



CEPI 2022-2026 Strategy

March 2021

Executive Summary

Since 2017, CEPI has established itself as an integral part of the global health security system. The response to COVID-19 has transformed both the landscape and CEPI's activities. CEPI provided early ignition funding for COVID-19 vaccine development, developed a technologically and geographically diverse COVID-19 vaccine portfolio, played a key role in the establishment of COVAX, and leveraged investments in scaling up and scaling out manufacturing capacity to secure global access commitments.

The 2022-2026 strategy was developed in the context of great political focus on health security, historic innovations in vaccine technology, strong industry engagement, unprecedented investments in vaccine R&D & manufacturing capacity, and the establishment of new regional and international collaborations.

The response to the pandemic is also revealing what more the world must do to improve national and global health security. CEPI is well positioned to help catalyse a post-pandemic consensus, weaving together the capabilities and expertise of public and private sectors to enhance global response capacity.

In light of experience gained responding to COVID-19, and in anticipation of the challenges of the next five years, CEPI has made modest revisions to its vision and mission statements, as follows:

CEPI's vision is a world in which epidemics and pandemics are no longer a threat to humanity.

CEPI's mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.

The world needs to raise the bar for developing and scaling vaccines and other promising biologics needing public funding. Over the next five years, CEPI will work toward the aspirational goal of reducing the time from pathogen characterisation to availability of data for assessing emergency use to 100 days. It will also make significant investments in dramatically reducing or eliminating the pandemic risk presented by a uniquely dangerous family of viruses (*Coronaviridae*).

To achieve its mission, CEPI has three **strategic objectives** for CEPI 2.0:

Prepare for known epidemic and pandemic threats by building on COVID-19 achievements and CEPI 1.0 to develop vaccines and promising biologics against the most prominent known threats, leveraging market forces where possible and making critical, catalytic investments where they are insufficient

Transform the response to the next novel threat by harnessing innovations in technology and response systems to prepare for and systematically reduce vulnerability to a broad range of viral threats

Connect to enhance and expand global collaboration by driving the development of a post-pandemic consensus and contributing to the design of a more robust and effective global preparedness and response architecture.

Partnerships are a critical element. CEPI will evolve as an organisation to both adapt to and influence the rapidly changing ecosystem, politics, policies, roles and responsibilities of key decision makers and partners. A key component of our approach to partnerships will be focussed on engagement with LMICs.

A detailed implementation plan for the CEPI strategy for 2022-26 will be developed in 2021, building from an assessment of implications and risks related to the new strategy and will include the updated governance structure, organizational arrangements, and decision-making processes to guide the implementation of the strategy starting in 2022.

The forecasted financial needs for the 2022-2026 business cycle are in the range of **US\$ 3.5 to 4 billion**.

Context

Outbreaks of infectious diseases are inevitable, given the rapid rise in urbanisation, changes in climate, and increasing contact patterns between people and animals. In a globally connected world, this also increases the risk for such outbreaks to become epidemics and even pandemics.

Historically, vaccine development has been a long, risky and costly endeavor. This is especially true when it comes to emerging infectious diseases (EIDs): risky development pathways and poor commercial prospects stall their development and hinder vaccine access, especially for people living in low-income and middle-income countries (LMICs).

CEPI was created in the aftermath of the 2014–2016 Ebola epidemic in three West African countries, resulting from a consensus that a coordinated, international, and intergovernmental plan was needed to develop and deploy new vaccines to prevent future epidemics. “Finishing the job on Ebola” was thus central to CEPI’s initial mission.

Since 2017, CEPI has established itself as an important part of the global health security system, through its leadership in advancing vaccine development against emerging infectious diseases and through its response to the COVID-19 pandemic.

From 2017 to 2019, CEPI pursued its mission of accelerating the development of vaccines against EIDs and enabling equitable access for vulnerable populations during outbreaks by funding programmes for a set of priority pathogens with the WHO R&D Blueprint as a starting point, and making targeted investments in novel rapid response platforms. Before COVID-19, CEPI had invested in 18 vaccine candidates against five priority pathogens¹ and three rapid response platforms².

At the beginning of 2020, CEPI expanded its remit to respond to the COVID-19 pandemic (see **Figure 1**). The WHO was alerted to the outbreak on 31 December 2019 and by 23 January, CEPI had announced three projects to develop vaccines against SARS-CoV-2. CEPI leveraged its existing investments in vaccines against MERS-CoV and novel platform technologies and was the first funder for 9 product developers, providing ignition capital that enabled rapid vaccine development. CEPI identified the need for and co-established a global financing and allocation system for manufacturing and procurement, while funding scale-up and scale-out of manufacturing capacity globally. CEPI has thus played a key role in cutting the time required to develop and deliver vaccines globally from a matter of years to ~12–18 months.

