

Call for proposals (CfP)

Topic: Vaccine development against prioritized epidemic infectious diseases

Reference number: CEPI-CfP-001

CEPI is pleased to announce its first funding opportunity for the development of vaccines against epidemic infectious diseases. This document describes the scope, requirements and processes for proposal submission, review and selection for funding.

There are two distinct steps in the application process as part of this funding opportunity:

1. **The first step** is a request for submission of preliminary proposals, whereby applicants are asked to describe their proposed preclinical and clinical studies and their scientific rationale for impact and feasibility of implementation, as well as demonstrate their experience in vaccine development through previous track record of activities in this space. The deadline for submission of preliminary proposals is 8 March 2017. Shortlisted applicants will be invited in April 2017 to submit full proposals.
2. **The second step** is an invitation of shortlisted applicants to submit full proposals, including detailed plans for product development and manufacturing, with a clear description of milestones, timelines and criteria for success, and a thorough assessment of risks and proposed mitigation measures to ensure their resolution. The deadline for submission of full proposals will be communicated to shortlisted applicants in April 2017.

Document Administration

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1. What is CEPI?

Epidemics of emerging infectious diseases (EIDs), such as those listed in the World Health Organization (WHO) process termed “[An R&D Blueprint for Action to Prevent Epidemics](#)”, are a significant and growing threat to individual life, societies and general prosperity. They are pressing health security issues that the world faces today and in a world with increased urbanization, mobility and ecological change, their potential disruptive impact is increasing.

CEPI – the Coalition for Epidemic Preparedness Innovations – is a new international non-profit coalition aspiring to build a system that can tackle the barriers to develop vaccines against those epidemic infections for which the usual commercial incentives for development are inadequate. CEPI will advance safe, effective and affordable vaccines that can help to contain outbreaks at the earliest possible stage. CEPI was founded in August 2016 by the Government of Norway, the Bill & Melinda Gates Foundation, the Wellcome Trust, the World Economic Forum, and India’s Department of Biotechnology.

CEPI aims to foster, finance and facilitate vaccine development against epidemic infectious diseases in cases where market incentives alone do not achieve this. In order to achieve its goal, CEPI will initially focus on two priorities: moving development of new vaccines from late preclinical studies to proof-of-principle and safety in humans including small scale stockpiles of vaccine material for large scale efficacy testing and potential emergency use in the event of epidemics; and support the development of vaccine technologies and manufacturing capabilities that can be deployed rapidly against outbreaks of known and unexpectedly emerging pathogens.

CEPI has already secured US \$ 460 million of funding to support its mission for the period 2017 – 2021. Part of this funding will be allocated to projects selected for funding under this Call for Proposals (CfP).

For more information on CEPI vision, mission, strategic objectives, policies and governance visit www.cepi.net. You can also directly access the preliminary business plan 2017-2021 [here](#).

2. Funding opportunity through this CfP

2.1. Objective

The objective of this CfP is to advance up to six vaccines from late preclinical through clinical Phase II development, with maintenance of sufficient vaccine stocks for Phase III clinical efficacy trials and potential broader emergency use. Preferred platform technologies and manufacturing processes are those that can be utilized for more than one pathogen and would enable rapid epidemic responses.

In the event of a disease outbreak relevant to a vaccine R&D candidate CEPI is supporting through this funding opportunity, CEPI reserves the right to negotiate terms and conditions for funding phase III trials outside the scope of this CfP.

2.2. Time horizon

Support for the proposed vaccine R&D projects should be in general no more than **five years in duration** in the first instance. The year to year continuation of projects, as well the extension of these beyond the five years, will be determined at pre-specified stage gates on the basis of clearly defined “go/no-go” decision criteria.

2.3. Disease scope

The current CfP is limited to the following diseases:

- Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
- Lassa Fever
- Nipah

2.4 Product scope

The current CfP is limited to human preventive vaccines for endemic and/or epidemic use that can address one or more of the prioritized diseases listed under section 2.3. Product and platform technology characteristics for the development of the proposed vaccines should meet the review criteria under section 4.

A key entry criterion for being funded through this call is to have data from a relevant animal model demonstrating immunogenicity and likely protective immunity. These data should preferably be based on studies with the pathogens targeted in this call, or on a pathogen relevant for vaccine development for these.

3. Who can apply?

The funding opportunity through this CfP is open worldwide to all types of private non-profit research organisations or for-profit multinationals including small and medium sized biotechnology companies, international organisations and foundations, joint R&D ventures, government research and academic institutions bringing the relevant expertise and experience to address challenges within the scope of this CfP.

Funding beneficiaries must be legal entities, or consortia of at least two legal entities. Applicant organisations or consortia of partnering organisations should have experience in vaccine development, demonstrated by a track record of bringing vaccine candidates through to human clinical trials in the last ten years. Applicant organisations or applicant consortia where such experience cannot be demonstrated among submitting organisations will not be eligible for funding.

