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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 20 June 2017

Contents

Overview

Below you will find answers to questions that the CEPI Secretariat received by 16 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 questions

1. The CEPI Budget Template requires a list of names for identification of personnel costs. Since such information is confidential, can a code system/ generic job title be used instead of individual staff names for this type of information?

Yes - a coded system is acceptable. However, we will require job titles to ensure assessment of salary rates. In case of vacant/proposed positions, please specify the Generic job title along with the status (Vacant/Filled).

2. The CEPI Budget Template requires a list of names for identification of personnel costs. Since information for all consortium members and partners shall be provided this will cause a significant issue related to personal data confidentiality. We will not be able to get such details (name-salary) from each partner. In addition for staff which shall be recruited individual names cannot be provided. Can a code systems be used instead of individual staff names for this type of information or can a generic job title be used?

See response to question 1.

3. In consortium structures, are awards transferred to the consortium leader who is mandated to distribute the budget among consortium members? Could awards be given to all consortium members individually, based on individual budget sheets, which can be summarized in an overall Budget Plan provided to CEPI?

We require a single consortium lead, or primary awardee who has responsibility to distribute and manage the budget to sub-awardees or consortium members. See instructions in relation to this on pages 17-18 of the Budget instruction document.

4. As indirect cost rates will vary for consortium partners, is it acceptable for CEPI to receive individual budget sheets by consortium partners for its own cost planning plus sub-awardee planning? If yes, is it acceptable to develop the project/program budget by consolidation as a second step?

We are asking for one overall budget per application/project/program. Partners can complete the same detailed budget template and budget narratives provided, with a template and narrative completed if they meet the sub-awardee criteria outlined in Question 1 of the Step 2 FAQs 1 (click web-link).

5. With regard to Sub-awardee budget planning: As market rates and full cost transparency may not be achievable, does the 100,000 USD / 5% clause apply to the level of budgetary detail for quotations from third parties? Will overall (project/program) budgets, timelines and milestones be harmonized between consortium partners?

As in the budget instructions, where it is not practical or meaningful to break a line item into component parts, you can use the budget narrative to explain the nature of the expenditure. However, we may request further information on this. CEPI will accept best estimates on conditional inclusion of a milestone checkpoint to get the 'finalised' budget at a specified later date. It is the primary awardee's responsibility to produce and share harmonized timelines and milestones with CEPI.

6. Sub-awardee budget planning: level of budgetary detail for quotations from third parties? Does 100K USD/5% clause apply here, too? We need to respect that these are market rates and full cost transparency may not be achievable.

See response to Question 5 above.

7. As consortium awards will go to consortium leaders and then be distributed among consortium members? Could awards be given to all consortium members individually, based on individual budget sheets, which can be summarized in an overall Budget Plan provided to CEPI?

No, we require a single consortium lead, or primary awardee who has responsibility to distribute and manage the budget to sub-awardees or consortium members.

CEPI will accept separate budget sheets for each partner (sub-awardee) using the same template. The Lead applicant must describe this within the primary awardee budget, where they list the sub-awardee values. In cases where primary awardee does not know exact sub-awardee costs, CEPI will accept best estimates on conditional inclusion of a milestone checkpoint to get the 'finalised' budget at a specified later date. .

8. Given indirect cost rates will be vastly different as are home currencies, is it acceptable to CEPI to receive individual budget sheets by consortium partners for its own cost planning plus sub-awardee planning? If this is a yes, would it be acceptable to develop the project/program budget by consolidation as a second step?

Sub-awardees can have separate budgets and budget narratives (see Question 1 of the Step 2 FAQs 1 (click web-link)), however the primary awardee should submit a consolidated budget at the same time as part of the Step 2 application.

Technical questions

9. Does CEPI object to the clinical strategy that includes two phase 1 trials? One for dose finding and one for dose interval.

CEPI recommends you evaluate a single vaccine injection also.

10. Does CEPI contemplate a strategy where it establishes a single Advanced Development and Manufacturing site (ADM) to ensure vaccine supply?

Not in the short term and not as part of this CfP. However it is part of CEPI's longer term thinking and the need for a sustainable network of committed ADM partners to support scale up and surge capacity in response to emergencies.

