



Call for proposals on platform technologies: Frequently asked questions (FAQs) - 1

Submitted by 15 September 2017

Overview

Below you will find answers to questions that the CEPI Secretariat received by 15 September 2017 with regards to the call for vaccine platform technologies (CfP2). One set of responses to all questions will be emailed to those who submitted questions. All responses to the rounds of questions will be published [here](#). Please note that these responses are in addition to the previously published application guidelines on the [CEPI Website](#).

Budget and financial questions

1. Is there a limit per year or in total to the funding request?

There is no upper budget limit per year or in total for step 1 of this call for proposals, and budgets will need to be commensurate with the technical performance of proposals. Specifically, CEPI will carefully consider the extent to which proposed budgets are based on valid assumptions, reflect an understanding of the technical milestones and objectives of proposals, are fully consistent with applicants' proposed activities, and are fully compliant with CEPI's guidelines on eligible costs (for more details see [CEPI's cost guidance](#)). Moreover, CEPI will consider the overall realism and transparency in the justification of overall cost estimates for completing the projects, including whether budgets are competitive and represent fair market value for the country/ region where the activities are performed, and whether there are additional funding sources to share the overall costs of completing the projects.

Contractual and procedural questions

2. Will a Letter of Commitment from a subcontractor or teaming partner be acceptable for Step 1 submission? What will be required with the submission of the full proposal?

A letter of intent or letter of collaboration is acceptable for both the step 1 and the step 2 application. We however expect an active and well specified collaboration of the consortium partners.

3. What type of gate reports and/or study reports (draft and/or final) would awardees be required to submit? How would these reports be submitted and reviewed? Would each process/protocol be reviewed prior to start of production and testing?

The reporting requirements will be discussed with those applicants selected for contract negotiation, after successful completion of Step 2.

4. For the phase I clinical study, does CEPI consider the last patient visit satisfy completion of a major activity for the phase I study within three-year period with the draft and final CSR submitted after the three-year period ends? If not, would an interim CSR with tables and lists satisfy the completion requirement?

For the Phase I clinical study, CEPI expects the Applicant to have completed LSLV including a minimum 4 weeks safety follow-up after last dose. Report for the clinical Phase I study (CSR) with detailed listing with timelines for finalization of the immunological analyses. An interim CSR with full safety data and interim immunogenicity data will be required as well as detailed timelines when final immunogenicity read-outs and final CSR will be available.

5. What role will CEPI play in regulatory submission? Do you have a regulatory affairs office to guide on regulatory submissions?

It is expected that the applicant has or acquires sufficient regulatory expertise in order to follow up the vaccine development project towards end of Phase I. We refer to the application template section 4.7 for further requirements.

6. Is there a preference for a FDA or an EMA submission?

No, CEPI has no preference and leaves it to the applicant to identify the most appropriate regulatory pathway which also could include other regulatory pathways beyond the two mentioned.

7. Are the two pathogens that will be evaluated in Phase I clinical trials to be selected by the applicant or by CEPI?

We expect the applicant to present a plan on which pathogens to proceed to clinical studies. The rationale for choice of pathogens needs to be described.

8. With respect to the R&D entity, would the primary legal entity discussed in Section 3 be the lead applicant or the partner?

In this case both would be a legal entity. In case there are more than one partners, the funding beneficiaries would be identified as a consortium of multiple legal entities, represented by one legal entity that has the contractual responsibility towards CEPI.

9. How many contracts will be awarded?

The number of contracts that will be awarded depends on the quality of the applications we receive, the requested budget of the proposals and the overall budget allocated to CEPI by its funders.

Scientific questions

10. In how much detail does the science behind the platform to be described in the proposal?

The platform needs to be described in such a way that a reviewer with expertise in vaccine development but with potentially limited knowledge about the specific platform can understand the principles, technology and advantages/disadvantages of the platform. Also, the maximum page limit for submissions needs to be strictly respected.

