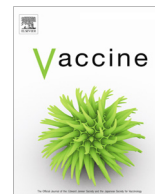




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## Review

# Innovation Partnership for a Roadmap on Vaccines in Europe (IPROVE): A vision for the vaccines of tomorrow

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## ABSTRACT

A clear vision for vaccines research and development (R&D) is needed if Europe is to continue to lead the discovery of next generation vaccines. Innovation Partnership for a Roadmap on Vaccines in Europe (IPROVE) is a collaboration between leading vaccine experts to develop a roadmap setting out how Europe can best invest in the science and technology essential for vaccines innovation. This FP7 project, started in December 2013, brought together more than 130 key public and private stakeholders from academia, public health institutes, regulators, industry and small and medium-sized enterprises to determine and prioritise the gaps and challenges to be addressed to bolster innovation in vaccines and vaccination in Europe. The IPROVE consultation process was structured around seven themes: vaccine R&D, manufacturing and quality control, infrastructure, therapeutic vaccines, needs of small and medium-sized enterprises, vaccines acceptance and training needs.

More than 80 recommendations were made by the consultation groups, mainly focused on the need for a multidisciplinary research approach to stimulate innovation, accelerated translation of scientific knowledge into technological innovation, and fostering of real collaboration within the European vaccine ecosystem. The consultation also reinforced the fact that vaccines are only as good as their vaccine implementation programmes, and that more must be done to understand and address vaccination hesitancy of both the general public and healthcare professionals.

Bringing together a wide range of stakeholders to work on the IPROVE roadmap has increased mutual understanding of their different perspectives, needs and priorities. IPROVE is a first attempt to develop such a comprehensive view of the vaccine sector. This prioritisation effort, aims to help policy-makers and funders identify those vaccine-related areas and technologies where key investment is needed for short and medium-long term success.

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Abbreviations: DG, Directorate General; EC, European Commission; EU, European Union; FP7, Seventh Framework Programme for Research and Innovation; GMP, Good Manufacturing Practices; IT, Information Technology; R&D, Research and Development; R&I, Research and Innovation; SME, Small and Medium size Enterprise; IPROVE, Innovation Partnership for a Roadmap on Vaccines in Europe; WHO, World Health Organisation.

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## 1. Vaccine R&D in Europe: need for a joint roadmap

Vaccination, together with hygiene and antibiotics has brought a reduction in child mortality over the past few decades and contributed to increased disability-free life expectancy in Western societies. However, for some important diseases there are still no vaccines, and for others, currently available vaccines could be improved. Therefore priority should be given to research and development of vaccines. Today, vaccine discovery is highly sophisticated, requiring a multi-disciplinary and public-private approach to both science and funding [1,2].

Europe has a long history of vaccine research, development and manufacturing, and a strong industrial infrastructure. More than 80% of vaccine doses from the major research manufacturers are produced in Europe and exported for worldwide use [3]. Europe's numerous centres of excellence in vaccinology and related disciplines give it the ability to lead discovery of the next generation of vaccines. A clear roadmap of vaccine R&D, political, legal, economic and structural measures was needed to incentivise, reward and accelerate research and maintain Europe's lead in this key sector.

Vaccine development can take 15–20 years with a further 6.4 years to achieve effective access for the population to be vaccinated. Several years of laboratory research are followed by clinical trials of the candidate vaccine that may involve thousands of volunteers. Vaccine manufacture is a complex process and, mainly due to extensive quality control measures, 6–24 months may elapse between availability of vaccine in bulk form and its distribution. Opening a new production facility may take more than 5 years and cost US \$100mio–600mio [4].

Given the complexity of vaccine research and development, a supportive and innovative R&D environment is critical for the development of new vaccine technologies, and to attract skilled scientists and sustainable investment. Strong partnerships and cooperation across academic, industrial, political, social and

economic fields are also essential [5]. To ensure continued vaccine innovation and efficient manufacture and supply – a European strategy covering all these aspects was needed.

## 2. The IPROVE approach

The IPROVE (Innovation Partnership for a Roadmap on Vaccines in Europe) FP7 project was conceived to propose a roadmap for European investment in innovative science and technology for vaccines [6]. It covers vaccine discovery, development, production and access and reflects on political, legal, economic and structural measures to incentivise, reward and accelerate the development of vaccines. IPROVE is the first EU-funded attempt to develop a holistic view of the vaccine sector. Its goal is to maintain Europe's competitive advantage in the development and delivery of innovative prophylactic and therapeutic vaccines. The IPROVE consortium consists of four leading European vaccines-related organisations: Vaccines Europe [3], European Vaccine Initiative [7], Sclavo Vaccines Association [8], and European Infrastructure for Translational Medicine [9]. Focused on key areas of unmet medical needs, rather than on disease-based approaches, the roadmap concentrates on technologies and transversal research, taking a helicopter view across innovative projects and collaborators.

IPROVE brought together over 130 key public and private stakeholders from academia, public health institutes, regulators, industry, small and medium-sized enterprises to determine the gaps and challenges to be addressed to boost innovation in vaccines and vaccination in Europe [10]. This consultation was structured into seven themes (i) Vaccine R&D; (ii) Therapeutic Vaccines; (iii) Production and Manufacturing; (iv) Infrastructures; (v) Vaccine SMEs needs; (vi) Training; (vii) Communications and Acceptance of Vaccination (see Fig. 1). Each theme was addressed through dedicated multi-stakeholder workshops (Supplement S1). The resulting draft roadmap was submitted to the IPROVE

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