



Programme coordination and analytical support for Lassa epidemiology studies in west Africa

Request for Proposals

Background

The Coalition for Epidemic Preparedness Innovations (CEPI) manages a portfolio of vaccines at various stages of development, targeting pathogens selected from the [WHO Blueprint list of priority diseases](#). Some vaccine candidates against Lassa fever have entered Phase I clinical trials in 2019 (with more planned in 2020). Subsequently, phase 2a safety / immunogenicity trials will be conducted in target populations.

To prepare for advanced stage clinical trials investigating vaccine efficacy in the field, suitable epidemiological data is needed to support trial design and strengthen site and investigator capacity to conduct these trials.

CEPI is therefore providing grants for epidemiological studies that will contribute these data. These two-year prospective studies will be performed in five countries in West Africa (Nigeria, Benin, Sierra Leone, Liberia, and Guinea), with the primary objective of assessing incidence of symptomatic Lassa fever cases as well as incidence of Lassa virus infection as well as secondary objectives informing additional aspects of future phase 2b/3 clinical trials.

In CEPI's role as the facilitator and funder for these epidemiology studies, CEPI now seeks to identify a qualified coordinating institution to support this large-scale, five-country programme from the planning and implementation phases through to close-out. This institution will develop and implement a coordination framework ensuring robust oversight, performance and capacity monitoring, and quality management of all activities across the five study countries for the duration of the Lassa epidemiology programme.

The identified institution will also facilitate the harmonized planning and analysis of study data, including the development of a programme statistical analysis plan and conduct of all programme-level analyses. Finally, the institution will provide support as needed in training curriculum development and provision, including harmonization of content and delivery across study consortia.

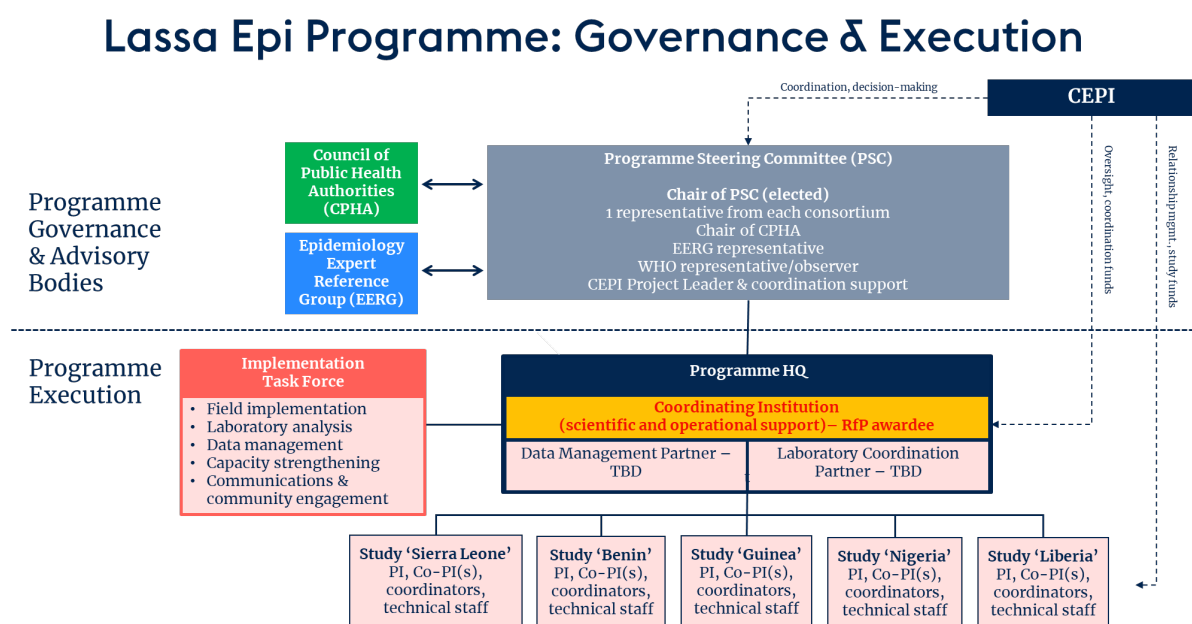
Programme overview

The Lassa epidemiology programme is currently in its final planning stages, with nearly all major partners signed. It is based on a core protocol which will be implemented in a set of studies conducted by five independent country consortia. These consortia are governed at the programme level by a Programme Steering Committee (PSC) comprised of representatives from the study country consortia, key scientific experts, and public health authorities in the study countries. Two advisory bodies provide expert epidemiological and strategic-level public health guidance to the PSC.

