



Enabling Equitable Access to COVID-19

Vaccines:

Summary of equitable access provisions in CEPI's COVID-19 vaccine development agreements

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Introduction

Every month that this pandemic continues, tens of thousands of lives are lost and healthcare systems are strained, in some cases beyond breaking point. In addition, the need to impose large-scale lockdowns and travel bans to reduce the spread of the SARS-CoV-2 virus that causes COVID-19 will have a profound and long-lasting economic impact. IMF estimates suggest that, for each month the pandemic persists, \$500 billion is lost from the global economy¹. Acting now to accelerate development, manufacture, and equitable distribution of COVID-19 vaccines will save millions of lives and protect the livelihoods of billions more. This is not a 'business as usual situation' and it requires a different approach to meet the challenge and avoid years of delay.

In the age of COVID-19 nobody is safe until everybody is safe. Making vaccines available to those who need them most is the fastest, as well as the fairest, way to bring the pandemic to an end. But if we are successful in developing a vaccine we are also going to face a situation where demand for COVID-19 vaccines will vastly outstrip supply.

To meet this challenge, while also ensuring we bring an end to the acute phase of the pandemic, we will need to carefully manage this scarce resource for the benefit of all and to prioritise protection of those who are most at risk. Every country on the planet will need access to vaccines at the same time. That means initial demand will outstrip supply, with the result that some countries will prioritise securing vaccine supplies for their own population. The result is a race to secure vaccines which risks pushing countries to the back of the queue if they can't afford to make deals with manufacturers, leaving many of those who are most vulnerable to the virus unprotected, and potentially escalating prices which further disadvantages less wealthy countries. We need to ensure that the skills, experience and resources of the world make this a race against the virus not against each other.

A Global Approach to COVID-19 Vaccine Development

On April 24th, WHO launched the Access to COVID-19 Tools (ACT) Accelerator, to accelerate the development, production, and deployment of safe and effective diagnostics, therapeutics and vaccines against COVID-19 – making them accessible to everyone, worldwide. CEPI, alongside Gavi and the World Health Organisation, launched COVAX – the vaccines pillar of the ACT Accelerator – with the aim of ending the acute phase of the pandemic by the end of 2021. COVAX aims to provide an 'end-to-end' solution to the challenge of vaccine development, manufacture and supply in this pandemic – bringing together the skills, expertise and resources of the public, private and philanthropic sectors on a global scale to meet the global need.

¹ IMF estimates, published on April 14 <https://blogs.imf.org/2020/04/14/the-great-lockdown-worst-economic-downturn-since-the-great-depression/>

Under the COVAX pillar each organization has a main responsibility related to equitable access. CEPI has the primary responsibility for creating an R&D portfolio of COVID-19 vaccines, and ensuring the vaccine developer commits to allowing COVAX a ‘first-choice’ in procuring vaccines developed through the partnering agreements. The procurement arm of COVAX (the COVAX Facility) is overseen by Gavi and performs a global procurement and deployment function for COVID-19 vaccines for participating countries of all income levels. Gavi is also responsible for the COVAX Advanced Market Commitment (AMC) which will support the participation of low- and middle-income countries in the COVAX Facility. WHO, among its many responsibilities, will establish the principles of fair allocation which ultimately will form the basis for the recommendations and decisions related to the allocation of vaccine to countries participating in the COVAX Facility.²

Vaccine development usually happens in a step-wise manner to lessen the risk of the substantial investments that must be made to develop a safe and effective vaccine, scale-up the manufacture and build the facilities, obtain licensure, and market the vaccine. For example, large investments in production facilities do not usually happen until there is compelling clinical data. However, in the case of COVID-19 vaccines, investments in production facilities are happening at financial risk and before there is clinical data so once the requisite safety and efficacy data has been accumulated there is no delay in scaling up mass manufacture of vaccines.

This is the ‘speed premium’ needed if we are to successfully bring a swift end to this acute phase of the pandemic. A “business as usual” approach is not fit for these circumstances, and could take 7-10 years until the world sees a safe and effective vaccine that is manufactured at scale. But through COVAX we have the opportunity to learn some of the lessons of past pandemics and accelerate manufacturing and distribution so that we are able to get safe and effective vaccines to the world – irrespective of income level.

CEPI’s Approach to Equitable Access

CEPI was established in 2016 to fill the gap in developing vaccines against emerging infectious diseases that have epidemic potential. From inception, CEPI has built a vaccine portfolio within a framework that enables equitable access to the vaccines in which it invests, especially for people living in LMICs³. An Equitable Access Policy⁴ was developed with input from key stakeholders and an Equitable Access Committee⁵ was formed as a sub-committee of the CEPI Board to involve those stakeholders in the oversight and application of CEPI’s equitable access policy. The primary objective of CEPI’s access commitment for COVID-19 is to enable equitable access to vaccines and to make sure no country is left behind in this time of global crisis.

² https://www.who.int/docs/default-source/coronaviruse/who-covid19-vaccine-allocation-final-working-version-9sept.pdf?sfvrsn=e1d0376_2&download=true

³ https://cepi.net/news_cepi/ensuring-the-world-has-access-to-cepis-vaccines/

⁴ https://cepi.net/wp-content/uploads/2019/03/Advancing-Equitable-Access_CEPI_29032019.pdf

⁵ <https://cepi.net/about/whoweare/>

The principle of equitable access is at the forefront of CEPI's decision-making process, from the moment a vaccine candidate is assessed for funding to the moment it is procured and distributed by other organisations. From the start of the COVID-19 pandemic, and subsequently with the establishment of the ACT-Accelerator and COVAX, CEPI's focus has been on starting projects rapidly, securing doses for fair allocation and purchase, and expanding manufacturing capacity in multiple geographic regions to provide the greatest hedge against vaccine nationalism, which could prevent countries—without manufacturing capability or resources to purchase vaccine— from having access.

