E-BOOK

SCIENTIFIC WORKSHOP

Assessing Consequences of Maternal Immunization on Foetal 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 COMMITTEE

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 Vaccine Data Network, U.S.A.**
Marco Cavaleri – **European Medicines Agency, UK**
Janet Englund – **Seattle Children's Hospital, U.S.A.**
Stephen Evans – **London School of Hygiene & Tropical Medicine, UK**
Tessa Goetghebeur – **Saint-Pierre Hospital, Belgium**
David Kaslow – **CBER FDA, U.S.A.**
Isabel Leroux-Roels – **Gent University, Belgium**
Arnaud Marchant – **Faculty of Medicine ULB, Belgium**
Pierrette Melin – **Liege University, Belgium**
Flor Muñoz – **Texas Children's Hospital, U.S.A.**
Lidia Oostvogels – **Minervax, Denmark**
David Radley – **Pfizer, U.S.A.**
Anna Seale – **Gates Foundation, UK**

Organizing Committee

Kathryn Edwards – **Vanderbilt University, U.S.A.**
Jennifer Griffin – **Global Vaccine Data Network, U.S.A.**
Kirsten Maertens – **Antwerpen University, Belgium**
Peggy Webster – **GSK, U.S.A.**
Nina Wressnigg – **CEPI, Austria**

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, IABS

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

Session Chair(s): TBC

9:10 - 9:25 **Vaccination of pregnant women: scientific context and scope of discussion**
Flor Muñoz, Texas Children's Hospital, U.S.A.

9:25 - 9:45 **Data and analysis from the GSK GRACE trial**
Jens-Ulrich Stegmann, GSK, U.S.A.

9:45 - 10:05 **Data and analysis from the Pfizer MATISSE trial**
David Radley, Pfizer, U.S.A.

10:05 - 10:20 **Role/perspective of DSMB's Chairs**
Flor Muñoz, Texas Children's Hospital, U.S.A.

10:20 - 10:50 **Morning Coffee Break**

10:50 - 11:10 **Summary of the RSV vaccine findings and how it informed impact studies**
Shabir Madhi, University of Witwatersrand, South Africa (virtual)

11:10 - 11:30 **Could statistical methods matter?**
Stephen Evans, London School of Hygiene & Tropical Medicine, UK

SCIENTIFIC PROGRAM

11:30 - 12:10 **Panel Discussion: Considerations from regulatory authority and vaccine recommending bodies considerations**
Marco Cavaleri, EMA, UK
Hanna Nohynek, Finnish Institute for Health and Welfare, Finland
James Southern, SAHPRA, South Africa
Madhava Ram Balakrishnan, WHO, Switzerland
Victoria Prudence Nambasa, AMA, South Africa
Gayatri Amirthalingam, UK HSA, UK (virtual)

12:10 - 1:10 Lunch Break

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

Session Chair(s): TBC

1:10 - 1:25 **Introduction Breakouts: How to assess safety in RCT's: possible endpoints/ outcomes and methodologies**
Steve Black,GVDN, U.S.A.

1:25 - 2:05 **Breakout (1): what outcomes related to prematurity to look at in RCT's**
Facilitator: Alex Duga, CDC, Ethiopia

2:05 - 2:55 **Breakout (2): what statistical methodologies can be used**
Facilitator: David Radley, Pfizer, U.S.A.

2:55 - 3:25 Afternoon Coffee Break

3:25 - 4:00 **Feedback from breakout sessions**
- **Statistics:** Delyth Jones, GSK, UK
- **Clinical:** Flor Muñoz, Texas Children's Hospital, U.S.A.

SCIENTIFIC PROGRAM

Session 3: Looking beyond RSV vaccines

Session Chair(s): TBC

4:00 - 4:20 **Immunogenicity and Safety assessment of GBS-NN/NN2 in Pregnant Women**
Lidia Oostvogels, Minervax, Denmark

4:20 - 4:40 **Planned safety assessment in Pfizer's Phase-3 GBS trial, BEATRIX**
David Radley, Pfizer, U.S.A.

4:40 - 5:00 **Safety and Immunogenicity of a two dose Ebola vaccine among pregnant women in Rwanda**
Julien Nyombayire, Center for Family Health Research, Rwanda

5:00 - 5:10 Sanitary Break

5:10 - 5:30 **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

5:30 - 5:50 **Pregnancy outcomes following maternal vaccination with a Pertussis-Only Vaccine: evidence from three observational studies**
Souad Mansouri, BioNet, Australia

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, IABS

Session 4: Looking beyond registrational RCT data sets

Session Chair(s): TBC

8:30 - 8:50 **Contextualising prematurity**
Jezid Miranda, Universidad de Cartagena, Colombia
Hannah Davies, University College London, UK

8:50 - 9:10 **What can be learned from vaccines already implemented?**
Janet Englund, Seattle Children's Hospital, U.S.A.