11. Does CEPI contemplate a strategy where it establishes a single reference laboratory to ensure assay uniformity across clinical studies?

Not at this stage. However, it is part of CEPI's longer term thinking and the need for a sustainable network of committed partners to support the standardization of biological standards, assays and preclinical animal models for our target pathogens.

12. Does CEPI contemplate a sublicense to the relevant IP to ensure vaccine supply?

Before discussing licensing, it should be understood that the specific terms of IP management will be negotiated on a case-by-case basis with each awardee, the default position of CEPI is not to seek ownership of background or foreground IP. There are two cases where CEPI may take a license to foreground IP. First, in cases where CEPI provides funding of a dedicated programme (that is 100% of the funding). Second, where CEPI may exercise its "step in rights" (such as where the awardee discontinues development of a promising vaccine candidate for reasons other than scientific failure, does not launch a vaccine within a specified timeframe, or does not meet commitments to manufacturing, affordability and availability. CEPI will seek a non-exclusive, sub-licensable, worldwide license on necessary background IP and foreground IP related to priority pathogens. In both cases CEPI may seek or exercise a non-exclusive, sub-licensable, worldwide license on necessary background IP and foreground IP to enable work to proceed.

13. Given the short time until the full proposals are due, what assurances must we supply at the time of submission? Will CEPI please provide guidance on what should be included in the IP section?

CEPI seeks assurance about the path forward, but recognises that sometimes agreements cannot fall into place until certain key de-risking activities have taken place, therefore we are flexible how applicants address these questions. Going forward, CEPI will take a collaborative and interactive approach with awardees in this process, and would like to agree plans and points of engagement (between CEPI and the awardee, and between the awardee and third parties) – with a view to maximising the probability of success for all.

Scenario 1> If you are going to take forward all of the development, and will just need to engage a CMO at a later stage then you should provide details around how and when you plan to engage with a CMO, which CMOs you might speak with and what early stage discussions with CMO have occurred to date.

Scenario 2 >If you do not have the capacity to take the IP forward beyond the CEPI funded project: We ask you to provide a description on plans to see the CEPI funded project further developed, and how far you can take the IP.

If a third party is to take over in the not too distant future, we would expect e.g. an MOU/letter of support in place to give CEPI assurance about the overall path. This would be supported by a brief outline on when the handover arrangements is planned to take place, and a back-up plan in case things do not go as planned.

14. Appropriate dose intervals for Phase 1 clinical trials—our team would suggest an accelerated 1-8 days schedule for the dose interval tested in the Phase 1 trial(s), given the need to quickly generate protective antibodies in order to meet the specifications in the draft WHO TPP for outbreak response.

Dose interval depends on the immunogenicity of the vaccine formulation, and the desired timing and response profile anticipated to provide immunological protection. CEPI thus cannot be prescriptive but the applicant needs to take into consideration also operational aspects of vaccine administration in public health programmes for vaccine delivery (see WHO TPPs). CEPI also encourages the applicants to study and document the kinetics of the immune response of their proposed schedule.

15. Pediatric testing—we also would suggest testing in children in an additional phase 1 study, once the safety, dose and schedule are determined in adults.

Testing a candidate vaccine early in a paediatric population is important if the disease epidemiology indicates a clinically relevant disease burden or involvement of disease transmission of this population. CEPI encourages early dialogue with regulatory agencies and ethical review boards to include paediatric studies early in the clinical development after demonstration of safety and immunogenicity in adults.

16. Phase 2 selection design—we would be interested in getting input on potential use of a selection design (somewhat similar to a factorial design) for the phase 2, which will determine the appropriate dose and schedule in an efficient way.

CEPI will not be prescriptive on design selections for phase 2 clinical development but encourages the applicant to offer creative solutions to ensure quick availability of data without compromising safety of the participants or data validity. CEPI encourages applicants to seek early dialogue with regulatory agencies on the intended study design and clinical development plan, and will make sure regulatory advice is integrated early on for our forthcoming projects to maximize chances for success. Factorial designs have been used in vaccine development and shown to be an interesting choice to fulfill above.

17. We believe that the rate of Lassa disease is sufficient to require that any vaccine be licensed through phase 3 efficacy testing. Does CEPI concur?

Yes