



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.

A. MORNING SESSION			
Registration & Networking Coffee			9:30 – 10:00
1	The need for vaccine benefit-risk surveillance to address public health issues in EU		10:00 – 11:00
	Opening of the meeting	June Raine (TBC)	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. Heiningen, P. Mauran, M. Votta and several others)	10:10 – 10:35
	Keynote “Vaccination: Promoting EU cooperation and addressing preventable diseases” a ROADMAP	Martin Seychell, Deputy Director-General for Health and Food Safety	10:35 – 11:00
Coffee break			11:00 – 11:30
2	Key Challenges and Key ADVANCE Solutions for Vaccines Benefit, Risk Monitoring		11:30 – 13:00
	Brief overview of ADVANCE mission and vision	Vincent Bauchau	11:30 – 11:45
	Public private partnership: <ul style="list-style-type: none"> Why are public health research institutes and vaccine manufacturers working together what are the benefits and risks? Opportunities and challenges of ADVANCE best practice solutions: regulatory perspective 	Piotr Kramarz (ECDC) (TBC) Xavier Kurz (EMA)	11:45 – 12:05
A. MORNING SESSION			
2	Use of real-world data from different countries to generate actionable evidence on vaccines: <ul style="list-style-type: none"> Meeting the requirements on quality and timeliness of evidence from heterogeneous existing health data for regulatory decision making ADVANCE solutions to generating evidence from heterogeneous health data 	Sabine Straus (CBG) Miriam Sturkenboom (P-95)	12:05 – 12:15
	Need to assess both benefits and risks of vaccines: <ul style="list-style-type: none"> How can HCPs be supported to explain vaccination to vaccine hesitant parents? A dashboard to visualize coverage, benefit and risks of vaccines 	David Salisbury Kaatje Bollaerts (P-95)	12:15 – 12:35
	Panel discussion about the challenges in EU public health and the solutions that ADVANCE has created	All speakers and invited panellists (M. Votta, P. Mauran, G. Rezza) & SAB members (D. Salisbury, J. Raine, F. DeStefano)	12:35 – 13:00

B. AFTERNOON SESSION		
Playing with the Advance Tools - a short overview (Miriam Sturkenboom)		13:00 – 13:05
Interactive Walking Lunch		13:05 – 14:30
3	ADVANCE– VAC4EU and solution for the needs of different stakeholders	14:30 – 16:15
	The Future of ADVANCE: VAC4EU	Patrick Mahy (Sciensano)
	Role of EMA and national regulators in VAC4EU	Xavier Kurz (EMA)
	Role of vaccine manufacturers in VAC4EU	Vincent Bauchau (GSK)
	Role of public health organizations in VAC4EU	Tyra Grove Krause (SSI)
Round-table about the future and possibilities of VAC4EU with speakers and invited panellists (J. Diez-Domingo, M. Votta, G. Rezza, P. Mauran and others)		15:30 – 16:15
Closure		16:15 – 16:30
Networking Cocktail		16:30 – 18:00