Call for Proposals: Innovative analytical technologies to improve vaccine manufacturing speed and equitable access

CEPI is pleased to announce a new funding opportunity aimed at developing innovative analytical technologies to enhance vaccine release speed, reduce costs, and improve deployment. This document outlines the scope, requirements, and processes for submission, review, and selection for funding. Further details can be found at https://cepi.net/calls-for-proposals.

The overall objective of this Call for Proposals (CfP) is to advance analytical technologies and innovations that can support outbreak response, including making scalable and globally accessible vaccines available within 100 days of a viral outbreak being identified. This CfP aims to advance analytical technologies and innovations in analytical technologies that contribute to the goals of:

- Reducing the time of vaccine development, manufacturing and release including, but not limited to:
  - Technologies that can replace cell-based bioassays as surrogate potency alternatives
  - Alternatives to current sterility methods, to avoid reliance on growth cultures
- Reducing the current personnel costs and skill requirements for running analytics related to vaccine attributes such as Identity, Content, Integrity, Purity, Potency, or Safety.
- Globally deployable technologies for equitable access and regional testing in LMICs (Low- and Middle-Income Countries).
- Technologies that provide new characterisation insights to the priority vaccine modalities of RNA/LNP, viral vectors and protein-based vaccines.

Applicants should submit the details of their project using the application and budget templates, as described in section 6 below. Application submission is followed by eligibility assessment, peer review and due diligence, during which a more detailed project plan and project budget may be requested from applicants who advance through the process. The total budget for this CfP is $10.7M, and projects should have a timeline not exceeding 30 months (total). Two stages are involved:

- **Stage 1**: For a budget not exceeding $0.2M, for up to 12 months, an initial "proof of concept" project will demonstrate that the technology can detect a vaccine relevant analyte to the expected levels (see Pharmacopeia requirements/literature examples) of sensitivity/specificity/quantitation as required.

- **Stage 2**: Applicants with technologies that show successful proof-of-concept, either following stage 1 completion, or where existing legacy data are available, are eligible to apply for up to $0.8M for an 18-month development phase to "commercial design freeze/ready for validation". It is expected that the successful applicants will be able to demonstrate equivalence data, against the traditional method, where applicable, using samples from in-process manufacturing, drug substance and/or drug product, which CEPI can assist to source.

This CfP is open for applications from 1st May 2025. An application may be submitted at any time and the review process will involve regular reviews, at least quarterly with the first round on 30th June 2025, throughout the 12-month application period. The call may be extended, amended or reopened depending on programmatic need.

1. Introduction

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. CEPI operates under the laws of Norway as a non-profit international association and has offices in Oslo (HQ), London, and Washington, DC. More details about CEPI and our mission can be found on our website: www.cepi.net.

Following the outbreak of COVID-19, which caused significant morbidity, mortality, and disruption of normal life around the world, CEPI has set out a 100-Days Mission aspiration to make vaccines available more rapidly in response to an outbreak of a new pathogen, referred to as Disease X. The aim is to have vaccines ready for initial authorisation and manufacturing at scale within 100 days of recognition of a pandemic pathogen, when justified by the severity of the situation. Coupled with improved surveillance, and swift use of non-pharmaceutical interventions, a vaccine developed in 100 days could defuse the threat of a new pathogen with pandemic potential.

Previously, CEPI published a Call for Proposals on vaccine manufacturability focused on speed, for technologies and innovations to accelerate the manufacturing of clinical trial material, in response to a new outbreak. Rapid manufacturing needs to be supported with analytics that can monitor the process and release the product at speed and scale. This call invites such proposals, to advance and implement innovative analytical technologies, contributing to speed of development, regional manufacturing, and equitable access to vaccines.

2. Objectives

The overall objective is to advance broadly applicable analytical **platform technologies** and innovations that can support making scalable and globally accessible vaccines available within 100 days of a viral outbreak. Two focus areas (FA) have been defined related to Speed & Access and Characterisation. This Call for Proposals seeks platform technologies that can be deployed across multiple vaccine candidates and **multiple CQAs/assays**, rather than solutions limited to a single method, and that are largely agnostic to vaccine modality (e.g., RNA/LNP, viral vectors, protein-based vaccines).

- Reducing the current **time** required to release manufactured vaccine product by enabling faster, more automated, and more widely deployable **platform analytics** (e.g., modular instruments and workflows that can be configured for different assays).
- Minimising **assay panel configuration** and deployment time by reducing dependence on bespoke biological reagents and method-by-method development, and enabling rapid adaptation of a platform to new targets/pathogens.
- Addressing the complexity and operator time required to execute analytics by prioritising platforms with improved usability, automation, and standardisation to reduce FTE costs, improve tech transferability, and improve quality through reduced human error.
- Providing improved product understanding through platform technologies that expand characterisation capability and generate actionable insights across vaccine modalities (e.g., enabling richer identity, purity, integrity, potency, and safety assessment with the same underlying platform).

