Call for Proposals:
Vaccine platform technologies for rapid response against SARS-CoV-2

CEPI is pleased to announce a new funding opportunity for vaccine development of platform technologies against SARS-CoV-2 and with the potential for use against other emerging infectious diseases (EIDs). This document describes the scope, requirements and processes for submission, review and selection for funding. Further details can be found at https://cepi.net/get_involved/cfps/

The Call for Proposals asks for an Expression of Interest (EOI) with a description of the current status of the project and the plans for preclinical studies and conduct of a phase I study.

CEPI asks for submissions of EOIs for platform technologies that:

- enable rapid vaccine development **and**
- elicit robust induction of protective immunity against SARS-CoV2 **and**
- offer scientific differentiation over existing approaches **and**
- are relevant for other potential outbreaks of known viruses as well as novel or previously unrecognised viruses, i.e. "Disease X" (www.who.int).

These can be novel vaccine platforms or existing (proven) vaccine platforms where improvements can be made in terms of safety, immune response, speed, costs and manufacturing scale-up, to respond to the COVID-19 pandemic and potentially other known and unknown diseases.

This Call is open for EOIs from **November 6, 2020 to November 19, 2020**. The call may be extended or amended depending on programmatic need.

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

Contents

1. Introduction

The ongoing COVID-19 pandemic is a public health crisis causing unprecedented disruption to human activity and costing huge numbers of lives. As national and regional governments continue to implement containment measures, it is thought that only widely available safe and effective vaccines used in conjunction with other public health measures, will allow a return to normal life and help stop further loss of life and economic disruption.

CEPI is striving to accelerate vaccine development and to ensure that associated manufacturing capabilities and capacities will meet global demand as quickly as possible.

To reach this goal, CEPI has, among several supporting activities, had 3 rounds of Calls for Proposals (CfPs) for vaccine development to stop the COVID-19 pandemic, launched in February, May and July 2020. In total CEPI has received and evaluated close to 200 applications.

This Call for Proposals builds on and expands the previous 3 rounds of COVID-19 vaccine CfPs in combination with an earlier Call for vaccine technology platforms with a focus on suitable rapid response platforms. With a portfolio of COVID-19 vaccine candidates already in clinical trials, CEPI sees a need to recruit additional technologies that may fill the gaps in the portfolio in terms of antigen target, improved or differentiated immune responses compared to current COVID-19 vaccine candidates in advanced development, versatility of the platform for Disease X, manufacturing advantages, and other potentially advantageous characteristics. The vaccine developers should have realistic plans for rapid and flexible manufacturing and the potential involvement of Developing Country Vaccine Manufacturer(s). Improvements of current effective platform technologies that render them suitable for outbreak responses or that substantially reduce the costs of production and ease of field delivery will also be welcomed.

To note, funding for this Call for Proposals will be provided by CEPI, supported in part by a grant from the Bill and Melinda Gates Foundation (BMGF).

2. Objectives

The primary objective of this Call for Proposals is to develop novel vaccine candidates against COVID-19 with scientific, technical or manufacturing differentiation from current COVID-19 vaccine candidates in advanced development, and additionally strive for platforms with potential for use against other EIDs (including Disease X). This Call for Proposals also supports CEPI's strategic goal of developing technology platforms as a toolbox and with preparedness for Disease X outbreaks. The broader goal of CEPI is to transform a selection of the platforms funded in this Call into a sustainable toolbox of active platform technologies that are ready for response.

Each platform will be evaluated against several criteria to assess its differentiation compared to our current portfolio of vaccines and for their versatility for future potential application against Disease X. The funding is for early development activities only at this stage (for example, preclinical work and Phase I clinical trials and associated CMC development) for an anticipated period of around 12 months.

3. Scope of the Call

This Call for Proposals is to identify novel or innovative technology platforms for developing vaccines that can be rapidly adapted for use against the ongoing COVID-19 pandemic and which also show differentiated value against current COVID-19 vaccine candidates in advanced development. Demonstration of versatility of the vaccine technology platform and its suitability for rapid response will also be evaluated.

