# eBook

www.iabs.org

International Alliance for Biological Standardization

## The Role of Real-World Evidence for Regulatory and Public Health Decision Making for Accelerated Vaccine Deployment

## September 19 – 20, 2023

ParkInn Hotel

**LEUVEN – BELGIUM**

**HYBRID MEETING**

# Table of Contents

# Sponsors

Back to Table of Contents

AstraZeneca

CEPI

sanofi

P95

TURNING DATA INTO EVIDENCE

# About the Conference

Back to Table of Contents

Real-world evidence for monitoring the safety and benefits of vaccination has an essential role to play in the accelerated development and deployment of vaccines. Recently, the COVID-19 pandemic showed the necessity and feasibility of having new vaccines rapidly available. Despite the tremendous success of having several COVID-19 vaccines authorized less than 12 months after the declaration of the COVID-19 global pandemic, many challenges have been faced in both high and low-and-middle income countries. Capitalizing on the massive efforts spent by all takeholders, it is timely to learn important lessons for the future on how to best use real-world evidence for regulatory and public health decision-making on vaccines and vaccination programs.

This hybrid meeting will bring together renowned vaccine experts from national and international public health authorities, regulatory bodies, industry, academia, and research organizations for developing recommendations on the best use of real-world evidence for vaccine decision making and a roadmap to further strengthen its use. The meeting brings an exciting mix of information sharing and discussion sessions among all key stakeholders from vaccine development till deployment.

# Scientific and Organizing Committee

Back to Table of Contents

**Nick Andrews,** UKHSA, United Kingdom

**Steve Black,** GVDN, USA

**Kaat Bollaerts,** P95, Belgium

**Madinina Cox,** IABS secretariat, France

**Hector Izurieta,** FDA, USA

**Pieter Neels,** IABS, Belgium

**Jeffrey Roberts,** Merck, USA

**Bob Small,** CEPI, USA

**Julia Stowe,** UKHSA, United Kingdom

**Miriam Sturkenboom,** UMC Utrecht, Netherlands

**Joris Vandeputte,** IABS Past President, Belgium

**Fran Van Heuverswyn,** Flanders Vaccine, Belgium

**Melinda Wharton,** CDC, USA

# Scientific Program

## Tuesday 19 of September, 2023

Back to Table of Contents

| | |
|---|---|
| 8:30 | Coffee and Registration |
| 9:15 | Welcome - **Joris Vandeputte, IABS Past President** |
| 9:25 | Bob Small Memorial - **Gabrielle Breugelmans, CEPI** |
| 9:35 | Objectives of the meeting - **Thomas Verstraeten, P95** |

### SESSION 1: The role of RWE for accelerating vaccine deployment

Chairperson: Thomas Verstraeten, P95

| | |
|---|---|
| 9:40 | Key note duo presentation: Accelerated vaccine development in pandemic situations: what is needed? Link to Ebola outbreak in West Africa, 2014- 2016? **Helen Rees, Wits RHI and Jakob Cramer, CEPI** |
| 10:10 | PCV20 and RSV in older adults: similarities and differences for RWE - **Brad Gessner, Pfizer** |

### SESSION 2: Emergency Use Authorization of COVID-19 vaccines: regulatory and public health perspectives and actions

Chairperson: Liz Miller, LSHTM

| | |
|---|---|
| 10:25 | EUA of COVID-19 vaccines: role of RWE and the EU Vaccine Monitoring Platform to evaluate safety and effectiveness - **Hector S Izurieta, FDA** |
| 10:45 | Coffee Break |
| 11:25 | COVID-19 vaccines: role of RWE for public health decision making **Tom Shimabukuro, CDC** |
| 11:40 | **BREAK OUT #1*:** Which successful and not-so-successful decisions were based on RWE in pandemic situations? What went well and not so well, and why? **Liz Miller, London School of Hygiene & Tropical Medicine (moderator), all** |
| 12:40 | Lunch |

# Scientific Program

Tuesday 19 of September, 2023

Back to Table of Contents

## SESSION 3: Experiences with using RWE for regulatory and public health decision-making on COVID-19 vaccines

Chairperson: Hector S. Izurieta, FDA

| | |
|---|---|
| 14:00 | RWE use for COVID-19 public health decision-making in the UK: experiences, lessons learned, remaining challenges - **Nick Andrews, UKHSA** |
| 14:15 | RWE use for COVID-19 regulatory decision-making in the UK: experiences, lessons learned, remaining challenges - **Katherine Donegan, MHRA** |
| 14:30 | VAC4EU: experiences, lessons learned, remaining challenges<br>**Miriam Sturkenboom, UMC Utrecht** |
| 14:45 | COVIDRIVE: experiences, lessons learned, remaining challenges<br>**Kaat Bollaerts, P95** |
| 15:00 | Coffee Break |
| 15:30 | Example of use of RWE that supported decision-making (VE against symptomatic infection, duration, mix and match, booster)<br>**Sylvia Taylor, AstraZeneca** |
| 15:45 | Global Vaccine Data Network: experience, lessons learned, remaining challenges - **Steve Black, GVDN** |
| 16:00 | ALIVE network: experience, lessons learned, remaining challenges<br>**Clare Cutland, Wits RHI** |

## SESSION 4: Improving the use of RWE for regulatory and public health decision-making (part 1)

Chairperson: Steve Black, GVDN

| | |
|---|---|
| 16:15 | **BREAK OUT #2*:** What is required and what are the main barriers experienced for a successful use of RWE for regulatory and public health decision making? - **Liz Miller, London School of Hygiene & Tropical Medicine (moderator), all** |
| 17:15 | End of day 1 |
| 19:30 | Dinner |

# Scientific Program

Wednesday 20 of September, 2023

Back to Table of Contents

## SESSION 5: Improving the use of RWE for regulatory and public health decision-making (part 2)

Chairperson: Nick Andrews, UKHSA

| | |
|---|---|
| 9:00 | The BeCOME project and its RWE roadmap - **Philip Bryan, GSK** |
| 9:20 | Brighton Collaboration's role in establishing a RWE infrastructure for vaccine safety during early deployment - **Bob Chen, BC** |
| 9:35 | Feedback from DAY 1, Introduction to break-outs - **Thomas Verstraeten, P95** |
| 9:40 | **BREAK OUT #3*:** How to overcome main "barrier # 1"** - **Liz Miller, London School of Hygiene & Tropical Medicine (moderator), all** |
| 10:40 | Coffee Break |
| 11:10 | **BREAK OUT #4*:** How to overcome main "barrier # 2"** - **Liz Miller, London School of Hygiene & Tropical Medicine (moderator), all** |
| 12:10 | Wrap up of the meeting, and next steps - **Liz Miller, London School of Hygiene & Tropical Medicine** |
| 12:25 | Lunch |

## SESSION 6: Experiences using RWE for health economics and public health decision- making on non-COVID-19 vaccination (by Flanders Vaccine)

Chairperson: Kaat Bollaerts, P95

| | |
|---|---|
| 14:00 | Welcome by **Fran Van Heuverswyn, Flanders Vaccine** |
| 14:05 | Exploring the Cost-Effectiveness of Respiratory Syncytial Virus (RSV) Preventive Interventions in children with Real-World Evidence (IMI-RESCEU project) **Xiao Li, Health economist, University of Antwerp, Belgium** |

# Scientific Program

Wednesday 20 of September, 2023

## SESSION 6: Experiences using RWE for health economics and public health decision- making on non-COVID-19 vaccination (by Flanders Vaccine)

Chairperson: Kaat Bollaerts, P95

| | |
|---|---|
| 14:30 | Public Health Impact and Return on Investment of Belgium's Pediatric Immunization Program - **Olivier Ethgen, Professor Health Economics, Université de Namur & André Bento, Associate Director, HEOR Manager at MSD** |
| 14:55 | PERCH (PartnERship to Contrast HPV) project - **Hélène De Pauw, Sciensano** |
| 15:15 | Coffee Break |
| 15:45 | Health information for policy & decision-making on vaccination - **Laura Cornelissen, Sciensano** |
| 16:15 | Improving quality of evidence for decision making through innovative design and collaborative studies leveraging RWE platforms - **Laurence Pagnon, Sanofi** |
| 16:40 | Closing – **Joris Vandeputte, IABS Past President** |

