Accelerated Development of Vaccine benefit-risk Collaboration in Europe

From 2013-10-01 to 2018-09-30, ongoing project

Objective

Aim: The ADVANCE vision is focused on Timely and Best Evidence on Vaccine Effects. Our mission is to establish a best practice framework to rapidly provide robust data on vaccine benefits and risks to support accelerated decision-making.

Approach: To achieve this vision through a public-private partnership, ADVANCE partners
1. establish common grounds and rules for collaboration between public and private stakeholders for best practice conduct of studies on the benefit-risk of vaccines.
2. map and promote synergies with pertinent other initiatives to maximize utilization of foreground and identification of gaps for program strengthening.
3. profile data sources that will yield rapid access to burden of disease, vaccine coverage, and benefits and risks of vaccines
4. adapt and develop new methods for integrated benefit/risk assessment
5. create the ADVANCE phase I and phase II data platforms to evaluate a code of conduct, data sources, and methods developed in other WPs via a series of public-private co-operative studies proof-of-concept studies.

ADVANCE partners embrace the enormous potential to improve public health across European Member States by collaboratively utilizing the rich information generated in clinical routine care and captured in health care databases. While the ADVANCE Forum concept engages all stakeholder groups in a parliament-like structure, specific representative committees drive the innovative progress. Specific attention will be given to workflows depending on the level of urgency and on who is requesting utilization of the framework: regulatory authorities, vaccine manufacturers, public health organizations.

ADVANCE partners leverage their recent pioneering achievements in establishing operative technological platforms, developing pharmaco-epidemiological methods for burden of disease, coverage, effectiveness and risk. ADVANCE partners also build on a track record of delivering results of ground breaking international collaborative studies of unprecedented population size. ADVANCE capitalizes on these achievements and tailors structures and processes to the needs of collaborative public-private vaccine benefit-risk assessment. ADVANCE partners will provide access to data on more than 40 million subjects for testing of methods and immediate studies.

The existing technical platform boosted by the strong connection to the IMI EMIF project and many other synergistic initiatives will allow ADVANCE to focus on creating access modalities and accelerating exploitation of both underutilized and established rich data sources, to test innovative methods for integrated and vaccine specific benefit risk assessment, and to undertake real life studies from the outset of the project.

Consortium: The ADVANCE Consortium is designed to engage all stakeholders in Europe, while ensuring project feasibility by careful selection of a small group of 15 partners driving progress. The ADVANCE consortium comprises partners in multiple...
domains that collectively will allow us to achieve the goals of the call. The first domain consists of European and national organizations responsible for vaccine product assessment and program evaluation. The second domain comprises renowned scientists at the forefront of providing innovative solutions for integrated vaccine outcome assessment. The third domain represents organizations with access to electronic health care records of large populations and with ample expertise in the statistical analysis of large observational data from a public health and pharmacoeconomic perspective. Finally, a partner with specific expertise on management, dissemination and exploitation of large, complex biomedical research projects ensures outcome oriented interaction in the Consortium and efficient progress towards the attainment of its vision. Recognizing that all stakeholders need to be involved, ADVANCE has created the associate partner role allowing a wide array of int

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