Request for Proposal

Consultancy service: Vaccine Development & Portfolio Management Experts

The Coalition for Epidemic Preparedness Innovations (CEPI) is an international coalition of governments, academic, philanthropic, private, public, and intergovernmental institutions whose mission is to prevent outbreaks of emerging infectious diseases from becoming humanitarian crises.

Our mission is to stimulate, finance, and coordinate vaccine development against diseases with epidemic potential. We identify priority threats and act when market forces fail to drive needed development.

The coalition has prioritised funding for vaccines against Middle East respiratory syndrome (MERS), Nipah, and Lassa viruses and is exploring how to help finish the job of developing vaccines against Ebola. Moreover, CEPI works to develop platform technologies that enable rapid vaccine development against known and unknown pathogens.

CEPI operates under the laws of Norway as a non-profit international association and has offices in Oslo (HQ), London, and Washington, DC.

Scope of tender

CEPI's Vaccine Science and Vaccine Development Units are responsible for the coordination of the coalition's portfolio of vaccine candidates in pre-clinical and clinical stages of development, up to licensure and use in an outbreak situation. These two units are also responsible for coordinating and funding critical elements to accelerate and ensure a rational decision making for the whole product development cycle of CEPI 'supported vaccine candidates; from disease burden and diagnostics to immunological evaluation and preparations for field efficacy testing and processes to facilitate their future use in outbreaks and potential regulatory licensing.

The CEO Office is responsible for the overall Portfolio Management decisions of the coalition and is establishing a portfolio management team.

To support these units' activities, we are seeking the consultancy services from experts with experience in the following disciplines: project and portfolio management; vaccine development; chemistry, manufacture and controls (CMC); non-clinical development; regulatory affairs; clinical development; clinical immunology; systems immunology and bioinformatics; and diagnostics for use in low and middle-income countries (LMIC).

We are seeking to engage with individual consultants, consultants who are established within a partnership, or with consultancy firms who can provide and commit resources for the duration of a project (i.e. up to a maximum of 3 years duration including annual evaluations).

The consultancy services are expected to blend seamlessly into CEPIs operations and may report to CEPI staff in either Oslo or London.

We are seeking consultancy services to support management of our growing vaccine portfolio and key strategic initiatives in the following areas and areas that closely link to these:

- **Project and grant management:** experienced Project Managers to manage our existing portfolio of international projects; to ensure that projects are delivered within the defined scope, time, and cost; to work with the CEPI team responsible for the projects; and to interact with partners. An in-depth understanding of and experience in project management will be required for this role. Project Managers should also have experience in management of grants (e.g. in EC and in the US) and projects in live science (i.e. ranging from basic science, academia to industry and public health), an ability to work in an international matrix organisation, and previous experience managing large international projects. Certification is a plus.
- **Portfolio management**: experienced Portfolio Management Consultants to support the management of our existing and growing portfolio of international projects. The Portfolio Management Consultants will work with CEPI's Portfolio Management Team (CEO Office) and Vaccine Science and Development Units, in order to: (1)

Further develop and implement standards for portfolio management and project management, ensuring projects' alignment with CEPI's strategy; (2) further develop appropriate analytics for Probability of Technical and Regulatory Success and Health Economics and Outcomes Research methods to demonstrate the value of CEPI investments and to support R&D decision making; (3) Build tools and procedures for the operational management of data to support effective analytics and visualizations across the CEPI portfolio. Portfolio Management Consultants will be reporting to the CEO Office. Interaction with Project Managers, internal committees and external experts will be required. Depending on roles undertaken, the following experience will be required: Advanced pharmaceutical R&D Portfolio Management experience, including previous experience managing large international portfolios (certification is a plus); Advanced expertise in HEOR methodologies and decision analytic modelling; Advanced expertise in building and supporting information technology/data management functions, particularly on health and pharmaceutical data sets. In addition, Portfolio Management Consultants should have some experience and understanding of vaccine development, and an ability to work in a matrix organisation.