Recognizing the potential of SARS-CoV-2 to rapidly evolve into a pandemic, CEPI moved rapidly, beginning its investments in COVID-19 vaccines on 23 January 2020 – just 13 days after the genetic code of the virus was made public. Within days of the release of the COVID-19 sequence data, the CEPI Secretariat put in place agreements for early development work to create vaccine constructs and to plan for or to conduct Phase 1 trials. Several of these projects built on the existing partnerships CEPI had created for platform technologies where the “Disease X” scenario was envisioned, which allowed for a very rapid start to the work on COVID-19 vaccines. Through a Call for Proposals launched on 3 February 2020 funding arrangements with new developers, including several multi-national corporations (MNCs), were formed. CEPI strived to adapt its partnering agreements to a situation that was evolving daily. As mentioned, there was an acute need to arrange for the scale-up of production to hundreds of millions of doses and to scale-out to other geographies to mitigate the risk of ‘vaccine nationalism’. CEPI's previous agreements had not covered these kinds of investments, and clauses in the partnering agreements were quickly adapted to accommodate these new requirements, through negotiations with vaccine developers. For example, CEPI included clauses in partnering agreements which included a manufacturing component to secure doses for “a global procurement and allocation entity” that had not yet been developed

In the rapidly evolving conditions of the COVID-19 pandemic, CEPI has held fast to its equitable access policy and principles. The aim of the COVAX Pillar, co-led by CEPI, is to secure 2 billion doses of vaccine in 2021 to be fairly allocated. Through its portfolio of COVID-19 vaccines CEPI aims to enable COVAX to secure enough doses to meet the challenge and ensure that LMICs are not left behind.

How CEPI is accelerating equitable access to its COVID-19 vaccines

CEPI weaves the principles of equitable access to COVID-19 vaccines throughout all of its work. The equitable access provisions we include as part of our partnering agreement are an important example of this. From supporting enabling science that benefits the entire field; providing loans to manufacture in multiple geographies to mitigate the risk posed by vaccine nationalism; to striving for ease of delivery in low-resource settings, CEPI looks at every way possible to develop vaccines in a manner that enables them to be available, affordable and accessible. The sections below highlight the specific ways CEPI seeks to enable equitable access to the vaccines in which it invests for COVID-19.

Ensuring End-to-End Coverage. Historically, vaccine development that is solely driven by public-sector investment has been fragmented and slow, with many different organisations responsible for various parts of the development process. In response to COVID-19, CEPI has played a central role in optimising the vaccine development process, coordinating development partners and manufacturers through its partnering agreements and working with the WHO and Gavi to enable procurement and allocation of vaccines via COVAX.

Funding and Access to Development Tools. CEPI's enabling science program provides the tools and knowledge for developers all over the world, including those in LMICs, to accelerate their programs and make smarter development decisions. This work involves developing standardized assays, developing animal models and enabling access to them, and creating a centralized laboratory infrastructure for sample testing. The importance of not just developing but also standardizing these vaccine development tools and resources to guide development and regulatory approval cannot be underestimated. CEPI's enabling science program is designed to benefit vaccine developers throughout the world, including those which are not part of the CEPI COVID-19 portfolio.

Target Product Profile. The ability to deliver a vaccine in a pandemic setting will be critical to the success of vaccination programs. Several leading candidates will be challenging to deploy for countries with limited infrastructure due to factors like cost and storage requirements at very low temperatures. Therefore, in addition to speed of development, CEPI is considering factors such as storage conditions, method and route of administration, cost of goods, and number of doses required when making initial investment decisions as well at stage gate reviews.

Clinical & Regulatory. CEPI engages in the clinical and regulatory aspects of COVID-19 vaccine development at both the project level and also within the broader environment of regulatory authorities. No regulatory authority has experience with licensing COVID-19 vaccines, and few have experience with licensing vaccines in pandemic settings.

As a project level example, CEPI has made its service provider, the Safety Platform for Emergency vaccines (SPEAC) Project (of the Task Force for Global Health), available to developers to enhance their regulatory strategy and submissions to licensing agencies as well as to obtain an overall safety database for clinical trials.

To accelerate access to vaccines in LMICs, COVAX facilitates interaction between regulatory agencies, e.g. African Vaccine Regulatory Forum, European Medicines Agency, US Food and Drug administration, to discuss regulatory approaches for vaccines against COVID-19. There is an urgent need for collaboration between regulatory authorities in developing an internationally harmonised approach to regulatory review of COVID-19 vaccines. This includes review of clinical trial applications, release of clinical trial material, safety and efficacy review, genetically modified organism (GMO)-classification and timely good manufacturing practices (GMP)-inspections and post-licensure commitments. This

is a particularly critical element to avoid delayed authorization and hence enable timely access in developing countries with less mature regulatory agencies and procedures.

Manufacturing. A unique challenge for the COVID-19 pandemic is the need to invest in manufacturing of hundreds of millions of doses of vaccine before having the vaccine development data a developer would usually have to guide those major investments. There are also challenges with gaining access to the raw materials needed to produce those large quantities of vaccines. There is a significant risk to global equitable access posed by some countries taking steps to protect their populations by directly securing supplies of vaccines. Accordingly, CEPI is making investments in manufacturing capacity for some of the developers it supports in parallel to their early stage vaccine development activities.

