May 2024

Request for Proposal

Partnership for strengthening clinical trial capacity for GCP-compliant late-stage vaccine trials, generation of real-world evidence and long-term research preparedness / emergency evidence generation readiness in East and Central Africa

Launched in 2017, the Coalition for Epidemic Preparedness Innovations (CEPI) is an international coalition of governments, academic, philanthropic, private, public, and intergovernmental institutions whose vision is to create a world in which epidemics and pandemics are no longer a threat to humanity. Our mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.

Vaccines can help prevent disease outbreaks from becoming humanitarian crises. CEPI supports the development of vaccines and platform technologies against known deadly disease-causing outbreaks for which no licensed vaccines are currently available. CEPI is also playing a leading role in delivering the '100 Days Mission' (100 DM) a goal to develop safe, effective, and globally accessible vaccines within 100 days in response to a future Disease X – an unknown pathogen with epidemic or pandemic potential.

To achieve both ambitious goals it will be necessary to ensure that the necessary clinical trial infrastructure and respective processes and procedures are in place to conduct advanced stage clinical vaccine trials in inter-epidemic periods in regions where priority diseases are endemic (*here: East and Central Africa*) and sustain key facilities over time to enable them to rapidly generate evidence in future emergencies caused by outbreaks of known and new pathogens. Similarly, infrastructure needs to be in place to rapidly gather and assess real world evidence, including by linking information on vaccination status to health system data.
To that effect CEPI has launched its "Research Preparedness Program" in the pilot region West Africa in 2023.

For both, the pilot region in West Africa as well as the regions East and Central Africa, activities will be harmonized and closely aligned with the Africa Centres for Disease Control and Prevention (Africa CDC) to optimally support its roadmap to optimize efficiency and impact in the African clinical research ecosystem.

CEPI is looking for a consortium led by a Technical Coordinating Partner (lead applicant). It resides with the applying entity to decide which and how many additional partners the consortium shall comprise of to meet the goals in a most comprehensive but at the same time efficient set up to manage it. The consortium will support CEPI in two areas:

i) **Track A: Routine Clinical Research Preparedness:** preparing clinical trial sites and facilities in East and Central African countries where CEPI's and Africa CDC priority diseases are present for the Good Clinical Practice (GCP)-compliant conduct of clinical trials of all phases, in particular Phase 2b / Phase 3 trials. A focus will be on advanced stage clinical trials around CEPI-funded priority pathogens including Rift Valley Fever (RVF), Mpox, Chikungunya and filovirus-associated diseases.
Preparation of trials targeting other diseases may be needed. *(Note: the actual conduct of a vaccine trial is not part of this Request for Proposals)*

and

ii) **Track B: Emergency Evidence Generation Readiness:** under guidance of countries and in close

alignment with Africa CDC as well as other stakeholders in the global ecosystem developing and advancing concepts specific for outbreak scenarios to prepare and sustain clinical trial facilities, implementing clinical research strategies and procedures to rapidly initiate clinical and/or real-world evidence generation around vaccines and other biological countermeasures in response to future health emergencies in support of CEPI's '100 Days Mission'.

TRACK	A *‚Interepidemic period'* Routine Clinical Research Preparedness	B *‚Outbreak'* Emergency Evidence Generation Readiness
Focus	Rift Valley Fever Mpox ChikV and filovirus-associated disease	Any pathogen with epidemic / pandemic potential in East and Central Africa
Ambition	To strengthen clincial trial capacity in East and Central Africa for GCP-compliant (advanced-stage) clinical trials	Support countries in East and Central Africa in their ability to generate emergency evidence in future outbreaks
Goal	Operational site readiness at shortlisted clinical trial sites in 2025 (final site selection resides with individual trial sponsor)	Support CEPI's 100 DM by establishing emergency evidence generation readiness (e.g. by conducting clincial trials or generating real-world evidence)

Table 1. CEPI's Research Preparedness and Evidence Generation Readiness Strategy: East and Central Africa

