

CfP3 related questions and answers

FAQ: version 1 on website

Scientific questions:

Q1:

Would CEPI be expecting a separate application for each pathogen, or a single application covering products for both pathogens?

A:

If you are working on vaccine candidates for the two pathogens in scope for this call using the same vaccine platform technology, we want you to submit separate applications for each pathogen specific vaccine candidate. Similarly, we want you to submit separate applications per vaccine candidate if you are proposing different vaccine technologies for the same pathogen. If the same institution is advised for funding from the review of two separate applications, synergistic efforts on partnering agreements will be sought by CEPI in dialogue with the applicant institution. We would also expect to see significant overlap between such applications (e.g. common core documents) and this is acceptable.

Q2:

We have read through the Call Specification document. Do we understand correctly that Phase I data should be available prior to submission? Our current vaccine has been developed and tested in animal studies where strong immune response was demonstrated. We will be requesting funds to move into a Phase I trial. Is this appropriate with regard to the CfP3 announcement?

A:

In line with the eligibility criteria (section 3 in the call text), CEPI will only consider funding CHIK vaccine candidates that already can demonstrate data from at least Phase I clinicals. For CHIK, CEPI will in this call not fund candidates that currently only have preclinical data. These criteria are driven by CEPI's mission and goals with respect to successful development of investigational vaccines and investigational stockpiles within a given timeframe.

Q3:

We have some constructs made for one of the pathogens and we were wondering if we are eligible for CfP3i funding. No animal study has been done yet.

A:

In line with the eligibility criteria (section 3 in the call text), CEPI will only consider funding RVF vaccine candidates that at least can demonstrate protective efficacy studies in relevant animal challenge models; and emphasizing the aim to accelerate clinical testing.

For CHIK vaccine candidates CEPI will only consider funding those candidates that already can demonstrate data from at least Phase I clinicals. For CHIK, CEPI will in this call not fund candidates that currently only have preclinical data. These criteria are driven by CEPI's mission and goals with respect to successful development of investigational vaccines and investigational stockpiles within a given timeframe.

CEPI plans further potential funding round, CfP3ii, to be launched in 2020.

Q4:

In order to be eligible for funding for RVF vaccine, is it required that preliminary data showing efficacy in relevant animal models be in a model of RVF? Would it suffice to have compelling data in a different model, e.g., Zika, and then propose to translate this vaccine platform to RVF indications?

A:

For RVF vaccine candidates CEPI will only consider funding those candidates that at least can demonstrate protective efficacy studies in relevant animal challenge models specifically for RVF; and emphasizing the aim to accelerate clinical testing. It will not be sufficient to have compelling data in a different virus model. These criteria are driven by CEPI's mission and goals with respect to successful development of investigational vaccines and investigational stockpiles within a given timeframe.

Q5:

Would CEPI consider funding some complementary epidemiology to identify sites where vaccine efficacy could be assessed?

A:

For this CfP3 call CEPI will only fund the proposals that aim to develop human vaccine candidates for RVFV and CHIKV and that are in line with eligibility criteria and will not fund epidemiology studies as a separate item.

Legal/financial questions:

Q6:

Could you give us some guidance on what percentage of total project costs would qualify as significant investment by the developer. Would personnel salaries paid by the university count as "in kind support".

A:

There is no fixed percentage. Investment in research and development by the consortium could include only costs directly relevant for this candidate (and including personnel salaries), however the assessment of significant investment is considered relative to the amount sought for funding by CEPI.

Q7:

How is CEPI defining “significant progress” in the language below from Cfp3? “Cfp3i projects must be completed within 3 years from January 2019 and should have made significant progress in the 12 to 15 months after the signing of a CEPI funding agreement.”

A:

By significant CEPI means that the most cost-intensive phase should be conducted during the first 12 to 15 months, and that the most critical milestones set by the project should be achieved in that period and new data is available so that CEPI can determine whether additional funding is warranted. Projects can still last until end of the projected funding period beyond these 15 months. This aspect is mainly relevant in order to facilitate applicants to be best positioned for further potential funding in the subsequent funding round (Cfp3ii), planned to be launched by the end of 2020. The date the project will start will be the date of signature.

Q8:

What does cost share mean in practical terms?

A:

CEPI’s principle is to fund activities that will help access for populations in LMICs as defined in the call. In order for the vaccine candidate to advance, additional vaccine development activities are needed and CEPI would like to see that this funding is being made available.

Q9 -10:

What is a reasonable range for proposal?

A:

There is no defined optimal/reasonable cost range of the proposal. It will depend on the stage of the applicant’s asset and what it requires to advance to a meaningful state.

Q11:

What is the timing of down selection and final deal signing?

A:

Following the receipt of applications on the submission deadline on March 5th, 2019, eligibility screening and review will take place until its SAC meeting on April 5th. Due diligence and negotiations on partnering agreements are aimed at completion with CEPI internal approvals by mid 2019.

Q12:

If a partner is selected for CfP3i does that guarantee they will receive CfP3ii?

A:

No, CEPI will evaluate the results of all programs and other potential applicants for CfP3ii at that time which will also be an open call.

Q13:

What types of strings are attached to the contract for CEPI and for EC?

A:

The EC has requirements of CEPI in terms of its funding processes for the call and project reporting. CEPI in turn has requirements of its partners that include its [policies](#) and in particular equitable access, which is referenced in the CfP3 announcement. There will also be some specific EC bodies' rights to information in the unusual cases of the need for audit or investigation of financial irregularities or fraud along with the usual requirement to acknowledge EC funding where appropriate.