9:10 - 9:30 **Assessing the Safety of Maternal Immunization in Observational and Real World Data: Lessons learned from a global study**
Benjamin Atkins, Global Vaccine Data Network, Australia

9:30 - 9:40 **Is a different methodology needed for RCT's and non RCT data sets?**
Stephen Evans, London School of Hygiene & Tropical Medicine, UK

9:40 - 9:50 **How to tackle caU.S.A.lity assessment: work done in WHO context**
Kathryn Edwards, Vanderbilt University, U.S.A.

9:50 - 10:10 **Morning Coffee Break**

10:10 - 11:00 **Panel Discussion: Regulatory perspectives on post-approval approaches for assessment of safety of RSV vaccination – What was learned**
Marco Cavaleri, EMA, UK
Hanna Nohynek, Finnish Institute for Health and Welfare, Finland
James Southern, SAHPRA, South Africa
Madhava Ram Balakrishnan, WHO, Switzerland
Victoria Prudence Nambasa, AMA, South Africa
Gayatri Amirthalingam, UK HSA, UK (Virtual)

SCIENTIFIC PROGRAM

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

Session Chair(s): TBC

11:00 - 11:50	**Breakout discussion: Brainstorming on how future data sets best are generated?** Facilitator: Anette Regan, Kaiser Permanente, U.S.A.
11:50 - 12:05	**Feedback from the breakout session** Jennifer Griffin, Global Vaccine Data Network, U.S.A.
12:05 - 12:25	**Strengthening quality assurance in clinical research in resource-constrained settings: The ethical imperative to develop, implement, and evaluate ancillary care policies"** Gwen Lemey, University of Antwerp, Belgium
12:25 - 1:25	**Lunch Break**

Session 6: Wrapping up

Session Chair(s): TBC

1:25 - 1:45	**Wrap-up: ways forward from a statistical/methodological perspective** Anette Regan, Kaiser Permanente, U.S.A.
1:45 - 2:05	**Wrap-up: ways forward from a clinical/medical perspective** Kirsty Le Doare, University of London, UK Flor Muñoz, Texas Children's Hospital, U.S.A.
2:05 - 2:25	**Ways forward from a regulatory and NITAG perspective** Marco Cavaleri, EMA, UK
2:25 - 2:40	**Actions to progress** Steve Black, Global Vaccine Data Network, U.S.A.
2:40	**Conclusion & End of the Meeting** Pieter Neels and Frank Vandendriessche, IABS, Belgium

UPCOMING IABS
CONFERENCES & WORKSHOPS

Assessing Consequences of Maternal Immunization on Foetal Outcomes

June 8-9, 2026
Zurich, Switzerland

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
Budapest, Hungary

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.

ON THE HORIZON

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

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.

ABSTRACT

Title: Assessing the Safety of Maternal Immunization in Observational and Real-World Data: Lessons Learned from a Global Study

Dr. Benjamin Atkins, Murdoch Children's Research Institute on behalf of Global Vaccine Data Network

Background: Findings from observational studies of maternal immunisation and preterm birth have been heterogeneous, raising questions about the extent to which variability reflects true effects versus differences in study design, analysis, and data structure. As observational, real-world data are essential for post-licensure safety evaluation, there is a need to better understand how these factors influence signal detection, comparability, and interpretation across settings.

Methods: Global Vaccine Data Network (GVDN) conducted a harmonised, multi-country retrospective cohort study using linked electronic medical records and registries. COVID-19 vaccination during pregnancy was modelled as a time-varying exposure within a distributed analysis framework, with site-specific estimates combined via meta-analysis. Analyses addressed methodological considerations, including fixed cohort bias, gestational age estimation, and cross-site heterogeneity in outcome and covariate definitions and availability.

Results: Estimates for preterm birth were broadly consistent with no increased risk following COVID-19 vaccination during pregnancy, although effect sizes varied across sites and analytic models. Across selected outcomes—including haemorrhage during pregnancy, postpartum haemorrhage, and hypertensive disorders—estimates were sensitive to analytic specification and differed between sites. For some outcomes, substantial heterogeneity persisted despite harmonised methods, highlighting the influence of confounding, outcome ascertainment, gestational age measurement, and site-specific data structures.

