SCIENTIFIC Conference

e-Book

International Alliance for Biological Standardization

2nd IABS Real World Evidence Workshop : The Role of Alternative Approaches to Phase 3 Clinical Trials for Vaccine Efficacy and Licensure

December 10-11, 2025

MONTREAL, CANADA

www.iabs.org

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CEPI

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About the conference

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Human randomized controlled trials (RCTs) have long been the gold standard for evaluating the safety and efficacy of medicinal products, including vaccines. However, their resource-intensive and time-consuming nature may render them impractical, prohibitively expensive, and too slow. As a result, there's increasing interest in exploring alternative approaches that can generate timely evidence of vaccine benefit prior to approval, complemented by real-world evidence (RWE) collection post-approval.

In the pre-approval context, several alternatives have been discussed in recent years. These include inferring vaccine efficacy by assessing immune response markers elicited by a candidate vaccine, relying on correlates of protection (CoPs) or surrogate markers as well as controlled human infection models (CHIMs). Under certain conditions, these approaches may provide sufficient reassurance of efficacy before approval, reducing or even eliminating the need for large phase 3 RCTs. While replacing phase 3 trials with such methods—or combinations thereof—remains challenging, there may be specific circumstances in which their use is not only preferable but also the only feasible and timely option. In such cases, a pre-agreed plan for verifying effectiveness post-approval using RWE would be essential.

The International Alliance for Biological Standardization (IABS) has a strong record of convening successful workshops on RWE, CHIMs, and CoPs. Building on this foundation, the upcoming meeting will bring together leading vaccine experts from these disciplines. Its objective is to develop recommendations and initiate a framework for the optimal use of diverse approaches to demonstrate vaccine benefit in the pre-licensure phase and to confirm benefit in the post-approval setting.

Scientific and Organizing Committee

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Scientific Committee

Kaatje Bollaerts - P95 (Co-Chair)
Danielle Craig - CEPI (Co-Chair)
Pieter Neels - IABS (Co-Chair)
Frank Vandendriessche - IABS (Co-Chair)
Dean Smith - IABS-NA
Marco Cavaleri - EMA
Miles Davenport - UNSW
Brad Gessner - Independent Consultant
Adam Hacker - CEPI
Hector Izurieta - FDA
Liz Miller - Independent Consultant
Carla Saenz - PAHO

Organizing Committee

Kaatje Bollaerts - P95 (Co-Chair)
Danielle Craig - CEPI (Co-Chair)
Pieter Neels - IABS (Co-Chair)
Frank Vandendriessche - IABS (Co-Chair)
Madinina Cox - Events Manager IABS/MC'Com
Camille Roux - Events Coordinator, IABS/MC'Com

Scientific Program

Wednesday, December 10, 2025

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9:00 AM

Opening of the meeting – Welcome

- Pieter Neels, IABS

SESSION 1

Vaccine approval in the absence of RCT efficacy data, challenges and overview

Session Chair: Laurence de Moerlooze, P95

9:05 AM

Introduction to the meeting objectives

- Laurence de Moerlooze, P95

9:10 AM

Developing a Group B Streptococcus vaccine for maternal immunisation: challenges for clinical development in a low-incidence, high impact infectious disease setting

- Lidia Oostvogels, Minervax

9:20 AM

Review of vaccines licensed in absence of a Phase 3 randomized controlled efficacy trial

- Danielle Craig, CEPI

SESSION 2

Alternative approaches to RCT efficacy data to demonstrate vaccine benefit for initial approval

Session Chair: Laurence de Moerlooze, P95

Scientific Program

Wednesday, December 10, 2025

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9:40 AM

Summary and insights from the EMA workshop (24-25 Nov 2025) on the use of animal models

- Marco Cavaleri, EMA

9:05 AM

Evidence on vaccine benefit from Human Infection Models: insights and considerations

- Robert Read, University of Southampton

10:40 AM

Coffee Break

11:00 AM

Evidence on vaccine benefit based on Correlates of Protection: insights and considerations

- Phil Krause, Independent Consultant

11:40 AM

Panel discussion: Dealing with uncertainty in vaccine benefit at initial approval and its consequences for post-marketing activities

- All Speakers and Dean Smith, IABS-NA, Hector Izurieta, FDA and Brenda Gomes Valente, ANVISA

12:10 AM

Lunch

Scientific Program

Wednesday, December 10, 2025

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SESSION 3

RWE to confirm vaccine benefit

Session Chair: Laurence de Moerlooze, P95

1:10 PM

Real-World Evidence from observational studies to pragmatic trials, supporting initial licensure to label expansion

- Kaatje Bollaerts, P95

1:20 PM

Real-world evidence confirming the vaccine benefit of the third-generation mpox vaccine mva-bn (Jynneos/Imvanex/Imvamune)

- Victoria Jenkins, Bavarian Nordic

1:40 PM

Role of Real-World Evidence in the 4CMenB Regulatory Journey Against Invasive Meningococcal Disease

- Ilaria Bartalesi, GSK

2:00 PM

Real-World Evidence to confirm vaccine benefit: Ebola vaccines

- Phil Krause, Independent Consultant

2:20 PM

Bridging Pre-Licensure and Post-Marketing Evidence: The CHIKV VLP Vaccine Journey

- Victoria Jenkins, Bavarian Nordic

2:40 PM

Coffee Break

Scientific Program

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3:10 PM

Progress of the Post-Approval Effectiveness Study (DEN-401) of TAK-003 Against Hospitalized, Virologically Confirmed Dengue in Pediatric and Adolescent Populations

- Suely Tuboi, Takeda

3:30 PM

Real-World Evidence to confirm vaccine benefit: Next generation pneumococcal vaccines

- Brad Gessner, Independent Consultant

3:50 PM

Real world measurement of COVID-19 vaccine effectiveness through the pandemic and beyond

- Alexander Allen, UKHSA

4:10 AM

Real-World Evidence to confirm vaccine benefit: Updating COVID-19 vaccines

- Kyla Hayford, Pfizer

4:30 PM

End of Day 1

Scientific Program

Thursday, December 11, 2025

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9:00 AM

Objectives of the day

- Laurence de Moerlooze, P95

SESSION 4

Pragmatic Randomized Controlled Trials for vaccine effectiveness

Phil Krause, Independent Consultant

9:10 AM

Lessons from the pragmatic randomized trials of high-dose vs. standard-dose influenza vaccine against severe clinical outcomes (FLUNITY-HD)

