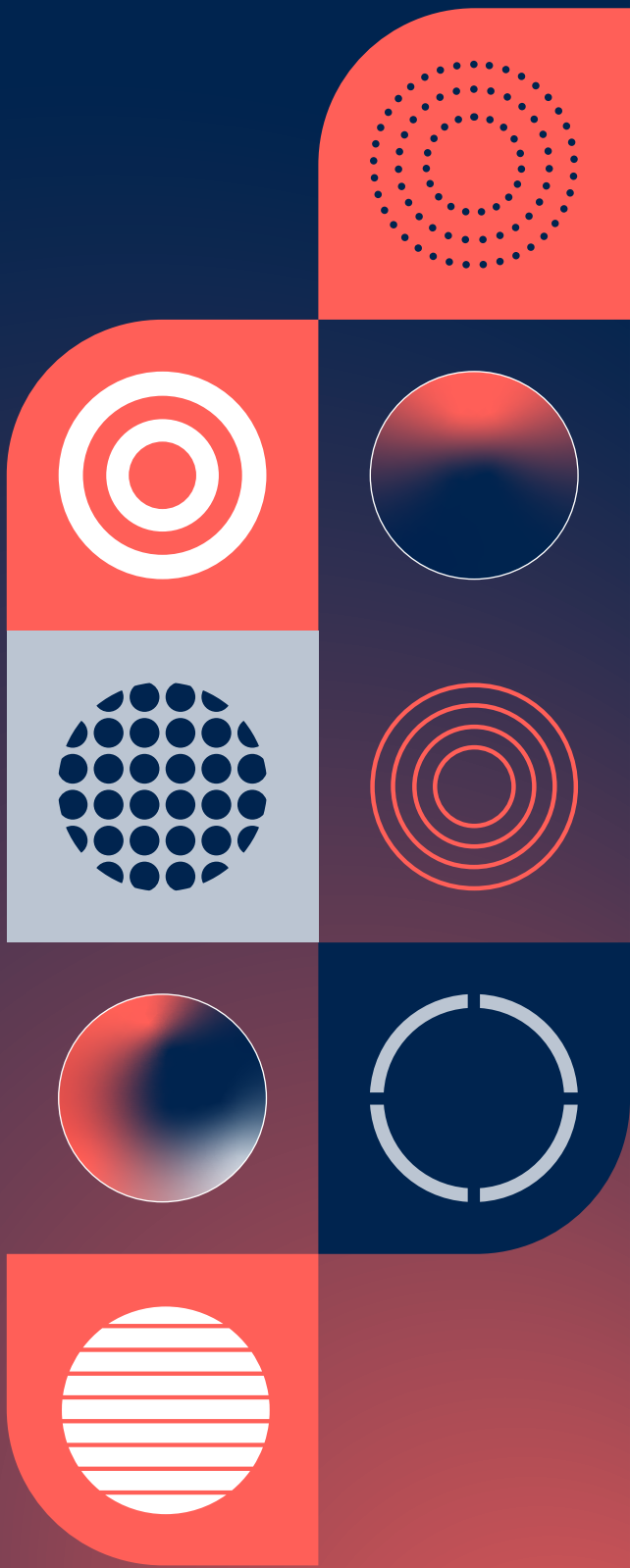
CEPI

2024

ANNUAL
PROGRESS REPORT



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Contents

Contents

Abbreviations

Africa CDC	Africa Centres for Disease Control and Prevention
AI	Artificial intelligence
AVAREF	African Vaccine Regulatory Forum
BARDA	Biomedical Advanced Research and Development Authority (U.S.)
BPCV	Broadly protective coronavirus
CEPI	Coalition for Epidemic Preparedness Innovations
CfP	Call for Proposals
CHIM	Controlled human infection model
CHMP	Committee for Medicinal Products for Human Use (EU/EMA)
CLN	Centralised Laboratory Network (CEPI)
CMC	Chemistry, Manufacturing and Controls (process development)
CORC	Collaborative Open Research Centres (WHO)
CoV	Coronavirus
COVID-19	Coronavirus disease 2019 (due to SARS-CoV-2 virus)
EA	Equitable Access
EAP	Emergency authorisation pathway
EC	European Commission
EDCTP	European and Developing Countries Clinical Trials Partnership (EC)
EPPR	Epidemic and pandemic preparedness and response
EU	European Union
FDA	Food and Drug Administration (U.S.)
FIND	Foundation for Innovative New Diagnostics
GPPS	Global Pandemic Preparedness Summit (CEPI)
GS LEARN	Global South Leaders in Epidemic Analytics and Response Network (CEPI)
H5N1	Avian Influenza or Bird Flu
HIC	High-income country
HIV	Human Immunodeficiency Virus
IAVI	International AIDS Vaccine Initiative
IC	Investors Council (CEPI)
iMCM Net	interim-Medical Countermeasures Network
INB	Intergovernmental Negotiating Body
IVI	International Vaccine Initiative
JCG	Joint Coordination Group (CEPI)
KPI	Key Performance Indicator
LMIC	Low- and middle-income country

mAb	Monoclonal antibody
MCM	Medical countermeasures
MERS	Middle East Respiratory Syndrome
MEL	Monitoring, Evaluation and Learning
MOU	Memorandum of Understanding
mRNA	Messenger ribonucleic acid
MTR	Mid-Term Review
NIAID	National Institute of Allergy and Infectious Diseases (U.S.)
OECD	Organisation for Economic Cooperation and Development
Opex	Operating Expenses
PAHO	Pan American Health Organization
PHEIC	Public Health Emergency of International Concern
PMN	Preclinical Model Network (CEPI)
PPR	Pandemic preparedness & response
R&D	Research and Development (product development)
RSV	Respiratory synctial virus
RVF	Rift Valley fever
RVM	Regional vaccine manufacturing
RVMC	Regionalised Vaccine Manufacturing Collaborative (hosted by CEPI)
SAC	Scientific Advisory Committee (CEPI)
SARS-COV-2	Severe acute respiratory syndrome coronavirus 2 (coronavirus strain that causes COVID-19)
ToC	Theory of Change
UNICEF	United Nations Children's Fund
VMFN	Vaccine Manufacturing Facility Network (CEPI)
WAHO	West African Health Organization
WHO	World Health Organization

Introduction from Dr. Richard Hatchett, CEO

The devastation of the COVID-19 pandemic faded further from global consciousness in 2024, overtaken—understandably—by immediate concerns about security challenges, fiscal pressures, and political upheaval as over 60 countries went to the polls.

Yet the threat posed by epidemics and pandemics has not receded; if anything, it is growing. 2024 was a banner year for viral threats, with outbreaks simmering—or surging—on every inhabited continent.

In Africa, an epidemic of a new, more virulent form of mpox spread rapidly, prompting Africa CDC and the World Health Organization (WHO) to declare Public Health Emergencies of Continental Security and International Concern (PHEIC), respectively. In South America, large outbreaks of the vector-borne diseases dengue, Chikungunya, Zika, and Oropouche fever occurred across the continent. Brazil reported over six million suspected dengue cases (a new and unwelcome record), with more than 5,000 lives lost.

In North America, H5N1 influenza spread into dairy cows and, by year's end, more than 60 people in the U.S.—in any one of which the virus might mutate—had fallen ill with the disease. In Asia, outbreaks of Nipah virus were reported in Bangladesh and India, and Saudi Arabia recorded multiple deaths from MERS. In Europe, West Nile virus continued its spread, affecting 19 countries—some for the first time.

These outbreaks were notable for their scale, geographic reach and virologic diversity. They are a stark reminder that CEPI's mission is more urgent and essential than ever.

Against this backdrop, in 2024 CEPI's work to advance epidemic and pandemic preparedness has continued at pace, advancing breakthroughs for priority pathogen vaccines, catalysing scientific innovations that could transform vaccine development and expanding critical capabilities for the 100 Days Mission.

CEPI's vaccine portfolio made major strides, bringing the prospect of protection against our priority pathogens closer than ever before, while making important contributions to the scientific knowledge and preparedness infrastructure that underpin the 100 Days Mission. A CEPI-supported Lassa vaccine became the first to reach Phase 2 trials, with Nipah and Rift Valley fever vaccines on the cusp of reaching the same milestone. In a first, CEPI launched a biologics partnership, with trials for a new Nipah monoclonal antibody set for 2025 in endemic countries. Meanwhile, the technology transfer of the world's first licensed Chikungunya vaccine to local manufacturers in endemic regions progressed rapidly.

The portfolio expanded to include mpox and additional studies on Filovirus vaccines, both of which caused significant 2024 outbreaks. BioNTech's CEPI-supported mRNA mpox vaccine entered Phase 2 trials and with European Commission (EC) support, CEPI launched an ambitious programme to develop broadly protective Filovirus vaccines that could protect against multiple deadly diseases—or even a "Filovirus Disease X"—in a single shot.

CEPI continued to build its global networks of facilities and laboratories with the capability to respond rapidly to outbreaks close to the source. We welcomed two new members to our Vaccine Manufacturing Facility Network (VMFN), now comprising five Global South partners spanning three continents, and eight partners to our Preclinical Model Network (PMN), bringing the total to 17.

We kicked off 10 new manufacturing innovations projects that, along with CEPI's expanded portfolio of next-generation vaccine platforms, will catalyse technologies that support our speed, scale and access goals and could revolutionise future outbreak responses.

And the Vaccine Library—a crucial pillar of CEPI's 100 Days Mission preparedness—continued to expand. State-of-the-art artificial intelligence tools were leveraged to accelerate and improve the design of exemplar vaccines for the Library and to predict and prepare for viral mutations and unknown threats.

Of course, CEPI's R&D programmes cannot—and do not—exist in isolation. In 2024, CEPI actively contributed to shaping global pandemic preparedness policy and building partnerships to deliver the 100 Days Mission.

Notably, CEPI's engagement with the Intergovernmental Negotiating Body (INB) helped to secure an important article calling for the inclusion of equitable access provisions in publicly-funded R&D within the draft Pandemic Agreement. Alongside WHO, CEPI drove consensus on the "pathogen family" approach to R&D—resulting in a global R&D collaboration framework launched at the CEPI-hosted Global Pandemic Preparedness Summit (GPPS) in Rio de Janeiro.

CEPI formalised ongoing partnerships with organisations including Africa CDC, Gavi, Nigeria CDC and The Pan American Health Organization (PAHO). These alliances will deepen collaboration to advance the 100 Days Mission and strengthen pandemic preparedness at global, regional and national levels.

And we put our partnerships, expertise and capabilities to the real-world test, activating our response teams during overlapping outbreaks of mpox, H5N1 and Marburg. Each response differed, yet all were characterised by taking early, no-regret actions, practicing components or elements of the 100 Days Mission, and anticipating future needs.

2024 was also a year of reflection and learning for CEPI. Conducted at the halfway stage of CEPI's second five-year strategy (2022-2026), the CEPI 2.0 Mid-term Review (MTR) recognised the notable progress and achievements that are being driven by CEPI's ambition. It offered a valuable opportunity to take stock and identify areas where the organisation needs to sharpen its focus or course correct to achieve its aims. Since its inception, CEPI has placed learning, evolving and striving to do better at the heart of its culture, so independent, external assessments like the MTR are a necessary and useful tool for us as an organisation, and for our Board and Investors.

In response, we have designed a robust action plan that will help CEPI to deliver results and impact during the remainder of the CEPI 2.0 period and ensure it is well equipped to develop and execute the CEPI 3.0 strategy – a core focus for CEPI in 2025 - that will guide the organisation's future direction. In line with the MTR recommendations, CEPI's Theory of Change and Results Framework will be updated in 2025, in parallel to the 3.0 strategy development process, to ensure they align with CEPI's long-term goals.

Strengthening the organisation and bolstering its leadership capacity were key priorities in 2024. New executive appointments, including Aurélia Nguyen as Deputy CEO, Rachel Grant as Executive Director of External and Investor Relations, and Emma Wheatley as Executive Director of Access and Business Development were made and several divisions were reorganised and reporting lines adjusted to improve focus and coordination, better positioning CEPI to achieve its mission.

While I take immense pride in CEPI's 2024 achievements, I am far from complacent about the complexity of the world in which we operate, the opportunities we have to strengthen our work, and the challenges that lie ahead.

In 2025, we must remain laser-focused on delivery while simultaneously shaping CEPI's future in an increasingly complicated and challenging geopolitical environment. In close consultation with our Board, Investors and stakeholders, we will strive to design a CEPI 3.0 strategy that meets the needs and expectations of an increasingly uncertain world that is also increasingly under threat from epidemics and pandemics.

This is no small task, but it is a powerful opportunity because our work has the potential to change the world. When CEPI first socialised the 100 Days Mission a few years ago it was an aspirational concept that existed only on paper. Today it is moving towards becoming a reality, with an increasing number of institutions around the world dedicated to medical countermeasures production, broad global support (including endorsement by WHO) of the viral families and prototype pathogen framework that CEPI has championed, and an increasing number of countries

specifically referencing the 100 Days Mission in their national pandemic preparedness and health security strategies. Recent modelling by Imperial College London, published in The Lancet Global Health in October, estimates that had the 100 Days Mission been achieved during the COVID-19 pandemic, it could have saved as many as eight million lives, with the greatest benefits in the Global South.

I end on a positive note, celebrating an example of the 100 Days Mission in action during Rwanda's first-ever Marburg virus outbreak in September 2024. Within just 10 days, frontline health workers began receiving an investigational vaccine in a CEPI-supported open label Phase 2 clinical trial. Only weeks earlier, CEPI and Rwandan officials had conducted a tabletop simulation of a 100 Days Mission outbreak response in Kigali, focusing on preparedness, practice and partnership, which laid the groundwork for the astonishingly fast-paced Rwandan response.

This swift response demonstrated significant progress in a key component of the 100 Days Mission — the rapid deployment of investigational vaccines into clinical trials — and not only helped contain the outbreak but also advanced development of an urgently needed Marburg vaccine candidate. In doing so, it both illuminated what can be achieved when governments invest in preparedness and developing 100 Days Mission capabilities, and demonstrated CEPI's unique value to the world as an essential global player in preventing pandemics and defending against disease.

I extend my warmest thanks to the outstanding CEPI team, our Board, Investors and partners. Your collaboration, energy, and commitment made the progress of the past year possible. Together, we are creating a safer, more resilient world. I look forward to continuing this vital work in 2025 and beyond.

Dr. Richard Hatchett,
Chief Executive Officer, CEPI

CEPI CEO Dr Richard Hatchett, Professor Muhammad Pate (centre) at the first meeting of the Lassa fever Coalition Governing Entity in Abuja, Nigeria.

2024: CEPI highlights in numbers

1
CEPI's first ever Biosecurity strategy launched

3
Teams activated in response to three infectious disease outbreaks

42
Active vaccine candidates and rapid response platform prototypes advanced

10
Days to support deployment of vaccines into a clinical trial as part of the Rwandan-led response to Marburg outbreak

5
High-risk viral families prioritised for investment

8
New partners now part of CEPI's Preclinical Model Network, bringing the total to 17

10
Cutting-edge manufacturing innovations projects advanced, bringing the total to 15

2
New members in the expanded global Vaccine Manufacturing Facility Network, bringing the total to 5

4
Agreements signed with key global partners to accelerate and deepen collaborative efforts

200+
Partnerships with life sciences organisations, with one-fifth based in the Global South

1
First ever Phase 2 Lassa vaccine trial launched

Professor Mario Moreira, President of Fiocruz, at the Global Pandemic Preparedness Summit in July 2024

CEPI's Mission and Vision

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.

Launched at the World Economic Forum in Davos in January 2017 as a response to the Ebola crisis and as a global 'insurance policy' against emerging infectious disease threats, CEPI's vision then, as it is now, was to create a world where epidemics and pandemics no longer pose a threat to humanity.

CEPI's Impact and Major Programmatic Achievements to Date

Since its inception in 2017, CEPI has catalysed action in support of our mission, establishing itself as a trusted and indispensable player in the global health architecture.

CEPI's unique role – as a coalition of vaccine developers, manufacturers, sovereign governments, philanthropies, civil society and global health organisations – and extensive networks allows CEPI to pool and deploy resources in ways that nation states often cannot, for the benefit of all.

By collaborating across public, private and philanthropic sectors, we've had an outsized impact. Our achievements to date span major advances in scientific innovation, equitable access, biosecurity and pandemic policy, while retaining the flexibility and agility to rapidly respond to newly emerging outbreaks.

2017 to end December 2024: CEPI's major programmatic achievements

ENABLING PROJECTS

Centralised lab network

Established a global network of **18 laboratories** to support priority pathogen vaccine R&D

Preclinical models network

Established a global network of **16 facilities**

Manufacturing network

Established a network of **5 Global South** manufacturing partners

Epidemiology study

Launched ENABLE, the **largest-ever** Lassa epidemiology study

CEPI FIRSTS

Rift Valley Fever

Advanced RVF vaccine into **Phase 1** trials

Nipah

Advanced the **first ever** Nipah vaccine into **Phase 1** trials

MERS

Advanced the **first ever** MERS vaccine into **Phase 2** trails

Lassa Fever

Advanced the **first ever** Lassa virus vaccine into **Phase 2** trails

Chikungunya

First **licensed** Chikungunya vaccine

Innovations

Supported the **first medical product designed using AI** to be approved for any indication anywhere in the world

CORONAVIRUSES

COVID-19

Supported **14** COVID-19 vaccine candidates

4 granted EUL

3 approved for domestic use

BPCV

World's leading funder of vaccine R&D, investing in 13 broadly protective coronavirus vaccine candidates

COVAX launched and co-led by CEPI

Nearly **2 billion** vaccines

shipped to **146 countries**

2.7 million deaths averted in lower-income countries

FILOVIRUSES

Ebola

Generated data to support **expanded access** and licensed vaccines

Marburg

10 DAYS

Supported **Rwandan-led** response which deployed vaccine into a clinical trial

The 100 Days Mission and CEPI's Strategy 2.0

Compressing vaccine development timelines to 100 days after the identification of a novel virus could potentially avert millions of deaths and trillions of dollars in economic damage. Research commissioned by CEPI and carried out by an independent group of infectious disease modellers at Imperial College London suggests that if safe and effective COVID-19 vaccines had been available within 100 days of the release of the genome sequence on 10 January 2020:

- 8.3 million excess deaths globally could have been averted by the end of 2021
- Almost US$ 1.4 trillion in productivity losses due to illness could have been averted along with over US$ 63 billion in hospitalisation costs
- In low- and middle-income countries (LMICs) alone 4.8 million lives could have been saved, 800 million COVID-19 infections prevented and 15.7 million COVID-19 hospitalisations by the end of 2021.

While the 100 Days Mission has been embraced by leaders of the G7 and G20 as well as pharmaceutical industry leaders, no single organisation, country or region can achieve the Mission alone. Success will require advances in the organisation, governance and financing of global preparedness systems, and multiple, interconnected collaborative efforts.

In pursuit of this goal, CEPI is working with partners to build capabilities in six key areas of innovation:

- **Creating a library of prototype vaccines for representative pathogens across multiple viral families** which can be quickly adapted in response to a future outbreak, accelerating the development of life-saving vaccines
- **Establishing effective clinical trial networks** that can spring into action to test experimental vaccines
- **Speeding up identification of immune response markers** to help provide early indication of vaccine efficacy
- **Expanding and sustaining global manufacturing capacity and innovations** to develop, manufacture and supply safe effective new vaccines quickly, in or near areas at high risk of disease outbreaks
- **Strengthening disease surveillance and global early-warning systems** to enable faster outbreak-alert triggers
- **Strengthening biosafety and biosecurity oversight and capacities** for responsible use of existing and new technologies.

Subsequent sections of this report provide an update on progress on the three strategic objectives that ground CEPI's 2.0 activities and contribute to the 100 Days Mission:

1) Prepare for known epidemic and pandemic threats by developing new vaccines and biologics against the most prominent threats, such as Chikungunya, Lassa fever and Nipah.

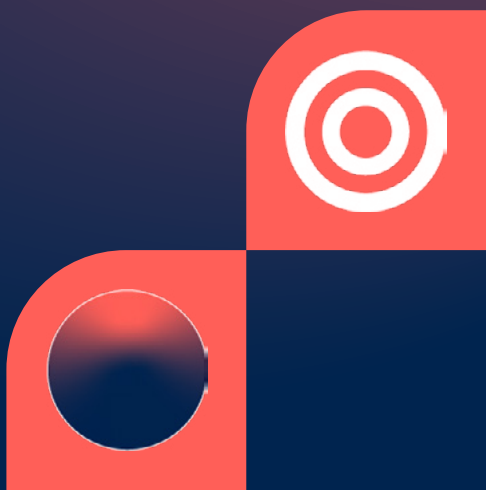
2) Transform the response to the next emerging pathogenic threat by harnessing innovations in technology and systems to significantly reduce global vulnerability.

3) Connect stakeholders and experts in emerging infectious diseases to enable rapid countermeasure development, effective response and equitable access for those in need.

Detailed progress against the Key Performance Indicators (KPIs) as described in the CEPI 2.0 Theory of Change and Results Framework can be found in the Monitoring, Evaluation and Learning (MEL) section of the report.

CEPI

Progress against CEPI's Strategic Objectives



Strategic Objective 1: PREPARE for known epidemic and pandemic threats

A core part of CEPI's mission is to support the development of promising vaccine candidates against known priority diseases to rapidly activate Research & Development (R&D) at the outset of an outbreak, with the ultimate goal of fast tracking the availability of vaccines that can be used to save lives and avert large scale epidemics or pandemics.

As of 31 December 2024, CEPI had an active R&D portfolio of 13 vaccine candidates for its initial high risk "priority pathogens" (Lassa, Nipah, MERS, RVF and Chikungunya) in addition to one mpox vaccine candidate and 11 broadly protective Pan-Sarbecovirus vaccine candidates. The wider portfolio contains a further 15 rapid response platform prototypes and two exemplar vaccines in preclinical development stage as part of work under the Vaccine Library (see the "Transform" section).

Each "priority pathogen" programme aims to:

1. **Develop product** – develop vaccines (and biologics in the case of Nipah) against the existing version of the priority pathogen with appropriate target product characteristics, use case and supply considerations.
2. **Develop product X** – develop vaccines (and biologics in the case of Nipah) against a mutated version "X" of the priority pathogen with consequent target product characteristics, use case and supply considerations[1].
3. **Drive 100 Days Mission** – concretely advance the 100 Days Mission pillars and supportive architecture.