Some COVID-19 vaccine developers have already planned for manufacturing and have access to the necessary expertise and facilities. In other cases, CEPI is making investments to provide manufacturing capacity to scale-up the developer's existing capacity. CEPI is also investing in manufacturing capacity to scale-out (expand production in other countries) to diversify locations of vaccine production to mitigate the risks of vaccine nationalism as the competition for doses is fierce. CEPI collaborates with developers in the selection of the additional manufacturers to enable sufficient manufacturing capacity and equitable access. Developers agree to technology transfer to trusted partners, and/or standing up manufacturing capacity in two or more jurisdictions, if applicable.

Jointly agreeing with developers, the sites for manufacturing and conditions under which CEPI will finance that work have been areas of major focus and negotiation. The Secretariat has focused on funding or shared-risk financing for increased production capacity in geographically dispersed manufacturing locations in return for a supply of doses to the COVAX Facility.

Competition for vaccine-related supplies is also fierce, particularly for the glass vials required to store vaccines. In response, the Secretariat has purchased 100 million 20-dose glass vials⁶ for use by CEPI's developers and lent funds to developers to pay to reserve or procure items in short supply from manufacturing capacity to raw materials.

Through CEPI's sustainable manufacturing program, the Secretariat has also undertaken matchmaking between developers and certain Contract Development and Manufacturing Organizations (CDMOs) for available manufacturing capacity. A significant hedge against the diversion of doses from the COVAX Facility may ultimately be where the doses are produced.

Special requirements have been included in CEPI's evolving vaccine development agreements that focus on manufacturing. Especially important have been efforts to manufacture large amounts of vaccines in parallel to safety and efficacy trials. In other

⁶ https://cepi.net/news_cepi/stevanato-group-signs-an-agreement-with-cepi-to-provide-pharma-glass-vials-for-2-billion-doses-of-covid-19-vaccines-under-development/

words, CEPI is making investments, at risk, in order to produce vaccines much sooner than would normally be the case through traditional vaccine development approaches. If the vaccine is successful, then the people who need the vaccines will not lose time waiting for the manufacturing process to be organized and implemented.

If a developer cannot use the CDMO manufacturing capacity reserved using CEPI funds, that capacity can be used as directed by CEPI for other vaccines. Termination for breach of contract or key development failures are included in CEPI vaccine development agreements, although it should be noted that given the degree to which activities are running in parallel even with early termination most of the investment would not be returned.

Supply of doses. The overarching principle in the CEPI partnering agreements is that all manufacturing output corresponding to the CEPI-funded part of development are to be offered first to the COVAX Facility.

As part of COVAX, CEPI's primary focus is accelerating the development of safe and effective vaccines and establishing sufficient manufacturing capacity to enable billions of doses of vaccine to be supplied.

Since Gavi will directly negotiate price and supply with developers, the Secretariat is working with Gavi to enable a smooth transition as part of the end-to-end coverage that is necessary to move quickly.

Agreement terms on supply cover the amount to be supplied globally during the "pandemic period," which is the time from when WHO declared a public health emergency of international concern (PHEIC) for COVID-19 and when they declare that it is over. Each agreement, where applicable, also agrees to the supply of a portion of vaccine production that will be available to LMICs (or to a purchasing agent on their behalf) in the "post-pandemic period."

Lastly, the Secretariat is participating in a COVAX working group to develop approaches to address indemnification and liability, including a compensation scheme. The presence of such legal provisions will be a prerequisite for industry partners to deliver vaccines under the COVAX Facility, and for distribution and deployment of vaccines in any country.

Pricing. CEPI has sought to enable low pricing both by requiring developers to enter into procurement deals with Gavi for the COVAX Facility, and sharing the risk of inventory build. Where CEPI's agreements require developers to enter into such procurement deals, the price will be determined in negotiations between the developer and Gavi on behalf of the COVAX Facility, consistent with the developer's commitment to CEPI's equitable access policy. If the COVAX Facility is not funded or does not enter into purchase agreements as anticipated, CEPI has the right to redirect the supply to another public sector procurer. All of the agreements require compliance with CEPI's equitable access policy and/or contain similar commitments in principle, including pricing at levels that are affordable to the people who need the vaccines. Where appropriate, commercial

benefits sharing is crystallised in a form most useful in the pandemic, including dose or price commitments. Several companies have declared publicly that they will sell vaccine at “no-profit, no-loss” pricing during the pandemic period.

Access to data and materials. In line with the COVID-19 Technology Access Pool (C-TAP) proposals, CEPI funding agreements contain requirements for awardees to publish and share data and materials to ensure that all can benefit from the work funded by CEPI. Those requirements include:

- Requiring partners to share Project Data, as agreed, 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 that clinical data and results (including negative results) must be disclosed publicly in as close to real time as possible in line with CEPI’s Clinical Trials Policy. 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).
- Requiring Project Data to 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.
- Requiring “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.

Intellectual Property and Project Continuity. CEPI does not seek to own the Intellectual Property (IP) developed from its partnerships. The reason for this is that contrary to the situation with small-molecule medicines, there are more barriers to development of vaccines than just patents, including know-how and trade secrets as well as access to biological materials (such as cell lines) and regulatory approvals for some platforms (in particular for adjuvants). Moreover, vaccine developers relying on a platform to develop COVID-19 vaccines will want to ensure that their technology is managed properly so that it is available to develop other vaccines. CEPI’s approach is to require awardees to manage their IP in such a way that equitable access can be realized, i.e doses are made available to the COVAX Facility for fair allocation and procurement. This is the most effective way of

delivering accessible vaccines as quickly as possible, without stifling innovation or delaying the urgent vaccine development process.

