

CfP3 related questions and answers

FAQ: version 2

Q&As from the open call sessions that were conducted on Friday, 25th January, 2019

Eligibility/Scope:

Q1:

The stated aim of CfP3i is to support the “most advanced” vaccine candidates for CHIK and RVF. If a company or institutions isn’t already in a possession of a “most advanced” candidate for CHIK should they bother responding to the Call for proposals?

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 Phase I data.

Q2:

If we have not yet collected CHIKV Phase I clinical data, is it possible, following completion of a Phase I study for CHIKV, to submit a proposal to CfP3ii that will be released in 2020?

A:

The CfP3i only funds CHIKV vaccine candidate projects that already have Phase I data. The anticipated second call in 2020 (CfP3ii) will be open for everyone and could provide additional funding to successful candidates but it will not be restricted to those that were submitting applications to the CfP3i. CEPI reserves the right to determine the scope and entry criteria until CfP3ii is launched.

Q3:

With regard to the specific criteria for the clinical trial work package, will only Phase II (or later) studies be funded or do the plans simply need to include a Phase II study?

A:

Conducting a phase II study is part of this WP. We encourage Product developers to have a comprehensive development plan to help vaccine candidates progress toward the end of phase II. Further phase I clinical studies can be funded if critical to the development plan.

Q4:

We have an existing vaccine batch suitable for a Phase Ib trial in an endemic country. Would CEPI be keen on funding an early Phase Ib before entering a larger Phase II trials? (for instance to assess vaccine in different target populations, age de-escalation, paediatric, in relatively small phase Ib trials). Or would CEPI be keen in supporting only larger Phase II trials?

A:

In general, we encourage the earliest possible generating data by undertaking trials in affected countries. We recognize that Phase Ib data might be a requirement to be allowed clinical testing in affected countries. If so, CEPI is prepared to fund this assuming that eligibility criteria are met and the trial is critical to the development plan.

Q5:

The continuing evolution of disease epidemiology requires surveillance. We have ongoing epidemiology studies in a CHIK virus endemic country, surveying incidence and prevalence. Would CEPI support the continuation and extension of such studies?

A:

For this CfP3i 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. Due to budget constraints we can in the CfP3i call not fund epidemiology studies.

Q6:

As part of the current epidemiology study in an endemic country, we sequence new and old isolates to survey virus evolution and assess genetic epidemiology. Would CEPI welcome these studies as part of a work package?

A:

Due to budget constraints we can in the CfP3i call not fund epidemiology studies. CfP3i can however fund research activities that directly facilitates product development (i.e. biological standards and correlates of protection).

Q7:

We have an ongoing project to improve diagnostic tools to become cheaper and easy to use at point-of-care settings, to support the clinical trials where infection has to be confirmed. Can this be made part of a work package and can CEPI support this additional study?

A:

No, this is not in the scope of this call.

Q8:

Do CEPI support macaque trials to develop correlates of protection specifically for Chikungunya?

A:

Yes, it might be as immune correlates/ immune bridging studies between animal and humans.

Q9:

Would it be acceptable to develop a thermo-stable product in the next funding cycle or is it required for this cycle?

A:

Yes this would be acceptable, and is not required for CfP3i. This approach will be more relevant in CfP3ii. For now, please follow WHO PQ and their recommendations.

Q10:

Will CEPI support a vaccine trial in natural animal host for RVF (to validate the vaccine) before going to human clinical trial?

A:

CEPI will fund animal studies to justify human clinical study/regulatory approval for human use if these are part of the integrated product development plan.

Q11:

Would CEPI support proposals aimed at establishing and validating in vivo models (including non-human primates) for the evaluation of RVFV and CHIKV vaccines – but without any direct vaccine development? The purposes being that vaccines developed by others could then be assessed independently using these models, and also offer an approach for vaccine licensure using the FDA Animal Rule. Additionally, these in vivo models would allow correlates of protection to be assessed.

A:

CEPI can only fund these activities if being part of applications with human vaccine candidates. Please seek out eligible partners who would include this activity in their proposal.

Q12:

What is exactly the mid-stage development mentioned in the Item 2? Phase II? A proposal without complete preclinical data is out of the scope of this call?

A:

This will be justified looking at individual applications. For entry criteria, please see section 3 in the call text.

Q13:

The Call states that CEPI will “Directly fund and coordinate vaccine development up to and including Phase IIb” (Section 1.1, pg. 3). However, in Section 3.2 on page 7 one of the work packages is described as “Clinical trials assessing vaccine safety and immunogenicity, as well as regulatory planning for execution of Phase II/III including affected countries and populations at high risk of infection.” Will this call fund Phase III clinical trials?