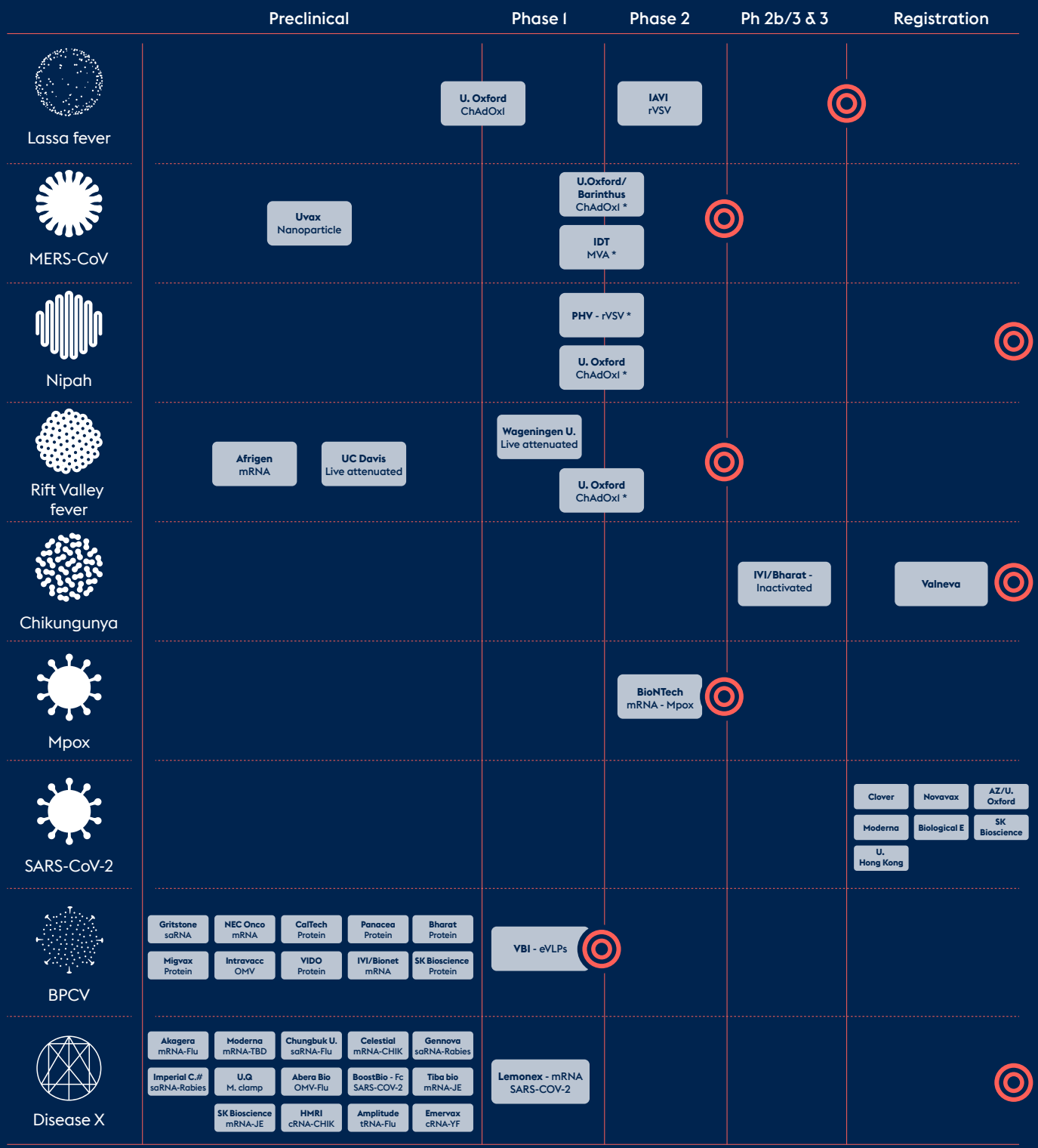
To support the likelihood of successful vaccine development, and help our partners in phase-appropriate vaccine development while upholding quality standards, CEPI developed and published a Chemistry, Manufacturing and Control Framework.

In 2024 CEPI achieved numerous global "firsts" and notable successes under the PREPARE Strategic Objective:

- The first-ever Phase 2 clinical trials for Lassa fever (IAVI) and Rift Valley fever (Oxford) vaccines
- Continued focus on transfer of technology of Valneva's Chikungunya vaccine to endemic regions and a focus on WHO prequalification
- Completion of the MERS vaccine Phase 1 clinical trial (IDT Biologika)
- Approval for Nipah Phase 2 trials to start in 2025 (PHV and Oxford)
- Targeted expansion of the portfolio including filling evidence gaps on mpox – reflecting the unmet medical need for effective vaccines in endemic countries – and initiated efforts with the EC to develop a broadly protective Filovirus vaccine, building on CEPI's prior work on Zaire Ebolavirus and responses to Sudan and Marburg Ebolavirus outbreaks.
- Activation of CEPI response teams and adoption of a 'no-regrets' approach in the face of three overlapping outbreaks: mpox, H5N1, and Marburg.

[1] Note that "product" and "product X" may be the same if the product provides suitably broad protection; but with the target product characteristics – the desired characteristics of a target product that is aimed at a particular disease or diseases - the use case and supply needs may differ considerably.

Figure 1: Portfolio overview - CEPI-funded vaccine candidate and Platform portfolio as of December 2024



*Approved to move to next phase. # To be initiated in 2025.

Portfolio progress in 2024

Lassa

CEPI is the world's leading funder of research into Lassa fever, a viral haemorrhagic disease belonging to the Arenavirus family that WHO has identified as in urgent need of R&D investment due to its epidemic potential. Climate change and population growth could further amplify the public health threat posed by Lassa fever. Outbreaks of Lassa fever occur regularly in parts of West Africa. The number of infections is estimated to range from 100,000 to 300,000 per year, though the real number is likely to be higher due to challenges in case detection, limited access to specialised laboratories and diagnostics in affected countries, and a lack of reliable reporting mechanisms.

Modelling has estimated that 3,300 lives could be saved across West Africa over a 10-year period from the introduction of a Lassa fever vaccine. Published in August 2024 by Nature Medicine, the study also found that deploying a safe and effective Lassa fever vaccine across 15 countries of continental West Africa could avert up to US$ 128 million in societal costs.

There are no Lassa fever vaccines currently licensed for human use. As such, CEPI's goal is to advance at least one vaccine candidate through to late-stage clinical development towards licensure, fill epidemiology gaps, strengthen clinical trial and regulatory capacity, and enable country and regional leadership to support effective programmatic delivery for vaccine developers. At the end of 2024, CEPI had invested in five vaccine candidates, two of which remain in active development:

- **1 vaccine in Phase 2a (IAVI)**
- **1 vaccine completed preclinical and ready to enter Phase 1 (Oxford)**

Following completion of a Phase 1a and Phase 1b study in the United States and Liberia, the International AIDS Vaccine Initiative (IAVI) commenced a Phase 2a study in March 2024 in Nigeria, Liberia and Ghana. This is the most advanced Lassa fever vaccine trial ever conducted to date and will further assess vaccine safety and immunogenicity in people living with HIV, adolescents and children, and support the dose selection level for advanced stage development. Interim data is expected to be available at the end of 2025.

The University of Oxford is developing a Lassa fever vaccine candidate based on the adenovirus vector platform ChAdOx1. This candidate has demonstrated promising vaccine safety, immunogenicity and efficacy in preclinical models. Oxford plans to commence a Phase 1a trial in the United Kingdom and Phase 1b trial in Ghana in mid-2025.

Looking ahead, CEPI will prioritise the lead Lassa candidate while continuing progression of a broader set of technology platforms, given the Lassa portfolio is currently composed of viral vector-based candidates only.

One mRNA-based candidate for Arenaviruses is under development at SK Bioscience as part of the Disease X programme – see the "Transform" section of this report for further details. Beyond this, CEPI will seek to expand investments including mRNA candidates, and potentially launch a call for proposals (CfP) for second-generation Lassa vaccine candidates in 2025.

Highlights of Lassa programme contribution to the 100 Days Mission

- **Vaccine Library:** CEPI is testing the development of mRNA Lassa vaccine candidates on SK Bioscience's rapid-response platform. If successful, the vaccine could also be adapted to protect against other viruses in the Arenavirus family. In addition to mRNA, Oxford's ChAdOx1 viral vector platform is being advanced as a potential rapid response vaccine platform.
- **Strengthening clinical trial capacity:** CEPI is supporting potential clinical trial sites in West Africa to carry out routine trials and to scale up in an emergency in collaboration with the International Vaccine Institute (IVI) and Gambia's Medical Research Council Unit. CEPI is also partnering with the Global Vaccine Data Network and local researchers in multiple African countries to support safety evaluation in clinical trials to support safety evidence generation at the time of vaccine deployment.
- **Bolstering regulatory capacity:** CEPI has continued regulatory capability strengthening activities with African regulatory agencies and Ethics Committees as part of a co-funded project with the European and Developing Countries Clinical Trials Partnership (EDCTP) 3 using Lassa fever as test case.

Building public health knowledge on the burden of Lassa fever disease

In 2024, the world's largest Lassa fever epidemiology study "Enable" was expanded further. First launched in 2019 to help inform outbreak preparedness efforts, the new research aims to improve scientific understanding on how frequently Lassa fever occurs; how rates of infection and symptoms vary across locations, age, sex and previous exposure; the extent of post-infection symptoms like hearing loss; and how often people may be co-infected with Lassa fever and malaria.

Insights gained will be crucial in building public health knowledge and guiding where future late-stage vaccine trials are conducted, and determine the priority groups for receiving a future licensed Lassa vaccine.

> *"This expanded investigation represents key progress in our battle against Lassa fever. We are improving our capacity to identify and recognise cases while preparing for future vaccine development by examining the disease's symptoms and its connection to other infections. The results of this work are vital for forming health practices and promoting the health of populations in Nigeria and West Africa."*
>
> **Dr. Jide Idris,**
> Director General of Nigeria Centre for Disease Control
> and co-chair of the Nigeria Lassa Vaccine Task Force

Lassa fever Coalition

CEPI has been engaging with stakeholders at country, regional and global levels to catalyse Lassa fever ecosystem partners and enable vaccine late-stage development and roll-out of a future Lassa vaccine. One example of this is CEPI's support to the Lassa fever Coalition, a pioneering group established by the West African Health Organization (WAHO) to build upon the efforts of national and regional Lassa fever initiatives, and ensure, at a regional level, that those affected by Lassa fever have a safe, effective and high-quality vaccine available to protect their populations in the future. The Coalition is a unique model designed to be country-led with a shared commitment to strengthening locally-led solutions and with an emphasis on driving forward a unified, regional and comprehensive response to Lassa fever.

Members of the Lassa fever Governing Entity include Ministers of Health across key Member States including Benin, Guinea, Liberia, Nigeria and Sierra Leone as well as senior representatives from CEPI, WAHO, WHO Headquarters and the World Health Organization African Region (WHO AFRO).
The Coalition's Governing Entity will provide country and regional leadership to the Coalition and ensure effective governance and delivery of its programmes.

CEPI CEO Dr. Ruchard Hatchett speaks at a CSO roundtable discussion titled "Civil Society Engagement in Lassa Vaccine Development—Perspectives from Nigeria" co-hosted by CEPI and Nigeria Health Watch in January 2025

Image credit: Nigeria Health Watch

Nipah

Nipah is a zoonotic virus which belongs to the Paramyxovirus family and is endemic in parts of Bangladesh, India, Singapore, Malaysia, Indonesia and the Philippines. Fruit bats are the natural hosts of the virus, which is spread to people from infected bats, pigs or other people. The case fatality risk is estimated between 40–75% and varies depending on the virus strain, access to and quality of healthcare, or the severity of illness. There are no approved treatments or vaccines available for Nipah virus, either for humans or animals. CEPI is one of the largest funders of Nipah virus research globally, committing over US$ 100 million to four vaccine candidates and one monoclonal antibody (mAB) as part of the organisation's Nipah programme.

CEPI's Nipah portfolio as of December 2024 includes:

- **2 vaccines ready to enter Phase 2 (Public Health Vaccines, Oxford)**
- **1 mAB (Sevare GMP)**

CEPI's investments have been catalytic in advancing a clinical development pipeline for Nipah vaccines and its two vaccine candidates are the most advanced in the global Nipah landscape. In early 2024, a vaccine candidate based on the University of Oxford's ChAdOx1 platform entered Phase 1 clinical trials and should advance into Phase 2 clinical trials in 2025. The Public Health Vaccines candidate also passed the Phase 1 stage gate to progress to Phase 2 in 2025. Two further vaccine candidates were down selected as part of CEPI's approach to portfolio management.

In 2024, CEPI made a first investment in the development of a mAb for Nipah by Sevare GMP. A Nipah mAb is intended to be used alongside vaccines in case of an outbreak, providing immediate protection prior to the onset of longer-lasting vaccine-induced immunity. A Phase 1b/2a trial is planned to take place in India and Bangladesh in late 2025.

CEPI's enabling sciences activities continue to support the advancement of Nipah vaccine candidates. Working with the Institute of Epidemiology, Disease Control and Research, icddr,b in Bangladesh and the University of Malaya in Malaysia, CEPI is seeking to advance our understanding of Nipah virus to inform late-stage vaccine development and guide future vaccine design. CEPI-funded research undertaken in 2024 found Nipah survivors in Malaysia report neutralising antibodies more than 25 years after they were infected, demonstrating long-term immunity. Work is ongoing to model different scenarios to assess optimal deployment strategies for Nipah vaccines and monoclonal antibodies.

Highlights of Nipah programme contribution to the 100 Days Mission:

- **Speeding up R&D by identifying immune markers:** Identification of correlates of protection – a reliable marker of immunity – could significantly reduce the cost and time taken to develop vaccines for diseases with low incidence or high case fatality rates by serving as alternatives to clinical endpoints, and guiding clinical trial design where efficacy testing would otherwise be unfeasible. To explore this further, CEPI launched a joint call with Wellcome Trust in 2024 for a first project to focus on correlates of protection for Nipah and other infectious diseases. The University of Oxford was selected to lead this area of work in relation to Nipah.
- **Supporting demand generation in endemic countries:** CEPI has been engaging with relevant stakeholders to explore use case scenarios in the event of a future outbreak. In April 2024 CEPI convened a planning and preparedness workshop to develop a shared understanding of how a vaccine would be used in the event of an outbreak with government research bodies from India and Bangladesh, WHO, the United Nations Children's Fund (UNICEF), regional stakeholders and disease experts.
- **Strengthening regional preparedness efforts:** Together with PATH, the first of a series of scenario-planning exercises took place in December 2024 to prepare for a possible large-scale regional outbreak of Nipah in Bangladesh, Malaysia or India. These efforts have been initiated to develop pre-approved outbreak protocols for appropriate vaccine efficacy evidence generation strategies.

Chikungunya

The disease caused by the Chikungunya virus is a major public health risk due to its high morbidity, serious economic impact and potential disease burden, with over a billion people living in areas where Chikungunya outbreaks occur – primarily in LMICs. Outbreaks have become more frequent and widespread, caused partly by viral adaptations allowing the virus to spread more easily by Aedes albopictus mosquitoes, and the virus has now been identified in over 110 countries. Climate change could further amplify the threat posed by Chikungunya. Since 2019 and with co-investment from the EC, CEPI has been advancing the development of promising Chikungunya vaccine candidates through late-stage trials, focusing on expanding access to vulnerable populations in endemic countries. An overview of the 2024 Chikungunya portfolio is as follows:

- **1 vaccine licensed in US, Canada, European Union (EU), UK (Valneva)**
- **1 vaccine candidate completed Phase 2b (Bharat/IVI)**

Following the world's first Chikungunya vaccine candidate IXCHIQ (Valneva) securing US U.S. Food and Drug Administration (FDA) approval in 2023, regulatory approval for the same vaccine was granted by authorities in Canada, Europe and the United Kingdom in 2024. CEPI actively supports approval regulatory processes by providing inputs and investing in clinical trial protocols necessary to accelerate the pathway to global licensure with a focus on endemic countries and regions.

In July 2024, CEPI and the EU announced an additional US$ 41.3 million partnership to support broader access to IXCHIQ in LMICs as well as post-marketing trials, and to enable potential label extensions in vulnerable populations namely children, adolescents and pregnant women. Clinical trials assessing the performance of Valneva's vaccine in adolescents in Brazil, in partnership with Brazil's Instituto Butantan, yielded positive Phase 3 trial data received in 2024 and has since led to a recommendation to expand access to the vaccine for use by 12-17 year olds in the EU by the Committee for Medicinal Products for Human Use (CHMP)[2], an important stepping stone that could help accelerate the approval of the vaccine in this age group in other regions, including endemic areas. CEPI will review the balance of candidates in the Chikungunya portfolio in 2025.

In December 2024, CEPI announced new research to investigate the case burden of Chikungunya disease in children and adults in East Africa. The study will characterise clinical manifestations and determine viral diversity to inform further vaccine development, deployment and use in East Africa. Known as the Accelerating Chikungunya burden Estimation to Inform Vaccine Evaluation (ACHIEVE) study, the project includes scientists at the University of Oxford, University of Nairobi, the Kenya Medical Research Institute (KEMRI)- Centre for Global Health Research, the KEMRI-Wellcome Trust Research Programme and the Ifakara Health Institute in Tanzania, and will broaden the understanding of the global disease burden.

H.E. Dr Jean Kaseya, Director-General, Africa CDC speaking during the signing of a Memorandum of Understanding between CEPI and Africa CDC in May 2024

[2] The CHMP is the European Medicines Agency's (EMA) committee responsible for assessing and authorising medicines in the EU. It also provides scientific advice, guidelines and cooperation on medicine development and regulation.

Equitable Access in Practice

Through CEPI's partnership with Valneva, Brazil's Instituto Butantan is committed to providing the Chikungunya vaccine drug product which will be developed and produced in Brazil at an affordable price for distribution in Latin American countries and selected LMICs.

In 2024, CEPI partners Valneva and Serum Institute of India entered into an exclusive license agreement for Valneva's Chikungunya vaccine that enables supply of the vaccine in Asia. The companies will work to bring the vaccine to the Indian market, and certain other Asian countries that are vulnerable to Chikungunya outbreaks, subject to local regulatory approvals. Under the agreement, Serum has committed to priority supply of the vaccine at an affordable price to public health markets in LMICs.

This is in addition to the technology transfer that is already underway to Brazil's Instituto Butantan to serve Latin American countries.

Highlights of Chikungunya programme contribution to the 100 Days Mission:

- **Speeding up regulatory processes by using immune markers:** CEPI has been supporting studies on correlates of protection and immune markers for Chikungunya that resulted in accelerated approval with regulators. Recognising that this is only one step in evidence generation, CEPI has committed to part-fund Phase 4 trials of the Valneva vaccine, including randomised controlled trials to assess vaccine efficacy, and real-world evidence studies to assess the safety and effectiveness of the vaccine while addressing stringent post-authorisation evidence generation requirements.
- **Supporting outbreak preparation efforts:** In 2024, given the importance of WHO prequalification as a critical milestone to ensuring access to a vaccine in the case of an outbreak, CEPI has been collaborating with WHO's Strategic Advisory Group of Experts on Immunization to establish pathways to prequalification. CEPI also had ongoing dialogue with WHO, PAHO, Gavi and UNICEF on the learning agenda for future investments. CEPI has also been collaborating with Cambridge University to model the global burden of disease, potential impact of vaccination campaigns and stockpiling needs following the large Chikungunya outbreak in Paraguay in 2022–2023.

Rift Valley fever

Rift Valley fever (RVF) is an acute viral haemorrhagic disease caused by the Rift Valley fever virus, which is part of the Phenuivirus family. It is endemic to tropical regions of eastern and southern Africa and the Middle East, and most commonly affects key livestock species such as cattle, sheep and goats, but also poses a serious threat to human health. Outbreaks in livestock can decimate herds, leading to significant economic losses for farmers and pastoral communities. In humans, the virus has potential to cause large outbreaks. Symptoms of disease range from mild to a severe haemorrhagic form of the disease that can have up to 50% fatality rate. While there are registered animal vaccines, these require improvement. There are currently no licensed vaccines available for human use.

CEPI takes a "One Health" approach to the RVF portfolio, noting the need to integrate human, animal and environmental health to prevent and predict the zoonotic threat from RVF. CEPI has committed over US$ 80 million in funding (including from the EC) to support the development of RVF vaccine candidates toward Phase 1 and Phase 2 clinical trials in endemic countries (Tanzania, Kenya, Uganda and South Africa). An overview of the RVF portfolio as of December 2024 is as follows:

- **1 vaccine in Phase 2a (Oxford)**
- **1 vaccine ready to enter Phase 2a (University of Wageningen)**
- **2 vaccines in preclinical evaluation (University of California, Davis and Afrigen)**

In October 2024, CEPI announced a Phase 2 trial of the University of Oxford's RVF ChAdOx1 vaccine in Kenya, which will be the most advanced clinical trial of a human RVF vaccine in any endemic country to date. Starting in May 2025, a total of 240 healthy adult participants will take part in the research which will assess vaccine safety and the ability of the vaccine candidate to elicit an immune response against RVF.

Recognising the relevance of epidemiology and modelling in the development, licensure and use of human RVF vaccines, CEPI is working with developers, partners and RVF-affected countries. In June 2024, CEPI supported a workshop for human RVF vaccine development in Nairobi, Kenya. Attended by more than 70 global health and RVF stakeholders including representatives from Africa CDC, WHO, the World Organisation for Animal Health and the UN Food and Agriculture Organization, the workshop surfaced key epidemiological and modelling gaps and priorities and informed the design of the 2024 CEPI RVF Epidemiology and Modelling Call for Proposals. Of the proposals received, 77% were from African-led research groups. Successful applicants will be announced in mid-2025.

> *"The launch of a Phase 2 clinical trial of a Rift Valley fever vaccine candidate in an endemic country is a crucial milestone in our efforts to control this disease. Africa CDC is proud to support this initiative that not only prioritises the health of our people but also demonstrates the continent's growing leadership in advancing clinical research."*
>
> H.E. Dr. Jean Kaseya,
> Director General of Africa CDC

Highlights of RVF programme contribution to 100 Days Mission:

- **Regulatory strengthening:** CEPI-enabled engagement with national and regional regulatory agencies and the African Vaccine Regulatory Forum (AVAREF) to support harmonisation and convergence. This includes working with the University of Wageningen to:

a. Develop a regulatory strategy to licensure for their Phase 2a clinical trial in Uganda and Kenya;

b. Gain approval from the Belgian regulatory authority for scientific advice and Phase 1 Clinical Trial Authorisation to be used for simulation purposes to strengthen the East African regulatory community.

- **Global South vaccine R&D and manufacturing:** CEPI is supporting Afrigen, a South African biotechnology company, to develop and manufacture the first-ever mRNA-based vaccine against RVF, aiming to progress the new vaccine candidate through preclinical development and into Phase I clinical testing. In line with CEPI's equitable access policy, the partnership commits Afrigen to the development of investigational stockpiles for any potential vaccine for use in outbreak situations, using affordable pricing mechanisms. Partnering with an African vaccine manufacturer supports production of a future vaccine close to where outbreaks may occur, thereby geo-diversifying manufacturing capability and supporting rapid access and deployment during outbreaks. The project also includes IVI as the clinical and regulatory partner.

> *South Africa is committed to innovation and the development of novel vaccines that counter the negative impacts on human health and economic development. The collaboration between CEPI and South Africa's flagship biotechnology research, development and manufacturing company Afrigen is valued and central to our commitment to develop and sustain local manufacturing capacity and capabilities on the African continent.*
>
> **Mr Parks Tau,**
> South Africa's Minister of Trade, Industry and Competition

Coronaviruses including MERS

The threat posed by coronaviruses (CoV) was made tangible to the world by the COVID-19 pandemic. Despite the devastation and over 7 million deaths reported since 2019, concerted global R&D efforts – including CEPI's rapid support for one of the world's largest portfolios of vaccines – enabled the development of the multiple safe and effective vaccines that are now available. CEPI's rapid mobilisation and support led to the approval of seven vaccines and the development of widely used open access tools critical for vaccine development – over 60 vaccine developers have accessed clinically validated assays, with over 70,000 clinical samples tested in globally distributed CEPI network laboratories to date – in addition to the building of critical infrastructure for variant monitoring and response. This achievement and its impact cannot be overstated.