As CEPI prepares for its replenishment campaign, it is important to note that to date a significant portion of CEPI’s funding has come from Overseas Development Aid (ODA) sources. CEPI has used these resources to secure social and economic benefits for developing countries by enabling access to future vaccines in areas where outbreaks occur.³ Whilst the principle of equitable access is core to CEPI’s mission and crucial to the prevention and management of future epidemics, the pandemic has underscored the need for a holistic, global approach to preparedness and response. Fostering cross-sectoral political support to maintain sustainable funding from a broad array of sources, including but extending beyond those dedicated to ODA, will be essential if CEPI is to achieve its goals in 2022–2026.

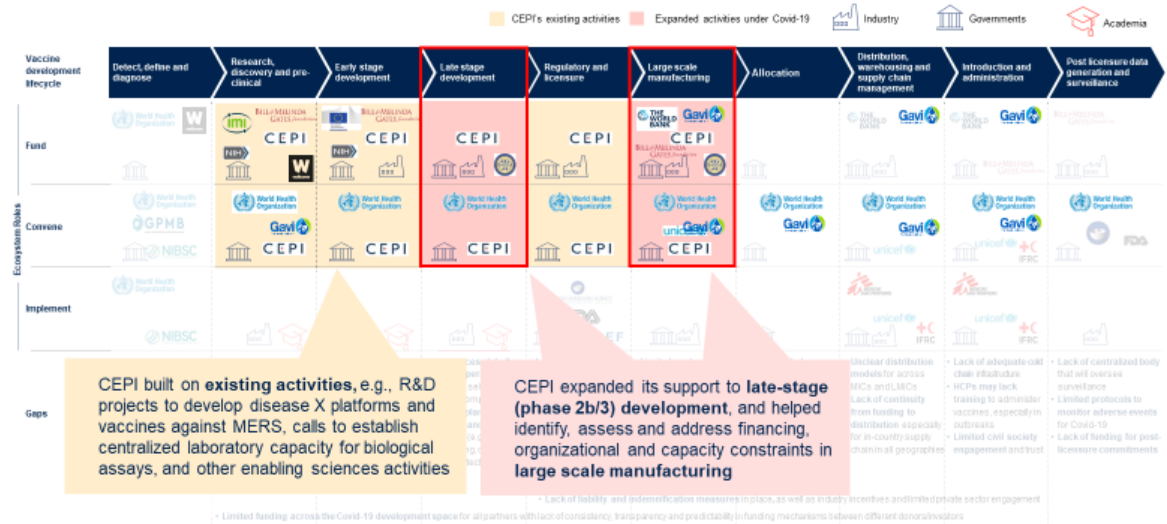
¹ The list of priority pathogens includes those which cause Lassa fever, Middle East Respiratory Syndrome (MERS), Nipah, Chikungunya and Rift Valley fever

² Refer to CEPI/B12/07.01 Core (Non-COVID-19) Portfolio Update for a complete description of CEPI’s investments to date.

³ 35% of CEPI funding for the core portfolio in the 2017–2022 comes from ODA sources. Of investments towards COVID vaccine development, approximately 40% came from ODA sources.

Figure 1: CEPI expanded its scope of activities to address COVID-19

To address Covid-19, CEPI moved to fill gaps in the ecosystem (incl. through COVAX) building on existing activities and expanding into new ones NOT EXHAUSTIVE



CEPI has also played a leading role to promote the fair global allocation of vaccines, in line with equitable access principles and co-convenes the ACT Accelerator's vaccine pillar "COVAX".

A Transformative Moment

CEPI now finds itself in the midst of rapid developments on several fronts, with intense political interest in its activities, new vaccine platforms being validated, high levels of industry engagement, domestic and regional investments in vaccine R&D and manufacturing capacity, and new forms of regional and international collaboration.

Technologically, COVID-19 has led to an unprecedented race to develop vaccines that will transform the science and economics of vaccine development and manufacturing. Given the broad array of vaccines being developed, we are likely to see the validation of several new platforms in connection with the pandemic. This should fundamentally restructure the R&D agenda for epidemic and pandemic preparedness and response. With the expanded toolkit provided by these newly validated platforms, it will be possible to develop vaccine candidates against a wide range of infectious diseases that present epidemic and pandemic threats. The development of such vaccines will contribute directly to the reduction of epidemic and pandemic risk while at the same time helping regulators better understand the performance and safety of the platforms and thereby gradually simplify the requirements and reduce the time for regulatory review of new vaccine candidates. This virtuous loop will shorten cycle times for the development of vaccines against truly novel threats.

