CEPI

Innovations to Prepare for Future Epidemics and Pandemics

Call for Proposals

Focus Area 2: Vaccine candidates for priority pathogens and viral families

1 Introduction

The Coalition for Epidemic Preparedness Innovations (CEPI) is an international coalition of governments, academic, philanthropic, private, public, and intergovernmental institutions whose vision is to create a world in which epidemics and pandemics are no longer a threat to humanity. Our mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need. CEPI operates under the laws of Norway as a non-profit international association and has offices in Oslo (HQ), London, and Washington, DC. More details about CEPI and our mission can be found on our website: www.cepi.net.

Following the outbreak of COVID-19, which caused significant morbidity, mortality, and disruption of normal life around the world, CEPI has set out a 100-Days Mission to make vaccines and other biologic countermeasures available more rapidly in response to an outbreak of a new pathogen, referred to as Disease X. The aim is to have vaccines ready for initial authorisation and manufacturing at scale within 100 days of recognition of a pandemic pathogen, when justified by the severity of the situation. Coupled with improved surveillance, and swift use of non-pharmaceutical interventions, a vaccine or other biologic countermeasure developed in 100 days could defuse the threat of a new pathogen with pandemic potential.

Achieving the 100-Days Mission will require transformative innovations in vaccine platform and manufacturing technologies, development of vaccines as well as monoclonal antibodies (mAbs) and other biologics against high-risk viruses, and the creation of a global vaccine library, including vaccine prototypes against high-risk viral families, to give a head-start on novel threats (Disease X). It will also require equitable access to these technologies and vaccines so that they are available to all who need them. Toward these ends, CEPI is particularly interested in technology innovations and vaccine candidates that can address the following needs:

- Speed: Development of a vaccine and other biologic countermeasures within 100 days of an outbreak.
- Safety/Efficacy: Acceptable safety/reactogenicity profile, reduction of viral transmission, protection against potential variants and related viruses, rapid-onset of protection, and long-duration of protection.

- Accessibility: Single-dose, low cost of goods, thermostable, and rapidly scalable manufacturing.

2 Objective for Focus Area 2

The objective for Focus Area 2 is to advance new candidates for CEPI priority pathogens and viral families, aligned with CEPI's strategic objectives to accelerate development of vaccines against known high-risk pathogens and to build a library of vaccine prototypes from high-risk viral families to give a head-start on novel threats (Disease X).

3 Scope of Focus Area 2

CEPI invites proposals to develop vaccine candidates for its priority pathogens and viral families, as described in further detail below. **Prior to preparing an application for Focus Area 2, all applicants are strongly urged to first contact CEPI at innovations.cfp@cepi.net to confirm that the proposed vaccine candidate and scope of work is aligned with current portfolio needs and priorities.** Proposals under Focus Area 2 that are not aligned with current internal priorities will be deemed ineligible for review. The scope of Focus Area 2 will be amended periodically in response to evolving portfolio priorities and needs.

CEPI may be able to support development through its centralized lab and animal model networks, and/or adjuvant library (that can be screened for optimal adjuvants for a particular candidate) where applicable. Applicants must discuss these opportunities with CEPI staff prior to application submission.

Global South developers are particularly encouraged to apply.

***Rift Valley Fever*:**

CEPI will consider proposals for discovery/exploratory, preclinical, and/or clinical development of a Rift Valley Fever (RVF) candidate. While CEPI is open to candidates from applicants/developers globally, preference will be given to proposals from groups based in RVF-endemic regions (i.e., Africa and the Middle East), or with plans to conduct clinical evaluation of candidates in endemic areas. CEPI is particularly interested in candidates that utilize RNA- (any modality), viral-vector-, or protein-based vaccine platforms.

Live attenuated RVF vaccine candidates, regardless of generation or development stage, are out of scope.

