

## Advancing Equitable Access to epidemic vaccines through CEPI's vaccine and platform development agreements

### Introduction

This document describes how CEPI is advancing equitable access to the epidemic vaccines funded through its partnering agreements. CEPI's mission is to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people, especially the poor and disadvantaged, during outbreaks. Our partnering agreements address how the vaccines will be first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay. It is the people in Affected Territories (defined as a geographic area where an outbreak occurs or is anticipated) who are the central focus of our work. CEPI's commitment to equitable access to these vaccines is at the heart of our work.

To date, CEPI has established 11 partnering agreements with private-sector, public-sector, and academic institutions around the world, with 21 vaccines now under development (see appendix). To date, we have vaccines under development against MERS-CoV, Nipah virus, and Lassa virus. In January 2019, we launched a new call for proposals to advance vaccines against Rift Valley Fever and Chikungunya viruses. Equitable access to epidemic vaccines by people in Affected Territories is woven into each of those agreements and means that the vaccines developed through CEPI funding will be first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of the recipients' ability to pay.

The key equitable access-related provisions in our partnering agreements are:

- 1) **Access to vaccine products and platforms.** An investigational stockpile of vaccines having completed Phase II clinical trials is established and is available for distribution free of charge upon the occurrence of a disease outbreak or for use in clinical trials, as needed. We also include contractual obligations to expand or replenish stockpiles as needed and to ensure access to vaccines if they successfully complete the necessary field efficacy trials. Those access conditions include agreed methodologies to determine the cost of vaccines and their price.
- 2) **Project continuity.** CEPI must be able to finish projects we start and to ensure that the equitable access obligations are met. We therefore include provisions that enable us to continue work on a project even in instances where our original partner is unable or unwilling to follow through on the agreed steps to develop the vaccines or to meet the equitable access obligations.
- 3) **Sharing of commercial returns.** Our funding focusses on the development of vaccines and ensuring their availability to end an outbreak or curtail an epidemic. In some cases, however, our funding may lead to the development of technology having some broader use or that otherwise might lead to commercial returns to our awardees. We establish mechanisms for determining and sharing such commercial returns to ensure that CEPI secures the full value of what is created from our funding and is able to reinvest those funds into other projects.
- 4) **Data sharing and sample sharing/transparency.** Providing public access to the outputs of the research we fund can accelerate scientific research in our field. We thus ensure the sharing of data and samples arising from our funding by requiring "open access" to publications, access to data arising from research, and access to biological samples—all subject to ethical constraints, such as the need to protect personal privacy.
- 5) **Monitoring implementation of Equitable Access.** We actively manage both the scientific progress of the projects we fund and how our equitable access requirements are being implemented in practice. We require partners to regularly report on what they have done to



date or to look ahead as to what they will do to meet vaccine stockpiling and other equitable access requirements.

All of the foregoing provisions are implemented in our agreements and what follows is a more detailed explanation of how we do so.

The appendix outlines the approaches we have taken in each of our partnering agreements to implement key equitable access provisions.

## Summary of CEPI partnering agreements

Two calls for proposals (CfPs) have been concluded: CfP1 for vaccine development against Lassa, MERS, and Nipah and CfP2 for development of platform technologies that can be deployed quickly against known and unknown pathogens (also referred to as Disease X). These CfPs have resulted in 11 partnering agreements with private-sector, public-sector, and academic institutions around the world, with 21 vaccines now under development.

All of the partnering agreements include legally binding commitments that ensure implementation of our [equitable access policy](#). Each of these partnering agreements address all five of the critical equitable access requirements outlined above (see appendix).

A third call for proposal, CfP3i—for the development of human vaccines against Rift Valley Fever and Chikungunya viruses—is now underway and we have posted the [template agreement](#) that serves as the starting point for those negotiations.

This template agreement builds on the experience of negotiating the CfP1 and CfP2 agreements and our learnings along the way. We have also posted an [overview document for the negotiations](#), which includes a roadmap as to how the equitable access policy will be implemented through the agreements.

The funding calls issued by CEPI implement our strategic objectives to advance access to safe and effective vaccines against emerging infectious diseases; accelerate the research, development, and use of vaccines during outbreaks; and create durable and equitable solutions for outbreak response capacity. The calls also reflect the engagement and input of [CEPI's Scientific Advisory Committee](#).

All applications for funding submitted to CEPI are subject to rigorous scientific assessment by internal and external expert review. Shortlisted proposals are subject to further in-depth legal, financial, and technical due-diligence processes. Once negotiations are concluded, the agreements are subject to a thorough review, before funding is released. The release of project funding is sequential and dependent on product development partners meeting key project milestones.