Individuals without an organisation registration number cannot apply for funding.

Proposals will be eligible for funding only if they are:

1. **Coherent** with the CfP objectives described in section 2.1.
2. **Relevant** to the CfP's disease scope focus, as described in section 2.3.
3. **Consistent** with the CfP timeline and award conditions as described in sections 2.2, 8 and 9.
4. **Complete** in terms of required content in the proposal templates described in section 6.

4. Review criteria

Preliminary proposals for funding that have met the eligibility criteria described under section 3 will be assessed against the following criteria:

CRITERION	DEFINITION
FEASIBILITY	<i>Likelihood of successful vaccine development, taking into account the scientific approach and evidence to date on knowledge of protective immunity after disease, vaccine design and characteristics, eventual adjuvants used, type of immune response induced and likely mechanism for conferring protection against disease, risks associated with product development, manufacturing and regulatory processes.</i>
INNOVATION AND APPLICATION POTENTIAL TO NEW PATHOGENS	<i>Extent to which the project will lead to significant advances in the establishment and validation of novel concepts, antigens, adjuvants, formulations, platform technologies and rapid manufacturing processes (scalability and speed). This also includes whether the platform technologies utilized and/or developed under the project could be used to address new pathogens.</i>
TIME TO COMPLETION	<i>Timeline requirements for successful advancement of proposed project from current R&D-stage to completed Phase II as well as prospects for future progress towards emergency use readiness or licensure (e.g. expectations for potential total lifecycle completion spanning beyond the scope and timeframe for CEPI funding under this call for proposals (e.g. additional timeline estimates required for stockpiling and rolling out vaccine product for Phase III trials).</i>
EXPERIENCE & TRACK RECORD	<i>Extent to which applicant organisation or consortium is capable of delivering the proposed activities, on basis of organisational profile, history of achievements, in-house or partnership arrangements for technical, financial and managerial capacities. This includes previous experience with bringing vaccine projects through clinical trials, and potential licensure, as well as experience with manufacturing and maintaining stockpiles.</i>
EXPECTED COST AND FUNDING AVAILABILITY	<i>Extent to which budget and financing plan are appropriate and adequate to achieve the stated objectives, including how CEPI funding will affect the project e.g. by triggering efforts and actions by the target group partners that would not be achieved if the support had not been granted.</i>
CAPACITY BUILDING POTENTIAL	<i>Extent to which the project can generate benefits or opportunities for strengthening vaccine development capacities and capabilities in regions where epidemic infectious disease outbreaks are likely to occur.</i>

The **level** and **quality** of the information made available by applicants to CEPI against the above criteria will help determine the expected performance of their proposals for funding and will inform subsequent investment decisions by CEPI. Information requirements to address the above criteria are provided in the document [‘Project description’](#).

5. Applicant guidelines

All communication of information and documents related to this CfP must be conducted in English. No costs incurred by the applicants will be covered for the development and submission of proposals or for contractual negotiations if applicants are selected for funding.

CEPI uses the online application system of the Research Council of Norway (RCN) for the submission of proposals under this CfP. Only proposal forms and related documents submitted through this system will be considered.

In case of any questions in relation to the electronic submission system, access to proposal form templates, or any other issue related to this CfP, please contact cfp@cepi.net. The CEPI secretariat

will address your questions within the shortest possible timeframe. Instructions for applicants as well as a summary of [frequently asked questions and answers](#) (FAQs) are uploaded on the CEPI website.

5.1. Preliminary proposal submission

Entities that want to respond to this CfP must submit their preliminary proposal to CEPI via the [online application system](#) of the Research Council of Norway before 4 p.m. CET¹ on 8 March 2017. Specifically, applicants are requested to complete the online application form and a series of attachments including: a completed project description form; a budget and financing plan; and CVs of Project Manager/Principal Investigator and up to six Co-Investigators or key staff working on this project. Templates for the required attachments are accessible via the [RCN website](#). The project description form cannot exceed 10 pages and should include evidence on existing preclinical and clinical data, a clear description of current R&D gaps, proposed preclinical or clinical studies under this project and their rationale, and a risk assessment of where failures are likely to occur and how applicants plan to address them. Applicants may choose to submit additional attachments to the online application form, including a risk assessment form, detailed milestone plan, and supplemental data on vaccine candidate (product, process, non-clinical and/or clinical data). There are no templates for these but applicants should follow the guidelines provided in the Project Description form in terms of content and page length per attachment, where this is relevant. In terms of the budget and financing plan template, applicants can refer to the [Cost guidance document](#) for more detailed instruction of cost items falling in scope or out of scope of this funding opportunity.