- **Vaccine development:** Project Leaders, with global experience in vaccine development, to represent CEPI as part of our Joint Management Committee in collaboration with our Partners. Project Leaders will oversee coordination and progress of projects. This role requires in-depth knowledge of vaccine development (from discovery to late-stage development, licensure, and implementation), the ability to represent CEPI to our partners and to external audiences, and the ability to manage a team of experts in a matrix, international environment. Experience working in southeast Asia, India, the Arabic Peninsula, or West Africa is a plus.
- **Chemistry, manufacture, and controls (CMC):** experts in CMC with a PhD and a minimum of 7 years in CMC in the vaccine pharmaceutical industry. CMC experts should have experience in process development, formulation development, analytical development, scale-up, supply-chain operation, regulatory CMC strategy and filing, project management, and coordination of various manufacturing and quality teams. Proven experience in Good Manufacturing Practices (GMP) setting responsibilities are required to ensure that the highest quality of manufacturing and development operations are applied for CEPI projects. CMC experts will also coordinate support in science, engineering, and GMP quality operations to adhere to regulatory and ICH GMP guidelines.
- **Non-clinical development:** experts in non-clinical development - including those with experience in animal-model development and toxicology. Individuals should have a minimum of 5 years' experience in vaccine non-clinical development either in industry, academia, or public sectors. An understanding of the constraints of studies conducted in high-containment is desirable. Working within the principles of NC3Rs is essential. Experts in non-clinical development should have broad knowledge of vaccine development and how non-clinical data can support clinical development, regulatory approval, and licensure.
- **Regulatory affairs:** experts in regulatory affairs who will provide input and guidance on regulatory issues throughout the product lifecycle (i.e. from preclinical development and experimental medicine to post-marketing stages). Regulatory affairs experts will work with external partners and internal project leaders. Strategic activities and cross-cutting activities will involve interactions with the World Health Organization and regulatory agencies in the US, Europe, and internationally. Experience working with national regulatory authorities in LMIC would be highly desirable.
- **Clinical development:** experts with an MD or PhD and a minimum of 5 years of vaccine clinical development experience gained in industry, public health, or public sector. Clinical-regulatory experience is a plus and international experience, including working in LMIC, is highly desirable. Key responsibilities include supporting the development and management of the overall clinical project strategy and clinical development plans and overseeing the execution of clinical work and associated budget of the awardees. Experts are expected to ensure the highest quality of clinical research and operations support is provided to all vaccine clinical development projects. All work will be performed in compliance with CEPI's clinical trials policy, standard procedures, regulations, and current ICH Good Clinical Practices guidelines, and to provide clear, timely, and consistent updates across all clinical trials of candidate vaccines in the portfolio.

- **Clinical Immunology:** experts in clinical immunology with experience in development, qualification, and validation of immunological assays and interpretation of related results. Specific experience in qualification of serum-based ELISA, antigen specific assay development, and/or cytokine profiling would be particularly appropriate. Experience of compiling scientific reports for regulatory agencies is highly desirable.
- **Systems immunology and bioinformatics**: experts in systems immunology, with the purpose to advice CEPIs Partners in refining exploratory research objectives to maximize insight in mechanisms for immunological protection for target diseases, and reactogenicity for vaccine candidates in CEPIs Partner projects. This requires strong insight and experience in defining exploratory research objectives, study designs, methodological approaches for exploring innate, humoral and cellular responses as well as bioinformatics approaches to identify and validate molecular, immunological, and clinical signatures of vaccine efficacy.
- **Diagnostics for use in LMIC**: experts in technologies suitable for diagnostic testing for CEPIs target diseases (Lassa, MERS-CoV and Nipah) in their respective affected geographic areas. Experts are expected to have experience in contributing to technical specifications, technology development and target disease adaptation, laboratory and field validation and/or guide product development to approval for clinical use. Experts are expected to support CEPIs in addressing the diagnostic needs that are critical for development of its vaccine portfolio, in the setting of creating an impactful partnership with other organisations specializing on diagnostics development.
- **Diagnostics for use in LMIC.** experts in technologies suitable for diagnostic testing for WHO priority pathogens in the Blueprint for R&D programme in their respective affected geographic areas. Experts are expected to have experience in contributing to technical specifications, technology development and target disease adaptation, laboratory and field validation and/or guide product development to approval for clinical use. Experts are expected to support CEPIs in addressing the diagnostic needs that are critical for development of its vaccine portfolio, in the setting of creating an impactful partnership with other organisations specializing on diagnostics development.
- **Epidemiology.** experts with experience in the design, implementation and analysis of epidemiological studies for infectious diseases, specifically in low and middle-income countries (LMIC) and outbreak prone diseases. Experts are expected to have experience in a variety of designs, such as incidence and seroprevalence studies, vaccine evaluation, cross sectional studies, infectious disease surveillance and outbreak response. Experience in the following epidemiology related areas would be beneficial; vaccine development and evaluation, clinical trials, laboratory methodology specifically for WHO priority pathogens, national infectious disease surveillance and outbreak response in LMICs.

