

Guidance on “Request for Information on Rapid Response Platform Technologies for Epidemic Preparedness”

Purpose of this request for information

The Bill & Melinda Gates Foundation (BMGF; also referred to as “*the Foundation*”) and the Coalition for Epidemic Preparedness Innovations ([CEPI](#)) are collaborating to develop a landscape assessment of the rapid response vaccine and monoclonal antibody technologies that could be used to address future emerging diseases. The Request for Information (RFI) will be used to populate that landscape, as well as to influence the development of a Call for Proposals (CfP) by CEPI on rapid response platform technologies specifically for vaccine development. The CEPI CfP is anticipated to be issued by early June 2017.

Background

The increased number of emerging infectious disease (EID) outbreaks over the past decade [1], exemplified by the 2014 Ebola virus disease (EVD) outbreak in West Africa and the Zika virus disease epidemic in the Americas [2], have highlighted the gaps in our ability to respond with interventions rapidly enough to reduce disease spread and associated morbidity and mortality. There is currently no way of predicting if emerging infectious disease pathogens will cause local outbreaks or widespread epidemics. Therefore, it is important to advance new technologies that reduce the total response time from recognition of a pathogen with epidemic potential to the achievement of protective immunity in the target population.

New vaccine technology platforms have been developed that can be used to rapidly make vaccines against newly identified pathogens. They have the potential to accelerate development timelines by relying on their track record in safety and immunogenicity from other relevant antigens and pathogens. This Request for Information (RFI) will support future investments into systems and technologies enabling rapid response vaccine development, production, and regulatory approval. The aim is to foster the development of vaccine platform technologies that can be adapted to novel antigens, produced at large scale, and that are likely to be safe and provide protection in humans.

CEPI plans to provide funding support for vaccine development through an open “Call for Proposals” process. A strategic objective of CEPI is to advance development of vaccine technology platforms that enable a rapid response to immunize at-risk populations against emerging infectious diseases. This objective comes in addition to improving preparedness by facilitating vaccine development for specific prioritized infectious diseases, as identified by the WHO R&D Blueprint. CEPI aims to fund candidates with data from late preclinical evaluation in relevant animal models and/or clinical phase I/II trials until they are ready for testing in clinical phase III trials.

Objective of this RFI

To encourage expressions of interest, and to generate information vital for the scoping and structure of the upcoming Call for Proposals to be issued by CEPI, focused on vaccine platforms for rapid response.

Disease scope

Respondents should indicate the pathogens for which their platform would be suitable. Safety and immunogenicity data with respect to these pathogens should be highlighted. The vaccine technology platforms should be also capable of being adapted to two or more of the WHO priority pathogens.

Intended recipients for this RFI

This RFI will be open for all interested parties within the field of vaccine development.

Information submitted through this RFI will be owned by CEPI and the Foundation, stored in a secure database and accessed only by the two organizations. None of the information obtained through this RFI will be shared publicly.

Minimum requirement for those submitting information to this RFI

- Organizations (not-for-profit, public, academic, NGO, governmental and other organizations) that can provide information needed to map the landscape of the rapid response technologies that could be used to address future emerging diseases.
- Preclinical data, ideally showing proof of concept of the platform, in relevant animal models

We are seeking developers who believe that their platform technology and manufacturing operations can eventually meet most (or all) the following attributes:

- Target a 16-week timeframe, ideally shorter, for release of product for clinical trials after identification of antigen
- Completion of phase II trials demonstrating clinical proof of concept within 2-3 years
- Produce sufficient doses (e.g. >1,000,000) rapidly enough to impact an emerging outbreak

Technology scope and use of information

The RFI will identify platform technologies and manufacturing capabilities that can potentially improve vaccine preparedness and response needs against priority emerging disease and as-of-yet unknown threats. CEPI and the Foundation will work closely to ensure alignment on design of a future CfP, funding and support activities, and all information from the RFI will be shared with both organisations.

Relevance of this RFI to future funding by CEPI

The information gathered in this RFI will be considered in the shaping of the scope, budget and evaluation criteria of the CEPI CfP on Vaccine Platform Technologies. The request will be launched in late May-early June and will be open to all entities that meet the criteria specified in the CfP. Applicants who submitted proposals to the CEPI Lassa-MERS-Nipah CfP issued on 19 January 2017 are encouraged to also adapt their applications to this RFI format for informing the upcoming CfP for Vaccine Platform Technologies. The upcoming CfP for Vaccine Platform Technologies will focus on demonstrating safety and immunogenicity of vaccine platforms suitable for multiple pathogens.

Key attributes to be addressed in the response

- Sound scientific rationale for the technical platform (e.g., why the products produced with this platform would be protective), based on:
 - Principle of antigen presentation, formulation, delivery and administration
 - Method of delivery and administration
- Feasibility of advancing platform from current readiness state of technology (stage of development) through to phase II including:
 - Details of development path through to regulatory agreement to deliver in an emergency response
 - Clear understanding and articulation of platform risks and reasonableness of proposed solutions to these challenges (most significant technical, regulatory & IP risks)

- Time to develop material for clinical evaluation, including Clinical Trial Material (CTM) availability - as defined as the time from sequence/organism definition to phase 1 CTM released.
- Manufacturing scalability and speed; including rationale for manufacturing processes/technologies supporting the platform and their suitability for large scale production and delivery in an emergency, timelines to manufacture different bulk/fill-finished dose equivalent volumes
- Application potential to new pathogens, including:
 - Types of epidemic/endemic disease the platform may be used for (e.g., viral, bacterial, mosquito-borne, parasitic, etc.)
 - Target antigens and diseases for which proof-of-concept data in animal models has been developed

How to respond to this RFI

An RFI template is attached with all fields being mandatory for completion. The RFI should communicate the proposer's concept/technology and prospects for clinical assessment and long term readiness capabilities of the technology. **The total length of the response should not exceed 5 (five) pages using the template and format (including font size) provided.** Submissions after the deadline or those that exceed five pages in length will not be accepted.

