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CEPI | New vaccines for a safer world

Coalition for Epidemic Preparedness Innovations

Responses to CfP1 - Step 2 questions sent to cfp@cepi.net by 29 June 2017

Contents

Overview

Below you will find answers to questions that the CEPI Secretariat received by 29 June 2017. One set of responses to all questions will be emailed to those who submitted questions at each date. All responses to the three rounds of questions will be published here.

Please note that these responses are in addition to the previously published application guidelines and frequently asked Questions on the CEPI Website.

Budgetary/financial/template questions

1. In your cost guidance version 14.02.2017 you indicate that whilst CEPI's preferred funding currency is USD, and you will consider requests for other funding currencies on a case by case basis. Is CEPI willing to consider for our proposal to be submitted in (and if successful paid in) GBP?

CEPI has finalized decisions on funding currency and we will make all contracts in USD. Applicants are required to apply in USD.

2. What will be the official terms of the grants, and when will they be finalized and available?

The CEPI Funding Agreements: Key terms can be found by following this web-link. The timeframe for drafts will depend on how many awards are to be made, and the level of complexity.

3. Concerning the partners or clinical trial sites in the countries affected by these 3 diseases that will be involved in the conduct of the different trials. Does CEPI expect/prefer that in the stage 2 proposal the particular partners or sites in the affected countries where clinical trials will be conducted are already identified? Or does CEPI suggest to wait with contacting potential clinical trial partner sites in affected countries until funding decisions have been taken from CEPI side and that only then the awardees should reach out to these sites, in order to avoid that the limited sites are available in these countries will be overloaded with request from different proposals?

We acknowledge the capacity constraints of potential trial sites and the unintended consequences that competition for these sites could have. CEPI is therefore currently in dialogue with the WHO on an approach for coordinating the recruitment of clinical trial sites in countries endemic for the diseases targeted by CEPI. CEPI anticipates that the outcome of the process will not be ready in time for the Step 2 application deadline. Applicants must still provide a proposed approach for clinical trial in the affected countries, and depending on the stage of an applicant's target, this should influence how advanced an applicant's planning is. A robust strategy and plan for phase I/II in the Step 2 application would include plans for study design, plans for establishing clinical trial sites and clinical trial execution; and, obtaining regulatory advice with respect to clinical development.

CEPI expects applicants to have considered potential capacity constraints with their clinical trial site partners and to demonstrate how they would tackle such risks in their risk mitigation plan submitted together with step 2 project descriptions.

During project implementation, CEPI will work closely with its awardees and with WHO to update strategies for affected country clinical trial sites engagement, depending on expected capacity constraints or efficiency gains across R&D programmes supported by CEPI.

4. Our proposal has over 100 embedded literature citations. We would like to put these in an appendix which would be excluded from our proposal description page count. Please advise

To ensure citations are included in your application CEPI recommends that you have hyperlinks to a web-page number so that independent reviewers can check the citation where needed. E.g. have one number that hyperlinks footnotes to references online (such as [1]), eliminating the need for a separate appendix.

5. Due to our proposal advancing two vaccines we are requesting in increase for document page limits?

All applicants have received information on the number of pages for their application. The guidance has been that, for applications:

- one target (50 pages),
- two targets (75 pages), and
- three targets (100 pages).

This page limit will include the *Project description template - step 2*, *Milestone template Step 2* and the *CEPI Budget Narrative*. CEPI cannot accept proposals longer than the designated number of pages communicated with you during your teleconference.

Please note that the CEPI budget template and sheets are not included in the page limits.

6. Indirect Costs: the budget template only allows for the budgeting of one indirect rate. Given our various rates are applied to different expense categories, we would like request approval to modify the budget template to reflect our rates correctly.

CEPI does not allow any modifications to the budget template. In addition, see previous responses to questions related to indirect costs Step 1 FAQs 1 and Step 1 FAQs 2.

7. Would it be acceptable to create additional spreadsheets to model different project development scenarios?

Yes.