Bidder qualifications

Eligible tender submissions can be accepted from either individual consultants, or by consortia or contract research organisations (partnerships or consultancy firms). To be considered for a contract award under this tender, all tenders must meet the following criteria:

- Experience in the relevant discipline or area (as noted above) with demonstrable technical capabilities and experience
- Documented experience in at least two similar types of projects and settings.
- Documented capabilities in terms of resource and time management.
- Individual consultants must be able to commit to the priorities and time-requirements of specific projects.
- Consortia, contract research organisations (partnerships or consultancy firms) must have the ability to mobilise resources to satisfy the needs of each project.
- Experience working in matrix, international, and multicultural environments is a must.
- Conduct efficient, productive and diplomatic communication with relevant internal and external stakeholders.
- Professional level of spoken and written English
- Ability to travel regularly to meetings with CEPI and CEPI's partners (throughout Europe, USA, and internationally).

Please note that as part of our assessment we may ask tenderers to provide references from clients you have worked with to validate your experience in similar work.

Tentative time plan

The following is the expected time scale for the procurement process. However CEPI reserves the right to change the time schedule at any time.

Activity	End Date
Request for proposals advertised	20 Aug 18
Deadline for submission of written proposal	**17 Sep 18 (23:59:59 UTC)**
Selection process completed	23 Sep 18
Contract initiation and agreement	30 Sep 18
Consultants Ready to Start	**From 1 Oct 18**

Tender instructions

To be considered for a contract award under this request for proposals, please submit the written proposal (not exceeding 5 pages + applicable resumes and annexes) in English.

The proposal must include the following information:

- Brief background information on the individual, consortia, partnership or firm, including details of previous experience in relevant specialties
- Documented ability and capacity to perform the work to a high standard, on time, and on budget
- An indication of the availability of each proposed resource and associated budget, including fee rates for additional services
- A general overview of the schedule and timing of invoices
- Estimate and general description of the expenses you expect to incur and bill to CEPI. If CEPI will be billed for expenses other than direct out-of-pocket expenses incurred in performance of services, please describe the costs.
- Two examples of similar work undertaken with similar clients (we may ask for relevant contact details should we decide to take up references.
- Completed tendered declaration form (appendix A below)

Deadline for submission is **Midnight (23:59:59 UTC) on Monday 17 September 2018**. Proposals received after the deadline will not be considered. Costs for the preparation of proposals will not be refunded.

Electronic copies of your proposals should be sent to: glenn.foster@cepi.net in PDF format.

Evaluation criteria

Our evaluation criteria include the areas of information solicited under the scope of tender and bidder's qualification. The contract will be awarded to the bidder who has supplied: (a) a proposal that meets the technical requirements and qualification; (b) the demonstration of capability and motivation to perform, and (c) the most economically competitive offer. Economic assessment of proposals will be based on qualifications (40%); probability of achieving expected outcome (30%); and total cost (30%).

Confidentiality

By accepting to take part in this RFP process, your firm agrees to keep in confidence all information imparted to you by CEPI during the period of consultancy, not to disclose it to third parties, and not to use it for any other purpose than for participation in the RFP process.