To be eligible, the Applicant must have at least preclinical proof of concept data to support the platform. Applicants (individual organisations or consortia) must provide information in their EOI that they meet the following **eligibility criteria**:

- Have preclinical data against SARS-CoV-2 indicating likelihood of improved or differentiated immune response (e.g., suggestive of durable protective immunity) from existing COVID-19 vaccine candidates; applicants should also have existing data (or plans to generate such data) on safety, immunogenicity, and efficacy for SARS-CoV-2 that could enable commencement of clinical testing within 6-9 months from date of funding. Faster timelines would be advantageous.
- Vaccine candidate may be based on the Spike (S) protein (or novel modifications/portions of S that address emerging structure/function investigations, glycosylation profile, etc.), but additional non-S-protein immunogens are also encouraged.
- Vaccine candidate has at least one or more of the following production advantages: simplicity of technology transfer (e.g. in-house, or established manufacturing relationship with partner), low cost, high productivity (e.g. potential for hundreds of millions to billions of doses per year), established regulatory pathway, potential partnership with Developing Country Vaccine Manufacturer(s).
- Platform must be applicable to other EIDs and Disease X.
- Provide evidence of other potentially advantageous characteristics such as (but not limited to):
    - Potential to protect after a single dose
    - Potential to prevent virus transmission (for example, induction of mucosal immune responses, or significant transcytosis, preventing viral excretion)
    - Plans for alternate routes of administration (e.g., intranasal or oral)
    - Suitability for heterologous prime-boost, including potential boost of prior heterologous immunizations
    - Proven thermostability at -20° C or 2-8° C
    - Potential for use in pregnancy (other specific safety features)
    - Potential for use in immunocompromised individuals (e.g., HIV+, etc.)
    - Simplicity of adjuvant use, or sparing of supply (if applicable).

- Present plans to enter Phase I clinical trial(s) (safety study and immunogenicity in healthy volunteers) within 6-9 months' time frame from date of funding. Faster timelines would be advantageous.
- Present plans to produce Good Manufacturing Practice (GMP) batch for clinical Phase I testing
- Present plans to integrate Phase I immunological testing which would utilize CEPI's available Centralised Laboratory network, and apply for sample testing, by completing and submitting the Sample Analysis Request Form.
- Indicate willingness for data sharing, use of common assays and international reagent standards, and contribution to COVAX Facility

Where an EOI does not meet all eligibility criteria it may still be considered if other aspects of the vaccine technology are deemed to be exceptionally strong and advantageous over the other criteria.

4. Applicant guidelines and the review process

The proposal must include essential evidence as required in **Section 3**, meet the presented timeline requirements, and contain sufficient information for review of the proposed vaccine development plans. 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) with costs in compliance with CEPI's Cost Guidance; and
- be written in English.

This Call for Proposals is open until November 19, 15:00 CET, 2020. All applications will go through eligibility screening for CEPI to assess if the application and the Applicants meet the eligibility criteria. Eligible applications will be sent for peer-review performed by CEPI's internal and external expert reviewers. Responses to Applicants will be issued as soon as they are available and preferably within a month from closing of the call. CEPI will make every effort to accelerate these review timelines as it recognises that every day counts.

While each circumstance is different, CEPI has a track record of rapidly putting in place contractual agreements that allow Applicants to proceed with work while details that may take longer to address are resolved. In other words, in line with its commitment to acceleration, CEPI intends to issue awards quickly but also expects Applicants to show willingness and flexibility.

The application template is accessible via the CEPI website. To respond to this Call for Proposals, Applicants 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 COVID-19 vaccine platform). The application should be uploaded via the secure portal in a pdf format. Do not send any additional documents to cfp@cepi.net. The application will be treated as confidential and personal data included in any proposal that is submitted will be handled according to CEPI's Privacy Notice.

This is a direct Call for Proposals, which means that no additional information should be submitted.