A:

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.

Q14:

Please distinguish between required animal model efficacy data to be included in the application with that expected to be generated under work packages 4., 5. and 7.

A:

The animal model experiments planned in each application would need to be justified in relation to, and be critical to inform the product development. Which data that are required will depend on each individual proposal.

Q15:

Would a vaccine candidate currently in preclinical stage of development be eligible for CfP3i funding?

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 Phase I data. For RVF vaccine candidates CEPI will only consider funding vaccine candidates that at least can demonstrate protective efficacy studies in relevant animal challenge models; and emphasizing the aim to accelerate clinical testing.

Q16:

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.

Q17:

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 demonstrating protection against RVF; and emphasizing the aim to accelerate clinical testing. It will not be sufficient to have compelling data in a different model with other pathogens.

Q18:

Concerning the CfP3 on CHIK can a non-vaccine (i.e. prophylactic mAb) project be considered for funding in this call?

A:

Prophylactic mAbs and other non-vaccine projects will not be funded in this call for proposals (CfP3).

Q19:

If CHIK Phase I clinical studies have not yet started, does this exclude the project? Or is it just that any existing phase I data have to be available?

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, or clinical data that is not related to CHIK.

Q20:

CEPI has made clear that CHIKV vaccine candidates must have demonstrated protection in animal studies. Our vaccine targets mosquitos, not the pathogen directly, and has demonstrated protection against malaria in animals. As this demonstrates the mechanism of vaccine effectiveness is this acceptable data? Or does it have to have been demonstrated specifically in a model of CHIK?

A:

In line with the eligibility criteria (section 3 in the call text), CEPI will in this call only fund candidates that have been proven to provide protection against CHIK in animal challenge models and have phase I clinical data.

Q21:

CEPI's CfP3 is supporting mid-stage and late-stage clinical CHIK vaccine development only reached by very few vaccines candidates developed in developed countries. Is there any flexibility to accept projects in LMIC in a less advanced stage of development?

A:

In line with the eligibility criteria (section 3 in the call text), CEPI in this call will only consider funding CHIK vaccine candidates that already can demonstrate data from at least Phase I clinicals regardless of where the candidate is from.

Q22:

Regarding the conduct of the clinical trial(s) in countries where CHIK cases have been reported, does CEPI prefer that in the proposal the particular sites where these clinical trial(s) will be conducted are already identified (and that possibly these sites are included as partners in the proposal)? Or does CEPI prefer that in the proposal only the country/ies for these trials are proposed and that the particular site selection will be agreed upon with CEPI during contract negotiation?

A:

The proposed site(s) will be assessed for quality during peer review and negotiation process. We expect applications to be as specific as possible to enable efficient review and project initiation.

Q23:

What about the value of different studies in different populations for the CHIK proposal?

A:

CEPI is interested in projects that bring access to affected territories, so it's in the scope to look at studies in LMICs. Populations included in suggested studies must be well justified in relation to product development.

Scientific

Q24:

Human monoclonal antibodies for both RVFV and CHIK with extraordinary potency have been discovered and are in early development. Delivering these molecules with 90-day half-life mutations in Fc might afford up to a year of protection in at-

risk populations. Are applications for passive vaccination development programs using human monoclonal antibodies responsive to this call?

A:

Monoclonal antibodies are out of the scope for this call.

Q25:

What is the scope of clinical trials you would like to see for this request

A:

WHO PQ says 3 000 subjects, and the number of study subjects should contribute towards this goal as far as possible and it depends on the project. The WHO's standards don't have to be met, but the number of subjects must be justified by applicant based on the endpoints to be assessed.

Q26:

Will projects that also consider other cross-reactive flavivirus vaccine use e.g. in CHIKV treatment or development of cross-reactive assays be considered?

A:

CEPI will fund vaccine candidates that can provide protection against CHIK or RVFV as a primary goal. Research that can contribute towards the facilitation of development of these vaccines will be limited to areas informing correlates of protection and biological standards.

Q27:

For scaling up plans, what scale do CEPI consider suitable? 5 000; 10 000; 30 000 vials are within the scope? Would CEPI fund the long-term stability studies initiated within this project, if such are due to finish beyond the project close? This is contingent to the material remaining within spec and the return of positive trial data that allows continuation of clinical development.

