



## Call for Proposals:

# Accelerating vaccine development and global manufacturing capacity to stop the COVID-19 pandemic.

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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 and an extension of the Call launched in May 2020. The Call will be open until September 28<sup>th</sup>, 15:00 CET, 2020.** Applications will be reviewed in batches every three weeks with the **first review cycle, starting July 27.** **Of note**, there are changes in the eligibility criteria to clarify the types of projects that will meet the aims of the Call.

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.

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## 1. Introduction

The ongoing COVID-19 pandemic is a public health crisis causing unprecedented disruption to human activity. As national and regional governments assess 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.

This is an extension of CEPI's second COVID-19 vaccine Call for Proposals launched in [May 2020](#) (the first Call was issued in [February 2020](#)). There are modifications to the criteria in order to adapt to the fast-moving environment of COVID-19 vaccine development.

## 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 authorisation 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](#), 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 organisations 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 / biologics developers with the capacity and experience to manufacture at scale to apply.

Applications will be evaluated according to 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. The 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 organisations 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, scale up of manufacturing and/or widen the geographical manufacturing footprint.

**To note**, funding for this Call for Proposals will be provided by CEPI with anticipated support towards the research and development aspects, including clinical trials, from the European Commission's Horizon 2020 programme. Costs related to scale up/out of manufacturing will be financed exclusively by CEPI.

### 3. Applicant eligibility criteria

The funding opportunity through this rolling Call is open worldwide, to all types of organisation: 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, 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 or consortium should meet the following requirements:**

1. Apply for one lead COVID-19 vaccine candidate
2. Have rights to a vaccine technology that has already been proven, or soon will be
3. Have preliminary preclinical efficacy data
4. Have clinical data Q1 2021 justifying start of Phase IIB/Phase III
5. Have experience in conducting/sponsoring international clinical trials
6. Have a proven track record in vaccine licensure and commercialisation
7. Be able to scale up/out in 2021 to more than 500 million doses (two dose regimens) or 250 million (single dose) annually. Single-dose vaccines will be more favourably reviewed.
8. Have a well characterised vaccine delivery system
9. Propose a [full development plan](#) with the following component(s):
  - a. Comprehensive and sufficient detailed clinical development plan to licensure 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 or specific populations
  - b. Parallel plans and costs to generate GMP grade materials 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
10. Be an organisation that has or a consortium that includes its own large-scale manufacturing capabilities and a mature supply chain or is able to expand upon its existing infrastructure/footprint
11. Be in a position for market readiness within the next 12-18 months or less

*Note: CEPI might fund a full development plan or some of its components.*

### 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 open until September 28<sup>th</sup>, 15:00 CET, 2020.** CEPI will review all applications submitted in batches in 3-week cycles starting on July 27<sup>th</sup>. Responses to applicants will be issued as soon as they are available and preferably within a month from submission date. CEPI will make every effort to accelerate these review timelines as we recognise that every day counts.

While each circumstance is different, CEPI has a track record of 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 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](mailto: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 via the secure portal in a pdf format. Do not send any additional documents to [cfp@cepi.net](mailto:cfp@cepi.net). The application will be treated as confidential and personal data included in proposal 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. Clinical	<ul style="list-style-type: none"> <li>Extent to which the technology will rapidly solicit immune responses providing protection/clinical benefit.</li> <li>Minimal number of doses required (<math>\leq 2</math> doses).</li> <li>Well-characterised delivery system.</li> <li>Objectives to secure licensure and label claims.</li> <li>Estimated probability of technical and regulatory success (PTRS).</li> </ul>
	1.2. Dosing regimen	
	1.3. Delivery system	
	1.4. Regulatory	
2. Safety potential	2.1 Clinical	<ul style="list-style-type: none"> <li>Safety profile of the vaccine platform/candidate in humans.</li> </ul>
3. Speed of development	3.1. Market readiness	<ul style="list-style-type: none"> <li>Extent to which the vaccine candidate will be ready for the markets within 12-18 months or less.</li> <li>Manufacturing scale-up and/or scale-out at risk during clinical development.</li> <li>Infrastructure, internally or through partnerships, to rapidly advance development.</li> </ul>
	3.2. Manufacturing strategy	
	3.3. Infrastructure	
4. Technical/ Manufacturing scalability	4.1. Quality	<ul style="list-style-type: none"> <li>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 500M drug substance equivalent doses or more (if two dose regimen), or 250M doses or more (if one dose regimen).</li> </ul>
	4.2. Formulation	
	4.3. Speed of production and scale	

Criterion	Assessment levels	Definition
	4.4. Scale of production	<ul style="list-style-type: none"> <li>Quality control to ensure comparability and a fast release process.</li> <li>FTE resources able to support any scale-up / scale-out plans, tech transfers, and experience doing so.</li> <li>If applicable, willingness to transfer the technology to a global network of large-scale manufacturers.</li> <li>Large-scale supply chain organisation.</li> </ul>
5. Access/Route to patient	5.1. Delivery 5.2. Sustainability of supply 5.3. Access	<ul style="list-style-type: none"> <li>Extent to which the technology can be delivered easily.</li> <li>Willingness to participate in the Access to COVID-19 Tools (ACT) Accelerator mechanism.</li> <li>Possibility of formulations and presentations with suitable storage conditions and stability.</li> </ul>
6. Partnership	6.1. Competency, experience and track-record	<ul style="list-style-type: none"> <li>Extent to which the partnership, its plans and procedures are viable and of sufficient quality to deliver on the proposed activities of the project.</li> </ul>

## 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 our [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](#) and work is ongoing to develop a global mechanism to procure and fairly allocate COVID-19 vaccines (COVAX Facility.) Awardees receiving funds through this Call for Proposals will be required to supply and sell vaccines to this mechanism 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.

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 from the vaccine manufacture during the pandemic period, focusing instead on ensuring global allocation needs are met. We have 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.

[The ACT Accelerator](#), which was recently announced, with the COVAX pillar, 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 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 the stipulated by CEPI's Third Party Code, which can be found on [CEPI's website](#)

Contracts 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](mailto:cfp@cepi.net)).