And yet, our preparedness work in this space has only begun. SARS-CoV2, the virus that caused COVID-19, is only one member of the large and diverse coronavirus family that has threatened humans for centuries. These viruses, which infect a wide range of both wild and domesticated and farmed mammals and birds, have highly adaptable genomes, allowing them to easily cross species barriers. Coronaviruses have spilled over into humans repeatedly, leading to several now-endemic diseases, and since 2000, multiple deadly outbreaks including SARS and MERS,the latter with case fatality rates of around 35%. With the changes in climate, wildlife habitat and human activity, spillover opportunities will increase, setting the stage for new outbreaks, the potential impact of which we are only too familiar with.

CEPI is leveraging investments and learnings generated during the pandemic to prepare for and prevent the catastrophic consequences that pre-emergent coronaviruses can engender. An overview of the CoV portfolio as of December 2024 is as follows:

- **1 vaccine in preclinical for MERS (UVax)**
- **1 vaccine completed Phase 1 for MERS (IDT Biologika)**
- **1 vaccine in Phase 1 for MERS (Oxford)**
- **11 vaccines in preclinical for broadly protective coronavirus (BPCV) (Gritstone, Migivax, VBI, Bharat, SK Bioscience, Panacea, CalTech, VIDO, Intravacc, NEC Onco, IVI/Bionet)**

CEPI's current coronavirus investments total over US$ 360 million of contracted funds and focus on the following:

Broadly protective vaccines: CEPI funds 11 projects focused on the development of BPCV vaccines. In 2024, key preclinical data has emerged from this work to suggest that development of vaccines protecting broadly against sarbecoviruses (the sub-genera including SARS and SARS-CoV-2) and possibly MERS, is feasible. Modelling efforts have underscored the potential positive impact on public health and reduced social and economic costs, should vaccines be made available at the start of a coronavirus outbreak. We look forward to transitioning the first vaccines of this kind into clinical testing in 2025.

MERS vaccines: CEPI funds the two most advanced MERS candidates in development in the world. The Oxford and IDT vaccine candidates have shown positive preclinical, safety and preliminary immunogenicity data in human Phase 1 clinical trials. In 2025, CEPI plans to hold a regulatory and use case workshop on MERS to inform the future development of these and other potential candidates. In addition, CEPI is also investing in UVax to broaden CEPI's MERS portfolio while advancing the platform potential of Uvax's nanoparticle technology.

Enabling activities in 2024 that support the CoV vaccine portfolio include a BPCV use case workshop and impact modelling study, development of essential assays and models to support the assessment of BPCVs and MERS vaccines. In 2024, as part of a consortium led by Imperial College London and with co-funding from the EC, an Omicron-based controlled human infection model (CHIM) was successfully developed. This model is specifically designed to provide insight into mucosal correlates of protection, as well as transmission dynamics following vaccination. Vaccine testing studies using this CHIM model and related studies are planned for 2025 and will inform the transmission-blocking potential of existing and innovative vaccine platforms. Knowledge that is generated from this work is anticipated to be broadly applicable to respiratory virus containment efforts.

Chair of CEPI's Board, Professor Jane Halton, at a biosecurity simulation exercise at the Munich Security Conference in February 2024

Highlights of Coronaviruses programme contribution to the 100 Days Mission:

- **Broadly protective vaccines:** The availability of broadly protective vaccine on Day Zero of a novel outbreak could significantly contribute to the 100 Days mission. CEPI is engaging with regulatory agencies to consider feasible pathways to use, as well as the potential applications of investigational vaccine reserves, looking at both the health benefits and economic impact of deploying these vaccines in response to an initial outbreak.

- **MERS vaccines:** MERS, which emerged in humans in 2012 and has caused recurrent and lethal outbreaks since then, is considered a priority pathogen of pandemic potential. This is because of its genetic plasticity, high case fatality rate and ability to transmit between humans in the absence of proper infection control measures and lack of any available medical countermeasures. Progressing the development of MERS vaccines in peacetime and through human trials will accelerate the deployment of such countermeasures in a time of need.

- **Vaccine Library:** Given the outbreak threat presented by diverse branches of the coronavirus family, CEPI initiated development of a coronavirus vaccine library. This is expected to generate shared data and tools to accelerate development of virus-specific vaccines in the event of a novel coronavirus outbreak, in much the same way as our prior knowledge of MERS vaccine development was key in achieving the rapid development of SARS-CoV-2 vaccines.

Filoviruses

CEPI expanded the number of viral pathogenic families of focus in 2023 to include the Filovirus family. This viral family includes the deadly haemorrhagic fever viruses Ebola and Marburg, which are endemic to West and Central Africa. These viruses cause frequent unpredictable outbreaks of varying size and duration with significant health and societal impacts – the fatality rate can be as high as 90%. Licensed vaccines currently protect only against the Zaire strain of the Ebola virus with access limited to certain population groups. CEPI's efforts in 2024 have focussed on supporting post-licensure studies to support extension to underrepresented groups alongside initiation of a programme to develop a broadly protective Filovirus vaccine to protect against a range of viruses in this family.

Filovirus achievements in 2024 include:

- **Completed two Phase 2 Ebola Zaire vaccine clinical trials in healthcare workers in Uganda and the Democratic Republic of Congo (Janssen-Cilag International NV)**
- **Completed a Phase 3 clinical trial of the Ebola Zaire vaccine in pregnant women in Rwanda (Janssen-Cilag International NV)**
- **Launched a CfP and selected awardees to commence a programme of activities to develop a broadly protective Filovirus vaccine in 2025**

Pregnant women and frontline healthcare workers are particularly vulnerable to Filoviruses, and CEPI has focussed efforts on supporting three clinical trials in endemic countries to gather the safety and immunogenicity data needed to enable access to vaccines for these underrepresented groups. Two Phase 2 trials and one Phase 3 trial with the prime-boost vaccine regimen Zabdeno® and Mvabea® were concluded in 2024.

A further clinical trial in the Democratic Republic of the Congo (DRC) to evaluate booster immunisation is in the preparatory stages with the Institute of Tropical Medicine in Antwerp, Belgium and Institut National de Recherche Biomedicale in Kinshasa. This upcoming trial is anticipated to generate data to inform policy on the expanded use of licensed vaccines, ERVEBO® (Merck) and Zabdeno® (Janssen-Cilag International NV).

With the support of the EC, CEPI launched a programme to develop a broadly protective Filovirus vaccine with the aim of using the future vaccines in preventive vaccination campaigns in regions where Filoviruses emerge, thereby protecting populations at risk. This work will include designing and testing several immunogens against a wide range of viruses with outbreak potential in the Filovirus family and could be instrumental in driving forward the 100 Days Mission.

Information on CEPI's role responding to the Marburg virus outbreak – a member of the Filovirus family – can be found in the section "Monitoring of high-risk pathogens and emergency response".

Highlights of Filovirus programme contribution to 100 Days Mission

- **Regulatory immunobridging strategies:** CEPI has been examining existing data and exploring new methods to identify immune markers and correlates of protection to support development of regulatory approaches in relation to Filoviruses. In close collaboration with global, regional and country-level regulatory agencies, a workshop was held in Washington D.C. in early 2024 to accelerate efforts.
- **Supporting demand generation**: In December 2024, CEPI brought together global, regional and local stakeholders in Rwanda to discuss future use of novel Filovirus vaccines. Participating policy-makers and immunisation programme managers from endemic African countries provided guidance on the preferred use cases of vaccines.

Mpox

The evolving epidemiology of mpox and the unmet medical need for effective vaccines in endemic countries led CEPI to add mpox as a priority pathogen in 2023. Efforts in 2024 focused on synthesising available data on licensed vaccines to support decisions on vaccine use by regulatory bodies and evidence generation studies, with the aim of expanding access to existing vaccines to help tackle the ongoing and deadly mpox outbreaks in the DRC and other countries.

A summary of the mpox portfolio in 2024 is as follows:

- **1 vaccine candidate progressed to Phase 2 clinical development (BioNTech)**
- **Post-licensure studies of a licensed vaccine to support extension to underrepresented groups (Bavarian Nordic)**

With CEPI funding, BioNTech initiated a Phase 1/2 clinical trial of the mRNA-based mpox vaccine candidate in 2023. BioNTech reported positive Phase 1 interim data for its mRNA mpox vaccine and has progressed to the Phase 2a study in 2024.

In 2024, CEPI also funded post-licensure studies of the Bavarian Nordic's MVA-BN® vaccine, the first to be prequalified by WHO. Children, pregnant women and infants are particularly vulnerable to mpox, but this group's access to vaccine is currently limited until there is more data about its safety and immunogenicity in these populations. CEPI's support includes:

- Funding together with EDCTP3 for a first-of-its kind trial to assess the safety and immunogenicity of the Bavarian Nordic vaccine in pregnant and breastfeeding women, and infants. Around 350 pregnant women and 250 children aged four months to 2 years are due to take part in the study in Boende, DRC, in 2025.
- CEPI initiated two other trials of MVA-BN® mpox vaccine in Africa. The first will generate evidence about the vaccine safety and immune response in children aged 2 to 12 years for non-inferiority to adults aged 18 to 50 years, to help inform vaccination strategies and accelerate additional regulatory approval of MVA-BN® in children. A second study aims to evaluate whether vaccination post-exposure to an infected individual in a household prevents mpox infection and/or severe disease.

CEPI's role in responding to the mpox outbreak as well as in wider preparedness efforts can be found in the report section below titled 'Monitoring of high-risk pathogens and emergency response'.

Highlights of mpox programme contribution to the 100 Days Mission:

- **Global manufacturing:** BioNTech has initiated activities for mRNA manufacturing expansion for clinical trial material and commercial scale in Rwanda. CEPI BioNTech candidate vaccines including mpox are considered as part of the pipeline of vaccines for the facility.
- **Accelerating regulatory processes to speed up vaccine approvals:** CEPI has been working with global, regional and country regulatory agencies to discuss approaches to an accelerated regulatory approval pathway for an mpox vaccine. A synthesis of existing available immunology data from mRNA mpox vaccine development will support future discussions.
- **Supporting stockpiling and market shaping:** CEPI continues to work with Gavi on the mpox learning agenda as well as establishment of the Gavi mpox stockpile. CEPI will work collaboratively with key stakeholders as the roadmap for market shaping and demand forecasting are developed, and plan to facilitate a use case workshop.
- **Generating real-world evidence during vaccine deployment:** CEPI partnered with Africa CDC, WHO AFRO, University of Kinshasa and PATH to collect safety data on adverse events following immunisation during deployment of mpox vaccines in the DRC, leveraging the Safety Platform for Emergency Vaccines project (SPEAC) for standardised case definitions and tools and the Global Vaccine Data Network.

Monitoring of high-risk pathogens and emergency response

To strengthen our ability to respond quickly and effectively to global health emergencies, CEPI led several scenario-based exercises with partners to test response mechanisms, decision-making processes and engagement, and identify and respond to gaps in response strategies with a focus on the 100 Days Mission and H5N1.

In 2024, CEPI continued to keep close track of emerging pathogens of interest and activated its response teams for three overlapping outbreaks: mpox, H5N1, and Marburg. Each response has been characterised by taking early, no-regret actions, practicing components of the 100 Days Mission, and anticipating future needs that were within CEPI's mandate to address.

Case study I: mpox

CEPI initiated early, no-regret actions when the world sounded the alarm on mpox in 2022 and designated mpox a priority pathogen in 2023; WHO declared the mpox outbreak a PHEIC in August 2024 after a surge in cases in the DRC and in over a dozen other countries.

Working closely with Africa CDC, WHO and other global partners, CEPI is funding R&D projects to fill in critical evidence gaps and generate data that could expand access to mpox vaccines in populations who need them most – by supporting clinical trials in children and pregnant women in endemic regions. CEPI has collated evidence on mpox vaccine performance and made this available to local regulators to accelerate regulatory approvals of vaccines, in alignment with the WHO mpox Research Roadmap.

Along with partners including Africa CDC and WHO, CEPI is a member of the Access and Allocation Mechanism (AAM) for mpox, a group which is collaborating with affected countries and donors to ensure needs-based, equitable and timely access to limited supplies of mpox vaccines. The AAM approved the first allocation of 900,000 doses of mpox vaccine to nine countries in Africa in 2024, representing a significant step towards a coordinated and targeted deployment of available vaccines to prevent the spread of mpox.

Case study 2: H5N1

In March 2024, the first-ever H5N1 infection in cattle was confirmed, marking the beginning of a concerning, widespread outbreak in mammals in close contact with humans. In June 2024, CEPI initiated a 'Level 1' outbreak response: convening a cross-departmental expert group; closely monitoring the H5N1 outbreak; and taking some initial "no-regret" steps designed to put the world ahead of the virus if it were to become a greater human threat. Efforts included:

- Advocating for the role of mRNA and other rapid response vaccine platforms in a pandemic flu scenario —which offer promise of a faster response, and, by addressing scarcity, can address one of the barriers to equitable access
- Using computer-assisted design to create H5N1 antigens to enhance the immune response and protection and therefore improve the effectiveness of pandemic flu vaccines. This work was carried out under CEPI's wider Disease X programme as described under "Transform"
- Engaging with CEPI's network of vaccine manufacturer facilities in the Global South through table top exercises to better understand and navigate barriers that might stand in the way of scaling up production of new H5N1 vaccines if they were needed
- Working with national governments and global health partners on how best to collaborate to improve H5N1 preparedness.

Case study 3: Marburg in Rwanda

In early September 2024, Rwandan scientists and health officials joined CEPI and private sector partners to walk through a "tabletop exercise" as part of 100 Days Mission preparedness efforts. It was through this in-person training exercise that key relationships between disease outbreak experts, Rwandan health authorities and researchers, vaccine developers and clinical trial specialists could be established. As soon as Marburg was detected and identified later that month, Rwandan health authorities moved quickly and began intensive surveillance, testing and contact-tracing operations.

Working with CEPI and the Sabin Vaccine Institute as the developer of the Marburg vaccine candidate, Rwanda was able to implement an emergency trial of the vaccine on 5 October 2024, 10 days after the outbreak was declared. Within six weeks, more than 1,700 people, most of them healthcare workers at highest risk of contracting the disease, had been vaccinated and the outbreak was officially declared over on 20 December 2024. This was a prime example of the 100 Days Misson in action.

Strategic Objective 2: TRANSFORM the response to the next novel threat

A key ambition of the TRANSFORM objective is to advance a paradigm shift in the preparedness and response architecture so that a safe and effective vaccine can be developed in a 100-day timescale from the notification of a novel Disease X – accessible to all people in need. CEPI contributions towards meeting this ambitious goal encompass both meeting the technical needs, as well as bolstering a global health ecosystem that can collaborate effectively on preparedness, readiness and response to make the 100 Days Mission a reality.

Vaccine Library

A key 100 Days Mission pillar is the development of a Vaccine Library targeting viral families at high risk of causing epidemics and pandemics. The Vaccine Library aims to generate state-of-the-art antigen designs for viruses from high-risk viral families and combine them with rapid response vaccine platforms – mRNA, viral vector and others – to quickly create vaccine candidates.

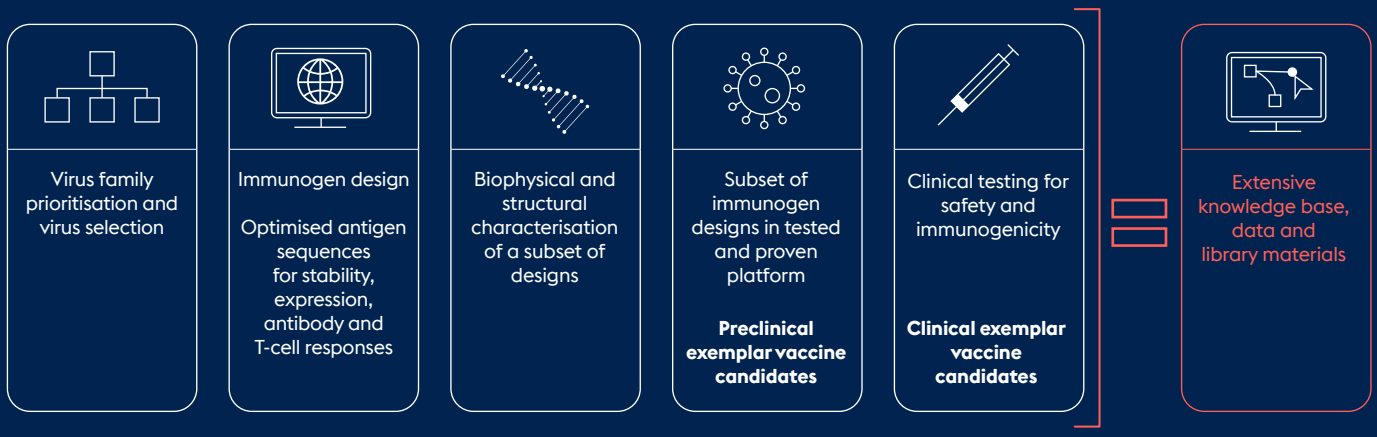
The Vaccine Library is envisaged as a repository of knowledge, seed materials and vaccine candidates based on smart antigen design combined with rapid response platforms to be able to respond to a Disease X more quickly. A key component of the Vaccine Library is the targeting of whole virus families with high risk of causing a Disease X outbreak, and the development of 'exemplar vaccines' against prototype pathogens representative of virus families through preclinical and clinical development. The iterative technical, safety and efficacy data gathered from developing preclinical and clinical exemplar vaccines for prototype pathogens on rapid response platforms will cumulatively add to the technical and regulatory experience with the relevant vaccine platform.

Vaccine Library materials could be leveraged in the event of an outbreak to get a "head start" on developing safe and effective vaccines in response to the outbreak. As Vaccine Library materials become more extensive and advanced over time, preparedness to respond against a broader range of pathogens will progressively increase, representing a critical contribution to the 100 Days Mission.

CEPI 2024 highlights:

- Increasing the Vaccine Library scope from four to five viral families, complementing the updated WHO Pathogens prioritization: a scientific framework for epidemic and pandemic research preparedness
- Integrating and leveraging the potential of artificial intelligence (AI) to accelerate and improve vaccine antigen design, and to better prepare for mutations and unknown threats
- Making important strides in core areas that support speed, scale and equitable access during a future outbreak response. This includes catalysing vaccine modality and manufacturing technology innovations and advancing enabling activities
- Evolving to play a greater role in advocacy and in catalysing public-private partnership, including with regulatory agencies, to transform regulatory pathways and enhance global readiness within the wider ecosystem for future pandemics.

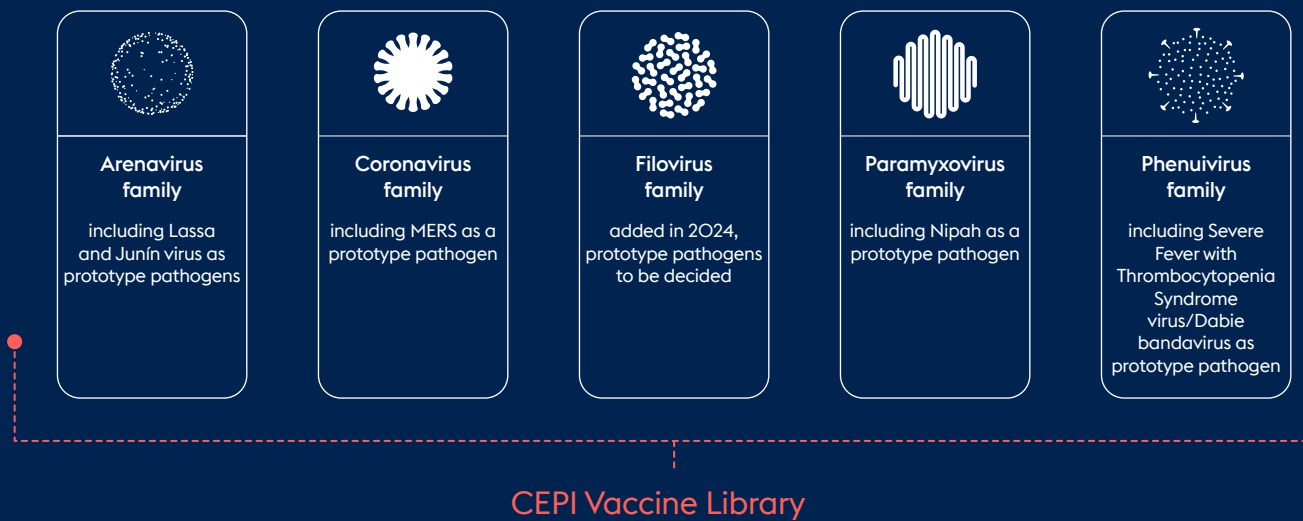
Figure 2: Components of a Vaccine Library



In August 2024, WHO published the outcomes of scientific pathogen prioritisation consultation as a new framework for epidemic and pandemic research preparedness. This replaced the previous WHO R&D Blueprint list of priority diseases which guided CEPI's selection of original priority pathogens. WHO proposes to establish decentralised Collaborative Open Research Centres (CORCs) across the globe to support development of roadmaps for each viral family and enable collaboration across developers and researchers. The publication of this framework represents an important validation of CEPI's early adoption of a viral family approach in CEPI 2.0. CEPI's Vaccine Library activities are well aligned with those of the CORCs, and CEPI continues to explore potential for coordination and mutual support.

CEPI has so far focused its efforts on five viral families and to develop exemplar vaccines against representative prototype pathogens. All five families are included in the list of prioritised high-risk viral families published by WHO, as can be seen in the figure below.

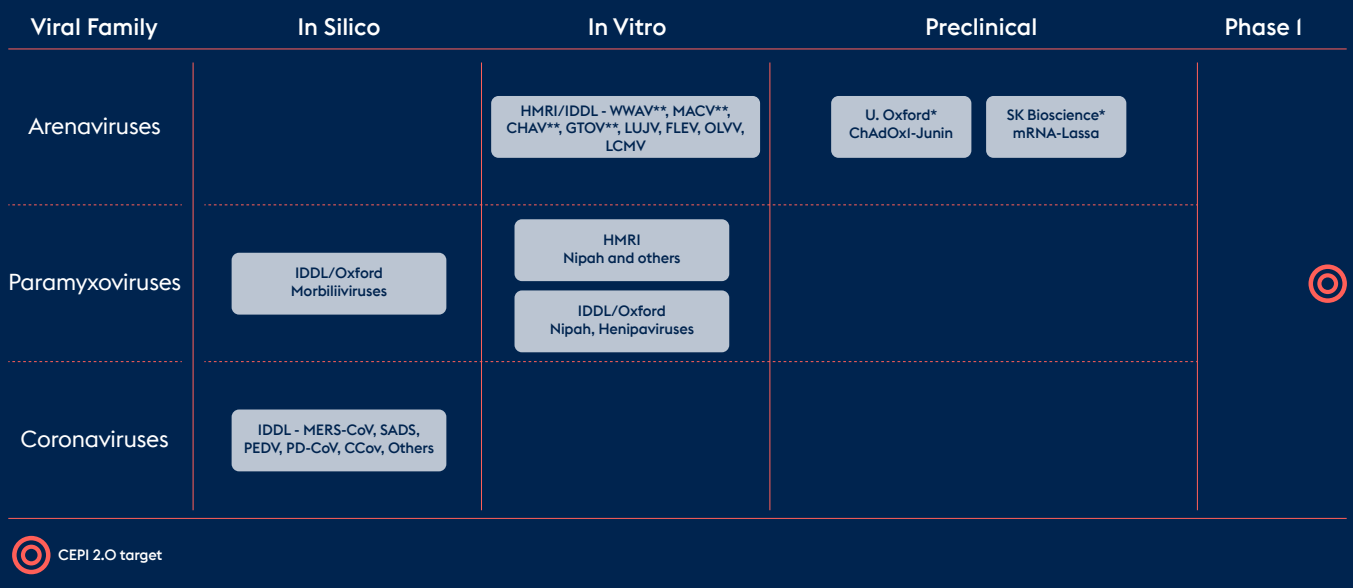
Figure 3: Viral families of focus to develop exemplar vaccines as part of CEPI's Vaccine Library



Advancements in 2024 include:

- Testing several novel antigen designs for Lassa and Junín as exemplar vaccines for the Arenavirus family, using mRNA (SK Bioscience) or ChAdOx (Oxford) platforms. Currently in the preclinical stage, models have shown that these vaccines generated effective immune responses associated with protection from viral infection. Both exemplar vaccines will progress to Phase 1/2 clinical trials with SK Bioscience and University of Oxford as developers for Lassa and Junín, respectively. Several designs are now available for other viruses in the Arenavirus family and are planned to be tested as preclinical exemplar vaccines.
- For the Paramyxovirus family, innovative antigen designs have been generated and tested in vitro, with a plan to transfer some of these designs to a developer, Gennova, for testing in their self-amplifying mRNA technology, including through a Phase 1 trial. The antigen design work continued for other viruses in this family.
- The design and testing principles established as part of the Disease X Vaccine Library approach are being applied to CEPI priority pathogens, notably for Filoviruses, Coronaviruses and for the no-regrets response to H5N1
- New viral families were added to CEPI's Disease X/ Vaccine Library programme, namely Phenuiviruses, with Dabie bandavirus as an exemplar vaccine candidate. Immunogen design work has started and vaccine developers have been identified.