We anticipate that there will be a new and stronger political commitment to address epidemic and pandemic risk. Several countries — many of which are current CEPI investors — are addressing national vulnerabilities deriving from limited capacity for R&D, lack of manufacturing capability, extended supply chains, and lack of enabling national policies and legislation. We are seeing increased investments in national capacities, which will improve the global capacity for outbreak response, especially if coordinated for the mutual and greater common good without infringing upon sovereign control. To realize their potential, and minimize duplication, newly created national or regional initiatives or agencies (e.g., the EU Health Emergency Preparedness and Response Authority (HERA)) will benefit from coordination with globally oriented entities like CEPI.

The pharmaceutical industry has played a critical role in the response to COVID-19, both through partnerships with the global health community as well as through bilateral agreements with governments. Large industry partners have previously lacked the necessary incentives to engage in the development of vaccines for EIDs, due to uncertain demand for such products, but new opportunities for collaboration have arisen as a result of partnerships forged in the response to COVID-19.

COVID-19 is also reshaping the global health landscape. Through the Access to COVID-19 Tools (ACT) Accelerator, organisations with related but separate missions are collaborating towards the common goals of accelerating development, production, and equitable access to COVID-19 tests, treatments, and vaccines. As part of the response, CEPI, alongside Gavi and the World Health Organisation, launched COVAX—the vaccines pillar of the ACT Accelerator – with the aim of providing an ‘end-to-end’ solution to the challenge of vaccine development, manufacture, and supply. This represents an unprecedented level of cooperation between global organisations and industry and will likely shape how partnerships are conceived and implemented moving forward, depending on the level of success achieved in meeting the objectives of the ACT Accelerator. COVID-19 has demonstrated that mechanisms to ensure collaborative solutions that leave no one behind can be created and will be required to effectively tackle future threats.

While vaccine development has benefited from much attention and investments during the COVID-19 pandemic, key gaps remain in the therapeutics and diagnostics ecosystems, with the most important challenges being in late-stage development and deployment. Additional biological prophylactics, such as monoclonal antibodies, are promising complementary approaches to vaccination for many outbreaks and will become increasingly important in the coming years. Recent technological advancements are opening opportunities to quickly develop therapeutic or preventative biologics at increasingly lower costs. These technologies will be critical for rapidly addressing epidemic and pandemic threats, but

there remain several barriers to enabling their development and access to those who need them⁴ and no international organization is currently charged with developing them for EIDs.

Overall, the COVID-19 pandemic has revealed how much more the world and governments can and must do to improve national and global health security. Epidemics and pandemics have devastating health, economic, and social consequences.⁵ The IMF projects a cumulative loss in global output of \$28 trillion by the end of 2025 due to COVID-19 but estimates that faster and more equitable access to medical solutions can reduce that impact by almost \$9 trillion over the same timeframe, benefitting all economies and reducing divergence.⁶ The impact of further reducing the timeline to develop a COVID-19, or any future pandemic, vaccine from the current 12-18 months on both human and socio-economic indicators would be dramatic.

Looking forward, governments and international agencies will strive to establish a post-pandemic consensus to enable collective action for reducing global epidemic and pandemic risk. CEPI has a critical role to play in the development of such a consensus. It has shown that it can act at pandemic speed and be an important connecting node within the evolving global preparedness and response architecture. In the next five years, CEPI can contribute substantially to the design of systems that bring together the capabilities and expertise of public and private sectors in a synergistic, amplifying and cost-effective manner, while helping governments fulfil their domestic obligations and achieve their collective goals.

⁴ IAVI/Wellcome (2020). “Expanding access to monoclonal antibody-based products: A global call to action.”

⁵ David E. Bloom, Daniel Cadarette, and Daniel L. Tortorice. “Our approach to vaccine finance is ill-suited to addressing epidemic risk.” *IMF Finance and Development*, September 2020, pp 54-57, <https://www.imf.org/external/pubs/ft/fandd/2020/09/vaccine-finance-epidemics-and-prevention-bloom.htm>.

⁶ International Monetary Fund, 2020. Transcript of October 2020 World Economic Outlook Press Briefing. [online] Available at: <https://www.imf.org/en/News/Articles/2020/10/13/tr101320-transcript-of-october-2020-world-economic-outlook-press-briefing> [Accessed 12 November 2020].

Vision and Mission

CEPI's vision is a world in which epidemics and pandemics are no longer a threat to humanity. Going forward, CEPI aims to raise the bar to develop and scale vaccines and other promising biologics even faster. The R&D community has moved with unprecedented speed in response to COVID-19, developing biological interventions like vaccines and monoclonal antibodies in less than 12 months. While these achievements are historic, what the world needs to avert the consequences of future epidemics and pandemics are countermeasures developed even faster.

