



Roadmap for the establishment of a European vaccine R&D infrastructure



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ABSTRACT

To consolidate the integration of the fragmented European vaccine development landscape, TRANSVAC – the European Network of Vaccine Research and Development, funded by the European Commission (EC) – has initiated the development of a roadmap through a process of stakeholder consultation. The outcome of this consultation highlighted the need for transnational cooperation and the opportunities that could be generated by such efforts. This cooperation can be achieved through the establishment of a European Vaccine Research and Development Infrastructure (EVRI). EVRI will support cooperation between existing vaccine Research and Development (R&D) organisations from the public and private sector and other networks throughout Europe. It will become sustainable over time by receiving support from multiple sources including the EC, European Union (EU) Member States, European vaccine companies, EVRI partner organisations, and by income generated. Different stakeholders have demonstrated support for the concept of a vaccine infrastructure and agree that such an infrastructure can function as leverage institution between public and private institutions thus making significant contributions to the vaccine field as a whole in its quest to develop vaccines.

EVRI will be launched in three phases: preparatory (during which the legal and administrative framework will be defined and a business plan will be elaborated), implementation and operational. If sufficient political and financial commitment can be secured from relevant national and European entities as well as from the private sector and other stakeholders, it could enter into operational phase from 2017 onwards. In conclusion, EVRI can make vaccine R&D more efficient and help address European and global health challenges, help alleviate the burden and spread of infectious diseases, thus contributing to the sustainability of public healthcare systems.

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1. Background

Children in all countries are routinely immunised against major diseases, and vaccination has become central to global public health efforts [1]. The impact of vaccines can be measured not just in terms of public health, but also in economic terms: reducing the cost of healthcare, decreasing lost labour force productivity and contributing to social and economic development.

In March 2000, the European Council of Lisbon set as a strategic goal that Europe become the ‘most competitive and dynamic

knowledge-based economy in the world’ by 2010. To achieve this objective, it created the European Research Area that contributes to strengthen the scientific and technological bases of the EU and its Member States, their competitiveness and their capacity to collectively address major scientific challenges. With over 15% of its revenues invested in R&D and over 20,000 employees in Europe, the vaccine industry is a major contributor to the knowledge-based economy [2]. Europe’s leading position in vaccines is, however, increasingly threatened by North America and BRIC (Brazil, Russia, India and China) countries [3], as evidenced for example by the decrease in the proportion of R&D projects located in Europe (down from 71% in 2006, through 58% in 2008, to 50% in 2010) [4], especially for R&D projects involving new antigens.

European scientists are leading many initiatives in vaccine design and development. While there are many vaccine candidates especially in early stages of the development process, translation

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of these candidates from discovery research through to preclinical and clinical development has turned out to be a major bottleneck. Several difficulties within this “translation gap” directly impact on vaccine development; these include for example the lack of access to innovative technologies or lack of financial support to acquire such novel technologies, lack of access to relevant expertise, and the lengthy regulatory authorisation process for the approval of new products. Vaccine development is a lengthy and iterative process requiring significant resources and expertise, and it can take over 10 years to bring a vaccine to market.

Translational research – taking ideas from the bench into clinical trials – is not attractive to scientists working in the public sector: it presents high risks of failure, has to comply with regulatory requirements, and is underrated for the development of a research career. Many programmes have been initiated in the United States (US) and the EU to foster and secure pipeline management and product development [3]. Although very welcome, these initiatives often have been limited: the organisations eligible to apply for funding are limited and funding usually does not exceed five years. In Europe, for example, projects are usually funded for periods ranging from three to five years, and possibilities to renew successful initiatives very frequently do not exist. A recent analysis of R&D patent and publication networks over 10 years suggests that the vision announced for a European Research Area has not yet been delivered and that Europe remains a collection of national innovation systems with cross-border collaboration below expectation for an integrated European Research Area [5]. This failure also affects the vaccine research area and warrants redress.