# Upcoming IABS Conferences and Workshops

Back to Table of Contents

## 2023

### 9th Annual IABS Statistics Workshop

Applying Statistics and Data Science to Evolving Technical and Regulatory Paradigms

**November 7-9, 2022**

# Biosketch


## Nick Andrews

Head of vaccines analysis
London, UK
UK Health Security Agency
Address: 61 Colindale Avenue
E-mail: nick.andrews@ukhsa.gov.uk


Prof Nick Andrews is Head of Vaccines Analysis within the Immunisation Department of the UK Health Security Agency. In this role he has worked extensively on post licensure real world vaccine safety, impact and effectiveness assessment, clinical trials and correlates of protection. He is currently part of the Global Vaccine Datanet, works on European influenza vaccine effectiveness projects with the IMove group, and was a member of the WHO Advisory Committee on Vaccine Safety (GACVS) from 2012-2018. He is on the WHO Ebola vaccine sub-committee and the WHO malaria vaccine advisory group. He is a project lead on a research collaboration on using electronic health records for vaccine assessment with the London School of Hygiene and Tropical Medicine (LSHTM). During the COVID-19 pandemic he has worked on sero-epidemiology, risk factors, excess mortality, and has published multiple studies on vaccine effectiveness and safety. He regularly provides evidence on COVID-19 vaccine effectiveness to the Joint Committee on Vaccination and Immunisation. He lectures at the LSHTM, New York University in London and on vaccine courses internationally. He has over 400 publications with more than half of these in the vaccine field.

# Abstract

## Nick Andrews

### RWE use for COVID-19 public health decision-making in the UK: experiences, lessons learned, remaining challenges.

Prof. Nick Andrews, UK Health Security Agency

**INTRODUCTION -** COVID-19 vaccines were rolled out in the UK from Dec 8th 2020.

**CHALLENGES -** The immediate questions related to safety, in particular anaphylaxis, and to the optimal use of the vaccines in terms of the effectiveness of the first dose and whether the interval between doses could be extended. Rapid assessment of real-world data was required to complement clinical trial data.

**APPROACH -** Rapid assessment was achieved using linked data on covid testing and vaccine registry data. The fastest method used the test-negative case-control design, with later assessments of effectiveness done using cohort studies. Real world data were also used to assess population immunity and vaccine immunogenicity and to identify those at highest risk of severe COVID-19.
Results by manufacturer using different severity end points and against different strains were presented regularly to JCVI who advised and continue to advice on the vaccine strategy. A UK wide working group was set up to evaluate UK and international studies on effectiveness and come to a consensus. On the safety side UKHSA worked with the MHRA and University research groups to evaluate safety signals and help with risk benefit assessment, such as the risk of VITT (Vaccine-induced thrombocytopenia and thrombosis). Results were presented to JCVI and the vaccine benefit-risk expert working group run by the MHRA.

**CONCLUSIONS -** We have learnt that having rapidly available linkable data along with appropriate statistical methods for analysis is hugely beneficial for decision making. Expertise to critique and understand limitations of methods and communicate these clearly is also needed. Challenges remain to continue to develop and improve these data sources and to retain/improve access. Also, to further understand the best ways to quantify and minimize bias. Designing vaccine roll out in ways that make evaluation less likely to be biased is attractive but often limited by practical considerations.

# Biosketch


## André Bento

Associate Director
Belgium
MSD
E-mail: andre.bento.abreu@merck.com


André Bento Abreu is an Associate Director at MSD Belgium; main activities include generation of economical evidence for Health Technology Assessment and research on Value Demonstration and Affordability.

# Abstract

## André Bento & Oliver Ethgen

Carrico et al., 'Public Health Impact and Return on Investment of Belgium's Pediatric Immunization Program', Front Public Health. 2023 Jun 22;11:1032385. doi: 10.3389/fpubh.2023.1032385

**BACKGROUND –** We evaluated the public health impact and return on investment of Belgium's pediatric immunization program (PIP) from both healthcare-sector and societal perspectives.

**METHODS –** We developed a decision analytic model for 6 vaccines routinely administered in Belgium for children aged 0-10 years: DTaP-IPV-HepB-Hib, DTaP-IPV, MMR, PCV, rotavirus, and meningococcal type C. We used separate decision trees to model each of the 11 vaccine-preventable pathogens: diphtheria, tetanus, pertussis, poliomyelitis, Haemophilus influenzae type b, measles, mumps, rubella, Streptococcus pneumoniae, rotavirus, and meningococcal type C; hepatitis B was excluded because of surveillance limitations. The 2018 birth cohort was followed over its lifetime. The model projected and compared health outcomes and costs with and without immunization (based on vaccine-era and pre-vaccine era disease incidence estimates, respectively), assuming that observed reductions in disease incidence were fully attributable to vaccination. For the societal perspective, the model included productivity loss costs associated with immunization and disease in addition to direct medical costs. The model estimated discounted cases averted, disease-related deaths averted, life-years gained, quality-adjusted life-years gained, costs (2020 euros), and an overall benefit-cost ratio. Scenario analyses considered alternate assumptions for key model inputs.

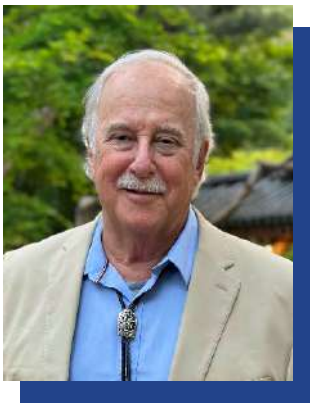
# Abstract

## André Bento & Oliver Ethgen

**RESULTS –** Across all 11 pathogens, we estimated that the PIP prevented 226,000 cases of infections and 200 deaths, as well as the loss of 7,000 life-years and 8,000 quality-adjusted life-years over the lifetime of a birth cohort of 118,000 children. The PIP was associated with discounted vaccination costs of €91 million from the healthcare-sector perspective and €122 million from the societal perspective. However, vaccination costs were more than fully offset by disease-related costs averted, with the latter amounting to a discounted €126 million and €390 million from the healthcare-sector and societal perspectives, respectively. As a result, pediatric immunization was associated with overall discounted savings of €35 million and €268 million from the healthcare-sector and societal perspectives, respectively; every €1 invested in childhood immunization resulted in approximately €1.4 in disease-related cost savings to the health system and €3.2 in cost savings from a societal perspective for Belgium's PIP. Estimates of the value of the PIP were most sensitive to changes in input assumptions for disease incidence, productivity losses due to disease-related mortality, and direct medical disease costs.warranted to sustain its positive public health and financial impact.

**CONCLUSIONS -** Belgium's PIP, which previously had not been systematically assessed, provides large-scale prevention of disease-related morbidity and premature mortality, and is associated with net savings to health system and society. Continued investment in the PIP is warranted to sustain its positive public health and financial impact.

# Biosketch



## Steve Black

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 USA and Honorary Professor of Pediatrics at the University of Auckland in New Zealand. He is editor in chief of the Pediatric Infectious Disease Journal.

# Abstract

## Steve Black

### Global Vaccine Data Network: experience, lessons learned, remaining

Steven Black, Helen Petousis-Harris, Jim Buttery
Co-Directors, GVDN

**BACKGROUND -** Following the initial detection of a possible relationship between receipt of ASO3 adjuvanted 2009 influenza vaccine and narcolepsy in Europe, multiple studies were conducted with different protocols yielding widely disparate results – some with a 16 fold increased risk and others with no increased risk. To try and address the need for globally coordinated studies with harmonized protocols, the Global Vaccine Data Network was established in 2019.