Figure 4: CEPI Disease X Vaccine Library portfolio



* Clinical exemplars
** Preclinical exemplars

Harnessing the Potential of AI in support of the 100 Days Mission

The potential for AI to advance epidemic and pandemic preparedness response efforts – from pathogen detection and early warning to vaccine design, planning clinical trials and supporting vaccination campaigns in outbreak regions – is tremendous. With its uses likely to increase exponentially over the coming years, CEPI is exploring where and how we may be able to support and leverage AI – to benefit the 100 Days Mission and accelerate equitable access. CEPI has partnered with leading scientific institutions to use AI and computational software to accelerate vaccine design. This could help to produce vaccines that elicit strong immune responses that can be designed and ready for a novel viral threat. There are several ways in which CEPI has leveraged this game-changing technology:

- A consortium led by the Houston Methodist Research Institute in the U.S. and the German-based Leipzig University is being funded to design stabilised and potentially more immunogenic antigens from viral proteins, and evaluate if these design principles apply throughout the Arenavirus and Paramyxovirus families.
- In recognition of the risk of fast-evolving SARS-CoV-2 variants evading available countermeasures, CEPI partnered with Harvard Medical School and Apriori Bio in 2024 to use their AI platforms to identify viral mutations that have the greatest 'escape potential'. Insights gleaned from this project can guide how new vaccines are designed and how existing vaccines are updated so that they can protect against variants for years to come. CEPI is also working with Argonne National Laboratory, which provides supercomputing capabilities and AI systems expertise to support the Vaccine Library activities.
- Joint work is also continuing with UC Davis to use its AI system to help identify the viral families most likely to cause the next pandemic. Their tool named 'Spillover' pools information on viruses, host and environment including viral transmission routes and data from recent disease outbreaks to analyse the viruses most likely to spread from animals or between people and generate epidemics. Having information on the most significant epidemic and pandemic threats tells us what pathogens to look out for and enables CEPI to better focus its efforts.

As a funder of AI development, CEPI recognises its critical responsibility to ensure its research investments are used safely and securely. In 2024, CEPI co-led development of the Responsible Principles for Biodesign, fostering the responsible adoption of AI in protein/vaccine design. Furthermore, in line with CEPI's new Biosecurity Strategy, we are working to operationalise commitments to the Responsible Principles, and inform CEPI's approach to strengthening biosafety and biosecurity oversight. Please see the section in "Transform" titled "Enhancing Global Biosecurity Capabilities in Support of the 100 Days Mission".

Advancing Vaccine Technology Innovations

In 2024 CEPI continued to support a wide range of viral-vector, nucleic-acid and recombinant-protein based vaccine technologies, which are yielding critical data and insights that will help the world accomplish the 100 Days Mission.

A total of seven active R&D technology innovations projects were funded via CEPI's vaccine platform innovations portfolio by the end of 2024. These include next-generation RNA technologies (e.g. self-amplifying, circular, trans-amplifying, novel delivery vehicles), novel nanoparticle and virus-like particle (VLP) technologies, and vaccine design innovations. CEPI has expanded its portfolio of mRNA investments, extending its partnership with Wellcome Leap by providing bridge funding towards a potential second phase of the R3 programme.

Efforts also continued to support transformative chemistry, manufacturing and controls (CMC) innovations in vaccine platform technologies, manufacturing processes and delivery devices. Throughout 2024, 10 projects underwent due diligence and agreements signed, bringing the active portfolio to 15 projects at the end of the year. Spanning awardees from 11 countries, these projects address one or more gaps related to equitable access and/or the 100 Days Mission for RNA, proteins and viral vectors vaccine modalities. Two projects in this portfolio reached funding continuation gates, one of which was selected and successfully matched with a vaccine platform developer to progress to preclinical development.

Figure 5: CEPI Manufacturing (CMC) innovations portfolio snapshot

Manufacturing Innovations projects that support the 100 Days mission advanced in 2024

CEPI made several investments in 2024 to push the boundaries of manufacturing innovations to improve vaccine scalability and equitable access including:

Protein production with plant cells

To support the 100 Days Mission, CEPI granted LenioBio GmbH up to US$2 million to provide preclinical proof-of-concept that their commercially available, plant-based technology can produce proteins for use in clinical trials testing vaccines against epidemic and pandemic threats in 20-40 days, potentially reducing vaccine proteins manufacturing time by up to 75% compared to traditional cell culture methods.

The technology known as ALiCE®—which stands for Almost Living Cell-Free Expression—uses the protein production machinery of plant cells such as enzymes and other biological components, to rapidly express proteins in a so-called 'cell-free' reaction. The CEPI-funded project aims to prove if ALiCE® can support the rapid and scalable development of viable protein-based vaccine candidates and move these promising candidates more quickly into clinical trials, pushing forward our goal to achieve the 100 Days Mission.

RNA patches for equitable access

RNA-based vaccines are one of the most important rapid response platforms, but RNA has clear barriers in terms of equitable access, such as the current need for ultra-low temperature storage, which complicates distribution in remote regions. CEPI granted Vaxxas up to US$4.9 million to develop a microarray patch presentation for RNA-based vaccines. They successfully demonstrated that mRNA-lipid nanoparticles can be stabilised for storage and distribution at temperatures up to 40°C, and effectively delivered in animal models. CEPI matched Vaxxas with SK Bioscience, to further advance the technology through preclinical development and Phase 1 readiness, bringing Vaxxas' patch equitable access benefits to SK Bioscience's mRNA rapid response platform.

In addition to thermostability, patches enable easy, needle-free administration, which do not require highly trained healthcare workers. The presentation also results in reduced wastage, and higher levels of uptake. Because of their thermostability and small size, patches are also ideal for stockpiling as an additional benefit.

Advancing vaccine technology platforms to increase speed to licensure and drive equitable access

Work with partners to build understanding and expertise with vaccine platforms as a crucial enabler of the 100 Days Mission. These technology platforms are systems that use the same basic components as a backbone but can be adapted for use against different pathogens by inserting new genetic or protein sequences. Vaccine platforms will be vital for pandemic preparedness because they support faster development and deployment of vaccines which is essential when facing novel threats. As global regulatory authorities gain experience with and gather data on a platform technology through its use, reviews can be optimised to rapidly moving new vaccines into clinical trials – helping to accelerate safe, effective vaccines to licensure, as well as enable the 100 Days Mission.

As of December 2024, CEPI had several projects with organisations that have potential vaccine platform technologies for mRNA, viral vector or protein subunit-based vaccines: SK Bioscience, BioNTech, Moderna, Gennova, University of Oxford. CEPI has entered into strategic partnerships with two of these organisations, Moderna and University of Oxford, as detailed under the "Connect" section of this report. In addition, CEPI is supporting clinical development of licensed viral-based vaccine products by Merck, Janssen and Bavarian Nordic to expand equitable access.

A platform readiness evaluation dashboard was developed identifying 21 areas for innovation and compare platforms to aid in decision-making for future outbreaks. The areas identified include platform adaptability, population compatibility, suitability for deployment, regulatory acceptance, manufacturability, and production capacity readiness.

Technology innovations projects were evaluated for potential use in next generation platforms. Key among these is a long-standing partnership with the University of Queensland in Australia, to advance development of their molecular clamp platform via streamlined downstream processing, thereby increasing production efficiency and speed.

Bolstering regulatory readiness to support the 100 Days Mission

Regulatory agencies are responsible for ensuring vaccines and other medical countermeasures are evaluated properly and meet necessary high standards of quality, safety, and efficacy. Strengthening regulatory harmonisation and emergency use pathways is critical to achieving the 100 Days Mission. In 2024, CEPI continued to engage with regulators worldwide. The focus has been on identifying and helping to overcome regulatory challenges and supporting efforts to align regulatory requirements. This has included engagement with CEPI's regulatory network and exchanges with regulatory agencies on regulatory pathways for priority pathogens, and to lay the groundwork so that vaccine development innovations will be accepted by regulators thus paving the way to rapid or emergency licensure.

CEPI worked with WHO to formalise the status of the Regulatory Advisory Group on Regulatory Preparedness and Response under the framework of the interim-Medical Countermeasures Network (iMCM Net). Co-chaired by CEPI and WHO and consisting of senior representatives from 13 LMIC regulatory authorities, the Regulatory Advisory Group aims to address various regulatory issues related to neglected diseases with pandemic potential, supporting a harmonised and effective approach – crucial to ensuring the success of the 100 Days Mission.

Figure 6: Regulatory Advisory Group membership

Engagements across the regulatory network included evaluating the "readiness" of each regulator to be able to respond to a future pandemic within 100 days. To support these assessments and drive progress, CEPI drafted a regulatory readiness "dashboard" identifying 25 areas including tools such as harmonisation, information sharing and safety. The dashboard will be rolled out in 2025 to regulatory network members and will feed into the work to monitor and improve global regulatory readiness with FRPath described below.

Efforts to develop a foundational database outlining emergency use legislation, including reliance provisions for each regulatory authority progressed well in 2024. Recognising the value of integrating this work with a broader educational and regulatory initiative, CEPI partnered with FRPath, an initiative led by the University of Southern California and co-funded by the Gates Foundation. FRPath serves as a long-standing global repository designed to inform regulators, industry, and NGOs on best practices.

CEPI made an important contribution to this resource by adding detailed Emergency Authorisation Pathway data across global jurisdictions. In January 2024, CEPI submitted the compiled Emergency Authorisation Pathway data to the FRPath team, who then conducted a thorough review and refinement of the data. The data were then fully integrated into the FRPath Portal, making Emergency use pathway information publicly accessible for the first time. This new resource enhances CEPI's ability to support regulatory engagement by offering a centralised, open access and up-to-date reference point for emergency preparedness frameworks across countries.

Scaling enabling sciences and R&D networks to further accelerate vaccine development

CEPI's enabling science programme spans the production of research tools such as standards and assays, preclinical models, epidemiology, predictive and mathematical modelling, as well as strengthening clinical research approaches, and diagnostics and are a critical enabler to CEPI's vaccine R&D.

2024 highlights include:

- Expanding and strengthening the Centralised Laboratory Network (CLN): As the world's largest network of vaccine clinical testing laboratories, the CLN supports developers globally to evaluate CEPI priority-pathogen vaccines and beyond – including vaccines for a future Disease X – against common protocols to ensure alignment and information sharing when identifying the most promising candidates. In 2024, more than 27,000 clinical samples were tested by developers for SARS-CoV-2 alone.

With one new member joining in 2024, 18 laboratories across 14 countries are now part of the CLN, in North America, Africa, Europe, Asia and Australia. An Advisory Council has been established to enable network facilities to be more actively involved in decision-making processes and facilitate collaboration to address scientific and logistic challenges, including assay development, validation and transfer, and simplifying processes to meet quality regulatory standards.

Figure 7: CEPI Centralised Laboratory Network as of December 2024

- Expanding and strengthening the Preclinical Model Network: CEPI has established and maintains a Preclinical Model Network (PMN) of biocontainment labs for developing models and testing preclinical vaccines against priority pathogens, coronaviruses, and virus families that may represent the next Disease X. These laboratories ensure compliance with high ethics standards, and support high-quality research using established quality systems or well-documented protocol-specified methods.

Eight new partners joined the PMN in 2024, bringing the total to 17 partners from 11 countries in North America, Europe, Africa, Australasia and Asia. In 2024, members of the PMN participated in a first-ever face-to-face meeting hosted by CEPI in Mexico City, Mexico. Stakeholders from the network laboratories and other CEPI partners such as UK NC3Rs, PAHO, the US National Institute of Allergy and Infectious Diseases (NIAID) and Biomedical Advanced Research and Development Authority (BARDA) emphasised the importance of continued collaboration and data sharing among CEPI laboratories, optimised research methodologies and a concerted effort to address emerging infectious threats globally.

- Advancing preclinical testing in assays and models: Through the CLN, CEPI supported WHO and others to obtain immunogenicity and efficacy data. Moreover, CEPI supported the development and implementation of over 30 assays for seven pathogens. New models were developed while existing models were refined through the PMN including models for Nipah, MERS, Lassa, SARS-CoV, numerous SARS-CoV-2 variants, and a Junín virus challenge model for the Disease X programme. Many of these models were used by Network partners to evaluate preclinical efficacy of developer vaccines/biologics (Barinthus, Gritstone, Intravacc, Mapp, Migvax, Oxford, Panacea). Discussions to develop Disease X-related models for Arenaviruses, Henipaviruses, and potential spillover coronaviruses have also been initiated.

- Supporting Global South Leaders in Epidemic Analytics and Response Network (GS LEARN). To support leaders in epidemic analytics and response in the Global South, strengthen technical expertise in infectious disease modelling and enhance interdisciplinary collaborations across regions, CEPI launched a call for proposals in 2024 to solicit applications from highly skilled global Implementing partners. Implementing partners will be selected in early 2025.

- Progress on Lassa and Nipah Diagnostics tests: With FIND, CEPI has been implementing a project which aims to develop and validate high-quality, rapid diagnostic tests for Lassa and Nipah viruses thereby enabling early detection and containment of outbreaks of these deadly diseases. Successful diagnostics will be advanced towards licensure, allowing for wider access and use in health-care facilities. By the end of 2024, landscaping of available point-of-care tests was completed.

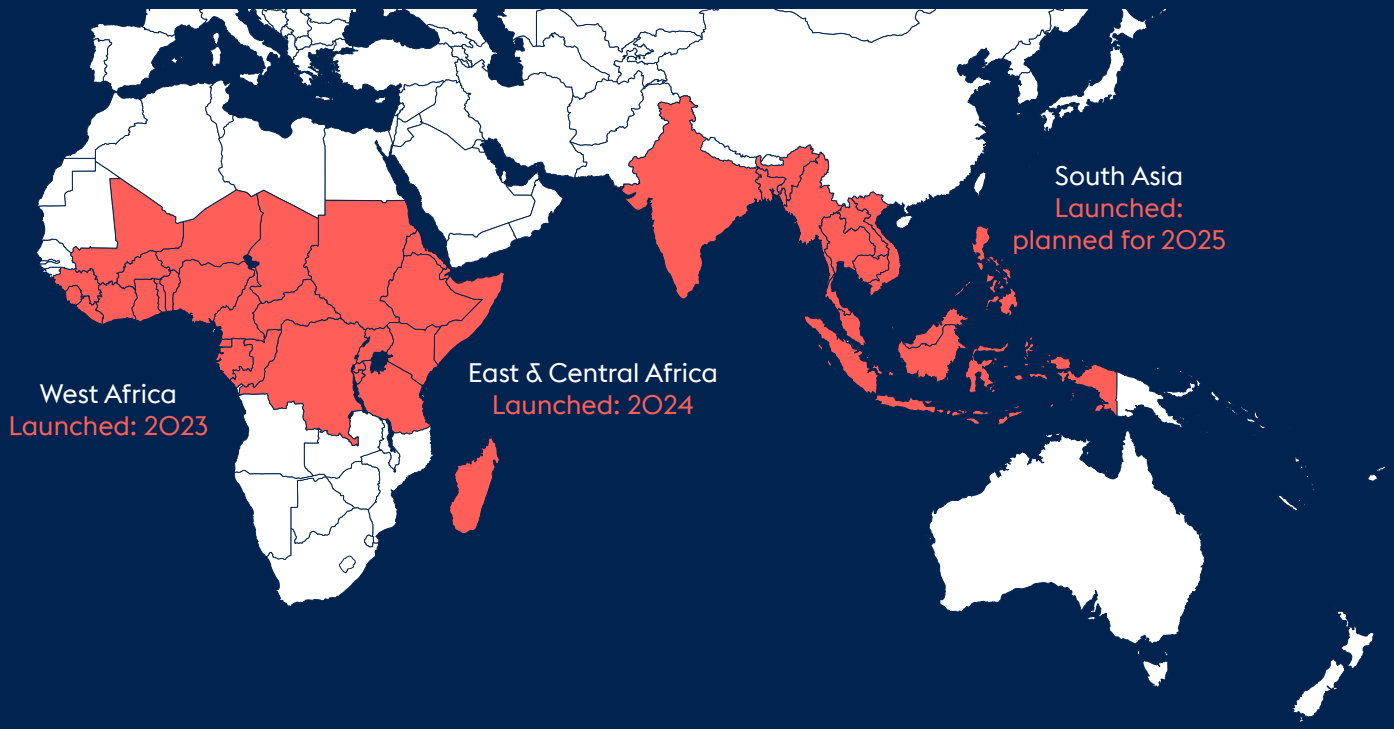
- Development and approval of two WHO International Standards, for SARS-1 and Marburg in collaboration with the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA). Work to bridge R&D product development to process development and manufacturability continues - see the "CONNECT" section of the report for more information.

Expanding CEPI's Research Preparedness Programme

In 2024, CEPI's Research Preparedness Programme in West Africa further expanded to East and Central Africa. The objective of the programme is to leverage investments for advanced-stage clinical development of CEPI's vaccines, to support countries in generating emergency evidence in future outbreaks in support of the 100 Days Mission. Designed as a multi-regional approach tailored to the specific needs of clinical research ecosystems, programme will initially focus on geographies where priority diseases are most prevalent or likely to cause outbreaks.

Technical Coordinating Partners are implementing the programme, which aims to bolster local clinical trial capacity and disease outbreak readiness through capacity strengthening and engaging with national governments, regional entities and other stakeholders to ensure sustainability of the programme activities. CEPI partners with regional and supra-regional public health agencies such as WAHO and Africa CDC to make sure that activities are aligned with their individual roadmaps for the region and wider continent. By mid-2025, the West Africa technical partners will have strengthened clinical trial capacity for a future late-stage clinical trial in support of CEPI's Lassa fever vaccine portfolio. A further expansion of the programme to the South Asia region is planned for 2025.

Figure 8: Research Preparedness Programme regions



AfricaCDC Centres for Disease Control and Prevention · West African Health Organization Promoting better health through regional integration · International Vaccine Institute · UKRI MRC Metabolic Diseases Unit · PATH

Enhancing Global Biosecurity Capabilities in Support of the 100 Days Mission

CEPI's dedicated Biosecurity function was established in 2023 enabled by the generous support of Global Affairs Canada. CEPI's first-ever Biosecurity Strategy was subsequently released on the sidelines of the UN General Assembly High Level Week in New York in September 2024. The Strategy was developed after a year of extensive consultation with governments, civil society and the private sector, and was informed by expert guidance from CEPI's Biosecurity Strategy Group of external advisors. CEPI's biosecurity focus is to "protect society from epidemic and pandemic threats, with an emphasis on preventing accidental and deliberate misuse of pathogens associated with CEPI-sponsored research" and identified five global biosecurity vulnerabilities relevant to CEPI's mission.

Figure 9: Global biosecurity vulnerabilities and priorities of CEPI's biosecurity strategy

Other progress in support of CEPI's Biosecurity Strategy includes:

- Strengthened CEPI's process to embed biosecurity and biosafety formally as organisational risks, and expanded application of biosecurity and biosecurity risk identification and mitigation into award reviews and during affiliation of facilities into CEPI laboratory networks (Priority 1).
- With the Nuclear Threat Initiative, launched a new Biotechnology Funders Compact at the Global Health Security Conference (Australia, June 2024) to demonstrate CEPI's commitment to prioritise biosecurity and biosafety risk reduction, and collaborate with other research funders to promulgate best practices (Priority 1).
- Catalysed health security partnerships and networks to accelerate implementation of performance-based standards for biosecurity and biosafety to advance the 100 Days Mission, including through an event at the Global Health Security Conference (Australia, June 2024) and convenings of the CEPI preclinical and CLNs (Priority 2).
- Signed a Memorandum of Understanding between CEPI and Munich Security Conference committing to partnership towards biosecurity and health security goals (Priority 2).
- Embedding equity in strategy implementation including by partnering with the Health Security Partnership in Africa and the Signature Initiative for Mitigating Bio Threats in Africa at their convenings (Ethiopia, March 2024), and leading a session on the benefits and risks of using AI for pandemic preparedness. In addition, CEPI's MoU with Africa CDC includes a dedicated biosecurity workstream to catalyse national and regional progress on strengthening biosecurity and biosafety.
- CEPI hosted two fellows – one from Uganda and one from Tunisia – through Brown University Pandemic Center's 'Biosecurity Game Changers' fellowship programme, designed to create opportunities for the next generation of biosecurity and pandemic preparedness leaders. (Priority 3).
- Enhanced monitoring and mitigating risks associated with emerging technologies such as AI through the co-development of responsible use principles for bio-design in vaccine development, working with partners to operationalise. CEPI is also part of wider efforts to develop a safe and secure global platform for AI vaccine design applications. (Priority 4).
- Convened and participated in high-profile events to advance the 100 Days Mission including a simulation exercise at the Munich Security Conference in February 2024 where experts discussed potential response to a biological weapon generated using AI technology.

Strategic Objective 3: CONNECT to enhance and expand global collaboration

The CONNECT strategic objective builds relationships to align CEPI's R&D and manufacturing partners with institutions and partners that shape the enabling environment for innovation and vaccine production, including public R&D funding organisations.

The three pillars that sit under CONNECT are: diversifying the global footprint of vaccine manufacturing; driving system-wide change to ensure epidemics and pandemics are responded to quickly and more equitably; and advocating for the sustainable financing of preparedness and response efforts.

