



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

19-20 September, 2023 – Leuven, Belgium

## Agenda

**19 September 2023, 8:30 – 17:15**

Time	Topic	Presenters
8:30	COFFEE and REGISTRATION	
9:30	Welcome	Pieter Neels (IABS)
9:35	Objectives of the meeting	Thomas Verstraeten (P95)
<b>SESSION 1:</b>	<b>The role of RWE for accelerating vaccine deployment</b>	
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 Kramer (CEPI)
10:10	PCV20 introduction	Brad Gessner (Pfizer)
<b>SESSION 2</b>	<b>Emergency Use Authorization of COVID-19 vaccines : regulatory and public health perspectives and actions</b>	
10:25	EUA of COVID-19 vaccines: role of RWE and the EU Vaccine Monitoring Platform to evaluate safety and effectiveness	Marco Cavaleri (EMA) and Hector S Izurieta (FDA)
10:45	COFFEE BREAK (30')	
11:15	EUA of COVID-19 vaccines: role of RWE for public health decision making	Tom Shimabukuro (CDC)
11:30	<b>BREAK OUT #1*</b> : 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 (moderator), all
12:30	LUNCH	
<b>SESSION 3</b>	<b>Experiences with using RWE for regulatory and public health decision-making on COVID-19 vaccines</b>	
14:00	RWE use for COVID-19 public health decision-making in the UK: experiences, lessons learned, remaining challenges	Nick Andrews (UKHSA)



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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 RHI)
<b>SESSION 4</b>	<b>Improving the use of RWE for regulatory and public health decision-making (part 1)</b>	
16:15	<b>BREAK OUT #2*</b> : 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 (moderator), all
17:15	END OF DAY 1	
19:30	DINNER	



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## 20 September 2023, 9:00 – 17:00

Time	Topic	Presenters
<b>SESSION 5</b>	<b>Improving the use of RWE for regulatory and public health decision-making (part 2)</b>	
9:00	The BeCOME project and its RWE roadmap	Heather Rubino (Pfizer)
9:20	Brighton Collaboration's role in establishing a RWE infrastructure for vaccine safety during early deployment	Bob Chen (BC)
9:35	Introduction to break-outs	Thomas Verstraeten (P95)
9:40	<b>BREAK OUT #3*</b> : How to overcome main "barrier # 1"***	Liz Miller (moderator), all
10:40	COFFEE BREAK	
11:10	<b>BREAK OUT #4*</b> : How to overcome main "barrier # 2"***	Liz Miller (moderator), all
12:10	Wrap up of the meeting, and next steps	Liz Miller
12:25	Closing	Pieter Neels (IABS)
12:30	LUNCH	
14:00	Symposium (3h)	Flanders Vaccine

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

\*\* Barriers as identified during DAY 1



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## Scientific Committee Members

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

## Break-out group facilitators

1. Kaat Bollaerts (P95)
2. Miriam Sturkenboom (UMC UTRECHT)
3. Nick Andrews (UKHSA)
4. Julie Stowe (UKHSA)
5. Hector Izurieta (FDA)
6. Jeffrey Roberts (Merck)
7. Bob Small (CEPI)
8. Steve Black (GVDN)
9. Melinda Wharton (CDC)
10. Thomas Verstraeten (P95)
11. Gabriele Breugelmans (CEPI)
12. Emmanuelle Espié (CEPI)
13. Chantal van Gils (NDA Group)