5. Review criteria

Proposals that have met the eligibility criteria described under **Section 3** will be assessed against the following criteria where applicable, depending on the full or partial scope of the development plan proposed:

Criterion	Assessment levels	Definition
1. Scientific merit and clinical development	1.1. Antigen target and immunogenicity 1.2. Platform versatility 1.3. Dosing regimen 1.4. Delivery system 1.5. Clinical 1.6. Regulatory	• Antigen(s) may be based on S protein or variants thereof, but not limited to S protein. • Extent to which the technology will rapidly solicit immune responses providing protection/clinical benefit, with the likelihood of improvement or differentiation from existing COVID-19 vaccine candidates in advanced clinical development. • Relevance of platform for Disease X. • Minimal number of doses required; potential for single dose. • Potential application as a booster for other primary schedules • Potential need of adjuvant and the complexity this adds to development / supply. • Description and characterisation of the proposed route of delivery and/or system. • Objectives to secure licensure and label claims. • Estimated probability of technical and regulatory success (PTRS).
2. Safety potential	2.1 Non-clinical 2.2 Clinical	• Safety profile of the platform in animal models and/or in humans • Potential for use in pregnant women

Criterion	Assessment levels	Definition
3. Speed of development	3.1. Phase I ready 3.2. Manufacturing strategy 3.3. Infrastructure	• Extent to which the vaccine candidate will be ready for entering Phase I within 6-9 months or less. • Plans for manufacturing scale-up and/or scale-out during clinical development. • Complexity of technology transfer plans. • Infrastructure, internally or through partnerships, to rapidly advance development.
4. Technical/ Manufacturing scalability	4.1. Quality 4.2. Formulation 4.3. Speed of production and scale 4.4. Scale of production	• Extent to which the technology and plans are expected to enable fast production in very large volumes sufficient to respond to COVID-19. • Adjuvant access and supply (if applicable) • Quality control to ensure comparability and a fast release process. • FTE resources able to support any scale-up / scale-out plans, tech transfers, and experience doing so. • Likelihood of lower costs.
5. Access/Route to patient	5.1. Storage and delivery 5.2. Sustainability of supply 5.3. Access	• Possibility of formulations and presentations with suitable storage conditions and stability. • Extent to which the technology can be delivered easily. • Willingness to participate in the Access to COVID-19 Tools (ACT) Accelerator mechanism.
6. Partnership	6.1. 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. The potential involvement of Developing Country Vaccine Manufacturer(s).

6. Note on vaccine access

CEPI is committed to the principle of universal, equitable and affordable access to vaccines, especially for the most vulnerable countries, as expressed in its Equitable Access Policy. CEPI's access policy with respect to COVID-19 requires that vaccines are allocated fairly based on public health need rather than ability to pay. CEPI is a co-lead on the vaccine pillar (COVAX) of the Access to COVID-19 Tools (ACT) Accelerator which has established a global mechanism to procure and fairly allocate COVID-19 vaccines (the COVAX Facility). Awardees receiving funds through this Call for Proposals will ultimately be required to supply and sell vaccines to this mechanism (or make available their technologies in order to do so) in quantities reflective of the funding received and at fair prices that are sustainable to the manufacturer. CEPI is also working with international partners towards establishing an appropriate liability and indemnification mechanism, recognising the importance to developers that such issues be addressed comprehensively prior to supplying vaccine.

Any successful Applicant will become an Awardee, and as such must have rights in order to develop, use, manufacture, and sell the vaccine proposed here for funding. CEPI will not take ownership of patents arising from its funded projects. CEPI will not seek a share of any commercial return from the vaccine manufacture during the pandemic period, focusing instead on ensuring global allocation needs are met. CEPI has a common interest with Awardees to ensure that project results are quickly and broadly made available to further scientific research on COVID-19 and that publications are 'open

access'. CEPI will work with Awardees to develop a plan to ensure that CEPI's investments result in vaccines which are licensed, including a clear pathway to successful conclusion of the development of vaccines, leading into their manufacture and global distribution.

7. Award conditions

Before submitting an application, Applicants should take note of two Award conditions. The first is that each Awardee recognises CEPI's governance, 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, in line with CEPI's Third Party Code, which can be found on CEPI's website

Contractual terms and conditions will need to be rapidly concluded in days or weeks and Awardees must be able to meet these pressing timelines given the urgency of the pandemic and the desire to start funding projects as quickly as possible.

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

8. Technical and administrative questions

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