In-scope activities include preclinical safety, immunogenicity and efficacy; immunogen and assay design; CMC development related to analytical methods, process optimization, characterization, and scale-up, and/or formulation; and clinical evaluation. **The timeline for proposed studies must not exceed 5 years.**

***Pan-Sarbecovirus or other coronaviruses*:**

CEPI will consider proposals for preclinical and/or clinical development of vaccine candidates covering Sarbecoviruses (including SARS-CoV-2 variants, SARS-CoV-1, and pre-emergent ACE-2 binding Sarbecoviruses) that have demonstrated preclinical proof-of-concept.

Development of SARS-CoV-2 seasonal variant vaccines/boosters is out of scope.

Beyond increased breadth, CEPI will prioritize candidates that have the potential to be non-inferior to standard of care SARS-CoV-2 seasonal boosters against circulating variants, show

improved durability of protection, and either have advanced into clinical development or for which clinical feasibility is likely, based, for example, on a previous vaccine candidate using the same platform.

In-scope activities include preclinical safety and efficacy studies to enable regulatory filing; CMC development related to analytical methods, process optimization, characterization, and scale-up, and/or formulation; and clinical evaluation. **The timeline for proposed studies must not exceed 5 years.**

CEPI may consider proposals for coronaviruses other than ACE-2 binding Sarbecoviruses (see above) with human spillover potential (e.g., Alphacoronaviruses, Betacoronaviruses such as MERS-CoV, and Deltacoronaviruses). Potential applicants working on these viruses should contact CEPI via **innovations.cfp@cepi.net** for more information.

Lassa Fever:

CEPI will consider proposals for preclinical and/or clinical development of a Lassa Fever vaccine candidate that has demonstrated preclinical proof-of-concept. While CEPI is open to candidates from applicants/developers globally, preference will be given to proposals from groups based in Lassa Fever endemic regions in West Africa, or with plans to conduct clinical evaluation of candidates in these endemic areas. CEPI is particularly interested in candidates that will address induction of cellular immune responses. The use of a Lassa vaccine is potentially limited to endemic areas so any technology used must be affordable for these regions and should address how reasonable cost of goods will be achieved.

In-scope activities could include preclinical safety, immunogenicity and efficacy; CMC development related to analytical methods, process optimization, characterization, and scale-up, and/or formulation; and clinical evaluation. **The timeline for proposed studies must not exceed 5 years.**

Nipah:

CEPI will consider proposals for clinical development of a Nipah vaccine candidate that has demonstrated preclinical proof-of-concept. While CEPI is open to candidates from applicants/developers globally, preference will be given to proposals with plans to conduct clinical evaluation of candidates in Nipah affected countries. CEPI is particularly interested in candidates based on vaccine platforms that have either have advanced into clinical development or for which clinical feasibility is likely, based, for example, on a previous vaccine candidate using the same platform or with advanced preclinical data.

In-scope activities could include preclinical safety, immunogenicity and efficacy; CMC development related to analytical methods, process optimization, characterization, and scale-up, and/or formulation; and clinical evaluation. **The timeline for proposed studies must not exceed 5 years.**

4 Eligibility criteria for Focus Area 2

Rift Valley Fever:

- Vaccine candidate is based on any platform which is **not** a live-attenuated platform.
- Vaccine candidate is intended for use in humans (CEPI will not support development of exclusively veterinary RVF vaccines).

Pan-Sarbecovirus:

- Vaccine candidate has preclinical proof-of-concept data, including evidence of neutralizing antibodies against SARS-CoV-2 variants of concern and efficacy in a suitable animal challenge model (e.g., hamster) against Sarbecoviruses known to infect humans. This data must be shown in the application.
- The applicant has advanced a SARS-CoV-2 candidate produced in the same platform into clinical development.

Other coronaviruses with human-spillover potential:

- Proposal targets coronavirus sub-genera or specific coronaviruses that pose a credible epidemic or pandemic threat to humans, other than ACE-2 binding Sarbecoviruses.

Lassa Fever:

- Vaccine candidate has demonstrated preclinical proof-of-concept, i.e., evidence of induction of antibody and T-cell responses.