3. Scope of the call

Applicants are encouraged to consider how their proposed **analytical platform technology** could be applied across the vaccine modalities below, and across multiple quality attributes and assay types (rather than addressing a single method in isolation):

- RNA vaccines.
- Protein based vaccines (i.e. protein subunits, VLPs, Mosaics and adjuvanted products).
- Viral vector vaccines.

The following link may help evaluate technological fit:
https://www.usp.org/sites/default/files/usp/document/our-impact/covid-19/vaccine-quality-assessment-toolkits-02-2022.pdf

Two focus areas have been defined, related to Speed & Access, and Characterisation:

- **Focus Area a: Minimising time/cost to release/develop vaccine:**
    - **Platform technologies that minimise vaccine release timelines:** Priority use-cases include sterility and mycoplasma testing (ideally locally deployable) and alternatives to slow, culture-dependent or cell-based release assays; however, proposals should be positioned as broadly reusable platforms that can support multiple release assays over time.
    - **Platform technologies that reduce the speed/cost/complexity of biological analytics:** Examples of platform classes include PCR (qPCR/dPCR), sequencing, immunoassay/ELISA platforms, bioassay platforms, flow cytometry, and biosensors for rapid PAT (in-process analytical testing). Platforms should be applicable across a broad range of CQAs and should be adaptable to different vaccine modalities.
    - **Platform solutions that reduce reliance on bespoke biological reagents:** This includes approaches that accelerate or avoid custom reagent generation (e.g., antibodies, reference reagents, cell lines), and/or enable standardised, quickly configurable assay panels for potency and identity (and other attributes) on a common platform.

Focus Area b: Vaccine Characterisation

- Platform technologies for characterising vaccine products are prioritised, including those applicable to mRNA/LNP, protein sub-units and viral vectors. Characterisation platforms should generate richer, transferable datasets that support comparability studies, process understanding, and tech transfer to LMIC facilities, ideally using standardised workflows that can be replicated across sites.

Technologies must be applicable to one or more proven vaccine modalities (RNA/LNP, Viral vector or Protein-based vaccines). **Technology platforms** should be able to benefit multiple vaccine candidates and be configurable for a range of CQAs/assay needs, including future development against novel viral threats (e.g., Disease X).

Activities in scope:

- Activities related to the development, optimization and repurposing of analytical platforms for vaccine manufacture, from sectors such as IVD/Defence/Water/Food etc, to demonstrate potential for implementation in a vaccine development and/or manufacturing campaign.
- Activities related to the implementation of in-line, at-line or near-line analytics/sensors for real time in-process control and monitoring of the manufacturing process.
- Comparability studies between the new technology and the established methods.

- Generation/supply of vaccine manufacturing in-process, drug substance and drug product mock samples.

Activities out of scope:

- Development of an analytical "Idea/concept" is out of scope. The proposed technology must have demonstrated that it works.
- Technologies that cannot be associated to known quality attributes of a vaccine.
- Technologies focused on manufacturing methods.
- Platforms that cannot show significant reduction in speed, CoGs (Cost of Goods) or FTE (Full Time Equivalent) burden.

4. Eligibility criteria

Applicants (individual organizations or consortia) developing analytical technologies, must provide information in their application to show that their proposal meets the following eligibility criteria:

- The technology is either already available on the market for applications other than vaccines or can be commercialized within three years, has shown that it works and can produce useful data for vaccine proof-of-concept purposes or is already used for other purposes and can be adapted for vaccine production.
- The technology substantially reduces the time and/or FTE burden required to generate a valid result from a sample (Focus area a).
- The technology reduces the reliance for the high skill level required, to run the traditional method (Focus area a).
- The technology can be developed into a single box or modular solution.
- The application describes a development plan to advance the technology, with a timeline not exceeding 30 months and a budget not exceeding $1 M.
- Applicants for novel characterisation (Focus Area b) must demonstrate what additional insights the technology brings, that aren't currently available and justify why this may be important.

In addition, the applicant should confirm:

- Willingness to allow use of the innovative technology to develop vaccines, either directly or through a jointly agreed third party, against high priority pathogens as part of CEPI's strategy to respond rapidly to future outbreaks.
- Willingness to commit to CEPI´s Equitable Access principles, which may include rights to intellectual property for the technology, and access to GMP-grade raw materials, or a clear pathway to achieve such access.
- Willingness to share data, samples, methods, etc. and to use standard methods and international reagent standards, under the appropriate confidentiality agreements.
- Willingness to engage with regulatory agencies, to discuss the innovative technology.
- Willingness to comply with applicable CEPI policies which can be found on CEPI's website.

