

# Equitable Access Framework

Published: May 2023

---

## Executive Summary

CEPI's Equitable Access Framework seeks to articulate CEPI's overall approach to enabling Equitable Access (EA), capture what EA means for CEPI under CEPI 2.0 and describe CEPI's scope of accountability for EA in relation to other stakeholders in the public health ecosystem.

CEPI's primary responsibility is to develop vaccines against emerging infectious diseases and to enable access to these products for the populations that need them. It cannot be responsible for the entire global health architecture, although CEPI's success ultimately depends upon that architecture and on partnerships to deliver its remit and enable EA.

It is abundantly clear that the way medical countermeasures development and production is currently configured and supported does not naturally produce EA as a system output. Enabling "system equity" by supporting structural change and improved connectivity between the different parts of the system, both to enable accelerated Research & Development & Manufacturing (R&D&M) and to enable timely availability of product, therefore, must be a long-term objective.

Two aspirations provide direction for CEPI's EA work. These aspirations are to make products available for use starting within 100 days; and to support the efforts of global health partners to establish agile, resilient, end-to-end outbreak response systems.

CEPI enables EA both directly through its financial investments and partnerships and indirectly through advocacy and its analytical and policy contributions to the evolving ecosystem. In laying out an EA Framework for CEPI 2.0, we describe key objectives which guide CEPI's decisions on individual projects, help secure a balanced R&D and manufacturing portfolio, and anchor CEPI's investments and activities. Considered in a continuum, these are:

1. Rapidly advance product development.
2. Secure the right to require timely production of that product for at-risk populations.
3. Make investments to increase utility of products for the Global South.
4. Support greater agility and resilience in regional R&D&M, supply chain and global health architecture to achieve the 100 Days Mission.

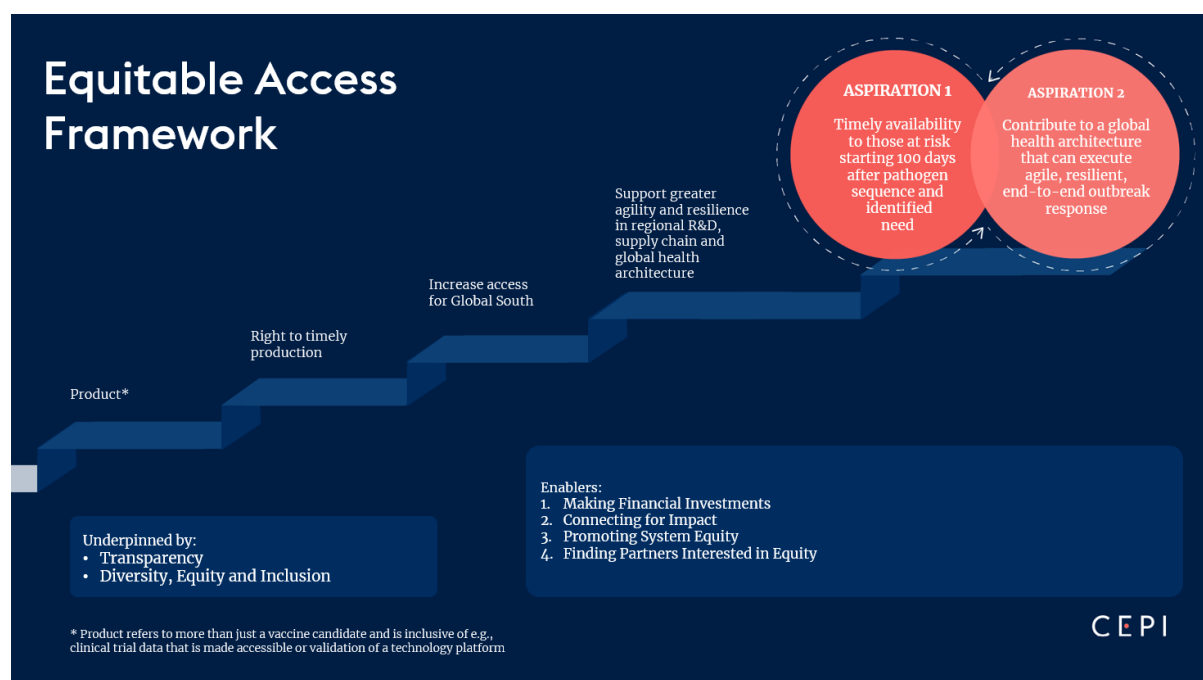
This continuum shapes CEPI's EA Framework. Four key enablers embed this Framework in our activities and investment agreements:

1. *Supporting System Equity in Outbreak and Pandemic Prevention, Preparedness, & Response (PPR) Ecosystem* describes ways in which CEPI helps to strengthen equity, agility and resilience in a PPR ecosystem directly through our investments in partners and technologies as well as indirectly through our stakeholder influence, policy and advocacy work.
2. *Connecting for Impact* describes the opportunity to connect, collaborate, and coordinate our efforts with other public stakeholders to strengthen the global health architecture for PPR in ways that promote EA as a natural output of the system.
3. *Making Financial Investments* outlines how CEPI makes financial investments to support its mission by incorporating access obligations and other contractual terms in all of its investment agreements in order to achieve its EA goals.
4. *Investing in Partners with an Interest in Equity* demonstrates how by choosing partners - private as well as public - with a shared vision of equity we can more effectively and efficiently deliver on our

mission. This section also describes how we are evolving our business models to broaden the potential for more sustainable EA based strategic partnerships.

CEPI’s activities are underpinned by an approach that emphasises Transparency, Diversity, and Inclusion as core principles of our EA governance process. CEPI reinforces these principles in our agreements and translates these through our connections and partnerships with other stakeholders to advance end-to-end system equity.

These themes and their connections are depicted in the graphic below.



With the EA Framework established, CEPI will work with the Equitable Access Committee on a full implementation plan that details the governance processes, appropriate partnership structures, and resources required to execute in the most efficient way.

## Introduction

In light of CEPI’s experience during the pandemic and the expansion of CEPI’s scope under CEPI 2.0 to include taking some products to licensure (or emergency use authorization), the Board asked management to prepare an EA Framework that captures what EA means for CEPI under CEPI 2.0 and how we will proactively operationalize key aspects of that Framework. This document responds to that request.

Particular areas requiring clarity are CEPI’s scope of accountability in relation to other stakeholders in the public health ecosystem and the differences in approach that may be required depending on variables such as the size of the outbreak, transmission potential and other characteristics of the pathogen, and region involved.

CEPI operates within an imperfect global health ecosystem, accelerating R&D and manufacturing (R&D&M) to prepare for and respond to emerging infectious disease threats with EA as a core mandate. The EA Framework articulates CEPI’s aspirations concerning EA, the reasons for those aspirations, and

the way in which CEPI will approach those aspirations. It goes on to look at the end-to-end life cycle process from creation to deployment of product with particular focus on how we make our investments with both public and private strategic partnerships and engage other stakeholders in strengthening the global health architecture to ensure clear and efficient hand-offs to public partners. Finally, it emphasizes the importance of promoting diversity, equity and inclusion through our efforts to achieve EA as well as transparency with respect to the commitments we obtain and the impact we have.

To achieve CEPI's 2.0 EA goals, the EA Framework adopts a systems approach. Some elements of this are led by CEPI and other elements, outside of CEPI's control or remit, may be stewarded or influenced by CEPI's actions and advocacy. Where CEPI can control outcomes through its investments, the framework reviews how we can best achieve our goals. Where CEPI does not control but can influence outcomes, the framework focuses on what CEPI needs from the ecosystem to be successful. This systems approach to EA alongside R&D and manufacturing, will enable CEPI to plan, prepare, and ultimately enable EA in outbreaks and epidemics in a robust manner.

## Aspirations and Approach

Two aspirations provide direction for CEPI's efforts:

- Directly – CEPI aspires to enable timely availability of CEPI-supported products to those at risk, starting just 100 days from pathogen sequence and identified need.
- Indirectly – CEPI aspires to support and contribute to a global health architecture that can execute agile, resilient, end-to-end outbreak response.