Furthermore, CEPI collaborates with partners in the selection of additional manufacturers to enable sufficient manufacturing capacity and equitable access. Developers agree to technology transfer to trusted partners, and/or standing up manufacturing capacity in two or more countries, if applicable.

Vaccine Purchase and Allocation. Under COVAX, the COVAX Facility has been established as a mechanism for procuring and ensuring a fair allocation of COVID-19 vaccines. The principal role of the COVAX Facility is to maximise the chances of people in participating countries getting access to COVID-19 vaccines as quickly, fairly and safely as possible. By joining the Facility, participating countries and economies will get access to a diverse portfolio of vaccines. CEPI's investments will enable access through the COVAX Facility to vaccines in CEPI's COVID-19 R&D portfolio.

Under COVAX, the WHO has published principles to enable fair allocation of successful COVID-19 vaccines, which will be the basis for COVAX Facility. The relevant mechanisms and methodologies required to prioritise vaccine supply according to these principles are currently being developed. Priority populations for the first round of vaccinations will likely include healthcare workers, adults over the age of 65 years, and other high-risk adults with underlying health conditions.

It is acknowledged that several countries have and will be negotiating bilateral deals with manufacturers in order to seek vaccines for their own population. Handling of bilateral deals will be part of the Facility discussions with participating countries. CEPI's overarching position is that the Facility discussions and coordination with individual participating countries shall be governed by the principle of fair access to vaccines, the COVAX Allocation Framework and the overall aim of COVAX which is that no country should be left behind.

Summary. The activities described above are all part of CEPI's end-to-end approach to equitable access. A key founding objective of COVAX was to avoid a situation in which people in developing countries were left behind in the scramble for COVID-19 vaccines, as was observed during the H1N1 pandemic of 2009. By 26th November 2020, 189 countries had committed to join or were eligible to receive vaccines through the COVAX Facility. This is a huge step towards realizing COVAX's ambition of mobilizing a global approach to the rapid development and fair allocation of safe and effective COVID-19 vaccines. Whilst many challenges are still to be overcome, this demonstration of global willingness to collaborate and support the principle of fair and equitable access in line with CEPI's mission is a significant accomplishment.

Individual Agreements

CEPI's COVID-19 vaccine development agreements are summarized in the table below. The agreements are each customized to the stage of vaccine development, the scope of work covered in the project, the budget, and the type of developer.

Partners	Technology	Agreement for COVID-19 Activities	Date Agreement Announced	Agreed budget (USD millions)
AstraZeneca	Viral vector	<ul style="list-style-type: none"> Supply of vaccine 	4 June 2020	383
Biological E Ltd	Protein	<ul style="list-style-type: none"> Scale-up of manufacturing 	29 December 2020	5
Clover Biopharmaceuticals	Recombinant protein, peptide	<ul style="list-style-type: none"> Vaccine development Scale-up of manufacturing Supply of vaccine 	8 July 2020	327.8
CureVac	mRNA	<ul style="list-style-type: none"> Vaccine development Scale-up of manufacturing Supply of vaccine 	31 January 2020	15.3
Dynavax	CpG 1018 adjuvant	<ul style="list-style-type: none"> Scale-up of manufacturing Supply of vaccine adjuvant 	1 February 2021	99
Inovio	DNA	<ul style="list-style-type: none"> Vaccine development 	23 January 2020	22.5
Institut Pasteur/ Themis/ University of Pittsburgh*	Measles virus vector	<ul style="list-style-type: none"> Vaccine development 	19 March 2020	4.9
Moderna	mRNA	<ul style="list-style-type: none"> Vaccine development 	23 January 2020	0.9
Novavax	Viral membrane glycoprotein produced in baculovirus	<ul style="list-style-type: none"> Vaccine development Scale-up of manufacturing Supply of vaccine 	11 May 2020	388
SK bioscience	Recombinant protein	<ul style="list-style-type: none"> Vaccine development Scale-up of manufacturing Supply of vaccine 	9 December 2020 & 10 March 2021	10 & 26.7
Univ. Hong Kong	Viral vector	<ul style="list-style-type: none"> Vaccine development 	18 March 2020	0.6
Univ. Queensland + CSL**	Protein	<ul style="list-style-type: none"> Vaccine development Scale-up of manufacturing Supply of vaccine 	5 June 2020	4.5
VBI Vaccines Inc	Enveloped Virus Like Particle	<ul style="list-style-type: none"> Vaccine development Scale-up of manufacturing Supply of vaccine 	10 March 2021	33

**It was announced on 25 January 2021 that the development of this vaccine candidate is being discontinued.
**It was announced on 11 December 2020 that the development of this vaccine candidate will not progress beyond the Phase 1 trial.*

Scope of CEPI's COVID-19 Agreements

Each of the 12 COVID-19 agreements entered into by CEPI to-date seeks to accomplish one or more of the following major objectives: (1) preclinical and clinical development and testing of candidate vaccines; (2) development and validation of a manufacturing process capable of producing large quantities of vaccines; and (3) the supply of vaccines by that manufacturing process.