- Joshua Nealon, Sanofi

9:30 AM

Lessons from the pragmatic randomized trial to evaluate RSV vaccine effectiveness against hospitalizations

- Brad Gessner, Independent Consultant

9:50 AM

Cracking the Code: Identifying RSV Correlates of Protection in a South African Vaccine Effectiveness Trial

- Alane Izu, Wits VIDA

10:10 AM

Pragmatic RCTs and the power of vaccine probe analysis: The experience from Finland

- Arto Palmu, FVR

10:30 AM

Coffee Break

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11:00 AM

Panel discussion: Barriers to and requirements for the use of pragmatic trials

- Marco Cavaleri, Robert Read, Dean Smith, Hector Izurieta, Brenda Gomes Valente

SESSION 5

Break Out Session

Session Chair: Laurence de Moerlooze, P95

11:30 AM

Introduction Break-Out (1): Towards a framework for alternative approaches to Phase 3 Vaccine Efficacy Trials

- Danielle Craig, CEPI

11:40 AM

Break Out (1): When are alternative approaches needed for vaccine licensure?

12:30 PM

Lunch

1:30 PM

Introduction Break Out (2): Towards a framework for alternative approaches to Phase 3 Vaccine Efficacy Trials

- Danielle Craig, CEPI

1:40 PM

Break Out (2): What are the alternative approaches and when are they acceptable?

Scientific Program

Thursday, December 11, 2025

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2:30 PM **Coffee Break**

3:00 PM **Group discussion: Next steps towards alternative approaches to Phase 3 Vaccine Efficacy Trials**

- Laurence de Moerlooze, P95

3:50 PM **End of Day 2**

Upcoming IABS Conference and Workshops

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Advances in Analytical Technologies for Biopharmaceutical Products

Virtual Meeting
June 3-5, 2026

ON THE HORIZON

Preterm Birth as a Sentinel Outcome in Maternal Immunization with focus on fetal outcomes – Methods and Context

Eastern Europe
May/June, 2026

Bovine Serum: challenges and opportunities in the research and development and manufacture of vaccines and other biological products

Budapest, Hungary
September, 2026

Biosketch

Kaatje Bollaert

P95

Kaat Bollaerts is a PhD-level biostatistician with over 20 years of experience in vaccine and infectious disease epidemiology. At P95, Kaat leads the Epidemiology Business Unit, overseeing business development, strategic direction and the delivery of high-quality Real World Evidence research for global clients, including pharmaceutical companies, governments, and public health institutions. Her work combines scientific expertise with practical insight to support post-authorization studies, vaccine impact assessments, and public health decision-making.

Kaat serves as Principal Investigator of COVIDRIVE/id.DRIVE (https://iddrive.eu/), a global public-private partnership generating Real World Evidence on infectious diseases and vaccine effectiveness. Kaat also contributes to international teaching programs on vaccine evaluation and co-authored the open access book Vaccination Programmes: Epidemiology, Monitoring, and Evaluation (https://doi.org/10.4324/9781315166414), a foundational resource for professionals in immunization program monitoring and policy

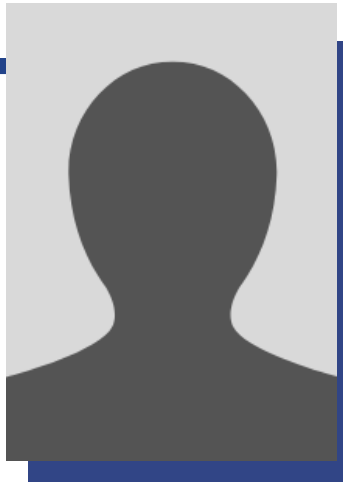
Biosketch

Dr. Pieter Neels

IABS

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



Dr. Frank M Vandendriessche

Ficaja Farma

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 Alexander Allen, MA BMBCh (Oxon) MPH MSc FFPH

Public Health Consultant, Consultant Epidemiologist
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I studied medicine at Oxford and did my junior doctor training in London. During this time, I realised that I enjoyed the aspects of medicine that focused on the more strategic and more data driven approaches to health care, making public health a natural specialty to pursue. During my time in public health, I have worked in local government, the NHS, at nation guidance organisation such as NICE. I also did extensive work in health protection both at the local and national level during the COVID-19 pandemic.

I currently work as a consultant epidemiologist at the UK Health Security Agency, the UK's national organisation responsible for the control of infectious diseases, where I lead on COVID-19.This includes the routine surveillance aspects, incident investigation and management, health inequalities and vaccine effectiveness.

Abstract

Alexander Allen

Real world measurement of COVID-19 vaccine effectiveness through the pandemic and beyond

The COVID-19 pandemic provided, and continues to provide, unique opportunities to develop methods for the real world assessment of vaccine effectiveness. The rapid evolution of the SARS-CoV-2 virus, with the constant parade of variants, and the attendant production of vaccines attempting to keep up with this, requires a rapid and agile approach to evaluating vaccines.

Randomised controlled trials/ phase III trials will be too slow to keep up with campaigns that often are targeted to take place multiple times per year, with a virus whose dominant variant can change within a month; alternative methods and on-going evaluation of current vaccination campaigns are vital.

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Vaccine Efficacy and Licensure: the role of Real World Evidence – December 10-11, 2025

Public health policy relies on making use of real world evidence to inform future policy and vaccine strategy; and will encompass vaccine coverage and cost effectiveness, alongside side vaccine effectiveness. Methods such as test negative case control studies, cohort studies, and age-discontinuity studies can all supply this essential information.

Biosketch

Ilaria Bartalesi, PhD

Global Regulatory Lead
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Ilaria Bartalesi serves as the Global Regulatory Lead at GSK Vaccines, Italy. She has over 23 years of experience in the pharmaceutical industry, with a specialized focus on regulatory strategy.

She holds a PhD in Chemistry and has contributed to scientific publications and congresses presentations. Her expertise spans marketing authorization processes, pediatric development support, referrals for urgent safety procedures, and registration of products/indications across US, EU and diverse global markets. She has also contributed to policy and regulatory discussions at EMA and EFPIA.

Her professional achievements include therapeutic areas such as analgesia, inflammation, allergy and vaccines.