More specifically, CEPI intends to engage with a **consortium** led by a ***Technical Coordinating Partner (TCP)*** and one or more additional partner(s) who already have a regional footprint. The TCP is expected to be the lead applicant responding to this Request for Proposals (RfP). The TCP is expected to work together with CEPI on both Tracks, as outlined above (Table 1). For Track A, the TCP will be responsible to conceptualize and guide the site mapping and evaluation of their readiness in areas known to be prone to outbreaks of CEPI's priority diseases (e.g. Rift Valley fever) as well as the site preparation process across countries. The TCP shall work in close collaboration with and be supported by one or more consortium partners with a regional footprint in East and Central Africa regarding the preparation of the GCP-compliant trial at the site-level. All partners will work in a consortium together with CEPI, Africa CDC and other stakeholders.
For Track B, CEPI will request the consortium led by the TCP to support countries in the region in developing a strategy for rapid generation of adequate evidence for future outbreak response in East and Central Africa, as outlined below.

All consortium partners must be familiar with the clinical trial (vaccines and/or therapeutics) landscape in East and Central Africa, should possess the scientific background and expertise in the conduct of late stage clinical (vaccine) trials as well as the capacity to support CEPI in conceptualizing and implementing an agile approach to ensure our goals are met. For the TCP, proven experience in overseeing and managing complex consortia will be mandatory.

The scope of this RfP focuses on the preparatory activities but does not include the actual conduct of any Phase 2b / Phase 3 vaccine efficacy trial. A separate process for conduct of such a trial will take place at a later stage, and both the TCP and additional partners will be eligible to apply through this funding scheme.

Please see www.cepi.net for further information about the organisation and mission.

Scope of Tender

The scope of this tender encompasses activities supporting CEPI in two areas:

1. **Clinical Research Preparedness (Track A):**
   Within its Rift Valley fever vaccine portfolio, CEPI is currently supporting the development of

multiple vaccine candidates. To prepare a pivotal Phase 2b / Phase 3 vaccine trial (or other measures for evidence generation) for one or more vaccine candidates, CEPI is looking for a consortium led by a TCP to establish operational site readiness for a potential multi-country trial in East and Central Africa. The scope of this tender therefore includes all preparatory work necessary to shortlist and prepare (e.g. strengthening physical and procedural capacity, training, etc.) a specific number of clinical trial sites in multiple countries to initiate a GCP-compliant Phase 2b / Phase 3 vaccine trial not before 2026.
Final selection of clinical trial sites, a Contract Research Organisation (CRO) and the actual conduct of the trial will reside with the not yet awarded sponsor of the individual clinical trial and is hence not within the scope of this RfP.

2. **Evidence Generation Readiness (Track B):**
To realize CEPI's 100 Days Mission' (https://100days.cepi.net/), CEPI, via technical partners and respective consortia, intends to engage with clinical research facilities in key geographies worldwide to support their capabilities to generate the required evidence to respond to future health emergencies. These could be centres developed in Track A or ones that have existing capabilities to be capacitated to timely and more efficiently generate evidence during outbreaks. Designed as a multi-regional approach, East and Centra Africa will be the second region where CEPI together with partners selected through a Request for Proposal, will develop a strategy to strengthen and leverage existing infrastructure and develop a tailored concept with local stakeholders to maintain readiness over time. It is the intention to assess existing capacities as well as emergency evidence generation strategies and plans and – in collaboration and alignment with Africa CDC and respective national authorities – support an enabling environment for the implementation of procedures that facilitate timely start of clinical research in future outbreaks in support of CEPI's '100 Days Mission'.

Procedures may include the identification of regional networks of trial sites, their support, and the establishment of a "stand-by governance" together with all relevant stakeholders and in support of responsible authorities in the region.
Also, the tailoring of outbreak scenario-specific evidence generation strategies incl. for example mock-up clinical trial protocols, the deployment of appropriate innovative clinical scientific as well as operational tools (e.g. mobile-phone based subject identification and retention) in inter-epidemic periods, etc., with identified partners may be needed.

