



## **EU ECOSYSTEM FOR MONITORING OF POST-LICENSURE VACCINE BENEFIT AND RISK: FROM ADVANCE TO VAC4EU**

**MARCH 6, 2019, BRUSSELS**

The ADVANCE public-private consortium was launched by the Innovative Medicines Initiative (IMI) in 2013 to bring together all major stakeholder groups interested in the post-marketing monitoring of the health benefits and risks of vaccines. The consortium has demonstrated that the wealth of existing real-world health care data in the EU can be used to generate actionable evidence on vaccine coverage, benefits, and risks.

We will present the key ADVANCE solutions for some key challenges that had been identified at the outset, we will allow for playing with some of the information technology tools that have been developed and present and discuss the VAC4EU association as a sustainable ecosystem for monitoring of post-licensure vaccine coverage, benefits and risk.

The event will address the importance of public private collaboration, heterogeneity of data sources, ability to use real world evidence in decision making in the context of the post-marketing vaccine benefit/risk monitoring.

### **OBJECTIVES OF THE MEETING**

- 1.** Demonstrate how ADVANCE has created solutions and a trusted environment to generate evidence on post-licensure coverage, benefits and risk of vaccinations from existing real-world data across different countries
- 2.** Debate whether and how this may help in maintaining confidence in vaccination programs, which is currently at stake with large impact on return of vaccine preventable disease throughout Europe;
- 3.** Demonstrate tools and best practices Increase chances of sustainable funding and support.
- 4.** Present and discuss the VAC4EU association which aims to implement the ADVANCE Blueprint.

<b>A. MORNING SESSION</b>			
<b>Registration &amp; Networking Coffee</b>			<b>9:30 – 10:00</b>
1	<b>The need for vaccine benefit-risk surveillance to address public health issues in EU</b> <i>Moderator: Miriam Sturkenboom</i>		<b>10:00 – 11:00</b>
	Opening of the meeting	June Raine, MHRA & SAB member	10.00 - 10.10
	Stakeholder perspective on the current EU issues and how ADVANCE system may be needed	Movie featuring stakeholder views: (H. Larson, G Rezza, M. Goldman, P. Meulien, U. Heininger, P. Mauran, M. Votta, P. Arlett, F deStefano)	10:10 - 10:30
	Keynote “Vaccination: Promoting EU cooperation and addressing preventable diseases” a ROADMAP	Martin Seychell, Deputy Director-General for Health and Food Safety	10:30 – 11:00
<b>Coffee break</b>			<b>11:00 – 11:30</b>
2	<b>Key Challenges and Key ADVANCE Solutions for Vaccines Benefit, Risk Monitoring</b> <i>Moderator: Eva Molero</i>		<b>11:15 – 13:00</b>
	Why ADVANCE and why a public private collaboration?	Vincent Bauchau, GSK	11:30 – 11:45
	Public private partnership: <ul style="list-style-type: none"> <li>Should and can public health research institutes and vaccine manufacturers work together: what are the benefits and risks?</li> <li>Opportunities and challenges of ADVANCE best practice solutions: regulatory perspective</li> </ul>	Hannah Nohynek (TBC)  Xavier Kurz, EMA	11:45 – 12:00
<b>A. MORNING SESSION</b>			
2	Use of real-world data from different countries to generate actionable evidence on vaccines: <ul style="list-style-type: none"> <li>Meeting the requirements on quality and timeliness of evidence from heterogeneous existing health data for regulatory decision making</li> <li>ADVANCE solutions to generating evidence from heterogeneous health data</li> </ul>	Sabine Straus, CBG & PRAC chair  Miriam Sturkenboom, P-95, UMCU	12:00 – 12:20
	Need to assess both benefits and risks of vaccines: <ul style="list-style-type: none"> <li>How can HCPs be supported to explain vaccination to vaccine hesitant parents?</li> <li>A dashboard to visualize coverage, benefit and risks of vaccines</li> </ul>	David Salisbury  Kaatje Bollaerts (P-95)	12:20 – 12:40
	Panel discussion about the challenges in EU public health and the solutions that ADVANCE has created <i>Moderator: Patrick Mahy</i>	Panel: F DeStefano, D. Salisbury, J Raine, B Mons, R Swierzewski & speakers	12:40 – 13:15

<b>B. AFTERNOON SESSION</b>			
<b>Playing with the Advance Tools - a short overview (Miriam Sturkenboom)</b>			<b>13:15 – 13:20</b>
Interactive Walking Lunch with opportunity to see ADVANCE posters, see & use ADVANCE tools (Codemapper, VaccO, Database characterization, Misclassification in vaccine effectiveness, B/R dashboard, Interrelations) and speak with investigators			13:20 – 14:30
3	<b>ADVANCE ends, what is next? VAC4EU (Vaccine monitoring Collaboration for Europe)</b> <b>Moderator: Vincent Bauchau</b>		<b>14:30 – 16:30</b>
	The ADVANCE Blueprint	Piotr Kramarz (ECDC)	14.30 - 15.00
	VAC4EU organization, governance & membership	Patrick Mahy (Sciensano)	15.00 – 15:15
	Perspective of EMA on VAC4EU	Xavier Kurz (EMA)	15:15 – 15:30
	Public health organizations, Joint Action & VAC4EU	Tyra Grove Krause (SSI)	15:30 – 15:45
	Citizen perspective	Mariano Votta	15.45-15.55
<b>Round-table about the future and possibilities of VAC4EU.</b> <b>Moderator: M. Sturkenboom</b> Panel: J. Diez-Domingo (DRIVE-project), M. Votta (Citizen), G. Rezza (ISS), P. Mauran (Vaccines Europe), G Ferreira (consultant, former SC), M. Greenberg (Sanofi, former SC) & speakers  <ul style="list-style-type: none"> <li>- What do different stakeholders gain/see in a collaboration such as in VAC4EU?</li> <li>- What are the opportunities for VAC4EU?</li> <li>- How to get support for VAC4EU</li> <li>- How does VAC4EU in the EU project/political landscape?</li> </ul>			<b>15:55– 16:45</b>
<b>Closure: Vincent Bauchau</b>			<b>16:45 – 16:50</b>
Networking Cocktail			16:50 – 18:00