



Coalition for Epidemic Preparedness Innovations

Responses to CfP1 questions sent to cfp@cepi.net by 23 February 2017

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Overview

Below you will find answers to questions that the CEPI Secretariat received by 26 February 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.

Scientific questions

1. Is Cfp1 more focused moving pre-clinical findings into clinical trials, rather than proof-of-concept work?

Yes. Cfp1 encourages vaccine developers to present a clinical development plan taking into account the process until (and including) phase II trials, and to outline plans until (and including) stockpiling for phase III trials and emergency use.

Moving a vaccine through the initial phases of clinical trials (Phase I & II); ready for efficacy trials and emergency use is CEPI's primary goal. Proof-of-Concept data is expected as part of the pre-clinical evidence base.

2. Does CEPI have any interest in funding studies toward creating a wildlife-targeted vaccine against Nipah virus?

The current call for proposals focuses on the development of vaccines for use in humans. We acknowledge animal vaccines as part of a comprehensive approach to prevent zoonotic transmission and disease burden in humans. The Scientific Advisory Committee may in the future consider revisiting this standpoint, dependent on the funders and CEPi's achievements in the first phase of operation.

3. Are programs that target multiple pathogens given preference over those that target each pathogen individually?

To some extent, as reflected in the CFP criteria, but vaccine development feasibility for the prioritized pathogens is critical. To support rapid response, CEPI is in the process of developing calls related to platform technologies.

4. In terms of the use of antibodies in passive immunization (as used routinely in rabies, recently in Ebola, and under development for HIV). Would this approach be included under the vaccine umbrella, or is CEPI considering a separate call relating to antibodies?

No, passive immunization is not within the scope of CFP1.

5. Would a strategy that provided antibodies for immediate protection coupled with a recombinant glycoprotein antigen for sustained protection be responsive?

Passive immunization outside of scope of the current CFP. If sustained immunity is induced by inclusion of an antigen presentation platform the approach is within scope.

6. Regarding the eligibility for projects. Is the committee considering proposals regarding vaccine candidates addressing other, similar diseases during this first call for proposals? If not to be considered now, will such diseases be considered in the near or distant future?

A key entry criterion to being funded through CfP1 is to have candidates for Lassa, MERs and Nipah viruses. Investment into other similar diseases may be explored in the future, however there is no intention for this at the moment.

Budgetary/financial questions

7. Is there a limit to the amount of funding per approved proposal?

We have not defined a funding ceiling per project at this stage. However, preliminary proposals will be assessed and compared against total vaccine development cost estimates, including size of budget required to achieve the stated objectives of each project, additional cost estimates above and beyond each project including for regulatory submissions, and stockpiling and emergency use if planned for.

8. Regarding External R&D costs, should external studies at a biosafety level 4 lab be included in cost category: Procurement of R&D services?

Yes. Any R&D services that the applicant organization or consortium intends to provide through their proposed projects for CEPI funding should be included under the cost category 'Procurement of R&D services', if these services are contracted out to third parties who are not part of the applicant organization or consortium in this call for proposals.

9. Regarding the funding plan, how can one split the project cost between international funding/own funding and CEPI funding, if it is unknown how much funding every (successful) project will receive.

Unless you have other known sources of funding, you should allocate all project cost as CEPI funding. Where you have other sources of funding and these are known, you should split project cost between CEPI and these sources of funding as they fit in the cost types provided in the application form. Funding should relate to total cost of development to meet the project's objectives.

10. Is the funding a percentage of total cost?

Costs have to match funding for every year in the template.

11. Is there a minimum/ maximum funding per project?

We have not defined a minimum/maximum funding per project. However, preliminary proposals will be assessed and compared against total vaccine development cost estimates, including size of budget required to achieve the stated objectives of each project, additional cost estimates above and beyond each project including for regulatory submissions, and stockpiling and emergency use if planned for.

12. Is the funding for the total project or is it split per quarter/ per year. Meaning if a certain work is planned for Q1 but is delayed to Q3, will it still receive funding?

In the budget template file costs should be entered quarterly in the sheet labelled 'Detailed process budget', whilst funding should be shown annually in the sheet labelled 'Funding plan'.