11. Does one of the pathogens taken into clinical studies need to come from the WHO list or can both come from Table 1 in the CfP2 call text?

The choice of the pathogens taken into clinical studies is up to the applicant but must be chosen either from the WHO priority list or from Table 1 in the CfP2 call text.

12. Can only 1 pathogen be chosen from the WHO R&D blueprint priority list? Would CEPI accept a proposal that chooses 2 pathogens from the WHO priority list and 1 from Table 1 while still complying with selection of viruses across the 3 virus families? Would CEPI accept a proposal that develops products to three different agents on the WHO priority list?

All applicants should include 1 pathogen from the WHO priority list and 2 pathogens from Table 1 in the CfP2 call text. The goal of this call is not only to show the versatility of the platform, but also to identify the mechanisms of action. This is more easily achieved using pathogens from Table 1. However, previous data generated on other pathogens on either list can be included as additional evidence to support the platform.

13. Can we submit an application describing technologies that support vaccine development or enable faster vaccine development, but that are not vaccine platforms according to CEPI's definition?

While we recognize the added value that such supportive technologies could contribute to rapid vaccine development, these technologies fall outside the scope of this particular call. We would like to emphasize that applications will be screened according to the eligibility criteria listed in the call text, and those that do not meet these criteria will not be peer-reviewed. Therefore, we would discourage submission of applications that do not fall within the scope of the call, such as those that only describe a supportive technology not presented in conjunction with a vaccine technology platform as here defined by CEPI.

14. The CEPI call text states that 'produce 100,000 vaccine doses within 8 weeks to impact an emerging outbreak (i.e. from Go-decision to scale-up to production, fill, finish, and release). What time point does the go decision relate to?

The 8 week production responsiveness platform attribute is independent of the 16 week clinical responsiveness platform attribute and the triggering event would likely be an order following clinical proof of concept (POC). CEPI would reserve the right to pursue orders prior to clinical POC in extreme circumstances once the platform is proven and scale is established.

15. Will a technology platform with unique advantages be considered responsive to the call if it requires 12-18 months from antigen identification to product release but this 12-to-18-month timeframe represents a dramatic improvement relative to the current state of the art for this class of product?

CEPI's goal with this call is to encourage vaccine developers to shorten the time from antigen identification to product release for clinical trials. We have set an aspirational goal of 16 weeks, since rapidity of the outbreak response is arguably the single most critical element in containing an outbreak. While the 16-week target is a goal to work towards and not a formal prerequisite to apply for this call, applications describing technologies that are more amenable to rapid response will be looked upon more favorably. A 12-18 months release timeframe could be long in an emergency situation.

16. Should an applicant focus on a novel pathogen, given that the platform they provide have already been tested out in the required pathogens given by CEPI?

It is not necessary to test your platform on a novel pathogen. We encourage you to use the candidates you have and focus on carefully assessing the immunological mechanism of action of

the platform technology in humans in the Phase I trials. However, you could choose to test the responsiveness of your platform with a new candidate from either the WHO priority list or table 1 in the CfP2 call text if you wish.

17. Are DCVMN partners preferred?

This call focus on the development of vaccine platform technologies which allow to fulfill the requirements set out in the call. Whilst we encourage DCVM to submit proposals, DCVM partnering is not a requirement for this call nor will this lead to preferential assessment.

18. In our platform we aim at different specific approaches of which one may not meet one of the specific time requests stated in the call. Should we exclude this approach?

The time requests stated in the call text are aspirational goals and we understand that many technologies may not be able to achieve all these goals simultaneously. During evaluation of the proposals we will look at the overall performance with regard to all these goals and the balance between them. For example, some technologies might not reach the 16 week target, but will induce a protective immune response within 2 weeks, whereas others might be able to produce clinical product more rapidly, but will need a second dose and therefore will take 6 weeks to induce a protective immune response. We encourage applicants to target all the requested goals, but emphasize that meeting all goals is not a prerequisite for application. Technologies that approach these goals will of course be looked upon more favorably, however.