Developing products and technologies for outbreak prone diseases, and our work on Disease X and prototype vaccines, provide CEPI and its partners the opportunity to practice and hone plans and processes that will support more rapid responses to future outbreaks.

Given the struggles of the existing health architecture to produce equitable outcomes during the pandemic, the question arises as to how CEPI should work on both short-term and long-term horizons and in the context of developing vaccines against different kinds of threats. The following objectives guide decisions on individual projects, help secure a balanced R&D and manufacturing portfolio, and anchor CEPI's investments and activities.

1. **Rapidly advance product development.** There can be no access without a product. Experience during the pandemic suggests that the first safe and effective products to market will garner most of the demand while products arriving later may struggle to establish themselves. During the COVID pandemic, factors that typically influence uptake in the global health context, such as product thermostability and price, proved to be secondary considerations. Countries established deployment systems that worked for the early products and demonstrated limited motivation, in the absence of significant clinical differentiation or price advantages, to adopt new products, especially when demand declined precipitously.
2. **Secure the right to require timely production and deployment of products for at-risk populations in LMICs no later than for others at similar risk level.** Since CEPI looks to Gavi, UNICEF, and others to manage the procurement and distribution of licensed products, the furthest CEPI can go in securing availability is to require manufacturing and stockpiling of investigational products for epidemic diseases and, in the event of a pandemic, to support scale up and scale out (i.e., technology transfer) of vaccine production. Scaling up and scaling out of vaccine production entails substantial investment at risk, as demonstrated by a number of CEPI's investments during the pandemic. CEPI's principles and approach to securing availability where it funds development or manufacture are set out more fully later in this paper. Changes in how the global health architecture and international PPR systems operate to promote EA could improve the chances of success here.

3. **Make investments to increase utility of products for the Global South.** Given the limitations of donor funding for vaccine procurement for the Global South and the challenges of deploying product in many locations, CEPI continues to work with developers to reduce the cost and optimize product characteristics of vaccines intended for the Global South. An increasing focus here is to invest in innovations that can be applied across multiple products, such as formulation work to enhance thermostability or to enable needle-free presentation or optimized dosing.
4. **Support greater agility and resilience in regional R&D&M, supply chain and global health architecture to achieve the 100 Days Mission.** Despite promising proposals such as the Berlin Declaration and the positive pronouncements made by HIC leaders, there remain few binding commitments to make products manufactured in HICs available to the Global South in a timely manner during conditions of scarcity. Through its investments and policy work, CEPI promotes the geodiversification of vaccine manufacturing and supports the evolution of a more resilient global health architecture to enable EA.

With these objectives as the backbone of our efforts, CEPI's EA Framework anchors our investments and other activities through four key enablers. These are underpinned by an approach that emphasises Transparency, Diversity, and Inclusion in our EA governance process.

## Key Enablers

### *Supporting System Equity in Outbreak and Pandemic PPR Ecosystem*

The current innovation ecosystem does not routinely or reliably result in EA to innovative new products. The causes of inequity are manifold and relate to the concentration of scientific and productive resources in certain regions, the fragility of healthcare delivery in others, the complexities and inertia of regulatory systems, the positive and negative incentives provided by current intellectual property regimes, differential access to capital, shifting political priorities, and other factors. Even as CEPI invests in specific vaccine development projects, where it can it must also seek to remedy these structural causes of inequity. While CEPI develops vaccines for specified outbreak prone diseases, it also invests in platforms and prototype vaccines for virus families as a means of improving global R&D robustness to support outbreak/pandemic response, in line with the 100 Days Mission. CEPI contributes to the development of an overall preparedness and response ecosystem that increasingly addresses system inequities and puts EA at the heart of future outbreak response. It is important to emphasize that while CEPI's primary focus remains the "product", it also works to strengthen the architecture and ecosystem in ways that help CEPI accomplish its mission with respect to EA.