Cancellation

CEPI reserves the right to change the time plan or cancel the competition without any obligation to cover any cost associated with the tender process.

Duration

The expected duration for the contract will reflect that of the project direction, with a maximum of three years, and an evaluation every 12 months (i.e. start 1 September, 2018, to 31 August, 2019) with the option to renew, replace or terminate, based on an evaluation process.

Additional information

If you have any questions, please contact glenn.foster@cepi.net

Appendix 1 - Tenderer Declaration Form

Before awarding any contract, and as part of the procurement procedure, CEPI, its Partners, representatives and Awardees will need to ensure that the candidates are not in any of the situation listed below. Written confirmation in the form of this signed document should be provided.

CEPI, its Partners and Awardees reserves the right, even if such confirmation is given, to investigate / audit any of the situations listed if it has reasonable grounds to doubt the contents of such confirmation. This right to audit is applicable for CEPI's supplier/ contractor and its supply chain.

For the purpose of the declaration signed below, the term "**the Tenderer**" refers to the following:

Name of Tenderer: .....

Registered Office Address: .....

Registration Number (as appropriate): .....

ELIGIBILITY

The Tenderer hereby declare that I/we agree(s) to participate in the **procurement procedure** in adherence to the principles stated in CEPI's Procurement Policy and Procedure and are fully aware that any failure to comply could lead to our exclusion from the tender process and to the rejection of our bid.

The Tenderer agrees to carry out our duties to the highest professional standards, with no consideration linked to possibilities for future contracts. **The Tenderer** commits to adhere to CEPI's Procurement principles and minimum standards throughout our commercial and procurement activities and have procedures in place to ensure that respect for these principles and standards is upheld by our staff and contractors.

I/we hereby furthermore declare that **the Tenderer:**

(a) is not subject to any conflict of interest in the ongoing procurement procedure for this contract and there has not been any misrepresentation in the information supplied along the process;

(b) is not bankrupt or being wound up or having its affairs administered by the courts. It has not entered into an arrangement with creditors or suspended business activities and is not the subject of proceedings concerning those matters;

(c) we or persons having powers of representation, decision-making or control over them have not been convicted of an offence concerning their professional conduct by a final judgment;

(d) has never been proven guilty of any grave professional misconduct;

(e) has not failed to fulfil their obligations relating to the payment of social security contributions or taxes in accordance with the legal provisions of the country in which they are established, or with those of the country where the contract is to be performed;

(f) has never been convicted for fraud, corruption, illegal activity, involvement in a criminal organisation or money laundering by a final judgment.

(g) does not make use of child labour or forced labour and/or practise discrimination, and/or disrespect the right to freedom of association and the right to organise and engage in collective bargaining pursuant to the core conventions of the International Labour Organization (ILO).

I/we agree to hold in trust and confidence any information or documents disclosed to us, discovered by us or prepared by us during the course of the tender and agree that it shall be used only for the purposes of this process and shall not be disclosed to any third party. I/we understand that any unauthorized disclosure by us may render **the Tenderer** liable to legal action.

Signed (on behalf of "The Tenderer"): ..... Date: .....

Name (block capitals): .....

LABOUR STANDARDS

Employment is freely chosen.

a. There is no forced, bonded or involuntary prison labor.

b. Workers are not required to lodge `deposits' or their identity papers with the employer and are free to leave their employer after reasonable notice.

Freedom of association and the right to collective bargaining are respected.

a. All workers, have the right to join or form trade unions of their own choosing and to bargain collectively.

b. Where the right to freedom of association and collective bargaining is restricted under law, the employer facilitates, and does not hinder, the development of parallel means for independent and free association and bargaining.

Working conditions are safe and hygienic.

a. A safe and hygienic working environment shall be provided. Adequate steps shall be taken to prevent accidents and injury to health arising out of, associated with, or occurring in the course of work.

b. Access to clean toilet facilities and potable water, and, if appropriate, sanitary facilities for food storage shall be provided.

c. Accommodation, where provided, shall be clean, safe, and meet the basic needs of the workers.