At the programme execution level, a Programme HQ will be created, comprised of a lead coordinating institution and two implementing partners (one for data management and another for laboratory support). An Implementation Task Force consisting of subject matter experts and country representatives will support the Programme HQ in the execution of key implementation workstreams. Each country consortium is then responsible for the conduct of their respective epidemiological study.

The following graphic describes the relationship of the governance bodies with the entities responsible for programme execution. This RfP seeks to identify a **coordinating institution** capable of managing multiple aspects of programme implementation, under the direction of the Programme Steering Committee and CEPI, and in collaboration with CEPI key partners and the study consortia. As indicated in yellow, the RfP awardee will manage the Programme HQ function, assuming a central role in ensuring the successful execution of the programme.

Figure 1. Programme governance and execution model



Scope of tender

Roles

As indicated in the diagram above, the Programme HQ is comprised of three key implementing partners servicing:

- i) overall programme coordination (the RfP awardee),
- ii) data management (including platform development, training, and support), and

- iii) laboratory support (including SOP harmonization, laboratory staff training, and field support).

The latter two partners are being contracted separately by CEPI. The RfP awardee will be responsible for coordinating among these entities to ensure harmonized execution of all activities.

The table below specifies which programme coordination roles are envisioned to be led by the coordinating institution during the ongoing transition from programme planning to implementation.

These roles are defined at the programme level; country consortia are principally responsible for the implementation of these duties at the study level, with support as needed from the RfP awardee.

Table 1. Programme coordination roles

	CEPI	Coordinating institution (selected through RfP)
Programme implementation oversight		
Monitoring & evaluation ¹	X	
Programme management (from implementation through analysis/close-out) ²		X
Quality management to ensure quality data is generated across programme (via monitoring visits, process reviews, regular quality reports, etc.) ³		X
Financial oversight		
Contract/grant management	X	
Financial evaluations and audits	X	
Regular programme financial monitoring		X
Procurement		
Contracting and centralized procurement ⁴	X	
Logistics and delivery support ⁵		X
Policies and procedures		
Policies and procedures development ⁶	X	
Policies and procedures implementation ⁷		X
Governance & relationship management		
Advise and manage Programme Steering Committee	X	
Report to and implement decisions made by Programme Steering Committee		X

¹Refers to strategic-level M&E activities including tracking of overall programme metrics and relevant CEPI performance indicators.

²Duties include harmonization and tracking of individual per-awardee project plans and reporting of overall programme progress and issues to CEPI project lead.

³The RfP awardee should engage other implementing partners as needed to satisfy all quality management needs for the programme.

⁴Centralized procurement refers to any study resource that is procured directly by CEPI instead of the study countries to ensure commonality of product quality and supply, such as diagnostic kits.

⁵The RfP awardee should engage other implementing partners as needed to address logistics and delivery issues.

⁶Includes standard operating procedures, study manual, overall project quality management plan, etc. To be developed by CEPI with input from all key partners including RfP awardee.

⁷To be supported by other partners depending on workstream (i.e., data management plan to be implemented by DM partner).

In addition to the overall programme coordination role, the awardee will also facilitate the harmonized planning and analysis of study data, including the development of a programme statistical analysis plan and conduct of all programme-level analyses. Statistical analyses are to be planned and conducted in close coordination with the data management partner.

Finally, the institution will provide support as needed in training curriculum development and provision, including harmonization of content and delivery across study consortia. While many trainings are conducted independently by the study consortia, certain trainings may benefit from harmonized curricula and centralized delivery. The awardee may be requested to provide support to these training activities given their expected regional presence and expert capacity. (Data management and laboratory trainings will be coordinated by the respective DM and laboratory partners.)

