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TRANSVAC research infrastructure – Results and lessons learned from the European network of vaccine research and development

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ABSTRACT

TRANSVAC was a collaborative infrastructure project aimed at enhancing European translational vaccine research and training. The objective of this four year project (2009–2013), funded under the European Commission's (EC) seventh framework programme (FP7), was to support European collaboration in the vaccine field, principally through the provision of transnational access (TNA) to critical vaccine research and development (R&D) infrastructures, as well as by improving and harmonising the services provided by these infrastructures through joint research activities (JRA). The project successfully provided all available services to advance 29 projects and, through engaging all vaccine stakeholders, successfully laid down the blueprint for the implementation of a permanent research infrastructure for early vaccine R&D in Europe.

1. Introduction

1.1. Background and rationale of TRANSVAC

Through the natural legacies of Edward Jenner (1749–1823), Louis Pasteur (1822–1895) and Emil von Behring (1854–1917), vaccine development in Europe has been deeply ingrained in life science research. A key role in the TRANSVAC network was played by state-owned R&D and production facilities, alongside academic and private partners. However, in the last decade this environment has been changing by the decision of European governments, mostly for economic reasons, to withdraw funding from state-owned vaccine production facilities [1,2]. This shift jeopardises the European vaccine R&D network and has increased the risk of a slow-down in innovative vaccine research and in products progressing through the development pipeline. This has an immediate effect on knowledge and competencies, and also increases the fragmentation of expertise and facilities. In addition, there is a lack of synergy

Abbreviations: AIDS, Acquired immunodeficiency syndrome; BCG, *Mucobacterium bovis* bacille calmette–guérin; DTH, Delayed type hypersensitivity; EC, European Commission; ELISpot, Enzyme-linked immunospot; EVRI, European Vaccine Research and Development Infrastructure; FP_7, Seventh framework programme (FP7); HIV, Human immunodeficiency virus; ICS, Intracellular cytokine staining; IFNγ, Interferon gamma; IGRA, Interferon gamma release assays; IL, Interleukin; JRA, Joint research activities; NHP, Non-human primate; pCD, Plasmacytoid dendritic cells; PPD, Purified protein derivative; R&D, Research and development; RI, Research infrastructure; RNA, Ribonucleic acid; SAC, Scientific Advisory Committee; SIV, Simian immunodeficiency virus; SOP, Standard operating procedures; TB, Tuberculosis; Th, T helper cells; TLR, Toll-like receptor; TNA, Transnational access; USP, User Selection Panel; VFL, Vaccine Formulation Laboratory; WP, Work package.

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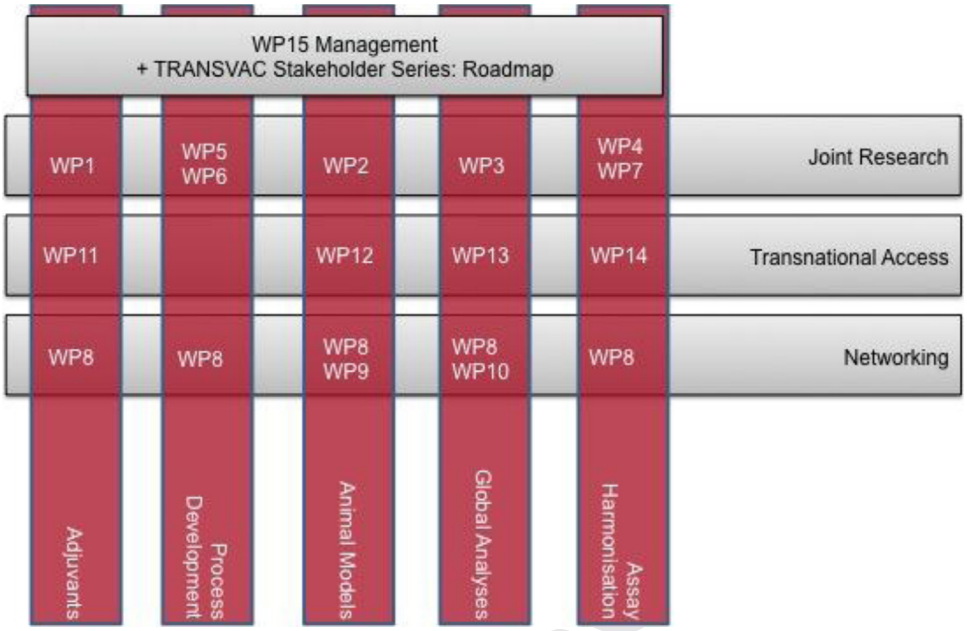