**CURRENT STATUS -** In 2021 the US CDC funded the GVDN GCoVS project to evaluate the safety of COVID-19 vaccines and the network has grown to include more than 30 countries. Since that time, harmonized protocols have been developed to develop background rates, observed versus expected ratios, and to conduct association studies for Guillain-Barré Syndrome, myo-/peri-carditis, VITT, VMED and the safety of maternal immunization. The first two studies are complete whereas data collection is ongoing for the association studies.

**LESSONS LEARNED -** The GVDN GCoVS study was funded one year after the start of the COVID pandemic. Without existing infrastructure, it was very time consuming to establish relationships, build trust and develop the protocols. While most protocols contemplated hands on medical record review, this has been difficult to achieve in a timely manner. Inclusion of low-income countries has required developing a separate data system.

**REMAINING CHALLENGES -** While the GVDN is successfully conducting investigator led global collaborative studies, the timelines for each project have been long. Work is in progress to develop a rapid response protocol to address new safety questions urgently. As always, availability of sustainable funding is an ongoing challenge.

# Biosketch


## Kaat Bollaerts

Head of Data Science
P95
Address: Koning Leopold III laan, 1, 3000 Leuven
E-mail: Kaatje.bollaerts@p-95.com


Kaat Bollaerts is a PhD-level biostatistician with over 15 years of experience in the field of epidemiology. After obtaining her PhD, she started working as a senior scientist at the Scientific Institute of Public Health, Belgium. Here she gained experience in diverse aspects of epidemiological research, ranging from setting up epidemiological studies to analyzing secondary databases. She holds leading positions in several European projects. She has plenty of experience in analyzing epidemiological data of all kinds and masters a wide variety of statistical techniques. Throughout her professional career, she is involved in consulting activities for private industry, governments and (inter)national public health institutions and teaches at national and international vaccine courses. Kaat joined P95 in September 2013, and is currently Head of Data Science supporting a team of >15 statisticians and data scientists within P95. She is also the Principal Investigator of the COVIDRIVE study estimating brand-specific COVID-19 vaccine effectiveness in Europe. Kaat co-authors the book "Vaccination Programmes: Epidemiology, Monitoring, Evaluation" (Hahné, Bollaerts, Farrington).

# Biosketch


## Gabrielle Breugelmans

Director of Epidemiology and Data Science
0277 Oslo, Norway
CEPI
Tel: + 47 477 93 433
Fax: +
E-mail: gabrielle.breugelmans@cepi.net


Dr Gabrielle Breugelmans is the Director of Epidemiology and Data Science at the Coalition for Epidemic Preparedness Innovations (CEPI). The Mission of the Epidemiology and Data Science department is to support CEPI, its partners, and stakeholders by bridging key epidemiological knowledge gaps for vaccine development and preparedness. Projects implemented by the department include amongst others the Enable Lassa fever programme. a large prospective cohort study in West Africa; development of a methodology to prioritize emerging pathogens for vaccine development; Covid-19 vaccine effectiveness studies in low-resource settings, and several modeling projects to assess vaccine impact and stockpile needs of CEPI's priority pathogens for routine and/or emergency use.

Dr. Breugelmans is an infectious disease epidemiologist with large expertise in global health, poverty-related diseases, access to medicines, and vaccinology in low-resource settings. She holds a Ph.D. and MPH in Epidemiology from the Johns Hopkins Bloomberg School of Public Health in the U.S. and a Master of Science degree in Health Sciences from the University of Maastricht in the Netherlands. Her research interests include epidemiological study designs, pharmacovigilance, pharmacoepidemiology, and epidemiological/ implementation issues related to the introduction of and access to new and improved medical interventions in low-resource settings.

# Biosketch

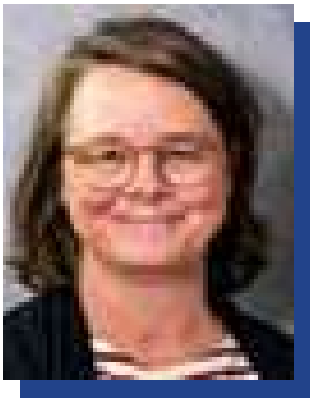

## Phil Bryan PhD

SERM Head, Executive Director
Viral and DTP combination Vaccines
GlaxoSmithKline

E-mail: philip.t.bryan@gsk.com


Phil is a Safety Evaluation & Risk Management Head (SERM) at GSK, overseeing a Group responsible for the safety of a range of vaccines including RSV, Zoster, Malaria and DTP combination vaccines. In the 20 years before joining industry, Phil was the UK MHRA lead on vaccine safety and worked closely with UK health authorities to develop and implement risk management strategies for the UK immunisation programme. He led the MHRA's COVID vaccine PV strategy, and was a member of the WHO GACVS COVID subcommittee. As an EU expert in vaccine safety, Phil co-authored several EMA guidelines on vaccines and biologicals pharmacovigilance, and has been actively involved in multistakeholder vaccine safety initiatives.

# Biosketch




## Rebecca Chandler

Clinical Development Vaccine Safety Lead
75591, SWEDEN
CEPI
Tel: + 46700244584
Fax: +
E-mail: Rebecca.chandler@cepi.net

# Biosketch


## Robert Chen

MD MA
Scientific Director
30330, Decatur, GA, USA
Brighton Collaboration, a program of the Task Force for Global Health
Tel: +1 678 490 8141
Cell: +1 678 662 0516
E-mail: rchen@taskforce.org


Dr. Chen has been active in research of vaccines and vaccine-preventable diseases for over 35 years, mostly at the US Centers for Disease Control and Prevention (CDC). He played key roles in modernizing the vaccine safety infrastructure in the U.S. and elsewhere. He has authored or coauthored over 300 publications. Dr. Chen is currently the Scientific Director of the Brighton Collaboration. He also Leads the Coalition of Epidemic Preparedness Innovation (CEPI)-funded Safety Platform for Emergency vACcines (SPEAC) Project, the US CDC-funded CARESAFE Project, and co-leads the COVAX Vaccine Safety Working Group.

# Abstract

## Robert Chen

### Brighton Collaboration's role in establishing a real world evidence (RWE) infrastructure for vaccine safety during early deployment.

Chen RT, Black S, Dekker C, Law B, Gurwith M, Nordenberg D, Munoz F, Chaudhary M, Stergachis A, Huang WT, Sturkenboom M, Chandler R

**INTRODUCTION -** The Brighton Collaboration (BC) was officially established in 2000 with the goal to advance the science of vaccine safety, focusing initially on developing standardized case definitions (CD) to harmonize safety assessments. Since then, the import of vaccine safety for vaccine confidence has continued to grow, especially in the context of a) progress towards elimination of many target vaccine-preventable diseases (VPD) through high vaccine coverage, and b) plans to develop new vaccines vs. emerging "Disease X" pathogens in 100 days ("100-Day Mission").

**CHALLENGES -** Historically, vaccine safety assessments within pre-approval clinical trials tended to be separate from post-approval RWE. A "life cycle" approach integrating both pre- and post-approval processes while ideal, was more an aspiration than a reality. Furthermore, doing so in low- and middle- (as well as high income countries adds another layer of difficulty.

**PROPOSED APPROACH -** The Coalition for Epidemic Preparedness and Innovation (CEPI) funded BC's Safety Platform for Emergency vACcines (SPEAC) project in May 2019. Based on the lessons learned from the COVID-19 pandemic, SPEAC (as SPEAC 2.0) was renewed and expanded in November 2022. Building upon its core of Adverse Events of Special Interest (AESI) CDs, the SPEAC 2.0 project aims to implement the use of standardized safety outcomes throughout the vaccine lifecycle, to ensure both the generation and interpretation of robust evidence of safety for CEPI 2.0's "100-day mission". For each CEPI-funded developer, SPEAC activities start during the pre-approval process (e.g., identify potential AESI for target pathogen and platform technology, develop standard BC CD if needed, identify background rates for AESIs, assign a meta-Data Safety Monitoring Board liaison member, complete vaccine profile template). Using this foundation, SPEAC continues through preparation for post-approval RWE active surveillance (e.g., mobile app for Cohort Event Monitoring, pregnancy exposure registry). Each Work Package is also planning "Living Labs" to Quality Assure and continuously improve their respective products for eventual use by the larger vaccine safety community. A digital transformation of BC CDs seeks to facilitate their greater use in existing processes and infrastructures used to perform vaccine safety surveillance.

