Request for Information:
Phase 1 Clinical Trial Capacity in Africa for Bundibugyo Ebolavirus Vaccines

CEPI's Research Preparedness Program seeks to identify Phase 1 clinical trial units across the African continent, for the possibility to conduct phase I clinical trials of Bundibugyo Ebolavirus vaccine candidates.

CEPI is requesting information from clinical research institutions across Africa capable of and interested in conducting rigorous, ICH-GCP-compliant Phase I safety and immunogenicity trials for epidemic vaccine candidates, including against Bundibugyo Ebolavirus. Information gathered will form the basis for potential partnerships to conduct Phase I trials in support of CEPI's 100 Days Mission. CEPI will compile information in a dashboard and share it with vaccine developers. This document describes the scope, requirements, and submission process for this Request for Information (RFI). The deadline is **26 June 2026 at 17:00 CET**. CEPI reviews information received on their merits against the stated criteria and portfolio priorities.

Introduction

On 15 May 2026, the Democratic Republic of the Congo and Uganda declared an outbreak of Bundibugyo virus disease (BDBV), which the WHO Director-General designated as a public health emergency of international concern on 17 May 2026. This represents the first major outbreak of Bundibugyo Ebolavirus in over a decade and underscores the pathogen's unpredictable threat to continental and global health security. As of 6 June, a total of 515 confirmed cases, with 91 deaths among these confirmed cases, have been reported from the Democratic Republic of the Congo; Uganda has reported 19 confirmed cases including two deaths, as well as one probable case who has died deaths have been reported (https://www.who.int/emergencies/disease-outbreak-news/item/2026-DON606). The outbreak is concentrated in Ituri Province in northeastern Democratic Republic of the Congo. The epidemic is caused by the Bundibugyo ebolavirus—a strain for which existing Ebola treatments, developed for the Zaire ebolavirus, are ineffective and for which currently no authorized vaccines are available.

Rigorous Phase I clinical evaluation is the critical gateway to advancing promising BDBV vaccine candidates toward regulatory approval and deployment. Phase I trials establish essential data on safety, tolerability, and preliminary immunogenicity—the foundational

evidence required before Phase II and Phase III evaluations can proceed. However, historically, vaccine development has relied on clinical trial infrastructure located outside the region, creating systemic deficits and reduced participation of African research communities. To overcome this bottleneck and strengthen continental clinical research capacity, CEPI is establishing a clinical trial site dashboard and will share compiled information of experienced Phase I clinical trial units with vaccine developers based on trial requirements and site capabilities. CEPI expects to provide financial support to a limited number of vaccine candidates. This approach will facilitate rapid, high-quality data generation while positioning African researchers and institutions as central partners in vaccine development—essential both for accelerating the 100 Days Mission and for building sustainable, locally-owned health innovation capacity on the continent.

The Coalition for Epidemic Preparedness Innovations (CEPI) is an international coalition of governments, academic, philanthropic, private, public, and intergovernmental institutions united by a vision to eliminate epidemics and pandemics as threats to humanity. CEPI's mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats, ensuring they are accessible to all people in need through its '100 Days Mission'—a commitment to deliver vaccines ready for initial regulatory authorization and manufacturing at scale within 100 days of recognition of a pandemic pathogen.

I. Objectives and scope of this Request for Information (RFI)

The objective of this RFI is to identify clinical research institutions across Africa with the capability, experience, and commitment to conduct rigorous, ICH-GCP-compliant Phase I safety and immunogenicity trials, including First-in-Human studies for epidemic vaccine candidates. Experienced Phase I clinical trial units are requested to elaborate on their personnel qualifications, regulatory relationships, and institutional capacity as described in section 3. The data provided will be reviewed by a CEPI expert panel and used to establish a clinical trial site dashboard.

Vaccine developers seeking to conduct Phase I trials will be invited to access the CEPI clinical trial site dashboard and identify potential partners based on geographic location, population characteristics, and site-specific capabilities. Importantly, any contractual agreement would be established between the clinical trial unit and the developer. There is no CEPI funding associated with this Request for Information (*CEPI may provide selected units and developers with targeted technical support, regulatory guidance, data management expertise, and capacity strengthening throughout the trial process but this will not be decided upon during this stage of applicant evaluation).*

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

CEPI invites submissions from individual clinical research institutions in Africa with experience in conducting Phase I trials. Suitable organisations include non-profit or for-profit entities, product development partnerships, government research organisations, academic institutions, or intergovernmental organisations. CEPI is interested in phase I units

that can demonstrate ability to conduct Phase I safety and immunogenicity trials for investigational vaccines or biologics in compliance with ICH GCP E6, a clear commitment to regulatory partnership with national health authorities, robust community engagement strategies, and a plan for sustainable capacity strengthening beyond CEPI funding. Organisations should have in place—or demonstrate capacity to rapidly establish—the personnel, infrastructure, and governance structures necessary to conduct rigorous Phase I trials in compliance with international standards and relevant national regulations.