1. **Vaccine development agreements** generally include these activities: preclinical studies, clinical trials, regulatory planning and development of the manufacturing process at a small scale.
2. **Scale-up of manufacturing agreements** focus on developing manufacturing processes that can provide much larger amounts of vaccine than the more limited manufacturing processes needed for vaccine development.
3. **Supply of vaccine agreements** focus on using large-scale manufacturing capacity to produce large amounts of vaccine and require adherence with CEPI equitable access policies at a minimum. For more sizable projects, specific commitments on supply to Gavi for the COVAX Facility were required.

Summary of Agreement with AstraZeneca

Scope of agreement

- Vaccine Development
- Scale-up of manufacturing
- ✓ Supply of vaccine

CEPI and AstraZeneca UK Limited (AZ) entered into a partnership on 4 June 2020 to support the manufacture of 300 million doses of the AZ's AZD1222 vaccine candidate. AZ is a publicly traded, multi-national corporation headquartered in Cambridge, UK. The agreements build upon CEPI's initial seed funding for this vaccine candidate, which supported the University of Oxford both for manufacturing development and to manufacture clinical trial materials. Following that initial investment by CEPI, Oxford partnered with AZ in a global development and distribution agreement for the vaccine. The funded project will result in greater manufacturing capacity and up to 300 million doses of vaccine to the COVAX Facility, with Gavi supporting the procurement. If the vaccine is approved by regulatory authorities, the aim is to provide initial doses in early 2021.

CEPI has agreed to fund AZ's technology transfer of vaccine production to additional manufacturing sites, the purchase of manufacturing materials, and the reservation of manufacturing slots. If AZ is unable to use the reserved manufacturing capacity, that capacity may be used at CEPI's direction for another CEPI project. The total funding amount is up to \$383m of which up to \$338 is shared risk and recoverable on product sales.

Where will the vaccine be made? Asia and Europe.

How much vaccine will be supplied to the COVAX Facility? AZ will offer to sell up to 300 million doses of vaccine to the COVAX Facility. An additional agreement between Gavi, the Bill & Melinda Gates Foundation and the Serum Institute of India secures additional doses of vaccine from the Serum Institute of India under licence from AZ for COVAX for LMICs.

How will be the price be determined? AZ will sell on a no-profit, no loss basis during the COVID-19 pandemic. CEPI has the right to audit to ensure compliance.

How will results support the research community? AZ has agreed to abide by the guidance provided by WHO, Wellcome, and additional CEPI obligations in the agreement regarding access to data, and to meet in good faith CEPI's requirements on open publication of research results.

Summary of Agreement with Biological E Limited

Scope of agreement

- Vaccine Development
- ✓ **Scale-up of manufacturing**
- Supply of vaccine

Biological E Limited (Bio E) is a private company headquartered in India. CEPI and Bio E announced a partnership on 29 December 2020 to advance the development and manufacture of Bio E's subunit vaccine candidate. CEPI has invested an initial sum of up to \$5m to support scaling up the process for manufacturing the vaccine, and will explore providing additional funding to Bio E with the goal of potentially enabling the production of hundreds of millions of doses in 2021.

Where will the vaccine be made?

Initial manufacture of the vaccine will occur in India.

How much vaccine will be supplied to the COVAX Facility?

If Bio E's vaccine is successfully scaled up and clinical trials are positive, hundreds of millions of doses could be available in 2021. Funding for the production of vaccine doses will be subject to an additional funding agreement, and Bio E will offer to sell the vaccine produced with CEPI's investment to Gavi for the COVAX Facility.

How will be the Price be determined?

The price will be determined in negotiations between Bio E and Gavi on behalf of the COVAX Facility, consistent with Bio E's commitment to CEPI's equitable access policy.

How will results support the research community?

Bio E has agreed to abide by the guidance on access to data and open publications provided by WHO and Wellcome, and additional CEPI obligations in the agreement.

Summary of Agreement with Clover Biopharmaceuticals

Scope of agreement

- ✓ Vaccine Development
- ✓ Scale-up of manufacturing
- ✓ Supply of vaccine

CEPI and Clover Biopharmaceuticals entered into a vaccine development agreement on 3 June 2020 to develop the Clover Trimer-Tag[®] COVID-19 vaccine. Clover is a private, venture backed company headquartered in China. This investment of \$324.3m builds on the previous investment of \$3.5 million used to start the Phase I trial in Australia (with Clover's Australian subsidiary). Activities covered by

this funding include: scale-up of the manufacturing process, pre-clinical studies, regulatory activities, and pivotal trials.

Where will the vaccine be made? Initial manufacture of the vaccine will occur in China, and some fill and finish (placing the final vaccine into vials and product packaging) capacity may potentially be established outside China. There is an optional work package for manufacturing outside China.

How much vaccine will be supplied to the COVAX Facility? If the Clover technology is successfully scaled up and clinical trials are positive, hundreds of millions of doses could be available in 2021. Clover will offer to sell the vaccine produced with CEPI's investment to Gavi for the COVAX Facility during the pandemic period. In addition, in the post-pandemic period they will sell up to 50% of their production capacity directly to LMICs.

How will be the Price be determined? The price will be determined in negotiations between Clover and Gavi on behalf of the COVAX Facility, consistent with Clover's commitment to CEPI's equitable access policy.

How will results support the research community? Clover has agreed to abide by the guidance on access to data and open publications provided by WHO and Wellcome, and additional CEPI obligations in the agreement.

