

Call for Proposal - Expanding the CEPI Centralized Laboratory Network

Webinars for the labs

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Q&A Asia (Dec 07th 2021)

1. **Is Hawaii considered Oceania?**

No, Hawaii is considered USA.

1. **What other immunological assays is CEPI looking for (other than ELISA/neutralization assay/ELISPOT)?**

We are interested in any immunological assay used in clinical trials for vaccines with high throughput and that can be easily modified to tackle different viruses.

1. **Is there any application example for reference?**

Unfortunately, not. But please feel free to reach out to us if you have any question (centralizedlab@cepi.net).

1. **Could China apply for the scope1?**

No, please apply for scope 2 “all pathogens”.

1. **What does CEPI expects regarding “production of reagents”?**

We would like to know if any of the laboratories are able to produce key reagents for the assay (e.g. ELISPOT peptides, ELISA coating antigens, live virus stocks, pseudo particles, etc ) in sufficient amount to be shared with all the other laboratories.

1. **Some of the assay reagents like pseudo particles are not commercially available, can other CEPI labs help to establish these assays by supplying these reagents?**

Yes, for this reason we are also looking for laboratories with the capacity to produce key reagents to be able to share them with the other laboratories.

1. **How do you want neutralizing Antibodies to be measured?**

Currently, we are focusing on wild type virus neutralization assay and pseudovirus neutralizing assay, but we are open to explore other technologies.

1. **Your priority areas are viruses mainly. Is there room for labs working on other pathogens?**

At the moment CEPI is only focusing on viruses.

1. **Can we apply for other pathogens such as HIV, HBV, HCV, RSV?**

Yes.

1. **Does the lab need to store viruses such as Nipah virus and SARS-CoV-2 for the live-virus neutralization assay?**

Yes, labs that have BSL3 or BSL4 capabilities can be asked to run wild type virus neutralization assay and, in that case, will have to handle live viruses. The virus stock will be provided.

1. **For new viral diseases, is CEPI looking for a network of labs like you have for COVID-19?**

Yes, we are looking to keep the same framework we already have in place for COVID-19.

1. **If a lab does not have an established or validated assay for COVID-19 but want to work on that, can it apply for the scope and be a recipient lab to build the needed capacity?**

Yes, if the lab is based in Africa, Oceania and South America.

1. **If we have GMP quality system (good manufacturing practice), we don't have GLP quality system, can we apply?**

Yes, we are looking for laboratories that have a quality system in place that assures data quality and integrity.

1. **If new assays need to be developed to be part of this network, who will provide the budget for implementation/validation of these assays?**

CEPI will fund assay development, qualification, and validation.

1. **There are these new surrogate SARS CoV2 neutralization assays, which uses ELISA based technology and do-not need WT or pseudo virus particles. What you suggest about these surrogate assays?**

We are definitely interested in hearing more about this, please apply.

1. **Will data analysis/interpretation of this immunological data be performed by CEPI scientist/bioinformatics teams? Or the vaccine developers?**

Only raw data are given back by the labs to vaccine developers. Vaccine developers are responsible to analyze their own data.

1. **Can a group of laboratories within the same area apply as a consortium?**

Yes.

1. **Are Arboviruses of interest?**

Yes.

1. **Vaccine research also involve tracking down breakthrough infection, would you support these kind of assay development and testing?**

The CEPI Centralized Laboratory Network is currently only focusing on immunological testing of vaccines.

1. **Is dengue virus a priority?**

We are interested in all virus families.

1. **Does budget include indirect costs for institution?**

Yes, up to 15%.

1. **Would assays for the measurement of Antibody Dependent Enhancement be helpful?**

Not at the moment, we are interested in immunological assay used in clinical trials for vaccines.

1. **Would CEPI consider assays evaluating host response? Eg. Cytokine and gene expression profiling?**

Not at the moment. CEPI has another initiative for this kind of analysis (Systems Immunology Network)

1. **If a lab has an established method but for high throughput data generation need funding for capacity development (e.g., buying instrument like FACS), will CEPI fund this?**

Yes, lab-specific support for instrumentation and software might be available.