Nipah:

- Vaccine candidate has demonstrated preclinical proof-of-concept, i.e., immunogenicity and, ideally, efficacy in an animal challenge model against one of the common Nipah strains.

5 Review criteria for Focus Area 2

Applications that have met the eligibility criteria described under Focus Area 2 will be assessed against the review criteria in Table 1:

Table1: Review criteria for Focus Area 2

	Description
Impact	- If successful, to what extent could the proposed vaccine transform outbreak response? - To what extent is the applicant well-positioned to make the proposed vaccine available and affordable in the Global South?
Innovation	- To what extent does the proposed vaccine offer a substantial versus an incremental advancement over alternatives that are currently available or in development? - To what extent does this proposal present a new paradigm or solve a critical technical challenge facing the field?
R&D Strategy & Feasibility	- How well do the provided data support the intended use of the proposed vaccine? - Are there any major problems inherent in the proposed vaccine that are unlikely to be resolved? - To what extent do the proposed studies demonstrate the feasibility of the vaccine and address key data gaps?

	- Is the proposed product/platform development plan, including efficacy and safety studies, CMC development, and regulatory pathway, feasible and rigorous based on the information provided? - How well are potential problems identified and alternative methods or approaches addressed?
Personnel & Environment	- How appropriate is the background and experience of key personnel for the successful completion of the proposed project? - How well do the facilities and infrastructure provide the necessary resources for the successful conduct and completion of the project (including collaborative arrangements)?
Budget	- Is the budget appropriate for the proposed project?

6 Applicant Guidelines for Focus Area 2

6.1 Submission and review process

Key Dates: Applications will be accepted beginning on 24 October 2023, with application deadlines at 23:59 CET on the dates indicated in the below table:

	Application Receipt Period*	Application Deadline	Review Period Starts
Innovative Vaccine Candidates	24 Oct 2023 – 14 Dec 2026	Quarterly Rolling	Second Monday of every third month beginning 8 Jan 2024

*Call closure deadlines may be subject to amendment

Applicants are strongly encouraged to first contact CEPI at **innovations.cfp@cepi.net** to confirm that the proposed vaccine candidate and scope of work is aligned with current portfolio needs and priorities.

For submissions to be accepted and registered, applications must fulfil the following criteria:

- All communication of information and application documents must be in English.
- All budget amounts must be submitted in US dollars.

6.2 Application Steps and Application Templates

Step 1:

- Applicants should inform CEPI of their intent to apply as soon as possible by email to: **innovations.cfp@cepi.net**.
- In the subject line of the email, applicants should note the Focus Area under which they intend to apply. *Applications to the call described in the text above should state* **Focus Area 2** *in the subject line of the email.*
- **Applicants intending to apply will receive instructions for uploading their completed template via CEPI's secure online portal.**

- Technical support or clarification on the submission process can be requested by contacting innovations.cfp@cepi.net. CEPI staff will address your questions within the shortest time possible.

Step 2:

All application documents must be uploaded in the file formats specified below:

- **Completed Focus Area 2 application template**
- A list of **relevant publications** in the last 5 years (Section 8 in the application template)
- A maximum of **8 CVs or biosketches** (max. 2 pages per CV/biosketch) for applicants, partners, and key experts. (Section 9 in the application template).

Step 3:

All applicants that advance to the due diligence stage may be requested to submit the additional documents specified below:

- **Project plan**, including an MS-Project format Gantt chart for proposals over $5M
- **Detailed budget** template with budget narrative
- Signed **letters of support for all partners** confirming their agreement to participate in the proposed projects and agreeing with the content of the proposal (PDF file)

It is the responsibility of the applicant to ensure that all requested documents are submitted and to contact CEPI in advance of the submission deadline in case there are any issues regarding the application submission process.

Any costs incurred by applicants in the development and submission of proposals to this call for proposals will not be reimbursed by CEPI.