After joining GSK in 2018, she focused on the meningitis vaccine franchise, contributing to numerous successful projects. Most notably, she took a lead role in achieved regulatory approvals for 4CMenB vaccine such as EMA and international label inclusion of real-world evidence. Beyond her professional success, Ilaria is passionate about nature and the outdoors, history, and traveling.

Abstract

Ilaria Bartalesi

Role of Real-World Evidence in the 4CMenB Regulatory Journey Against Invasive Meningococcal Disease

Serogroup B invasive meningococcal disease (MenB IMD) is a rare but potentially life-threatening condition. 4CMenB is a broadly protective vaccine against MenB IMD, currently registered in 59 countries worldwide. Due to the low incidence of MenB IMD, conducting phase 3 randomized clinical trials to assess vaccine efficacy prior to licensure was not feasible. As a result, 4CMenB was approved based on safety and immunogenicity data, using a recognised surrogate of protection (1).

Following licensure, large-scale immunization programs were implemented, and postauthorization commitments were established to generate real-world evidence (RWE) on vaccine effectiveness (2).

Widespread use of 4CMenB has led to the accumulation of extensive RWE, demonstrating reduction of MenB IMD by 50%-100% and vaccine effectiveness ranging from 59%-100% (3).

These findings have contributed to amendments to the product information (PI), ensuring healthcare providers to have access to update RWE data (4).

This workshop will highlight the key role of post- licensure RWE in confirming pre-licensure expectations established by clinical trials and vaccine strain coverage prediction, informing updates to PI, and enhancing understanding of vaccine performance in real-world settings for a rare disease. We will also explore how different health authorities incorporate RWE into regulatory decision-making, reflecting the evolving landscape for uncommon disease evaluation. Beyond demonstrating direct protection, RWE informs immunization policy, strengthens vaccine confidence and supports adaptive strategies for disease control. Looking ahead, the continued generation and integration of real-world data will be essential to guide broader and more effective use of 4CMenB, reinforcing its contribution to public health.

Abstract

(1) Borrow R, Carlone GM, Rosenstein N, Blake M, Feavers I, Martin D, Zollinger W, Robbins J, Aaberge I, Granoff DM, Miller E, Plikaytis B, van Alphen L, Poolman J, Rappuoli R, Danzig L, Hackell J, Danve B, Caulfield M, Lambert S, Stephens D. Neisseria meningitidis group B correlates of protection and assay standardization--international meeting report Emory University, Atlanta, Georgia, United States, 16-17 March 2005. Vaccine. 2006 Jun 12;24(24):5093-107. doi: 10.1016/j.vaccine.2006.03.091. PMID:16838413.

(2) EMA-EPAR link: https://www.ema.europa.eu/en/documents/assessment-report/bexsero-epar-public-assessment-report_en.p...

(3) Martinón-Torres F, Banzhoff A, Azzari C, De Wals P, Marlow R, Marshall H, Pizza M, Rappuoli R, Bekkat-Berkani R. Recent advances in meningococcal B disease prevention: real-world evidence from 4CMenB vaccination. J Infect. 2021 Jul;83(1):17-26. doi:10.1016/j.jinf.2021.04.031. Epub 2021 Apr 30. PMID: 33933528.

(4) EMA-PI link: https://www.ema.europa.eu/en/documents/product-information/bexsero-epar-product-information_en.pdf

Date of preparation: October 2025
Content Lab code: NX-GBL-MNU-ABST-250001

Abstract

Suely Tuboi, Takeda

Progress of the Post-Approval Effectiveness Study (DEN-401) of TAK-003 Against Hospitalized, Virologically Confirmed Dengue in Pediatric and Adolescent Populations

Background: TAK-003 is a live-attenuated tetravalent dengue vaccine, approved in over 40 countries and available in more than 25. The DEN-401 study (EUPAS1000000218, NCT06843226), a post-approval effectiveness regulatory commitment, is designed to complement DEN-301 (NCT02747927) by providing data on hospitalization and severe dengue, particularly in baseline seronegative individuals and for dengue virus serotypes DENV-3 and DENV-4.

Methods: Conducted in collaboration with health authorities and academic institutions, this multi-country, nested case-control study is embedded within a community-based cohort of 70,000 participants aged 6–12 years, with primary data collection. TAK-003 will be provided through vaccination programs following WHO/SAGE recommendations. Three years of hospital-based active surveillance will identify hospitalized and severe dengue cases among both vaccinated and unvaccinated participants. Seven catchment areas have been identified: three in Thailand (35,000 participants, 7–10 years), three in Indonesia (30,000, 6–10 years), and one in Malaysia (5,000, 7–12 years).

Results: Cohort enrolment and vaccination programs are scheduled for completion by Q1 2026. The programs are community-based in Thailand (Ministry of Public Health), school-based in Indonesia (provincial health offices), and part of a community-based health promotion and dengue prevention program in Malaysia. Final results will be reported in 2029 following the completion of data collection and analysis.

Conclusion: Innovative solutions supporting this complex real-world project include feasibility assessments, novel frameworks for collaboration with Ministries of Health, local authorities, and academia, collection of cohort data and biological samples, and adapted site and laboratory monitoring. Key lessons learned will be presented.

Funding: Takeda

Keywords (max 5):

Dengue, Vaccination, Clinical Research, Effectiveness, Real-world evidence

Biosketch

Danielle Craig

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Danielle is the Head of the Regulatory Affairs Americas team at the Coalition for Epidemic Preparedness innovations. She studied genomics and molecular genetics at Michigan State University before starting her career in quality and regulatory affairs. Prior to joining CEPI, she worked in the pharmaceutical industry leading regulatory strategies for Phase 1 to Phase 4 programs for medical products, including vaccines, monoclonal antibodies, immunoglobulins and plasma-derived products. In her current role, she partners with vaccine developers and regulators to further CEPI's mission of accelerating "the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks."

Biosketch

Marco Cavalieri

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.

Abstract

Marco Cavaleri

Summary and insights from the EMA workshop (24-25 Nov 2025) on the use of animal models

The increase in global emergencies and the need to prepare for health threats—from emerging infectious diseases to bioterrorism, radiological, nuclear and chemical threats (CBRN)— advocates for efficient regulatory and scientific pathways for licensing medicinal products when human efficacy trials are not feasible because of absence of affected patients, or not ethical as humans cannot be challenged with threats for which there is no effective vaccine or treatment. In these scenarios, regulators traditionally have relied on non-clinical data (usually animal models) as key demonstration of efficacy for decision-making in the intended indication(s). In the two decades since the first medical countermeasures were approved based on non-clinical data, the scientific, regulatory, and societal contexts have evolved substantially, and there is now the possibility to discuss and critically review, based on concrete cases, the outcomes, translation, and methodology around non-clinical data as key evidence of efficacy for medical countermeasures.