CEPI believes **100 days** from the time of pathogen characterisation to availability of clinical data for deciding emergency use listing **should be the aspiration**. This “moon-shot” target focusses on shortening timelines by advancing vaccines platforms so that during outbreaks, the world can specifically channel resources towards generating sufficient safety data related to the specific pathogen before vaccines can be deployed. This will radically reduce global risk for epidemics and pandemics, be they due to natural, accidental or deliberate causes. Such an ambition, once unthinkable, is now within reach, because technologies such as mRNA vaccines have revolutionised vaccine development and manufacturing processes, and validation of the technology has now been achieved.

To get safe and effective vaccines at this speed, CEPI needs to expand its reach and increase its funding to transform outbreak preparedness and response. It will be critical to innovate across research, development, and manufacturing areas, advance the regulatory understanding of the new platforms, prepare clinical trial networks, develop vaccines against prototype viruses from the viral families of greatest concern, and coordinate scalable on-demand manufacturing networks. To accomplish such ambitious goals, CEPI must build a strong, truly global coalition to push for collaboration and solutions that will enable a faster system-wide response.

CEPI's mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need.

Pandemics impact the entire world, and resolving the threat anywhere requires preparedness and response everywhere. CEPI's unique value-add is to complement the market-driven availability of appropriate countermeasures in high-income countries and ensure that they are accessible to all populations that need them, without financial constraints.

Our activities will continue to address the three key areas in which the market fails global needs for vaccines targeting EIDs by ensuring **speedy response** to outbreaks through rapid vaccine and related countermeasure developments; making every effort to **enable globally fair and equitable access** to vaccines and targeted biologic countermeasures; and ensuring that in the mid-to-long-term, **appropriate vaccines** and promising biologics exist that can address the needs of all populations in all relevant geographies.

Strategic Objectives

To achieve its mission, CEPI has defined three strategic objectives:

1. **Prepare for known epidemic and pandemic threats** by building on COVID-19 achievements and CEPI 1.0 to develop vaccines and promising biologics against the most prominent known threats, leveraging market forces where possible and making critical, catalytic investments where they are insufficient
2. **Transform the response to the next novel threat** by harnessing innovations in technology and response systems to prepare for and systematically reduce vulnerability to a broad range of viral threats

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3. **Connect to enhance and expand global collaboration** by driving the development of a post-pandemic consensus and contributing to the design of a more robust and effective global preparedness and response architecture.

Prepare for known epidemic and pandemic threats

With the advantage of the technology leap enabled by COVID-19 achievements in the development of vaccines and other biologics, we will finish the work initiated during CEPI 1.0 against the most significant known threats and dramatically reduce or eliminate the pandemic risk presented by a uniquely dangerous family of viruses (Coronaviridae). Specifically, we will:

- **Help end the acute phase of the COVID-19 pandemic** by ensuring equitable access to a portfolio of COVID-19 vaccines addressing the needs of all, especially populations in LMICs. This means supporting the next wave of vaccines against COVID, ideally with single-dose, long acting, and thermostable characteristics.
- **Systematically eliminate the risk of further coronavirus pandemics**, using the acceleration in vaccine technologies and methods due to COVID-19 response to reduce the risk of future coronavirus pandemics and, if possible, develop a broadly effective beta-coronavirus vaccine.
- **Accelerate the development of vaccines and other biologics against other known high-risk pathogens**, completing vaccine development and manufacturing scale-up against multiple known threats such as Lassa, MERS, Nipah, Rift Valley Fever and Chikungunya.

We recognize the importance of biological therapeutics for responding to emerging infectious diseases, especially in LMICs. The synergies between biological prophylactics and therapeutics and vaccine development and the need for cost-effectiveness of and access to such tools make a careful expansion into this area appropriate, in close collaboration with organizations already active in the space.

In the short-term, CEPI will focus on biologics, making investments in capabilities for prophylactic vaccine-like technologies (e.g., monoclonal antibodies) where this makes sense for rapid response, with the aim of innovating towards driving down costs and making these technologies accessible to all. We will also create capacity to make catalytic, modest investments to establish a global network of diagnostics partners that will evaluate assays for priority pathogens, and support platform-based assay development. In the long-term we will continue to monitor the need to invest in other innovative diagnostic and therapeutic technologies with a focus on maximising synergies with core vaccine development activities, and in close collaboration with Coalition partners (e.g. IAVI, PATH, FIND) to avoid duplication of effort.