Fig. 1. PERT diagram of project.

between the private and public sector, and a lack of commonly defined strategies by the public sector of European Union member states. A supra-national action plan for the vaccine development community is required to combat this situation. The European vaccine development community could benefit from the establishment of an efficient, sustainable and collaborative research infrastructure (RI) based on shared and goals in order to create a common agenda, address existing and future challenges, pool resources, and develop cost- and time-efficient strategies [3].

RIs play an important role in the advancement and exploitation of knowledge and technology. Aside from researchers and institutions, large RIs are often a vital requirement for a more effective scientific system in which, for example, overcapacity can be more easily distributed and regulatory compliant quality systems for products and processes can be implemented and maintained. RIs can provide quick leverage for new applications that extend beyond their original purpose and thus act as a structuring force in the scientific system. Altogether, a complex process like vaccine development can be most effectively supported by a multi-disciplinary RI.

TRANSVAC, a collaborative RI project funded under the EC FP7, operated between 2009 and 2013 as a joint effort of European groups in the field of vaccine R&D with a total budget of Euro 9.9 million. It was aimed at accelerating the development of promising vaccine candidates by developing, optimising and standardising state-of-the-art processes and facilities available to vaccine developers to bridge the gap between bench research and clinical assessment of novel vaccines.

This improvement occurred at three levels (Fig. 1): (1) TNA: provided researchers with free access to vaccine development services such as adjuvant formulation, animal models, reference reagents/standards and global analyses (e.g. transcriptomics). As core services of the consortium, these were made available free of charge to European vaccine R&D groups. Through a competitive peer-review process, European groups working in vaccine development could benefit from the expertise, reagents, and facilities of the TRANSVAC consortium. (2) JRA: within the consortium the focus of internal research was on improving the use of global analysis platforms, adjuvants and animal models. All project efforts in JRA were designed and executed on the basis of applicable regulatory requirements. Therefore, inter-laboratory harmonisation, qualification and standardisation through the development of standard operating procedures (SOPs) and provision of standardised reagents were key objectives. (3) Networking: the consortium provided training in vaccine development, harmonisation of assays and global analyses (e.g. microarrays), and optimal use of animal models. Finally, to ensure leverage of the scientific and operational lessons learned, the consortium engaged in stakeholder consultations with key representatives from academia, public health institutions, pharmaceutical industry, funding organisations and regulators, and developed a European roadmap for vaccine R&D infrastructures [4].

The programme work plan included work packages (WPs) in the following six activities:

1. Coherent development of novel and improved vaccine formulations (WP 1, 8 & 11).
2. Development and production of recombinant vaccine candidates and cell substrates for the manufacture of vaccines (WP 5, 6 & 8).
3. Evaluation of vaccine candidates in different animal models (WP 2, 8, 9 & 12).
4. Definition of biomarkers of protective immunity through global analyses of host responses after vaccination (WP 3, 8, 10 & 13).
5. Harmonisation of immunological assays for preclinical studies and clinical trials (WP 4, 7, 8 & 14).
6. Project management; TRANSVAC stakeholder consultation (WP15).

2. Results and milestones reached

2.1. Transnational access

The core of the TRANSVAC project consisted of providing access to services crucial to early-phase vaccine development, such as adjuvants, animal models, reference reagents and global gene expression platforms (e.g. microarrays and next generation deep sequencing) to vaccine R&D projects from European research groups (Table 1).

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