

ADVANCE

Accelerated development of vaccine benefit-risk collaboration in Europe

Summary

Vaccines are one of the most effective public health measures out, saving some two to three million lives worldwide every year. However, in Europe, public distrust in immunisation programs is limiting high vaccine uptake, resulting in outbreaks of vaccine-preventable infectious diseases that had almost disappeared. Bringing together the European Centre for Disease Prevention and Control and the European Medicines Agency, as well as national public health and regulatory bodies, vaccine manufacturers and academic experts, the ADVANCE project will develop and test methods and guidelines in order to pave the way for a framework capable of rapidly delivering reliable data on the benefits and risks of vaccines that are on the market. This framework should both help regulators and public health authorities make decisions on vaccination strategies, and help maintain public confidence in immunisation as an effective public health tool to control infectious disease.

Immunisation prevents two to three million deaths worldwide every year from diseases such as diphtheria, tetanus, pertussis (whooping cough) and measles. Millions more are spared the long-term health consequences of vaccine-preventable infectious diseases; the WHO estimates that due to the Global Polio Eradication Initiative, five million people are walking today who would otherwise have been paralysed by the virus.

In Europe, one of the greatest barriers to the wider uptake of immunisation is distrust, among some sections of the public, of immunisation programmes. This is due largely to fears surrounding vaccine safety. In fact, serious side effects are very rare. Nevertheless, as vaccines are given to healthy people, public acceptance of the risk of any adverse reaction is much lower than for medicines designed to treat sick people; the trade-off between benefit and risk is different.

At the same time, some vaccines have been around for so long that many people have no personal experience of the diseases prevented, and so are unaware of just how serious the illness can be.

Restoring trust

Vaccines undergo rigorous safety testing before they are approved for public use. Currently, efforts to monitor the coverage, benefits and risks of vaccines after approval are rather fragmented.

The goal of ADVANCE is to review, develop and test methods, data sources and procedures which should feed into a blueprint of an efficient and sustainable pan-European framework that can rapidly deliver robust quantitative data for the assessment of the benefits and risks of vaccines that are on the market. Such a framework would allow regulators and public health authorities to make fast, informed decisions regarding vaccination strategies, and help to maintain public confidence in vaccines, particularly when questions are raised in the media about the safety of specific vaccines.

For example, such a framework could have more rapidly assessed and quantified the benefits and risks of the measles, mumps and rubella (MMR) vaccine, uptake of which fell in the UK in the years following the claim that it causes autism. Although that claim is now discredited and the doctor behind the claims has been struck off the medical register, uptake of the vaccine remains below the recommended threshold of 95%. A recent measles outbreak centred around the city of Swansea in south Wales (where vaccination levels were particularly low) saw over 1 200 people fall ill, of which 80 were hospitalised and 1 died.

The good news is that pilot studies have demonstrated the feasibility of setting up the components of such a framework in Europe, although turning it into a sustainable reality will not be easy. Data on vaccine-preventable diseases, vaccination coverage and adverse reactions to vaccines exist in many places and diverse formats, such as electronic health records, disease surveillance systems, and other healthcare databases. The ADVANCE team will have to identify and profile data sources capable of yielding rapid access to information on the burden of

disease, vaccine coverage, and the benefits and risks of vaccines. Another challenge for the team will be developing the tools to link up this data and analysing it, taking into account the interoperability of the data sources and associated ethical and legal issues.

The project will run a number-of-proof of concept studies to ensure the platform meets the needs of its users. In order to cover the most common situations, these studies should ideally cover different age groups (e.g. infants / children, adolescents and adults / the elderly), different risk groups (e.g. pregnant women, people with other underlying health problems), and different vaccination scenarios (e.g. vaccinations given annually such as the flu jab, or vaccines introduced into the routine immunisation programme).

ADVANCE will also set out the framework's core values, covering issues such as scientific best practice, a code of conduct, and rules for interactions between the different stakeholders.

In all aspects of its work, ADVANCE will build on the results of, and exploit synergies with, related projects. For example, the team will work closely with IMI's EMIF project on data frameworks, and draw on the PROTECT project's expertise in analysing and visualising the benefits and risks of medicines.

Collaboration is key

If the ADVANCE blueprint is to be adopted and implemented following the end of the project, it must be accepted by all stakeholders, including the European Centre for Disease Prevention and Control, national public health bodies, the European Medicines Agency, national regulatory agencies, health ministries, insurance companies, vaccine manufacturers, healthcare providers, and of course the general public. Collaboration between these diverse groups is very sensitive; by bringing them together around the neutral platform offered by IMI, ADVANCE is in a unique position to pave the way for a framework that will improve our ability to rapidly assess the benefits and risks of vaccines and help maintain public confidence in immunisation as a successful and effective public health tool to control infectious disease.

Participants

EFPIA

- Crucell Holland BV, the Netherlands
- GlaxoSmithKline Biologicals S.A., Belgium
- Novartis Pharma AG, Switzerland
- Pfizer Limited, UK
- Sanofi Pasteur MSD S.N.C., France
- Sanofi Pasteur, France
- Takeda Pharmaceuticals International GmbH, Switzerland

Universities, research organisations, public bodies, non-profit groups

- Aarhus Universitetshospital, Aarhus Sygehus, Denmark
- Agencia Espanola de Medicamentos y Productos Sanitarios, Spain
- Azienda Sanitaria Locale della Provincia di Cremona, Italy
- Erasmus Universitair Medisch Centrum Rotterdam, the Netherlands
- European Centre for Disease Prevention and Control, Sweden
- European Medicines Agency, United Kingdom
- Institut Scientifique de Sante Publique, Belgium
- Karolinska Institutet, Sweden
- London School of Hygiene and Tropical Medicine, UK
- Medicines and Healthcare Products Regulatory Agency, UK
- Rijksinstituut Voor Volksgezondheid en Milieu (National Institute for Public Health and the Environment), the

Netherlands

- Royal College of General Practitioners, UK
- Statens Serum Institut, Denmark
- Tampereen Yliopisto, Finland
- The Open University, UK
- Universität Basel, Switzerland
- University of Surrey, UK

SMEs

- P95, Belgium
- Societa Servizi Telematici SRL, Italy
- Synapse Research Management Partners S.L., Spain

Associate partners

- Brighton Collaboration Foundation, Switzerland
- Center for Public Health Research, Spain
- French Medicines Agency, France
- Hellenic Medicines Agency, Greece
- Hellenic Center for Disease Control and Prevention, Greece
- Imperial College London, UK
- Irish Medicines Board, Ireland
- Italian Medicines Agency, Italy
- National Centre for Epidemiology, Hungary
- National Institute for Health and Welfare, Finland
- National School of Public Health, Department of Public Health, Greece
- Navarra Public Health Institute, Spain
- Polish Medicines Agency, Poland
- Public Health England, UK
- Slovenian Medicines Agency, Slovenia
- State Medicines Control Agency, Lithuania
- Swedish Institute for Communicable Disease Control, Sweden
- University of Athens, Greece

Facts & Figures

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EFPIA in kind*	5 017 353
Other	736 897
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