Call for Proposals:

Proven vaccine technologies, applicable for large scale manufacturing, for rapid response against novel coronavirus, 2019-nCoV

CEPI is announcing a funding opportunity for the development of vaccine against the 2019 novel corona virus, 2019-nCoV. This document describes the scope, requirements and processes for submission.

This call is open for 2 weeks. The deadline for application is February 14, 15:00 CET. The call may be extended or amended depending on programmatic need.

CEPI reviews and evaluates applications on their merits and in the context of stated eligibility criteria and CEPI's overall project portfolio. Regardless of eligibility at any stage of a funding call, CEPI reserves the right to consider and to decline proposals in its sole discretion.

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1. Introduction

The rapid global spread and unique epidemiological characteristics of 2019-nCoV virus is deeply concerning.

In coordination with WHO, as it leads the development of a coordinated international response, CEPI is promoting the development of new vaccines against the emerging threat of 2019-nCoV virus.

2. Objectives and the scope of this Call

The objective of this Call for Proposals is to rapidly develop and manufacture a proven vaccine approach that can be used against the 2019-nCoV. This call aims to complement CEPI's 2019-nCoV portfolio and candidates should have large-scale manufacturing capabilities for 2019-nCoV. The organization must be willing to transfer their vaccine technology to a global network of large-scale manufacturing.

Vaccine candidates will be evaluated against several criteria to assess the utility of the product candidate and the speed with which it can be developed and tested and induce a 2019-nCoV virus-specific response. The technology will also be judged against its proven ability to be manufactured at large scale.

The suggested vaccine-technology performance will be considered towards the following guidelines:

- Speed from sequence of pathogen availability to clinical-trial testing
- Number of doses needed – to gain clinical benefit
- Scale of manufacturing
    - In the current situation CEPI will be aiming for a capacity of production of millions of doses

Supporting the development of vaccines that can prevent or stop an outbreak is a key part of CEPI's mission. An equally critical part of the mission is to ensure that the vaccine is available and equally accessible to those who need them. Thus, in addition to the criteria of speed and versatility the vaccine technology must be able to be delivered to individuals easily in an outbreak setting and to be at a cost of goods that does not preclude broad access. See CEPI's Policies for more detail.

3. Applicant eligibility criteria

The funding opportunity through this Call is open worldwide, to all types of non-profit research organisations, for-profit companies, international organisations and foundations, joint R&D ventures, government research organisations, and academic institutions ideally having a geographical footprint internationally.

Applicants must be legal entities, or consortia comprised of legal entities. At least one of the partners in the applicant organisations or consortia of partnering organisations should have experience in **human vaccine development** and have a track record of bringing vaccine candidates through to human clinical trials in the past 10 years.

The applicant should also have a manufacturer with a track record of vaccine production identified within the consortium.

To be eligible to submit a proposal the applicant should:

1. Hold a vaccine technology that has already been proven
    a. Licensed product based on the same technology or

   b. Relevant data from clinical trials of a vaccine candidate based on the same technology
2. Propose only one 2019-nCoV vaccine candidate per application
   a. Include plans and costs for preclinical studies (toxicology / PoC / challenge / immunotoxicology)
   b. Include plans and costs to conduct Phase I studies
   c. Include parallel plans and costs to generate GMP grade material for Phase II
   d. Indicate final scale-up and include plans, costs, and timelines to generate final manufacturing scale material
   e. Propose how you would accelerate the pathway to licensure of your vaccine candidate
3. Have the capacity to start vaccine manufacturing in at short notice
4. Be an organization that must be willing to transfer their vaccine technology to a global network of large-scale manufacturers and ideally has its own large-scale manufacturing capabilities

4. Applicant guidelines and the review process

The proposal must include essential evidence as required in section 3, meet the presented timeline requirements for completion, and contain sufficient information for review of the proposed vaccine development process. Any claims made within the proposal must be supported by evidence.

The proposal should:

- be no longer than 10 pages (excluding references)
- include high-level budget (in USD)
- be in **English**

This call is open for 2 weeks. The deadline for application is February 14, 15:00 CET. The review will be done on the rolling basis therefore responses received within those days will be reviewed immediately.

The application template is accessible via CEPI website. To respond to this Call for Proposals, entities must submit their application to CEPI via a secure portal. Please send an email to cfp@cepi.net to be provided with a secure link to upload your application to the secure portal (in the Subject field indicate: Application for 2019-nCoV vaccine). The application should be uploaded in a pdf format. Do not send any additional documents. Personal data included in proposal will be handled according to CEPI's Privacy Notice on www.cepi.net/terms/.

This is a direct Call for proposals, which means that no additional information should be submitted, or a preparatory meeting requested.

No costs incurred by the applicants for the development and submission of application will be covered by CEPI. However, CEPI will consider relevant pre-award costs for successful candidates.

5. Review criteria

Proposals that have met the eligibility criteria described under section 3 will be assessed against the following criteria:

Criterion	Assessment levels	Definition
1. Immunogenicity/ Efficacy potential and speed	1.1. Non-clinical 1.2. Clinical 1.3. Speed of protection	• Extent to which the technology will rapidly enable immune responses providing protection/ clinical benefit against 2019-nCoV

Criterion	Assessment levels	Definition
2. Safety potential	2.1. Non-clinical 2.2. Clinical	• Safety profile of the vaccine platform/candidate in animal models and/or in humans
3. Technical/ Manufacturing scalability and speed	3.1. Quality 3.2. Formulation 3.3. Speed of production and scale 3.4. Scale of production	• Extent to which the technology is expected to enable fast production in volumes sufficient to respond to 2019-nCoV
4. Access/ Route to patient	4.1. Delivery 4.2. Sustainability of supply 4.3. Equitable access	• Extent to which the technology will enable uncomplicated delivery of vaccine product in an outbreak response under extreme conditions and that it will remain in use and accessible and affordable
5. Partnership	5.1. Competency, experience and track-record	• Extent to which the partnership, its plans and procedures are viable and of sufficient quality to deliver on the proposed activities of the project. Willingness to transfer the technology to a global network of large-scale manufacturers

6. Award conditions

Before submitting an application, applicants should take note of two key award conditions. The first is that each awardee must adhere to CEPI's policies, which can be found on CEPI's website. The second is that any funding is dependent on the signing of an award agreement, which provides the terms and conditions under which the award will be made. CEPI is committed to achieving equitable access to all CEPI-supported programmes including vaccines, platforms, data, results, and materials. Specifically, equitable access to epidemic vaccines in the context of an outbreak means that appropriate products are first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay. To ensure that CEPI delivers on its commitment to equitable access, CEPI must include access considerations as a component of any agreement with an awardee.

Applicants unable or unwilling to meet these requirements should not submit an application.

7. Technical and administrative questions

Technical and administrative questions about this Call should be directed to the CEPI Secretariat (cfp@cepi.net).