We believe that CEPI can most effectively contribute to strengthening what we have described as "system equity" by concentrating its efforts on:

- Geographical diversification
- Policy engagement and advocacy
- Co-amplification of resources and efforts of key stakeholders
- Regulatory readiness
- Networked, collaborative approaches.

**Geographical diversification.** The regional distribution of the resources and capabilities required to support end-to-end development and delivery of vaccines and other targeted biologic countermeasures would strengthen regional self-sufficiency and increase EA. Such distribution can be achieved through technology transfers or increasingly by de novo innovation and investment within regions, as demonstrated in many locations during the pandemic. In either case, if the goal is to promote self-sufficiency, there will also be a need to strengthen supply chains within the recipient countries and regions. Ideally, CEPI-funded technology transfers to the Global South should lead to learning and

ultimately support R&D originating in the target region that addresses local needs and requirements. CEPI's investment should also ensure essential and appropriate innovative technologies it funds are tuned to the exigencies of LMIC deployment (thermostability, etc.).

**Promoting a preparedness and response architecture with EA at the core through policy engagement and advocacy.** Key areas of focus for CEPI include:

- Promoting strengthened political leadership and solidarity through strengthening preparedness and response architecture, including strengthening IHR, establishment of a new pandemic treaty, and a global health threats council or board at the head-of-state level.
- Promoting leverage of R&D and procurement agreements by public funders, countries, and regions to enable EA by contractual obligations (e.g., conditions for rapid data/sample sharing, tech transfers, volume allocations, pricing).
- Advocating for predictable and sustainable end-to-end financing for preparedness and response, including for R&D response activities, manufacturing 'at-risk' and advanced purchase agreements. These will incentivize R&D and manufacturing of, and facilitate EA to, medical countermeasures.
- Advocating for an ecosystem supporting sustainable geo-diversified manufacturing, including regulatory readiness and trade policies to facilitate the free flow of medical countermeasures and critical supplies across borders.
- Advocating for the establishment of risk sharing, no-fault compensation and indemnification and liability measures for new medical countermeasures.
- Promoting equity, inclusion, and diversity in global governance processes.

**Amplifying the resources and efforts of stakeholders.** CEPI's contributions to system equity are a mix of financial and intellectual components. CEPI can and must strengthen equity, agility, and resilience in the health ecosystem through our partnerships as we cannot do it all. Coordinating efforts with other funders (e.g. BMGF, Open Society) and facilitating organizations (e.g. WHO, PAHO, AU, Africa CDC, GAVI, UNICEF) who share our commitment to EA and make complementary investments downstream from CEPI is essential to achieving wider and deeper reach for our own investments.

**Regulatory readiness that enables rapid response.** CEPI seeks to engage regulatory agencies to develop harmonised, outbreak-ready regulatory pathways, that will enable rapid and timely access to new medical countermeasures. Partner commitments to pursuing authorization for use (including WHO EUL/prequalification) in countries where need is critical are a key enabler of timely availability and use in LMICs. Eventually, the need to grow and mature LMIC regulatory systems to support tech transfer and innovation origination will enable quicker local decision making and result in greater self-sufficiency from a regulatory perspective.

**A strengthened networked collaborative approach.** CEPI's investments in enabling science activities and knowledge sharing through a geographically diverse network of laboratories and clinical trial centres in the Global South can be leveraged to enhance collaboration and scientific productivity by LMIC researchers. CEPI's requirement for sharing knowledge (via the sharing of data, research results, biological materials, and publications) and investments in human capacity strengthening through education, training, internships, and sponsorships are essential to improve the collective knowledge base in LMICs and speed up diversification and access to interventions for all.

## ***Connecting for Impact***

The emergence of SARS-CoV-2 dramatically increased the number of public stakeholders interested in outbreak and pandemic PPR. This presents both a challenge and opportunity for CEPI – a challenge, as several global institutions are now active or indicating a willingness to be involved in the area which makes it imperative for CEPI to have a clear value proposition to both private and public partners and be able to differentiate its role; and an opportunity, as the pandemic has highlighted the need to collaborate with these public stakeholders to strengthen the global health architecture and invest in pandemic PPR, with organizations such as WHO, HERA, SCARDA, BARDA, TLS, Africa CDC, Gavi, World Bank and others

working on new PPR initiatives. Each of these organizations has a unique role, institutional memory, and expertise.

