CfP3 related questions and answers

FAQs 3

Q1:

For CHIK, is it mandatory to conduct a clinical trial in the first 15 months of the project?

A:

No, what is required is to make significant progress in a proposed development plan.

Q2:

For cost sharing, can development of the platform be considered for cost sharing?

A:

If you can demonstrate that there is a direct benefit/savings for the CHIK project then this can be considered in the cost sharing. Cost sharing sum should only include the portion within proposed development scope and timeline.

Q3:

Do you anticipate working on corelates of protection across projects or can we include some correlate work?

A:

With any vaccine candidate, specific work on correlates of protection should be anticipated. In addition, correlates of protection will likely also be evaluated in cross cutting activities.

Q4:

If an antigen has been found to be protective in a relevant animal model, but the vaccine developer wishes to deploy said antigen in a well-established vector/delivery platform (successfully used in animal model, and proven in humans with other antigens) that was not part of the preclinical testing, is their flexibility to consider this approach for RVF under CfP3?

A:

The approach is eligible for vaccine development if the developer can present evidence that the vaccine candidate (i.e. antigen expressed in vector) is demonstrated to provide protection in a relevant animal challenge model.

Q5:

Based on CEPI Budget and Financial Reporting Instructions, Section 2.3.8 Page 13 of 27, please provide clarification between Sub-Award Type ("Sub-grantee" vs. "sub-contractor")?

A:

A sub-grantee will be reimbursed on the basis of actual costs incurred. Applicants are required to provide separate budgets in the format of the CEPI budget template for sub-grantees. A sub-contractor would be working on a fee basis (e.g., fixed fee, hourly rates). Applicants will be required to provide quote documents or similar to demonstrate the expected sub-contractor cost.

Q6:

Section 9 of Cfp3i highlights NC3Rs resources and best practices guidelines for the use and care of animals. Are equivalent US guidelines such as IACUC and NIH guidelines acceptable?

A:

No, the guidelines are not equivalent, but CEPI will accept "best efforts" to match the UK guidelines.

Q7:

In the answer to FAQ2 Q13 CEPI writes: "CEPI will consider vaccine development up to and including Phase IIb clinical trials and regulatory planning for execution of Phase II/III trials. If this does not address the question, please submit another question to cfp@cepi.net." To be clear, can you confirm our interpretation that CEPI will not fund any costs related to the execution of a Phase III clinical study? Specifically, can CEPI comment on funding for Phase III safety and immunogenicity trials (not field efficacy trials) that support the goal of generating an adequate pre-licensure safety database?

A:

CEPI will consider funding Phase III safety and immunogenicity trials (not field efficacy trials) that support the goal of generating an adequate pre-licensure safety database.

Q8:

CEPI Cost Guidance, Sub-awardee costs states that "Contract arrangements are expected to be applicable to a small number of organizations, such as service providers". Can CEPI clarify what is considered a service provider vs. sub-awardee?

A:

Service providers would be organisations from which you are intending to procure services. They would generally be considered to be organisations providing a limited input to the project (e.g., site audits, document translation). CEPI requests that, to the extent possible, collaborators/consortium members for the project (i.e., those providing substantial technical or intellectual input and undertaking a defined portion of the activities set out in the iPDP) work on a sub-grantee basis.

Q9:

In the budget-file, the WPs are pre-populated with the proposed structure and cannot be changed. To optimise the structure of the project, we would need to introduce changes to this structure. Is there a way to make these modifications?

A:

You cannot change the pre-populated WP structure in the budget file. You may assess what you consider relevant to be included in the scope of each work package, but you may not make amendments or additions to the work package structure set out in the call text.

Q10:

Should in-kind contributions be captured as "funding from sources other than CEPI" on the budget template? If not, how should they be included?

A:

In kind contributions may be captured in the Total Funding Plan table at the top of the Budget Summary tab in the Excel budget template. However, please also provide a detailed description of the in-kind contribution (including how the value of the contribution has been determined) in Section 9 of the Budget Narrative document. Also note that in-kind contributions may be included only to the extent that such costs are incurred after the submission of your application.

Q11:

Is section 2.1, "about the applicant organization…" expected to be a separate 2-3 page document included as an appendix to the project description?

A:

The text is to be included in the Project description document with a total page count of 40 pages (appendixes included).

Q12:

If the in-kind contribution is work being done in support of the funded activities, are the in-kind contributions intended to follow the same timeline as the activities for which funding is requested? Can the in-kind work start in advance?

A:

You may include in-kind contributions incurred in advance of the period for which funding is requested from CEPI, but only to the extent that such costs are incurred after the submission of your application.

Q13:

Can you clarify if scientific references can be an appendix excluded from the page limit?

A:

Scientific references (only) can be an appendix excluded from the page limit.