Summary of Agreement with CureVac

Scope of agreement

- ✓ Vaccine Development
- ✓ Scale-up of manufacturing
- ✓ Supply of vaccine

CureVac is a private company headquartered in Germany. CEPI and CureVac had previously entered into an agreement to develop their mRNA platform technology, and that agreement served as the basis for extending that previous program toward the development of a vaccine against COVID-19, based on the mRNA platform. This expanded program includes additional initial funding of up to \$15.3 million by CEPI for the accelerated vaccine development, manufacturing and phase 1 clinical trial.

Where will the vaccine be made? It is anticipated the vaccine will be manufactured in Europe, however this decision will be made by CureVac.

How much vaccine will be supplied to the COVAX Facility? Relevant portions of the original agreement between CEPI and CureVac predate the COVID-19 pandemic and thus, also, the COVAX Facility for allocation and purchase decisions. An amendment to the original agreement stipulates that CureVac will make a proportion of its total capacity available to the COVAX Facility. In 2021, 10% of CureVac's total produced doses will be available to COVAX. In 2022 and 2023, 15% of total produced doses will be made available.

How will be the price be determined? The price will be determined in negotiations between CureVac and Gavi on behalf of the COVAX Facility. The price will be tiered based on country income levels, and will be no higher than the lowest price charged by CureVac for the sale of the vaccine to a third party of a similar volume and to a country of a similar income level.

How will results support the research community? CureVac has agreed to follow CEPI's requirements for access to data and open publication of results under the terms of the original agreement.

Summary of Agreement with Dynavax

Scope of agreement

- Vaccine Development
- ✓ Scale-up of manufacturing
- ✓ Supply of vaccine adjuvant

Dynavax is a public company with its headquarters in Emeryville, CA USA. CEPI and Dynavax entered into an agreement on September 8, 2020 to fund scale-up of the manufacturing capacity for Dynavax's CpG 1018 vaccine adjuvant and subsequently announced an agreement on 1 February 2021 to secure CpG 1018 adjuvant in 2021 by way of an interest free, forgivable loan of up to \$99m to Dynavax which is recoverable upon product sales. This adjuvant investment is fully fungible between CEPI-funded COVID-19 vaccine development programmes and represents a key strategic investment to increase overall 2021 dose availability from the R&D Portfolio.

Where will the adjuvant be made? USA

How much adjuvant will be supplied to the COVAX Facility? Secured adjuvant will first be made available to CEPI-funded COVID-19 vaccine development programmes. These vaccine development programmes will offer to sell the vaccine produced with CEPI's investment to the COVAX Facility.

How will the Price be determined? The CEPI-funded vaccine developers will enter into direct Commercial Supply Agreements with Dynavax to set a price per adjuvant dose based upon their program needs. The pricing to CEPI-funded vaccine developers will be tiered according to country economic level with supply available to all levels and must be consistent with the pricing agreed in the agreement between CEPI and Dynavax with respect to the material funded by CEPI.

How will results support the research community? CEPI-funded vaccine development partners have agreed to abide by the guidance on access to data and open publications provided by WHO and Wellcome, and additional CEPI obligations in their agreements.

Summary of Agreement with Inovio

Scope of agreement

- ✓ Vaccine Development
- Scale-up of manufacturing
- Supply of vaccine

Inovio is a public company with its headquarters in Pennsylvania, USA. Inovio and CEPI had an existing agreement to develop non-COVID-19 vaccines. An initial investment of \$9m was made under a new agreement to fund the phase 1 clinical trial of the COVID-19 vaccine. The nucleic acid vaccine requires a device for delivery and funding of \$5m was provided to develop the device. A further \$8m was provided in support of manufacturing work. CEPI's funding ends upon completion of the phase 1 trial.

Where will the vaccine be made? USA

How much vaccine will be supplied to the COVAX Facility? Inovio agreed to develop an appropriate Equitable Access Plan with CEPI which may include offering doses to the COVAX Facility both during the pandemic and after the pandemic.

How will be the Price be determined? The agreement defines Equitable Access as meaning that appropriate products are first available to populations when and where they are needed and at prices that are affordable to the populations at risk, especially Low-income and Middle-income Countries, or to public sector entities that procure on their behalf. Thus, Inovio has agreed contractually with CEPI's equitable access principles.

How will results support the research community? Inovio has agreed to abide by the guidance on access to data and open publications provided by WHO and Wellcome, and additional CEPI obligations in the agreement.

Summary of Agreement with Institut Pasteur for its work with Themis and University of Pittsburgh

Note that Merck Sharpe & Dohme (MSD) acquired Themis on 19 June 2020. The information below summarises the agreement with Institut Pasteur for its work with Themis and University of Pittsburgh prior to the acquisition; and a subsequent Memorandum of Understanding agreed between CEPI and MSD.

It was announced on 25 January 2021 that development of this vaccine candidate would be discontinued.

Scope of agreement

- ✓ Vaccine Development
- Scale-up of manufacturing
- Supply of vaccine

CEPI provided \$4.9m funding to a consortium of Institut Pasteur, Themis and the University of Pittsburgh for the development of a vaccine against COVID-19 based on a measles vector platform.

At this time no further work with Institut Pasteur is planned.

Where will the vaccine be made? Not yet known.

How much vaccine will be supplied to the COVAX Facility? The agreement predates the creation of the COVAX Facility. Accordingly, it does not specifically address current global vaccine allocation mechanisms.

Institut Pasteur has agreed to CEPI's equitable access principles meaning that appropriate products are first available to populations when and where they are needed and at prices that are affordable to the populations at risk, especially low- and middle-income countries or to public sector entities that procure on their behalf.