Deadline

Submissions should be received by 3 pm U.S. Pacific Standard Time on 24th of April 2017. Submit the completed RFI template directly to EpidemicRFP@gatesfoundation.org. Your submission should include only a completed RFI template. Other attachments, including cover letters and supplemental information will not be accepted or reviewed.

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/therapeutic for an "as of yet" unknown pathogen with accelerated timelines.

"Platforms" may include expression systems, vectors, delivery technologies, adjuvants and other approaches linked to vaccine development against target pathogens. The underpinning technologies should be applicable to vaccine candidates for two or more pathogens.

"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 or therapeutic to have a meaningful impact in outbreak settings. In addition, regulatory acceptance will be affected by safety and immunogenicity track record. Therefore, the timelines related to development, production scale-up, clinical testing, and regulatory review are important elements when evaluating the capability of a specific technology to improve response time.

Guidance on Request for Information template

General Information, Prospective Grantee/Vendor Information, Submission Information

- Please provide the requested organizational information
- The amount of funding requested, as well as the duration of the project, must be included

1. Concept Statement:

Please provide the following information:

- Key features of the platform technology, including an overview of the proposed mechanism of target antigen presentation, supported by an analysis of rationale, key assumptions and any source data from previous or current application of the platform on other diseases. Include a summary of available proof-of concept preclinical and clinical data for the platform. Include an assessment of strengths and limitations of the proposed platform technology and its characteristics.
- List of infectious pathogens that could be used for demonstration of the platform properties and allow for its evaluation in terms of feasibility and anticipated use potential in an outbreak setting. Include rationale, key assumptions and any existing evidence on platform performance to support your suggested list of pathogens against which the platform has application potential.
- Please describe any prior interaction with and current guidance from competent regulatory authorities about the development of the candidate platform as well as the proposed regulatory pathway and rationale for accelerating regulatory approval of candidate vaccines during an epidemic response. Specifically address the question of why regulatory authorities should be comfortable granting conditional approval and/or licensure for a vaccine developed against a novel disease using the candidate platform without traditional large safety and efficacy evaluations.
- Manufacturing processes/technologies for the platform and their suitability for scale-up production and delivery in response to an outbreak. Include a description of timelines for bulk and fill-finish manufacturing, including ramp-up times to meet pilot scale demand of 200,000 doses and surge demand of 1 million+ dose scenarios. Note: Surge capacity of 2-5 million and > 5 million doses should be highlighted, if achievable. Provide an outline of current in-house manufacturing capacities or existing contract manufacturing partnerships to meet pilot scale and surge demand.
- Clarify feasibility of process scale-up with existing in-house capacity or contract manufacturing partnerships and any need to establish new capacity required to meet pilot scale and surge demand scenarios respectively.

2. Organizational capabilities, experience and track record:

The purpose of this section is to allow the applicant to provide a brief, high-level summary of their organization's technical capabilities and track record for research and development.

3. Risks/Challenges:

The purpose of this section is to encourage the applicant to provide a balanced and logical risk assessment for the proposed concept/technology. A preliminary, high-level mitigation plan for key risks is also requested.

4. Sub-awards:

Partners and/or vendors that will be engaged and paid by the applicant to complete the Project Scope should be listed under “sub-awards”, with one line per sub-awardee (please add rows as necessary, but do not exceed the guidelines for overall document length). For example, a CMO may be engaged to manufacture test batches or engineering runs.

5. Level and sources of support for this project:

In this section please describe the total cost estimate, how much is already covered and what funding level you are likely to require through a potential investment opportunity issued by CEPI or BMGF.

In this description please outline contingency plans and alternate funding options. The extent of the anticipated cost requirements already covered by other funding sources to advance the platform from current to future state must be disclosed, and distinguished from the potential need for funding from CEPI to possibly advance the platform concept to a defined readiness state.

In addition, requests for funding from other sources which overlap with the funding requested in this proposal should be noted. Applications to BMGF, Wellcome Trust, BARDA and CEPI as additional funding sources must be disclosed.

Important information for applicants:

- 1. The applicant must have freedom to operate as related to IP, including consent from others where applicable.*
- 2. Your concept note submissions should not contain sensitive or confidential information - responses will be reviewed by BMGF and CEPI, and could be shared with other partners to these organisations.*
- 3. The RFI process does not constitute a guarantee of funding in any CFP process that arises from the data gathered here.*

References

1. Jones, K.E., et al., *Global trends in emerging infectious diseases*. Nature, 2008. **451**(7181): p. 990-3.
2. Sands, P., C. Mundaca-Shah, and V.J. Dzau, *The Neglected Dimension of Global Security--A Framework for Countering Infectious-Disease Crises*. N Engl J Med, 2016. **374**(13): p. 1281-7.