As in the [CEPI funding agreements: key terms](#) document: CEPI shall pay tranches of the award amount to the Awardee only if CEPI determines that the Awardee has successfully achieved the Project Milestones by the agreed dates. Where planned work for an activity is delayed and has no critical impact as determined by CEPI on subsequent milestones for the successful achievement of the project within the agreed timeframes awardees will still receive funding.

13. The Indirect Costs section refers to “an agreed allocation methodology”, please provide additional guidance for this methodology?

The methodology included in the budget proposal should be based on the direct relationship with the direct eligible costs being attributed to the project. It is up to each organization to propose how best to calculate this based on its own circumstances, however this should be based on actual indirect costs incurred which can be identified and verified by its accounting system.

14. Appendix A Staff Related Cost refers to “industry standards as determined by CEPI.” Please provide additional guidance on how CEPI will make this determination; salary rate caps, workable hours per year allocations etc.

CEPI will make its assessment based on standard industry practice on a country specific basis, taking into account local employment laws and practices.

15. With regards to the functionality of the excel Budget Model, the ‘Cost Type (drop down)’ field in Column F of the budget model is not working. There is no drop down menu. Therefore, what categories of costs are looking to have labeled here?

We are sorry that you had difficulties with the functionality of the budget template. Regarding the quarterly cost estimates, we have updated the template to a new version so that they are not hidden under ‘detailed process budget’. The drop-down menu includes the following:

Drop-down menu
Payroll expenses
Procurement of R&D services
Equipment
Travel
Material and consumables
Animals and maintenance
Miscellaneous

16. Regarding budget requirements for CEPI-CfP-001, is a complete budget required at the time of preliminary proposal submission? If shortlisted, can a revised budget be submitted with the full proposal submission?

A preliminary budget is required at the time of preliminary proposal submission, providing an indication of costs for all key activities and milestones proposed in the project description. A more detailed budget will be required at the time of full proposal submission, and a deviation of the total budget between the preliminary and final proposal submission will generally not be allowed.

Contractual and procedural questions

17. Can you please clarify in detail what is meant by capacity building “spill-overs” in section 2.5 of the project description template?

Section 2.5 of the project description template allows for awardees to enter details of expected outcomes. Included in this list, amongst other expected outcomes CEPI would like to receive information on ‘*key public health, innovation or other capacity building benefits*’. However, in addition to that, CEPI would like to know of other capacity building outcomes from conducting the vaccine research and development, particularly in low and middle income countries, that not only accrue to project partners but that also spill over to third parties who are not necessarily directly involved but whose capacities are strengthened as a result of the project.

Application questions

18. Can you please list what items are considered acceptable under this proposal to be included under the "Other Items" online section?

The following documents are to be submitted under the ‘attachments section’ on the RCN portal:

- A completed project description (saved in PDF format)

Under ‘Other items’

- completed budget (excel sheets saved in PDF format), and
- any other items are relevant to the application.

Applicants are advised that:

- Attachments larger than 40Mb are not accepted by the RCN portal.
- To upload more than one file, click on the button ‘Add new line’. A maximum of 20 files are accepted by the RCN portal, however for step 1 we are seeking preliminary proposals and therefore ask applicants to keep attachments to a minimum.

Please see the ‘attachments section’ on the RCN portal for guidelines.

19. What attachments are permitted? Can you put additional information about partners as attachments?

See question 17.

20. If we have capabilities and would like to seek funding for all 3 prioritized epidemic infectious diseases, should we submit 3 individual proposal responses?

You are encouraged to submit separate applications, but where relevant you can demonstrate linkages between the proposals.

21. We’re a company based in the United States. Do we need to register with the Norwegian government to be able to submit a proposal?

No.

22. Shortlisted applicants will be invited in April 2017 to submit full proposals according to CEPI CFP document (Page 1,5 & 7), but June 2017 according to FAQs document (Page 3)- Which date is accurate please?

We apologise for the confusion, those applicants who are invited to Step 2 will be contacted mid-May 2017 and will have six weeks to complete a full proposal.

23. The attachment template hyperlink links to the RCN site but does not link to a CV template and there is more than one CV template available on the RCN website. Could you specify which one to use (title of CV form and direct link) please?

Applications to CEPI CfPs do not require a specific CV template, please note that for step 1 we are seeking preliminary proposals and therefore ask applicants to keep attachments to a minimum.