Procedures must be prepared for a wide variety of region-, outbreak- and pathogen-specific scenarios and will not only include plans for randomized controlled clinical trials, but also alternative clinical evidence generation approaches (incl. Real World Evidence).
Eventually, rapid clinical evidence generation strategies in the context of CEPI's '100 Days Mission' will depend on innovative approaches conceptualized by the TCP and respective partners.

Similar to Track A, it will be key for Track B to align concepts with CEPI's partners and governments in the region. Furthermore, all concepts, strategies and infrastructure should be developed as part of a global approach in alignment and collaboration with supra-regional health authorities and normative bodies including Africa CDC and with the World Health Organization.

Technical Coordinating Partner (TCP)

The responsibilities and requirements for the TCP are described below. Some of these tasks may be referred to additional partner entities proposed by the TCP in the respective proposal. The list is non-exhaustive, further activities may be suggested by the applying consortium.

a) Roles and responsibilities

Based on a strong footprint in the region and extensive previous experience and track record in conducting multi-country clinical vaccine trials, the TCP will be responsible for conceptualizing the operational Phase 2b / Phase 3 trial preparedness. In parallel, the TCP shall, together with the countries as well as CEPI, Africa CDC and other partners, explore a strategy to identify and maintain clinical research infrastructure across the region to ensure *emergency evidence generation readiness* when future outbreaks occur. It is CEPI's expectation that the applicants collaborate and communicate closely with national authorities as well as regional public health organisations. In particular, the long-term activities related to *Evidence Generation Readiness* must be aligned with planned and existing activities both in individual countries as well as the region.

Additional partners, as suggested by the TCP and CEPI, may take on some of the responsibilities and tasks listed below.

Track A: Clinical Research Preparedness

- to identify clinical trial sites in countries of East and Central Africa suitable for a late-stage clinical vaccine trial to support CEPI's portfolio vaccine candidates.
- to assess their vaccine trial-related capabilities (clinical, laboratory, data management, etc.) as well as existing gaps, and
- to guide their preparation in line with ICH-GCP, if necessary.

Together with additional local/regional partners, the TCP will oversee and manage the entire process of site preparation including but not limited to supporting regional CROs, and local partner(s) with their tasks (e.g. facilitate availability of necessary infrastructure at the site level; create/update/maintain SOPs, quality control procedures; establish standard workflows for trial procedures; and provide GCP training for staff).

CEPI will request the TCP to manage a complex international consortium of partners to provide coordination within and between countries, facilitate adaptation of a co-developed master clinical trial protocol to country-specific requirements and regulations and ensure alignment with clinical trial procedures prior to the conduct of the trial, etc.

The TCP will be responsible for ensuring that clinical trial sites are available in the designated target countries in due course to conduct a Phase 2b / Phase 3 vaccine trial including one or multiple vaccine candidate(s) of CEPI's portfolio.

Track B: Emergency Evidence Generation Readiness:

- together with CEPI and its partners' and in close collaboration with regional and national authorities, experts in the field as well as in alignment with existing plans and strategies, develop and advance a strategy to support existing scientific and clinical trial infrastructure and capacity in East and Central African countries to enable local stakeholders to quickly respond to future health emergencies by generating clinical evidence in support of vaccine use.
- to identify clinical research facilities and academic institutions that have a track record of clinical trials/vaccine research, generation of real-world evidence, pre-existing infrastructure, and capacities as well as established relationships with respective local, national and regional authorities/public health agencies across East and Central Africa, that could support future outbreak response as part of a broader framework established together with Africa CDC

- as part of a larger outbreak response framework to i) establish and test respective emergency evidence generation procedures and ii) to support the building, expansion and strengthening of a network of agile and capable research sites across the region.
- together with CEPI and its partners as well as local/national/regional stakeholders develop and implement procedures for rapid evidence generation, data management and quality control incl. innovative clinical research tools and concepts, logistics and emergency ethical clearance procedures.
- to support research projects in 'interepidemic periods' (e.g. other vaccine trials with pathogens of concern to the country/region, vaccine safety monitoring, pharmacovigilance, translational immunology, etc.) at selected locations which can inform future emergency evidence generation.
- to support selected clinical trial facilities in developing a business model to become self-sustained entities which are locally owned and can operate independently.