A:

Regarding scale, applicants are not asked to plan for a specific scale or stockpile and each individual applicant needs to justify the specific numbers of doses. Regarding stability studies beyond the project close – this will be dealt on a case-to-case basis, but technically this is out of the scope of this call.

Q28:

Please provide guidance on the number additional of doses of RVF vaccine stockpile needed via this grant, and the scale of production anticipated for future stockpile use.

A:

Regarding scale, there is no specific size defined in CfP3i, and each individual applicant needs to justify the specific numbers of doses. Depending on regulatory pathway/population/TPP and other criteria, the number of doses will be adjusted later in the negotiation process.

Q29:

Does CEPI favour certain technology/platform technology for the development of the vaccines?

A:

No

Q30:

If we have worked on the same platform but with different virus, is that work relevant?

A:

Without the data on CHIK or RVF this does not fall in to the Cfp3 scope.

Q31:

Are there set numbers for vaccine doses to be stockpiled?

A:

No

Application

Q32:

Can we submit on CHIKV vaccine development alone or must the proposal include development of RVFV vaccine as well?

A:

There is no need to cover both CHIKV and RVFV. Applicants can submit one proposal. If submitting both on RVF and CHIK, there must be separate proposals per pathogen/candidate.

Q33:

Is the proposal expected to cover all work packages?

A:

No, the proposal is not expected to cover all work packages.

Q34:

If there are proposals from two applicants that align and could possibly work together as a larger project would CEPI consider introducing the two parties to work together?

A:

CEPI will not do the matchmaking.

Q35:

To what extent can we deviate from the predefined work packages?

A:

It is up to applicant to assess the scope of each WP and CEPI will consider the applications later in each individual case.

Q36:

Is there a weight division among the review criteria? Some more important than others?

A:

The weight of the different criteria will be elicited from the independent reviewers. Qualitative expert review will be the main focus.

Q37:

Is it possible to propose more than one Phase II trial?

A:

Yes, several phase II studies may be required if justified in the product development plan.

Q38:

a) Can CEPI support more than one proposal in this call? b) Should we link these proposals or present them in an independent way?

A:

Yes, applicants can have multiple independent proposals. The proposals should not be linked but present independently.

Q39:

The Call states that “all available Phase I data must be available and shared with CEPI on submission date of this call and will be evaluated for quality” (Section 3.2, pg. 7). However, in Section 5.1 on page 9 Phase I data is not listed in the requested uploaded documents and it states, “No additional documents should be submitted”. When and how should the Phase I data be submitted?

A:

Yes, it is required that Phase I data is available for CEPI for review. For submission we expect the summary of findings to be described in the project description and referral to the documentation this is derived from. The full dataset or study report may be requested to be shared with CEPI after submission.

Q40:

The Project Description Template includes Section 8 Budget and sources of funding but references the Excel budget file and budget narrative. Is it requested that these documents are referenced in Section 8 of the Project Description rather than included in Section 8?

A:

Yes, it is requested that it is referenced but please upload budget templates and narratives separately.

Q41:

For RVF projects what is the order of work packages desired relative to the listings in Table 1?

A:

There is no order as how work packages should be listed/prioritized.

Q42:

Are proposals to cover all work packages?

A:

No, a proposal is not required to cover all work packages.

Q43:

We have been approached by several groups to participate in the most recent CEPI call for proposals. In these cases, X would be providing cGMP Manufacturing and/or product development services. Reading through your requirements, would a group like ourselves be considered a service provider?

A:

You will not be considered if submitting alone as a service provider. You will be considered if you submit together with a vaccine developer having a specific CHIV or RVF vaccine candidate.

Q44:

What are acceptable pre-award activities?

A:

CEPI has provided a cost guidance document. Please keep in mind that any such activities are at applicant's risks. It is acceptable for costs directly related to furthering the project itself but does not include legal or administrative costs.

Q45:

Do all collaborators need to be named at intention to apply stage or is there flexibility to change when application is due?

A:

CEPI requires that partners are named on submission. Changes may occur during the due diligence phase if this process justifies it.

Budget

Q46:

How is “significant progress” as related to showing significant progress in 12-15 months being defined?

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.

Q47:

Is the budget going to be evenly split between the 2 pathogens? If not, how will it be divided?

A:

There is no set budget allocated per pathogen.

Q48:

Does CEPI envision co-funding to be provided at the same level across the entire proposed project or can the level of co-funding vary across the duration of the project?

A:

The level of co-funding can vary across the duration of the project and will be adjusted in each individual case.

Q49:

The amount of the budget seems to have changed on CEPI’s website?

A:

The budget is specified to 48 mUSD for CfP3i.