5.2. Full proposal submission

Shortlisted applicants must submit their full proposals to CEPI via the online application system of the Research Council of Norway via www.cepi.net - on a date to be communicated to them by the CEPI secretariat in April 2017. A full proposal form with detailed planning requirements for non-clinical and clinical R&D, Chemistry, Manufacturing and Control (CMC) and regulatory approval will be provided by the secretariat to shortlisted applicants in April 2017. Requirements on milestones and “go/no-go” decision criteria as well as templates for proximity to WHO Target Product Profiles will be provided. In case of consortia of partnering organisations, co-applicants must provide electronic copies of signed letters of intent, confirming their willingness to participate in the proposed projects and agreeing with the content of the proposals. Full proposal template forms should not exceed 30 pages and should include a thorough analysis of risks and mitigation measures where failures are likely to occur, including measures applicants plan to take to mitigate them. The Scientific Advisory Committee may conduct interviews with representatives of shortlisted applicant organisations when felt necessary and appropriate to ensure that the total evidence is presented prior to concluding its scientific opinion.

¹ Please be aware that the given dead-line is absolute. Potential applicants are recommended to complete and submit the proposal in good time before the dead-line. Please use the “Check-Page” function frequently during creation of the electronic application.

6. Review

6.1. Eligibility screening and review of preliminary proposals

The CEPI secretariat will screen the eligibility of preliminary proposals according to the criteria described in section 3. Secretariat staff may request additional information or clarifications to determine whether applicants and their proposals meet Cfp's eligibility criteria. Reviews of preliminary proposals will be conducted by individual independent experts assigned and convened by the SAC as suitable to the topics of the proposals. The experts will provide technical recommendations to the SAC on the basis of which it will shortlist eligible applicants. Preliminary proposals will be reviewed according to the criteria described in section 4. Applicants who do not qualify on these criteria will not be considered further for funding. Preliminary reviews will be concluded in April 2017.

6.2. Review of full proposals

The SAC will undertake a full review of shortlisted applications following submission of full proposals, including interviews with representatives of shortlisted applicant organisations when felt necessary and appropriate to ensure that the total evidence is presented prior to concluding its scientific opinion. Reviews of full proposals will be facilitated by individual independent experts assigned and convened by the SAC as suitable to the topics of the proposals. The SAC will make final recommendations for funding to the Board in July/August 2017.

6.3. Funding decisions

The Board will make final investment decisions, building on SAC recommendations, business and strategic considerations.

The CEPI secretariat will support the SAC and the Board in assessing cost/risk/benefit profiles of shortlisted proposals and in concluding the business case for investment on each of these proposals to the CEPI Board.

6.4. Review of selected projects

The SAC will meet on a semi-annual basis to routinely review progress of CEPI's project portfolio. Progress reviews of individual projects will be implemented on a tailored basis against pre-defined milestones and go/no go decision criteria agreed with each applicant during the award notification phase. CEPI reserves the right to terminate agreements where progress milestones are not met, under the guidance of the SAC (ref. section 8).

7. When will applicants be notified of the award decision?

The anticipated date for notification of results of the proposal process is contingent on the CEPI Board's decision in September 2017. The decision will be published on CEPI's webpages, and applicants will be notified as soon as possible.

The CEPI secretariat will facilitate direct negotiations, due diligence, final contracting and follow up of funded proposals.

8. Award conditions from funders

Following Board funding decisions, the CEPI secretariat will provide feedback to applicants receiving an award decision. Applicants and their partners, in case of consortia, are expected to sign a contractual agreement with CEPI within three months from award notification and must designate a representative for contract negotiations with the CEPI secretariat.

Funding will in general be for three years and not for more than five years and must reflect the proposed activities and agreed conditions of the award decision made by the CEPI Board. CEPI reserves the right to terminate agreements according to “go/no-go” decision criteria which are reviewed by the SAC.

CEPI will make use of a number of different funding options to share the risk and investment required to develop a vaccine for a non-commercial market and so achieve equitable access, and to also share in any commercial benefits should they arise from CEPI’s investments. CEPI will negotiate with each awardee to optimize and reach an agreement on the ownership and management of intellectual property. Optimal management will safeguard against the use of intellectual property in a manner that impedes equitable access to the vaccine.

More details on award conditions will be available in CEPI policies (to be released on CEPI’s website mid- February):

- Equitable access policy, including data sharing
- Shared risks/shared benefits policy
- Management of intellectual property (IP)

9. Technical and administrative questions

Technical and administrative questions about this CfP should be directed to CEPI secretariat (cfp@cepi.net).

10. Key CfP dates

19 January 2017	CfP launch
3 February 2017	First deadline for questions submitted to cfp@cepi.net
20 February 2017	Second deadline for questions submitted to cfp@cepi.net
8 March 2017	Deadline for submission of preliminary proposals
April 2017	Screening of preliminary proposals for eligibility, preliminary SAC review and shortlisting of applicants for full proposals
(date TBC)	Deadline for submission of full proposals
August	Full proposal review and eventual interviews by SAC completed, including SAC recommendations for funding to the Board
September 2017 (date TBC)	Project selection completed, investment decisions made, and award notifications sent (based on CEPI Interim Board Meeting timetable)
Autumn 2017	Contract negotiations. Project start-up expected on signing of contracts.