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# Systems immunology partners for vaccine evaluation

## Request for Proposals

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### Background

The Coalition for Epidemic Preparedness Innovations (CEPI) has a portfolio of vaccines in development against SARS-CoV-2 and many of the other pathogens on the WHO R&D Blueprint [list](#). We have [partnered with several laboratories worldwide](#) to offer SARS-CoV-2 vaccine developers standardized testing of their samples from clinical trials and preclinical studies using ELISA, neutralization assays, and ELISpot. While these traditional assessments are vital for vaccine evaluation and advanced product development, integrating them with additional multivariate analyses using a systems approach can reveal immunological signatures predictive of a given outcome, such as protection from severe disease, protection from infection, etc. These additional data could be especially critical as new variants of SARS-CoV-2 continue to arise and have the potential to evade neutralizing antibody responses established by previous vaccination or even prior infection with an ancestral strain.

CEPI is also investing in developing platform technologies that can be rapidly adapted to new antigens in response to an outbreak of an emerging or re-emerging pathogen (“Disease X”). The more thoroughly these vaccines and platforms are characterized beforehand, the smoother deployment in an outbreak will be, both from a scientific and regulatory perspective. Therefore, CEPI plans to use a systems immunology approach to gain mechanistic insight into the immune pathways and networks modulated by the vaccine candidates, which have implications for reactogenicity as well as immunogenicity.

CEPI is therefore seeking partnerships with state-of-the-art laboratories that can perform multivariate analysis of vaccine responses in a rigorous and standardized way. Sought-after assays include, but are not limited to:

- Functional analysis of antibodies, in addition to neutralization (e.g., ADCC, ADCP, etc.)
- Proteomics
- Transcriptomics
- Metabolomics
- B- and T-cell repertoire analysis
- Other immunologic assays for generating high-dimensional data (e.g. flow cytometry, CyTOF, etc.).

Prospective partners should also have the ability, either internally or through external collaborations, to perform integrative data analysis using machine learning techniques that would allow a functional interpretation of the analyses.

## Eligibility criteria

Applicants must meet the following minimum eligibility criteria:

- Applicant laboratories must have a track record in performing one or more of the assays listed above.
- Applicant laboratories must be able to perform studies using a quality system that assures data quality and integrity, including appropriate certifications for handling clinical trials samples.
- Applicants must have in place a robust strategy for data analysis, either through in-house bioinformatics/computational biology and statistics capacity, or through established collaborations with appropriate parties.
- Applicants must be willing to work with CEPI and CEPI vaccine development partners to collaboratively design the most relevant immunological assays for the purpose, and to ensure analytical plans are aligned with clinical protocols and ethics applications for trials.

## Evaluation criteria

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

- Applicant competencies, experience, and track record
- Applicant capacity
- Demonstrated utility of the approaches proposed in the application (e.g., through publications)
- Appropriate quality systems in place. It will be considered an advantage if the assays proposed for use in the application have been previously qualified or validated in other disease contexts, if not for the disease in question.
- Competitive pricing

Although not a requirement to apply (and therefore not a formal evaluation criterion), possession of or access to interesting sample sets from clinical trials or preclinical NHP studies with leading SARS-CoV-2 vaccines will be viewed favorably. However, applicants that do not have access to such sample sets will not be penalized during the review process.

## Information requested

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 key activities related to evaluation of vaccines
- **Capacity**
  - Available types of assays
  - Data analysis approach
  - Typical wait time
  - Constraints on priority setting or freedom to operate
- **Access to samples**
  - Samples from clinical trials with leading SARS-CoV-2 vaccines
  - Samples from NHP studies with leading SARS-CoV-2 vaccines
  - Other sample sets potentially of interest to CEPI
- **Quality systems in place**
  - Capabilities for performing GLP-compliant studies or using high-quality systems that assure data quality and integrity.

- Standard Operating Procedures and documentation of study deviations
- Operation of the Quality Assurance Unit
- Data management and document retention
- **High-level description of estimated budget**
  - A description of assays and basic estimated cost in the proposal template is appropriate at this stage

For awareness, CEPI requires use of a budget template complying with our [cost guidance](#) to negotiate project budgets once contracts are awarded.

## Submission guidelines

**Please submit the application in PDF form, maximum 10 pages (plus appendices), to [systemsimmunology@cepi.net](mailto:systemsimmunology@cepi.net) on or before the following deadline: March 29, 2021, 15.00 GMT. Applications will be reviewed on a rolling basis as they are received.**

For the submissions to be accepted and registered, applications must fulfil the following norms:

- Submission must be completed by the specified deadline. We encourage you to submit well in advance of the deadline to avoid encountering last-minute technical difficulties.
- All communication of information and documents related to this call must be conducted in English.
- All budget proposals must be submitted in US Dollars.

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 completeness of the submission. All applications will be stored in a restricted access repository.

## Next steps

CEPI will contact successful applicants once their submitted proposals have been reviewed.

CEPI intends to implement framework agreements with successful applicants, to cover potential future provision of services as detailed in this request for proposals.

Laboratories that are awardees or sub-awardees in consortia with pre-existing grants from CEPI to conduct a defined scope of work will not have that work affected by the new framework agreements.

## 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.

**Procurement:** Institutions awarded funding for purchase of goods or services must follow CEPI regulations for any procurement conducted using funds from CEPI.

**Applicant organizations:** This request for proposals is open worldwide to relevant entities that bring the necessary 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.