Transform the response to the next novel threat

Response to an unknown pathogen requires the necessary tools to speed vaccine development. To ensure a step change in the world's ability to rapidly respond to threats of novel pathogens, we will harness innovations in vaccines development and manufacturing to dramatically reduce the global impact from unknown pathogens. We will do so by:

- **Using vaccine development innovations to give us a head-start on other novel threats.** We will use the new vaccine platforms to develop clinical-stage vaccine candidates against pathogens representing a broad range of virus families which can be rapidly developed to licensure if needed or adapted if a novel but related threat emerges. We will further characterise innovative technologies (e.g., mRNA vaccines) that enable rapid response at scale to reduce the development process while focusing on safety by:
 - **Leveraging more priority pathogens** to further develop and characterise platforms to enable rapid development of vaccines or monoclonal antibodies and using such innovative technologies to develop vaccines against viable targets with a path to licensure and of value to LMICs
 - **Creating 'libraries' of vaccine candidates targeting different virus families** and developing those vaccines through phase 1 evaluation.

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- **Investing and scaling research capabilities which underpin rapid vaccine development.** We will invest in a global network of labs with innovative and standardised lab technologies, needed animal models, and regulatory and other critical enabling science. We will work with partners to ensure that clinical trial capacity is in place and with regulators to ensure that, where possible, critical regulatory questions are addressed in advance.
- **Investing in innovations to ensure vaccine manufacturing is cheaper, faster, and closer to an outbreak.** We will seek out and support the development of manufacturing innovations that can accelerate response or enable the scaling of production, particularly in LMIC settings. We will seek strategic alliances with and help coordinate across key manufacturing capacity holders (vaccine manufacturers, countries, etc).

Connect to enhance and expand global collaboration

To maximize their impact and reach, the products resulting from CEPI's stewardship should be deposited into a global system with pre-agreed governance and financing, allocation, and distribution mechanisms to govern their ultimate use. In the next business cycle, CEPI will take greater accountability for contributing to and shaping a post-pandemic consensus, creating a well-prepared system able to react quickly without leaving anyone behind.

We will:

- **Build a strong, post-pandemic global coalition,** connecting countries, industry, public & private sectors from all over the world, and global health partners to develop vaccines and build commitment to preparedness and access.
- **Push for collaboration and solutions which will enable a faster system-wide response.** We will push for rapid-response outbreak protocols and solutions to systemic bottlenecks (e.g., financing for at-risk manufacturing), support regulatory science, including through advocacy and contributions to global regulatory discussions, and help develop durable systems to address liability and indemnification concerns.
- **Coordinate a scalable on-demand manufacturing network.** We will work across the public and private sector to ensure economically and practically viable ready manufacturing capacity across the world.

Our greater commitment to catalyzing optimal global preparedness and response systems will be implemented through a partnership strategy described below.

Partnerships

Expanding CEPI’s partnerships and developing the partnership methodology

CEPI’s coalition partners include global health organisations, vaccine developers and manufacturers, academic institutions, governments, philanthropies and civil society. For CEPI 2.0 the ambition is to more explicitly connect countries’ resources and capacities as they relate to EIDs across countries of all income characteristics, with global industry partners – not least those located in developing countries, academic institutions and other public and private organisations in the global health ecosystem. This will require a more detailed and focused strategic collaboration with specific partners, and the strengthening of internal structures to manage these partnerships (see **Table 4**, next page).

Figure 4: Development of partnership methodology from CEPI 1.0 to CEPI 2.0

	CEPI 1.0	CEPI 2.0
Organizations	Type of partners <ul style="list-style-type: none"> Strong focus on R&D and contractual relationships Difficulty partnering with MNCs despite efforts to understand challenges and find compromises Europe/US focused partnerships Less focus on partnerships to drive outbreak preparedness and response through policy and advocacy 	<ul style="list-style-type: none"> Broader and deeper partnerships which help us deliver across the CEPI 2.0 strategic activities and the coalition’s priority topics: Global and regional partnerships (<i>where possible</i>) to scale impact and not spread CEPI’s resources thinly Invest in partnerships which help us deliver across the CEPI 2.0 agenda e.g.: <ul style="list-style-type: none"> Partnerships with industry players and MNCs across Vx and Tx R&D and manufacturing, e.g. DCVMN, IFPMA Partnerships with PDPs, e.g. IAVI on mAbs, PATH and FIND on diagnostics Develop partnerships to push the outbreak preparedness agenda through policy and advocacy <ul style="list-style-type: none"> Selective engagement with high-credibility partners e.g., socio-economic organizations (development banks), GHOs and alliances, CSOs
	Partnership management approach <ul style="list-style-type: none"> Lack of strategic “one-CEPI” approach towards partners <ul style="list-style-type: none"> Limited categorization/segmentation and prioritization of key partners Current culture and approach to relationship management results in a lack of cross-cutting alignment on key priorities for collaboration Strong presence at international conferences and high levels of engagement with industry forums 	<ul style="list-style-type: none"> Strong strategic approach towards relationship management which enables simplification and focus <ul style="list-style-type: none"> Create clear prioritization of key partners across three tiers (Essential, Important and Key) Differentiate resource investment and partnership management based on segmentation Aligned assessment of the actions to pursue with each partner and the nature of each partnership (defining the partner as a convener, implementor or funder/ donor) Clear joint engagement plans with partners that include aligned objectives, timeframes, and proposed outcomes
Governments	HICs <ul style="list-style-type: none"> Good relationships with governments primarily limited to investor-investee dynamic Large % on ODA investments from HIC countries (e.g. UK, Japan, US and Germany) Engagement with governments mostly channeled through Ministries of Health 	<ul style="list-style-type: none"> Build strategic partnerships/ relationship with governments Leverage a diverse range of investments <ul style="list-style-type: none"> Financial (ODA and non-ODA/ health security focused funding) Technical Adopt a whole government engagement approach through connecting with Ministries of Finance, Ministries of Health, Development offices (e.g. USAID, DFID) and other relevant ministries
	UMICs/LMICs <ul style="list-style-type: none"> Minimal investments from LMICs Limited engagement with LMICs as partners Minimal LMIC presence in CEPI and within CEPI’s governance structures 	<ul style="list-style-type: none"> Consider nominal investments from UMICs/LMICs Increased engagement with UMICs/LMICs through ministries of Health and development offices, which is anchored in a set of principles and focus areas <p><i>Full details on LMIC engagement captured in the board paper</i></p>