Data protection

- All applications will be stored in a restricted access repository.
- Personal data included in applications will be handled according to CEPI's Privacy Notice www.cepi.net/terms/.
- All project materials will be considered confidential and proprietary.

7 Award conditions

Funding must reflect the proposed activities and agreed conditions of the award decision made by CEPI. CEPI reserves the right to terminate agreements according to mutually agreed "go/no-go" decision criteria.

CEPI's commitment to enabling equitable access through all CEPI-supported programmes is a cornerstone of its mission. Specifically, for awards made under this announcement, equitable access outcomes will be focused around the goals of the particular Focus Area. These may include but are not limited to:

	Stage of Funded Work	Equitable Access Outcomes
Focus Area 2	Pre-clinical	• Open access publication of results

		• Data available to inform global and regional decision and policymakers • Data shared with CEPI
	Clinical	• Open access publication of results • Data available to inform global and regional decision and policymakers • Data shared with CEPI • Resulting Product is accessible and affordable for and available to low-income and middle-income countries in a timely manner • Supported by a sustainable business case

Through its role as a funder of R&D for pandemic preparedness, CEPI will work with key stakeholders, including the awardee, to enable equitable access to a reserve of investigational vaccines ready for use in a clinical trial setting during an outbreak using an unbiased allocation and distribution process, in accordance with CEPI's Equitable Access Policy and CEPI's principles for maintenance and use of a clinical trial ready reserve.

If you have specific questions regarding the equitable access policy, please contact CEPI at **innovations.cfp@cepi.net**.

CEPI maintains the following research-related policies to provide further guidance to its research partners on:

- Animal research
- Clinical trials (including transparency requirements)
- Equitable access policy
- Scientific integrity/open access policy

Other policies/guidance designed to support CEPI partners on general administrative issues and ensure investor requirements and industry best practices include:

- Anti-corruption
- International sanctions
- Managing conflict of interest
- Procurement
- Travel
- Transparency and confidentiality
- Cost guidance
- European Union regulatory bodies rights of review and audit plus acknowledgement of EU funding.

8 Animal Welfare and Well-Being

The National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs) is collaborating with CEPI to embed the 3Rs into CEPI funded projects. The collaboration focuses on reviewing proposals to ensure that animal welfare standards are genuinely high and exceed the legal minima, local issues relating to poor practice are addressed, and overseas work is conducted to standards equivalent to those in the UK (https://www.nc3rs.org.uk/integrating-3rs-publicly-funded-research).

In CEPI's call for vaccine and mAb development, the NC3Rs will only evaluate **proposals entering due diligence/contracting processes** and that include projects involving the use of animals highlighted by NC3R (i.e., non-human primates (NHPs), cattle, dogs, cats, pigs, and equines). Based on the review,

the NC3Rs will provide recommendations to CEPI, including advice on opportunities to implement the 3Rs, raise specific animal welfare concerns, highlight where good practice is not being adopted, and monitor the implementation of specific policies and guidance. This advice will be used during decisions on funding and when drafting the terms and conditions of grant awards.

To prepare your proposal for this review process, please consider the following guidelines:

- NC3Rs Guidelines: Non-human primate accommodation, care, and use
- Responsibility in the Use of Animals in Bioscience Research, which applies to use of any vertebrate species.
- ARRIVE Guidelines on the reporting of *in vivo* studies.

Implementation of the principles in these guidelines is a condition of receiving funds from CEPI.

Other information that will be considered during the review can be found on the NC3Rs website:

- Directive 2010/63/EU
- Scientific literature on applying the 3Rs in drug development.
- NC3Rs resources on best practice – including those on improving non-human primate welfare (such as the Macaque Website)

In addition, the NC3Rs has produced a PDF presentation to remind applicants of the required animal welfare standards and to provide advice on choosing appropriate contractors. Applicants contracting out animal research or collaborating with other laboratories (regardless of species) are advised to view the presentation well in advance of submitting their application.

9 Technical and administrative questions

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