

TUESDAY 19 OF SEPTEMBER, 2023

- 08:30** **Coffee and Registration**
- 09:15** **Welcome** – Joris Vandeputte, *IABS Past President*
- 09:25** **Bob Small Memorial** – Jakob Cramer, *CEPI*
- 09:35** **Objectives of the meeting** – Thomas Verstraeten, *P95*

SESSION 1: The role of RWE for accelerating vaccine deployment

Chairperson: Thomas Verstraeten, P95

- 09:40** **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 (Virtual)* and Jakob Cramer, *CEPI*
- 10:10** **PCV20 and RSV in older adults: similarities and differences for RWE** – Brad Gessner, *Pfizer (Virtual)*

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, *LSHTM (moderator)*, all
- 12:40** **LUNCH**

*Split in groups of 8-10 people, every group addresses the same questions.
Summaries from individual breakout groups on flipcharts. Plenary discussion afterwards.

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
Miriam Sturkenboom, *UMC Utrecht*
- 14:45** COVIDRIVE: experiences, lessons learned, remaining challenges
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) - 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
Clare Cutland, *Wits-Alive*

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, *LSHTM (moderator)*, all
- 17:15** END OF DAY 1
- 19:30** GROUP DINNER AT MYKENE RESTAURANT

WEDNESDAY 20 OF SEPTEMBER, 2023

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, *LSHTM (moderator)*, all
- 10:40** **COFFEE BREAK**
- 11:10** **BREAK OUT #4*: How to overcome main “barrier # 2”****
Liz Miller, *LSHTM (moderator)*, all
- 12:10** **Wrap up of the meeting, and next steps** - Liz Miller, *LSHTM*
- 12:25** **LUNCH**

** Barriers as identified

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, *University of Antwerp*
- 14:30** **Public Health Impact and Return on Investment of Belgium’s Pediatric Immunization Program**
Olivier Ethgen, *Université de Namur* & André Bento, *MSD*
- 14:55** **PERCH (PartnERship to Contrast HPV) project** - Hélène De Pauw, *Sciensano*
- 15:20** **COFFEE BREAK**
- 15:50** **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 Torcel-Pagnon, *Sanofi*
- 16:40** **Closing** – Joris Vandeputte, *IABS Past President*

Scientific Committee Members

- Nick Andrews (UKHSA)
- Steve Black (GVDN)
- Kaat Bollaerts (P95)
- Hector Izurieta (FDA)
- Pieter Neels (IABS)
- Jeffrey Roberts (Merck)
- Bob Small (CEPI)
- Julia Stowe (UKHSA)
- Miriam Sturkenboom (UMC UTRECHT)
- Joris Vandeputte (IABS Past President)
- Melinda Wharton (CDC)

Break-out group facilitators:

- Nick Andrews (UKHSA)
- Steve Black (GVDN)
- Kaat Bollaerts (P95)
- Gabrielle Breugelmans (CEPI)
- Philip Bryan (GSK)
- Rebecca Chandler (CEPI)
- Hector Izurieta (FDA)
- Miriam Sturkenboom (UMC UTRECHT)
- Julia Stowe (UKHSA)
- Thomas Verstraeten (P95)