**Notification of pending open request for proposal to develop platform technologies for pandemic preparedness**

**Background**

The Bill & Melinda Gates Foundation is a founding member of the Coalition for Epidemic Preparedness Innovations (CEPI)[[1]](#footnote-1) - a global non-profit public-private partnership founded by the Government of Norway, the Government of India, the Wellcome Trust and the World Economic Forum. CEPI believes that proactive vaccine development can prevent infectious disease outbreaks from becoming humanitarian crises. Faster access to vaccines for full clinical testing will contain loss of life, limit social and economic damage, and provide protection against future epidemics.

The foundation provides support for vaccine development through grant-making, Program Related Investments and other mechanisms and programs such as Grand Challenges. Grantees and partners are encouraged to engage with the foundation through regular structured interactions as well as multi-party convenings and meetings. At the foundation’s 2016 Product Development Workshop, teams of foundation partners and grantees proposed several projects that were selected for funding. *Platform technologies that could increase the response speed for vaccine development in the event of an epidemic or pandemic situation* was identified by the group as the most compelling opportunity for accelerated product development for global health.

**Definitions**

The term “rapid response platform technologies” refers to technological approaches to vaccine research, development, testing and manufacturing that may lead to development of a vaccine for an “as of yet” unknown pathogen with accelerated timelines.

“Platforms” may include expression systems, vectors, delivery technologies and other approaches. Ideally the underpinning technologies could be applied to multiple pathogens or vaccine candidates.

“Rapid response” refers to the time from identification of the pathogen/genetic sequence to develop, produce, and release supplies for clinical evaluation as well as the time required to produce sufficient quantities of vaccine to have a meaningful impact in outbreak settings. Therefore, both the development timeline and the production scale-up timeline are important considerations for applicants.

**RFP Objective and Scope**

The foundation will manage the initial reviews related to an open, multi-phase RFP to support early stage development of pandemic platform technologies. CEPI will issue the RFP for the second stage of the review process (full proposals) leading to final awards. The goal of this investment program is to support platform development for accelerated response to pandemics, and ideally to be able to have vaccine available for clinical trials during the first pandemic wave.

Funding will be provided to successful applicants to develop early stage platform technologies up to and including readiness for phase I studies. Successful applicants may have an opportunity to seek additional funding from the foundation or other partners to complete their subsequent research and development efforts, subject to the foundation’s “stage gate” approach to product development. More detail on the stage gate approach, and specific research and development activities that should be included in proposal budgets will be provided later as part of the RFP process.

In order to solicit a comprehensive body of proposals, the foundation will invite organizations (not-for-profit, public, academic, NGO, governmental and other organizations) that are interested in seeking grant funding to apply for support.

This multi-phase RFP will result in platform technologies that will help CEPI achieve its strategic objectives. The foundation will continue to work closely with CEPI as a partner to ensure alignment of funding and support activities. This invitation is made in close collaboration with the CEPI Interim Board during their constitutive meeting in London 31 August 2016, and is aligned with the CEPI board’s planned support of other research and development activities as announced at the 2017 World Economic Forum meeting in Davos.

CEPI plans to fund several projects based on several rounds of application and applicant review and diligence, provided that a sufficient number of applicants meet the specifications of the RFP. The duration of awards will be 5 years or less. However, the number and amount of the awards will be within the sole discretion of CEPI.

**High level assessment attributes of the technology will be:**

1. Clinical responsiveness - as defined as the time from sequence/organism definition to phase 1 supplies released for clinical evaluation.
2. Sound rationale and timelines for scale up for phase 3 and licensed production.
3. Sound scientific rationale for the technical platform (e.g., why the products produced with this platform would be protective).
4. Types of pandemic/endemic disease the platform may be useful for (e.g., viral, bacterial, mosquito-borne, parasitic, etc.)
5. Clear understanding and articulation of platform risks (most significant technical, regulatory, IP risks).

**Intended RFP Recipients**

This will be an open multi-phase RFP. As such it will be posted on the foundation’s website and sent to stakeholders including:

* Organizations that have engaged with CEPI, including those that have executed a Memorandum of Understanding
* Bio
* DCVMN
* Existing grantees

Organizations that have already expressed interest in funding of this nature will also be included in outreach activities. These include organizations that:

* Have applied for funding through the foundation’s Grand Challenges programs
* Have been referred by partner organizations including CEPI and others
* Have been identified by foundation staff and partners based on publicly available information including but not limited to company reports, filings, web pages and publicly-available industry information

**Anticipated Process**

A request for concept notes will be released in the coming weeks, and will provide guidance for applicants, including a concept note template and budget spreadsheet template. Thereafter, applications will be reviewed and a subset of applicants will be invited to provide a more detailed proposal, which will be reviewed under the auspices of CEPI.