Conclusion: In this multi-database study, no safety signal is evident for preterm birth; however, complementary analyses across multiple outcomes demonstrate that observational estimates are sensitive to analytic choices and between-site heterogeneity. Careful interpretation of realworld evidence and continued methodological refinement is critical to improving signal detection, supporting benefit–risk assessment, and strengthening confidence in maternal immunisation programmes globally.

BIOSKETCH

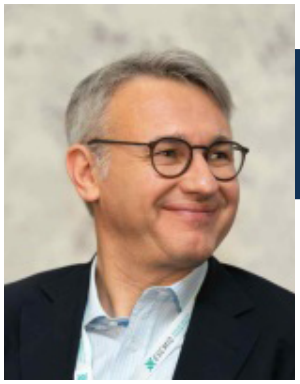
Steve Black

GVDN, 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.

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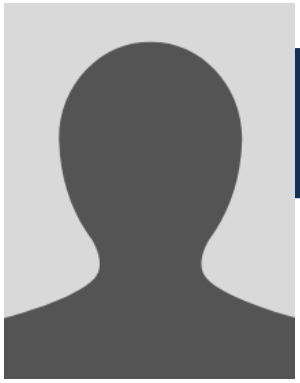

Hannah Davies

LSHTM, UK

BIOSKETCH

Dr. Alemayehu Duga

Africa CDC

Alemayehu is a pharmacist and pharmacoepidemiologist with expertise in pharmacovigilance and vaccine safety. He currently serves as a Senior Pharmacovigilance 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

Pr. Emerita 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.

BIOSKETCH

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.

BIOSKETCH

Pr. 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.

BIOSKETCH

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

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.

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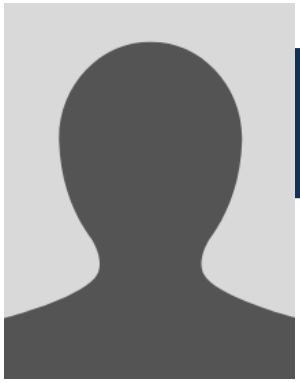

David Kaslow

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

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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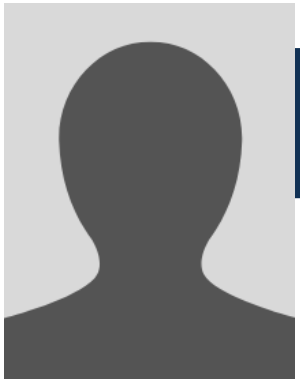

Isabel Leroux-Roels

Gent University, Belgium

BIOSKETCH

Pr. Kirsty Le Doare

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.

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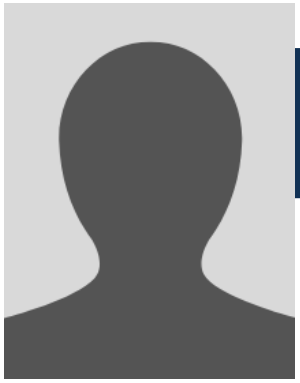

Pr. Shabir Madhi

University of Witwatersrand, South Africa

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, respiratory syncytial virus, influenza virus, rotavirus, Group B streptococcus and Covid-19.

BIOSKETCH

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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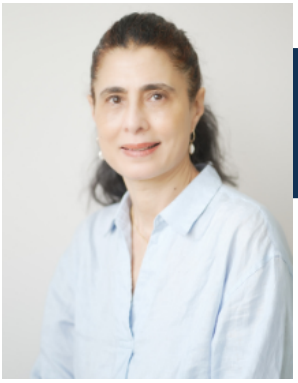

Mrs. Souad Masouri

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 Pichailuck1, Surasith Chaithongwongwatthana2, Librada Fortuna3, Chawanee Kerdsomboon3, Vilasinee Yuwaree3, Souad Mansouri3
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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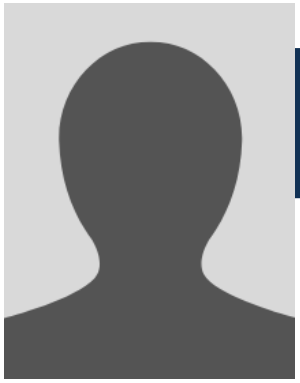

Arnaud Marchant

Université Libre de Bruxelles, Belgium

BIOSKETCH

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.