Key achievements in 2024 include:

- Sustaining momentum for pandemic preparedness through co-hosting the Global Pandemic Preparedness Summit with the Government of Brazil, during Brazil's G20 Presidency
- Deepening key global partnerships and actively participating in high-level health security discussions in fora including the World Health Assembly, G7, United Nations General Assembly, World Economic Forum and World Health Summit
- Driving the system-wide change needed to respond more quickly and more equitably to future pandemics through advocacy including toward the Pandemic Agreement negotiations
- Advancing game-changing strategic partnerships with University of Oxford, BioNTech, IQVIA, and Moderna to accelerate progress towards the 100 Days Mission
- Boosting critical global manufacturing capabilities including through the expansion of Vaccine Manufacturing Facility Networks, funding to establish sustainable mRNA vaccine production capacities in Africa, and hosting the Regionalized Vaccine Manufacturing Collaborative (RVMC).

Advancing global pandemic preparedness: The Global Pandemic Preparedness Summit

In July 2024, CEPI convened a Global Pandemic Preparedness Summit, in Rio de Janeiro, Brazil, representing an important contribution to the evolving global health ecosystem. Co-hosted with the Ministry of Health of Brazil – in the year of its G20 Presidency - and Fundação Oswaldo Cruz (Fiocruz), the Summit aimed to reinvigorate momentum for the global pandemic preparedness agenda to help ensure the world can tackle future outbreaks and pandemics faster and more equitably. The Summit brought together stakeholders including FIND, the International Pandemic Preparedness Secretariat (IPPS), PAHO, Unitaid and WHO, and over 350 R&D and manufacturing experts, government officials, civil society representatives and leaders from industry and the global health community across 50 countries.

The Summit centred on seeking alignment on progress as well as articulating barriers and solutions across the three themes:

- enhancing global disease surveillance
- delivering the 100 Days Mission for vaccines, diagnostics and therapeutics
- enabling equitable access to vaccines, medicines and other health technologies through strengthening local and regional R&D and production capacity.

Global health partners used the unique Summit platform to announce new commitments and initiatives to advance global pandemic preparedness, including the publication of the WHO-led work on pathogen families – a significant contribution to the global ecosystem that signals broader global consensus on this approach and provides a framework for collaboration. Further information can be found in the Global Pandemic Preparedness Summit 2024 Outcomes Report.

Rick Bright speaks at a panel event as part of the Global Pandemic Preparedness Summit in July 2024

Post-COVID, we've learned that equitable R&D, investment and access are crucial for public health. We cannot work only within our countries; we must think beyond borders. It's time for science, technology, and innovation to unite for robust public health policies. We must work together in global health so that it becomes a reality.

Dr. Nisia Trindade Lima,
Former Minister of Health, Brazil

Building a global manufacturing network and driving sustainable regional vaccine manufacturing

Expanding and diversifying the global footprint of vaccine manufacturing—particularly in underserved regions—is a cornerstone of CEPI's goal of enabling equitable access vaccines and will be critical to the success of the 100 Days Mission. Highlights in 2024 include:

Boosting global vaccine manufacturing capabilities

Through the global Vaccine Manufacturing Facility Network (VMFN), CEPI is supporting capability strengthening activities of vaccine manufacturers in Global South countries with a focus on regions where CEPI's priority pathogens are endemic. In the event of an outbreak, CEPI-backed developers will quickly be able to transfer their technology to pre-selected manufacturers with the right expertise, technology and optimal geographical position to enable rapid production and equitable distribution of vaccines to affected populations. In addition to establishing new vaccine capabilities, the VMFN members are committed to reserving capacity for CEPI to manufacture and supply vaccines to the Global South in response to future disease outbreaks.

In 2024, CEPI continued to work closely with existing network members while expanding VMFN membership to a total of five by the end of December 2024:

- Serum Institute of India: As the world's largest vaccine manufacturer, the addition of the Serum Institute of India (SII) to the manufacturing network represents a significant boost to vaccine production efforts in Global South regions. CEPI's investments will build upon SII's proven track record of rapid response to outbreaks of infectious disease, expanding the company's existing ability to swiftly supply investigational vaccines in the face of epidemic and pandemic threats. With CEPI's funding, SII is also supporting the development, stockpiling and licensure of new vaccines against CEPI's priority pathogens as described under PREPARE.

- Bio-Manguinhos/Fiocruz: As one of the largest publicly-philanthropically funded vaccine manufacturers, the inclusion of Brazil's Bio-Manguinhos/Fiocruz in CEPI's manufacturing network significantly boosts vaccine production efforts in Latin America. Announced at the 2024 Global Pandemic Preparedness Summit, the focus of the investment is on expanding new rapid-response mRNA and viral vector vaccine technology platforms against disease outbreaks. CEPI funding will also optimise manufacturing processes and technological capabilities to strengthen regional vaccine supply, as well as enhance end-to-end capabilities by supporting 'fill-and-finish' of vaccines.

Providing significant support to BioNTech to establish mRNA vaccine R&D and GMP (Good Manufacturing Practices) manufacturing capabilities at a new site in Kigali, Rwanda

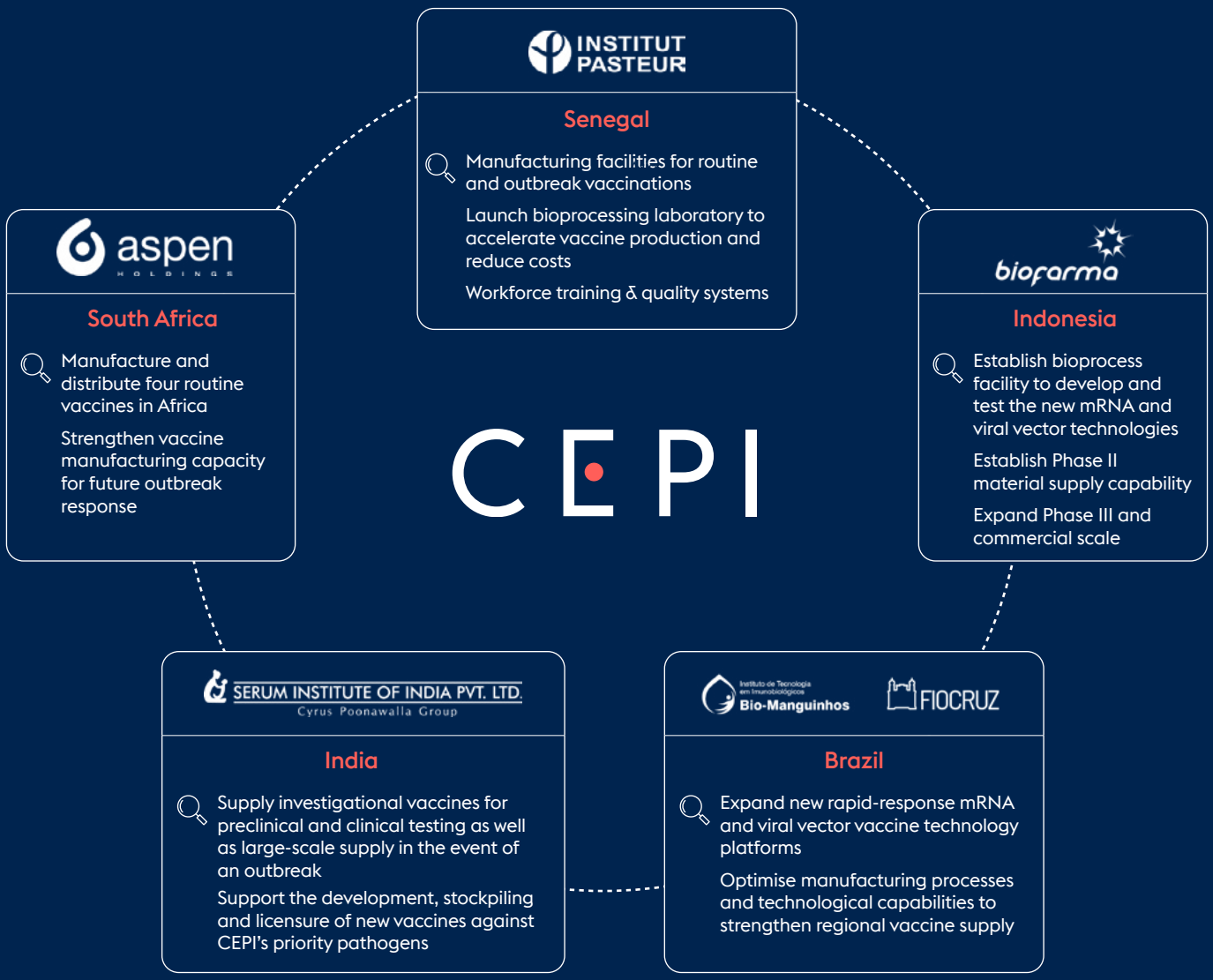
These capabilities will contribute to efforts to better prepare for potential future epidemic and pandemic threats in Africa while building on other CEPI investments to support Africa CDC's ambition towards vaccine self-reliance and goal of producing 60 percent of total vaccine doses required on the African continent by 2040.

Enabling equitable access is a fundamental principle of the partnership and BioNTech intends to provide affordable access to LMICs of vaccines manufactured at the Kigali facility if developed and authorised, such as vaccines against malaria, mpox and tuberculosis, with priority supply to African countries.

See the "PREPARE" and "TRANSFORM" sections of the report for more information on support to SK Bioscience, Biological E, and Instituto Butantan to enhance manufacturing capabilities and position them to respond more effectively to future outbreaks.

CEPI has also continued to coordinate with relevant stakeholders such as the RVMC and WHO, DCVMN, Africa CDC, and PAHO on supply chain enablers, such as coordination of access to input materials and critical consumables for vaccine manufacturing and establishment of input supply chain models to support regional sustainability.

Figure 10: Members of CEPI's Vaccine Manufacturing Facility Network as of December 2024



Driving efforts to achieve strengthened regional vaccine manufacturing

CEPI was a co-founder of the Regionalized Vaccine Manufacturing Collaborative (RVMC) in 2022, with the World Economic Forum and U.S. National Academies of Medicine. RVMC is dedicated to establishing sustainable regional vaccine manufacturing (RVM) and supply chain networks capable of producing vaccines for routine use with readiness for outbreak manufacturing. As of February 2024, CEPI established, and is hosting the RVMC Secretariat.

In January 2024 and following consultation with subject matter experts and policymakers, a Framework for the essential components needed to realise regionalised vaccine manufacturing was published. In July 2024, the Secretariat released its Strategy, defining its priorities for 2024–2027. A call for action following the RVMC event hosted on the sidelines of the 79th Session of the UN General Assembly was also published.

RVMC follows a regionally-led approach and has worked to establish partnerships across Africa (in partnership with Africa CDC), Latin America and the Caribbean (in partnership with PAHO) and Southeast Asia (in partnership with Thai NVI as the focal points for the ASEAN Vaccine Security and Self-Reliance (AVSSR) initiative.

Through advocacy during at the G20 under Brazil's Presidency, both CEPI and the RVMC secured seats on the Advisory Committee of Brazil's Global Coalition for Local and Regional Production, Innovation, and Equitable Access – the Production Coalition – which aims to ensure regional manufacturing efforts are well-distributed, efficient, stable, and meet sufficient demand to sustain production. CEPI and the RVMC were engaged in the development of the Coalition and are recognised in the Rio Health Ministers' Declaration as Production partners.

Supporting system-wide change to achieve Equitable Access

Equitable Access (EA) is core to CEPI's vision of a world in which epidemics and pandemics are no longer a threat to humanity. The way medical countermeasures development and production is currently configured does not naturally produce equitable access 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 R&D&M and to enable timely availability of product is, therefore, a long-term objective.

In 2024 CEPI continued to progress towards aligning with other stakeholders on much-needed end-to-end solutions, with an increasing focus on where CEPI should fund, catalyse or advocate, and where it should not. Our work is guided by the Equitable Access Policy, and CEPI's Equitable Access Framework is overseen by the Equitable Access Committee.

In 2024 CEPI focussed attention on:

1. **Securing an initial commitment from three high-income countries to reference EA provisions when making new financial commitments for vaccine development.** Leading by example, CEPI has shared its methods and worked with governmental and other non-governmental funders to adopt proven methods for partnering for EA bilaterally through a draft white paper, dialogue and responding to requests for information on the approaches to enable EA through bilateral agreements. The U.S. National Institutes of Health (NIH) indicated at the end of 2024 that it would issue its new Intramural Research Program Access Planning Policy, to expand equitable patient access to products that emerge from NIH-owned patents. Two other high-income countries also expressed interest, one of which is in active dialogue with CEPI and another non-governmental funder around approaches that support EA and the global resilience it can bring.

2. **Developing a framework to guide CEPI's end-to-end approach to EA**: In 2024, CEPI began to systematically build out a framework approach for embedding an end-to end approach to equitable access. Responding to recommendations from CEPI's 2.0 Mid-Term Review, this framework will provide clarity on access challenges through the creation of pathogen 'archetypes', CEPI's investment needs and understanding the commercial model and potential partners for economically sustainable solutions to deliver EA. At the end of 2024, the pathogen archetypes were nearing finalisation with other areas of work ongoing into 2025.

3. **Additionally, an end-to-end access roadmap** is being built for at least one pathogen across the access challenges to align with other key stakeholders on appropriate and realistic solutions. Access roadmaps will identify what needs to happen to enable EA for vaccines against the relevant disease overall across the ecosystem, supporting CEPI's decision-making and articulating where CEPI will act and where other actors are better placed to do so.

Advocating for a more robust and equitable PPR framework

Building on previous advocacy, in 2024 CEPI continued to engage with the Intergovernmental Negotiating Body (INB) in 2024 to promote a Pandemic Agreement that is resilient, promotes equitable access and has the capacity to implement some of the lessons learned from COVID-19. CEPI participated in the INB and shared comments on the draft Pandemic Agreement with Investors as well as other governments and partners at each negotiation round. CEPI focused on three key policy asks:

1. Sustaining preparedness investments in R&D and ensure that government R&D funding agreements include contractual requirements to support equitable access

2. Supporting a network of partnerships for end-to-end collaboration on medical countermeasures, and promote strategic investments in economically sustainable, geographically distributed vaccine manufacturing facilities with capability for rapid response

3. Establishing a multilateral system that supports rapid and efficient sharing of samples and data on pathogens with pandemic potential to expedite R&D for medical countermeasures.

The INB reached an initial agreement on Article 9 (Research and Development) during its 12th meeting on 4-15 November 2024. CEPI played a key role in securing provisions that support equitable access to products from clinical trials, promote information sharing and accelerate R&D in a way that takes into account biosecurity obligations and laws. The INB also reached initial agreement on Article 10 (Sustainable and geographically diversified local production) during its 12th meeting. This will be the first internationally binding commitment to support the geographical diversification of production, potentially reducing the gap between supply and demand during pandemic emergencies. These areas of notable progress helped pave the way for the final Agreement which is hoped to be adopted by the World Health Assembly in 2025[3].

Building effective partnerships to strengthen global epidemic and pandemic preparedness and response

Planning and implementation of CEPI's mission takes place as part of complex and dynamic ecosystems across public, private and non-state sectors including civil society. The decisions CEPI makes in terms of its investments are simultaneously informed by and can shape the ecosystem, and how we connect with or hand-off to others. As a Coalition, CEPI has built partnerships with international, regional and national actors where we share common objectives on improved epidemic and pandemic preparedness and response (EPPR). Highlights from 2024 include:

1. **R&D Funders Roundtables:** CEPI co-chaired two Medical Countermeasures (MCM) R&D Funders' Roundtables in 2024. The first was held in South Africa in March with the South Africa Medical Research Council, and focused on sustainable approaches for mRNA vaccine manufacturing and new tools for innovation including AI-assisted immunogen design to accelerate product development. A second Roundtable took place with WHO and GLOPID-R in December in Geneva and focused on the WHO CORCs and how the work of CORCs could inform funding decisions on R&D for viral families and initial lessons learned from the response to the 2024 mpox outbreak. Both Roundtables provided the opportunity for funding organisations to share information, problem solve together and identify opportunities for collaboration and complementarity.

[3] The publishing of this report follows the adoption of the Pandemic Agreement at the 78th World Health Assembly.

2. **MoUs and Partnership Agreements:** 2024 saw the formalisation of several key partnerships that deepen collaborative efforts and will contribute to the 100 Days Mission. Agreements were signed with:

   Gavi, the Vaccine Alliance: CEPI and Gavi formalised a partnership to accelerate equitable, large-scale vaccine development, procurement and delivery as part of national, regional, and global responses to outbreak, epidemic and pandemic threats. Areas of collaboration include strengthening global PPR architecture for example through the iMCM Net, Pandemic Agreement INB engagement, as well as market shaping.

   Africa CDC: With an MoU and Funding Agreement signed in May and December 2024, this partnership aims to enhance regional leadership and capacity in vaccine research, development and sustainable manufacturing across Africa, enabling faster and more equitable responses to emerging infectious disease threats. Collaboration is aligned with the Africa CDC Strategic Plan 2023–2027 and includes manufacturing and supply chain, regulatory systems strengthening and policy development.

   Nigeria CDC: this partnership focuses on bolstering CEPI's in-country partnerships and ensuring sustained national commitment to critical programmes. Areas of collaboration include the Lassa ENABLE programme and Lassa response initiatives; coordination with the Nigeria Lassa Vaccine Taskforce Secretariat and the Research Preparedness in West Africa programme.

   PAHO: Building on an MoU in December 2023, CEPI and PAHO developed an aligned work plan which supports regional preparedness and regulatory strengthening in the Latin America and Caribbean region. Areas of particular focus include regulatory systems and convergence, epidemiology and data science, clinical trials and pharmacovigilance.

3. **Global South Fellowship**: The Global South Fellowship Programme is an initiative aimed at building capacity for future global health leaders and fostering knowledge exchange to enhance readiness for the 100 Days Mission. Launched in partnership with the Indian Council of Medical Research-National Institute of Virology in India, Institut Pasteur de Dakar in Senegal, and the University of Nairobi in Kenya, the programme welcomed three fellows in 2024, one from each partner institution in India, Senegal and Kenya for a period of 12 months.

"This fellowship has been an incredible learning experience, equipping me with invaluable skills that will undoubtedly shape my future contributions. I'm currently learning about infectious disease modelling, a critical tool for predicting and managing future outbreaks in India.

It's also provided invaluable exposure to diverse teams tackling a range of priority pathogens, giving me a front-row seat to cutting-edge R&D efforts. I've even had the opportunity to contribute to the planning and discussions surrounding the development of a Nipah vaccine trial protocol. This sort of protocol would allow India to hit the ground running with a vaccine trial during a future Nipah epidemic."

Dr. Rima Sahay,
Global South Fellow based in Epidemiology and Data Science team

4. **CEPI's strategic partnerships enable it to work with partners with unique capabilities or technologies** that we know are vital to the success of the 100 Days Mission in a flexible and agile way. As with our other CEPI-funded projects and initiatives, CEPI's Strategic Partners are subject to robust project oversight and management, including stage-gated funding, and their performance is monitored by the CEPI Board. 2024 highlights of the activities under each strategic partnership include:

Moderna: In 2024, via Moderna's mNA access programme which gives investigators access to a validated mRNA platform, CEPI's investments achieved preclinical proof of concept of a vaccine candidate against Junín, a member of the Arenavirus family.

BioNTech: In 2024, progress was made to support BioNTech to establish mRNA vaccine R&D, clinical and commercial-scale manufacturing capabilities at the company's facility in Kigali, Rwanda. Notably, the BNT166 vaccine candidate successfully concluded Phase 1, and Phase 2 clinical trials were initiated in the last quarter of 2024.

IQVIA: Areas of collaboration in 2024 include IQVIA acting as 'Global Service Provider' in the Clinical Research Preparedness Programme, which includes the provision of surge capacity when needed as well as deployment of a tailored suite of tools and technologies for expedited and quality implementation and oversight of clinical trials. In addition, IQVIA was a core member of the 100 Days Mission partnership led by the Ministry of Health of Rwanda, participating in a series of operational exercises culminating in a tabletop exercise in Kigali in September 2024. With onset of the Marburg outbreak in September 2024, IQVIA pivoted to adapt the existing Sabin Vaccine Institute Phase 2 protocol for use to vaccinate frontline health workers. In parallel, IQVIA established a full clinical trial team, set up a database and put in place or monitored all critical elements of Good Clinical Practice required to ensure an appropriate and quality clinical trial initiation. This resulted in the clinical trial being initiated, and first subject vaccinated, 109 days after the outbreak was declared.

University of Oxford: Highlights in 2024 include:

- **Disease X Library advancement:** Deploying Oxford's ChAdOx technology to build vital components of the Vaccine Library. With a specific focus on ChAdOx1 Junín Vaccine as an exemplar of the New World Arenaviruses, the data and materials generated by this project could give the world a head start in rapidly developing safe and effective vaccines against Arenaviruses within 100 days of their identification. Preclinical models to assess safety risks related to vaccines on the viral vector ChAdOx platform were also developed in 2024.

- **Portfolio diversification and advancement:** CEPI is investing up to US$ 3.7 million to conduct of a Phase 2 trial of the ChAdOx1 RVF Vaccine to confirm single dose immunogenicity in healthy adults. The Phase 2 trial will be the most advanced clinical trial of a human RVF vaccine ever carried out following successful Phase 1 trials in the United Kingdom and Uganda.

- **Mathematical Modelling and Simulations (PRESTO):** Ongoing development of a graphical interface for each of CEPI's priority pathogens and ultimately Disease X to compare suitable clinical trial designs based on virus-, disease- and outbreak-specific parameters.

5. **The civil society community is integral to a strong EPPR ecosystem**, and the organisation continued to deepen its collaboration with CSOs in 2024. Key initiatives in 2024 included co-hosting of a roundtable on trust-building in vaccine development and the 100 Days Mission at the World Health Summit in Berlin in October 2024, alongside the International Federation of Red Cross and Red Crescent Societies, Deutsche Stiftung Weltbevölkerung and the German Alliance for Global Health Research.

Securing financing for epidemic preparedness and response

2024 was marked by ongoing crises and economic downturns in many areas of the world. Many of the traditional leaders in global investment have turned their focus inward. In this context, global momentum for health security and pandemic preparedness has slowed—if not stalled entirely. This is also evident in financing trends. As summarised by the Organisation for Economic Cooperation and Development (OECD):

> *"... despite broad political commitments in the wake of the COVID-19 pandemic to ensure better preparedness for health threats to come, the scale of investment required to fill current and future financing gaps for global health security remains largely unmet, or at best aspirational."*[4]

Against this backdrop, CEPI has benefited from a stable funding base made possible through the trust and support of our Investors. The diversity of CEPI's investment base is frequently cited as a model for financing global public goods such as pandemic preparedness. Forty percent of CEPI's investments are sourced from or attributable to Official Development Assistance (ODA), whether from the development, foreign affairs or health sectors. The remaining 60% primarily originates from health (non-ODA), research, innovation and science sectors in sovereign governments across the globe.

By the end of 2024, nearly US$ 2 billion had been pledged toward CEPI's second strategic cycle, CEPI 2.0 (2022–2026). Five financial contribution agreements were signed in 2024, amounting to US$ 82.65 million (see the Funding and Finance section).

With Spain joining as a new member of the Investors Council (IC) in December 2023, CEPI's IC comprised 23 members by the end of 2024: 21 sovereign governments and two global health foundations. The IC convened 11 times throughout the year, approving three strategic or large-scale funding decisions amounting to US$ 433.60 million. Its unique composition—comprising ministries and departments of research, health and foreign affairs—enables well-rounded inputs into critical CEPI processes, including the Mid-Term Review of the CEPI 2.0 strategy and planning for the next strategic cycle, which continues into 2025.