**CONCLUSIONS -** BC and CEPI are using SPEAC to establish a "life cycle" approach to vaccine safety, including RWE infrastructure during early deployment.

# Biosketch


## Laura Cornelissen

Scientific Expert and team leader for vaccine-preventable diseases
Department of epidemiology, Sciensano
Belgium
E-mail: Laura.Cornelissen@sciensano.be


Dr. Laura Cornelissen is a medical doctor with a specialist degree in Obstetrics & Gynecology (KU Leuven) and an MSc in International Health (LSHTM). Since 2019, she is working at the Belgian Public Health Institute, Sciensano, at the department of epidemiology of infectious diseases, where she now leads the team of vaccine-preventable diseases.

As co-lead of the Belgian Risk Assessment Group and member of the Belgian NITAG, Dr. Cornelissen has first-hand experience with the challenges of advising policy makers in uncertain times. She acts as Belgian National Focal Point for vaccine-preventable diseases for ECDC and as such is also a member of the newly founded European Immunization and Vaccine Monitoring Board and the representative of Belgium in the EU-NITAG collaboration. As the scientific secretariat of the Belgian Elimination Committee for Measles & Rubella, she has a particular interest in these two diseases, but is strongly convinced of the importance of a holistic approach to vaccination programs.

# Abstract

## Laura Cornelissen

Laura Cornelissen, Scientific Expert and team leader for vaccine-preventable diseases, Department of epidemiology and public health, Sciensano
Dieter Vercauteren, Department of epidemiology and public health, Sciensano
Joris van Loenhout, Department of epidemiology and public health, Sciensano
Koen Blot, Department of epidemiology and public health, Sciensano

**Background -** To inform decisions on vaccination, adequate, granular, timely and representative data is required. In Belgium, diverse types of data are currently being collected through various networks, ranging from passive surveillance, citizen and lab reporting over administrative data to wastewater surveillance.

**Challenges –** Unfortunately, challenges are numerous. There is a wealth of information available in administrative data, such as cause-specific death certificates or healthcare reimbursement, but this data often only becomes available after a delay of several years. Case definitions are not always respected, data input comes in heterogenous forms or data is not centralized. Also, issues with data registration sometimes relate back to rudimentary issues such as access to a computer for the vaccinator. A particularly big challenge is the lack of clear guidance on processing personal data for public health use. Especially with regards to linking data from several databases, current procedures in Belgium lack transparency, are administratively heavy and time-consuming.

**Proposed solutions –** Many aspects of data collection and reporting during the COVID-19 pandemic can be seen as best practice for other diseases and have created a precedent. At the same time, resource and capacity constraints means that it is neither feasible nor desirable to implement the same level of surveillance. Choices will thus have to be made. A particular advantage is that each Belgian citizen has a unique national number of social security which can be used to link databases. A clear legal framework and mandate for the Belgian public health institute could help in simplifying and speeding up approvals for linking databases whilst protecting data safety and confidentiality. To increase public acceptance, the opt-out system, as currently under discussion in the framework of the European Health Data Space, might be of value.

**Conclusion –** High-quality data is paramount for decision-making but many challenges remain. The COVID-19 experience and European push for more secondary use of health data provides momentum to improve current practices. Data collection, interpretation and reporting come with a cost and sufficient resources should be foreseen.

# Biosketch


## Jakob Cramer

Director of Clinical Development
Coalition for Epidemic Preparedness Innovations
Coalition for Epidemic Preparedness Innovations (CEPI)
Address: 215 Euston Rd.; London NW1 2BE; UK
E-mail: jakob.cramer@cepi.net


Dr Jakob Peter Cramer is a medical doctor specialised in internal medicine, tropical medicine, travel medicine and infectious diseases. He joined the Coalition for Epidemic Preparedness Innovations (CEPI) as Director of Clinical Development in June 2019.

Prior to his role at CEPI, Jakob was Head of the Tropical Medicine Section at the University Medical Center Hamburg-Eppendorf as well as the Clinical Research Unit at the Bernhard Nocht Institute for Tropical Medicine (BNITM) in Hamburg, Germany, where he founded the clinical trials unit and conducted Phase 1/2/3 vaccine trials against various infectious diseases (including influenza, rabies, Japanese encephalitis, meningococcal diseases, travellers' diarrhoea). During his 14 years in academia, he engaged in epidemiological and investigator-initiated clinical research in Africa. From 2014 to 2019, Jakob held the position of Medical Director, Clinical Development, Vaccine Business Unit, Takeda Pharmaceuticals International AG, Zurich, Switzerland where he was actively involved in Takeda's norovirus and dengue as well as the BMGF-funded polio vaccine development programmes.

He is a lecturer at the BNITM in Hamburg as well as on the MSc Course in Vaccinology at the University of Siena, Italy. He is also a member of a number of infectious diseases societies.

# Biosketch


## Clare Cutland

Scientific coordinator, Wits-Alive
Johannesburg, Gauteng, South Africa
African Leadership in Vaccinology Expertise, University of the Witwatersrand
Address: Faculty of Health Science
Tel: +27-828096032
E-mail: clare.cutland@wits.ac.za


Dr Clare Cutland is the Scientific Coordinator of the Wits African Leadership in Vaccinology Expertise (Wits-Alive) consortium (Since Nov 2018). Previously, she spent 18 years as a clinical researcher in vaccinology at the Respiratory and Meningeal Pathogens Research Unit (RMPRU, now Wits-VIDA), at Chris Hani Baragwanath Academic Hospital (CHBAH), Soweto, South Africa.

She was an investigator on numerous phase I, II and III paediatric, maternal and COVID-19 clinical vaccine trials, and was the clinical lead for several large grant-funded neonatal sepsis prevention studies, maternal-neonatal sepsis surveillance studies and maternal immunization trials (Influenza, GBS, RSV). She was a member and lead of several GAIA Brighton collaboration definition working groups (2014-2020), and was elected as a member of the scientific board of the Brighton collaboration in 2018.

She coordinates a biennial short course in vaccinology (Afro-ADVAC) and a Masters of Science (Med) in the field of vaccinology at The University of the Witwatersrand, and is the chair of the International Collaboration on Advanced Vaccinology Training (ICAVT).

She is coordinating the Gavi-funded African COVID-19 Vaccine Safety Surveillance (ACVaSS) project in 8 African countries. She is author or co-author on over 120 peer-reviewed journal articles.

# Abstract

## Clare Cutland

### Active COVID-19 safety surveillance in Africa: update & lessons learnt

Clare Cutland, Scientific coordinator
African Leadership in Vaccinology Expertise, University of the Witwatersrand (Wits-Alive)

**BACKGROUND -** Pharmacovigilance (PV) systems in low and middle income countries (LMICs) are limited due to resource and expertise constraints. The disparities between PV systems globally were highlighted during the COVID-19 pandemic. Two demonstration projects were established in Africa to estimate the risk of predefined adverse events of special interest (AESIs) with acute onset and short period of increased risk following immunization of the COVID-19 vaccine using a self-controlled risk interval (SCRI) study design. Predefined AESIs included generalized convulsions, myocarditis, pericarditis, anaphylaxis, thrombocytopenia, thrombocytopenia syndrome (TTS), Guillain Barré syndrome (GBS), Miller Fisher Syndrome (MFS), Acute Disseminated encephalomyelitis (ADEM), encephalitis, and myelitis.

**METHODS -** Hospital-based sentinel active COVID-19 vaccine safety surveillance studies were established at facilities across nine African countries: (i) Active COVID-19 vaccine safety surveillance (ACVaSS) in eight COVAX-92 Advanced Market Commitment (AMC-92) eligible countries including Ethiopia, Ghana, Kenya, Mali, Malawi, Mozambique, Nigeria and Eswatini and (ii) the South African COVID-19 vaccine safety surveillance study. Patients presenting to hospital with an acute illness suggestive of a predefined AESIs were screened for study participation, and eligible, consenting patients were enrolled between October 2021 (SA)/ April 2022 (ACVaSS) and March 2023. Data were collected from medical records, COVID-19 vaccination cards and registers, and from the patient and entered into a study-specific, centralised REDCap database, and were analysed using R software version 4.3.1. Brighton Collaboration case definitions were used. The ACVaSS study was funded by Gavi, The Vaccine initiative, and the South African study was funded by the Global Vaccine Data Network (GVDN). GVDN provided technical support to both studies.

