

Call for Proposals:

Achieving an unprecedented acceleration of vaccine development and global manufacturing capacity to prevent COVID-19.

CEPI is announcing a funding opportunity for the rapid development of vaccines against COVID-19. This document describes the scope, requirements and processes for submission.

This is a rolling call now open till at least June 30th, 2020. Applications will be rapidly reviewed in batches every two weeks. The call maybe extended if needed.

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

Contents

1. Introduction.....	3
2. Objectives and the scope of this Call	3
3. Applicant eligibility criteria.....	4
4. Applicant guidelines and the review process.....	5
5. Review criteria	6
6. Note on vaccine access	7
7. Award conditions	7
8. Technical and administrative questions.....	7

1. Introduction

The ongoing COVID-19 pandemic is a public health crisis causing an unprecedented disruption to human activity with more than 3.9 billion people, around half the world's population, under direction or orders to stay at home by governments to contain the spread of the virus. As national and regional governments assess containment measures, it is thought that only widely available safe and effective vaccines 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.

This is CEPI's second COVID-19 vaccine Call for Proposals (the first was issued in February 2020).

2. Objectives and the scope of this Call

The objective of this Call for Proposals is to support the rapid development of vaccines with a goal of achieving licensure/emergency authorization in 12-18 months or less and to ensure the availability of sufficient doses for wide-spread global deployment as soon as possible in 2021. This call is being issued in conjunction with the establishment of the Access to COVID-19 Tools (ACT) Accelerator ([https://www.who.int/who-documents-detail/access-to-covid-19-tools-\(act\)-accelerator](https://www.who.int/who-documents-detail/access-to-covid-19-tools-(act)-accelerator)), a public-private partnership committed to speeding the development of and global access to diagnostics, therapeutics, and vaccines.

CEPI's core goal in releasing this call for proposals is to accelerate the development of safe and effective vaccines by organizations who can rapidly deliver at scale and to ensure that the supply of vaccine doses is made available to meet the public health need on a worldwide basis during the pandemic.

We encourage all Multi-National Companies (MNCs), companies in the Developing Countries Vaccine Manufacturers Network (DCVMN), and other vaccine / biologic developers with the capacity or potential to manufacture at scale to apply.

Applications will be evaluated specified criteria to assess the probability of success, the realistic speed of development and licensure plans, and the potential and capability to manufacture at scale within a timeframe relevant to the pandemic. CEPI embraces and supports novel technologies but proposals will be judged principally on their ability to advance rapidly through development, secure licensure and reach a significant scale of production. Applicants can apply for funding of their complete development plans, or parts of development plans.

This Call will be of potential interest to organizations who have already secured resources for a vaccine candidate for a given COVID-19 target indication or region, and now seek additional support, based on the above principles, to aid expansion of global development plans, support large clinical trials, and/or widen the geographical manufacturing footprint.

3. Applicant eligibility criteria

The funding opportunity through this rolling Call is open worldwide, to all types of organization: for-profit companies; non-profit organisations; international institutions and foundations; joint R&D ventures; government research organisations; and other vaccine developers.

Applicants must be independent legal entities, or consortia comprised of legal entities. The main applicant, or for a consortium at least one of the members, must have experience in human vaccine development and have a track record of bringing vaccine candidates through development, ideally including licensure and manufacturing.

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

To be eligible to submit a proposal the applicant should meet the following requirements:

1. Have rights to a vaccine technology that has already been proven, or soon will be:
 - a. Licensed product based on the same technology or
 - b. Relevant clinical trial data based on the same technology or
 - c. If funded, preliminary clinical data from a COVID-19 vaccine candidate by the 4Q'2020.
 - d. Well characterized vaccine delivery system
 - e. Feasibility of large-scale manufacturing.
2. Apply for one lead COVID-19 vaccine candidate
3. Propose a full development plan, or one or more of the following component(s) as part of a development plan depending on the application scope¹:
 - a. Plans and costs to conduct clinical trials. From the application it should be clear how these trials contribute to the overall Clinical Development Plan (CDP) that constitutes pivotal trials for licensure and / or supports the expansion of the desired product label for multiple geographical regions, for example.
 - b. Parallel plans and costs to generate GMP grade materials and comparability for clinical studies
 - c. Scale-up and/or scale-out plans, including costs and timelines to generate final manufacturing scale material presented in suitable containers
 - d. Plans that support the ideal storage requirements for final product.
 - e. Plans to specifically accelerate the pathway to licensure and market readiness
4. Be an organization that has its own large-scale manufacturing capabilities and a mature supply chain, or is able to expand upon its existing infrastructure/footprint, or has a proven track record of transferring its vaccine technology to a global network of manufacturer(s).
5. Be in a position for market readiness within the next 12-18 months or less.