Duties

The successful applicant will undertake a broad range of duties, including but not limited to those listed below. The duties below are derived from the Roles section above, consolidated into three workstreams.

Programme coordination duties

- Manage existing scientific workstreams, including responses to ethics review feedback on core study documents (protocol, case report form, etc.)
- Coordinate (or complete based on prior work by CEPI) the development of a Study Manual and Study Monitoring Plan
- Execute quality management activities including site monitoring, provide monitoring reports; identify and communicate data and programme quality issues to CEPI and Programme Steering Committee
- Support CEPI on the financial monitoring and follow-up of projects, e.g. through site visits when needed, and support on other finance related tasks if necessary
- Communicate scientific issues and problems to the Programme Steering Committee and CEPI
- Coordinate all supply shipment, customs clearance, storage, and consumption of supplies at site/country level; engage laboratory support partner as needed to facilitate resolution of any laboratory supply issues

Statistical analysis duties

- Draft and coordinate (or complete based on prior work by CEPI) programme statistical analysis plan development
- In coordination with data management partner, harmonize per-country data management and statistical analysis plans (i.e., ensure that planned per-country analyses are coherent with programme statistical analysis plan, data management plan, data capture forms, and database structure)
- Conduct the central data analysis and post-hoc exploration of the central database to inform future vaccine field efficacy trial design

Training support duties

- As needed, support training curriculum development / sourcing, including harmonization of content and delivery across study consortia
- As needed, conduct and/or coordinate staff training activities via appropriate delivery methods (e.g. online / distance learning, centralized regional trainings / training-of-trainers, on-site training, etc.)

The trainings which may require the above support from the RfP awardee include but are not necessarily limited to:

- Community engagement
- Risk communication and counselling
- Study protocol orientation

- Project management methods and coordination (to ensure awardee receives timely and regular updates on project status in an appropriate format)

Eligibility criteria

Applicants must meet the following minimum eligibility criteria:

- Able to address all of the roles and duties explicitly defined in this RfP, as well as all additional duties identified by the applicant as necessary to be undertaken in assuming the coordinating institution role.
- While an applicant is permitted to specify co-applicants in their submission to facilitate completion of all roles and duties specified in this RfP, **all** co-applicants must be identified from within CEPI's existing programme partner list. This is required in order to minimize the number of external entities involved in programme coordination. The partner list will be provided as part of the application form package (see Submission Guidelines below).
- Willingness to accept oversight by both CEPI and a Programme Steering Committee comprised of representatives from the study country consortia, key scientific experts, and public health authorities in the study countries
- Possess capacity to identify and correct issues and risks occurring at country / site levels; management of programme-level risk register
- Possess expertise in planning, implementation and conduct of large multi-country clinical or (preferably) field epidemiological studies
- Documented experience / track record in West Africa, preferably in conduct / oversight of large-scale epidemiological studies and clinical trials
- Capacity to conduct all activities, including document / curriculum development as necessary, in English and French
- Able to accept expedited timeframe for contracting and onboarding
- (Preferable) Expertise in Lassa and/or other viral haemorrhagic fevers

Proposal requirements

Technical proposal

All applicants must use a CEPI template, provided upon request (see Submission Guidelines below).

Using this template, applicants should provide the following information:

- Overview of applicant key competencies and track record in relevant/related projects and contexts
- Applicant capacity to achieve tasks as outlined above, independently or with support from existing programme partners as listed in the application package provided to applicants
- Proposed concept and work plan, including:
 - An organization chart and RACI matrix framing the applicant's interactions with CEPI and partners within the governance and execution framework defined in the Programme Overview section above
 - A narrative description and timeline graphic (Gantt chart or similar) explaining how the applicant intends to operationalize all roles and duties defined in the RfP (including programme coordination, statistical analysis, and training support)
- Procedures for quality control of deliverables (reports, documents, drawings), including those prepared by associates, sub-awardees and local partners, before submission to CEPI
- CVs/biosketches for principals
- Risk register with appropriate risk mitigations

Financial proposal

All applicants must complete the CEPI Overall Budget template and Budget Narrative (see Submission Guidelines below). This should include full details of the financial offer, capturing fixed costs and any variable costs.