The workshop brought together academics, regulators, developers and healthcare professionals to:

- Discuss the current regulatory frameworks for approval of medical countermeasures when no human efficacy studies can be conducted
- Review the translational outcomes of non-clinical data utilized in regulatory decisions as key evidence of efficacy
- Discuss how to: establish and choose non-clinical models that could reliably predict efficacy in humans; interpret and to bridge non-clinical results to expected clinical efficacy; identify success criteria for regulatory decision-making
- Review alternative approaches to the use of animal models and their potential for use in regulatory decision-making on medical countermeasures
- Consider options for confirmatory clinical studies during emergencies.

Biosketch

Adam Hacker PhD

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Adam Hacker, PhD is a highly effective leader in the pharmaceutical industry, specializing in regulatory affairs. Since January 2021, Adam has been serving as the Director and Head of Global Regulatory Affairs & Quality at the Coalition for Epidemic Preparedness Innovations (CEPI), a not-for-profit vaccine R&D funding organization. In this role, Adam leads global regulatory networks driving discussion on epidemic and pandemic emergencies and preparedness for future outbreaks and has developed a broad collaborative network of regulatory authorities around the world

With a career driven by increasingly strategic roles, Adam has more than 25 years of experience across a diverse range of departments and therapeutic areas, covering innovative technology and product classes in both regional and global roles. Adam has held senior positions at Autolus Ltd, Janssen (Johnson & Johnson), Biogen Idec, GE Healthcare, and GlaxoSmithKline Pharmaceuticals and has led departments in regulatory affairs, quality and medical affairs.

Adam is also the Chair of the MHRA Review Panel, providing oversight to MHRA decision-making. Additionally, Adam co-chairs the Regulatory Advisory Group alongside the WHO Director of Regulation & Pre-Qualification, working with thirteen regulatory authorities in low, middle, and high-income countries to drive alignment and consensus on key COVID- and pandemic preparedness related topics.

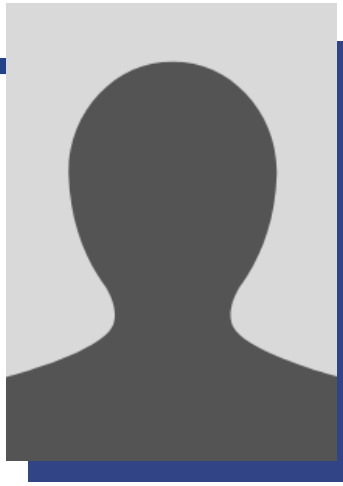
Biosketch

An experienced public speaker, panellist, chair, and moderator, Adam has contributed to numerous scientific meetings and conferences. Adam's extensive experience includes providing regulatory oversight to over 70 vaccine development programs, developing CEPI's regulatory pandemic preparedness plan, and driving all vaccine development acceleration initiatives and 100-days regulatory strategy.

Adam holds a PhD in molecular developmental biology from the National Institute for Medical Research, London. He also earned an MA / BA Degree in Pure and Applied Biology from The Queen's College, Oxford University. Adam has published more than 20 papers.

Most recently Adam was appointed as co-Chair of the European Platform for Regulatory Science Research facilitating collaboration between academic researchers, not-for-profit researchers, regulators, and other stakeholders.

Biosketch



Victoria JENKINS PhD

VP Regulatory Affairs, (ad interim)
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Victoria Jenkins is an accomplished leader in the biotechnology sector, spanning regulatory affairs, clinical development, clinical operations, biometrics and programme management. Currently serving as Vice President, Head of Regulatory Affairs, Clinical Operations & Biometrics at Bavarian Nordic, she is responsible for the operational and regulatory oversight of multiple clinical studies across all phases, including post-marketing research, as well as the regulatory life cycle management of Bavarian Nordic's commercialised vaccines.

Victoria has played pivotal roles in the successful licensure and launch of vaccines in the US and Europe, including the recent review and approval of the Chikungunya vaccine VIMKUNYA by the FDA, EMA, and MHRA.

Prior to her current role, she held positions at Bavarian Nordic and GSK, where she led global medical affairs activities for vaccines such as Tdap, Shingles and influenza. Her early career included a PhD and postdoctoral research in tuberculosis drug discovery.

Victoria holds a PhD in Molecular Microbiology from Imperial College London, a BA in Natural Science from the University of Cambridge, and an MBA from IE Business School.

Abstract

Victoria Jenkins

Real-world evidence confirming the vaccine benefit of the third-generation mpox vaccine mva-bn (Jynneos/Imvanex/Imvamune)

Background: Randomized controlled trials for mpox prevention are not feasible due to ethical and epidemiologic constraints. Real-world evidence (RWE) therefore plays a pivotal role in establishing the effectiveness and safety of the third-generation, non-replicating Modified Vaccinia Ankara–Bavarian Nordic (MVA-BN) vaccine, developed to protect against orthopoxvirus infections with an improved safety profile compared to earlier smallpox vaccines.

Methods and Findings:
Twelve independent RWE studies from Israel, the United States, the United Kingdom, Canada, Spain, and Germany (2022–2025) consistently demonstrate high vaccine effectiveness (VE) and favorable outcomes. Single-dose VE ranged from 58–86%, while two-dose VE reached 75–88%. Protection was maintained regardless of administration route (label approved subcutaneous SC or off-label intradermal ID) and in people living with HIV. Vaccinated individuals had markedly lower rates of hospitalization, disease severity, and breakthrough infection (<1%), which were generally mild. Two systematic reviews (Mason 2024; Pischel 2024) corroborate these findings.

Discussion: Correlates of protection for mpox remain undefined due to limited case numbers, lack of standardized neutralization assays, and the multifaceted nature of immune responses (humoral, cellular, mucosal). Consequently, RWE serves as the most pragmatic and ethically appropriate framework to assess real-world vaccine performance.