Research infrastructures play an increasingly important role in advancing research and innovation and in shaping and integrating scientific communities across borders. These infrastructures can be defined as facilities, resources, systems and related services that are used by research communities to conduct research and foster innovation in their respective fields [6]. TRANSVAC – the European Network of Vaccine Research and Development – is a collaborative infrastructure project funded under the EC’s 7th Framework Programme for Research and Technological Development. The mission of TRANSVAC (www.transvac.org) – which brought together 14 partner organisations and five interested parties from seven different EU Member States – was to integrate capacities existing in different EU Member States with the aim to support European networking and transnational access to vaccine development facilities and/or related services, and to improve the services provided by these infrastructures through joint research activities (a summary of the services provided and research conducted by TRANSVAC will be reported elsewhere; under preparation).

In order to address the translational gap and other issues impacting on vaccine R&D, TRANSVAC set out to identify currently existing major bottlenecks and barriers in translational vaccine development, based on a bottom-up stakeholder consultation process. The objective of the first stakeholder meeting held in October 2010 was to define how best to support, improve and accelerate vaccine R&D in Europe [7]. In a series of subsequent workshops conducted in 2011 and 2012, TRANSVAC stakeholders analysed the needs previously identified and discussed how they could be addressed through a pan-European collaborative effort. Their conclusions were translated into a draft proposal for the establishment of a European vaccine R&D infrastructure, which was submitted end of 2013 for comments and validation to a wider group of stakeholders. A detailed questionnaire that was part of the consultation process led to the identification of priority areas for EVRI. Finally, an advanced draft of the TRANSVAC Roadmap was publicly presented and discussed during a final stakeholder workshop in Brussels in June 2013 (see Ref. [7] for further information about agendas and participants in all workshops organised during TRANSVAC). This consultation process culminated in the preparation of a roadmap

for the establishment of a EVRI [7] which is briefly outlined in this article. The roadmap will serve as a blueprint for the development of a sustainable infrastructure for vaccine R&D in Europe and will serve as a reference document to inform national and European policy makers and funding bodies.

2. EVRI – European Vaccine R&D Infrastructure

EVRI strives to be a pan-European infrastructure that can accelerate product development and at the same time reduce costs through the optimal use of existing national research capacities. It will build on existing networks, capacities and platforms such as those developed by TRANSVAC and others and will provide a full range of services to further test and advance the development of vaccines candidates. EVRI’s activities will address the various phases of pre-competitive vaccine development: basic research, discovery, pre-clinical and early clinical research, as well as supporting tools, technology and expertise, including bioinformatics. Both human and veterinary vaccines will be within the scope of EVRI, including prophylactic as well as therapeutic vaccines for disease targets in humans.

EVRI will facilitate the development of vaccine candidates from proof-of-concept in animals to proof-of-concept in humans and contribute to bridging the recognised translational gap between preclinical and clinical research. Further clinical evaluation and vaccine commercialisation will require links to other networks and industrial partners. In addition to the various scientific disciplines related to vaccinology (e.g. microbiology, immunology etc.), EVRI will address other areas such as ethics, epidemiology, pharmacoeconomy, public policy, sociology and regulatory science.

More specifically, EVRI has as objectives to:

- Provide a full range of vaccine R&D services.
- Improve the services provided by conducting internal research.
- Conduct regulatory science by functioning as a reference vaccine research platform for the European Medicines Agency (EMA).
- Reinforce education in multidisciplinary vaccinology.

2.1. Vaccine R&D services

EVRI will link and align human and financial resources and drive long-term co-operations between research programmes with shared objectives. It will help Europe create platforms and networks of excellence to overcome and avoid duplication and to improve efficacy and effectiveness of research efforts throughout Europe by providing access to services including, but not limited to:

- Tools and platforms relevant for vaccine research, e.g. bioinformatics, in vivo imaging technologies, microarrays and systems vaccinology.
- Animal models (e.g. mice, ferrets, non-human primates, pigs) and platforms for pre-clinical safety and immunogenicity studies in animal models.
- Immunological assays/identification of correlates of protection/identification of biological markers of diseases and protection/identification of efficacy criteria and endpoints.
- Early clinical trial expertise and infrastructures to optimise translation from animal models to humans.
- Advanced, GMP-compatible, expression systems (yeast, bacterial, mammalian cells, recombinant vectors).
- Vaccine formulation services, including characterisation and analysis of fluid, adsorbed and dry formulations, adjuvation, freeze and spray-drying methods; innovative technology

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