Detailed review criteria will be established prior to issuing both the concept note request and the request for detailed proposals. More detail on the assessment categories will be shared with applicants during the process.

Applicants may propose more than one platform technology – however each application must be made separately.

**The anticipated issue date for the 1st phase of the RFP process (request for concept notes) is early February 2017. Concept notes will be requested in a timeframe of approximately 3-4 weeks.**

*Important information for applicants:*

1. *Only proposals for technologies that are not constrained by third party IP rights will be considered. The applicant must have freedom to operate including consent from others where applicable.*
2. *The foundation may modify or cancel the RFP process at any time, based on the number and quality of responses, or for other reasons.*
3. *Your concept note submissions should not contain sensitive or confidential information - responses may be shared with CEPI and other foundation partners. Additional guidance will be provided for applicants that are invited to submit a more detailed proposal.*
4. *Intellectual property rights and the management of IP rights are likely to play an important role in achieving the goals of this project. To this end, the foundation requires that all applicants carefully consider their willingness to submit a response in compliance with the foundation’s Global Access requirements. “Global Access” means: (a) the knowledge and information gained from this project will be promptly and broadly disseminated; and (b) the funded IP will be made available and accessible at an affordable price to people most in need within developing countries.*

 *5. The RFP will contain additional terms and conditions in addition to those described here.*

**APPENDIX**

**Bill & Melinda Gates Foundation**

Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy, productive lives. We work with partner organizations worldwide to tackle critical problems in four program areas. Our Global Development Division works to help the world’s poorest people lift themselves out of hunger and poverty. Our Global Health Division aims to harness advances in science and technology to save lives in developing countries. Our United States Division works to improve U.S. high school and postsecondary education and support vulnerable children and families in Washington State. And our Global Policy & Advocacy Division seeks to build strategic relationships and promote policies that will help advance our work. Our approach to grantmaking emphasizes collaboration, innovation, risk-taking, and, most importantly, results.

**Coalition for Epidemic Preparedness Innovations (CEPI)**

CEPI is a new alliance to finance and coordinate the development of new vaccines to prevent and contain infectious disease epidemics. CEPI will create an innovative partnership between public, private, philanthropic and civil organisations. It is ambitious in its scope and in the breadth of the organisations involved

* **CEPI’s mission:** CEPI’s mission is to stimulate, finance and coordinate vaccine development against emerging infectious diseases of epidemic potential when development is unlikely to occur through market incentives alone, by aligning industry and academic expertise with a public health mission. CEPI coordinates resources from industry, academia, governments, philanthropies, and NGOs to facilitate the advanced development of vaccines for EIDs. CEPI will focus on development and manufacturing platforms that are industrially validated; are potentially multi-purpose; and can potentially produce vaccines rapidly against known and unknown EIDs.
* **CEPI’s vision:** Infectious disease outbreaks can be managed at the earliest possible stage so that they do not become public health emergencies of international concern. CEPI believes that proactive vaccine development can prevent infectious disease outbreaks from becoming humanitarian crises. Faster access to vaccines for full clinical testing will contain loss of life limit social and economic damage and provide protection against future epidemics.
* **CEPI’s scope:** CEPI takes an end-to-end approach from vaccine discovery to application, focusing on essential gaps in product development where market incentives are limited. The initial focus is to move new vaccines through development from late preclinical to proof of principle in humans and the development of platforms that can be used for rapid vaccine development against known and unknown pathogens. CEPI funds all the development steps from late-stage preclinical development through to clinical phase I and II safety and efficacy trials with pilot stockpiles and regulatory and phase III clinical trial planning in the event of an epidemic; and it coordinates with others who otherwise fund independently of CEPI early discovery research and product delivery. CEPI assesses the feasibility of vaccine development against priority pathogens identified in the WHO R&D blueprint as a starting point and funds or coordinates vaccine preparedness efforts accordingly.
* **CEPI’s strategic objectives**
	+ **Preparedness**: Advance late-stage vaccine development to enable testing in the initial stages of an outbreak.
	+ **Response speed**: Build technical and institutional platforms to accelerate research, development, manufacturing, and clinical evaluation in an outbreak.
	+ **Market predictability**: Secure industry participation through partnerships that share the risks and benefits of vaccine development.
	+ **Equity**: Support the long-term development of regional capabilities for EID vaccine preparedness.
1. For more information, see the CEPI website: [www.cepi.net](http://www.cepi.net) [↑](#footnote-ref-1)