CEPI connects with those organisations in 3 spheres:

1. Technology
2. Geography
3. End-to-end hand-offs.

**Technology:** Of the few organisations with a global remit, only CEPI is singularly focused on the acceleration of R&D and manufacturing for vaccines and other biological medical countermeasures for emerging infectious disease outbreaks. Given this, CEPI can partner with others to facilitate and coordinate discussions and in some cases, decisions, on where R&D and manufacturing investments are best made and who might make them. Examples of these collaborations include CEPI's close work with organizations such as WHO, NIH, etc. to align on developing Target Product Profiles (TPP) for the leading pathogens CEPI funds to ensure all stakeholders are developing products of similar profile with favorable product characteristics, such as number of doses, storage condition, shelf life, etc., that may render the product suitable for use in LMICs. Regarding manufacturing, CEPI's focus is on (1) installing or otherwise securing agile capacity to enable rapid outbreak response; and (2) investments that enable flexible reservations of capacity close to outbreak prone areas (potentially through strategic partnerships).

**Geography:** Historically, public-sector partners have been driven by the current priorities of the countries that they support, rather than the potentially volatile and uncertain future needs for outbreaks, and this reality makes private-sector development and manufacturing partners unwilling to commit given the lack of clarity on future demand. This dynamic can lead to a system which is disjointed and unprepared to deploy products in the event of an outbreak. The emergence of new regional entities such as HERA and SCARDA, focused solely on health security threats relevant to their respective regions, may provide encouragement to private sector partners that their governments are now seriously focused on the threat.

In comparison with some of the agencies mentioned, CEPI engages more with LMICs and UMICs at risk of outbreaks of CEPI's priority pathogens to achieve better PPR and will bring a network enriched by such partnerships to negotiations with regional entities. Whereas the national medical countermeasure authorities will prioritize diseases relevant to their own populations, CEPI prioritizes the diseases that threaten LMICs. One example of CEPI's approach is our Lassa ENABLE study which is building and strengthening epidemiological capacity in Lassa endemic countries in West Africa. The output from the ENABLE study will guide the clinical trial licensure plan for Lassa vaccines along with a potential deployment strategy.

**End-to-end hand-offs:** CEPI's role early in R&D&M and its focus on EA gives it a privileged vantage point from which to assess the productivity of the system as a whole, so CEPI often becomes aware of issues related to hand-offs or gaps in the "chain of custody" for a given product. CEPI highlights these gaps to relevant stakeholders and works to address them through multilateral stakeholder dialogues in forums such as CEPI's Joint Coordination Group (JCG), COVAX, WHO's Product Development for Vaccines Advisory Committee (PDVAC), etc. Where CEPI is not accountable for an activity, CEPI should:

1. Be clear as to what is needed, when and from whom to achieve timely availability of safe and effective product for those in need.
2. Be clear on CEPI's contribution and mandate and where that ends.
3. Use every opportunity to practice the envisaged hand-off ahead of that activity so that those hand-offs become faster and more effective.
4. Encourage strong, long-term relationship management with the relevant stakeholder.

CEPI recognizes that on certain occasions other institutions it seeks to partner with may not be ready or aligned with its goals of EA, due to the use of different criteria to prioritize diseases, unclear responsibilities, or lack of mandate. CEPI will engage with endemic countries and other organizations such as PAHO or UNICEF to apprise them of vaccine availability and potential procurement mechanisms

that can be utilized to access the vaccine. This style of approach had some success with Gavi during the SARS-CoV-2 pandemic.

Hand off of responsibility could be the key enabler of success in achieving timely access and deployment. For investigational stockpile vaccine doses in Phase II (for outbreak management), CEPI will continue to request vaccine manufacturers to store the doses, while for licensed vaccines, CEPI will assess whether WHO's International Coordination Group (ICG) on vaccine provision can take over the stockpile storage, disbursement, and replenishment responsibilities as it has done for the Oral Cholera Vaccine (OCV), Yellow Fever vaccines, and Meningococcal vaccines.

