New anti-infective agents for prevention and/or treatment of neglected infectious diseases (NID)

The topic bridges the gap between preclinical and early clinical development of drugs and/or vaccines against neglected bacterial and parasitic diseases[[For the purpose of this call, eligible neglected diseases are: childhood diarrhoeal diseases, kinetoplastid diseases (human African Trypanosomiasis, leishmaniasis, Chagas disease) and helminth (Schistosomiasis, soil-transmitted helminthiases, food-borne trematodiases, filariasis, Onchocerchiasis, taeniasis/cysticercosis, dracunculiasis, echinococcosis) diseases, as well as bacterial diseases like Buruli ulcer, leprosy, yaws and mycetoma. Neglected viral diseases are specifically excluded from this topic.]]. Therefore, the proposed actions should focus on late preclinical (e.g. validation in animal models, toxicology, Good Manufacturing Practices (GMP) production, preparation of Investigational Medicinal Product Dossier) and early clinical (up to phase 1) development of already existing lead drug and vaccine candidates. Multidisciplinary platforms bringing together academic and industry research teams, from European and disease-endemic countries, with the capacity to exploit existing experience and propose innovative solutions addressing several relevant pathogens are particularly encouraged. Sex and gender differences should be taken into account where relevant.

The downstream constraints of candidates for the effective deployment and uptake by limited-resources public health systems should be taken into account by the proposed action:

- It should address the following key elements of the target-product profile (TPP): suitability, acceptability, adaptability of the intervention to be developed for different population groups, including particularly vulnerable ones (e.g. women and children), served by under-resourced health systems.
- It should also address issues that permeate and often impede access such as: optimal route and dosing or immunization regime, up-scaling of manufacturing, registration and pre-qualification, distribution and field-deployment logistics (e.g. storing temperatures), and the predicted cost per patient of the final product.

- Ultimately, the proposed action should include a clear pathway through the different necessary steps (research, manufacturing, regulatory approvals and licensing, IP management, pricing etc.) in order to allow uptake by health systems in limited-resource settings.

Due to the specific challenge of this topic, in addition to the minimum number of participants set out in the General Annexes, proposals shall include at least one participant from disease-endemic countries.

Please note that this topic is part of the lump sum funding pilot scheme. Funding for grants awarded under this topic will take the form of lump sums as defined in Commission Decision C(2017)7151 of 27 October 2017. Details of the lump sum funding pilot scheme are published on the Participant Portal together with the specific Model Grant Agreement for Lump Sums applicable.

The Commission considers that proposals requesting a contribution from the EU of between EUR 5 and 10 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Neglected Infectious Diseases (NIDs) diseases are responsible for a significant health and socioeconomic burden in large parts of the world, particularly in resource-poor countries, however some (e.g. leishmaniasis, Chagas disease) are increasingly becoming a concern for Europe too, driven by factors like the climate change and globalization. Despite a significant effort to develop new drugs to treat these diseases over the past 10 years, existing therapies suffer from various shortcomings, namely, a high degree of toxicity and unwanted effects, as well as treatment regimens often lengthy or parenteral that discourage compliance and increase the emergence of resistance. Vaccines can also be a major tool for the control of NIDs, particularly given the limitations of mass drug administration strategies, but currently the only major NIDs for which licensed vaccines exist are rabies and dengue. Development of new, more effective, safe and affordable treatments and vaccines for NIDs is therefore an urgent need.

In the last few years, increased awareness and funding for NIDs has resulted in the identification and preclinical development of several treatment and vaccine candidates against various NIDs. However, the typical NIDs 'market failure' (i.e. high risk and low potential return) discourages the uptake and costly further development of these candidates by pharmaceutical and biotechnology companies. Targeted public funding is therefore necessary to bridge the gap between preclinical and clinical development, and help advance existing candidates along the development pipeline.

- Increase the number and quality of treatment and vaccine candidates for neglected infectious diseases appropriate for implementation and uptake by health systems with limited resources.

- Reduce the NIDs disease burden and their social and economic consequences, and thus contribute to achieving the United Nation's Sustainable Development Goals 1 (No Poverty), 3 (Good Health and Well-being), 5 (Gender Equality), 10 (Reduced Inequalities) and 13 (Climate Change).
- Strengthen the pipeline of products available to proceed into further development and clinical testing and, if appropriate, within the context of the European and Developing Countries Clinical Trials Partnership (EDCTP2).

Last update: 12 April 2024

Permalink: https://cordis.europa.eu/programme/id/H2020_SC1-BHC-15-2018