¹ If the application is seeking funding for part of a development plan, the application should nevertheless submit the complete development plan overview so that CEPI can judge the overall context.

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](#)
- be in English

This is a rolling call that is now open to at least June 30th, 2020. CEPI will review all applications submitted in batches in 2-week cycles starting 11th May. Responses to applicants will be issued two to three working days following a 2-week review period. For example, an application received on May 8th would enter a review cycle starting May 11th and ending May 22nd. A response would then be issued May 25-27th. CEPI will make every effort to accelerate these review timelines as we recognize that every day counts.

While each circumstance is different, CEPI has a track record of very rapidly putting in place contractual agreements that allow companies 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 very quickly.

The application template is accessible via the [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 COVID-19 vaccine). The application should be uploaded in a pdf format. Do not send any additional documents. The application will be treated as confidential and 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.

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. Clinical	<ul style="list-style-type: none"> Extent to which the technology will rapidly solicit immune responses providing protection/clinical benefit Minimal number of doses required (≤ 2 doses). Well-characterized delivery system. Objectives to secure licensure and label claims Estimated probability of technical and regulatory success (PTRS)
	1.2. Dosing regimen	
	1.3. Delivery system	
	1.4. Regulatory	
2. Safety potential	2.1. Clinical	<ul style="list-style-type: none"> Safety profile of the vaccine platform/candidate in humans
3. Speed of development	3.1. Market readiness	<ul style="list-style-type: none"> Extent to which the vaccine candidate will be ready for the markets within 12-18 months or less. Manufacturing scale-up and/or scale-out at risk during clinical development Infrastructure, internally or through partnerships, to rapidly advance development
	3.2. Manufacturing strategy	
	3.3. Infrastructure	
4. Technical/ Manufacturing scalability	4.1. Quality	<ul style="list-style-type: none"> Extent to which the technology and plans are expected to enable fast production in volumes sufficient to respond to COVID-19; in 2020/2021, minimally able to deliver 200M drug substance equivalent doses or more (if two dose regimen), or 100M doses or more (if one dose regimen). 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. If applicable, willingness to transfer the technology to a global network of large-scale manufacturers Supply chain organisation
	4.2. Formulation	
	4.3. Speed of production and scale	
	4.4. Scale of production	
5. Access/Route to patient	5.1. Delivery	<ul style="list-style-type: none"> Extent to which the technology can be delivered easily. Willingness to participate in the Access to COVID-19 Tools (ACT) Accelerator mechanism. Possibility of formulations and presentations with suitable storage conditions and stability.
	5.2. Sustainability of supply	
	5.3. Access	
6. Partnership	6.1. Competency, experience and track-record	<ul style="list-style-type: none"> Extent to which the partnership, its plans and procedures are viable and of sufficient quality to deliver on the proposed activities of the project.

6. Note on vaccine access

The international community through the 'Access for COVID-19 Tools' (ACT) Accelerator, including CEPI, is working to develop an advance market or purchase commitment to ensure funds for procurement and a mechanism for the fair global allocation of vaccines for COVID-19. Awardees receiving funds through this call for proposals will be required to supply and sell vaccines to this mechanism in quantities and at fair prices that are sustainable to the manufacturer. This is in keeping with CEPI's Equitable Access Policies that require vaccines to be first available to populations when and where they are needed to end or curtail a pandemic, regardless of ability to pay. CEPI is also working with international partners towards establishing an appropriate liability and indemnification mechanism, recognizing the importance to developers that such issues be addressed comprehensively prior to supplying vaccine.

The Awardee must have rights 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 during the pandemic period, focussing instead on ensuring global allocation needs are met. We have a common interest with Awardees to ensure that project data, results and materials are quickly and broadly available to further scientific research on Covid-19. CEPI will work with Awardees to develop a plan to ensure that CEPI's investments result in vaccines which are either licensed or ready for use under emergency authorization, including a clear pathway to successful conclusion of the development of vaccines, leading into their manufacture and global distribution.

The ACT Accelerator which was recently announced, with a pillar for vaccines, will positively impact conditions for the global deployment of vaccines.

7. Award conditions

Before submitting an application, applicants should take note of two award conditions. The first is that each awardee recognizes 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.

Contracts will need to be rapidly negotiated 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).