**RESULTS -** A total of 60 511 patients were screened on hospital admission, of whom 12 756 were enrolled into the studies. Challenges encountered included delays in obtaining ethics approvals and establishing sites; limited laboratory- and imaging capacity and limited access to medical- and vaccination records.

**CONCLUSIONS -** These studies have demonstrated that establishment of sentinel active surveillance sites is feasible in LMICs, despite challenges encountered.

# Biosketch


## Hélène de Pauw

Scientist at the Unit of Cancer Epidemiology
Belgium
Sciensano
E-mail: helene.depauw@sciensano.be


Hélène De Pauw is a Research Scientist at Sciensano.

Hélène graduated with a Bachelor of Science in Nursing (HENALLUX, 2014) and a master's degree in Science of Public Health (UCLouvain, 2017). She works for Sciensano since October 2017. She first integrated the Unit of Healthcare-Associated Infections and Antimicrobial Resistance (NSIH). Since 2019, she works in the Unit Cancer Epidemiology, which is part of the Belgian Cancer Centre. Her research activities focus on cervical cancer screening and HPV vaccination. She is currently working on the PERCH (Partnership to Contrast HPV) project. The overall aim of this project is to contribute to the implementation of the European Plan to beat cancer, which seeks to support Member States' actions to strengthen routine HPV vaccination in order to eliminate cervical cancer and other cancers caused by HPV over the next decade.

Hélène is Board member of the CCR (Centre Communautaire de Référence pour le dépistage des cancers) which is an accredited non-profit organisation responsible for managing breast and colorectal cancer screening programmes in Wallonia. She also represents Sciensano in Belgian association, such as BRUPREV, which is an association in charge of organising cancer screening and prevention in the Brussels Region. Hélène is also investigating, through various projects, the use of self-sampling in an organised cervical cancer screening programme.

# Abstract

## Hélène de Pauw

PERCH (PartnERship to Contrast HPV) project

Hélène De Pauw[1], Louise Mathieu[1], Sophie Denoël[1], Marc Van Den Bulcke[1], Jenny Chung[1], Pegah Rousta[1], Nina Dhollander[1], Raffaella Bucciardini[2], Urška Ivanuš[3], Maria Brotons[4], Claudia Robles[4], Laia Bruni[4], Benedetta Mattioli[2], Anastasia Balasopoulou[5], Yvette Shajanian Zarneh[6], Miriam Gerlich[7], Marc Arbyn[1]

[1]Unit Cancer Epidemiology, Belgian Cancer Centre, Sciensano ,Brussels, Belgium
[2]Istituto Superiore di Sanità, National Centre For Global Health, Roma, Italy
[3]Institute of Oncology Ljubljana (OI Ljubljana), Department For Cancer Screening, Ljubljana, Slovenia
[4]Institut Català d'Oncologia (ICO), Cancer Epidemiology Research Program, Barcelona, Spain
[5]1st Regional Health Authority of Attica 1st YPE, Directorate Of Public Health, ATHENS, Greece
[6]Federal Centre for Health Education (BzgA), Task Planning, Strategy, Knowledge Transfer And International Relations, Colonia, Germany
[7]Federal Centre for Health Education (BzgA), Sexual Health, Prevention Of HIV And Other STI, Colonia, Germany
(Grant Agreement: 101075314)

**Background -** In 2020, cervical cancer (CC) ranked as the 4th most common cancer in women worldwide. While highly preventable through HPV vaccination and CC screening, it remains a significant public health issue, worldwide but also in Europe. Despite the availability of HPV vaccines since 2006, and its introduction into national immunisation plans, many countries have yet to reach optimal vaccination coverage. To meet WHO's 90% coverage target for HPV vaccination by 2030, actions are needed by countries to improve their specific vaccination coverages.

# Abstract

## Hélène de Pauw

**Methods -** The Project PERCH (PartnERship to Contrast HPV) is a European Joint Action which involves 34 organisations from 18 European countries (17 participating countries and Ireland as an associate partner) for a duration 30 months. PERCH Grant Agreement was signed in September 2022. The activities of PERCH are distributed into seven complementary and interconnected Work Packages (WPs): WP1 Coordination, WP2 Dissemination, WP3 Evaluation, WP4 Integration and Sustainability, WP5 Monitoring, WP6 Improving Knowledge and Awareness to Increase Vaccine Uptake, WP7 Training and Support in Vaccine.

**Results -** All the activities planned within PERCH are designed with the aim of achieving sustainable results at short, mid and long-term perspective. The preliminary results will be available through the official website https://www.projectperch.eu .

**Conclusions -** PERCH will develop an Integration and Sustainability Plan including integration of HPV vaccination in the routine immunisation schedule in all member countries, applying strategies to reach or maintain high vaccination coverage, and improving data collection and data linkage to monitor the process and impact of vaccination. This plan will also provide guidance for tailored HPV vaccination implementation based on local requirements and best practices. Funded by the European Union. Views and opinions expressed are those of the author(s) only and neither the EU nor the HaDEA can be held responsible for them.

# Biosketch


## Olivier Ethgen

Professor of Health Economics
University of Liège, Belgium
Invited lecturer at Department of Pharmacy and Department of Biomedical Science, University of Namur, Belgium
E-mail: o.ethgen@serfan.eu


Olivier is Associate Professor of Health Economics at the Department of Public Health Sciences, Faculty of Medicine, University of Liège in Belgium. He is also an invited lecturer at the Department of Pharmacy and the Department of Biomedical Sciences, Faculty of Medicine, University of Namur in Belgium. He lectures in health economics (theory & applied modeling), decision sciences and pharmacoepidemiology. Olivier holds a PhD in Public Health Sciences from the University de Liège and an MSc in Mathematical Economics from the University of Paris I - Panthéon Sorbonne. His research interests include financial modeling of patients and market access strategies and population-based modeling. His experience spans all types of healthcare technologies including drugs, biologics, vaccines, devices, and diagnostics.

# Biosketch


## Hector Izurieta

Associate Director OVRR/CBER/FDA

10903, New Hampshire Ave, Silver Spring, MD, 20993, USA

Tel: +2404028663
Fax: +
E-mail: Hector.Izurieta@fda.hhs.gov


Hector S. Izurieta, MD, MPH, PhD, is an Associate Director for Novel Clinical Investigations at the Office of Vaccine Research and Review (OVRR), in CBER, FDA. He has extensive U.S. and international vaccine research and public health experience, having also worked at CDC (including in the EIS program), PAHO, WHO, Médecins Sans Frontières and other organizations. His publications include over 90 manuscripts on COVID-19, Influenza, Herpes Zoster, Measles, Tetanus, Diphtheria, Pertussis, and on vaccine and real-world evidence study methods.

# Biosketch


## Xiao Li

Health Economist
2000, Antwerp, Belgium
University of Antwerp
E-mail: Xiao.Li@uantwerpen.be


Dr. Xiao Li is a health economist at the Centre for Health Economics Research and Modelling Infectious Diseases, Vaccine and Infectious Disease Institute, University of Antwerp, Antwerp, Belgium. She is specialised in modeling and cost-effectiveness analyses for infectious diseases. She has more than 14 years of experience in conducting multi-country health economic evaluations on several vaccines, including respiratory syncytial virus, hepatitis B, human papillomavirus, rotavirus, pertussis, varicella and influenza. She is also a member of RESCEU (REspiratory Syncytial virus Consortium in Europe) and PROMISE (Preparing for RSV immunisation and surveillance in Europe).