In 2024, CEPI began applying macroeconomic and integrated epidemiological–economic models that had been developed in 2023 to estimate global costs and impact of all-risk pandemic preparedness investments. These models estimate the costs and value of advanced investments in R&D and manufacturing preparedness against a hypothetical SARS-X pandemic. The findings demonstrate the value of investing in research and development and have informed engagement with key global policy stakeholders including WHO, the World Bank, OECD, and G7/G20.

CEPI also played a pivotal role in contributing to the two key deliverables of the G20 Joint Finance and Health Task Force, notably the Global Report on Framework for Economic Vulnerabilities and Risks and the Operational Playbook on Pandemic Response Financing. These tools are designed to equip governments and various finance and health stakeholders with insights and frameworks needed to enhance the speed, scale and coordination of financing for future pandemic responses. As a result of joint advocacy of CEPI, Gavi and the Global Fund, international organisations were formally recognised in the Chair's Statement of the 2024 G20 Joint Finance and Health Ministerial Meeting. The Joint Finance and Health Task Force is being carried over by the Government of South Africa through their G20 presidency in 2025 and is expected to run a country pilot to help assess pandemic risks and preparedness and a simulation exercise to improve coordination,

[4] Reference: OECD Health Working Papers No. 175, https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/03/smart-spending-to-combat-global-health-threats_9985a31e/166d7c57-en.pdf (accessed 3 May 2025).

decision-making, and immediate actions to strengthen Day Zero response and surge financing mechanisms.

Furthermore, CEPI is an implementing entity to the Pandemic Fund and acknowledges this catalytic funding mechanism as a vehicle to garner additional political support and international financing for pandemic preparedness. CEPI has been contributing to the development of its emergency financing procedure, highlighting the need for a simplified process with clear operational triggers and organisational mobilisation to enable swift disbursement of funds in emergency situations where existing Pandemic Fund proposals do not address the evolving threat. CEPI remains motivated to support countries in their applications to the Pandemic Fund where we can provide added value to their priorities.

Dr Chikwe Ihekweazu speaks at a panel event as part of the Global Pandemic Preparedness Summit in July 2024

CEPI

Monitoring, Evaluation and Learning

Monitoring, Evaluation and Learning

The Theory of Change (ToC) for CEPI 2.0 outlines the organisation's pathway to achieving its intended impact during the 2022–2026 strategic period. Developed and piloted over the first three years of the cycle, the ToC – together with the accompanying Results Framework – provides a structured foundation for monitoring, evaluation, and learning (MEL), enabling CEPI to track progress, adapt strategies and strengthen its impact over time.

In 2024, CEPI commissioned an independent Mid-Term Review (MTR) to assess progress through the end of 2023. The review highlighted some of the many programmatic achievements that have been driven by CEPI's ambition, including significant progress in vaccine development for our priority pathogens and the expansion of critical capabilities and innovations in support of the 100 Days Mission. These include the registration of SARS-CoV-2 vaccines supported by CEPI, continued progress in vaccine development made for BPCV, Lassa fever, and RVF, as well as the advancement of plans to adapt a licensed Chikungunya vaccine to ensure it is accessible to LMICs and underrepresented populations. It also includes the expansion of the VFMN, initiation of several innovation projects as well as the establishment of laboratory, clinical and regulatory networks to strengthen global preparedness and response.

Importantly, the MTR identified key areas for adjustments or additional effort, notably, the need for a clearer articulation of CEPI's strategic goals and a more coherent, learning-oriented Results Framework. Core recommendations included:

- Strengthening the alignment between CEPI's stated goals and its intended global impact
- Realigning its key performance indicators (KPIs) to ensure they are well-defined, context-appropriate, and fit for purpose
- Developing a structured learning agenda to guide adaptive management and continuous improvement across CEPI's work.

Informed by these findings, CEPI launched a process in late 2024 to revise its MEL framework in alignment with lessons learned, organisational developments and the shifting global health landscape. **A revised ToC, updated Results Framework and Learning Agenda are expected by late 2025, in line with CEPI's Management Response to the MTR.**

The updated ToC will play a central role in shaping CEPI's next strategic cycle—CEPI 3.0 covering the period 2027–2031. Recognising the importance of learning and adaptability in strategic planning, CEPI will undertake the ToC revision and CEPI 3.0 strategy development in parallel throughout 2025. This integrated approach is designed to ensure coherence between CEPI's long-term vision and the pathways to achieving measurable, global impact. The long-term nature of the ToC aligns with CEPI's commitment to sustained, multi-year efforts that continually build on scientific advances and strategic collaborations.

This report presents progress to date against the existing CEPI 2.0 Results Framework, with the understanding that the framework will be revised in 2025 to improve its relevance, usability and alignment with CEPI's long-term goals and global mission. Due to the structure of the existing ToC, it is worth noting that several outcome (OC)-level KPIs are inclusive of a subset of output (OP) KPIs. Some duplication in the KPI table may be apparent.

In broad terms, Outcomes 1.1, 1.2 and 1.3 align with activities and progress outlined in the "Strategic Objective 1 - Prepare" chapter of this report; Outcomes 2.1, 2.2 and 2.3 correspond to the "Strategic Objective 2 - Transform" chapter, and Outcomes 3.1, 3.2 and 3.3 to the "Strategic Objective 3 - Connect" chapter of this report.

CEPI 2.0 Key Performance Indicators progress as of end December 2024

CEPI 2.0 Outcome	KPI OC = Outcome OP = Output	2026 Targets	Progress update end of 2024	Status
1.1 **Acute phase of Covid-19 pandemic ended**	**OC – 1.1** Number of CEPI-funded SARS-CoV-2 licensed vaccines that are favourable for LMICs and available for use	Two variant-proof broadly protective SARS-CoV-2 candidates demonstrate clinical proof of concept (by end 2023)	Target achieved. Following WHO's announcement in May 2023 that the acute phase of the COVID-19 pandemic had ended, CEPI continued to support COVAX Facility operations until its closure in December 2023. See OP-1.1.1 below for specific milestones.	✓ Completed
	OP – 1.1.1 Percent of interim milestones achieved for advancing CEPI-funded COVID-19 portfolio favourable for LMICs	100% of milestones achieved	100% of milestones achieved by end 2023. Seven licensed vaccines by the end of 2023, six of which are favourable for LMICs according to the WHO Target Product Profile (TPP): • There are a total of seven licensed COVID-19 vaccines (Moderna, AstraZeneca/Oxford, Novavax, SK bioscience, Biological E, Clover, University of Hong Kong/Wantai) • Of these, three licensed vaccines (AstraZeneca/Oxford, Moderna, and Novavax) were granted emergency use listing by WHO, and one vaccine (University of Hong Kong/Wantai) was one of the first intranasal vaccines, which utilised a platform funded by CEPI	✓ Completed
	OP – 1.1.2 Number of CEPI-funded enabling science programmes and innovative tools available for use in COVID-19 vaccine candidate development	At least three CEPI-funded enabling science programmes and innovative tools available for use in COVID-19 vaccine candidate development	Target achieved by end 2023, with continued work into 2024 based on evolutionary changes in the SARS-CoV-2 virus. Seven preclinical models have been developed in various species for the original SARS-CoV-2 prototype. CEPI supported nine vaccine developers with the use of these models for vaccine efficacy testing. 17 SARS-CoV-2 variant models were developed and used for vaccine efficacy testing in preclinical studies performed through the PMN by the end of 2024. As part of the evolution of the BPCV portfolio and exceeding the target set for this measure, investments in preclinical model discovery have been made for MERS-CoV, SARS-CoV and other pre-emergent coronaviruses.	✓ Completed

CEPI 2.0 Outcome	KPI OC = Outcome OP = Output	2026 Targets	Progress update end of 2024	Status
1.2. **Development of vaccines and other biological countermeasures against high-risk pathogens accelerated**	**OC – 1.2** Number of CEPI-funded vaccine candidates and other biologic countermeasures for priority pathogens ready for use	At least two vaccines reaching licensure for two or more priority pathogens, including at least one WHO Prequalification At least two monoclonal antibodies for two priority pathogens ready to use under outbreak conditions	For priority pathogens (Lassa, MERS, Nipah, Chikungunya, RVF, and mpox - added in 2024): Preclinical: Four active for Lassa, MERS and RVF Phase 1: Six active for MERS, Nipah, RVF; one active mAb for Nipah Phase 2: Two active for Lassa and mpox Phase 3: One active for Chikungunya Registration for marketing authorisation: One active for Chikungunya As of end 2024, there were five candidates ready to enter Phase 2 and two ready to enter Phase 1. Pipeline gaps exist in mid/late-stage development due to attrition, and a licensed vaccine is unlikely before the end of 2026 for a second priority pathogen other than Chikungunya due to multiple factors, including unmitigable project delays. It is worth noting that CEPI initiated a programme to develop a broadly protective filovirus vaccine in 2024. CEPI also initiated a Phase 1 Nipah mAb study in 2024 and is due to onboard an additional partner to work on Nipah mAb in early 2025. A licensed mAb is unlikely before the end of 2026 given that a Phase 1b/2a trial is planned to start in late 2025.	In progress - delayed
	OP – 1.2.1 Number of CEPI-funded vaccine candidates advanced for each priority pathogen	Two licensed vaccines, additional two vaccines in Phase 3 and four vaccines through Phase 2 with ready reserve of vaccine for use in an outbreak	See OC 1.2 above	In progress - delayed
	OP – 1.2.2 Number of CEPI-funded monoclonal antibodies advanced for each priority pathogen	At least two monoclonal antibodies ready for use in an outbreak situation	See OC 1.2 above	In progress - delayed

CEPI 2.0 Outcome	KPI OC = Outcome OP = Output	2026 Targets	Progress update end of 2024	Status
1.3. **Risk of other coronavirus pandemics reduced**	**OC – 1.3** Number of CEPI-funded broadly protective Betacoronavirus vaccines (BPCV), favourable for LMICs, assessed for clinical proof of concept	Two CEPI-funded broadly protective Betacoronavirus vaccines, favourable for LMICs, assessed for clinical proof of concept	The portfolio includes 11 candidates in preclinical phase, of which eight are fully funded and three are seed-funded projects. One of these 11 has a precursor candidate in Phase 1 trial and four projects have been terminated or are in the process of being closed out. None have yet reached clinical proof of concept.	In progress - on track
	OP – 1.3.1 Number of CEPI-funded broadly protective Betacoronavirus vaccine candidates, favourable for LMICs, advancing through preclinical and Phase 1	Two CEPI-funded broadly protective Betacoronavirus vaccines, favourable for LMICs, assessed for clinical proof of concept	See OC 1.3 above	In progress - on track

CEPI 2.0 Outcome	KPI OC = Outcome OP = Output	2026 Targets	Progress update end of 2024	Status
2.1. **Vaccine prototype and vaccine innovations used to give a head start on novel threat**	**OC – 2.1** Number of CEPI-funded innovations that can be rapidly adapted against unknown pathogens	Two licensed vaccines against viable targets for LMICs using prototype and/ or platform innovations Clinical proof of concept for four virus family vaccine libraries	Four new prototype vaccine development projects for Chikungunya, influenza and SARS-CoV-2 were onboarded in 2024. In total, 14 prototype vaccines (one of them was reinitiated in early 2025) against the following pathogens are in development, with one candidate in Phase I: • Japanese Encephalitis • SARS-CoV-2 • Chikungunya • Rabies • Yellow Fever • Influenza There was one additional platform contracted in 2024 for which work will commence once a specific pathogen for platform development is identified. As these pathogens are well-characterised with existing licensed vaccines, CEPI's work with these pathogens facilitates the validation of the platforms for adaptability and use against other pathogens. The licensure target of two licensed vaccines will not be met by end 2026 due to unmitigable project delays. In the Arenavirus family, several antigen designs for Lassa and Junín viruses were tested in preclinical models. All demonstrated good immunogenicity and from there candidates were down selected for further testing into efficacy models. Clinical evaluation is planned in 2026 and 2027, for the Junín and Lassa exemplar vaccines, respectively. Antigen design was also completed for several other viruses in the Arenavirus, Paramyxovirus, Coronavirus and Phenuivirus families, progressively building the knowledge base for vaccine libraries and supporting capabilities for rapid vaccine development for these virus families. The target number of vaccine exemplars having successfully completed preclinical and Phase I studies for four virus families will likely be difficult to meet by end 2026 due to delays in the start of the Immunogen Design projects.	In progress - delayed
	OP – 2.1.1 Number of virus family vaccine libraries which have demonstrated proof of concept for viruses with high probability of inducing outbreaks	Clinical proof of concept (completion of Phase 2 clinical testing) for four virus family vaccine libraries and preclinical proof of concept for additional six virus family vaccine libraries	See OC 2.1 above	In progress - delayed
	OP – 2.1.2 Number of prototype vaccines for existing vaccine preventable diseases (with prevalence in LMICs) using rapid response vaccine platforms	Two licensed vaccines against viable targets for LMICs using prototype and/ or platform innovations	See OC 2.1 above	In progress - delayed

CEPI 2.0 Outcome	KPI OC = Outcome OP = Output	2026 Targets	Progress update end of 2024	Status
2.2. **Enabling sciences scaled to further accelerate vaccine development**	**OC – 2.2** Enabling science programmes and innovative tools actively used by CEPI-funded developers to further accelerate vaccine development	Three or more of the enabling science tools developed through CEPI funding used by one or more of CEPI-funded vaccine developers	Multiple enabling science tools, including standards, assays, serum reagents and preclinical models, developed through CEPI funding, were made available from laboratory network partners as part of the Centralised Laboratory Network to support at least 19 CEPI vaccine developers. This work enabled developers to accelerate their data collection, address critical gaps in their preclinical or clinical programmes and support submissions to national regulatory agencies. See OP 2.2.1 below for further detail on specific achievements and progress made across CEPI's enabling science programmes.	In progress - on track

	OP – 2.2.1
	Number of enabling science programmes and innovative tools to accelerate vaccine development advanced
		Standards, preclinical models, assays, translational immunology, correlates of protection, Sentinel safety surveillance and epidemiological, mathematical models and studies advanced for all CEPI priority pathogens and the virus family approach	1. International standards and sample collections
			• Two new international antibody standards released for SARS-CoV-1 and Marburg
			• Serum collection expanded to 10 countries covering the following 14 pathogens: Lassa, MERS, Nipah, RVF, SARS-CoV-2, Marburg, Sudan virus, Crimean-Congo hemorrhagic fever, Machupo, Chapare, Oropouche, mpox, Bundibugyo and SARS-CoV-1
			2. Pathogen surveillance and data sharing
			• Retrospective analysis of Nipah virus in survivor samples completed in Bangladesh and Malaysia
			• Nipah virus sequence data uploaded to GenBank, an open access database
			3. Modelling and analytics
			• Harvard Predictive Modelling Group delivered:
			  • A mid-term report for Phase 1 of its SARS-CoV-2 project and early warning software for SARS-CoV-2
			  • Immune-broadening models for H5N1 influenza
			• Impact Assessment Modelling Project (IAMP) publications:
			  • Impact of a 100-Day Mission COVID-19 response in the Lancet Global Health
			  • Lassa vaccination impact in Nature Medicine
			  • Chikungunya vaccine impact – publication pending
			  • Sarbecovirus vaccine modelling (for SARS-CoV-1, SARS-CoV-2 and MERS) – in medRxiv preprint
			• Disease burden studies underway:
			  • Global burden of Chikungunya (Cambridge University)
			  • Global burden of Lassa fever (University College London)
			  • ACHIEVE study launched to measure Chikungunya disease burden in East Africa
			4. Clinical trial preparedness
			• Enable 1.5 study (for Lassa fever) launched in Liberia, Nigeria and Sierra Leone, building on learnings from Enable 1.0
			• Enable 1.0 study (for Lassa fever) concluded, with peer-reviewed publications in development
			5. Vaccine evaluation and design
			• Vaccine effectiveness and safety monitoring ongoing for SARS-CoV-2 with support from the International Vaccine Access Center at the Johns Hopkins University Bloomberg School of Public Health
			• COVID-19 Correlates of Protection study completed in nonhuman primates
			• Mpox real-world evidence study underway in Rwanda
			• Mpox study launched in DRC to evaluate the effectiveness and safety of the Japanese LC16m8 mpox vaccine
			• Workshop held on RVF epidemiology and modelling to inform human vaccine development; call for proposals subsequently launched with projects to be selected in 2025
			• Vaccine trial simulations launched for CEPI priority pathogens and Disease X
				In progress - on track

CEPI 2.0 Outcome	KPI OC = Outcome OP = Output	2026 Targets	Progress update end of 2024	Status
2.3. **Vaccine manufacturing transformed (cheaper, faster and closer to an outbreak)**	**OC – 2.3** Number of new technologies demonstrating manufacturing cheaper, faster or closer to an outbreak	At least three innovations which demonstrate manufacturing cheaper, faster or closer to an outbreak	There were 15 active manufacturing innovations projects as of the end of 2024, all enabling different innovative aspects of manufacturing, including thermostability (five projects), speed (seven projects), and scale, access and other attributes (three projects). Ten of these projects were signed in 2024. Of these, one has reached preclinical stage and the rest are technical proof of concept, with all projects being seed funded. CEPI's manufacturing innovations projects span 11 countries.	In progress - on track
	OP – 2.3.1 Number of manufacturing innovations advanced	5 manufacturing innovations projects advanced	Progress on this measure is well underway, with 10 additional manufacturing innovations projects signed in 2024, increasing the total number of projects to 15 by end 2024. The manufacturing innovations projects span 11 countries and enable different innovative aspects of manufacturing, including thermostability (five projects), speed (seven projects), and scale, access and other attributes (three projects). Innovation projects in the thermostability portfolio were advanced, generating data on RNA-based vaccine stabilisation and delivery in dried and liquid formulations. One project succeeded in showing proof of concept and progressed to preclinical development, while another project failed to demonstrate proof of concept and was terminated. Most of the speed, scale and access projects kicked off in 2024, and are starting to generate initial data showing production of comparable RNA-, protein- and viral vector-based vaccine candidates, with faster, cheaper and more scalable processes.	In progress - on track

CEPI 2.0 Outcome	KPI OC = Outcome OP = Output	2026 Targets	Progress update end of 2024	Status
3.1. **Funding for epidemic preparedness and response secured**	**OC – 3.1** New financing mechanisms include funding for vaccines and other biologic countermeasures preparedness and response R&D	Funding for vaccine and other biologic countermeasures preparedness and response R&D	In 2024, CEPI continued advocacy work in the global fora to prioritise and improve the effectiveness of investments in R&D for new vaccines and other countermeasures. This includes support for work by Imperial College and University of Chicago to model the health and economic benefits of investment in EPPR R&D to strengthen the investment case for R&D. This work is informing engagement with the G20 Joint Health and Finance Taskforce and the finalisation of the World Bank's "Pandemic Playbook." CEPI supported a G7 Development Finance Institutions (DFIs) initiative to develop collaborative surge financing mechanisms to scale up vaccine supply capacity in pandemics, with proposals presented at UNGA in 2024. CEPI has started discussions with the World Bank and Regional Development Banks (RDBs) on approaches to informing concessional lending programmes to support EPPR innovation, regulatory and manufacturing capabilities in Asia, Africa and Latin America. CEPI co-convened two MCM R&D Funders' Roundtables in 2024, one co-chaired with South Africa Medical Research Council and another with WHO and GLOPID-R. These brought together leading MCM R&D funding agencies to focus on shared challenges and opportunities to increase the effectiveness and coordination of EPPR R&D funding investments, covering topics including the potential of AI, collaborative research priorities setting and approaches to increase collaboration with the pharmaceutical industry. Looking ahead to 2025, CEPI will continue engagement activities including with the World Bank Group, RDBs and DFIs to agree on collaboration on the design of lending operations and surge financing mechanisms.	 In progress - on track
	OP – 3.1.1 CEPI fully funded for 2.0	US$ 3.5 billion in commitments	By December 2024, close to US$ 2.0 billion was raised toward the revised target of US$ 2.6 billion in commitments received for CEPI 2.0. Looking ahead, CEPI will need to have secured new funding by 2027 to ensure continuity of programmes and sustain progress toward CEPI's mission. CEPI is actively engaging with the Board and Investors to discuss potential scenarios for future financing.	 In progress - delayed

CEPI 2.0 Outcome	KPI OC = Outcome OP = Output	2026 Targets	Progress update end of 2024	Status
3.2. **Coordination among key stakeholders enables system readiness**	**OC – 3.2** Alignment on key elements of a target ecosystem to accelerate development and promote equitable access of emerging infectious disease countermeasures	RACI(s) for 80% of key elements in place (where key elements of the future target ecosystem are articulated and CEPI's and others' roles are clarified through partnership agreements)	In 2024, CEPI continued to work with key public partners to plan scenarios and clarify roles and synergies in preparedness and response to outbreaks, epidemics and pandemics. CEPI and vaccine partners mapped respective triggers and actions, jointly participated in the WHO-led interim Medical Countermeasures Network to define clearer roles across the ecosystem as well as addressing steps in the value chain. A multi-departmental team at CEPI has been working on identifying hand-off options for CEPI's successful vaccine candidates based on the types of product and access challenges they may encounter. Scenarios and options from this work will continue in 2025 and inform prioritised engagement with key global and regional partners. MoUs and other agreements have been signed with key partners including Gavi, the Vaccine Alliance, PAHO and Africa CDC, outlining areas for collaboration and respective roles.	In progress - on track

	OP – 3.2.1
	Number of identified areas with funded global networks established (or expanded)
		At least three networks established or expanded	1. Preclinical Models Network (PMN)
			• Seven new partners were added in 2024, bringing the total to 17 implementing partners in 11 countries, including three LMICs, with an additional South American laboratory to be added to the network in 2025
			• CEPI developed and/or supported:
			  • Rhesus and marmoset models for MERS
			  • Adjuvant comparison protocols for testing using adjuvants stored at CEPI's partner laboratory
			  • Rodent models and pseudovirus assays for coronaviruses
			• A Chikungunya preclinical study was completed and a draft report submitted
			2. Centralised Laboratory Network (CLN)
			• One new partner was added in 2024, bringing the total to 18 implementing partners in 14 countries, including six LMICs
			• 27,000+ sample runs across 17 studies for 12 vaccine developers for SARS-CoV-2
			• New immunological assays developed in 2024 for Nipah and mpox, with others planned for 2025
			3. Global South Leadership in Epidemic Analytics and Response Network (GS Learn Network)
			The GS Learn Network was established to build modelling capacity, enhance technical expertise, and foster leadership in the Global South. The initiative was launched in 2024, and implementation partners will be selected in 2025 following a CfP published in 2024. The overall aim is to establish integrated, locally led networks to inform vaccine R&D, guide early outbreak responses, and support evidence-based decision-making.
			4. Vaccine Manufacturing Facility Network (VMFN)
			See OP 3.3.2 for expansions in the VMFN and progress made at each facility to build up manufacturing capacity in support of LMICs.
				In progress - on track

