

Vaccine development for malaria and/or neglected infectious diseases

Proposals will have to address bottlenecks in the discovery, preclinical and early clinical development of new vaccine candidates (antigens/adjuvants) for malaria and/or neglected infectious diseases[[Neglected Infectious Diseases for the scope of this call: In addition to the 17 Neglected Tropical Diseases prioritized by WHO, also eligible are childhood diarrhoeal diseases and neglected viral emerging epidemic diseases.]]. Filoviral diseases are specifically excluded from this topic.

Depending on the maturity of the research landscape for each disease, proposals may range from large research platforms developing multiple vaccine candidates and/or vaccines for multiple diseases, to proposals specifically focused on one disease.

a) The larger platforms proposals should among others:

Take advantage of recent advances in vaccinology (e.g. in silico analysis and novel in vitro and in vivo immunoscreens) or establish completely new approaches for the discovery and selection of novel, appropriately immunogenic antigens, and/or novel formulations/combinations for the generation of new vaccine candidates.

2. Include a systematic approach and define key gate-criteria for selection across each step of the research and development pipeline they address. Based on these criteria the most promising new vaccine candidates, should be able to be compared as early as possible in an objective and transparent process according to their merit in line with effective vaccine portfolio management.

b) Smaller proposals specifically focused on a single disease and/or a single vaccine candidate should adopt similarly innovative and comprehensive approaches to tackle one or more of the major bottlenecks in vaccine development for the specific disease.

For all antigen/vaccine candidates and for all diseases, it is necessary to ensure that a protective immune response (in the specific target population of the vaccine

candidate) is adequately understood and that the candidate can elicit such a response.

Depending on the development stage, the downstream constraints of vaccine candidates for effective deployment and utilisation in resource-poor settings should be taken into account. This might include (as early clinical pipeline gate-criteria) considerations of the optimal route and immunization regime, field-deployment logistics (e.g. storing temperatures), as well as an evaluation of the predicted cost and affordability of final vaccine products. If relevant, an assessment of the target population risk-perception attitudes and immunization behaviours should be made and sex- and gender differences should be taken into account.

Both types of proposals should take into account existing mapping exercises on vaccine candidates, as well as the current vaccine development roadmaps and target product profiles for each disease (e.g. Malaria Vaccine Technology Roadmap).

The Commission considers that proposals requesting a contribution from the EU of between EUR 3 and 5 million for smaller specifically focused proposals, and between EUR 15 and 20 million for the larger platform proposals, would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Vaccines offer a safe and cost-effective way to protect large populations against infectious diseases. Yet, many poverty-related and neglected infectious diseases continue to escape attempts to develop effective vaccines.

Disappointing results of recent clinical trials point to bottlenecks in identifying viable candidate vaccines, which, if unaddressed, will continue to present significant risks of failure at relatively late stages of the development process.

The specific challenge will be to shift this “risk curve” in order to better select successful vaccine candidates (and discard those with a higher risk of failure) at an earlier stage of the vaccine development pipeline.

- Proposals should deliver new vaccine candidates or move existing ones along the vaccine candidate pipeline in support of the sustainable development goal No. 3.3 i.e. to end by 2030 the epidemics of malaria and neglected tropical disease
- This should provide reduction in the cost associated with late stage vaccine failure, increasing the number of other candidates which can be tested with the same resources, thus increasing the chance of discovery of an effective vaccine.
- Increase the number and quality of vaccine candidates for malaria and neglected infectious diseases available to proceed into further development and clinical testing, if appropriate within the context of the European and Developing Countries Clinical Trials Partnership (EDCTP2).

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