CEPI partnering agreements include provisions that allow us to closely manage the technical and financial aspects of the projects we fund. They also include detailed provisions on equitable access that are designed to ensure 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*.

The following is a summary of those provisions we have included in partnering agreements for CfP1 and CfP2.

## I. Access to vaccine products and platforms

### 1.1. Establishing emergency stockpiles of vaccines

A central goal of CEPI's vaccine development agreements (in particular those addressing CEPI's priority pathogens) is to establish investigational stockpiles of vaccines that can be distributed for use in clinical trials upon the occurrence of a disease outbreak or as needed.

CEPI's agreements include provisions that allow us to establish multiple stockpiles of experimental vaccines for use in an outbreak situation—which may be replenished as necessary through additional work packages agreed to with our partner. If used during an outbreak, whether as part of a clinical trial or otherwise, these vaccines would be available free of charge to public-sector agencies.

## Example contract text:

“Establish directly or...enter into an agreement with CEPI, a Public Sector Agency or another third party, for supply of Product into an Investigational Stockpile before the first subject receives the first dose in a Phase II Clinical Trial [NB: The actual establishment of the stockpile would occur following the Phase II Clinical Trial – but the agreement for its establishment must be in place earlier.]

Additional Work Package. During the course of this Agreement, CEPI may determine that it requires an Additional Work Package to be agreed between the Parties, such agreement not to be unreasonably withheld, delayed or conditioned, for technology transfer to manufacture in additional manufacturing site(s) and/or to stockpile Product at additional stockpiling site(s) in a country or countries that CEPI, on the basis of relevant scientific rationale and advice has deemed to be at risk, at a reasonable cost. The work in this Additional Work Package will be distinct from any other work contemplated.”

## 1.2. Ongoing access to vaccines

CEPI’s agreements also include provisions to ensure ongoing access to vaccines, beyond the term of the current partnering agreement. For example, in some instances we have agreed with a partner that they shall ensure that the first 50% of vaccine doses manufactured in the first 5 years after scale-up (which in all cases is beyond the scope of the current partnering agreements) shall be provided as directed in writing by CEPI.

## Example contract text:

“The Partner shall ensure that the first 50% of doses of Product Manufactured in the first 5 years after scale-up shall be provided as directed in writing by CEPI in accordance with the CEPI Equitable Access Policy.”

Partners have also agreed to measures that will ensure that the vaccine price is at a level public-sector agencies agree is affordable for use in the Affected Territories. Furthermore, we do include measures—such as so called step-in rights—for use when this obligation is not met by a partner and clear methodologies to determine the cost of goods against which such prices are measured.

## Example contract text:

“If the Partner has not developed a Manufacturing process for the Product which meets the estimated capabilities disclosed under [the relevant] Clause by [date], (i) the Partner shall provide CEPI with full details of the obstacles to meeting such requirement and all related Data within ten (10) Business Days after such date; and (ii) CEPI may at its sole discretion (a) grant an extension of time and require the Partner to consult with experts in the field approved by CEPI or (b) exercise its step-in rights.

CEPI step-in rights and Conditions Precedent. CEPI shall not be entitled to Develop, Market or otherwise exploit Product whether itself or through third parties unless and until one or more of the events set out below occurs [including that the Partner is not] able to manufacture or deploy the Product in appropriate timescales and quantities or at a reasonable cost appropriate to the Outbreak or Increased Outbreak Preparation Need.”

## 1.3 Equitable Access to platforms

To ensure equitable access to platforms (which can be used to develop vaccines against multiple diseases) developed under CfP2 agreements, CEPI includes terms such as those included in CfP1 agreements as well as the following:

- A progress report on the scale-up of the platform for manufacturing and a good-faith estimate of the cost of the scale-up where such scale-up is necessary
- An estimate of the number of doses of each of the Project Vaccines (defined as vaccines developed as part of the funded project to develop the platform) that may be produced using the platform, and dates by when a partner estimates such volume will be achieved

- An estimate of the cost of goods of doses of each of the project vaccines for both the investigational stockpile and any additional doses
- The documents and information any estimates are based upon together with any information on any factors that may impact the cost of each of the project vaccines
- In the event of an outbreak or risk of outbreak in the Field (generally relating to pathogens on the [WHO R&D Blueprint list of priority diseases](#)), CEPI and the partner will discuss and agree to an appropriate work package and budget (which itself would need to comply with CEPI's equitable access and other policies) in order to develop a vaccine candidate for use in Affected Territories.