# Abstract

## Xiao Li

### Exploring the Cost-Effectiveness of Respiratory Syncytial Virus (RSV) Preventive Interventions in children with Real-World Evidence generated by the IMI-RESCEU project

Authors: Xiao Li [1], Zhuxin Mao[1], Lander Willem[1,2], Joke Bilcke[1] and Philippe Beutels [1]

[1]Centre for Health Economics Research and Modelling Infectious Diseases (CHERMID), University of Antwerp, Belgium

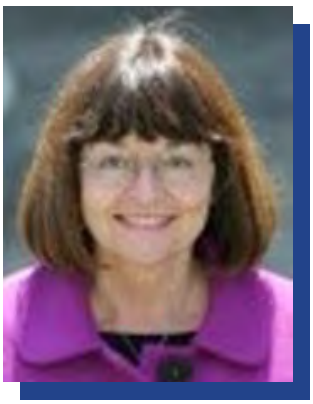
[2] Family Medicine and Population Health (FAMPOP), University of Antwerp, Belgium

**BACKGROUND -** Respiratory syncytial virus (RSV) leads to a large burden in paediatric wards across Europe. A monoclonal antibody (mAb) and a maternal vaccine (MV) have demonstrated effective protection against RSV among vulnerable infants in their clinical trials, hence, the recommendation and implementation of RSV prevention strategies are under consideration by public health decision makers. The cost-effectiveness of the interventions using robust and up-to-date real-world evidence (RWE) is imperative to inform decision making. Methods: The REspiratory Syncytial virus Consortium in EUrope (RESCEU), funded by Innovative Medicines Initiative (IMI), aimed to generate robust evidence on the disease burden and economic impact of RSV involving multi-stakeholders across Europe. A large amount of RWE was generated in multiple countries from national registries, and prospective observational studies. We developed a decision analytical model to evaluate potential MV and mAb programmes applying the RWE as model inputs. We estimated the RSV-related economic burden and assessed the cost-effectiveness of various programmes in Norway, Denmark, England, Scotland, the Netherlands, and Finland. We also made multi-model comparisons utilising available RWE.

**RESULTS -** At a common price of €50 per dose, seasonal mAb (October to April), and seasonal mAb plus a catch-up program in October can be cost-effective from payers' perspective, depending on the country and the willingness-to-pay threshold. Year-round MV can also be preferred in most countries if priced lower than mAb. From a full societal perspective (including leisure time lost), the seasonal mAb plus catch-up program was cost saving for all countries except the Netherlands. Apart from interventions' characteristics (price, efficacy, and duration of protection), the results are also sensitive to RSV hospitalisation estimates and quality-adjusted life year losses.

**CONCLUSIONS -** RWE generated by RESCEU supports the decision-making process in multiple countries regarding the implementation of RSV prevention strategies. However, there are still large data gaps, especially on RSV disease burden and intervention effectiveness. More RWE is urged to further inform decision makers, the scientific community, and the general public.

# Biosketch




## Elizabeth Miller

Elizabeth (Liz) Miller BSc, MBBS, FRCPath, FMedSci
Position: Academic Professor
London School of Hygiene and Tropical Medicine, Keppel Street, London, WC1E 7HT United Kingdom
Tel: +447974355138
E-mail: liz.miller@lshtm.ac.uk


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



## Helen Rees

Executive Director,
Wits RHI University of Witwatersrand,
Johannesburg, South Africa

GCOB OBE Officier de l'Ordre national du Mérite France
D.Sc Medicine (hc) LLD (hc) MRCGP, MA and MB BChir
(CANTAB) DCH DRCOG

Professor Helen Rees is internationally recognised as an award-winning global health and medical practitioner who has dedicated her professional career to improving public health in Africa. Professor Rees is the Founder and Executive Director of Wits RHI, the largest research Institute at the University of Witwatersrand in Johannesburg, South Africa. Professor Rees is widely respected for her ability to synthesize recommendations from multifaceted inputs and to link research to policy and has successfully chaired many national, regional and global committees in deliberations that have changed key strategies and policies in the African region, and has served on expert structures and committees for WHO, UNAIDS, UNICEF, the Global Alliance for Vaccines and Immunisation and BMGF.

Professor Helen Rees is the Founder and Executive Director of Wits RHI, the largest research Institute at Wits University in Johannesburg, South Africa. A medical doctor by profession, Professor Rees is a Personal Professor in the University of Witwatersrand's Department of Obstetrics and Gynaecology, Co-Director of the Wits African Leadership in Vaccinology Expertise, Honorary Professor in the Department of Clinical Research at the London School of Hygiene and Tropical Medicine and an Honorary Fellow at Murray Edwards College, Cambridge University, UK. She holds a Doctor of Science (Medicine) honoris causa from the University of London and a Doctor of Laws honoris causa from Rhodes University.

# Biosketch



Professor Rees has served on and chaired many national and global scientific committees and boards. She is the board chair of the South African Health Products Regulatory Authority. She chairs the WHO's African Regional Technical Advisory Group on Immunization. For the past fifteen years she has played a major global role on global vaccine committees. She has contributed to the evolution of HIV and STI vaccine research through chairing or membership of WHO and UNAIDS expert committees. Combining her VPD and SRH interests, she has been PI or co- investigator on HPV vaccine studies. She chairs a BMGF committee on HPV vaccines and is a member of a WHO HPV vaccine expert committee and chairs the South African NITAG's HPV technical working group. She is co-chair on two studies exploring HPV vaccine impact among girls in communities with high HIV prevalence, and on the effectiveness of a single dose of HPV vaccine. She is the Chair of the Gavi Vaccine Investment Strategy that is developing a priority list for procurement of vaccines between 2025-2030 for the world's poorest 71 countries. She chairs the MedAccess Board which is a global organisation that identifies and funds access to neglected therapeutics and diagnostics required in low- and middle-income countries.

Professor Rees has won many international and national awards for her contribution to global health and to science, including being made an Officer of the British Empire (OBE) in 2001 by Queen Elizabeth II. In 2016 she was awarded the South African National Order of the Baobab for her contribution to medicine and to medical research. In 2022 Professor Rees was made an Officer of the French National Order of Merit by President Macron for her contribution to global health and to the COVID-19 response, and also received the Platinum South African National Batho Pele Award for excellence in contribution to the South African COVID-19 response. In 2022 she was named a 'standout voice' in African public health by Harvard Public Health.

# Biosketch


## Tom Shimabukuro

Director, Immunization Safety Office
U.S. Centers for Disease Control and Prevention (CDC)
1600 Clifton Road
Atlanta, GA, USA 30329
Tel: +1 404-498-0679
E-mail: TShimabukuro@cdc.gov


Dr. Tom Shimabukuro is the director of the Immunization Safety Office at the U.S. Centers for Disease Control and Prevention (CDC). He has been with the Immunization Safety Office since 2010 where he has served in a variety of positions to include senior medical officer, Vaccine Adverse Event Reporting System (VAERS) team lead, acting Vaccine Safety Datalink (VSD) team lead, vaccine safety team lead in the CDC COVID-19 Vaccine Task Force, deputy director, and director.

# Abstract

## Tom Shimabukuro

### Real-world vaccine safety evidence and public health decision making in the United States during the COVID-19 vaccination program

Dr. Tom Shimabukuro, Director, Immunization Safety Office U.S. Centers for Disease Control and Prevention (CDC)

The U.S. Centers for Disease Control and Prevention (CDC) uses multiple, complementary public health surveillance systems and programs to monitor the safety of vaccines authorized or licensed for use in the United States. COVID-19 vaccines were administered under the most intensive vaccine safety monitoring effort in U.S. history. During the pandemic vaccination program, >676 million COVID-19 vaccine doses were administered in United States and 81.4% of the population received at least one dose of a COVID-19 vaccine. Two examples highlight the effectiveness of CDC's vaccine safety monitoring programs in generating actionable real-world evidence, myocarditis following the Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines and thrombosis with thrombocytopenia syndrome (TTS) following the Janssen adenoviral-vectored COVID-19 vaccine. In these two examples, CDC vaccine safety monitoring systems detected and assessed safety signals and quantified the risk of these adverse events following vaccination. This real-world evidence contributed to regulatory and public health action. Warnings were added to regulatory documents, clinical considerations were updated, and vaccine recommendations were issued, including an eventual preferential recommendation for the use of mRNA COVID-19 vaccines over the Janssen adenoviral-vectored COVID-19 vaccine. These actions informed healthcare providers and policy makers and protected and informed the public.

