

GLOBAL VACCINATION SUMMIT



European
Commission



World Health
Organization

BACKGROUND PAPER ROUNDTABLE 2

The magic of science: boosting vaccine research, development and innovation

Panel participants are invited to discuss how to provide new models and opportunities for stepping up vaccine development and making it more effective.

THE VACCINE DEVELOPMENT CYCLE: MAJOR CHALLENGES TO DEVELOPING EFFECTIVE VACCINES

Vaccination is an impactful and cost-effective medical intervention, which along with antibiotics, sanitation, and clean water has drastically reduced or eliminated a number of infectious diseases. It also has an important role to play as a complement to antibiotics in the global fight against antimicrobial resistance, by protecting against specific infections that exhibit resistance and by reducing the frequency of illnesses for which antibiotics are prescribed. Despite global research efforts, there are no licensed vaccines yet for major infectious diseases such as HIV, RSC and HCV and, for other, improvements in efficacy and delivery through new or modified products could substantially enhance their impact. Other important gaps also need to be addressed, such as vaccines for the elderly and vaccine R&D on pathogens of epidemic potential that pose a public health risk (i.e. those in the WHO R&D Blueprint for Action to Prevent Epidemics, list of priority diseases). Vaccine development is a lengthy and complex process with a high risk of failure. A number of clearly identified scientific challenges to developing new and better vaccines remain. These span all stages of the vaccine development pipeline from antigen discovery to clinical trial implementation, and include vaccine formulations, vaccine delivery systems, platforms to test the immunogenicity of vaccine candidates, suitable animal models and good manufacturing practices. This should lead us to revisit current models and development paradigms, and rethink vaccine design and clinical trial acceleration.

FINANCIAL INVESTMENT AND FRAGMENTATION: MODELS AND PARTNERSHIPS IN SUPPORT OF VACCINE RESEARCH, DEVELOPMENT AND INVESTMENT

Financial investment in vaccine research is key to vaccine development. In general, developing a vaccine from discovery to licence can cost over a billion euro, take over ten years to complete and carry a high risk of failure. Both the private and public sectors have invested in vaccine development in Europe and elsewhere, but the research and investment landscape for vaccines is fragmented, with private investment predominantly focused on vaccines for high-income settings. Development of vaccines for low-income settings generally receives only minimal private-sector investment, having to depend on public-sector investment that is often insufficient to support large-scale studies. The pharmaceutical industry, small and medium-sized enterprises and academia all have their expertise and various roles to play, and this is reflected in the financing methods designed for, and used to support, vaccine research and innovation. A number of partnerships and models have been created to enable more effective types of cooperation and create incentives for industry investment in vaccine development.

- ▶ Since its inception in 2003, the European and Developing Countries Clinical Trials Partnership has focused on accelerating the development of vaccines for poverty-associated and neglected infectious diseases through a long-term public-public partnership between Europe and sub-Saharan Africa, designed to improve the research environment and clinical trials infrastructure in the region.
- ▶ The Innovative Medicine Initiative, a public-private partnership between the EU and the European Federation of Pharmaceutical Industries and Associations, was created to speed the development of innovative medicines, including vaccines, and patient access to them. It has shown potential to produce benefits of a scale and impact that could not have been achieved by parties working on their own, and offers an opportunity to encourage innovation and engagement by key players in the public and private vaccine sectors.
- ▶ Another approach aiming to accelerate vaccine R&D is the product development partnership model, in which stakeholders from the private and non-profit public sectors join forces to research, develop and support access to new vaccine technologies. A lesson of the 2014 Ebola outbreak was the recognition that the usual market processes for developing vaccines do not lead to products for diseases with epidemic potential. The Coalition for Epidemic Preparedness Innovations, an innovative global partnership between public, private, philanthropic and civil society organisations, was established in 2016 to remedy this. Its aim is to develop vaccines in preparation for outbreaks of epidemic infectious disease and enable global access to these vaccines during outbreaks.
- ▶ Financial incentives, other than profit in the marketplace, have an important role to play in overcoming the problem of highly risky investment in vaccine RD&I due to the high failure rate during the product development pipeline. One example of this is the Risk Sharing Finance Facility (RSFF), jointly implemented by the European Investment Bank (EIB) and the European Commission, which is designed to improve access to debt financing for all types and sizes of private companies and public institutions which undertake RD&I projects, in order to lower risks and facilitate investment. The Facility has recently also been used for vaccine research.

These are some examples of different models for supporting vaccine RD&I. Many more exist on a global scale.

THE WAY FORWARD: HORIZON EUROPE IN THE GLOBAL LANDSCAPE FOR BOOSTING RESEARCH INNOVATION AND PUBLIC HEALTH BENEFITS

Horizon Europe, the new EU research and innovation programme, is under preparation. With its three pillars – Open Science, Global Challenges & Industrial Competitiveness, and Open Innovation – Horizon Europe can build on the efforts and successes of the previous programme and provide new models and opportunities to boost vaccine development and make it more effective. Efficient use of Horizon Europe will be instrumental in further stimulating and fostering cross-fertilisation and international collaborations to bring public health benefits. Horizon Europe is one of many funding programmes that are pursuing the same objectives: supporting R&D and ensuring collaborative efforts.

In the light of this new EU funding programme, other funding mechanisms and the international landscape of partnerships, the aim of this roundtable is to facilitate a discussion among vaccine community leaders on how to address key challenges (scientific, financial, capacity), boost vaccine development and cross-sectorial cooperation, and make funding and clinical testing more effective.

OBJECTIVES:

1. Discuss the vaccine development cycle and major challenges to the development of effective vaccines, and determine which vaccines are needed;
2. Discuss the efficient use of existing and novel models for funding vaccine R&D and stimulating international collaborations for public health benefits;
3. Identify opportunities for and major challenges to having a vaccine RD&I that responds to global public health needs;
4. Capitalise on Europe's expertise in the global environment and make funding, vaccine development and clinical testing more effective through Horizon Europe.