## 2. Ensuring project continuity

Once a project starts, it is essential that CEPI can enable a clear path towards its completion. Therefore, for the CfP1 agreements, CEPI includes measures to protect its investments from the possibility that the chosen partners cannot or will not complete their development obligations under the partnering agreements.

The development obligations also include responding rapidly in the event of an outbreak. There are a variety of ways in which such measures have been built into our partnering agreements, including so-called step-in rights or setting up a Preferred Partner (defined as an entity jointly agreed to by CEPI and the original partner) arrangement as described as follows.

### 2.1 Step-in rights

One approach is for CEPI to retain step-in rights. If the partner is in breach of its obligations or cannot, will not, or has not used reasonable efforts to fulfil its obligations under the partnering agreement, then CEPI has the right to “step in” and continue the development of the vaccines with another partner. Once triggered, the step-in rights allow CEPI to use and/or sublicense intellectual property rights and access the materials and data needed to move forward with another partner.

### 2.2 Preferred partner

Another approach is to ensure that the work on the project will be continued by using a Preferred or Trusted Partner. This would be an entity jointly agreed to by CEPI and the original partner and to which necessary intellectual property licenses and technology transfer would be provided by the original partner to enable the research or manufacturing to continue.

### 2.3 Project continuity for platform-related projects

The CfP2 platform-development agreements include remedies to move forward with the development of the platform and related project vaccines in the event a partner is unable or unwilling to do so.

As in the case of the CfP1-related agreements, CEPI includes special provisions in its CfP2 agreements that enable us to move forward quickly with the development of Project Vaccines in the event of an outbreak. We have developed several measures in our agreements to enable us to ensure continuity for both project vaccine development (including in outbreak scenarios) and platform development, including:

- A “Public Health License” granted to CEPI, which includes necessary intellectual property licenses to develop the platform and manufacture products for use in the Field in the Affected Territories
- Establishment of a Trusted Manufacturer (like a Preferred Partner, an entity jointly chosen by CEPI and the original partner) to develop the platform and/or manufacture vaccine products for use in the Field in the Affected Territories.

## 3. Sharing of commercial returns

Technology arising from CEPI’s investment (whether or not protected by intellectual property) might have uses in either vaccines or vaccine development for diseases other than the pathogens that CEPI focusses on and such uses may have commercial applications. We have taken a variety of approaches to recognise such commercial returns and take them into account during negotiations.

In some cases, we have agreed with our partner that it is premature to identify commercial returns arising from our funding and to allocate them between CEPI and our partner. Rather, we defer addressing any commercial returns to a point when they arise (whether during the term of the agreement or later). We do, however, agree to standards on how such returns would be recognised and allocated between CEPI and the partner through means such as those identified below.

### 3.1 General standard on sharing of commercial returns

The following is contract language that lays out the general standard on the sharing of commercial returns to be applied in allocating commercial returns (or “benefits”) should they arise:

#### Example contract text:

“The Parties shall agree in good faith how such benefits (if any) arising are to be managed in a fair, equitable and proportionate manner, taking account of the financial contribution of each of the Parties to the Product Background IP and Product Foreground IP being exploited, the public and philanthropic nature of the CEPI Funding, the public benefit derived from the proposed Development and Exploitation, and any private or ancillary benefit that may arise. Any benefits sharing shall be subject to a separate agreement that the Parties shall execute in a timely manner.”

### 3.2 Specific requirements on sharing of commercial returns

In other agreements we have included language to provide for the identification of specific requirements on the sharing commercial returns including, for example, proceeds from the sale of a [priority review voucher](#) and royalties generated outside of Affected Territories resulting from the use of intellectual property arising from CEPI funding. Any such commercial returns that flow back to CEPI will be used to further our mission to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks.

In some agreements we have captured the value of potential commercial returns by negotiating further concessions from partners. These concessions include the provision of additional work outside the scope of the original CEPI-funded project or work for the general return of the global-health field, such as capacity building in regions most likely to be impacted by an outbreak. Capacity-building initiatives in these regions include sharing of epidemiological data and animal models, along with building localised capacity (CROs, research organisations).

CEPI is cognisant that the results from platform development agreements under Cfp2 may have an even broader potential to result in commercial returns—such as the use of the platform to develop vaccine or non-vaccine products outside the Field. In those agreements we take steps to capture the full value of any such potential “Platform Commercial Returns” arising from our funding, which may include extending our rights to use the platform for broader global health applications and even after the expiry of our partnering agreement.