CEPI 2.0 Outcome	KPI OC = Outcome OP = Output	2026 Targets	Progress update end of 2024	Status
3.2. **Continued**	**OP – 3.2.2** Regulatory database available and accessed by developers	Database available as a pilot to CEPI-funded developers by 2023 with view to wider roll-out towards 2026	Partnership with FRPath — an initiative led by the Erudee Foundation in collaboration with the DK Kim International Center for Regulatory Science at the University of Southern California and co-funded by the Gates Foundation is ongoing. FRPath serves as a long-standing global regulatory repository designed to inform regulators, industry, and NGOs on best practice in relation to regulatory topics. This new resource enhances CEPI's ability to support regulatory engagement by offering a centralised, up-to-date reference point for emergency preparedness frameworks across countries while serving as an open access regulatory knowledge base. In January 2024, CEPI submitted the compiled EAP data with data fully integrated into the FRPath Portal by September 2024, making emergency use pathway information publicly accessible for the first time. To ensure internal uptake and use, CEPI staff were trained on use of the portal in late 2024.	 **In progress - on track**

CEPI 2.0 Outcome	KPI OC = Outcome OP = Output	2026 Targets	Progress update end of 2024	Status
3.3. **Equitable access principles as the foundation of any effective response**	**OC – 3.3** Removing at least one key systemic obstacle to access for LMICs	Three G20 countries making new funding and/or procurement commitment for vaccines development include reference to access provisions Guidance available to address potential injuries caused by vaccines/to establish a no-fault compensation mechanism	Progress made to catalyse and advocate for removing systemic obstacles includes: CEPI engaged with U.S. NIH regarding the development of their access policies, successfully contributing insights on equitable access provisions and approaches that could be incorporated into R&D. This successfully contributed to their published policy, including terms for equitable access in their licensing agreements. CEPI convened and attended numerous global scientific and policy meetings, including the G20 Health Working Group and EC Navigator Expert Group discussions, where CEPI played a role in advancing multi-sector dialogues on equitable access by design. This was a strong feature of the CEPI-convened Global Pandemic Preparedness Summit in Brazil, co-hosted with numerous regional and global partners in 2024. At the multilateral level, CEPI actively engaged in the WHO Intergovernmental Negotiating Body (INB) process, and specifically with a number of G20 countries (e.g., Norway, Mexico and Brazil), towards ensuring the successful inclusion of Article 9.5 in the Pandemic Agreement, which addresses policies regarding the inclusion of equitable access provisions in publicly funded R&D agreements. At the end of 2024, this work was ongoing. The publishing of this report follows the adoption of the Pandemic Agreement at the 78th World Health Assembly.	 In progress - on track
	OP – 3.3.1 Percent of CEPI-funded products/platforms with relevant access plans in place	100%	Review of CEPI's existing agreements related to products has been initiated against the relevant equitable access outcomes to assess whether CEPI is on track for achieving the equitable access components. An initial report is expected in Q2/Q3 2025. Work to refine the equitable access outcomes for Disease X-related technologies in relation to the 100 Days Mission is underway.	 In progress - on track

CEPI 2.0 Outcome	KPI OC = Outcome OP = Output	2026 Targets	Progress update end of 2024	Status
3.3. **Continued**	**OP – 3.3.2** Number of agreements in place that support manufacturing capacity strengthening in order to support LMICs	At least 5 agreements in place that support manufacturing capacity strengthening in order to support LMICs over 2 regions	CEPI led work to support manufacturing capacity strengthening in LMICs through its VMFN and support of the RVMC Secretariat. **VMFN**: Two new funding agreements were signed in 2024 with manufacturing partners in the VMFN, including the Serum Institute of India (SII)(India) and Bio-Manguinhos/Fiocruz (Brazil), bringing the total to five agreements across three regions. Through 2024, work progressed with each VMFN partner as follows: Aspen (South Africa) (Gates Foundation co-funded) - GMP (Good Manufacturing Practices) formulation, fill-finish of liquid (suspension) vaccines and progress made in regulatory licensure in South Africa, to conclude in 2026 Institut Pasteur Dakar (Senegal) – viral vector pilot underway for commercial manufacturing initially for Measles and Rubella vaccine, now transitioning to Marburg vaccine and, potentially, to include Lassa vaccine in the future BioFarma (Indonesia) – mRNA and viral vector pilot underway for commercial manufacturing of dengue, rabies and malaria vaccines and, potentially, MERS vaccine once the technology is established and validated for use SII (India) – multiplatform (mRNA, viral vector, recombinant protein) outbreak response readiness using pandemic influenza as an exemplar, and production of supply of ChAdOx-Nipah vaccine for clinical trials with University of Oxford Bio-Manguinhos/Fiocruz (Brazil) – mRNA (candidate vaccine in preclinical testing) and viral vector pilot to scale manufacturing, commercial fill-finish (lyophilised and liquid) for SARS-CoV-2, RSV, yellow fever and Chikungunya vaccines **RVMC**: In February 2024, CEPI established and began hosting the RVMC Secretariat. In January 2024, a 2.0 Framework was published. In July, RVMC released its strategy for 2024-2027. RVMC strengthened partnerships in Africa (with Africa CDC), Latin America and the Caribbean (with PAHO) and Southeast Asia (with Thai NVI under the ASEAN Vaccine Security and Self-Reliance initiative). By late 2024, RVMC completed key work that led to a Lancet Commentary and prepared the ground for its full Vision document.	 Completed

CEPI

Funding and Finance

Funding and Finance

Figures presented in this section represent cash flows (except for operating expenses) and are expressed in US$ equivalents using actual exchange rates for the years 2017–2024, and 2025 budget rates for years beyond 2024.

Further details on CEPI finances can be found in Appendix 1: Supplementary Financial Information, which includes reference to CEPI's Annual Audited Accounts and Board of Directors Report 2024.

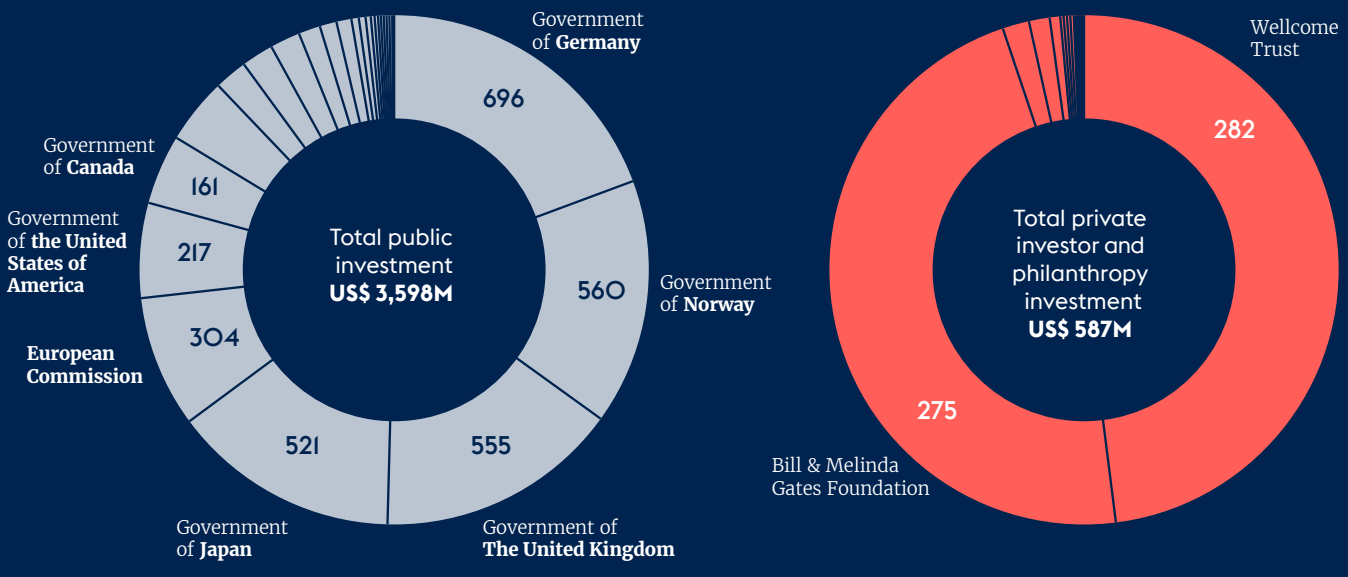
Contributions from Investors

By the end 2024, close to US$ 2 billion have been raised towards CEPI's second strategic cycle, CEPI 2.0 (2022–2026). Of this figure, only US$ 0,04 billion are pending contract signature.

CEPI receives funding from sovereign investors, the European Commission, philanthropies and private organisations. Sovereign public investors represent the largest investor group, with 86% of the US$ 4.2 billion pledged to CEPI since its launch in 2017 (see Appendix 1: Supplementary Financial Information).

The overall number of individual contributors has grown from 14 at the end of 2019, to 80 at the end of 2024[5]. Almost all donations are pledged to CEPI's common pool of funds. Earmarked funds, including funds softly earmarked toward activities that are considered ODA eligible, are pooled and spent on eligible groups of projects[6].

Figure 11: Total contributions and pledges to CEPI as of 31 December 2024



[5] Including sovereign, philanthropic and private sector contributions.

[6] The overall OECD ODA co-efficient for CEPI 2.0 portfolio is 88% (see Appendix 1).

R&D and Manufacturing Project disbursements

CEPI portfolio at the end of 2024

At the end of 2024, CEPI had entered partnership agreements with total investment commitments[7] of up to US$ 3.151 million and has disbursed US$ 2.237 million in funding across its portfolio. Approximately 23% of the funds remaining to be disbursed are gated (US$ 208 million of US$ 917 million), the release of which is conditional on key milestones that awardees will have to meet.

COVID-19, MERS and broadly protective coronavirus (BPCV) represent the largest signed budget in the portfolio accounting for approximately 58% (US$ 1.832 million) of the total commitments. Priority pathogens[8] account for around 19% (US$ 584 million) of the total commitments, with the largest proportion of the priority pathogen budget signed to Lassa projects (US$ 235 million). The Disease X portfolio investment has been rapidly increasing and currently represents approximately 9% (US$ 289 million) of the total commitments. In terms of its financial allocations, approximately 60% (US$ 1.879 million) of the signed portfolio supports vaccine development, while around 24% (US$ 762 million) has been allocated to enabling science projects. Many of CEPI's vaccine development investments are long-term, multi-phase investments and therefore the release of funding tranches is contingent on key milestones that awardees will have to meet as they transition between phases of development ('stage gates'). Therefore, not all contracted funding is expected to be committed and disbursed, as CEPI's portfolio management approach considers expected phase-to-phase attrition.

CEPI's investments in 2024

As noted in last year's Annual Progress Report, CEPI did not meet its investment expectations in 2023 and initiated steps, such as bolstering the portfolio, entering into strategic partnerships and enhancing the investment management to address the shortfall. In 2024, CEPI disbursed in total US$ 309 million to its awardees, exceeding the forecast by approximately US$ 20 million, indicating that the steps taken in the latter half of 2023 have been successful. Among the success factors for increasing disbursements and exceeding the budget were a significant increase in the contracting (above US$ 550 million of projects were contracted in 2024), improved control over the investment budgets and better forecasting accuracy throughout the year. As CEPI as an organisation is maturing, so are its processes, and the organisation remains vigilant in maintaining and improving its investments-related processes.

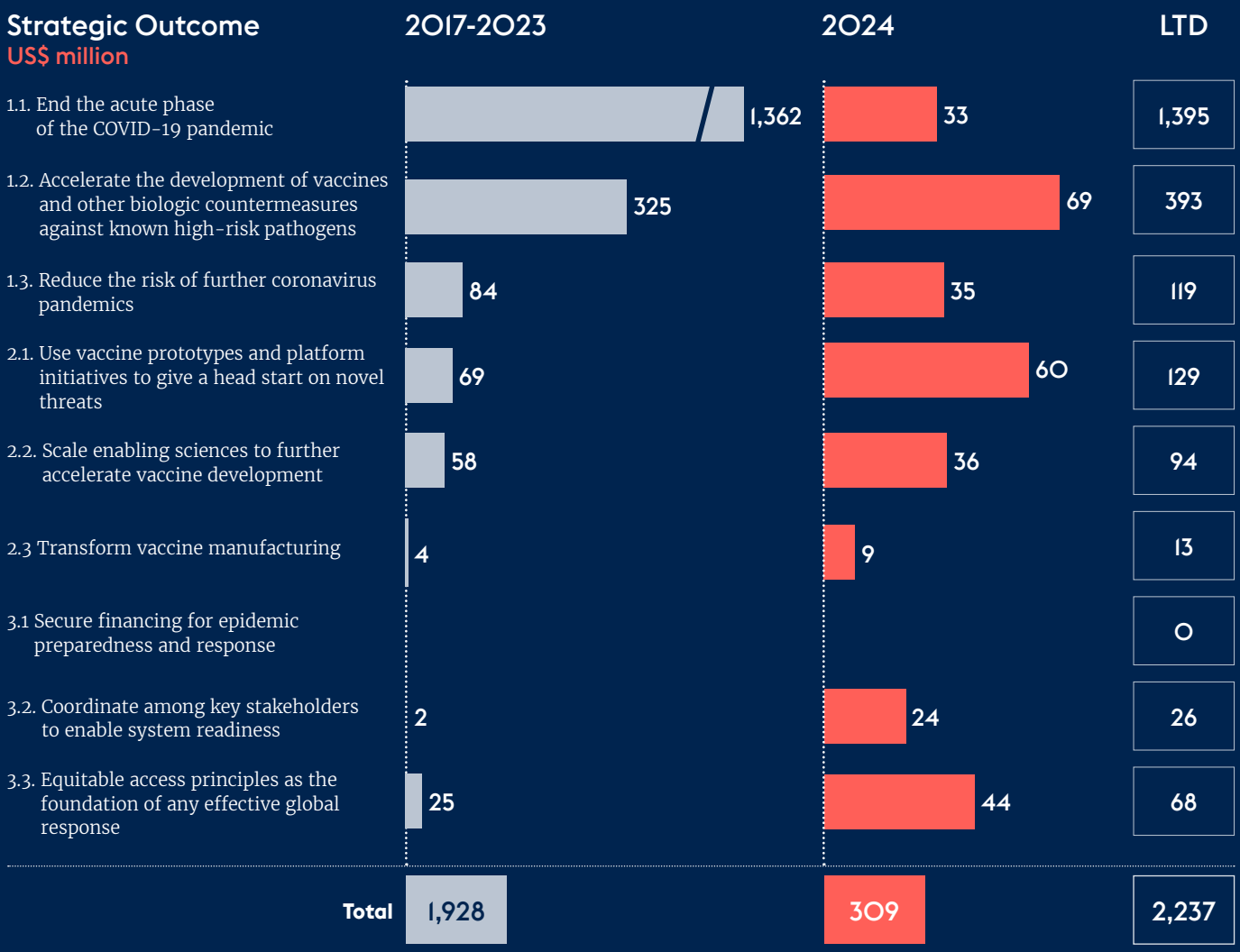
Of the US$ 309 million disbursed in 2024, a significant portion of the disbursements, approximately US$ 69 million or 22%, went towards the target of accelerating the development of vaccines against known high-risk pathogens (Outcome 1.2). This included funding for late-stage development projects for Lassa fever (US$ 16.5 million), Chikungunya (US$ 11.8 million), and Rift Valley fever (US$ 10.0 million). Although COVID-19 investments (Outcome 1.1) are winding down, there is still ongoing activity including for clinical trials and the CLN; US$ 30 million went towards advancing broadly protective Betacoronavaccine vaccines (Outcome 1.3), including transmission-blocking approaches. CEPI is continuing to fund numerous enabling sciences initiatives to accelerate vaccine development (Outcome 2.2), amounting to US$ 36 million in 2024. Additional funds were directed towards initiatives that utilise vaccine prototypes and platform technologies to address emerging threats (Outcome 2.1), amounting to US$ 60 million or 19% of total disbursements. A significant investment in 2024 under Outcome 2.1

[7] Of which, US$ 2.994 million is committed, and US$ 208 million is gated

[8] Includes the following pathogens: Chikungunya, Filovirus, Lassa, Mpox, Nipah and Rift Valley fever

is the BioNTech mpox programme. Disbursements under Outcome 3.2 increased in 2024 to US$ 24 million, driven by an increase in Regulatory projects, continued investments in setting up the Regionalized Vaccine Manufacturing Collaborative (RVMC), Clinical Preparedness in West Africa and the Africa CDC investment. Lastly, CEPI's commitment to equitable access principles as a cornerstone of an effective global response (Outcome 3.3) resulted in total disbursements of US$ 43.4 million to various initiatives. Allocations include BioNTech's manufacturing facility in Kigali, Rwanda, as well as expansion of CEPI's global Vaccine Manufacturing Facility Network to facilities with partners such as Serum Institute of India, Institut Pasteur de Dakar, and PT Bio Farma.

Figure 12: R&D&M Project disbursements 2024 – by Strategic Outcome

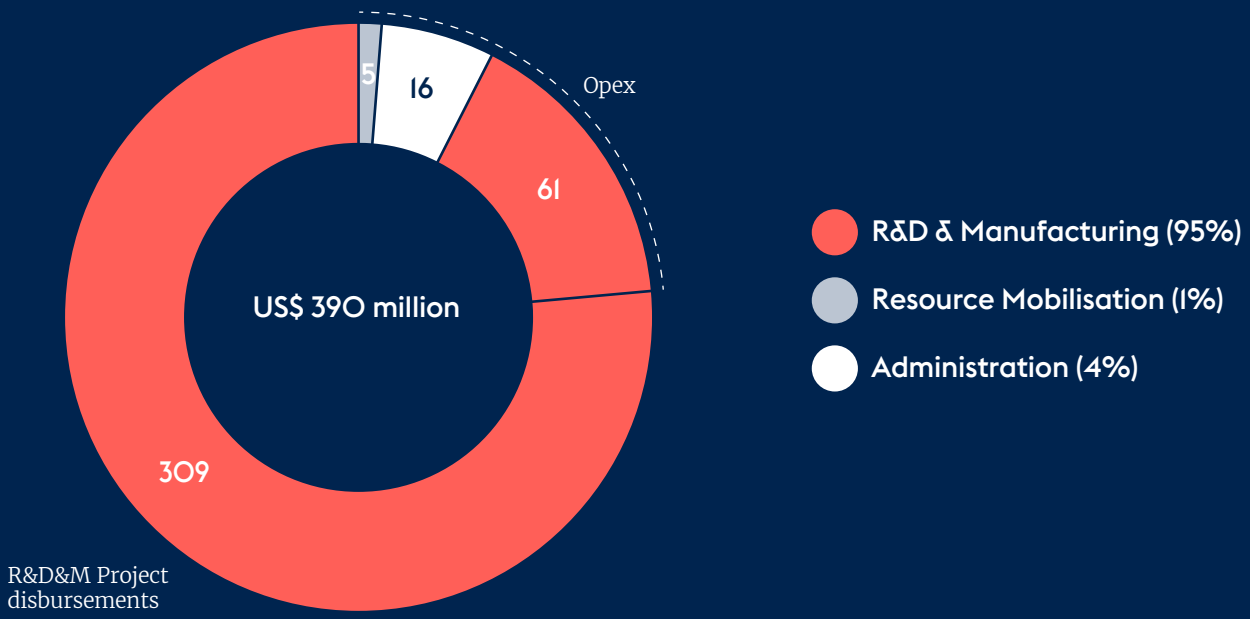


Operating expenses (Opex) and total expenditure

Out of the overall expenditure for 2024, CEPI spent 95% on its main activities in relation to vaccine R&D and Manufacturing, leaving a spend of 5% on overheads (resource mobilisation and administration). With this, CEPI has continued to demonstrate the ability to keep administrative costs low, while continuing to increase its portfolio and build the organisation accordingly.

The significant year-on-year increase in staff since inception continued in 2024, reflecting CEPI's ambition to build a fit-for-purpose organisation to implement the CEPI 2.0 strategic cycle. Opex amounted to US$ 81 million in 2024, an increase of 18% over 2023. The increase in Opex for 2024 was mainly driven by continued hiring and the full-year impact of 2023 headcount growth. Staff growth will be limited in 2025 to reflect that CEPI is approaching its targeted size in terms of staffing. The overall expenditure is depicted below by activity and refers to whether an expense is channelled towards R&D and Manufacturing, project disbursements and project support, resource mobilisation[9] or administration[10]. This provides insight into whether Opex are directed towards adding value to the portfolio of investments through project support, or to raising funds, organisation management and administration. Organisation management and administration are typically labelled overhead costs. Of CEPI's Opex, 75% relates to R&D project support which is largely driven by CEPI's Vaccine R&D and Manufacturing and Supply Chain Departments, staffed with technical experts responsible for launching CfPs and conducting technical follow-up of CEPI's portfolio of projects.

Figure 13: Total expenditure by activity as of 31 December 2024



[9] Refers to CEPI's efforts to increase ongoing, and secure new funding commitments.

[10] Shared costs like IT, Office facilities, Finance & Operations and HR are distributed to the different activities. Total shared costs for 2024 was US$ 17.1 million.

CEPI

Risk Management and Organisational Update

Risk Management

Risk management, ethics and compliance, and internal audit processes are key components in assuring that proper governance and monitoring are in place and continuously improved in CEPI.

Ensuring robust risk management, ethical conduct and compliance with laws and regulations is critical to CEPI's operations and central to CEPI's Risk Management Strategy.

Risk Management

CEPI Management has prioritised the continuous improvement of the Risk Management Framework through which to adopt a structured and consistent approach to identifying, assessing and managing risk. Following an external and independent review of the Risk Management Framework in 2022, significant progress has been made to mature and operationalise the Framework in 2023 and 2024. This includes development and roll-out of the Risk Appetite Framework; adoption and approval of the updated Risk Policy and Procedure; and strengthened monitoring and oversight including from the Audit and Risk Committee.

In the context of an evolving ecosystem in which CEPI operates, a thorough review of CEPI's Organisation Level Risks was undertaken in 2024 to ensure that it continues to remain fit for purpose and responsive to both internal and external developments. The result is a revised list of 28 risks for 2024–2025 that will be monitored by the Executive Directors group following approval by the Audit and Risk Committee and the Board in August 2024, to ensure focus on the risks of greatest importance. These risks align closely with CEPI's wider organisational priorities including those related to strategic clarity, Biosecurity and Biosafety strategy, portfolio and portfolio performance, financial management, operational efficiencies, and compliance and investor requirements.

The reporting cadence on the risks has evolved with a detailed risk report to be shared with the Board twice a year, the first in March 2025. This shift will enable a closer monitoring of the Organisational Risks, progress on the mitigating actions and attention to risks where the risk exposure exceeds CEPI's agreed threshold for risk appetite.

Figure 14: Future reporting cadence on Organisational Risks

Ethics and Compliance

In 2024, CEPI made significant strides in several key areas, reinforcing our commitment to ethical practices and sustainability. Highlights include:

Organisational Code of Conduct Update: CEPI's Code of Conduct was revised ensuring it reflects the latest standards and best practices in ethics and compliance for CEPI employees and consultants. This update has strengthened our organisational integrity and provided clear guidelines for all employees and stakeholders on ethical decision-making. The revised Code of Conduct reaffirms CEPI's commitment to an inclusive workplace, financial integrity and includes stronger positions on critical human rights issues. The roll-out involved mandatory sign-off by all employees and was accompanied by a mandatory eLearning module on CEPI's online learning platform.

Financial Crime Risk Assessment: An assessment was conducted to identify vulnerabilities within CEPI's operations, focusing on fraud, bribery, and corruption. It highlighted areas for enhanced controls, particularly in financial reporting, third-party interactions, and internal processes. Improvements were recommended in staff training, awareness, and monitoring mechanisms. The assessment's actionable recommendations included developing a counter-fraud policy and associated procedures to bolster CEPI's financial crime risk management framework. The Counter-Fraud Policy was published in Autumn 2024.