## ***Making Financial Investments***

CEPI makes investments with the aim of being prepared for outbreaks, accelerating development/innovation, and making the outputs available (be they product, technology, enabling science or results). Alternatively, that funding may be to support a technical capability needed to respond to an outbreak. Outbreaks of a particular pathogen are, by their nature, likely to reoccur and financial investment early in an outbreak to support product development or manufacture and secure timely availability of that product may also support preparedness for future outbreaks.

CEPI incorporates obligations and other terms in all its R&D&M and other investment agreements in order to achieve its EA goals with each Awardee and project. These terms, or EA building blocks, differ depending on the goals of the investment, the nature of the partner and the relative leverage in the negotiations, among other considerations.

**Bespoke EA solutions using EA building blocks:** The CEPI EA Policy includes a set of principles that help to provide guidance and guardrails and allow for measurement of success. From an investment standpoint, multiple functional teams within CEPI (Research and Development, Manufacturing, Access and Private Partnerships) focus on ensuring EA is enabled for any given CEPI investment. CEPI's resulting agreements with Partners must include specific and measurable objectives as captured in an EA Plan, including obligations and deliverables as part of performance of each stage of the project.

Each CEPI deal is bespoke, based on CEPI's EA Policy and draws on CEPI existing practical learnings. Many building blocks can be viewed as must-haves or nice-to-haves depending on the vision of the project and the overall CEPI portfolio needs. Furthermore, these blocks can also be seen as having gradients or levels of importance, with variables such as the size of investment and whether there is co-funding which will influence the X% of doses that are first made available to LMIC purchasers, for example, based on the anticipated outbreak response needed. Each CEPI investment agreement can use a different combination of tools to achieve a result that, when combined with other CEPI deals, makes for a balanced portfolio across all investments. Specific examples of these tools are described in detail in Appendix A.

**Lifecycle management and monitoring project EA:** Throughout the lifecycle of CEPI projects there is a required evaluation of EA goals as part of the Stage Gate process and using tools such as the project Target Product Profile, EA Plan and [EA Dashboard](#). This type of system monitoring can often provide early warning indications if, for example, dose Cost of Goods might be too high due to certain raw materials; or formulation stability is no longer suitable for LMIC environments; or if a partner fails to deliver on access obligations such as timely endemic product registration. CEPI can then course correct as needed or terminate the program if it is unlikely to deliver on the EA goals.

## ***Investing in Partners with an Interest in Equity***

Engaging with the most appropriate industry partners is critical when implementing the CEPI 2.0 strategy and 100 Days Mission to achieve CEPI's EA goals. While CEPI 1.0 primarily involved developing vaccines on promising but unvalidated platforms against pathogens with limited commercial interest, CEPI 2.0's aspirations and goals are being pursued in the more competitive space of rapid response platforms, including those that have achieved commercial validation during the SARS-Cov-2 pandemic. In addition, CEPI's goal of EA sometimes works at cross purposes with the goals of other systems. For example, university technology transfer offices maximizing profit and not including EA considerations in out-licenses, or G7 countries using the leverage of substantial financial resources purely for their own procurement without global access commitments serve as barriers to EA. Reforms of these systems to create a more uniform set of obligations concerning EA as a requirement of public funding may increase the probability of private partners being open to working with CEPI and in particular committing to EA.

**Broader and more strategic partnerships** with select industry partners. CEPI's ability to form and sustain a mutually beneficial agreements depends on both the needs and aspirations of the commercial partner and CEPI. Finding a business model that supports preparedness and end-to-end EA and balances these priorities with the partners' 'peacetime' business is crucial. Moving to broader, more strategic transactions that transcend individual projects and allow the introduction of other elements with more certain revenue potential for partners may enable CEPI to secure the most appropriate and capable partners.