24. Is the additional “risk assessment” document mentioned in the CEPI CFP document (Page 5) included within the 10 page limit for the “Project Description Step 1” document or is this without a page limit and additional to the (1 Page) “Project Description Step 1”-Item 4 Risk assessment section?

A high level risk assessment table is required as part of the 10 page project description template. Applicants may choose to provide a more detailed risk assessment plan as a separate attachment. Such attachment, if provided, will not count as part of the 10 page limit of the project description template. We will request a more detailed risk assessment if your proposal is selected for Step 2.

25. Is the additional document “detailed milestone plan” CEPI CFP document (Page 5) is the “Project Description Step 1”- Item 3 Risk Implementation plan. If this is correct, is this “detailed milestone plan” included in the 10 page limit of the “Project Description Step 1” document?

No, attachments of detailed milestone plan and risk assessment plan will not count as part of the 10 page limit of the project description template. However, high level descriptions of milestone plan and risk assessment plan are required as part of the 10 page project description template. Attachments of more detailed plans are not a requirement and applicant may choose not to provide such additional attachments. We will request a more detailed milestone plan if your proposal is selected for Step 2.

26. There is no section in the “Project Description Step 1” which appears to provide further information on what “supplemental data on vaccine candidate” [CEPI CFP document (Page 5)] may be provided. Is there a page limit on this supplemental data or are there any restrictions on the amount of data that can be provided?

Please see question 17.

27. The RCN portal indicates that for projects with a set deadline proposals can be submitted repeatedly and only the last submission before the deadline will be counted as the final version- is this true for this CEPI submission?

Yes.

28. No specific guidance is provided in the “Guidelines for online application” document on completing the online “Allocations sought from the Research Council” section. Does the section in the guidance form under Funding Plan (page 8) that reads: “From Research Council interpret this as contribution from CEPI” apply to this section or only the Funding Plan Section? If it only applies to the Funding Plan Section what if any actions need to be taken for the “Allocations sought from the Research Council” section?

CEPI applicants are advised to treat the “Allocations sought from the Research Council” in the same manner as the funding plan. References to ‘From Research Council’ should be interpreted as contribution from CEPI.

29. The online “Referees” section is not mentioned in the “Guidelines for online application” document. Does this need to be completed and if so what are the guidelines for completion?

No, this is not relevant to applicants.

30. The “Confirmation from partner(s)” section is not mentioned in the discussion of partners (Page 8) in the “Guidelines for online application” document. Does this need to be completed and if so what are the guidelines for completion?

Please refer to page 5 of the Call for Proposals text. “In case of consortia of partnering organisations, co-applicants must provide electronic copies of signed letters of intent, confirming their willingness to participate in the proposed projects and agreeing with the content of the proposals.”

These can be submitted as under Other Items on the ‘attachments section’ on the Research Council of Norway portal.

31. Do we have to submit the complete “summary budget” and “detailed process budget” also for step 1 applications?

Yes.

32. Are applicants expected to fill in the boxes of the application template or create their own document following the outline presented in the template?

Applicants are expected to fill in the boxes of the project description template.

33. Regarding partners, in the contact information for the partner's organization in the Online Form: Is it the Researcher in the Partner Organization or the legal representative who signs the forms?

Partnerships need to be confirmed by the legal representative of an organisation.

34. Are letters of support from partners needed in this EOI?

See question 29.

35. In the project description: are pictures and/or diagrams permitted?

Yes.

36. Can you please clarify the terms of confidentiality that apply to the CfP response, specifically around disclosure of applicant's previous reviews, appraisals or assessments of the project by other entities outside of CEPI?

Proposals will be read by:

- selected members of the CEPI Secretariat,
- 3-4 Expert evaluators, and
- CEPI Scientific Advisory Committee members who have no conflicts of interest.

All parties are bound by CEPI's [Confidentiality and Transparency policy](#), and they are required to follow CEPI's conflict declaration process, assessed by the CEPI Secretariat prior to every Call for Proposals (see CEPI's [Col policy](#)).

In addition, all parties are required to agree to the following non-disclosure:

By accessing and reviewing proposals submitted to a CEPI call for proposal, you are agreeing to hold in confidence any detail(s) of the proposal, related meeting(s), discussions and agreements, such as ongoing processes and outcomes. This applies to all information and material that may be shared with you during the meeting.