Costs should be presented in the following categories:

- **Personnel:** salary costs for the estimated time to be spent on the CEPI project per period, for staff on your organization's payroll. Time should be expressed as a fraction of a full work year.
- **Travel:** any associated travel costs on the CEPI project for your organization's personnel. Travel costs must be in accordance with [CEPI's travel policy](#). You should provide details of the number of people travelling and duration / frequency of the trip(s).
- **Consultants:** costs for any individuals not on your organization's payroll (for example, a subject matter expert brought to train staff on data analysis platforms). You may state consultant fees as hourly/daily/monthly rates or as a fixed fee. Travel costs for consultants can also be included in this section.
- **Other direct costs:** consumables, materials and other items not meeting the definition of equipment.
- **Equipment:** capital expenditure on items with a unit cost greater than \$250 and with a useful life of more than one year.
- **Sub-awards:** costs for organizations that will receive a sub-grant or sub-contract to perform part of the activities.

Note: All applicants should be able to fulfill all coordination roles and duties specified in this RfP independently or with support only from existing programme partners as listed in the application package provided to applicants. This is required in order to minimize the number of external entities involved in programme coordination. Any sub-awards will therefore be evaluated in part on the role of the sub-awardee with respect to the centralized programme coordination framework.

Evaluation criteria

We will assess the proposals against the information presented per the proposal requirements, eligibility criteria, and scope of tender detailed above.

A service contract will be awarded by CEPI Norway (HQ) to the bidder who has demonstrated ability to successfully deliver against the scope at the best value for CEPI. All proposals will be assessed based upon the following criteria:

Technical criteria (70%)

- a) Coordination framework appropriateness and feasibility
- b) Demonstrated understanding of and ability / capacity to operationalize all duties and roles specified
- c) Appropriate methods proposed for undertaking the work
- d) Demonstrated ability to develop and perform necessary programme statistical analyses
- e) Qualifications of the team as defined in eligibility criteria, including CVs of key experts

Financial criteria (30%)

- a) Overall budget amount
- b) Realistic costing of the different activity categories proposed in the scope of tender

If the service provider would like CEPI to consider any other criteria during the decision-making process, it should notify CEPI in writing when confirming intent to participate. **Any agreed-upon additional criteria will be communicated to all applicants by 10 January.**

Next steps and timeline

CEPI will contact successful applicants once it has reviewed all submitted proposals.

CEPI intends to implement framework agreements with the successful applicant(s), to cover potential future provision of services as detailed in this request for proposals.

Successful applicants with pre-existing grants from CEPI to conduct a defined scope of work will not have that work affected by the new framework agreements.

Activity	Date
Requests for proposals advertised	20 December
Deadline for email request for application materials	6 January
Deadline for proposal submission	31 January
Selection process completed and awardee notified	14 February
Contract negotiation and due diligence	17 February
Contract execution	3 March

Submission guidelines

If you are considering submitting a proposal, please send an email to epidemiology@cepi.net by **6 January 2020**.

You will receive a response with the following documents:

- Application form;
- Budget template (Excel);
- Budget narrative form;
- List of current project partners (to aid in determining whether to include co-applicants or sub-awardees); and
- Lassa epi programme core protocol.

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

- **Submissions must be sent to tenders@cepi.net and received by 31 January 2020 23:59 Central European Time.** We encourage you to submit well in advance of the deadline.
- 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 epidemiology@cepi.net. The CEPI secretariat will address your questions within the shortest possible timeframe. Questions and responses that are relevant for all applicants will be published anonymized as FAQs on our website (<https://cepi.net/tenders/>) on **10 January 2020**. Please note that CEPI offices are closed between 23 December 2019 and 02 January 2020 so questions received during this period will not be answered until offices re-open.

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.

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 Third Party Code of Conduct, available on [CEPI's website](#).

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 infrastructure and/or training 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 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.