A key component of our approach to partnerships will depend on focussed engagement with LMICs

To become a truly global organisation we must expand our reach and relevance, especially through deeper engagement and programmes with LMICs in the activities we fund, convene, and implement. Our approach to engaging LMICs will build on the following key principles:

- Creating selective **win-win partnerships**
- **Engagement not only through investments** but also through policy and advocacy
- Ensuring **sustainability of impact** through **co-ownership and shared accountability between CEPI, LMICs and partner groups**

Concretely, we have identified seven areas for stronger interactions with LMICs.

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1. **Strengthen clinical trial networks through engaging with national partners and product development partnerships (PDPs) in multiple continents:** leveraging synergies in networks between EIDs and neglected diseases.
2. **Fund manufacturing innovations and develop partnerships to coordinate capacity:** CEPI will work with organisations like DCVMN to strengthen partnerships through which CEPI supports technology transfer and coordinates manufacturing capacity. Furthermore, CEPI will encourage partnerships between biotech companies and vaccine manufacturers to advocate for validated technologies and manufacturing innovations which support the needs of LMICs, for example to enable lower cost-of-goods sold (COGS) through innovation.
3. **Proactively engage priority regional and country-level organisations for outbreak preparedness:** CEPI will engage with regional social and economic bodies, including multilateral development banks to advocate for financing products to support outbreak preparedness. Furthermore, CEPI will selectively work with priority country-level organisations or in-country partners on the outbreak preparedness agenda through advocacy and policy support.
4. **Improve opportunities for LMIC talent within the coalition:** CEPI will contribute to further develop LMIC talent by offering both long-term and short-term opportunities. For example, we will collaborate with universities in LMICs to set up technical training programmes for young scientists. We will also strive to offer secondment opportunities to promising young scientists from LMIC universities and organisations to work for CEPI on short-term fellowships.
5. **Include LMIC experts and researchers in projects relevant to them:** where relevant, we may include criteria whereby developers must demonstrate meaningful LMIC engagement with a relevant role in the research consortium (e.g., epidemiology, preclinical and clinical R&D, community engagement, training, capacity building).
6. **Increase CEPI's presence in LMICs:** CEPI will consider opportunities to improve our presence in LMICs, for example by co-locating or operating through a partner's office, and /or having consultants on-ground on a need basis.
7. **Improve LMIC representation in the CEPI secretariat:** our aim from the outset has been to build a diverse and inclusive organisation that reflects all aspects of the populations we serve. One in five CEPI employee now comes from an LMIC. Our aim is to ensure we develop and implement a comprehensive plan to ensure that the goal of improving diversity, inclusion and equity at all levels of the organization is achieved over time and that we utilize our influence to contribute to that goal.

Throughout the next business cycle, we will take a phased approach to implementing these activities. As we learn more about the opportunities for partnerships, we will also retain flexibility to adjust our scope of ambition when needed.

Implementation

The expanded ambition and scope of activity for CEPI in the next business cycle will have significant implications on **CEPI's governance structures**. This includes updating SAC membership to reflect a wider and more diverse range of expertise and assessing the fitness for purpose of the JCG to deliver on the new strategy in a post-COVAX context.

The **CEPI Secretariat** underwent several increases in the first years of its existence and as a result of the COVID-19 pandemic. The strategy for 2022-26 requires new capabilities and capacities, including in the areas of Disease X vaccine development, late-stage development, biologics, diagnostics, regulatory science, operations and advocacy, manufacturing capacity and innovations, and advocacy. As an epidemic preparedness and response organization, CEPI will continue to retain its nimbleness as it builds the capabilities needed for effective operations, sound investment management, and active engagement with coalition partners.