Abstract

Victoria Jenkins

Bridging Pre-Licensure and Post-Marketing Evidence: The CHIKV VLP Vaccine Journey

VIMKUNYA® (CHIKV VLP, Bavarian Nordic) is the first recombinant virus-like particle (VLP) vaccine approved for the prevention of chikungunya virus (CHIKV) infection in individuals aged 12 years and older. Licensed in early 2025 under accelerated pathways in the United States, European Union, and United Kingdom, VIMKUNYA's approval was supported by immunogenicity endpoints derived from serum neutralising antibody (SNA) titres, validated through passive transfer studies in non-human primates.

Phase 3 clinical trials demonstrated a rapid and robust seroresponse, with 97.8% of participants achieving protective antibody levels by Day 21, and a favourable safety profile with no treatment-related serious adverse events. As part of post-marketing commitments, Bavarian Nordic has initiated a Phase 3b efficacy study designed to confirm clinical benefit in real-world settings. The study's implementation is contingent on outbreak occurrence in endemic regions such as Thailand and the Philippines, and leverages simulation modelling and seroepidemiological assessments to optimise trial design and site selection.

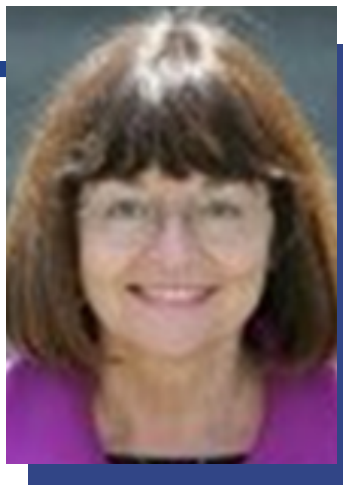
A key learning from the VIMKUNYA programme has been the importance of early and sustained regulatory engagement, as well as harmonised global licensure strategies to facilitate rapid access and uptake. This presentation will explore how post-marking evidence complements pre-licensure clinical trial data, and the role it plays in confirming vaccine benefit.

Biosketch

Phil Krause, M.D.

While at FDA, Phil performed vaccine-relevant research and had close involvement with all aspects of the review process, including CMC, preclinical, clinical, and post-marketing. As He left Deputy Director of the Office of Vaccines and Research and Review for about 10 years, Phil played a role in evaluation and licensure of many important vaccines, including those for Covid-19. Since that time, Phil has been a consultant on vaccine regulatory and strategic issues, including as a key advisor to the WHO R&D Blueprint for outbreak preparedness and response. Phil has also been a member of the CEPI Scientific Advisory Committee since its inception.

Biosketch



Elizabeth Miller

London School of Hygiene and Tropical Medicine

Professor Elizabeth Miller is an infectious disease epidemiologist who has worked on vaccines and immunisation programmes for over 40 years. She was the former Head of Immunisation at Public Health England and is now a professor in the department of Infectious Disease Epidemiology at the London School of Hygiene and a visiting professor at the School of Public Health a Tel Aviv University. She has considerable experience in evaluating vaccine safety and effectiveness and served as a member of the WHO Strategic Advisory Group of Experts (SAGE) on Immunisation and was a founder member of the WHO Global Advisory Committee on Vaccine Safety (GACVS). In response to the SARS-CoV-2 pandemic she lead the PHE (now UKHSA) studies of household transmission of the virus and the effect of vaccination in the household setting and is currently working with UKHSA colleagues on various studies of COVID-19 vaccine safety. She is also working for the WHO in assessing COVID-19 vaccines
that are candidates for inclusion in the WHO efficacy trials (SOLIDARITY) that are being conducted in low and middle income countries, and candidate vaccines for evaluation in viral haemorrhagic outbreaks.

Biosketch

Joshua Nealon

Medical and Evidence Generation Lead, COVID-19 and pre-licensure flu vaccines

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Medical and Medical Evidence Generation Lead, COVID-19 and mRNA Flu vaccines

Joshua Nealon is responsible for public health and medical aspects of COVID-19 and pre-licensure influenza vaccines for Sanofi Vaccines. He has spent a total of 10 years at the company having previously led Medical Evidence Generation activities for influenza vaccines, working as an epidemiologist to support dengue vaccine launch in 2015, and on other vaccine-preventable diseases. He has recently re-joined the company from an epidemiology/biostatistics research and teaching position at the University of Hong Kong where he was focused on vaccine effectiveness and the epidemiology of COVID-19 during the pandemic.

Joshua joined Sanofi from the World Health Organization where he worked as a Technical Officer in vector-borne disease control in Cambodia, Philippines and across the Western Pacific Region, and he has experience in a Hong Kong-based biotech start-up focusing on PCR-based diagnostics and RNA-based therapies. Joshua holds a B.Sc. in Medical Microbiology, an M.Sc. from the London School of Hygiene and Tropical Medicine and his Ph.D. from the University of Edinburgh.

Abstract

Joshua Nealon

Lessons from the pragmatic randomized trials of high-dose vs. standard-dose influenza vaccine against severe clinical outcomes (FLUNITY-HD

Background
The burden of hospitalized influenza, including influenza-attributable cardiovascular disease burden, has been recognized through epidemiological excess morbidity and mortality studies for nearly a century. The benefits of routine vaccination for reducing those events has been documented mostly through observational studies. Individually randomized studies to confirm causal benefits of vaccination against severe, rare events require large sample sizes.

Methods
Large-scale, pragmatic, individually-randomized trials against hospitalisation outcomes have been conducted in Denmark and Spain to measure the relative vaccine effectiveness (rVE) of high-dose (HD-IIV) vs standard dose (SD-IIV) influenza vaccines against severe clinical outcomes in older adults aged 65 years or older during the 2022–23, 2023–24, and 2024–25 influenza seasons. Participants were randomly assigned (1:1) to receive either HD-IIV or SD-IIV and followed up until May 31 the following year. The primary endpoint was hospitalisation for influenza or pneumonia. Secondary endpoints were cardiorespiratory disease, laboratory-confirmed influenza, all-cause hospitalisation, all-cause mortality, hospitalisation for influenza (ICD-10), and hospitalisation for pneumonia (ClinicalTrials.gov, NCT06506812).