b) Requirements

For-profit and non-for-profit organizations can be considered as TCP under this *Request for Proposals.* The partner should be able to provide the following services to CEPI, i.e. meet the following criteria:

- Track record:
    - The TCP should have a track record in preparing clinical trial sites for the conduct of advanced-stage GCP-compliant clinical trials, ideally clinical efficacy trials in the context of vaccine development in resource-limited settings in the global South.
    - It is expected that the TCP has in-depth experience in managing all aspects in preparation of a GCP-compliant advanced-stage vaccine trial in low-resource settings including but not limited to:
        - Sound scientific landscaping of potential clinical trial sites based on epidemiological data from national disease surveillance programs as well as previous and ongoing work conducted by CEPI and its partners.
        - Rigorous, unbiased, and standardized assessment of capabilities and infrastructure at potential clinical trial sites adhering to very ambitious timelines.
        - Shortlisting of trial sites for an advanced stage vaccine trial against stringent pre-defined criteria including a risk analysis, appropriate mitigation strategies, a site contingency plan, and a trial rescue strategy (addition of sites in case of insufficient study participant recruitment).
        - Cost-efficient evaluation and preparation of clinical trial sites to develop their capacity.
        - Assisting clinical trial sites in recruiting, training and retaining of health professionals and laboratory staff capable of conducting GCP-compliant clinical trials. Highly experienced trainers with local/regional expertise should be accessible *(possibly via additional regional/local partners).*
        - Building and maintaining necessary capacity (infrastructure, knowledge, administration, accounting, data management, etc.) to conduct the actual trial *(possibly via additional regional/local partners).*
        - Develop and implement SOPs, Quality Control measures at the site level and ensure that they adequately applied *(possibly via additional regional/local partners).*
    - The TCP should have proven experience in writing and submitting clinical trial applications / protocol amendments to Ethics Committees (EC)/Institutional Review Boards (IRBs) and regulatory applications to (stringent) national regulatory authorities (NRAs) as well as in managing the entire correspondence with these entities. Previous communications and interactions with regional regulatory authorities in East and Central Africa as well as

AVAREF are desirable.
    - The TCP should have appropriate experience to support CEPI and its partners in tailoring co-developed master clinical trial protocols to country-specific needs and requirements.
    - The TCP must have proven track record of having managed complex clinical trial consortia and must be able to oversee and guide rapid decision-making processes and provide regular reports to CEPI and its partners.
    - Experience with real-world evidence generation for vaccines (ideally in LMICs) would be beneficial.

- Scientific capacity
    - The TCP must have a scientific background and respective experts to support CEPI and its partners in drafting and revising clinical trial protocols, statistical analysis plans, develop statistical approaches for placebo-controlled randomized clinical trials, innovative trial concepts, Real World Evidence studies, conduct literature research of epidemiological data (e.g. incidence, prevalence data, burden of disease data, etc.).

- Logistical capacity
    - All partners are expected to work towards ambitious timelines and must provide evidence of sufficient workforce internationally and/or in the region to meet the provided deadlines.
    - Administration and project management: the TCP must prove to have the administrative capacity and experience to perform tasks including, but not limited to the following:
        - Contract management incl. ability to issue contracts to sub-awardees, sub-contractors.
        - Proven experience in oversight and management of multi-national clinical trial consortia in resource-limited settings.
        - Accounting, regular financial reporting to CEPI, incl. preparation of sub-awardees and sub-contractors for internal and external audits.
    - CEPI expects all its partners to be able to quickly respond to unforeseen changes in plans and therefore requires a certain degree of surge capacity from the TCP.
    - All partners are expected to have the experience and capability to operate in the relevant geographies from a logistical and security standpoint, without incurring unnecessary or unconsidered delays, losses, or security risks. This may include leveraging existing mechanisms (e.g. a travel security program) or establishing new mechanisms (e.g. a project-specific security management plan), in line with the determined project operations.