Processes guiding investments and decision-making will also need to be adapted to the needs of the next business cycle.

Finally, we will update our **theory of change and results framework** in light of the new strategy.

A detailed implementation plan for the CEPI strategy for 2022-26 will be developed in 2021, building from an assessment of implications and risks related to the new strategy and will include the updated governance structure, secretariat set-up, and decision-making processes to guide the operationalisation of the strategy starting in 2022.

Financial implications

The preliminary forecasted financial needs for the 2022-2026 business cycle are approximately **US\$ 3.5 to 4 billion**. This amount includes funding to replace resources previously repurposed in the first business cycle to support COVID-19 activities.

The base case funding scenario is depicted in **figure 4**.

Figure 4: CEPI 2.0 requires approximately USD 3.5 billion in 2022-2026



Annex 2 describes the detailed segmentation of the financial ask per expected outcomes, and **Annex 3** describes three funding scenarios for CEPI 2.0 with a description of the scope of activities to be achieved under each scenario.

Vision	CEPI's vision is a world in which epidemics and pandemics are no longer a threat to humanity		
Mission	Our mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need		
Strategic objectives	Prepare for known epidemic and pandemic threats	Transform the response to the next novel threat	Connect to enhance and expand global collaboration
	<i>Develop vaccines and promising biologics against the most prominent known threats, building on COVID-19 achievements and CEPI 1.0</i>	<i>Harness innovations in technology and systems to significantly reduce the global vulnerability to threats of novel pathogen outbreaks</i>	<i>Drive the development of a post-pandemic consensus and design a more robust and effective global preparedness and response architecture</i>
	<ul style="list-style-type: none"> • End the COVID-19 pandemic • Eliminate the risk of coronavirus pandemics • Accelerate development of vaccines and other biologics against known high- risk pathogens 	<ul style="list-style-type: none"> • Use vaccine development innovations to give us a head-start on other novel threats • Invest and scale critical research innovations which underpin rapid vaccine development • Invest in innovations so vaccine manufacturing is cheaper, faster, and closer to an outbreak 	<ul style="list-style-type: none"> • Build a strong, post-pandemic global coalition • Push for collaboration and solutions which will enable a faster system-wide response • Coordinate a scalable on-demand manufacturing network