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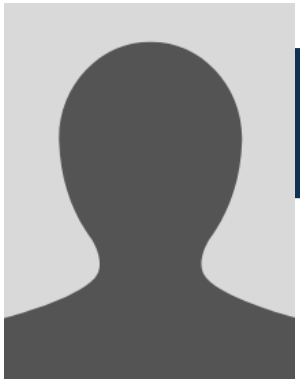

Solange Milolo

Kinshasa University, Congo

ABSTRACT

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

Mrs. Paulina Morales Ruiz, Global Health Institute, University of Antwerp, Antwerp, Belgium.
Paulina.moralesruiz@uantwerpen.be
Mrs. 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: Pregnancy outcomes following maternal vaccination with recombinant pertussis vaccines: evidence from three observational studies in Thailand

Chenchit Pichailuck1, Surasith Chaithongwongwatthana2, Librada Fortuna3, Chawanee Kerdsomboon3, Vilasinee Yuwaree3, Souad Mansouri3
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.

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)

Mrs. Paulina Morales Ruiz, Global Health Institute, University of Antwerp, Antwerp, Belgium.
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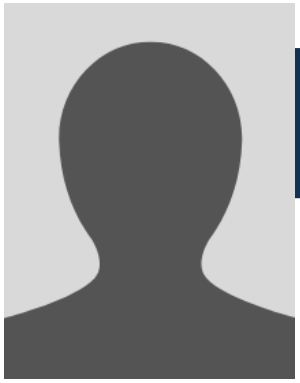

Flor Muñoz

Texas Children Hospital, U.S.A.

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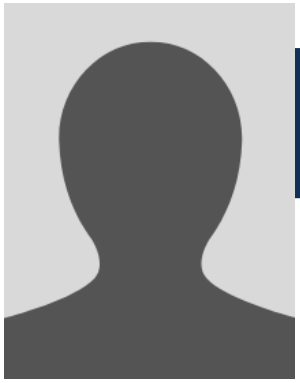

Pieter Neels

ABS, Belgium

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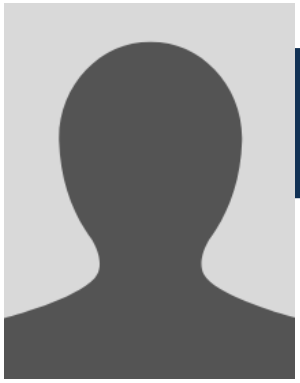

Hanna Nohynek

Finnish Institute for Health and Welfare, Finland

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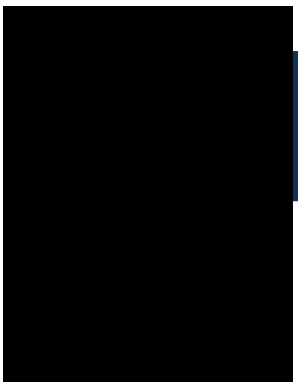

Julien Nyombayire

Center for Family Health Research, Rwanda

BIOSKETCH

M.D. 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.

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.

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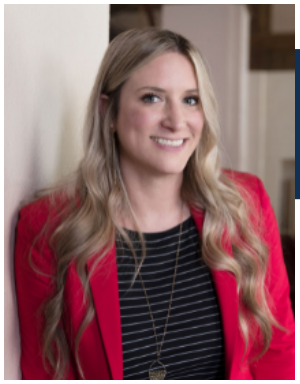

Dr. Annette Regan

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

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).

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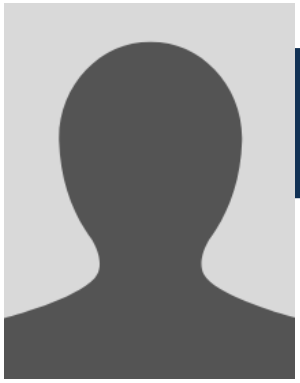


DR (PhD) James Southern

SAHPRA

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:

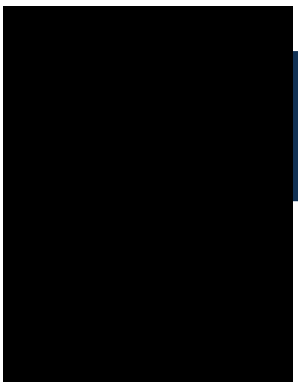
• a part-time "expert" reviewer for the South African Medicines Regulatory Authority for license of Biological Medicines, and approval of Clinical Trials - mostly vaccines. This is an ongoing commitment.
o I have recently supported the SAHPRA interactions with the African Vaccines Regulatory Forum (AVAREF) 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



Geeta Swamy

Duke University, U.S.A.

BIOSKETCH

Frank Vandendriessche

Ficaja Farma, 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

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

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.