**Promoting the adoption of EA measures in commercialization of academic research.** Governments and regional institutions can play an important role in enabling faster and broader EA to MCMs in ongoing and future outbreaks by embedding EA measures into funding agreements for research and development or related legislation where they play a major role. Similarly, academic institutions, whether required to by their funder or not, could include EA measures in the commercialization of their research outputs. If one or both these steps is taken, industry will take on the technology with obligations around EA, making them more likely to accept a continuation of those commitments.

**Promoting the adoption of EA measures in government procurement terms.** Governments and regional institutions have another opportunity to enable EA to MCMs in outbreaks by embedding EA measures into procurement agreements and advance purchase agreements. This has been suggested by the G7 Pandemic Preparedness Partnership, the Global Preparedness and Monitoring Board and The Independent Panel for Pandemic Preparedness and Response, among others.

**Public partnerships.** CEPI advocates for changes, where it has leverage, which have the biggest impact on its ability to deliver timely availability of its portfolio and other MCMs. EA is a focus area in the ongoing discussions on the future pandemic and response ecosystem, the Intergovernmental Negotiating Body discussions on a Global Accord for pandemics, the WHO's plan for a safer world, as well as the G20 work on health and finance. Public partners including governments and regional organisations also play a crucial role in supporting EA through a global health architecture that is responsive to EA, such as through financing, trade policies on exports, harmonization of regulatory requirements and legislation enabling risk sharing mechanisms appropriate for outbreak situations.

## Underpinning Principles

### *Diversity, Equity and Inclusion in EA Governance*

Enabling EA to products can be complex in outbreaks given the volatility, uncertainty and ambiguity involved. We need to review these challenges, which are often multifactorial, from all angles to solve them effectively. To do that we will include diverse perspectives in our oversight structures and governance bodies, including by gender, race and different individuals and entities from different



sectors of society. This is with the intent that CEPI's governance is representative of the world we aspire to serve as well as each part of the value chain.

Specifically, CEPI will work to ensure that the Board, including the EA Committee, the Scientific Advisory Committee and Joint Coordination Group as well as the Stage Gate Review Committees include sufficient representatives with appropriate experience in the area of EA and representatives from the Global South and are conducted in such a way as to enable the diverse perspectives to be assimilated.

## ***Transparency***

A demonstrable commitment to transparency must underpin CEPI's EA Framework, thereby enhancing the accountability of CEPI and its vaccine development partners for enabling EA; and ensuring better understanding of CEPI's approach to this complex issue amongst investors, partners, stakeholders and the broader public. CEPI's existing [Transparency and Confidentiality Policy](#) is based on the premise that the effectiveness of CEPI's programmes is strengthened by public access to information about the organization's activities and the EA commitments secured. CEPI's Transparency and Confidentiality Policy recognizes that CEPI must ensure confidentiality of business-sensitive information, including technical and in some cases financial information. CEPI must, therefore, balance the need for and benefits of transparency with the requirement to keep commercially sensitive information confidential so as not to preclude critical partners from working with CEPI. Details of CEPI's approach to transparency to date and recommendations for the future are in Appendix B.

## APPENDIX A – FINANCIAL INVESTMENTS, SPECIFIC EXAMPLES

Selected specific examples of how tools (building blocks) which represent intellectual outcomes or physical products are included in CEPI agreements:

### Access to and sharing of data and information, publication (open access)

- Requirements for data sharing, e.g., mandated registration of data in public clinical trial registers and publication in open access journals in a timely fashion so that all developers can benefit from current knowledge of a disease and interventions. Providing public access to the outputs of the funded research can accelerate scientific research in this field.
- Requirements for publication of key deal terms. For example, awareness of which products in what quantities were being sold in which markets would have greatly improved the ability of countries and COVAX to plan and negotiate their own agreements.