Q&A Latin America (Dec 08th 2021)

1. **Regarding pricing, are the 1000 samples sent as a batch or should they be priced as though they are analyzed individually?**

Samples will be received in batches. Please, specify if any discount based on batch size applies.

1. **For assay development, does CEPI provide a protocol for the assay?**

No, when CEPI asks a lab to develop an assay, the expectation is that the lab would develop its own protocol. The developing lab will then transfer the protocol to the other labs of the network.

1. **There is a section which says: "Applicants must be able and willing to prioritize CEPI work over other on–going projects". How this prioritize will be evaluated? Is there any strict timeline which should be fulfilled by the lab?**

Labs will be asked to stick to timelines where provided during the project. We are asking applicants to in principle to work with CEPI to prioritize this work over other ongoing projects.

1. **Will CEPI consider granting orders to companies who have novel standardized assays like the VaxArray Multiplexed Assay, if yes, would CEPI want the standardized assay kit to be used by other labs?**

Yes.

1. **Is GLP certification a pre-requisite?**

We are looking for laboratories that have a quality system in place that assures data quality and integrity.

1. **Our laboratory is part of the national laboratory network, would that be a problem?**

Not for CEPI. Check the requirement on your institution’s side.

1. **Does the laboratory have to be accredited?**

Not necessarily, but we are looking for laboratories that have a quality system in place that assures data quality and integrity.

1. **Will CEPI help samples import/export between the countries?**

Yes, we’ll do our best.

1. **How many laboratories do you intend to support in this call?**

We do not have a fixed number; it depends on how many good applications we get.

1. **Does CEPI pay an annual fee to the laboratory to keep them as part of the network, or is it only for work they receive/bid on?**

The current arrangement we have does not pay for fees. We pay per service.

1. **Does CEPI have plans to expand labs in Asia/South East Asia (outside of China)?**

Yes, for viruses other than SARS-CoV.2.

1. **You are looking to increase your testing capacity for COVID-19 (and other viruses) samples, do you have an idea of the expected number of samples - per area (e.g. Africa) per month/year or so?**

Unfortunately, this is very difficult to predict. For COVID-19 in one year we have allocated more than 21.500 samples.

1. **For samples being sent to labs is the contract between the lab and CEPI, or between the sample provider and the lab?**

CEPI and the lab will sign a contact. The lab and the sample provider will sign an MTA.

Q&A Africa & Europe (Dec 09th 2021)

1. **Which animal species you are most interested in?**

NHPs, rodents and any animal model relevant for vaccine development.

1. **Will those labs in the network already be able to submit a shortened application?**

If you are already in the network, please provide us only the updates we are not yet aware of.

1. **How do you standardize methods? do you have a reference lab developing / validating other labs?**

Yes, usually one chosen laboratory develops the assay method and then tech transfer it to all the other labs.

1. **What is the typical price for 1 ELISA test or 1 ELISPOT test that a lab gets?**

It varies among labs, depending on where they are based. **Are you working with other initiatives for standardization? such as EQAPOL, HIV vaccine network?**

For COVID-19 we have been in connection with GH-VAP/BMGF and former Operation Warp Speed. For new pathogens, we are looking forward to connecting with other initiatives.

1. **You mentioned BSL3 and BSL4 related assays, would you require the consortium have BSL3 and 4 laboratory structure either by partnership or self-owned?**

It is for sure a plus to have BSL3/BLS4 facility but is not required.

1. **As part of the budget, how will labor cost be accounted?**

Labor cost will have to be included in the testing/assay development/tech transfer price.

1. **How do you monitor the performance of participating labs?**

Through proficiency testing run every 6 months.

1. **Is the application made at laboratory level (division or department in the university) or at institutional level?**

It is really up to the lab, CEPI will consider both.

1. **Major reagents for immunological assays will be provided centrally by CEPI for participating labs, (e.g. test /vaccine Antigens for e.g. EliSpot))?**

Yes.

1. **What validation process is needed after tech transfer of a fully an assay?**

None, the tech transfer process qualifies the lab to run the assay and analyze samples.

1. **Does the CEPI audit labs from the network?**

Yes, during the due diligence process.

1. **Is there a confidentiality agreement set in place when CEPI chooses its labs?**

CEPI and each lab will sign a contract that deals with confidentiality.