Annex 2 - Outcomes across the base case financial envelope for CEPI 2.0

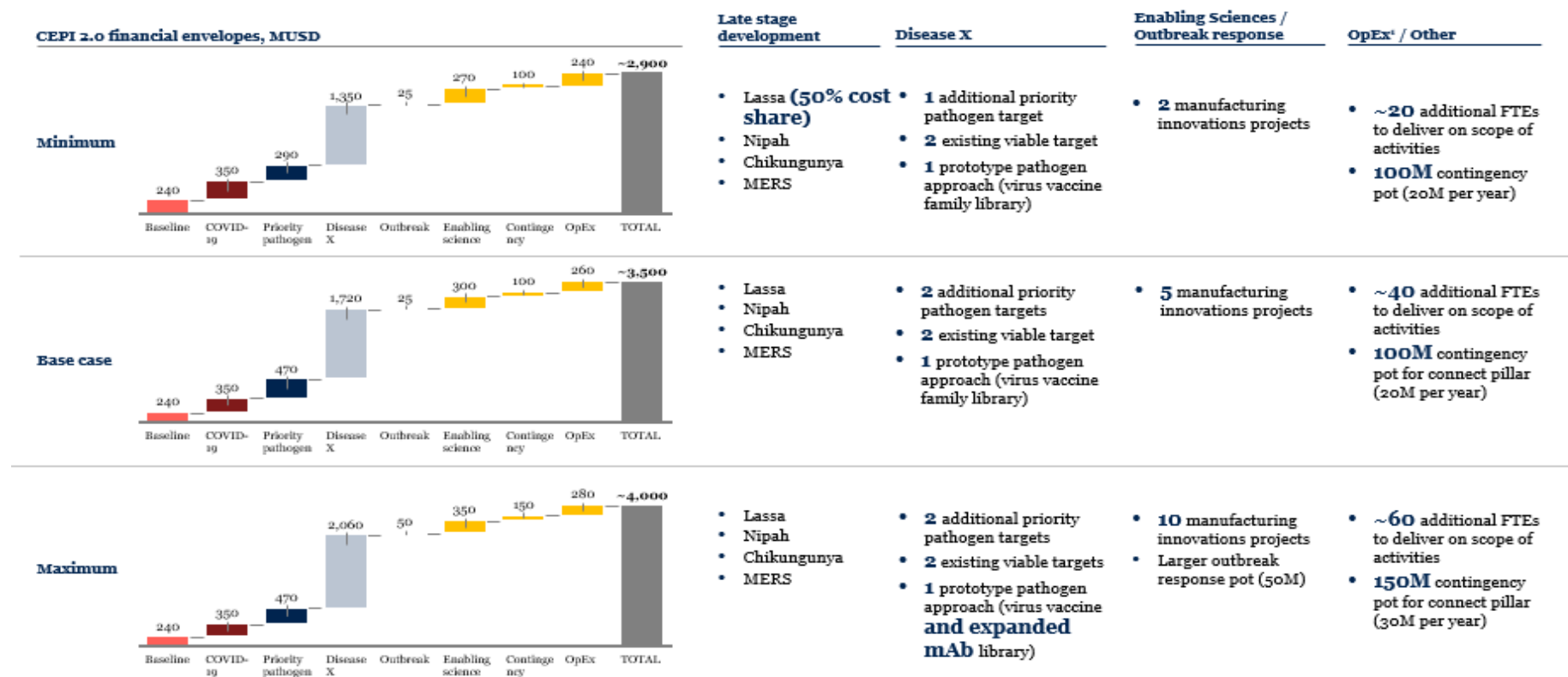
Outcomes against the strategic framework		Total envelope for CEPI 2.0, MUS\$
CEPI 1.0 baseline¹	<i>Includes early-stage R&D projects committed for priority pathogens</i>	~240
COVID-19 Wave 2 funding	• Portfolio of COVID-19 vaccines with improved characteristics (single dose, long acting, thermostable, for broad use in entire population)	~350
A C Priority pathogens – late stage development	<ul style="list-style-type: none"> • Lassa – 1 licensed vaccine based on field efficacy for routine immunisation • Nipah – 1 licensed vaccine or prophylactic mAb • Chikungunya – 1 licensed vaccine under WHO PQ • MERS – stockpile • RVF – preclinical proof-of-concept 	~500
B C Investments in platforms for Disease X²	<ul style="list-style-type: none"> • 1 licensed pan coronavirus vaccine and 1 additional new priority pathogen vaccine • 2 licensed vaccines with viable targets of value to LMICs (e.g. yellow fever, rabies, JEV) • Virus family vaccine libraries developed through prototype pathogen approach (in collaboration with an alliance) 	~1700
D Diagnostics innovations	• Moderate, selective investments, develop diagnostic assays for clinical trials, epidemiology and support platform-based assay development for rapid response	~30
E Outbreak response	<ul style="list-style-type: none"> • Engage in preparedness activities during peace time, e.g., response frameworks • Establish resources globally on genome sequencing, animal models, lab systems and clinical trial protocols + keep warm for rapid response 	~25
F1 Regulatory	<i>Enabling for the strategic outcomes</i>	~1
F2 Manufacturing innovation	<ul style="list-style-type: none"> • ~5 manufacturing innovations projects supporting programs and new platform tech • Scale-ups/outs for Disease X platforms (manufacturing capacity kept warm with commercial products) 	~70
F3 Lab capacity, animal models, standards & assays	<ul style="list-style-type: none"> • Animal model development for 4 pathogens, standards and reagents being developed for 2-4 new priority pathogens and centralized labs for 4 priority pathogens • Support innovation and facilitate creation and maintenance of network of labs 	~170
F4 Epidemiology	• Capacity strengthening, Epi preparedness, Epi innovations and selected post licensure studies	~35
Total OpEx costs³	<i>OpEx costs considered from 2022-26</i>	~260
Contingency	<i>Includes activities that support global collaboration, preparedness and access</i>	~100
TOTAL		~3500

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Annex 3 - Financial envelopes range from 2.9B USD to 4.0B USD for CEPI 2.0

The preliminary financial envelope accounts for several considerations made with regards to the implementation of the strategy. They reflect the potential for CEPI to co-fund certain programmes (e.g., second wave of COVID-19 vaccines) with other partners and make strategic choices that are more or less ambitious in scope, for example in our approach to engagement with LMICs.

CEPI management has developed a mechanism describing what programmes would be prioritised in case of failure to raise the totality of the funding envelop required for the implementation of the strategy in the next business cycle. A lower funding envelope of US\$ 2.9 billion would lead to significantly less investments in Disease X programmes and would require 50% of co-funding in order to achieve a licensed Lassa vaccine. On the other hand, with funding of US\$ 4 billion, CEPI will - in addition to the activities described in Annex 2 - progress more manufacturing innovations and capacity scale-out projects, and reserve more funds for rapid outbreak response.



¹ Aside from base case, OpEx FTE numbers and the costs (MUSD) on the waterfall chart are illustrative only