## 4. Data and sample sharing/transparency

In support of its access and transparency policies and goals, CEPI supports the widest sharing of data and responsible sample sharing in line with its confidentiality obligations, academic freedom to publish, evolving legal and policy standards and the needs of its partners and stakeholders.



This requirement advances the entire field of global health, including the work of other funders, by ensuring that data related to the successes and failures of our vaccine-development projects are shared as openly as possible with other developers.

Partnering Agreements require data to be shared with CEPI and for it to be publicly accessible under “open access” conditions. Such sharing is subject to certain constraints, notably ethical constraints necessary to protect personal privacy and the like. CEPI also requires broader sharing including requirements for prompt publication of clinical data in line with good practice and WHO guidance.

Open access provisions in all of our Partnering Agreements address the following points:

- Requiring Partners to share Project Data relevant to topics of interest to the research community, such as disease-specific assays, animal models, correlates of protection or diagnostics and epidemic preparedness mechanisms, subject to reasonable protection for partners’ rights of confidentiality and ownership rights under the Agreements.
- Requiring compliance with CEPI’s [Clinical Trials Policy](#) that clinical data and results (including negative results) must be disclosed publicly in as close to real time as possible. Accordingly, such data must be shared through an easily discoverable public route (website or system) that includes a metadata description, where patient privacy is upheld, and the system follows a request-for-information approach (where requests are fulfilled subject to an independent review and approval step).
- Project Data will be shared in accordance with [WHO’s 2016 Guidance for Managing Ethical Issues in Infectious Disease Outbreaks](#) and [2016 WHO guidance on good participatory practices in trials of interventions against emerging pathogens](#).
- CEPI requires “Open Access” for published results arising from our funding. This means that a copy of the final manuscript of all research publications, journal articles, scholarly monologues and book chapters published must be deposited into PubMed Central (or Europe PubMed Central) or otherwise made freely available upon acceptance for publication or immediately after the publisher’s official date of final publication. Moreover, all peer-reviewed published research that is funded, in whole or in part, by CEPI shall be published in accordance with [the principles of “Plan S”](#) regarding access to scientific publications.
- Dissemination and sharing of project materials: Partners may be asked to share Project Results in the form of animal models, biological samples, candidate vaccines and other tangible materials produced under the Project.

## 5. Monitoring implementation of Equitable Access in vaccine manufacturing and scientific work

In addition to the reporting requirements on technical developments under the project and finances, CEPI has also included reporting obligations specifically focussed on the equitable access obligations. These include reporting requirements on readiness to proceed with the necessary manufacturing to meet the stockpiling and other vaccine need requirements. CEPI is also taking steps through its periodic review processes to ensure that, at the same time we are monitoring progress on the scientific work, we are also continuously focussing on and moving towards achieving equitable access. One such step is to include a review of compliance with equitable access in our stage gate reviews, which are reviews conducted by CEPI at key points in the technical development of vaccines or platforms we fund. And throughout all of the work by the CEPI Secretariat, the CEPI Board maintains oversight on implementation of the equitable access policy through reviews of how the CEPI Secretariat is addressing equitable access through provisions in the Partnering Agreements it concludes.

## Appendix I

### Summary of CEPI vaccine development partnerships (March 2018 to February 2019).

Each partnership summary includes information related to the level of funding, the technical scope of the work, and the date the partnering agreement was announced. It also includes references back to sections in this document that correspond to the approaches taken in each agreement to implement the key equitable access provisions.

**Themis Biosciences:** Up to \$37.5 million to develop a vaccine against Lassa virus and MERS-CoV using a Measles vector technology (partnership announced March, 2018).

Approaches to equitable access taken include: access to vaccine products and platforms (sections 1.1 and 1.2), project continuity (section 2.1), sharing of commercial returns (section 3.1), data sharing and sample sharing/transparency (Section 4: all), monitoring implementation of Equitable Access (section 5: all).

**Inovio:** Up to \$56 million to develop a DNA vaccine against Lassa virus and MERS-CoV (partnership announced April, 2018).

Approaches to equitable access taken include: access to vaccine products and platforms (sections 1.1 and 1.2), project continuity (section 2.1), sharing of commercial returns (section 3.1), data sharing and sample sharing/transparency (section 4: all), monitoring implementation of Equitable Access (section 5: all).

**IAVI:** Up to \$54.9 million to develop a vaccine against Lassa virus using a replication competent Vesicular Stomatitis Virus vector technology (partnership announced May, 2018).

