CEPI

Innovations to Prepare for Future Epidemics and Pandemics

Call for Proposals

Focus Area 1: Innovative vaccine platforms that can transform outbreak response

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 Objectives for Focus Area 1

The objective of Focus Area 1 is to advance vaccine platforms that can transform outbreak response to Disease X, addressing needs for speed, safety/efficacy, and access. Through proposals awarded under this Focus Area, CEPI aims to build significant preclinical, CMC, clinical, and regulatory expertise with vaccine platforms that could be leveraged for rapid adoption in an outbreak and made accessible to all populations that need them.

3 Scope for Focus Area 1

CEPI invites proposals to advance vaccine platforms through Phase I proof of concept. Developers with very early-stage technologies can apply for an **Exploratory Award** of up to US $1M over a maximum of 18 months to assess the feasibility of their technology and address key data gaps. Applications for Exploratory Awards will be accepted on a rolling basis and reviewed monthly.

Applications for Exploratory Awards under Focus Area 1 may include *in vitro* and/or *in vivo* studies to assess immunogenicity, efficacy, safety, and/or mechanism-of-action as well as exploratory CMC studies.

All other applications under Focus Area 1 (i.e., for platform development) may seek initial funding of up to US $5M for a maximum of 36 months, though exceptions may be considered on a case-by-case basis. If this initial investment yields promising results, CEPI may consider further investment in the platform. In-scope activities include preclinical studies, studies that support regulatory filing (e.g., IND-enabling studies), CMC development, platform optimization, manufacture of GMP material for Phase I studies, and conduct of Phase I studies.

Successful applicants may be able to utilize CEPI-provided assays, standards, animal models for select pathogens, and/or an adjuvant library that can be screened to select the optimal adjuvant for a particular vaccine candidate.

Applicants are encouraged to contact CEPI at **innovations.cfp@cepi.net** to discuss suitability of their potential innovation prior to submission.

Developers based in the Global South are particularly encouraged to apply.

4 Eligibility criteria for Focus Area 1

To be deemed within scope of Focus Area 1 and eligible for review, applications must meet **all** of the following eligibility criteria:

1. Proposed technology satisfies all three (3) of the following requirements for an eligible vaccine platform:
    a. The technology facilitates the presentation of an immunogen to the immune system in such a way that elicits a desirable immune response.
    b. The technology can be utilized to develop vaccines against a variety of viral pathogens and antigens.
    c. The technology employs a standard manufacturing process and quality control that can be utilized for different vaccines, ideally with minimal to no antigen-dependent modification.
2. Application includes data that support the rationale for use in outbreak response. Applications for Exploratory Awards may present *in vitro* and/or *in vivo* data. All other applications must show evidence of immunogenicity, at a minimum.

3. Proposed studies are conducted with a vaccine candidate for a well-characterized virus—i.e., a virus for which there are licensed human vaccines and generally accepted correlates of protection (CoP; Table 1). This enables the selection of a validated antigen and demonstration of initial clinical proof-of-concept of the platform in a phase I study.

Table 1: Eligible Viruses for Focus Area 1

Virus	Virus family	Note
SARS-CoV-2	*Coronaviridae*	Licensed human vaccines; generally accepted CoP to prevent infection
RSV	*Pneumoviridae*	Licensed (non-maternal) human vaccine; immunogenicity data available associated with protection from lower respiratory trat infection in adults
Rabies	*Rhabdoviridae*	Licensed human vaccine; generally accepted CoP
Yellow Fever	*Flaviviridae*	Licensed human vaccine; generally accepted CoP
Chikungunya	*Togaviridae*	No licensed vaccine; *no generally accepted CoP; biomarker closely associated with protection; CEPI priority pathogen
Japanese Encephalitis	*Flaviviridae*	Licensed human vaccine; generally accepted CoP
Hepatitis B	*Hepadnaviridae*	Licensed human vaccines; accepted CoP
Influenza	*Orthomyxoviridae*	Licensed human vaccines; generally accepted CoP
Measles	*Paramyxoviridae*	Licensed human vaccines; generally accepted CoP
Other virus - with CEPI consent**	*To be determined*	Clear path to licensure

*Discussions with regulatory authorities would be required to determine the design of pivotal trial and route to licensure.
** If the applicant prefers to use a virus not listed in Table 1, please email CEPI at **innovations.cfp@cepi.net** prior to proposal development to confirm suitability.

5 Review criteria for Focus Area 1

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

Table 2: Review Criteria for Focus Area 1

Criterion	Description
Impact	- If successful, to what extent could the proposed technology transform outbreak response to Disease X (addressing needs for speed, safety, efficacy, and access – including thermostability and anticipated cost of vaccine)? - To what extent is the applicant well-positioned to make the proposed technology available in the Global South? *
Innovation	- To what extent does the proposed technology 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 technology? - Are there any major problems inherent in the proposed technology that are unlikely to be resolved? - To what extent do the proposed studies demonstrate the feasibility of the technology and address key data gaps? - Is the proposed 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?

* Global South developers can request additional support in identifying potential collaborators or other requirements before submitting a proposal by reaching out to **innovations.cfp@cepi.net**.

** Not applicable to applications for Exploratory Awards.

6 Applicant Guidelines for Focus Area 1

6.1 Submission and review process

Key Dates: Applications will be accepted beginning on 24 October 2023:

	Application Receipt Period*	Application Deadline	Review Period Starts
Exploratory Awards	24 Oct 2023 – 14 Dec 2026	Monthly Rolling	Second Monday of every month beginning 8 Jan 2024
Platform Development	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

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 1** 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 1 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:

- **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.

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 CfP 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 for Focus Area 1

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 1	Pre-clinical	• Open access publication of results • Data available to inform global and regional decision and policymakers • Data shared with CEPI
	Clinical	• Data sharing as outlined for pre-clinical work • Available to progress CEPI vaccine projects in a rapid response to an outbreak • Ready to be used to develop future products that are accessible to low-income and middles income countries (LMICs) • Willing to make future products available to LMICs in a timely and affordable manner

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 this Call for Proposal, 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 for Proposal should be directed to **innovations.cfp@cepi.net**.