CEPI's Child Protection Statement: A statement was published on CEPI's website, outlining its zero-tolerance stance and expectations regarding child protection as specified in various policies.

Roll out of CEPI's first compliance-based partner assurance projects: CEPI's Third Party Code of Conduct consists of a set of principles and requirements to ensure alignment by CEPI's partners with CEPI's standards, mission, and values. In 2024 CEPI implemented a number of pilot assurance projects with partners to ensure adherence to the Third Party Code of Conduct. This compliance assurance initiative began in 2024 and will continue throughout 2025. In 2025, CEPI will also update its Third Party Code of Conduct.

Human Rights Gap Analysis Project: In 2024 CEPI undertook a human rights gap assessment with external consultancy support, which was focused on evaluating CEPI's human rights framework and identifying areas for improvement. The assessment benchmarked CEPI's current human rights approach against donor requirements and the United Nations Guiding Principles on Business and Human Rights. The overarching assessment was that CEPI had many of the key elements in place, including robust policies and a good integrity due diligence process, with some recommendations aimed to enhance CEPI's human rights framework and ensure alignment with international standards and donor expectations. Implementation of these recommendations began in 2024 and will continue in 2025.

Environmental Impact and Climate Risk Assessment: CEPI recognises the importance of environmental sustainability and the need to address climate-related risks to support our mission of creating a safer, more sustainable, and equitable global health landscape. In 2024, CEPI undertook an environmental impact and climate risk assessment. This assessment evaluated the vulnerability of our projects to climate change and identified potential impacts on the environment, including through CEPI's operations. Mitigating actions have been identified and are being considered to address these risks, demonstrating our commitment to environmental safeguarding and sustainability.

Data Protection and Privacy: Since 2022, CEPI has significantly strengthened its data protection compliance framework to meet legal and ethical responsibilities, reduce risks, and build trust. This includes the recruitment of a dedicated expert, development of internal policies, data protection notices, governance tools, and structured risk management, along with targeted training and guidance tailored to CEPI's operations and risks. Over the last year, CEPI has delivered on several initiatives including a revision of its Data Protection and Privacy Policy and related procedures, and integration of data protection controls into IT and AI projects, including alignment with EU AI Act.

CEPI has a central framework for data protection compliance, integrating it with broader governance, risk, and compliance processes. This framework promotes consistent and sustainable risk-based decision-making across functions.

In parallel with meeting its compliance obligations, CEPI is laying the foundation for a broader, values-led approach to data ethics and technology use. As we implement advanced digital solutions, including artificial intelligence and federated data models, we will prioritise the internal FAIRAI[11] principles in both policy and practice, for example by ensuring they are embedded into CEPI's operational and decision-making frameworks.

In 2025, CEPI will continue efforts to align internal practices with FAIRAI principles. CEPI will also continue to evolve this approach by engaging with partners to explore ethical and responsible approaches to technology and innovation. The updated Third Party Code of Conduct to be published in 2025 will reflect this evolution.

CEPI's Ethics and Compliance team also continued to deliver on day-to-day activities including integrity, due diligence and monitoring on CEPI's partners, delivering business integrity training and undertaking key policy updates, ensuring that CEPI policies align with evolving regulatory requirements and industry standards.

Internal Audit and Partner Assurance

The Internal Audit and Partner Assurance (IA/PA) function supports CEPI in growing responsibly by protecting its assets, ensuring operational efficiency, and providing stakeholders with confidence through independent assurance and advice. It offers independent, risk-based objective assurance, advice and insight into CEPI-related activities to Leadership Teams and directly to the CEPI's Board Audit & Risk Committee.

The 2024 audit and assurance plans were developed by reflecting on the organisational risks, CEPI's core assets, stakeholder input, industry benchmarks, and programme-specific considerations for the partner-related audits. The plan included eight primary assignments covering CEPI's management of procurement, the CLN, cyber security, investment management oversight, conflict of interest, Stage Gate review process for ongoing investments, and travel expenses. For the assurance assessment of CEPI's partners, the scope has been focused on financial management with an increasing focus on addressing other risk areas related to CEPI-funded programmes. This approach will be further developed in 2025.

The annual assurance plan was approved by the Audit and Risk Committee, and the progress of the assessment and the actions to close any identified gaps or findings have been monitored by Management and the Audit and Risk Committee.

[11] FAIRAI principles are: Fairness, Accountability, Integrity, Respect, Achievement and Innovation

Security and organisational resilience

CEPI is committed to establishing a safe and secure working environment for employees, associates and partners. In 2024, CEPI's security and resilience function consolidated efforts to bolster the security of our offices, travelling colleagues, and events – improving the professionalism of our operations. The function also conducted updates of our business impact analyses, business continuity plans, and organisational crisis management plans.

These updates were accompanied by relevant training and awareness initiatives, ensuring CEPI can respond more effectively to the realisation of some risks, including severe incidents or disruptions. In addition, the function provided more robust support to CEPI's investments, improving our identification and management of security risks which could impact the success of our programmes.

Organisational Update

2024 has been a significant year marked by growth and transformation, with a focus on refining CEPI's organisational and leadership capabilities. Key changes were made to CEPI's Extended Leadership team with the appointments of Aurélia Nguyen as Deputy CEO; Kent Kester as Executive Director of R&D; Rachel Grant as Executive Director for the newly formed External and Investor Relations Division; and Emma Wheatley taking on new responsibilities as Executive Director for Access and Business Development. Additionally, Dr. Amadou Sall, will join CEPI in the second quarter of 2025 as Executive Director of the organisation's Manufacturing and Supply Chain Division. To support the growing scale of CEPI's staff and operations, the Human Resources function is being elevated, with recruitment underway for an Executive Director for People and Organisation.

Staff well-being has been a high priority, with minimum requirements and operational responsibilities for health and safety covering both physical and mental health defined across all CEPI offices. Health and well-being within the workforce continue to be monitored and promoted at CEPI, with several internal well-being opportunities for employees offered over the course of 2024. The Working Environment Committee plays a crucial role in following up on health and well-being topics, ensuring a supportive and positive workplace for staff.

CEPI has successfully relocated its office in London, which has positively impacted the organisation's culture and work environment. A move to a new, fit-for-purpose office in Washington D.C. is planned for March 2025.

A review by management has thoroughly analysed the growth assumptions for 2025 and, in agreement with the Board, has agreed on a moderate increase in operational expenditures of 7.4% over 2024. For further details please view the 'Operating expenses (Opex) and total expenditure' section within 'Funding and Finance'.

Human Resources

The CEPI workforce is a talented team who are passionate about creating a future where epidemics and pandemics are no longer a threat to humanity. In 2024, CEPI experienced significant growth, expanding its workforce from 257 to 330 employees. This includes 26 employees engaged through an Employer of Record service or non-resident payroll. Throughout the year, CEPI welcomed 88 new starters and saw 15 employees leave.

The organisation's overall turnover rate decreased to 4.77% in 2024, down from 8.9% in 2023, 13.1% in 2022, and 8.8% in 2021. The peak in 2022 aligns with broader industry trends. CEPI's global reach and operational flexibility are further enhanced by a strong cadre of expert consultants.

CEPI's workforce is truly global, with employees hailing from 60 different countries. About 30% of the employees come from the Global South, a figure that has steadily increased since CEPI's inception: 13% in 2018, 22% in 2020, 25% in 2021, and 29% in 2023. CEPI remains committed to improving this diversity through extensive outreach and partnerships with globally-reaching organisations. Gender balance is also a priority for CEPI including at senior leadership level, with 61% of its employees being female.

Life at CEPI is collaborative, agile and inclusive. We believe our culture, mission, projects and people make CEPI an exceptional place to work. As a global organisation, we strive to ensure our colleagues feel connected wherever they are and are committed to creating a workplace that enables us to prioritise our well-being while advancing our high-performing and caring culture.

Governance Update

CEPI Board Summary

In 2024 the CEPI Board met six times with two in-person meetings, three virtual meetings and one hybrid meeting held during the course of the year. Headline topics discussed by the Board included:

March 2024
- Portfolio/Annual Portfolio Review
- Investments
- Ecosystem
- Accounts & Audit

April 2024
- Investment approval

May 2024
- Investment approval
- SAC Membership

June 2024
- Half-year Finances
- Biosecurity strategy draft
- Response (Mpox/H5N1 flu)

August 2024
- Portfolio and investment areas Intellectual Property
- Mid-term Review
- Risk review
- Board effectiveness

December 2024
- Closed session – nominations.

There were a number of changes to membership in 2024. The CEPI Board saw one voting member step down due to capacity constraints (Soumya Swaminathan), and the renewals of three Board members for a further term of five years from 6 May 2024:

- Samba Sow
- Cyrus Ardalan
- Githinji Gitahi

An external adviser was appointed to support the work of the CEPI Nominations, Compensation, Diversity and Inclusion Committee (NCDIC), Natalie Bickford Chief People Officer of Sanofi.

Table 1: Members of CEPI Board as of December 2024

Name	Affiliation
Independent Members	
Jane Halton	Board Chair, EIC Chair
Cyrus Ardalan	Chair ARC
David Reddy	
Professor Samba Sow	
Dr. Jeanette Vega Morales	
Dr. Githinji Gitahi	Chair EAC
Rajeev Venkayya (Chair NCDIC)	Chair NCDIC
Investor Representatives	
Dr. Yasuhiro Suzuki	International University of Health and Welfare, Japan
Dr. L. Rizka Andalucia	Pharmaceutical and Medical Devices at the Ministry of Health of the Republic of Indonesia
Veronika von Messling	German Federal Ministry of Education and Research
Alex Pym	Wellcome Trust
Non-voting Members	
Richard Hatchett	Coalition for Epidemic Preparedness Innovations CEO
Emmanuel Hanon	SAC Chair
(Cherry) Gagandeep Kang	JCG Chair
Dr. Mike Ryan	WHO
Juan Pablo Uribe	World Bank

Summary of Scientific Advisory Committee

In 2024, CEPI's Scientific Advisory Committee (SAC) met four times – twice in person and twice virtually. Discussion topics included:

January 2024 (Annual Portfolio Review, London)
- Platform portfolio
- Manufacturing platform innovations and networks portfolio
- Enabling sciences portfolio
- Chikungunya portfolio
- Rift Valley fever portfolio
- Nipah portfolio

April 2024 (Virtual)
- Mpox as a priority pathogen

July 2024 (Rio De Janeiro)
- Mpox
- Leveraging AI to support the 100 Days Mission
- CMC investments for accelerating vaccine development and deployment
- Broadly protective coronavirus portfolio strategy
- CEPI's role in H5N1 pandemic influenza response
- Zika

October 2024 (Virtual)
- Ongoing outbreak response activities related to Marburg and H5N1
- Real-world evidence generation in outbreak situations

Table 2: Members of CEPI Scientific Advisory Committee as of December 2024

Name	Affiliation
Alash'le Abimiku	International Research Center of Excellence, Institute of Human Virology, Nigeria
Ifedayo Adetifa*	FIND, Switzerland
Vincent Ahonkhai	Gwynedd Consultancy Group, LLC, USA
Vineeta Bal	Indian Institute of Science Education and Research, Pune, India
Rick Bright	Bright Global Health, USA
Paula Bryant	National Institute of Allergy and Infectious Diseases, National Institutes of Health, USA
Yunlong Cao	Peking University, China
Beth-Ann Coller*	BGC Vaccine Consulting LLC, USA
Peter Dull	Bill & Melinda Gates Foundation, USA
Azra Ghani	Imperial College London, United Kingdom
Paula Goldin*	PPD at Thermo Fisher, Argentina
Rebecca Grais	Pasteur Network, France
Glenda Gray	South African Medical Research Council, South Africa
Ana Maria Henao Restrepo	WHO, Switzerland
Emmanuel Hanon (Chair) – 2022-25	Vicebio, Belgium
Kevin Kee-Jong Hong*	Gachon University College of Medicine, Republic of Korea
Ken Ishii	International Vaccine Design Center, The Institute of Medical Science, The University of Tokyo, Japan
Amine Kamen	McGill University, Canada
Michael King – 2022-25	University of Virginia, USA
Gary Kobinger	Galveston National Laboratory/Institute for Drug Discovery, University of Texas Medical Branch, USA
Philip Krause	WHO, USA
Luciana C. C. Leite*	Instituto Butantan, Brazil
Marc Lipsitch	Harvard T.H. Chan School of Public Health, USA
Andre Siqueira*	Fundação Oswaldo Cruz, Brazil
Dominique Maugeais	RH Solutions, France
Placide Mbala*	Institut National de Recherche Biomedicale, Democratic Republic of the Congo
Sly Ngoni Mutyavaviri*	Medicines Control Authority of Zimbabwe and SADC Medicines Regulatory Harmonisation, Zimbabwe
Laura Palomares Aguilera – 2022-25	Instituto de Biotecnología, Universidad Nacional Autónoma de México, Mexico
Peter Paradiso	Paradiso Biologics Consulting LLC, USA
Stanley Plotkin	University of Pennsylvania, USA
Marie Jose Quentin-Millet	MJQuentinMillet Consulting, France
Rino Rappuoli	Fondazione Biotecnopolo di Siena, Italy
Lynda Stuart	FFS , USA
Linfa Wang	Duke-NUS Medical School, Singapore
George Warimwe	KEMRI-Wellcome Trust Research Programme, Kenya and University of Oxford, United Kingdom

*Joined in 2024
Renewed in 2024 (3 years)

Summary of Joint Coordination Group

In 2024, CEPI's Joint Coordination Group (JCG) met twice – once in person and once virtually. Discussion topics included:

January 2024 (London)

- Progress in regulatory innovation
- CEPI networks
- Mpox
- Chikungunya
- The XVAX Network and the Regionalized Vaccine Manufacturing Collaborative (RVMC)
- T24: A 100 Days Mission Tabletop Exercise

June 2024 (Virtual)

- Mpox
- Chikungunya
- Investigational reserves and stockpiles
- Evidence generation

Table 3: Members of CEPI Joint Coordination Group as of December 2024

Name	Affiliation
Cherry Kang (Chair)	Bill & Melinda Gates Foundation
Chinwe Iwu-Jaja	African Vaccine Regulatory Forum (AVAREF)
Rajinder Suri	DCVMN
Marco Cavaleri	European Medicines Agency
David Kaslow	United States Food and Drug Administration
Sergio Carmona	Foundation for Innovative New Diagnostics (FIND)
Derrick Sim	Gavi, the Vaccine Alliance
Hamilton Bennett	International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
Petra Khoury	International Federation of Red Cross and Red Crescent Societies
Nathalie Ernoult	Médecins sans Frontières
Andrew Jones	UNICEF
Titus Divala	Wellcome Trust
Scott Pendergast	World Health Organization
Magnus Lindelow	World Bank

CEPI

Appendix

Appendix 1: Supplementary Financial Information

Table 4: Total Contributions and pledges by 31.12.2024 with expected received year (in US$ million)

Investor	2017 - 2023	2024	2025 - 2026[1]	Total contributions & pledges[2]	% of Total contributions & pledges
European Commission	181.61	21.23	100.78	303.61	7.25%
Government of Australia	43.09	22.90	9.32	75.31	1.80%
Government of Austria	5.78	1.71	-	7.49	0.18%
Government of Belgium	6.04	-	-	6.04	0.14%
Government of Canada	103.92	15.03	42.26	161.21	3.85%
Government of Denmark	1.45	-	-	1.45	0.03%
Government of Ethiopia	0.40	0.10	0.10	0.60	0.01%
Government of Finland	8.64	1.08	2.08	11.80	0.28%
Government of Germany	654.68	-	41.55	696.22	16.64%
Government of Greece	1.78	-	-	1.78	0.04%
Government of Hungary	0.84	-	-	0.84	0.02%
Government of Iceland	1.92	-	-	1.92	0.05%
Government of Indonesia	3.00	1.00	2.00	6.00	0.14%
Government of Italy[2]	25.78	-	12.98	38.76	0.93%
Government of Japan	334.27	60.00	127.00	521.27	12.46%
Government of Kuwait	10.00	-	-	10.00	0.24%
Government of Lithuania	0.22	0.11	-	0.33	0.01%
Government of Luxembourg	1.37	0.22	0.42	2.00	0.05%
Government of Malaysia[3]	3.00	1.00	2.00	6.00	0.14%
Government of Mexico	1.25	0.65	-	1.90	0.05%
Government of Kingdom of the Netherlands	64.02	3.34	6.23	73.59	1.76%
Government of New Zealand	13.25	1.25	2.25	16.75	0.40%
Government of Norway	488.55	9.54	61.46	559.55	13.37%
Government of Philippines	0.01	-	-	0.01	0.00%
Government of Portugal	0.34	-	-	0.34	0.01%
Government of Romania	0.24	-	-	0.24	0.01%
Government of Senegal	-	-	1.00	1.00	0.02%
Government of Serbia	1.23	-	-	1.23	0.03%
Government of Singapore	8.01	3.00	6.00	17.01	0.41%
Government of Spain	-	43.84	24.97	68.81	1.64%
Government of Switzerland	21.10	11.15	-	32.26	0.77%
Government of the Republic of Korea	33.00	18.00	-	51.00	1.22%
Government of the United Kingdom	407.39	70.76	76.66	554.81	13.26%
Government of the United States of America	117.00	100.00	-	217.00	5.19%
Kingdom of Saudi Arabia	150.00	-	-	150.00	3.58%
Total Public Investors	**2,693.18**	**385.91**	**519.05**	**3,598.14**	**85.98%**

1) The payment schedules of several agreements extend beyond 2026, including the contribution from the Government of Spain to be received via IFFIm.

2) Contributions received are expressed in US$ equivalents using the exchange rates on the dates funds are received. Contributions Funds pledged but not yet received are expressed in US$ equivalents using CEPI Budget 2025 exchange rates.

3) Includes EUR 5M contribution in 2021 received via the International Finance Facility for Immunizations (IFFIm).

Table 4: Total Contributions continued

Investor	2017 - 2023	2024	2025 - 2026[1]	Total contributions & pledges[2]	% of Total contributions & pledges
Avast	8.00	-	-	8.00	0.19%
Bill and Melinda Gates Foundation	185.28	30.00	60.00	275.28	6.58%
Fidelity Charitable gift funds	1.49	-	-	1.49	0.04%
Goldman Sachs Gives	1.63	-	-	1.63	0.04%
Nestlé	1.04	-	-	1.04	0.02%
Paul G. Allen Family Foundation	3.50	-	-	3.50	0.08%
Sumitomo Mitsui Banking Corporation	1.14	-	-	1.14	0.03%
UN Foundation CI9 Solidarity Fund	10.00	-	-	10.00	0.24%
Wellcome Trust	130.85	25.69	124.98	281.52	6.73%
Other Private Investors and Philanthropies[4]	3.28	-	-	3.28	0.08%
Total Private Investors & Philanthropies	**346.21**	**55.69**	**184.98**	**586.88**	**14.02%**
Total Contributions & Pledges	**3,039.39**	**441.60**	**704.03**	**4,185.02**	**100.00%**

4) Includes contributions of NOK 600 million frontloaded in 2019 through IFFIm, and NOK 2B frontloaded through IFFIm for COVID-19 in 2020

5) Private Investors with contributions of less than US$ 1 million are grouped under "Other Private Investors and Philanthropies".

Table 5: R&D and Manufacturing Project disbursements 2024 per Strategic Outcome

Strategic Roadmap US$ million	2024 Actual	2024 Budget	2024 Variance
1.1. End the acute phase of the COVID-19 pandemic	33.2	42.7	-9.5
1.2. Accelerate the development of vaccines and other biologic countermeasures against known high-risk pathogens	68.9	80.6	-11.7
1.3. Reduce the risk of further coronavirus pandemics	35.0	29.5	5.5
2.1. Use vaccine prototypes and platform initiatives to give a head start on novel threats	59.6	53.5	6.1
2.2. Scale enabling sciences to further accelerate vaccine development*	36.1	26.2	9.9
2.3 Transform vaccine manufacturing	9.0	13.4	-4.5
3.1 Secure financing for epidemic preparedness and response	0.0	0.0	0.0
3.2. Coordinate among key stakeholders to enable system readiness	23.7	9.7	14.0
3.3. Equitable access principles as the foundation of any effective global response	43.5	33.8	9.7
Total R&D&M projects/investments	**309.1**	**289.5**	**19.6**

*Disbursements to the CEPI networks partly included under 2.2, but also relevant for 3.2 (the Manufacturing network is included under 3.3)

Table 6: CEPI 2.0 ODA eligible project disbursements as at 31.12.2024

ODA Group	ODA %	Project disbursements (US$ million)
1. Priority pathogens	100%	52.1
2. BPCV	55%	35.1
3. Disease X – viral families	68%	31.9
4. Rapid response platforms for LMICs	100%	24.7
5. Monoclonal antibodies	100%	1.6
6. Manufacturing networks	100%	42.0
7. Manufacturing Innovations	68%	9.0
8. LMICs capabilities and engagement	100%	5.7
9. Benefits both PP and Disease X	90%	30.6
Total ODA eligible investments	**88%**	**232.7**

The OECD has assigned an ODA eligibility co-efficient of 88% to the overall CEPI 2.0 investment portfolio and has further split the portfolio into groups with an individual eligibility co-efficient.

Table 7: Operating Expenses (Opex) 2024

Opex US$ million	2023 Actual	2023 Budget	2023 Variance
Employment	43.8	44.6	-0.8
Consultancy	16.2	14.8	1.4
Travel	5.9	5.9	0.1
Infrastructure	8.9	8.3	0.6
Other	6.5	5.9	0.6
Total Opex	**81.3**	**79.4**	**1.9**

Opex for 2024 was higher than budget by US$ 1.9 million, of which US$ 1.4 million is purely nominal and related to FX effects, mainly the strengthening of the GBP vs. US$. The deviation is a reporting effect of currency translation. Additionally, US$ 1.6 million from the CEO Reserve fund was allocated for non-budgeted spend, including an increased scope for the Global Preparedness Summit (GPPS2), unforeseen legal fees and Artificial Intelligence (AI) initiatives aimed at increasing efficiency and effectiveness around CEPI's awardee facing processes.

The negative FX effect is more than offset by a positive FX effect on GPB contributions received in 2024.

Management of Financial Risk

CEPI currently receives its donations predominantly in US$, NOK, GBP, and EUR, and makes grants to awardees in US$. CEPI has a Trustee agreement with the World Bank through which most of the committed funds to CEPI are channelled.

Available funds are invested in the World Bank or with selected commercial banks, with the main investment goal being capital protection. CEPI has also set up a fixed income portfolio with Citibank to further spread its cash reserves and connected risk, and invested US$ 20 million in the Global Health Security Fund (GHSF).

To cover operational costs and to minimise the currency risk, CEPI is keeping cash in the donated currency for natural hedging purposes. CEPI has also established a hedging facility with its current commercial bank, as a means to minimise currency risk caused by a mismatch between funding received and grant currencies.

Annual Accounts and Board of Directors Report

CEPI's Annual Accounts and Board of Directors Report can be found on CEPI.net. In the Annual Accounts, revenue and costs are recognised in accordance with the Norwegian Accounting Act and Generally Accepted Accounting Principles for Non-profit Organisations.

As CEPI usually prepares its internal and external reporting based on a cash flow principle for revenue and investments, the Annual Accounts profit and loss deviate from CEPI's other financial reports, including the Annual Progress Report.

CEPI