Approaches to equitable access taken include: access to vaccine products and platforms (sections 1.1 and 1.2), project continuity (section 2.1), sharing of commercial returns (section 3.1), data sharing and sample sharing/transparency (section 4: all), monitoring implementation of Equitable Access (section 5: all).

**Profectus Biosciences, Emergent:** Up to \$25 million to develop a recombinant subunit protein vaccine against Nipah virus (partnership announced May, 2018).

Approaches to equitable access taken include: access to vaccine products and platforms (sections 1.1 and 1.2), project continuity (section 2.1), sharing of commercial returns (sections 3.1 and 3.2), data sharing and sample sharing/transparency (section 4: all), monitoring implementation of Equitable Access (section 5: all).

**Profectus Biosciences, Emergent:** Up to \$36 million to develop an attenuated VesiculoVax™ vaccine against Lassa virus (partnership announced August, 2018).

Approaches to equitable access taken include: access to vaccine products and platforms (sections 1.1 and 1.2), project continuity (section 2.1), sharing of commercial returns (sections 3.1 and 3.2), data sharing and sample sharing/transparency (section 4: all), monitoring implementation of Equitable Access (section 5: all).

**IDT Biologika:** Up to \$36 million to develop a vaccine against Lassa virus using a recombinant Modified Vaccinia Ankara (MVA) vector technology (partnership announced, August 2018).

Approaches to equitable access taken include: access to vaccine products and platforms (sections 1.1 and 1.2), project continuity (section 2.1), sharing of commercial returns (sections 3.1 and 3.2), data sharing

and sample sharing/transparency (section 4: all), monitoring implementation of Equitable Access (section 5: all).

**University of Oxford and Janssen:** Up to \$19 million to develop a vaccine against Lassa virus, MERS-CoV, and Nipah virus using a simian adenoviral vaccine vector technology (ChAdOx1; partnership announced September, 2018).

Approaches to equitable access taken include: access to vaccine products and platforms (sections 1.1 and 1.2), project continuity (sections 2.1 and 2.2), sharing of commercial returns (section 3.1), data sharing and sample sharing/transparency (section 4: all), monitoring implementation of Equitable Access (section 5: all).

**Imperial College:** Up to \$8.4 million to develop a self-amplifying RNA vaccine platform, known as RapidVac, which enables tailored—just-in-time—vaccine production against multiple viral pathogens (including H1N1 influenza, Rabies virus, and Marburg virus; partnership announced December, 2018).

Approaches to equitable access taken include: access to vaccine products and platforms (sections 1.1 1.2 and 1.3), project continuity (sections 2.1 and 2.2), sharing of commercial returns (section 3.1), data sharing and sample sharing/transparency (section 4: all), monitoring implementation of Equitable Access (section 5: all).

**University of Queensland:** Up to \$10.6 million to develop a “molecular clamp” vaccine platform, a transformative technology that enables targeted and rapid vaccine production against multiple viral pathogens (including Influenza virus, Middle East Respiratory Syndrome coronavirus, and Respiratory Syncytial virus; partnership announced December, 2018).

Approaches to equitable access taken include: access to vaccine products and platforms (sections 1.1, 1.2, and 1.3), project continuity (sections 2.1 and 2.2), sharing of commercial returns (sections 3.1 and 3.2), data sharing and sample sharing/transparency (section 4: all), monitoring implementation of Equitable Access (section 5: all).

**University of Tokyo:** Up to \$31 million to develop a vaccine against Nipah virus by inserting the Nipah-virus G gene (Malaysia strain) into a measles vector (Edmonston B strain; partnership announced, February, 2019).

Approaches to equitable access taken include: access to vaccine products and platforms (sections 1.1 and 1.2), project continuity (section 2.1), sharing of commercial returns (section 3.1), data sharing and sample sharing/transparency (section 4: all), monitoring implementation of Equitable Access (section 5: all).

**CureVac:** Up to \$34 million to develop The RNA Printer™ prototype—a transportable, down-scaled, automated messenger RNA (mRNA) printing facility, which can rapid a supply of lipid-nanoparticle (LNP)-formulated mRNA vaccine candidate that can target known pathogens (including lassa fever, yellow fever, and rabies) and prepare for rapid response to unknown pathogens (ie, Disease X; partnership announced February, 2019).

Approaches to equitable access taken include: access to vaccine products and platforms (sections 1.1, 1.2 and 1.3), project continuity (sections 2.1 and 2.2), sharing of commercial returns (section 3.1 and 3.2), data sharing and sample sharing/transparency (section 4: all), monitoring implementation of Equitable Access (section 5: all).