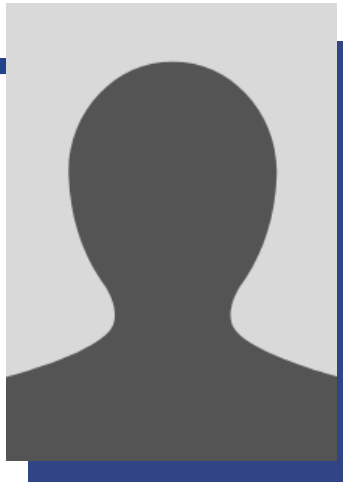
Results
The analysis included 466320 participants. The primary endpoint occurred in 1312 (0·56%) of 233311 participants in the HD-IIV group compared with 1437 (0·62%) of 233009 participants in the SD-IIV group (rVE 8.8%, 95% CI: 1.7 to 15.5; p=0.0082). HD-IIV also reduced the incidence of cardiorespiratory hospitalisation (rVE 6.3%, 2.5 to 10.0), laboratory-confirmed influenza hospitalisation (31.9%, 19.7 to 42.2), and all-cause hospitalisation (2.2%, 0.3 to 4.1).

Abstract

Conclusion
Large, randomized, pragmatic trials can be used for causal vaccine inference. In this prespecified analysis, HD-IIV demonstrated superior protection compared with SD-IIV against hospitalisation for: influenza or pneumonia; cardiorespiratory disease; laboratory-confirmed influenza and all-causes.

Funding: Sanofi funded study

Biosketch



Lidia Oostvogels, MD

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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, meningococal, 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

Lidia Oostvogels

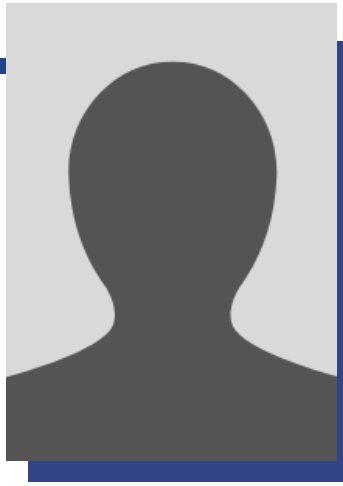
Developing a Group B Streptococcus vaccine for maternal immunisation: challenges for clinical development in a low-incidence, high impact infectious disease setting

Streptococcus agalactiae (Group B Streptococcus, GBS) is a major cause of neonatal sepsis and meningitis worldwide and is responsible for an estimated 0.49-0.53 cases of invasive GBS disease per 1,000 live births worldwide, with the highest incidence in Sub-Saharan Africa. Early-onset disease (EOD) is transmitted vertically during labour, late-onset disease (LOD) arises up to three months postnatally. GBS meningitis contributes significantly to long-term neurodevelopmental impairment. Current prevention, based on intrapartum antibiotic prophylaxis (IAP) for women who test positive for GBS or are at high-risk, have reduced EOD incidence but not LOD, stillbirths, or preterm delivery. In addition, IAP poses challenges such as antimicrobial resistance, microbiome disruption, and is not feasible in lower-resource settings.

A maternal GBS vaccine could provide durable protection for mothers and, through transplacental antibody transfer, for their infants. However, classical efficacy trials are infeasible because of the low incidence of invasive GBS disease. A minimum of 60,000 pregnant women would be needed to have sufficient statistical power to demonstrate clinical protection in a randomised controlled trial. In recognition of these challenges, regulatory agencies, including EMA and FDA, endorse alternative licensure pathways based on validated immunological surrogate efficacy markers (SEMs). Functional antibody assays measuring maternal and infant responses are promising SEMs.

Defining and validating SEMs that can predict protection across diverse populations reliably is a key scientific and regulatory priority to enable timely licensure of maternal GBS vaccines. This approach could be a model for vaccine development against other low-incidence but high-impact infectious diseases.

Biosketch



Arto Palmu, MD, PhD

university lecturer in clinical epidemiology, specialist in public health medicine
Currently: Chief Research and Medical Officer, FVR - Finnish Vaccine Research
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Dr Palmu's key research interests are in pneumococcal and influenza infections and their prevention by vaccines, and he has published over 100 papers in peer-reviewed journals. Recently, he has also published on COVID-19 vaccine effectiveness and vaccine safety and SARS-CoV2 serology.

With a strong background in infectious diseases and public health, his primary expertise is on clinical trials and register-based research, and he has been pivotal in the development of pragmatic vaccine field trials using the combination of clinical trial design with real-world evidence (RWE) from the national health registers.

Dr Palmu graduated from the Medical University of Tampere in 1993 and has worked as a researcher at the Finnish Institute for Health and Welfare (THL) based in Tampere since 1995. Since April 2022, he joined the FVR - Finnish Vaccine Research Ltd as the Chief research officer. FVR was established to merge THL commercial vaccine research group and Tampere University teams working on clinical vaccine research conducted in collaboration with the vaccine manufacturers. Now FVR is a leading organization dedicated to advancing vaccine research and development.

Biosketch

Arto A. Palmu was the primary coordinator and co-investigator for the pivotal Finnish Invasive Pneumococcal (FinIP) disease vaccine effectiveness trial which was the first RCT to measure the effectiveness of PCV10 against IPD in a real-life situation and the largest trial ever conducted in children using pneumococcal vaccines. He was the principal investigator in the Finnish pragmatic trial of high-dose influenza vaccine (FinFluHD trial) and has also led register-based research projects on the burden of vaccine-preventable diseases and the impact of vaccines in reducing this burden. He is continuing this work and pursuit for better public health as a dynamic leader and innovator in the field of advancing vaccine science.

Abstract

Arto Palmu

Pragmatic RCTs and the power of vaccine probe analysis: The experience from Finland

Finland has a unique position for large field vaccine trials with a history of over 70 years after participation in the polio Salk trial in the 1950ies, followed by large pragmatic meningococcus A, Haemophilus influenzae type b, pneumococcal, HPV and influenza vaccine trials.
Finland has developed multiple health care, social care and population registers since 1960ies. All registers are nationwide, linkable with each other, and affordable. Data collection in all registers is mandatory, electronic, automated, structured and, in most cases, real-time. Due to the national health insurance coverage of all permanent residents and accessible public healthcare, the registers capture the healthcare events without selection bias. Additionally, the the data collection can be augmented by using biobanks and nationwide patient-file data using The Patient Data Repository of the Kanta Services.

