CEPI Coalition for Epidemic Preparedness Innovations

Call for proposals on platform technologies: Frequently asked questions (FAQs) - 2

Submitted by 29 September 2017

Overview

Below you will find answers to questions that the CEPI Secretariat received by 29 September 2017 with regards to the call for vaccine platform technologies (CfP2). One set of responses to all questions will be emailed to those who submitted questions. All responses to the rounds of questions will be published here. Please note that these responses are in addition to the previously published application guidelines on the CEPI Website.

Budget and financial questions

1. Are all indirect costs capped at 15%?

Please see updated Cost Guidance document. http://cepi.net/governance#Governing-documents: where it states: (as of August 2017) CEPI is now setting an indirect cost rate (of total direct eligible costs) of up to 15%.

2. Is a profit fee allowed on top of its direct and indirect R&D costs under CEPI funding?

We are not sure what exactly what the term 'profit fees' refers to, however we recognize that covering costs can be challenging and that companies exist to make a profit. That said, as CEPI would be paying for the development, and required volumes of an eventual vaccine may be significant, we expect the cost of vaccine to be as close to the actual cost of goods as is sustainable for the partner or manufacturer. Ultimately the price of vaccine to be used for stockpiling or an emergency response in an affected country will be a matter for negotiation with public service agencies such as GAVI and UNICEF. Costs that CEPI will pay within the actual development stage of the project can be found here:

Contractual and procedural questions

3. Will the 3 selected pathogens be considered for future product development under CEPI's shared risk/shared benefits policy, or is this only applicable for the target WHO priority pathogen(s)?

This is an issue that will be discussed with the applicants should their award application be approved, but in principle, where CEPI's funding is contributing to the development of the underlying technology this could be considered a shared risk/benefits arrangement of the technology alone, although CEPI will only be interested in future full product development using the technology in the appropriate neglected disease areas."

4. Is the intellectual property status of the technology a concern?

Intellectual property may be an important aspect for the development of a vaccine. Background Intellectual Property and Foreground Intellectual Property shall normally be retained and protected by the Awardee, in accordance with CEPI's policies on Equitable Access, Shared risks/shared benefits and IP management, as available here. If the Awardee does not own the IP for the technology, they must demonstrate freedom to operate, e.g., by providing an appropriate letter from the entity that does own the IP.

5. What is the difference between Consultants, Subcontractors and Sub-Awardees?

Consultants: individuals (but not employees), or independent contractors (falls under column H "Other direct costs" in the budget templates).

The Subcontractors, such as commercial entities performing contracted activities in relation to the proposed studies (e.g. nonclinical challenge studies, clinical Contract Research Organizations (CROs) should be listed as sub-awardees (falls under column L "Subawardee" in the budget template)

Sub-awards: are contracts or awards that the primary awardee has negotiated (or will negotiate) with other organizations who contribute to the completion of this project and/or who form part of the consortium (falls under column L "Subawardee" in the budget template).

6. Does CEPI allow a prime awardee to charge the indirect costs fees on top of Sub-Awardees costs?

Yes, in Step 2 of this process we will ask for that distinction. See Cost Guidance document: http://cepi.net/governance#Governing-documents and the section on indirect costs.

7. Does CEPI accept proposals that provide access through a non-exclusive, sub-licensable, worldwide license on necessary background IP (and foreground IP) related to the specific priority pathogens developed under CEPI funding and in the event the awardee will decline to further develop/manufacture the particular vaccine candidate?

CEPI's mission involves ensuring those who need vaccines have access to them. The exact details by which such an IP access 'trigger' might operate would be covered by the terms of the funding agreement for a successful proposal, however, this will primarily be in circumstances where the company is unable or unwilling to develop the potential vaccine further, according to the agreed plans.

8. Can access to the manufacturing process be limited under the funding contract to tech transfer to a third party manufacturer agreed upon with the awardee and only upon the "trigger" event that the awardee declines to manufacture the relevant vaccine candidate (for whichever reason)?

The need for access is determined by the disease burden, governments of affected countries and preparedness plans, and includes timeliness, volume and cost of manufacture as well as the partner's willingness to manufacture. If the partner cannot manufacture enough affordable vaccine fast enough to meet the need, then CEPI is bound to explore alternatives to facilitate access (e.g. transfer manufacturing to a large scale facility). Whichever alternative is used will obviously need to be considered carefully as there will be many issues around this choice, including quality, timeliness and the partner's desire to protect its valuable IP; which CEPI is sensitive to. Ultimately, this will need to be a decision for CEPI but it would anticipate that in such a scenario the partner will be involved in a dialogue reaching a rational decision to facilitate access.

Scientific questions

9. In which preclinical and clinical phase I data of an eligible well-characterized pathogen have been generated prior to the start of the CEPI project, will CEPI also have step-in rights in case such a vaccine candidate progresses to a market product?

Data generated without CEPI funding will only be used as background information and support for the proposed vaccine platform but could consequently form part of the Background IP. CEPI might therefore need to execute "Step-In" rights according to the progress plan and deliverables granted in the Project Plan and the funding agreement. For vaccine formulations developed outside the CEPI funded project, non-exclusive "Step-In" rights will be sought if they are necessary for regulatory approval, manufacture and distribution of the vaccine being developed under the CEPI-funded Project Plan and associated agreement.