Child Labor shall not be used.

a. The International Labor Organization ("ILO") defines “child labor” as work that deprives children of their childhood, their potential and their dignity, and that is harmful to physical and mental development. It refers to work that:

- Is mentally, physically, socially or morally dangerous and harmful to children; and
- Interferes with their schooling by depriving them of the opportunity to attend school; obliging them to leave school prematurely; or requiring them to attempt to combine school attendance with excessively long and heavy work.

b. There shall be no recruitment of children and children under 18 years of age shall not be employed at night or in hazardous conditions, including any work which is likely to jeopardize children’s physical, mental or moral health, safety or morals.

Living wages are paid

a. Wages and benefits paid for a standard working week meet, at a minimum, national legal standards or industry benchmarks, whichever is higher.

b. In any event wages should always be high enough to meet basic needs and to provide some discretionary income.

Working hours are not excessive

a. Working hours comply with national laws and benchmark industry standards.

b. In any event, workers shall not on a regular basis be required to work in excess of 48 hours per week and shall be provided with at least one day off for every 7-day period on average.

c. Overtime shall be voluntary, shall not exceed 12 hours per week, shall not be demanded on a regular basis and shall always be compensated at a premium rate.

No discrimination is practiced.

There is no discrimination in hiring, compensation, access to training, promotion, termination or retirement based on race, caste, national origin, religion, age, disability, gender, marital status, sexual orientation, union membership or political affiliation.

Regular employment is provided.

To every extent possible work performed must be on the basis of a recognized employment relationship established through national law and practice.

No harsh or inhumane treatment is allowed.

Physical abuse or discipline, the threat of physical abuse, sexual or other harassment and verbal abuse or other forms of intimidation shall be prohibited.

ENVIRONMENTAL STANDARDS

Suppliers should as a minimum comply with all statutory and other legal requirements relating to the environmental impacts of their business and should aim to address at least the following:

Waste Management.

Waste is minimized and items recycled whenever this is practicable. Effective controls of waste in respect of ground, air, and water pollution are adopted. In the case of hazardous materials, emergency response plans are in place.

Packaging and Paper.

Undue and unnecessary use of materials is avoided, and recycled materials used whenever appropriate.

Conservation.

Processes and activities are monitored and modified as necessary to ensure that conservation of scarce resources, including water, flora and fauna and productive land in certain situations.

Energy Use

All production and delivery processes, including the use of heating, ventilation, lighting, IT systems and transportation, are based on the need to maximize efficient energy use and to minimize harmful emissions.

TRANSPORT & CARGO STANDARDS

Any transport services shall be provided by a company which adheres to the highest possible safety and employment standards and which commits to respect human rights and observe international humanitarian law. It is preferred that the company can demonstrate it has an effective ethical policy in place, particularly if the company is a broker or freight-forwarder, to ensure that standards are met. If the supplier of the goods is arranging transport then the supplier should ensure that transport services also meet these standards.

Where air transport is required, preference shall be given to providers who are not on the EU Safety Ban List and whose aircraft are registered in countries which meet the International Civil Aviation Organization's standards.

The supplier shall not engage the services of a transport provider known to also transport illicit or illegal goods such as narcotics or to transport arms, ammunition or other conflict-sensitive materials to or from territories subject to a UN or EU embargo.

The supplier shall not engage in the sale or transport of arms or conflict-sensitive supplies to governments which systematically violate the human rights of their citizens; or where there is internal armed conflict or major tensions; or where the sale of arms may jeopardize regional peace and security.

WHISTLEBLOWING CHANNELS & DUTY TO INFORM

It is everyone's responsibility to ensure that CEPI and its partners remain in compliance with these Principles. You are strongly encouraged to report any intentional or unintentional non-compliance with these Principles to CEPI Governance, Risk and Compliance Manager (beate.hvam-axelsen@cepi.net). If you are concerned about retaliation and prefer to report anonymously, you can do so through the implemented Whistleblowing Channels implemented at CEPI. Please see www.cepi.net for further information regarding the Whistleblowing Channel available. Rest assured, CEPI will not tolerate any retaliation against anyone who has reported an actual or suspected violation in good faith.