- Embedment in regional ecosystem
    - CEPI expects the TCP to act in a constructive and collaborative spirit with local/national/regional partners and stakeholders as well as operate in line and in support of planned and existing concepts and structures put in place by local/national public health authorities to leverage on / expand existing infrastructure in East and Central Africa.
    - The TCP must act in line with CEPI's mission to leverage existing local infrastructure, previous investments and support local ownership and guidance as well as individual national health priorities.

- Emergency evidence generation readiness
    - Together with CEPI, Africa CDC and other partners, the TCP shall develop an ambitious strategy to ensure that selected facilities across East and Central Africa are ready to respond to future outbreaks, generate valuable evidence and eventually conduct clinical vaccine trials. To reach this goal, CEPI expects that the TCP can think out of the box, explore new and innovative pathways and cross traditional boundaries in ways of capacity development in low-resource settings with support of institutions in the Northern hemisphere.
    - The TCP must have the scientific and creative capacity as well as staffing to create these innovative concepts and align them with other stakeholders in the ecosystem to create as

many synergies as possible.

- Consultation with international experts, other funders, TCPs and in particular stakeholders and experts in the region will be key for success. CEPI expects the TCP to actively pursue this strategy without any reservations or biased views.
- The TCP should have the capacity, legal status, and track record to/of sponsor(ing) a clinical research activity and must have the ability to adopt a sponsor role for an emergency evidence generation trial study.
- CEPI requires a close collaboration of the TCP for East and Central Africa with TCPs in other key geographies (e.g. West Africa) to ensure leveraging of lessons learnt, maximisation of the impact of the investments and the program and optimal support to CEPI's work on a global outbreak response strategy.

Successful proposals

CEPI's intention is to engage with a consortium led by a TCP to help CEPI and its partners to i) advance the development of portfolio vaccines (against Rift Valley Fever, Mpox, Chikungunya and other filovirus-associated diseases) in East and Central Africa (Track A) and ii) develop a strategy as well as appropriate procedures building on experiences in West Africa for mid-to-long-term emergency evidence generation readiness (Track B) at selected clinical research facilities across the region. CEPI expects the consortium to demonstrate particular strength in three areas: Firstly, the consortium should be based on scientific and operational excellence, possess an aligned view of CEPI's mission https://cepi.net/equitable-access and a proactive mindset to help CEPI and its partners with developing vaccines and to contribute to the development of a sustainable concept around clinical evidence generation in future outbreaks. Secondly, a collaborative spirit and the openness to involve and collaborate with Africa CDC and other local, national, and regional partners as well as the willingness to accept guidance from local, national, and regional authorities is critical. Flexibility and agility as well as drive to explore innovative concepts and tools are a third core area that characterises a successful consortium. The lead applicant responding to this RfP shall be an organization which will act as a TCP, as described above, leading a consortium. It resides with the applying entity to decide which and how many additional partners the consortium shall comprise of to meet the goals in a most comprehensive but at the same time efficient manner.

After review of all proposals and selection of the most promising consortium CEPI may suggest inclusion of additional partners as part of the Due Diligence process.

The proposal must be submitted by using the application template.

Funding to successful applicants will be stage gated. For Track A and B the first tranche of funding will be awarded for a preparatory stage where a strategy for both Tracks will be developed together with partners in the region and in line with activities in West Africa. As one of the key deliverables of this preparatory stage the TCP will be required to provide a comprehensive capacity development and site preparation strategy for shortlisted sites including a detailed budget for the capacity development (Track A) and a high-level strategy for *Evidence Generation Readiness* (Track B).

A high-level budget for this preparatory stage (Work packages 1 & 2) with a total duration of approx. 12 months must be provided as mandatory part of the proposal.