Large post-licensure vaccine trials are powerful tools, especially when the best possible study design, a randomized controlled blinded trial is meticulously conducted. This will allow the use of vaccine probe design to estimate the disease burden (vaccine-preventable disease incidence, VPDI) for outcomes of unknown etiological fraction by comparing the incidence in vaccinated and unvaccinated trial arms. A pragmatic trial of a pneumococcal conjugate vaccination in infants will be presented to demonstrate the low yield of the conventional definition of invasive pneumococcal disease (IPD) due to poor detection of septic syndromes by blood culture.
Using vaccine probe design, sensitive detection will result in proper estimation of the disease burden and will promote the introduction of vaccination programs to gain public health benefits.

Biosketch

Professor Robert Read

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Robert Read is Professor of Infectious Diseases at the University of Southampton, and Honorary Consultant Physician in Infectious Diseases at University Hospital Southampton, United Kingdom. An NIHR Senior Investigator, Read conducts early phase vaccine research and in particular uses controlled human infection models to investigate potential novel vaccines, microbial pathogenesis, mucosal immunity and novel diagnostics. In parallel with this, Read collaborates with engineers to test novel diagnostic technologies. He has published over 300 peer reviewed papers with an H index of 77. His experience in meningococcal, influenza and pneumococcal disease research, and clinical trials expertise have led to membership of the UK Joint Committee for Vaccination and Immunisation (JCVI) (2013-2024), and expert advisory groups of the European Medicines Agency (2011-2016) and the UK Commission on Human Medicines (2008-2014). He is Editor in Chief of Journal of Infection and *Current Opinion in Infectious Disease*.

Abstract

Robert Read

Evidence on vaccine benefit from Human Infection Models: insights and considerations

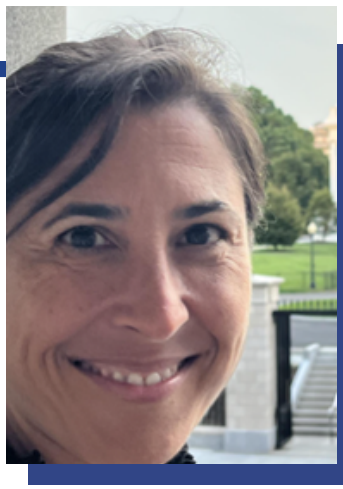
Although the primary evidence for efficacy for full regulatory approval of the overwhelming majority of vaccines has been traditional large-scale Phase 3 field trials, **controlled human infection** is a feasible technique to help rule out or support likelihood of novel vaccine benefit. Human Infection models can be broadly classified into **disease** models, in which experimentally-inoculated participants experience disease symptoms as well as infection, and **colonisation** models in which participants become infected without the infection causing, or being permitted to cause, disease. For vaccine evaluation, the technique is particularly useful when natural disease is so sporadic as to render RCTs of vaccine efficacy unfeasible. A good example of this is the licensure of Vaxchora oral cholera vaccine in June 2016, using evidence of protection in a disease model of diarrhoea caused by an oral challenge with Vibrio cholerae in a relatively small cohort, together with extensive safety testing in larger groups of unchallenged volunteers. Human Infection Models are also useful to identify correlates of protection which can subsequently be used to measure efficacy in large scale population based studies. Controlled human infection models have assessed the role of multiple cell types (B cells, CD8+ T, T_{regs}, MAIT, Monocytes and DC) during Salmonella Typhi infection, showing that baseline antigen-specific responses can correlate with clinical outcomes. Using the same model, the Typbar-TCV typhoid conjugate vaccine was pre-qualified by the WHO in 2017 after a Phase 2b human challenge study demonstrated protection against a composite of fever and bacteraemia in healthy adult volunteers. Disease models have been extensively used commercially to down-select multiple vaccine candidates – good examples being malaria and influenza. More controversial is the use of colonization models to study diseases in which colonization of a mucosal site is a prerequisite to disease, eg nasopharyngeal colonization by Streptococcus pneumoniae or Bordetella pertussis, with the notion being that vaccines that inhibit colonization will reduce transmission (and thereby enhance herd immunity) as well as disease.

Biosketch

A human controlled infection study showed that a glycoconjugate pneumococcal vaccine protected against pneumococcal colonization and reduced bacterial density. The pneumococcal model is currently being used to investigate pneumococcal vaccine in an African population in Africa- a site of high rates of disease incidence. My group has developed a B.pertussis human challenge model which has identified potential correlates of protection against infection and also been used to demonstrate that a live attenuated nasal vaccine can protect against Bordetella respiratory tract infection.

The **strength** of human controlled infection studies is that they permit prospective evaluation of human responses to defined challenges together with full characterization of the host and pathogen. The **weaknesses** include consideration of small cohort sizes, wider applicability, use of defined pathogens (usually a single strain) that may not be representative of all natural challenges, and participants who may not reflect the natural target population in diverse localities. Finally, such studies can only be conducted at specialist sites by highly trained staff.

Biosketch



Carla Saenz, PhD

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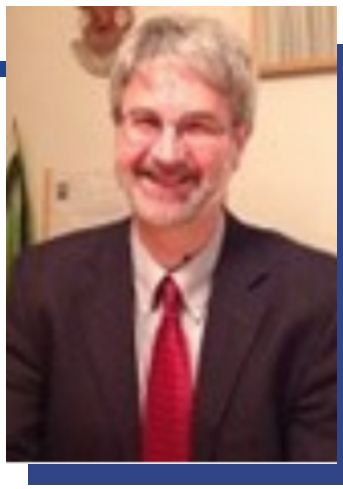
Carla Saenz is responsible for the Regional Program on Bioethics of the Pan American Health Organization (PAHO), which supports countries in the Americas primarily on research ethics and public health ethics. An elected fellow of the Hastings Center since 2019, she was responsible for the development of the Organization's ethics guidance for zika and COVID-19, including Catalyzing Ethical Research in Emergencies. Ethics Guidance, Lessons Learned from the COVID-19 Pandemic, and Pending Agenda. Carla serves on the board of the International Association of Bioethics and the Steering Committee of the Global Forum on Bioethics in Research. She is a native from Peru and holds a PhD in Philosophy from the University of Texas at Austin. Before joining PAHO, she was a postdoctoral fellow at the Department of Bioethics of the National Institutes of Health (NIH) and in the faculty in the Philosophy Department at the University of North Carolina at Chapel Hill.