# Biosketch


## Julia Stowe

Senior Epidemiologist
London UK
UK Health Security Agency
61 Colindale Avenue, NW9 5EQ
Tel: +2083277485
E-mail: julia.stowe@ukhsa.gov.uk


Dr Julia Stowe has worked at UK Health Security Agency since 1999 on vaccine effectiveness and post-licensure epidemiological vaccine safety studies addressing pertinent vaccine safety concerns using routinely collected and electronic healthcare data. Routinely collected and electronic healthcare data is an indispensable tool for epidemiological research but especially in vaccine safety surveillance. These databases can never be used without the consideration of a great number of factors specific to the disease and vaccine. Her PhD assessed the methodological challenges in post-licensure vaccine safety studies and the epidemiological methods employed to quantify a risk, if any, of an adverse event after vaccination. These methods are employed to address the many sources of bias that are inherent when studying such complex conditions in a challenging setting.

Many of the epidemiological challenges are unique to vaccine safety surveillance due to a number of factors and methods employed in the surveillance of therapeutic drugs cannot be automatically transferred. These challenges and the need to be able to respond to vaccine safety concerns in a timely and methodological robust manner need to be balanced. Julia has expertise in the use, implementation and management of large electronic datasets and has worked on many high-profile studies. She manages, designs, analyses and reports using these data carrying out epidemiological studies. She has also led the development of research proposals, writing scientific reports and papers for publication and presented epidemiological findings nationally and internationally at meetings and conferences.

# Biosketch

## Miriam Sturkenboom

Head of the Department of Datascience
& Biostatistics
University Medical Center Utrecht
The Netherlands

Miriam Sturkenboom is professor in Real World Evidence, a pharmacoepidemiologist, and head of the department of Datascience and Biostatistics at the Julius Center of University Medical Center Utrecht in the Netherlands. She was professor in Observational Data Analysis at the department of Medical Informatics at Erasmus MC until 2017. She is past president of the International Society for Pharmacoepidemiology. Her research interests focus on knowledge discovery from data collected in routine health care to improve evidence on drug and vaccine safety in particular in vulnerable populations (children, pregnancy and elderly). She is coordinator of the European commission funded ConcePTION project aiming to establish a tested system for the monitoring of benefits and risks of medicines in pregnancy, and is co-founder and president of the Vaccine Monitoring Collaboration for Europe (VAC4EU), she coordinated several EMA funded studies on COVID-19 vaccines. In terms of quantitative research outputs: she supervises/d more than 50 PhD students, has more than 400 peer reviewed papers in the area of pharmacovigilance, pharmacoepidemiology and medical informatics and an h-index of 93.

# Abstract

## Miriam Sturkenboom

### VAC4EU: experiences, lessons learned, remaining challenges

Pr. Miriam Sturkenboom, Head of the Department of Datascience & Biostatistics, University Medical Center, Utrecht, The Netherlands

The Vaccine Monitoring Collaboration for Europe was established as a non-for profit international association to generate best evidence about vaccines, post-marketing, in a collaborative manner. It was incorporated as legal entity in Belgium early 2020, just prior to the start of the Covid-19 pandemic. It is based on the blue print that was written by ECDC as part of the IMI-ADVANCE project.
Currently 31 research and public health organizations are a member. Vaccine manufacturers and publicly listed organizations cannot be a member of VAC4EU. VAC4EU members conduct studies on vaccines, using real world data. Data may be already collected (e.g. from electronic health records) or be collected de novo (e.g for cohort event monitoring). VAC4EU used principles of transparency and open science.
All protocols are listed on the EU PAS register, and project outputs (statistical analysis plans, code lists, scripts and reports) are posted on the zenodo public repositories in the VAC4EU community. VAC4EU conducts studies through a common protocol, a common data model (ConcePTION CDM), and common analytics, work groups define codelists, functions, algorithms and validation tools, which can be shared among members and publicly when finalized. Currently VAC4EU has supported four COVID-19 vaccine studies funded by EMA, and 6 studies requested by vaccine manufacturers as post authorization safety studies.

# Biosketch


## Sylvia Taylor

Infectious disease epidemiologist
Head of Medical Evidence
Vaccine and Immune Therapies Unit
AstraZeneca
E-mail: sylvia.taylor@astrazeneca.com


Sylvia Taylor, PhD MPH MBA is an infectious disease epidemiologist and currently Head of Medical Evidence for AstraZeneca's Vaccines and Immune Therapies Unit that was formed in November 2021.

She is passionate about vaccines and preventive interventions for infectious diseases and has spent more than 20 years working on related global health initiatives in both the private and public sector. She initially joined AstraZeneca in 2020 as the lead epidemiologist for AstraZeneca's COVID-19 vaccine program, playing a key role in the distribution of >3 billion vaccine doses worldwide.

She was previously also a senior epidemiologist for GlaxoSmithKline Vaccines, leading epidemiology strategy/activities for late and early-stage vaccines, including HIV, Ebola, TB, HPV, RSV, and Streptococcus Pneumoniae, over a period of 8 years. She has additionally worked as a Senior Technical consultant for the United Nations' International Organization for Migration, collaborating with the US Centers for Disease Control on community-based surveillance among Venezuelan migrants in Colombia, and as a research scientist at the Institut Pasteur in Paris, with focus on epidemiology and prevention of HIV, TB, and Hepatitis C. Originally from the United States, she has spent the last 17 years working/living abroad, including in Belgium, Cameroon, Cambodia, Colombia, Egypt, England, France, and Peru. During 2017-2019, while on sabbatical in Cameroon, she completed a TRIUM Global Executive MBA – a joint program with the London School of Economics, HEC Paris, and New York University Stern School of Business – and worked on several business development projects in Cameroon, China, and Europe.

# Abstract

## Sylvia Taylor

### Example of use of RWE that supported decision-making (VE against symptomatic infection, duration, mix and match, booster)

Sylvia Taylor
PhD MPH MBA, Infectious disease epidemiologist Head of Medical Evidence Vaccine and Immune Therapies Unit, AstraZeneca

**BACKGROUND -** AZD1222 (ChAdOx1 nCoV-19; Vaxzevria; AstraZeneca) is a COVID-19 adenoviral vector vaccine, first approved for use in the United Kingdom on 30 Dec 2020 and European Union on 29 Jan 2021. More affordable and stable at ambient temperatures than mRNA vaccines, during the pandemic, >3 billion doses were distributed to >180 countries, with two-thirds going to low/middle-income countries, resulting in >6 million lives saved during the first 12 months of use. Similar to mRNA vaccines, expert review of 79 real-world evidence (RWE) studies showed 93% protection against COVID-19 hospitalization for the primary series, with effectiveness waning over time. Further effectiveness studies suggest that booster dose protection against severe disease was equivalent to monovalent mRNA vaccines.

**CHALLENGES -** Due to the rapidly changing variant landscape, there has been increasing reliance on real world evidence to demonstrate COVID-19 vaccine effectiveness and inform decision making. However, according to the International Vaccine Access Center, of the 495 COVID-19 vaccine effectiveness studies in preprint/published literature as of 05 Sep 2023, 73% were conducted in Europe or North America, having impact on global decision making for vaccines used primarily in low/middle income countries. This is due in part to the stronger health research infrastructure of North American/European countries, facilitating large scale studies of vaccine effectiveness using secondary data sources for example, but also earlier vaccine access/faster initiation of vaccination/booster programs in those countries.

**PROPOSED APPROACH -** Efforts are needed to build up post-marketing research infrastructure and capabilities in low/middle income countries to more rapidly assess vaccine effectiveness and support study designs that do not fully rely on primary data collection. Creation of real-world evidence hubs in key, early adopter countries could be warranted.