8. Please clarify if all contracted service providers to be used by the applicant to deliver the project endpoints, including laboratories (BSL 2 to 4), animal facilities and containment level, vaccine manufacturing facilities (including pilot, scale-up and GMP) should be specified at this time. Many of these contracts go through a formal internal process for due diligence selection and negotiations. What if actual budgets differ from projected budgets?

Related to responses from Step 1 FAQs 2, Step 2 budgets should be based on Step 1 applications. Funding decisions and contract negotiations will be based on application budgets.

9. In case of a portfolio application in which vaccine candidates for MERS, Nipah and Lassa are combined in a single application, should each of the individual vaccine candidates have its separate milestone table/sheet or should all candidates be combined in the same milestone sheet in the excel template provided by CEPI?

Applicants can choose the best method to present milestones per target and can opt for a single sheet or separate milestone table/sheet if this is most suitable for the individual vaccine candidates. The key concern for CEPI is to enable reviewers to both assess each candidates on their own, plus the alternative scenario of assessing how the applicant has planned to implement multiple candidates in parallel. In terms of a portfolio approach, applicants are also encouraged to add any additional milestones that are relevant for parallel or sequential development of candidates.

Scientific/Technical questions

10. Does CEPI require the inclusion of Non-human primates as MERS-CoV animal challenge model in the preclinical development plan in the CFP1 Step 2 applications, if not already undertaken to this date?

CEPI is aware that there are ongoing efforts in assessing existing evidence on suitable MERS animal challenge models and attempts to generate consensus, and we therefore encourage applicants to justify their choice and hereby inform that inclusion of additional studies can be negotiated in at the contracting stage if consensus guidance emerges in the interim.

11. Please clarify which of the quantities of vaccine for emergency use in a response to a disease outbreak you are requesting?
    - *Call for proposals (CfP) Step2 and Product description template* states: ≤50k doses; ≤200k doses; ≤1m doses
    - *C EPI Budget Template Section 10 states (1) under 100 thousand, (2) 500 thousand and (3) 1 million dose scenarios.*

CEPI apologizes for the discrepancy. The correct scale categories are listed in the Project description template: ≤50k doses; ≤200k doses; ≤1m doses.

12. Do the amounts of vaccine that we should plan for differ for a pathogen like Lassa where you might want Phase III supplies plus an additional stock pile?

CEPI has developed a working group on stockpiling and this process will include the estimation the number of doses planned to be requested for stockpiling. This process is however not ready to communicate its outcomes and CEPI recommends applicants provide production plan and cost estimates based on alternative scale categories (e.g. ≤50k doses; ≤200k doses and ≤1m doses).

13. Will CEPI require the use of common preclinical/clinical assays across funded groups? Since we feel this will be important, can we include assay validation costs in our proposal?

CEPI is in the process of establishing a working group on Biological standards, assays and animal models and CEPI's practice with respect to assay development may evolve over time. For the time being, however, please include assay validation costs in your budget proposal for Step 2.

14. If regulatory feedback necessitates a larger study or additional work, how will this be dealt with by CEPI in terms of resources/funding?

CEPI will enter into contract negotiations with applicants who appear most likely to succeed in developing vaccines against its target diseases and will involve regulatory experts in the review of proposals to assess the reasonableness of the regulatory and clinical development plans. CEPI will implement a stage-gate review process to inform funding of options beyond the contract's base period of performance. Option periods will be individually negotiated prior to being exercised and CEPI reserves the right to either reduce or provide additional funding depending on the status of the individual project and its requirements. As part of their step 2 proposal submissions, applicants are expected to have identified potential risks, and to have proposed measures to mitigate against these risks if and when they materialize.

15. Please clarify desired regulatory planning horizon: a) sufficient preliminary nonclinical and clinical data (safety and proof of concept efficacy) to support a pivotal trial in a pandemic situation, or b) up to marketing authorization.

The regulatory planning should be in line with CEPI's mission, which is to advance at least four vaccine candidates against two to three priority pathogens to proof-of-concept in five years and to enable clinical efficacy testing in the initial stages of a potential outbreak.