

## Overview of CEPI's "CfP3i" Call for RVF and CHIK Vaccine Proposals

**CEPI's vision is a world in which epidemics are no longer a threat to humanity. TOGETHER** we can move a step further towards making this vision a reality by accelerating development of vaccines against RVF and CHIK and providing equitable access to resulting vaccines for those who need them.

**OPPORTUNITIES AND CHALLENGES:** Your success as an awardee is vitally important to CEPI and its mission. This CfP-3i Programme offers the chance to **progress your field of expertise and be recognized for it**, with **non-dilutive funding** (of both direct and a proportion of indirect costs) and the opportunity to **own and use all resulting IP, data and materials**. Projects under the CfP-3i Programme may lead to the manufacture of an investigational stockpile of vaccine at CEPI/other funder's cost and ultimately licensure and stockpile of an approved product.

**CEPI'S POLICIES:** CEPI has adopted policies and procedures that align with our unique role in global health and the requirements of CEPI's donors. Your obligations as a CEPI awardee reflect our commitments to:

- ❖ **Equitable access to the outputs of all CEPI-supported programmes including vaccines, platforms, data, results, and materials.**
  - Equitable access to epidemic vaccines in the context of an outbreak means that appropriate vaccines are first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay. CEPI facilitates equitable access to epidemic vaccines by:
    - Funding the development of vaccines and maintaining investigational stockpiles, to be used free of charge in clinical studies when an outbreak occurs.
    - Coordinating with others in the global health community to facilitate licensure of vaccines funded by CEPI, including by securing resources for pivotal clinical trials.
    - Collaborating with others in the global health community to ensure the procurement, allocation, deployment and administration of licensed vaccines to protect global health, at a price that does not limit equitable access and is sustainable to the manufacturer.
  - For CfP-3i that means:
    - Planning for you to see the Project through and have an opportunity to undertake future funded activities.
    - Agreeing to the selection of a back-up, trusted collaborator in case you are unavailable or cannot meet capacity requirements. We refer to these arrangements as a Public Health Licence permitting use of Project Results and Enabling Technology to develop,

manufacture and market a Product for use in preparation for or response to an Outbreak or Increased Outbreak Preparation Need.

- Committing to make any final vaccine product partially developed with CEPI funding and manufactured after scale-up available to those who need it (including in Low and Middle Income Countries) at a price which is sustainable for the manufacturer and still consistent with Equitable Access to the Product. When assessing cost of goods, that assessment should be consistent with The Bill & Melinda Gates Foundation's approach to determining appropriate product costs found here:

[https://docs.gatesfoundation.org/Documents/Production\\_Economics\\_Vaccines\\_2016.pdf](https://docs.gatesfoundation.org/Documents/Production_Economics_Vaccines_2016.pdf)

- Using Sub-Awardees in “Low and Middle Income Countries” to build infrastructure and personnel experience and skills in the relevant territory.

❖ **Open access to data, results and publications arising from its funding and facilitate access to materials to accelerate vaccine development.**

➤ For CfP-3i that means:

- Publishing details of clinical studies before subject recruitment.
- Submitting clinical data and results for publication within 12 months after study completion.
- Subject to confidentiality, enabling CEPI, through a neutral third party laboratory to assess data and samples for the comparison of equivalent vaccine candidates within CEPI's portfolio.
- Making a copy of the final manuscript of all research publications freely available upon acceptance for publication or immediately after publication;
- Sharing Project Data, as agreed, with other awardees under the CfP-3i Programme relevant to issues such as disease-specific assays, animal models or diagnostics and epidemic preparedness mechanisms including stockpiling, subject to reasonable protection for Awardee's rights under this Agreement.
- Sharing Project Materials with CEPI's independent third party assessor to enable the comparison of vaccine candidates in the funded disease area.

❖ **Compliance and fiscal prudence**

➤ CEPI was created by international governmental and philanthropic donors and has a responsibility to be a good steward of those funds. Some of those funds come with obligations related to compliance and fiscal prudence, in particular:

- CEPI will only fund if you are in good financial standing.
- to ensure the funds are used for the greatest benefit to the Project and that awardees must abide by CEPI's procurement and anti-corruption policies.
- the Budget will not automatically be increased.
- [http://cepi.net/sites/default/files/CEPI%20eligible%20cost%20guidance\\_Version%2029\\_06\\_2018\\_1.pdf](http://cepi.net/sites/default/files/CEPI%20eligible%20cost%20guidance_Version%2029_06_2018_1.pdf)

➤ Commercial benefit sharing - Although CEPI's awards are expected to result in vaccines for Outbreaks, there may be some markets in which Project Results will have commercial value,

for example, in the production of vaccines or other products appropriate for non-Outbreak purposes. Under CEPI's policies, the benefits of any such commercial uses ("Commercial Benefits") will be shared with CEPI – whether in the form of revenue shared with CEPI as a way to support CEPI's future awards or through a balance struck in relation to Equitable Access. In determining appropriate Commercial Benefits, CEPI will work with Awardee to ensure that the risks, costs and benefits of product development and commercialization are shared proportionately.

You likely have formal or informal policies within your organization designed to safeguard your own mission. CFP3i may challenge you to revisit the reasons for those policies in a CEPI context. CEPI encourages you to share those reasons with the CEPI team which has put in place agreements for over 87% of successful product development focused projects with industry and non-profits including academic institutions in ways that respect both CEPI's policies and those of its awardee organisations.