**CONCLUSIONS -** With the increasing importance of RWE to inform decision making, it is important to consider the balance between effectiveness data from high versus low/middle income countries and ensure that the most appropriate, timely data are available to inform global-level decisions.

# Biosketch


## Laurence Torcel Pagnon

Epidemiologist
Sanofi
E-mail: laurence.pagnon@sanofi.com


Laurence Torcel-Pagnon is an Epidemiologist (MSc). She has been working in industry on vaccine preventable infectious diseases for 15 years collaborating in several epidemiological studies and international projects. For the last 10 years, she has been more specifically engaged in European and worldwide public-private partnerships (ADVANCE, DRIVE, COVIDRIVE, GIHSN, BeCOME), co-leading the development of large Real World Evidence platforms for disease surveillance and vaccine effectiveness monitoring (Flu, COVID, RSV and other respiratory viruses). She has co-developed governance guidance and open data frameworks to foster multi-stakeholder collaborations between Public health institutes, Regulatory authorities, Academia, International organizations and vaccine companies for evidence generation and public health benefit. She is acting as Executive Officer at the Foundation for Influenza Epidemiology supporting the Global Influenza Hospital Surveillance Network.

Currently, Laurence is coordinating the evidence generation strategy for Sanofi influenza vaccines (licensed products), working in close collaboration with internal experts/functions and maximizing collaborative approaches with external stakeholder networks and platforms.

# Abstract

## Laurence Torcel Pagnon

### Improving quality of evidence for decision making through innovative design and collaborative studies leveraging RWE platforms: sharing experiences from Influenza vaccine effectiveness evaluation

Authors: Laurence Torcel-Pagnon*, Matthew Loiacono*, Rob van Aalst* and Rebecca Harris*
*Global Medical Evidence Generation, Influenza, Sanofi

**BACKGROUND -** The digital expansion in healthcare offers the possibility to generate real-world evidence (RWE) on the use and performance of vaccines in a real-world setting, complementing evidence from randomized controlled trials (RCTs). While the use of RWE for informed decision making is not new, as it has been largely used for safety signal evaluation, potential for bias and confounding pose additional challenges for vaccine effectiveness (VE) evaluation.

**CHALLENGES OR ISSUES -** Influenza vaccine performance varies across seasons, populations, settings, and outcomes. RCTs, while the gold-standard, are often highly selective in terms of subjects, may not be representative of the general population with various medical conditions, and limit the assessment of broader clinical outcomes and number of seasons. Assessing influenza VE in counties or region with scattered vaccine type utilization, heterogeneous policies and uptakes further underscores the need for wide RWE platforms to produce robust vaccine performance estimates.

**PROPOSED APPROACH -** We tested two proofs-of-concept aiming to improve the quality of RWE for VEE. The DANFLU-1 study aimed to assess the feasibility and scalability of an individually randomized pragmatic framework to demonstrate the relative VE of a high-dose influenza vaccination against broader, clinically meaningful endpoints. This platform utilized scalable, innovative methods (electronic consent, digital invitations, randomization integrated into routine clinical practice, and follow-up via national registries) to create a minimally invasive experience for participants and simultaneously generate robust RWE. DRIVE was an Innovative Medicines Initiative project aiming to set up a multi-stakeholder, collaborative pan-European RWE platform for robust influenza VE monitoring. Over 5 years, this project has shown the value of a large and experienced surveillance network, implementation of a master/generic protocol, pre-defined pooled analyses, and multi-stakeholder dialogue to deliver timely RWE for informed decision making.

**CONCLUSIONS -** These two proofs-of-concept offer promising solutions to change the use and perception of RWE to support influenza vaccination programs and vaccine coverage. Implementation and acceptance warrant further steps and multi-stakeholder discussions to move to actionable decision-making.

# Biosketch


## Fran Van Heuverswyn

Project Manager, Flanders Vaccine
Agoralaan A-bis, 3590 Diepenbeek, Belgium
Tel: +32 11 28 69 04
E-mail: fran.vanheuverswyn@flandersvaccine.be


Fran Van Heuverswyn is the Project Manager of Flanders Vaccine, a non-profit organisation, working cross-sectoral (academic, industry, government) to foster collaborations within the field of vaccines and immunotherapeutics. Fran leads the organisation and her primary responsibilities encompass the daily management, coordination, and execution of projects pivotal to the R&D of preventive and therapeutic vaccines within the veterinary and human field.

She has a background in Biomedical Science and obtained a PhD in 2007 at the University of Montpellier II, France. She reported for the first time the discovery of HIV-1 group O related viruses in wild gorillas in south west Africa, indicating the precursor of HIV-1 group O viruses in humans. Further, she holds a degree in Third World Studies – Biology and a Master in Biological Science from the University of Ghent in Belgium. She is author or co-author on several peer-reviewed journal articles, including Nature and Science.

She has more than 15 years of experience working in several domains related to microbiology, infectious diseases and vaccines. At BioMaric NV, Belgium, she contributed to advanced HIV diagnostics and she has played a prominent role as project officer for the production of reference materials and the standardization of practices within the microbiological field at the European Commission, Joint Research Centre, Geel, Belgium.

# Biosketch



## Joris Vandeputte

Past President, IABS
Belgium

Joris Vandeputte was elected President of IABS (International Alliance for Biological Standardization) in June 2016. He is founding member of IABS-EU the European affiliate of IABS. IABS-EU implements the objectives of IABS at European level. IABS-EU is partner of the EU IMI (Innovative Medicines Initiative) projects ZAPI and VAC2VAC (www.IMI.eu, www.zapi-imi.eu, www.vac2vac.eu).

IABS hold its founding congress in Lyon in 1955. It is the global independent platform, interface, where stake-holders meet for exchange of science and issues related to vaccines, cell and gene therapy and human Biotherapeutics. IABS stimulates consensus building which might eventually be translated in regulatory frameworks and advises to decision makers.

Joris Vandeputte is also founder and president of TRIVAROP, a public affairs consultancy advising companies and associations in the area of global healthcare. Joris has more than 40 years industry and international organisation's experience in vaccines, conceiving and developing vaccine policies at global level and towards developing countries in particular. Working with European institutions and policy-makers on innovation, health and development is his main activity.

As a virologist at Ghent University (1976-1980), Joris discovered H1N1 flu as a pathogen for swine leading to a better understanding of H1N1 as a zoonosis. After his assignment as Veterinary Officer to control animal diseases in Belgium

# Biosketch



and the EU, Joris joined Institut Mérieux animal health which became Rhône Mérieux and later on Merial, where he occupied leading positions in global vaccine development, strategy, regulatory affairs, marketing and production,for animal vaccines and flu vaccines.

In 2001 he joined The Vaccine Fund, where he coordinated relations with European institutions which led to substantial funding by the EU and European governments to GAVI. At Tuberculosis Vaccine Initiative (TBVI) in Lelystad, the Netherlands, Joris developed, with EU institutions, a financial and strategic framework about funding translation of innovation into vaccines for tuberculosis which would be accessible to global markets.

Joris is consultant for international organisations with particular emphasis on zoonoses, one Health approaches and health in developing countries.

# Biosketch


## Thomas Verstraeten

CEO
3001 Leuven, Belgium
P95
Koning Leopold III Laan 1
Tel: +32 474 53 48 68
E-mail: Thomas.Verstraeten@p-95.com

# Biosketch


## Melinda Wharton

Associate Director for Vaccine Policy
Atlanta, Georgia 30329 USA
National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention

Address: 1600 Clifton Road NE
Tel: +4046398755
Fax: +
E-mail:mew2@cdc.gov


Dr. Melinda Wharton currently serves as the Associate Director for Vaccine Policy and Executive Secretary of the Advisory Committee on Immunization Practices in the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention. She joined CDC as an Epidemic Intelligence Service Officer in 1986 and has worked in CDC's immunization program since 1992. She previously served as a member and as chair of WHO's Global Advisory Committee on Vaccine Safety and as a member of FDA's Vaccines and Related Biological Products Advisory Committee.