APRIL 10, 2017

RAPID RESPONSE RFI Q&A

This Question & Answer (Q&A) summary is designed to provide potential applicants with answers to questions that are commonly asked, have come from other applicants or that could clarify areas of uncertainty with respect to the Request for Information (RFI).

QUESTIONS & ANSWERS	DATE RECEIVED/ ANSWERED
Q. How will the submissions be evaluated/scored?	From prior RFI/RFPs
A. Submissions will be assessed and scored by reviewers from both CEPI and the Bill & Melinda Gates foundation.	
Q. Is the template the full submission or will we need to include additional documents?	From prior RFI/RFPs
A. The provided template is the full submission. No other documents are needed.	
Q. How strict is the 5-page limit?	From prior RFI/RFPs
A. All information related to answering the RFI must be contained within 5 pages. Any application over 5 pages will not be assessed	
Q. I submitted my response but did not receive a confirmation. How do I know if my Proposal went was received?	From prior RFI/RFPs
A. You will receive an email confirmation within 24hrs of your submission. If you do not receive this confirmation, please contact us at EpidemicRFP@gatesfoundation.org to confirm your application was received.	
Q. Is it acceptable to leave any sections of the template blank?	From prior RFI/RFPs
A. We expect respondents to complete all sections to allow for consistent reviews. If a section is deliberately left blank, please provide a brief explanation.	
Q. Antibody therapeutics is mentioned briefly in the guidance document but most of the content focuses on vaccines. Are you interested in antibodies?	03/30/2017
A. This request for information is open to antibodies and vaccines. However, CEPI's scope of funding is for development of human vaccines.	03/30/2017
Q. Does the scope of "technology platforms" include more upstream technologies (e.g. rapid identification of protective antigens) or exclusively on delivery platforms?	03/30/2017
A. This request for information is focused on platforms that can develop and manufacture a vaccine.	03/30/2017

QUESTIONS & ANSWERS	DATE RECEIVED/ ANSWERED
Q. Do you prefer multiple different approaches to vaccine development or a more integrated end-to-end approach?	03/30/2017
A. All approaches that meet the specified criteria are encouraged to apply.	03/30/2017
Q. Is the location of facilities factored into the evaluation of submissions?	03/30/2017
A. No	03/30/2017
Q. Given cold chain challenges, will any preference be given to lyophilized vaccines?	03/30/2017
A. No specific advantage at this stage but this is certainly worth highlighting in your submission.	03/30/2017
Q. Is there a list of pathogens that are of interest for showing pre-clinical data?	03/31/2017
A. We are interested in pre-clinical data on any pathogen, but the disease scope of the upcoming CEPI RfP will request platform technologies that can be adapted to the WHO priority pathogens.	03/31/2017
Q. Should we identify other funding (e.g. various US Government agencies) funding that may be pursued for the same work?	03/31/2017
A. Yes, please include this information in your submission.	03/31/2017
Q. Are there any additional details we should be aware of beyond the key product attributes listed in the Guidance Document?	03/31/2017
A. No, all key details for the RFI are included in the Guidance Document.	03/31/2017
Q. What activities should be included in the budget estimate?	03/31/2017
A. Detail is not required for this RFI, but please describe your main assumptions and scope used to develop the high-level budget.	03/31/2017
Q. What is the advantage for organizations to submit a response to the RFI vs. waiting for the RFP?	03/31/2017
A. While there is no formal advantage, it is important to note that the responses to this RFI will inform the content and key parameters of the forthcoming RFP from CEPI. Additionally, having your technology/organization reviewed and noticed earlier is a potential benefit.	03/31/2017
Q. Is there a timeframe for the duration of funding (e.g. 5 years) that would be provided in the full RFP?	03/31/2017
A. This is not yet defined and will be addressed in the CEPI CfP. It is likely that it will be dependent on the scope of the proposal and stage of development, with a preference for staged funding commitments to reach development milestones.	03/31/2017
Q. We are currently in the process of generating pre-clinical data that will be available prior to the release of the full CEPI CfP, are we eligible to participate in the RFI?	03/31/2017
A. Yes, please submit to the RFI and specify the date when preclinical data will be available.	03/31/2017
Q. We do not yet have the capability to run an integrated development and manufacturing platform, but are interested in partnering our technology with other organizations. Will there be an opportunity to be matched with other organizations?	04/10/2017

QUESTIONS & ANSWERS	DATE RECEIVED/ ANSWERED
A. We encourage you to submit to ensure awareness of the technology you believe would be beneficial in a rapid response platform. We also encourage you to reach out to other organizations that may have the capabilities you would need to propose an effective platform solution.	04/10/2017
Q. What is the intended scope of the cost estimate? Would this include activities through licensure?	04/10/2017
A. Please estimate the cost associated with the scope and development phases you are proposing. Please note that the scope of CEPI funding is through Phase 2.	04/10/2017
Q. What is the type of feedback we can expect for our proposals?	04/10/2017
A. We will only acknowledge receipt of proposal. Due to the anticipated volume of responses and that this is only an RFI, we do not plan to provide any additional feedback.	04/10/2017
Q. What happens after submission of the RFI? Is this a one-step process or will applicants have the chance to submit additional information?	04/10/2017
A. Responses will be reviewed by a team from CEPI and the BMGF. Information derived from these proposals will be used to shape the forthcoming CfP from CEPI. This RFI itself is a one-step process.	04/10/2017
Q. If an applicant responded to the CfP in the future, would applicants have the chance to revise the information submitted in the RFI?	04/10/2017
A. Yes	04/10/2017
Q. Is the pre-clinical data critical or would clinical data be more valuable?	04/10/2017
A. We encourage applicants to present their existing preclinical and clinical data on the vaccine platform. Whereas clinical data would be superior to enable a safety assessment of the platform, pre-clinical data may be more informative to assess efficacy.	04/10/2017
Q. Would a clinical program be expected to be included in the RFI response?	04/10/2017
A. Yes, we would expect most submissions to describe a clinical development plan into phase 2.	04/10/2017
Q. To meet the 16 week response requirement, is it assumed that a tox-study would be included in the timeline?	04/10/2017
A. We assume a tox study would be required unless it has already been completed or there is a plan to obtain data supporting the argument that a tox study would not be needed.	04/10/2017
Q. Is the focus of the RFI on a development and manufacturing platform or a true end-to approach including consortiums that would identify and sequence pathogens, etc.	04/10/2017
A. Focus of the RFI is the capacity to develop and manufacture a vaccine rapidly from a given pathogen and related antigen, whereas more upstream technologies such as pathogen sequencing is out of scope.	04/10/2017
Q. For section 5 (level and sources of support) cost estimate, can you confirm we should submit a program designed to address one of the WHO priority pathogens as an example?	04/10/2017
A. Data addressing a WHO priority pathogen would be preferable. However, data against any pathogen are of interest for assessing the feasibility of the platform.	04/10/2017
Q. Is there an interest in combination vaccines?	04/10/2017

QUESTIONS & ANSWERS	DATE RECEIVED/ ANSWERED
A. *The focus is on rapid response vaccine technologies. Development of combination vaccines is currently out-of-scope.*	04/10/2017