HORIZON-HLTH-2022-DISEASE-06-03-two-stage:

Vaccines 2.0 - developing the next generation of vaccines (RIA)

Subsidy: €8M
Funding rate: 100%
Deadline: First stage: 1 February 2022
Second stage: 6 September 2022
Duration: No limit; up to 4 years is recommended
Total budget: €40M

Consortium:
At least three legal entities established in different Member States or Associated Countries.

Scope

Infectious diseases, including antimicrobial resistant (AMR) infections, remain a major threat to health and health security in the EU and globally. The availability of more effective, accessible and affordable vaccines would provide the most cost-effective preventive measure against the health threat of epidemics and AMR pathogens. Vaccines against diseases, such as AIDS, tuberculosis (TB), malaria, neglected tropical diseases, hepatitis C and water-borne diseases are essential to achieve the WHO targets to control the spread of infectious diseases. The first generation of vaccines against some of the pathogens have proven to be suboptimal and not effective enough to protect the population. Many viruses of pandemic potential are variable in their surface antigen composition, and novel technologies are required to develop efficient vaccines against each new variant efficiently and in a short timeframe. To ensure that more effective, accessible and affordable vaccines against all major infectious diseases become a reality, it is essential to sustain a diverse and modernised vaccine development pipeline.

Proposals should aim to diversify and accelerate the global vaccine research and development pipeline, and to strengthen the current leading role of the EU in vaccine research and development. Proposals should cover those pathogens, which still lack

vaccines of sufficient efficacy, but where earlier efforts have already produced promising vaccine candidates.

The proposals should address several of the following areas:

- Innovation and integration of expertise and capabilities, including alignment of preclinical and clinical models, biomarker studies and new vaccine approaches from discovery to late stage development, from bench-based research to clinical development of promising preventive candidates.
- Application of iterative processes (including cross-learning, back-translation steps, integrative analysis of data) to allow exploitation and integration of novel findings between clinical, preclinical and discovery research and development.
- Deciphering mechanisms of protection of candidates, new approaches to antigen discovery and immunogen engineering, reverse vaccinology, evaluation of vaccines in novel platforms and technologies, novel adjuvants, innovative vaccine manufacturing approaches, relevant animal models, evaluation of alternative vaccine delivery routes.
- Effective, evidence-based decision-making for progression of vaccine candidates in the pipeline based on transparent and objective portfolio management. Regulatory requirements be considered. Sex, gender, age and socio-economic factors should be taken into account.

Expected Outcome

This topic aims at supporting activities that are enabling or contributing

to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- The scientific and clinical communities use the increased knowledge on pathogens and better understanding of the immune system's role in infectious diseases to develop vaccines with improved efficacy.
- Vaccine manufacturers use more innovative and sustainable manufacturing technologies and improved GMP manufacturing know-how for producing the next generation of vaccines.
- A diversified portfolio of vaccine candidates ready for testing in clinical trials help policy makers and funders to make informed decisions about support to vaccine development.
- New innovative and improved design of preclinical/clinical studies that match the features of the next generation of vaccines is available for clinical community and regulators, and will shorten vaccine development time.