



Centralized laboratory for measurement of immune responses elicited by SARS-CoV-2 vaccine candidates

Request for Proposals – Extension of Original Scope

Background

The Coalition for Epidemic Preparedness Innovations (CEPI) has a portfolio of vaccines at various stages of development targeting pathogens selected from the WHO Blueprint list of priority diseases. CEPI's portfolio also includes vaccine candidates against the novel virus responsible for Coronavirus Disease 2019 (COVID-19), Severe acute respiratory syndrome coronavirus 2 (**SARS-CoV-2**). At the same time, many developers worldwide are now focusing on developing SARS-CoV-2 vaccines.

Comparing immune responses against different vaccine candidates intended for the prevention of SARS-CoV-2 is challenging. Biological variation and technical differences (how and where specimens are collected, transported, stored, and analysed) impacts the quality and usefulness of the data produced and makes comparisons between measurements in individual laboratories difficult. Moreover, SARS-CoV-2 vaccine candidates worldwide include different technology platforms (e.g. recombinant viral vectors, live attenuated vaccines, recombinant proteins and nucleic acids) and the evaluation of the true potential for each of the vaccine formulations becomes very complex.

Original Request for Proposals (RfP): RFP-CL-01-COVID

In order to reduce some of this complexity, better compare the immunological profile of each vaccine candidate, and provide robust assays for regulatory purposes, CEPI has previously published a Request for Proposals (RfP) to select potential laboratory partners to test the immune response elicited by different vaccines in **preclinical studies** as well as **Phase I and II clinical studies** in the same (centralized) laboratory (RFP-CL-01-COVID).

Extension of Original RfP Scope: RFP-CL-02-COVID

CEPI is now extending the scope of the previously published RfP to include the testing of the immune response elicited by different vaccines in Phase III and beyond.

The types of studies that pre-approved providers might be asked to perform could include, but are not limited to, the following:

- **ELISA assays**
- **Wild type (BSL-3) and pseudo-virus neutralisation assays (BSL-2)**
- **T-cells ELISPOT assays**

New applicants must submit a full application using the [CEPI template for RFP-CL-02-COVID](#) to provide the information requested.

Laboratories which have previously applied to the first RfP (**RFP-CL-01-COVID**) and would like to be considered for the scope extension are requested to submit an expression of interest for the extended scope, noting any relevant changes to their original application in the context of the scope extension.

Eligibility criteria

Applicants must meet the following minimum eligibility criteria:

- Applicants must have the ability to perform one or more vaccine-relevant immunological assays, and ideally all listed above.
- Applicants must have the ability to perform those assays for preclinical and/or human samples, and ideally both.
- Applicants must have the ability to perform those assays testing immunity against SARS-CoV-2.
- Applicants must have the assay(s) proposed already in place and be willing to run comparability studies with other laboratories in different geographical regions or able to fast tech transfer the assay(s) from other laboratories.
- Applicants must be able to perform studies under GLP/GCLP conditions or a quality system that assures data quality and integrity and must demonstrate experience with immunological assays use during advanced product development testing.
- Applicants must be willing to work with CEPI to collaboratively design the most relevant immunological assays for the purpose.
- Applicants must be able and willing to prioritise SARS-CoV-2 work over other on-going projects when samples are ready for testing.
- Applicants must support preclinical and clinical programmes to ensure protocols and ethics applications for trials are aligned with the analytical plans.

Evaluation criteria

All applications will be reviewed based on the following evaluation criteria:

- Applicant competencies, experience and track record.
- Adequate capacity for the studies.
- Ability to prioritise analysis of samples from SARS-CoV-2 vaccines trials over any other on-going projects.
- Appropriate quality systems in place.
- Proven ability to maintain sufficient reagent stocks.
- Appropriate project management capabilities.
- Proven record of receiving samples from multiple geographical locations.
- Ability to work in a network of international labs to harmonise protocols, reagents and data.
- Competitive pricing.

Information requested to new applicants

We request that all applicants use [the CEPI template](#) to provide information on:

- **Applicant competencies, experience and track record**
 - Identification of key personnel
 - Experience with performing various types of immunological assays in the context of vaccine pre-clinical and clinical trials
 - Experience and track record performing on contracts, or otherwise working with vaccine developers and regulatory agencies
 - Experience in working in a network of international labs to harmonise protocols, reagents and data
- **Capacity**
 - Available types of assays
 - Typical waiting time and speed of testing
 - Constraints on priority setting or freedom to operate
- **Quality systems in place**
 - Capabilities for performing GLP/GCLP-compliant studies or using high-quality systems that assure data quality and integrity. A data quality plan should be outlined.
 - Standard Operating Procedures and documentation of study deviations
 - Operation of the Quality Assurance Unit
 - Data management and document retention

- Track record of study reports submitted to or audited by regulatory agencies
- Track record of accreditation and GLP inspections by regulatory agencies
- **Budget**

Submission guidelines

Please submit the application in PDF format within max 10 pages, to centralizedlab@cepi.net before 15:00 CET on Sunday 4 October 2020. The relatively short deadline for submissions reflects the urgency of this project, as many COVID-19 vaccine development projects are moving towards the efficacy phase of clinical development.

All communication of information and documents related to this call must be conducted in English. All budget proposals must be submitted in US Dollars.

In case of questions in relation to the submission system, access to proposal form templates, or any other issue related to this request for proposals, please contact valentina.bernasconi@cepi.net. It is the responsibility of the applicant to ensure that all requested documents are submitted within the deadline, and to contact CEPI in advance of the submission deadline in case there are any issues regarding the completion of the submission. All applications will be stored in a restricted access repository.

Additional Guidance

Confidentiality: All internal and external experts that participate in the review process will be evaluated for any potential conflicts of interest and are required to sign non-disclosure agreements. All information submitted via this Request for Proposals will be handled as confidential. CEPI may publish names of pre-approved providers after contracts are signed.

Compliance with CEPI policies: Successful applicants must comply with CEPI's policies, available on CEPI's website at <https://cepi.net/about/governance>

Costs of proposal development: CEPI will not cover any costs incurred by the applicants for the development and submission of proposals.

Cancellation: CEPI reserves the right to change the timelines or cancel the grant prior to signature of agreements without obligation to cover any cost for the applicants' work on the call.

Applicant organisations: This request for proposals is open worldwide to relevant entities that bring the relevant expertise and experience to address challenges within the scope of this call. Funding beneficiaries must be legal entities. CEPI may conduct due diligence reviews for feasibility verification, legal, business and financial compliance before awards are made.