

Expression of Interest:

Sponsor and CRO for clinical trials with COVID-19 candidate vaccines

CEPI is requesting information from entities able to serve as possible sponsors or to provide operational trial support (Clinical Research Organizations) for clinical trials involving vaccine candidates against COVID-19. This document describes the scope, requirements and process for submission of information.

This Expression of Interest (EOI) has a deadline of Sunday 19th April 2020, 15:00 CET. Information gathered through this EOI will be the basis for a procurement process to secure the services of one or more trial sponsors and CROs.

1. Introduction

The rapid global spread and unique epidemiological characteristics of the COVID-19 virus is deeply concerning.

In coordination with the World Health Organization (WHO), as it leads the development of a coordinated international response, CEPI is promoting the development of new vaccines against the emerging threat of COVID-19. CEPI has funded several COVID-19 vaccine development projects and intends to broaden this portfolio of vaccine candidates further. CEPI will also consider supporting trials for vaccines that have not previously received CEPI support. In anticipation of clinical trials of COVID-19 vaccines, CEPI is seeking to identify, in advance of need, entities that could serve as sponsors or provide clinical research organization (CRO) support for such trials. CEPI envisions that in many circumstances, the developer would be the sponsor of a trial but may need CRO support. CEPI also anticipates that some trials may include more than one vaccine and use a shared control or comparator group; in this case, a single company cannot be the sponsor and a neutral entity will need to fill that role. For the latter circumstance, we are seeking to identify potential sponsors as well as CROs. Since it is not yet clear where (in what countries) trials will be conducted, we are seeking information from applicants with either country, regional or global reach. Applications from LMIC-based entities are encouraged.

2. Objectives and scope of this Expression of Interest (EOI)

The objective of this EOI is to identify organisations with capability and interest in acting as sponsors or CROs for clinical trials involving one or more COVID-19 vaccine candidates. The sponsor will take on the responsibility defined in ICH GCP Guideline (https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf).

According to this guideline, the sponsor can also delegate responsibility and tasks to a CRO. For this reason, sponsor may be involved in selecting CRO for the clinical trials. However, we are also interested in identifying CROs that could support other vaccine developers, when they themselves are able to serve as the sponsor. Information collected through this EOI will be the basis for issuing a Request for Proposal or another procurement mechanism. Following an evaluation process, CEPI intends to implement framework agreements with one or more sponsors and CROs. Information collected through this EOI may also be made available directly to COVID-19 vaccine developers or shared with other organizations contributing to COVID-19 vaccine development.

3. What kind of organisations does CEPI request information from?

The sponsor may be a non-profit or for-profit organisation, product development partnership, government research organisation or intergovernmental organisation. Sponsors and CROs must be legal entities with **experience in clinical trials with human vaccines**.

4. Information requested

Please provide information on the following:

- The geographical reach of your organisation
- The experience in sponsoring or supporting work in LMICs
- Your Quality Management System and Data Management System
- How you ensure compliance with ICH-GCP, and your track record in doing so

- Your experience and track record with regulatory and ethics submissions and processes in the countries in which you have worked

For sponsors:

Please provide additional information on the following:

- In which countries have you been sponsor for clinical trials?
- Track record of sponsorship for human vaccine clinical trials during the last five years
- If your organisation were given the role as sponsor for CEPI funded clinical trials, what responsibilities would you delegate to a CRO?
- Do you have a preferred CRO based on experience from collaboration?

For CROs:

Please provide additional information on the following:

- In which countries have you performed clinical trials?
- Track record of human vaccine clinical trials you have done during the last five years

5. Submission of information

Please submit information in PDF format within max three pages, covering the questions above to eo@cepi.net before **15:00 CET on Sunday 19th April, 2020**.

All information submitted will be stored in a restricted access repository.

6. Technical and administrative questions

Technical and administrative questions about this EOI should be directed to the CEPI Secretariat (eo@cepi.net).