

ADVANCE project on vaccines

Report from Jose Drabwell from the International Patient Organisation for Patients with Primary Immunodeficiencies (IPOPI) on the patient's perspective

ADVANCE Project – 13 and 14 November 2014

In November 2013 a five year ADVANCE (accelerated development of vaccine benefit-risk collaboration in Europe) project was launched to deliver a blueprint for a pan-European framework, monitoring the benefits and risks of vaccines throughout their lifecycle and for communication these benefits and risks. This project is supported by the Innovative Medicines Initiative (IMI), bringing together the EMA, European Centre for Disease Prevention and Control (ECDC), vaccine producers, national public-health and regulatory bodies, academic experts and small-medium size enterprises (SME).

The goal of ADVANCE is to review, develop and test methods, data sources and procedures that will guide the development of a European framework which can deliver data for the assessment of the benefits and risks of vaccines. During the H1N1 pandemic it became clear that a system was needed to monitor the benefits and risks of vaccines after its approval.

WP1 has been working on best practice, code of conduct and communication strategy around the benefits and risks of vaccines. The four working groups had been collecting existing guidelines on Code of Conduct, Quality Control and Assurance, Governance (key roles and functions) and Communication Strategy. The guidelines on the following subject were then discussed in detail: Roles and Responsibilities, Research contracts, Transparency, Conflict of Interest, Confidentiality, Scientific Independence, Development of Study protocol, Study Conduct, Writing a study report, Publications and communications, Ownership of results and Access to Data.

Quality control and Assurance was presented with a possible ISO accreditation option and a minimal accepted standard of quality criteria would be considered for the immediate future.

Social media and its role will be reviewed on how this tool is used in EU countries to monitor concerns and communication on vaccines. Guidelines on effective communication are needed.

The framework for the blue print for this project is to process the evidence for developing vaccines and its specific dosing in order to support decision making and contribute to reliable data on benefit and risk for informed choice.

Marco Greco from EFCCA and Jose Drabwell from IPOPI were represented at this workshop.