10. How does CEPI plan to work with awardees to monitor technical progress?

CEPI will have a product development team that will work with the applicant and monitor the technical progress. A CEPI project manager will be assigned to an awardee as point of contact for their project, with regular follow-up though teleconferences and face-to-face meetings. CEPI will expect to be involved in certain key 'go' or 'no go' decisions.

11. Could CEPI please clarify the definition of LSLV (last subject last visit) for the planned Phase I clinical studies: should the safety follow-up period be completed and the final CSR [clinical study report] submitted within the three-year period? If not, would an interim CSR with tables and lists satisfy the completion requirement?

For the Phase I clinical study, CEPI expects the applicant to have completed LSLV, including a minimum 4 weeks safety follow-up after last dose, within the 3-year period. An interim CSR with 4 weeks safety data and interim immunogenicity data will be required as well as detailed timelines when final immunogenicity read-outs will be available. If an applicant plans to assess 12 months safety, which for novel technologies is in general a sensible approach, the applicant should submit these data in the final CSR. If safety signals appear during the long-term follow-up, the applicant is requested to inform CEPI at the same time as study governance bodies are informed.

12. Would it be acceptable to develop potential back-up pathogens up to Phase I readiness under the scope of CEPI CfP-2?

Developing potential back-up pathogens for your vaccine platform is not expected within the scope of this call. CEPI funding will, in the first instance, be related to the three proposed pathogens in the project description.

13. We wonder if the data we must show to demonstrate the immunogenicity of the proposed vaccine in a relevant animal model, should be from our results, or could be published by others.

For eligibility, we will need immunogenicity data from the exact vaccine *platform* (but not necessarily the specific vaccine *candidate*) you are using in your proposal. We encourage you to provide all relevant data on the platform, which can include data generated by others (as long as the platform is identical) and/or data you have previously generated on vaccine candidates that use the same platform but that are not included in this proposal. It is however crucial for CEPI that Applicants in the Project description text clearly distinguish which data were generated by the members in the Applicant consortium (own data), and which data were generated by others.

14. For section 3.3, how much pre-clinical evidence should we provide? How many pathogens would you like us to present? Is the number of pathogens for which we have data, the diversity of virus families, or the stage of development the most important?

Applicants should provide the data necessary to describe the platform's versatility and technical feasibility, including anticipated potential use in outbreaks and manufacturing scalability. For the candidates intended for a phase I trial, the extent of preclinical data generated is also determined by the requirements for submitting a clinical trial application. We have no specific requirement with regards to number of pathogens. The combination of number of pathogens, diversity of pathogens and stage of development will be taken into account when reviewing the proposals.

15. For section 3.2, is it expected that we include details about the challenge model or simply note that it is ongoing or finished?

Please include details on the challenge experiments, with aspects such as study design, animal and pathogen species/strains, vaccination dose and schedule, endpoints and results.

16. Is there a preference for the location for the Phase I clinical trial? Would a trial in Europe/Western world be acceptable for the first-in-human trial of each individual candidate vaccine?

For ethical reasons, CEPI requires that first-in-human trials be conducted in a country with robust ethical oversight and regulatory authorities experienced in approving vaccine clinical trials, as well as access to relevant expertise, resources and facilities to deal with serious adverse events, should they occur.

17. Conformity with European legislation whereby one toxicology study (single and repeated dose-toxicity study and local tolerance study in one animal model) is sufficient for human vaccines will be required. Is that acceptable also under this call?

The applicant can choose which regulatory pathway to follow, CEPI has no preference of which regulatory pathway as long as the regulatory agency involved is in a country with robust ethical oversight and regulatory authorities experienced in approving vaccine clinical trials. The proposed studies must be in line with their requirement.

18. How does CEPI anticipate working with awardees to make key program decisions, e.g. which candidates to advance to clinical trials? Could we decide to advance a candidate to our 3rd pathogen into clinical trials if its preclinical data shows better efficacy?

We request to be involved with you to make the decision on which candidate you plan to take into phase 1 clinical trials. If you initially have planned taking two candidates into clinical trials, but for reasons such as those suggested in the question decide to change, it may be possible to switch if the results at that stage suggest it makes most sense. CEPI will have a project management team that will work closely with you on such decisions.

19. As monkeypox is used as the animal model for smallpox, can this be used for preclinical testing of a smallpox vaccine?

Yes.

20. Is the clinical development plan a vital component of the application or is CEPI willing to provide assistance in these areas based on solid pre-clinical data?

The clinical trials are indeed an important component of the proposal since a priority for the Phase I trials is to investigate the safety and immune mechanism of action of your platform. This will involve more detailed immunologic analyses than are typically carried out in Phase I trials. Applicants without this experience should find partners with relevant clinical and regulatory competence.

Application questions

21. Will the “Project description template” and all its content be treated with confidentiality?

ALL CEPI SAC members, members of the CEPI secretariat, external reviewers, and observers are bound by CEPI’s Confidentiality and Transparency policy and have declared any conflicts of interest. All application related information is handled as sensitive and therefore confidential.

22. The guidelines ask for bio sketches for the project leader/principle investigator, including up to five co-investigators/key staff. Can you please confirm whether this refers to the inclusion of five or six bio sketches in total?

Applicants can include up to six bio sketches in total. Please note that bio sketches should not exceed 1 page each.

23. The budget template has a summary error.

Thank you. We have uploaded a new budget spread and have fixed the summary error.