19. In case a relevant animal model is lacking, will initial experiments in mice be accepted?

Yes, but only if there is indeed no accepted relevant animal model.

20. In the preclinical proof of concept studies, is it sufficient to evaluate the surrogate marker for protection (for instance nAb) after vaccination for the pathogens listed in table 1 of the CfP or is it necessary also to demonstrate protection after challenge with the pathogen?

Data provided on previous preclinical studies can include data from preclinical proof of concept studies including only a surrogate marker for protection. However, applicants are encouraged to include plans for animal challenge studies for the projects for which they are requesting funding through the call.

21. In the project description template, section 4.4, it is asked to describe the potency assay and the potential for validation. Does validation mean validation of the method (detection limit, linearity etc.) or validation of the parameter as surrogate marker for protection?

In this case we are asking for the validation of the method.

22. What level of animal data is needed for eligibility?

To be eligible for the call, you need to provide data from a vaccine candidate on the proposed platform that demonstrate immunogenicity using a relevant animal model. These data could be based on studies with the pathogens targeted in this call, or on another pathogen.

23. Are multiple animal models required?

For eligibility of this call, we do not require multiple animal models. However, we encourage submission of all the data you have supporting your platform, either from multiple animal models or multiple pathogens to provide evidence of the versatility and feasibility of the proposed platform.

24. Would preference be given to those projects that have human data already for one of the proposed viruses on either list, or human data for a virus NOT on the provided lists but a public health pathogen developed or in development using the same platform?

We encourage applicants to submit all data they have on candidates using the proposed platform and we do not have a preference whether these are pathogens targeted in this call.

25. Is it correct to assume the funding may be contracted regardless of the nature of the platforms under consideration?

Yes, we will evaluate and select proposals based on the quality of the proposals and the criteria specified in the call text, regardless of the type of platform as long as that proposed platform meets call criteria.

Application questions

26. Are we allowed to apply for the CfP2 when we have already applied to CfP1 (MERS, Lassa, Nipah)?

Yes. Just be aware that we are not providing additional funding through this call for vaccine projects funded under CfP1, as stated in the call text: "All organizations with platforms that meet the stipulated goals of this call are encouraged to respond, but CEPI will not provide additional funding through this call for vaccine development projects funded under CfP1 to develop MERS, Nipah and/or Lassa vaccines."

27. What will be the main criteria for the reviewers of the proposals? Can you share these details?

The criteria are given in the call text under point 6. The criteria are feasibility to meet the 3 years timeline, anticipated potential use, manufacturing and scalability, experience and track record as well as budget will be used for evaluation of the Step 1 Proposals.

28. The milestone template lists space for all 3 pathogens to go through the end of Phase 1, but the budget and CfP mention that only 2 pathogens will go into clinical development. Should the milestone template be completed with the plan to take all 3 pathogens to the end of Phase 1?

No, it is only necessary for the applicant to describe the 2 pathogens that they are planning to take into clinical trials.

29. If an applicant has already completed research through IND-enabling Preclinical Studies or other milestones then can the applicant list those milestones as already completed? If so, then can the applicant budget solely for the milestones and activities remaining?

Yes, you can include milestones that are already completed in the milestone plan. The budget should only include the milestones and activities for which the applicant requests funding from CEPI.

30. How much time should be budgeted for milestone review?

The applicant should estimate time allocated to milestone review based on their own experiences.

31. The layout of the milestone template document is locked. Are the applicants permitted to modify the layout to include additional milestones and make more descriptive of individual projects?

In the Step 1 application, the information in the milestone template is the only information necessary. Applicants can add a more detailed description of their plan to the project description template but must respect the maximum page limit for the application. Applicants invited to Step 2 will be requested to provide a more detailed milestone and budget plan at that time.