**Stockpile commitments:** As part of its CEPI 1.0 outbreak preparedness requirements, CEPI secured the right to call for clinical trial ready reserves of a vaccine candidate, upon successful completion of Phase II clinical trials, for use in Phase III clinical trials or for distribution in the event of an outbreak if authorized by local regulators. These commitments are typically in the range of 100k to 200k doses, for example, as reflected in an agreement in which CEPI secured a commitment to manufacture, fill, finish and release 100,000 doses in an affected territory within 8 weeks of demonstration of clinical benefit. CEPI can use the stock in an outbreak and seek replenishment on request, subject to paying the cost of production, while the partner can use the product for its commercial market subject to replenishment at its own cost.

**Affordable & sustainable pricing:** CEPI funding agreements typically explicitly acknowledge that the price of project vaccines is critical to achieving EA and commit to a methodology to determine the cost of vaccines, and their price, considering the need to balance availability and affordability for populations in need, with financial sustainability for manufacture and supply. Increasingly, CEPI seeks to cap the price at COGs + X% for allocation to LMICs and requires that purchases by CEPI or GAVI, or their respective designees, cannot be higher than the lowest price at which an Awardee sells a project vaccine to any third party in any LMIC. Where possible, CEPI also obtains the right to audit COGs.

**Preparedness and response obligations:** Obligations in the case of future outbreaks, with defined triggers, such as scaling up production, allocation of manufacturing capacity, or access to platforms through mandated technology transfers to trusted partners.

**Continuity in product development, manufacture and supply:** Traditionally CEPI relies on step-in-rights enabled by CEPI's public health license to ensure continuity in product development, manufacture and supply. Multi-national corporations and those working on vaccine platforms resist such rights because of their strategic impact. Intended as a measure of last resort in the event of non-performance or in response to an outbreak, in practice, exercising these rights can also be challenging if there is a funding gap and an awardee continues development independently of CEPI. Recent funding agreements strengthen continuity and bridge the gap with this measure of last resort by contemplating additional work packages subject to further funding by CEPI, or by securing a "first right to fund" that ensures CEPI shall have the first right (but not the obligation), to further fund the development, manufacture and deployment of a project vaccine.

## APPENDIX B – Transparency

### CEPI's approach to transparency to date

CEPI has taken the following approach to transparency regarding EA to date:

- Announced all vaccine development partners via a press release and on the CEPI website, with a short statement about how access will be achieved or a joint commitment to access.
- Published a summary of [CEPI's approach to enabling access for its CEPI 1.0 priority pathogens](#), including a brief indication of which terms are included in which partnership agreements.
- Published a summary of [CEPI's approach to enabling access for its COVID-19 portfolio](#), including a brief summary of the terms in each partnership agreement.
- Published a [EA Dashboard](#) and an [independent EA review](#) of CEPI's COVID-19 agreements.
- Published details of CEPI governance and decision-making bodies, and minutes of Board and EA Committee meetings.

This approach has been broadly acceptable to most stakeholders but has been criticized as inadequate by some access advocacy groups. The CEPI 1.0 independent outcome evaluation report noted that some stakeholders commented on a lack of transparency on CEPI's access provisions and recommended greater communication and transparency regarding CEPI's EA Policy in line with the approach taken in COVID and how it plans to achieve EA.

### Recommended approach to transparency and EA

The following recommendations have been developed after careful consideration of the strategic value of transparency to enabling EA.

- Create and maintain a section of the CEPI website dedicated to access with a clear narrative explaining CEPI's approach to access, and signposting to all relevant published documents.
- Replicate the approach taken for COVID-19 by publishing summaries of access terms in CEPI funding agreements for other work areas.
- Publish explainers on the CEPI website and social media channels which describe how CEPI makes key decisions that influence access, e.g., CEPI's process for making investment decisions from Call for Proposals through governance.
- Continue to convene the EA Committee (EAC), ensure that CEPI's approach to access is anchored in guidance from this committee and that committee members have access to information when public disclosure is not possible in line with current practice.
- Continue to publish Board and EAC minutes and commit to doing so in a timely fashion.
- Replicate the approach taken for COVID-19 by commissioning independent EA reviews of each of CEPI's priority pathogens. Publish these reviews in full alongside actions to address findings.
- Host roundtables with relevant stakeholders including CSOs to discuss further strengthening access and transparency within the limitations discussed in this document.