5. Review criteria

Applications that have met the eligibility criteria described under section 4 will be assessed against the following criteria.

Criterion	Definition
FA(a): Minimising time/cost to release/develop vaccine	• Reduction in product release timelines. • Reduction in time required to develop analytical methods. • Reduction in user time needed to generate a valid result. • Technologies enabling rapid refinement/adaptation and of the assay to other pathogens is desirable.
FA(b): Vaccine Characterisation	• Platform technologies that provide novel and suitable characterisation of priority vaccine modalities (mRNA/LNP, viral vectors, and protein-based vaccines). Platforms that can be applied across **multiple CQAs/assays** and that improve comparability, tech transfer, and decision-making will be prioritised. •
Innovativeness	• Extent to which the technology is innovative and transformative, offering a substantial, versus an incremental advancement over current technologies is desirable.
Route to implementation	• Extent to which the technology has been proven with relevant vaccine candidates or products. • Extent to which the project proposal includes relevant vaccine candidates. • Feasibility of the development plan to advance the technology to the next stage, addressing key data gaps towards implementation. • Plausible path to regulatory approval for use of the technology in clinical trials and for marketed/authorized vaccines.
Partnership	• Capabilities, capacity and experience of the applicant / consortium to meet the above criteria. • Willingness to make the technology available for vaccines against high priority pathogens as part of CEPI's strategy to respond rapidly to future outbreaks.

CEPI evaluates proposals based on their merit, alignment with the stated eligibility criteria, and their fit within CEPI's overall project portfolio. Please note that at any stage of the funding call, CEPI, at its sole discretion, retains the right to select any applicant it deems appropriate and even if an applicant meets all the stated criteria, CEPI reserves the right not to select them for the opportunity.

6. Applicant guidelines

Applicants should inform CEPI of their intent to apply as soon as possible by registering on CEPI's secure online portal (click on 'Register now' on the portal CfP page), ensuring to specify the relevant CfP. Applicants should use the application template for this call, which can be downloaded from the portal or the CEPI website. Proposals should include essential evidence as required in the template, and contain sufficient detail for review of the proposed technology development. Any claims made within the proposal must be supported by evidence.

For submissions to be accepted, applications must be submitted via the portal and fulfil all the following criteria:

- All application and applicant eligibility criteria must be met.
- Applications must not exceed the maximum page length as defined in the template.
- Completed application templates must be uploaded using the CEPI portal.
- All communication with CEPI and application documents must be in English.
- All budget amounts must be submitted in US dollars.

Submissions that do not meet all the above criteria will generally not be considered for review. Applications that fall outside the scope of a Focus Area will also be deemed ineligible for review. Regardless of eligibility at any stage of a funding call, CEPI reserves the right to consider and to decline proposals at its discretion based on programmatic needs and priorities.

Following a positive review, developers will be asked to provide CEPI with an Integrated Technology Development Plan and a more detailed project budget, and to answer Due Diligence questions related to technical, financial, integrity, business development and equitable access aspects of the project.

It is the responsibility of the applicant to ensure that all requested documents are submitted and to contact CEPI via innovations.cfp@cepi.net in advance of the submission deadline in case there are any issues regarding the application submission process.

All applications will be stored in a restricted access repository. Personal data included in applications will be handled according to CEPI's Privacy Notice https://cepi.net/cepi-external-privacy-notice. All project materials will be considered confidential and proprietary. Any costs incurred by applicants in the development and submission of proposals to this CfP will not be reimbursed by CEPI.

For any questions related to this Call for Proposals, technical or administrative, please contact innovations.cfp@cepi.net.

7. Award conditions

Before submitting an application, applicants should take note of two Award conditions. The first is that each Awardee adheres to CEPI's policies, which can be found on CEPI's website. The second is that any funding is dependent on the signing of an Award Agreement, which provides the terms and conditions under which the Award will be made, in line with CEPI's Third Party Code, which can be found on CEPI's website.

CEPI is committed to achieving equitable access to all CEPI-supported programmes including vaccines, platforms, data, results, and materials. Specifically, equitable access to vaccines in the context of an outbreak, epidemic or pandemic means that appropriate products are first available to populations when and where they are needed, regardless of ability to pay. To ensure that CEPI delivers on its commitment to equitable access, CEPI must include access considerations as a component of any agreement with an Awardee.

Applicants unable or unwilling to meet these requirements should not respond to this CfP.