3. Information requested

To submit a response to this Request for Information, please complete the questionnaire provided. We seek information on the following:

1. Unit Overview

Provide a brief description of your organisation and Phase I clinical trial unit, including:

- Institution, host organisation, location and website
- Years of operation
- Therapeutic areas of expertise
- Experience with healthy volunteer and/or patient-based Phase I studies
- Overview of any experience with vaccine trials for highly contagious infectious disease pathogens (e.g., Ebola, measles, or other WHO-priority pathogens)

2. Geographical Reach and Population Access

Please describe:

- Location of the clinical trial unit
- Access to healthy volunteers and target patient populations for recruitment
- Experience working with local communities and your community engagement approach

3. Previous Phase I Clinical Research experience

Provide information on:

- Early-phase studies conducted within the last five years incl. First-in-Human (FIH) studies, Single Ascending Dose (SAD) studies, Multiple Ascending Dose (MAD) studies, Bioavailability/bioequivalence studies, Vaccine Phase I trials, Challenge studies conducted (if applicable)
- Experience with vaccine trials for highly contagious infectious disease pathogens
- Studies conducted under sponsor, CRO, academic, or industry partnerships

4. Facilities and Infrastructure

Describe:

- Inpatient bed capacity dedicated to clinical research, outpatient facilities available
- Pharmacy facilities for investigational product handling and dispensing
- Sample processing, laboratory capabilities and biological sample storage
- Laboratory facilities available (specify BSL level or WHO equivalent) and documented infection control protocols suitable for blood borne infections (handling highly contagious pathogens)
- Emergency response and resuscitation facilities, incl. intensive care capacity or hospital referral and transfer arrangements

- Material Transfer Agreement (MTA) processes and any barriers to international sample shipment
- Electronic Data Capture (EDC) systems used (specify platform)

5. Quality Oversight

Describe:

- The quality assurance for the Phase I unit
- Standard Operating Procedures (SOPs) for critical trial functions and compliance with ICH-GCP E6(R3) guidelines for investigators
- Staff training and competency assessment processes

6. Regulatory and Ethical Compliance

Describe:

- Processes to ensure compliance with ICH-GCP standards
- Regulatory submission experience and typical timelines for review by national competent authorities
- Ethics committee submission experience and typical timelines for approval
- Commitment to supporting expedited regulatory review for phase 1 clinical trials for BDBV vaccine candidates
- Inspection history (by MHRA, FDA, EMA, or local regulators)
- Safety reporting procedures
- Any previous experience (e.g. from COVID-19) on expedited joint regulatory/ethics review processes during outbreak situations and average timelines
- Processes and experience with Investigational Product importation requirements

7. Clinical and Scientific Expertise

Provide details of:

- Principal investigator(s) and relevant experience, including experience with Phase I vaccine trials for highly contagious infectious disease pathogens
- Research physicians, Research nurses, Pharmacists and Laboratory personnel (all with documented expertise in infectious disease and biosafety protocols)
- Data management and biostatistics support (in-house or through documented partnerships)
- Medical monitoring capabilities and oversight arrangements
- Potential existing relationships with local/regional CROs

8. Participant Safety and Risk Management

Describe:

- Medical oversight arrangements
- Emergency response procedures (incl. Serious Adverse Event (SAE) management procedures), including procedures specific to highly contagious pathogen exposure
- 24-hour medical coverage availability and Hospital transfer agreements (if applicable)
- Occupational health and safety protocols specific to highly contagious infectious disease research, including staff vaccination requirements, post-exposure prophylaxis availability, and incident reporting procedures (if applicable and available)
- Data Safety Monitoring Board (DSMB) experience or commitment to DSMB engagement

Applicants are requested to describe their Phase I unit capabilities in the RFI questionnaire provided. The information received by CEPI will be shared with vaccine developers based on trial requirements, geographic location, population characteristics, and site-specific capabilities. Also, the information may be made available to the public unless respondents opt out of this as indicated on the RFI questionnaire.

Terms and conditions:

Respondents should note that CEPI is permitted to disclose the confidential information contained within their response to this Request for Information, unless they opt out of this by indicating their preference on the RFI questionnaire.

https://cepi.net/cepi-external-privacy-notice

4. Submission of information

Please submit information by using the RFI questionnaire provided (as a PDF), to AfricanPhase1RFI@cepi.net **before 17:00 CET on Friday 3 July 2026.**

5. Technical and administrative questions

Technical and administrative questions about this RFI can be submitted using this Support Form