Bidder qualifications

Eligible tender submissions can be accepted from for-profit, non-for-profit organizations or consortia with expertise outlined under the section *Scope of Tender.* In case of consortia, the lead applicant is

expected to be the TCP and must represent a legal entity. To be considered for a contract award under this tender, applicants must meet the following criteria:

- Documented capabilities in terms of resource and time management.
- Willingness to comply with CEPI policies (e.g. CEPI's Equitable Access policy, compliance policies, etc.)
- Partners and their project staff must be able to commit to the priorities and time requirements of specific projects.
- Partners must have the ability to mobilise human and technical resources to satisfy the needs of each project as well as requirements listed above.
- Experience working in matrix, international, and multicultural environments and in different time zones.
- Ability to conduct efficient, productive and constructive communication with CEPI and other relevant stakeholders.
- Professional level of spoken and written English and French.

Please note that as part of our assessment we may ask applicants to provide references from clients they previously worked with to validate the applicants' experience in similar work.

Specifically, we request entities applying as Technical Coordinating Partner to use the application template and address the following:

1. **Comprehensive description of the institution applying as TCP,** its areas of expertise, departmental organisation (incl. organogram), scientific capabilities, workforce, international representation, strategy, etc.
2. **Comprehensive description of additional (local/regional) partners and the intended consortium structure,** including for example area(s) of expertise and capacities of partner entities, roles, and responsibilities within the consortium, a list of all proposed consortium partners and their affiliations, etc.
3. **Experience and detailed track record in advanced-stage clinical vaccine development**, including for example preparing and conducting vaccine trials in various settings (incl. low-resource settings), vaccine trials of various stages (Phase I-IV), large (multi-national) clinical vaccine trials, managing multi-national consortia including partners from industry, academia, and public health agencies, dealing with regulatory authorities, health authorities and governments in East and Central Africa, etc.. Experience in developing real-world evidence capabilities would be highly beneficial.
4. **Scientific capacity**, including for example previous scientific contribution in the field of vaccine development, capacity, and proven experience to conduct standardized systematic literature reviews, statistical support (incl. compilation of SAPs), medical and clinical trial protocol writing, etc.
5. **Logistical capacity,** including for example provision of evidence that the work described in the section "Scope of tender" can be conducted efficiently towards ambitious timelines. The *TCP* is required to provide evidence that the applying entity has a legal status and can provide the full range of project administration and management, including contracting and project accounting and the ability to issue contracts to sub-awardees, sub-contractors, etc.
6. **Regional footprint/knowledge of the ecosystem,** e.g. including for example previous successful work in East and Central Africa / engagement with East and Central African institutions and authorities, successful design and conduct of community engagement programs, previous participation/leadership in consortia which promoted regional guidance and local ownership, etc.

For detailed information please adhere to the requirements described in the application template.

Eligibility criteria

Successful proposals must meet the following eligibility criteria and clearly describe the capabilities and previous experiences of the applying entities:

- TCP must represent a legal entity.
- TCP must be able to establish a legal relationship with clinical trial sites and other partner institutions in East and Central Africa, if needed, and they must be able to contract partners and sub-contractors, purchase and ship goods in line with CEPI's terms of reference.
- TCP must have proven ability to manage and steer complex, multi-national consortia, incl. project accounting and reporting.
- TCP must have track record of experience in the execution of government-funded public projects and/or in liaising / collaborating with governments, health authorities and public health agencies in the global South and preferably in target countries of this RfP.
- All partners within the consortium should have a proven track record of implementing and/or conducting GCP-compliant advanced stage clinical trials and a profound understanding of vaccine development in LMICs and preferably in a multi-country setting. Experience in Phase 2b / Phase 3 vaccine efficacy trials in LMIC would be preferred.
- All partners within the consortium must have proven work history in Africa, preferably in East and Central Africa.
- At least through local/regional partners the consortium must have sufficient core staff (permanent or deployable) in relevant countries in East and Central Africa
- The TCP must have the potential capacity to act as a sponsor for a vaccine trial

CEPI reserves the right at its sole discretion to approve applicants for the next step. 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. CEPI will also carry out due diligence screening and where appropriate, ask you to complete a due diligence questionnaire.