How will be the Price be determined? The price will be determined in negotiations between the manufacturer and Gavi on behalf of the COVAX Facility.

How will results support the research community? Institut Pasteur has agreed to abide by the guidance on access to data and open publications provided by WHO and Wellcome, and additional CEPI obligations in the agreement.

Memorandum of Understanding between CEPI and Merck Sharp & Dohme

CEPI and Merck Sharp & Dohme (MSD) entered into a Memorandum of Understanding (MOU) on 25 May 2020. This MOU describes the contemplated path forward and key outcomes for the development, manufacture and global access to a vaccine candidate under development by Institut Pasteur and Themis Bioscience GmbH. At the time of signing of the MOU, MSD was in the process of acquiring the

entire issued share capital of Themis, which acquisition was completed on 19 June 2020. CEPI previously had provided funding to Themis to develop vaccine candidates based on Institute Pasteur technology for Lassa, MERS and Chikungunya and those agreements remain in place following the acquisition.

Summary of Agreement with Moderna

Scope of agreement

- ✓ Vaccine Development
- Scale-up of manufacturing
- Supply of vaccine

CEPI provided \$0.9m in gap funding to Moderna for the manufacture of an mRNA vaccine against COVID-19 for the conduct of the phase 1 trial only. The Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health, collaborated with Moderna to design the vaccine. Funding for this project is complete.

At this time no further work with Moderna is planned.

Where will the vaccine be made? USA

How much vaccine will be supplied to the COVAX Facility? The agreement predates the COVID-19 PHEIC and the creation of the COVAX Facility. Accordingly, it does not specifically address current global vaccine allocation mechanisms.

Moderna has agreed to CEPI's equitable access principles meaning that appropriate products are first available to populations when and where they are needed and at prices that are affordable to the populations at risk, especially low- and middle- income countries or to public sector entities that procure on their behalf.

How will be the Price be determined? The price will be determined in negotiations between Moderna and Gavi on behalf of the COVAX Facility.

How will results support the research community? Moderna has agreed to publish project results under the requirements of NIAID.

Summary of Agreement with Novavax

Scope of agreement

- ✓ Vaccine Development
- ✓ Scale-up of manufacturing
- ✓ Supply of vaccine

Novavax is a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases. CEPI has invested up to \$388m to accelerate the development and manufacture of Novavax's NVX-CoV2373 vaccine candidate against COVID-19. \$142.5m of this funding is a forgivable loan which is recoverable on product sales. This investment will support preclinical studies and phase 1 and phase 2 clinical trials as well as manufacturing activities. Operation Warp Speed is funding the pivotal trial.

Where will the vaccine be made? CEPI's investment will fund the transfer of NVX-CoV2373 technology to manufacturing partners in Europe and Asia, for large-scale production of vaccine. Additionally, CEPI funding will enable large-scale production of Novavax' saponin-based Matrix-M™ adjuvant in

Novavax' manufacturing facility in Uppsala, Sweden. CEPI's additional funding will allow Novavax to accelerate manufacturing with the goal of ramping up to large-scale production in 2021.

How much vaccine will be supplied to the COVAX Facility? Gavi, on behalf of the COVAX Facility, and Novavax announced a Memorandum of Understanding on 18 February 2021 to make a cumulative volume of 1.1 billion doses of NVX-CoV2373 available to the COVAX Facility. This cumulative volume will be made available to the Facility via both a final advance purchase agreement with Novavax, and an existing agreement between Gavi and the Serum Institute of India (SII) made possible by a technology transfer agreement, at no cost, between Novavax and SII.

How will be the Price be determined? The price will be determined in negotiations between Novavax and Gavi on behalf of the COVAX Facility, consistent with Novavax's commitment to CEPI's equitable access policy.

How will results support the research community? Novavax has agreed to abide by the guidance on access to data and open publications provided by WHO and Wellcome, and additional CEPI obligations in the agreement.

Summary of Agreement with SK bioscience

Scope of agreement

- ✓ Vaccine Development
Scale-up of manufacturing
- ✓ Supply of vaccine

SK bioscience is a private company headquartered in the Republic of Korea. CEPI and SK bioscience entered into a vaccine development agreement on 9 December 2020 to advance the development the GBP510 vaccine candidate. GBP510 is a next-generation, or 'Wave 2', vaccine candidate. CEPI's 'Wave 2' vaccine investments are supported by a grant of up to \$20m from the Bill & Melinda Gates Foundation.

CEPI will invest up to \$10m towards a Phase 1/2 study of GBP510, and manufacture of clinical trial materials needed for the Phase 1/2 and Phase 3 trials.

CEPI announced an expansion of this partnership on 10 March 2021. CEPI will also invest up to \$14.3m to adapt the GBP510 candidate against variants of concern, and up to \$12.5m to support manufacturing scale-up to produce hundreds of millions of doses.

Where will the vaccine be made? South Korea

How much vaccine will be supplied to the COVAX Facility? If the SK bioscience vaccine candidate is successful, SK bioscience will offer to sell the vaccine to Gavi for the COVAX Facility. It is anticipated that this supply could be hundreds of millions of doses per year, beginning in 2022.

How will be the Price be determined? The price will be determined in negotiations between SK bioscience and Gavi on behalf of the COVAX Facility. The price will be reasonable for countries of all economic levels, based on a Cost of Goods + % approach.

How will results support the research community? SK bioscience has agreed to abide by the guidance on access to data and open publications provided by WHO and Wellcome, and additional CEPI obligations in the agreement.