Biosketch



Dean Smith

IABS-NA

Advisor to the Director and Sr. Evaluator in the Center for Vaccines, Clinical Trials and Biostatistics at Health Canada. He has over 25-years of experience in research and regulatory science in support of innovation for vaccine development, manufacturing and quality control. He is active in the development / implementation of related guidance, and has a wide range of biologics-based scientific and regulatory experience from his Sr. Scientific Evaluator and management roles in Centre Divisions including Viral and Bacterial Vaccines, Hemostatic Agents & Blood Substitutes, as well as the Clinical Evaluation Division-COVID.

Representing Health Canada, he has contributed to WHO's smallpox and rabies vaccine guidance, the Extended Controlled Temperature Conditions (ECTC) guidance in support of innovative vaccine stability
assessment for vaccination campaigns over the "last mile" with limited cold chain. Additionally, he contributed to WHO's R&D Blueprint International COVID-19 vaccine consultations during the pandemic, and since 2018 has been engaged in the regulatory / industry patient-centric harmonized specification exchanges in line with an assumed intent of ICH Q6B.
Smith is Health Canada's representative to the European Directorate of Quality of Medicines (EDQM) Group 15 (Vaccines and Sera) of the European Pharmacopeia. He has served on the Science and Ethics.

Biosketch

Advisory Committee for VAC2VAC under the European Vaccines Initiative to substitute more appropriate in vitro QC methods for existing in vivo vaccine QC methods, on the Regulatory Advisory Group to WHO and CEPI (Coalition for Epidemic Preparedness Innovations) during the COVID-19 pandemic, and most recently on the current EDQM mRNAVAC-Working Party.

Smith's Ph.D. in Immunology is from the University of Alberta, Canada, where his research dealt with vaccine antigen discovery, autoimmunity and viral vector-based gene therapy. He was a Research Associate at the National Research Council's Institute of Biological Science, Vaccine Design Group in Ottawa, prior to joining Health Canada.

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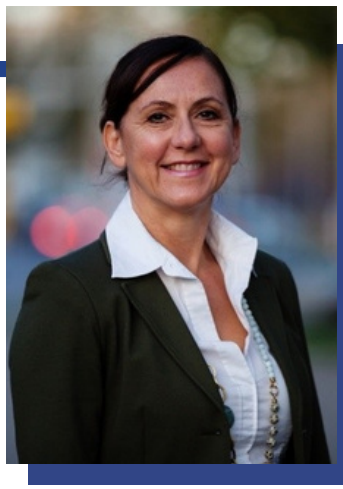

Laurence de Moerloze

Chief Medical Officer, P95

Laurence De Moerlooze serves as Chief Medical Officer at P95, drawing on more than two decades of experience in vaccine R&D and clinical leadership. She began her career at GSK Biologicals, where over 15 years she played a central role in regulatory, medical, and strategic functions. Contributing to the development of several high-impact vaccines, including one targeting HPV. Her work later expanded at Takeda, where she led global vaccine programs focused on Zika and Norovirus. Before joining P95, Laurence spent four years as Executive Vice President and CMO at Bavarian Nordic, guiding the company's clinical pipeline across infectious disease areas. She holds a PhD in Virology from the University of Liège and completed postdoctoral research in Canada, the UK, and Belgium.

Biosketch

Brenda Gomes Valente

ANVISA

Brenda Valente is a Pharmacist with a postgraduate specialization in Pharmaceutical Technology and Health Surveillance and holds a Master's Degree in Microbiology from the Federal University of Minas Gerais (UFMG). She is a Health Regulation and Surveillance Specialist at the Brazilian Health Regulatory Agency (ANVISA), where she has served since 2005 at the Biological Products Office. Her work includes the regulatory evaluation of efficacy and safety data for biological products.

In addition, she has extensive experience in monitoring and evaluating the development of biological products throughout their life cycle. She also contributes to strengthening regulatory convergence and alignment with other national regulatory authorities

Biosketch

Alane Izu

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Dr. Alane Izu is a Biostatistician at the Vaccine and Infectious Disease Analytics (VIDA) Research Unit at the University of the Witwatersrand. Dr Izu's research focuses particularly on vaccine impact, infectious disease epidemiology, immunogenicity and colonisation studies in South Africa. Among her notable contributions are longitudinal analyses of pneumococcal conjugate vaccine (PCV) impact in children, and work on serological thresholds associated with risk reduction of invasive Group B Streptococcus (GBS) disease.

In her current role at Wits-VIDA, Dr. Izu supports analytical methods for both observational studies and clinical trials within the unit. She contributes to the design and analysis of vaccine effectiveness and immunogenicity studies focused on pneumococcal disease, GBS, and respiratory tract infections in infants and young children. Her recent methodological work includes developing approaches for establishing serological thresholds of risk reduction (SToRR) for Klebsiella pneumoniae and E. Coli and identifying correlates of protection for respiratory syncytial virus (RSV) associated illness and enteric diseases. Her research contributes directly to evidence-based vaccine policy in low- and middle-income countries and supports global health efforts to reduce the burden of childhood infectious diseases.

Abstract

Alane Izu

Cracking the Code: Identifying RSV Correlates of Protection in a South African Vaccine Effectiveness Trial

Phase III trials for three different RSV vaccines have been completed to date. One of these trials was halted early due to a potential signal of increased risk for preterm birth in low- and middle-income countries (LMICs). A bivalent RSV A/B prefusion F protein vaccine (Abrysvo™) was shown to be efficacious against RSV severe-LRTI. Nevertheless, due to limited enrolment from low-middle income countries (LMIC) in the phase III study, WHO Strategic Advisory Group of Experts (SAGE) request further investigation of the vaccine in LMIC. Also, a higher rate of preterm birth was observed only in upper-middle income countries, which too warrants further investigation.

Consequent to the SAGE recommendation, we are conducting a multi-site Phase IIIb randomized clinical trial across four African countries. We are in a unique position, operating in the post-licensure, pre-introduction window -- a narrow but valuable phase that allows us to answer important questions related to safety, efficacy, and correlates of protection, within a setting that more closely reflects real-world conditions than a traditional pre-licensure trial. Embedded in our trial is a case-cohort sub-study designed to investigate correlates of protection against RSV severe-LRTI, which has not yet been established.

In the presentation, we will describe the study design, key scientific and statistical considerations, and the operational challenges of conducting a post-licensure randomized controlled trial aimed at strengthening the evidence base for maternal RSV vaccination.