVI, South Korea

Katerina Rok Song, MD, MPH, is a research scientist at the International Vaccine Institute (IVI). She trained in Obstetrics and Gynecology and pursued subspecialty fellowship in Obstetrics. She began her career in vaccines at GlaxoSmithKline (GSK), initially working on HPV vaccines and later expanding her role to a broad vaccine portfolio as a Vaccine Medical Director at GSK Korea. She subsequently transitioned to the public sector, joining the Korea Disease Control and Prevention Agency (KDCA) where she worked in the National Immunization Program (NIP) and Vaccine-Preventable Diseases (VPD) divisions as an Epidemic Intelligence Service (EIS) officer/VPD team manager before and during the COVID-19 pandemic. She has now been working at IVI for five years and has led multiple clinical trials as a project lead, including the Phase 3 Euvichol-S (oral cholera vaccine) study in Nepal and a Hecolin (hepatitis E vaccine) trial among pregnant populations in Pakistan.

BIOSKETCH

Prof. Anna Seale

Gates Foundation, U.S.A.

Anna is Principal Officer, Maternal Immunization Product Development and Surveillance at the Gates Foundation. She is an Honorary Professor of Public Health at the University of Warwick and the London School of Hygiene & Tropical Medicine.

Anna is clinically qualified and specialized in paediatrics prior to public health. She has worked extensively on the epidemiology of perinatal infection, particularly Group B Streptococcus. She has set-up surveillance platforms in East Africa, and studied outbreaks, leading an analytical team in the Department of Health, UK, at the height of COVID-19. She currently leads the Maternal Immunization and Group B Streptococcus Vaccine Initiatives at the Gates Foundation. She is now based in the UK, having lived for several years in East Africa (Kenya and Ethiopia).

BIOSKETCH

Dr. James Southern

SAHPRA , South Africa

James Southern PhD: Retired in 2000 – now a part-time consultant, living in Cape Town, South Africa. Born in Cape Town, South Africa 03 March 1945.
Most of my working life has involved the development, manufacture and quality control of vaccines and related materials in the UK and South Africa.
Prior to retirement I was Operations manager for the South African Vaccine Producers, based in Johannesburg. Our products included childhood diptheria-tetanus-whooping cough vaccines, and the African Snake-bite antivenoms.

Since retirement I have been:

• a part-time "expert" reviewer for the South African Medicines Regulatory Authority for license of Biological Medicines, and approval of Clinical Trials - mostly vaccines. This is an ongoing commitment.
o I have recently supported the SAHPRA interactions with the African Vaccines Regulatory Forum (AVAREF) in development of harmonized regulatory procedures – particularly related to COVID vaccines and potential MPOX vaccines.
• an expert reviewer for the Dept of Agriculture for safe import and release of genetically modified organisms – mostly human and animal vaccines,
• a Temporary advisor for the World Health Organization;
o drafting guidelines and standards for vaccines and biologicals,
o a Pre-Qualification reviewer of vaccines for purchase by UN Agencies,
o a WHO Training course developer and presenter.
o chair of the Developing Country Vaccine Regulators' Network 2006 – 2016

BIOSKETCH

Dr. Jens-Ulrich Stegmann

GSK, U.S.A.

BIOSKETCH

Dr. Frank Vandendriessche

Ficaja Farma, IABS, Belgium

Frank Vandendriessche graduated as pharmacist at the KULeuven (B) where he also obtained a PhD degree in pharmaceutical sciences based on medicinal chemistry research work on antiviral nucleosides and oligonucleotides. Between 1994 and 2014, he worked in the pharmaceutical industry for three vaccine companies i.e. Pfizer Animal Health, GSK Biologicals and Merck/MSD where he was continuously involved in quality and regulatory aspects of vaccines. Since 2014 he works as consultant in regulatory affairs, with continued activities in the same area of both prophylactic and therapeutic human vaccines, for large pharmaceutical companies, small biotech start-ups as well as NGO's. He has been regularly assigned as regulatory project lead and contact person to the European Regulatory Authorities. In addition to projects related to vaccines, he provided support for other biologicals and biosimilars as well as human medicines in the oncology and anti-infectious disease areas. He followed additional courses on EBM as well as HTA.

His primary role since 2022 has been to act as Chief Regulatory Officer of Vicebio, a start-up working on vaccines for prevention of respiratory viral infections and diseases.

Since mid 2024 he supports the IABS Human Vaccine Committee as a volunteer.

BIOSKETCH

Dr. Conall Watson

UKHSA, UK

Conall Watson is a consultant epidemiologist in the UK Health Security Agency, RSV lead in the Immunisation and Vaccine-Preventable Diseases Division and joint head of the Respiratory Viruses Surveillance Section. Conall's team have provided evidence and clinical leadership for the introduction and expansion of the UK national RSV immunisation programmes, and are responsible for impact surveillance in England. He was previously clinical lead for the UK influenza vaccination programmes, including pandemic disease, and a co-investigator in the Ebola ring vaccination trial. He has a PhD in infectious disease dynamics from the London School of Hygiene and Tropical Medicine after first training as a clinical pharmacist and in public health.

BIOSKETCH

Dr. Peggy Webster

GSK, U.S.A.

Peggy Webster, MD, MBA, is a pediatrician (previously board certified) with more than two and one-half decades of experience in the biopharmaceuticals industry as a medical safety officer and leader of teams and functions responsible for pharmacovigilance and safety risk management.

She is currently Vice President and Head of Clinical Safety and Pharmacovigilance for Vaccines and Infectious Disease at GSK and is located in the Boston, Massachusetts area. She has experience in a broad range of therapeutic areas including vaccines, immunology, infectious diseases, rare diseases, and oncology, and has supported products at all lifecycle stages.

BIOSKETCH

Dr. Nina Wressnigg

CEPI, Austria

Dr. Nina Wressnigg joined the Coalition for Epidemic Preparedness Innovations (CEPI) as Head of Clinical Development Science in March 2023.
Nina is an infectious disease vaccinologist with extensive expertise in clinical strategy developing vaccines from preclinical to late-stage development. She conducted her PhD at the Mount Sinai School of Medicine (MSSM), New York, U.S, developing live-attenuated influenza vaccine candidates by reverse genetics and obtained her PhD in microbiology and genetics from the University of Vienna, Austria.

Nina spend more than 15 years in various preclinical and clinical development roles of increasing responsibility in vaccine industry. From 2016 to 2022, during her last appointment as Director Clinical Strategy at Valneva, Austria, she was responsible for progressing the Chikungunya vaccine from preclinical stage to late-stage clinical development. In addition, she worked on early-stage Zika vaccine candidate development and scientific engagement for Valneva's inactivated COVID vaccine.

Her prior research at Baxter International Inc. (now Takeda) from 2010 to 2015 involved the clinical development and life-cycle management of vaccines for several infectious diseases at various stages of development including Chikungunya (Phase 1), Zika (Phase 1), Ross-River (Phase 3), Tickborne Encephalitis (Phase 4), seasonal and pandemic Influenza (Phase 3), Meningococcal C (Phase 4) as well as Lyme Borreliosis (Phase 3-ready). Following her PhD, Nina worked in pre-clinical development at the biotechnology start-up, AVIR Greenhills Biotechnology, Austria, conducting research on live-attenuated influenza vaccine candidates.