Summary of Agreement with University of Hong Kong

Scope of agreement

- ✓ Vaccine Development
- Scale-up of manufacturing
- Supply of vaccine

CEPI invested an initial sum of \$0.6m in a partnering agreement with The University of Hong Kong (HKU) to rapidly develop a vaccine candidate against COVID-19. This agreement provides initial funding to HKU to undertake preclinical testing of their vaccine candidate. CEPI will consider additional funding for further clinical testing pending results of these preclinical studies.

Where will the vaccine be made? Not included in the small proof of concept study. Future opportunities for scale-up are being explored.

How much vaccine will be supplied to the COVAX Facility? Will be negotiated if the project continues.

How will the Price be determined? Will be negotiated if the project continues.

How will results support the research community? University of Hong Kong has agreed to abide by the guidance on access to data and open publications provided by WHO and Wellcome, and additional CEPI obligations in the agreement.

Summary of Agreement with University of Queensland + CSL

Note that it was announced on 11 December 2020 that development of this vaccine candidate will not progress beyond the Phase 1 trial. The information in this section summarises the partnership agreement which will therefore not be continued.

Scope of agreement

- ✓ Vaccine Development
- ✓ Scale-up of manufacturing
- ✓ Supply of vaccine

CEPI, CSL and The University of Queensland entered into a partnering agreement to accelerate the development, manufacture and distribution of a COVID-19 vaccine candidate under development at UQ. The agreement formalises the support provided by CSL to UQ for COVID-19 vaccine development at the outset of the pandemic earlier this year.

CEPI and CSL both will fund the development and manufacture of UQ's "molecular clamp" enabled vaccine for COVID-19. Funding contributions will be used to provide support for the phase 1 safety study being led by UQ, followed by subsequent later stage clinical trials, and also industrial-scale manufacturing to allow the production of potentially millions of doses a year.

The initial phase of large-scale production of the UQ COVID-19 vaccine is planned to take place in Australia. While there are a number of critical milestones to be met before the vaccine can be considered successful, CSL anticipates that the production technology can be scaled to produce up to one hundred million doses towards the end of 2021. CSL would also subcontract other global manufacturers to increase the number of doses that can be produced and broaden the geographical distribution of vaccine production. Should clinical trials be successful, a vaccine could be available for distribution in 2021.

Where will the vaccine be made? Australia

How much vaccine will be supplied to the COVAX Facility? CSL will offer to sell 50% of doses of vaccine produced in their facility to Gavi for the COVAX Facility. Non-CEPI funding has been leveraged for the project so CEPI's investment risk has been decreased.

How will be the Price be determined?

The price will be determined in negotiations between CSL and Gavi on behalf of the COVAX Facility, consistent with CEPI's equitable access policy.

How will results support the research community? University of Queensland and CSL have agreed to abide by the guidance on access to data and open publications provided by WHO, Wellcome, and additional CEPI obligations in the agreement.

Summary of Agreement with VBI Vaccines Inc

- ✓ Vaccine Development
- ✓ Scale-up of manufacturing
- ✓ Supply of vaccine

VBI Vaccines Inc is a public company headquartered in Cambridge, MA USA, with research operations in Ottawa, Canada and a manufacturing facility in Rehovot, Israel. CEPI and VBI announced a vaccine development agreement on 10 March 2021 to develop VBI's enveloped virus like particle (eVLP) vaccine candidates against SARS-CoV-2 variants, including the B.1.351 variant, also known as 501Y.V2, first identified in South Africa.

CEPI will provide up to \$33m to support the advancement of VBI-2905, a monovalent eVLP candidate expressing the pre-fusion form of the spike protein from the B.1.351 strain, through Phase 1 clinical development. As part of the agreement, this funding will also support preclinical expansion of additional multivalent vaccine candidates designed to evaluate the potential breadth of VBI's eVLP technology. This preclinical expansion is intended to develop clinic-ready vaccine candidates capable of addressing emerging variants.

Where will the vaccine be made? Initial manufacture of the vaccine candidates will be in Canada.

How much vaccine will be supplied to the COVAX Facility? If VBI's vaccine candidates are successful, VBI will offer to sell the vaccine to Gavi for the COVAX Facility. It is anticipated that this supply could begin in 2022.

How will be the Price be determined? The pricing will be as reasonably required to achieve equitable access for populations in need, an appropriate return on investment, and commercially sustainable ongoing vaccine supply. VBI has agreed to limit the sale price of the vaccines covered by the Agreement during the Pandemic Period, and after the Pandemic Period for certain low- and middle-income countries, according to a formula and the economic circumstances of the country of allocation.

How will results support the research community? VBI has agreed to abide by the guidance on access to data and open publications provided by WHO and Wellcome, and additional CEPI obligations in the agreement.

Version Control		
Version	Date	Changes/ Comments
1.0	17 December 2020	First version
2.0	26 January 2021	Updated to include summary of agreement with Biological E Ltd, and note that development of V591 vaccine candidate, has been discontinued by Merck Sharpe & Dohme.
3.0	22 February 2021	Updated to include: <ul style="list-style-type: none"> • Summary of agreement with Dynavax for CpG 1018 adjuvant • Update to summary of agreement with Novavax, adding details of MoU with Gavi announced on 18 February 2021.
4.0	18 March 2021	Updated to include: <ul style="list-style-type: none"> • Update to summary of agreement with SK bioscience to include expanded partnership announced on 10 March 2021. • Summary of agreement with VBI Vaccines announced on 10 March 2021.