Regulatory/legal

Q50:

What is needed to demonstrate an “intent to pursue WHO prequalification and/or local licensing in affected countries, including specific development plan elements for this purpose, or evidence of interactions with regulatory authorities on CMC and plans for licensing in line with national and international guidelines”?

A:

CEPI encourages to read and follow WHO PQ guidelines and to document how this has been integrated in plans provided.

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What is CEPI's perspective towards consortia? Any opinion about number of partners?

A:

CEPI does not have specific perspective or requirement on the number of partners. The consortium should be comprised of competent partners across areas of expertise that are needed for the project. Also, CEPI does not have any restrictions on where partners are located. The key factor for evaluation will be their ability to perform the activities needed.

Q52:

Are there any requirements for the next funding cycle of anticipated European Commission funds with respect to inclusion of coalition members from Europe?

A:

No, there are no specific requirements.

Q53:

Do CEPI have particular CRO organisations that they prefer us to work with at the vaccine clinical trial stage or is this left entirely to the applicant to find?

A:

CEPI does not have any particular/preferable CRO organisations.

Q54:

Can an institution send proposals with different partners, and different projects?

A:

Yes, you can send proposals with different partners and different projects.

Q55:

What regulatory guidance is to be followed for vaccine development (FDA, EU, other?)?

A:

Regulatory requirements applicable where activities will occur (consistent with WHO, national and international regulatory agencies).

Q56:

Are coalition partners in Europe required?

A:

Rule for the current round Cfp3i and Cfp3ii is that there is not a requirement for EC state entity be part of the award.

Q57:

Can you confirm that non-participation in the present call would not exclude us from applying for the planned 2nd call in 2020?

A:

CEPI confirms that applications for funding for this call (CfP3i) is not a precondition to apply for the second planned call in 2020 (CfP3ii).

Q58:

If some key team members in the applicant organisation have vaccine development experience, is this sufficient? Or does the applicant organisation per se have to have a track record of bringing vaccines into human testing?

A:

In line with the eligibility criteria mentioned in the call text, at least one partner/organisation that is a legal entity should have experience in human vaccine development and have a track record of bringing vaccine candidates through to human clinical trials in the past 10 years.

Timeline

Q59:

Is this statement right: Projects must be completed within 3 years from January 2019?

A:

Yes. The duration of projects will be up to 3 years (until end of 2021), beginning from the date of an award (that is the effective date of the agreement with a successful CfP3i awardee). An award agreement may also allow a period of up to six months extending past the maximum 3-year (mid-June 2022) period of project duration to allow for the completion of analysis and reporting of the results of the project. Any such retention may be subject to a retention of some funding provided by CEPI pending receipt of such reports of results. There is an expectation that applicants will undertake the most cost-intensive part of their projects within the first 12 to 15 months of the project.

Q60:

a) The start date for an award is not clear from the call for proposals. Please clarify a realistic start date for award of the grant, as this is critical to the budget and schedule for submission. b) Please clarify if the three-year maximum project timeline begins upon contract/award, rather than January 2019.

A:

The duration of projects will be up to 3 years (until end of 2021), beginning from the date of an award (that is the effective date of the agreement with a successful CfP3i awardee). An award agreement may also allow a period of up to six months extending past the maximum 3-year (mid-June 2022) period of project duration to allow for the completion of analysis and reporting of the results of the project. Any such retention may be subject to a retention of some funding provided by CEPI pending receipt of such reports of results. There is an expectation that applicants will undertake the most cost-intensive part of their projects within the first 12 to 15 months of the project.

Q61:

Regarding results of clinical trials conducted under this proposal: would it be acceptable to provide a summary report of top-line results (after data base lock and generation of TFLs within the 3-year period of performance (POP), and provide the full clinical study report as soon as possible but after the POP?

A:

The duration of projects will be up to 3 years (until end of 2021), beginning from the date of an award (that is the effective date of the agreement with a successful CfP3i awardee). An award agreement may also allow a period of up to six months extending past the maximum 3-year (mid-June 2022) period of project duration to allow for the completion of analysis and reporting of the results of the project. Any such retention may be subject to a retention of some funding provided by CEPI pending receipt of such reports of results. There is an expectation that applicants will undertake the most cost-intensive part of their projects within the first 12 to 15 months of the project.

Q62:

What is a realistic start date?

A:

CEPI anticipates that a realistic start date may be Q3 2019, with the due diligence and contracting to finalize by end of Q2 2019. Retrospective funding of pre-award cost could be considered (see section 1.4 in the call text).