Tentative time plan

The expected time scale for the procurement process is summarised in the table below. However, CEPI reserves the right to change the time schedule at any time.

Activity	End Date
Request for proposals advertised	**10th May 2024**
Deadline for submission of written proposal	**21st June (23:59:59 GMT)**
Selection process completed	As soon as practicable
Contract initiation and agreement	As soon as practicable

Tender instructions

To be considered for a contract award under this request for proposals, please submit the written proposal (not exceeding 10 pages + applicable resumes and annexes) in English.

The proposal must include the following information:

- Completed Application template

- Completed tender declaration form (appendix A below)
- Completed Supplier Details (appendix B below)

Deadline for submission is **Midnight (23:59:59 GMT) on the date shown in the time plan above**. Proposals received after the deadline will not be considered. Costs for the preparation of proposals will not be refunded.

Applications can only be submitted after registration through the following link:

https://cepi.my.site.com/portal/s/registration

To apply to this Request for Proposals through the Portal, you will need to be set up as a Portal User. This will give you the option to apply for Calls, follow the status of your proposal, and check in on project data if receiving funding from CEPI.

To be set up as a Portal User please click on the 'Register Now' button on the page and complete the registration form. Please provide as much detail as possible in your message for the team to review your registration request and grant you access to submit a full application.

When set up, you will receive a confirmation email from CEPI, with guidance on how to use the new CEPI Portal and how to submit your application. A separate auto-generated email will be sent with a link for you to log on and create a password.

Evaluation criteria

We will assess the proposals against the information presented in the Scope detailed above. The contract will be awarded to the tenderer(s) who: have demonstrated that they can meet the technical capabilities and qualifications detailed in the scope (80%) and have provided an economically competitive offer (20%).

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 duration of any Framework Agreement awarded under this Request for Proposals will be tailored to each track. For Track A the duration will be defined in accordance with the clinical development plan (to be agreed with CEPI and its vaccine development partners). The Framework Agreement for Track B will be stage-gated and discussed as part of any successful applicant project plan. Significant achievements and milestones are to be made within the CEPI 2.0 funding period which ends 2026. Individual Call Offs (specific projects or elements of work awarded under the terms of the framework agreement) will vary in value and duration according to their content and complexity.
Performance under the Framework Agreement will be evaluated regularly and the option to renew, replace or terminate may be provided based upon that evaluation.

Additional information

For support or any other questions, please feel free to use our dedicated Support form to submit an enquiry, where a member of the team will be in touch to provide any clarifications.

Appendix A – Tender 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 comply with the **CEPI Third Party Code** in force from time to time (available here). Written confirmation in the form of this signed document should be provided to confirm this.
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 / Organisation: _____

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 the CEPI Third Party Code 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 the CEPI Third Party Code 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) 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.
(h) 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.
(i) 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.

AVAILABILITY OF WHISTLEBLOWING CHANNEL

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

DECLARATION CONCERNING CONFIDENTIALITY

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.

SIGNATURES

Signed on behalf of **the Tenderer**: _____

Name (block capitals): _____

Date: _____

Appendix B – Supplier Details Form

CEPI completes checks on all suppliers to ensure that we are engaging in accordance with good practice and relevant legislation.

Please can you provide the following information so that we can undertake these checks as soon as possible.

Organisation Name:			
Name of Key Contact:			
Organisation Registration Number:			
Jurisdiction of Registration:			
Date of Registration:		Number of Employees:	
Registered Address:			
Telephone:		Mobile:	
Email address:			
Website:			
Completed by:		Date:	

Please ensure that you inform CEPI if any of the parameters above change.

For office use only:

Supplier, PE and PAYE Check Comments:			
OK / not OK:		Completed by:	
Signed:		Date:	